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## Editorial :

# Vandalism In Health Care And Related Laws

\*Dr Sayali Jahagirdar \*\*Dr Manish Machave

Received for publication : 11<sup>th</sup> March 2023 Peer review : 21<sup>st</sup> March 2023 Accepted for publication : 29<sup>th</sup> March 2023

### Keywords -

Medical Vandalism, Service providers, safe environment, Verbal abuse

### Introduction-

Medical vandalism has become a major matter of concern in today's world [1]. In the bygone era doctors were treated as Gods, and medical profession was considered a noble one, which is no longer now. With the Health Care Professionals (HCP) coming under the axe of Consumer Protection Act, we are expected to be service providers to patients as clients or consumers. The sanctous relationship has drastically come to an end and fear of litigation has crept in. Mismatch between unrealistic expectations of consumers from godly service providers is a leading cause of increasing number of violent mob attacks on doctors and other medical personnel both in government as well as private setups. This trend is having a negative impact on the proper functioning of healthcare system thus affecting the quality of care and treatment.

### Constitutional Rights of Healthcare Workers:

The doctors and other healthcare workers are constitutionally entitled to be protected from violence. Apart from holding the perpetrators of violence liable under criminal law, which has been primarily done in most cases, it is important that the State is also brought to question for failure to protect the fundamental rights of the healthcare personnel.

Article 19(1)(g) of the Indian Constitution guarantees the right to practice any profession. In Vishaka v. State of Rajasthan, the Supreme Court had held that the fundamental right to carry on any

profession depends on the availability of a 'safe' working environment which has not been a case for the healthcare personnel. Violence against them is, further, a clear violation of Article 21's Right to Life and Liberty, which the State was obligated to protect.

### Definition-

Vandalism includes threat, verbal and physical abuse, damage or destruction of hospital property, defamation, hindrance to HCP to resume their work which in turn may affect treatment of other patients attended by the HCP [2].

### How common is it???

A study conducted by the Indian Medical Association (IMA) shows that more than 75% of the doctors face violence at work at some point in life. Verbal abuse is the most common form of violence. Escorts of patients have committed nearly 70 % of such violence. Nearly 50 % of such violence has been reported from intensive care units or post-surgery[3].

Peak hours and the transfer of critical patients to other hospitals are most susceptible to violence. Violence against nurses has an incidence rate of 25 per 10,000. Highest rates of violence occur in the Obstetrics Gynecology practice, followed by Medicine and Surgery.

### Trigger Factors For Violence Against HCP (Seven Ds)

- |   |
|---|
| 1. Sudden <b>DEATH</b>                                    |
| 2. <b>DOCTOR ON DUTY</b> was not available                |
| 3. <b>DELAY</b> in providing care                         |
| 4. <b>DENIAL</b> of admission                             |
| 5. Nonavailability of essential <b>DRUGS</b> or equipment |
| 6. <b>DEFICIENCY IN DUTY</b> of nursing staff             |
| 7. Limited understanding of <b>DISEASE</b>                |

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### **Impact of Vandalism-**

- Loss of life or permanent or temporary disability of HCP.
- Damage and loss of property and financial loss.
- Defamation leading to mental stress and depression.

Being a doctor is the most noble and coveted profession of mankind, to get vandalized by patient or public without sufficient reason is the worst mental trauma to undergo.

### **Measures to curb Vandalism**

#### **(A) Responsibilities of HCP-**

- Answer all queries and doubts of patients. Be polite with patients and their kin.
- Communication and consents should be clear and concise.
- Document all facts on paper. Empathise with your patient in times of death or disaster.
- Good rapport with seniors, colleagues working in tertiary care hospital.
- Invest in Indemnity and good Insurance cover .
- Keep watch on problem patients and relatives.
- Limit your practice to your speciality.
- Medical equipment and essential drugs to be available at all times.
- No loose talk about any other colleague.
- Oust all malpractices like overcharging, cut practice, overconfidence.

**Peaceful relations with 3P s – Patient, Police & Politician** of your locality. Respond to emergency calls by patients and colleagues . Be a part of Rapid Action team. Communicate clearly with staff and subordinates. Understand the laws related to your profession.

### **Measures to curb Vandalism-**

#### **(B) Responsibilities of Patients -**

Be truthful with their physicians and strive to express their concerns clearly. Physicians likewise should encourage patients to raise questions or concerns. Patients should provide as complete a medical history as they can, including providing information about past illnesses, medications, hospitalizations, family history of illness, and other matters relating to present health.

Patients should cooperate with agreed-on treatment plans. Since adhering to treatment is often essential to public and individual safety, patients should disclose whether they have or have not followed the agreed-on plan and indicate when they would like to reconsider the plan.

Accept care from medical students, residents and other trainees under appropriate supervision. Participation in medical education is to the mutual benefit of patients and the health care system; nonetheless, patients' (or surrogates') refusal of care by a trainee should be respected in keeping with ethics guidance. Patient should meet

### **MEASURES TO IMPROVE HEALTH CARE SYSTEM**

1. Recruitment of adequate HCP to reduce demand-supply gap.
2. Improve working condition of doctors and providing facilities for their families especially in rural and remote areas
3. Increase in allocation of health budget at present it forms only 1% of GDP
4. Ensuring safety and security to all HCP and providing them indemnity cover.
5. Timely upgradation of PHC, UHC and District hospitals and Medical Colleges and ensure their smooth functioning
6. Public awareness programs to bridge gaps and improve doctor patient relationships
7. Enforcement of law at ground level and strict action against those instigating vandalism
8. Public -Private Partnerships for providing speciality health care to all
9. Central Act to prevent and penalize those guilty of vandalizing HCP and health setups and ensuring security to doctors

their financial responsibilities with regard to medical care or discuss financial hardships with their physicians. Patients should be aware of costs associated with using a limited resource like health care and try to use medical resources judiciously.

Refrain from being disruptive in the clinical setting and report illegal or unethical behavior by physicians or other health care professionals to the appropriate medical societies, licensing boards or law enforcement authorities.

#### **Measures to curb Vandalism-**

#### **(C) Responsibilities of Government and Judiciary-**

In order to ensure quality health care delivery for all strata of people in society and doctors to utilize their optimum skills and expertise for the benefit of patients, they should be allowed to work in a stress-free environment. The biggest role of the Government and Judiciary is to provide such favourable environment.

#### **Laws Pertaining To Safeguard Doctors From Vandalism**

##### **A) The Indian Penal Code, 1860**

The Indian Penal Code (IPC), 1860 is the main criminal code of India. It is a comprehensive code intended to cover all substantive aspects of criminal law. The code was drafted in 1860 on the recommendations of the First Law Commission of India established in 1834 under the Chairmanship of Lord Macaulay. It came into force in the year 1862.

1. S-96 to S-106 : Gen Exceptions- Deals with prevention of violation against person and loss of property and gives a person right to fight, even to the extent of causing death of the assailant.
2. S 350 : Criminal Force- Whoever intentionally uses force on any person, without that person's consent, in order to the committing of any offence or intending by the use of such force to cause or knowing it to be likely that by the use

of such force he will cause injury, fear or annoyance to the person to whom the force is used, is said to use criminal force.

3. S-351, S-352: Assault or preparation to make assault and Penalty- 3 months imprisonment and Rs. 500 fine
4. S-499, S-500: Defamation and Punishment for defamation - 2 yrs imprisonment and fine.
5. S-503, S-504: Criminal intimidation and punishment - 2 yrs imprisonment and fine.

#### **B) Protection of Medicare Service Persons and Medicare Service Institutions (Prevention of Violence and Damage to Property) Act, 2010- also known as the Medical Protection Act (MPA).**

The Act covers doctors affiliated to institutions as well as independent practitioners, outlaws attacks against physicians and damage to their property. Offenders can get a jail term of up to three years and a fine.

**Objective:** Whoever, endangers the life of or causes any harm, injury, intimidation, obstruction or hindrance to any medicare service person in the discharge of duty or damage to any property in medicare service institution, commits an act of violence which shall be an offence under this Act[4].

#### **Who all are covered under the act???**

Medicare service institution owned or controlled either by the State Government or Central Government or any person or individual. Medical service person, Registered Medical Practitioners (including those having provisional registration), registered nurses; medical students; nursing students and para-medical workers.

#### **Type of offence :**

**Cognizable** – Can be arrested without warrant and **Non-Bailable** – Bail is not granted as a right and has to be contested. Shall be tried in court of Judicial Magistrate of First Class.

### Punishments under the act-

Imprisonment for a term of three years and Rs 50,000/- to Rs 2,00,000/- fine, plus a compensation of twice the amount of purchase price of medical equipment damaged and loss caused to the property as may be determined by the competent court. If a person fails to pay the penal

in health care system and resort to legal ways of addressing their grievances. Bridging gaps in doctor patient communication, infusing trust in doctor patient relationship will help in abolishing vandalism against doctors. Strengthening the existing laws shall go in a long way to achieve this difficult goal.

Step by step- Vandalism management
1. Call for help -Rush team.
2. Call police - Dial 100
3. Call your good offices who you think may help.
4. Keep calm-Use hospital staff to protect you and property - SOS Bouncers.
5. The Indian penal code, 1860 gives you permission to counter attack for defence.
6. Sometimes running away also is beneficial- therein go to police station.
7. Click photos and take detailed video of all damages. That is evidence.
8. Lodge a formal complaint under IPC and MPA act as above. See that FIR is registered.
9. FIR can be registered against unknown people too. Give police CCTV coverage - Audio and Video... but keep a copy with yourself.
10. Call and discuss with media ( <i>the ones you are in good terms with</i> )

amount the said amount shall be recoverable as if it were arrears of land revenue.

**The provisions of this Act shall be in addition to and not in derogation of the provisions of any other law, for the time being in force.**

### Conclusion

Violence in any form against HCP is unpardonable and should be condemned by all means. In order to prevent vandalism, positive steps need to be taken by HCP as well as due support needs to be given by government and ensure affordable and quality health care services to all strata of society. Patients need to be made aware their rights and responsibilities, have a reasonable amount of patience, awareness of ground realities

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Review Article :

## How important is it medico-legally to get patient KYC done ?

Dr. Mahesh Baldwa

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### Keywords

Patient's KYC, Criminal responsibility, Valid document, Medico-Legal

### Introduction

Many a times the doctors do not know exact age, marital status and socio-economic background of the patient. There are several laws like MTP Act [1,2], POCSO Act [3,4], PCPNDT Act [5,6] where age and marital status of patient are medico-legally important if rape is alleged by patient party. Age is important from the point of view of valid consent. Age for a valid consent is 18 years. In case the patient is less than 18 years then one has to obtain a proxy consent from legally authorized person like parents, guardian or a court order.

**Medicolegal importance of Age :** Evidence of age is medio-legally important in following situations:

#### 1] Criminal responsibility-

In India, under section 82, IPC [7], a child under the age of 7 year is incapable of committing an offence. Under section 83 IPC, a child above 7 years and below 12 years of age, is presumed to be capable of committing an offence. Under section 89 IPC, a child under 12 years of age cannot give valid consent to suffer any harm which can occur from an act done in good faith and for its benefit, as for example, a consent for a surgical operation. Only a guardian can give such consent. Under section 87 IPC, a person under 18 years of age cannot give valid consent, whether express or implied, to suffer any harm which may result from an act not intended or not known to cause death or grievous hurt.

#### 2] Kidnapping –

Under section 369 IPC, to constitute a crime of kidnapping or abducting a child with the intention of taking dishonestly any moveable property from its person, the age of such a child

should be under 10 years. Section 361- 366 IPC lay down that it is a crime to kidnap or abduct a minor from lawful guardianship if the age of boy is under 16 and that of a girl under 18 years. Section 366A, 372, 373 IPC lay down that it is an offence to procure a minor girl for illicit intercourse or to sell or buy a minor girl for purpose of prostitution, if her age is under eighteen years. Section 366 B IPC lays down that it is an offence to import into India from foreign country a girl for purpose of illicit intercourse, if her age is less than 21 years.

#### 3] Rape -

Under section 375 IPC Rape is defined as unlawful sexual intercourse by a man with a woman without her consent and against her will or with her consent obtained by force, fear or fraud or a sexual intercourse with any woman below the age of 18 years with or without consent. In case of wife, it does not constitute rape unless she is below 15 years.

#### 4] Marriage –

Indian law under the Hindu Marriage Act [8] 1955 has defined the marriageable age of a boy and girl. Legally a boy in India needs to be at least 21 and girl needs to be at least 18 years of age at the time of marriage. Under the Child Marriage Restraint (Amendment) Act [9] 1978, a male who has not completed 21 years and a female who has not completed 18 years of age, shall be considered a child, and any marriage in which one of the spouse is a 'child', will be considered as a child marriage and the parent or guardian of such a child shall be liable for punishment.

#### 5] Attainment of majority -

Under Indian Majority Act [10] 1875 person domiciled in India attains majority on completion of eighteen years, except when under a guardian appointed by a court, or under a Court of

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Wards, when the individual attains majority on completion of twenty one years. Persons under this age are minors. After attainment of majority, a person acquires full civil rights and responsibilities. The Protection of Children from Sexual Offences Act, 2012 is to protect children under 18 years from offences of sexual assault, sexual harassment and pornography and provide for establishment of Special Courts for trial of such offences.

#### **6] Competency as a witness-**

Under section 118 IEA[11], no age limit is laid down for this purpose. Under the Indian Oaths Amendment Act [12], the unsworn evidence of a child under 12 years of age is admissible

#### **What are officially valid documents for KYC?**

Following are the Officially Valid Documents (OVDs). Patient is requested to provide a self-attested copy of any one of these amongst other proofs

1. Passport [13]
2. Voter's Identity Card [14]
3. Driving Licence [15]
4. Aadhaar Card [16]
5. NREGA Card [17]
6. PAN Card [18]

Additional KYC procedures help prevent future medico-legal damage

Mobile Number, Email id, socioeconomic status and family Income Range are necessary for future medico-legal cases

It is important to identify as many of these risk factors as possible.

- ☐ Legal risks – unwed pregnant
- ☐ Regulatory risks – age proof under MTP Act, PCPNDT Act, POCSO Act
- ☐ Co-morbidity risks- previous prescriptions, imaging and laboratory Reports
- ☐ Current illness risks- brought in dying –found dead, emergency, critical serious condition
- ☐ Past illness and treatment risks HTN, DM,

Obesity, hypothyroidism

- ☐ Socioeconomic risk self declaration of family income.

#### **Conclusions**

Proper KYC shall be useful when medico-legal case is filed against them. KYC shall forewarn doctors about age, marital status, and income range, co-morbidities, past & current illness along with socio-economic background of patient. A forewarned doctor is forearmed to deal with medical litigation.

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18. Income tax act and rules 1961 as amended



**Case Report :**

## **Autonomy versus Beneficence: The Consent Conundrum**

**Kattamreddy Ananth Rupesh**

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**Key words :** Autonomy, Beneficence, Justice, Non- Maleficence, Consent, Section 92 IPC

**Abstract:**

Let us imagine a scenario where a conscious adult male patient in health emergency refuses to give consent to the treating physician. Despite explaining the grave outcome of the illness, patient is reluctant and adamant towards consenting for the treatment plan and also voices his informed refusal. In his personal capacity with all autonomy and liberty, he has the right to give or refuse consent. Medical care as we know is bound by the prescribed set of well-defined rules and procedures to follow, as per the various statutes which regulate them. In such situations several questions may crop up in our minds as to how to take a decision which is practical, legal as well as ethical. Here, we discuss a case-situation with solution which prompts beneficence, which is non-maleficence, overrides the patient's autonomy but finally delivers justice.

**Introduction:**

'Consent' is an essential prerequisite for framing a contract of care between a doctor and the patient. The current medical practice is no longer parentalistic (to be gender neutral, we disregard the use of word paternalism) and is perfectly grounded on the doctrines of high degree of patient autonomy and a clear informed consent. Needless to say, the age old principles of 'primum non nocere' and justice continue to champion the cause of ethical medical practice at least in theory. A thorough information on four pillars of medical ethics and the recent addition of 'distributive justice' as fifth pillar can be accessed from this publication[1]. However, we as medical practitioners face a

constant ethical and legal dilemma in prioritizing between 'beneficence to the patient' and 'patient's autonomy'. Let us reflect upon this subtle yet persisting 'consent' conundrum in the context of a real case.

**Case Summary:**

Mr. A got his left leg injured in a road traffic accident. The accused responsible for the accident admitted him in a private hospital, paid the initial advance and fled away. The private hospital treated him initially and eventually shifted Mr. A to a government institution as he was not in a position to bear further costs of hospital stay. By the time he was received in the government institution, he developed gangrene of left leg because of compound comminuted fractures of both bones of left leg. He didn't disclose anything about his whereabouts nor was he in a position to convey anything about his kith and kin. He was agitated and irritable all the time during the stay. The orthopedic surgeon advised for above knee amputation in his case and asked him to give consent for the same. Mr. A was reluctant and eventually turned adamant to give consent for amputation. He was also explained about the aggravation of gangrene and consequential septicemia which may cause his death. Unfortunately, he didn't budge a bit in spite of counseling by the psychiatrist as well. He was fully conscious and coherent and in full senses till he died one un-fateful morning having given informed refusal for amputation more than ten times in writing as well. Sadly, all the efforts of hospital authorities and police in tracing his relatives ended in no result.

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## Discussion:

### Ethics Perspective:

Restricting to the ethics angle in this case, the important question to be answered is, to what extent patient autonomy is to be honored? What is the exact point where beneficence overrides autonomy? We don't want to bring in too much bioethics jargon here because jargon further entwines our questions. Is parentalism a compromise or an inevitable reconciliation in such cases? In the present case, there is a transient inadequacy of capability on part of Mr. A to take a decision that benefits him though he is in full

capacity i.e. *compos mentis* to take a decision. How can a surgeon forcefully proceed for the procedure if his patient is not willing for it? The question of his relatives doesn't arise because Mr. A is in full senses.

A general sense of conflict between the principles of medical ethics is encountered in various degrees in our day to day practice. But the most dreaded dilemmas are the ones that border between life and death.

Let us apply the four quadrants approach to understand the intricacies of this case [2].

MEDICAL INDICATIONS	PATIENT PREFERENCES
<p><i>Beneficence and non-maleficence</i></p> <ul style="list-style-type: none"> <li>• Patient is having compound comminuted fractures of both bones of left leg with gangrene.</li> <li>• The diagnosis is an acute condition that can turn critical at any point of time with a consequence of loss of life.</li> <li>• Treatment goal is above knee amputation.</li> <li>• There is a reasonably high probability of success and less chance for therapeutic failure in the proposed goal of treatment.</li> <li>• The proposed treatment is the only way for the patient to survive.</li> </ul>	<p><i>Respect for patient autonomy</i></p> <ul style="list-style-type: none"> <li>• The patient is legally competent and mentally capable to give consent.</li> <li>• Patient prefers not to get his left leg amputated.</li> <li>• Patient has been informed of benefits and risks, however his understandability is questionable. He prefers to die with complications of gangrene rather than getting amputated.</li> <li>• No question of surrogate consent as patient is in full senses.</li> <li>• Patient has preconceived stigma towards living with an amputated leg.</li> <li>• In sum, patient's right to choose to die is not good in either ethical or legal point of view.</li> </ul>
QUALITY OF LIFE	CONTEXTUAL FEATURES
<p><i>Beneficence, non-maleficence and respect for patient autonomy</i></p> <ul style="list-style-type: none"> <li>• The prospect of returning to normal life without treatment is impossible.</li> <li>• With successful amputation, the patient is likely to experience a physical handicap of left lower limb, mental trauma because of loss of body image and also a social deficit regarding enjoying company of others, leisure and sports.</li> <li>• There are no biases that might prejudice the provider's evaluation of the patient's quality of life.</li> <li>• Patient is concerned about the undesirable outcome of physical handicap after the surgery.</li> <li>• There is no plan or rationale to forego the treatment.</li> <li>• There are plans for comfort and palliative care.</li> </ul>	<p><i>Loyalty and fairness</i></p> <ul style="list-style-type: none"> <li>• As the patient hasn't informed us anything about his family, we aren't aware of any family issues that made patient refuse treatment.</li> <li>• There are no health care provider issues that might influence the treatment decisions.</li> <li>• There are some financial economic factors with respect to life care planning after the surgery but there aren't any such issues with respect to surgical costs.</li> <li>• We aren't aware of any cultural and religious factors that played a role in patient's decision.</li> <li>• No confidentiality issues involved, no issues pertaining to allocation of resources, no clinical research issues involved, no conflict of interest on the part of care providers or the institution.</li> <li>• Law doesn't allow the patient's wishes to be realized in this case. Article 21 of the Indian constitution guarantees right to life which doesn't include right to die.</li> </ul>

### **Indian Legal Perspective:**

#### **Section 92 of Indian Penal Code-**

Addresses the Act done in good faith for benefit of a person without consent. Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit.

In our present case, how can surgeon proceed for amputation when the case does not fit in to the 'circumstances' as described in the Section 92 IPC? The above mentioned general exception of IPC works very well in settings where patient is not in compos mentis to give consent and his next of kin aren't available when there is a medical emergency. During such scenarios the treating doctor has an emergency privilege to proceed with the best possible plan of care for the patient to save life. It is to be noted that, incapacity to consent is not an all or none phenomenon and it spreads over a spectrum of grey areas. In our case, there is a stark inadequacy of capability on the part of the patient in deciding for the benefit of himself. The doctor attending to him or the head of the institution where he is being treated will have to turn into his loco parent to decide the best possible treatment plan in good faith.

Even in cases of passive euthanasia permitted after Aruna Shanbaug judgment, [3] neither the patient alone, nor the treating doctor alone can decide about stopping or refraining from a particular plan of treatment. Only the territorial high courts have jurisdiction to decide on passive euthanasia on a case to case basis as per a specific laid down stringent procedure of Supreme Court. So, any patient can't decide to end up his life in the event of any circumstances and no doctor can ever permit that under the India law. Though every

citizen is a free man, his 'life' is the property of the state (in the sense he can't take away his life at his will).

However, with changing times, patient autonomy has gained great importance in law. The best example is the recent Mental Health Care act 2017 wherein immense importance was given to 'advance directive' and 'nominated representative'. The crux of the law is that, in the event of a person becoming mentally ill, he will be treated as per his choices in the advance directive and only his nominated representative can decide on matters unspecified by him in such directive[4]. But, a point worth mentioning here is that such an advance directive shall not apply to the emergency treatment given to a psychiatric patient. This is a perfect way of balancing conflicting principles of bioethics. However, the scenario of mentally ill can't be applied on a general basis because there's a hell lot of difference between incapacity to consent and incompetence to consent.

The nature of express consent differs in the UK and the USA, being "real consent" in the former and "informed consent" in the latter. In the Samira Kohli case, valid or real consent was given preference to the informed consent. The judgment consciously preferred the "real consent" concept evolved in Bolam and Sidaway over the "informed consent" concept in Canterbury, referring to the Indian situation[5]. The unwilling patient if forced for surgery as in present case may sue the surgeon for battery and assault. However, the principle of emergency privilege may be a good defence for the surgeon considering the critical lifesaving necessity in our case. As it is rightly said, consent is a propositional attitude, so intransitive; complete wholly specific consent is an illusion [6]. It is very difficult to obtain informed consent in emergency settings.

If a person is conscious and refuses treatment without which that person might endanger his/her life, then the medical practitioner



can inform the jurisdictional magistrate and get the sovereign power of guardianship over persons under disability (*parens patriae*)[7]. In another case, even though consent was not taken, it was considered only as a technical lapse and doesn't constitute medical negligence in view of the emergent circumstances of the case [8].

The Law Commission of India in its 201<sup>st</sup> report has also recommended for enacting a statute on the lines of EMTALA (Emergency Medical Treatment and Labour Act) of the USA in our country. The draft legislation also proposed that failing to provide appropriate care to accident victims shall be made a criminal offence [9].

It is also to be noted that the Supreme Court of India has given a force of law to the "Good Samaritan" protection brought forward by the Ministry of Road Transport and Highways which clearly shows that courts consider saving the life is utmost priority of all of us and nobody should be penalized for that including a doctor acting in good faith [10].

#### **Recommendation:**

The best way out in the above described Mr. A's case is, hospital authorities moving the jurisdictional lower court for permission to proceed with amputation surgery to save the life of the patient. Unfortunately, hospital authorities have an inherent fear in moving courts. The court is a temple of society that will come to our rescue in times of need and none of us should undervalue its importance. As the subject matter concerns life of a citizen, courts respond within hours and issue a clearance. In all situations of dealing with consent related difficulties as in our case, a green channel should be established between the hospital authorities and the jurisdictional judicial magisterial courts. Precedents to this extent if established will save many lives.

#### **Conclusion:**

We can debate the ethicality, practicality,

legality and prudence of proceeding with surgery in situations like Mr. A's case at a later date only if the individual survives. Nothing will make sense in the aftermath of death of the individual. It is high time, institutional bioethics committees in hospitals should sensitize clinicians on the importance of consent related technicalities and guide them in times of need. A predefined standard operating procedure for situations arising with respect to different scenarios needs to be worked before hand.

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Perspective :

**Is pharmaceutical industry uncontrollable or not being controlled ?**

Dr. Yash Paul

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**Keyword:** Pharmaceutical Industry, Overseeing Authorities, deaths due to drugs.

**Abstract**

Diethylene glycol (DEG) is an industrial solvent, which is harmful to human beings resulting in harm and even deaths. In 1937 mass poisoning and deaths occurred in the United States. Following this incidence, changes were made regarding the working of the overseeing authority in 1938 with increased focus on safety of drugs and no such incidence has occurred in the United States since then.

First incidence of DEG death occurred in India in 1972 in Madras, subsequent incidences occurred in 1986, 1988, 1998 and 2019. In October 2022, 66 Gambian children and in December 2022, 18 children from Uzbekistan died due to DEG. The overseeing authorities in India failed to control this crime.

**Introduction**

Recently Indian Pharmaceutical Industry has been in the news for all the wrong reasons. Uzbekistan a country in Central Asia reported death of 18 children in December 2022. In October 2022, 66 Gambian kids were reported to have died following consumption of cough syrups made in India. These deaths occurred because of high quantity of diethylene glycol (DEG) and ethylene (EG) in cough syrups.

A report by the Indian Express dated February 26, 2020 titled 'Under scanner 11 deaths, 3400' bottles of cough syrup sold' stated "Between December 2019 and January 2020, at least 17 children experienced adverse effects in Ramnagar area of Udhampur district in Jammu region. Eleven of these children died from acute kidney failure."

The product under question was called COLDBEST a combination of Paracetamol, Phenylephrine Hydrochloride and Chlorpheniramine Malate manufactured by Digital Vision. The Regional Testing Laboratory, Chandigarh reported for three samples of same batch positive for 34.24% 34.97% and 35.87% of diethylene glycol (DEG).

Diethyleneglycol is a powerful industrial solvent. In India upper limit for its combination in medicines is 2.0%. Ideally it should be avoided. Was the COLDBEST syrup tragedy first incidence in India? Answer is No. The first incidence took place in Madras in 1972, killing 15 children after they had consumed a cough syrup called Pipmol C that had been adulterated with DEG. The second event took place in Mumbai in 1986 at the famous J.J. Hospital killing 14 patients after they consumed glycerine that had been adulterated with DEG. The third mass DEG poisoning took place in Bihar in 1988 killing 11 patients. The fourth event took place in Gurgaon, a district neighbouring Delhi, in 1998 when 33 children between the ages of two months and six years died after consuming a cough syrup adulterated with DEG. The event in Jammu in December 2019 was therefore the fifth such mass-poisoning event in India.

**Is DEG poisoning a recent phenomenon?**

DEG poisoning is a well-known and well-documented problem within the pharmaceutical industry since 1937, when the first mass DEG poisoning event took place in the United States.

The first batch of 'Elixir Sulfanilamide' entered the American market in October, 1937, and in a matter of a few days, doctors reported the death of six patients who consumed Massengill's drug.

Despite a frantic recall effort, a total of 105 patients, including 34 children were killed in the United States after consuming Massengill's cough syrup. (SE, Massengill of Bristol, Tennessee was the manufacturer of the above mentioned drug). An additional "Victim" was the Chief Chemist at Massengill who killed himself while awaiting a trial before the court of law, for his role in the incidents. The deaths of those patients provoked an overhaul of the Federal Food, Drug and Cosmetics Act in 1938 with an increased focus on safety. The United States has never experienced another mass DEG poisoning event after 1937.

It would help to understand the problems associated with bad drugs and pharmaceutical industry by having a look at brief history of pharmaceutical industry and Regulatory agencies. British brought modern (allopathic) medicines in India. At that time drugs were imported from England. Substandard drugs were found during 1920s in India.

Example of Quinine for treatment of malaria is being cited here. Quinine was imported. It was found that Quinine bisulphate contained 3.5 grains of chalk, 1 grain of alum or some other substance to lend taste, thus had only 1 grain or less of the required ingredient of 5 grains.

Sir Haroon Jaffer (1881-1930) a legislator from Bombay Presidency had moved a resolution on the 9<sup>th</sup> March 1927, before the Council of States to regulate standardisation of the drugs. Major General T.H. Symons who was then the Director General of the Indian Medical Services firmly supported the resolution.

The United States had enacted laws to regulate the manufacture and sale of medicinal drugs: The Biological Control Act 1902. The British enacted Therapeutic Substances Act 1925. But the British Government was not interested to introduce any such measure in India. Although there were many voices in favour of introducing such laws there were also voices against such Act.

Bengal Chemicals & Pharmaceuticals Limited was established in 1901 by Acharya Prafulla Chandra Ray. The Indian Medical Association (IMA) was formed in year 1928. Many stakeholders and Indian Medical Association had the perception that regulatory laws would aim at local pharmaceutical houses so were opposed to bring such laws.

On 29<sup>th</sup> March 1931 the Drug Inquiry Committee recommended that a Drug Control Legislation be enacted for India, was established in 1940, known as the Drug Act 1940. The sad reality is that Drug Regulatory Authorities have failed to regulate the pharmaceutical industry.

On its part the pharmaceutical industry plays victim card that Multi National Corporations (MNCs) make allegations against Indian Pharmaceutical Industry to check its progress for their own benefits

In India we have three Regulatory Authorities for pharmaceutical industry :

**1. Licencing Authority-** Drug Controller General of India (DCGI) and State Drug Controllers (SDCs).

The author cites three combination formulations having different quantities of the ingredients all can not be right combinations.

- A. Ofloxacin and Tinidazole in Table no 1.
- B. Amoxicillin and Clavulanic Acid in Table no. 2.
- C. Doses of Cefixime and Ofloxacin in children are 4mg/kg BD and 7.5mg/kg BD respectively. Pediatric formulations of these combinations contain equal quantity of both salts.

**2. Quality Controlling Authority-** Central Drugs Standard Control Organization (CDSCO). Quality control of drugs in India needs no comments.

**3. Price Regulatory Authority-** National Pharmaceutical Pricing Authority (NPPA). The author cites here three examples of similar drug formulation having different MRPs.

- A. Cefexime Tablets 200mg.10 Tablets MRP Rs. 89.00 to Rs. 106.96.
- B. Paracetamol 500mg Tablets MRP Rs.9:30 to Rs.15.00 for 10 tablets.
- C. Azithromycin 500mg Tablets. MRP Rs.56.00 to Rs. 78.00 for three tablets.

Germany prepared a drug called Thalidomide as sedative, tranquilizer and to control nausea in general and during pregnancy. It was used in 46 countries resulting in about 10,000 babies born with phocomelia and other defects and about 10,000 abortions.

**Table No 1. OFLOXACIN AND TINDAZOLE COMBINATIONS**

Manufacturer	Form	Brand Name	OFLOXACIN	TINIDAZOLE
CIPLA	Tablet	OFLOX-TZ	200mg	600mg
MERCK	Tablet	HARPOON TZ	400mg	600mg
NORDIC	Tablet	OFLO-TZ	200mg	300mg
CIPLA	Syrup	OFLOX-TZ	50mg	150mg
ZEE LAB	Syrup	ZEVID-TZ	50mg	100mg

Adult Dose OFLOXACIN 400 mg, TINIDAZOLE 2 gm per day.

**Table No. 2 AMOXICILLIN AND CLAVULANIC ACID COMBINATIONS**

Manufacturer	Form	Brand Name	AMOXICILLIN	CLAVULANIC ACID
MACLEODS ACUPHAR	Tablet	ACUCLAV	500mg	125mg
MACLEODS ACUPHAR	Tablet	ACULAV TAB	875mg	125mg
MACLEODS ACUPHAR	Tablet	ACUVLAV TAB	250mg	125mg

Source: CIMS Therapeutic Index: Jan-Mar.2022.

It would be imperative to mention here 'Thalidomide Tragedy' which occurred worldwide during late 1950s and early 1960s. In 1950s a German Pharmaceutical House called Chemic Grunethal Gmb Hi West-

In 1960 Dr. William Griffith Mc Bride an Australian Obstetrician began to associate use of Thalidomide during pregnancy with phocomelia and published a Letter in the Medical journal 'Lancet' in December 1961,



pointing out link between Thalidomide use and birth defects . At the same time a German doctor Widukind Lenz also raised this issue.

It took five years for the connection between Thalidomide and phocomelia to be established. Credit for this goes to Dr. Frances Oldham Kelsey, Candaian born American Pharmacologist and Physician. In 1960 the Cincinnati manufacturer Wilam S. Merret applied to the Food and Drug Administration (FDA) of the United States to sell Thalidomide by brand name 'Kevadon'. Dr Kelsey who was working with FDA was assigned the job. Dr. Kelsey sought some details regarding the drug, including its effects and side effects from the company officials, but they refused to answer. On the other hand, they complained to her superiors to pressurise her to approve the drug, but she refused.

In the United states only 17 babies were affected by Thalidomide due to free samples of the drug provided to the doctors because of heroic and diligent work of Dr. Kelsey.

In the 2019 published book titled 'Bottle of Lies', the author Katherine Eban states on page XV: “As one Ranbaxy staffer told the company

executive Dinesh Thakur before he became a whistle blower, testing the drugs for India was just a waste of time because no regulators ever look at the data. What was needed to get approval from the Drug Controller General of India was not real data, but good connections, the man explained”.

In year 2013 in an article titled 'Need for safe and doctor friendly drug formulation' the author had stated: “It appears that safety of patients has taken a back seat. Question arises: What is the role and necessity of Drug Controller General of India? A patient takes a drug prescribed by a doctor because patient has full faith in the treating doctor knowing that a doctor would abide by the cardinal principle of medical profession 'cause no harm.' A doctor prescribes drug believing that any drug which has been licensed must be safe and approved. Is it a misplaced trust ?[1]

Question arises: Is pharmaceutical industry uncontrollable or not being controlled ?

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## **Medicolegal News**

**Compiled by : Dr. Santosh Pande**

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### **Negligence In Care Of Diabetic Patient: NCDRC Upholds Rs 10 Lakh Compensation To Patient Whose Fingers Got Amputated Due To Gangrene**

**New Delhi:** Opining that there was failure of duty of care, the National Consumer Disputes Redressal Commission (NCDRC) recently upheld the State Commission order holding Mata Chanan Devi Hospital guilty of negligence while providing treatment to the patient.

During the treatment, the patient developed gangrene in her hand during the ICU stay at the treating hospital and she later had to get the fingers of her hand amputated at Apollo Hospital. While considering the matter, the NCDRC bench has upheld the Rs 10 lakh compensation awarded by the State Commission.

The matter goes back to 2001, when the Complainant, who suffered vomiting and general malaise, had been admitted to Mata Chanan Devi Hospital. There, Dr Jain had examined her. It was alleged in the complaint that despite informing Dr Jain about her diabetic status for the last 4-5 years, the doctor had allegedly advised to put the patient on glucose drip instead of saline.

Thereafter, her condition deteriorated and the doctor maintained silence when he had been questioned why the patient had been given glucose. Soon after, the blood glucose level shoot up to 465% and the patient became pale. Allegedly the doctor did not make any attempt for reducing the blood sugar.

After 1 hour, at about 2.00 pm, the patient had been shifted to ICCU. X-ray chest had been taken and it showed features of broncho-pneumonia. The patient suffered respiratory arrest, she was intubated and put on ventilator.

Meanwhile, Dr Chhabra visited the patient and advised Dr Jain to tie up the hands of the patient with the bandage to the fence of the bed to avoid pulling of urinary tube. It was alleged that the hands of the patient had been tied to the bed from 2.00pm till next early morning and it led to swelling and impaired circulation in hands. It resulted in to gangrene of the left hand and the fingertip of the left hand allegedly turned bluish purple, the fingers became stiff and had no life.

Allegedly, the doctors delayed to examine her cyanosed left hand and the patient became very weak and drowsy. Since there were no Super Specialists available in the hospital and the condition of the patient deteriorated further, she had been shifted to Apollo Hospital. At Apollo, the clinical notes mentioned that there was gangrene of the left hand up to the left wrist possibly as a result of long term compression of blood flow, because of venous edema.

After shifting the patient from the ICCU to private ward, Dr Chacko, the senior Vascular Surgeon had advised 10 days of treatment of gangrene by hyperbaric oxygen therapy, which was very expensive. Therefore, the fingers of the left hand had to be amputated.

Being aggrieved by the medical negligence of the doctors of Mata Chanan Devi Hospital, the Complainant approached the State Commission, Delhi.

On the other hand, the hospital denied any negligence during the treatment of the patient and it was submitted that the patient had come to the hospital in a very critical stage and stayed in the hospital for less than 24 hours, without giving reasonable time for the treatment. However, she stayed in Apollo Hospital for 2 weeks and

amputation was done after 20 days of her leaving the Mata Chanan Devi Hospital.

While considering the matter, the State Commission allowed the Complaint with a direction to the hospital to pay Rs 10 lakh as compensation along with interest @9% per annum. In addition, the State Commission had also sent a copy of the Order to the Medical Council of India for initiating proper action against Dr Jain and Dr Chhabra.

Both the Hospital and the Complainant approached the NCDRC bench challenging the State Commission order. While the Complainant prayed for an enhancement of compensation to Rs 50 lakh, the Hospital prayed for setting aside the order.

After perusing the Medical Record, the top consumer court referred to the issue of development of gangrene of fingers of left hand and noted, "it is pertinent to note that the Complainant's husband Mr. Vinod Kumar, in his affidavit of evidence, stated that at the time of discharge, Dr. Sudhir Chhabra at OP hospital did not disclose that the patient was suffering from gangrene because of wrong instructions i.e. tying of hand. Even the Medical Superintendent Dr. Kochhar was also reluctant to allow the patient to go to Apollo Hospital as it would have exposed their wrong treatment and gross negligence. This evidence was not rebutted by the OP hospital."

Further referring to the fact that the Complainant took LAMA discharge and admitted his wife in the Apollo Hospital the NCDRC bench also observed, "The doctors of OP have not issued discharge summary, which is a deficiency on the part of the OP Hospital. The OP Hospital did not issue the discharge certificate at the time of referring to the Apollo Hospital."

The bench also referred to the discharge summary of the Apollo Hospital, New Delhi and

noted that one of the diagnoses made was "ischemic necrosis – left hand".

Noting that during hospitalisation, she had also been examined by respiratory consultant, endocrinologist and vascular surgeon, the top consumer court observed that it was also recorded that "she on admission was also found to have gangrene of left hand possibly as a result of long term compression of blood flow because of venous edema."

"On bare reading of the findings of Apollo Hospital, the inference can be drawn that the gangrene was developed due to tight tying of the hands gangrene in whole night on 29.04.2001. It went unnoticed and unmonitored throughout the night by the ICU staff, it amounts to failure of duty of care. The higher duty of care was expected from the ICU staff as such the instant patient was critical," noted the Apex Consumer Court."

Holding the hospital guilty, the bench further observed, "Considering the entirety of the case, the patient was a known case of diabetes mellitus (NIDDM) and was admitted in OP hospital on 29.03.2001 and got discharged LAMA on the next day. She stayed there for 24 hours only. During that period, her condition was critical due to highly diabetic status. I don't accept the contention of the Complainant that the doctors have not taken steps to reduce the blood sugar of the patient is not acceptable. From the medical record, it is evident that proper doses of insulin were given and the doctors efficiently managed the critical condition of the patient. However, she developed gangrene of fingers in left hand during her ICU stay. The possibility of such gangrene was due to compromised state of the patient (diabetic, ketones and generalized infection - septicemia). But the evidence of patient's husband about tying the hands cannot be brushed aside. It was the onus upon the OP to explain the cause of gangrene, but

failed to prove."

"Based on the discussion above, I find there was failure of duty of care from the ICU staff in the OP hospital. The Order of the State Commission is reasoned and awarded just and adequate compensation to the Complainant. I do not find any reason to enhance the compensation," it added.

**Ref.:** <https://medicaldialogues.in/news/health/medico-legal/negligence-in-care-of-diabetic-patient-ncdrc-upholds-rs-10-lakh-compensation-to-patient-whose-fingers-got-amputated-due-to-gangrene-107346> Accessed on 25/02/2023

### **Orthopedic Surgeon Guilty Of Medical Negligence, Liable To Pay Rs 15 Lakh Compensation: Consumer Forum**

**Nagpur:** Holding medical negligence by an orthopaedic surgeon during fracture surgery, the Nagpur-based Disputes Consumer Redressal Forum has granted compensation of Rs 15 lakh to a patient.

The patient filed a plea before the Forum asking for compensation of Rs 20 lakhs against the orthopaedic surgeon and the insurance company, which indemnified the doctor during treatment, alleging that the surgeon was negligent in discharging his duties.

The case goes back to the year 2012 when the patient who was a mason by profession met with an accident and received a fracture injury on his right leg. He, therefore, approached Hirachand Munot Criticare Hospital where he was admitted from 15<sup>th</sup> Feb to 4<sup>th</sup> March 2012.

It was submitted in the plea that the patient got operated on 20<sup>th</sup> Feb and 24<sup>th</sup> Feb 2012 for compound fracture shaft tibia right side with fracture left side and later underwent another surgery on 11<sup>th</sup> Nov 2012 but could not get any relief. Later, he again went to the orthopedic surgeon for consultation and was operated for the fourth time on 11<sup>th</sup> March 2013 for non-union

subtrochanteric fracture femur right side.

Even after four repeated surgeries when the patient did not recover well, he sent a legal notice to the orthopedic surgeon on 9th April 2015 which was replied to by the doctor on 17th April 2015.

Left with no choice, the patient approached Consumer Forum and filed a plea for compensation for the damages caused to him due to medical negligence. The patient submitted in his plea that he had spent a sum of Rs 5 lakh as medical expenses for his treatment and was a mason by profession but because of the said operation he could not do his livelihood work and sustained a huge loss.

Responding to the plea, the Counsel for the surgeon and the insurance company denied the allegations of medical negligence. It was submitted that the patient was operated on with all care and caution and guidelines of anatomy and the regeneration of the bones and the recovery of each person depends upon the health of that patient.

It was also alleged by the opposite Counsel that the patient was facing anemia and was a chronic alcoholic and that there could be a possibility that he did not follow day-to-day advice given to him by the Orthopedician or might have just slipped in the house.

It was stated that the Orthopedic Surgeon was not responsible for the pain of the patient and the matter was also referred to the medical board, Nagpur who had clearly opined that the fracture injury of the patient was cured and there was no negligence on the part of the Orthopedic Surgeon.

Hence, the Opposite Counsels requested the Forum to dismiss the plea filed by the patient. Hearing both sides, the forum noted down that the defence taken by the Counsel for the Orthopedic Surgeon being a chronic alcoholic was not accepted and it was held that the Orthopedic Surgeon conducted four surgeries one after the



other while the fracture had not healed.

The Forum made a conclusion that the surgeon was negligent and was trying to resile from his responsibility and that right before the fourth surgery the X-Ray of the patient showed that the fixation screw was broken.

The Forum was of the opinion that the patient at the time of the operation was 35 years old with no ailment and at that age, the healing rate of any patient is higher than other patients and that it was a blunder mistake by the Orthopaedic Surgeon. "On either account, we hold that it was blunder mistake of Opponent-Doctor by leaving the patient in pain. When the screw of the operations was broken then nobody other than the Opponent seems responsible. We don't find any impediment on the part of Complainant in healing that the fracture injury. In these circumstances we hold that because of negligence of the Opponent-Doctor, the Complainant suffered mental agony and pain for life. It has deprived the Complainant to do his day to day business and livelihood. Ultimately we hold compensation is required to be fastened on the Opponent no 1. However the Opponent no 2 insurance company has indemnified profession of the Opponent no 1. Hence it would be the joint responsibility of the both the Opponents to pay the compensation."

Hence, the Forum held the Orthopaedic Surgeon negligent and was of the view that the opinion of the medical board was in an attempt to protect him. Therefore, it was ordered that the patient was allowed the compensation for the medical expenses, loss of livelihood work, and mental agony of Rs 15 lakhs jointly by the Orthopaedic Surgeon and the insurance company as he was indemnified by the company during the course of treatment of the patient. "After considering all the facts, circumstances and available evidence on record, we hold that the

Complainant has established the fact that the opponent doctor was negligent in performing his duties. Therefore the compensation of Rs.10/- lakh towards compensation and Rs.5/- lakh towards medical expenses can be fastened on both the opponents. In view complaint deserves to be allowed".

**Ref.:** <https://medicaldialogues.in/news/health/medico-legal/orthopedic-surgeon-guilty-of-medical-negligence-liable-to-pay-rs-15-lakh-compensation-consumer-forum-108179> Accessed on 13/03/2023

**Broken Needle Left Inside Patient During Episiotomy: Commission Directs MGMRI To Pay Rs 12.25 Lakh Compensation.**

**Cuddalore:** Observing that entering into an agreement for free treatment after causing injury to the patient, will in no way alter or change the liability on the hospital and their team of doctors, the District Consumer Disputes Redressal Commission (DCDRC) has directed the Mahatma Gandhi Medical College and Research Institute (MGMCRI) to pay Rs 12 lakh as compensation for alleged medical negligence while performing an episiotomy.

Besides, a sum of Rs 25,000 was also awarded by the forum to the Complainant as legal expenses. The Commission headed by president and Judge D. Gopinath held the hospital liable for unfair trade practices and medical negligence leading to deficiency in services.

The case concerned a 36-year old woman of Cuddalore who gave birth to a baby boy on December 11, 2016 in the private medical college hospital in Puducherry. In her petition, the Complainant Santhi, registered that the broken part of a needle was left inside her body after an episiotomy was done on her at the time of her delivery by a team headed by a gynaecologist in MGMCH & RI.

Thereafter, citing some complications, the baby was moved to an intensive care unit and the woman and family members were allegedly barred from seeing the baby. On December 13, 2016, an x-ray report revealed that a part of the needle, which was broken, was nestled in the woman's perineum. The hospital doctors tried to remove the needle but in vain. Later, they informed the petitioner that they will operate and remove the needle after three months.

As per various media accounts, the hospital authorities while discharging the Complainant also executed an agreement with her family that they will provide free treatment and medical expenses at the hospital for removing the needle and if any pain or discomfort arises to the Complainant, she could approach them for free treatment and management.

Aggrieved, the petitioner filed a complaint before the DCDRC in Cuddalore. On the other hand, the hospital in its submission held that it was only an accident and not an act of negligence.

MGMCH & RI, while admitting that a small part of the needle was lodged in the perineum of the woman, said the needle was not traceable during the subsequent surgery due to inflammation in the area. The surgical team decided to leave the piece of needle temporarily to avoid more damage to the reproductive organs. The hospital, which claimed that the patient and relatives were explained about the situation, said the issue could be sorted out only after a period of three months.

The Commission noted that a doctor has the 'duty of care' while treating his patients, and if any injury happens to the patient during treatment, it is the duty of the doctor to explain how the injury happened. However, in the instant case the hospital has not explained how the injury occurred and has not produced any medical records, the forum added. The Commission also held that entering into

an agreement for free treatment after causing injury to the patient, will in no way alter or change the liability on the hospital and their team of doctors.

Consequently, the Commission directed the hospital to pay Rs 12.25 lakh in compensation for medical negligence, unfair trade practices, and for causing pain, suffering, and mental agony to the Complainant.

**Ref.:** <https://medicaldialogues.in/news/health/medico-legal/broken-needle-left-inside-patient-during-episiotomy-commission-directs-mgmri-to-pay-rs-1225-lakh-compensation-108339>  
Accessed on 15/03/2023

### **Surgeon, UP Hospital Told To Pay Rs 50 Lakh Compensation Over Wrong Diagnosis, Treatment Of Breast Cancer Patient.**

**Lucknow:** Holding that there was negligence at the primitive level, the State Consumer Disputes Redressal Commission, Uttar Pradesh has directed Kamla Nehru Memorial Hospital in Prayagraj to pay a fine of Rs 50 lakh to the kin of a breast cancer patient who eventually died due to alleged wrong diagnosis and treatment.

Commission members justice Rajendra Singh, and justice Sushil Kumar observed that the concerned doctor failed to diagnose the breast cancer and due to his negligence and carelessness, medicines were given for another disease (Filaria) for a long time. Meanwhile, the cancer cells continued to increase which ultimately caused the death of the patient.

The case is that, in 2012, a patient Geeta Devi Dwivedi along with her husband with complain of a very small lump under the left armpit and inside the left breast with a little bit of pain visited the doctor who is a general surgeon in the said hospital. As advised by the doctor, Ultrasound and Mammography of both the breast of the patient was done. The doctor diagnosed the lump as disease of filaria and started the treatment of filaria

and prescribed medicines for 21 days and asked the patient to visit after 21 days.

The condition of the patient started deteriorating and the pain in the lump increased and redness and swelling spread in the left breast with inflammation in the left breast. The patient again visited the doctor, however, he repeated the same medicine for next one month.

Within a week, the condition of patient became worse and blackness, hardness and swelling spread in the right breast also and swelling and pain in both the breast was continuously increasing. Once again, the doctor repeated the same medicines for next seven days.

The deteriorating condition of patient and unbearable pain in both the breast made Complainant and patient apprehensive about the treatment given by the doctor and they consulted Dr. H.S. Shukla, Cancer Specialist at Sir Sunder Lal Chikitsalay, Kashi Hindu Vishwavidyalay, Varanasi and showed him all the prescriptions.

After preliminary examination, the patient was advised to visit Tata Memorial Hospital at Mumbai immediately. At Tata Memorial Hospital, after conducting various tests breast cancer in the last stage was diagnosed by the doctors. It was also informed by the doctor at Tata Memorial Hospital that the cancer has spread to other parts of the body also like in liver, heart, lungs and bones of hands and legs.

Thereafter, chemotherapy was started, however, after fifth chemotherapy condition of patient became worse and she finally died in 2013. Accusing the hospital management of neglect, the kin of the deceased lodged a complaint with the commission in 2015. They sought monetary relief amounting to total Rs.5,610,000/- for various heads.

It was submitted that the lump growth was cancerous in July, 2012 when patient had first

visited the doctor but due to wrong diagnosis and treatment of the doctor and radiologist, the patient suffered and her disease became incurable. Further, the doctor has committed gross negligence by overlooking deteriorating condition of the patient.

"The law expects a duly qualified doctor to use that degree of skill and care which an average man of his qualifications ought to have and in this case the doctor and the hospital failed to do so. The conduct of the doctor and the hospital, clearly reflects that they had been negligent and ignorant from the very beginning. The hospital and the doctor did not take proper care in diagnosis of the lump even when it was spreading all over the breast and failed to bring to their task a reasonable degree of skill and knowledge," the complainants added.

On the other hand, the hospital and the doctor filed their written statement stating that there was no medical negligence or deficiency in service on their part.

Perusing all the pleadings, evidences, arguments and documents on record the Commission firstly observed that the medicines prescribed were tablet Banocide forte, Levoflox 750 mg, Cap Cobadex forte and Tab Tramadol 50mg. However, none of these medicines were for breast cancer but for Filaria. It is clear that till 17 September 2012 the concerned doctor was treating the patient as if she's a patient of Filaria but not of breast cancer, the court concluded.

The Commission further noted that; "In the instant case the report of Mammography was there and inspite of it the concerned doctor failed to diagnose the breast cancer and at that time it was not very serious and may be cured but due to his negligence and carelessness, medicines were given for other disease for a long time and during this period the cancer cells continue to increase and they also spread other breast and other parts of the body which ultimately caused the death of the patient."

Opining that the instant case comes under the maxim *res ipsa loquitur*, the Commission observed that; "Opposite party – 1(Hospital) and 2(Doctor) were careless in the treatment of the patient who ultimately died of breast cancer on 08.05.2013 just at the age of 44 years. We have discussed the Mammography in the very beginning and this report clearly indicated the possibility of breast cancer but the concerned Dr did not go forward for breast cancer and he took it very lightly presuming it to be a disease of Filaria . From so many dates he never came to understand the problem of the patient and wrote prescription in a stereotype manner without going to the root of the disease. Here circumstances speak themselves that the doctor was careless in toto."

It added, "The primary responsibility of a doctor is to ensure they can provide their patients with the best level of care. A talented doctor can perform these tasks efficiently while practising a range of soft skills, such as effective communication. When considering a career in medicine, it may be helpful to know the basic duties a doctor performs daily."

The court further remarked; "In this case, the doctor has said that if the Complainant had any interest from the very beginning or they had lost faith in him at any point of time during their visits, as mentioned in the complaint, they could have consulted any other doctor. The Complainant has stated these words when he came to know that his wife was suffering from breast cancer and the treatment was given that is of Filaria , thereafter he reiterated these words. But opposite party – 2 is a doctor and it was his primary responsibility to satisfy the patient and if he found that the medicines were not responding well and as per the report of Mammography, there might be some chance of breast cancer, he would have referred the patient to the oncologist for his opinion but he did

not do so. The patient has faith in Dr and he visited the doctor again and again on the advice of the doctor. When the doctor has asked him to come after some date for follow-up checkup, he must come for follow-up checkup but when ultimately he believes that there is no improvement in the health of his wife, he will take any other recourse for further treatment. But it is the doctor whose primary responsibility is to satisfy fully the patient who has come before him. As per tests and reports of Ultrasound and Mammography, there was indication of cancer because the size of the lymph node et cetera indicate the possibility of cancer and the matter is related to the breast and as we know breast cancer is very common so it was the duty of the concerned Dr to take the opinion of oncologist at the earliest in which he failed totally."

After going and considering all the facts and circumstances of the case, the consumer body noted; "It shows that there was negligence at the primitive level. So the first responsibility was opposite parties – 1(Hospital) and 2(Doctor) to examine the patient with great care and caution and it should have been referred to oncologist for the confirmation of breast cancer which they did not to or in other words they did not discharge their duty with responsibility and loyalty. The doctor is responsible for showing negligence and carelessness and the hospital is vicariously liable for the acts and omissions of the doctor. Thus opposite parties – one and two are responsible for showing evidence towards the patient. Opposite party – 3(Radiologist) has no role in negligence or carelessness because he is radiologist and he performed his duty and submitted the report to the concerned Dr/patient."

Subsequently, the Commission directed the hospital and the doctor to pay Rs.50 lakhs to the Complainant towards cost of medical expenses, mental agony, physical pain, depression and



harassment, loss of income and companionship, cost of litigation with interest. It held; "It is clear that negligence has shown by the doctor, we are of the view that Complainant is entitled for total compensation of Rs.50 lakhs with interest at a rate of 10% per annum from 07.08.2012 payable within 45 days from the date of judgment of this complaint otherwise the rate of interest shall be 15% per annum payable from 07.08.2012 till the date of actual payment. The complaint case is decided accordingly."

**Ref.:** <https://medicaldialogues.in/news/health/medico-legal/surgeon-up-hospital-told-to-pay-rs-50-compensation-over-wrong-diagnosis-treatment-of-breast-cancer-patient-108531>  
Accessed on 20/03/2023

**Delay In Cesarean Delivery: NCDRC Upholds State Commission Order, Doctor Liable To Pay Rs 3 Lakh Compensation For Negligence**

**New Delhi:** Observing that the doctor did not attend to the patient immediately when she was in severe labour pains but the patient was left in the hands of assistants who were neither qualified nor trained, the apex consumer court bench recently upheld the District and State Consumer Commission's order holding the doctor of guilty of negligence for the delay in performing the cesarean delivery.

The National Consumer Disputes Redressal Commission (NCDRC) has dismissed the revision petition of a UP-based doctor, who was directed to pay Rs 3 lakh to the Complainant after being held negligent by a district forum. Presiding Member S M Kantikar heard the appeal of a doctor of a Nursing home based in Lakhimpur Kheri in Uttar Pradesh.

The case is that of a patient who was admitted to the doctor's nursing home and her condition deteriorated during delivery. It has been alleged by the patient that the doctor did not respond and instead told her assistants not to disturb her.

The patient claimed that her condition continued to deteriorate, following which the doctor "eventually" came to the labour room, and thus because of delay and negligence on the part of the doctor and her assistants, the child born was dead and there was the injury to her uterus during the cesarian operation.

Thereafter, the Complainant's husband filed an FIR under Sections 316, 326 of IPC against the OP. Further being aggrieved, the patient filed the Complaint before the District Forum, Lakhimpur. Countering the allegations and denying any negligence, the doctor said she had performed a caesarian operation only after the patient's written consent and there was no damage to the patient's uterus. The operation was successful, but unfortunately, the child could not be saved.

The doctor submitted that no fees were charged due to a good relationship and trust between the Complainant from the past and her elder brother-in-law who promised to make the payment later on, but he failed. The doctor further denied any involvement of her maid-servant or assistant during the delivery. She also denied that her ureter was damaged during the operation and as a result urine was leaking continuously.

After discharge from the nursing home, the patient did not come for follow-up and the complaint was filed with a "bad intention to defame the doctor and nursing home", the doctor argued.

In its order, the District Consumer Disputes Redressal Forum, Lakhimpur held the doctor negligent and directed her to pay a compensation of Rs 3 lakh, along with Rs 15,000 as litigation cost. Against the district consumer forum order, the doctor filed the first appeal before the State Consumer Disputes Redressal Commission in Lucknow, which dismissed the petition, saying she had committed deficiency in service and there was no scope for any intervention.

The Order of the District Forum was affirmed by the state commission with the following observation:-

“From the entire facts of the case, it is evident that in case of the Appellant/Opposite Party conducting delivery without the help of any trained or untrained nurse and without any nurse, then she committed gross negligence and she carried out operation in the morning of 14.01.2004 hurriedly without finding out in time the status of the child and from these we find that in the instant case the Opposite Party No. 1/Appellant has committed deficiency in service and we find that the Judgment and Order passed by the District Consumer Forum against the Opposite Party No. 1/Appellant in this regard is legally sustainable and there is no scope for any intervention. The appeal filed by the Appellant deserves to be dismissed.”

Aggrieved with the State Commission order, the doctor then moved to the NCDRC, where her advocate argued that the patient had failed to produce any evidence of negligence and that the State Commission did not rely upon the medical literature filed by the doctor about the risks of ureteral injury during obstetric and gynaecological operations.

The Counsel further argued that an unfortunate incident or death did not necessarily amount to negligence and the award of compensation was excessive. However, the Counsel appearing on behalf of the patient argued that the doctor was negligent and performed the operation hastily and negligently, thus resulting in the loss of her child and causing damage to the urinary tract.

He further argued that the doctor's negligence was the sole cause of the Complainant's suffering and that if the doctor had fulfilled her duties properly, the Complainant would have been able to have a child and live a happy life without the

need for costly medical treatment.

In conclusion, the top consumer court found the revision petition filed by the doctor devoid of merit and juked the plea. “Considering the evidence on record and the entirety of the facts in my view, there was a failure of duty of care from the opposite party 1 (the doctor). She did not attend to the patient immediately when she was in severe labour pain...the patient was left in the hands of (her) assistants, who were neither qualified nor trained and the caesarian operation was performed hurriedly at delayed stage which was the cause of foetal death,” the honourable presiding member observed.”

In the instant case, both the Fora have given concurrent findings on the facts and there is no error apparent to interfere in the reasoned orders under the revisional jurisdiction of this Commission under Section 21 of the Act, 1986. The revision petition, being misconceived and devoid of merit and is dismissed,” he added.

**Ref:** <https://medicaldialogues.in/news/health/medico-legal/delay-in-caesarean-delivery-ncdrc-upholds-state-commission-order-doctor-liable-to-pay-rs-3-lakh-compensation-for-negligence-108981?infinitescroll=1> Accessed on 24/03 2023  
**NCDRC Holds No Medical Negligence, Relief Of Rs 17 Lakh To Orthopaedic Surgeon, Nursing Home**

**New Delhi:** The National Consumer Disputes Redressal Commission (NCDRC) recently exonerated a Bengal based Orthopaedic Surgeon and Nursing home from charges of medical negligence while treating the femur fracture of a patient.

Previously District Consumer Court, Hooghly and the State Consumer Court had held the doctor and the clinic guilty of medical negligence while providing treatment to the patient, who ultimately died undergoing treatment

at CMC Vellore. They had been told to pay Rs 17, 91,000 as compensation to the wife and children of the deceased patient.

However, while considering the matter, the NCDRC bench opined that the "State Commission has failed to appreciate the facts and medical record. The opinion of expert committee and treatment done by OP-1 was as per the reasonable standard of Orthopedic Practice. The aneurysm of Profunda Femoris is rare and incidental finding revealed post operatively. It has no nexus with the act of OP-1."

The matter goes back to 2005 when the husband of the Complainant had sustained fracture of right femur and was operated by Dr Bhaskar Das at Bagbazar Nursing Home. The patient was discharged after four days with an advice to review after six weeks. Thereafter, the patient had blood stained serious discharge from the operative site.

So, the doctor advised the patient for regular dressing at a nearby clinic. Regular dressing was done for almost fifteen days. Ball bandage was put but the patient was continuously dislodging dressing. One unit of blood was transfused to correct anemia.

After this, the patient telephonically informed the treating doctor that there was sudden bleeding from the operated area and therefore fresh dressing was done and the patient was again admitted to the clinic where exploration of wound was done under general anesthesia and the patient was discharged on the same day.

However, there was bleeding again from the wound and the patient was advised to get admitted to the Nursing Home, where the patient was diagnosed as secondary hemorrhage. Two units of blood were transfused, however, again fresh bleeding was seen and fresh sutures were put.

Following this, the treating doctor consulted a senior Orthopaedic Surgeon at Kolkata and

decided to shift the patient to Kolkata. Accordingly, the patient was admitted in M.B. Nursing Home at Kolkata under Dr Indrajit Sardar, who diagnosed it as a secondary hemorrhage and three units of blood were transfused that the OT was fixed for debridement on the next date.

However, the patient took discharge and approached CMC Vellore for further management. However, during treatment, the patient expired in November 2005. Aggrieved by the alleged negligence during the treatment at the treating nursing home, the wife and minor children of the patient filed the complaint before the District Forum.

Holding negligence against the doctor and the nursing home, the District Forum had directed them to pay Rs 17, 91,000 to Complainants and this order was affirmed by the State Commission. Following this, the doctor and the nursing home, approached the NCDRC bench.

Meanwhile, during the proceedings before the District Forum, the treating doctor, Dr Das had approached West Bengal Orthopaedic Association for seeking expert opinion. Consequently, an expert committee was formed with four Senior Orthopedic Surgeons, who referred to the fact that an angiogram done at Vellore revealed that the rare condition of an aneurysm of profunda femoris artery. The aneurysm was excised & the bleeding was controlled. Unfortunately, the patient died.

Referring to this, the Expert Committee opined, "In our opinion the development of an aneurysm of profunda femoris is an extremely rare occurrence. Naturally it does not come in the mind of a surgeon."

It had further observed that Dr Das, the treating doctor "...took adequate care in treating this patient and there was no professional negligence on his part. In fact if the patient's party had followed the expert opinion of Dr. Indrajit

Sardar, the aneurysm could have been detected earlier and treated properly by a vascular surgeon with fair chance of his survival."

While considering the matter, the apex consumer court perused the entire medical record of the nursing home and the clinic and noted, "As there was repeated bleeding at the operated site, therefore OP-1 suspected it secondary hemorrhage and therefore, referred the patient to MB Nursing Home at Kolkota under care of Dr. Indrajit Sardar for further management."

Referring to the medical record and death summary issued at CMC Vellore, the NCDRC bench noted that Angiogram of the common femoral artery had been performed at CMC. "It showed pseudo-aneurysm (26 x 25 mm) arising from right Profunda Femoris artery with narrow neck. The patient was treated with embolization procedure. The complete occlusion of the pseudo aneurysm was achieved with 3 steel coils x proximal right Profunda Femoris followed by injection gelfoam. The wound debridement and the bedsores were also treated. Thereafter, the patient was transferred under plastic surgery for further care. However, on 30.11.2005 at 11.30 am, the patient suffered respiratory arrest, which could not be revived and he expired," noted the bench.

While considering the question if the act of the treating doctor constituted medical negligence, the Commission noted, "Firstly, the OP-1 performed ORIF with DHS for fracture of Rt trochanter. It was the correct line of treatment, the operation was uneventful. I do not find any negligence or deviation from the standard of practice of the OP-1. It is evident that patient had anxiety disorder and repeatedly tampering with the dressing. The regular dressing of surgical wound was performed, but the bleeding from the wound was seen, therefore OP-1 referred the patient to

Dr.Indrajit Sardar. In my view the referral was correct and made at appropriate time."

The bench further addressed the question whether there was any nexus between the surgery performed by the doctor and the aneurysm of right Profunda Femoris artery. At this outset, the bench referred the Campbell's Orthopedics and few articles on the subject which stated about very unusual and rare incidence of aneurysm of Profunda Femoris artery.

Referring to the articles, the bench observed, "Based on the discussion the District Forum as well as the State Commission has failed to appreciate the facts and medical record. The opinion of expert committee and treatment done by OP-1 was as per the reasonable standard of Orthopedic Practice. The aneurysm of Profunda Femoris is rare and incidental finding revealed post operatively. It has no nexus with the act of OP-1. The CMC Vellore also did not give any findings or negligence caused by the OP-1 while operating the patient."

Exonerating the doctor, nursing home and the clinic from the charges of medical negligence, the Commission stated, "Based on the discussion above, there was neither failure of duty of care nor deficiency in service from the OPs. Thus no negligence is attributed upon the OPs. The Order of the State Commission is set aside and both the Revision Petitions are allowed. Consequently, the Consumer Complaint No. CDF No. 35 of 2006 filed before the District Forum, Hooghly stands dismissed."

**Ref.:** <https://medicaldialogues.in/news/health/medico-legal/delay-in-caesarean-delivery-ncdrc-upholds-state-commission-order-doctor-liable-to-pay-rs-3-lakh-compensation-for-negligence-108981?infinitescroll=1> Accessed on 24/03 2023

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- 3) National Statistics Online - Trends in suicide by method in England and Wales, 1979-2001. [www.statistics.gov.uk/downloads/theme\\_health/HSQ20.pdf](http://www.statistics.gov.uk/downloads/theme_health/HSQ20.pdf) Accessed Jan 24, 2005.

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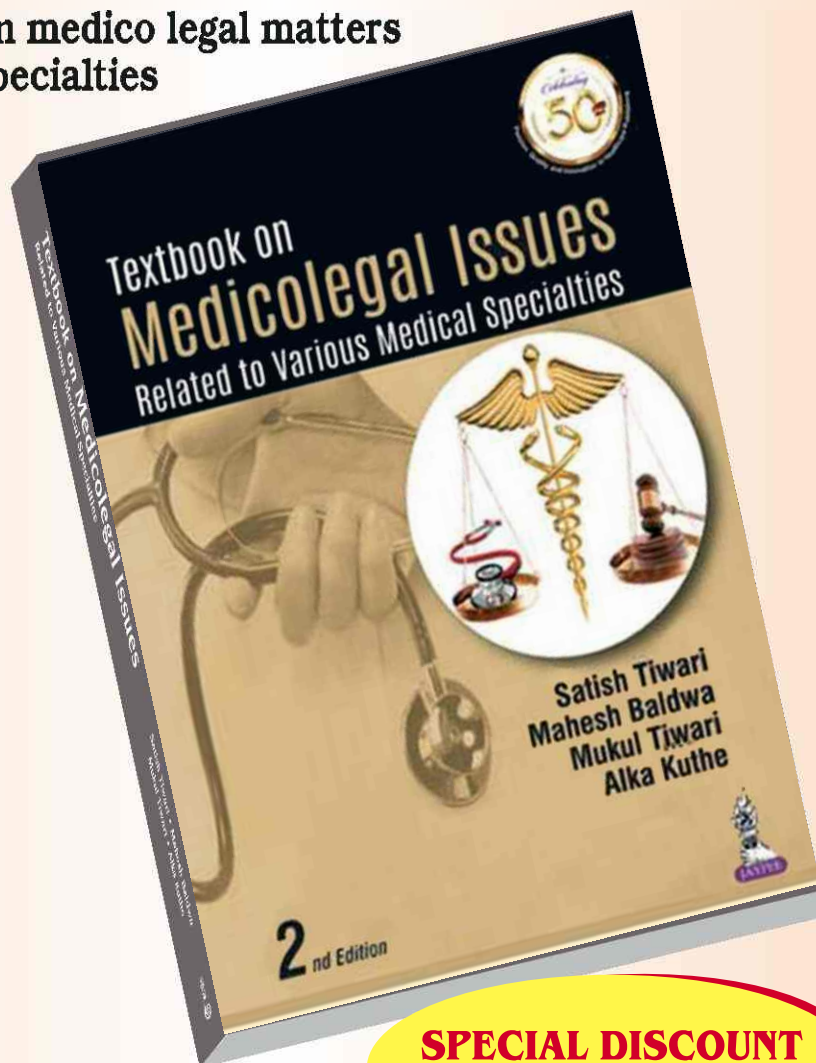
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