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Disclaimer

Address for correspondence :
Dr. Asok Datta,
Email:asokdatta31@yahoo.com
Ph. 08170993104.
Dr Sheikh Minhaj Ahmed
Email:minhaj1609@gmail.com
Ph. 9869660060

Journal of Indian Medico Legal And Ethics Association

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JIMLEA is now Indexed with IP Indexing

Dear Members, Warm regards

We are pleased to inform you that the Journal of Indian Medico- Legal & Ethics Association (JIMLEA) is now indexed with IP Indexing. The highlights of the journal include:

i) Open Access, Peer- reviewed quarterly journal in print form.

ii) The journal is available on the website **(www.imlea-india.org)** of the association.

iii) Topics related to medico-legal and ethical issues can be submitted for publications. This is one of the few journals which publish topics on ethical issues in medical practice.

iv) The ISSN registration number is: 2347- 7458 Print version.

v) This is official publication of Indian Medico- Legal & Ethics Association; a national academic organization working for issues related to Doctor- Patient Relationship, Communication skills, Professionalism, medical negligence, Consumer Protection Act, ethical issues in practice of medicine, quality care and other related issues.

vi) The journal editorial board or the association doesn't charge any money for peer review or publication.

vii) The journal committee doesn't accept advertisement from any companies which manufacture or promote infant milk substitutes and are banned under IMS Act of India.

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Thanks for your contribution, support & cooperation.

Editoral Board, JIMLEA

Editorial :

Laws to Curb Unethical Practices by Pharmaceutical Industry

Dr Yash Paul

Received for publication : 5th Nov. 2020 Peer review : 15th Nov. 2020 Accepted for publication : 27th Nov. 2020

Keywords :

Licensing Authority, DCGI, NPPA, Spurious drugs, Substandard drugs

After qualifying, a doctor takes Hippocratic Oath 'Cause No Harm'. Should the phenomenon to cause no harm be confined to medical doctors only or be applied to other commercial activities including pharmaceutical industry also?

There are three government regulatory bodies viz 1) Licensing Authority- Drug Controller General of India (DCGI) and State Drug Controllers; 2) Central Drugs Standard Control Organization (CDSCO) for quality control of drugs; and 3) National Pharmaceutical Pricing Authority (NPPA) for price regulation, which oversee Pharmaceutical Industry. Despite presence of these regulatory bodies, the doctors face following problems: (i) spurious drugs, (ii) substandard drugs, (iii) unapproved drugs, (iv) irrational drug formulations,(v) potentially harmful drug formulations, (vi) different prices for same drug formulations prepared by different drug houses, and (vii) misinformation by drug manufacturers.

Any drug can cause adverse drug reaction varying from mild symptoms to severe reactions and even death. For this a doctor cannot be held responsible. A doctor is liable for punishment in case a doctor prescribes wrong dose or drug to a person when it is contraindicated because of age or presence of co-morbidity when that drug is contraindicated.

A pharmacist is liable for punishment if she/he sells expiry date drugs or drug formulation which is different from the drug formulation prescribed by the doctor.

A doctor should have full knowledge about the drug he/she prescribes. It is ideal, but not so easy to practice as new drugs are launched in rapid succession. So doctors rely on information provided by the literature and Medical Representatives of the drug manufacturers. The author would like to take up issues of unapproved and harmful drug formulations and issue of misinformation by drug manufacturers.

A report by The Indian Express dated February 26, 2020 titled “Under scanner for 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 cough syrup in question is Cold Best-PC manufactured by Himachal Pradesh based Digital Vision Pharma. It happened due to presence of about 35 percent of diethylene glycol (DEG) an antifreeze chemical that can cause kidney failure. It should be presumed that diethylene glycol got mixed with the preparation inadvertently. This raises serious concern regarding checks and safety measures followed by the manufacturer.

Flucold AF Drops manufactured and marketed by Wallace Pharmaceutical Ltd, contains Chlorpheniramine and Phenylephrine HCl. Chlorpheniramine is not recommended below one year of age and Phenylephrine HCl is not recommended below two years of age. Dosage recommendation as printed on the packing is: 1-6 months- 0.1 ml; 7-12 months -0.1-0.2 ml; 1-3 years 0.2 -0.4 ml and 3-6 years 0.3 -1ml 4 times in 24 hours.

Who should be held responsible in case adverse reaction occurs to 8 months old baby? The prescribing doctor who followed guidelines provided by the manufacturer; drug manufacturer who has stated wrong guidelines; or the licensing authority who has issued license for this drug formulation for children one month and above.

Multidrug antibiotic therapy is recommended for treatment of tuberculosis, malaria, serious

Practising Pediatrician, Jaipur Email : dryashpaul2003@yahoo.com

infections in neonates. Trimethoprim with Sulphamethoxazole in 1:5 ratio is an approved combination. Presently many antibiotic combinations are available. There are two fold problems with these combination products i) do these combination formulations provide any real benefit? And (ii) quantity of drugs in these combination formulations is such that if dose is calculated according to one molecule, dosage may not be correct for other molecule. Many products contain Cefexime and Ofloxacin, where quantity of both molecules is 100mg per 5 ml. Recommended dose of Cefexime is 4 mg per kg BD and 7.5 mg per kg BD for Ofloxacin. If one calculates required dose according to Ofloxacin, administered dose of Cefexime would be almost double of the recommended dose and may cause toxicity and if required dose is calculated according to recommended dose of Cefexime, Ofloxacin would be administered under dose and may result in antibiotic resistance.

It would be pertinent to state that in 1981, then Prime Minister, Mrs. Indira Gandhi had stated at World Health Organization "My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death".

Acts to govern Pharma Industry :

In December 2014, the Government of India notified' Uniform Code of Pharmaceutical marketing Practices (UCPMP) for voluntary compliance by industry for six months starting January 1 2015. This period of voluntary compliance was extended many times, and in June 2016, voluntary code was indefinitely extended. On May 15, 2016 it was stated in Lok Sabha "Code was reviewed and it was now decided to make it statutory. Once the code is made statutory it is expected that the unethical practices could be controlled more effectively". In June 2016 in Rajya Sabha, then Minister Shri Ananth Kumar had stated 'that the voluntary code introduced previous year (2015) was not working well so the government is considering to make it compulsory'.

In September 2017 Department of Pharmaceuticals prepared 'mandatory code under Essential Commodities Act'. In December 2017 final draft code called Essential Commodities (Control of Unethical Practices in marketing of Drugs) order 2017 was sent to Law Ministry. The Law Ministry rejected the idea of putting it under Essential Commodities Act. The bill was sent to Niti Aayog. This act deals mainly with bribes to doctors, but the issue of drug safety also should be incorporated in the bill.

As stated already, voluntary act was indefinitely extended. As of today, Pharma and Medical Devices Association can 'only do naming and shaming and suspend or expel the offender company from the association, but the offending company would remain in the market and continue unethical activities'.

Pharma Industry should emulate Petroleum Industry. Petrol available all over the country is of uniform quality.One may buy from Hindustan Petroleum, Bharat Petroleum or Indian Oil outlet. Petroleum authorities are very vigilant regarding quality of petrol, so that no damage occurs to the engines of vehicles.Price of petrol available at different petrol pumps in an area is same. It seems that motto of some pharmaceutical houses is 'earn more and more money, do not bother about science or safety of people'. Issue of grave concern is that if one industry takes care not to harm machinery on the other hand another industry which caters to human beings knowingly makes products which endanger the lives of people.

For punitive action against a doctor, apart from courts of law, case can be lodged with National Medical Council (NMC), which has replaced Medical Council of India (MCI) w.e.f 29th September 2020. But for any punitive action against a pharmaceutical house there is no authority other than courts of law.

Thus it is very necessary that the government should enact some laws to control pharmaceutical industry and also hold licensing authority accountable. Products having same formulations should have same price.

Review Article:
Consent Forms - Whats Latest ?

*** Mahesh Baldwa **Varsha Baldwa *** Namita Padvi**

Received for publication : 10 Aug. 2020 Peer review : 18th Nov. 2020 Accepted for publication : 25th Dec. 2020

Keywords :

Pre-printed consent forms. Supreme Court, National commission, unfair trade practice.

Pre-printed consent forms for time being is allowed

Pre-printed consent forms remained invalid between 6th July 2020 NC judgment to 18-11-2020 when; order disallowing pre-printed consent forms got interim stay on RG stone [1] by Supreme Court [2]. The final hearing is pending before Supreme Court. It is further discussed in detail after brief discussion on medical consent in general.

Consent as such a creature of law and ethics:

Consent as such a creature of law and ethics. Consent in some form, be it tacit or written has been integral part of medical practice since time immemorial. This appears to be guided by many medical oaths including Hippocratic Oath and lately code of medical ethics. It revolves around ethical principles of patient autonomy, beneficence to patient and non- maleficence (do no harm).

Each and every medical procedure including prescribing drugs is fraught with risks, however minimal they may be. The central idea of consent to apprise patient party of risks to achieve ***consensus id idem*** (doctor and patient both agree on the points of benefits and risks involved).

The Pre-printed and printed consent forms in 1st world countries:

World over consent forms and formats are being made uniform. Government of Queensland Australia [3] has done exhaustive work on this tedious issue. No countries in the world have declared them as unfair trade practice. Pre-printed and printed consent forms are used as routinely as customarily in medical practice. This has been in customs and uses in medical profession from 1969 when I entered medical college.

Position of implied Consent is valid:

World over consent forms and formats are being made uniform. Government of Queensland Australia [3] has done exhaustive work on this tedious issue. If pre-printed and printed consent forms with fill in the blanks are unfair trade practice then what about implied consent, tacit consent? The new dilemma shall remain unanswered. What about proxy consent? What should be language of consent viz; vernacular or English? Will all consent be hand written? If hand written then by whom? Hand writing of patient or hand writing of doctor or anyone else? What about legibility of hand written consent?

Pre-printed consent Forms not discussed in:

In Samira Kohli vs. Prabha Manchanda Dr. 1(2008) CPJ 56 SC [4] judgment, India's Supreme Court has elaborated on different aspects of consent taking. SC says Samira Kohli judgment does not comment upon pre-printed consent forms. This is a reasoned judgment on consent. It does not refer pre-printed consent form. The said landmark Judgment of honorable Supreme Court had laid down the law regarding consent in India and same is not overruled till date. The two issues which are relevant for our purpose and raised before the Bench were:

[i] Whether informed consent of a patient is necessary for surgical procedure involving removal of reproductive organs? If so, what is the nature of

* Pediatrician and medico legal consultant Email : drbaldwa@gmail.com
** Pathologist, presently at Melbourne, Australia *** Consultant Anaesthetist, presently at Dubai, UAE

such consent?

[ii] When a patient consults a medical practitioner, whether consent given for diagnostic surgery can be construed as consent for performing additional or further surgical procedure - either as conservative treatment or as radical treatment - without the specific consent for such additional or further surgery?

The judgment is about diagnostic laparoscopy which was converted to therapeutic surgery without any emergency or life threatening situation. The initial consent for diagnostic laparoscopy was obtained, under general anesthesia, which was converted to therapeutic hysterectomy and removal of both ovaries for frozen pelvis due to endometriosis in 44 year unmarried women suffering from pain and menstrual problems. Hysterectomy consent was obtained from the patient's mother while patient was under anesthesia. The Supreme Court held the doctor liable for malpractice overruling the order passed by the National Commission. The Supreme Court held surgery may be beneficial to the patient in reducing pain, and suffering, additional surgery and saving time, expenses is no ground for defense to changing diagnostic laparoscopy which was converted to therapeutic surgery. Judgment reviewed all aspects of medical consent for India in reference to the aspects of consent in the United Kingdom, Australia, Canada, and the United States.

Supreme court …… observed that courts in Canada and Australia have moved towards Canterbury standard of disclosure and informed consent - vide Reibl v. Hughes (1980) 114 DLR (3d.) 1 [5] decided by the Canadian Supreme Court and Rogers v. Whittaker - 1992 (109) ALR 625 [6] decided by the High Court of Australia. Even in England there is a tendency to make the doctor's duty to inform more stringent than Bolam's test [7] adopted in Sidaway [8]. Lord Scarman's minority view in Sidaway favoring Canterbury, in course of time, may ultimately become the law in England. A beginning has been made in Bolitho v. City and Hackney HA- 1998 1 AC 232 [9] and Pearce v. United Bristol Healthcare NHS Trust 1998 (48) BMLR 118[10]. We have however, consciously preferred the 'real consent' concept evolved in Bolam and Sidaway in preference to the 'reasonably prudent patient test' in Canterbury, having regard to the ground realities in medical and health-care in India. But if medical practitioners and private hospitals become more and more commercialized, and if there is a corresponding increase in the awareness of patient's rights among the public, inevitably, a day may come when we may have to move towards Canterbury. But not for the present.……

Real versus informed consent:

The judgment showed difference between Informed consent and real consent. Supreme Court expressed great concern about Indian patients' confusion when it came to knowing what they should sign, and thus concluded the form of consent be real consent and time is not ripe for informed consent in 1971 US judgment in Canterbury. In ***obiter dicta*** and ***ratio decidendi*** neither pre-printed consent forms were discussed or challenged. Hence by default stand allowed. Hence this 2008 three judge bench of Supreme Court is still valid and not over-ruled.

National Commission Judgment:

Now question is 6th July 2020, NCDRC labels use of printed consent forms as unfair trade practice slaps 10 lakhs- in backdrop of previous landmark 3 judge bench of Supreme Court judgment of Samira Kohli related to consent. There is shock and denial amongst medical fraternity after reading judgment by NCDRC in Vinod Khanna vs R.G. Stone Urology and Laparoscopy about use of pre-printed consent forms as unfair trade practice slaps 10 lakhs. But fortunately it ended on 18-11-2020, when Supreme Court has granted interim stay on

order.

NCDRC's suo – moto use of unfair trade practice:

"Unfair trade practice" always existed in CPA-1986 but suo moto use by NCDRC in medical negligence case where no negligence or deficiency is found on part of hospital and doctors. The above judgment of NCDRC against R G Stone about use of uniform pre- printed consent form with limited select handwritten entries and signatures for different procedures was held to be unfair trade practice. NCDRC where patient has not alleged nor medical board says anything about printed consent form then also a sum of Rs 10 lacs was asked to be deposited in the Consumer Legal Aid Account by the hospital. In this case, however, no deficiency in service or medical negligence was found on part of opposite party hospital. Also the judgment held the consent in question to be an "informed consent" containing no inappropriate or irrelevant matter or material.

Assumption of "Such consent form fits into any procedure, any doctor, and any patient"

"….that it is a pre-printed form- 'informed consent cum undertaking' having blank spaces for limited selective handwritten entries and for the signatures. The main body of the form is fixed pre-printed. Such consent form fits into any procedure, any doctor, and any patient". No wrong is observed except this and labeled unfair trade practice.

Doctors at loss as to write each consent in hand writing or specifically print patient to patient? This Question needs to be answered clearly. The National Commission held that having a fixed pre-printed consent form to be - administrative arbitrariness and one-sided high handedness-', and to be unfair and deceptive, on the part of the hospital. It is not clear in the order of the National Commission if such consent forms would amount to 'administrative arbitrariness.'? It is pertinent to state that the National Commission had clearly recorded that though the patient had not been prejudiced in this particular case due to the pre-printed form. What was deceptive and unfair in pre-printed consent form was not elaborated. It said "the uniform use of this pre-printed and fixed 'informed consent cum undertaking' form on the part of the hospital to be unfair trade practice" and a direction to the hospital to discontinue the unfair trade practice with immediate effect. An amount of Rs. 10 lakhs is to be paid to consumer welfare fund by the hospital. The RG stone appealed against judgment and on 18th November 2020, National commission order was granted interim stay.

Printed versus hand written consent form-which one is legal?

In the judgment by the honorable commission, RG stone labeled use of printed consent form as unfair trade practice. In this case ideal preprinted consent form was used, with hand written entries. Now discrediting ideal printed consent form is discredited as unfair trade practice thus leaving a feeling of helplessness restlessness to get all consent forms be hand written is the question the medical fraternity is asking? Surprisingly the reasoned judgment does not refer to 2008 supreme court judgment of the Samira Kohli. Is this judgment in line with 2008 supreme court judgment of the Samira Kohli? The said landmark Judgment of honorable Supreme Court had laid down the law regarding consent in India and same is not overruled till date.

NC observation for pre-printed consent:

Printed or Preprinted consents where blank spaces are being filled by hand written appropriate matter are unfair practice. The honorable court has not found any discrepancy in the matter, material or signature etc which is routinely followed uniformly across the country as legal "custom and uses' in medical fraternity from long time. Hand written consent is rarity. This consent form is faulted just because it is pre-printed. This appears to be beyond logic and reasonableness when matter, material of consent form was just and appropriate. Judgment does not find fault with matter, material of printed

consent form so where is unfair trade practice? Printed consent forms with fill in the blanks is the usual practice which forms legal "custom and uses" in medical fraternity in professional work.

The Commission agreed that it was a valid informed consent even though what was required by law was a real and valid consent. Despite holding it to be a valid consent the commission described the practice of taking such consent as an unfair trade Practice. It further says "we cannot ignore the peculiarity of the 'informed consent' in the instant case which needs prompt and proper rectification."

Supreme Court has granted interim stay:

1. RG stone and IMA Haridwar has challenged the judgment separately and got interim stay.
2. Doctors may continue pre-printed consent forms since NCDRC judgment is granted interim stay.

The judgment is challenged on following grounds:

a. Does not violate act- The National Commission has held pre-printed consent form to be unfair and deceptive on the part of the hospital under section 2 [r] of the Consumer Protection Act, 1986. There is no finding that there was any misleading information, or any false representation made in the pre-printed consent form used. This has not caused any harm to patient party. This is absolutely non-medical part of judgment in a case of alleged medical negligence case.

b. Custom and usage for so many years- The Pre-printed contracts are a normal use in professional medical practice. This is also normal practice in housing, electricity, banking, insurance and many other service contracts.

c. Waste of time, money, energy promoting cut and paste or giving work to person with good handwriting to write what doctor gives to write- It is not only specific relevant information to be filled in selective blanks to minimize errors. The information is relevant to the patient that is handwritten specially. This information is name, age, address, email, mobile, ailment of the patient, the procedure planned to be performed, the surgeon performing the surgery and the benefits, risks and possible complications associated with the procedure or operation are either common or specially added to the pre-printed forms in the blanks specifically designed for such information are left. The names of the patient, surgeon, and name of witness are left for their signature along with date to minimize errors.

d. High patient load -For government and corporate hospitals with high patient load- the doctors and the hospitals would be put to severe hassles of hand written forms or cut-paste computerized forms which will cause waste of time, money and physical strain. Especially a department for obtaining consent needs to be opened just like department for registration of patients.

e. Allegation of illegibility- there are going to be new allegations in handwritten consent forms that they are not legible causing misinterpretation and misguidance.

Expert opinion of medical board:

We have perused the report (opinion) of the medical board constituted three independent Doctors at Maulana Azad Hospital, New Delhi namely

1) Dr. R.K Jindal, Director Professor (Surgery) as Chairman,

2) Dr. M.K Daga, Director Professor (Medicine) and 3) Dr. Anubhav Vindal, Associate Prof (Surgery) as members. The board examined the medical records of the case in detail and had not found any negligence in this matter. So pre-printed consent forms were not found to be wrong or illegal.

What's happening abroad in western countries?

Numerous judgments in west may be taken up by Supreme Court and may not enforce ban on pre-printed consent forms but pave way for informed

consent. From our point of view and interest is British 2015 Montgomery consent law, paves way for in a way about informed consent as a general duty to attempt the disclosure of risks.

In this case, panel of seven Law Lords on a UK Supreme Court (UKSC) appeal hearing. Decision will not only affect the UK, but also influence many courts in 'common law' jurisdictions like Australia, Canada, India, Kenya and even the USA.

The Montgomery case [11] firmly rejected the application of Bolam to consent, establishing a duty of care to warn of material risks. The test of materiality defined in the Montgomery ruling was whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it." Even this judgment does not discuss about pre-printed versus handwritten.

Summary and conclusion:

As of now Supreme Court has granted interim stay on RG stone judgment of pre-printed consent forms on 18-11-2020. But Supreme Court going to take it up since a number of petitions is pending. May be pre-printed consent forms may be allowed with specifications and informed consent may pave it's way in India.

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Contribution in JIMLEA

All the readers of this issue and the members of IMLEA are invited for contributing articles, original research work / paper, recent court judgements or case laws in the forth coming issues of JIMLEA. This is a peer-reviewed journal with ISSN registration. Please send your articles to Dr. Asok Datta,

email : asokdatta31@yahoo.com

Review Article :
Medical Negligence to the Extent of Vicarious Liability

***Dr. Nidhi Yadav **Dr. Ragini Agrawal**

Received for publication : 13th June 2020 Peer review : 19th Dec. 2020 Accepted for publication : 31st Dec. 2020

Key words :

Medical Negligence, Vicarious liability, ROP (Retinopathy of prematurity), Duty of care

Abstract :

Medical Negligence is done by a medical professional not practicing standard of care. Indian Penal Code, 1860 (IPC) provides section 304-A under which doctors can be held liable and punished for such criminal negligence. Whereas Vicarious Liability is a liability to an individual who has a specific superior legal relationship to the person whose negligent act caused the harm. The legally superior person doesn't cause the injury himself. The services of the doctors are covered under the provisions of the Consumer Protection Act, 2019 and a patient can seek redressal of grievances from the Consumer Courts. Case laws are an important source of law in adjudicating various issues of negligence arising out of medical treatment.

Introduction :

As Sir James Paget quotes- "Being a doctor offers the most complete and constant union of those three qualities which have the greatest charm for pure and active minds- Novelty, Utility and Charity". "General awareness to public about consumer forum and law and regulations has nowadays led the doctors and hospitals to a vulnerable stage. There have been cases where it is decided and explained the different versions of medical negligence and vicarious liability depending upon the facts and circumstances of the cases, wherein many a times a single suit has been filed imposing both the liabilities of medical negligence and vicarious liability or just any one of them, as the case may be, holding a doctor or a hospital or both liable. These liabilities are well explained and established by Justice Uday Umesh Lalit & Justice Indu Malhotra ***in vide*** Judgement **Maharaja Agrasen hospital v Pooja Sharma & other 2019 SCC** [1]. , a well-established judgement reminding medical professionals of many lacunas that doctors and hospitals may create during maintenance of documentations, medical records, and standard of care. The Aim is to provide knowledge to the entire medical fraternity in such a way that the medical negligence can be avoided ***in Toto.***

Facts

The child in this case was born prematurely at 32 weeks' gestation, with a weight of 1.49 kg at the time of birth, later after 4 hours of birth the baby was referred to a super specialty hospital, Maharaja Agrasen Hospital where the child was kept in NICU (Neonatal Intensive Care Unit) and was discharged after 27 days of birth. Neither during stay or at the point of discharge, nor during two follow-up visits (at 4 weeks 4days old and at 14 weeks old respectively) with the pediatrician in the same hospital, was the single mother of the child advised of any examination for ROP (retinopathy of prematurity) which was a very probable risk to the baby considering the gestational age and birth weight of the baby. Also the discharge slip neither mentioned any ROP examination done during the stay at the hospital nor any ROP examination was advised on further follow up dates. In November, 2005 mother noticed abnormal visual response after which she had put in a request for medical records from the hospital in spite of which no records were made available to her by the hospital. Later, the child was diagnosed with ROP by

* Private Practitioner, Gurugram Email : yadav.nidhi0903@gmail.com
** Consultant Obstetrician, Gurugram

an ophthalmologist in another hospital, the Shroff Charity Eye Hospital, wherein B-scan was done which pointed that the condition had already progressed to bilateral ROP stage 5 i.e. total retinal detachment leading to complete blindness. A legal Notice to hospital was sent for providing in the medical record of baby which hospital failed to provide after which a complaint was filed in Delhi Medical Council (DMC) regarding the same. Later after 4 months' hospital provided with case summary showing ROP examination conducted during the hospital stay of the baby by an ophthalmologist. A complaint was filed by mother for medical negligence and deficiency in service on hospital and doctors including gynecologist, two pediatricians and ophthalmologist for compensation of permanent physical disability, mental agony, social stigma, deprivation of normal human life, companionship, torture, harassment.

Contentions

The learned Counsel of the petitioner defended themselves with a strong contention taking in account the expert opinion which DMC (Delhi Medical council) has received from AIIMS. Counsel emphasized that the baby was given utmost care and attention by the Doctors of the Hospital and parents were counselled about all probable risk to the preterm baby. Ophthalmologist advised, performed and documented ROP on the patient. The discharge summary also advised BERA and ROP. It was further submitted that it was not required to record the method of dilation of the pupil and the chemical solution used such as tropicamide and phenylephrine is available in nursery and use of indirect ophthalmoscope, which is available with all ophthalmologists. Counsel blamed the mother for being non compliant to the follow-up advice of the doctor as per the discharge slip.

The learned counsel of the complainants submitted that the baby has become permanently blind on account of the gross medical negligence by the Hospital, and the three specialist doctors i.e two consultant Pediatricians, and the Ophthalmologist. Doctors did not at any stage conduct the ROP examination of the baby. In this Discharge Slip, there is no advice of ROP having been conducted, or follow-up of ROP, nor was the risk of ROP explained by the pediatrician to the mother. Hospital had deliberately withheld the medical records for over two years after discharge. Also medical records, which were provided after 2 years of putting in the request, had been fabricated and interpolated.

The Complainants have supported their submission on the basis of: (i) the progress sheets, which contain no details of the ROP examination; (ii) there is no mention of the ROP examination in the Nurses' Daily Record; (iii) ROP exam is conducted with the help of dilation by using Cyclopentolate (0.5%) and Phenylephrine (2.5%) drops to be applied 2 to 3 times, about 10-15 minutes apart. There is no record with respect to the administration of these medicines to the baby; (iv) there is no mention of the ROP test in the Discharge Slip. The Complainants contended that if the standard protocol had been carried out by the Doctors, the ROP would have been detected at an early stage, and could have been cured, since it is medically known to be reversible at the early stages.

Judgement

Analysis and judgment of National Commission-

A medical practitioner,being considered prudent, knowledgeable and skilled in examining and treating a patient owes certain duties towards the patient, 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. A breach of any of these duties gives a right of action of negligence against him. The medical practitioner has a discretion in choosing the treatment which he proposes to give to the patient and such discretion is wider in cases of emergency.

National commission explained the responsibility of the medical practioner under standard of care to screen every baby who has a potential risk to develop any health problem and should refer the case to respective speciality for the appropriate examination and treatment as a standard of care

provided to the patient. It has an immense medico legal implication because if a child goes blind due to missed or late screening, then the pediatrician and the ophthalmologist are at a very high risk of being sued for medical negligence.

National commission on the basis of the evidence affirmed that the doctor neither performed ROP screening nor advised follow up of ROP for the child establishing a medical negligence. Hence, both the Pediatricians along with ophthalmologist were held liable.

With respect to the opinion given by committee of AIIMS, National commission pointed out that the aim of an expert committee is to guide the court in the right direction with the help of evidences which are better comprehended by a medical person of expertise than a legal person such as judge and should bring their knowledge together to help impart the justice[3].

Hence, it was clear that, ophthalmologist and both the pediatricians in the instant case failed to exercise reasonable care and skill. Hence liable for medical negligence.

Vicarious Liability:

It was held that hospital, being a service provider to the patient is vicariously liable for the reason that the surgeons, physicians are employed by the hospital, hence following principle-agent or master-servant relationship,hospital is being held vicariously liable,where a negligent act is being done without keeping a due diligence care and caution. It is no more a defence stating that the medical professional is not a servant employed by the hospital [3].

Compensation

Court granted compensation to victim and his mother for medical negligence in lieu of their acute mental agony and the lifelong care and attention they would have to give to the child. Court also recognised the financial hardships faced by the parents, in terms of lost wages and time[4]. National commission applied the multiplier method in assessment of damages. Total compensation granted by national commission was Rs.64,00,000/- along with the interest.

However, the hospital along with three other doctors filed an appeal in the Supreme Court against the order passed by National commission.

Analysis and judgement of Apex Court

Supreme Court emphasized on the Regulation 1.3.2 of the Medical Council of India(MCI) Regulations which casts a statutory obligation upon every doctor/hospital to provide medical records within 72 hours of the request being made by the patient and states that withholding the medical records of the patient, who was a premature baby, for a period of over 2 years, would constitute grave professional misconduct under Regulation 7 of the Medical Council of India(MCI) Regulations which talks about the commission or omission would constitute professional misconduct rendering him/her liable for disciplinary action and punishment under Regulation 8 of the MCI Regulations, apart from being a gross deficiency in service on the part of the Hospital and its management.

On reviewing various literature, Court supported its view pertaining to the guidelines to be followed by the doctors in the diagnosis of ROP. All infants with a birth weight of less than 1500 grams, or gestational age of less than 32 weeks, are required to be mandatorily screened for ROP, which usually takes about 4 to 5 weeks to be diagnosed. Along with mentioning the many Protocol to be followed in the screening and diagnosis of ROP, the Court specifically mentioned it is mandatory to start the screening of the child no later than 4 weeks. As per the report of AIIMS given in this case "it may not be possible to exactly predict which premature baby will develop ROP and to what extent and why ?". This would necessitate the need for a regular check-up (inclusive of in-patient and follow up after discharge) in all such cases to rule out ROP completely. The responsibility of recognition of infants for screening lies with the pediatrician/neonatologist. It was established that discharge slip provided to the mother of the baby at the time of discharge does not mention any advice

specifically pertaining to the follow-up for test of ROP. However, the Discharge Slip only mentioned the advice to bring the baby for a review to the Pediatric unit of general OPD on Wednesday or Saturday at 4 P.M. It is also validly clear from the original medical record provided by the hospital that the baby was taken twice to the Pediatric Unit of the General OPD Clinic at the age of 4 weeks and 13.4 weeks respectively, when the onset of ROP could have been detected. There was no advice for a test of ROP was given by the treating doctors i.e. the Consultant Pediatricians, or Ophthalmologist to conduct the ROP test during the follow up visits. However, the BERA test was advised by the pediatrician on the second follow up visit of the patient to the Pediatrics Unit General OPD clinic. Court also commented that AIIMS Report stating that the baby was not taken to the Pediatrics OPD is wholly illegitimate and irrational. It is well-settled that a court is not bound by the evidence of an expert, which is advisory in nature. The Apex court supported the view of National commission pertaining to the duty of an expert witness (opinion of medical board constituted by AIIMS) [5]. Hence, the contention of the hospital, pediatrician and the ophthalmologist is rejected. Moreover, court acknowledged the fact that the pediatrician, ophthalmologist and hospital owed a legal duty of care to the victim i.e. the baby and his mother as there is no justification for not conducting the standard protocol of screening of ROP for the baby while baby was under the direct care and supervision of doctors and hospital for three and a half months. This amounts to gross negligence by the doctors and deficiency of the service by the hospital.

Communication with the parents regarding timely screening for ROP, seriousness of the issue, possible findings and consequences is extremely important. The failure to inform mother of the probable risk involved and necessity to have the ROP test conducted in the case of a pre-term baby with the weight of 1.5kgs which could lead to total blindness, was a breach of duty on the part of the pediatricians.

Regarding the progress notes and documentation of consulting ophthalmologist to rule out ROP, following findings were noticed by the apex court, (i) no time is mentioned in the progress notes against such noting as per original medical records provided by the hospital (ii) entry in the progress sheet/ treatment sheet is not recorded in the same sequence as all previous and subsequent noting (iii) The Nurses' Daily Record or Treatment Sheet also do not mention about the dilation of the pupils of the baby or administration of any related medicine to conduct the test of ROP (iv) The consultants' notes seem fabricated and interpolate. Such documents, hence cannot be honoured in defence to ophthalmogist claiming the test of ROP done by him during the stay of the baby in the hospital.

The negligence on the part of the medical professional is judged on the basis of exercise the ordinary skills performed by the ordinary person exercising the ordinary skills in the profession. A skilled medical professional decides on the basis of his professional skill to undertake the case, provide a standard care to the patient while deciding on the appropriate treatment to be given and how the treatment should be given after applying all the skills to examine and diagnose the patient and provide all the information to the patient using his skilled knowledge. Medical professional becomes liable for actionable medical negligence only where his conduct falls below the standard of a reasonably competent practitioner.

Medical Negligence, in this case constitutes lack of standard duty of care by the medical professional and the failure to inform the mother of the child leading to cause irreversible damage or injury to the patient giving rise to an actionable claim of negligence. However, the burden of proof lies on the complainant in a case of Medical Negligence to prove the claim.

The principle of *Bolam Test* is applied as a rule of practise or of evidence and not as a rule of law.

Bolam test is the standard of ordinary skilled man practising and the professing to have that special skill. it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art. *Bolam Test* states that a OP should be alert to the hazards and risk in any professional task he undertakes to the extent that other ordinarily competent members of the profession would be alert. He must bring to any professional task he undertakes no less expertise, skill and care than other ordinarily competent members of his profession would bring, but need bring no more. The standard is that of the reasonable average [6].

It is noted by the apex court that *Bolam test* is inconsistent with the right to life (Article 21).

Bolam Test was however discarded in court of England stating that the logical analysis is given preference over professional opinion of what would an ordinary skilled professional do? According to the Court of England, patients are now regarded as person holding rights rather than in the positive recipient of the case of medical profession. Australian court emphasised that the paramount consideration that a person is entitled to make his own decision about his life.

Doctor is under the duty to take reasonable care to ensure that the patient is aware and is being communicated of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.

Supreme court stated that so long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed. When it comes to the failure of taking precautions, what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial.

Accordingly, the hospital, two pediatricians and the ophthalmologist are held liable for medical negligence since the mother was never guided and advised about the possibility of occurrence of ROP in a premature baby nor was the baby examined by the Ophthalmologist as per standard protocol lacking in their duty to care leading to gross deficiency in service leading to total irreversible blindness to the baby, giving rise to actionable claim of negligence.

Vicarious liability

Sometimes called "imputed liability," attachment of responsibility to a person for harm or damages caused by another person in either a negligence lawsuit or criminal prosecution. Thus, an employer of an employee who injures someone through negligence while in the scope of employment (doing work for the employer) is vicariously liable for damages to the injured person. For the most purposes the duty of care owed by the hospital authority is co-extensive with the duty owed by the medical staff for whom it is vicariously liable[7]. Since the doctor and the nurse were employees of the hospital, the hospital is responsible and liable for the consequences[8]. While applying vicarious liability practically and extensively, even the Managing Director and Medical Director of the accused hospital can be also held vicariously liable[9].

In support of the application of vicarious liability principle, In Wilsher v Essex AHA,[10] two of the Appeal Court Judges positively asserted that vicarious liability did exist [11].

While commenting on the vicarious liability, with the help of a citation Supreme court quoted -

It is well established that a hospital is vicariously liable for the acts of negligence committed by the doctors engaged or empanelled to provide medical care[12]. It is common experience that when a patient goes to a hospital, he/she goes there on account of the

reputation of the hospital, and with the hope that due and proper care will be taken by the hospital authorities[13]. If the hospital fails to discharge their duties through their doctors, being employed on job basis or employed on contract basis, it is the hospital which has to justify the acts of commission or omission on behalf of their doctors.

Correspondingly, Hospital is held vicariously liable for the acts of omission and commission committed by two pediatricians and the ophthalmologist. Therefore, hospital, two pediatricians and the ophthalmologist were held jointly and severally liable to pay compensation to the complainant.

Compensation

Compensation in cases of Negligence is attributed to the consumer as defined in Consumer Protection Act, 2019. Where a young child was taken to a private hospital by parents and treated by the doctor, held, not only the child but his parents also were "consumer".In Sarla Verma v Delhi Transport Corporation, the apex court sought to define the expression "just compensation"[14]. In Raj Rani v. Oriental Insurance Co. Ltd, the court observed that there is no restriction that the compensation could be awarded only up to the amount claimed by the claimant[15].

Supreme court did not agree with National commission regarding the applicability of the multiplier method in assessment of damages. Apex court has affirmed the principle regarding determination of the just compensation in a number of cases that inflation should be considered with deciding quantum of compensation. Award of interest on compensation amount to be from the date of filling of the original complaint up to the date of payment of the entire compensation to the claimant.A total amount of Rs.6,08,00,550 was awarded as compensation to the claimant with 6% interest per annum from date of application in 1999 till date of payment.

Compensation calculated and granted is based on the principle of *restitutio in integrum*[16]. The said principle provides that a person is entitled to damages which should as nearly as possible get that sum of money which would put him in the same position as he would have been if he had not sustained the wrong[17]. The complainant claimed Rs.13025000/- as compensation before national commission. In conclusion the compensation awarded by national commission is further enhanced by Rs.12,00,000/-. Hence, the total amount awarded by Supreme court is Rs.76,00,000/-. Judges also directed the court towards the utilisation of the total sum awarded keeping in account the future financial security, daily expenditure of the victim by building up monthly income coming out of the annual interest of the amount awarded. Court also directed the money to the mother to help carry on the smooth life of the victim with respect to education, welfare and self-reliant life of Master Rishab Sharma.

Conclusion:

Screening for ROP should be performed in all preterm neonates who are born less than 34 weeks' gestation and/or less than1750 grams' birth weight; as well as in babies 34-36 weeks' gestation or 1750-2000 grams' birth weight if they have risk factors for ROP. The first retinal examination should be performed not later than 4 weeks of age or 30 days of life in infants born more than or at 28 weeks of gestational age. Follow up examinations should be based on the retinal findings and should continue until complete vascularization or regressing ROP is documented or until treated based on the ETROP guidelines [18].

More guidance to medical law is the key to success in such scenario. It is the responsibility of the pediatrician to initiate screening by referring to an ophthalmologist and it is the responsibility of the ophthalmologist to do correct screening and treatment. This has immense medico legal implications because if a child goes blind due to missed or late screening, then the pediatrician and the ophthalmologist are at a very high risk of being sued and undergo litigation. Proper medical documentation of doctor's visitation, consultation, procedure details and a detailed discharge summary

is of prime importance. Hence a standard of care and standard protocols are to be followed by the treating doctor. The documentation plays a very important role in establishing the cases. Documentation should be proper and exhaustive in nature. Documents should never be fabricated and interpolated.

Medical records should be provided to the authorities or to the patient by the hospital within 72 hours of such notice by law. Hospitals are the service providers and can be held vicariously liable as an employee for the act of the doctor and nurse staff employed by the hospital in case of any proved negligence.

Compensation can be awarded to the claimant by the court in case the Negligence is proved to compensate the damages caused due to negligent act.In criminal Negligence,the accused can also be punished with imprisonment or fine or both.

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Medicolegal News

Compiled by Dr. Santosh Pande

Death due to Amniotic Fluid Embolism - NCDRC gives relief to Gynecologist, quashed state commission order

Lucknow: Holding the verdict of State consumer forum as mistaken, the National Consumer Disputes Redressal Commission has granted major respite to a Gynecology and Obstetrics consultant, who was accused of committing medical negligence allegedly leading to the death of a patient due to Amniotic Fluid Embolism.

The court overruled the state commission's verdict observing that the blame of tragic misfortune for unexpected, unavoidable, unpredictable, unpreventable Amniotic Fluid Embolism (AFE), most of the times the obstetrician is a scapegoat. Unfortunately, in some cases, despite the doctor's best intentions, patients suffer injury or die, and the clinicians involved often become the secondary victims.

The case goes back to the year 2012 when the pregnant patient with contractions was admitted to the nursing home of the doctor. In spite of good labour pains, there was no progress of cervical dilatation and in view of fetal distress, the patient and relatives were informed of the need for lower segment cesarean section (LSCS). However, they were reluctant to give consent for the same. It is only when they were told to either give consent or take the patient to another hospital did they relent and gave their informed consent and the operation was commenced under spinal anesthesia administered by an anesthetist. A healthy female baby was delivered but soon after, the patient suddenly developed cardio-respiratory arrest. CPR was initiated and the patient was intubated. Later, positive pressure respiration started. However, amniotic fluid embolism was suspected. The patient responded to the resuscitative measures and the operation was speedily completed.

The relatives were informed of these sudden happenings and the serious condition of the patient and the need to transfer the patient to a tertiary care hospital. Accordingly, the patient was shifted to the nearby Yashoda hospital in an ambulance accompanied by the doctor. The patient was put on ventilator support. Subsequently, the patient did not recover from the cerebral hypoxia and continued to be comatose.

Thereafter the relatives filed a complaint before the UP State Consumer Forum alleging negligence and deficiency in service (including incompetence and lack of facilities in the Nursing home) and seeking a compensation of Rs 99 lakhs. The complainant also filed a complaint before the UP State Medical Council for disciplinary action.

On 16th May 2018, the State Commission, Lucknow held the doctor and Nursing home liable for negligence and awarded compensation.

Aggrieved with the forum decision, the doctor appealed against this judgment before the National Consumer Disputes Redressal Commission in Delhi.

During the hearing of the case before the bench of honourable Justice RK Agarwal as President and Dr SM Kantikar as a member, the counsel on behalf of the petitioner alleged as the patient suffered the cardiac arrest, the doctors unnecessarily wasted crucial time inside the operation theatre which later on worsened the condition of the patient. The counsel further submitted that one male person (non-doctor) was present in the OT with the doctors till the shifting of the patient to Yashodha Hospital. The hospital has no facilities up to the mark. It was a failure in the

*Practicing Anesthetist & President IMLEA, Amravati Branch E mail:drpandesr@gmail.com

duty of care from the doctor and the hospital. The counsel brought our attention to the order passed by U.P. Medical Council which observed that the facilities available in the hospital were not up to the mark.

In response, the counsel from the respondents (doctor, hospital) submitted that the doctor is qualified as MD (Obst. & Gynae) having 17 years' speciality fell below the standard of reasonable practice. After taking note of all the submissions and contentions put forward by both the sides, the bench went on to make its observations on the case. It marked,

"On perusal of the medical record of hospital, it is apparent that on 04.11.2012 at 12.15 pm, OP-1 examined the patient and noted the cervix was closed and the head of fetus was high. The FHS was 170/minute, regular. The patient and her attendants were informed and advised for LSCS. The indication for LSCS mentioned as "non-progress of labour with fetal distress". The decision taken by OP-1 to do emergency LSCS cannot be faulted. The attendant gave the consent at 12.45 PM and then the patient was shifted to OT. As per the anesthetist's note, the blood investigation like Hb%, TC, DC, the blood sugar, urea and creatinine were normal. The surgery was performed by the OP-1, it was assisted by Dr***, the anesthetist, Dr ***. The pediatrician, Dr *** was also present in OT. The LSCS was performed under spinal anesthesia; a full term female baby was delivered at 1.14 pm. The Injection Synto – 10 units in drip started and injection Prostodin 1 ampule (250 microgram). Suddenly, patient showed fall in BP (90/60 mm of Hg), bradycardia, feeble pulse and fall in SPO2 level (90%). The patient became unconscious, started with labored breathing. The patient was immediately intubated with ET number 7.5 and connected to boyles trolly with circuit and IPPR done with 100 % oxygen. The doctors in OT also gave injection Atropine, Termine and Adrenaline. The cardiac massage was also done. At 1.20pm, the patient was revived from the arrest, the LSCS was completed, and placenta was delivered. She was unconscious and having slow respiration. The ambulance was called and at 1.35 pm the patient was shifted to higher centre with ventilatory support. The patient was responding to long painful stimuli."

On the occurrence of Amniotic Fluid Embolism, the bench observed: We have gone through the literature on Amniotic Fluid Embolism from the various published Articles and medical text from William's Obstetrics (23 edi). It is stated therein that Amniotic fluid Embolism is a rare but often fatal complication of pregnancy and its onset can neither be predicted nor prevented. AFE is an infrequent, unpredictable, and the catastrophic complication of pregnancy in which amniotic fluid, fetal cells, hair, or other debris enters into the maternal pulmonary circulation, causing cardiovascular collapse. AFE is a syndrome typically occurs during labor, soon after vaginal or cesarean delivery, or during second trimester dilation and evacuation procedures. It is virtually impossible to predict which patients are at risk for AFE.

Diagnosis must be based on a spectrum of clinical signs and symptoms and by exclusion of other causes. Most cases of AFE are associated with dismal maternal and fetal outcomes, regardless of the quality of care rendered. Early recognition of AFE with prompt intervention is paramount to a successful outcome. Management is resuscitative, geared towards maintaining vital signs and treating hemodynamic and coagulopathy derangements as they occur. A team approach among obstetrician, anesthesiologist and intensivist is necessary for a successful outcome. Despite early intervention, maternal and fetal mortality remain high. Thus, owing to its uncertain etiology, varying symptoms, rapid onset, and high fatality rate the AFE is one of the most challenging obstetric emergencies leading to cardiac arrest. The Cardiac arrest is a devastating event. Despite improving resuscitation practices, mortality is high with many survivors being left with severe neurological impairment. However, some do

make a good recovery and return home to a meaningful quality of life. The pathophysiology of hypoxic ischemic brain Injury encompasses a heterogeneous cascade that culminates in secondary brain injury and neuronal cell death. The long-term consequences will depend on the severity of the cerebral anoxia and on how much irreversible damage has occurred in the brain. If there has only been mild or short-lived anoxia, there may well be recovery back to a normal or near normal level of functioning. However, if the anoxic injury has been more marked the outcome is less certain and there are likely to be long-term effects. The nature of these problems will vary from person to person, depending on the severity of the injury and the brain areas affected. Accurately predicting those who will achieve a good neurological outcome in post-arrest comatose patients is difficult.

The bench then noted that the UP Medical Council has not held the doctor for procedural lapses or negligence while performing LSCS and held: The Cardiac arrest is a devastating event. Despite improving resuscitation practices, mortality is high with many survivors being left with severe neurological impairment.

The bench then noted that the UP Medical Council has not held the doctor for procedural lapses or negligence while performing LSCS and held: "AFE is an unpredictable complication, and it was managed duty of care from the treating doctor is not visible."

Further, the bench emphasised the aspects of medical negligence allegations and said: In order to succeed the claim in medical negligence case three requirements need to be met. One the accidental nature of the misconduct on the part doctor, second the existence of proven damage and third its direct relationship. The doctor shall put in place all necessary measures as to the current scientific knowledge. We note the doctor performed her duty with reasonable standards and as per accepted practice. The patient was appropriately referred to the higher centre.

Concluding the case, the bench set aside the order of the state consumer commission while allowing the appeal made by the doctor and held, "The doctor is qualified as an obstetrician and experienced one. LSCS was performed as per standard procedure, but unfortunately, the patient suffered cardiac arrest due to unpredictable Amniotic Fluid Embolism (AFE). Though immediately resuscitative steps were performed by the doctors in OT, but the patient suffered cerebral hypoxia. It was not due to negligence or deficiency while conducting the LSCS or management of AFE. The State Commission has erred in law to hold it as a medical negligence."

Ref.: https://medicaldialogues.in/news/health/medico-legal/death-due-to-amniotic-fluid-embolism-ncdrc-gives-relief-to-gynaecologist-quashed-state-co…Accessed on 08/09/2020.

NCDRC Relief To Orthopedic Surgeon Told To Pay Compensation To Patient For Second Surgery For Fracture.

UP: Holding that the doctor is not guilty of medical negligence, the NCDRC has rejected the claim of the patient where it was alleged that he had to go through surgery twice due to the inefficiency and negligence of the doctor.

The court observed that no deficiency or medical negligence on the part of the doctor was established.

The case goes back to the year 2000 when the patient went through a scooter accident and suffered a fracture to his left hand. Initially, he consulted a doctor at Deoria. X-ray showed a fracture of Humerus (arm) and took treatment for 4 days. Thereafter, he approached another doctor at his Orthopaedic Hospital at Gorakhpur. The doctor examined the patient and advised for surgical correction of the fracture and the patient got admitted in the particular Hospital.

The patient underwent surgery on

13.08.2000 and fixed the Titanium Closed Interlocking Rod in the fractured Humerus bone. In his complaint, he alleged that the rod and the screws were oversized and were not fixed properly. It was further alleged that the doctor examined the X-ray of the patient's left arm which showed the interlocking rod and screws were oversized and a gap visible between the broken bones but he was discharged from the hospital a few days later.

Thereafter, when his condition did not improve, the patient got himself examined in the District Hospital, Deoria and the fresh X-ray showed that the gap was more and the bones were not united and he had to undergo another operation.

Opposing the allegations of the petitioner, the hospital and the doctor stated that the operation of Titanium closed interlocking rod was done as per the standard procedure. Moreover, the patient did not follow the instructions for physiotherapy. He was in good condition when the stitches were removed, they submitted. They also said that the patient, over the phone, informed Opposite Party No. 2 that he fell down from his bed and suffering from pain in his left hand.

After considering the submissions of both the parties, the state commission ordered "The Complaint is allowed. The OPs are severally and jointly directed to pay Rs. 96,686.00 and further a sum of Rs. 1 lakh as compensation and Rs. 10,000/- as cost to the Complainant No. 1 within a month otherwise the OPs shall be liable to pay interest @ 10% p.a. on the entire awarded amount."

Finding the order unjust, the doctor turned to the National Consumer Dispute Redressal Commission. It was contended that the doctor experienced Orthopaedic Surgeon. He performed the operation under C-Arm vision screen and there was no chance of procedural mistake. The X-rays were examined before and after the operation. There was no gap after the operation. The Opposite Party No. 2 neither used oversized Titanium interlocking rod nor the oversized screws. The union of bone was not guaranteed and the gap seen may be due to various reasons such as pressure, fall, cohabitation, any hit / trauma to the fractured bone and due to non-formation of callous in normal manner.

The bench noted: It is pertinent to note that the patient did not follow the medical advice for exercise and the physiotherapy. Moreover he fell , fractured bones. However, it is evident from X-ray dated 11.11.2000 there was proper bone alignment and the rod in proper shape. We do not find any cogent evidence produced by the Complainant that the rod or screws used during surgery were oversized.

The doctor who is a qualified and experienced Orthopedician followed the accepted standard method to treat the fracture Humerus with use of C-Arm during the procedure. The new bone (callus) formation at fractured site takes long period and thus the patient was advised to wait and do regular exercise and physiotherapy.

The bench then observed: What may appear as a heroic `early second intervention` which has palpably caused a positive impression on the patients mind cannot be used as a weapon to castigate the original surgeon or his methods who was following a well-accepted treatment plan including `watchful expectancy`. Such an assumption based on `what could have been…` is too presumptuous, simplistic and thus, untenable. It has become all too common for some medical personnel to present a `one up `view of their own practice to impress or convince a patient of additional treatments or alternative remedy, which may be in essence unrequired at that point of time. Such a patient intent on blaming someone for their misfortune and possibly arisen to a combination of his injury mechanism or complex pattern, his existing co-morbidities, in combination with slower biology by many other variables, is now

all too ready to blame the original Surgeon and thereby cause injustice to the actually prudent practitioner of medicine.

Dismissing the plea of the patient, the bench then granted relief to the doctor and said:

"The doctor is not liable for negligence if he performs his duty with reasonableness and with due care. The mode of treatment and skill differ from doctor to doctor." "the doctor treated the patient as per the standards. There was no negligence while performing the fracture operation and fixing the Titanium interlocking rod and screws to the Humerus. On the basis of the examination made above, deficiency / medical negligence is not established. We set aside the Order passed by the State Commission and dismiss the Complaint. Parties to bear their own cost."

Ref.: https://medicaldialogues.in/news/health/medico-legal/no-negligence-ncdrc-relief-to-orthopedic-surgeon-told-to-pay-compensation-to-patient-for-se… Accessed on 10/09/20

WBCERC Directs Hospital To Pay Rs 1 Lakh Compensation, Forwards Case To Medical Council.

West Bengal: The West Bengal Clinical Establishment Regulatory Commission has directed a private hospital of Parkcircus to pay the sum of Rs 1 lakh as compensation to a patient's family as an interim directive. Besides, the commission has forwarded this case to the West Bengal Medical Council and has decided to take the final call based on its verdict.

This came in the wake of a complaint with the States Regulatory commission by a patient's kin who previously received treatment in the hospital and later died in another hospital.

The petitioners stated that the patient, an 81-year-old resident of Shreerampore was suffering from several age-related problems and comorbidities, hence he was admitted to the neuroscience speciality hospital from another private hospital on January 13th.

Times of India reported that the family, in the petition, alleged that the hospital kept the patient in the emergency without any proper warm covers and only with a white sheet which resulted in the patients being affected with pneumonia. Moreover, the petitioner claimed that during extubation the patient also suffered vessel injury and after that, his family shifted the patient to a local nursing Home in Shreerampore after 7 days where he eventually passed away.

According to the daily, after considering the submissions of both the parties, justice Ashim Kumar Banerjee, the chairman of WBCERC stated that the commission will forward the case to the West Bengal Medical Council for disposal and until the disposal of the case the private hospital should pay 1 lakh rupees as compensation to the patient's family.

The Court stated: "while we have forwarded the case of medical negligence to the West Bengal medical council, we have asked the hospital to pay compensation of rupees 1 lakh as an interim directive. We have asked the patient party to come back to us with the medical council's verdict after which we will take the final call."

Ref.: https://medicaldialogues.in/state-news/west-bengal/wbcerc-directs-hospital-to-pay-rs-1-lakh-compensation-forwards-case-to-medical-council-69784 2/6 Accessed on 23/09/2020

WBCERC Decisions: 3 Hosptials Fined For Medical Negligence, 1 Nursing Home For Refusing Patient

West Bengal: Cracking a whip on three private hospitals and a nursing home for denying to treat COVID patients and being negligent in patients' care, the West Bengal Clinical Establishment Regulatory Commission (WBCERC) has imposed fines on all these facilities including Fortis Hospital, Anandapur; All Asia Medical Institute in Gariahat; R Flemming Hospital in Topsia and Midland Nursing Home in Belghoria.

A sum of Rs 1 lakh has been levied on Fortis hospital, while the All Asia Medical Institute and R Fleming hospital has been directed to pay Rs 50000 each, further, the nursing home in Belgharia has been slapped a fined Rs 5 lakhs.

This came in wake of a batch of complaints moved with the state health regulatory commission by patients kin.

The Belgharia based Midland nursing home has been pulled in a case where the parents of an 18-year-old patient alleged in their complaint that the hospital did not attend to their son who was clearly struggling to breathe, rather they asked them to take him to a higher facility as they did not have treatment facilities for COVID victims in the hospital.

The patient was facing respiratory trouble hence he was taken to the ESI hospital Kamar Hati on July 10. However, he was transferred to the Belgharia based private hospital who ran rapid testing on the patient, and the patient was found to be COVID positive after which they allegedly refused to treat the patient.

Finding no solution, the parents rushed the patient to Calcutta Medical College, where he passed away within hours of admission.

On the other hand, the rest of the three hospitals have been fined in connection with a case where a seventy-eight-year-old resident of Rishra, Hoogly was allegedly denied admission and further received no assistance in his transfer.

Filling a complaint, the daughter of the patient alleged that his father was facing health issues following which the patient was rushed to the Fortis hospital but the hospital authority denied him admission. When the patient was taken to Fortis Hospital, he was suspected to be suffering from Covid-19. He tested positive for the disease at the Ekbalpore nursing home.

The hospital had justified their denial stating that no ICU beds were available for the patient after which the patient was taken to All Asia Medical Institute. The institute firstly assured to admit the patient, however, on reaching the hospital they too denied admission to the patient on the same ground.

Thereafter, the patient was then taken to R Flemming hospital in Topsia which accepted the patient but did not provide him an ICU facility in spite of his grave condition and informed the family members that he had to be kept in a general bed. The complainant alleged that the hospital did not pay due attention to the patient.

The Commission heard the case and gave its final judgment. It told the Fortis Hospital that they should have arranged an ICU at another hospital before transferring the patient. It found some negligence on the part of the other two hospitals as well.

In the first case, taking cognizance of the concerns, Justice Ashim Kumar Banerjee, the chairman of WBCERC criticized the act in the case of the nursing home and stated that "the nursing home should have stabilized the patient before sending it to a higher setup. The commission directs the nursing Home to deposit a sum of rupees 5 lacs with us within a week till the hearing is over." The commission also instructed the facility to deliver an affidavit explaining the incident.

Expressing the case pertinent to three private hospitals, Banerjee while considered the submission of the complainant criticized the hospitals for not ensuring the ICU facility for the patient and denying admission to him.

He told The Telegraph, "We told the hospital they should have made arrangements for the man's admission at another hospital if there was no ICU bed in their hospital. The hospital said they had tried to do so. But we felt the hospital could have done more."

Commenting on the matter, an official at Fortis told The Telegraph that "The patient was brought to the hospital around midnight and stayed at

our emergency for three hours, during which time our doctors stabilized him. We arranged for an ambulance. We also inquired with neighboring hospitals but none had an ICU bed vacant…. We called up the family when an ICU bed became vacant in our hospital, but unfortunately, the person had passed away by then."

Meanwhile, an official of All Asia Medical Institute said they would appeal against the fine and informed a daily that "The complainant could not give any evidence. We don't have any record with us that shows that the patient had come to our hospital and refused admission. We had asked for some evidence so that we could inquire on our own, but the complainant was unable to give any evidence like call records or emergency unit records."

Ref.: https://medicaldialogues.in/state-news/west-bengal/wbcerc-decisions-3-hosptials-fined-for-medical-negligence-1-nursing-home-for-refusing-patien…Accessed on 23/09/2020

Cardiologist, Hospital Asked To Pay Rs 12 Lakh Compensation On After Patient Death

Nashik: Holding a cardiologist and hospital guilty of medical negligence the Maharashtra State consumer commission has directed them to pay Rs 12 lakh compensation to the patient who died during treatment at the facility.

The case goes back to the year 2012 when the 69 Years old patient was admitted to the Nashik based referral hospital with complaints of heaviness in the chest. As per the report of the angiography a day before the admission, it was diagnosed as Single vessel disease, the patient was treated with angioplasty (PTCA for LAD) the next day in which stent was passed in Left Anterior Descending Artery, which was performed by the Cardiologist.

After the angioplasty, the patient's health started deteriorating with a rapid drop in the blood pressure (hypotension) and other vital parameters for treating doctors tried to investigate by abdominal sonography to find out the source of bleeding inside the body to find out the reason for the drop in blood pressure, intensive care treatment was given, Cardiothoracic Surgeon was consulted. But despite all possible efforts to treat the patient, he succumbed and died 2 days later.

Aggrieved by the death of the patient, the wife of the deceased and son, filed a complaint at the State Consumer Disputes Redressal Commission alleging negligence in the treatment. Whereas the hospital and the doctor opposed the complaint by filing written statements and evidence, medical literature along with expert opinions.

During the hearing, the counsel on behalf of the deceased patient's kin submitted that, during the angioplasty, when the catheter was inserted in the femoral artery, which was ruptured and there was dissection of the artery pressure, further lead to critical condition and since this was not diagnosed in time and the investigations like CT Scan was not done immediately, the patient died as no timely surgical exploration could be done and thus saving of life of the deceased was not possible.

It was also submitted that a renowned cardiologist from Aurangabad, who suggested that the CT Scan of the abdomen should have been done at the earliest. Thus, valuable time was lost and the most essential test of CT Scan of the abdomen to diagnose the cause of bleeding was not performed in time and thus there was a delay in diagnosis and treatment.

It was further submitted that another Cardiologist was telephonically consulted by the treating doctor and the cardiologist had advised to do CT Scan. Since this advice was neglected by the hospital, there was a delay in diagnosing as well as treating the patient, he alleged adding that there was non-availability of battery back up due to which there was delay in taking patient to CT Scan. Additionally, when the CT Scan of the abdomen was done over at 10 pm on that day, the patient was operated on next day indicating the negligence of the hospital.

However, the counsel for the hospital and the doctor averred that these were fabricated reports and the abdominal CT Scan was never advised, instead, it was wrongly informed that Sonography was performed.

Maintaining their stance, the doctor and the hospital presented a few expert opinions in support of their contentions which were however not considered by the court.

The relevant are as follows: "A Cardiothoracic Surgeon from Nashik, with 6 years of experience, stated that the treating doctor has adopted best possible treatment and is in line with the academic books and any reputed doctor would have acted on the same line considering the situation. At the end he has also mentioned that, "as patient's coagulation profile and renal parameters were deranged

Another expert opinion was by a doctor of DNB Cardiology, with 6 years of experience as Cardiologist, mentioned as the treating doctor has treated the patient according to the academic books. This opinion is replica of the opinion given by the cardiothoracic surgeon. Both the opinions presented by the petitioners do not explain the delay in advising CT Scan and then delay in performing the exploration operation of the patient, it was stated.

Considering the rival contentions of both parties, submissions made, the bench perused the records presented before it and reviewed the concept and settled principles in deciding the negligence by highly skilled medical professionals. It observed: "The concept of medical negligence is being dealt with settled principles of the law that govern it. Reasonable degree of care and skill means that the degree of care and competence that an "ordinary competent member of the profession who professes to have those skills would exercise in the circumstance in question." The burden of proof is correspondingly greater on the person who alleges negligence against a doctor than a charge of negligence against the driver of motor car."

Believing that the doctor is not liable for every injury suffered by the patient, the bench said; "The liability of a doctor arises not when the patient has suffered any injury, when he is treated in good faith but when the injury has resulted due to the conduct of the doctor, which has fallen below that of reasonable care. Thus, the doctor is not liable for every injury suffered by a patient. He is liable for only those that are a consequence of a breach of his duty. Hence, once the existence of a duty has been established, the complainant must still prove the breach of duty and the causation. In case there is no breach, or the breach did not cause the damage, the doctor will not be liable. To show the breach of duty, the burden on the complainant would be to first show what is considered as reasonable under those circumstances and then that the conduct of the doctor was below this degree."

Reaching its verdict, the bench relied on several observations made by the Supreme Court on the skill of a doctor and the brevity of medical negligence. Relevant is as follows, " the skill of a medical practitioner differs from doctor to doctor and it is incumbent upon the Complainant to prove that a doctor was negligent in the line of treatment that resulted in the life of the patient. It is for the Complainant to prove the negligence or deficiency in service by adducing expert evidence or opinion and this fact is to be proved beyond all reasonable doubts."

"A simple lack of care, an error of judgment or an accident is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed. When it comes to the failure of taking precautions what has to be seen is whether

those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial. Similarly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that particular time (that is, the time of the incident) at which it is suggested it should have been used."

Taking all the submissions, discussions and the record into account, the bench noted:

"The hospital, the treating cardiologist, after performing the angioplasty, did not come to the conclusion about the source of bleeding inside the human body and thus went on doing introducing the same into the artery. investigations that weren't necessary. Also, he neglected the advice given by the senior Cardiologist. He advised the CT Scan of Abdomen very late on the post-angioplasty day, on 8thMay 2014, by late evening. The CT scan was not possible as there was no battery backup to shift the patient down in the hospital where the CT Scan Department was situated. After the diagnosis of the bleeding source on CT Scan, the patient was not operated immediately in the night but next day, the reason given was the operation theatre was not ready for the operation for various reasons. We are of the opinion that, the OP no.2 was liable due to act of omission, while the OP no.1 the Regional Referral Centre, Nashik and the OP no.3 State Government were liable again for act of omission, not providing the facility necessary for emergency lifesaving treatment, even when the service to provide emergency treatment was charged; thus more responsible than the treating doctor himself. Thus, there was negligence in providing the emergency treatment and identifying as well as treating the complication of angioplasty, injury to the femoral artery by the sheath and catheter while introducing the same into the artery.

The bench held that there were acts of omission by the treating cardiologist, hospital and thus liable for the loss of life, that could have been avoided by vigilant and timely action by them. The doctor was liable for not taking proper steps to diagnose early the reason for unresponsive hypotension that the patient suffered from and the hospital and state were vicariously responsible for the act of omission of the hospital as well as the inadequate infrastructure of the hospital, in spite of the hospital being tertiary care hospital.

Considering the prior health of the deceased, the loss of life, loss of the pension income to the family and the mental agony-harassment associated, the bench ordered the hospital and the doctor to pay Rs 12 lakh compensation along with other costs to the patient and concluded on the case.

Ref.: https://medicaldialogues.in/news/health/medico-legal/cardiologist-hospital-asked-to-pay-rs-12-lakh-compensation-on-after-patient-death-69943 Accessed on 30/09/2020

Doctor Suspended By Medical Council For Discussing Post mortem On TV, Court Upholds Decision

Chennai: Refusing to set aside the punishment given by the Tamil Nadu Medical Council in suspending him for discussing a post mortem report during TV debate, the Madras High Court has directed the doctor to stay away from medical practice for a month as held by the council.

The bench headed by the Honourable Justice Parthiban has further directed the medical council to file a detailed report on the issue and submit before the court.

Earlier, the Tamil Nadu medical council suspended the license of the doctor as a punishment for discussing the contents of a post mortem report in a TV debate. Aggrieved by the council's decision, the doctor had moved the High Court seeking relief.

The infamous debate was held as a discussion on the suspicious death of a woman. On June 24, when the woman and her disabled father were sleeping outside their house, their relative raised an alarm claiming that the woman had killed herself. However, it was later found that relative and his brother allegedly committed the murder. Subsequently, a post mortem was conducted by the forensic experts.

During the hearing, the state medical council affirmed before the bench that the doctor participated in a Tamil TV program and discussed the suspicious death of the woman. He commented that the post mortem certificate issued by the government hospital was substandard, and had a lot of flaws.

The counsel appearing on behalf of the TNMC said that the doctor raised doubts on the post mortem certificate, without actually being part of the PM team or knowing the facts first hand. The case that was discussed in the show is still under investigation and the PM report alleged to be flawed by him is a confidential document. Accessing such confidential documents unofficially and discussing the content in public forums is an intrusion of privacy and is likely to affect the investigation and trial of the case, the council The TNMC, in its order stated: "Blatant accusations of defective post mortem based on the examination report can instigate unwarranted pressure on the part of the affected family and all those involved. When the police investigations are on and the case is under the purview of our reputed judicial system, Dekal's act was uncalled for by a registered medical practitioner,"

However, the council refused to accept his explanation and passed an order suspending his license to practice for one month.

After hearing submissions from both sides, the bench then refused to interfere in the order of the state medical council.

According to TOI report, while refusing to set aside the punishment and denying to issue interim relief to the doctor, the Madras HC stated: "Concurring with the stand of the council that a post mortem report is a confidential document and, therefore, accessing it unofficially and discussing the content in public forums is intrusion of privacy"

Further, the court directed the counsel to file a detailed counter by October 29.

Ref.: https://medicaldialogues.in/state-news/tamil-nadu/doctor-suspended-by-medical-council-for-discussing-postmortem-on-tv-court-upholds-decision-…Accessed on 30/09/2020

Getting Information About Medical Bills, Fundamental Right Of Patient: Hospital Slapped Rs 25,000 Compensation

Punjab: Holding that it is the fundamental right of the patient to acquire detailed information regarding his medical bills and treatment, the District Consumer Disputes Redressal Commission directed Chandan Hospital to provide all medical bills as well as treatment charts and the bills of the medicines to the patients and pay a compensation of Rs 25000 for unnecessary harassment.

This came after one of the patients who received treatment for in a private facility sought the direction of the Consumer Forum to acquire detailed information about his medical bills.

The patient submitted that he received treatment at Chandan Hospital in May2017 for cardiac problems. He alleged that he went to the hospital on19.05.2017 and was admitted on the same day. He informed the hospital that he has a valid insurance policy for his medical treatment. However, the hospital stated that their hospital is not empanelled with the insurance company.

The patient paid rupees Rs 1.50 lakh for his treatment in total. The patient alleged that despite his several requests to the hospital and even after service of legal notice through an Advocate, the hospital did not provide the bills for which the patient had already paid the money through various modes. Due to the non-supply Commission of bills, the patient could

not avail any reimbursement from the insurance company.

The court observed that the hospital and its authority have chosen to remain ex-parte and were proceeded against ex-parte vide order dated 13.08.2019 of this Commission. Complaint against OP No.3 was not admitted vide order dated 29.05.2019 of this Commission. Further, there was no explanation why the hospital and its Chairman chose to remain ex-parte and have not come forward to contest the claim of the CC. "We feel, that the complainant is successful in proving his allegations against the OP No.1 and 2," the court noted.

After considering the submission of the petitioner, the Commission stated that "since the entire evidence of the complainant is on the file and the hospital and its Chairman are already ex-parte, we feel that no prejudice is going to be caused to any of the parties if the present complaint is decided on merits. Otherwise also the present Consumer Protection Act is a Special Act that is enacted to provide speedy justice to the parties."

The Commission observed, "As per the new Consumer Protection Act,2019 rights of consumers are very carefully protected. Moreover, the Consumer Protection Act is a beneficial legislature intended to protect the fundamental and natural rights of the consumers. We feel, that it was a fundamental and natural right of the CC to get bills and details of medical treatment. To our mind, OP No.1 and 2 can never be permitted to withhold the medical treatment details as well as bills from its consumer "the CC". The cases before the Consumer Commissions are of summary nature and the Consumer Commissions are supposed to decide the matters in a summary way by appreciating the contents of the complaint as well as documents attached with the complaint."

Hence, the commission instructed the hospital to handover all medical bills as well as treatment charts and the bills of the medicines to the patient within 30days from the date of receipt of a free certified copy of this order.

The court further added, “Since the oppositions have unnecessarily caused harassment to the complainant, who is a heart patient, it is ordered that OP No.1 and 2 will also compensate him with consolidated amount of compensation to the tune of Rs.25,000/- (Rs. Twenty Five Thousand only) for mental harassment and litigation expenses. OP No.1 and 2 are further directed to pay this compensation within 30 days from the receipt of free certified copy of this order and submit the receipt before this Commission, failing which the CC will be entitled to interest @ 12% per annum. Certified copies of this order be sent to the parties free of cost as per rules. The file be indexed and consigned to the record room”

Ref.: https://medicaldialogues.in/news/health/medico-legal/getting-information-about-medical-bills-fundamental-right-of-patient-hospital-slapped-rs-250…Accessed on 07/10/2020

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Reference from journal: 1) Cogo A, Lensing AWA, Koopman MMW et al —Compression ultrasonography for diagnostic management of patients with clinically suspected deep vein thrombosis: prospective cohort study. BMJ 1998; 316: 17-20.

Reference from book: 2) Handin RI—Bleeding and thrombosis. In: Wilson JD, Braunwald E, Isselbacher KJ, Petersdorf RG, Martin JB, Fauci AS, et al editors—Harrison's Principles of Internal Medicine. Vol 1. 12th ed. New York: Mc Graw Hill Inc, 1991: 348-53.

Reference from electronic media: 3) National Statistics Online—Trends in suicide by method in England and Wales, 1979-2001. www.statistics.gov.uk/downloads/theme_health/HSQ 20.pdf (accessed Jan 24, 2005): 7-18.

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Review article- 4000 words, unstructured abstract of 150 words with up to 30 references in Vancouver style & 3-5 keywords

Chief Editor, JIMLEA

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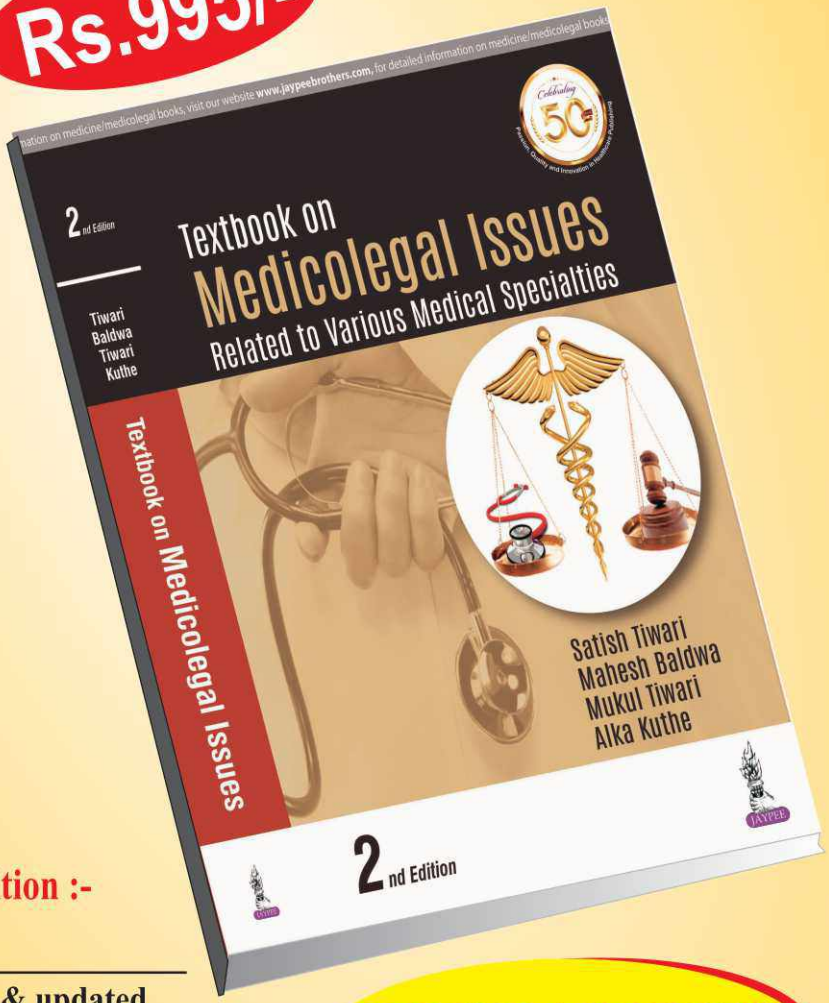

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3)	Dr. Rajendra Borkar	(Wardha)	9822240837
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