Medicolegal Corner

NEVER GO AGAINST THE RECOMMENDATIONS OF THE MANUFACTURER

All drugs/devices are accompanied with labeling or full prescribing information or the package insert, which includes directions for use, warning and precautions and dosage and administration. This package insert is for the doctor as the "learned intermediary", who can evaluate this information and sift out that which is relevant for his patient and accordingly balance the dangers of the drug against the benefits of its use. This is because prescription drugs and devices can be obtained by patients only when prescribed by their treating doctor. So, once the doctor has been warned, the duty to use the drug properly and to warn the patient about any risks is lies upon the physician.

One should never go against manufacturer's recommendation or DCGI (Drugs Controller General of India) approval, with regard to:

- Dose of a drug as approved by DCGI
- Indication/s approved by DCGI
- Reuse of disposables or device if written "for single use only"
- Off-label use of a drug needs informed consent.

If you do not do so, it will be termed as a trial and will require informed consent and approval of the Institutional Ethics Committee.

In the case of Balram Prasad vs. Kunal Saha & Ors on 24 October, 2013 in the Supreme Court of India: Civil Appellate Jurisdiction: Civil Appeal No. 2867 of 2012, the Apex Court has held as follows:

> *"73. He has also placed reliance upon in justification of his claim of exemplary or punitive damages. A claim of US $ 1,000,000 as punitive damages has been made against the AMRI Hospital and Dr Sukumar Mukherjee as provided in the table. In support of this contention he placed strong reliance on Landgraf Vs. USI Film Prods[29] and this Court's decision in Destruction of Public and Private Properties Vs. State of A.P.[30], wherein it is held that punitive or exemplary damages have been justifiably awarded as a deterrent in the future for outrageous and reprehensible act on the part of the accused. In fact punitive damages are routinely awarded in medical negligence cases in western countries for reckless and reprehensible act by the doctors or Hospitals in order to send a deterrent message to other members of the medical community. In a similar case, the Court of Appeals in South Carolina in Welch Vs. Epstein[31] held that a neurosurgeon is guilty for reckless therapy after he used a drug in clear disregard to the warning given by the drug manufacturer causing the death of a patient. This Court has categorically held that the injection Depomedrol used at the rate of 80 mg twice daily by Dr Sukumar Mukherjee was in clear violation of the manufacturer's warning and recommendation and admittedly, the instruction regarding direction for use of the medicine had not been followed in the instant case. This Court has also made it clear that the excessive use of the medicine by the doctor was out of sheer ignorance of basic hazards relating to the use of steroids as also lack of judgment. No doctor has the right to use the drug beyond the maximum recommended dose."*
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> 111. *"159. When Dr Mukherjee examined Anuradha, she had rashes all over her body and this being the case of dermatology, he should have referred her to a dermatologist. Instead, he prescribed "depomedrol" for the next 3 days on his assumption that it was a case of "vasculitis". The dosage of 120 mg depomedrol per day is certainly a higher dose in case of a TEN patient or for that matter any patient suffering from any other bypass or skin disease and the maximum recommended usage by the drug manufacturer has also been exceeded by Dr Mukherjee. On 11-5-1998, the further prescription of depomedrol without diagnosing the nature of the disease is a wrongful act on his part.*
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> *147. Therefore, a total amount of Rs. 6,08,00,550/- is the compensation awarded in this appeal to the claimant Dr Kunal Saha by partly modifying the award granted by the National Commission under different heads with 6% interest per annum from the date of application till the date of payment."*

So, before prescribing a drug, read the manufacturer/DCGI recommendations and prescribe the dose and/or use the device as per those recommendations. Failure to do so may make you liable for medical malpractice.

THE PATIENT WAS NOT GETTING CURED. CAN THIS BE TERMED AS MEDICAL NEGLIGENCE?

No doctor can give 100% guarantee about the treatment or surgery. The only assurance which a doctor can give or

can be understood to have given by implication is that he is possessed of the requisite skill in that branch of profession which he is practicing and while undertaking the performance of the task entrusted to him he would be exercising his skill with reasonable competence.

The Hon'ble Apex Court in various judgments has duly held that no guarantee is given by any doctor or surgeon that the patient would be cured.

1. In the matter titled as "**P. B. Desai versus State of Maharashtra, AIR 2014 SC 795**, the Hon'ble Apex Court has held that:

> *"39. It is not necessary for us to divulge this theoretical approach to the doctor-patient relationship, as that may be based on model foundation. Fact remains that when a physician agrees to attend a patient, there is an unwritten contract between the two. The patient entrusts himself to the doctor and that doctor agrees to do his best, at all times, for the patient. Such doctor-patient contract is almost always an implied contract, except when written informed consent is obtained. While a doctor cannot be forced to treat any person, he/she has certain responsibilities for those whom he/she accepts as patients. Some of these responsibilities may be recapitulated, in brief:*
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> *a. to continue to treat, except under certain circumstances when doctor can abandon his patient;*
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> *b. to take reasonable care of his patient;*
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> *c. to exhibit reasonable skill: The degree of skill a doctor undertakes is the average degree of skill possessed by his professional brethren of the same standing as himself. The best form of treatment may differ when different choices are available. There is an implied contract between the doctor and patient where the patient is told, in effect, "Medicine is not an exact science. I shall use my experience and best judgment and you take the risk that I may be wrong. I guarantee nothing."*
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> *d. Not to undertake any procedure beyond his control: This depends on his qualifications, special training and experience. The doctor must always ensure that he is reasonably skilled before undertaking any special procedure/treating a complicated case.*
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> *e. Professional secrets: A doctor is under a moral and legal obligation not to divulge the information/ knowledge which he comes to learn in confidence from his patient and such a communication is privileged communication."*

2. In the matter **Malay Kumar Ganguly vs. Sukumar Mukherjee & Ors. AIR 2010 SC 1162, the Hon'ble Supreme Court of India** has held that:

> *"INDIVIDUAL LIABILITY OF THE DOCTORS There cannot be, however, by any doubt or dispute that for establishing medical negligence or deficiency in service, the courts would determine the following:*
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> *i. No guarantee is given by any doctor or surgeon that the patient would be cured.*
>
> *ii. The doctor, however, must undertake a fair, reasonable and competent degree of skill, which may not be the highest skill.*
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> *iii. Adoption of one of the modes of treatment, if there are many, and treating the patient with due care and caution would not constitute any negligence.*
>
> *iv. Failure to act in accordance with the standard, reasonable, competent medical means at the time would not constitute a negligence. However, a medical practitioner must exercise the reasonable degree of care and skill and knowledge which he possesses. Failure to use due skill in diagnosis with the result that wrong treatment is given would be negligence.*
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> *v. In a complicated case, the Court would be slow in contributing negligence on the part of the doctor, if he is performing his duties to be best of his ability.*
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> *Bearing in mind the aforementioned principles, the individual liability of the doctors and hospital must be judged."*

3. In the landmark judgment of **Jacob Mathew Petitioner v. State of Punjab & Anr. 2005(3) CPR 70 (SC) the Hon'ble Supreme Court of India** has held that:

> *"Para 28: No sensible professional would intentionally commit an act or omission which would result in loss or injury to the patient as the professional reputation of the person is at stake. A single failure may cost him dear in his career. Even in civil jurisdiction, the rule of res ipsa loquitur is not of universal application and has to be applied with extreme care and caution to the cases of professional negligence and in particular that of the doctors. Else it would be counterproductive.* ***Simply because a patient has not favourably responded to a treatment given by a physician or a surgery has failed, the doctor cannot be held liable per se by applying the doctrine of res ipsa loquitur."***

4. In the matter titled as **"Martin F. D'Souza versus Mohd. Ishfaq, 2009(3) SCC 1" the Hon'ble Supreme Court** has held that:

> *"Para 124: It must be remembered that sometimes despite their best efforts the treatment of a doctor*

fails. For instance, sometimes despite the best effort of a surgeon, the patient dies. That does not mean that the doctor or the surgeon must be held to be guilty of medical negligence, unless there is some strong evidence to suggest that he is."

5. In the matter titled as **"Lok Nayak Hospital versus Prema, RFA No. 56/2006" the Hon'ble High Court of Delhi vide judgment dated 06.08.2018** has held that:

"8. Firstly, it is to be noted that the only allegation of negligence alleged by the respondent/plaintiff against the appellant/defendant is that the tubectomy/sterilization operation failed. ***Since medically there is never a 100% chance of success in sterilization operations, the mere fact that the operation was not successful, that by itself cannot be a reason to hold the appellant/defendant and its doctors guilty of negligence.***

This aspect is no longer res integra and is so held by a Division Bench of this Court in the case of Smt. Madhubala Vs. Govt. of NCT of Delhi, 118 (2005) DLT 515 (DB)."

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Risk Factors for Readmission in Children with ARDS

About half of children who are discharged after admission for acute respiratory distress syndrome (ARDS) were at high risk of being hospitalized within 2 months of discharge, according to a new study published in *JAMA Network Open*.[1] The probability was higher in children who were hospitalized for ≥14 days or those who required a tracheostomy or had a complex medical condition at the time of initial hospital admission.

To determine the factors that may increase the probability of re-hospitalizations in children who survived ARDS, Garrett Keim from the Dept. of Anesthesiology and Critical Care Medicine, Children's Hospital of Philadelphia in Philadelphia, USA and colleagues conducted a retrospective study using data from an insurance claims database.

The researchers also investigated three factors related to the index hospitalization viz. presence or development of a complex chronic comorbidity (respiratory or extrapulmonary), tracheostomy and duration of hospitalization were linked to re-hospitalization. Children aged ≥28 days to <18 years, with ARDS, who needed mechanical ventilation were included in the study group. The primary outcome of the study was defined hospital readmissions at 1 year due to any cause. Children who were hospitalized again on the day of discharge were not included in the trial.

Between 2013 and 2017, a total of 14,890 children were found to have been hospitalized with ARDS. Out of these, 13,505 children survived and were discharged and were included in the analysis; nearly 60% of them were boys. After 1 year, 3748 children (27.8%), median age 4 years, were re-hospitalized within 1 year of discharge. The likelihood of 1-year re-admission was found to be 30.0% on survival analysis with 50% of readmissions taking place within 61 days of discharge from the index hospitalization.

More than 75% of children who were admitted again had complex chronic conditions (vs. 64% of those not readmitted). Nearly 22% of them had respiratory conditions (vs. 11% of those not rehospitalized). Children with chronic complex respiratory conditions were more than 2.5 times likely to require readmission within 1 year with adjusted hazard ratio (aHR) of 2.69, while children with chronic complex nonrespiratory conditions were at nearly 2 times risk of readmission with aHR of 1.86. The aHR for new tracheostomy was 1.98 and 1.87 for hospitalization duration of ≥14 days. Even when children with chronic medical conditions were excluded, the association of probability of readmissions remained significant for length of hospital stay of ≥14 days with aHR of 1.92.

This study has identified factors that were associated with the likelihood of children being re-hospitalized after discharge from the index hospitalization. Close follow-up of these patients after discharge along with timely interventions, as needed, "may reduce the readmission burden facing pediatric ARDS survivors", which increases health care costs. This however needs to be validated in future studies, concluded the researchers.

Reference

1. Keim G, et al. Readmission rates after acute respiratory distress syndrome in children. JAMA Netw Open. 2023;6(9):e2330774.