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National Medical Commission

Professional Conduct Review

(Lessons from Case Archives)

by

Ethics & Medical Registration Board

Volume-II
2024

Publication Division, National Medical Commission
Pocket-14 , Sector-8, Dwarka Phase-1, New Delhi–110077, INDIA

Professional Conduct Review

(Lessons from Case Archives)

राष्ट्रीय आयुर्विज्ञान आयोग

National Medical Commission

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Professional Conduct Review

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व रसायन एवं उर्वरक
भारत सरकार
Minister
Health & Family Welfare
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Government of India

Message

I am pleased to know that National Medical Commission (NMC) is bringing out the second edition of "Professional Conduct Review-(Lessons from Case Archives)" comprising the real-life cases adjudicated by seasoned professionals with an objective to enhance awareness, mitigate professional errors and safeguard patient from potential ethical lapses.

I understand that the publication would promote high ethical value in Medical Practitioners and fulfil the requirements of moral, ethical, social values and ethos of our diverse population. I am confident that this effort to compile real life cases on professional conduct for our medical professionals will ultimately result in providing good doctors to our needy population and will be helpful in achieving the very objective of our Government for providing better treatment to all.

I congratulate and praise the efforts of the NMC for this initiative and their efforts to ensure that doctors work in partnership with patients in an ethical manner in order to maintain and improve public trust towards Good Medical Practice. I hope that the second edition of this publication will go a long way towards improving overall healthcare service delivery and the health ecosystem in the country.

(Dr. Mansukh Mandaviya)

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सचिव
Sudhansh Pant
Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Message

I express my appreciation for the National Medical Commission (NMC), New Delhi, for publishing the second edition of the "Professional Conduct Review-Lessons from Case Archives".

I am confident that this publication will enhance awareness among all medical professionals, mitigate professional errors and provide guidance and safeguard from potential ethical lapses. The inclusion of lessons from case archives would be helpful to our doctors in identifying areas for improving their professional knowledge and make their skills up-to-date.

This second edition will continue to guide and promote good partnerships between professionals and their patients and colleagues, thereby serving to strengthen the trust of the public in doctors and the medical profession. It is expected that all Registered Medical Practitioners (RMPs) will use their professional judgment and expertise to apply the principles elaborated in this guidance document to various situations in their field of profession.

I congratulate all officers and supporting staff from the NMC for the timely publication of this important document.

Sudhansh Pant

Dated 7th December, 2023

(Sudhansh Pant)

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सत्यमेव जयते

आज़ादी का अमृत महोत्सव

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National Medical Commission
Ministry of Health & Family Welfare
Government of India

MESSAGE

I am happy to write this forward for the second book that is being released by the Ethics & Medical Registration Board (EMRB) of National Medical Commission.

The professional conduct review provides lessons from the archives of the cases that have been examined and decided upon in the appeals at the EMRB. As expected the second list of such collection is very rich with respect to the experience that it provides to the practicing doctors.

The cases emphasis the importance of informed consent and documentation to mitigate avoidable medico-legal concerns. Following accepted clinical guidelines in patient care is another lesson one can learn from these cases. It is required that medical practitioners should ordinarily become well-versed with the advances in the sciences related to their specialty. Even more so if these developments bring better outcome in the patient. For this reason, the National Medical Commission found it necessary to mandate credits for professional developments even if one has received the qualifying degree.

As is well said, a medical doctor is a life-time learner; learning not only in their specialty but also in areas that promote ethical and legal practice.

I congratulate the Ethics and Medical Registration Board for successfully bringing the second volume of this series.

(**Dr. B.N. Gangadhar**)

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Editor's Note

The resounding success of Volume 1 of our case series on medical ethics has highlighted the profound need for comprehensive, nuanced guidance in the field. The enthusiastic response from the medical community underscores the critical importance of such resources in navigating the complex ethical landscape of modern healthcare. As we present Volume 2, we are thrilled to announce significant expansions and advancements that will further enrich our collective understanding and application of medical ethics.

Recognizing the demand and importance of expert opinions in misconduct matters, our team has been significantly expanded. The Ethical and Medical Review Board (EMRB) has taken a pioneering step in not only producing this vital series but also in training experts to provide sound opinions in misconduct and medical-legal cases. This initiative is essential given that doctors often face scrutiny in multiple forums, including state medical councils, district consumer forums, civil and criminal courts, the National Human Rights Commission (NHRC), and other quasi-judicial bodies. Each of these entities frequently requires meticulously reasoned and evidence-backed expert opinions.

Understanding the gravity and complexity of these requirements, the EMRB has launched a nationwide training program aimed at equipping experts with the necessary skills to deliver logical, evidence-based opinions. This initiative ensures that every opinion is comprehensive, considering both supporting and opposing evidence, and articulates a clear, well-founded rationale.

Training sessions have already been conducted in several states, including Delhi, Rajasthan, Madhya Pradesh, Telangana, Andhra Pradesh, Goa, Maharashtra and Haryana & Punjab, with plans to extend this initiative to remaining states. These sessions have been meticulously designed to cover a wide range of scenarios and legal contexts, thereby preparing our experts to handle diverse and challenging cases with confidence and precision.

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The expansion of our expert team and the initiation of this comprehensive training program mark significant milestones in our commitment to enhancing medical ethics and supporting our colleagues in the medical profession. By equipping experts with the skills to provide well-reasoned medico-legal opinions, we aim to foster a more robust, fair, and transparent adjudication process across various forums.

Volume 2 of our case series on medical ethics builds on the foundation laid by its predecessor, incorporating new insights and developments from our expanded team of experts. Each case is carefully analyzed, presenting balanced arguments and evidence, thereby providing readers with a thorough understanding of the ethical principles at play.

We extend our gratitude to all contributors, trainers, and participants who have made this initiative possible. Together, we are advancing the field of medical ethics, ensuring that practitioners are not only well-informed but also well-prepared to uphold the highest standards of ethical practice in the face of legal scrutiny.

Yogender Malik

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National Medical Commission

Professional Conduct Review

(Lessons from Case Archives)

Volume-II

(2024)

Professional Conduct Review

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CASE 1

Allegation of Wrong Treatment and Negligence

- **Keywords:** Wrong Treatment, Medical Negligence, Lower Segment Caesarean Section.
- **Context:** Patient Care.
- **Abstract:**

A young woman with a family history of tuberculosis, was being treated by Dr. 'A' for infertility, and finally conceived. She received hormonal therapy in her first trimester as she had signs of a threatened abortion. At 32 weeks of gestation, she was admitted in Hospital 'X' with symptoms indicating premature labor and foetal distress, and an emergency Lower Segment Caesarean Section (LSCS) was done by Dr A after taking high-risk consent. Post-operatively, she developed urinary incontinence, due to a Vesico-vaginal Fistula (VVF). Dr. 'A' performed a corrective surgery for VVF at Hospital 'Y'. Several months later, symptoms persisted and a diagnosis of Ureterovaginal Fistula (UVF) was made at Hospital 'Z', where Dr. 'B' performed the surgical repair for UVF. The patient alleged that there was medical negligence by Dr. A.

- **Case Summary:**

A young woman, with a family history of tuberculosis, was undergoing infertility treatment under Dr. 'A' at Private Hospital 'X'.

After a course of treatment, she successfully conceived. In the first trimester, she received hormonal therapy as she developed signs of a threatened abortion. At 32 weeks of gestation, she was admitted in the emergency department of Hospital 'X' with abdominal pain and vaginal leakage. A diagnosis of preterm labor with premature rupture of membranes was made, appropriate investigations done and treatments were administered immediately. Due to fetal distress, an emergency Lower Segment Cesarean Section (LSCS) was performed under spinal anesthesia, with a high-risk consent taken by Dr. 'A'. Postoperatively, the patient experienced urinary leakage, prompting a urological consultation that diagnosed an overactive bladder. She was subsequently discharged in a stable condition. However, a few days later, the patient returned to Dr. 'A' with persistent urinary incontinence. Further urological evaluation revealed a vesicovaginal fistula (VVF) and a repair was performed by Dr. 'A' but at another private Hospital 'Y'; once more she was discharged in a stable condition.

Approximately six months after the VVF repair, the patient consulted Dr. B, an urologist at Hospital 'Z', as she had hematuria and abdominal pain, which was identified as menstrual blood in urine. She was diagnosed with ureterovaginal fistula (UVF), and repair of the fistula was conducted under general anesthesia by Dr. 'B'.

Following these events, the patient filed a medical negligence petition against Dr. 'A' and Hospitals 'X' and 'Y' with the Medical Council of India (MCI), which was initially referred to the State

Medical Council. Due to the State Medical Council's failure to resolve the case within six months, the patient appealed to the MCI to assume jurisdiction over the matter. The case was eventually taken over and resolved by the Ethical and Medical Registration Board (EMRB) of the National Medical Commission (NMC).

- **Discussion:**

The patient alleged that during the emergency Lower Segment Cesarean Section (LSCS) performed by Dr. 'A', the doctor had inadvertently damaged her bladder, resulting in urinary leakage. As a consequence, she underwent two additional surgeries to repair vesicovaginal fistula (VVF) and ureterovaginal fistula (UVF). The patient claimed that the surgeries conducted by Dr. 'A' at both Hospital 'X' and Hospital 'Y' were improperly executed, which she further believed placed her life in jeopardy. The patient initiated a medical negligence case against Dr. A, with the (former) Medical Council of India (MCI).

In response, Doctor 'A' submitted a statement to the State Medical Council explaining that the patient developed a vesicovaginal fistula following premature labour and lower segment cesarean section (LSCS), for which a surgical repair was subsequently performed. The case was then transferred to the State Medical Council by the Medical Council of India for further evaluation.

Due to the State Medical Council's failure to resolve the case within six months, the patient escalated the matter by filing an appeal with the former Medical Council of India. The Ethics and Medical

Registration Board (EMRB) subsequently admitted the case for review. Section 8.4 of The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, a decision on a complaint against an accused physician must be made within six months' time frame.

- **Decision of The Ethical and Medical Review Board (EMRB), NMC:** The patient was undergoing treatment of infertility and she conceived during this period. She had premature rupture of membranes for which emergency LSCS was performed. A premature baby was delivered. VVF is a known complication of prolonged labor, due to pressure of the baby's head. The Patient later (after six months) developed UVF which could be because of Stenotic Cervix, unrelated to VVF.

  i. Standard protocols were followed during the treatment and also while handling the complications of the treatment.

  ii. The doctor has written a different procedure to reduce medical expenditure of the patient on humanitarian grounds. EMRB instructs the RMP to mention only the original procedure in record and find other alternatives to financially assist such patients.

  iii. Dr. 'A' is exonerated of the charges of medical negligence. However, she is warned to be more careful in medical record keeping in future.

- **Lessons from the Case:**

  Informed Consent: The patient must be fully informed about the diagnosis, the nature and specifics of the proposed treatment, and the

potential risks and benefits of the procedure. Furthermore, any alternative options should be clearly explained and documented. This ensures that the patient's consent is well-informed and legally robust. In India, the apex court expects to follow ‘real consent as described in the case ‘Samira Kohli vs Dr. Prabha Manchanda’

Documentation: Maintaining accurate and comprehensive clinical records is fundamental to professional practice and the delivery of quality healthcare. Proper documentation is a vital defense for the treating physician in cases of medical negligence and legal proceedings (IMC 2002)

Proper Communication: Communication with patients and their relatives or attendants about possible complications or medical or surgical treatment is essential. Clear communication can prevent misunderstandings and foster trust in the doctor-patient relationship. This can be crucial when complications arise.

Medical Negligence: The medical professional is expected to bring a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence, judged in the light of the particular circumstances of each case, is what the law requires. Negligence cannot be attributed to a doctor so long as he performs his duties with reasonable skill and competence. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession. (Kusum Sharma & Ors vs Batra Hospital)

The case underscores the importance of informed consent, meticulous documentation, and effective communication in healthcare. Properly informing patients, accurately documenting treatments, and ensuring clear communication with patients and their families are essential practices that contribute to trust and legal protection in the medical profession.

Reference:

1. Samira Kohli vs Dr. Prabha Manchanda & Anr AIR 2008 SUPREME COURT 1385.

2. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (Amended in 2016).

3. Kusum Sharma & Ors vs Batra Hospital & Med.Research Centre 2010 (3) SCC 480.

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CASE 2

Deficiency of services in Management of Obstetric emergency

- **Keywords:** Obstetric emergency, Negligence, Blood bank, Lack of Infrastructure.
- **Context:** Patient Care.
- **Abstract:**

An emergency cesarean section was performed on a woman at 32 weeks of gestation, due to fetal distress, at an urban private hospital. The procedure revealed a ruptured scar from a previous Lower Segment Cesarean Section (LSCS) and significant abdominal bleeding. The premature infant was successfully delivered, resuscitated, and transferred to the neonatal ICU of another hospital. During the surgery, the patient's uterine bleeding, exacerbated by adherent placenta, could not be controlled, necessitating a subtotal hysterectomy. Despite immediate requisition of blood from a nearby blood bank and intensive management with fluids, blood transfusions, ventilation, and vasopressors, the patient stabilized but remained unconscious. Due to the absence of an ICU at the hospital, she was transferred to another hospital for intensive care and later referred to a tertiary care center in a major metropolitan area for advanced management of her neurological and pulmonary complications. The patient did not regain full consciousness and required long-term home care. Dissatisfied with the medical outcome

and the resultant dependency of his wife, the husband lodged a legal complaint against the treating physicians, alleging service deficiency and negligence.

- **Case Summary:**

An unbooked pregnant woman at 32 weeks gestation with a history of previous LSCS was admitted to an urban private hospital with symptoms of abdominal discomfort, vomiting, and low urine output. The patient had low blood pressure and was dehydrated. Initial treatment and investigations were directed toward a provisional diagnosis of acute cholecystitis, as premature labor was ruled out. An ultrasound scan yielded inconclusive results due to distended bowel loops. The patient's condition improved slightly with NG aspiration and IV fluids, but the next day, a decrease in fetal heart rate and movement was detected during routine obstetric monitoring. The attending physician promptly informed the patient and her husband that an emergency cesarean section was necessary to save the child, and consent was obtained.

During the surgery, performed under spinal anesthesia, uterine scar dehiscence and bleeding into the peritoneal cavity were observed. The preterm infant was delivered and successfully resuscitated by the pediatrician. Due to the lack of a Neonatal ICU at the hospital, the infant was transferred to a nearby facility for intensive care. The obstetric surgeon faced difficulties with placenta removal due to adherence in the lower segment, leading to postpartum hemorrhage and a drop in the patient's blood pressure. The anesthetist responded by intubating the patient, initiating

ventilator support, and administering fluids and vasopressors. A subtotal hysterectomy was performed to control the bleeding, and blood was urgently sourced from a nearby blood bank, after which three pints were transfused. Although the patient's vital signs stabilized, she did not regain consciousness.

Since there was no ICU in the hospital, the patient was transferred to another hospital for further intensive care. While in the ICU, she developed neurological deficits from hypoxic brain damage and contracted pneumonia. The husband was subsequently advised to move his wife to a tertiary care hospital in the nearest metropolitan city. Despite extended treatment, the patient remained in an unresponsive wakeful state and was discharged, still requiring continuous home care. The infant, however, responded well to neonatal care and was discharged.

Distraught over the events and the wife's irreversible condition, the husband contended that there was gross negligence in the pre-operative and operative management by the medical staff. He filed a complaint to the State Medical Council. He cited multiple instances of service deficiency and negligence by the doctors: a) Unwarranted Cesarean section at 32+ weeks without indications b) Failure to diagnose anaemia and arrange blood before surgery c) Lack of blood bank facility, neonatal facility and ICU facility in the Hospital, d) Mismanagement during surgery leading to subtotal hysterectomy, and hypoxic brain damage without consent and e) the anesthetist was also made co-accused of negligence in managing hypotension and failing to secure separate consent for anesthesia. He also lodged an

FIR at the local police station and pursued compensation claims through the National Consumer Disputes Redressal Forum, seeking around 2 crores for hospital fees and treatment costs.

In response, the treating team stated that it was an emergency situation in which fetal distress was noted, and an emergency cesarean section at 32+ weeks was done after explaining to the patient and their family members and getting consent. Despite being preterm, the baby was successfully delivered and resuscitated. Unexpected excessive bleeding during surgery caused by a low-lying anterior adherent placenta led to a decision to do a subtotal hysterectomy. The excessive bleeding and hypotension could have caused the subsequent hypoxic brain damage. The non-availability of various facilities like ICU, Blood bank and neonatal care facility was defended by the doctors stating that these were unexpected emergency complications that led to the need for ICU care, and which was not usually encountered. The treating team also reported that consent for anesthesia was taken along with consent for surgery because it was an emergency situation, and there was no time for separate consent. During surgery, when there was a drop in blood pressure due to bleeding, the protocol of care was followed to resuscitate, using fluids, oxytocin, vasopressors, and conversion from spinal anesthesia to general anesthesia ventilation with oxygen.

- **Decision of State Medical Council (SMC):** After reviewing the written complaints, respondents' responses, medical records, affidavits, evidence, documentation, the arguments of the complainant, and the explanations given by the accused doctors, the

State Medical Council (SMC) decided that there was no medical negligence in the case.

- **Decision of The Ethical and Medical Review Board (EMRB), NMC:**

The husband appealed to the Ethics and Medical Regulation Board of the National Medical Council against the decision of the SMC. After hearing the submission of both parties and reviewing all the relevant records and also the opinions of experts, the Ethics and Medical Registration Board (EMRB) decided that the obstetric surgeon should have been more cautious in the circumstances and made active efforts to arrange for blood. The surgeon could have considered the option of referral in this high-risk case in the absence of critical care facilities. The medical records should have been more elaborate and clear. The surgeon was warned to be more careful in the future.

- **Discussion:**

To assess the need for emergency cesarean section performed at 32 weeks gestation and further management of the patient using Bolam's test, one must evaluate whether the actions of the medical professionals involved align with the standard practices accepted by a responsible body of medical opinion in the same specialty. Bolam's test (Bolam v. Friern Hospital Management Committee) serves as a benchmark to ascertain if healthcare providers have fulfilled their duty of care by comparing their actions to those of reasonably competent peers in similar circumstances. The emergency cesarean, were prompted by signs of fetal distress such as reduced fetal movements and a falling fetal heart rate, which are recognized

indicators for such intervention. The subsequent complications highlight the complexities involved in managing high-risk pregnancies and unforeseen complications like uterine scar dehiscence and placental adherence.

These complications can appear to be a departure from standard care, particularly in situations requiring rapid and extensive postoperative management. The scenario's complexities were compounded by the patient's unbooked status and the emergency nature of her presentation, which might influence the interpretation of the standard of care. Given the critical and time-sensitive context, the medical decisions made before, during, and after the cesarean section, though resulting in negative outcomes, were evaluated using Bolam's test to determine adherence to professional standards.

Considering all factors, the regulatory body concluded that there was no negligence in this case. The medical team's response to the acute developments during surgery, although resulting poor consequences, was determined to be within the bounds of acceptable medical practice given the emergency circumstances and the standards upheld by similarly skilled peers in the field. However, EMRB has made significant observations that the surgeon could have considered the referral option in this high-risk case in the absence of critical care facilities.

- **Take home messages:**

Legal Framework and Medical Accountability: The fact that a doctor charged with negligence acted according to the general and approved practice, is enough to clear him of the charge. Two things are pertinent in medical negligence. Firstly, when assessing the

practice adopted, the standard of care is judged in the light of knowledge available at the time (of the incident), and not at the date of trial. Secondly, 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 the time on which it is suggested as should have been used." (Martin F D'Souza v Mohd. Ishfaq)

Criminal Negligence: For every mishap or death during medical treatment, the doctor cannot be blamed and prosecuted for negligence. Criminal prosecutions of doctors without adequate medical opinion to support negligence, would be doing great disservice to the community at large. If the courts were to impose criminal liability on hospitals and doctors for everything that goes wrong, the doctors would be more worried about their own safety than giving the best treatment to their patients. (Suresh Gupta v. Government of NCT, Delhi)

Importance of Comprehensive Facility Resources: The absence of critical services like a blood bank or neonatal ICU in facilities where high-risk cesarean sections are performed highlights a significant systemic issue in resource availability within healthcare settings. This underscores the crucial need for strategic healthcare planning and infrastructure enhancement, particularly in facilities that manage high-risk cases. It also emphasizes the necessity to establish protocols for referring such cases to better-equipped centers if the required facilities are not available onsite, ensuring patient safety and optimal care outcomes.

References:

1. Bolam v. Friern Hospital Management Committee (1957) 1 WLR 582.

2. Martin F D'Souza v Mohd.Ishfaq AIR 2009 Supreme Court 2049.

3. Suresh Gupta v. Government of NCT, Delhi, (2004) 6 SCC 422.

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CASE 3

Documentation and Communication

- **Keywords:** Premature Rupture of Membranes, Forceps delivery.
- **Context:** Patient Care.
- **Abstract:**

A 37-year-old woman, at 33 weeks of gestation, arrived at the emergency room with vaginal fluid discharge. She was diagnosed to have Premature Rupture of Membranes (PROM), and a forceps delivery was conducted. The neonate was admitted to the Neonatal Intensive Care Unit (NICU) but succumbed 10 days post-delivery. Subsequently, the father filed a case of negligence against the doctor. However, the case was dismissed by both the State Medical Council (SMC) and the National Medical Council (NMC) as negligence could not be established.

- **Case Summary:**

A 37-year-old woman, known to be diabetic and with childhood burn scars over her extremities and abdomen, presented at 33 weeks gestation with leaking per vaginum in the emergency room of a hospital. Her obstetrician made a diagnosis of Premature Rupture of Membranes (PROM) and preterm labor. A trial of labor was initiated, which was closely monitored and documented on a Partogram. A

forceps delivery was successfully performed by a trained obstetrician.

The newborn appeared lethargic with a poor APGAR score at birth and required immediate resuscitation, which was administered by a qualified pediatrician present in the labor room. Due to respiratory distress, the neonate was transferred to the Neonatal Intensive Care Unit (NICU). After a stormy clinical course the baby succumbed on the tenth day post-birth. Birth asphyxia with sepsis was documented as the cause of death. An allegation of negligence was subsequently filed by the family against the treating doctor.

The State Medical Council (SMC) reviewed the case and concluded that there was no negligence on the part of the treating doctor, noting that treatment records were well-documented and there was adequate evidence of communication with the relatives. The Ethical and Medical Registration Board (EMRB) upheld SMC's decision.

- **Discussion:**

A case was filed in court by the relatives of a 33-week pregnant woman, for negligence related to delivery of her second child in an emergency situation. The patient had a documented history of diabetes and childhood burn scars on her extremities and abdomen. She experienced leaking per vaginum due to Premature Rupture of Membranes (PROM) and was admitted by the doctor to manage the natural progression of labor and further care.

As labor did not progress as expected, the obstetrician decided to perform a forceps delivery, having informed the attending pediatrician. The relatives' request for a cesarean section (LSCS) was deferred, and pre-ordered blood was not used. The hospital records meticulously documented these decisions and obtained informed consent, detailing the potential risks to both mother and child.

The baby was born preterm with a delayed cry, and low APGAR score necessitating admission to the Neonatal Intensive Care Unit (NICU). Despite all efforts, the baby passed away after 10 days in the NICU. The loss deeply affected the relatives who lodged a complaint against the obstetrician. They questioned the doctor's qualifications to perform the forceps delivery. They also criticized the decision not to proceed with a cesarean section, when that was an option and blood was arranged for surgery. They called for removal of the doctor's name from the state medical register.

- **Decision of State Medical Council (SMC):** SMC reviewed the case and found no evidence of negligence. It confirmed that the obstetrician's qualifications were adequate and noted that the medical records were well maintained, with clear communication to the relatives about the treatment. EMRB upheld the decision of SMC after obtaining expert opinion on the subject.
- **Decision of The Ethical and Medical Review Board (EMRB), NMC:** EMRB also supported the SMC's decision, reinforced by an expert opinion on the matter.

- **Take home messages:**

Standard of care: The Bolam test is a legal principle derived from the 1957 English case, Bolam v. Friern Hospital Management Committee, which sets the standard for assessing professional negligence in medical malpractice cases. It states that a medical professional is not guilty of negligence if they acted in accordance with a practice accepted as proper by a responsible body of medical practitioners skilled in that particular art, even if there is a body of opinion that contradicts this practice. In the present case forceps delivery was an alternative to a cesarean section. If the doctor's decision and actions met the standard of a responsible body of medical opinion, then he is not considered negligent. The unfortunate outcome of the newborn's death was unforeseen despite all efforts. However, under the Bolam test, the focus is on the standard of care provided rather than the outcome of the treatment.

Performing the duty of care: Negligence cannot be attributed to a doctor so long as he performs his duties with reasonable skill and competence. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action he decided was acceptable to the medical profession. (Kusum Sharma & Ors vs Batra Hospital & Med.Research Centre)

Documentation and communication: Proper documentation and timely communication with relatives regarding the treatment approach can safeguard the doctor in challenging situations. In medical negligence cases, the quality of documentation significantly influences the decision of the Council. In the court of law regarding

medical negligence cases - Good documentation contributes to good defense, poor documentation is a poor defense and no documentation is no defense.

References:

1. Bolam v. Friern Hospital Management Committee (1957) 1 WLR 582.

2. Kusum Sharma & Ors vs Batra Hospital & Med.Research Centre 2010 (3) SCC 480.

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CASE 4

Allegation of inadequate experience of doctor and inadequate consent

- **Keywords:** Medical Negligence, Informed Consent, Inadequate professional experience.
- **Context:** Patient Care.
- **Abstract:**

An elderly patient with diabetes mellitus was admitted to the emergency department of a private hospital with breathlessness, but no chest pain. He was diagnosed with acute coronary syndrome, left heart failure, pulmonary oedema, and chronic kidney disease. After stabilizing the patient and obtaining proper informed consent, a coronary angiography was done, which revealed multi-vessel coronary artery disease, including the left main artery. The benefits and risks of both coronary angioplasty and bypass surgery were thoroughly explained to the patient's attendants. Subsequently, the patient underwent coronary artery stenting but developed hypotension and ventricular tachycardia after the procedure. Despite immediate intubation and resuscitation, he could not be revived. Following these events, the patient's son filed a complaint with the State Medical Council, alleging that the treating doctor lacked adequate experience for the complex case and that proper informed consent was not obtained before the angioplasty. However, the State

Medical Council found no evidence of medical negligence. The complainant then appealed to the erstwhile Medical Council of India, which upheld the initial decision of the State Medical Council.

- **Case Summary:**

  An elderly patient with a history of diabetes mellitus was admitted in the emergency department of a private hospital with acute onset of breathlessness, throat pain on exertion, and a persistent cough for two weeks. After examination, he was diagnosed with acute coronary syndrome—non-ST elevation myocardial infarction, pulmonary edema with left ventricular systolic dysfunction (acute heart failure), and chronic kidney disease. He was admitted under the care of an interventional cardiologist. The following day, after obtaining informed consent, coronary angiography was performed, revealing multi-vessel coronary artery disease with significant occlusions in four main coronary arteries. The patient and his relatives were informed about the options for early revascularization—either multi-vessel angioplasty or coronary artery bypass grafting—and the associated risks and benefits of each. They opted for multivessel angioplasty.

  Shortly after the procedure, the patient developed sudden hypotension. Despite investigations for common post-angioplasty complications like pericardial effusion and bleeding, no causes were identified. He was immediately intubated and resuscitated by the anesthesiologist, started on mechanical ventilation, and a temporary pacemaker was inserted. However, within half an hour in the cardiac ICU, he developed ventricular tachycardia and, subsequently, had a

cardiac arrest. Despite 30 minutes of CPR, there was no return of spontaneous circulation. Following these events, the patient's son filed a medical negligence complaint against the interventional cardiologist with the State Medical Council.

- **Decision of State Medical Council (SMC):** The state medical council conducted the inquiry on the complaint made by the patient's son and decided after reviewing the evidence, that there was no professional negligence on the part of the treating doctor. However, the complainant was not satisfied with the verdict of the SMC and disagreed with the reasoning for the decision; he appealed to the EMRB, NMC
- **Decision of The Ethical and Medical Review Board (EMRB), NMC:** After getting the opinion of expert cardiologists and hearing all aspects of the case, the EMRB concurred with the decision of the state medical council and found no evidence for the allegations levied by the complainant.
- **Discussion:**

  The complainant raised several concerns regarding the treatment of his father, an elderly patient with complex health issues. He alleged that the medical care and intervention provided were neither timely nor adequate, and questioned the qualifications and experience of the treating cardiologist. Furthermore, there were serious issues raised about the informed consent process, particularly the absence of the patient's signature on the consent form, which was instead signed by the patient's son. The complainant also claimed that

CPR was improperly administered by a junior anesthesiologist, which he believed contributed to his father's unfavorable outcome.

In response, the doctors replied that it was a complex case in which the elderly person was suffering from diabetes, acute coronary syndrome, left heart failure, pulmonary edema, and chronic kidney disease. The medical records and testimony from the hospital staff indicated that all treatments, including emergency interventions and follow-up care, were conducted appropriately under the supervision of qualified medical experts. The treating cardiologist and anesthesiologist were well-qualified and experienced in managing such complex cases, as corroborated by his credentials and past successful procedures.

Regarding the informed consent, it was detailed and clearly outlined the risks and procedures, allowing the patient's next of kin to sign on his behalf, which is a standard and acceptable practice in situations where the patient is unable to sign. The procedure was carried out successfully and all due clinical protocols were followed. This adherence to established medical practices and procedures suggests compliance with the Bolam standard, which recognises the actions as appropriate if they align with the consensus of a responsible body of medical opinion.

- **Take home messages:**

It must be remembered that sometimes, despite the best efforts, the treatment of a doctor fails to produce the expected results, for various other reasons. 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 guilty of medical negligence unless there is some strong evidence to suggest it. (Martin F D'Souza v Mohd.Ishfaq)

The Supreme Court emphasized the importance of obtaining informed consent from a patient before proceeding with any medical treatment or surgery. Performing any additional procedures without patient explicit consent will be deemed unauthorized, making the hospital and the doctor liable for the lack of informed consent (Samira Kohli vs Dr. Prabha Manchanda)

Only common complications of diagnostic and interventional procedures or surgeries should be described in detail to the patient and relatives. Not every remote complication needed to be mentioned.

In case of criminal medical negligence, the following steps should be followed as per the Supreme Court of India (Jacob Mathew vs State of Punjab)

a) A private complaint may not be entertained unless the complainant has produced prima facie evidence before the Court in the form of a credible opinion given by another competent doctor to support the charge of rashness or negligence on the part of the accused doctor. The investigating officer should, before proceeding against the doctor accused of rash or negligent act or omission, obtain an independent and competent medical opinion, preferably from a doctor in government service qualified in that branch of medical practice who can normally be expected to give an impartial and

unbiased opinion applying Bolam's test to the facts collected in the investigation.

b) A doctor accused of rashness or negligence may not be arrested in a routine manner (simply because a charge has been leveled against him). Unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigation officer feels satisfied that the doctor proceeded against would not make himself available to face the prosecution unless arrested, the arrest may be withheld.

References:

1. Martin F D'Souza v Mohd. Ishfaq AIR 2009 Supreme Court 2049.
2. Samira Kohli vs Dr. Prabha Manchanda & Anr AIR 2008 SUPREME COURT 1385.
3. Jacob Mathew vs State of Punjab & Anr AIR 2005 SUPREME COURT 3180.

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CASE 5

Allegation of delayed diagnosis and treatment leading to death

- **Keywords:** Delay in diagnosis, Delay in treatment, Negligence.
- **Context:** Patient Care.
- **Abstract:**

A young woman was admitted to a private hospital with symptoms of fever and cough for 4-5 days, along with breathing difficulties. She had been seen in the emergency room the previous day, at which time she was found to be clinically stable and hence discharged with medications. She was admitted the next day in the same hospital with worsening symptoms and breathing difficulty. She was diagnosed with viral pneumonia (Influenza) in respiratory distress. Immediate treatment included antiviral therapy, oxygen support, and admission to the ICU. Despite the initial use of non-invasive ventilation, her condition deteriorated, necessitating intubation and mechanical ventilation. With no signs of improvement, she was moved to another private hospital by her mother, but the patient passed away after six days in hospital. Subsequently, her mother filed a complaint against the attending pulmonologist, accusing him of medical negligence and unethical conduct.

- **Case Summary:**

A 20-year-old woman was brought to the emergency room of a private hospital at 8 am with a 4-5 day history of fever and cough. After receiving symptomatic treatment, she was clinically stable and discharged on antibiotics and anti-allergics, with instructions to follow up in the ENT outpatient department. However, her condition did not improve and she returned to the pulmonology OPD the next day. This time the patient clarified that she had cough, fever, shortness of breath and dyspnea on exertion for the past 9-10 days. Since she had tachycardia with low oxygen saturation, she was immediately admitted to the emergency room for treatment. A provisional diagnosis of acute bronchitis with lower respiratory tract infection and respiratory distress (suspected influenza), was made. She was started on oxygen therapy and Oseltamivir, and a flu panel was advised.

In the ward, her condition worsened and she was moved to the medical ICU with chest x-ray findings that showed bilateral pneumonia, requiring ventilation. The family was informed of her deteriorating condition and the need for non-invasive or invasive ventilation. In the ICU, she was managed with non-invasive ventilation and medications. On day 4 in the ICU, a test confirmed Influenza A, supporting the initial diagnosis and treatment approach. Despite continued treatment and further investigations, her condition worsened, leading to intubation and invasive ventilation after consent from the family. Attempts at prone ventilation were made due to persistent hypoxemia, despite maximal ventilator support.

A multidisciplinary team meeting, including the treating pulmonologist, a critical care expert, and the patient's mother, discussed her continued deterioration and the need for Extracorporeal Membrane Oxygenation (ECMO) support. As ECMO was unavailable at the hospital, the family was offered a transfer to another hospital within the same network, or to another of their choosing, that could provide ECMO. The complainant decided to shift her to another private hospital. The patient was transferred under advanced cardiac life support conditions in an ambulance equipped with a ventilator and monitored by a doctor who provided a detailed handover upon arrival. Unfortunately, she passed away six days later in the ICU of the second hospital.

Following her death, the patient's mother filed a police complaint alleging medical negligence against the pulmonologist at the first hospital. The case was subsequently referred to the State Medical Council to assess whether there was any medical negligence by the treating physician.

- **Decisions of State Medical Council (SMC) and Ethics and Medical Registration Board (EMRB), NMC:**

The five-member executive committee of the SMC reviewed the complaint lodged by the patient's mother, the written statements from the concerned doctors, the patient's medical records, and other relevant documents. They noted that the patient had received treatment in accordance with the standard protocol for viral pneumonia during her stay at the hospital. She was admitted to another hospital where treatment continued under the same standard

protocol. She passed away after six days due to the severity of her underlying condition, which had a poor prognosis despite the appropriate treatment provided.

Following thorough deliberations, the SMC found no prima facie evidence of medical negligence by the treating doctors and dismissed the case. Dissatisfied with this outcome, the patient's mother appealed to the EMRB. After a careful review of all records and expert opinions, the EMRB agreed with the SMC's decision, affirming that the medical care provided was appropriate and there was no basis for a negligence claim.

- **Discussion:**

To determine medical negligence in a case involving a patient with viral pneumonia using the Bolam test, one must assess whether the medical professionals' actions are aligned with the standard of care approved by a responsible body of medical opinion. In the present case, the patient initially presented with mild respiratory distress symptoms, was deemed clinically stable, and received symptomatic treatment and antibiotics. This initial response must be evaluated against the standard practices for treating mild viral respiratory conditions. Upon her return with worsened symptoms, the patient was diagnosed with hypoxemic respiratory failure and received escalating care, including oxygen therapy, non-invasive, and, later, invasive ventilation, reflecting a standard escalation in response to deteriorating conditions.

Moreover, the ongoing communication about the patient's worsening prognosis and the treatment decisions made were in line with what

would be expected from competent medical practitioners, ensuring the patient and her family were well-informed. Despite all appropriate measures, the patient's condition deteriorated leading to her death, which under the Bolam test does not necessarily indicate negligence. This outcome suggests the severity and unpredictability of the illness rather than a deviation from standard medical care. The medical team's actions, from diagnosis through escalating care and communication, adhered to accepted medical practices, indicating no evidence of negligence as per the Bolam test criteria. Additionally, the consistency in the line of treatment between the initial hospital and the subsequent hospital where the patient eventually succumbed further supports the conclusion of adherence to standard medical protocols.

- **Lessons from the Case:**

1. The initiation of litigation in response to a negative treatment outcome, despite the dedicated efforts of medical professionals, does not inherently suggest negligence. However, clear and effective communication can mitigate misunderstandings between patients, their families, and healthcare providers, thereby reducing distrust towards the treating doctor and legal action. Further, unrealistic expectations from family members may also contribute to the decision to litigate.

2. Doctors should avoid making negative comments to patients about clinical decisions or procedures done by other professional colleagues. This will help maintain the trust in the medical fraternity. In the present case, a comment by a treating physician against the previous team triggered the case. Further, one of the complaints in

this case was the unkind behaviour of the doctors. A good doctor-patient relationship fosters more trust between doctors and patients. Any deficiency in trust can invite litigation.

3. Proper patient examination, treatment and regular documentation of the clinical findings is the best defense of a treating doctor in medical negligence cases and in the court of law. The procedures must also be documented and communicated to the patient/family.

4. In an apex court judgment, the court has clearly said that the medical professional is expected to bring a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires. The medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. (Kusum Sharma & Ors vs Batra Hospital & Med.)

References:

1. Kusum Sharma & Ors vs Batra Hospital & Med. Research 2010.

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CASE 6

Misdiagnosis of congenital anomalies

- **Keywords:** Antenatal Scan, Congenital Anomaly, Radiodiagnosis.
- **Context:** Patient Care.
- **Abstract:**

A 27-year-old woman gave birth to a child with a congenital heart defect and cleft lip and palate. She accused the diagnostic centre of negligence for failing to detect these conditions in the Level II antenatal scan. This oversight led to the birth of a child with congenital anomalies, causing significant distress to the family. The State Medical Council concluded that the radiologist involved had committed a professional error and suspended his medical license for three months. An appeal was filed by the affected doctor with EMRB against the order of the State Medical Council.

- **Case Summary**

A 27-year-old woman gave birth to a child with congenital heart disease and cleft lip and palate. She had done three ultrasound scans during the antenatal period at a recognised private diagnostic centre in the state capital. The Level II scan conducted at 19 weeks of gestation, was expected to detect congenital anomalies. The radiologist reported “Foetal cardiac activity is present, foetal cardiac anomalies cannot be excluded without Foetal Echocardiography, and "no cleft is seen, nasal bone appears normal." The mother alleged

that the negligence of the doctor resulted in the continuation of the pregnancy and resulting birth of a child with a cleft lip & palate and cardiac anomalies with the heart on the right side. There was also a renal abnormality which was missed.

After birth, the child's oxygen saturation level was around 70%, raising concerns about the child's development. The mother claimed that when confronted, the diagnostic centre acknowledged the error. The family experienced considerable physical, emotional, financial, and social distress, and the mother was seeking punitive measures against both the radiologist and the diagnostic centre, for not detecting the congenital anomalies during the scan. She also demanded appropriate compensation for the family's suffering and the child's treatment.

- **Decision of State Medical Council (SMC):** The SMC concluded that there was medical negligence and recommended removal of the radiologist's name from the State Medical Register for a period of three months. They also directed him to undergo fresh training in Radiology for a period of one month from any competent centre of his choice.
- **Decision of Ethics and Medical Registration Board (EMRB), NMC:** On receiving the appeal, EMRB upheld the decision of SMC based on the facts, and evidence produced after hearing of the case.
- **Discussion:**

In cases where a doctor misses the diagnosis of 'cleft lip, cleft palate, cardiac abnormality, and renal abnormality' during a Level II scan, the question of whether they can be punished for medical

negligence depends on several key factors. Applying the Bolam's test (Bolam v. Friern Hospital Management Committee) It needs to be established that the doctor failed to act according to the standards that a reasonably competent professional in a similar position would have maintained. Conditions like cleft lip and cleft palate are usually visible during a detailed anomaly scan if the foetus is in a favorable position. Cardiac and renal abnormalities can be more challenging to detect and may require more specific imaging techniques or follow-up scans. Proper documentation of the scan findings and any recommendations for further testing (foetal echocardiography for suspected heart issues) are crucial. A failure to recommend further investigation where there are signs of possible anomalies could also be seen as a breach of duty. Inability to detect significant findings can affect the radiologist's professional reputation, as well as the trust placed in them by patients and colleagues.

In his defense, the radiologist presented medical literature indicating that the diagnostic accuracy for detecting cleft lip and palate using 2D scans ranges from 9% to 50%. The type of ultrasound used (2D or 3D) was not specified in the scan reports; however, from the attached images, it is apparent that the scans were performed using 2D technology. The literature also highlights that 3D ultrasound scans enhance accuracy in diagnosing cleft lip and palate. Despite this knowledge, the doctor did not inform the patient about the more accurate 3D scanning technology's availability and benefits, which could have led to a more definitive diagnosis. For cardiac anomalies, the doctor noted that "Foetal cardiac anomalies cannot be excluded without Fetal Echocardiography." However, according to

standard guidelines for a Level II scan, a detailed assessment, including comments on the situs, cardiac axis, four-chamber view, three-vessel view, and outflow tracts, is expected. The doctor failed to provide these essential details in his report. The Level II ultrasound initially reported both kidneys as normal. Yet, postnatal imaging revealed an empty right renal fossa and crossed fused ectopia of the right kidney. Level II scan should have identified and reported the absence of the kidney in the right renal fossa. The failure to detect and document this significant anomaly further underscores that the reporting on the Level II scan did not adhere to the standards of care.

In applying the Bolam test to this case, the key question is whether the doctor's conduct during the Level II scan met the standards that a reasonable body of medical experts would deem acceptable. This includes the thoroughness of the cleft lip, cleft palate, cardiac and renal evaluations, the choice of imaging technology, and the communication regarding diagnostic options. The Bolam test also evaluates whether the doctor communicated effectively about the limitations of the scans and the availability of better diagnostic options. Not informing the patient of the availability of more accurate technology (3D scans) for specific conditions could be seen as a deviation from standard care if most competent professionals would have shared this information. In cases where the doctors act carelessly and in a manner that is not expected of a medical practitioner, then in such a case an action in torts would be maintainable (Achutrao Haribhau Khodwa vs State Of Maharashtra)

- **Take home messages:**

The case involving the missed diagnoses of fetal anomalies during a Level II scan highlights several critical take-home messages for medical practice, patient care, and the legal framework governing medical negligence.

Importance of Adhering to Standard Guidelines: Medical professionals are expected to be competent and skilled, andstrictly adhere to established guidelines and protocols, especially in diagnostic settings. This case underlines the need for thorough assessments and comprehensive reporting, as outlined by standards for Level II scans, which include detailed evaluations of cleft lip and palate and fetal cardiac and renal anomalies.

Communication with Patients: Clear and thorough communication with patients regarding the limitations of diagnostic tests, potential uncertainties, and the availability of more advanced or accurate diagnostic options is crucial.

Documentation and Transparency: Proper documentation of all medical findings, recommendations, and patient communications is essential.

This case stresses the necessity for professional competence, rigorous adherence to medical standards, appropriate use of technology, effective communication, and diligent documentation in medical practice.

References:

1. Bolam v. Friern Hospital Management Committee (1957) 1 WLR 582.

2. Achutrao Haribhau Khodwa vs State Of Maharashtra 1996 SCC (2) 634.

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CASE 7

Allegation of Missed diagnosis and Tampering with Medical Records

- **Keywords:** Micro Incision Cataract Surgery (MICS), Eye Tumour, Informed Consent, Documentation, Retinal Detachment.
- **Context:** Patient care.
- **Abstract:**

The patient presented at Institute-Y with complaints of diminished vision in her left eye and was seen by Doctor-X, who diagnosed retinal detachment. She was recommended a two-stage surgical intervention: initially, a Micro Incision Cataract Surgery (MICS) with foldable intraocular lens and vitrectomy, followed by a Retinal Detachment Surgery at a later date.

Following all required protocols, including informed consent, counseling, and necessary medical investigations, the first stage of the surgery was completed successfully. The second stage was performed a month later to correct the retinal detachment. The patient initially recovered well but developed severe pain in her operated eye fifteen days postoperatively. Doctor X ordered an MRI scan at a private lab, which was reported as normal by the consulting radiologist.

As the pain persisted, the patient sought a second opinion from Doctor Z at a leading ophthalmology institute. Another MRI was

conducted, and this time, the in-house radiologist identified a choroidal hemangioma - an eye tumor. Subsequently, the patient went through multistage laser therapy, which successfully alleviated her pain. Following these events, the patient filed a complaint with the State Medical Council (SMC) against Doctor X, alleging medical negligence.

- **Case Summary:**

The patient visited Doctor X at Hospital Y, a specialized Laser Eye Institute, complaining of blurred vision and pain accompanied by watering in the left eye, persisting for 8-9 months and 2-3 months, respectively. Examination revealed a posterior subcapsular cataract and hazy media in the left eye. Further clinical assessment indicated a retinal detachment accompanied by anterior vitreous hemorrhage. The intraocular pressure measured was 15 mm Hg. There was only light perception present in the left eye, with inaccurate ray projection in one quadrant and no vision improvement with refractive correction.

The patient was advised to undergo left eye surgery in two stages. The first stage included Micro Incision Cataract Surgery (MICS) with the insertion of foldable intraocular lenses (IOL) and an anterior vitrectomy. The second surgery planned was vitrectomy with Retinal Detachment Surgery. Diagnostic A/B scans confirmed the vitreous hemorrhage and retinal detachment. At the same time, optical coherent tomography (OCT) indicated normal vision in the right eye but could not be assessed in the left eye due to hazy media. Before proceeding, written informed consent was obtained in the patient's

mother tongue, Hindi, explaining the surgical procedures and the necessity for subsequent surgery to address the retinal detachment and vitreous hemorrhage.

The first surgery (MICS with foldable IOL and anterior vitrectomy) was performed successfully, and the patient was discharged the same day. Follow-up visits showed no signs of infection and proper intraocular lens positioning. The patient was informed about the need for the second stage of surgery for the retinal detachment.

Fifteen days after the initial surgery, a re-examination confirmed the presence of a previous total retinal detachment in the left eye. The patient was then readmitted for the second stage of the surgery which included retinal detachment repair, vitrectomy, and anti-glaucoma procedures. The patient and her relatives were thoroughly informed about the expected outcomes and the surgical process, and informed consent was obtained before the second-stage surgery.

Ten days after the surgery (Stage-2), the patient experienced severe pain, and was advised an MRI to rule out potential intra-cranial or orbital tumors in the left eye. The MRI showed no signs of intra-cranial or intraocular tumors. However, examination revealed elevated intraocular pressure and high blood pressure. The patient was prescribed anti-glaucoma medication and scheduled for a follow-up visit after a week. Unfortunately, she did not attend the scheduled follow-up.

As the severe pain in her eye continued, the patient sought a second opinion from another Doctor Z at a premier ophthalmology

institute. During this visit, a repeat MRI revealed a choroidal hemangioma, a type of eye tumor. The patient was treated with multistage laser therapy, which effectively relieved her pain. Despite the successful outcome, the patient decided to file a complaint with the State Medical Council (SMC) against Doctor-X, accusing him of medical negligence.

- **Decision of State Medical Council (SMC) -** The SMC made the following remarks-

1. Written consent was obtained, but it did not mention the visual prognosis.
2. It is difficult to comprehend why Doctor X suddenly suspected the complainant was suffering from an intraocular tumor (choroidal haemangioma) after he had done two intraocular surgeries and later ordered an MRI scan. Choroidal haemangioma must have been present throughout but, for some reason, was not picked by USG and MRI at hospital Y.
3. The Informed Consent had a handwritten insertion that noted 'prognosis-poor and guarded,' which was not there in the Informed Consent Form submitted earlier.

   Going by the above observations, SMC ruled against the doctor, as there was tampering with medical records, and ordered the temporary erasure of registration.

- **Decision of Ethics and Medical Registration Board (EMRB), NMC:** After hearing the submission by both parties and perusing all the relevant records as also the opinions of the experts, the following observations were made-

- Due process and protocols were followed in treating the patient as per the standards prescribed, and the opinion of experts also concurs with this.
- Doctor X has admitted to submitting two different consent forms and mistakenly encircling, double ticking, and writing "Prognosis Poor & Guarded." However, the doctor had already written "Prognosis poor" in the patient record. So, this could be termed manipulation from a treatment point of view. Doctor X was warned to be careful in the future regarding documentation and exonerated of all the charges, including the temporary erasure of his name from SMC
- **Discussion:**

  The patient charged Doctor X with service deficiency and negligence in her complaint to the State Medical Council. She claimed that after examining her, Doctor X noted her defective vision in the left eye and recommended immediate surgery, suggesting that a successful lens implant would eliminate the need for further procedures. However, Doctor X clarified that during her initial consultation, she had already been experiencing pain, watering, and vision loss, leading to a diagnosis of cataract and retinal detachment. He advised a two-stage surgical intervention, explaining that no guarantees were possible about vision recovery after surgery.

  The patient also contended that she needed to be informed about the nature and quality of the lens to be implanted. In response, Doctor X asserted that full details regarding the Intraocular Lens (IOL) and its insertion were provided, with additional information included on the discharge summary's sticker. After the first surgery, which

involved Micro Incision Cataract Surgery (MICS) with foldable IOL and vitrectomy, the patient reported no vision in her left eye. Despite this, Doctor X had already communicated the poor prognosis and clarified that the second surgery was aimed at correcting the retinal detachment, not to restore vision.

Doctor X had suspected an orbital tumor after the first surgery cleared the field, and advised the MRI. Although the MRI results were normal, Doctor X continued to suspect a tumor, adjusting the patient's medication and promising pain relief and vision restoration, which led to a misunderstanding as the patient did not return for a follow-up.

Additionally, the patient noticed alterations in her medical records, including overwriting on the consent form and scribblings in the case sheet. Doctor X acknowledged that these were made during discussions about the surgery's possible outcomes or during a review of the medical records. He emphasized that these were unintentional and did not result in any substantive changes or legal misconduct.

This series of events led to a complex situation with regard to communication and procedural clarity. Doctor X maintained that his actions were up to medical standards, aiming to address the severe conditions affecting the patient's vision while ensuring informed consent and understanding of the treatment's scope and possible outcomes.

- **Take home messages:**

1. Taking consent cannot be reduced to a mere formality of just taking a signature on a document. Informed consent is a process of exchanging information between the patient and the physician. Counseling and one-to-one discussions are necessary in all cases of guarded prognosis, particularly with vital organs like the eye, and must be appropriately documented.

2. Consent is procedure specific. Consent given only for a diagnostic procedure cannot be considered consent for the treatment. Consent given for a specific treatment procedure will not be valid for conducting some other procedure (Samira Kohli vs Dr. Prabha Manchanda & Anr).

3. Apex court in a landmark judgment Kusum Sharma & Ors vs Batra Hospital & Med. Research Centre.

   a) In the realm of diagnosis and treatment, there is scope for genuine difference of opinion, and one professional doctor is not negligent merely because his conclusion differs from that of another professional doctor.

   b) The medical professional is often called upon to adopt a higher element of risk, which he believes provides greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Just because a professional looking to the gravity of illness has taken a higher element of risk to redeem the patient out of his/her suffering, which did not yield

the desired result, it may not amount to negligence (Kusum Sharma & Ors vs Batra Hospital).

References:

1) Samira Kohli vs Dr. Prabha Manchanda & Anr AIR 2008 SUPREME COURT 1385.

2) Kusum Sharma & Ors vs Batra Hospital & Med. Research Centre 2010 (3) SCC 480.

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CASE 8

Forceps delivery and Hypoxic brain injury in a newborn

- **Keywords:** Birth Asphyxia, Forceps Delivery, Microcephaly, Medical Records.
- **Context:** Patient care.
- **Abstract:**

A 28-year-old woman pregnant with her first child, arrived at the hospital at term. She was in labor and had elevated blood pressure. After examination, the doctor decided to attempt normal vaginal delivery. However, during the second stage of labor, there was foetal distress and the doctor used forceps to assist delivery. After birth, the baby had a low APGAR score, and developed seizures, as a result of severe hypoxic ischemic injury and microcephaly. The mother filed a complaint alleging negligence during forceps delivery, but the State Medical Council concluded there was no negligence. Dissatisfied with the decision, the mother appealed to the EMRB NMC. The EMRB upheld the SMC's decision.

- **Case Summary:**

A 28-year-old primigravida at term went to a private hospital with abdominal pain, and was attended by a qualified gynaecologist. She had elevated blood pressure of 140/90 mm Hg, but other vital signs were normal. Examination revealed cervical effacement with one finger dilatation, and a pelvic assessment suitable for vaginal

delivery. The foetal condition appeared normal with a heart rate of 100 bpm. A sonogram conducted a day earlier showed no abnormalities. Opting for vaginal delivery, the labor progressed without initial complications.

During the second stage of labor, the patient experienced exhaustion and the fetus showed signs of distress, including a decreasing heart rate and caput formation. The gynecologist decided to perform a forceps-assisted delivery at this stage, with the active phase lasting 3 hours and 21 minutes. On delivery, the newborn had a delayed cry, required resuscitation and later developed seizures, leading to NICU admission. Despite initial care, the neonate's condition worsened over three days, prompting a transfer to a tertiary centre. Four months later, an MRI scan revealed microcephaly, a thickened calvarium, and signs of severe hypoxic ischemic injury along with a bilateral frontal extradural late subacute hematoma.

The patient filed a complaint with the Medical Council of India, which was referred to the State Medical Council (SMC). The complainant alleged that the forceps delivery resulted in the baby's hypoxic brain injury. The SMC concluded that the forceps delivery was executed correctly, as there was no initial indication for a cesarean section, and found no negligence. Dissatisfied, the patient appealed to the EMRB NMC.

- **Decision of the Ethics & Medical Registration Board (EMRB), NMC:** Upon thorough examination of all pertinent records and consultations with experts, the Ethics & Medical Registration Board supported the doctor's decision for a normal delivery, noting there

was no clear indication for a cesarean section.The use of forceps was also deemed justified and within standard clinical guidelines. It is challenging to definitively attribute the neonate's condition to the use of forceps or to mismanagement of labor alone. The etiology of cerebral palsy can be influenced by prenatal, intranatal, and postnatal factors. An MRI conducted four months post-delivery indicated microcephaly and perinatal hypoxic brain injury. The hospital's discharge diagnosis included craniosynostosis, which suggests a potential genetic contribution to the condition.

However, EMRB board noted that there were significant lapses in maintaining proper medical records. The prenatal check-up records, intranatal records were found interleaved with the baby's pediatric notes, suggesting they were inserted post-facto. Additionally, the resuscitation of the neonate was not recorded by the pediatrician. The presence of unqualified staff in the hospital, as noted by the CMO inquiry, and the unsigned consent form, further highlight procedural shortcomings.

Finally, the board determined that the use of forceps cannot be solely blamed for the neonate's condition. Nevertheless, it issued a caution to the gynecologist about the importance of meticulous record-keeping and the need for obtaining written informed consent.

- **Discussion:**

Childbirth is a significant event for women, and an increasing number are choosing cesarean delivery over vaginal birth. This trend is influenced by perceptions that cesarean sections are safer for the child and more successful, despite the historical view of vaginal birth as the natural and preferred method. Cesarean delivery, an operative

procedure, was traditionally considered risky and reserved for specific medical conditions.(1) Applying the Bolam test, which evaluates if a healthcare professional's actions align with standards accepted by a responsible body of medical experts, provides a structured analysis of the gynecologist's decisions and practice in this case.

First, concerning the initial assessment and decision to proceed with a normal delivery, the gynecologist's choice to rely on a recent ultrasound and clinical evaluation instead of insisting on previous antenatal records is potentially justifiable under the Bolam test. This approach appears to adhere to contemporary medical guidelines, suggesting that it reflects a standard of care endorsed by a reasonable body of obstetricians. Provided that relying on such immediate, clinically relevant information without older antenatal records is common practice.

Secondly, the application of forceps during labor due to foeto-maternal distress is supported by the medical literature as a reasonable response to the conditions presented during the second stage of labor. The Bolam test would likely find this intervention acceptable, as using forceps in such scenarios is a standard practice backed by a significant segment of medical professionals.

The newborn’s complications that arose post-delivery, though severe, are described as uncommon outcomes of forceps use, which further supports the notion that the gynecologist’s decision falls within the realm of acceptable medical practice. The known complications of forceps delivery are perineal tears or lacerations,

maternal discomfort or pain, fetal bruising, facial marks, or, in rare cases, skull fractures and unsuccessful delivery (2,3). Those complications were not noted in this case. Also microcephaly could have occurred due to other processes such as inflammation, traumatic, toxic or teratogenic agents, or exposure to irradiation during the first two trimesters of gestation and congenital infections (4).

However, there are notable concerns regarding record-keeping, informed consent, and communication. The lack of comprehensive records, including the absence of a signed consent form and inadequate documentation of neonatal resuscitation, falls short of the meticulous standards required in medical practice. These procedural lapses do not meet the standards expected under the Bolam test, as proper documentation and informed consent are universally acknowledged essentials in clinical settings. Furthermore, the insufficient communication about the risks and benefits associated with different delivery options, particularly regarding the use of forceps, likely fails to meet the informed consent standards expected by the medical community. Hence, the warning was issued to the treating doctor.

- **Take home messages:**

1. As per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 Clause 1.3.1 - Every physician shall maintain the medical records pertaining to his / her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard proforma laid down by the Medical Council

of India and attached as Appendix 3. Clause 1.3 also gives other obligations of RMP regarding record keeping.

2. The Bolam test, a fundamental legal doctrine in medical negligence, stipulates that a physician cannot be held liable for negligence if their actions adhere to any of the standards of practice that are both prevalent and deemed appropriate by a responsible body of medical professionals at the time
3. Effective communication with patients is essential not only for gathering accurate medical histories but also for ensuring patients understand their illnesses, significantly aiding their recovery. Most negligence cases arise not from the clinical quality of care provided but from shortcomings in communication (5).

References:

1. UON Network. Tackling Unmet Need for Major Obstetric Interventions. Concepts, General Principles and International Network, 2018.

   http://www.uonn.org/wp-content/uploads/2018/09/guide1.pdf

2. ACOG Practice Bulletin No. 154: Operative Vaginal Delivery. Obstet Gynecol. 2015 Nov;126(5):e56-e65

3. Muraca GM, Sabr Y, Lisonkova S, Skoll A, Brant R, Cundiff GW, Joseph KS. Perinatal and maternal morbidity and mortality after attempted operative vaginal delivery at midpelvic station. CMAJ. 2017 Jun 05;189(22):E764-E772

4. Risk factors of birth asphyxia among newborns in public hospitals of Central Zone, Tigray, Ethiopia 2018. Tasew H, Zemicheal M, Teklay G, Mariye T, Ayele E. BMC Res Notes. 2018;11:496.

5. T Hegan. The importance of effective communication in preventing litigation. Med J Malaysia. 2003 Mar; 58 Suppl A:78-82

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CASE 9

Consent in Infertility and InVitro Fertilization

- **Keywords:** Consent, Guideline, Ethics, Assisted Reproduction, Oocyte Sharing.
- **Context:** Patient care.
- **Abstract:**

The Public Grievances Monitoring System forwarded an anonymous complaint to the State Medical Council (SMC) regarding Dr. K, a gynecologist accused of acquiring oocytes without proper consent during IVF treatment conducted by Dr. G, and subsequently using them for her own patients. SMC sought explanations from both doctors and temporarily removed Dr. K's name from the medical register for 30 days based on their responses.

Dr. K appealed this decision to the Ethics and Medical Registration Board (EMRB), contesting the allegations as well as the adequacy of inquiry by SMC. While acknowledging the unethical conduct of Dr K, EMRB also considered Dr. K's intention to assist patients facing IVF challenges. Consequently, Dr. K received a warning from EMRB, emphasizing the importance of ethical conduct over the intent to help the patient.

- **Case Summary:**

  Mrs. X was taking IVF treatment for infertility at Government Hospital 'H' under Dr. G's care. During the procedure, oocytes were extracted from Mrs. X. Subsequently, surplus oocytes were transferred to Dr. K, who utilized them for IVF treatment for two financially disadvantaged patients who had repeated IVF failures. An anonymous complaint lodged with the State Medical Council (SMC) alleged that Dr. K had obtained oocytes from a patient under the care of another physician without proper consent. This complaint triggered a suo-moto notice from the Public Grievance Monitoring system to Dr. K for the misappropriation of oocytes. The complaint highlighted the absence of informed consent from Mrs. X or the treating physician, Dr. G.

- **Decision of State Medical Council (SMC):** The matter was investigated through a designated committee at the SMC. The committee asked for an explanation from both Dr. K and Dr. G. Based on their response, the committee came to the conclusion that the use of oocytes by Dr. K for the IVF procedure was done without proper informed consent from the patient or from the treating physician Dr G. The practice of oocyte sharing was unethical and in violation of ICMR guidelines. Hence, the SMC removed Dr. K 's name from the medical register for 30 days.

- **Decision of Ethics and Medical Registration Board (EMRB), NMC:** Dr. K lodged an appeal with the EMRB against the State Medical Council's (SMC) verdict, contending that the accusations were unfounded and a proper inquiry had not been conducted. Dr. N

further argued that the imposed punishment was unjustified as it relied on anonymous, unsubstantiated, and malicious allegations. After conducting a comprehensive investigation, the EMRB confirmed the lapse in the entire IVF process involving Mrs. X. The sharing of oocytes occurred without proper consent from the donor, the recipients, and the treating physician, which violated guidelines of the Indian Council of Medical Research (ICMR) and was deemed unethical.

However, it was noted that Dr. K's actions were motivated by altruism rather than monetary gain, as she aimed to assist financially challenged couples struggling with recurrent IVF failures. Additionally, the oocyte sharing did not adversely affect the donor's outcome. Considering these factors, the EMRB warned Dr, K, to abstain from engaging in such unethical practices in the future. This decision aimed to balance accountability for the lapse with understanding of the context and intentions involved.

Considering these factors, the EMRB warned Dr. N to abstain from engaging in such unethical practices in the future.

- **Discussion**:

1. In India, Assisted Reproductive Technology (ART) is regulated by the Indian Council of Medical Research (ICMR) through guidelines established in 2005. These guidelines emphasize the necessity of obtaining comprehensive written informed consent from both the oocyte or sperm donor and the couple undergoing the treatment (ICMR ART Regulation guideline 2005, para 3.3.11).

2. The provision of IVF treatment requires a collaborative effort from a multidisciplinary team of specialists. Effective communication and coordination among team members are paramount for achieving successful outcomes. It is imperative that all team members are well-versed in the institute or department's standard operating procedures (SOPs), with clear delineation of responsibilities among them.

3. A crucial point to note is that oocyte (egg) sharing is deemed unethical by the Indian Council of Medical Research (ICMR), even when conducted with proper written informed consent (ICMR ART guideline 2005, para 1.6.11.3, pg 34 & para 3.9.3). Furthermore, any surplus oocytes (or embryos) should either be returned to the donor (or recipient couple) or stored for up to five years for potential future use. After this period, specific protocols are in place for their safe disposal (ICMR ART guideline 2005, para 3.11).

4. Furthermore, the Indian Government has introduced the Assisted Reproductive Technology (Regulation) Act, 2021. This act is designed to safeguard the rights of infertile couples and donors while also regulating the operation of IVF clinics and banks. It aims to ensure fair and ethical practices in assisted reproduction. Any violation of this law will not only be unethical but also illegal.

- **Take home messages:**

1. Even when actions are undertaken with good intentions if they violate ethical principles or professional standards, they can still be subject to disciplinary action and consequences.

2. Informed consent empowers patients to make autonomous decisions about their healthcare, their bodies and their cells/tissue,

respecting their rights and autonomy. Medical procedures could be considered unethical without proper informed consent, and potentially expose healthcare providers to legal and ethical consequences.

3. When healthcare providers communicate empathetically and respectfully with their patients, it enhances trust, understanding, and collaboration. Patients feel more comfortable expressing their concerns, asking questions, and actively participating in their own care. This leads to better health outcomes, improved adherence to treatment plans, and increased patient satisfaction

4. The Assisted Reproductive Technology (Regulation) Act of 2021 must be followed in word and spirit.

References:

1. Gazette of India. Ministry of Law and Justice (Legislative D) The Assisted Reproductive Technology (Regulation) Act, 2021 (NO. 42 OF 2021). https://artsurrogacy.gov.in/NationalArtSurrogacy/faces/HomePage.xhtml
2. National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India. 2005. https://main.icmr.nic.in/sites/default/files/art/ART_Pdf.pdf

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CASE 10

Allegation of negligence and inadequate qualification

- **Keywords:** Medical Negligence, Inadequate Qualification, Cost Manipulation.
- **Context:** Patient care.
- **Abstract:**

A 23-year-old woman diagnosed with Acute Lymphoblastic Leukemia was initially treated with immunotherapy but experienced a relapse. Dr. M was consulted for a Bone Marrow Transplant (BMT). After attempts to find a sibling match failed, a search was initiated for a Matched Unrelated Donor (MUD) through a global gene registry. Although a donor was located in Germany, logistical challenges delayed stem cell procurement, necessitating additional immunotherapy and expenses. Tragically, the patient succumbed to Graft versus Host Disease (GVHD) after the BMT. Allegations of medical negligence, inadequate information disclosure, nursing staff and team incompetence, and Dr. M's absence during critical periods were made by the family. They sought recourse by approaching various authorities for redressal.

- **Case Summary:**

A 23-year-old woman was diagnosed with Acute Lymphoblastic Leukemia and treated at a specialty hospital. Initial therapy included two cycles of immunotherapy; however, the leukemia relapsed. Hence, the patient was referred to Dr M, a hematologist for a Bone Marrow Transplant (BMT). Human Leukocyte Antigen (HLA) typing was conducted, but there was no suitable sibling match. The possibility of finding a Matched Unrelated Donor (MUD) was explored. Consequently, the patient was referred to a nonprofit global gene registry, which specializes in locating potential unrelated donors from around the world. A suitable donor was located in Germany, but logistical challenges arose when the donor relocated to the USA, delaying the stem cell procurement. This delay necessitated a third cycle of immunotherapy, escalating the treatment costs from 10 to 42 lakhs. Later, after the BMT, the patient developed Graft versus Host Disease (GVHD) and succumbed to the complications.

The patient's family accused the doctor of negligence, claiming they were not adequately informed about the potential complications of Bone Marrow Transplant (BMT) or the failure rates associated with immunotherapy. They also expressed doubts about the competency of the nursing staff and the medical team. Their objections extended to Dr. M's absence, alleging that his week-long leave and non-availability on phone were unacceptable despite being informed of the leave and the assignment of two qualified hematologists to oversee the case.

Furthermore, the patient's family alleged that the administration of Peglec before colonoscopy led to persistent diarrhea and subsequent ICU admission. However, this claim was refuted by the treating gastroenterologist, who stated that a colonoscopy was a necessary diagnostic procedure, and Peglec was normally prescribed. Additionally, concerns were raised about delays in gene mapping, leading to a delay in the BMT process. They questioned the increased cost of donor stem cells and the necessity of an additional cycle of immunotherapy, arguing that gene mapping is typically only performed when relapse is suspected to avoid unnecessary expenses. For these reasons the patient's family pursued legal actions for medical negligence against the healthcare providers, involving the Police, State Medical Council, National Medical Commission, and the Ministry of Health and Family Welfare, Government of India.

- **Decision of State Medical Council (SMC):** The SMC conducted an inquiry into the matter, forming a committee to hear from both the patient's party and the medical professionals involved. After careful consideration, the committee found no evidence of negligence in the treatment provided. The gastroenterologist confirmed that Peglec is routinely used for bowel preparation before colonoscopy procedures. Cost Escalation by the NGO Gene registry organization and hospital fell outside its jurisdiction. However, SMC raised concerns about the cost and billing. This matter was referred to the income tax authorities for further investigation. Upon investigation, it was found that the treating Dr. M's Course Completion Training (CCT) in Haematology from GMC UK in 2010 was not registered with the

SMC. As a result, the hospital was reprimanded for employing Dr.M as a haematologist without proper registration, and the committee recommended the hospital's de-empanelment for six months from the government. Additionally, Dr. M's medical registration was suspended for one year.

- **Decision of Ethics and Medical Registration Board (EMRB), NMC:** After considering arguments from both parties, the EMRB aligned with the State Medical Council's (SMC) findings, affirming that there was no negligence in the patient's treatment. Regarding Dr. M's qualifications for performing Bone Marrow Transplant (BMT), the EMRB referenced ICMR requirements and determined that Dr. M possesses the necessary qualifications for conducting BMT procedures. Although Dr. M's additional qualification was not registered with the regulatory body, that did not undermine his competency. The EMRB absolved Dr. M of all charges and reinstated his registration but issued warning for not registering his higher qualification. It also admonished the hospital for neglecting to verify Dr. M's qualifications and registration status before his employment. Furthermore, the EMRB stated that the issue of overcharging by the treating hospital and NGO Gene Registry falls outside the scope of its jurisdiction.
- **Discussion:**

The decision of both regulatory bodies SMC and EMRB did not find negligence in the treatment provided. Further, both the regulatory bodies made observations of overcharging by the hospital and NGO. They referred the matter to other authorities for further investigation. They also reprimanded the hospital for employing Dr.

M without looking into his registration status. They also warned Dr. M for not registering his qualification with the regulatory bodies. EMRB also noted that the Medical Council of India (MCI) Code of Ethics did not make the registration of higher educational qualifications mandatory. Hence, only a warning was given to Dr. M.

Regarding the complaint that Dr. M was unavailable for consultation during the crucial period, the regulatory bodies noted that Dr. M had informed the patient parties about his leave and that two qualified haematologists were assigned to oversee the case during his absence. This suggests that appropriate arrangements were made for continuity of care.

EMRB also emphasised the necessity for comprehensive consent procedures and full data disclosure in cases involving diseases with high mortality rates and costly treatments. The treating physician is responsible for providing detailed explanations and ensuring thorough understanding. Additionally, it is crucial for the physician to personally sign all consent forms, underscoring their accountability in the consent process.

- **Take home messages:**

1. Medical practitioners are obligated to register both their graduation and post-graduation qualifications with the regulatory authorities without exception

2. Physicians are responsible for ensuring continuity of care for their patients, even during their absences or leaves from work. This obligation entails making essential arrangements, like appointing

qualified substitutes or offering precise instructions to the healthcare team, to guarantee a smooth transition and uninterrupted medical attention for patients.

3. Healthcare facilities must adhere to regulatory standards and ensure that all medical practitioners are appropriately qualified and registered, avoiding potential legal and ethical issues.

4. Healthcare institutions must uphold fair pricing practices and maintain transparency in billing to prevent overcharging, as this can significantly add to the families financial burden. Moreover, such practices can erode trust between patients and healthcare providers, potentially leading to litigation

References:

1) The National Guidelines for Hematopoietic Cell Transplantation (NGHCT) in India, released in 2021. Available online at https://main.icmr.nic.in/sites/default/files/upload_documents/Nat_Guide_HCT.pdf Last accessed on 3 May 2024

2) The National Guidelines for Stem Cell Research (NGSCR-2017) by ICMR & DBT. Available online at https://nirrch.res.in/wp-content/uploads/2023/10/National-Guidelines-for-stem-cell-research-2017_Part-1.pdf Last accessed on 3 May 2024

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Citation as follows: Malik Y (2024) Professional Conduct Review-Volume II by Ethics and Medical Registration Board, National Medical Commission, New Delhi.

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Ethics & Medical Registration Board

Regulate professional conduct and promote medical ethics in accordance with the regulations made under NMC Act 2019:

- *Provided that the Ethics and Medical Registration Board shall ensure compliance of the code of professional and ethical conduct through the State Medical Council in a case where such State Medical Council has been conferred power to take disciplinary actions in respect of professional or ethical misconduct by medical practitioners under respective State Acts;*
- *Develop mechanisms to have continuous interaction with State Medical Councils to effectively promote and regulate the conduct of medical practitioners and professionals*

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National Medical Commission

Publication Division, National Medical Commission
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