राष्ट्रीय आयुर्विज्ञान आयोग

National Medical Commission

Professional Conduct Review

(Lessons from Case Archives)

by

Ethics & Medical Registration Board

Volume-I
2023

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Volume-I

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Professional Conduct Review

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National Medical Commission

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Professional Conduct Review

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★★★★★

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DR. MANSUKH MANDAVIYA

सत्यमेव जयते
आज़ादी का अमृत महोत्सव

मंत्री
स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक
भारत सरकार
Minister
Health & Family Welfare
and Chemicals & Fertilizers
Government of India

Message

I am happy to know that the Ethics & Medical Registration Board (EMRB), National Medical Commission is bringing out the National Good Medical Practice Guidelines for Patients who need good doctors. It's a very important step towards ensuring that our patients get good doctors and the best treatment. Good doctors are the backbone of our healthcare system as their first and foremost concern is providing quality care to patients.

Ethics & Medical Registration Board (EMRB), NMC is one of the medical regulatory bodies in India and is the apex body in India for formulation, and cooperation. I understand that the guidelines of Good Medical Practice have been prepared considering the moral, ethical, social values and ethos of our diverse population.

I congratulate and praise the efforts directed by EMRB, NMC for the 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 am confident that the release of these very important guidelines will go a long way towards improving overall healthcare service delivery and the health ecosystem in the country.

Best Wishes for future endeavours.

(Dr. Mansukh Mandaviya)

20 July, 2023.

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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 deep appreciation to Prof. (Dr.) Yogender Malik, Member, EMRB, National Medical Commission, (NMC), New Delhi, for his keen interest in publishing this document. The publication of this document would not have been possible without the commitment and contribution of all the members of Expert Committee who represent various reputed Medical Colleges/Universities and Organisations.

A good doctor should take full care of patient; be competent and keep professional knowledge and skills up to date; take prompt action for patient safety; establish and maintain good partnerships with patients and colleagues; ensure the strengthening of public's trust in doctors and the medical profession by being open, honest and act with integrity. It is expected that all Registered Medical Practitioners (RMPs) will use professional judgement and expertise to apply the principles elaborated in this guidance document to the various situations in medical life.

It is hoped that the lessons of this publication will be put into practice in everyday life of all RMPs. I am grateful to Prof. (Dr.) Suresh Chandra Sharma, Chairperson of National Medical Commission (NMC), under whose stewardship these steps are being taken.

I would also like to thank the division staff from the NMC, Publication Division Cell for the preparation and finalization of this document.

Date : 7th June, 2023
Place : New Delhi

(Rajesh Bhushan)

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Government of India

Message

The National Medical Commission (NMC) has brought out the publication on Good Medical Practice standards recently. This book of case studies will augment our understanding of the nuances of good clinical practice. In medical training we learn to use evidence-based clinical applications in practice. Unintended errors or adverse events are not uncommon. The training prepares us to minimize the latter and obtain best remedial effects from our action. Dedicated teachers and obliging patients make the training comprehensive. Thanks to the UG and PG divisions that dynamically update this curriculum from time-to-time.

The icing on the cake in the curriculum is training in the art of communication and ethics through the AETCOM modules. Medical students and early career medical practitioners learn these attributes from their mentors. Learning from case examples is a value addition. Senior clinicians document or use such examples while 'training' their students. The ethics and Medical Registration Board of the National Medical Commission has a rich archive of such case examples.

NMC would fail in its duties if it fails to 'educate' clinicians on good clinical practice standards using such real-life case examples. The members of the Ethics Board have done a commendable job of compiling such cases into this first in a series of short publications. The cases illustrate the complexities that arise in practice that can drag the practitioner into a 'legal' battle; either with the State or National Medical Councils. Learning from the experiences of others will help us in mitigating such predicaments in our profession.

I would strongly urge my professional colleagues to read this short book and benefit from the cases the experts have described here. They have taken care to anonymise the involved persons and institutions. More examples should be added in forthcoming books.

I wish all readers an educative reading.

Dr. (Prof.). B.N. Gangadhar

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Message

Ethics and Medical Registration Board (EMRB) has been entrusted with the responsibility of regulating professional conduct and promoting medical ethics under Section 27 of National Medical Commission (NMC) Act 2019. The section says EMRB also has appellate jurisdiction with respect to actions taken by a State Medical Council and a quasi-judicial function. Based on its regulatory and quasi-judicial experience, EMRB has come out with this Case Series on Professional Conduct. It has nine case studies based on real cases dealt with by EMRB and/or State Medical Councils. Dr. Yogender Malik and Dr Vijaya Lakshmi Nag, with their long professional experience as medical professionals, teachers and members of the EMRB have edited the case series and presented every case in a very simple way, that provides a clear message for all medical professionals. This case series will be very useful for every medical professional and specially the doctors pursuing their MD/MS or DM/MCh as each case will enhance understanding of ethical responsibility, which will guide them to excel in their professional career. Medical teachers may also communicate these real cases to their students in class room or informal teaching as a message by a teacher can have more value than mere reading. I wish EMRB under the exemplary guidance of Dr. Yogender Malik and Dr. Vijaya Lakshmi Nag should come out with more such series for the benefit of the medical fraternity.

Vijay. V. Oza.

(Dr. Vijay Oza)

President,
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Message

The National Medical Commission came in to existence on 25th September, 2020 with the establishment of NMC Act 2019 by the Parliament of India. For smooth and effective discharge of its various duties, four autonomous Boards were created, Ethics and Medical Registration Board (EMRB) is one such board. Amongst its other functions, it also deals with qualified doctors in discharge of their duties towards patients.

Maharshi Charak shapath and the Hippocrates oath, both have described the ideal demeanor of a Physician. They declare the first and the ultimate duty of a Physician is to take care of physical and mental well-being of his patient.

Prof. Yogender Malik and Prof. Vijayalakshmi Nag have compiled case studies of some interesting cases received by the Board as appeals. This publication, to be followed by several more in future, can become a guiding light for young doctors and a reference guide for senior medical practitioners.

The case studies cover a wide range of situations, like effective communication with patient's family. This has been covered in the undergraduate medical education in the form of AETCOM (Attitude, Ethics and Communication) modules that train and mould a young medical student to become an effective healthcare leader. Doctors try to give the best service and care in treating a patient, but the doctor is also a human being and may not be able to prevent death in very dire conditions. Patient's relatives in their desperation or frustration are likely to blame the treating doctors. Communication skill is necessary to prevent catastrophic situations of attack on treating doctors.

An interesting episode discussed in the eighth chapter of Mahabharata in Van parva; Yudhishthira, the eldest of Pandavas is brought to test his ethics and morals by Yaksha. To a question raised by Yaksha, the answer by Yudhishthira is given below:

यक्ष उवाच- ... आतुरस्य च किं मित्रं किंस्विन्मित्रं मरिष्यतः ।।

Who is the friend of a sick man and who is a friend of a dying man?

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युधिष्ठिर उवाच–... आतुरस्य भिषङ्मित्रं दानं मित्रं मरियतः।।

Yudhishthira replies:

...Physician is the true friend of a sick man and compassion is friend of a dying man.

This is the quintessential knowledge for the human race especially for the persons involved in health care. Specialty practice should be initiated only after adequate training. Clinical drug trials should be clearly understood by Practitioners, following all necessary guidelines and rules. Elective caesarean section can lead to maternal death, and is a serious risk for which Practitioners should be well prepared. Proper documentation of a surgical procedure is an art and skill to be mastered by every Doctor.

One of the serious issues that has cropped up in the recent times is mis-representation of qualifications and overcharging by medical practitioners. This could be one of the most unwanted toxic side effects of expensive, out of reach medical education. The medical fraternity has to protect itself from such unpleasant scenarios.

I wish the publication of this series a grand success. May it serve as a guiding light for all stake holders including medical practitioners discharging their duties in this noble profession.

Dr. Aruna V. Vanikar,

President, Undergraduate Medical Education Board,

14th July, 2023.

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सत्यमेव जयते

आज़ादी का अमृत महोत्सव

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Preface

The Medical profession is one of the noblest professions in India. For a patient, the doctor is almost like God; infallible. Yet doctors, like any human being, can also make errors.

In the era of evidence-based practice, is essential for ensuring that our clinical care is effective and evidence-informed. This "Case Series on Professional Conduct" carries examples from real life on professional errors and consequences, and are meant to provide lessons to others. By understanding how these professionals fell short, we can mitigate such errors and protect our patients from similar ethical lapses.

This publication contains summaries of actual cases that have been adjudicated by the expert professionals in the field, and are organized into main themes: -

Communication between doctors and patient/relatives - This is a doctor's first duty is towards the patient. It needs to be balanced with respect to, and understanding of, the network of people who provide care and emotional support to the patient. Communication should also said rapport, faith and trust between doctor and patient.

Wrong diagnosis- This can be due to human error or poor knowledge/skill. It may have serious consequences; even the minor error by a doctor can have life-altering effects on the patients. It is important for doctors to be careful and vigilant to avoid them.

Specialty practice without qualification- Every RMP shall practice the system of medicine in which he/she has trained. A certified RMP shall not claim to be a clinical specialist unless he/she has NMC recognized training and qualification in that specific branch of modern medicine. The Case No.3, 5, 6 and 8 are the best examples given here.

Role of doctors in clinical trials- the principal investigator (PI) is responsible for the conduct of a clinical study at a site. They should be aware of research guidelines, and their responsibilities and limitations before undertaking such research.

Documentation - This is a record of the care that was provided to the patient and can affect subsequent decisions and care. Even the slightest error in documentation can have serious consequences in management of illness, and can lead to litigations.

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When a doctor treats a patient there is an implied undertaking that the doctor possesses the skill and knowledge to give that treatment. The degree of skill must be reasonable as compared with peers and peer knowledge. Whether treatment was free or paid, the liabilities would be the same.

I hope this publication of real-life case summaries will help medical professionals to reflect on their own ethical practices and make best decisions. By studying these cases, professionals can learn about ethical standards that are expected, and the consequence of failing to uphold those standards.

Dr Vijaya Lakshmi Nag
Member, EMRB

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Editor's Note

NMC Act 2019 has given responsibility to maintain a National Register of all licensed medical practitioners, regulate professional conduct and promote medical ethics; ensuring compliance of the code of professional and ethical conduct through the State Medical Council 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; exercise appellate jurisdiction with respect to the actions taken by a State Medical Council to Ethics and Medical Registration board (EMRB).

As an appellate body we have been hearing cases of misconduct and passing judgements. The need to disseminate the learnings from the complaint cases against Doctors (RMPs) was felt right from the beginning. The thought was shared with the board and a group of experts was formed. They worked very hard, going through hundreds of pages of each case, and summarizing them without losing the essence of the case and the message. There were apprehensions regarding the identity of doctor and patient, but anonymizing solved this problem.

Medical fraternity must understand that it is very difficult for a patient to differentiate between ethics, conduct and negligence. Then there is the issue related to patient's understanding of constraints of the hospital system; they don't understand duty shifts of doctors and expect the same doctor to be available 24x7 for their patient, especially in corporate hospitals. The patients feel dejected when they don't find the behavior of doctor up to their expectations.

Doctors too feel that patients have no right to complain unless there is harm.

Apart from known causes of litigation against doctors like problems related to communication consent and medical records etc. a new problem faced by us is fixing responsibility when the treatment is by a team of doctors. A doctor may attend only for a consultation and will not own responsibility for the rest of the treatment protocol.

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The problem of understanding with respect to differentiation of ethics, conduct and negligence exists even among experts. They sometime go too deep into legal aspects of ethical problems by citingearlier court cases, that essence of the problem at hand is lost.

We have come up with conduct regulations, guidelines for teachers and students for good professional conduct. We have prepared modules for subject experts in complaint cases to bring clarity on various issues.

I have found this experience at EMRB NMC of dealing with complaint cases enriching and it has opened new horizons of thought for me.

I hope this booklet will be read in the right spirit and bonafide criticism and comments are welcome for improving the next issue.

Yogender Malik

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CASE 1

Communication Between Doctor and Patient's Relatives

- **Keywords:** Communication; timely referral; patient care
- **Context/Category:** Patient Care
- **Summary of the Case:**

A 14-year-old boy was brought to a Primary Health Centre (PHC) with complaints of diarrhoea, fever, dizziness, and light-headedness. He was found to be febrile with low blood pressure and was advised of blood investigations and medications for the same. The patient returned to the PHC with persistent symptoms. He was found hypotensive. Malaria and dengue infections were ruled out. He was referred to the District Government Hospital on the same day, where he was managed with IV fluids, antibiotics, and symptomatic treatment. Patient's condition did not improve and he was referred to a tertiary care hospital in a state of shock with a provisional diagnosis of acute gastroenteritis with thrombocytopenia and leucopoenia. The patient was admitted and investigations were done. Subsequently, he developed severe breathing difficulty and was shifted to ICU for intensive care. Patient's condition continued to deteriorate despite ventilatory support and intensive care. Poor prognosis was explained to the relatives. He died soon after.

Patient's relative filed a complaint of medical negligence against the doctors of tertiary care center with the State Medical Council (SMC). After hearing and due diligence, the SMC found no evidence of medical negligence and exonerated the doctors.

Patient's relative appealed to Ethics and Medical Registration Board, National Medical Commission (NMC) against the SMC order. EMRB, NMC upheld the SMC decision and found no evidence of medical negligence.

- **Discussion**

Patient was initially taken to the primary center, where the patient was managed and a timely referral was made to the District Hospital. At the District Hospital, appropriate investigations and treatment were carried out. Despite this, the patient's condition continued to deteriorate, and was promptly referred to a tertiary care hospital. The patient was investigated and treated promptly with the standard of care acceptable in such cases. But unfortunately, the patient died and this negative outcome led to litigation. SMC exonerated the doctors and opined that there was no medical negligence.

The doctors should be aware that in spite of adequate care and their best intentions, litigations may occur. Effective communication and proper documentation will mitigate the risk of such litigations.

- **Take Home Messages**

1. Doctor-patient relationship is very unique in itself. It requires lot of trust between doctors and patients. If there is trust deficit, it leads to litigation against the doctors. In majority of cases, the most common cause of complaints against doctors is due to a communication gap.

2. In most instances, doctors fail to explain to the patients and their relatives about diagnosis, treatment plan etc. in spite of their good intentions.

3. The Medical Professional is expected to bring a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither a very high 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. A Medical Practitioner would be liable only when his conduct falls below that of the standards of a reasonably competent practitioner in his field.

4. Medical Professionals are entitled to get protection as long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for the Medical Professionals.

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CASE 2

Allegation of Wrong Diagnosis Leading to Delay in Treatment

- **Key Words:** Wrong diagnosis, Delay in treatment, Medical Negligence, ICU
- **Context:** Patient Care
- **Abstract:**

A young male patient reported to the emergency department of a private hospital (X) with fever, abdominal pain, and 2 episodes of vomiting. Investigations revealed thrombocytopenia and hypotension, leading to a provisional diagnosis of dengue fever. Due to the unavailability of an ICU bed, he was stabilized and shifted to another private hospital for ICU care(Y). In hospital Y, he received care for four days in the ICU. He continued to receive treatment for Dengue fever under a team of pulmonologists and gastroenterologists. The patient was symptomatically better at the time of discharge on the 4th day. However, within 36 hours, he was rushed to another private hospital (Z) with severe abdominal pain. At this hospital, a diagnosis of volvulus, small intestine obstruction & gangrene was made necessitating emergency laparotomy and bowel resection. Patient's parent filed a case of negligence against the private hospital(Y) for wrong diagnosis leading to delay in treatment.

- **Summary:**

A young male patient presented, with fever, abdominal pain, and 2 episodes of vomiting for two days, to the emergency medicine department of a private hospital X. As the patient had hypotension and thrombocytopenia, a provisional diagnosis of dengue fever was made and symptomatic treatment was initiated. Due to the non-availability of the ICU beds at Hospital X, the patient was shifted to another private hospital (Y) on the same day for further management.

The patient was admitted in the ICU of Hospital Y under a Pulmonologist. He continued to receive treatment for Dengue fever under a team of pulmonologists and gastroenterologists. The patient was referred to a Gastroenterology consultation for abdominal pain and he was managed conservatively with antibiotics, antipyretics, and IV fluids.

A series of investigations were done including USG which indicated cystitis & Dengue NS1 was negative. The patient was accepting a soft bland diet and passing flatus during the stay. The patient improved and was discharged after four days. The discharge summary mentioned acute febrile illness or acute gastritis with dehydration, UTI, or Cystitis.

The patient had a relapse of abdominal pain within 36 hours of discharge. He was admitted again to another private hospital (Z). A diagnosis of intestinal obstruction with ischemic bowel due to volvulus was made. CT abdomen and pelvis showed dilatation of small bowel loops with features of small intestinal obstruction. An emergency laparotomy was done with resection of the small bowel

and anastomosis. His condition improved and was discharged after six days.

The patient's father filed a petition before the erstwhile Medical Council of India (MCI) after seven months as a prima facia case of medical negligence against the treating doctors i.e. two pulmonologists and one gastroenterologist of the hospital (Y).

- **Discussion:**

The patient's father is a doctor and alleged that the two pulmonologists and a gastroenterologist at the hospital Y failed to diagnose and treat early intestinal obstruction, which led to life-threatening small bowel gangrene. This resulted in emergency laparotomy, resection & anastomosis of the small bowel. He also alleged that the patient was admitted/treated in the wrong specialty (pulmonology), hence pulmonologist missed the past history of abdominal surgery and failed to observe the abdominal scar. This led to wrong diagnosis and delay in treatment.

The patient's father directly filed a medical negligence case before the erstwhile MCI. The petition was forwarded to the State Medical Council by the Indian Medical Council. The accused doctors submitted an internal inquiry report of the hospital to the State Medical Council stating the diagnosis of acute febrile illness and no deficiency in service to the patient. The State Medical Council failed to conclude the matter within the stipulated time of six months. Ethics & Medical Registration Board (EMRB), NMC took over the case and directed the petitioner and doctors from Hospital Y to appear before the committee.

- **Decision of EMRB, NMC:**

EMRB observed that the patient was treated at the hospital (Y) by qualified doctors who were competent enough to attend to the patient and the patient was fit for discharge making the diagnosis of treating physicians justifiable.

Even if it was an intestinal obstruction, it may have been partial and not persistent, therefore justifying conservative treatment. Further, the EMRB observed that the petitioner himself as a senior doctor had no complaints at the time of discharge of the patient. Previous operating history/abdominal scar does not itself make the diagnosis of intestinal obstruction. The point of doing or not doing an X-ray/CT scan is a debate on under or over-investigation. Volvulus of the small intestine is a rare acute condition and can result in small bowel gangrene. Worsening of the symptoms occurred after discharge from the hospital Y. Such instances of evolving dynamic diseases leading to errors in diagnosis do not necessarily justify the case of medical negligence. The doctors in the present case had provided a reasonable degree of care. On the basis of all the facts and hearing of the case, EMRB decided to exonerate the doctors of Hospital Y.

- **Lessons learned from the case:**

➲ Clinical diagnosis and the human body are very complex. Two different diseases can occur in the same patient in a short span of time. In clinical medicine, it is a practice as far as possible to try and explain all symptomology through a single disease etiology. This may lead to wrong diagnosis and delay in treatment. 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 medical professional.

- History/examination findings should be documented meticulously - One of the allegations was a history of previous abdominal surgery and the inspection finding of the abdominal scar was not documented by the treating physicians at hospital Y. Proper documentation is the best defence of a treating physician in the medical negligence cases and in the court of law. There should not be a mismatch between the physician's clinical notes and the nurse's progress notes.

- Proper communication - The condition of the patient should be briefed to the relatives/attendants of the patient regularly. Proper communication may avoid misunderstandings among relatives/attendants of the patient and lead to trust in the doctor-patient relationship. Even though the petitioner is a doctor in this case, he alleges that the condition of the patient was not properly explained.

- Negligence is the breach of a duty exercised by omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do. 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. A medical practitioner would be liable only when his conduct falls below that of the standards of a reasonably competent practitioner in his field.

(Supreme Court judgment in Kusum Sharma & Ors vs Batra Hospital & Med. Research 2010)

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CASE 3

Specialty Practice-Without Adequate Qualification/Training

- **Keywords:** PCPNDT Act; Radiology; Training;
- **Category/Context**: Patient Care
- **Abstract:**

Dr. R was practicing as a Consultant sonologist without a Postgraduate qualification. He had obtained 6 month ultrasonology training certificate according to Preconception and Prenatal Diagnostic Technique Act, 1994 (PCPNDT Act, 1994). A petition was filed by IMA against him in the State Medical Council (SMC). SMC removed his name from the State Medical Register for 2 months. Dr. R appealed against this order in the Hon'ble High Court which redirected the matter to the Ethics & Medical Registration Board (EMRB), National Medical Commission(NMC). EMRB, NMC pronounced its verdict after hearing Dr. R.

- **Summary of the Case:**

Dr. R was in private practice as a Consultant sonologist since 2004 without the required qualification/ training. After obtaining an MBBS degree, he did 6 months of certificate training in ultrasound according to the PCPNDT Act. However, such training does not permit him to practice as a consultant radiologist/sonologist in areas beyond his certification. However, he was performing ultrasound for

other illnesses beyond the scope of this specific certificate training under the PCPNDT Act. The IMA took cognizance of this malpractice and filed a complaint with the SMC. SMC after due deliberations removed his name from the State medical Register for 2 months and warned him to refrain from practicing as a Consultant Sonology/Radiologist. Despite an order of SMC, Dr. R continued to perform ultrasound for other indications beyond his training and use the title of consultant sonologist and appealed in the Hon'ble High Court against this order. The Hon'ble High Court directed the case to EMRB, NMC.

After hearing and due deliberations, EMRB, NMC directed Dr. R to submit an undertaking to not go beyond the PCPNDT Act and refrain from using the title 'Consultant sonologist' in the future.

- **Discussion:**

With the introduction of short-term certificate courses in ultrasonology for specific purposes, many Medical Practitioners misuse this certification to extend their expertise to areas beyond the scope of training. This can be intentionally misleading to the patient who is not in a position to verify and discern the qualification and can lead to wrong diagnosis and harm to the patient.

This unethical practice can jeopardize the reputation of the medical fraternity in the eyes of the public and undermine trust in the profession.

Medical Practitioners may acquire skills and training in various areas related to a particular field to benefit the patient. However, the

use of the title 'consultant/specialist' should be restricted to those who are qualified in the particular specialty. Care should be taken not to mislead the public through sign boards, visiting cards, announcements, etc.

- **Take home messages:**

A physician shall not claim to be a specialist unless he/she has a special qualification in that branch, according to clause 7.20 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. In view of this clause, Registered Medical Practitioners should register their additional qualification with the respective medical councils.

According to clause 7.13 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, it is improper for a physician to use an unusually large sign board and write on it anything other than his name, qualifications obtained from a University or a statutory body, titles, and name of his specialty, registration number including the name of the State Medical Council under which registered. The same should be the contents of his prescription papers. It is improper to affix a signboard on a chemist's shop or in places where he does not reside or work.

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CASE 4

Clinical Drug Trial and Role of Registered Medical Practitioners

- **Key Words:** Clinical Drug Trial, Pharmaceuticals, Registered Medical Practitioner
- **Context:** Medical Research
- **Abstract:**

Dr. X, a well-known clinician, academician, and researcher was working in a Government Medical College, as a faculty for the past two decades. He was actively involved in clinical work and teaching students at the medical college. He was also involved in conducting clinical trials at the Institute for the past two decades. A complaint was raised by an advocate against Dr. X, for unethical conduct and receiving kickbacks for conducting illegal clinical trials including frequent foreign tours/travels. We are discussing this case to highlight best practices in Medical research to be followed by a Registered Medical Practitioner.

- **Summary:**

Mr. M, a practicing advocate filed a complaint in August 2014 against Dr. X, before various agencies including the erstwhile Medical Council of India (MCI) with allegations that Dr. X,

(a) had conducted over a dozen illegal clinical trials without proper permission, sponsored by both International and Indian pharmaceutical companies

(b) conducted these clinical drug trials during working hours and with wrongful usage of the Government Medical College premises for research.

(c) has received funds for conducting such trials directly into the personal bank account, without any permission from the government or institution.

(d) received huge kickbacks for conducting these illegal clinical trials including frequent foreign tours/travels.

Mr. M urged the Government and State Medical Council (SMC) to take action against Dr. X for violating CCS (Conduct) Rules and clause 6.8.1(d) of Indian Medical Council (Professional Conduct, Etiquettes and Ethics) Regulations, 2002.

Dr. X responded to the complaint filed against him in the SMC that he did not conduct any trials in an individual capacity but as part of his duty as faculty of a Government Medical College. He also reported that he had followed the prevalent practice for conducting clinical trials during that period, had conducted the annual audit for all the clinical trials, and not misused any funds of the clinical trial. He also submitted a copy of the documents such as permission to conduct the clinical trial in compliance with the Drugs & Cosmetics Act 1940, Drugs & Cosmetic Rules 1945, as per the 'standard operating procedures' prescribed under Schedule Y, the Indian Council of Medical Research (ICMR) Guidelines on "Ethical Guidelines for Biomedical Research on Human Subjects", and the ICH-GCP Guidelines. Dr. X, clearly stated that the funds were transferred into the principal investigators' bank account because there was no mechanism in place or account to deposit the funds for clinical trial funds. He also highlighted that many of the drug trials conducted at the Government Medical College followed the above

regulations and norms. He submitted all the permission letters from the required authorities during the inquiry.

- **State Medical Council Decision**

During the hearing of the case, Mr. M withdrew the case and filed an affidavit mentioning that the filing of the case was politically motivated. However, the SMC continued the case against Dr. X, despite the case being withdrawn.

The SMC, after conducting the inquiry, held that Dr. X violated protocol for having received funds from the Pharmaceutical Companies in his personal bank account. Further, the SMC ordered the removal of the registration of Dr. X from the State Medical Register for one year.

Dr. X appealed to the Ethics Medical Registration Board (EMRB) of the National Medical Commission (NMC) against the decision of the State Medical Council and the penalty.

- **The decision of the Ethics and Medical Registration Board of NMC:**

EMRB observed that research is an integral part of medical college's function apart from education and clinical care. To allege that bonafide research should not continue as it affects patient care holds no ground. The Board is of the view that if due procedure with regards to institute ethics committee permission and Clinical Trial Registry are followed then the above allegation does not hold ground. Further, the complainant had withdrawn the complaint on affidavit, the SMC continued to pursue the case considering the merit of the case.

The penalty clause in clause 6.8.l (d) of the Regulations came into effect in 2016, much after Dr. X had stopped conducting clinical

trials in 2015. Dr. X had not conducted any clinical trials or received any funds in that connection since 2015. However, the penalty provision was enacted by the amendment dated 01.02.2016. A retrospective application would violate the 'ex-post facto law' contained in Article 20(1) of the Constitution and is thus an unsustainable proposition in law.

EMRB urged that authorities investigating such allegations first-hand must ensure that the allegations have substance and are bonafide. Otherwise, the research environment of the institute suffers which is not desirable. Researchers have to constantly update their knowledge not only about the technical aspect of research but also about the process and procedure specified by regulatory bodies about all aspects of research. Dr. X had taken institute permission, Ethics committee approval, and DCGI approval. He had complied with all the rules, regulations, and ethical guidelines prevalent at that time, hence he was exonerated from all charges.

- **Discussion and Analysis of the case:**

The complaint was filed by Mr. M against Dr. X. in August 2014. Since then, there has been the evolution of guidelines, rules, and regulations regarding clinical trials. The important question to be answered was if Dr. X violated any rules or regulations existent at the time of the complaint and misused the funds allocated for a clinical drug trial.

Dr. X had conducted the clinical trial in compliance with the Drugs & Cosmetics Act 1940, Drugs & Cosmetic Rules 1945, as per the 'standard operating procedures prescribed under Schedule Y, the ICMR Guidelines on "Ethical Guidelines for Biomedical Research on Human Subjects", and the ICH-GCP Guidelines. He submitted all

permission letters to the investigating agencies. There were no research conduct guidelines by the Government Medical College. Moreover, the Government Medical College did not have any guidelines, rules, or regulations regarding the financial aspects of the clinical trial during that time. However, the College issued a circular regarding the guidelines for Research Project/ Clinical Drug Trials in 2016. Moreover, the college's dedicated bank account for clinical trials was opened only in 2018. Dr. X stopped conducting clinical trials after September 2015 and also deposited unspent research funds into the bank account of the Government Medical College. Further, during the hearing of the case at the State Medical Council, the complainant withdrew the case and filed an affidavit mentioning that the filing of the case was politically motivated against the Registered Medical Practitioner (RMP).

Under Laws: RMPs involved as research investigators in any clinical trials must make sure that they comply with the country's regulatory requirements. In the past decade, several changes have occurred in the regulatory landscape of clinical drug trials in the country. RMP should obtain necessary permission from the Central Drugs Standard Control Organization (CDSCO), the National Regulatory Authority in India, wherever applicable. The Drugs Controller General of India (DCGI) is an official of the CDSCO which is the final regulatory authority for the approval of clinical trials in the country.

Ethics Regulations: Clause 6.8 of the Indian Medical Council (Professional, Conduct, Etiquette, and Ethics) Regulations, 2002 was amended in 2009, where after Clause 6.8.l(d) read as: "Cash or

Monetary grants: A Medical Practitioner shall not receive any cash or monetary grants from any Pharmaceutical and allied health care industry for individual purpose in individual capacity under any pretext. Funding for medical research, study, etc. can only be received through approved institutions by modalities laid down by Laws/Rules/guidelines adopted by such approved institutions, transparently. It shall always be fully disclosed." There was one more amendment on 01.02.2016 to the said provision. The amendment added punishment for violating the provision.

RMP should follow good clinical practice, obtain written informed consent from participants, and report serious adverse events that occur during a clinical trial, and under any circumstances, patients should not be exploited under the name of clinical drug trials or research.

- **Take home messages:**

Registered Medical Practitioners need to follow:

(a) The ethical guidelines in research and regulations of the National Medical Commission regarding the professional conduct of RMPs, as and when they are notified.

(b) The ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants-2017 (1) and seek approval from the institutional ethics committee before proceeding with clinical trials

(c) The Clinical Trials Registry-India (CTRI), which is formed to encourage all clinical trials conducted in India to be prospectively registered with full disclosure of the researchers, trial data set,

and other details. The Registration of trials will ensure transparency, accountability, and accessibility of clinical trials. The registration has been made mandatory by the Drugs Controller General of India (DCGI) from 15 June 2009 (2)

(d) The New Drugs and Clinical Trials Rules, 2019 (NDCT Rules) under the Drugs and Cosmetics Act, 1940 (D & C Act) (3). They also need to follow COSCO GCP guidelines.

(e) The funding from the pharmaceutical industry could be by way of the provision of drug supplies, monetary support, or both. RMPs should maintain proper accounts, maintain audits, and file utilization certificates regularly. Transparency is the key in any Clinical Drug Trial.

(f) The question of medical ethics is not simply a technical question of making laws, setting up regulatory bodies, and following those regulatory mechanisms. Medical ethics goes beyond that. RMPs need to recognize the power relationships that operate between physician investigators and patient participants in clinical trials. Hence, RMPs conducting clinical trials should understand their ethical responsibilities in research.

(g) In the above case, Dr. X followed all the prevailing rules & regulations. However, taking any money into a personal bank account in the name of a clinical drug trial was unprofessional and the same should have been in the account of the college administration. Although Dr. X was exonerated in the absence of any such account made available for clinical drug trial, it is

expected that it is the responsibility of Dr. X to advocate a change in protocol in order to avoid ethical conflicts.

(h) In professional practice it is not a remote possibility that motivated complaints may be made even though unwarranted. Doctors should uphold the high standards of ethical practice in clinical and research settings in order to protect their interests. In relation to a motivated wrongful complaint, the SMC has the power to take appropriate action as deemed fit and promote public awareness.

- **References:**

1.	National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)	**Available online at** https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
2.	Handbook for Applicants and Reviewers of Clinical Trials of New Drugs in India (2017). Published by ICMR, CDSCO & Department of Health Research & Director General Indian Council of Medical Research, New Delhi.	**Available online at** https://main.icmr.nic.in/sites/default/files/reports/Handbook%20for%20Applicants%20and%20Reviewers%20of%20Clinical%20Trials.pdf
3.	The New Drugs and Clinical Trials Rules, 2019.	**Available online at** https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

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CASE 5

Elective LSCS done by a General Surgeon Leading to Maternal Death

- **Keywords:** Elective LSCS, Consent, Medical records, Maternal death.
- **Category/Context:** Patient Care
- **Abstract:**

Dr. A, a qualified gynaecologist was providing regular antenatal care to Ms. Y. On the scheduled day of elective LSCS due to unavailability of Dr. A, the LSCS was performed by general surgeon Dr. B assisted by Dr. C (MBBS). After the surgery, Ms. Y developed bleeding complications for which the patient was shifted to another hospital for further care where she expired. The matter was brought to the notice of the State Medical Council (SMC) and the names of Dr. B and Dr. C were removed from the State Medical Register for 30 days as they had operated beyond their qualifications and competency in an elective surgery.

- **Summary of the Case:**

A 31-year-old lady, Ms. Y was receiving antenatal care from a gynaecologist Dr. A at a private hospital. The couple requested an elective LSCS on a date of their choice. Dr. A informed the couple about her non-availability on that date but assured them that Dr. B and Dr. C would provide care in her absence.

Ms. Y was admitted on the date agreed upon and was operated on by Dr. B and Dr. C after obtaining written consent from the husband. In the post-operative period, the patient developed bleeding

complications from the operation site for which another surgical procedure was performed by the same medical team. The patient did not improve and became critical due to further bleeding at which point she was shifted to another hospital for further management where she died.

According to the post-mortem report, the cause of death was "DIC consequent upon LSCS".

The husband filed a case with SMC.

- **Discussion:**

The primary allegation by the husband in the case was medical negligence leading to the death of his wife. During the trial, the doctors tried to defend their case by saying that it was an emergency LSCS and that the gynaecologist was unavailable at that time. However, the review of the case records did not reveal any indication of emergency LSCS. Moreover, written informed consent indicated that it was for elective LSCS to be performed on the pre-decided date.

The likely cause of the patient's deterioration was post-operative blood loss which went undetected because of improper monitoring.

Based on the above facts, SMC held Dr. B and Dr. C responsible for venturing into the field beyond their competence and removed their names from the State Medical Register for 30 days as a penalty.

- **The Order of State Medical Council / Ethics & Medical Registration (EMRB), NMC**

SMC removed the name of the Surgeon and assisting lady doctor from the State Medical Register for 30 days for venturing into the field of medicine which is beyond their competence. Both the aggrieved doctors appealed to EMRB, NMC against the order of SMC.

After hearing the case, EMRB upheld the decision of SMC.

- **Take home points:**

  - The readers are requested to go through the Hon'ble Supreme Court in landmark judgment given in Samira Kohli vs Dr. Prabha Manchanda to understand the importance and implications of obtaining real and valid consent.

    (https://indiankanoon.org/doc/438423/)

  - All elective procedures should be performed by a doctor qualified in that particular specialty. In this case, elective LSCS was performed by a General surgeon who was not qualified to undertake such a procedure. No efforts were made to refer to another gynaecologist for the planned LSCS. Even if the consent is taken for the procedure to be performed by an unqualified Medical Practitioner, such consent would be invalid.

  - Valid real informed consent is to be taken in all cases. The patients must sign the consent in all elective cases unless the patient is minor, unconscious, or incompetent. In this case, the consent form did not have a signature or thumb impression of the patient despite her being fit to give the consent. Instead, the consent was signed by the husband only.

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CASE 6

General Surgeon doing Hysterotomy

- **Keywords:** Emergency, MTP, Consent, maternal death, medical records.
- **Context:** Patient care
- **Abstract:**

A pregnant woman at 19+ weeks with bleeding in her vagina due to Placenta Previa was treated by a surgeon in a private hospital and medical termination of pregnancy was done through hysterotomy. The bleeding did not stop due to adherent placenta and the patient was shifted to a Government hospital where she was operated on again, but passed away after 5 days. The police filed a case against the doctors of the private hospital. The patient's husband, who arrived later, also charged the same doctors with medical negligence. The State Medical Council (SMC) passed an order that was upheld by the Ethics & Medical Registration Board (EMRB), NMC.

- **Summary of the case:**

A 32-year-old woman arrived at a private hospital at night with abdominal pain and bleeding from the vagina. An ultrasound done elsewhere revealed placenta previa grade IV and the duty doctor immediately called for a gynaecologist to attend to the patient. As no gynaecologists were available at the Hospital, a General Surgeon working at the hospital was called to treat the patient. After examination, he recommended an emergency hysterotomy and termination of the pregnancy to save the life of the mother.

Consent was taken from the patient's attendant and Form 1 for Medical Termination of Pregnancy was signed by Surgeon and duty doctor. The dead fetus was extracted from the uterus, but the placenta could not be removed completely as it was adherent. The uterus continued to bleed and the patient's condition worsened despite resuscitation and blood transfusion.

The patient was finally transferred to the Government Hospital for expert care. The Government Hospital recorded that the patient's condition was critical and in hypovolemic shock on arrival. The patient was put on a ventilator in the ICU.

The duty team decided to operate in order to stop the internal bleeding. A Laparotomy, Hysterectomy, and Bilateral Iliac Artery Ligation were done after obtaining high-risk consent from the bystander. After surgery, the patient was in the ICU but did not recover and expired after 5 days. The post-mortem report stated multi-organ failure due to Disseminated Intravascular Coagulation (DIC) and hypovolemic shock.

The husband arrived from abroad and filed a case against the doctors of the private hospital. Based on the information provided by the government hospital doctors a case of medical negligence was registered by the police against the doctors of the private hospital. The police referred the case to the SMC for expert opinion.

After hearing the case, the decision passed by the SMC was that the Surgeon's name should be removed from the State Medical Register for 6 months, and he should not undertake any gynecological procedure in the future. The Anaesthetist and the junior doctor were issued a warning. A copy of the order was sent to the State Directorate of Health and Family Welfare requesting them to take appropriate action against the private hospital.

The Surgeon, Anaesthetist, and junior doctor appealed to the EMRB of the NMC, against the Order of the SMC. After hearing, and reviewing the evidence and opinion of experts, the EMRB upheld the decision of the SMC.

- **Discussion:**

In relation to the case presented the following medico-legal issues emerged. At the private hospital, the patient should have been seen by a gynaecologist as she was almost 20 weeks pregnant, with abdominal pain and bleeding. She was seen by a junior duty doctor who called the general surgeon working at the hospital. The reason for referral to the general surgeon was that the two gynecologists working at the hospital were not available. Although the surgeon was experienced, and did the best he could under those circumstances, the patient should have been referred to another hospital, as specialist expertise was required in this case. There were other hospitals in the vicinity that could have provided appropriate specialist care. Another reason for referral was the nature of the case requiring medical termination of pregnancy under the Medical Termination of Pregnancy (MTP) Act, 1971 which requires an opinion of two gynecologists at that stage of pregnancy.

The decision for medical termination of pregnancy was made by the duty doctor and the General surgeon, and Form l (MTP Act) was signed by them. The treating team had time to take informed consent for the MTP rather than referring to the nearest available specialist care. Since the pregnancy was in the 19th week, it should have been terminated in these circumstances, by a practitioner qualified in obstetrics and gynecology according to the MTP Act. In the appeal, the surgeon changed his statement and said that the hysterectomy was done to save the life of the patient, and not to terminate the pregnancy.

There was a question about informed consent in this case. It was signed by a person who accompanied the patient and posed as a husband but later denied the same. There was no separate consent for anesthesia.

The case records, admission notes, and surgical notes were brief and incomplete. Anesthesia chart and notes were unavailable. The explanation by the surgeon and anesthetist was that it was an emergency situation. All the above issues were noted by the Medical Council before coming to their decisions.

- **Lesson from the Case:**

In this case the Medical Termination of Pregnancy Act 1971 applies and was amended in 2021. There should be compliance with the law even in emergency situations. Hospitals are required to be registered under the MTP Act, procedures to be done by a qualified specialist and requisite consent forms should be signed. Specific informed consent must be taken from the patient for termination of pregnancy, or from husband or next of kin in case the woman is unable to give consent.

In a surgery like Hysterotomy, there should be a separate general anesthesia consent form that ensures the patient understands the risks and type of anesthesia planned and should carry the name and signature of the anesthetist, in addition to the name and signature of the patient.

The patient chart and admission notes are important evidence that will be called for and used in medicolegal cases. Even in emergency situations, notes can be prepared after the patient is stabilized. Admission notes are vital for the subsequent proper management of the patient. The Government hospital alleged that there were inadequate information and referral notes at the time of handover of

the case. The patient was just left in the emergency room along with the attendant without any adequate communication from the private hospital to the duty team.

When transferring/referring the patient during the emergency, the doctor must ensure that the referral hospital is informed, the patient and attendants are informed, and appropriate medical notes need to accompany the patient. The referring doctor should also ensure that the patient is received at the referral hospital with documentation and communication maintained between doctors of both hospitals so that continuity of care is established and the patient does not suffer.

- **References:**
  - Medical Termination of Pregnancy (MTP) Act and Amendment Rules, 2021
  - Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

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CASE 7

Documentation of Surgical Procedure

- **Keywords:** **Urology. Renal stone, Medical Records**
- **Context:** **Patient care**
- **Abstract:**

A 55-year-old male was admitted to a private hospital and diagnosed to have renal stone at the right Pelvi-Ureteric Junction with hydroureteronephrosis. The urologist, Dr. U, attempted a percutaneous nephrolithotomy for stone removal but was unsuccessful. In the same sitting, he performed Retrograde Intrarenal Surgery (RIRS) for stone removal with stenting, which was not communicated to the patient or documented.

The patient had a recurrence of pain and consulted another doctor, which resulted in a cascade of events and litigation. This case highlights the importance of thorough documentation and communication.

- **Case Summary:**

A 55-year-old male was admitted to a private hospital with right-sided abdominal pain. On investigation, he was diagnosed to have a renal stone at the right Pelvi-Ureteric Junction with hydroureteronephrosis. The urologist, Dr. U, attempted a percutaneous nephrolithotomy for stone removal but was unsuccessful. In the same sitting, he performed RIRS for stone removal with stenting. At discharge, the patient was informed that the stone was removed and advised to return for stent removal. He was also advised to report to emergency in case of pain and fever.

When the patient had a recurrence of pain after four days, he consulted a Urologist at another private hospital. There he was informed that there was no evidence of prior surgery. He was also informed that fragmented stones were visible on CT scans at the calyx and vesicoureteric junction.

The patient alleged that the surgeon at the first private hospital did not operate on him and falsely claimed to have removed the stone and charged fees accordingly for the procedure. He approached the media, lodged a FIR with the police, and complained to the State Medical Council (SMC).

During the hearing at the SMC Dr. U, responded that the patient and family were informed about the Percutaneous Nephro-Lithotomy (PCNL) with or without RIRS and consent was taken for the same.

Dr. U, also clarified that he attempted PCNL, which was unsuccessful and the procedure may not leave any visible scar. He then performed RIRS to remove the stone with stenting. He explained that some remaining fragmented stones can migrate to ureters after the procedure. This could cause a recurrence of pain and is reported in the literature. Moreover, the subsequent CT scan showed the DJ stent in place with fragmented stones.

Dr. U admitted that documentation was done by a junior colleague, who did not mention RIRS in the medical records and the discharge summary. The patient was charged only for PCNL and DJ stenting whereas the discharge summary only mentioned PCNL.

SMC noted that there was a discrepancy between the procedure done, operation notes, and statement given in on online hearing. In view of this, Dr. U's name was removed from the register for two months.

Dr. U appealed to the EMRB, NMC against the order of SMC. After due diligence, EMRB noted that surgery and stenting had been

done after taking consent. There was no deficiency in the clinical services. However, EMRB noted documentation lapses and poor communication with patients/relatives. Further, they also noted that contradictory statements were given to statutory bodies. In view of this, Dr. U's name was removed from the register for 7 days and issued a warning.

- **Take Home Messages:**

Document the communication, communicate the Documentation - The doctor did not document the procedure and sequence of surgical decisions in the medical records. There was inadequate communication between doctor and patient about the procedure performed. Information to the patient should include the procedure and foreseeable failures/ complications of the proposed procedure It is important that there should be no discrepancy between the procedures done, procedure documented, nurse notes, discharge summary, procedure bills, and receipts. Procedure records should be maintained meticulously.

If there is adequate documentation there will be consistency in the statements made to patients and statutory bodies. Acknowledging the lapses or errors of judgment will mitigate the chances of litigation.

Doctors should avoid making negative statements to patients about clinical judgments and procedures performed by professional colleagues. This will preserve trust in the medical fraternity.

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CASE 8

Misrepresentation of Qualification and Alleged Overcharging by a Medical Practitioner

- **Keywords:** **Non-specialist, hospital charges, fraud.**
- **Context:** **Patient care**
- **Abstract:**

A COVID-19-positive couple was admitted to a private hospital under the care of Dr. X. It was alleged that the doctor refused to provide receipts for the full amount paid to him and the amount was in excess of the ceiling on treatment charges decided by the Municipal Corporation for COVID-19 patients. In an inquiry into this matter City Municipal Corporation also discovered that the doctor had posed as a critical care specialist without possessing requisite qualifications. The State Medical Council (SMC) removed the name of Dr. X from the State Medical Register for three years for unethical conduct. Dr. X appealed to EMRB, NMC against the SMC order.

- **Summary of the Case:**

In a case pertaining to a private hospital setting, Mr. M consulted Dr. X for treatment of his COVID-19-positive parents. Dr. X admitted both patients to a private hospital. Mr. M alleged that Dr. X asked him to deposit Rs. 19.5 lakh in two bank accounts, details of which were given by Dr. X. After multiple requests, only receipts for Rs. 14.6 lakh were provided. Receipts for the balance amount paid were not provided. Mr. M further alleged that the amount charged

was in excess of the ceiling of treatment charges set by the Municipal Corporation for COVID-19 patients and demanded a refund of the excess amount.

The hospital also filed a police complaint against Dr. X for fraud and unauthorized use of the hospital name and its seals on fabricated bills and receipts. This has been done without the notice and consent of authorities of the said hospital. A doctors' association in the city also filed a police complaint against Dr. X for fraud and misrepresentation of his qualifications.

City Municipal Corporation conducted an inquiry in which it was revealed that an excess dosage of tocilizumab was administered to the patient.

Dr. X pleaded that proper history, examination, and investigations were done after obtaining the written consent of the patients. They were attended to promptly and his treatment decisions were in line with the evolving COVID-19 treatment guidelines from ICMR from time to time.

The SMC removed his name from the State Medical Register for three years for unethical conduct. Dr. X appealed against the SMC order to EMRB, NMC.

During the hearing, EMRB, NMC could not find any evidence to substantiate the allegations of overcharging. The charges of medical negligence could not be established. The matter of fraud and unauthorized use of hospital name and seal is subjudice.

In its final order, EMRB, NMC directed the SMC to restore his registration number in the State Medical Register. However, NMC issued a warning to Dr. X to refrain from claiming to be a specialist without requisite qualifications.

- **Discussion:**

In this case, there are four important ethical and legal issues - overcharging, fraudulent use of hospital name and seal, overdosage, and misrepresentation of qualification.

- **Overcharging:**

The allegation of financial irregularities is outside the jurisdiction of EMRB, NMC. The matter is pending before the consumer forum.

- **Fraudulent use of hospital name and seal**

This allegation by the hospital is under investigation by the police.

- **Overdosage-**

This particular case was unique because of the prevailing COVID-19 pandemic during which the treatment guidelines were frequently changing and doctors were treating patients according to the available evolving information from different sources. There was no evidence-based standardized treatment for the same. For this reason, the accusation of overdosage in this particular case could not be held against the doctor. However, as far as possible, treatment in every context should be evidence-based or according to best practices.

- **Misrepresentation of qualification**

Regarding Dr. X who claimed to be a specialist in the absence of requisite qualification, EMRB, NMC took cognizance of this unethical behaviour and issued a warning.

- **Take Home Points:**

  - According to the Clinical Establishment Act 2010, all professional charges and hospital charges should be displayed and made known to the patient before the treatment is initiated. Overcharging is an unethical practice and Registered Medical Practitioners must avoid exploitation of patients during emergencies or otherwise. All payments should be billed and receipts provided by individual doctors or hospitals, as the case may be.

    (http://clinicalestablishments.gov.in/WriteReadData/969.pdf)

  - A physician shall not claim to be a specialist unless he/she has a special qualification in that branch, according to clause 7.20 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. In view of this clause, Registered Medical Practitioners should register their additional qualifications with the respective Medical Councils.

    (https://www.nmc.org.in/rules-regulations/code-of-medical-ethics-%20regulations-2002/)

  - Every Registered Medical Practitioner should establish a firm written contract with a hospital / clinical establishment regarding his terms of employment/association for the purpose of consultation, admission, and/or operation as a temporary/ permanent/ visiting doctor. All modalities of payment by the patient should be decided and approved in advance and receipts should be provided.

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CASE 9

Life-Threatening Events: A Dilemma for Patient Family

- **Keywords:** **Myocardial infarction, angioplasty, coronary stent, rescue angioplasty, multiorgan catastrophic events.**
- **Context:** **Patient care**
- **Abstract:**

A 58-year-old male suffered Acute Ml, thrombolysis done but failed, and underwent angiography followed by rescue angioplasty in view of hemodynamic instability. The patient had a cardiac arrest on the 3rd day after angioplasty while still in the hospital. He was revived with energetic efforts and became conscious but remained hypotensive despite Intra-aortic Balloon Pulsation, medications, and medical management. Succumbed to multiple organ dysfunction 10 days later. Relatives believe negligent management by Cardiologists in using less than optimal size stents that are required for the size of the coronary artery and overcharging them for procedure and clinical management. RMP put forth his view, maintained that there was no negligence, and defended his team and hospital in providing the best care to their capability. This was further corroborated by the expert. The RMP was exonerated by both the State Medical Council (SMC) and the EMRB, National Medical Commission (NMC). The case highlights the importance of documentation and communication with the patient and relatives with empathy.

- **Summary:**

A 58-year-old male with no co-morbidities presented with chest pain, perspiration, and ECG revealed Myocardial Infarction.

Thrombolysis was attempted but the pain persisted. The patient was referred to a tertiary care hospital, where angiography and angioplasty were carried out by a qualified cardiologist. The patient was recovering well and shifted to a ward on 3rd day but later in the night collapsed while coming from the washroom. Resuscitated with Defibrillator, CPR, and a repeat angiography showed still patent stent without evidence of thrombus or blockage. Managed in ICU on ventilator and inotropic, and regained consciousness on 3rd day but had poor perfusion.

Later he developed renal failure with fluid overload, managed on slow dialysis, developed multiple organ dysfunction, and died. Upset over the death of her husband, the wife started finding fault in the hospital and RMP. They suspected that stent use for angioplasty was less than the size of the artery, and poor management in ICU. They were also disturbed by the fact that they were overcharged and were threatened by the hospital to withhold treatment for defaulting on payment of fees due to the hospital. The matter was heard by the SMC and later by EMRB, NMC. Based on the case, hearing of both parties and experts' opinions, it was decided that all Standard procedures were followed and RMP was exonerated in the case.

- **Discussion:**

Myocardial infarction is one of the catastrophic events that require immediate management through qualified health professionals and involves quick, accurate decisions with foresight of complications and their appropriate management and an ongoing line of communication. The caregivers need to be appropriately informed. This case highlights that condition can be perceived differently by the family and may not be correct when compared to scientific evidence even if all standard operating procedures are followed by qualified RMPs and their team. At times, it may be possible they are

misinformed by limited knowledge available on the internet and other resources. The stent was kept after angioplasty to prevent collapse of the narrowed vessel which was also found to be patent during check angiography. The decision of treatment was made by RMP and multi-disciplinary team of ICU doctors and experts and was appropriate in the given situation. All Standard Operative Procedures were followed. The case was also heard adequately by the SMC as well as the EMRB, NMC corroborating with the opinion of a senior cardiologist.

- **Takeaways:**
  - A continuous communication channel must always be available in case of any emergency.
  - Documentation, as has happened in this case, is an integral part of avoiding litigations.
  - Besides documentation, understanding the state of the family in catastrophic events and dealing with them with compassion and empathy will always make an RMP a "Good Doctor".

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