

Medico Legal Issues in Obstetrics and Gynecology

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ABSTRACT

Aims: To highlight the principles and practicalities of the law and how medical negligence claims are addressed in court.

Methods: Literature and legal case search.

Results: This review discusses preventative modalities on legal complaints and summarizes the rationale and implementation of key legal standards used to rule medical negligence, namely, the Bolam, Montgomery and Bolitho principles. Practicalities describing relevant routine factors that impact health care delivery and medico-legal litigation are outlined with suggestions on how they may be effectively implemented.

Conclusions: The improved knowledge of healthcare professionals on the up- to-date Clinical Guidelines along with the law of Land concerning medico Legal issues will be constructive in health service delivery by reducing the amount of litigation in Obstetrics and Gynecology. Appropriate use of informed consent, counseling, documentation and proper record keeping is a top priority. Telephone consultation and Telemedicine may attract various liability issues. Hospital administration policy of risk management including regular audits, near-miss investigation, mortality-morbidity discussions, and timely reviews of Clinical guidelines will help reduce litigation in these fields. Further research into medico-legal cases and policy making is a necessity.

Keywords: Bolam, Bolitho, Medico legal, Montgomery, Prevention

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Editor's note: Identifying names of individual and hospital have not been disclosed.

INTRODUCTION

Obstetrics and Gynecology are some of the medical fields with the highest rate of litigation.¹ Practice of medicine ethically may not stop the consumers to sue a doctor.² Vandalism of the institution's physical structure; mob attacks on hospital staff and doctors even by meddlers for any financial negotiation in cases of any undesired outcome have become regular media coverage. The fear of litigation causes psychological stress, mortality, and morbidity to doctors.³⁻¹² This may compel doctors to practice defensive medicine, raising the pressure on the health care system.¹³⁻¹⁴

Medical practitioners' attitude, skills of communication, empathy, and honest apologies on errors while being vigilant with documentation, correct writing of prescriptions, identifying complications, and their follow-up are basic rules to maintain the standard of practice.¹⁵⁻¹⁹

“Ignorance of law is no excuse” is the dictum in law. However, the knowledge on medical ethics and medical law among practicing doctors are not adequate.^{20,21} Understanding the manners in which a claim will be analyzed will assist clinicians when they get involved in legal cases. This will furthermore serve to reduce litigation and be profitable for strategic defense. Therefore, it is important that clinicians have a basic understanding of legal principles and the concept of material contributions in litigation.

Medical negligence and litigation is dealt under the Criminal Justice System in Nepal.²²⁻²⁴ The burden of proof of negligence, carelessness and insufficiency lies on the complainant. Therefore, ensuring the maintenance of standard by risk management, timely review of guidelines, research, and through audit and scrutinizing the practice by an independent body is important.²⁵⁻³⁰

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METHODS

The literature searches were carried out in PubMed, Google Scholar and search, and other relevant websites using the words: Medico legal, Obstetrics Gynecology. Ethical approval was not required as this study is based on publicly available secondary data and information.

RESULTS

A valid malpractice claim must have four elements: Duty, Breach, Damages, and Causation.

Duty

It is mandatory to hold a valid professional medical license to practice in a defined area of practice with specified set boundaries and codes of ethics.^{31,32} Once a patient comes to the health care institution to see a doctor, a contract is made between the doctor and the patient; it is the duty of the doctor to care within the codes of ethics: beneficence & non-maleficence, autonomy, justice, value and sanctity of human life, and, truth and integrity. Professional standards refer to the level of skill and care that a reasonably competent practitioner in that particular branch of health care would be expected to demonstrate. The medical council has authority in ensuring licensure, authorizing restrictions on practice, and to redress for wronged practice.

The test for professional negligence as it pertains to medical practitioners is an objective test comparing the conduct of a particular practitioner to the conduct of the hypothetical reasonable practitioner in the same circumstances. It is therefore important to understand what professional negligence and the standard used to measure such negligence entail.

The doctrine of informed consent is a common basis for malpractice lawsuits.³³

Communication in each and every step from history taking, clinical examination, medication, procedures, to plans should be clear, targeted, effective, flexible and emphatic to share a common language; thus, to encourage making shared decisions.¹⁵

There are two claims a plaintiff can make against an obstetric provider who prescribes medication: negligence for prescribing a medication that causes harm to a patient and the failure in obtaining

adequately informed consent.

In a Nepalese Supreme Court case, the doctor was held guilty as he failed to counsel the client regarding the possible side effect on vision with Carbamazepine; failed to scrutinize paramount follow up, thus missed the rare side effects of the drug; unfortunately, the client suffered the damage caused. The doctor was held negligent.

There are also two standards for failure to obtain informed consent. The “prudent obstetric provider standard” is the majority standard applicable in most cases. Disclosure should include the theoretical risks associated with exposure to certain drugs during pregnancy, including the limitations of the available data, that is, that many studies are plagued by recall bias, as well as the risks for the patient and her fetus associated with untreated conditions during pregnancy.

This claim requires expert testimony by an obstetric provider as to what a prudent obstetric provider should disclose to a patient.³⁴

The other standard is the “reasonable patient standard” and requires the obstetric provider to disclose those risks a reasonable patient would want to know, including medication risks and the alternatives to the medication. The reasonable patient standard is the minority standard and unlike the prudent obstetric provider standard, does not require expert testimony.³⁵

The Bolam Test³⁶

The Bolam test is the principle used by the court to test the standard of care given by a clinician dealing with a patient. The standard of care which is accepted by a responsible body of medical opinion at the relevant time. The body of opinion need not be a majority body.

In the Nepalese Medical Negligence case (NKP, 2074, DN 9814), Nepal Medical Council failed to submit the expert opinion requested; thus the court continued the verdict without the expert opinion. The court took evidences of failure to follow up patient after surgery, failing to delegate other doctors when he plan for a leave thus neglecting to take care of complication of surgery that was performed; leading to gangrene of limb needing amputation. The inappropriate negligent behavior of the operating doctor caused

physical, psychological and long lasting disability to the patient. Thus the court held the doctor negligent and made to pay compensation of Rs. 9, 20,000(Nine lakhs and Twenty thousand rupees).

Whereas, in a case (072-CI-0548, 0552, 0549) where a thirty weeks premature delivered baby developed bluish discoloration of lower limb following several days of hospital admission, needed subsequently amputation of limb in Children's hospital. The unhappy parents sued the doctors in the birthing hospital for negligence in caring the baby thus suffered the amputation of limb. The expert opinion indicated that the doctors have not done anything differently. The verdict of guilty in District Court and to pay compensation of Rs 10, 0000 (Ten Lakhs) was appealed to Higher Court. The Higher Court placed the decision to bring the Expert Witness for Court hearing for the fair trial. This will guide as precedent for future. The case awaited the final verdict.

The Bolam principle emphasized that if the doctor has adopted a practice that is considered proper by a responsible body of medical professionals who are skilled in that particular field, he or she will not be held negligent only because something went wrong. However, there is criticism on expert opinion on reasonable man's test, in that doctors are over-protective of their peers and courts were been dictated (Bolitho factor).

Therefore, the Obstetrician Gynecologist must practice in accordance to the standard accepted, expected by reasonable and respectable bodies of medical opinion using logical analysis.

The Montgomery test³⁷

The Montgomery test highlights the importance of consent and discussion; where only the principle of Bolam ensuring the standard of care does not suffice.

The case Montgomery versus Lanarkshire was decided by Scottish Supreme Court in 1999 and since then the principle has been widely accepted. In this case Nadine Montgomery, a primi short statured diabetic lady had expressed her concern to her doctor about vaginal delivery but was reassured. The doctor defended that too many women would want cesarean delivery. The risk of shoulder dystocia and the option of cesarean delivery to prevent such possible adverse events were not discussed despite her background.

The lady delivered vaginally, and with 12 minutes delay in head to shoulder delivery the baby suffered cerebral palsy. The experts agreed that the risk of shoulder dystocia in such case is 9-10%. The patient would have accepted cesarean delivery if only it was offered, thus suffered the damage. The Supreme Court decided to award Nadine Montgomery 5.25 million pounds in damages.

The Supreme Court of Nepal has used this principle in the case where the client lost the eye sight due to inadvertent use of Tergretal, stating that "One development which is particularly significant in the present context is that patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has underpinned some of the developments in the provision of healthcare services"

These cases highlight how a clinician should regard the importance of discussing treatment options, the nature of discussion, explanations of risks and benefits, noting her reaction to the information, and finally drawing a jointly agreed treatment plan.

Alan Merry & Alexander McCall Smith in the book, "Error, Medicine and Law describe blame as a powerful weapon. Its inappropriate use distorts tolerance and constructive relations between people. Distinguishing between (a) accidents which are life's misfortunes for which nobody is morally responsible, (b) wrongs amounting to culpable conduct and constituting grounds for compensation, and (c) those (wrongs) calling for punishment of being gross or a very high degree requires and calls for careful, morally sensitive and scientifically informed analysis; else there would be injustice to the larger interest of society.

Causation

Res ipsa loquitur doctrine

Another matter that warrants further investigation is the res ipsa loquitur doctrine and its application thereof in medical negligence cases. The term res ipsa loquitur translates as "the thing speaks for itself" or "the case speaks for itself". The effect thereof is that an inference of negligence is made if an event occurs in a manner that would not usually occur unless there

has been negligence, but there is not necessarily direct evidence of the negligence.

In the Nepalese Medical negligence case (Supreme Court DN 10061), 19 years old Primi developed Vaginal tear and vulval hematoma went into shock; after primary resuscitation referred to higher center. The postpartum 19 year old died due to “Postpartum Sepsis with Shock with Renal failure with low General condition” in Gorakhpur hospital, India. Even though the client died in India after going to two different hospitals in Nepal, the Court made the first hospital where she delivered made responsible as *Res ipsa loquitur* doctrine, and made the hospital liable.

Damage due to the breach in standard of care usually involves the careful consideration of the timing in the particular case in question. Timing should be based upon the performance of a reasonable practitioner and how quickly they would balance the probability.

For example, acute hypoxia causes central brain damage compared to chronic hypoxic brain damage, which is evident in brain MRI. MRI have revealed that there is deep grey mater damage (10-25 minutes of acute profound hypoxia) compared to hypoxic damage to the peripheral part of brain in chronic hypoxia (intrauterine chronic hypoxia). Therefore, the expert will like note how long was it before an emergency cesarean section took place once the decision for urgent delivery was decided for hypoxia.

Significant progress has been made in the ability to detect fetal anomalies by ultrasonography.³⁸ Not all the anomalies can be revealed during the routine anomaly scan performed at 18 to 22 weeks of gestation, since some may be evident only late in pregnancy. Various intrauterine insults can cause developmental malformation in the developing fetus depending upon the mechanism, extent and the time of insult. Sometimes, insults in early pregnancy can manifest only in later pregnancy. Thus, the Court needs to be vigilant in the interpretation of the damage causation aspect in the verdict. Similarly, the Obstetrician should be vigilant regarding these aspects of limitations, counsel the patients appropriately, and document competently.

The concept of the developmental natural course of fetal anomalies in utero must be recognized to lead to a new nomenclature for fetal anomalies: clinical,

diagnostic and medico-legal implication.

Similarly, ovarian cancer is detected in late stages due to the fact that symptoms of ovarian cancer are mild, non-threatening till in later stage.

Record keeping thus is important. Fabricating and altering documents is a crime. There are many ways that an investigating officer in criminology can identify falsification of documents.

The Bolitho test³⁶

The Bolam test of reasonable man’s test can be departed by the court on the basis of illogical, irresponsible and indefensible reasoning grounds. The principle of Bolitho states that only focusing on Bolam for the final verdict does not protect the community against unsafe medical practices. The right based society to dismiss a patient’s concerns if only Bolam test is taken into consideration. In Bolam-Bolitho framework directs the signpost for the lawyers, categorization of Bolitho factors and shows that one side’s opinion need not be followed where a conflict in the expert opinion exists. Therefore, there is a two-step procedure in determining medical negligence: The first step is whether the doctor has acted in accordance with the practice accepted as proper for an ordinary competent doctor by a reasonable body of medical opinion. If yes, then the second step would be, whether the practice survived Bolitho judicial scrutiny as being responsible or logical.

Bolitho factors: There are seven different scenarios to say that a doctor is illogical and indefensible: the peer professional opinion has overlooked that a “clear precaution” to avoid the adverse outcome for the patient was available; there is a question of resources and conflict of duty; there is failure to weigh the comparative risks and benefits of the chosen course of conducts; where the accepted medical practice contravenes widespread public opinion; where the doctors peer opinion cannot be correct when taken in the context of the whole factual evidence; when the doctor’s expert medical opinion is not internally consistent; and lastly, the peer professional opinion has adhered to the wrong legal test.

In an age when patient-based rights seem to be in the ascendancy, it is worthwhile emphasizing that the medical profession has “rights” too, one of which is a

clear exposition and application of legal principle as to when, and why, Bolam evidence will not “carry the day” and absolve a defendant doctor of breach.

Practicalities

There are a number of factors more of general nature that may have an impact on health service delivery and medico-legal litigation.

Patients sue because of a feeling that they were not heard, that their needs were not attended to, and that nobody seemed to care, and as a result, a bad outcome resulted due to a mistake or negligence.³⁸

Active listening to patient’s concern by giving adequate time demonstrating compassionate and empathetic care is one of the most important skills that prevent dissatisfied patients threatening to sue. The rightful attitude of a doctor refraining from blaming other health care providers for adverse outcomes; giving prompt and clear information of errors if any, and honest apologies to the client are mostly appreciated.¹⁵⁻¹⁸

Referred with medical errors: Policies and interventions that structure the approach to this is sometimes difficult, yet critically important. Opportunities for reducing medical errors warrant investigation as potential mechanisms by which to improve consistency and quality of care while maintaining positive professional relationships.³⁹

Prescription errors are common for litigation. Clear legible writing, checking medications after dispensing from the pharmacist, counseling regarding side effects and timely follow-up help avoiding mishaps.^{40,41}

Alexander Graham Bell invented the telephone and he himself was the first person (in 1876) to get telephonic medical consultation after he spilt sulphuric acid on himself. Since then telephonic consultation (TC) is alternate for visiting a doctor’s clinic. However, the reasons of TC for cutting down financial burden and reducing workloads are controversial. TC highly depends on the bilateral hearing, understanding, comprehending the signs and symptoms; doctor may need to assess depending on the tone of the voice and the content of the speech. Errors in such cases may have larger repercussions. It is advisable that, no prescription should ordinarily be given without actual examination. The tendency to give prescription over

the telephone, except in an actual emergency should be avoided.⁴²

Telemedicine is useful for consultation between a doctor and a paramedic, or between a doctor and a super-specialist especially in the rural setting. However, there may be issues of privacy and confidentiality. Both parties can be vicariously responsible for the negligence.⁴³ The Law of Land on regulatory and legal issues to manage compliance, reimbursement issues and contractual arrangements are advisable. In India, TC amounts to culpable negligence.

Medical errors are known to be one of the important causes for morbidity and mortality. Full and honest disclosure of errors is most consistent with the mutual respect and trust patients expect from their physicians.

Doctors have to work with several constraints and limitations; be it from aspects of medical technology, logistics or an administrative end. The medical service is a huge institution with various medical and non-medical expertises; but only doctors are unfairly victimized as culprit for any adverse outcome. The poor infrastructure in a hospital, overcrowded emergency rooms, wards, and unhygienic sub-standard environments created by hospital management for doctors to work in will be the cause of many undesirable outcomes such as septicemia and hospital-acquired infection. The blame goes to the doctors for infection on the surgical site, for example. The Court verdicts on the case, Supreme Court DN 10061, the Hospital was made liable to pay the compensation of NRs. 45,000 (Forty Five thousand) due to sub-standard sterilization leading to Septicemia despite correctly performed standard of care by doctors and nurses.

Clinical Guidelines

In the medical negligence claim, the court takes into consideration if the care was given according to the guidelines. This is taken as the standard of care at the time of the index clinical event to assess if the questionable practice was in alignment with the accepted standard.

Documentation

“If you have not written, you have not done” is the maxim in medical record. Documentation has legal

credibility when it is contemporaneous, accurate, truthful and appropriate. Charting accurately will help in answering the questions raised months or years after the event has occurred. One cannot rely on the memory of the facts.

Obstetric anesthesia remains an area of significant malpractice liability where competent documentation should be applied. Mandatory use of standard check list will help keep vigilance and prevent pitfalls.⁴⁴

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Policy and Law:

There is an increasing trend of making “Medical service as any other food and beverages commodity; and litigate doctors and institution for any adverse outcome by implementing Consumer Protection Act, 2054 BS, in the absence of proper Act addressing doctor patient relationship. The Consumer Protection Act undermines the gravity of seriousness present in the management of life and death in the issues of Medical care.

The then residing Judges in the Supreme Court of Nepal, in the case 063-CI-0159 expressed the need of separate “Self Contained Act” addressing doctors and patient relation.

CONCLUSIONS

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In the fields of Obstetrics and Gynecology, some of the highest numbers of litigations take place. Practice of medicine ethically may not stop consumers suing doctors for outcomes less than perfect. Knowledge of Law of Land, vigilance to preventive modalities on legal complaints, along with application of up-to-date guidelines will reduce undue adverse outcomes. Better knowledge of legal implication of informed consent, counseling, documentation, and proper record keeping is a priority. Telemedicine and telephone consultations may attract vicarious liability. Ignorance of Law is no excuse therefore; improved training on the Bolam, Montgomery, and Bolitho tests will help improve the monitoring of doctors and their clinical attitude appropriately.

Hospital administrative policy including risk management, regular audit, discussion of near-miss cases, regular mortality-morbidity meetings, and timely review of the Clinical guidelines will help provide information for defense upon litigation and ensure the maintenance of the quality of health-care services. The concept of independent bodies of expertise like Clinical Governance to objectively evaluate the overall quality of the institution will be highly valuable. Further research into medico-legal cases for academic and policy-making purposes is of great necessity.

Appropriate Policy and Act by the Government will decrease the meddlers and medical vandalism.

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