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Review Article

Medico-legal safeguards in obstetrics and gynaecology: a narrative review of legislative frameworks and preventive strategies

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ABSTRACT

Obstetrics and gynaecology (OB-GYN) is recognized as one of the most litigious medical fields worldwide. The nature of care often involves two lives simultaneously, with high emotional and ethical implications, which makes it vulnerable to legal scrutiny. Legal actions usually arise from allegations of medical negligence, improper consent, or failure to meet standard protocols during antepartum, intrapartum, or postpartum care. However, understanding the application of relevant legal frameworks can help mitigate the risk of litigation. Any guidelines or acts stated by the government, if diligently followed, significantly reduce the risk of litigation by promoting transparency, ethical standards, patient safety, proper documentation and accountability. This narrative review was conducted through a systematic search of PubMed, Medline, and Google Scholar, supplemented by Government of India legislative documents and guidelines from professional bodies including FOGSI, WHO, and ICMR. Nine key legislative frameworks were identified as relevant to OB-GYN practice in India-the medical termination of pregnancy (MTP) act (1971, amended 2021), pre-conception and pre-natal diagnostic techniques (PCPNDT) act (1994, amended 2003), assisted reproductive technology (ART) Act (2021), surrogacy (Regulation) act (2021), protection of children from sexual offences (POCSO) act (2012), Family planning indemnity scheme (FPIS) (2005), clinical establishments act (2010), Indian medical council ethics regulations (2002), and the consumer protection act (CPA) (1986, amended 2019). Common medicolegal pitfalls included deficiencies in informed consent, inadequate documentation, errors in foetal and neonatal management, surgical oversights, and delayed emergency referrals. Comprehensive understanding of applicable laws, combined with clinical documentation, valid informed consent, and systematic risk management, substantially mitigates medicolegal vulnerability in OB-GYN practice.

Keywords: Medical negligence, Informed consent, Obstetrics, Gynaecology, MTP act, PCPNDT act, ART act, Surrogacy, Litigation, Consumer protection act

INTRODUCTION

Medicolegal challenges in obstetrics and gynaecology (OB-GYN) have become a critical concern worldwide. As a specialty that plays vital role in maternal and child health, it is also one of the most vulnerable to litigation. According to American college of obstetricians and gynaecologists (ACOG, 2015), nearly 80% of practitioners face legal action at least once during their careers. In fact, OB-GYN is ranked as the most litigious medical specialty.[1]

Since the inclusion of the medical profession under the Consumer Protection Act of 1986, there has been a marked rise in patient-initiated legal claims, many of which have resulted in compensation being awarded for proven negligence. Hospital authorities are increasingly facing allegations concerning the quality of care, professional standards, and the appropriateness of diagnostic and therapeutic interventions. Defense organizations such as the NHS Litigation Authority handle thousands of claims

annually, although only 1-2% proceed to court. Notably, about 70% of these cases are successfully defended.[2]

Therefore, it is crucial to review and understand the various legal acts, as their proper knowledge can significantly aid in preventing litigation and promoting safer medical practice. Familiarity with legal frameworks not only helps in avoiding potential litigation but also supports safer, more transparent and ethically sound patient care.

LITERATURE REVIEW

This narrative review was conducted by systematically retrieving, selecting, and analysing literature relevant to the intersection of obstetrics, gynaecology, and medico-legal frameworks. Relevant articles were sourced from electronic databases including PubMed, Google Scholar and Medline. Government guidelines and national health policy documents were also reviewed. A combination of keywords and Boolean operators was used: medicolegal issues in obstetrics OR legal challenges in gynaecology, MTP Act, PCPNDT, consent in OB-GYN, risk management, and preventive legal practices. Search was limited to English-language articles with all the updates. Studies were included if they discussed legal, ethical, regulatory, or policy-related issues in OB-GYN; provided guidelines or position statements from recognized professional organizations such as FOGSI, WHO, and ICMR; or presented case studies, review articles, and Government of India documents addressing preventive medico-legal practices. Articles focusing exclusively on non-obstetric and non-gynaecological specialties, non-peer-reviewed blogs, editorials lacking supporting evidence, and unrelated legal cases were excluded from the review. Findings were summarized, focusing on preventive strategies, ethical implications, legal safeguards, and practical applications. Laws were contextualized within the Indian healthcare system.

COMMON MEDICOLEGAL PITFALLS IN OB-GYN PRACTICE

Recognition of the circumstances most commonly precipitating litigation is prerequisite to their prevention. The following categories represent the most frequently encountered medicolegal vulnerabilities in OB-GYN practice. (Table 1).[3,4]

Table 1: Medicolegal risks in obstetrics and gynecology.[5]

Category	Key issues	Examples/risks
Consent issues	Inadequate or overreaching consent	Poor disclosure, lack of understanding, procedure beyond consent
Postoperative failures	Missed complications	Internal hemorrhage, bladder/ bowel/ ureter injury
Foetal and neonatal negligence	Substandard perinatal care	Missed anomalies, delayed C-section, poor resuscitation
Surgical errors	Preventable intra-operative mistakes	Retained swabs/ instruments, mismanaged PPH
Emergency prepardness	Delay or inadequate setup	Late referral, lack of blood, oxygen, transport
New born identification errors	Incorrect identification	Mislabeling, missing details, no footprints

Incomplete or inadequate informed consent

Inadequate informed consent remains the leading cause of medicolegal claims in OB-GYN. Legally valid informed consent must satisfy three core requirements: adequate information disclosure, comprehension by the patient, and voluntary agreement. Disclosure of information include the diagnosis and nature of the condition, the proposed procedure, material risks and complications, probability of success, consequences of declining treatment, and available therapeutic alternatives. Information must be communicated in plain, non-technical language, ideally in the patient's language. Consent must further be capacity-based, confirming that the patient is legally and cognitively competent to decide.

Misapplication or overreach of consent

Consent is procedure-specific and failure to observe this principle constitutes an actionable breach. For example, a consent obtained for diagnostic laparoscopy does not imply a consent for hysterectomy, unless there is an immediate life-threatening emergency. Any surgical extension beyond the scope of the documented consent requires additional, separately recorded authorisation.

Postoperative oversight and complications

Litigation frequently arises from failures in postoperative care including undetected internal haemorrhage following hysterectomy or vaginal surgery, and missed iatrogenic injuries to adjacent visceral structures (bladder, ureters, or bowel) during laparoscopy, particularly when postoperative symptoms are inadequately investigated.

Negligence in foetal and neonatal management

Failure to meet the standard of care for the foetus and neonate is a significant source of medicolegal exposure. This includes delayed or missed antenatal diagnosis of

congenital anomalies, inadequate management of foetal distress or perinatal hypoxia, delay in performing emergency caesarean section resulting in neonatal brain injury or cerebral palsy, and the non-availability of trained neonatal resuscitation personnel at high-risk deliveries.

Surgical errors and oversights

Avoidable intra-operative errors are source of litigation. Retention of surgical materials (swabs, instruments) constitutes negligence per se under the doctrine of res ipsa loquitur. Inadequate monitoring and delayed intervention in postpartum haemorrhage (PPH) represent another high-risk area, which can be rapidly fatal without timely and aggressive management.

Deficient emergency preparedness and referral

Delay in referring critically ill patients to adequately equipped higher-level facilities is another frequent medicolegal complaint. Performing high-risk obstetric procedures in inadequately equipped facilities lacking oxygen supply, emergency blood products, or ambulance support may constitute institutional negligence, irrespective of the treating clinician's competence.

Newborn identification errors

In maternity units, errors in newborn identification carry serious legal and ethical consequences. All neonates must be accurately labelled with the parental names, sex, birth weight, date and time of birth, and, where feasible, a footprint impression.

KEY LEGISLATION GOVERNING OB-GYN PRACTICE

The following legislative frameworks are directly applicable to the practice of OB-GYN in India. Familiarity with these statutes is essential for both clinical compliance and medicolegal protection.[6]

The MTP act, 1971 (Amended 2021)

The Indian Parliament passed the MTP Act in 1971, which lays out a structured legal and medical framework for abortion in India. Before this law, abortion was a crime under the Indian Penal Code of 1860, unless it was done to save the woman's life. The 2021 amendment significantly broadened the scope of the Act to ensure safer, more inclusive, and accessible reproductive healthcare.[7,8]

Objectives

The Act aims to provide safe, legal, and accessible abortion services; reduce maternal morbidity and mortality associated with unsafe procedures; uphold women's reproductive autonomy; legalize abortion under specific conditions and ensure confidentiality and dignity for women seeking termination.

Key provisions

Gestational age limits

Termination up to 20 weeks requires the opinion of one registered medical practitioner (RMP). Between 20 and 24 weeks, the opinion of two RMPs is required, and termination is restricted to specific categories of women as defined under Rule 3B.

Beyond 24 weeks, termination is permissible only for substantial foetal anomalies, upon approval by a state-level Medical Board comprising a gynaecologist, paediatrician, radiologist and additional specialists as notified.

Eligible categories for 20-24 weeks (Rule 3B)

Survivors of rape, incest, or sexual assault; minors; women with physical or mental disabilities; women experiencing change in marital status (widowhood or divorce during pregnancy); pregnancies involving late-diagnosed foetal anomalies; and pregnancies arising in humanitarian, disaster, or government-declared emergency settings.

RMPs

Abortions must be conducted at government hospitals or approved private facilities only by qualified RMPs who hold an MBBS degree with specific training or experience in obstetrics and gynaecology.

Consent requirements

For adult women, only the woman's own consent is required. For minors or persons with mental illness, guardian consent is mandatory.

Confidentiality (Section 5A)

Disclosure of the identity and personal details of the woman undergoing abortion is strictly prohibited and constitutes a punishable offence, with imprisonment up to one year, fine or both.

Record maintenance and forms

Specific prescribed forms are mandatory for legal compliance: Form C (consent); Forms I and II (medical opinion and monthly reporting); Form III (admission register); Forms D and E (for Medical Board cases).

Penal provisions

Termination outside legal indications or by unqualified personnel may lead to criminal prosecution, including imprisonment and fine.

Unauthorized disclosure of patient identity is punishable with up to one year imprisonment or fine or both.

The PCPNDT act, 1994 (Amended 2003)

The PCPNDT Act was first introduced in 1994 as the PNDT Act and updated in 2003 as to include rules for pre-conception techniques as well. This law was made to stop the practice of selecting a baby's sex before or after pregnancy and to prevent the wrong use of medical tests that check the baby before birth.[9,10]

Objectives

Objectives were to ban sex selection and sex determination, control the use of medical tests that check for birth defects or genetic problems in baby, stop female foeticide and protect unborn girls and to hold doctors and clinics responsible for how they use prenatal tests.

Key provisions

Prohibited activities

It prohibits sex determination and sex selection at any stage, whether pre-conception or during pregnancy, by any means including spoken, written/symbolic communication.

Permitted diagnostic uses

Ultrasound, amniocentesis, chorionic villus sampling, and allied techniques are permissible only for detection of genetic disorders, chromosomal abnormalities, inherited metabolic diseases, haematological conditions (e.g., thalassaemia), sex-linked diseases, structural birth defects.

Registration requirements

All facilities employing these technologies must be registered under the Act. Operation without registration constitutes a cognizable, non-bailable, and non-compoundable offence.

Record maintenance

Clinics must complete prescribed forms (A through H), with Form F mandatory for every patient undergoing prenatal testing. Records must be retained for a minimum of two years and produced upon official request.

Formation of appropriate authorities

The central and state governments must appoint officials to enforce and monitor this law. They have the power to inspect, search, seize, seal, or cancel the registration of any place that breaks the rules.

Informed consent

Written informed consent using Form G is mandatory prior to any invasive diagnostic procedure.

Penalties

First offence: imprisonment up to three years and fine up to ₹10,000. Repeat offence: imprisonment up to five years and fine between ₹50,000 and ₹1,00,000. Convicted practitioners additionally face suspension of medical registration by the State Medical Council. Every offence under this act shall be cognizable, non-bailable and non-compoundable.

The ART act, 2021

Enacted by the Parliament of India to regulate the rapidly expanding field of ART services, including in vitro fertilisation (IVF), intrauterine insemination (IUI), gamete donation, and embryo transfer. It aims to ensure ethical practices, protect the rights of commissioning couples and donors, and prevent exploitation in ART services.[11,12]

Objectives

Objectives were to regulate ART clinics and ART banks, ensure safe and ethical ART practice, protect the rights and well-being of donors, commissioning couples, and children and to establish a national ART registry for oversight and data management.

Key provisions

Registration of ART clinics and banks: All ART clinics and banks must be registered with the national ART and surrogacy board and are required to maintain proper records and submit data to the national ART registry.

Eligibility

ART services are available to married heterosexual couples (women aged 21-50 years; men aged 21-55 years) and single women who are widowed or divorced (aged 21-50 years). Single men, same-sex couples, and cohabiting partners are excluded under the current legislation.

Gamete donation

Donors may contribute sperm or oocytes only once in a lifetime and to a single commissioning couple. Sperm donors must be aged 21-55 years; oocyte donors must be aged 23-35 years. Mandatory medical and genetic screening, written informed consent, and strict maintenance of donor confidentiality are required. Commissioning couples must provide insurance coverage to the oocyte donor for health complications arising from donation.

Rights of ART-born children

A child born through ART is deemed to be biological and legal child of the commissioning couple, entitled to all rights and inheritance as a natural-born child. Donors retain no parental rights or obligations.

Record maintenance

ART records must be preserved for ten years, after which they are transferred to the national registry under strict confidentiality.

Penalties

Violations including unregistered operation, unauthorised gamete donation, or confidentiality breaches attract rigorous imprisonment up to ten years and fines up to ₹25 lakh.

Surrogacy (Regulation) act, 2021

Enacted to address the absence of a formal regulatory framework governing surrogacy in India, this act permits only altruistic surrogacy while prohibiting commercial. It aims to prevent exploitation of surrogate mothers and children born through surrogacy, and establish standardised frameworks for eligibility, consent, and registration.[13]

Objectives

Objectives were to prohibit commercial surrogacy and allow only altruistic surrogacy, protect the rights and interests of the surrogate mother and the child, regulate and monitor surrogacy clinics and to establish National and State Surrogacy Boards for oversight and policymaking.

Key provisions

Eligible intended parents

Married Indian couples (male aged 26-55 years; female aged 23-50 years) with proven infertility, and single women who are widowed or divorced (aged 35-45 years), using self-oocytes with donor sperm. The 2024 amendment permits use of donor gametes in married couples where one partner has a documented medical condition, certified by a District Medical Board.

Surrogate mother criteria

A surrogate must be a married woman aged 25-35 years with at least one biological child, able to act as surrogate only once in her lifetime. Mandatory medical and psychological evaluation and written informed consent are prerequisites. The surrogate retains the right to withdraw consent prior to embryo implantation.

Legal status of the child

The child born through surrogacy is the biological and legal child of the intending couple, with full legal and inheritance rights. Commercial surrogacy, surrogacy for cosmetic or convenience purposes, and surrogacy by single men, same-sex couples, live-in partners, or foreign nationals are prohibited.

Prohibitions

Surrogacy is not allowed for single men, live-in couples, homosexual couples, or foreigners, couples with existing biological or adopted children (with exceptions for disabled children or life-threatening illnesses) and for convenience or cosmetic purposes.

Penalties

Engaging in commercial surrogacy, unlicensed practice, or advertising surrogacy services may attract imprisonment up to ten years and fines up to ₹10 lakh. All offences are cognizable, non-bailable, and non-compoundable.

The POCSO act, 2012

The POCSO act provides a comprehensive legal framework for the protection of children under 18 years of age from sexual abuse, assault, and exploitation, and mandates child-sensitive judicial procedures. The act applies uniformly irrespective of gender.[14]

Objectives

Objectives were to protect children from offences of sexual assault, sexual harassment, and after pornography. It provides special procedures for the recording of evidence and conduct of trial, ensure the safety, dignity, and rehabilitation of the child during and after legal proceedings and to mandate the reporting of such offences by any person, including medical professionals.

Key provisions

Mandatory reporting (Section 19)

All persons, including medical professionals, are legally obligated to report suspected or confirmed child sexual abuse to the police or the Child Welfare Committee. Failure to report is a punishable offence carrying imprisonment up to six months and/or fine.

Medical examination (Section 27)

Examination must be conducted by a female doctor (mandatory where the survivor is female), preferably in the presence of a parent or trusted person, using the least traumatic approach and with full respect for the child's privacy and consent.

Judicial safeguards

Child statements must be recorded at the child's chosen location or residence, not at a police station. Direct confrontation with the accused is prohibited during trial.

Special courts are designated for expedited proceedings to be completed within one year.

Burden of proof

Under sections 29 and 30, the burden of proof may shift to the accused in specified circumstances. Importantly, the Supreme Court has affirmed that the absence of physical injury does not invalidate a complaint, and that a minor's verbal testimony holds substantial evidential weight. Consent by a minor is legally void (Table 2).

Table 2: POCSO act 2012: summary of offences and penalties.

Offences	Punishment
Penetrative sexual assault	Minimum 10 years to life imprisonment + fine
Aggravated penetrative assault	20 years to life or death penalty
Sexual harassment	Up to 3 years + fine
Failure to report	Up to 6 months + fine
Malicious false complaint	Up to 6 months imprisonment + fine

FPIS, 2005

Objectives

The FPIS aims to promote confidence in sterilization procedures by providing financial safeguards to both beneficiaries and healthcare providers, thereby supporting broader objectives of India's family planning programme.[1]

Key provisions

Beneficiary compensation

Death during or within seven days of the procedure: up to ₹4,00,000. Death within 8-30 days: up to ₹1,00,000. Failure of sterilisation: ₹60,000. Treatment of complications: actual expenses up to ₹50,000.

Provider indemnity

Healthcare providers performing sterilisation under the scheme receive indemnity cover up to ₹4,00,000 per claim, with a maximum of four claims annually per provider, protecting against liability arising from failure of sterilisation or resultant complications.

Administration

The scheme is funded through the National Health Mission (NHM) under State Programme Implementation Plans and administered by state and district health authorities.

The clinical establishments (Registration and Regulation) act, 2010

This act mandates registration and adherence to minimum prescribed standards for all clinical establishments in India, encompassing hospitals, nursing homes, clinics, diagnostic laboratories, and imaging centres.[16]

Objectives

It aims to ensure uniformity in healthcare quality and to protect patient interests.

Key provisions

All establishments must register with the designated state or union territory authority and comply with prescribed standards relating to infrastructure, personnel qualifications, hygiene, equipment, and patient care protocols. Mandatory maintenance of records and display of relevant institutional information promotes transparency and facilitates regulatory oversight. Non-compliance may result in de-registration and legal liability.

The Indian medical council (professional conduct, etiquette and ethics) regulations, 2002

Framed under the Indian Medical Council Act of 1956, these regulations constitute the code of professional conduct for all registered medical practitioners in India.[17]

Key provisions

Duties of physicians

Obligations extend to patients (competent; compassionate care; confidentiality; informed consent), to other professionals (mutual respect; avoidance of unjustified criticism) and to society (public health promotion; disaster response; medical education).

Professional misconduct

Defined acts of misconduct include negligence or malpractice, breach of patient confidentiality, unethical advertising or self-promotion, acceptance of commissions or referral fees, and performance of procedures beyond one's competence.

Disciplinary consequences

The National Medical Commission and State Medical Councils are empowered to issue warnings, suspend practice, or permanently remove a practitioner from the medical register. Breach of these regulations may also attract civil or criminal liability.

The CPA, 1986 (Amended 2019)

The CPA, 2019, which replaced the 1986 legislation and came into force on 20 July 2020, significantly strengthened consumer rights and introduced the Central Consumer Protection Authority (CCPA). Under this act, patients who pay for healthcare services are classified as consumers, and medical services rendered for a fee

constitute "services." Clinicians and institutions are thus directly accountable under consumer law.[18]

Key provisions

Grounds for complaint

Deficiency of service (improper treatment, inadequate facilities), unfair trade practices (misleading information, overcharging), and medical negligence (surgical errors, absence of informed consent) are actionable under the act.

Dispute redressal

Claims are adjudicated by hierarchical consumer dispute redressal commissions: District (up to ₹50 lakh), State (₹50 lakh to ₹2 crore), and National (above ₹2 crore). These bodies follow simplified quasi-judicial procedures and are mandated to resolve complaints within three months (without expert evidence) or five months (with expert evidence).

Legal principles applied

Res IPSA loquitur (negligence apparent without expert testimony, e.g., retained surgical foreign body); the Bolam test (a practitioner is not negligent if their conduct conforms to practice accepted by a responsible body of medical opinion); and the Bolitho addendum (the accepted practice must additionally withstand logical scrutiny).

STRATEGIES FOR THE PREVENTION OF MEDICOLEGAL LITIGATION

Adherence to standard clinical protocols

Strict compliance with nationally and internationally accepted clinical guidelines -issued by ACOG, FOGSI, RCOG, WHO, and the government of India leads to equality in standard of care. It acts as primary defence against allegations of negligence.[19,20]

Informed and valid consent

Informed consent must be obtained prior to every diagnostic or therapeutic intervention and must address: the diagnosis and nature of the proposed procedure; its risks and complications; probability of success; available alternatives; and consequences of declining treatment. Consent must be recorded contemporaneously, signed by the patient and a witness, and filed as part of the permanent medical record.

Proper documentation

Accurate, legible, and contemporaneous medical records represent the single most important defence in medicolegal proceedings. Records must be dated, timed, and signed. Mandatory retention periods are as follows: Indoor patient records: 3 years, OPD records: 5 years in hospitals, 2 years in clinics, obstetric records: Preferably for 21 years, MTP records: 5 years, PCPNDT records: 2 years and ART records: 10 years.

Emergency preparedness and timely referral

Medical facilities must be adequately equipped to manage obstetric emergencies. In situations where necessary infrastructure (e.g., blood bank, ICU, neonatal care, oxygen supply) is unavailable, a timely referral to a higher-level centre is both legally and ethically required. Delayed or inappropriate management in such cases may amount to negligence.

Risk communication and patient counselling

Thorough pre-procedural and perinatal counselling enhance patient trust and promotes shared decision-making. All counselling should be documented, highlighting the patient's understanding and acceptance of risks and alternatives. Regular updates to the family during critical care are essential to prevent allegations of withholding information.

Respect for patient rights

Medical practitioners must comply with the Charter of Patient's Rights issued by the Ministry of Health and Family Welfare (MoHFW), which enshrines the right to informed consent, privacy, confidentiality, non-discrimination, second opinion, and emergency medical care.

Legal and ethical compliance

Failure to adhere to the laws may result in criminal or civil liability and professional disciplinary action. Practitioners must maintain compliance with all relevant medico-legal statutes.

Periodic legal and ethical training

Continuous medical education (CME), legal workshops, and medico-legal audits equip healthcare professionals with updated knowledge on law and ethics. Regular training enhances risk awareness and encourages safe clinical practices.

Use of safety checklists and protocols

In urgent obstetric situations, certain tools can make a big difference by helping doctors and nurses act quickly and correctly. Checklists are especially helpful in guiding the team step-by-step, making sure nothing important is missed.

They help everyone stay focused and work together smoothly, even in stressful moments. For example-WHO surgical safety checklist or PPH emergency response bundles.

Professional conduct and communication

Empathy, transparency, and professionalism must underpin all patient interactions. Maintaining respectful and honest communication, even during complications or adverse outcomes, helps mitigate legal hostility. Avoid criticism of fellow professionals in front of patients, as it may escalate distrust and litigation.

CONCLUSION

The relationship between law and medical practice in obstetrics and gynaecology is both complex and unavoidable. In today's healthcare environment, being legally informed isn't just about protecting oneself from liability-it's also about building trust with patients and delivering better, safer care. As medico-legal cases become more frequent, doctors need to stay aware of the laws that guide their work, act ethically, maintain thorough and honest records, and communicate openly with patients. These habits are not just legal safeguards-they're the foundation of responsible, compassionate, and sustainable clinical practice. Future research should focus on prospective evaluation of the impact of structured medicolegal education programmes on litigation rates and patient outcomes in this specialty.

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