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Womb & Wellness

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स्त्रिया: हिताय प्रवतमाल:
Striving For The Betterment Of Woman

The POGS Chronicle ♦ Issue 11, February 2026

POGS App

On the auspicious occasion of Gudi Padwa, we are thrilled to announce the launch of the brand-new POGS App, set to debut at our 40th POGS Installation CME!
For the very first time, POGS is bringing you a state-of-the-art mobile application available on both Android and iOS. This app is designed to centralize all POGS-related information, making it easier than ever to stay connected and engaged.
Overview:
• Seamless New Member Registration: Join our community with just a few taps.
• Easy Conference Registration: Book your spots for upcoming events right at your fingertips.
• Monthly Quiz: Test your knowledge and win exciting prizes!
• Digital Library: Access monthly newsletters, a video library, and recordings of past conference lectures

Get ready to experience the convenience and innovation of the POGS App. Stay tuned and be prepared to take your POGS experience to the next level!

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General Secretary
POGS 2025-26
POGS App Team
Dr Mahima Lalwani
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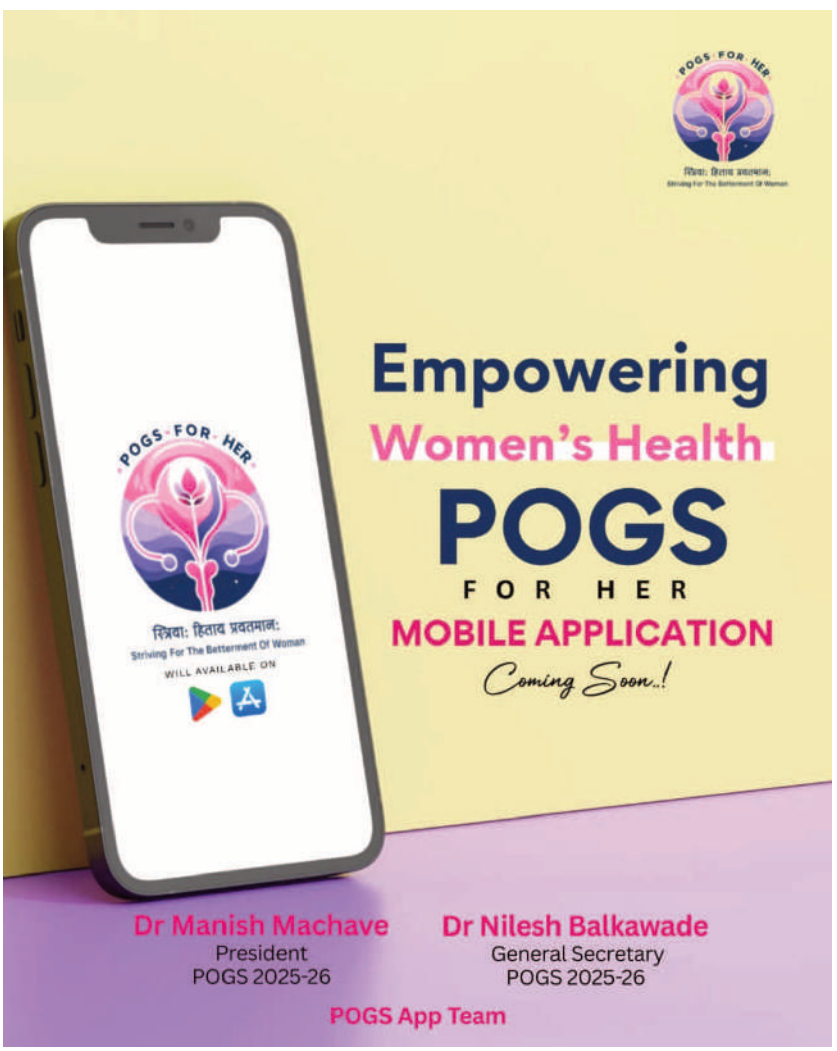

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Presidential Address

Dr Manish Machave
President, POGS

Dear esteemed members of POGS,,

Greetings from the team,
This is our ELEVENTH, theme based, dedicated and all-encompassing newsletter of POGS.
I begin with enriching words,
IT IS BETTER TO PREPARE AND PREVENT THAN REPAIR AND REPENT.
In today's rapidly evolving healthcare environment, medical practice extends beyond clinical expertise to include a clear understanding of legal and ethical responsibilities. Medicolegal issues have become an integral part of day-to-day medical practice, influencing decision-making, documentation, patient communication, and professional accountability.
This newsletter is an effort to create awareness and provide practical guidance on common medicolegal challenges faced by healthcare professionals. By addressing frequently encountered scenarios, recent legal developments, and best practices, we aim to empower doctors to practice medicine with confidence, clarity, and compassion—while safeguarding both patient rights and professional integrity.
Knowledge of medicolegal principles is not meant to instil fear, but to promote safe, ethical, and transparent medical care. Staying informed helps prevent misunderstandings, reduces the risk of litigation, and strengthens the trust that forms the foundation of the doctor–patient relationship.
We hope this newsletter serves as a useful resource and encourages continuous learning, open discussion, and responsible medical practice in an increasingly regulated healthcare system.

Do take out time and post us a feedback.
Happy reading.
Looking forward to see you all soon.
TILL THEN '' BIS DANN"
NAMASKAR…..

Dr Manish Machave
President, POGS

Dr Nilesh Balkawade
Secretary, POGS

Secretary's Address

"Alone we can do so little; together we can do so much."

Dear Esteemed Members,
As we step into February, it gives me immense joy to reflect on a month filled with meaningful beginnings, academic excellence, and collective strength—true to the spirit of POGS.

We began the New Year on a truly inspiring note with the Heritage Walk at Bharat Itihas Sanshodhak Mandal, guided by Shri Pandurang Balkawade ji, on the first Sunday of the year. Walking through history, culture, and values together, it was immensely gratifying to start the year with such a refreshing and thoughtful experience—a new year with a new beginning.

Academically, the Internal Iliac Artery Ligation Workshop conducted in collaboration with AFMC was a phenomenal success. With 120 registrations, outstanding participation, and an amazing faculty lineup, the workshop set new benchmarks in hands-on learning. Heartiest congratulations and kudos to the convenors Dr. Kalyani Ingale and Dr. Laxmikant Behele for their tireless efforts and flawless execution.

I would also like to express my heartfelt gratitude to all our new members who participated enthusiastically in the POGS Membership Drive, making it a massive success. As many as 80 doctors joined POGS as Lifetime Members—a truly proud moment for all of us.
Responding to public demand, we have extended the POGS Membership Drive. Let us keep this momentum going and make it even bigger!

POGS, along with AMOGS, continued its strong commitment to society through a remarkable Public Awareness Initiative in collaboration with the Rotary Club of Pune Sanskruti. A large-scale health camp and awareness program reached nearly 2500 college-going girls, focusing on Menstrual Health, HPV Vaccination, Fertility Awareness, and the Mi Manasvi initiative. I thank Dr Kiran Kurtkoti, President AMOGS, Dr Manish Machave, President POGS, Dr Vaishali Biniwale for guiding all girls in the program along with me!!

Such programs reflect the true soul of our society—service with purpose.
Let us unite with renewed energy and enthusiasm to conduct many more impactful academic and public awareness programs in the coming months.
I sincerely urge each one of you—
👉 Let's make more POGS members.
👉 Help at least one friend join POGS and strengthen our fraternity.

Ending with a Thoughtful Verse
"One step together, a journey begins,
Many hands joined, that's how change wins.
In unity there's power, in bonding there's grace, POGS grows stronger when each finds a place".

With warm regards and collective optimism,

Warm regards
Dr Nilesh Balkawade
General Secretary POGS

Editorial

Dr Kalyani Ingale
Editor

Greetings from Team POGS!!!
This month we have brought a power packed information wrapped in this newsletter for you all…
Beyond the Clinical – The 2026 Mandate for Defensive Documentation and Informed Consent
Obstetrics and Gynaecology has always been a high-stakes specialty, operating at the intersection of profound joy and devastating loss. However, as we move through 2026, the landscape of practice has shifted from purely clinical excellence to a hybrid model demanding high-level legal awareness. With litigation rates rising and patient expectations reaching an all-time high, lack of awareness of the law is no longer a valid defence.
The modern medicolegal environment is often dominated by issues surrounding the "maternofetal unit," where adverse outcomes - genuinely rare but often unexpected - lead to high-value lawsuits. Studies suggest that a significant percentage of claims are indefensible, inspite of good medical care & treatment, due to poor documentation. In the age of digital health, our notes are often the only witness to our diligence. Incomplete documentation, poor communication, and failure to document informed consent remain the primary culprits.
Furthermore, as Telemedicine expands, we must be vigilant about the liability issues it attracts.
Moving Forward: The Proactive Approach
To protect our practice and our patients, we must transition from passive care to proactive risk management.
In this chronicle of POGS the articles are exactly directing us as to how shall we mould out approach towards modern day practice.
This one is an indispensable piece in your collection, the newsletter of February 2026 on Medicolegal aspects. This is compiled beautifully to have a safe journey ahead.
As we navigate this challenging terrain, let us not be driven by fear, but by knowledge. A "litigation-free" practice is achieved through superior documentation, clear communication, and informed consent.
Wish you all a very safe reading!!

Dr Kalyani Ingale
Editor

Co-Editorial

Dr Meenakshi Deshpande
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Consulting obstetrician, gynaecologist
High Risk pregnancy Consultant and Colposcopist
Chairman POGS Medicolegal Committee 25-26
Medicolegal Counsellor

Dear friends and colleagues ,

Namaskar to you all ,
It gives me immense pleasure to present this issue of POGS Womb and Wellness on Medicolegal issues .This is conceived and planned as a ready reckoner for day to day issues troubling obgyn. colleagues in practise and medical life .
With the advent of CPA , our legal accountability has increased tremendously and it is our federal duty to know the rules and regulations of the land . NO EXCUSES ALLOWED !,

• 1] Ignorantia juris non excusat....a Latin maxim phrase means " ignorance of Law is NOT an excuse
• 2] Nemo censetur ignorare legem: "Nobody is thought to be ignorant of the law".
• 3] Ignorantia iuris nocet: "Not knowing the law is harmful".
• 4] Dura lex sed lex: "The law is harsh, but it is the law"—often used to emphasize that laws must be followed regardless of personal awareness or feelings of fairness.
• A practising treating doctor and even government appointed doctors , even an intern must be aware as what are the responsibilities so as to have a safe and litigation free practice, a shield against patient dissatisfaction and how to avail of Legal Protection & Defences. Staying Updated, preventing Errors, knowing patient's and doctor's rights and responsibilities , proper communication , documentation of communication , mandatory reporting , taking well informed consents and ethical practices are your kavach kundals in this era of medical practice.

So Let's Act , Let's change ourselves , Let's be aware , knowledgeable regarding rules and regulations which are part and parcel of our practice .
That's why this Manual of Medicolegal Issues affecting Obgyn practice has been thoughtfully created and I thank President Dr Manish Machave with Dr Nilesh Balkawde, Dr Kalyani Ingle and Cochair Dr Tanuja Joshi for all the encouragement and support for this issue .

I would like to sincerely appreciate and am eternally grateful to all the contributors and authors who have taken out time from their busy schedule to send articles in time .I hope this booklet serves it's purpose and becomes a desk companion to practising gynaecologists .

Wishing you all readers a Happy and litigation free New Year 2026
Signing off....

Dr. Meenakshi Deshpande
Co-Editor

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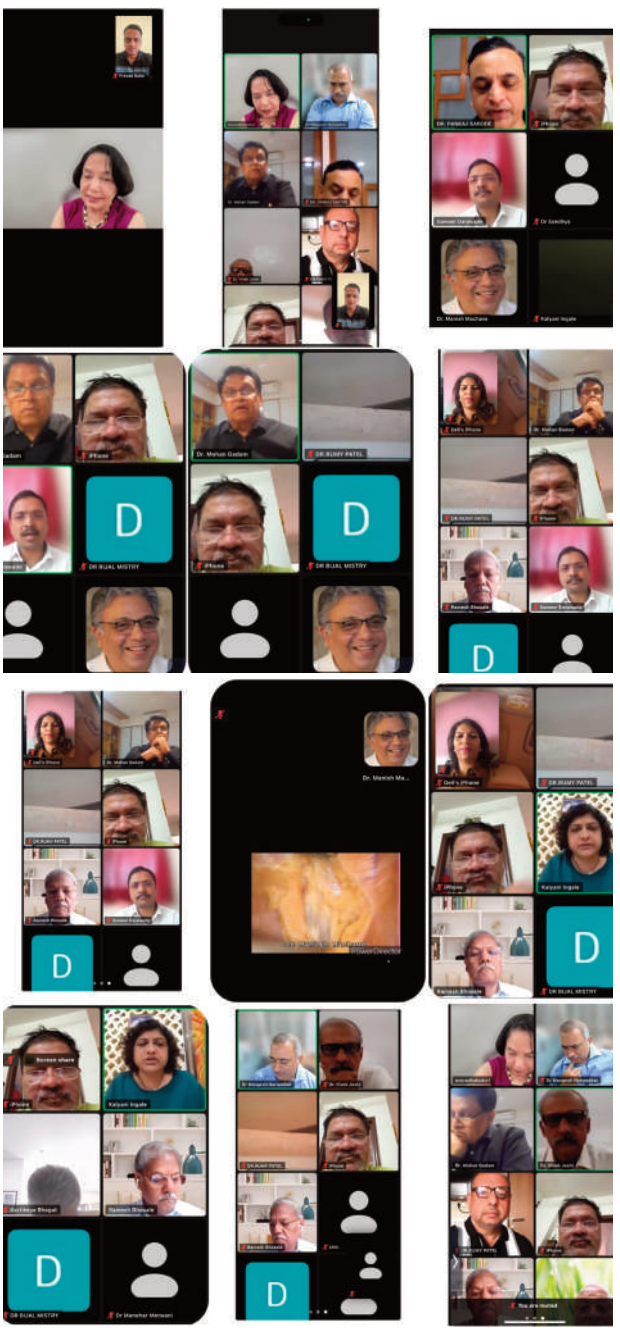
POGS MANAGING COMMITTEE

11th January 2026 — EVENT ORGANISED BY POGS IN COLLABORATION WITH THE DEPARTMENT OF OBGY OF ARMED FORCES MEDICAL COLLEGE PUNE

It gives me a pleasure to give you an overview of the event organised by POGS in collaboration with the department of OBGY of armed forces medical College Pune on 11th of January 2026
It is said that because God could not be everywhere, He made mothers!
Hence, it is our prime duty as obstetricians to take care of all the would-be mothers and to see that no mother loses her life due to postpartum haemorrhage or for any other reason.
Hence, the event on cadaveric dissection of internal iliac artery!
The event was very well received and almost 135 delegates participated in the event
It was graced by the dean, AFMC - VSM Atul Seth, Sir….
Who inaugurated the event by traditional lamp lighting along with Dr Charuchandra Joshi, Col Madhusudan Dey (HOD), Uma Wankhede- president elect-2026, Dr Ramesh Bhosle, Dr Pradeep Sambarey
and a few others.
We had the lectures right from understanding the basics of internal iliac artery followed by surgical approaches to its ligation and it was followed by actual cadaveric dissection.
The lectures on the anatomy of internal iliac artery through the scope by our President Dr Manish Machave Sir, and the step-by-step procedure of ligation of the internal iliac artery by Dr Harshad Parasnis was very well received.
Delegates did enjoy actual cadaveric dissection for almost one hour.
There was also the official release of the speculum for the month of December 2025.
The event was followed by delicious lunch.
All in all it was a successful academic event
Col Vinod Dalal help a lot in coordination of the event which made it successful.
Vote of thanks were given by Convenors Dr Kalyani Ingale and Dr Laxmikant Behele

25th January 2026 — Webinar by SOVSI (Maharashtra chapter) in association with POGS and AMOGS

SOVSI (Maharashtra chapter) in association with POGS and AMOGS organised a webinar on 25th January 2026 , Sunday from 10 am to 1 pm. The topic for the webinar was Decoding stress urinary incontinence. The webinar started by seeking blessings of almighty. Dr Manohar Motwani , General secretary SOVSI, Maharashtra chapter welcomed all delegates and dignitaries. Dr Mohan Gadam, President SOVSI (Maharashtra chapter), Dr Kiran Kurtkoti(President AMOGS), Dr Nilesh Balkawade (General secretary POGS) and Dr Pankaj Sarode (AMOGS vaginal surgery committee chairperson and Convenor) welcomed all and urged everyone to attend this webinar on a very important but neglected topic of SUI. The webinar had 3 sessions, first was about the basics , second was about the management of SUI and 3 rd session included demonstration of videos of various surgeries for SUI. The scientific programme was as follows:



Session 1

1. Anatomy and physiology of urinary incontinence - Dr Anil Sakhare.
2. Terminology of Urinary incontinence- Dr Bijal Mistry.
3. Understanding Patho physiology of SUI- Dr Milind Dugad
4. Evidence based surgical management of SUI - Dr Anuradha Koduri
5. Medical management of Urinary incontinence- Dr Mangesh Narvadkar
6. Adjuvants in management of SUI- Dr Kalyani Ingale

Surgical management videos demonstration

1. Successful Burch colposuspension- Dr Vivek Joshi
2. Laparascopic Burch colposuspension- Dr Manish Machave
3. Meshplasty - Dr Rajendra Saraogi
4. TVT & TVT O - Dr Mohan Gadam
5. TOT - Dr Sameer Daravde

The sessions were chaired by senior vaginal surgeons like Dr Ramesh Bhosale, Dr S N Agarwal,Dr Manik Gurram, Dr Rumy Patel, Dr Rakesh Pandia, Dr Kartikeya Bhagat and Dr Abhijeet Wadate. Their inputs and interaction were well appreciated.

The programme garnered an excellent response and was highly appreciated. Almost 250 delegates attended the webinar . 2 MMC, 2 ICOG and 2 MCOG points were granted for the webinar .

28th January 2026 —

‘Suraksha Kawach – Mi Manasvi’ Public Awareness Program at SNDT College, Pune

A meaningful and impactful Public Awareness and Health Camp was successfully conducted at SNDT College, Pune, under the banner of ‘Suraksha Kawach – Mi Manasvi’, jointly organized by the Public Awareness Committees of AMOGS and POGS, in collaboration with the Rotary Club of Pune Sanskruti.

The program was graced by the presence of Dr Kiran Kurtkoti, President – AMOGS, and Dr Manish Machave, President – POGS.

Also present were Dr Nilesh Balkawade, General Secretary – POGS and 2nd Joint Secretary – AMOGS, and Dr Vaishali Biniwale, Chairperson, Public Awareness Committee – POGS, along with other office bearers.

The event witnessed enthusiastic participation from nearly 2,500 college girls of SNDT College, making it a truly large-scale and impactful initiative. The program aimed not only at health screening but also at empowering young women with knowledge, confidence, and awareness about their health and future.

A series of interactive and informative awareness talks were delivered on:

Menstrual health and hygiene, addressing myths and encouraging open conversations

AMOGS ‘Suraksha Kawach’ initiative on HPV vaccination, highlighting prevention of cervical cancer

‘Mi Manasvi’ program on fertility awareness, understanding reproductive health and future planning

Importance of a healthy lifestyle, mental well-being, and self-care

The response from students, faculty, and college authorities was overwhelmingly positive. The program was widely appreciated for its relevance, simplicity, and compassionate approach toward young women’s health issues.

The Rotary Club of Pune Sanskruti played a pivotal role in the seamless planning and execution of the event and made commendable efforts to ensure its success. The Rotary team expressed their heartfelt gratitude to the office bearers of POGS and AMOGS for their guidance, support, and commitment to public health and awareness.

The 'Suraksha Kawach – Mi Manasvi' initiative stands as a strong step toward building a healthier, informed, and empowered generation of young women.

Warm Regards,
Dr Kiran Kurtkoti
President – AMOGS
Dr Manish Machave
President – POGS
Dr Bipin Pandit
Secretary General – AMOGS
Dr Nilesh Balkawade
General Secretary – POGS
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Director: Gupte Hospital and centre for research in reproduction
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Dr. Gayatri Venkataraman
MD (ObGyn)

Patient Safety in Obstetrics and Gynecology:

From Knowledge to Trust – A Medicolegal Perspective

Are our patients at war with us? Why are we losing their trust?
These are difficult but unavoidable questions confronting modern obstetricians and gynaecologists. Despite rapid advances in medical science, technology, and subspecialisation, complaints, conflicts, and litigation against clinicians—particularly in obstetrics—continue to rise. Many doctors feel increasingly vulnerable, scrutinized, and mistrusted.
A closer examination of medicolegal cases, however, reveals a consistent truth: most disputes do not arise from lack of knowledge or intent to harm, but from patient safety failures compounded by communication gaps. Patient safety, therefore, is not merely a clinical concept—it is a professional, ethical, and legal imperative.

The Patient's Perspective: What Does a Patient Want?
The patient's perspective must remain central to any discussion of quality healthcare. From a patient's viewpoint, quality care includes:
• Responsiveness and empathy
• Clear, honest, and timely communication
• Adequate information and involvement in decision-making
• Appropriate and evidence-based treatment
• Relief of symptoms and improvement in health
• Above all, safety and freedom from medical injury
Patients rarely expect perfection. What they expect is concern, transparency, and safety. When these expectations are not met, trust erodes rapidly.

Medicolegal Highlight:
Most medicolegal complaints arise not because a complication occurred, but because the patient felt unheard, uninformed, or misled.

The Four Pillars of Patient Safety
Patient safety rests on four interdependent pillars:
1. Knowledge
Knowledge forms the foundation of safe care. Continuous medical education, awareness of updated guidelines, and evidence-based practice are essential.
2. Communication
Communication failures are the most common root cause of adverse events and litigation. Communication is not merely telling—it is ensuring understanding.
3. Safe Procedures
Standardized procedures, protocols, and checklists reduce variability and minimize preventable errors.
4. Implementation
• Compliance by doctors
• Compliance by patients
Even the best guidelines fail if they are not implemented consistently.

Knowledge Alone Is Not Enough
James Reason, the pioneer of human error theory, emphasized that:
• Fallibility is intrinsic to the human condition
• We cannot change human nature
• We can change systems and working conditions
Complacency often follows experience. Knowledge without reinforcement through practice, audit, and feedback can paradoxically increase risk.

Medicolegal Highlight:
Courts increasingly recognize system failure, but accountability still rests with the treating physician unless robust safety systems are demonstrably in place.

Why Do Errors Occur?
Medical errors rarely result from a single lapse. They are usually the culmination of multiple interacting factors:

Contributing Factors	Examples
Clinical complexity	High-risk pregnancy, emergencies
Incomplete information	Missing allergy or drug history
Lack of standardization	Variable practices
Inadequate supervision	Junior staff without oversight
System gaps	Poor handovers, missing SOPs

Attentiveness, Distraction, and Presumptions
Distraction
In busy OPDs, labour rooms, and operation theatres, clinicians are frequently interrupted. Routine but critical steps may be overlooked under pressure. Missing a single key element can cause significant harm.
Presumptions
Presuming that "nothing will go wrong" leads to shortcuts:
• Skipping drug sensitivity testing
• Assuming correct endotracheal tube placement without auscultation
Small omissions can have catastrophic consequences.
Medicolegal Highlight:
Skipping a "routine" step is indefensible if it is part of accepted standard care.

Culture of Medicine and Cognitive Bias
Medicine has long promoted the myth of physician infallibility. This discourages:
• Discussion of errors
• Reporting near misses
• Learning from failures
Experience, while valuable, can also be misleading. As Charles Mayo said:
"Experience can mean doing the wrong thing over and over again."

Common Cognitive Biases
• Anchoring bias: Fixation on an initial diagnosis
• Last bad experience bias: Overcorrection based on a previous adverse outcome
Such biases are particularly dangerous in complex gynecological surgeries and obstetric emergencies.

Staff Factors and Teamwork Deficits
Errors are amplified by:
• Understaffing
• Fatigue and circadian rhythm disruption
• Frequent shift changes
• Poor communication
In large hospitals, constantly changing operating teams impair teamwork and accountability.

Classification of Medical Errors (Leape et al.)
Diagnostic Errors
• Delay or failure in diagnosis
• Failure to use appropriate tests
• Failure to act on results
Treatment Errors
• Procedural or operative errors
• Drug dosage or administration errors
• Avoidable delays
• Inappropriate care
Preventive Errors
• Failure to provide prophylaxis
• Inadequate monitoring or follow-up
Other Errors
• Communication failures
• Equipment and system failures

Operational Subcategories of Hospital Errors
Medicolegal Highlight:
Inadequate documentation often converts a defensible case into an indefensible one.

Category	Examples
Medication	Wrong drug, dose, patient
Surgery	Incorrect count, return to OT
Anesthesia	Intubation/extubation issues
Blood	Wrong blood, transfusion reactions
Laboratory	Mislabeling, delays
Equipment	Monitor failure
Records	Missing consent, poor documentation

Building a Safer Healthcare System
Core Strategies
• Reduce complexity → SOPs
• Optimize information → Checklists and protocols
• Reduce human factors → Simulation training and drills

BOX 1: Pre-Operative Checklist (OBGYN)
- Patient name, diagnosis, procedure
- Pre-op instructions followed (NBM, medications)
- Drugs to continue or withhold
- Investigations and imaging reviewed
- Physician and anesthetist clearance
- Informed/high-risk consent
- Blood group, cross-match, blood ready
- Allergy and risk assessment
- Antibiotic prophylaxis
- Equipment and instrument check
- Neonatal team preparedness

BOX 2: Post-Operative Checklist
- Sponge and instrument count
- Vitals and PPH monitoring
- Urine output and color
- Specimens sent (HPE, cord blood)
- Baby identification and labeling
- Anesthetist clearance before shifting
- Complete documentation

Standard Clinical Practice and SOPs
Adherence to evidence-based guidelines:
- Improves outcomes
- Reduces variation
- Provides strong medicolegal defense

SOPs must include admission protocols, rounds, sterilization, diagnostics, interdepartmental coordination, and staff behavior training.

Emergency Drills: Preparedness Saves Lives
Regular drills should address:
- Cardiac arrest
- Pulmonary embolism
- Anaphylaxis
- Postpartum hemorrhage

Medicolegal Highlight:
Documentation of regular drills demonstrates institutional commitment to safety.

Communication: The Core of Patient Safety
Over 80% of sentinel events reported by The Joint Commission (USA) involve communication failures.
Surveys reveal:
- 85% patients feel inadequately informed
- Over 50% do not understand explanations
- 40–45% do not comply with instructions

Communication is not a one-time act—it is a process involving understanding, perception, memory, and compliance.

BOX 3: Communication Checklist for Doctors

Item
Explained diagnosis clearly
Discussed indication for treatment
Explained procedure simply
Discussed risks and benefits
Answered patient queries
Explained post-treatment care
Informed about return to work
Summarized discussion

Patient Engagement and Shared Responsibility
Patients and families are valuable allies in safety:
- They observe system failures
- They provide early warnings
- Their involvement improves outcomes

Tools such as patient health cards, written instructions, and consultation checklists reduce errors significantly.

Time Constraints and the Team Approach
Short consultations compromise listening and diagnosis. A team-based approach, involving nurses, counselors, and educators, improves safety without overburdening clinicians.

Conclusion: A Call for a Patient Safety Movement
We began with the question: Does communication skill matter? The answer is unequivocal:
Communication is the only thing that truly matters.
Patient safety is not about avoiding blame—it is about building systems, trust, and partnerships. In obstetrics and gynecology, where stakes are high and emotions intense, patient safety is the strongest shield against litigation and the surest path to professional satisfaction.

The patient safety movement has begun.
We invite you to join it.

References
1. Leape LL et al. Preventing Medical Injury. Qual Rev Bull. 1993;19(5):144–149.
2. Reason J. Human error: models and management. BMJ. 2000;320:768–770.
3. The Joint Commission. Sentinel Event Data Root Causes. USA.
4. Cook RI, Render M, Woods DD. Gaps in the continuity of care and patient safety. BMJ. 2000.

Dr Manish Y Machave
President POGS

Dr Priyanka M Machave
Intern BVDUMC, Pune

Notice received, what next?

An adverse outcome is not synonymous with negligence, and a legal notice is not a final judgment.

Introduction

Obstetrics and gynaecology is one of the most litigated medical specialties due to high patient expectations, emotionally charged outcomes, and the dual responsibility toward both mother and fetus. For a practicing obstetrician or gynaecologist, receiving a legal notice is therefore not uncommon. While distressing, a legal notice does not always mean negligence or professional misconduct. It is a formal initiation of a legal process seeking explanation, accountability, or compensation. A clear understanding of its implications and an appropriate response are essential components of modern clinical practice.

Medicolegal notices have become an increasingly common reality in obstetric and gynaecological practice. With rising patient awareness, easy access to legal forums, and unrealistic expectations from medical care, even the most diligent clinicians may receive a legal notice at some point in their career. While such a notice does not automatically imply negligence, an inappropriate response or lack of one can significantly worsen the situation. A clear understanding of the nature of notices, their legal standing, and the correct stepwise response is therefore essential for every practising obstetrician and gynaecologist

1. What is a Notice?

A legal notice is a formal written communication alleging deficiency in service, medical negligence, or professional misconduct, and seeking an explanation or redressal. It is often the first step before initiation of legal proceedings. Notices may be sent under civil law, criminal law, consumer protection law, or professional regulatory mechanisms. Importantly, receipt of a notice does not necessarily mean guilt, but it does require a timely, cautious, and legally sound response.

2. Who All Can Send Notices?

Legal notices may be issued by:

Patients or their relatives, usually through an advocate
Consumer forums under the Consumer Protection Act
Civil courts
Criminal courts or police authorities (often under BNS sections)
Medical Council / State Medical Council
Hospital administration or employer
Insurance companies seeking clarification

Understanding the source of the notice and its legality is crucial, as the response strategy differs significantly for each.

3. Legality of a Notice

A notice is a legally recognized communication but not a judgment. It is an opportunity to present your version of events before escalation. Failure to respond within the stipulated time may result in adverse inference and further legal action. However, a poorly drafted or emotionally charged reply can be equally damaging and may be used as evidence against the doctor later. Hence, the legal value of a notice lies not just in its receipt, but in how it is handled.

Under BNSS 2023, police notices commonly cite sections 94,179,180,181,185 and 190 which generally mandate co-operation in inquiry and not immediate arrest.

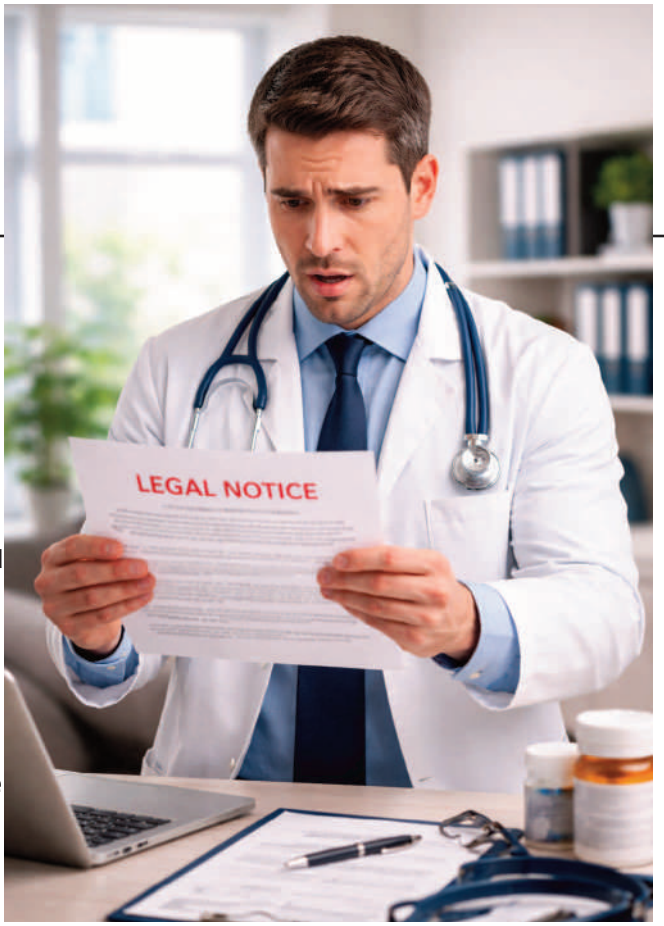
Verbal phone calls have no legal validity and appearance should be only after a written notice. Informal police requests often begin politely but may unexpectedly end up in an arrest on appearing in the police station. Hence one must never visit a police station alone, especially after or around 3pm and on Fridays., insist on written communication and may seek a revised date and time based on his/her convenience.

Early consultation with a medicolegal consultant before FIR registration is crucial to avoid escalation.

4. Step-by-Step: What to Do After Receiving a Notice

a. Do Not Panic

Panic leads to impulsive decisions verbal and unnecessary explanations, informal apologies,



or document alterations all of which can be disastrous. Maintain composure and treat the notice as a professional challenge, not a personal attack.

b. Read the Notice Carefully
Read the notice multiple times. Note the following:
*Allegations made
*Dates and events mentioned
*Legal provisions
*Time period given for reply
Often, factual inaccuracies or assumptions are evident at this stage.

c. Analyse the Contents of the Notice
Break down the notice into clinical allegations, administrative lapses, consent-related issues, and communication gaps. In obstetrics, notices commonly arise from adverse maternal or neonatal outcomes, emergency interventions, consent disputes, or alleged delay in decision-making.

d. Collect Patient Details and Records
Immediately secure all related documents:
OPD/IPD notes
Consent forms
Investigation reports
CTG records, operative notes
Discharge summaries
Referral notes and communication records
Ensure records are complete, chronological, legible, and unaltered. Any post-event modification can severely compromise defence.
Documentation: The legal GOLD.
"If you've documented it...you've done it"
Legible, dated, and timed entries significantly strengthen legal defence to a great extent.

e. Consult a Medicolegal Consultant / Lawyer
Never reply independently. Engage a lawyer experienced in medical negligence cases or a medicolegal expert. Clinical facts must be translated into legally defensible language this is a specialized skill. Early expert involvement often prevents escalation.

f. Drafting the Reply: Rules to Follow
Reply within the given time
Stick strictly to facts supported by records
Avoid emotional language, blame, or criticism of the patient
Do not admit negligence or express regret that implies fault
Avoid speculative statements or assumptions
Ensure consistency with medical records
A well drafted reply often determines whether the matter proceeds further.

g. Inform the Indemnity Insurance Provider
Immediately notify your professional indemnity insurer. Delay may lead to denial of coverage. Insurers often provide legal support and guidance, which can be invaluable in prolonged litigation.

h. Be Prepared for Appearance in Court
A notice may or may not culminate in legal proceedings, but mental preparedness is essential. Court appearances require patience, consistency, and reliance on documentation rather than memory. Regular interaction with your legal counsel helps reduce anxiety and errors.

Conclusion
For the practicing obstetricians and gynaecologists, receiving a legal notice is an occupational reality rather than a proof of incompetence. Timely, informed, and professional handling of such notices which are supported by meticulous documentation, valid consent, ethical practice, and compassionate communication forms the strongest medicolegal defence. In any obstetric practice, legal awareness is not optional; it is integral to safe, confident, and sustainable medical care. An adverse outcome is not synonymous with negligence, and a legal notice is not a final judgment.

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Pillars of Trust Patient Privacy & Confidentiality

"The Pillars of Trust and Guardians of Dignity": Patient Privacy and Confidentiality in Medical Practice in view of the DPDP Act 2023

Introduction:
Patient privacy and confidentiality are the foundations of medical practice. They foster trust. When patients are assured that their health information will be kept private, they are more likely to share sensitive details, leading to better diagnosis and treatment outcomes.

Evolution of Patient Privacy to Constitutional level.
Hippocrates era fostered utmost secrecy. Patient was protected from information which would make them anxious or worried. Therapeutic privilege was the
accepted norm in an age where the patients were illiterate and had utmost faith and trust in the decisions of doctors. Divulging of patient information was usually done among peers and was not specifically considered unethical.
The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002: Regulation 7.14 explicitly states that a registered medical practitioner must not divulge any patient information / secrets acquired during professional treatment. Violation can lead to disciplinary action, including suspension or revocation of medical license.
The Digital Personal Data Protection (DPDP) Act was enacted in 2023 and though it is not a healthcare specific act, like the Health Insurance Portability and Accountability Act (HIPAA) in the USA, it has a profound impact on the healthcare industry in India. It strictly regulates the processing of personal data which include medical records which are in the digital format (not physical documents). **This Act makes patient confidentiality and patient privacy not just an ethical duty but a legal obligation** which is enforceable through heavy financial penalties. This provision will seriously affect the way doctors, patients, and data organizers such as hospitals, health-tech companies, and insurance firms handle patient's digital data.

The Landmark Judgement delivered by a 9-judge Constitution Bench with a unanimous decision (9-0), declaring privacy a fundamental right.
Justice K.S.Puttaswamy(Retd) And Anr. vs Union Of India And Ors. on 24 August, 2017.
Facts of the Case-
The Petitioner: The case was initiated by Justice K.S. Puttaswamy, a 91-year-old retired judge of the Karnataka High Court. In 2012, he filed a writ petition challenging the constitutional validity of the Aadhaar scheme, arguing that the mandatory collection of biometric data (fingerprints and iris scans) violated a
citizen's right to privacy.
The Government of India argued that the Constitution did not explicitly grant a "Fundamental Right to Privacy," citing two earlier Supreme Court judgments:
M.P. Sharma (1954) and Kharak Singh (1962).
The Court declared that the Right to Privacy is an intrinsic part of the Right to Life and Personal Liberty under Article 21 and is protected by the freedoms guaranteed in Part III of the Constitution. The Court ruled that privacy is not just a "legal luxury" for the elite but a core component of human dignity. The court rejected the government's argument that poor people should choose "welfare benefits over privacy".
The judgment explicitly overruled the decades-old findings in M.P. Sharma and Kharak Singh, which had previously held that privacy was not a fundamental right. The Court specifically called for the government to enact a comprehensive data protection regime, which eventually culminated in the DPDP Act 2023.
The "Triple Test" for Restricting Privacy: The Court acknowledged that privacy is not an absolute right and can be restricted by the State. However, any such restriction must pass a

three-fold test:
1. Legality: There must be an existing law.
2. Legitimate Aim: The restriction must serve a valid state objective (e.g., national security or digital healthcare).
3. Proportionality: There must be a rational connection between the objective and the means used, ensuring the least amount of privacy is compromised.

There are Multiple Dimensions of Privacy:

The judgment expanded the definition of privacy into three main categories:
1. Bodily Privacy: Protection against unauthorized physical touch or medical procedures.
2. Informational Privacy: Control over personal data and how it is used. Individuals should have the power to control their digital trail.
3. Privacy of Choice: The right to make personal decisions regarding one's body, diet, and sexual orientation. (patient autonomy for choosing the treatment.)

Healthcare implications: This landmark ruling established that every individual, including patients, has a constitutionally protected right to privacy, which includes the protection of personal and health information. Privacy also protects physical aspects, including bodily exposure and participation in procedures which highlight the importance of autonomy.
1. Patient privacy protects sensitive personal and health information.
2. Patient autonomy affirms the patient's right to self-decide
3. And informed consent operationalizes autonomy by requiring disclosure and voluntary agreement.

Together, they form a foundational ethical triad that supports respectful, ethical, and legally compliant healthcare.

Understanding Patient Confidentiality:

A patient shares his sensitive information with doctors in trust. It is the duty of the doctor to safeguard this sensitive health information. The core principle is that such information cannot be disclosed to any unauthorized third party without the patient's explicit consent. Today, Clinical Photographs, Videos and audio recordings (Consent) Printouts from monitors, emails, text messages, scanned physical documents , even bills are considered as patient identifying Information (PII), and fall under the ambit of this law and need to be kept confidential. (DPDP sec 3 a)

Under Indian law, doctor-patient confidentiality is not absolute and there are specific exceptions where disclosure of patient information is permitted or required. These exceptions are grounded in legal, ethical, and public interest considerations.

Confidentiality In special circumstances:

• In reporting child abuse under POCSO Act 2012 - Indian courts have rarely allowed the disclosure of a child's identity under the POCSO Act,

and such exceptions are only made where the court determines that it is in the best interest of the child
• Reporting infectious diseases and during epidemics and pandemics confidentiality may be breached.
• Confidentiality can be breached under specific orders of the court: for Criminal proceedings, RTA investigations, Mental status confirmation, and decisions in Labor courts.

Provisions under the DPDP Act 2023 affecting patient Privacy in healthcare:
Patient privacy is ensured by this Act whereby the patient is the owner of their information the Data Principal (DPDP Act sec 2 j)and doctor or hospital is the temporary trustee the Data fiduciary (DPDP Act sec 2 i).
Important considerations for Doctors (Healthcare Providers) :
Confidentiality is no longer just "between the doctor and patient " It now extends to every software, cloud server, and diagnostic lab, insurance company and even AI applications involved in patient care. Healthcare providers are legally required to implement "reasonable security safeguards" to protect the confidentiality of digital records of patients from breach.
(DPDP Act sec 4,5,6,7,8)
Lawful Processing: Doctors can collect and process a patient's personal data only for lawful purposes such as medical treatment and healthcare services.
Data minimization. Doctors / Hospitals must collect only necessary data for specified purposes. They must not unnecessarily collect PAN card no, bank details for a consultation when Name and Age proof from an Aadhar card is enough.
Consent Requirement: Explicit and informed consent from patients is necessary before collecting, sharing or processing their personal data.
Limited Purpose Use: Patient data cannot be used for purposes beyond treatment without specific consent. (For research purposes or shared with pharmaceutical company for ads)
Storage Limitation : Privacy includes the "Right to be Forgotten." Once your treatment is over and the legal retention period expires, the hospital's right to hold your data ends. Privacy is violated if your data "lives forever" on a server where it is no longer needed.
Data Security: Doctors must implement security measures to protect patient records from breaches or unauthorized access. (DPDP Act sec 8)

2. Provisions for Patients (Data Principals) (DPDP Act sec 11)
Right to Privacy: Patients have the right to know how their personal health
data is collected, stored, and used. Patients now have the right to control when, how, and to what extent their personal information (including medical data, and personal choices) is shared or accessed. The patient can decide what can be done with his/her data, who can use it and for how long.
Right to Consent: Patients must provide explicit consent before their personal data is processed. gives the Right to Withdraw Consent. Eg for health marketing. The law mandates that withdrawing the consent must be just as easy as it was to give it.
Right to Data Portability: Patients can request their data from healthcare providers and transfer it to another provider if needed.
Right to Erasure & Correction: Patients can request correction or deletion of their personal data unless legally required to be retained. (DPDP Act sec 12)
Access & Correction : Privacy is the right to look at your digital file and say, "This diagnosis is recorded incorrectly; change it," or "I want to know which lab you shared my reports with."
Grievance Redressal: Patients can file complaints with data fiduciaries (hospitals, clinics, etc.) or escalate to the Data Protection Board in case of violations. (DPDP Act sec 13)
Accountability for "Harm"
The Act introduces a legal definition of Harm (DPDP Act sec 2(t)) that includes "mental agony" and "loss of reputation." A privacy breach is seen as a physical/emotional injury. If a hospital leaks your psychiatric history, the Act recognizes that the "harm" to your dignity is as real as a surgical error.
Data Breach Notification (DPDP Act sec 8(6): Because privacy is so vital, the doctor/ hospital must have mandatory security measures to protect sensitive data from breach. In case of a data breach, healthcare providers must promptly notify both the Data Protection Board of India and the affected patients.

3. For Data Organizers (Hospitals, Health-Tech Companies, Insurance Firms)
Data Fiduciary Responsibilities: These entities must comply with data protection norms while handling sensitive health information.
Importance of Data Storage & enhanced Security: Strong encryption and security measures must be in place to prevent data breaches.
Restriction on Cross-Border Data Transfer: Data can

be transferred abroad only as per government-approved policies.

Special Provisions for Children's Data (DPDP sec 9)

Protection of data related to child or person with disability- The Data Fiduciary shall, before processing any personal data of a child or a person with disability who has a lawful guardian, obtain verifiable consent of the parent or lawful guardian." No processing of personal data which is likely to cause any
detrimental effect on child's well-being. No profiling, tracking, behavioral monitoring, or targeted advertising directed at children. Hospitals are banned from "tracking" or "behavioural monitoring" of children through health apps.

Use of Patient Data in AI applications:

AI models thrive on large-scale patient data which is used to train AI without patient consent. AI applications in healthcare collect large amounts of data which is not secure and exposed to data breaches due to unauthorized access. AI companies must now obtain free, specific, informed, and unambiguous consent for commercial use. If the company wants to use a patient's X-ray to train a diagnostic model, the patient must specifically agree to that purpose through consent managers. ;

Anonymized patient data processed in accordance with prescribed standards for research, are exempt from certain restrictions.

Consequences of breach of confidentiality:

Healthcare data is the most sought-after data in the dark web market. India ranks second in cyberattacks on the health system.

JULY 24, 2023 Breech of data from CoWIN Data portal. The chief Sharma's own data was exposed via the Telegram app.

AIIMS New DELHI Data breech 2022. Lab data and Patient records of high security persons were hacked. This exposed data related to physical or mental health, organ donation, blood donation, race, ethnicity, religion can be used to cause social embarrassment, discrimination. It can also be used to threaten, cause violence and harm like identity theft.

Non-compliance with the provisions of the Act can attract financial penalties up to 250 crore rupees. The penalty is decided on the nature, duration of breach and the gravity of the loss or significant gain from the breach. There is no criminal penalty. (DPDP Act sec 33 Schedule).

Indian Statutory laws and Case Laws related to Patient Privacy and confidentiality

• Mr. X v. Hospital Z (1998): The Supreme Court held that unauthorized disclosure of a patient's HIV status by a hospital violated the patient's right to privacy and confidentiality. The court noted an exception that disclosure is permissible when public interest or to protect others health. Privacy right is not absolute. Balancing fundamental rights- where the appellant's right to privacy conflicts with Ms Ys right to life. The latter prevails.

• Justice K.S.Puttaswamy(Retd) And Anr. vs Union Of India And Ors. on 24 August, 2017. Explained above.

• The Medical Termination of Pregnancy (MTP) Act, as amended in 2021,Section 5A , includes specific provisions to protect patient privacy and confidentiality for women seeking abortion services in India. These provisions are designed to prevent stigma, discrimination, and unauthorized disclosure of sensitive information.

• Telemedicine Practice Guidelines (2020): These guidelines set standards for data security during remote consultations, reinforcing the need for confidentiality in digital healthcare.

• Right to Information Act (RTI) Cases: Indian courts have consistently ruled that personal medical information is exempt from disclosure under RTI unless there is a compelling public interest or court order, further protecting patient confidentiality.

It is need of the hour to spread Awareness of the implications of the DPDP Act 2023 and highest priority must be given to Implementation of Data.

Security and Safeguards

Healthcare Providers must implement privacy-by-design principles in their systems and processes.

Robust security measures to protect health data:

• Enable encryption, multi-factor authentication, secure servers, audit logs, and regular cybersecurity assessments.

• Unauthorized access to medical records must be strictly restricted and enforce role-based access

• Must not share patient data via WhatsApp or other unsecure social media platforms.

• Must not use public Wi-Fi to share patient data

• Apps which are used must not collect data not needed for healthcare use. (Contacts from the phone.)

Breaches of confidentiality is an additional liability and can lead to action for professional misconduct , legal action, financial penalties, and reputational damage for professionals and healthcare institutions.

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Legal Issues in ART and Surrogacy

Executive summary
India's legislative framework for assisted reproductive technologies (ART) and surrogacy was comprehensively overhauled by two central Acts passed in late 2021 — The Assisted Reproductive Technology (Regulation) Act, 2021 and The Surrogacy (Regulation) Act, 2021 — together with rules notified subsequently (ART Rules 2022; Surrogacy Rules 2022) and later amendments. These laws create a statutory regime for registration, governance, eligibility, record-keeping, donor/surrogate safeguards, penalties and a national registry to curb exploitation and misuse of ART services and commercial surrogacy. Implementation has required clinics, ART banks and practitioners to rework policies, documentation, informed consent procedures and compliance pathways; enforcement and interpretation continue to evolve through government notifications, rules, administrative registries and courts. This article explains the legal architecture, key obligations for clinicians and clinics, disputed/ambiguous areas (age limits, single/transgender access, cross-border issues), enforcement mechanisms and practical compliance guidance for practitioners.

Background — why specific laws were introduced
Rapid growth of fertility clinics and transnational surrogacy in the 2000s–2010s, variable standards of record-keeping, documented cases of exploitation and "rent-a-womb" commercial transactions prompted a policy shift from ad-hoc regulation toward a statutory framework. Earlier ICMR guidelines and voluntary registries (National ART Registry) laid the groundwork, but Parliament enacted two dedicated laws in 2021 to provide mandatory registration of clinics and banks, define offences, set eligibility criteria for commissioning parents and surrogates/donors, and create national and state boards to supervise the sector. The ICMR continues to issue technical guidance and related ethical standards.

The legal architecture — Acts, Rules and Portals (what to read)
Primary statutes
• Assisted Reproductive Technology (Regulation) Act, 2021 — regulates ART clinics and ART banks; registration; offences for misuse; constitution of National and State ART & Surrogacy Boards.
• Surrogacy (Regulation) Act, 2021 — regulates surrogacy arrangements, prohibits commercial surrogacy, defines eligibility for altruistic surrogacy, and prescribes rights and protections for surrogate mothers.
Secondary instruments
• Assisted Reproductive Technology (Regulation) Rules, 2022 — procedural rules for registration, maintenance of records, eligibility criteria, forms and appeals.
• Surrogacy (Regulation) Rules, 2022 and Surrogacy (Regulation) Amendment Rules, 2023/2024 — operationalize the Act; subsequent corrigenda and amendments clarify transitional arrangements, forms and state-level issues.
(Central portal and notifications maintained online.)
Official portals
• National ART & Surrogacy Portal / National Registry — centralised online registry for clinic/bank registration, reporting and monitoring; mandatory enrolment of clinics and banks. Practitioners must familiarise themselves with portal processes.

Who and what is covered
Entities covered
• All ART clinics and ART banks operating in India (public and private) must register and comply with the ART Act and Rules; the Surrogacy Act covers surrogacy arrangements and clinics handling surrogacy coordination.
Persons covered
• Commissioning couple — defined under the Acts; eligibility criteria include Indian citizenship/residency requirements (and marital status).
• Altruistic surrogate — the Surrogacy Act allows only altruistic surrogacy (no commercial remuneration beyond medical expenses and insurance), and sets eligibility criteria (age, parity, prior live birth, certain family relationship requirements in specified cases).
• Donors (oocyte/sperm) — are subject to age

and screening criteria; donation permitted but commercial sale is restricted and strict records are required.

Key legal obligations for clinics, banks and practitioners

Clinics and banks face layered obligations. The most important practical duties are:

1. Registration: No ART clinic or bank can operate without registration from the Appropriate Authority; registration details must be maintained and periodically renewed. National and State Boards supervise the process.
2. Record-keeping and reporting: Comprehensive records of all procedures, donors, surrogates and outcomes must be maintained and reported to the National Registry as per prescribed formats. This extends to traceability of gametes/embryos and informed consent forms.
3. Eligibility checks: Before offering ART/surrogacy services, clinics must verify eligibility under the Act (age limits for women patients, marital status rules, surrogate criteria, etc.) and produce documentary evidence when required. Courts have on occasions entertained petitions for exceptions (see later).
4. Informed consent and counselling: Professionals must ensure documented informed consent for procedures, gamete/embryo storage, donor anonymity/rights, and counselling for physical/psychological aspects. ICMR guidance remains relevant for best practice.
5. Insurance and medical care for surrogates: The Surrogacy Act mandates health protections for surrogates, including insurance coverage during and after pregnancy; clinics must ensure these safeguards are in place.
6. Prohibition of commercial surrogacy and penal provisions: Charging or commercial arrangements for surrogacy beyond permitted reimbursements is an offence; the Acts prescribe penalties and criminal liability for agents, clinics or individuals who facilitate commercial surrogacy.

Eligibility, age limits and contentious criteria

The Acts and Rules set specific eligibility criteria that have created clinical dilemmas and litigation:

• Women patients: The ART Act includes age-related limits (e.g., women above a specified age may be restricted in accessing certain ART services). State and court orders have occasionally allowed exceptions (for example, High Courts granting treatment shortly before a statutory age cutoff). Practitioners must be aware that individual cases may attract judicial review.
• Commissioning couples: The Surrogacy Act limits commissioning parents in specific ways—eligibility is generally confined to heterosexual married couples meeting residency/citizenship and other conditions; single men and many transgender persons are presently excluded under the statutory scheme, an issue currently the subject of litigation and policy debate. Recent affidavits filed by the Union Government before High Courts confirm that transgender persons currently cannot access ART/surrogacy under existing laws, pending policy review.
• Surrogates: The laws prescribe surrogate eligibility (minimum/maximum age, parity requirements, prior live birth, nearest family relationship restrictions in some cases) and prohibit commercial inducements. Clinics must ensure surrogate documentation and family counselling.

Practical note: Because these eligibility rules directly bear on patient access, clinics should maintain up-to-date checklists, counsel patients about statutory constraints, and be prepared to present eligibility evidence to Appropriate Authorities if required.

Donor anonymity, compensation and ethics

• Sperm and oocyte donors: Donation is permitted but commercial trade or "sale" is prohibited. The Rules require donor screening, counselling, and maintenance of donor records for the national registry. While anonymity is preserved in many respects, record retention provisions mean traceability is possible for authorised legal purposes (e.g., medico-legal investigations or identity requests under judicial orders). Ethical standards from ICMR and international bodies supplement statutory duties.
• Compensation: Only reimbursements for expenses and medical care are permissible for surrogates; any advertisement or middle-man profiteering is expressly outlawed. This has reduced the prior commercial market but created challenges for prospective surrogates in economically vulnerable groups—an ethical and socio-legal tension regulators seek to manage.

Cross-border ART, foreign commissioning parents and export/import of gametes

• The Acts and Rules restrict certain cross-border activities. Clinics must obtain permission for transfer of gametes/embryos outside India (or acceptance from foreign commissioning parents) and comply with the registry and inter-governmental procedures. The National ART & Surrogacy Portal includes specific forms and procedures for cross-border requests. Failure to follow statutory export/import procedures can attract penalties.
• "Fertility tourism" that flourished earlier has been curtailed: commercial surrogacy for foreign commissioning parents is effectively prohibited under the current legal regime, and documentation requirements for cross-bor-

der cases are stringent.

Enforcement, penalties and criminal liability

• The Acts provide for regulatory enforcement through Appropriate Authorities, State Boards and a National ART & Surrogacy Board. Power to inspect clinics, suspend or cancel registrations, and impose penalties rests with these bodies. National registry data is a compliance backbone.

• Penal provisions: Offences include unregistered operation of clinics/banks, commercial surrogacy, sale of human gametes/embryos, fake or forged documents, and facilitating unauthorised transfer of embryos/gametes. Criminal penalties and fines may apply to clinics, agents and individuals. The Acts also provide for appeals and administrative review.

• Investigations and media incidents: Recent enforcement action and criminal investigations into alleged surrogacy/IVF frauds (for instance, reported cases leading to arrests and state inquiries) underline active enforcement and the real risk of legal exposure for non-compliance. A notable recent case prompted a state-level high-level committee to inspect fertility centres. Practitioners must take complaints seriously and cooperate with authorities.

Judicial interaction — examples and trends

Courts have been called upon to interpret and apply the Acts in cases raising urgent medical and rights questions:

• Age-limit exceptions: High Courts have granted treatment in exceptional circumstances (e.g., allowing a woman to undergo a fertility procedure days before reaching a statutory age limit), illustrating that courts may exercise equitable discretion in life-changing fertility matters. Clinicians should be aware that statutory limits have been and can be judicially challenged.

• Access for transgender and single persons: Litigation is pending in multiple courts seeking access to ART and surrogacy for transgender individuals and unmarried persons; Government filings indicate the current statutory scheme excludes transgender persons and that policy review is pending. These cases may lead to legislative or rule changes, or judicial directions altering access in the future. Clinicians must monitor judgments closely and advise patients about current legal status.

• Fraud and custody disputes: Cases arising from alleged switching of infants, embryo mix-ups or deception have triggered criminal investigations and civil litigation — reinforcing the necessity of traceability, chain-of-custody, and robust consent/identification processes. Recent news stories show that failures in documentation and operation can have grave legal consequences.

Practical compliance checklist for clinicians and clinics

Below is an operational checklist clinics should adopt to reduce legal risk and to align with Acts/Rules and ICMR guidance:

1. Register immediately on the National ART & Surrogacy Registry; retain registration certificates and renew timely.
2. Maintain mandated records (patient files, donor records, surrogate records, consent forms) in the statutory formats and make timely reports to the National Registry.
3. Standardize consent forms to explicitly include: identity verification steps, storage duration, use of gametes/embryos, research/use permissions (if any), disclosure about non-commercial nature of surrogacy, and limits on third-party access. Align forms with ICMR templates where available.
4. Document eligibility checks: maintain copies of identity, marital status, medical reports, age verification for commissioning couples, donors and surrogates. Create a digital audit trail.
5. Implement chain-of-custody protocols for gametes/embryos including labeling, storage logs, access logs and video/audio audit where feasible. This reduces risk in alleged mix-up or fraud claims.
6. Insurance & medical safeguards for surrogates: purchase and retain evidence of insurance covering maternity and post-delivery complications as required by the Surrogacy Act.
7. Staff training & policies: train staff in statutory compliance, patient counselling, record retention periods and reporting obligations. Keep a legal liaison or compliance officer.
8. Stop unlawful advertisements for surrogacy or donor recruitment that resemble commercial solicitation. Ensure recruitment follows permitted norms only.
9. Legal help & escalation: develop relationships with lawyers experienced in health law/medical litigation; maintain templates for responses to investigations and for court applications in urgent situations.

Ethical and public-policy issues still under debate

Several legal and ethical tensions remain unresolved or contested:

• Access and equality: The exclusion of single men, many transgender persons and some unmarried individuals raises equality and human rights challenges; advocates argue for broader access while policy makers cite child welfare and social implications. Litigation and policy review are active areas.

• Altruistic-only surrogacy: Banning commercial surro-

gacy protects against exploitation but may reduce surrogate protections by driving arrangements underground or excluding economically vulnerable women from regulated benefits. Policy debates continue about whether a tightly regulated compensated model could better protect surrogates.
• Data privacy vs. traceability: National registry traceability is essential for oversight and medico-legal accountability, but it raises concerns about donor/surrogate privacy and long-term data governance. Clear rules on access, retention and permissible disclosures are crucial.
• Transnational disputes: Conflicts over parentage, citizenship and child welfare when foreign commissioning parents or cross-border donors are involved remain complex and can produce protracted litigation.

Recent regulatory updates and notable enforcement cases (2023–2025)
Practitioners must track notifications and state advisories.
• ART and Surrogacy Rules (2022) were the initial operational rules under the Acts and included formats and registration modalities.
• Surrogacy (Regulation) Amendment Rules, 2023/2024 — subsequent amendments and corrigenda clarified procedural and technical matters; clinics should monitor the official portal for updates.
• Active enforcement: State-level inquiries and criminal probes into alleged surrogacy/IVF frauds have occurred (e.g., a high-profile investigation in Telangana leading to a high-level committee and arrests). These underscore the enforcement climate and the need for strict compliance.

How to handle complaints, investigations and medico-legal emergencies
1. Immediate steps: preserve all relevant records; do not delete digital logs. Appoint a responsible officer to handle communications.
2. Notify Appropriate Authority where required by Rules and cooperate with inspections; follow the registry's prescribed response mechanisms.
3. Patient communication: offer transparent updates to affected parties, while balancing privacy/confidentiality obligations. Document all communications.
4. Legal counsel: seek early legal advice; consider voluntary internal inquiry and corrective action if non-compliance is identified.
5. Media & public response: designate a single authorised spokesperson; avoid speculative statements; ensure compliance with confidentiality laws. Recent enforcement episodes show that mishandled public communications aggravate legal exposure.

Recommendations for policymakers and professional bodies
• Clarify access rules for transgender and single persons through consultative rule-making or legislation that balances child welfare and non-discrimination. Pending litigation suggests policy change may be necessary.
• Consider a regulated compensation framework for surrogates to protect surrogate dignity and reduce underground markets while retaining safeguards against exploitation.
• Strengthen data protection and governance of the National Registry to balance traceability with privacy and create transparent access rules for donor-conceived persons seeking identity information in future.
• Invest in capacity building for Appropriate Authorities and State Boards so inspection and compliance can be consistent across states.
• Create standardized ICMR-aligned templates for consent, counselling and chain-of-custody protocols to reduce legal disputes arising from inconsistent clinic practices.

Conclusion
India's ART and surrogacy laws create one of the most structured statutory frameworks globally for regulating fertility services and curbing commercial exploitation. For clinicians and administrators the immediate priority is strict statutory compliance — registration, robust records, documented informed consent and surrogate protections — while also watching rapidly developing litigation and policy debates over access (transgender and single persons), surrogate compensation and cross-border practices. The legal landscape is still maturing: proactive compliance, transparent counselling to patients about statutory limits, and liaison with legal counsel and regulators will be essential to reduce risk and to provide ethical, high-quality reproductive care.

References:
1. The Assisted Reproductive Technology (Regulation) Act, 2021 — Gazette / PDF (full Act).
2. The Surrogacy (Regulation) Act, 2021 — Gazette / PDF (full Act).
3. Assisted Reproductive Technology (Regulation) Rules, 2022 — Rules and formats.
4. National ART & Surrogacy Portal / Registry — registration, notifications and corrigenda.
5. Surrogacy (Regulation) Amendment Rules, 2023/2024 — official amendments and summaries.
6. ICMR guidance and contextual notes — ICMR explanatory pages and earlier technical guidelines for ART/ethical practice.

Emergency Obstetric Practice: How to keep it medicolegally safe

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In a retrospective analysis of all Medical judgements related to medical negligence in South India passed between 2008 to 2013 , Gowda et al2 have reported the highest litigation and negative judgment rate for complaints involving Obstetricians. Nearly a quarter of all complaints ended with negligence being proven. While tubectomy failure was the most common cause for complaints being filed, maternal deaths, issues related to medical termination of pregnancy (MTP), postpartum complications, and procedures done without valid consent were the predominant situations where adverse verdicts were passed against the medical professionals.

Obstetric emergencies are critical , life threatening situations which arise during the course of a pregnancy , labour , or in postpartum period which endangers life of pregnant woman and / or child. These conditions can escalate rapidly, leading to maternal death, severe morbidity, or fetal demise. Effective management requires rapid diagnosis, multidisciplinary teamwork (doctors, nurses, anesthesiologists), lifesaving techniques, resuscitation challenges and access to emergency obstetric care (EmOC).

Common Obstetric Emergencies are 1] Ectopic pregnancy , Molar pregnancy, Abortion 2] Severe PV Bleeding Antepartum hemorrhage, postpartum hrrage, 3] Eclampsia : Severe hypertension with seizures 4] Shoulder dystocia 5] Amniotic fluid embolism 6] Cord Prolapse 7] Uterine rupture

All above conditions can give rise to shock and disseminated intravascular coagulation .Thus

Basic Resuscitation Apparatus and essential Training is a MUST:

This is a recent judgement :

The Delhi Consumer Redressal Commission New Delhi on 01/12/24 , recently slapped this judgement to a city based hospital and it's gynaecologist and doctors for undertaking surgery without proper equipment , requisite skills , and documentation.

"Surgery undertaken without necessary skill, records manipulated! Delhi Doctors, Hospital slapped Rs 48 lakh compensation for misconduct,and negligence" . They claim that no documentation of events was done for this case , no proper progress notes, mismatched nursing notes , no reports .

TIPS TO SAFEGUARD AGAINST LITIGATIONS IN EMERGENCY OBSTETRIC PRACTICE :

● KEEP YOUR HOSPITAL UPDATED :

1] PLAN proper triaging system so that immediate medical attention can be given to emergency patients entering the hospital.

2] Invest in CCTV camera s at key places with preferable sound recording. Also need to invest in proper security and bouncers if needed.

3] The Operation Theatre and hospital Infrastructure should have an appropriate physical layout, including adequate space for Emergency Patient Checking , counselling , preparedness for OT with proper ventilation, lighting, temperature control, and infection control measures. There should be separate dedicated OT for emergencies , and like each OT should have an anteroom, scrub area, and changing room.

4] Emergency Preparedness: Such OTs should have protocols and systems in place to handle emergencies and unexpected situations. This includes proper CHECKLISTS , emergency drug supplies, adequate oxygen supply , well working resuscitation equipment, trained staff, and well-defined procedures for handling emergencies during surgeries. Stabilize and deliver

as early as possible .
5] Equipment: NABH emphasizes the availability and maintenance of essential equipment and instruments . This includes anesthesia machines, surgical lights, operating tables, surgical instruments, patient monitors, Defibrillator s, AEDs and emergency equipment, among others. Regular maintenance and calibration of equipment should be conducted. AMC reports should be preserved.
6] Staffing: The OT should have appropriately qualified and trained staff, including house surgeons, multiple anesthetists, nurses, technicians, and other supporting personnel. Their qualifications, certifications, and training records should be maintained, updated and staff should be provided with regular training drills on emergency procedures, and safety protocols. eg Eclampsia drill , Code Blue drill etc.
7] Stringent Infection Control practices are vital in OTs. The NABH guidelines stress the implementation of standard precautions, hand hygiene protocols, sterilization and disinfection procedures, waste management, and aseptic techniques. Regular surveillance and monitoring of infection rates should be carried out.
8] Correct patient safety practices in pre-OTs : This includes patient identification protocols, especially age ,preoperative assessment, correct site marking, time-out procedures before surgeries, prevention of wrong surgeries, prevention of retained foreign objects, and safe medication practices.
9] The NABH emphasizes Quality Improvement: There must be a system for continuous quality improvement. This involves periodic audits, clinical indicators monitoring, adverse event reporting, analysis of incidents, and implementation of corrective and preventive actions.

● KEEP YOURSELF AND STAFF UPDATED :
1] Always keep a female chaperone especially for male doctors.
2] Yours and your assistants, visiting doctors degree registrations , MMC registrations must be valid .
3] Practice in your field of knowledge and training

● KEEP DOCUMENTATION UPDATED :
1] Remember : No Documents = No Defense ,
2] Document what you communicate, Communicate what you document.
3] Document what you do , chronologically.
4] Keep Forms , papers ready to TAKE HIGH RISK CONSENT , DEATH CONSENT , ALSO CONSENTS FOR BLOOD TRANSFUSION , ALLERGIES / ANAPHYLAXIS , PROCEDURES what and which may be required , Anaesthesia , Risk of comorbidities .
5] Consent: In Emergencies, if the patient is incapacitated and no surrogate is available, providers can act to save life, but consent for non-urgent procedures (like tubal ligation) requires counseling and written consent.
6] Take proper informed consent with sign and thumb impressions of the patient and also relatives of the ailing patients .
7] Comprehensive documentation is essential for maintaining quality standards. This includes maintaining patient records, consent forms, anesthesia records, surgical checklists, equipment maintenance records, incident reports, and policies and procedures manuals.
8] Maintain and preserve all records for 5 years and if any Medicolegal case comes up , till your lifetime
9] Always maintain all records in the clinic in hard copy especially the consent forms
10] Remove all expired medicines, drugs in time and

keep all registers ..Indent , Drugs , Fumigation, CSSD, birth death , MTP , pcpndt , sterilization well compliant.
11] Always take Refusal of Consent or Advice document and get it signed by two disinterested witnesses.

PROCEDURE SPECIFIC PRECAUTIONS :
1] As per the case ,it's advisable to take decisions well in time and advance directives to be considered .If the case requires second gynaecologist , surgeon , urologist , oncosurgeon , emergency physician and for resuscitation second paediatrician , anaesthetist , do give them calls and well in time.
2] If patient is too much critical, vitals are not ok , no Blood arrangements , think of referring to nearest tertiary care .
3] Transfer of critical patient : Always do so well within time , prerably with following precautions. A) in a cardiac ambulance , B) copies of Notes on admission , with treatment given or done during the course in casualty , referral notes , and reports . C) Accompanying resident or senior doctor with the patient till hand over is must. D) Keep record of personal phone calls done to doctors in tertiary hospitals , so that patient is not neglected .
4] Always Call For Help ….keep friends and acquaintances informed and GIVE IMMEDIATE CALL FOR HELP.
5] ANTICIPATE Blood , blood products , volume expanders requirements and order lab people to do needful .
6] Keep Documentation alert s chronologically .
7] Instructions to Staff , ayahs what to communicate to relatives .
8] Take close relatives in confidence and under camera inform them regarding emergency situation and remedies .
9] Utilize communication skills and skills to break bad news if any
10] Always keep your Indemnity Insurance updated with retroactive date .Renew within time and take maximum cover as per your practice with added untrained staff cover .
11] In case of any unprecedented risk by the course or relatives ,inform your insurance agents stat.
12] Inform Police by mail and preserve the copy or acknowledgement.
13] Never give backdated certificates.
● Certificates format must be followed : take identification proofs , adhar card copy , person's signatures , write vitals , important notes .
● Never issue certificate without checking and documenting.
14] Take adequate precautions while Transfer of a critical patient :
1] Stabilize First (ABCDEs):
○ Airway: Secure it (intubate if needed), confirm placement (X-ray), avoid intubation en route.
○ Breathing: Ensure adequate ventilation/oxygenation (check ABGs/sats).
○ Circulation: Optimize resuscitation, secure IV access (large bore), monitor vitals.
○ Disability: Monitor GCS, pupils, provide sedation/analgesia.
○ Exposure/Environment: Prevent heat loss, immobilize trauma.

2. Document Everything:
○ Transfer Note: Detailed history, diagnosis, interventions, meds, vitals, investigations.
○ Continuity of Care: Records prove care continuity and inform the receiving team.
○ Checklists: Use formal checklists for equipment, meds, and patient status.

3. Communication & Handover:
○ Formal Handover: Structured process between teams.
○ Informed Consent: Explain procedure to patient/family.
○ Receiving Team: Confirm they are ready to receive.

4. Personnel & Equipment:
○ Competent Team: Experienced staff trained in critical care transfer.
○ Functional Equipment: Verify all life support, monitoring, and drug functionality before leaving.

5. Clinical Governance:
○ Senior Decision: Transfer decisions by senior staff.
○ Follow Policy: Adhere to hospital/national governance standards.

6. MLC Specifics:
○ Police Notification: Inform police if it's a Medico-Legal Case.

REFERENCES
1. National Institute of Health NIH guidelines

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Medicolegal Implications of Anaesthesia in Obstetric and Gynaecological Practice

Introduction: Why Anaesthesia Matters Medicolegally in OBG Practice?

Among all allied specialties, anaesthesia plays a major role in achieving good outcomes in obstetrics and gynaecology. However, it is also true that anaesthesia makes the Gynaecologist vulnerable to medicolegal hassles. A safe surgery can turn catastrophic within minutes if an anaesthetic complication occurs; conversely, timely anaesthetic intervention can be lifesaving for both mother and fetus.

With over three decades of clinical practice, leadership roles in professional bodies, and sustained involvement in medicolegal dispute resolution, I have observed that adverse outcomes attributed to "anaesthesia issues" frequently become the reason of litigation against obstetricians, gynaecologists, anaesthesiologists, and hospitals alike. Importantly, many such disputes arise not from true negligence, but from gaps in communication, documentation, consent, teamwork, and understanding of legal responsibilities.

This article aims to sensitise practising obstetricians and gynaecologists to the medicolegal implications of anaesthesia in day to day practice, highlight common risk areas, and suggest practical strategies to reduce avoidable legal exposure, while reinforcing respectful, ethical, and patient centred care.

Anaesthesia as an Independent Specialty: Shared Care, Shared Responsibility

Anaesthesia is a highly specialised discipline with independent professional and medicolegal responsibility. Courts in India have repeatedly recognised anaesthesiologists as independent service providers who owe a direct duty of care to the patient. They can not hide from medicolegal implications of a mishap with the argument that the patient had basically entered in contract with the surgeons and not them

However, in obstetric and gynaecological settings, particularly in emergency labour rooms and smaller nursing homes, patients and relatives often perceive the obstetrician as the "captain of the ship." When an adverse event like maternal collapse, failed intubation, aspiration, delayed recovery, or neonatal compromise occurs, the obstetrician is almost invariably named as a party in litigation, even when the event is primarily anaesthesia related.

From a medicolegal standpoint, therefore, obstetricians must understand that:

• Anaesthesia complications can expose the obstetrician to vicarious liability, especially in institutional or team based practice. They thus are vicariously liable for any civil wrong done by the anaesthesiologist even if the patient has not entered in to any contract with the anaesthesiologist. However criminal liability rests with the anaesthesiologist.

• In present day practice for abundant caution a Pre-anaesthetic check up and anaesthesia consent is insisted upon. This proves that there was a contract between the patient and anaesthesiologist too.

• Courts often assess team communication, preparedness, and coordination, not isolated professional actions.

• Poor documentation or absence of joint decision making can weaken the defence of all treating doctors.

High Risk Nature of Anaesthesia in Obstetrics and Gynaecology

Anaesthesia in OBG practice carries inherent risks due to:

• Physiological changes of pregnancy (airway edema, aspiration risk altered drug pharmacokinetics etc)

• Emergency and time sensitive nature of many obstetric procedures gives lesser time for pre-anaesthesia preparations

• Limited fasting status

• High emotional expectations and low tolerance for adverse outcomes

Common anaesthesia related scenarios attract-

ing medicolegal scrutiny include:
• Failed or difficult airway during emergency LSCS
• High spinal or total spinal anaesthesia
• Anaesthesia related maternal cardiac arrest
• Aspiration pneumonitis (Mendelson's syndrome)
• Delay in decision to delivery interval due to anaesthetic issues
• Neonatal compromise attributed to maternal hypotension or hypoxia
It is essential to recognise that anaesthesia is an inexact science, and complications can occur despite reasonable care. Courts evaluate whether the complication was foreseeable, whether risks were explained, and whether the response was timely and appropriate.

Consent: A Major Source of Medicolegal Vulnerability
One of the most common reasons for adverse legal findings against doctors in India is invalid or inadequate consent.
Need for Separate Anaesthesia Consent
In contemporary practice, a separate, procedure specific anaesthesia consent is strongly recommended. Consent for surgery cannot automatically be presumed to include consent for anaesthesia, especially when:
• Regional vs general anaesthesia options exist
• Emergency conversion is possible
• The patient has comorbidities increasing anaesthetic risk
Courts increasingly expect that anaesthesia related risks, such as airway difficulty, need for ventilation, ICU admission, or rare but serious complications are explained by the anaesthesiologist and documented. "Uniform FOGSI consent" include consent for Ob Gyn anaesthesia. It is recommended that these consents are adhered too before every surgery under anaesthesia or with anaesthesiologist as standby.
Consent as a Process, Not just a Signature
Consent is not merely a signed form. It is a process of communication and shared decision making. Hence in addition to the 'undertaking' signed by the patient (and relative/accompanying person as a witness) FOGSI recommends a signature from the patient about receipt of 'information' for specific surgery/procedure. Such consents with 'information' has been drafted for over 30 ObGyn surgeries by FOGSI as per the guidelines given in the Supreme Court case of Sammera Kohli vs Prabha Manchanda. "Uniform FOGSI Consent" also includes consent with both 'undertaking' and 'information' document for anaesthesia in ObGyn. For obstetricians, this has practical implications:
• Encourage pre anaesthesia counselling whenever feasible. It can also be done during antenatal period while conducting the antenatal classes (Lamaze classes)
• Encourage the anaesthesiologist to assertively talk about all possible risks of anaesthesia in a soft and positive language that will not put un called for stress on the patient to an extent that she refuses a relatively safe anaesthesia option.
• Document discussions, especially in high risk cases. Use of CCTV recording with the permission of the patient and relatives is also prudent in such situations.
In emergencies, the law permits treatment in good faith to save life and limb. However, documentation of the emergency nature is critical for legal defence.

Emergency Obstetrics and the Law
Labour room emergencies often unfold rapidly, leaving little time for elaborate consent processes. Indian courts have consistently upheld that:
• Saving life takes precedence over procedural formalities
• Doctors acting in good faith are protected under law
That said, common medicolegal pitfalls include:
• Failure to document urgency
• Absence of senior consultation records and at time absence of multidisciplinary approach despite having access (especially in corporate hospitals)
• Lack of postoperative explanation to relatives
A brief note stating "Emergency LSCS performed in maternal/fetal interest; consent obtained to the extent possible" can significantly strengthen legal defence. Another way to strengthen defence in such situation is to obtain 'Consent for vaginal child birth" as is recommended by FOGSI in its "Uniform FOGSI consent". In the 'information' document of this consent, most indications for instrumental deliveries and emergency LSCS and most possible complications of child birth are also included.

Documentation: The Silent Defender
In medicolegal disputes, records speak louder than recollections. Poor documentation is one of the strongest predictors of adverse verdicts.
From an obstetrician's perspective, key documentation from anaesthesia point of view that can act as safeguards include:
• Pre operative risk assessment and PAC document
• Anaesthesia consent
• Anaesthesia plan noted in records
• Time stamped intraoperative events
• Postoperative handover and monitoring notes
• Clear documentation of adverse events and management
Courts do not expect perfection; but they do expect evidence of vigilance, monitoring, and timely intervention.

Criminal vs Civil Liability: Understanding the Distinction

Most anaesthesia related litigations fall under civil negligence (consumer complaints). Criminal prosecution is justified only when the court is convinced by the opinion of medical board (usually from medical college) that there was gross negligence or recklessness.
Supreme Court guidelines for criminal proceedings of doctors being investigated for medical negligence mandate that:
• Doctors should not be arrested routinely for medical outcomes
• Expert medical opinion is required before proceeding in criminal cases
Despite this, obstetric emergencies with maternal death often trigger FIRs. Proper documentation, early legal advice, and professional body support are essential for protection. The confusion with the police over the section of IPC (304 part 2 or 304 A) to govern death during medical treatment is now finally settled after BNS has codified criminal 'medical negligence' under BNS 106(2) which is similar to the old IPC 304 A. The only problem with it is that AYUSH doctors are excluded from the definition of registered medical practitioner under BNS 106(2)

Teamwork, Communication, and Shared Defence
Courts increasingly assess healthcare delivery as a team function. Fragmented practice, poor communication, or blame shifting among specialists weakens defence.
Practical recommendations:
• Pre operative team briefing in high risk cases
• Unified communication with relatives
• Avoid contradictory statements in records
• Support colleagues during medicolegal crises
As someone who has helped colleagues across the country in resolving medicolegal disputes free of charge, I can state with conviction that unity and transparency save careers.

Ethical Dimensions Beyond Law
Ethics often demand more than what law mandates. Respect for patient autonomy, dignity, and honesty builds trust and reduces litigation risk.
Commercial pressures, defensive medicine, and corporatisation must not dilute ethical responsibility; particularly in obstetrics, where two lives are involved and outcomes are emotionally charged.

Infrastructure Readiness in Small Nursing Homes: A Medicolegal Imperative
A significant proportion of obstetric and gynaecological care in India is delivered in small nursing homes, standalone maternity centres, and peripheral hospitals. These facilities play a vital role in improving access to maternal healthcare, especially in tier 2 and tier 3 cities. From a medicolegal standpoint, however, outcomes in such setups are scrutinised closely, particularly when a patient deteriorates and requires transfer to a tertiary care centre.
Courts do not expect small nursing homes to match the resources of corporate hospitals. What they do expect is reasonable preparedness, adherence to accepted standards of care, and evidence that best possible measures were taken within available infrastructure.

Anaesthesia Workstation: More Than Equipment—A Legal Safeguard
The availability of a modern anaesthesia workstation with an in-built ventilator is no longer a luxury; it has become a medicolegal necessity. In anaesthesia-related emergencies, such as high spinal block, failed airway, aspiration, or perioperative cardiac arrest, the ability to ventilate the patient effectively until definitive transfer is arranged can be decisive for both clinical outcome and legal defence.
From my experience in defending colleagues, documentation that the patient was continuously ventilated and monitored till the arrival of an ambulance or during inter-hospital transfer carries significant weight in court. It allows the treating team to credibly state that:
• The patient was not abandoned during deterioration
• Airway and ventilation were maintained as per standard practice
• Transfer was organised responsibly and not as an act of panic
In contrast, absence of ventilatory support or reliance only on oxygen supplementation may be interpreted as infrastructural inadequacy contributing to adverse outcome.

Advance Life Support Readiness in Every OBG Setup
Every obstetric and gynaecological facility offering operative services must be capable of initiating basic and advanced life support without delay. This is both a clinical and medicolegal expectation.
Minimum essential airway and resuscitation equipment should include:
• Functional anaesthesia workstation or ventilator
• Bag–mask device with oxygen source
• Laryngeal mask airways (at least two sizes)
• Endotracheal tubes of different sizes with laryngoscope
• Suction apparatus
• Defibrillator with adult paddles
• Emergency drugs tray, clearly labelled and checked regularly
Courts assess not only the availability of equipment but also whether it was immediately accessible, functional, and familiar to the team. Regular checking, documenta-

tion of crash cart readiness, and staff orientation are therefore crucial.

Simulation-Based Training: Preparing for the Rare but Catastrophic

Anaesthesia-related catastrophes in obstetrics are rare but sudden and unforgiving. High spinal block, failed intubation, anaphylaxis, amniotic fluid embolism, or maternal collapse leave little room for hesitation or improvisation.

Simulation-based scenario training is one of the most effective strategies to prepare small nursing homes for such events. From a medicolegal perspective, simulation training demonstrates:

- Proactive risk management
- Commitment to patient safety
- Institutional effort to prevent adverse outcomes

Regular mock drills and simulation sessions focusing on:

- Failed airway management
- Maternal cardiac arrest
- Massive obstetric haemorrhage
- Transfer protocols and team communication

help transform theoretical knowledge into reflex action. In medicolegal defence, documented evidence of periodic training and drills strongly supports the argument that the adverse event was not due to ignorance or unpreparedness.

As someone involved in mentoring young consultants and setting up IVF and maternity facilities, I firmly believe that simulation training should become an integral part of FOGSI Manyata and similar accreditation initiatives.

Team-Based Preparedness and Communication

Anaesthesia emergencies in obstetrics demand seamless teamwork. Clear role allocation during crises, a designated team leader, and rehearsed communication pathways reduce errors and confusion.

Importantly, courts increasingly examine whether:

- The obstetrician and anaesthesiologist functioned as a coordinated team
- Timely senior help was sought
- Relatives were kept informed during critical phases

A united, transparent approach not only improves outcomes but also significantly reduces medicolegal vulnerability.

Conclusion: Building Safe Systems, Not Just Defences

Medicolegal challenges related to anaesthesia in obstetric and gynaecological practice cannot be addressed by documentation and consent alone. They require system-level preparedness, appropriate infrastructure, trained teams, and ethical practice.

Small nursing homes need not fear litigation if they can demonstrate that reasonable standards of anaesthesia care were met, emergencies were anticipated, and life-sustaining measures were promptly intituted until higher care was available.

For obstetricians and gynaecologists, investing in anaesthesia infrastructure, life support readiness, and simulation-based training is not merely a clinical upgrade; it is a long-term medicolegal safeguard.

In an era of increasing scrutiny, good intentions must be supported by good systems. That, ultimately, is the message this chapter seeks to convey to the FOGSI fraternity.

This article is intended for academic guidance and professional awareness and does not substitute for individual legal advice.

References

1. Indian Medical Association vs. V.P. Shantha & Ors. (1995) 6 SCC 651 – Supreme Court of India.
2. Jacob Mathew vs. State of Punjab & Anr. (2005) 6 SCC 1 – Supreme Court of India.
3. Samira Kohli vs. Dr. Prabha Manchanda & Anr. AIR 2008 SC 1385 – Supreme Court of India.
4. Kusum Sharma & Ors. vs. Batra Hospital & Medical Research Centre (2010) 3 SCC 480 – Supreme Court of India.
5. Mumbai Grahak Panchayat vs. Dr. (Mrs.) Rashmi B. Fadnavsis & Anr. (1998) 1 CPJ 49 (NCDRC).
6. World Health Organization. Safe Surgery Saves Lives: WHO Surgical Safety Checklist. WHO Press, 2009.
7. American Society of Anesthesiologists. Standards for Basic Anesthetic Monitoring. Updated periodically.
8. National Medical Commission. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (as amended).
9. Ministry of Health and Family Welfare, Government of India. Patient Rights Charter, 2018.
10. Federation of Obstetric and Gynaecological Societies of India (FOGSI). Manyata Initiative – Standards for Labour Room and Maternity Care.
11. "Uniform FOGSI Consent" – www.fogsi.org

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How to start your own Nursing Home/Hospital Guide for Gynaecologists

Running a maternity hospital in India requires multiple licenses under national and state regulations to ensure compliance with healthcare standards, safety, and specialized services like obstetrics, Sonography, MTP, ART. Requirements vary by state (e.g., Maharashtra has specific nursing home rules like BNHA, Maharashtra nursing home Rules) and facility size, but core licenses apply universally where the Clinical Establishments Act is implemented. Maternity hospitals, classified as clinical establishments, must register and meet minimum standards for infrastructure, staff, and services.
First we have to finalise a property for which we have to keep in mind weather that property has Occupation certificate and Change of user if it is a residential property where you are planning to start your nursing home to avoid future issues. In the beginning itself take a NOC from the society/Builder that you are starting nursing home to avoid unnecessary issues with the society later as society members always want nursing home near them to help them in emergencies but never in their own building where they are staying.
Once you have finalised the property collect all its documents like floor Plan, Fire exit plan, OC coin name for your nursing home creates your stamp, File and Letterhead depending private company or LLP or individual or partnership.
Maharashtra Nursing Homes Registration (Amendment) Rules, 2021, notified on January 14, 2021, update the 1973 rules under the 1949 Act, raising fees, staffing minima, and infrastructure for nursing homes including those with OTs. These apply statewide, easing some norms for small facilities amid IMA feedback, but enforce fire safety, BMW, and patient rights. Rule 3 revised for graded fees: Rs 5,000 (Grade A, municipal areas, 1-5 beds); additional Rs 1,000 per 5 beds; renewals at 25% extra. Registration/renewal via local authority (e.g., MCGM); display charter of patient rights, tariff list. Violations trigger inspections, show-cause, fines up to Rs 5 lakh, or sealing.
Infrastructure Standards Like Waiting/exam rooms at 140 sq ft min; 6-ft bed spacing, nursing station per 5 beds; OT zones with ventilation, sterilization. Fire NOC, structural audit, BMW mandatory; relaxations proposed for <10-bed homes.
Fire safety clearance, building permission/occupancy certificate and local trade/health licence from the municipal corporation as per city bye laws. A form is issued at the beginning by the Fire Department. Then every 6 months inspection by fire department authorised agencies who will be issuing form B every 6 monthly.
MPCB issues Consent to Establish (CTE) and Consent to Operate (CTO). For a running hospital, you usually need CTO (along with BMW Authorization).
Maharashtra Pollution Control Board (MPCB) issues biomedical waste authorizations for all healthcare facilities, including hospitals and maternity homes, under the Bio-Medical Waste Management Rules, 2016. MPCB acts as the prescribed authority per Government Resolution (ENV/1098/559/P.K.259/T.C.1, dt. 10.04.2003), granting authorizations via online portals after reviewing Form II applications, site inspections, and fees. Regional/Sub-Regional Offices (e.g., Mumbai, Thane) handle local applications and issue letters like MPCB/SRONM-I/BMW/Auth. Facilities submit proof of agreement with Common Biomedical Waste Treatment Facilities (CBMWTF), waste quantities, and consents under Water/Air Acts; approvals are valid for synchronized periods with operator consents, typically within 90 days. Recent updates waive separate BMW fees, requiring only combined consent fees. Apply at mpcb.gov.in/consentmgt/authorize-bmw.

Biomedical waste authorisation from the State Pollution Control Board for collection, storage and disposal of biomedical waste generated by the ART lab and OT.

Hospitals, nursing homes, clinics ARE COVERED

under the **Shops & Establishments Act** for employment regulation, even though they are medical establishments can be applied online Municipal Portal In Maharashtra.
Electricity Dept + MPCB + Fire + Municipal compliance is critical for hospitals for getting Diesel Generation set permission.
Structural Stability Certificate (SSC) for a hospital / clinic / nursing home is issued by A Licensed Structural Engineer who is Registered with the Municipal Corporation Or approved by PWD / local authority.
Electrical Audit Certificate for a hospital / nursing home / clinic An Electrical Audit Certificate certifies that Electrical installations are safe & compliant Load, wiring, earthing & protection systems are adequate Risk of fire, shock, equipment damage is minimized.

Drug licence for in house pharmacy from State Drug Controller, with registered pharmacist and storage norms.
Hospitals may need public performance licenses like PPL (for sound recordings) or IPRS (for live/composed music) if playing copyrighted music via TV in public areas, though patient treatment settings often qualify for exemptions. CINEFIL tariffs specifically apply to hospitals showing films on TV/LCD for staff or public, indicating a requirement for cinematographic content licensing. No explicit cinematography license mandate exists for hospitals; focus remains on copyright compliance for content played.

India's four consolidated Labour Codes, effective from November 21, 2025, apply to hospitals as establishments, replacing 29 older laws and regulating wages, social security, industrial relations, and occupational safety. These codes ensure minimum wages, working hours (up to 8-12 hours daily, 48 weekly), overtime, social security like ESIC/EPF, and safety measures for healthcare workers, including those in hazardous roles. Hospitals must comply with electronic record-keeping for attendance, wages, and grievances, with thresholds varying by code (e.g., ESIC for 10+ employees, safety committees for 500+).
Code on Social Security, 2020: Expands ESIC pan-India (even for 1 hazardous worker), EPF (20+ workers), gratuity after 1 year, and maternity benefits up to 26 weeks.
Occupational Safety, Health and Working Conditions Code, 2020: Brings hospitals under safety norms for the first time, requiring training, PPE, risk assessments, annual health check-ups, and welfare facilities; critical for high-risk hospital tasks like maintenance
Industrial Relations Code, 2020: Covers dispute resolution, standing orders (for 300+ workers), and contract labour rules; prohibits contracts in core activities unless exempted
Code on Wages, 2019: Mandates timely wages, minimum wage floors, and bonus for eligible employees; applies universally to hospitals.

The Medical Termination of Pregnancy (MTP) Act 1971, amended in 2021, governs registration for hospitals and clinics providing MTP services up to 24 weeks (or beyond via Medical Boards). Facilities must secure approval from the District Level Committee (DLC) to ensure qualified staff, infrastructure, and compliance with forms like A (application) and B (approval certificate). Government hospitals are auto-approved, but private ones apply via the Chief Medical Officer. Submit Form A with documents including doctor qualifications (MBBS/MD/DGO in gynecology), Maharashtra Medical Council registration, nursing home license, biomedical waste authorization, blood bank tie-up, and equipment lists. The DLC inspects for emergency facilities like shock treatment and transport; approval yields Form B for display. In Maharashtra, apply at local health offices (e.g., F/South Ward, Mumbai) with undertakings against unapproved procedures. One registered medical practitioner (RMP) opinionfor up to 20 weeks; two for 20-24 weeks. RMPs need specific training (6-12 months in gynecology) and MMC registration; display certificates prominently. Beyond 24 weeks requires state Medical Board approval. Maintain Form I/II (opinions/reports), Form C (consent), and Form III (admission register) for 5 years; submit monthly Form II to district CMO. Keep patient details confidential, using serial numbers only. Display registration and qualifications in waiting areas.

The PCPNDT Act 1994 mandates registration for any facility using ultrasound (USG), imaging, or genetic diagnostics, including MTP centers with sonography for gestation checks. In Maharashtra, violations like sex disclosure lead to 3-5 years imprisonment and fines up to Rs 1 lakh; renew every 5 years via District Appropriate Authority (DAA), often the Chief Medical Officer. Display the certificate, Act copy, and "No Sex Selection" notice prominently. Submit Form A (duplicate) to district DAA with site plan, equipment list (USG make/model), and fee (Rs 3,000-4,000 in Maharashtra). DAA inspects for compliance within 90 days, issuing Form B if approved or Form C for rejection.

Required Documents Ownership proof (rent agreement, property card, society/trust registration). Affidavit from owner undertaking no sex selection.Operator's Maharashtra Medical Council registration, MBBS/MD (Radiology/Gynecology), and 300-hour USG training certificate. USG machine quotation/invoice from authorized dealer. Nursing home license (if applicable) and biomedical waste authorization

To start an Assisted Reproductive Technology (ART) centre in India, you must obtain specific ART law registrations in addition to routine clinic/hospital licences and biomedical, lab and safety compliances. Assisted Reproductive Technology centres are governed primarily by the Assisted Reproductive Technology (Regulation) Act, 2021 and the Assisted Reproductive Technology (Regulation) Rules, 2022, along with the Surrogacy (Regulation) Act, 2021 where applicable. These laws make registration of every ART clinic and ART bank compulsory and lay down standards for staff qualifications, infrastructure, record keeping and patient protection.
Every ART clinic and ART bank must be registered with the National Registry of Banks and Clinics of India through the National ART & Surrogacy Registry portal (artsurrogacy.gov.in)
The application is filed online to the "Appropriate Authority" designated by the State, which then inspects the premises and, if compliant, issues a certificate of registration under section 16 of the ART Act and Form 3 of the Rules.
Registration is mandatory before commencing any ART procedures, and the Authority is expected to process applications within a defined time frame, generally 30 days, subject to rectification of defects if any.
The Rules classify ART establishments into Level 1 and Level 2 clinics, each with minimum infrastructure such as microscopes, incubators, laminar airflow, cryopreservation facilities and specified lab space. Key personnel must meet defined qualifications and experience, for example a gynecologist with postgraduate qualification and documented experience in oocyte retrieval, andrologists/embryologists with prescribed training.
ART centres must follow ICMR/NAMS National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, which address ethical practices, patient counselling, consent formats and oversight mechanisms. The ART Act and Rules require maintenance of detailed records in specified forms, establishment of a grievance redressal cell and readiness for inspections by the State Board, National Board and National Registry.
Staff qualifications and HR records 1. Copies of registration certificates and postgraduate qualification degrees of the gynecologist(s), embryologist, andrologist and other key staff, along with experience certificates as per ART Rules.
2. List of all clinical and lab personnel with designation, registration numbers (MCI/NMC/State Council) and duty hours, plus appointment letters/HR undertakings
The exact document list can slightly vary and the State ART cell's latest checklist should always be cross checked.
There are core licences and specific as the facilities to be added to the centre.

QUIZ ANSWERS (QUIZ ON PAGE 53)

Question no.1- A
Question no.2- A
Question no.3- D
Question no.4- B
Question no.5- C
Question no.6- A
Question no.7 - B
Question no.8- C
Question no.9-D
Question no.10-C
Question no.11-C
Question no.12-C
Question no.13-C
Question no.14-C
Question no.15-C
Question no.16-C
Question no.17-B
Question no.18-C
Question no.19-C
Question no.20-D
Question no.21-D

THE SCIENCE OF GOOD DOCUMENTATION

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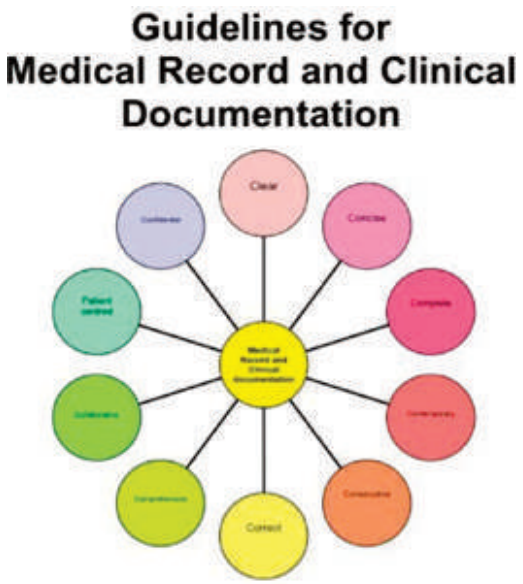

The palest ink is better than the best memory " is an old Chinese proverb that still holds true today and is applicable considering the importance of medical record documentation.
It is rare to find a doctor or any health care provider who will admit enjoying documentation and charting. Half of the work time is spent not on caring for the injured or sick, but instead is lost finishing reams of paperwork. But documentation is one of the most important parts of the job, and it is necessary in order to protect the patient, the provider, and the institution.

Introduction
When a patient leaves your OPD, he or she expects that the problems should improve . In many cases, they do. In other cases, problems may emerge again later or your treatment might not reach the patient's goals for overall health and wellness.
With proper documentation, you will ensure that you, your patient, and any future doctor the patient consults, have accurate information about any care that was given, including treatment attempted. As a result, you will improve your patients' ability to receive high- quality medical care in the future, whether they come to you with the same symptoms again or they are visiting another specialist with their medical records in hand.
The medical record is the basic legal document in the medical litigation lawsuit. A well organised well written record is the best defence for the competent healthcare provider. It should be assumed that, any and all clinical documents may be scrutinized at some point. Documentation was a factor that contributed to patient harm in 19% of all claims and suits file from 2010 to 2019.Key deficiencies included lack of documentation of clinical findings clinical rationale and informed consent.
The quality of documentation also affects the way a jury perceives the defendant doctor and if flawed may undermine the credibility of the doctor .
Therefore improper documentation may invite medical litigation at any point of time.

Importance of good record keeping
Medical record keeping has evolved into a science of itself. Put thoughts to paper. Make your clinical documentation complete, accurate and precise.
Proper documentation helps in:
1. The Scientific evaluation of patient management
2. Plan treatment protocols
3. Analyse the treatment results
4. Helps in providing documentary evidence which is most important where medical negligence is alleged by the patient.
Remember poor records means poor defence and no records means no defense.
Medical records include a variety of docum- entation like
1. Patient' s history
2. Clinical findings
3. Diagnostic test results
4 Informed consent
5. Pre operative care
6. Operative notes
7. Postoperative care
8. Daily notes of patients progress and medication given
9. Prescriptions
10. Referral papers
11. Discharge summary
12. Medical certificates
13. Audio and video tapes
14. Electronic fetal heart monitoring charts, X-rays , ECG etc.
15. Emails, text messages, any printouts, images (photographs and diagrams), observation

charts, and check lists .

Basic Principles of good documentation

Consistent , current and complete documentation in the medical record is an essential component of quality patient care.

Documentation should be factual, accurate, true, legible and retrievable.

Following are the basic principles of clinical documentation :

1. The registration and admission process should be documented.

Each page of the medical record must include the patient's name and medical record number / UHID .

All entries into the record must be signed, with name, date and time. Include original signature, full name and professional title (or electronic signature if electronic health record used).

2. Make entries immediately or as soon as possible after the care is given.

3. Prompt documentation reduces the risk of forgetting key details. It ensures that all other team members are aware of any changes in the patient's condition or management plan.

4. Administration of medication includes correct documentation of the time route meditation name and signature of the staff for each of the drugs administered

5. Be thorough, accurate, legible and objective.

6. Only use approved abbreviations.

Description of drugs should be written in capital letters.

Check dictated notes. Check reports in detail.

7. If an addendum is made, this should also be verbally communicated to other team members and nursing staff. Sign off any addenda with the time.

8. If a mistake is made, correct it with a single strike-through. Follow that by clearly signing and dating the correction.

9. Informed consent should be taken in the language understandable by the patient or relatives. Consent regarding any treatment for procedure or surgery should be taken by the treating doctor. Consent should be taken before blood transfusion also.

10. Document all procedures clearly in the patient notes from IV cannulation to more complex bedside procedures such as lumbar punctures.

11. The discharge summary is the most comprehensive document. The most important points to include in a discharge summary are principal diagnosis, co- morbidities, procedures, complications, discharge medication list, follow-up appointments and instructions to return to the hospital.

WAYS TO IMPROVE DOCUMENTATION

The **SOAP** method

The acronym SOAP stands for Subjective, Objective, Assessment, and Plan.

Each category is described below:

A) Subjective:

It includes the patient's chief complaints, including onset, chronology, quality, and severity. It reflects the history and interval history of the condition. The patient's presenting complaints should be described in detail in the notes of each and every visit and use of the patient's own words is best.

B) Objective

Record the objective observations about how the patient is progressing.

This section, also includes observations and vital signs and findings from a physical examination.

C) Assessment

Summarise the salient points and the primary medical diagnosis in this section. Comment on whether the patient is clinically improving or deteriorating.

D) Plan

Document a clear plan, including further investigations, referral procedures, and new medications to be charted. Include an estimated discharge date.

Electronic Medical Records (EMR)

The electronic storage of clinical information will create the potential for computer-based tools to help providers significantly enhance the quality of medical care and increase the. efficiency of medical practice.

Use of EMRs will improve quality of care, reduce errors, improve quality of practice, and increase productivity.

To summarise

Documentation should be clear, concise, consecutive, correct, contemporaneous, complete, comprehensive, collaborative, patient-centred and confidential.

"If it is not documented, then it didn't happen!" We've all heard this mantra.

It is used almost threateningly to junior doctors to encourage them to strive for better clinical documentation to protect against potential lawsuits.

The young undergraduate students should be trained in the field of documentation.

As junior doctors make the greatest contribution of entries to medical notes, it is this group that should be targeted to obtain the greatest improvement in standards.

Developing and adopting good practice at the start of a medical career engenders lifelong behaviour.

When recording medical information, remember to keep it simple, and be mindful that the quality of the case record is assumed to reflect the quality of care delivered. Write down what you said, what you did, what you were told, and what you observed. Spending 15 minutes writing an accurate and detailed note can save a huge amount of thinking time 15 years later.

Dr Jayant Navarange
MD, DCH, LL.B.

Cardinal Principle in Medicolegal issues: Concept of MEDICAL NEGLIGENCE

Litigations and legal and regulatory headache against doctors and clinical establishment are increasing at an unprecedented alarming rate. Even a single litigation can negatively impact not just the professional, but also the personal life of the doctor. We need to accept that litigation is a true indicator of what a patient expects and what the judges endorse as acceptable or substandard practice. Litigation and fear of large compensations is also a driver for the change in the way we practice.

[Wherever, the word "doctor" is there, please use it inter-changeably with hospital or medical establishments)

Medical Negligence is the central concept on which in >90% cases, doctors are hooked in civil and criminal liabilities, heavy compensations and hanging sword of imprisonment..

Let's first define Medical Negligence:

1. Medical Negligence is defined as

a. Want of reasonable degree of care or Willful neglect, on part of a doctor,

b. With whom, there is an established Doctor-Patient (DP) relationship and,

c. The alleged act of Negligence can be either in the form of 'res ipsa loquittor' i.e. facts of the case speak for themselves—no further proof is required to make allegations

OR

Subtle—i.e. a lot of scope is there for deliberations to defy the charges, which in turn can be an Act of Omission or Act of Commission—e.g. Not doing biopsy before radical mastectomy in a case of Ca-breast—not doing biopsy would be act of omission and doing mastectomy without biopsy would be act of commission which other prudent doctors would not do. Similarly, a full term primi with breech presentation is a standard indication to do an elective LSCS—not doing it, instead doing a vaginal delivery and resulting damage to baby or mother or both would mean an act of commission (i.e. doing vaginal delivery instead of CS OR omitting to do what others would, an act of omission to do CS)

AND

d. Resultant damage- Nexus between the alleged act of negligence and resulting damage (to the patient—physical/mental/economic/reputation/emotions). The alleged act has to be the basic cause of damage and not the remotest or imaginary.

Medical Negligence can be simplified in a different manner also—there are '3 Ds'—1. Duty of care; 2. Dereliction of that Dury by the doctor (/hospital etc.); 3. Damage as a consequence of that Dereliction.
Unless all these 3 components are fulfilled, the definition of Medical Negligence is incomplete and hence doctor will be exonerated.
However off late, it's seen time and again that patients are being compensated only on humanitarian grounds and for delays (which usually result from judicial delays) with a clear pronouncement of 'no negligence'—and more particularly, after 2019 amendment in CPA that for ging in appeal to higher commission or court, 50% of the amount awarded by the lower commission has to be deposited. The higher commissions or courts are trying to compel the doctor/hospital to forgo the deposited amount in favor of patient, despite declaring them non-negligent. And one more issue in this situation is whether the Indemnity Insurance will cover such 'awards' as their clause mentions that they will indemnify the doctors/hospitals if proved negligent.
Examples of Gross negligence or res ipsa loquittor—(fortunately rare]—wrong identification of patient leading to wrong surgery on him; Amputating wrong limb, leaving foreign body inside body e.g. during laparotomy; Not doing test dose in a potentially anaphylactogenic drug and so on.

2. Medical Negligence is defined by SC in 1959 in Dr Trimbak Bapu Godbole v Dr Laxman Balkrishna Joshi as follows: A doctor who wishes to treat a patient has 4 responsibilities (duties) to his patient◊
-1. Any person who is ready to give treatment is duly holding necessary qualifications and registration (And acting in Good Faith)
2. He has to determine if he will undertake the care of the given patient (unless there is life threatening emergency—esp. Road traffic accident or RTA)—so that is discretion of a doctor to deny treatment in a given patient or choose his patient
3. Once decided that the doctor is ready to undertake treatment, to determine what treatment
AND
4. To execute the determined treatment—how to administer, dose, route of administration etc (here comes the role of assistants, nurses, house staff, RMOs etc.)
Any breach in any of these duties constitutes Medical Negligence.

3. Another way to look at Medical Negligence is to check if the doctor followed the principles of medical practice and treatment which is prevalent in that time era and locality—not the very best nor lower level of treatment is acceptable. Comparison is done with your peers and here is the role of expert opinions. This test of prudency is called as 'Bolam's principle' which was first uttered in England Bolam v Friern Hospital Management Committee, 1957
This test expects standards which must be in accordance with a responsible body of opinion, even if others differ in opinion. In other words, the Bolam test states that "If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent". Because of the nature of the relationship between a medical practitioner and a patient, it is reasonable for the patient to rely on the advice given by the practitioner. This relation is called 'fiduciary' i.e. a professional knows much more in the concerned subject than an average citizen and hence there is obligation on him to inform the person (in our case, a patient) about his ailment and treatment plan and prognosis so that the person takes informed decision. Thus, Bolam applies to all the acts and omissions constituting diagnosis and consequential treatment.
Bolitho principle says that it is up to judiciary to rely on expert opinion or otherwise—so the concept of Expert body or Committee—
• (Bolitho v City and Hackney Health Authority [1997] 4 All ER 771: A two-year-old boy suffered brain damage as a result of the bronchial air passages becoming blocked leading to cardiac arrest. It was agreed that the only course of action to prevent the damage was to have the boy intubated. The doctor who negligently failed to attend to the boy said that she would not have intubated had she attended. There was evidence from one expert witness that he would not have intubated whereas five other experts said that they would have done so. The House of Lords held that there would have to be a logical basis for the opinion not to intubate. This would involve a weighing of risks against benefit in order to achieve a defensible conclusion. This means that a judge will be entitled to choose between two bodies of expert opinion and to reject an opinion which is 'logically indefensible'. This has been interpreted as being a situation where the Court sets the law, not the profession.)
Our courts have fairly relied only on Bolam principle so far, though in last couple of years, Bolitho is applied in 3 cases so far by Supreme Court.

Going forward, now the judicial system is becoming more active, rathe proactive by applying ratios laid

down on Rogers vs Whitaker (1996) and Montgomery (2016) overseas. This is making practice more difficult and accountable. This makes the standard practice not only for diagnosis and treatment only, but to investigate, history taking and examination, counseling, consent, prognosis etc. also. Fortunately, these are not applied by our courts yet.
The new principles laid down in Montgomery (2016) applies to all advisory activities involving the communication of diagnosis and prognosis, giving of advice on both therapeutic and non-therapeutic options for treatment, and disclosure of relevant information to obtain informed consent. This radical shift has occurred from 'doctor centric' to 'patient centric.' So far there is no case decision based on these two as of Jan. 2026

Why Criminal Liability in doctors' cases? No doctor or medical establishment would commit a willful negligence so as to harm his patient in any way and remarkably, there is albescence of 'intention' or mens rea'—then why doctors or hospitals have to face criminal prosecution? The answer is, in the absence of usual essential component of mens rea, the test applied is 'Reasonable Foreseeability' of imminent or consequential or potential dangers of medical management e.g. not doing pre-operative investigations, not remaining vigilant or recording vitals during anesthesia, leaving mob during laparotomy or Caesarean etc. Also, special laws like PCPNDT, MTP, Bio-Medical waste disposal etc, are strict laws where there is no scope for short cuts or not following in spirit or words, criminal liability sets in.

Burden of proving negligence is on the patient (alleger), but this reverses in a few situations like in res ipsa loquittor; and in cases where there is no free access to patient like OT, ICUs, Labor rooms etc., the burden shifts to doctor i.e. he has to prove his non-negligence (prove diligence) by proving that he had taken all possible precautions or acted with diligence and even then poor result has occurred. Or being alleged.
Every sore end result like death or temporary/permanent disability is not the same as Medical Negligence.
To minimize chances of litigation, following acronym is important to remember and follow:
A) Attention (to patient complaints) and Additional (timely) opinion, Appreciate the previous doctor and treatment (NO medical jousting)
B) Behavior of the (doctor and staff); Bills (give a fair estimate in planned cases).
C) Communication; Consent (& denial); Compassion, Counseling
D) Documents (the only friends in case of medico-legal crisis and worst foes if not there), Doctor Patient relationship (DP relations)
E) Empathy (towards the patient suffering); Efficiency, Ethics and Equipment
G◊Good Faith (S.52 of IPC or S8 of BNS)—have proper degree, registration, updating, registration of nursing homes, BMW etc., F for Family doctor
H◊Hospitality, esp. Reception area and general curtsey
I◊Identity (by government approved photo-id like Adhar card), Indemnity Insurance coverage for individual and hospital etc. of adequate amount coverage

Following are non-negligence though they appear like:
1. Difference of opinion
2. Wrong result despite diligence and scientific (evidence based) treatment
3. Following one of the standard lines of treatment for the same disease
4. Bills
5. MISTAKE OR MISADVENTURE
6. INHERENT RISK IN MANAGEMENT
7. ACTS DONE IN GOOD FAITH
8. ACCIDENT
9. Period Of LIMITATON—usually from date of discharge(Oct 2007-NC-Saroj Chandoke vs Sir Gangaram)2 yrs in Consumer; 3 yrs in Civil—no limitation for criminal liability
10. CONTRIBUTORY NEGLIGENCE—can save the doctor
11. ERROR OF JUDGEMENT-if NOT GROSS or palpable

Deficiency◊ Consumer Act 1986 has brought concept of Deficiency (S.2d(g)) which has wider connotation than crystallized definition of Medical Negligence. Whatever services are promised like food, laundry, air conditioning, availability of assured consultants, appointments etc are covered under this—but by and large, as of today, the cases revolve around proving Medical Negligence
The highest compensation awarded is against AMRI hospital in Kolkata—11.5 crores! (in 2014)
We strongly suggest individual coverage of 1 crore for operating surgeons, 2 cr for super-specialists, 50 lacs for non-operating medical consultants, and similar amounts for hospitals. Also, Family practitioners should insure for 10 lacs.. + additional cover for hospitals.
What needs attention is the interest burden in Medical Negligence Compensation—usually, it takes minimum

5 years for disputes to be settled In courts and whatever damages are awarded, interest burden is added to that at around 9% i.e. if compensation is allowed of Rs 5 lacs, it becomes 10 lacs at the end of 8 years! Interest component is applied very arbitrarily. And these delays are due to court procedures or from complainant's side in most situations.

Simultaneous legal actions:

It is also important to note that a doctor can be booked under various laws simultaneously for the same set of facts e.g. for a case of mishap or negligence, he can face trial by Medical council, consumer act, local licensing body like municipal corporation, Human rights commission, right to information and by police!

So, the understanding of concept of Medical Negligence is the most important aspect of any medicolegal seminar or workshop and it has may angles and corners. Medicolegal experts try to prove that there was no negligence, but all due diligence was observed.

Medicolegal Accountability & Liability in special situations:

1. Consultant & Hospital Relations: When a consultant is appointed as a 'visiting consultant' i.e. either he is allowed to run his OPD in the hospital facility and/or allowed to keep his patients indoor, or operate or use hospital services in any other manner or is called for his opinion as a referral from hospital, he is supposed to follow all natural ethical principles as an individual doctor. He must attend in time, carefully examine and treat the patient, write the clinical and other notes carefully, look after the consent matters etc. Usually, the hospitals make an MOU stating that for any legal matters arising out of any such use of facilities in that hospital, the consultant himself will be entirely responsible and liable and is indemnifying the institute of any consequences and compensations. They would take a copy of Professional Indemnity policy of the visiting consultant, his credentials, updated medical registration etc. In spite of such an MOU and documentation that the hospital will not be liable at all, the courts have usually NOT absolved the hospital but taken them fully answerable and liable on the principle of vicarious liability, though there is no master-servant relationship. If there is any legal matter as a consequence of the visiting doctor's patient, hospital is made a 'necessary' party and If the judicial decision is that of medical negligence, the liability is carefully apportioned between the Consultant and Hospital. Courts have taken a view that if the hospital has allowed the Consultant to make use of their facilities, hospital is also liable and usual proportion is 60:40, I.e. 60% by the hospital. In short, there is no real meaning to the clause in Mou that it will be entirely a 'consultant's liability'. The apportionment also checks to what extent the consultant's own actions were responsible for the medical negligence and to what extent services provided by the hospital were responsible e.g. emergency services, nursing care, sterilization, maintenance of equipment etc.

Of course, it is reiterated that there should be excellent coordination, dialogue and cooperation between the consultant and the hospital. Also, criminal liability cannot be shared and there is no principle of vicarious liability.

2. Consultant in employment (as an employee): There is an increasing tendency to get employed as a full-timer or part timer in a corporate or government hospital for various reasons. Here, for the compensation part, the employer has to settle the decreed amount to the complainant (Patient or his next of kin) on the basis of vicarious liability of the employer. However, it is important to note that employer in turn can recover that amount form the employee doctor. They may additionally remove him from service, make adverse remark in release letter etc. Therefore, it is essential that such employed consultants have their own professional indemnity cover like a private practicing doctor.

3. It is emphasized that any consultant should carefully preserve all the documents, MOUs, agreements, appointment letters etc. done with the hospital form day 1 till the end! HE should obey hospital rules agreed a upon and follow their instructions of administration. Whatever disputes, including payment, should be carefully documented and followed.

4. Certain times, a Consultant feels about malfunctioning equipment or non-availability of certain facilities, or incompetent staff—and the repeated requests to improve these are falling on deaf ears of the superiors or administrators or employers. If after repeated verbal requests, no attention is paid or improvements done, which might result in poor patient care, it is essential to report such matters in writing. That will only save a visiting or employed consultant from legal wrath. If a consultant knowingly keeps mum, the law will not spare such a 'spectator consultant'.

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Post-Mortem Examination in Obstetric and Gynecological Deaths: Protocols and Medicolegal Significance

Abstract
Background: Post-mortem examination remains the gold standard for investigating maternal and gynecological deaths, particularly when clinical diagnosis is uncertain or medicolegal implications exist.
Objectives: To review autopsy methodology, viscera collection protocols, and medicolegal significance of post-mortem examinations in obstetric and gynecological deaths.
Methods: A narrative review integrating forensic textbooks, Royal College of Pathologists guidelines, maternal death studies, and national review frameworks was conducted.
Results: Autopsy examination significantly enhances cause-of-death determination, frequently revealing findings unidentified ante-mortem. Standardized protocols improve toxicological and histopathological analysis while structured audits enhance maternal care quality.
Conclusion: Rigorous autopsy and audit guidelines can substantially improve maternal death surveillance and reduce preventable mortality.
Keywords: Maternal autopsy, Viscera collection, Maternal mortality review, Obstetric death, Medicolegal autopsy

Introduction

Maternal mortality represents a critical public health and medicolegal challenge worldwide. The World Health Organization defines maternal death as death of a woman while pregnant or within 42 days of termination of pregnancy, from causes related to or aggravated by pregnancy or its management, excluding accidental causes.
Post-mortem examination plays a pivotal role in determining cause and manner of death in women dying during pregnancy, childbirth, or the postpartum period. Despite technological advances, significant discrepancies persist between clinical and autopsy diagnoses. Autopsy yields critical pathological data that can alter cause-of-death attribution, facilitate medicolegal adjudication, and guide clinical and public health strategies.
This review examines practices in post-mortem examinations for obstetric and gynecological cases, emphasizing viscera collection protocols, maternal death audits, and examination procedures for special circumstances including family planning-related deaths, criminal abortion, and deaths following sexual offenses.

Materials and Methods

A narrative review was performed utilizing standard forensic medicine textbooks, Royal College of Pathologists autopsy guidelines, peer-reviewed maternal death studies, national maternal death review guidebooks, and international surveillance frameworks. The review synthesizes evidence on autopsy methodology, pathological findings, viscera collection techniques, and audit practices.

Results and Discussion

Epidemiological Patterns in Maternal Deaths
Retrospective autopsy studies demonstrate that post-mortem examination frequently elucidates causes of maternal death not recognized clinically. Indian studies identified hypertensive disorders (24.2%) and anemia (14.7%) as predominant contributors, with disseminated intravascular coagulation and thromboembolic events frequently detected on histopathology. North East India studies report hemorrhage and amniotic fluid embolism as leading direct obstetric causes.
Direct obstetric causes include hemorrhage, hypertensive complications, embolism, sepsis, and uterine rupture. Indirect causes involve pre-existing conditions aggravated by pregnancy, including cardiac disease and infections.

Standard Autopsy Methodology in Maternal Deaths

Authorization and Team Composition

Maternal death autopsies constitute high-stake medicolegal cases, often involving allegations of negligence or inadequate care. In India, mandatory police inquest under Section 174 CrPC is required, with intimation to hospital authorities, District Health Officer, and Maternal Death Review Committee.
Maternal death autopsies should employ a multidisciplinary team including one Forensic Medicine expert (mandatory), one Obstetrician/Gynecologist (highly recommended), and one Pathologist for histopathology correlation. This approach enhances diagnostic accuracy and reduces professional bias.

Pre-Autopsy Preparation
Comprehensive review of clinical history, maternal health records, and circumstances surrounding death is essential. Documentation should include antenatal complications, obstetric interventions, operative procedures, anesthetic administration, and laboratory findings. Adequate refrigeration and minimal delay preserve tissue integrity.

External Examination
Systematic external examination must assess signs of anemia, edema, cyanosis, medical interventions (injection marks, IV sites, surgical wounds), features suggesting pregnancy, hemorrhagic manifestations, operative scars, and perineal or abdominal trauma.

Internal Examination
Thoracic Cavity: Assess lung parenchyma for pulmonary embolism, cardiac evaluation for structural abnormalities, pleural cavity inspection, tracheal examination for aspiration, and evidence of amniotic fluid embolism.
Abdominal and Pelvic Cavity: Evaluate uterine size, tone, and integrity; placental examination; broad ligament hematoma; quantify intraperitoneal hemorrhage; assess surgical sites; and examine ovarian and adnexal pathology.
Cranial Examination: Assess cerebral edema, intracranial hemorrhage (particularly in eclampsia), cerebral vessel thrombosis, and pituitary gland pathology.
Histopathological Examination
The Royal College of Pathologists recommends routine histological examination of uterine wall, placental tissue, liver, lungs, kidneys, brain tissue, heart, and any grossly abnormal tissue.

Viscera Collection Protocols
Rationale
Viscera collection enables toxicological and biochemical analyses detecting drug and anesthetic toxicity, poison exposure, metabolic derangements, and therapeutic drug levels. Given complex physiologic adaptations during pregnancy, even therapeutic medications may contribute to fatal outcomes.

Recommended Specimens
For thorough analysis, collect:
• Blood: Central and peripheral samples, 10-20 ml each
• Urine: 30-50 ml
• Liver: Approximately 500 grams
• Kidney: One complete kidney or representative sections
• Stomach contents and upper small intestine: Complete collection
• Bile: 10-20 ml
• Vitreous humor: For postmortem biochemistry
• Brain tissue: If neurological involvement suspected

Preservation and Documentation
Use saturated common salt solution for viscera preservation. Add sodium fluoride (10 mg/ml) to blood samples for volatile substance stabilization. Never use formalin for toxicological specimens; it is appropriate only for histopathology.
Each specimen container must be labeled with complete identification, case number, anatomical source, collection date/time, collector signature, and preservative type. Maintain meticulous chain of custody for medicolegal validity.

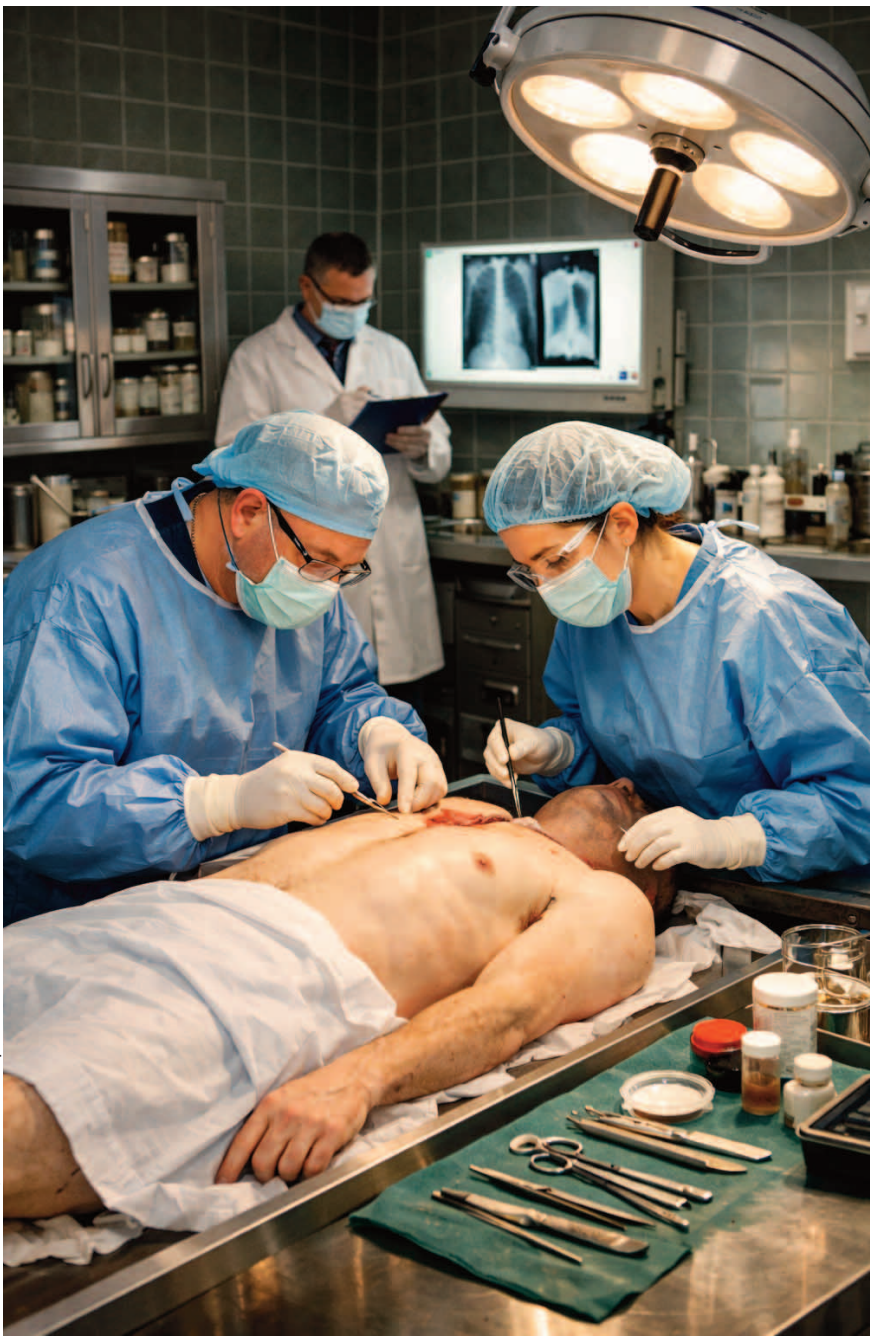
Post-Mortem Examination in Special Circumstances
Family Planning-Related Deaths
Deaths following family planning procedures (tubectomy, vasectomy, IUCD insertion, medical termination) raise questions regarding procedural safety and potential negligence.
Documentation Review: Examine consent forms, sterilization technique documentation, anesthetic records, and facility standards.
External Findings: Document surgical incisions, systemic infection evidence, injection site reactions, and anaphylaxis signs.
Internal Examination Priorities:
• Pelvic assessment: tubal ligation integrity, peritonitis, bowel injury, hemoperitoneum
• Systemic findings: septic shock, multi-organ dysfunction, anaphylaxis, cardiovascular complications
Medicolegal Determination: Distinguish between death from recognized complications, procedural neg-

ligence, or unrelated causes. This determination is essential for compensation claims and liability assessment.

Criminal Abortion Deaths
Criminal abortion remains a significant maternal mortality contributor, typically performed by unqualified practitioners in unhygienic conditions.
External Evidence: Active vaginal bleeding, perineal injuries, instrument marks, concealment evidence.
Internal Findings:
• Uterine pathology: perforation, cervical lacerations, retained products, endometrial injury
• Abdominal cavity: hemoperitoneum, peritonitis, bowel/bladder injury
• Systemic complications: septicemia, air embolism, hemorrhagic shock
Evidence Collection: High vaginal swabs, products of conception, foreign materials, toxicological samples, DNA evidence.
Medicolegal Significance: Establish illegal termination, identify method and instruments, determine cause of death, and fix criminal liability.

Deaths Following Sexual Offenses
These cases involve sexual violence potentially complicated by homicide, requiring utmost sensitivity and precision.
Examination Team: Forensic expert, gynecologist, mandatory female attendant, police representative, photographer.
External Examination:
• Genital injuries: vulvar trauma, hymenal tears, perineal injuries, anal injuries
• Extragenital injuries: defensive wounds, bite marks, restraint marks, asphyxia signs
Internal Examination: Vaginal wall tears, cervical lacerations, rectal injuries, internal hemorrhage.
Cause of Death: Mechanical asphyxiation, blunt force trauma, sharp force injuries, poisoning, hemorrhagic shock.
Evidence Collection: Vaginal/anal/oral swabs, fingernail scrapings, pubic hair combings, blood samples, clothing preservation. Strict chain-of-custody ensures admissibility in criminal proceedings.

Maternal Death Audit - Purpose
Maternal death audit represents systematic, confidential review designed to evaluate clinical care quality, identify avoidable factors, strengthen health systems, inform policy development, and prevent future deaths.



Assessment Domains
Clinical Factors: Antenatal care adequacy, high-risk pregnancy recognition, management appropriateness, diagnostic accuracy, guideline adherence.
Institutional Factors: Blood bank availability, ICU capacity, staff competency, medication availability, operating theater readiness, referral systems.
Forensic Evaluation: Autopsy completeness, viscera collection adequacy, histopathological-toxicological correlation, cause-of-death certification accuracy.

Administrative Compliance: Maternal Death Review guideline adherence, notification timeliness, family communication, informed consent documentation.

Preventability Assessment
Systematically determine whether death was preventable, presence of delays (patient, transport, facility levels), whether different interventions could have altered outcome, identification of substandard care, and systemic failures requiring intervention.

Action Planning
Translate findings into practice improvements, training needs, infrastructure enhancement, protocol revisions, resource allocation, and implementation follow-up mechanisms.

Challenges and Future Directions
Current Barriers
Despite established autopsy value, significant barriers persist: cultural and religious objections, shortage of trained forensic pathologists in rural areas, limited toxicological laboratory access, infrastructure deficiencies, incomplete death registration, and inadequate funding.

Improvement Strategies
Capacity Building: Enhanced pathologist training programs, specialized obstetric pathology training, regional forensic centers, telemedicine consultation networks.
Community Engagement: Culturally sensitive communication regarding autopsy benefits, religious leader involvement, family counseling, public awareness campaigns.
System Strengthening: Laboratory infrastructure investment, autopsy protocol standardization, digital death certification, maternal mortality surveillance integration, research funding.

Conclusion
Post-mortem examination, incorporating rigorous methodology, comprehensive viscera sampling, and structured audit processes, remains indispensable in obstetric and gynecological death investigations. Standardized autopsy protocols enhance diagnostic accuracy, contribute to maternal mortality reduction strategies, and strengthen medicolegal death certification systems.
Through meticulous post-mortem examination, the deceased becomes a silent yet truthful witness, ensuring justice is not denied to victims whose voices have been silenced. Autopsy findings provide objective event reconstruction, scientific cause-of-death determination, biological evidence preservation, and accountability in negligence or criminal conduct cases. Implementation of evidence-based autopsy guidelines, forensic infrastructure investment, and integration with maternal death review mechanisms can significantly improve maternal health outcomes and advance the global agenda for reducing preventable maternal mortality.

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Conflict of Interest
The authors declare no conflict of interest.
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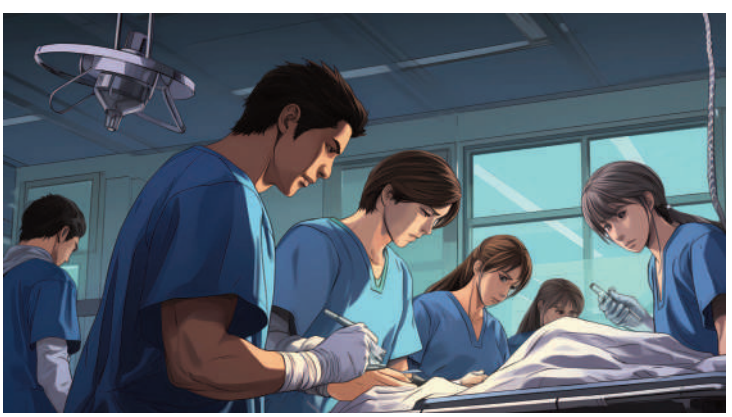
References
1. Rushton DI, Dawson IMP. The maternal autopsy. J Clin Pathol. 1982;35(9):909-921.
2. Autopsy study of maternal deaths. Int J Gynecol Obstet. 2003.
3. Maternal deaths: medicolegal autopsy study. J Med Soc. 2022;36(1).
4. Maternal Death Review Guidebook. National Health Mission, Government of India; 2013.
5. Guidelines on Autopsy Practice: Maternal Death. Royal College of Pathologists; 2024.
6. Analysis of maternal deaths: autopsy study. Int J Reprod Contracept Obstet Gynecol.
7. Medico-legal aspect of maternal death. Int J Res Med Sci.
8. Verbal autopsy validity for institutional maternal death. PubMed.
9. Confidential Enquiry into Maternal Deaths (MBRRACE-UK). Annual Reports 2018-2023.
10. World Health Organization. ICD-10: Maternal Mortality. Geneva: WHO; 2016.



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Understanding the PCPNDT Act: An Essential Guide for Obstetricians in India

"It is our ethical responsibility to ensure that no one from our profession indulges in unethical and unlawful practices."
The PCPNDT Act is central to day-to-day obstetric practice in India, and non-compliance exposes practitioners to severe criminal, professional, and reputational consequences. Obstetricians need to understand not only the text of the law but also its interpretation in case law, documentation, its administrative requirements, and its user interface interaction with the ART regulation. Thus, the Act demands high vigilance, accurate record-keeping, and strict compliance with procedural safeguards.

The Legislative Background and Purpose
The PCPNDT Act was introduced in 1994 against the backdrop of stark gender imbalances revealed by the 1991 census data. The Act was later amended in 2003 to strengthen regulatory mechanisms and explicitly include pre-conception sex selection techniques and ultrasound technology within its ambit.

Core Provisions Relevant to Obstetric Practice
Below are the key statutory provisions every obstetrician must understand:
• Ban on Sex Selection
Section 3A prohibits any procedure aimed at determining or selecting the sex of the fetus or embryo, whether done pre-conception (e.g., sperm sorting, PGD for sex selection) or post-conception (ultrasound, amniocentesis, and chorionic villus sampling, etc). Obstetricians must never conduct, facilitate, or communicate sex determination, results, including through peripheral signals or hints.
• Permitted Uses of Diagnostic Techniques
The Act allows the use of prenatal diagnostic techniques only for specific medical purposes, such as detecting:
Chromosomal abnormalities, Genetic metabolic diseases, Congenital malformations, Haemoglobinopathies, Sex-linked genetic disorders and other conditions as specified by the Central Supervisory Board.
This means that all ultrasounds and related procedures must have clearly documented clinical justifications that fall within these categories.
• Prohibition on Communication of Fetal Sex
Section 5 explicitly bans the communication of the fetus's sex to the pregnant woman or relatives by any means whatsoever (including print, electronic media, signboards, or word of mouth inducements).
Even unintended cues may be interpreted as violations.
• Mandatory Registration
Any facility where prenatal diagnostic techniques are conducted—including ultrasound clinics—must be registered under the Act. Working in an unregistered unit is a punishable offence.
Registration: The Foundation of Compliance
A Central Supervisory Board and State Supervisory Boards oversee implementation, while appropriate Authorities license, inspect, suspend/cancel registrations, and file complaints in court. The AA is empowered to conduct surprise inspections at least once in 90 days, seize records and equipment, and issue search warrants if sex selection is suspected.

Registration Requirements
Obstetricians should confirm that:
• The clinic or facility is registered under the PCPNDT Act.
• All ultrasound machines used are declared and covered under that registration.
• Each registered practitioner's name, qualifications, and status are updated in the appropriate government records.

What Happens if Unregistered
• Performing diagnostic procedures in an unregistered facility can lead to sealing and seizure of equipment, penalties, and the need to pay a penalty of up to five times the registration fee to

have the machine released.
Tip for practice: Always verify the validity of the registration certificate and its expiry date from time to time.
Record-Keeping: The Most Critical Compliance Pillar
Incomplete, inaccurate, or missing records are treated as violations under the Act and can attract criminal penalties.
• Detailed record keeping is mandatory: maintenance of registers, copies of referral slips, Form F for each pregnant woman undergoing an ultrasound or prenatal diagnostic procedure, consent forms for invasive tests, and display of mandatory notices.

• Every obstetric ultrasound must be accompanied by a "Form F" entry documenting:
• Patient details, Clinical indications, Date and time of procedure, Details of referring and performing doctors.
• A clear record of why the scan was clinically necessary is mandatory.
• Form F must be fully and legibly filled, capturing indications, obstetric history, declaration of non disclosure of sex by both doctor and patient, and signed by the responsible practitioner; these records must be preserved for at least two years or longer if proceedings are pending.
Non maintenance or incomplete maintenance of records is treated as a substantive offence under the Act, not merely a clerical lapse, with a presumption that the offence of sex selection may have occurred.

Penalties and Consequences
i) For Obstetricians and Clinic Owners
• First offence: Up to 3 years' imprisonment and a fine of up to ₹10,000.
• Subsequent offence: Up to 5 years' imprisonment and a fine of up to ₹50,000.
• The practitioner's name may be reported to the State Medical Council, leading to license suspension for up to five years or permanent removal after subsequent convictions.
ii) For Individuals Seeking Sex-Selection Services
Individuals seeking prohibited services are criminally liable, though the pregnant woman herself is not treated as an offender.
iii) Advertisement Violations
• Advertising facilities for sex determination—whether in print, electronic, or social media—is an offence carrying imprisonment and fines.
iv) General and Minor Violations
• Lesser contraventions, such as failure to display required notices or maintain copies of the Act, can still result in fines, short imprisonment, or show-cause notices and temporary suspension of registration.

Nature of Offences
Every offence under the Act is cognizable, non-bailable, and non-compoundable, meaning that arrest can follow without warrant and compromise settlements are not permitted.

Judicial Interpretation and Compliance Standards
Indian courts have consistently adopted a zero-tolerance approach. Even minor or inadvertent errors can trigger prosecution once prima facie violations are established.

Practical Challenges for Obstetricians
While the legal framework is clear, implementing it in busy clinical settings can be challenging. Common areas of struggle include:
-Administrative Overload
Ensuring every procedure is fully documented in Form F and that records are audit-ready demands administrative focus and training of staff.
- Fear and Misunderstanding Among Patients
Due to strict penalties, patients and families sometimes conflate lawful diagnostic practice with illegal conduct, increasing social pressure on clinicians.
-Non-Designated Courts
Cases under the PCPNDT Act are spread across various district and session courts—without a dedicated tribunal—making follow-up and defence coordination difficult.

Burden of proof and strict compliance
• The Act reverses the usual criminal law presumption: the burden of proof lies on the accused doctor or centre to show that prenatal diagnostic techniques were not used for sex selection and that records were duly maintained.
• Even "minor" violations such as non display of the registration certificate, non display of the "sex determination not done here" board, or incomplete forms may lead to prosecution and suspension of registration.
• These features make the statute stringent, requiring a culture of meticulous documentation rather than post hoc rationalisation once an inspection or complaint occurs.

Key court decisions shaping practice
Supreme Court: FOGSI Constitutionality Challenge (2021)
1. FOGSI v. Union of India (Supreme Court, 2021)
The Supreme Court upheld the constitutionality of Sections 23(1) and 23(2), rejecting arguments that documentation lapses should be treated leniently. It held that non-maintenance of records is a "springboard" for foeticide and justifies shifting the burden of proof to practitioners. This judgment reinforced earlier directions in CEHAT v. Union of India (2001) and strengthened enforcement nationwide.
2. Hisar Diagnostic Centre Case (Punjab & Haryana HC, 2025)
After 19 years of litigation, the doctors were acquitted because the complaint was not filed by a properly constituted Appropriate Authority. The court held that procedural defects in initiating prosecution rendered the case invalid.
Legal nuance: Compliance does not end at clinical practice — procedural correctness in initiating prosecution is essential. Errors in authority appointment or statutory process can overturn convictions years later.
Earlier Supreme Court directions in public interest litigations have pushed states to strengthen enforcement, including active inspections, tracking of ultrasound machines, and cracking down on illegal centres, which has increased regulatory pressure on obstetric and radiology practices.

Practical do's for obstetricians.
• Ensure that the ultrasound unit and any facility where invasive prenatal diagnostic procedures are performed are properly registered under PCPNDT, with the registration certificate prominently displayed in patient areas.
• Display the text of the PCPNDT Act and a clear board stating that sex determination is not done and is punishable by law, in language easily understood locally.

Patient Communication
• Clearly explain to patients that sex determination is prohibited by law.
• Provide signed consent forms acknowledging understanding of the purpose and limitations of prenatal diagnostics.

Thorough Documentation
• For each prenatal ultrasound or diagnostic procedure, fill Form F completely, legibly, and contemporaneously, capturing indication, gestational age, past obstetric history, and the patient and doctor declarations, and store these records safely for the mandated period.
• Maintain backup digital records and secure physical filing.
• Obtain written informed consent (in a language the woman understands) for invasive procedures like amniocentesis and CVS, and give the patient a copy as required by the Rules.
• Review records regularly for completeness.
• Train all staff, including receptionists and technicians, on the legal prohibition of sex determination and ensure that no employee communicates or hints at fetal sex in any mode, including gestures or coded language.

Compliance Officer
• In larger facilities, appoint a PCPNDT compliance officer responsible for audits and inspections.
• Cooperate fully with inspections by the Appropriate Authority, making all records, machines, and premises available; maintain an internal log of inspections and promptly address any deficiencies pointed out.

Stay Updated
• Keep abreast of changes in rules, notifications from State PCPNDT cells, and supervisory board directives.

Critical don'ts for obstetric practice
• Do not disclose the sex of the fetus to the patient, relatives, or referring doctor in any form—oral, written, by gestures, or via suggestive comments or images.
• Do not perform prenatal diagnostic procedures for non medical reasons such as curiosity or family preference; restrict such procedures to the indications permitted by the Act and Rules.
• Do not display or allow any advertisement, pamphlet, or online content that directly or indirectly offers sex determination or hints at sex selection services.
• Do not delegate signing of Form F or consent forms to unqualified/untrained staff; the responsible obstetrician or sonologist must personally sign and take responsibility for entries.
• Do not ignore or delay responses to show cause notices

from the Appropriate Authority; such inaction can accelerate suspension or cancellation of registration and prosecution.

Common pitfalls and nuances in daily practice

• Documentation is often viewed as a low priority task, yet under PCPNDT, even small omissions (missing indication, absent signatures, incomplete address) can trigger criminal proceedings and professional sanctions.
• Many obstetricians mistakenly assume that once they never reveal fetal sex, they are "safe" However, the legal risk often arises from registration lapses, incomplete records, and staff conduct rather than overt sex disclosure.
• The law treats centres and practitioners as jointly responsible, meaning ownership, employment status, and supervisory roles all carry potential liability for violations, which makes corporate and partnership arrangements legally sensitive.

Interaction with the MTP Act

While the Medical Termination of Pregnancy (MTP) Act allows legal abortion under certain conditions, using the PCPNDT Act to "track" pregnancies or restrict MTP access to prevent sex selection is considered a misuse of the law. Obstetricians must distinguish between the two: MTP is for maternal health/rights, while PCPNDT is solely to prevent sex-selective discrimination.

Interface with ART and surrogacy regulation

• Since PCPNDT covers pre conception techniques with potential for sex selection, ART and IVF centres fall within its ambit if they use or could use methods such as pre implantation genetic diagnosis (PGD) or sperm selection to influence fetal sex.
• ART related legislation and guidelines, including the Assisted Reproductive Technology (Regulation) Act and surrogacy laws, converge with PCPNDT in prohibiting sex selection and requiring registration and reporting of procedures.
• Pre implantation genetic testing is legally permissible for avoiding serious genetic diseases, including some sex linked conditions, but using it solely to choose the sex of the child is banned and can attract action under PCPNDT as well as ART regulations.
• ART clinics must maintain detailed records of indications for PGD/PGT, embryo selection criteria, and counselling notes to demonstrate that no sex selection for non medical reasons has been undertaken.
• Obstetricians who collaborate with ART centres—by providing antenatal care, ultrasound, or invasive testing for ART conceived pregnancies—should ensure that the treating chain complies with both PCPNDT and ART laws because joint practice arrangements are often scrutinized.
• Any arrangement where prospective parents request selection of a "male" or "female" child through IVF, sperm sorting or embryo selection must be firmly declined, with clear documentation of counselling and refusal.

Risk management strategies for clinicians and institutions

• Establish written standard operating procedures (SOPs) for all PCPNDT related processes: registration, display requirements, Form F completion, consent, archiving, and response to inspections.
• Conduct periodic internal audits of records, forms, and consent to detect and correct gaps proactively; many centres use checklists at the time of every ultrasound to ensure that all mandatory fields are completed.
• Invest in continuous training and sensitisation, emphasising the ethical rationale of preventing gender biased sex selection, which helps staff see PCPNDT compliance as a professional duty rather than a bureaucratic burden.
• Engage with professional bodies and legal counsel to stay updated on amendments, state specific rules, and key judgments affecting enforcement standards and documentation expectations.
• Ensure that practice agreements, employment contracts, and partnership deeds clearly define responsibilities and expectations regarding PCPNDT compliance, including consequences for willful violations by any partner or employee.
• Maintain a respectful, non confrontational stance with regulators and inspectors, while using available appellate mechanisms if orders of suspension or cancellation appear disproportionate or legally flawed.

Ethical and Social Responsibility

Beyond legal compliance, obstetricians carry a moral responsibility to combat gender bias and female foeticide. Active participation in patient education, community awareness, and ethical care delivery aligns clinical practice with the spirit of the Act.

Conclusion

The PCPNDT Act remains a cornerstone of Indian reproductive law, shaping how prenatal diagnostics are performed and regulated to eradicate sex-biased practices. For obstetricians, mastering its nuances — from form completion to legal compliance — is essential. When combined with the newer ART and Surrogacy Acts, medical professionals operate within a broader ecosystem of reproductive ethics and gender equity. Together, these laws aim to balance technological advances in prenatal and reproductive medicine with the protection of individual rights and societal interests.

Death with Dignity: Saga of my judicial Activism

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Honorary Professor of health Law: Maharashtra National Law University

Summary
The landmark judgment delivered by the Bombay High Court on 17 April 2025 in response to Public Interest Litigation No. 3 of 2024 filed by Prof Dr Nikhil Datar marks a significant advancement in the legal framework surrounding passive euthanasia in India. Building on the Supreme Court's recognition of passive euthanasia as a constitutional right, this case sought to establish mechanisms to operationalise Advance Directives (Living Wills), appoint custodians, digitise storage systems, and amend the Code of Medical Ethics.

Introduction:
Date: 17th April 2025 | Time: 11:00 AM | Venue: Court Room No. 46, Bombay High Court
A historic moment unfolded as the bench of the Hon'ble Chief Justice and Justice Karnik heard the government pleader and my arguments in PIL/3/2024, and delivered a landmark judgment. For me, it was a moment etched in memory—a culmination of all the efforts including those of arguing the matter myself in front of the Court. I am happy that this public interest litigation promises to transform end-of-life care in Maharashtra and across the country. This article provides an insight into this legal battle, its achievements, and its limitations.

Do Citizens Have the Right to Die in India?
The Supreme Court of India has ruled that the right to passive euthanasia is a fundamental right, in Miscellaneous Application No. 1699 of 2019 in Writ Petition (Civil) No. 215 of 2005. To implement this right, the Court devised a framework:
• Citizens must create a "Living Will" or "Advance Directive",
• The State must establish a mechanism to ensure that the provision is not misused.
Importantly, the Supreme Court has categorically stated that active euthanasia is not permitted in India.

Understanding Passive Euthanasia in Medical Context
Medical professionals are familiar with the distinction between active and passive euthanasia. The latter refers to withholding or withdrawing treatments that only serve to meaninglessly prolong a patient's life.
In simple terms, the Supreme Court has legalized the commonly used medical directive: "Do Not Resuscitate (DNR)". Although medically accepted, this concept lacked legal recognition. Consequently, doctors, fearing legal consequences, would often deescalate the ventilatory support but seldom had the courage to officially stop it.
This ambiguity left doctors with just two options:
1. Continue treatment until the patient's death, or
2. Allow relatives to take the patient home Against Medical Advice (DAMA).
This lack of legal clarity caused emotional, ethical, and legal distress for patients, relatives, and doctors. Some doctors even faced criminal charges—often due to internal family disputes. Hence, a legitimate and robust system was urgently needed. That system has now been laid down by the Supreme Court.

PIL No. 3 of 2024: Prayers to the Court
The petitioners—Prof. Dr. Nikhil Datar, Anand Raut, and Garima Pal—filed PIL/3/2024 against the State of Maharashtra, Government of India, Municipal Corporation of Greater Mumbai, and the National Medical Commission (NMC) in the High Court at Bombay judicature in November 2023.
Our primary plea was to direct all respondents to create a mechanism that would effectively implement the right to die with dignity, as recognized by the Supreme Court. The key demands in the PIL were:

1. The State should appoint custodians to receive citizens' Living Wills.
2. The State should create a digital repository to store these documents, ensuring accessibility and authenticity.
3. A system should be created for the appointment of a Registered Medical Practitioner (RMP) representing the Chief Medical Officer (CMO) in every district, to facilitate medical decisions about withdrawal or withholding of treatment in accordance to the Apex Court's order.
4. The National Medical Commission (NMC) should amend the Code of Medical Ethics, which, under 2002 regulations, considers withdrawal of ventilatory care (except in brain dead and for organ donation) an "unethical act."

The order by the Court:

The Hon'ble High Court accepted all our prayers. Following actions have been/ are going to be taken in near future.

• Demand 1: Custodians Appointed

The Government of Maharashtra has designated 413 officers as custodians to receive Advance Directives. In Mumbai, Medical Officers from each ward are now empowered to act as custodians.

• Demand 2: Digital Storage

The State has been directed to create a web portal for storing Advance Directives within four months. It also undertook to prepare Standard Operating Procedures (SOPs) for implementation. Although, I have been shown the prototype which looks impressive, it has gone beyond the deadline given by the Court.

• Demand 3: Medical Board

A previous Government Resolution (GR) released by the department of medical education in this regards, was challenged by me in the court , the state presented a revised GR in the court. I believe it still needs further refinement.

• Demand 4: Ethical Code Reform

The Court ordered the NMC to amend the Code of Medical Ethics accordingly.

Earlier, the Court acknowledged that I had raised a "good public cause." It directed me to submit my suggestions to the State and granted me the liberty to file further petitions if needed. Importantly, the Court set specific time limits for State compliance.

Next Steps:

We must celebrate this historic judgment, especially for its impact on senior citizens and terminally ill patients. But celebration alone is not enough. With the PIL now disposed of, it is our collective responsibility to ensure the State follows through.

In March 2024, I was the first person to submit my Advance Directive to the Municipal Corporation. Since then, many others across the State have done the same. However, issues persist.

• Information gaps at the level of custodian:

• Citizens often don't know who the custodian is in their area.

• Transfers and retirements of designated officers add confusion.

Implementation challenges at the medical board level:

The Supreme Court has stated that there should be medical boards primary and secondary in the hospital where patient is taking treatment. Only one physician from the boards should act as a representative of CMO of the district. However, the GR (Code: 202412121646008713) presented to the Court states:

"Medical Boards will be established at the institutional level in government medical colleges and hospitals under the Department of Medical Education and Drugs."

Many questions emerge out of this:

• Will passive euthanasia only be permitted in government hospitals?
• What does this mean for non-government hospitals?
• Will such institutions have their own committees?
• Who will constitute them?
• Will government committees visit private hospitals?
• Will government committee be able to visit a patient at any hospital within 48 hours, as directed in the GR?
• How will doctors in these committees be trained in medical, legal, and ethical aspects of withdrawal of care?

These questions remain unanswered. Interestingly, neither the Supreme Court nor the draft guidelines of the Union Government have imposed such restrictions. In fact, the Central guidelines discourage excessive governmental interference.

Conclusion: A Fight Well Begun

The first part of this battle is won—and what a victory it is. As doctors, we understand this issue from both sides: as caregivers and as potential patients. I now appeal to all members of the medical fraternity to:

1. Draft your own Advance Directive and submit it to the custodian.
2. Encourage your patients, especially senior citizens, to do the same. Ensure they keep a copy with family members.
3. In situations that require passive euthanasia, strictly follow the legal protocol.

I am more than willing to assist you pro bono in such matters.
Let us honour the right to die with dignity by ensuring that no patient suffers needlessly, and no doctor acts in fear.
Let us lead this transformation—ethically, legally, and compassionately.

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QUIZ SECTION

Question 1: A patient alleges that a retained sponge was left in abdomen after a cesarean section. What is this an example of?
A) Res ipsa loquitur
B) Informed consent
C) Medical negligence
D) Vicarious liability

Question 2: What is the most important document required for informed consent in OBGYN procedures?
A) Patient's signature on a consent form
B) Detailed medical records of the procedure
C) Witness statement
D) Doctor's explanation of risks and benefits

Question 3: In a case of alleged medical negligence, what is typically required to prove liability?
A) Expert testimony
B) Patient's medical records
C) Witness statements
D) All of the above

Question 4: What is the age of consent under the POCSO Act?
A) 16 years
B) 18 years
C)20 years
D) 21 years

Question 5: What is the punishment for penetrative sexual assault under the POCSO Act?
A) 5-7 years imprisonment
B) 7-10 years imprisonment
C) 10 years-life imprisonment
D) Life imprisonment

Question 6: What is prohibited under the PCPNDT Act?
A) Sex selection
B) Prenatal diagnosis
C) Ultrasound technology
D) All of the above

Question 7: What is the penalty for violating the PCPNDT Act?
A) Rs10, 000 fine
B) Rs 1 lakh fine and/or 3 years imprisonment
C) Rs5 lakh fine and/or 5 years imprisonment
D) Life imprisonment

Question 8: Up to how many weeks can a pregnancy be terminated under the MTP Act?
A) 12 weeks
B) 20 weeks
C)24 weeks
D)28 weeks

Question 9: A 22-year-old unmarried woman, 22 weeks pregnant requests MTP after contraceptive failure.Correct approach?
A. Not permitted
B.Needs court permission
C.Permitted with opinion of 1 RMP
D.Permitted with opinion of 2 RMPs

Question 10: A 26-week pregnant woman with lethal fetal anomaly detected on anomaly scan. What is required ?
A. 2 RMP opinions
B. Court order
C. State medical board opinion
D. Not permitted

Question 11: Who can sign consent for MTP in a mentally sound adult woman?
A.Husband
B.Parents
C.Woman herself
D. Judicial magistrate

Question 12: Which situation allows MTP at any gestational age without Board approval?
A. Rape survivor
B. Severe fetal anomaly
C. Immediate threat to mother's life
D. Contraceptive failure

Question 13: Which statement is TRUE regarding MTP Act 2021?
A.Unmarried women cannot seek MTP for contraceptive failure
B. Court approval is mandatory beyond 24 weeks
C.Privacy and confidentiality of woman must be maintained

D.Husband's consent is compulsory

Question 14: A woman at 21 weeks with divorce finalized after conception seeks MTP. Is it allowed?
A.No
B.Yes, with 1 RMP
C.Yes, with 2 RMPs
D.Only with court order

Question 15: A16-year-old married girl presents pregnant at 10 weeks. Husband is 22 years old. What is the legal obligation of doctor?
A.Maintain confidentiality
B.Inform police only if patient agrees
C.Mandatory reporting under POCSO
D.Refer only to court

Question 16: In the above case, refusal to report is punishable under:
A.IPC312
B.MTP Act
C.POCSO Act
D.CrPC

Question 17: Correct legal steps when a minor pregnant girl presents to OBGYN?
A. Treat only, no documentation
B. Mandatory police intimation + child protection services
C.Refer to court first
D.Ask parents to file FIR

Question 18: Can MTP be done for a minor rape survivor?
A.No
B.Yes, only till 12 weeks
C.Yes, as per MTP Act provisions
D.Only with court order

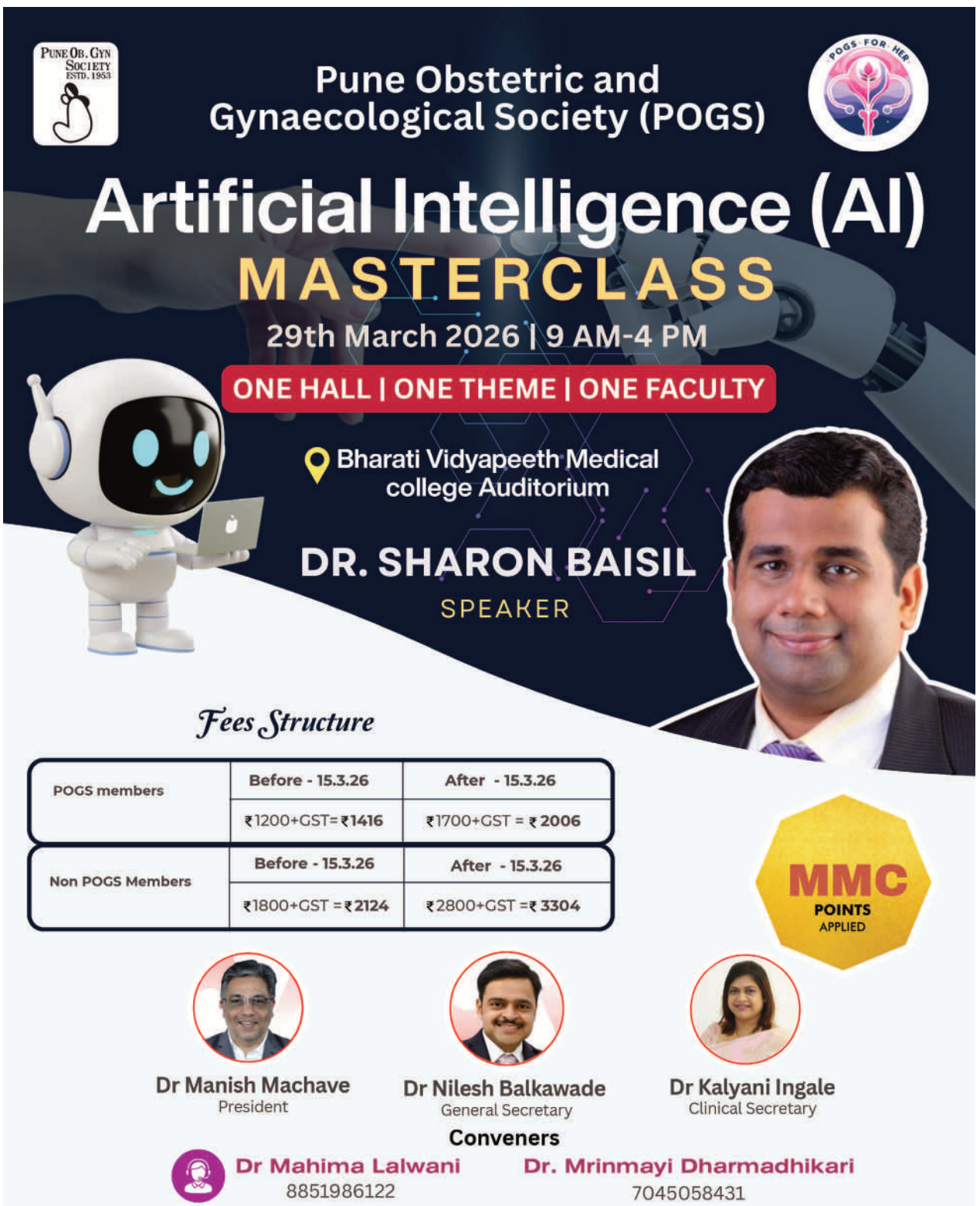
Question 19: One Stop Crisis Centre (OSCC) in India is established under which initiative?
A.National Health Mission
B.Beti Bachao Beti Padhao
C.Nirbhaya Fund
D.National Commission for Women

Question 20: Which of the following services is NOT a function of One Stop Crisis Centre (OSCC)?
A.Medical examination and treatment
B.Police facilitation and FIR registration
C.Legal aid and counselling
D.Issuing judicial orders for MTP

Question 21: A16-year-old married girl presents pregnant at a district hospital. As per best medico-legal practice in India, she should be linked to:
A. Family court
B.State Medical Board
C.Child Adoption Agency
D. One stop crisis centre (OSCC)

Answers on page 35

UPCOMING EVENT



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Vitamin B6 (Pyridoxal-5-phosphate)	2.3mg	100
Vitamin B12 (Cyanocobalamin)	2.45mcg	100
Glycine	10mg	#

*%RDA calculated as per basis ICMR guidelines (pregnant women)
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