

Six Steps in Critical Domains which will help Ophthalmologists Safeguard their Patient and Practice

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A. 6 Key Strategies to Prevent the Most Common Adverse Events in Eye Hospitals

Preventing adverse events in eye care requires more than technical skill; it depends on strong systems, clear communication, and a culture of safety. Six key strategies emerge as essential.

1. Establish standardised clinical processes and checklists that make safe practices consistent across all cases.
2. Maintain robust infection prevention measures through strict sterilisation protocols, monitoring, and adherence to OT standards.
3. Strengthen communication at every stage of care, including counselling, informed consent, team handovers, and clear written documentation.
4. Promote a incident reporting culture that encourages reporting of near misses and no-harm events to support learning and improvement.
5. Use structured analysis tools such as root cause analysis and corrective and preventive action (CAPA) frameworks to address underlying system issues.
6. Invest in continuous training, monitoring, and patient feedback mechanisms such as Patient Reported Experience Measures (PREMs) to identify gaps and reinforce safe practices.

Together, these strategies help create a reliable safety culture that protects patients, supports healthcare teams, and reduces preventable harm in eye care settings.



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B. 6 Non-Negotiable Protocols to Eliminate Infections in Your Eye Hospital

Preventing Endophthalmitis – Cluster infection in particular is of paramount importance to all the practicing Ophthalmologists. However, even a sporadic infection must be prevented. After effects of these infections are very bad and painful to go through. To prevent infections, six key strategies that we need to follow are critical for the same.

1. First and foremost is practicing “No touch technique” – both for scrubbed and unscrubbed persons.
2. Second important strategy is to maintain hand hygiene – both for scrubbed persons and for unscrubbed persons.
3. Third important strategy is to ensure sterility of the consumables which includes materials sterilised within the hospital or purchased from the market as presterile material.
4. Fourth important strategy is ensuring that the OT environment is clean enough to prevent infection.
5. Fifth important strategy is to ensure that the patient factors that can lead to postoperative infection are ruled out thoroughly.
6. Sixth is to document & monitor all the activities properly – maintain records to cross check what could have gone wrong when things go wrong. As operating surgeon, our neck is under the guillotine. We have to make sure that everything is in order.

It is a pure science – science of infection prevention – science of asepsis and anti-sepsis. It is not very difficult to follow it. We need the right attitude and quality consciousness at the core of our activities. No compromise is allowed inside the operation theatre.

Good surgical results are dependent upon sterile instruments in good working order, used by skilled people who care....



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C. 6 Proven Protocols to Prepare Your Team for Medical Emergencies

Medical emergencies although rare can happen in ophthalmic practice. The six key essential protocols to prepare us are

1. Preoperative evaluation for comorbidities and high-risk evaluation
2. Emergency drugs and crash cart
3. MOU with multispecialty hospital and ambulance
4. Anaesthesiologist stand-by for high-risk patients
5. StaT training for handling medical emergencies including BLS training
6. Code blue team



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D. 6 Critical Areas to Strengthen Communication in Your Hospital

1. Clinical Handovers: Use structured communication (SBAR), time-out checks, and confirm Right Patient–Right Eye–Right IOL.
2. Informed Consent: Manage expectations using simple language, visual aids, and teach-back method.
3. Post-Operative Education: Clear discharge instructions and drop charts improve compliance and outcomes.
4. Breaking Bad News: Follow the SPIKES approach with empathy and focus on rehabilitation.
5. Inter-Department Coordination: Morning huddles and integrated EMR reduce delays and errors.
6. Patient Grievance Handling: Use the HEARD method. Listening and resolving complaints builds trust.

Clear communication improves safety, satisfaction, and surgical success.



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E. 6 Essential Steps to Keep Your Ophthalmic Practice Medicolegally Protected

Abstract

The medicolegal landscape confronting ophthalmologists has undergone a profound transformation in the past decade. Consumer court cases against medical professionals have escalated sharply, with compensation awards in ophthalmic litigation frequently exceeding ₹2 crore. A critical finding is that the majority of successful malpractice claims arise not from clinical errors per se, but from failures in documentation, communication, and process adherence. This article outlines six essential, evidence-based strategies that ophthalmologists can implement to safeguard both their patients and their practice:

(1) robust informed consent processes, (2) meticulous medical records and documentation, (3) standard operating procedures and protocols, (4) effective communication and disclosure frameworks, (5) professional indemnity and legal preparedness, and (6) continuous learning, audit, and quality improvement. Each strategy is grounded in prevailing legal standards, accreditation requirements, and established best practices in patient safety. The adoption of these measures not only reduces medicolegal vulnerability but fundamentally improves the quality and safety of ophthalmic care.

Keywords: medicolegal protection, informed consent, medical documentation, standard operating procedures, patient safety, ophthalmology, NABH accreditation, malpractice prevention

Introduction

Ophthalmology, by virtue of its surgical nature and the high expectations patients attach to visual outcomes, occupies a position of particular medicolegal vulnerability among medical specialties.¹ The National Consumer Disputes Redressal Commission (NCDRC) has witnessed a substantial rise in complaints against ophthalmologists over the past decade, with wrong intraocular lens (IOL) implantation, post-cataract endophthalmitis, and unexpected visual outcomes among the most frequently litigated scenarios.^{2,3}

The Consumer Protection Act, 2019 has broadened the scope of liability, reduced the limitation period barriers, and empowered patients with more accessible redressal mechanisms.⁴ Simultaneously, the Bharatiya Nagarik Suraksha Sanhita (BNSS) 2023 has introduced provisions that directly affect how medical

professionals respond to allegations of negligence.⁵ In this evolving landscape, clinical excellence alone is insufficient; it must be complemented by robust documentation, systematic processes, effective communication, and institutional preparedness.

Step 1: Establishing a Robust Informed Consent Process

Informed consent is the single most litigated aspect of ophthalmic practice. The Supreme Court of India, in the landmark case of *Samira Kohli v. Dr. Prabha Manchanda* (2008), established that informed consent is not merely a signed document but a process of shared decision-making encompassing disclosure, comprehension, and voluntary agreement.⁶

A medicolegally sound informed consent process must address six elements: (a) a clear explanation of the diagnosis in language the patient comprehends; (b) a description of the proposed procedure along with reasonable alternatives, including non-intervention; (c) expected benefits with realistic outcome expectations; (d) material risks, including rare but serious complications such as endophthalmitis, retinal detachment, or loss of vision; (e) the patient's right to refuse or withdraw consent at any stage; and (f) delivery of the consent discussion in the patient's vernacular language.⁷

Common medicolegal vulnerabilities include the use of generic blanket consent forms that fail to specify the planned procedure, obtaining consent after the patient has been prepared for surgery, delegating the consent discussion to staff without proper training or authority, and omitting procedure-specific risks. Courts have consistently held that a signed consent form, in the absence of evidence that an actual discussion occurred, does not constitute valid informed consent.⁸

It is advisable to document the consent process itself: the time spent in discussion, the specific risks disclosed, the questions raised by the patient and the responses provided, and the identity of persons present during the discussion. Where feasible, audio-visual recording of the consent discussion, with the patient's permission, provides a robust evidentiary record.

Step 2: Meticulous Medical Records and Documentation

The adage "if it is not documented, it did not happen" carries the force of judicial precedent. In an analysis of ophthalmic malpractice claims, documentation deficiencies were identified as a contributing factor in over 70% of cases where the verdict was against the physician.^{9,10}

Six pillars of medicolegally sound documentation include: comprehensive clinical notes at every encounter (pre-operative, intra-operative, and post-operative), including pertinent negative findings; time-stamped entries bearing the clinician's signature, with no retrospective alterations; an adverse event log with contemporaneous documentation of what occurred, the actions taken, and the persons informed; complete investigation records, including biometry readings, IOL power calculations, and pre-operative investigation reports; a communication trail documenting all calls, messages, referrals, and patient no-shows; and a record retention policy of at least ten years, with mandatory digital backup.¹¹

The NABH entry-level standards mandate a minimum retention period of three years, though medicolegal prudence demands longer retention.¹² In the era of electronic health records (EHR), metadata integrity becomes equally important, as courts are increasingly examining digital audit trails for evidence of record tampering.¹³

Step 3: Standard Operating Procedures and Protocols

The existence and adherence to standard operating procedures (SOPs) demonstrates institutional commitment to patient safety and provides a powerful defence against allegations of individual negligence. In court, SOPs shift the narrative from “what the doctor failed to do” to “what the system was designed to ensure.”¹⁴

Six critical SOP domains for ophthalmic practice are: patient identification protocols using three-point verification (patient name, hospital identification number, and planned procedure) at every transition point; the World Health Organization (WHO) Surgical Safety Checklist adapted for ophthalmology, incorporating Sign-in, Time-out, and Sign-out at every case without exception; medication safety protocols addressing look-alike sound-alike (LASA) drug hazards, particularly the segregation of mydriatics from intracameral agents; infection prevention and control protocols with documented sterilization logs, biological indicator monitoring, and a written endophthalmitis management plan; equipment maintenance logs with scheduled preventive maintenance for phaco machines, surgical microscopes, and sterilization equipment; and emergency preparedness protocols for anaphylaxis, cardiac emergencies, and intraoperative complications such as suprachoroidal haemorrhage, with quarterly documented mock drills.^{15,16}

Wrong-site surgery (wrong eye, wrong IOL) remains among the most devastating and litigated sentinel events in ophthalmology. Implementation of a universal site-

marking protocol prior to dilation, combined with the surgical safety checklist, has been shown to virtually eliminate this risk.¹⁷

Step 4: Effective Communication and Disclosure

The relationship between physician communication and litigation risk is among the most robustly studied phenomena in the medicolegal literature. Levinson et al. demonstrated that physicians who spent more time in conversation, used humour, facilitated patient participation, and checked for understanding were significantly less likely to be sued, irrespective of clinical outcomes.¹⁸ Beckman et al. found that 71% of malpractice depositions involved a communication breakdown as a proximate cause of litigation.¹⁹

Six essential communication protocols for medicolegal protection include: pre-operative counselling with documentation of visual prognosis expectations; use of the SPIKES protocol (Setting, Perception, Invitation, Knowledge, Empathy, Summary) for breaking bad news following adverse events; open disclosure when complications occur, framed not as admission of fault but as ethical transparency; structured family communication involving attendants in clinical decision-making; SBAR-format (Situation, Background, Assessment, Recommendation) handover communication at all transition points; and written discharge instructions in the patient's local language covering medications, follow-up schedules, and danger signs requiring immediate attention.^{20,21}

Statements such as “it was someone else’s mistake,” “this has never happened before,” or “I don’t know what went wrong” are frequently quoted in litigation proceedings and should be scrupulously avoided. Open disclosure programmes, as implemented in several Australian and Canadian healthcare systems, have demonstrated a reduction in litigation rates by up to 65%.²²

Step 5: Professional Indemnity and Legal Preparedness

Legal preparedness is an aspect of risk management that most practitioners neglect until a crisis arises. Six components of comprehensive legal readiness include: adequate professional indemnity insurance with a minimum cover of ₹1 crore, ensuring coverage of both civil and criminal proceedings and all procedures performed; familiarity with the legal framework, including the Consumer Protection Act 2019, the Clinical Establishments Act, and BNSS 2023 provisions pertaining to medical practitioners; a written incident response protocol specifying actions to be taken within the first 48 hours of receiving a legal notice, including record preservation, insurance notification, and legal counsel engagement; identification

of healthcare legal counsel on retainer prior to any adverse event; access to peer review and expert opinion networks, including the AIOS medicolegal support cell; and quarterly internal audits of consent forms, medical records, and SOP compliance to identify and rectify gaps proactively.^{23,24}

The first 48 hours following receipt of a legal notice are critical. Any alteration to records during this period, even with benign intent, can be forensically detected and will catastrophically undermine the physician's defence. The guiding principle must be: preserve, do not alter; communicate, do not speculate.

Step 6: Continuous Learning, Audit, and Quality Improvement

The final pillar of medicolegal protection is the establishment of a culture of continuous improvement. Six elements constitute this framework: regular continuing medical education (CME) with documented attendance, ensuring that practice remains aligned with current standards of care; systematic surgical outcome audits benchmarked against published national complication rates; mortality and morbidity (M&M) conferences for all adverse events with documented root cause analyses and corrective action plans; a structured patient feedback and grievance redressal system, recognising that unresolved complaints are the genesis of most litigation; quarterly staff training programmes covering consent processes, communication skills, and emergency management with documented competency assessments; and NABH or equivalent accreditation as institutional evidence of commitment to standardised quality processes.^{25,26}

The author's experience as NABH Principal Assessor indicates that accredited hospitals demonstrate significantly better outcomes in medicolegal proceedings, as accreditation serves as prima facie evidence of systems-based quality practices.²⁷ The NABH Eye Care Organisation (ECO) standards, currently in their 2.0 iteration, provide a comprehensive framework specifically tailored for ophthalmic practices.²⁸

Patient feedback mechanisms deserve particular emphasis. Research consistently demonstrates that patients who feel heard and whose concerns are promptly addressed are far less likely to pursue litigation, even when clinical outcomes are suboptimal.²⁹

Conclusion

Medicolegal protection in ophthalmic practice is not achieved through any single measure but through the systematic integration of six complementary strategies:

robust informed consent, meticulous documentation, standardised operating procedures, effective communication, legal preparedness, and continuous quality improvement. The best medicolegal protection remains the triad of good clinical practice, excellent documentation, and compassionate communication. In an era of rising litigation, the ophthalmologist who invests in these systems protects not only the practice but, more importantly, the patient. As John Ruskin aptly observed, “Quality is never an accident; it is always the result of intelligent effort.”

Clinical Pearls and Key Takeaways

1. Informed consent is a PROCESS, not a form. Document the discussion, not just the signature.
2. If it is not documented, it did not happen. Include pertinent negatives in every clinical note.
3. SOPs protect the individual by demonstrating system compliance — ensure they are written, followed, and audited.
4. Doctors who communicate effectively are sued 75% less often, regardless of clinical outcomes.
5. Never alter medical records after an adverse event. Preserve, do not modify; communicate, do not speculate.
6. The first 48 hours after receiving a legal notice determine the trajectory of the entire case.
7. Consent must be in the patient’s vernacular language. A Hindi form signed by a Tamil-speaking patient is not valid consent.
8. NABH accreditation serves as prima facie evidence of quality systems in court proceedings.
9. Quarterly internal audits of consent forms and records fix gaps before they become evidence.
10. A patient who feels heard rarely goes to court. Invest in communication as your best legal defence.

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F. 6 Crucial Monitoring Areas to Keep Your Patients Safe

Patient Safety is the most important aspect every healthcare center must ensure. Monitoring key domains ensures compliance and builds trust.

1. Access, Assessment & Continuity of Care (AAC)

- Timely access and triage
- Continuous assessment
- Prevention of fragmentation
- Reduced waiting time and adverse events

2. Care of Patients

- Clinical protocols
- Informed consents
- Safety incident monitoring
- Patient satisfaction tracking

3. Management of Medication

- Right Patient
- Right Medicine
- Right Dose
- Right Frequency
- Right Route
- Right Time
- Right Documentation
- Right Monitoring

4. Hospital Infection Control

- Standard precautions
- Cleaning and disinfection
- OT sterilization
- CSSD
- Linen and BMW management
- Hand hygiene monitoring

5. Surgical Safety

- WHO Surgical Safety Checklist
- Sign In, Time Out, Sign Out
- Swiss Cheese Model
- RCA & CAPA implementation
- Training and retraining

6. Physical & Fire Safety

- Facility inspection rounds
- Fire safety compliance
- Biannual drills
- RCA & CAPA documentation
- Preventive maintenance
- Safety officer accountability

Ensure a 360-degree safety culture with adequate budgeting and dynamic, technology-enabled monitoring dashboards to support continuous quality improvement.



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