KARNATAKA STATE OBSTETRICS AND GYNECOLOGY ASSOCIATION
ETHICS AND MEDICOLEGAL COMMITTEE

# MEDICOLEGAL BULLETIN

**Week30:Surgical Specimen Mislabeling and Lost Histopathology: When a Laboratory Error Becomes a Gynecologist's Legal Problem**

## 1.REAL LIFE CASE SCENARIO( ILLUSTRATIVE )

A 42-year-old woman undergoes laparoscopic hysterectomy for abnormal uterine bleeding. The uterus is sent for histopathological examination (HPE). Six weeks later, she returns with persistent symptoms; the pathology report cannot be traced. The operating surgeon discovers that the specimen container carried an incomplete identifier and the laboratory has no reliable record of receipt.
The patient asks: "Was my specimen tested? What if there was an unexpected cancer?"
The immediate issue is not only who misplaced the tissue, but whether a safe specimen-identification, transfer, result-tracking and patient-notification system existed.

## 2.MEDICOLEGAL RISKS IN SUCH CASES

Wrong-patient or wrong-site specimen labeling may lead to an incorrect diagnosis, unnecessary treatment or a missed malignancy. A lost or unprocessed specimen can make definitive diagnosis impossible.
Potential allegations include negligent identification or handling, failure to communicate an important result, delayed cancer diagnosis, inadequate documentation and lack of a reliable follow-up system. Responsibility may be shared among the surgeon, theatre team, hospital and laboratory depending on the facts; a laboratory mistake does not automatically absolve or implicate the surgeon

## 3. WHAT THE LAW AND PROFESSIONAL STANDARD EXPECTS

Indian negligence assessment is fact-specific: whether the professional acted with reasonable skill and care in the circumstances, whether there was a breach, and whether that breach caused compensable harm. An adverse outcome alone is not proof of negligence.
Key legal principles: Jacob Mathew v. State of Punjab (2005) distinguishes civil negligence from the higher threshold for criminal medical negligence; Kusum Sharma v. Batra Hospital (2010) discusses the standard of reasonable professional care. Neither judgment creates a special automatic liability rule for lost histopathology.
The practical standard is a dependable system that links the right specimen to the right patient, confirms laboratory receipt, tracks pending reports, reviews significant results and communicates them promptly.

## 4. DOCUMENTATION – THE DOCTOR'S STRONGEST DEFENSE

Record the operation, organs/tissues removed, specimen site and laterality where applicable, whether separate specimens were submitted, and any intraoperative concern for malignancy.
Use at least two independent patient identifiers on the container and requisition according to institutional policy; include specimen description, anatomical site, laterality, date/time, relevant clinical history and the requesting clinician.
Do not rely on bed number alone.
Document handover and laboratory accession/receipt, the expected report-review process, the result itself, clinical interpretation, patient communication and any referral or further investigation. Preserve an audit trail when correcting a genuin labeling error; never silently relabel or backdate records.

## 5. PRACTICAL SAFE PRACTICE – WHAT TO DO

Before the specimen leaves theatre: the operating surgeon and circulating nurse should verify aloud patient identity, exact tissue/site and laterality against the container and request. Label the container at the point of collection, not later in a batch.

For multiple specimens, use separate clearly labeled containers; avoid ambiguous labels such as “mass” or “tissue.” Document whether tissue is sent fresh or in fixative, and follow pathology instructions for suspected malignancy, frozen section and special studies.

Create a pending-HPE register or electronic work queue with assigned ownership and escalation for overdue reports. Review all results, particularly unexpected malignancy, dysplasia, positive margins or discordant findings. Communicate actionable results directly and record the communication.

In low-resource settings, a numbered paper specimen dispatch register with date/time, patient identifiers, specimen, receiver’s signature, report due date and closure signature is preferable to an informal verbal handover.

## 6. IF THE SPECIMEN IS MISSING OR MISLABELED

•Act immediately: inform the pathology lead, operating consultant and hospital quality/incident team. Quarantine potentially affected specimens and reports pending reconciliation; do not guess identity or issue a speculative report.

Preserve the container, labels, requisitions, theatre records, accession logs and relevant communications. Investigate traceability without altering original entries. If a report has already been issued in error, coordinate a formal corrected report and notification process.

Explain the confirmed facts to the patient promptly, acknowledge uncertainty, document disclosure and arrange a clinically appropriate plan. Options may include review of imaging/operative findings, retrieval of tissue blocks or slides if available, expert pathology review, surveillance or further diagnostic procedures only when justified. Do not subject a patient to repeat surgery merely to repair paperwork.

## 7.COMMON MISTAKES TO AVOID

- Labeling specimen containers after the procedure rather than at collection.
- Using only the patient’s name or ward/bed number.
- Omitting site/laterality for paired organs or separate lesions.
- Assuming “the laboratory will call if abnormal.”
- Filing a report without clinician review or patient communication.
- Treating an unexpected cancer report as routine.
- Silently replacing labels or retrospectively changing records.
- Blaming another department before investigating the chain of events.

## 8.CLINICAL–LEGAL PEARL / COURT INSIGHT

Histopathology is not complete when the tissue leaves the operation theatre. The diagnostic pathway closes only when the specimen is reliably identified, the report is reviewed, and clinically important findings are acted upon.Indian Supreme Court decisions such as Jacob Mathew and Kusum Sharma support fact-specific assessment of reasonable professional care; they should not be cited as if they specifically adjudicated specimen mislabeling. A defensible process needs traceability, timely response and honest disclosure.

**9.TAKE-HOME MESSAGE**

• Identify → Label at source → Verify → Transfer with traceability → Track → Review → Communicate → Act.

The safest medicolegal defense is not a disclaimer saying "laboratory responsibility." It is a reliable shared system that prevents errors, detects them early and protects patients when something goes wrong.

**References and further reading**

Jacob Mathew v. State of Punjab & Anr., (2005) 6 SCC 1 (Supreme Court of India).

Kusum Sharma & Ors. v. Batra Hospital & Medical Research Centre & Ors., (2010) 3 SCC 480 (Supreme Court of India).

WHO. Surgical Safety Checklist and Implementation Manual (2009): specimen labeling as part of sign-out.

College of American Pathologists: laboratory accreditation principles for specimen identification and tracking (institutional protocols should govern local implementation).

**Next Week's Topic (Week 31): Missed or Delayed Follow-Up of an Abnormal Endometrial Biopsy – Cancer Diagnosis and Medicolegal Accountability**

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