Biomedical Consulting Services

INVESTIGATION AND LITIGATION OF MEDICAL INJURIES

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1. The steps in an injury investigation
   a. Discovery of injury
   b. Reporting
   c. Documenting
   d. Sequestering
   e. Inspection and testing
   f. Event analysis
2. Discovery of Injury
   a. Staff observation (e.g. Post-op ESU burn)
   b. Patient symptoms
   c. Patient complaint
   d. Delayed reports
   e. Complaints by others (e.g. patient relatives, attorney)
3. Reporting Routes
   a. Verbal report to department manager/supervisor where injury occurred
   b. Written confidential report to risk manager or administrator
   c. Word of mouth to manufacturer representative
   d. MDR reports to manufacturer and/or FDA as required by Safe Medical Devices Act
   e. Reports to manufacturer's Regulatory Affairs department
   f. Patient complaint to M.D. at follow-up visit
   g. Third person (friend/relative) complaint to provider, manufacturer or FDA
   h. Litigation notice to manufacturer or provider
4. Documentation Methods
   a. Chart entries
   b. Physician/surgeon notes/reports
   c. Photography (injuries, wounds, burns)
   d. Diagnostic imaging
   e. Documentation of settings, dosages, etc. immediately upon discovery
5. The Sequestering Process
   a. Document item and associated supplies
      i. Item name
      ii. Manufacturer
      iii. Model, Part or Catalog number
      iv. Serial or lot number
      v. Expiration date (if applicable)
      vi. User identifications (property tag number, inventory number, tracking number)
   b. Remove item from use immediately

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c. Don’t change settings
d. Don’t allow staff to do checks until authorized
e. Save associated supplies and accessories used
f. Don’t clean items (ex. Blood and tissue rinsing)
g. Protect from changes In condition
h. Notify staff that the item is being investigated
    I. Label it!
    ii. Wrap and seal if feasible
i. Sequester item
    i. Store in a locked storage area
    ii. Control access (e.g. lab sample discarded in routine purging of specimens)
    iii. Do not release until all inspections/evaluations completed by all concerned.
    iv. Document chain of custody
j. Other considerations
    i. Spoliation of evidence
    ii. Provisions for transporting to test/inspection sites
    iii. Battery charging
    iv. Fluid evaporation
    v. Biologic spoilage, degradation
    vi. Rental or consignment of replacement equipment

6. Inspection and testing considerations
    a. Destructive vs. non-destructive testing
    b. Qualifications of inspector or test facility
        i. Staff training
        ii. Equipment and facilities
    c. Spoliation of evidence considerations
        i. Sampling
        ii. Destructive testing
        iii. Loss of memory contents
        iv. Failure during testing
        v. Damage during autopsy
    d. In house testing vs. outside service or expert
        I. Do not use manufacturer if possible
        ii. Service contractor conflict of interest
        iii. Monitoring of manufacturer testing where necessary
        iv. In house staff satisfactory for minor events, low probability of litigation
        v. Best to use neutral third party expert for major events, high probability of litigation or action already filed
    e. Need to expedite agreements on testing
    f. Determine standards to be used in testing
    g. Approval of test protocols
    h. Agreement on fee payments for outside services
    i. Observation by qualified representatives of involved parties
    j. Useable documentation of results
        i. Readable printouts and notes
        ii. Measurement conversions
        iii. Graphical and tabular presentations
        iv. Photographic documentation
7. Analysis
    a. Is it really an injury? (e.g. external causes, pre-existing conditions)

b. Test evaluations
c. Staff interviews
d. Medical record and accident report reviews
e. Performance vs. known effects, complications, contraindications
f. Product failure vs. patient anomalies vs. user error (soft palate burn case)

8. Final Report
   a. Summary of event
   b. Identification of item involved
   c. Inspection results (Include photograph copies)
   d. Test results
   e. Observations
   f. Conclusions

9. Litigation considerations - See Flow Sheet
   a. Involvement
      i. Estimated frequency of major event in community hospital - I every 3-5 years (higher for larger, specialty, university hospitals)
      ii. Chances of your paperwork or reports being reviewed - 90%
      iii. Chances of you being interviewed by hospital risk manager/attorney - 50% +
      iv. Chances of you being deposed - 5%
      v. Chances of you testifying at trial -2%
   b. Secure all documentation - legally protected from discovery by opposing side
   c. Participate in legal investigation
   d. Refer all outside parties to attorney or risk manager
      I. Physicians
      ii. Manufacturer reps
      iii. Investigators
      iv. FDA staff
      v. Attorneys
      vi. Experts
   e. Do not discuss event or investigation with others - will be brought out by opposing side
   f. Confidential meetings with risk manager, attorney, administration - work product
   g. What if you are deposed?
      i. Gather and review all documentation
      ii. Meet with risk manager and attorney to review
      iii. Preparation meeting with attorney
      iv. Rest the night before - no alcohol!
      v. You are the star - settle in and relax (???) before starting
      vi. Average time = 2-4 hours
      vii. Have water, soda, etc. available
      viii. Speak up! - Don't mumble or turn away
      ix. Think about the questions - pause before answering
      x. Wait until the attorney is finished asking question - don't jump
      xi. Minimize answers - Yes/No - don't editorialize
      xii. Stop at objections, follow your attorney's instructions
      xiii. You are a percipient (fact) witness - do not express opinions!
      xiv. Don't let opposing counsel trap you
      xv. Don't speculate - it will wreck your credibility
      xvi. Ask for breaks, conferences with attorney
      xvii. Break opposing counsel's rhythm - ask a question be repeated
      xviii. Have lunch! (The attorney should buy!)

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LITIGATION FLOW CHART

Patient Injury Occurs
/
Reported to Risk Management
/
Patient/Relatives Advised
/
Internal Investigation
/
Injured Party Decision to Seek Counsel
/
Plaintiff Counsel Review of Merits
/
Plaintiff Counsel Decision to Pursue
/
Filing of Complaint
/
Defendants Advised of Allegations
/
Interrogatonies
/
Request for Production of Documents
/
Retention of Experts
/
Expert Reviews
/
Testing and Inspection of Device(s)
/
Expert Reports
/
Percipient Witness Depositions
/
Expert Witness Depositions
/
Settlement Negotiations
/
Mediation~ Arbitration
/
Trial Testimony
/
Jury Verdict

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