OB/GYN and Medical Malpractice Litigation

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“Carrying a deep pocket is tempting to a public that has access to pickpockets for hire.”

Constance Uribe, M.D.


Disclaimer

- This talk provides only general legal information
- Laws change frequently and they can be interpreted differently by different people
- For specific advice geared to a specific situation, consult a knowledgeable, properly licensed lawyer in your jurisdiction
- Neither I nor my spouse have any relevant financial relationships with any commercial interests
Objectives

- List the common lawsuits that OB/GYN providers are involved in
- Review competent documentation
- Tips on communicating adverse events
- Informed consent elements
- Note cultural differences in communication
- Highlight electronic medical record issues
- Awareness of “emerging” areas of litigation

General Medical Malpractice

- Medical office > hospital based lawsuits
  - Many allege a failure to or delay in diagnosis
    - Of those, cancer most frequent
- OB/GYNs
  - Sued on average, every 4 years¹
  - 69% had been sued²
  - Over 50% had been sued 2+ times²
  - By age 40, more than 50% have been sued²


General Medical Malpractice

- Many claims do not involve any malpractice
  - National study reviewed 1452 closed malpractice claims
    - 37% involved no errors
    - Yet, 1 in 4 resulted in a patient payment
    - 3% no identifiable medical injury
    - 60% of plaintiffs were women
    - 19% newborns
    - Median plaintiff age 38
    - ≤ 1% alleged only a lack of consent issue
    - OB/GYNs most frequently sued physicians (19%)

At trial, physicians “win” 50% of time even when there is strong evidence of medical negligence.

1. True
2. False

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General Medical Malpractice

National jury experience:
- Physicians prevail approximately
  - 80-90% of time where weak evidence of negligence
  - But lose 10-20% of these as well....
  - 70% of time where 50/50 evidence of negligence
  - 50% of time where strong evidence of negligence


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ACOG’s OB Med Mal Issues

- Obstetrical claims
  - 31% Neurologically impaired infant
  - 16% Stillbirth or neonatal death

- Other primary factors
  - 23% Fetal monitoring
  - 17% Shoulder dystocia/BP injury
  - 16% Resident care

ACOG’s GYN Med Mal Issues

Gynecology claims
- Major patient injury (27%)
- Delay in or failure to diagnose (24%)
  - Cancer (54%)
    - Breast/cervical/uterine/ovarian
  - Other (46%)
    - Reproductive/GI/Urology

American College of Obstetrics and Gynecology. 2009 professional liability survey. Available at: www.acog.org

Hospital Corporation of America’s OB Medical Malpractice Issues

Areas identified as at increased risk for an adverse outcome and litigation:
- If one of these medications used
  - Oxytocin, misoprostol or magnesium
- Operative vaginal deliveries
- Management of shoulder dystocia
- Abnormal FHTs


My List of OB/GYN Med Mal Issues

OB
- Prenatal
  - Ultrasound follow up
- L&D
  - Shoulder dystocia
  - FHT/Delay in delivery
  - VBAC
- Post delivery
  - Post partum hemorrhage
  - Retained foreign body
  - Circumcision

GYN
- Surgical Complication
  - Injury to adjacent organs
  - Bleeding
  - Infection
  - Retained foreign body
- Delay/failure to dx
  - Cancer
  - Breast
  - Ectopic
  - Failed sterilization
Shoulder Dystocia Case

- 29 yo gravida 3, para 2
  - Ultrasound 1 week prior EFW 3900gm
    - Mother expresses concern about size of baby
  - Old charts document 2 large babies
    - Unclear as to any problems
    - Not obtained or reviewed
  - Excessive weight gain?
    - 5'6" from 195 (BMI 31.5) to 230 (BMI 37.1)
  - Post dates? 41+ weeks
  - EFW by L&D triage nurse of 3000gm
    - No reference to earlier US EFW

Management:

1. Perform elective C section
2. Trial of labor

L&D

- Prolonged second stage?
  - Labor pattern not well established
- Poor delivery note
  - No documentation of call for assistance, time from delivery of head to delivery of fetus, or order of maneuvers
  - (Excessive) Downward traction vs. guidance of head
- Delivery video
  - Who is in charge?
    - Panic/Yelling/Disorganized
    - Fundal vs. Suprapubic pressure
  - FW 4650gm
Shoulder Dystocia

Common allegations
- Failure to assess or to accurately predict
- Application of fundal pressure
- Excessive downward traction
- Failure to institute corrective measures
- Failure to perform C section
- Delay in call for assistance

Recommendations
- Early call for help
- Avoid excessive traction and fundal pressure
- Provide emergent care as needed
- Document events, interventions and time between delivery of head and body
- Standard form
- If suprapubic pressure used, note it to avoid later allegation of fundal pressure

Retained Foreign Body Case

Significant risk factors for unintentionally retained foreign body:
1. Duration of surgery
2. Unexpected change in type or extent of surgery
3. Hour surgery performed
4. All of the above
Retained Foreign Body Case

- 45 yo for exploratory laparoscopy by OBGYN, but ends up with general surgeon doing an appendectomy
- Office follow up by surgeon, not OBGYN
  - CT obtained for persistent abdominal pain
    - Pessary or diaphragm identified by radiologist
- 3 months later seen for Pap smear and reports recent increase in pelvic pain
  - Uterine manipulator cap found and removed

Retained Foreign Body Case

- CT obtained for persistent abdominal pain
  - Pessary or diaphragm identified by radiologist

Retained Foreign Body

- Common allegation
  - Failure to perform counts
  - Failure to diagnose afterward
- Recommendations
  - Recognize high risk situations
    - Emergency surgery
    - Unexpected change in type, extent or nature of surgery
    - Obese patient
  - Assure counts correct
  - Imaging if question
  - Medical device parts

VBAC Case

➤ 29 yo gravida 2 para 1 “desires” VBAC
- Providers planned to get prior C section records but never obtained
- Poor documentation of VBAC informed consent discussion
  • No signed consent form
- Admitted for induction b/o non-reactive non-stress test

VBAC Case

➤ Misoprostol use in VBAC situation:
  1. Contraindicated
  2. If given, must do C section
  3. If given, must disclose to patient
  4. All of the above

VBAC Case

➤ On L&D
- Admitted by 1st year FP and 2nd year OB resident
  • OB never talked to or examined patient
  • VBAC status not clearly identified
- Patient put far away from “C section” rooms
- Misoprostol ordered and given
  • When identified decide trial of labor
  • Patient not informed if at increased risk
- Pitocin ordered
  • Not clear how high a dose
  • Not documented if stopped w/ FHT showing hyperstimulation
- Prompt recognition of rupture?
- Delay in neonatal response/resuscitation?
Vaginal Birth After C Section (VBAC)

- **Common allegations**
  - Failure to fully inform
  - Use of prostaglandins
  - Excessive oxytocin
  - Failure to recognize and treat rupture in timely manner
  - Failure to have appropriate equipment and personnel “immediately available”

- **Recommendations**
  - Document informed consent discussion
  - Follow ACOG recommendations for appropriate candidates
  - Avoid prostaglandins and excessive use of oxytocin
  - Have full surgical team in house and ready
  - Simulation practice

FHTs

1. Pseudosinusoidal pattern
2. True sinusoidal pattern
3. Unable to diagnose from tracing

Fetal Heart Rate Patterns

- **Common allegations**
  - Failure to assess deteriorating fetal condition
  - Failure to appropriately treat
  - Failure of nurse to communicate to provider
  - Failure of provider to respond appropriately

- **Recommendations**
  - Adopt and use common terminology
  - Establish FHT educational programs
  - Document fetal well being during labor
  - Establish intervention protocols
  - Encourage open communication
  - SBAR
30 Minute “Rule”

- **Common allegations**
  - Failure to start C section in a timely manner
    - 30 minutes – decision to incision
  - Some situations require quicker response
    - VBAC with uterine rupture

- **Recommendations**
  - Ensure emergency C sections can be started within 30 minutes of decision
  - Appropriately transfer high risk patients
  - Practice
    - Simulation
    - Early anesthesia involvement

High Risk Pregnancies Pointers

- **Pre Delivery**
  - Thorough history
    - Get prior medical records
  - Appropriate clinical evaluations/testing
  - Informed consent driven by risk factors
  - Communicate with covering physician(s)
  - Predetermined plan
    - Anticipate problems, prepare accordingly and react promptly

- **Post Delivery**
  - Obtain cord gases
    - More likely to help defend care than hurt
  - Consider sending placenta for pathology exam
  - Appropriate delivery note
    - Clinical information/decision making rationale
    - Calls for assistance/consultation(s)
    - Interventions/responses
    - Birth weight, Apgar scores, cord pH/deficit, complications
      - Consistency with other providers
    - Timely
      - Late notes seen as self-serving and biased

Adverse or Unanticipated Outcome

- If adverse or unanticipated outcome
  - Notify Risk Management/insurance carrier
  - Coordinate communications
    - Within Kaiser Permanente, Healthcare Ombudsman Mediator/Situation Management Team assistance
  - Prepare beforehand
    - Patients want:
      - Statement of empathy/sympathy
      - Different from admission of liability
      - Explanation of what happened
      - Don’t guess, speculate or blame
      - Assurance will not happen to others
      - Financial compensation

Hospital Corporation of America’s Response To Med Mal Environment

- Established specific protocols
  - Checklists commonly used
- Documentation templates
  - Standardized delivery note for shoulder dystocia
- Developed education modules
- Provide 24 hour in house OB coverage
- Effective local and national peer review
  - When identified, offer concrete recommendations

Medical Malpractice

- Issues for all specialties:
  - Test ordering/follow up
  - Failure to or delay in diagnosis
  - Communication with patient, nurses and/or other providers
  - Complications
    - Typically, it is not the complication but the delay in diagnosing and treating that results in litigation
  - Altering your clinical practice to accommodate patient request or patient’s schedule
    - Reasonable medically?
  - Informed consent
    - Uncommon by itself; usually raised together with a “bad” outcome
Failure/Delay in Diagnosis

- Common allegations
  - Failure or delay in diagnosis led to delayed or improper treatment
    - Cancers
    - Ectopic

- Recommendations
  - Use of protocols and guides
  - Follow complaint to a full diagnosis
  - Note rationale
  - Expand differential
  - Timely consultation/referral
  - Person to person communication
  - Eliminate “No news is good news”


Surgical Complication Case

- 51 yo for TVT, bladder suspension, cystoscopy and cystocele repair
  - Op note unclear as to repair of bladder injury and whether or not second cystoscopy performed
- Discharged home next day by on-call OBGYN
  - Post operative course some spasm
  - Seen at 10 (assistant surgeon) for “leakage”
    - No fistula

Surgical Complication Case

- Patient admitted one week later for SOB to IM; treated for PE
  - OB/GYN surgeon seeks patient for “leakage”
    - Orders IVP
    - Patient discharged without IVP results being reviewed
    - Shows hydronephrosis
  - Post surgery, both Urologist and OB/GYN surgeon document in medical record “an obstructing suture”
  - Cause of obstruction never clearly identified

- Patient admitted about one week later for fever/chills/back pain
  - CT/KUB shows increased hydronephrosis
  - Treated by Urology
Surgical Complication Case

- Responsibility for following up on the IVP was on the:
  1. Ordering (OB/GYN) physician
  2. Hospitalist
  3. Radiologist
  4. Nurse
  5. On call physician
  6. All of the above

Informed Consent

- In California, informed consent:
  1. Must be done by the treating provider
  2. Is non delegable
  3. Must disclose conflicts of interest
  4. Must be done if patient refuses treatment
  5. All of the above

- It is a discussion, not a signature on a form
  - Must be done by the treating physician
    - NOT delegable
  - Use to manage and set reasonable patient expectations
Informed Consent

➢ In California, practitioner must:
  ● Explain in language the patient can understand
  ● Give as much “material” information as needed
    • Information that would influence a reasonable patient’s
decision to accept or reject the proposed treatment/procedure
    • Including any risk a reasonable person would consider important
  ● Tell of any other information a skilled practitioner would
disclose in the situation
  ● Must tell patient of any risk of death/serious
injury/significant potential complications
    • NOT required to explain unlikely, minor risks

Cobb v. Grant (8 Cal.3d 229) 1972

Informed Consent

➢ Such information typically includes:
  ● Nature of the procedure
  ● Risks/complications/expected benefits of the procedure
    • Outcome vs. mechanism of injury
    • Death, disability, disfigurement, pain
  • Other related to specific procedure
  ● Any legal alternatives including doing nothing
    • Informed refusal
  • Potential conflicts of interests
    • Financial/research

Informed Consent

➢ Emergency exception or Consent implied
in law when:
  1. Emergency and
    • Life threatening, serious disability or relief of
    severe pain
  2. Time is of the essence and
    • Minutes to hours
  3. Reasonable person would consent and
    • This patient has not previously refused
  4. Patient is unable to consent
Informed Consent Case

- 54 yo patient seeks out doctor at medical center with reputation for laparoscopic experience/expertise
- During surgery, a resident, while introducing morcellator, injuries iliac vein
- Patient alleges lack of informed consent regarding resident’s role/participation

Informed Consent Issues

- Common allegation
  - Failure to provide
  - Failure of patient to understand or to appreciate
  - Physician other than one authorized performed the surgery/procedure
- Recommendations
  - Set reasonable expectations
  - Document discussion
  - Answer questions
  - Do early on and may need repeating
    - Health literacy
    - Cultural differences
    - Language assistance
  - If multiple providers, clarify role in patient’s care

Informed Consent

- In California, special consent is required for certain procedures:
  - Sterilization
  - Hysterectomies
  - Blood transfusions
  - Abortions
  - Assisted reproductive procedures
  - Pelvic examination of an anesthetized or unconscious female
  - Mandatory patient information with gynecological examinations
"If nothing goes wrong, then nothing matters. If anything goes wrong, then everything matters."

Frederick A. Berry, M.D.

Your relationship with a patient may help to keep you out of a lawsuit, but your medical record documentation will help you to win it.

- The patient’s attorney’s first glimpse of you and your medical care
  - Sloppy, incomplete or illegible documentation will be equated with inattentive, superficial and cursory medical care

Documentation

Objective

- No jousting, blaming, or derogatory remarks
- Avoid superlatives
- Watch use of templates/cut and paste/smart phrases
  - Applicable to this patient and/or situation?

- Use only medical center approved abbreviations
- Include rationale/thought process
- Incorporate phone calls/e-mails
- Do not inappropriately alter!!
- “Adequate and accurate”
Electronic Medical Record

Issues

- Data entry errors
  - Wrong patient
  - Wrong report
  - Wrong box/order/dose/drug...
- System assisted documentation
  - Check boxes or include items not actually done
  - Use of templates/smart phrases that don’t make sense
- Inadequate user knowledge
- Turning off or ignoring system generated warning messages
- Not monitoring and responding to “In basket” mail

“Emerging” Issues/Areas

- Medical record privacy issues
  - Only access those records you need to for patient care
  - Social website use
- California's “Never Events”
- Effect on medical malpractice litigation unclear
- Inappropriate behavior/Internet website access
- Failure to make legally required reports
  - Suspected elder/spousal/child abuse/DMV lapses of consciousness
  - FYI - Maternal substance abuse¹
    - A positive toxicology screen at the time of the delivery is not in and of itself a sufficient basis for reporting child abuse or neglect
    - Any indication of maternal substance abuse requires an assessment of the needs of the mother and child
    - If other factors are present that indicate risk to a child, then a report shall be made

¹ From California Penal Code §11165.13

Believe it or not, things have improved ....

- Code of Hammurabi (~1780 BC)

§218 “If the doctor has treated a gentleman with a lancet of bronze and has caused the gentleman to die, or has opened an abscess of the eye for a gentleman with a bronze lancet, and has caused the loss of the gentleman's eye, one shall cut off his hands.”


Berry, Frederick. What to Do After an Adverse Outcome. ASA Refresher Course Lecture 134. 2007.


