Medicolegal Liability in Ob/Gyn Ultrasound

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Outline
• Malpractice, as it relates to ultrasound
• Areas that pose the greatest risk with ultrasound
• Most common errors that lead to litigation
• Practices that can help reduce your exposure to litigation
• Case examples

Novel Areas
• Keepsake ultrasounds
• Insurance fraud
• Video taping of the ultrasound exam

Legal Concept
Malpractice
Elements of Negligence
1. Duty
2. Breach of that duty
3. Proximate cause of injury
4. Damages

Medical malpractice
• Civil action
• Burden of proof = "preponderance of the evidence"
• Something > 50%
Cases by Specialty Area

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Types of Errors

- Perception errors
- Interpretation errors
- Failing to suggest the next appropriate procedure
- Failure to communicate


Perception Errors

The abnormality is seen in retrospect but it is missed when interpreting the initial study.

- Question: Was it below the standard of care for the physician not to have seen the abnormality.
- Most suits are settled – 80% are lost if cases go to jury verdict


Interpretation Errors

The abnormality is perceived but is incorrectly described

- Most often occur due to lack of knowledge or faulty judgment
  - Malignant lesion called benign
  - Normal variant is called abnormal
- The best defense is an appropriate differential diagnosis, preferably including the correct diagnosis
- Lawsuits involving an interpretation errors – 75% are won if cases go to jury verdict

Missed Diagnosis

New Jersey

- Four ultrasounds performed during pregnancy
- Images lacked clear anatomic landmarks, thus no accurate measurements of fetus made
- Physician reviewed one ultrasound
- Sonographer reported on three ultrasounds
  - "Structural irregularities that require further evaluation"
- Physician told the patient the "ultrasounds were completely normal"

Missed Diagnosis

New Jersey

- Midline facial defect
- Cleft palate
- Club foot
- Lower-limb anomalies
- Limited cognitive and communication skills
**Missed Diagnosis**

New Jersey

- Suit against physician
- Suit against professional group he owned
  - Performs ultrasounds
- Settlement = $1.98 million

**Ultrasound - Liability**

- Failure to conduct additional testing upon inability to visualize all four chambers of the heart during a routine sonogram.
  - $4,200,000
- Failure to detect meningomyelecele on ultrasound at 15 weeks. Ultrasound reported as normal.
  - $4,350,000
- Failure to detect severe hydrocephalus
  - $5,500,000

**Misdated Fetus**

28 y.o.G3P2002 (Prior C/S x 2)

- LMP = 7/05/08
- EDD = 4/12/09
- Oligomenorrhea

**Misdated Fetus**

10/31/08

- EGA = 16w4d
- PE: Unable to palpate fundus due to body habitus.
- FHT’s = 160

**Misdated Fetus**

11/02/08 Ultrasound

- Small for dates
- EGA (dates) = 17 weeks
- "Live, intrauterine pregnancy with a gestational age of 9w4d ± 6 days. The EDD is 4/10/09,"
  - EGA (US) = 9w4d
  - EDD (US) = 6/03/09
Misdated Fetus

12/14/08
• Office visit for abdominal pain
  – 15 5/7 weeks by ultrasound
  – 23 2/7 weeks by dates
• Exam: “Uterus is normal”

4/05/09 Elective repeat C-Section
• 39 2/7 weeks by dates
• 31 6/7 weeks by ultrasound
• Male
  – Weight = 1710 gm
  – Apgar = 9, 9
  – Ballard 31 weeks

Newborn Course
• Prematurity
• Respiratory distress syndrome
• Necrotizing enterocolitis

Misdated Fetus
• Deposition
• Review of records
  • FH < EGA on a consistent basis
• Settled $980,000

Failure to Communicate
• Final written report is considered the definitive means of communicating the results of an imaging study or procedure
• Direct or personal communication must occur in certain situations
  – Document communication
• Cause of action: Failure to communicate in a timely and clinically appropriate manner

Failing to Suggest the Next Appropriate Procedure
The prudent radiologist/physician will suggest the next appropriate study or procedure based upon the findings and the clinical information.
• The additional studies should add meaningful information to clarify, confirm or rule out the initial impression
• The recommended study should never be for enhanced referral income
• Generally, the radiologist is not expected to follow up on the recommendation.
  – Exception: Beware of reinterpreting images on multiple occasions

2 ACR Standard for Communication.
The estimated gestational age by ultrasound is 9w4d. This is not consistent with the estimated age by dates. ACOG recommends adjusting the EDD if the discrepancy is more than 7 days when the gestational age is between 9w0d and 13w6d. With an ultrasound EGA of 9w4d, the EDD should be adjusted to 6/03/09. The adjusted EDD should be confirmed on subsequent ultrasound studies.

- Consider nuchal translucency at 11-14 weeks EGA
- Anatomic survey recommended at 18-20 weeks EGA

**Recommendations**

- Sonologist
  - Make specific recommendations when appropriate
- Clinician
  - Read the entire radiology report, not just the summary diagnosis
  - Correlate the radiologic diagnosis with the clinical findings

**Failure to suggest next procedure**

- 33 y.o. G3P2002
- Quad screen at 15 weeks
  - Risk of Down Syndrome = 1/1100
- US performed at 19w1d in radiology
- Report: "Normal IUP at 19w1d, consistent with dates."
- No mention of subtle findings
  - UPJ = 4.3 and 4.4
  - EIF noted

**Likelihood Ratios for DS with Isolated Markers**

<table>
<thead>
<tr>
<th>Marker</th>
<th>AAURA</th>
<th>Nyberg</th>
<th>Bromley</th>
<th>Smith-Brindman</th>
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<td>Nuchal fold</td>
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<td>2.2</td>
<td>1.5</td>
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<td>2.0</td>
<td>1.8</td>
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<td>1.5</td>
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<tr>
<td>Normal</td>
<td>0.4</td>
<td>0.36</td>
<td>0.22</td>
<td>??</td>
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</table>

**Isolated Marker**

- EIF
  - LR = 1.4 – 2.8
  - Adjustment
- Risk of Down’s
  - Originally 1 in 1100
  - Adjusted 1 in 392-785
- No amnio

- UPJ = 4.3 and 4.4
- Pyelectasis
  - LR = 1.5 – 1.9
  - Adjustment
- Risk of Down’s
  - Originally 1 in 1100
  - Adjusted 1 in 579-733
- No amnio
Prevalence of Markers and Likelihood Ratios

<table>
<thead>
<tr>
<th># Markers</th>
<th>DS = 164</th>
<th>Nml = 656</th>
<th>LR</th>
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<td>0</td>
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<td>575</td>
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<td>3</td>
<td>40</td>
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</table>

*Individual LR better


Failure to Communicate

- 33 y.o. G3P2002
- Quad screen at 15 weeks
  - Risk of Down Syndrome = 1/1100
- 2 markers: LR = 6.2
- Adjusted Risk for DS = 1/177
- Amniocentesis would be appropriate

Failure to Communicate

- Radiologist
  - They rounded to the nearest whole number.
  - This patient’s UPJ’s were thus 4 and WNL
  - The UPJ dilation was < 5 mm, which is “normal” in their lab
  - EIF is a worthless marker and of no consequence
  - It is the obstetrician’s duty to recommend amniocentesis to the patient

Failure to Communicate

- Obstetrician
  - The radiologist’s report was “normal” with no mention of subtle markers for DS.
  - I had no reason to recommend amniocentesis
  - Had I known of the subtle findings I would have recalculated the patient’s risk and would have recommended amniocentesis

Failure to Communicate

- Radiologist
  - The UPJ dilation was < 5 mm, which is “normal in their lab”

Plaintiff’s cross

- The defendant radiologist had provided the syllabus from a recently attended CME course provided by the parent institution, that indicated that ≥ 4 mm was abnormal for < 20 weeks EGA

Failure to Communicate

- EIF is a worthless marker. We don’t even mention it.

Plaintiff’s expert

- As an isolated finding, EIF is a very poor marker. However, it should at least be mentioned in the report. Further, in the presence of additional markers, for example pyelectasis, EIF carries more significance.
- Both subtle findings should have been noted in the report and recommendations made to recalculate the patient’s risk for DS and amniocentesis if appropriate
**Failure to Communicate**

**Verdict**

Obstetrician

**Defense Verdict**

Radiologist

**Plaintiff Verdict**

– Mislabeled the images
– Duty to report the findings to the obstetrician. If he had done so, the duty for further counseling, evaluation, and treatment would have transferred to the obstetrician.

**Verdict**

Plaintiff Verdict

Radiologist

– Failing to appropriately communicate the findings to the obstetrician resulted in the continuation of an abnormal pregnancy that the patient, had she known of the abnormality, would have terminated.

**Wrongful Birth**

“A claim for relief by parents who allege they would have avoided conception or would have terminated a pregnancy but for the negligence of those charged with prenatal testing, genetic prognosticating, or counseling parents as to the likelihood of giving birth to a physically or mentally impaired child.”

Keel v. Banach, 624 So. 2d 1022 (Ala. 1993)

**Interpretation Errors**

8/01/05

- LMP = 6/09/05
- EGA = 7w5d
- EDD = 3/16/06

Ultrasound

- Small fetal pole with cardiac activity
- EGA = 5w2d
- EDD = 3/29/06

**Interpretation Errors**

9/26/05

- LMP = 6/09/05
- EGA = 15w5d (dates)
- EGA = 13w4d (ultrasound)
- No physical examination documented
- “Offered expectant management vs. D&C.”
- “Rx: Cytotec”

**Interpretation Errors**

9/06/05

- EGA = 12w5d (dates); 10w5d (US)
- Ultrasound
  - No images were documented
  - No formal report
  - Written note
    - “1x1 cm yolk sac. No fetal pole. No CA”
Interpretation Errors

9/30/05
• Passed 61 gm male fetus
• 13-16 weeks with no grossly evident congenital abnormalities

Interpretation Errors

Settlement

$600,000

Interpretation Errors

9/06/05
• EGA = 12w5d (dates); 10w5d (US)
• Ultrasound
  – No images were documented
  – No formal report
  – Written note
    • "1x1 cm yolk sac. No fetal pole. No CA"

Recommendations

• Clinician
  – Was the 1x1 yolk (gestational) sac a Nabothian cyst?
• Avoid "quick peeks" with the ultrasound
• Confirm findings that do not correlate with prior findings
• Document properly
• Examine patients

Image Retention

• Retain images
• Preferably digital capture
  – PACS
  – Cloud-based storage
  – Record DVD every month
• Maintain for the specific SOL for your state (jurisdiction)

Delay in Diagnosis
North Carolina

• 46 year old patient presented with abnormal uterine bleeding
• Physician assistant saw patient
• No biopsy performed
• Ultrasound = negative
  - Subsequently could not produce photograph taken at the time of ultrasound
Delay in Diagnosis
North Carolina

- 18 months later presented with persistent bleeding
- Physician assistant again saw patient
- No biopsy performed
- Ultrasound = negative
  - Photograph for second ultrasound found

Delay in Diagnosis
North Carolina

- After another 10 months, sought care from another physician
- Physician performed biopsy
- Endometrial carcinoma
- Patient died from disease

Delay in Diagnosis
North Carolina

- Suit filed against 1st physician
  - After defendant physician’s deposition
  - No expert testimony required
- Settled for $800,000

Legal Concepts

- Res ipsa loquitur
  - But for the failure to exercise due care the injury would not have occurred
  - Delay in diagnosis and subsequent death
- Respondeat superior
  - An employer is liable for the wrong of an employee if it was committed within the scope of employment

Ultrasound Examination

- Personnel
  - Training
  - Supervision
- Performance of the study
  - AIUM guidelines
  - Appropriate images
Image Retention

- Preferably digital capture and retention
- Maintain for the specific SOL for your state (jurisdiction)

Invented Lesions

![Chart showing number of cases from 1983 to 2002](chart.png)

Invented Lesions

- Fetal abnormality
- IUGR
- Fetal Death
- Normal Pregnancy
called Ectopic MTX


“Ectopic Pregnancy”

8/6/20XX
- 37 y.o. G1P0 presents to ED (paramedics) with c/o abdominal pain and vaginal bleeding, with a positive home pregnancy test.
- hCG = 6,326
- Patient states does not want to keep pregnancy

Ultrasound in radiology

“Uterus normal sized, with a small fluid collection with what appears to be a decidual reaction within the uterine fundus, but no yolk sac or fetal pole are identified. A large amount of free fluid is seen in the cul-de-sac and there is a left adnexal mass adjacent to the ovary measuring 3.0 x 2.3 x 3.6 cm … the finding would be compatible with the presence of an ectopic. Both ovaries do have flow and were identified on this evaluation.”

Impression

“Left adnexal ectopic pregnancy with a parovarian mass measuring 3.6 x 2.3 x 3.0 cm.”

Lab
- Hct = 40.5
- Blood type: A negative

Treatment
- Methotrexate: 80 mg IM (50 mg/m²)
- Rhogam

Quantitative hCG
- 8-06-XX 6,326 (MTX)
- 8-10-XX 16,069
- 8-13-XX Seen at another physician’s office

Ultrasound
- Definite IUP with a yolk sac, fetal pole, and cardiac activity. CRL = 3.4 mm, c/w 6w0d.
- Left adnexal mass: not visualized
- Subsequently miscarried
“Ectopic Pregnancy”

Notice of claim
• While her pregnancy was not planned, it was not unwelcome
• She missed the opportunity, perhaps her only opportunity, to become a parent, truly one of life’s greatest joys
• Counseling and therapy
• Anti-depressants
• Pain and suffering

“I think this case has great jury appeal.”
Settlement offer $145,000

“Ectopic Pregnancy”

Initial review
• The ultrasound films in radiology could not be found

Expert review
• It is possible that the fluid within the uterine fundus was an early gestational sac.
• Left adnexal mass. If this was part of the ovary, most likely a corpus luteum.
• The suspicion is that this is an early IUP with a left corpus luteum.

The lack of the original films places the physicians and facility in a compromised position.

“Ectopic Pregnancy”

Case update
• Radiology films were located
Independent review of radiology study (8-6-XX)
• Probable IUP with a well-formed gestational sac. Probable yolk sac in one view. No definite fetal pole or cardiac activity is identified.
• It is not possible from the films to determine if the left adnexal mass is attached to or part of the ovary, or distinctly separate. Further, I cannot determine if this might be bowel.
• In my opinion the study was read incorrectly

With the lack of definitive diagnosis, the radiologist should have recommended clinical correlation, serial hCG levels, and a f/u ultrasound study.

Settled for $95,000

Errors
• Perception error
  – Intrauterine gestational sac + yolk sac
• Interpretation error
  – Hemorrhagic corpus luteum called an ectopic pregnancy
• Failure to suggest the next appropriate procedure
  – Serial hCG levels and repeat ultrasound
34 y.o. G1P0 presents to ED with c/o abdominal pain and vaginal bleeding.
- Underwent IVF ~ 2 weeks earlier
- hCG = 4,654

Ultrasound in radiology
“Uterus normal sized with a thickened decidual reaction in the uterus. No fetal pole is identified. There is a moderate amount of fluid in the cul-de-sac. There is a right adnexal mass = 2.2 x 1.9 x 2.1 cm. These findings could be compatible with the presence of an ectopic. Clinical correlation and, if indicated, serial hCG levels and follow-up ultrasound studies should be considered.”

Patient is clinically stable
Lab
- Hct = 38.9
- Blood type: O positive
Treatment
- Methotrexate: 80 mg IM
- Excellent MTX consent form reviewed and signed by patient

Quantitative hCG
- Day 0: 4,654 (MTX)
- Day 4: 16,069
- Day 7: 42,125

Ultrasound
- Twin IUP with two yolk sacs and possible cardiac activity.
- Twin IUP at ~ 5 weeks of gestation

Ultrasound 2 weeks later
- Twin IUP with two yolk sacs, two fetuses, both with cardiac activity, c/w 7 weeks of gestation
- Patient referred for counseling re: risks of fetal anomalies associated with MTX

Perinatal counseling
- Risks of MTX very low
- Fetal anomalies associated with MTX can be seen on ultrasound
Recommendation
- Serial ultrasounds
- Reassurance
Twin IUP + MTX

Ultrasound at 16 weeks
• Normally growing twin gestation with no abnormalities visualized
• Reassured

26 weeks – Perinatologist B
• Ultrasound
  – Shortened limbs
  – Small chins
  – One fetus: echogenic bowel
  – One fetus: 2 vessel cord

Genetic counseling
• Potential risk of MTX exposure
• Greatest risk at 6-8 weeks after conception

Delivered by C-section
• Hypotonia
• Micrognathia
• Short limbs
• Dysmorphic facies

Growth and development
• Feeding difficulties
• Growth delays
• Developmental delays

Suit filed against
• Radiologist
  – Misdiagnosis
• REI Gynecologist
  – Misdiagnosis
  – Inappropriate treatment with MTX
  – Wrongful birth
• Perinatologist A
  – Wrongful Birth

Plaintiff
• With h/o IVF, twin gestation more likely
• Thus, high level of hCG without demonstrable IUP is not uncommon
• Patient was stable, thus immediate intervention was unnecessary
• If follow-up hCG and ultrasounds would have been obtained, the correct diagnosis of a IU twin gestation would have been made

Trial
• MTX was the proximate cause of the observed fetal anomalies
• Perinatologist A was negligent in providing inadequate and inaccurate counseling as to the risks of MTX.
• Had the patient been appropriately counseled she would have terminated the pregnancy
Twin IUP + MTX

**Defense**
- Use of methotrexate for treatment of suspected ectopic pregnancy is within the SOC
- The risk of fetal anomalies with MTX is low
- The patient received appropriate counseling and signed a written consent for use of MTX

**Trial**
- Use of methotrexate for treatment of suspected ectopic pregnancy is within the SOC
- The risk of fetal anomalies with MTX is low
- The patient received appropriate counseling and signed a written consent for use of MTX

MTX and Anomalies

**Aminopterin/MTX Syndrome**
- Dose effect (threshold)
  - > 10 mg/week
- Timing
  - 2-2.5 weeks
  - Undifferentiated cells
  - All or none effect (SAB)
  - 4-10 weeks (6-8 weeks)
- Effect on differentiating cells


**Effects of Methotrexate**
- IUGR
- Abn head shape
- Larger fontanelles
- Craniosynostosis
- Ocular hypertelorism
- Low set ears
- Micrognathia
- Limb abnormalities
- Developmental delays

**Our Babies**
- Hypotonia
- Micrognathia
- Short limbs
- Dysmorphic facies
- Feeding difficulties
- Growth delays
- Developmental delays

Exhibit 3A

Treatment of Ectopic Pregnancy with Methotrexate

Patient Information and Consent

You have been diagnosed with an ectopic pregnancy, or a pregnancy in the fallopian tube. Pregnancies in the tube cannot develop normally. The pregnancy cannot be moved from the tube to the uterus, or womb.

Options to treat an ectopic pregnancy include observation, surgery, and medications.
- **Observation** may not be recommended as the tube can rupture or burst if the pregnancy continues to grow. This can create a situation where emergency surgery is required. There are reports of women dying from a ruptured ectopic pregnancy.
- **Surgery** is usually performed via a laparoscope, or lighted tube, which most people know as “belly button surgery.” This surgery involves either removing the tube, removing a portion of the tube where the pregnancy is located, or removing the pregnancy from the tube and leaving the remainder of the tube.
- **Medical treatment** involves one or two injections with a methotrexate, a medicine that blocks chemicals critical to pregnancy development. In most cases surgery can be avoided with the use of methotrexate.
Effectiveness

In properly selected patients, methotrexate successfully treats ectopic pregnancies in 95% of patients.

Blood tests

Blood tests are required before treatment to determine if your liver and kidneys are functioning normally. Additional blood tests will be drawn at 4 days and 7 days after treatment to determine if the medication is successfully treating the ectopic pregnancy. Following the levels of hCG, the pregnancy hormone, is critical and requires that you keep all follow-up appointments.

Ultrasound

Ultrasound may be required in the future to determine the status of the ectopic pregnancy, if there are any signs of rupture, or if surgery may ultimately be required.

Side effects

Patients commonly experience increased abdominal pain during the first week after receiving the medication. This pain should not be severe. If it is you should notify us immediately. Rarely patients experience nausea, vomiting, or diarrhea. Even less common is the development of ulcers in the mouth. (This is a very rare side effect when using a single or double dose of methotrexate).

Risks

Methotrexate is harmful to normal pregnancies. Some birth defects have been described when intrauterine pregnancies have been treated with methotrexate. If you are found to have an intrauterine pregnancy after methotrexate treatment it is recommended to receive counseling to determine if the pregnancy should be terminated.

You cannot consent a patient to negligence

Judge Harry Rein, M.D. J.D.
Florida

Twin IUP + MTX

Trial

Defense

• Ultrasound is useful in detecting potential fetal anomalies
• The ultrasound at 16 weeks was normal
• This was a highly desired pregnancy and it is likely that the patient would not have terminated the pregnancy even if abnormalities were visualized

What was the verdict for the parties?
Twin IUP + MTX

Verdict

Radiologist
• Defense verdict

Twin IUP + MTX

Verdict

REI
– Plaintiff verdict
– Misdiagnosis of ectopic pregnancy/twin gestation
– Negligent in the use of MTX

Twin IUP + MTX

Verdict

• Perinatologist A
  – Plaintiff verdict
  – Negligent counseling
  – Wrongful birth

Twin IUP + MTX

Verdict

• Joint and Severally Liable
  – Pain and suffering
  – Long-term support and therapy of two infants with anticipated life-span of 72 years
  • $73 million

Keepsake Ultrasounds

“Keepsake” Malpractice

Any malpractice claim concerning keepsake video production will be a case of first impression.
Entertainment Ultrasound
Case of First Impression

Colorado 2009
• Down’s Syndrome
• Alleged missed anomaly during “Keepsake Ultrasound” in the 3rd trimester

Entertainment Ultrasound
Case of First Impression

Colorado 2009
• Shorten femur at 31 weeks
• Termination is available up to 34 weeks in Boulder, Colorado

The Story

Entertainment ultrasound is not an approved medical practice

Question
– Was this medical malpractice?
– Was this a case of commercial negligence?
– Was this a breach of an entertainment agreement?

COPIC Insurance Co.
Coverage Limitations

“Your professional liability policy covers acts of negligence in the course of providing medical care. This type of activity may fall outside this definition; therefore you may be denied coverage.”

Copiscope, No. 114, July 2003.

Entertainment Ultrasound

Settled for undisclosed amount, rumored to be $1 M
Liability Risks

Different scenarios

- Untrained technician-no physician oversight
- RDMS sonographer-no physician oversight
- RDMS sonographer-physician oversight
  - No prior physician-patient relationship
    - Current patient
- RDMS sonographer-physician oversight

Types of Health Care Fraud

- Billing/Insurance Fraud
- Upcoding
- Unbundling
- Kickbacks
- Consulting agreements

Least

Most

Possible Sanctions

- Civil Penalties
  - Up to $11,000 for each item or service
- Criminal Penalties
  - Fines up to $250,000
  - Imprisonment x 5 years
- Forfeiture of the clinic/office

Possible Sanctions

- Exclusion for Medicaid and Medicare
  - 3 to 5 years
- Suspension
  - Immediate: U.S. Attorneys’ Offices
- Injunction
  - Branch of the DOJ
- Civil Penalties
  - Up to $11,000 for each item or service

Billing Fraud

- M-mode billed as echocardiogram
- >1200 ultrasounds billed with echocardiography (76825)
- Generated ~ $44,000 income
- Qui tam action
- Potential fine: $13,200,000
- Settled: $589,000

Billing Fraud

- Always perform an Abdominal Ultrasound at the time of Vaginal Ultrasound
- Routinely performing “unnecessary procedures”
- Long Island practice was fined for inappropriately adding TAS to all pelvic ultrasounds
Billing Fraud

• Engaged in the practice of routine practice of submitting claims to Medicaid and Medicare for imaging services that were not medically necessary or not actually ordered by a referring physician.
• Medically unnecessary or elective services are not covered by these programs.
• Also provided kickbacks to physicians based on the number of referrals for diagnostic imaging.

Billing Fraud

• Federal government $13.65 million
• New York $1.85 million
• New Jersey $1.85 million
• TOTAL $15.50 million
• Three whistleblowers $2.77 million (total - 17.8%)

Insurance Fraud

• Order both a vaginal and abdominal study
• Order vaginal ultrasound, with an abdominal ultrasound if clinically indicated (A protocol can be developed for this)
• Contact the ordering physician or their office and obtain an order (very cumbersome)

Billing Fraud

Added statements

• An abdominal ultrasound was required due to the inability to adequately visualize one or both ovaries on the vaginal study
• An abdominal ultrasound was required due to the inability to adequately visualize the uterus on the vaginal study
• An abdominal ultrasound was required due to the inability to adequately evaluate the pregnancy on the vaginal study
• A vaginal ultrasound was performed to evaluate cervical length

Video capture during US

• The patient’s mother is using her phone to video the ultrasound
• How do you respond to patient families/spouses that want to video the ultrasound study?

Video capture during US

• Mother posts a picture of the ultrasound on her Facebook page
• Includes the patient’s face
• Includes your face in the picture
Video capture during US

- **Benefits**
  - Enhanced patient experience
  - Enhance bonding for the patient and her family
- **Risks**
  - HIPAA/HITEC violation

Confidentiality

- **HIPAA**
  - Health Insurance Portability and Accountability Act
- **HITECH**
  - Health Information Technology for Economic and Clinical Health

Confidentiality

Both include

- Privacy provisions
- Security requirements (encryption)
- Maintain security and privacy of health information
- May not transmit (even unintentionally) such information to others without patient permission or legal authority.

Health care provider responsibilities

- Maintain security and privacy of health information
- May not transmit (even unintentionally) such information to others without patient permission or legal authority.


Penalties for Violations

- Range from $100 to $50,000 per violation (or per record), with a maximum penalty of $1.5 million per year for each violation.

Penalties for Violations
HIPAA criminal penalties

- **Tier 1:** Reasonable cause or no knowledge of violation  
  Up to 1 year in jail
- **Tier 2:** Obtaining PHI under false pretenses  
  Up to 5 years in jail
- **Tier 3:** Obtaining PHI for personal gain or with malicious intent  
  Up to 10 years in jail

Privacy Concerns

- Posting patient information on a social media site is worse than screaming the patient’s information on a street corner
- It reaches more people
- It is enduring

Recommendations

- Written policy specifically addressing the use of photography or video capture during ultrasound studies
- Patient’s signed acknowledgement
- Includes policy that the ultrasound study will be terminated if such actions occur
- Employee training regarding the policy
- The practice (physicians) must support the employee’s actions

Check state laws

- Mutual agreement re: video taping
- California requires mutual agreement.


Ultrasound Examination

- California's wiretapping law is a "two-party consent" law. California makes it a crime to record or eavesdrop on any confidential communication, including a private conversation or telephone call, without the consent of all parties to the conversation. See Cal. Penal Code § 632.
- AIUM Accreditation
- Establishes policies and procedures
  - “Best Practices”
Ultrasound Examination

- Performance of the study
- Interpretation of the study
- Communication of results
- Documentation

Equipment

- Contemporary equipment
- Proper maintenance (PM)
- Image capture and retention

Defensibility

- If the components of a complete examination are documented, appropriately interpreted, and communicated the case is more defensible.
- The lack of any component places the case at risk.

Summary

- Malpractice
- Most common errors that lead to litigation
- Practices that can help reduce your exposure to litigation

Thank You