Liability in Ob-Gyn Ultrasound

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Disclosures:
• Consultant: GE Ultrasound
• Speaker: Philips Ultrasound

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

Burden of Proof

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


**Legal Concepts**

- Wrongful Birth
- Wrongful Life
- Wrongful Death

**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)*

**Wrongful Life**

A cause of action for wrongful life arises in favor of a special needs child who claims damages because he was conceived or was not aborted due to the negligence of the physician.

*Kimble, 55 Ala. Law 84 (1994)*

**Wrongful Death**

A cause of action for wrongful death arises when an otherwise normal pregnancy, which has reached viability, is terminated as a result of a misdiagnosis.

— i.e. renal agenesis

*Lollar v. Tankersley, 613 So. 2d 1249 (Ala. 1993)*

**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


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

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

Missed Diagnosis


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 meningomyelocele 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
- EDC = 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”

**Newborn Course**

- Prematurity
- Respiratory distress syndrome
- Necrotizing enterocolitis

**Misdated Fetus**

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
**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

**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
- Reported as "normal"
- 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-Bindman</th>
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<tbody>
<tr>
<td>Nuchal fold</td>
<td>18.6</td>
<td>11</td>
<td>12</td>
<td>17</td>
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<tr>
<td>Hyperechoic bowel</td>
<td>5.5</td>
<td>6.7</td>
<td>NA</td>
<td>6.1</td>
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<tr>
<td>Short humerus</td>
<td>2.5</td>
<td>6.1</td>
<td>5.8</td>
<td>7.5</td>
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<tr>
<td>Short femur</td>
<td>2.2</td>
<td>1.5</td>
<td>1.2</td>
<td>2.7</td>
</tr>
<tr>
<td>EIF</td>
<td>2.0</td>
<td>1.8</td>
<td>1.4</td>
<td>2.8</td>
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<tr>
<td>Pyelectasis</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
<td>1.9</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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</tbody>
</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

Pyelectasis

- 7400 patients
- 25% of patients with Down’s had pyelectasis
- Incidence of Down’s = 3% if pyelectasis is present
- Abnormal:
  - 15-20 weeks ≥ 4 mm
  - 20-30 weeks ≥ 5 mm
  - > 30 weeks ≥ 7 mm


Isolated Marker

- **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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<tbody>
<tr>
<td>0</td>
<td>32</td>
<td>575</td>
<td>0.2</td>
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<tr>
<td>1*</td>
<td>32</td>
<td>66</td>
<td>1.9</td>
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<tr>
<td>2</td>
<td>20</td>
<td>13</td>
<td>6.2</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
<td>2</td>
<td>80</td>
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</tbody>
</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

Defense
- Radiologist
  - They round 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

**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

**Radiologist**
- 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

**Verdict**

**Obstetrician**
- Misinterpreted 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.

**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.

**Plaintiff Verdict**
- Reed v. Campagnolo
  The court ruled that “… parents may maintain an action for wrongful birth if the physician fails to disclose the availability of tests which would have detected birth defects present in the fetus and if the woman would have had an abortion had she known the fetus’s deformities”  
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

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"

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"

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

$600,000
Recommendations

- Clinician
  - Was the 1x1 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

- Preferably digital capture and retention
- 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: showed existence of tumor

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


“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
“Ectopic 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.”

“Ectopic Pregnancy”

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

“Ectopic Pregnancy”

Quantitative hCG
• 8-06-XX  6,326 (MTX)
• 8-10-XX  16,069
• 8-13-XX  Sealed 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
• “I think this case has great jury appeal.”
• Settlement offer $145,000

“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

“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.

Case update
- Radiology films were located
- Copies of ultrasounds obtained from outside physician’s office

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
Independent review of radiology study (8-6-XX)

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

Independent review of office ultrasound study 8-13-XX

- Definite IUP with a yolk sac, fetal pole, and cardiac activity. CRL = 3.4 mm, c/w 6w0d.
- Previously identified left adnexal mass is not seen on this study.
- The previously identified echogenic cul-de-sac fluid is not visualized, consistent with reabsorption.

Independent review of office ultrasound study 9-3-XX

- Study after episode of heavy vaginal bleeding
- IUP not identified
- Consistent with an interval miscarriage

Expert opinion

- The treating physicians relied upon the radiologist's interpretation
- SOC does not require non-radiologists to review all radiologic images. Physicians routinely rely upon the interpretation of radiologists.
- The ultrasound images on 8-6-XX were adequate to make the diagnosis of an IUP

MTX is contraindicated in an IUP and may lead to miscarriage or, if the pregnancy continues, a risk of fetal anomalies.

MTX may not have been the sole cause of the patient’s miscarriage:
- Advanced maternal age
- Inherent rate of miscarriage

There is no evidence to substantiate an allegation that the patient will be unable to have children in the future.

Settled for $95,000
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

Errors

- Interpretation error
  - Intrauterine gestational sac + yolk sac
- Perception error
  - Hemorrhagic corpus luteum called an ectopic pregnancy
- Failure to suggest the next appropriate procedure
  - Serial hCG levels and repeat ultrasound

“Ectopic Pregnancy”

- 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.”

“Ectopic Pregnancy”

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

“Ectopic Pregnancy”

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

Twin IUP + MTX

Perinatal counseling
- Risks of MTX very low
- Fetal anomalies associated with MTX can be seen on ultrasound

Recommendation
- Serial ultrasounds
- Reassurance

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

Twin IUP + MTX

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
Twin IUP + MTX

Plaintiff
- With h/o IVF, twin gestation more likely
- Thus, high level of hCG without demonstrable IUP is not unusual
- 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

 Plaintiff
- 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

Defense
- The original ultrasound was interpreted by the radiologist
- REI-gyn
  - Relied upon the radiologist’s diagnosis
- Radiologist
  - The interpretation of the ultrasound was correct, particularly in light of the hCG levels. F/U recommendations were appropriate.

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

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


<table>
<thead>
<tr>
<th>Effects of Methotrexate</th>
<th>Our Babies</th>
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<tr>
<td>IUGR</td>
<td>Hypotonia</td>
</tr>
<tr>
<td>Abnormal head shape</td>
<td>Micrognathia</td>
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<td>Larger fontanelles</td>
<td>Short limbs</td>
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<td>Craniosynostosis</td>
<td>Dysmorphic faces</td>
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<td>Limb abnormalities</td>
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Twin IUP + MTX Trial

**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

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**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.

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**Exhibit 3B**

**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.

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**Exhibit 3C**

**Side effects**

Patients commonly experience increased in abdominal pain during the first week after receiving the medicine. 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.

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**You cannot consent a patient to negligence**

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

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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
When abnormalities were identified at 26 weeks the patient still had the option of terminating pregnancy.

The fetal anomalies seen can occur even without exposure to MTX.

What was the verdict for the parties?

**Twin IUP + MTX**

**Defence**
- When abnormalities were identified at 26 weeks the patient still had the option of terminating pregnancy.
- The fetal anomalies seen can occur even without exposure to MTX.

**Verdict**
- Radiologist
  - Defense verdict

**Verdict**
- REI
  - Plaintiff verdict
  - Misdiagnosis of ectopic pregnancy/twin gestation
  - Negligent in the use of MTX

**Verdict**
- Perinatologist A
  - Plaintiff verdict
  - Negligent counseling
  - Wrongful birth

**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” 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

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
Case of First Impression

• 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?
**Liability Risks**

Different scenarios

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

**Entertainment Ultrasound**

- Settled for undisclosed amount, rumored to be $1 M

**Types of Health Care Fraud**

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

**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

- Abdominal Ultrasound at the time of Vaginal Ultrasound
- Long Island practice was fined $10M for inappropriately adding TAS to all pelvic ultrasounds
- Routinely performing "unnecessary procedures"

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

- An abdominal ultrasound was required due to the inability to adequately visualize one or both ovaries (uterus) on the vaginal study

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

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

- Mother posts a picture of the ultrasound on her Facebook page
- Includes the patient’s face
- Includes your face in the picture
Confidentiality

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

Both include
- Privacy provisions
- Security requirements (encryption)

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.

Video capture during US

- The patient did not specifically consent to her mother’s posting of the photo
- Inadvertent violation of the patient’s PHI
- Mother did not have your express and written consent to use your “likeness”

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

- 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 must support the employee’s actions

Ultrasound Examination

- 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