

Medicolegal Liability in Ob/Gyn Ultrasound

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Medicolegal Liability in Ob/Gyn Ultrasound

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Consultant:
• GE Ultrasound
• Siemens Ultrasound
• Femasys

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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

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Novel Areas

- Keepsake ultrasounds
- Insurance fraud
- Video taping of the ultrasound exam

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Legal Concept Malpractice



Elements of Negligence

1. Duty
2. Breach of that duty
3. Proximate cause of injury
4. Damages

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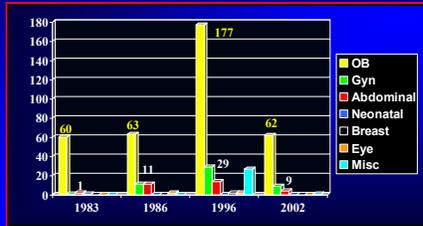
Burden of Proof

Medical malpractice

- Civil action
- Burden of proof =
"preponderance of the evidence"
- Something > 50%

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Cases by Specialty Area



RC Sanders, J Ultrasound Med 2003; 22: 1009-15.

Types of Errors

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

M.M. Raskin, *Liability of Radiologists*, in Legal Medicine. Am College of Legal Med. 6th edition, 456-460.

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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

¹ Berlin and Hendrix. *Perceptual Errors and Negligence*. Am J Roentgenol 1996;170:863-67.
² L. Berlin. *Malpractice Issues in Radiology: Defending the "Missed" Radiographic Diagnosis*. Am J Roentgenol 2001; 176: 317-32.

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

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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

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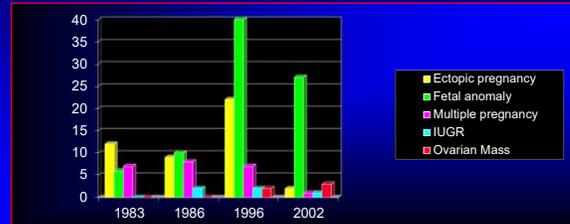
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Missed Diagnosis New Jersey

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

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Missed Diagnosis



RC Sanders, J Ultrasound Med 2003; 22: 1009-15.

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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

Courtesy of Steven Warsof, M.D.

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Misdated Fetus

- 28 y.o. G3P2002 (Prior C/S x 2)
- LMP = 7/05/08
 - EDD = 4/12/09
 - Oligomenorrhea

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Misdated Fetus

- 10/31/08
- EGA = 16w4d
 - PE: Unable to palpate fundus due to body habitus.
 - FHT's = 160

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Misdated Fetus

- 11/02/08 Ultrasound
- Small for dates
 - EGA (dates) = 17 weeks
 - "Live, intrauterine pregnancy with a gestational age of 9w4d \pm 6 days. The EDD is 4/10/09."
 - EGA (US) = 9w4d
 - EDD (US) = 6/03/09

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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"

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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

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Newborn Course

- Prematurity
- Respiratory distress syndrome
- Necrotizing enterocolitis

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Misdated Fetus

- Deposition
- Review of records
 - FH < EGA on a consistent basis
- Settled \$980,000

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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

¹ M.M. Raskin. *Why Radiologists Get Sued*. Applied Radiol 2001; 30: 9-13.
² ACR Standard for Communication

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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 ¹

¹ *Montgomery v. South County Radiologists, Inc.*, 49 S.W.2d 191 (2001).

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Recommended Report



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

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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

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Failure to suggest next procedure Failure to communicate

- 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

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Likelihood Ratios for DS with Isolated Markers

Marker	AAURA	Nyberg	Bromley	Smith-Bindman
Nuchal fold	18.6	11	12	17
Hyperechoic bowel	5.5	6.7	NA	6.1
Short humerus	2.5	5.1	5.8	7.5
Short femur	2.2	1.5	1.2	2.7
EIF	2.0	1.8	1.4	2.8
Pyelectasis	1.5	1.5	1.5	1.9
Normal	0.4	0.36	0.22	??

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Isolated Marker

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

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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

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Prevalence of Markers and Likelihood Ratios

# Markers	DS = 164	Nml = 656	LR
0	32	575	0.2
1*	32	66	1.9
2	20	13	6.2
3	40	2	80

Benacerraf et al. Radiology 1994; 193: 135-140

* Individual LR better

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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

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Failure to Communicate

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

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Failure to Communicate

Defense

- 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

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Failure to Communicate

Radiologist

Defense

- 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

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Failure to Communicate

Radiologist

Defense

- 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

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Failure to Communicate

Verdict

Obstetrician

Defense Verdict

Radiologist

Plaintiff Verdict

- 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.

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Failure to Communicate

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.

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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)

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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

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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”

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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”

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Interpretation Errors

9/30/05

- Passed 61 gm male fetus
- 13-16 weeks with no grossly evident congenital abnormalities

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Interpretation Errors Settlement

\$600,000

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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"

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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

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Image Retention

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

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Delay in Diagnosis North Carolina

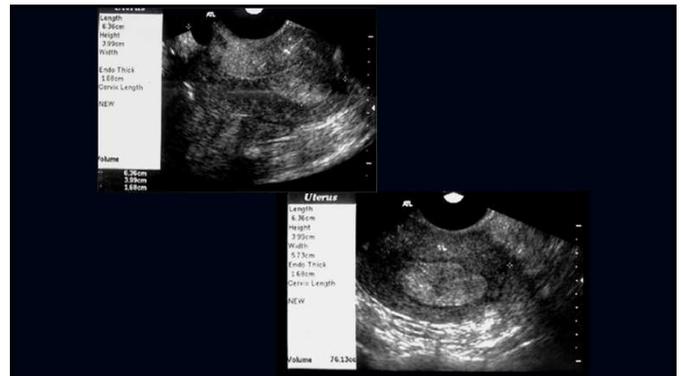
- 46 year old patient presented with abnormal uterine bleeding
- Physician assistant saw patient
- No biopsy performed
- Ultrasound = negative
 - Subsequently could not produce photograph taken at the time of ultrasound

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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

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Delay in Diagnosis North Carolina

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

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Delay in Diagnosis North Carolina

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

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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

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Ultrasound Examination

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

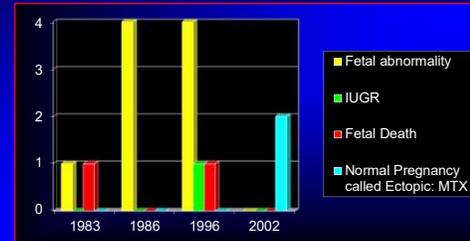
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Image Retention

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

55

Invented Lesions



RC Sanders. J Ultrasound Med 2003; 22: 1009-15.

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"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

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"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."

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"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

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"Ectopic Pregnancy"

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**

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“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

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“Ectopic Pregnancy”

Notice of claim

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

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“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.

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“Ectopic Pregnancy”

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

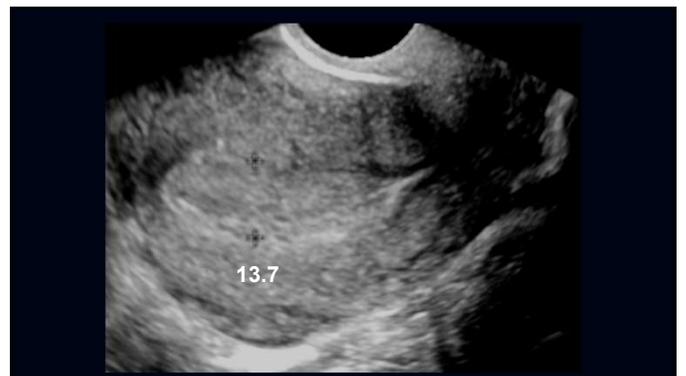
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“Ectopic Pregnancy”

Case update

- Radiology films were located

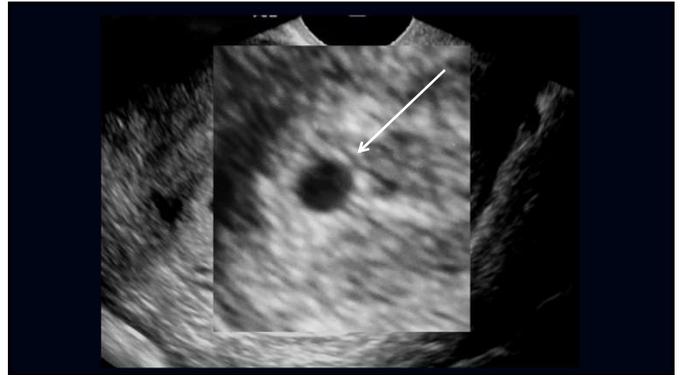
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"Ectopic Pregnancy"

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

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"Ectopic Pregnancy"

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.

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"Ectopic Pregnancy"

Settled for \$95,000

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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

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Twin IUP + MTX

Ultrasound at 16 weeks

- Normally growing twin gestation with no abnormalities visualized
- Reassured

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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

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Twin IUP + MTX

Delivered by C-section

- Hypotonia
- Micrognathia
- Short limbs
- Dysmorphic facies

Growth and development

- Feeding difficulties
- Growth delays
- Developmental delays

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Twin IUP + MTX

Suit filed against

- Radiologist
 - Misdiagnosis
- REI Gynecologist
 - Misdiagnosis
 - Inappropriate treatment with MTX
 - Wrongful birth
- Perinatologist A
 - Wrongful Birth

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Twin IUP + MTX

Trial

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

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Twin IUP + MTX

Trial

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

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Twin IUP + MTX

Trial

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.

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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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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

Clayton et al. Obstet Gynecol 2006;107:598-604.

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MTX and Anomalies

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

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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

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Twin IUP + MTX

Trial

Defense

- 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

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What was the verdict for the parties?

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Twin IUP + MTX

Verdict

Radiologist

- Defense verdict

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Twin IUP + MTX

Verdict

REI

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

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Twin IUP + MTX

Verdict

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

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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

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Keepsake Ultrasounds



FETAL FOOT IN MOUTH

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“Keepsake” Malpractice

Any malpractice claim concerning keepsake video production will be a case of first impression.

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Entertainment Ultrasound Case of First Impression

Colorado 2009

- Down's Syndrome
- Alleged missed anomaly during "Keepsake Ultrasound" in the 3rd trimester

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Entertainment Ultrasound Case of First Impression

Colorado 2009

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

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The Story

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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?

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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.

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Entertainment Ultrasound

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

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Liability Risks

Different scenarios

- Least
- 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
- Most

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Types of Health Care Fraud

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

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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

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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

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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

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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

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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

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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%)

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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)

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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

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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?

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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

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Video capture during US

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

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Confidentiality

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

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Confidentiality

- 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.

U.S. Department of Health & Human Services (HHS). Health information privacy: Covered entities and business associates. HHS website. <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/>. Published March 14, 2012. Accessed August 21, 2017.

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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"

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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.

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Penalties for Violations



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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

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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

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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

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Check state laws

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

Mary Castaldo et al. Can Patients Make Recordings of Medical Encounters? What Does the Law Say? JAMA, July 2017 DOI: [10.1001/jama.2017.7511](https://doi.org/10.1001/jama.2017.7511)

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- 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.

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Ultrasound Examination

- AIUM Accreditation
- Establishes policies and procedures
– "Best Practices"

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Ultrasound Examination

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

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Equipment

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

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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.

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Summary

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

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Thank You



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Thank You



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