

Medicolegal Issues Related to OB/GYN Ultrasound

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Disclosures

James M. Shwayder, MD, JD

Relevant Financial Relationships: None

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Learning Objectives

After completing this presentation, the learner will be able to:

1. Explain liability, as it relates to ultrasound
2. Recognize those areas that pose the greatest risk for liability with ultrasound
3. Reiterate the most common errors that lead to litigation
4. Employ practices that can help reduce one's exposure to litigation

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Outline

- Define malpractice
- Specialty exposure
- Type of errors leading to litigation
- Legal concepts
- Measures to reduce litigation risk/successful litigation
- Coding and billing
- Case examples

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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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Standard of Care Applied

- No longer local or regional
- National standard of care is applied¹
 - Advances in communication
 - Dissemination of medical information

¹Chervenak FA and Chervenak JL. Medical Legal Issues in Obstetric Ultrasound. Clin Perinatol 2007;34:299-308

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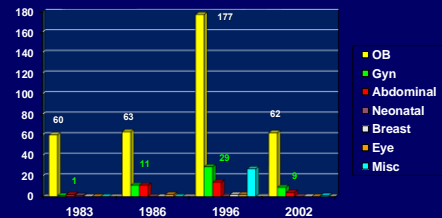
Burden of Proof

Medical malpractice

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

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Cases by Specialty Area



Sanders RC. Changing Patterns in Ultrasound-Related Litigation
J Ultrasound Med 2003; 22: 1009-15.

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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.

- Error rate in radiology is ~ 30%¹
- Question: Was it below the standard of care for the physician not to have seen the abnormality?²
- 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.

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Perception Error Missed Diagnosis

- 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”

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Perception Error Missed Diagnosis

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

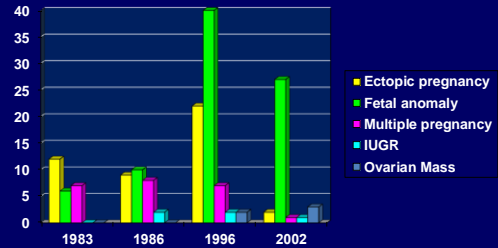
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Perception Error Missed Diagnosis

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

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Missed Diagnosis



Sanders RC. Changing Patterns in Ultrasound-Related Litigation
J Ultrasound Med 2003; 22: 1009-15.

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Ultrasound – Liability Perception Error

- 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. (coupled with lack of AFP testing)
 - \$4,350,000
- Failure to detect severe hydrocephalus
 - \$5,500,000

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Delay in Diagnosis Missed Diagnosis

- 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

- 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

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Delay in Diagnosis

- 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

- 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

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Legal Concepts

- **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-Insure adequate**
 - Training
 - Supervision
- **Performance of the study**
 - AIUM guidelines
 - Appropriate images

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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 interpretation errors
 - 75% are won if cases go to jury verdict

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Vaginal Bleeding

- 36 y.o. G3P2002
- Seen in ED on May 29 (Saturday)
- c/o spotting on Thursday and Friday
- No LMP noted

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Vaginal Bleeding

Examination

- VSS
- Point tenderness in the RLQ and suprapubic region
- No vaginal bleeding
- No cervical motion tenderness
- No adnexal fullness

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Vaginal Bleeding

- hCG = 209
- H/H = 12.7/35.9

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PAIN R/O ECTOPIC BETA 209

PELVIC ULTRASOUND

The uterus is normal. The endometrial canal is empty and about 1.1 cm in depth. No intrauterine gestational sac is seen.

The ovaries are normal in size. In the right ovary there is a 1.5-cm cyst/follicle.

No significant free pelvic fluid.

No abnormal pelvic mass.

IMPRESSION: Mild thickening of the endometrium. No intrauterine gestational sac is seen. In a pregnant patient the above findings are consistent with an early intrauterine gestation, an ectopic pregnancy or abortion. Correlation with quantitative beta-hCG levels as well as clinical follow-up is recommended and depending upon the clinical situation, follow up ultrasound may be helpful.

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ED visit June 4

- ED: RLQ Pain
- Rating: 8
- No vaginal bleeding
- Exam: "Abdomen: Mild tender, no tenderness in the right inguinal area. There is no abdominal tenderness. No guarding or rebound."
- NOTE: No pelvic performed in the ED

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Lab

- hCG = 2399
- H/H = 12.6/36.0

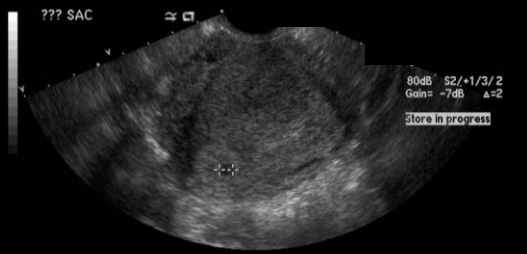
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June 4



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June 4



GS = 0.49 cm
MA = Out Of Range

WL: 128 WW: 256 [D]

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June 4



WL: 128 WW: 256 [D]

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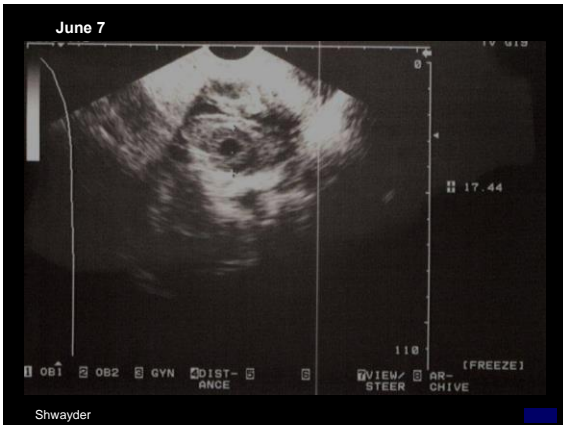
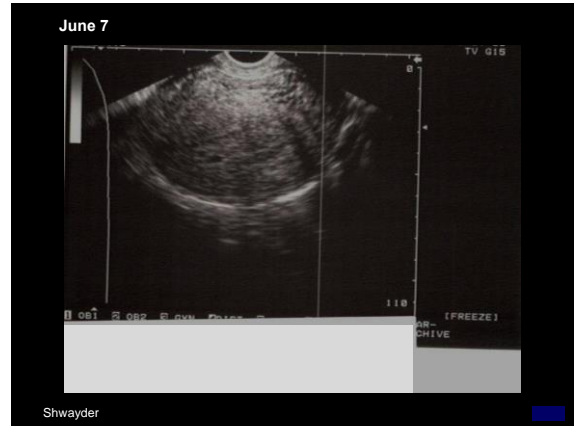
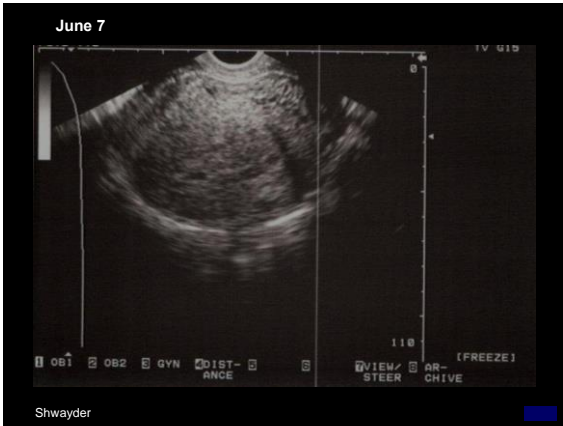
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Physician's office June 7

- 36 yo. f/u from ED
- No bleeding
- Menstrual-like cramping
- "Seen in ER for pain."
- "Last hCG – 2399"
- "RT OVARIAN CYST WAS SEEN. NO FF"
- VSS

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The vagina was normal.
Cervix normal, the uterus was normal, and the uterine adnexae were normal.

LMP: 4/27/2010.
US SHOWS NO IUP. THERE IS A DOUBLE RING LIKE STRUCTURE SEEN ON U/S TODAY < 2. CM NO FF. Chaperone present.

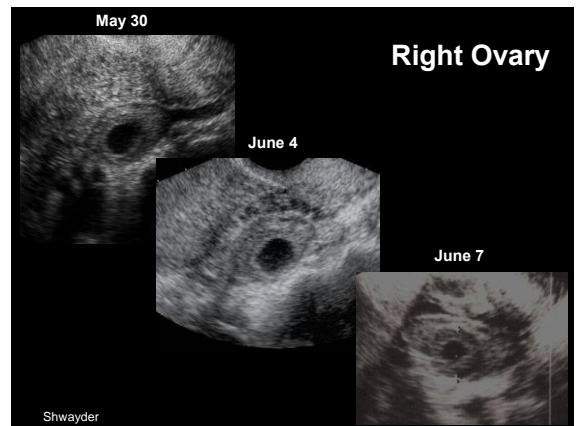
Assessment

- Ectopic pregnancy

Plan

- Serum HCG, beta subunit, quantitative
- Follow-up visit 4 DAYS

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hCG summary

- May 30 209
- June 4 2,399
- June 7 Methotrexate given
- June 7 6,484

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Physician's office June 14

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June 14



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June 14



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June 14



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Physician's office June 14

Sterile speculum exam:
VAG US/ EMPTY UTERUS; NO FREE FLUID 3 CM RT CYST BUT OVARIES BILAT WNL

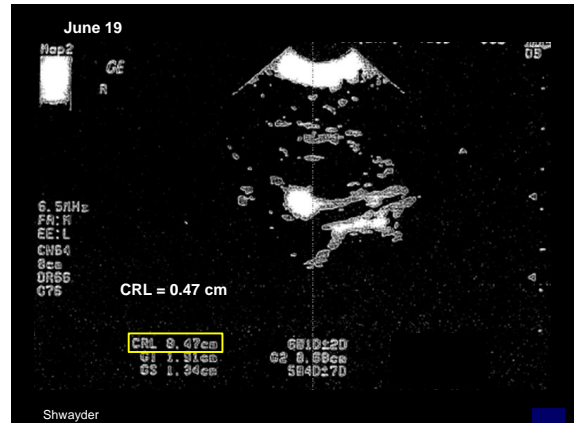
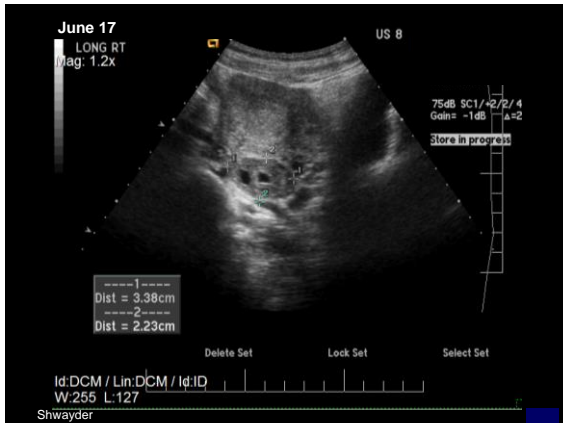
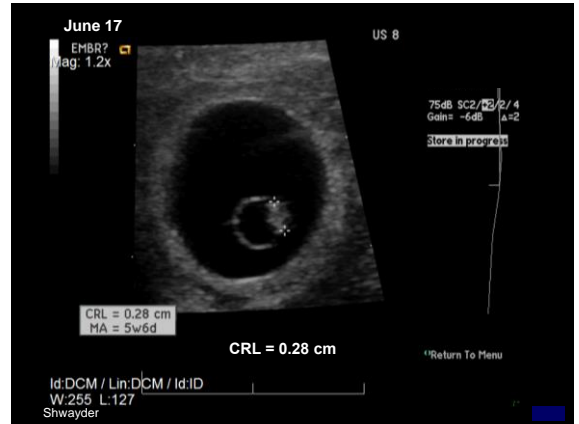
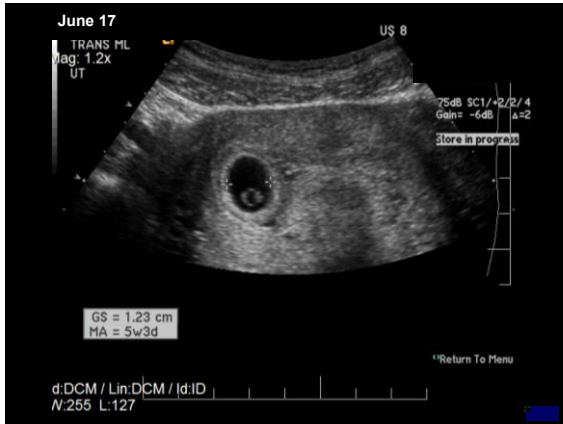
Impression: Postop Check

PLAN:
Return in

7 DAYS RPT BETA CALL ON WEDS FOR RESULTS>>>EXPECT ABOUT 650

Additional Notes:
ECTOPIC PREC

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Performance

- Incomplete study
- Poor image quality

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Equipment

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

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Image Retention

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

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Interpretation Errors

- Fluid within the endometrium
- Cyst in right ovary
- Did not review the prior images when interpreting the current study

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“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

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“Ectopic Pregnancy”

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.”

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“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

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“Ectopic Pregnancy”

Quantitative hCG

- Day 1 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

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"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

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Twin IUP + MTX

Perinatal counseling

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

Recommendation

- Serial ultrasounds
- Reassurance

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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
 - Dymorphic 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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Legal Concepts



- Wrongful Birth
- Wrongful Life
- Wrongful Death

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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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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)

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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)

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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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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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Interpretation Errors

August 1

- LMP = June 9
- EGA = 7w5d
- EDD = March 16

Ultrasound

- Small fetal pole with cardiac activity
- EGA = 5w2d
- EDD = March 29

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Interpretation Errors

Sept 6

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

*CA = cardiac activity

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Interpretation Errors

Sept 26

- LMP = June 9
- EGA = 15w5d (dates)
- EGA = 13w4d (ultrasound)
- No physical examination documented
- “Offered expectant management vs. D&C.”
- “Rx: Cytotec”

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Interpretation Errors

Sept 30

- 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

Sept 6

- 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 gestational sac a Nabothian cyst?
- Avoid “quick peeks” with the ultrasound
- Confirm findings that do not correlate with prior findings
- Document properly
- Examine patients

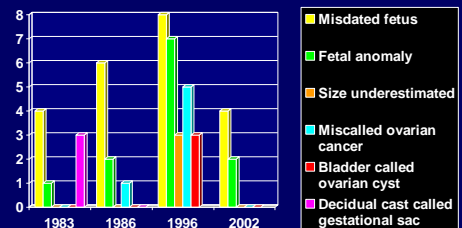
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Image Retention

- Preferably digital capture and retention
- Maintain for the specific statute of limitations for your state or jurisdiction

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Misinterpreted Images



Sanders RC. Changing Patterns in Ultrasound-Related Litigation
J Ultrasound Med 2003; 22: 1009-15.

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US adjusted EGA

- 43 week IUP referred for evaluation of fluid
- Misdiagnosed as being 37 weeks
- Post-dates fetus with oxygen deprivation
 - O₂ deprivation = paraplegic and speechless
- \$27 million award

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US adjusted EGA

- \$1.4 million for special education
- \$65,000 annually until patient is 73
- Lump sum payments of \$100,000, \$200,000, and \$300,000 at ages 5, 10, 15
- \$13 million against Director of Ultrasound

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Misdated Fetus

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

- LMP = July 5
- EDC = April 12
- Oligomenorrhea

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Misdated Fetus

Oct 31

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

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Misdated Fetus

Nov 2 Ultrasound

- Small for dates
- EGA (dates) = 17 weeks
- "Live, intrauterine pregnancy with a gestational age of 9w4d \pm 6 days. The EDD is April 10."
- EGA (US) = 9w4d
- EDD (US) = June 03

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Misdated Fetus

Dec 14

- 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

- April 5 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 sonologist 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 sonologist is not expected to follow up on the recommendation.
 - Exception: Beware of reinterpreting images on multiple occasions¹

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

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Recommendations

- **Sonologist**
 - Make specific recommendations when appropriate
- **Clinician**
 - Read the entire ultrasound report, not just the summary diagnosis
 - Correlate the ultrasound 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**
- **Reported as “normal”**
- **No mention of subtle findings**
 - UPJ* = 4.3 and 4.4
 - EIF* noted

*UPJ = Ureteropelvic Junction
 EIF = Echogenic Intracardiac Focus

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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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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

Benacerraf et al. Obstet Gynecol 1990; 76: 58.
(Current literature at the time of this case)

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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 (LR)

# 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

* Individual LR better
Benacerraf et al. Radiology 1994; 193: 135-140

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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

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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 Down's Syndrome
 - 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

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"

Reed v. Campagnolo, 810 F. Supp. 167 (D.Md. 1993)

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Ultrasound Examination

- AIUM Accreditation
- Establishes policies and procedures
 - “Best Practices”

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Equipment

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

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Ultrasound Examination

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

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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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Non-medical use of Ultrasound



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“Keepsake” Malpractice

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

*J Shwayder - 2003

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Entertainment Ultrasound Case of First Impression

Colorado 2009

- Alleged missed anomaly during “Keepsake Ultrasound” in the 3rd trimester

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Entertainment Ultrasound Case of First Impression

- Ultrasound was performed on a Sunday by the patient’s neighbor
- The neighbor was a sonographer at an ob-gyn practice (not the patient’s ob-gyn)
- The sonographer gave the patient a copy of the study on a CD, with 3D images

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Entertainment Ultrasound Case of First Impression

Colorado 2009

- Baby born with Down’s Syndrome
- Shorten femur at 31 weeks
- Termination is available up to 34 weeks in Boulder, Colorado

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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
- RDMS sonographer-physician oversight

Most

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The screenshot shows the top portion of a CNNMoney.com article. The header includes the CNNMoney.com logo, a search bar with the text 'Symbol' and a 'Get Quo' button, and a navigation menu with links for Home, Business News, Markets, Personal Finance, Retirement, and Technology. The article title is 'Health care: A 'goldmine' for fraudsters' and the author is identified as Parja Kavilanz, dated January 13, 2010. The article text begins with 'NEW YORK (CNNMoney.com) -- There's a group of people who really love the U.S. health care system -- the fraudsters, scammers and organized criminal gangs who are bilking the system of as much as \$100 billion a year.'

Types of Health Care Fraud

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

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Scenario

- Pennsylvania company would establish 3D capabilities in offices
 - Negotiate ultrasound lease
 - Train personnel in performing 3D ultrasound
 - Train office staff on billing for 3D

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Billing Fraud

- M-mode could be billed as echocardiogram
- >1200 ultrasounds billed with echocardiography (76825)
- Generated ~ \$44,000 income

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Billing Fraud

- Qui tam action
 - Individual reports billing fraud to government
 - In this case, a receptionist that was terminated from the Pennsylvania company

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Possible Sanctions

- **Civil Penalties**
 - Up to \$11,000 for each item or service
- **Criminal Penalties**
 - Fines of the \$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

- **DOJ investigated all practices that used the services of the company**
- **Solo practitioner**
- **Potential fine: \$13,200,000**
- **Settled: \$589,000**

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Conclusions

- **Perform US when clinically indicated**
 - Must temper “over-utilization”
- **Consider consent for ultrasound examinations**
 - Check with malpractice carrier
- **Chaperone**
 - Consider chaperone consent

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Conclusions

- **Adequately trained personnel**
 - Sonographers
 - Physicians
- **Perform US in accordance with current guidelines**
 - **Supervision**
 - General supervision except sonohysterography
 - **Documentation**
 - AIUM Practice Parameter: Documentation of an Ultrasound Examination - 2014

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Conclusions

- **Proper interpretation of the sonogram**
 - Appropriate training and referral
- **Use modern equipment**
 - Properly maintained
- **Communicate findings**
 - To referring physician or representative
 - To patient, when appropriate
 - Formal report should be explicit
- **Code properly**

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Medicolegal Issues Related to OB/GYN Ultrasound

Thank you

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Key References

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