

Liability in Ob-Gyn Ultrasound: Minimizing Risk and Improving Outcomes

James M. Shwayder, M.D., J.D.
Professor and Chair
Department of Obstetrics and Gynecology
University of Mississippi Medical Center
Jackson, Mississippi

Liability in Ob-Gyn Ultrasound: Minimizing Risk and Improving Outcomes

James M. Shwayder, M.D., J.D.

Disclosures: None

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

Legal Concept Malpractice



Elements of Negligence

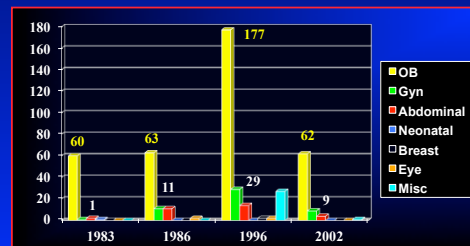
1. Duty
2. Breach of that duty
3. Proximate cause of injury
4. Damages

Burden of Proof

Medical malpractice

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

Cases by Specialty Area



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.

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.

Missed Diagnosis New Jersey

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

Missed Diagnosis New Jersey

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

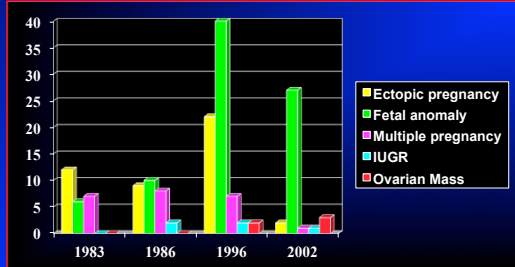
Missed Diagnosis New Jersey

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

Ultrasound - Liability

- Failure to conduct additional testing upon inability to visualize all four chambers of the heart during a routine sonogram
 - \$4,200,000
- Failure to detect meningocele 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

Missed Diagnosis



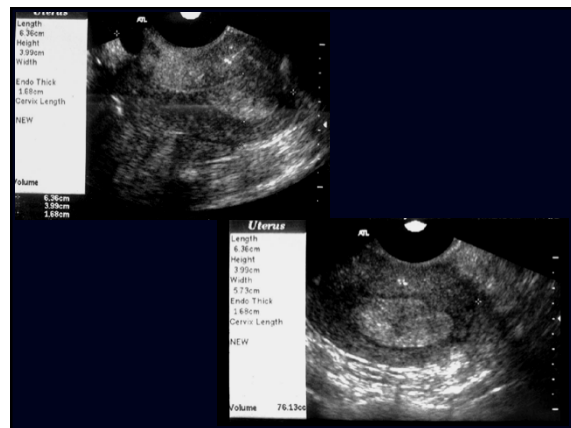
RC Sanders. J Ultrasound Med 2003; 22: 1009-15.

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

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

Vaginal Bleeding

- 36 y.o. G3P2002
- Seen in ED on 5/29/10 (Saturday)
- c/o spotting on Thursday and Friday
- No LMP noted

Vaginal Bleeding

Examination

- VSS
- Point tenderness in the RLQ and suprapubic region
- No vaginal bleeding
- No CMT. No adnexal fullness

Vaginal Bleeding

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



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.

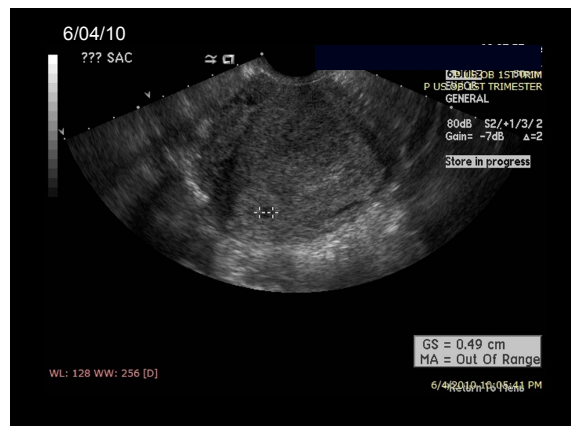
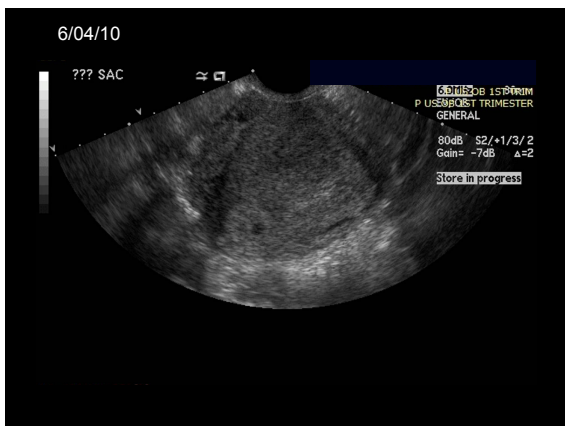
IMPRESSION: Mild thickening of the endometrium. No intrauterine gestational sac is seen. In a pregnant patient the above findings are consistent with an early intrauterine gestation, an ectopic pregnancy or abortion. Correlation with quantitative beta-hCG levels as well as clinical follow-up is recommended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

**ED visit
6/04/10**

- 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**

Lab

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



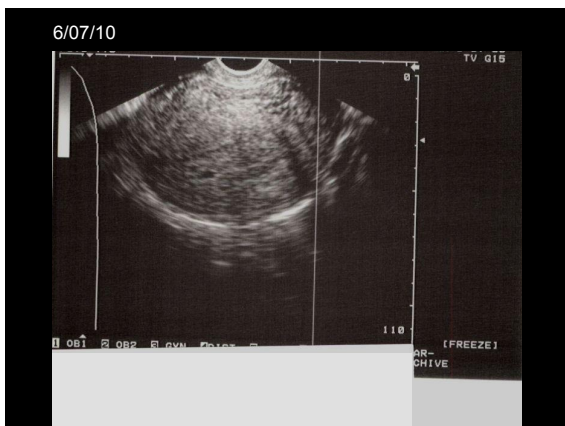


Clinical History / Indication for Exam:
RLQ PAIN, R/O ECTOPIC

-Compared to the previous ultrasound report, there has been development of a small fluid collection within the endometrial cavity which may represent early gestational sac estimated to be 5 mm in diameter which is too early to determine fetal age Follow-up ultrasound is recommended
-1.2-cm right ovarian cyst
-No free fluid identified

**Physician's office
6/07/10**

- 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



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

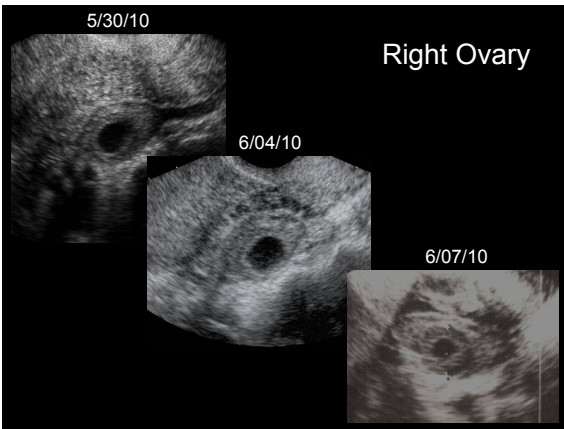
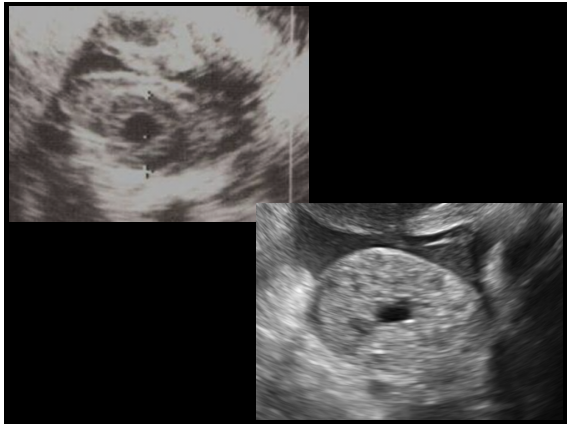
LMP: 4/27/2010.
 U/S SHOWS NO IUP. THERE IS A DOUBLE RING LIKE STRUCTURE SEEN ON U/S TODAY <2. CM NO FF.
 Chaperone present.

Assessment

- Ectopic pregnancy

Plan

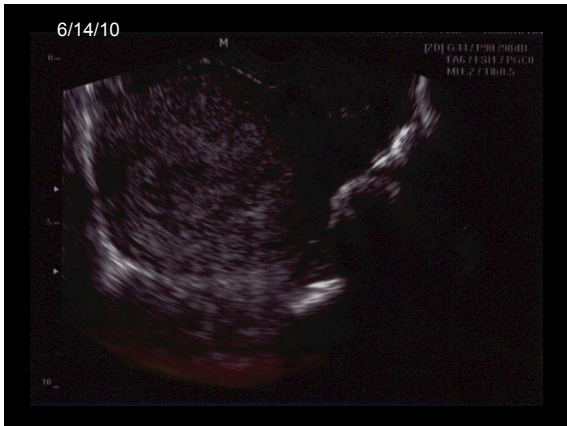
- Serum HCG, beta subunit, quantitative
- Follow-up visit 4 DAYS



**6/19/10
 hCG summary**

• 5/30/10	209
• 6/04/10	2,399
• 6/07/10	Methotrexate given
• 6/07/10	6,484

**Physician's office
 6/14/10**





Physician's office
6/14/10

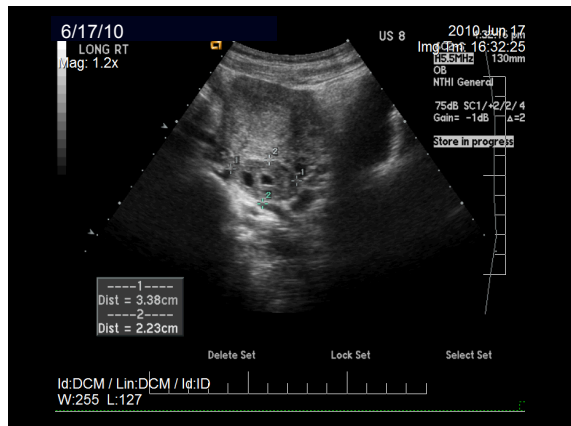
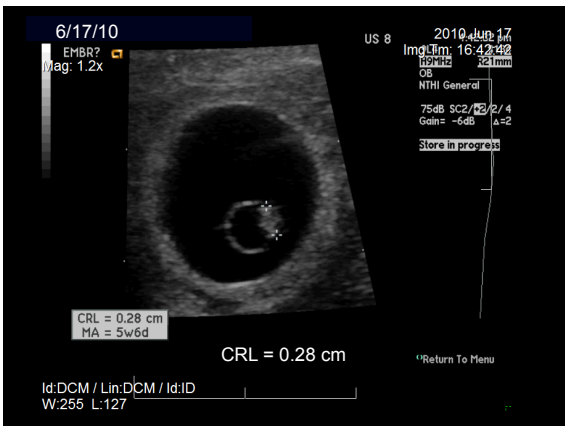
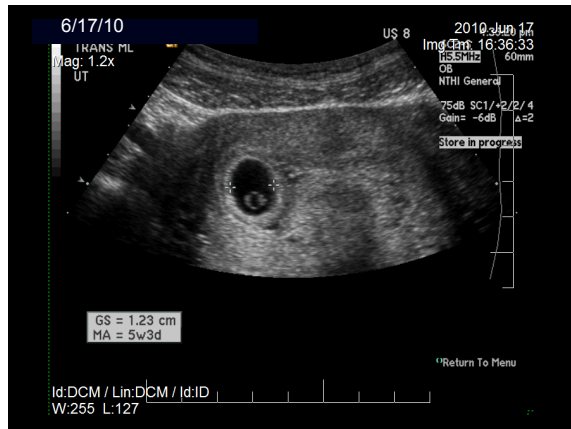
Sterile speculum exam:
VAG US EMPTY UTERUS; NO FREE FLUID 3 CM RT CYST BUT OVARIES BILAT WNL

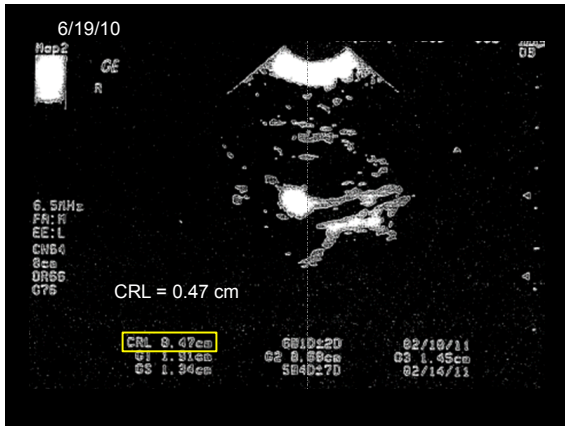
Impression: Postop Check

PLAN:
Return in

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

Additional Notes:
ECTOPIC PREC





Performance

- Incomplete study
- Poor image quality

Equipment

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

Image Retention

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

Interpretation Errors

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

Interpretation Errors

- 8/01/05
- LMP = 6/09/05
 - EGA = 7w5d
 - EDD = 3/16/06
- Ultrasound
- Small fetal pole with cardiac activity
 - EGA = 5w2d
 - EDD = 3/29/06

Interpretation Errors

9/06/05

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

Interpretation Errors

9/26/05

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

Interpretation Errors

9/30/05

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

Interpretation Errors Settlement

\$600,000

Interpretation Errors

9/06/05

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

Recommendations

- Clinician
 - Was the 1x1 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)

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 \pm 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"

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

Newborn Course

- Prematurity
- Respiratory distress syndrome
- Necrotizing enterocolitis

Misdated Fetus

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

Failure to Communicate

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

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

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).

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 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

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	??

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

Benacerraf et al. Obstet Gynecol 1990; 76: 58.

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

# 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

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

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

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

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

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

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.

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.

Wrongful Birth

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"

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

Ultrasound Examination

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

Equipment

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

Ultrasound Examination

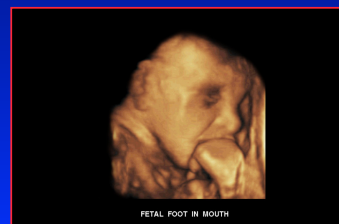
- Performance of the study
- Interpretation of the study
- Communication of results
- Documentation

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.



Keepsake Ultrasounds



“Keepsake” Malpractice

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

Entertainment Ultrasound Case of First Impression

Colorado 2009

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

Entertainment Ultrasound Case of First Impression

Colorado 2009

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

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?

COPIC Insurance Co. Coverage Limitations

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

Copiscope, No. 114, July 2003.

Entertainment Ultrasound

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

Liability Risks Different scenarios

Least

- 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

Most

Outline

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



Thank You

