4th Annual
Texas Two Step Conference:
Medicolegal Issues in Ob/Gyn

Friday and Saturday, February 28 – March 1, 2014
This activity is approved for 15.25 AMA PRA Category 1 Credits™
AGENDA • SATURDAY, MARCH 1, 2014

8 – 8:15 a.m.    Welcome, Introductions and Announcements
                 Sean Blackwell, M.D.

8:15 – 9 a.m.    Preventable Adverse Outcomes Related to Obstetrical Hemorrhage
                 Baha Sibai, M.D.

9 – 9:45 a.m.    Anatomy of Medical Malpractice Lawsuit
                 W. Russ Jones, J.D.

9:45 – 10 a.m.   BREAK

10 – 10:45 a.m.  How to Avoid Being Sued for Injury Related to Infections and Sepsis in Obstetrics
                 John Barton, M.D.

10:45 – 11:30 a.m. Missed or Delayed Diagnoses in Gynecologic Cancer: How to Avoid
                    Joseph Lucci, III, M.D.

11:30 – 12:15 p.m. Medicolegal Issues with Shoulder Dystocia and Brachial Plexus Impairment
                    Suneet Chauhan, M.D.

12:15 – 1 p.m.   LUNCH

1 – 1:45 p.m.    FHR Monitoring and Interpretation: Lessons Learned from Medicolegal Process
                 Sean Blackwell, M.D.

1:45 – 2:30 p.m. Risk Management Issues Related to OB Triage
                 George Saade, M.D.

2:30 – 2:45 p.m. BREAK

2:45 – 3:30 p.m. Medical Errors in Benign Gynecology
                 Randa Jalloul, M.D.

3:30 – 4:15 p.m. Strategies and Solutions on How to Avoid and /or Survive Medical Malpractice Allegation
                 W. Russ Jones, J.D.

4:15 – 5 p.m.    What Would You Do? OB Case Studies
                 Moderator: Baha Sibai, M.D.

5 p.m.           CONCLUSION
Course Description

Obstetrics and Gynecology is one of the highest at-risk specialties for legal litigation, as there remains a high acuity and case complexity rate for women (pregnant and non-pregnant). Although rates are improving, there remain multiple areas of opportunity to reduce the frequency of near misses and medical errors, therefore preventing unnecessary harm.

The two-day conference will include experts in Obstetrics and Gynecology providing current perspectives, guidelines and best practices for significant healthcare liability concerns in OB/GYN.

Target Audience

Physicians, nurses and other healthcare providers, as well as lawyer, risk managers and paralegals interested in medical malpractice in OB/GYN.

Continuing Education Hours for Nurses

Memorial Hermann-Texas Medical Center is an approved provider for continuing nursing education by the Texas Nurses Association, an accredited approved by the American Nurses Credentialing Center Commission on Accreditation.

This activity is approved for 15 total contact hours.

Continuing Education Hours for Physicians

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Texas Medical Association (TMA) through the joint sponsorship of Memorial Hermann Health System and the University of Texas Health Science Center at Houston. Memorial Hermann Health System is accredited by TMA to provide continuing medical education for physicians.

Memorial Hermann Health System designates this live activity for a maximum of 15.25 AMA PRA Category 1 Credits™. Participants should only claim credit commensurate with the extent of their participation in the activity.
Preventable Adverse Outcomes Related to Obstetrical Hemorrhage

Baha Sibai, M.D.
Preventable Adverse Outcomes Related to Obstetrical Hemorrhage

Baha M. Sibai, MD
Professor, MFM Division
Principal Investigator, Eunice Kennedy Shriver NICHD Maternal-Fetal Medicine Network
Director, Maternal-Fetal Medicine Fellowship Program

Mechanisms to identify patients at risk for obstetric hemorrhage using color codes

**Antepartum**

<table>
<thead>
<tr>
<th>CODE RED</th>
<th>CODE ORANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Placenta accreta/percreta</td>
<td>• Multiple cesarean sections ≥ 3</td>
</tr>
<tr>
<td>• Complete placenta previa</td>
<td>• Preexisting J/T/classical uterine scar</td>
</tr>
<tr>
<td>• Any placenta previa plus ≥ 1</td>
<td>• Prior uterine rupture</td>
</tr>
<tr>
<td>prior cesarean sections</td>
<td>• Any placenta previa with prior bleeding</td>
</tr>
<tr>
<td>• Vasa previa</td>
<td>• Sickle cell disease with preexisting rare antibodies</td>
</tr>
<tr>
<td></td>
<td>• Prolonged fetal death (≥ 2 wks)</td>
</tr>
<tr>
<td></td>
<td>• Patient receiving therapeutic dose anticoagulation</td>
</tr>
</tbody>
</table>

**Intrapartum**

<table>
<thead>
<tr>
<th>Code red</th>
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</thead>
<tbody>
<tr>
<td>• Abruptio placenta with fetal death</td>
</tr>
<tr>
<td>• Suspected abruptio placenta</td>
</tr>
<tr>
<td>• Previous C/S and previa with bleeding</td>
</tr>
<tr>
<td>• Patients at risk for uterine rupture</td>
</tr>
<tr>
<td>• Acute fatty liver of pregnancy</td>
</tr>
<tr>
<td>• HELLP syndrome with platelet count &lt; 50k/mm3</td>
</tr>
<tr>
<td>• Suspected amniotic fluid embolism</td>
</tr>
<tr>
<td>• Receiving full anticoagulation</td>
</tr>
</tbody>
</table>
Early detection & preparation is critical

Have written action plan & protocols for:

- Monitoring of such patients
- Indications for hospitalization
- Indications for delivery & GA for planned delivery
- Mode of delivery / CS hysterectomy
- Availability of blood / blood products
- If patient presents as an emergency
  • What to do?
  • Whom to call?

Risk Factors for Postpartum Hemorrhage

- Prolonged labor: Prostaglandins, oxytocin
- Uterine relaxing agents: MgSO₄, betamimetics
- Uterine over distension: Multifetal gestation, Polyhydramnios
- Previous history
- Morbid obesity, AMA
- Chorioamnionitis
- Abnormal Placentaition/Lacerations

Postpartum Hemorrhage

- Assess blood loss & vital signs
- Call for help
- Large bore IV access + fluids
- Obtain blood/products

Establish etiology

- Retained tissues
- Previa-accreta
- Lacerations
- Cervical/vag
- Perineal
- Extension at c/s
- Uterine rupture

Surgery

- Medical
- Surgical

- Coagulopathy
  - Abruptio
  - AFE/AFLP
  - Anticoagulation
  - Bleeding
  - VW disease

Blood products
- Resuscitation
- Supportive care
### Clinical Staging of Postpartum Hemorrhage

<table>
<thead>
<tr>
<th>Severity</th>
<th>Findings</th>
<th>Blood loss</th>
</tr>
</thead>
</table>
| Mild     | HR < 100 bpm  
Mild hypotension  
vasoconstriction | 15-20% |
| Moderate | HR = 100-120 bpm  
SBP = 90-100 mmHg  
Restlessness  
Oliguria | 25-35% |
| Severe   | HR > 120 bpm  
SBP < 60 mmHg  
Altered Consciousness  
Anuria  
Air hunger | ≥ 35% |

### Signs & Symptoms of Hypovolemic Shock

**Signs**
- SBP ≤ 90 mm Hg
- DBP ≤ 50 mm Hg
- HR ≥ 110 bpm
- RR ≥ 24
- **Narrow pulse pressure**
- Cold/clammy
- Pale
- Oliguria - anuria

**Symptoms**
- Anxiety
- Confusion
- Lethargy
- Air hunger
- Tachypnea
- Dizziness

### Clinical Findings in Different Etiology of Shock

<table>
<thead>
<tr>
<th></th>
<th>Hypovolemia</th>
<th>Sepsis</th>
<th>Cardiogenic</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>↓</td>
<td>↑, N, ↓</td>
<td>↓</td>
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<tr>
<td>SVR</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>CVP</td>
<td>↓</td>
<td>↓, N, ↑</td>
<td>↑</td>
</tr>
<tr>
<td>Pulse</td>
<td>Faint</td>
<td>Bounding</td>
<td>Bounding</td>
</tr>
<tr>
<td>Skin</td>
<td>Cold/clammy</td>
<td>Warm/flushed</td>
<td>--</td>
</tr>
<tr>
<td>Rx</td>
<td>Volume +</td>
<td>Volume +</td>
<td>Inotropic</td>
</tr>
<tr>
<td>Replacement</td>
<td>Vasopressors</td>
<td>agents</td>
<td></td>
</tr>
</tbody>
</table>
Management of Obstetric Hemorrhage

**Sibai’s Guidelines**

**Fill tank**
- **Fluids**
- **Blood**
- **Products**

**Find leaking holes**
- Check tone, vessels

**No systemic vasoconstrictors**
- Reduce tissue perfusion
- Ischemia
- Acidosis
- Endothelial damage

Preparation for Severe Peripartum Hemorrhage

- 2 short, large-bore IV catheters
- Arterial line: BP, Lab tests
  - Hgb, coagulation
  - ABG, electrolytes
- Automatic rapid infusion system
- Fluid & blood warm
- Forced-air warming device
- Monitoring of core temp
- Blood & blood products

Postpartum Hemorrhage Tray

- **Uterotonic drugs**
  - Methergine/Oxytocin
  - Hemabate (4 ampules)
  - Misoprostol (600 µg)
- **Uterine packing balloons**
  - Foley, Bakri, BT, Ebbs
- **Large speculum, retractors**
- **Uterine compression sutures**
- **Topical hemostatic agents**
  - Thrombin, floseal
Medical Management of PPH

- Continuous monitoring
  - Vital signs/blood loss
  - Coagulation studies
  - Urine output, mental status

- Resuscitation
  - Fluids, blood/products

- Uterine Compression/Packing
  - Uterotonics
  - Uterine tamponade

- Replace uterus if inversion

Uterine atony

- Uterine compression
  - Uterotonic agents
  - Vital signs/blood loss
  - Blood/products

- Balloons
  - Bakri
  - BT-catheter
  - Foley bulb
  - Ebbs

- Sutures
  - B-lynch
  - Hayman
  - Cho
  - Ouahba

- Arterial Occlusion
  - Uterine
  - Utero-ovarian
  - Hypogastric

Embolization
- Only if stable

Hysterectomy
- Clinical Condition/ Future Fertility

Foley, Bakri, Rusch, Condom
Surgical Management of PPH

- D&C if retained products
- Repair of lacerations
- Uterine compression sutures
- Arterial ligation
  - Uterine, tubo-ovarian
  - Hypogastric
- Hysterectomy
- Embolization (only if stable)
Uterine Compression Suturing Techniques

- **Patient in frog leg position**
  - Observe for effectiveness
  - Observe for bleeding
- **B-Lynch Brace : requires Ut. incision**
- **Hayman : No Ut. incision**
- **Cho : Multiple squares**
- **Ouahba : 2 transverse & 2 lateral**
Blood Supply to Uterus, Cervix, & Vagina

- **Uterine fundus**
  - Uterine arteries: 70-80%
  - Ovarian arteries: 20-30%
    - From aorta
- **Internal iliac artery**
  - Uterine artery
  - Cervical branches
  - Vaginal branches
- **Multiple collaterals**

Surgical ligation locations of uterine blood supply

Uterine Lacerations

- **Transverse Laceration**
  - Uterine Vessels
  - Vertical Laceration
  - Ureter
Puerperal Uterine Inversion: risk factors

- Premature traction on cord
- Fundal pressure
- Short cord
- Placenta accreta
Resuscitation & monitoring
- Vital signs, intake-output
- Secure blood & blood products
- Rapid infusion of crystalloids

Uterine relaxation

Attempt manual replacement

Failed

Attempt O’Sullivan hydrostatic pressure
Management of Uterine Inversion

- Resuscitation & monitoring of hemodynamic status
  - Vital signs, intake-output
  - Secure blood & blood products
  - Rapid infusion of crystalloids
  
  - Attempt manual replacement
    - Failed
  
  - Attempt O’ Sullivan hydrostatic pressure
    - Failed

- Laparotomy for uterine replacement
  - Vacuum suction cup applied to cervical ring
  - Huntington procedure
  - Haultain procedure
Risks Factors for Adherent Placenta

- Placenta previa
- Prior accreta
- Prior uterine surgery
  - Cesarean section
  - Myomectomy
  - Suction curettage
  - Cornual resection
  - Hysteroscopy
- Advanced age
- Increased parity
Frequency of placenta accreta by # of C/S and presence or absence of placenta previa

<table>
<thead>
<tr>
<th>C/S</th>
<th>Placenta previa</th>
<th>No previa</th>
</tr>
</thead>
<tbody>
<tr>
<td>First (primary)</td>
<td>3.3%</td>
<td>0.03%</td>
</tr>
<tr>
<td>Second</td>
<td>11%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Third</td>
<td>40%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Fourth</td>
<td>61%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Fifth</td>
<td>67%</td>
<td>0.8%</td>
</tr>
<tr>
<td>≥ Sixth</td>
<td>67%</td>
<td>4.7%</td>
</tr>
</tbody>
</table>

Adapted from SMFM. Am J Obstet Gynecol 2010
Society for Maternal-Fetal Medicine
Ultrasound Findings Suggestive of Accreta

- Placental lacunae
- Loss of retroplacental hypoechoic zone
- Previous cesarean & previa
  - Low-lying gestational sac
  - Intraplacental lakes with turbulent flow
  - Absent decidua basalis
    - Myometrial thickness < 1 mm
- Loss of smooth interface with bladder
- Focal nodular projections into bladder
  - Percreta
Placenta percreta reaching bladder serosa

Complications
Accreta/Percreta

Massive tx of blood/products
Acute tubular necrosis
Repeat surgical intervention

Death

Pelvic infection abscess
Severe Intrapartum postpartum bleeding
Bladder/Urteral bowel injury
Pulmonary edema
Hypoxic ischemic encephalopathy
Admission to ICU

Planned Management of Accreta-percreta
Reduces risks of adverse outcome
- Proper counseling
  - Potential loss of fertility/PTD
  - Early & prolonged hospitalization
    — Need for tx of blood/products
    — Admission to ICU/organ injury
- Delivery in well-equipped & staffed O.R.
- Availability of blood/products
- Avoids chaos/multidisciplinary team
  - Skilled surgeon/Anesthesia
  - Gyn oncologist/Urologist
  - Nursing/OR/blood bank personnel
  - Intervention radiology
GA at Delivery in Known Placenta Accreta (n=62)*

- Planned at 34-35 wk (n=53)
- Mean at delivery 33.9 ± 1.1 wk
- 22 (35%) required emergency C/S
- Planned at ≥ 36 wk (n=9)
  - 4 of 9 had emergency hemorrhage

*Data from Warshak et al (Obstet Gynecol 2010;115:65)

Management of Placenta Percreta

- Counseling
  - Risks
  - Fertility
- Abnormal Placenta
  - Bleeding?
  - Extirpative Approach
    - Hysterectomy
    - Partial Cystectomy
    - Balloon Catheter
    - Embolization
    - Pelvic Packing
    - Aortic Clamping
- Recruit/Plan
  - Blood/Products
  - Subspecialists
- Planned delivery
  - Extrauterine invasion?
  - Yes
  - Conservative Approach
    - Supplemental MTX
    - Serial HCG’s and Coags
    - Lower perfusion pressure
  - No
  - DIC
  - PPH

Surgical Options for Accreta/percreta

- Hysterectomy
  - Total
  - Supracervical
  - Partial
- Hysterectomy + partial bladder excision
- Leave placenta in situ
  - Hysterectomy 1 wk later
  - Hysterectomy & bladder dissection
  - Hysterectomy if needed
    - Bleeding
    - Infection
Management of Unsuspected Placenta Increta-percreta

- Assess location & extent of invasion
- Evaluate for active bleeding
- Inquire about assistance/resources
- Delay uterine incision if looks abnormal
  - Distorted lower segment
  - Blood vessels on uterine serosa
  - Invasion into bladder or surrounding tissue
- Patient is stable & facility is not prepared
  - Cover uterus with warm towels & call for help
  - Close abdominal incision & consider transfer

Omental adhesions

Percreta replacing lower segment

Normal myometrium at fundus
Management of Placenta Left In-situ

- Ligate cord in proximity to insertion
- Close uterine incision
- Broad spectrum antibiotics
- Prolonged hospitalization (7-10 d)
- Methotrexate 50 mg/m² IM/ wk
- β-HCG titer, CBC, coagulation, liver enzymes q wk
- Serial sonography (3-D angiography)
Complications of Leaving Placenta In-situ

- Profuse hemorrhage (3 hr to 7 wk)
- Delayed DIC (3–6 wks)
- Need for relaparotomy
- Late-onset sepsis (case reports)
- Methotrexate side effects
  - nausea & vomiting
  - oral stomatitis
  - cough or shortness of breath
  - Leucopenia/abnormal liver enzymes

Management of severe PPH

Life Saving Measures

- Recognition of hypovolemic shock
  - Blood loss > 2000 cc
- Recognition of tissue ischemia
- Recognition of DIC
- Treatment of hypovolemia & DIC
- Beware complications of massive TX.

Treatment of Hypovolemic Shock & DIC

Medical

- PRBC’s
- Platelets
- FFP
- Cryoprecipitate
- Recombinant F VII (60-90 µg/Kg)
- Correct: hypothermia, acidosis, Ca, K
- Correction of cause
Massive Transfusion Protocol

Activation

- Active moderate bleeding
- SBP < 80 mmHg
- Pulse > 120 bpm
- pH < 7.1
- Base deficit > 6 meq / L
- INR > 2
- Fibrinogen < 100 mg/dl
- Platelets < 50,000 / mm³
Massive Tx Protocol for Severe Hemorrhage

<table>
<thead>
<tr>
<th>Cycle #</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC</td>
<td>6u</td>
<td>6u</td>
<td>6u</td>
</tr>
<tr>
<td>Plasma</td>
<td>4u FFP</td>
<td>4u FFP</td>
<td>4u FFP</td>
</tr>
<tr>
<td>Platelets</td>
<td>5u pooled</td>
<td>5u pooled</td>
<td>5u pooled</td>
</tr>
<tr>
<td>Cryo</td>
<td>--</td>
<td>10u pooled</td>
<td>10u pooled</td>
</tr>
<tr>
<td>rFVIIa</td>
<td>--</td>
<td>Consider Administer</td>
<td></td>
</tr>
<tr>
<td>Fibrinogen concentrate</td>
<td>--</td>
<td>5 g</td>
<td>4 g</td>
</tr>
</tbody>
</table>

Target Blood Test during Massive Tx Protocol

- Hgb $\geq$ 7 g/dl
- Fibrinogen $> 150$ mg/dl
- PT & PT $< 1.5 \times$ mean control
- Platelet count $> 50,000/mm^3$
- Normal calcium levels
- Serum K$^+$ $< 5$ mEq/L
- Normal ABG

Complications from Massive Tx of PRBCs (> 6 units)

- DIC: dilutional
- Hypothermia: blood stored at 1-6 C
- Acidosis: pH of PRBC = 6.9-7.0
- Hypocalcemia: citrate binds to Ca$^{++}$
- Hyperkalemia: K$^+$ leaves RBC in stored blood
- ARDS: antibody-antigen mediated
Preventing adverse outcome in obstetric hemorrhage

**Timely delivery**

- Accreta/ percreta: 34 wk
- Total anterior previa: 34-35 wk.
- Total posterior previa: 35-36 wk.
- Partial previa: 37 wk.
- Prior uterine rupture: 36-37 wk
- Prior classical c/s: 36-37 wk.

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Avoiding adverse outcome in HDP

**Timely delivery**

- GHTN/Preeclampsia: 37 wk.
- Preeclampsia + severe features ≤34 Wk.
- Chronic hypertension
  - Control on no medication: 39 wk
  - Control on one drug: 37-38 wk
  - Control on 2 drugs: 36-37 wk
  - CHTN + diabetes ≤37 wk.
- Superimposed preeclampsia: 37 wk.
- Superimposed+ severe features ≤34 wk.

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The End
Anatomy of a Medical Malpractice Lawsuit

W. Russ Jones, J.D.
Disclosure Statement

- I do not have relevant financial relationships with commercial interests related to the content of this presentation.
Learning Objectives

• 1) List the key elements that have to be identified and included to meet the standard for medical malpractice by the plaintiff in order for the lawsuit to move to litigation;
• 2) Describe the anatomy of a medical malpractice lawsuit and the steps for both the plaintiff and defendant to take in preparing for the lawsuit.

Statutory Pre-requisites to a Medical Malpractice Lawsuit

• Suits are governed by the Texas Medical Liability Act, Chapter 74 of the Texas Civil Practice & Remedies Code
• Section 74.051 requires written notice of the claimant’s intention to file a healthcare liability claim to be served on the defendant healthcare provider at least 60 days prior to filing suit
• Section 74.052 requires the notice letter to enclose a signed HIPAA compliant authorization for the release of protected health information on the patient

Effect of Giving Timely Notice and a statutorily compliant Authorization

• “Tolls” the limitations period for 75 days (i.e., the statute of limitations of action is extended from 2 years to 2 years plus 75 days)
• Notice letter must be sent within the original 2 year limitations period, or the limitations period is not extended
• Claimant must enclose a signed HIPAA consent to give effective notice (written notice letter without HIPAA consent = no notice)
FORWARD THE NOTICE TO YOUR LIABILITY CARRIER IMMEDIATELY!

• Failure to timely notify your insurance carrier *can void your insurance protection* if the carrier’s rights are prejudiced by a delay in the carrier’s receipt of notice of the claim
• “Claims made and reported” policies require you to give notice of the claim *during the policy period*. Failure to report a known claim during the policy period *can void coverage* under the policy.

If the claim is not settled, suit may be filed against you

• The County Constable, Deputy Sheriff, or a private process server may personally serve you with “process” (a citation to appear in Court and a copy of the lawsuit papers filed against you)
• You may be served with process by Certified Mail/Return Receipt Requested
• Your Professional Association (or other form of business entity) may be served through your Registered Agent for service of process

What to do when you get served with a lawsuit

• You must “appear” in Court by 10:00 a.m. on the first Monday following 20 days from the date you were served with process
• Failure to timely appear in Court can result in a “Default Judgment” against you (Game over, you lose)
• Therefore, as soon as you are served, fax or hand deliver a copy of the citation and suit papers to your liability insurance carrier and request that they assign defense counsel to enter a timely appearance on your behalf
The Plaintiff’s “Original Petition”

- Cause Number, Court & style of the case
- The Discovery Control Plan requested
- The Parties’ identities and location
- Statement of Jurisdictional Bases of the suit
- Venue allegations
- Factual Statement (“fair notice” pleading)
- One or more “Causes of Action” being asserted
- Damages being claimed (by type of damage claim, not amount)
- Compliance with Statutory Pre-requisites (“Conditions Precedent”)
- Prayer for Relief
- Signed by the Plaintiff or her attorney

Statutory Expert Report Requirements

- Within 120 days of filing suit, the Plaintiff must file a written report of a “qualified expert” which: (1) demonstrates to the Trial Court that the claim has merit; and (2) which gives the Defendant fair notice of the specific conduct called into question.
- Defendant can move to dismiss the case with prejudice, at Plaintiff’s expense, for fatal deficiencies (insufficient report or unqualified expert)
- 30 day “grace period” to cure defects on a finding of a “good faith effort” at statutory compliance
- Report must delineate, in detail: (1) the S.O.C.; (2) the specific manner in which the defendant breached same; and (3) the causal connection between said breach and the injury, illness or condition for which the Plaintiff seeks damages.
- “Conclusory opinions”-not a good faith effort at compliance

The Negligence Cause of Action

- 4 Essential Elements:
  - Duty-the existence of a legal duty of care owed by the physician to the patient
  - Breach-the defendant physician breached her duty of care to the patient
  - Proximate Causation-“but for” the physician’s breach, the Plaintiff’s injuries and damages would not have occurred PLUS it was reasonably foreseeable to the defendant physician that his breach of the accepted standard of care would cause harm
  - Damages
The **Patient-Physician relationship** creates a legal duty to exercise **reasonable** care and prudence.

You don’t have to be Albert Einstein to meet the standard of care which your duty requires (only “reasonable” care required)

But let’s not push it...
S.O.C.=Ordinary Care/Reasonable Care under same or similar circumstances

**Breach**

- The failure to exercise ordinary care under the same or similar circumstances (Failing to meet the S.O.C.)
- Breach by *acts of commission* (doing what a reasonable MD would not do under the circumstances)
- Breach by *omission* (failing to do what a reasonable MD would do under the same circumstances)

**PROVING BREACH**

- Medical expert testimony required because lay jurors and judge are not trained to know what the S.O.C. demands of the physician
- If a specialist, *held to the S.O.C. required of a reasonable and prudent specialist* acting under the same or similar circumstances
- Defendant physician’s *care is evaluated based on the information reasonably available to her at the time* (Can’t use the old “Restrospectoscope”)
- Strategies to avoid “Outcome Bias”
Common Sources for Standards of Care?

• Peer reviewed medical literature & authoritative treatises (e.g., The Journal of Maternal-Fetal and Neonatal Medicine, Williams Obstetrics)
• Clinical Practice Guidelines (e.g., A.C.O.G.)
• Protocols & Algorithms (e.g., ACLS)
• Hospital Policies & Procedures
Proximate Causation

- "But for" causation ("cause-in-fact")
- +
- Reasonable foreseeability ("legal cause")

No Cause-in-Fact . . .
“Lost Chance of Survival” Doctrine

• Rejected in Texas

• If the patient was, in reasonable medical probability, going to die anyway, then the negligence of the defendant healthcare provider can not have been a proximate cause of the death as a matter of law.

• Rationale: No “But for” Causation

• Examples: Cancer cases; Sepsis with multi-organ failure and D.I.C.

Reasonable Foreseeability (Legal Cause)

• There must always be a direct causal connection between the Defendant’s negligent act or omission and the injury, illness or condition made the basis of the lawsuit (“But for” causation of “cause-in-fact”)

• But, if the causal connection between the negligent act/omission is so long and attenuated that the injury was not a reasonably foreseeable consequence of the Defendant’s conduct, then there is a “break” in the “chain of causation” and no proximate cause of the injury
Damages

- Plaintiff has the Burden of Proof (by a Preponderance of the Credible Evidence)
- Pecuniary (Economic) Damages
- Non-Pecuniary (Non-Economic) Damages
- Limitation of Liability “Caps” on Non-Economic Damages
- Pre- and Post-Judgment Interest

Pecuniary (Economic) Damages

- Easily quantifiable (Can be added up on a calculator)
  - Lost Wages or Loss of Wage Earning Capacity
  - Medical Bills
- Not “capped” (No limitation of liability provision)
- Must be reduced to present value in recognition of the time-value of money
- Future economic damages can be annuitized for the patient's lifetime
- Life Expectancy & Life Care Plans = Huge Issue

Non-Pecuniary (Non-Economic) Damages

- “Fuzzy” Damages—Can’t total on a calculator
- Amount left to discretion of Jury
  - Pain & Suffering
  - Mental Anguish
  - Loss of Companionship & Society
  - Physical Impairment
  - Loss of Consortium
- “Capped” at 250k for all claimants against all physicians (i.e., 1 250k cap irrespective of # of claimants or # of defendant doctors in the case)
After you have been served with a lawsuit, forward the suit papers immediately to your liability insurance carrier and defense counsel has been retained, what happens next?

Defense Counsel “Appears” on your behalf

“Defendant’s Original Answer” is filed with the Clerk of the Court

The Defendant’s Pleadings

• Any Dilatory Pleas
  • Rule 120a Special Appearance
  • Motion to Transfer Venue
  • Motion to Dismiss for Want of Jurisdiction
  • Motion to Quash Service of Citation
• Defendant’s “Original Answer”
  • TRCP Rule 92 “General Denial”
  • Affirmative Defenses (Defenses “in bar”)
  • Inferential Rebuttal Defenses (Defenses of “confession and avoidance”)
  • Requested instructions or legal applications
Phase One: “Paper” Discovery

- TRCP Rule 194 Request for Disclosures
- TRCP Rule 196 Requests for Production (and Inspection of Documents, Tangible Things and Entry upon Property)
  - No limit in number of requests
  - Must be reasonably calculated to lead to discoverable evidence
- TRCP 197 Interrogatories
  - Must be answered under oath
  - 25 interrogatories “per party”
- TRCP 198 Request for Admissions
  - Must be answered within 30 days, or “deemed admitted.”

Obtaining Pertinent Records

- Party retains a Court Reporting Service to issue a Notice of Intention to take a “Deposition on Written Questions” of the Custodian of Records of pertinent businesses—to obtain records in admissible form for use at trial
- Patient’s Medical Records (& Billing Records)
- Income Tax Returns
- Detailed Earnings Information from SSA
- Employment & Personnel Records
- Pharmacy records (good source of info)
- Health Insurance records, etc.

Phase Two: Depositions

- Sworn testimony of the parties, key fact witnesses and experts in the case
- Taken informally in the lawyers’ offices
- Your deposition is the key to your case
- Without adequate preparation it is never a pleasant experience
What you need to know before your deposition

• How the process works.
• What to expect from those present.
• How to dress and act.
• Your responsibility and role in the case.
• Ways to help your attorney defend you.
• Your actions and your rationale.
Like all human reactions, first impressions are vitally important.

How should you dress for your deposition?
Purposes of a Deposition

- Obtain Admissions as to S.O.C., Breach, Causation & Damages
- Discredit you (impeachment)
- Flush out the underlying facts
- Tie you down on key facts
- Solicit your testimony against others
- Intimidate you?

How Important is Your Deposition?

- A very poor deposition can make a defensible case virtually indefensible.
- A really good deposition can make a very difficult case very defensible.
- Arguably, your deposition is the single most important event in your case.

Significance of Deposition Testimony

- “Married” to the Deposition Transcript for Life
- Establishes your “Defense”
- Educates and assists your Expert Witnesses in the defense of your care
Inherent Problems caused by Human Nature

- “If I just explain what happened to the Plaintiff’s lawyer, he will see that I did nothing wrong and the case will be dropped.”
- “I am smarter than the opposing attorney, and I will prove it.”
- “There are no weaknesses to my case.”

The Pre-Deposition Preparation (a.k.a. “Woodshedding”)

- Develop / reacquire a full knowledge of the patient’s chart (especially your care)
- Develop a “Theory of Defense”
- Anticipate and learn how to handle problem areas
- Recognize and prepare for common and anticipated Deposition Techniques & Tactics
- Videotaped “Mock Cross-examination” sessions with feedback & critique

- You should be able to support your care fact by fact – But only if asked (The Cardinal Rule of “A.T.F.Q.”)
  - Absolute familiarity with your care (and the rationale therefore) is essential
  - A good working familiarity with others’ care is beneficial
  - There is no substitute for preparation
  - Treat your deposition like your board exam
  - Defense counsel should be your new best friend- Work with him/her to prepare!
Recognizing & Handling Difficult Questions

- “Leading” Questions - “Is it fair to say...”
- “Compound” questions - One transcribed Answer
- “Repetitious” Questions - asking the same thing over & over again in an effort to obtain a favorable response (an “admission” of fact)
- “Authoritative Treatises” questions
- Questions which ask you to assume unestablished facts
- Questions which ask you to assume incorrect facts
- Bogus Hypotheticals - questions asking you to assume numerous “facts” and then agree with the cross-examiner’s “conclusion”

Deposition Do’s and Don’ts

- Answer only the question asked (“A.T.F.Q.”)
- Keep your answers brief.
- Do not “volunteer” information.
- Never say “never”.
- Do not guess or speculate.
- Feel free to rely on your customary habit and routine.
- Refer to the Chart - It’s NOT a memory test
- Don’t argue with opposing counsel

More Deposition Do’s and Don’ts

- Understand the question before you answer it (Don’t guess or speculate).
- Look at the examiner...the answer will not be on your lawyer’s face.
- Stay within your field of expertise.
- Don’t answer a question with a question.
- Be truthful (Better to forget all else than to tell a lie!) (Yes, you WILL get caught).
- Be Responsive (not evasive).
Attendance at Trial

• The typical medical malpractice trial takes 1-2 weeks to finish (possibly longer in complex cases)
• The jurors have to be there all day, every day - and they will not look kindly on a Defendant who is not there every day, too
• “If the doctor doesn’t care about his case, why should I?”
• You will likely be called as an “adverse witness” in the Plaintiff’s case-in-chief, and may be called to testify again during your case-in-chief (particularly if you did well the first time)

Post-verdict Proceedings

• If the jury reaches a verdict, the prevailing party moves for entry of a “Final Judgment” based on jury findings
• Either side has the right to appeal the jury verdict if there is a good faith belief that there was reversible error committed by the trial judge, jury misconduct, or other grounds for reversal
• If the jury fails to reach a verdict, the trial court can declare a “mistrial” and the case is scheduled to be tried again!
How to Avoid Being Sued for Injury Related to Infections and Sepsis in Obstetrics

John Barton, M.D.
How to Avoid being Sued for Injury Related to Infections and Sepsis in Obstetrics

John R. Barton, M.D.

Disclosure of Relevant Financial Relationships

Research support
- Alere, San Diego (BIOSITE)

Clinical advisory board
- NX PharmaGen Inc
- Pluristem Therapeutics
  (Biomarkers and therapy for preeclampsia)

Learning Objectives

- Discuss the pathophysiology of sepsis
- Discuss goal-directed therapy in the treatment of severe sepsis
- Identify most common causes of maternal sepsis during pregnancy
- Develop diagnostic and treatment strategies for unexplained fever in pregnant women in order to avoid development of maternal sepsis
BACKGROUND

Global

- Puerperal sepsis
  - 75,000 maternal deaths / year
- Puerperal infections
  - 16% of maternal deaths
  - 5-10% of maternal morbidity

Medico-Legal Risks in Sepsis

- Failure to diagnosis sepsis *
- Delay in initiation of septic bundle
- Delay in initiation of antibiotic therapy
- Delay in search for correctable origin of infection
- Lack of prevention of infection
Systemic Inflammatory Response Syndrome (SIRS or SSI)

- Inflammatory process
  - Infection
  - Noninfectious (burns, trauma)
- Requires 2 or more of following:
  - Temp > 38°C or < 36°C
  - HR > 90 bpm
  - RR > 20/min or PaCO₂ < 32 mmHg
  - WBC > 12,000, < 4,000 or > 10% bands
- Criteria may differ with physiology of pregnancy
  - HR >110 bpm, RR >24/min, Temp > 39°C
  - WBC > 15,000

Definitions

- Sepsis
  - SIRS due to infection
- Severe Sepsis
  - Sepsis associated with:
    - Organ dysfunction
    - Hypotension
    - Hypoperfusion
  - Hypoperfusion abnormalities include:
    - Lactic acidosis
    - Oliguria
    - Acute alteration in mental status

Bone et al. Chest 1992

Definitions

- Septic Shock
  - A subset of severe sepsis
  - Sepsis-induced hypotension persisting despite adequate fluid resuscitation
  - Requirement for vasoactive medications

Bone et al. Chest 1992
The fundamental clinical problem of sepsis was readily apparent even to the casual observer over 500 years ago.

“Hectic fever (sepsis) at its inception is difficult to recognize but easy to treat. Left untended, it becomes easy to recognize but difficult to treat.”

- Circa 1498

Niccolo Machiavelli
The Prince, Book III

Steven M. Opal, MD
International Sepsis Forum Symposium
Sept. 27, 2007

Diagnosing Sepsis

• Recognise inpatient deterioration
• Attention to common symptoms
  – fever, chills, rapid RR and HR
• Get patients with community-acquired sepsis to hospital
  – Telephone triage
  – Prenatal instructions
Case History

- Class B IDDM at 37 wks gestation
- Previous cesarean section x 1
- Maternal weight 200 kg (BMI 65)
- TOLAC: 7 cm cx dilatation for 5 hrs
  - "we wanted to avoid c/s with obesity"
- Post-op excuses
  - Incision "not red"
  - Uterus "not really tender"
  - On antibiotics "just takes awhile to work"
  - WBC 65,000 to 3,000
Medico-Legal Risks in Sepsis

- Failure to diagnosis sepsis
- Delay in initiation of septic bundle *
- Delay in initiation of antibiotic therapy
- Delay in search for surgically correctable origin of infection
- Lack of prevention of infection
**Time Sensitive Interventions**

- **AMI**
  - “Door to PCI”
  - Focus on the timely return of blood flow to the affected areas of the heart (< 1 hour).

- **Stroke**
  - “Time is Brain”
  - The sooner that treatment begins, the better are one’s chances of survival without disability (< 3 hours to TPA).

- **Trauma**
  - “The Golden Hour”
  - Requires immediate response and medical care “on the scene.”
  - Patients typically transferred to a qualified trauma center for care.

- **Sepsis**
  - “Time is Tissue”

**Early Goal Directed Therapy**

- Early provision of time sensitive therapies (within 6 hrs)
- Aggressive hydration
- Initiation of antibiotics
- If indicated
  - Vasopressors
  - Transfusion
  - Inotropes

For flow diagram see: Rivers E et al. N Eng J Med 2001

**The Importance of Early Goal-Directed Therapy (EGDT) for Sepsis Induced Hypoperfusion**


NNT to prevent 1 event (death) = 6 to 8

- Standard therapy
- EGDT

Mortality (%)

- In-hospital mortality (all patients)
- 28-day mortality
- 60-day mortality

<table>
<thead>
<tr>
<th>Mortality (%)</th>
<th>In-hospital mortality</th>
<th>Standard therapy</th>
<th>EGDT</th>
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<tbody>
<tr>
<td>60</td>
<td></td>
<td></td>
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<tr>
<td>10</td>
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</tr>
</tbody>
</table>

54
Septic Shock Standard Orders

- Your hospital should have them
  - But do you know where they are?

Algorithm for Septic Shock in Pregnancy

1. Assess airway
2. Administer oxygen if needed
3. Assess breathing
4. Intubation if needed
5. Administer oxygen
6. Activate Septic Shock Standard Orders
7. Stat cultures, labs and antibiotics (within 1st hour)
8. Identify source of infection
9. Initiate IV fluid bolus
10. 20 ml NS/kg over 1 hour
11. Assess volume status
12. Obtain central venous access (CVP, ScvO2)

Barton, Sibai. Obstet Gynecol 2012

Serum lactate as a predictor of mortality in patients with infection

- Low (0 - 2.0)
- Intermediate (2.1 - 3.9)
- Severe (>4.0 mmol/L)


n=1,177
**Fluid Resuscitation**

- Central line placement
- Bolus fluids early in resuscitation
  - Substantial volumes needed (6-10 L NS)
- Colloids are not superior to crystalloids
- Warm IV fluids
- CVP and PCWP “normal” do not exist
- Physiologic perfusion endpoints
  - MAP ≥ 65 mmHg
  - UOP ≥ 25 ml/hr (≥ 0.5 ml/kg/hr)

**Medico-Legal Risks in Sepsis**

- Failure to diagnosis sepsis
- Delay in initiation of septic bundle
- Delay in initiation of antibiotic therapy *
- Delay in search for surgically correctable origin of infection
- Lack of prevention of infection

**Antimicrobial Therapy**

- Prompt cultures
  - Don’t delay therapy
  - Often (1/3) blood cultures negative
- Prompt empiric antibiotic therapy
  - Each hour’s delay in administering antibiotics in septic shock, mortality increases by 7.6%
Cultures

- Urine
- Endometrium
- Wound or episiotomy site
- Blood
  - Minimum 2 blood cultures
  - 1 percutaneous
  - 1 from each vascular access (>48 hr)
- Amniotic fluid
- Other (e.g., sputum, drains)

Empiric Antimicrobial Therapy

- Gentamycin 1.5 mg/kg IV, then 1 mg/kg IV every 8 hours (or 5 mg/kg IV q day)
- Clindamycin 900 mg IV every 8 hours
- Penicillin 3,000,000 units IV every 4 hours
  or
- Vancomycin 15 mg/kg IV then dosing by pharmacy
- Zosyn 4.5 gm IV STAT, then every 6 hrs
  or
- Your hospital’s septic protocol

Early initiation of appropriate antibiotic therapy for septic shock and survival.

Deresinski S Clin Infect Dis. 2007;45:S177-S183
© 2007 by the Infectious Diseases Society of America
Clinical Infections Diseases
Medico-Legal Risks in Sepsis

- Failure to diagnosis sepsis
- Delay in initiation of septic bundle
- Delay in initiation of antibiotic therapy
- Delay in search for correctable origin of infection *
- Lack of prevention of infection

Don’t be satisfied with a diagnosis of sepsis and no source

- Search for origin of infection
  - Acute appendicitis
  - Retained products of conception
  - Uterine microabscess / gas gangrene
  - Pelvic abscess
  - Necrotizing fasciitis
  - Infected episiotomy site
  - Pyelonephritis
  - Cholecystitis with bile duct obstruction
- Aggressive use of imaging (CT, MRI)
- Debridement of infected tissue

Vulvar necrotizing fasciitis
Post-op C/S

Multilocular abscess
Displaced uterus

Obstructive Hydronephrosis

Acute lobar nephronia (focal infection without liquefaction)

H1N1 influenza-associated ARDS: Bilateral infiltrates
Lap sponge count correct?

URFO
Unintended retention of foreign objects

**Medico-Legal Risks in Sepsis**

- Failure to diagnosis sepsis
- Delay in initiation of septic bundle *
- Delay in initiation of antibiotic therapy
- Delay in search for surgically correctable origin of infection
- Lack of prevention of infection

![Flowchart](chart.png)

MAP $< 50 \text{ mmHg}$?
Consider vasopressor.

MAP $50-65 \text{ mmHg}$ or CVP below $8 \text{ mmHg}$?

MAP $> 65 \text{ mmHg}$?

- Yes
  - NS $500 \text{ mL}$ over $30 \text{ minutes}$
  - MAP $> 65 \text{ mmHg}$, urine output $> 25 \text{ mL/hr}$

- No
  - MAP $> 65 \text{ mmHg}$
  - Observe need for further IV fluid bolus

No

- MAP $< 50 \text{ mmHg}$?
  - Consider vasopressor

- MAP $50-65 \text{ mmHg}$ or CVP below $8 \text{ mmHg}$?
  - NS $500 \text{ mL}$ over $30 \text{ minutes}$

- MAP $> 65 \text{ mmHg}$?
  - Observe need for further IV fluid bolus

- No
  - Evaluate need for delivery

- Yes
  - Norepinephrine
  - Vasopressin
  - Steroids for refractory shock

- No
  - Evaluate need for delivery
Do you have enough fluid?
Are your organs being perfused?
Are you using the oxygen being delivered?

Maintenance Phase
Anticipation of complications

- Fetal heart rate, uterine activity monitoring
- Lung protective ventilation for pts with ARDS
- Transfuse PRBC, Hgb < 7.0 gm/dl
- Glucose >180 mg/dl, initiate insulin
- Stress ulcer prophylaxis
- DVT prophylaxis
- Consider inotropic agent

Barton, Sibai Obstet Gynecol 2012
Presentation: Temp 103.5, severe flank pain, N and V
Diagnosis: Pyelonephritis
Treatment: IV Fluids, Acetaminophen, IV Antibiotics

3 hrs post therapy: Note resolution of tachycardia and tachysystole

Indications for Delivery

• Maternal
  – Intrauterine infection
  – Development of DIC
  – Compromised cardiopulmonary function by uterine size and/or peritoneal fluid
    • Compartment syndrome
    • Multifetal gestation
  – Severe ARDS/barotrauma
  – Cardiopulmonary arrest

• Fetal
  – Fetal demise
  – Gestational age associated with low neonatal morbidity/mortality
Medico-Legal Risks in Sepsis

- Failure to diagnosis sepsis
- Delay in initiation of septic bundle
- Delay in initiation of antibiotic therapy
- Delay in search for surgically correctable origin of infection
- Lack of prevention of infection

It’s easier to stay out of trouble, than to get out of trouble.

Influenza vaccine safe in any trimester
Prevention of Surgical Site Infection

- Treat infections remote to surgical site before elective surgery
- Shower with antiseptic agent the night prior to surgery
- Abstain from smoking (30 d)
- Glycemic control in diabetics
- Hair removal around incision by electric clippers not razor
- Antiseptic skin prep

www.cdc.gov/ncidod/dhqp/gl_surgicalsite.htm

Prevention of Surgical Site Infection

- Preoperative antibiotics
  - 1-3 gm cefazolin
  - 1-3 gm cefotetan
- Higher dose for obese patients
  - BMI > 30
  - Weight >100 kg, >120 kg
- Up to 60 min before skin incision
  - Compared to Ab at cord clamping
  - 48% reduction in surgical site infection*

*Kitter et al Obstet Gynecol 2012

Outcome
Missed or Delayed Diagnoses in Gynecologic Cancer: How to Avoid

Joseph Lucci, III, M.D.
Missed or Delayed Diagnoses in Gynecologic Cancer: How to Avoid

Joseph A. Lucci III, MD
Professor, Division of Gynecologic Oncology
Department of Obstetrics, Gynecology and Reproductive Sciences

Study Overview

• In this analysis of data from a national liability insurer, 7.4% of physicians faced a malpractice claim each year, although 78% of claims did not result in payments to claimants.
• The authors estimate that 75 to 99% of physicians will face a malpractice claim by the age of 65.
Proportion of Physicians Facing a Malpractice Claim Annually, According to Specialty.

Amount of Malpractice Payments, According to Specialty.

Cumulative Career Probability of Facing a Malpractice Claim or Indemnity Payment, According to Risk of Specialty and Age of Physician.
Conclusions

- There is substantial variation in the likelihood of malpractice suits and the size of indemnity payments across specialties.
- The cumulative risk of facing a malpractice claim is high in all specialties, although most claims do not lead to payments to plaintiffs.
Diagnostic Errors

- A. Elstein: 10 – 15% (1)
- Autopsy reports: 10 – 20% (2)
- Standardized Patients: 13%
- Quality Assurance: 10 – 30%
- Delay in Dx: 3 years or 7 visits


Definitions

- Diagnostic Error – a diagnosis that is missed, wrong or delayed as detected by a subsequent definitive test or finding.
- Misdiagnosis Related Harm – preventable harm caused by a delay or failure to treat a condition that is present or as a result of treatment of a diagnosis that was not present.

Diagnostic Errors
NPDB 1986 – 2010 Claims Paid

- 350,706 Claims Paid
- 100,249 Diagnostic Errors
- Representing
  - 28.6% of Claims Paid
  - 35.2% of all Payments
- $38.8 Billion (Adjusted)

Diagnostic Errors
NPDB 1986 - 2010

- Resulted in Death 40.9% vs. 23.9%
- 68.8% Outpatient with 36.9% Lethal
- 31.2% Inpatient with 48.4% Lethal


Gynecologic Cancers 2014

<table>
<thead>
<tr>
<th>Site</th>
<th>New</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine</td>
<td>52,630</td>
<td>8,590</td>
</tr>
<tr>
<td>Ovary</td>
<td>21,980</td>
<td>14,270</td>
</tr>
<tr>
<td>Cervix</td>
<td>12,360</td>
<td>9,020</td>
</tr>
<tr>
<td>Vulva</td>
<td>4,850</td>
<td>1,030</td>
</tr>
<tr>
<td>Other</td>
<td>3,170</td>
<td>880</td>
</tr>
<tr>
<td>Total GYN</td>
<td>94,990</td>
<td>28,790</td>
</tr>
<tr>
<td>Breast</td>
<td>232,670</td>
<td>40,000</td>
</tr>
</tbody>
</table>

Common Sites

- Ovary
- Endometrium
- Breast
Case 1

- 65 yo G3P3 postmenopausal woman presents with 6 months of bloating and reflux symptoms
- Her PCP has been treating her with a variety of antacids without improvement
- PMH: Frequent UTI lately, in good health, exercises regularly

Case 1

- OB/GYN: 13y/28d/5d/55, 3 NSVDs, no hormones, BTL with last child
- FM Hx: Paternal Aunt with Breast CA @ 58, Paternal Uncle with Prostate CA, Maternal side with CAD
- Physical Exam:
  - WDWN F in NAD, NI VS, BMI 22
  - Abdomen soft, NT but seems slightly distended
  
Case 1

- Pelvic Exam:
  - NI external genitalia and vagina
  - Cervix 3x3 cm displaced anteriorly
  - Uterus not clearly palpated separate from a mass filling the pelvis about 8 x 8 cm, slightly mobile
  - Lymph: normal
Case 1
What to Order?

A. CA-125, Ultrasound
B. CA-125, HE-4, OVA1, Ultrasound
C. TM, CT Chest/Abdomen/Pelvis
D. MRI Abdomen/Pelvis
E. Endoscopy

Ovarian Cancer

Median Age at Diagnosis = 63

Ovarian Cancer Percent New Cases by Age Group

Ovarian Cancer Percent Deaths by Age Group

Median Age at Death = 71


<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased abdominal size</td>
<td>61</td>
</tr>
<tr>
<td>Bloating</td>
<td>57</td>
</tr>
<tr>
<td>Fatigue</td>
<td>47</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>36</td>
</tr>
<tr>
<td>Indigestion</td>
<td>31</td>
</tr>
<tr>
<td>Urinary frequency</td>
<td>27</td>
</tr>
<tr>
<td>Pelvic Pain</td>
<td>26</td>
</tr>
<tr>
<td>Constipation</td>
<td>25</td>
</tr>
<tr>
<td>Back Pain</td>
<td>23</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>17</td>
</tr>
<tr>
<td>Unable to eat normally</td>
<td>16</td>
</tr>
<tr>
<td>Palpable mass</td>
<td>14</td>
</tr>
<tr>
<td>Vaginal Bleeding</td>
<td>13</td>
</tr>
<tr>
<td>Weight Loss</td>
<td>11</td>
</tr>
<tr>
<td>Nausea</td>
<td>8</td>
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<td>Post-Coital Bleeding</td>
<td>3</td>
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<tr>
<td>Diarrhea</td>
<td>1</td>
</tr>
<tr>
<td>DiT</td>
<td>1</td>
</tr>
<tr>
<td>None</td>
<td>5</td>
</tr>
</tbody>
</table>

Ovarian Cancer Symptoms

- 95% Have Symptoms for 3 – 6 Months
- 44% of Cancer Patients have Symptom Triad
  - Bloating, Increased Abdominal Girth, Urgency
- Most frequent Misdiagnosis:
  - Irritable Bowel Syndrome
  - Stress
  - Gastritis
  - Depression
Goff Index

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Back Pain</td>
<td>45%</td>
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<tr>
<td>Fatigue</td>
<td>34%</td>
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<tr>
<td>Bloating</td>
<td>27%</td>
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<tr>
<td>Constipation</td>
<td>24%</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>22%</td>
</tr>
<tr>
<td>Urinary Symptom</td>
<td>16%</td>
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</table>

Goff et al, JAMA 291(22):2705-12, June9, 2004

Goff Index

- Any one of the symptoms occurring more than 12 times per month
- Present for less than 1 year
- Sensitivity: 70%
  - Early Stage: 57%
  - Late Stage: 80%
- Specificity: 86%
- Results in 4% referral for testing


Goff Index with Tumor Markers

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tbody>
<tr>
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<td>88.3</td>
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<tr>
<td>CA-125</td>
<td>81.1</td>
<td>94.9</td>
</tr>
<tr>
<td>HE-4</td>
<td>77.0</td>
<td>94.9</td>
</tr>
<tr>
<td>CA-125 or HE-4</td>
<td>89.2</td>
<td>89.8</td>
</tr>
<tr>
<td>Si and CA-125</td>
<td>91.9</td>
<td>83.2</td>
</tr>
<tr>
<td>Si and HE-4</td>
<td>91.9</td>
<td>84.7</td>
</tr>
<tr>
<td>Any 1 of 3</td>
<td>84.6</td>
<td>79.6</td>
</tr>
<tr>
<td>Any 2 of 3</td>
<td>83.8</td>
<td>98.5</td>
</tr>
<tr>
<td>Si + 1</td>
<td>58.1</td>
<td>98.5</td>
</tr>
</tbody>
</table>

Andersen, Goff, et.al, Gynecol Oncol. 2010 March ; 116(3): 378.
Risk of Malignancy Index

- Formula: \( U \times M \times CA125 \)
- Ultrasound score
  - Multilocular, solid areas, bilateral, ascites, mets
- Menopausal status
  - Pre, post
- CA125 value (U/mL)


<table>
<thead>
<tr>
<th>RMI</th>
<th>Cutoff</th>
<th>US</th>
<th>Mono</th>
<th>Size</th>
<th>CA125</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jacobs 1990</td>
<td>0, 1, 3</td>
<td>1, 3</td>
<td>NA</td>
<td>U/mL</td>
<td>&gt;200</td>
</tr>
<tr>
<td>2</td>
<td>Tingulstad 1996</td>
<td>1, 4</td>
<td>1, 4</td>
<td>NA</td>
<td>U/mL</td>
<td>&gt;125</td>
</tr>
<tr>
<td>3</td>
<td>Tingulstad 1999</td>
<td>1, 3</td>
<td>1, 3</td>
<td>NA</td>
<td>U/mL</td>
<td>&gt;200</td>
</tr>
<tr>
<td>4</td>
<td>Yamamoto 2006</td>
<td>1, 4</td>
<td>1, 4</td>
<td>1, 2</td>
<td>U/mL</td>
<td>&gt;450</td>
</tr>
<tr>
<td>5</td>
<td>Lee 2010</td>
<td>?</td>
<td>?</td>
<td>NA</td>
<td>U/mL</td>
<td>?</td>
</tr>
</tbody>
</table>

*<7 cm or ≥7 cm

Risk of Malignancy Index

Cutoff = 200

HE4

- Antigen derived from:
  - Human epididymis protein
- Product of the WFDC2 (HE4) gene that is over-expressed in patients with ovarian carcinoma
- FDA-cleared to monitor cancer treatment with other clinical methods
- HE4 not for monitoring mucinous or germ cell ovarian cancers
- Neither a screening nor a diagnostic test

1. Quest Diagnostics Website: www.questdiagnostics.com
2. He4 Product Insert, Fujirebio Diagnostics, Inc.

Risk of Malignancy Algorithm

- CA125 and HE4
- Accrual from tertiary centers

<table>
<thead>
<tr>
<th></th>
<th>All Subjects (N=503)</th>
<th>Premenopausal (N=236)</th>
<th>Postmenopausal (N=267)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>89</td>
<td>76</td>
<td>92</td>
</tr>
<tr>
<td>Specificity</td>
<td>75</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>PPV</td>
<td>60</td>
<td>34</td>
<td>74</td>
</tr>
<tr>
<td>NPV</td>
<td>94</td>
<td>95</td>
<td>93</td>
</tr>
</tbody>
</table>

Prevalence= 34%


U.S. Food and Drug Administration

FDA NEWS RELEASE
For Immediate Release: Sept. 11, 2009
Media Inquiries: Peper Long, 301-796-4671, mary.long@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Clears a Test for Ovarian Cancer
Test can help identify potential malignancies, guide surgical decisions
The U.S. Food and Drug Administration today cleared a test that can help detect ovarian cancer in a pelvic mass that is already known to require surgery. The test, called OVA1, helps patients and health care professionals decide what type of surgery should be done and by whom.
OVA1 trial

- 27 sites throughout United States
  - 516 patients, 161 malignancies
  - 52% from primary care providers
- Preoperative evaluation
  - Physician assessment
  - Imaging, serum
- Biomarker assays - Quest laboratories
  - Johns Hopkins Biomarker Discovery Center
  - Specialty Laboratories
- Independent data analysis
  - Applied Clinical Intelligence

Presented at SGO Annual Meeting, San Francisco, CA, March, 2010

ACOG Revisited
OVA1 replacing CA125

<table>
<thead>
<tr>
<th></th>
<th>All subjects</th>
<th>Premenopausal</th>
<th>Postmenopausal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=516</td>
<td>N=235</td>
<td>N=281</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>94</td>
<td>91</td>
<td>95</td>
</tr>
<tr>
<td>95% CI</td>
<td>89 to 97</td>
<td>79 to 97</td>
<td>89 to 98</td>
</tr>
<tr>
<td>Specificity</td>
<td>35</td>
<td>43</td>
<td>26</td>
</tr>
<tr>
<td>95% CI</td>
<td>30 to 40</td>
<td>36 to 50</td>
<td>19 to 33</td>
</tr>
<tr>
<td>PPV</td>
<td>40</td>
<td>28</td>
<td>47</td>
</tr>
<tr>
<td>95% CI</td>
<td>35 to 45</td>
<td>21 to 35</td>
<td>41 to 54</td>
</tr>
<tr>
<td>NPV</td>
<td>93</td>
<td>95</td>
<td>88</td>
</tr>
<tr>
<td>95% CI</td>
<td>87 to 96</td>
<td>89 to 98</td>
<td>75 to 94</td>
</tr>
</tbody>
</table>

Presented at SGO Annual Meeting, San Francisco, CA, March, 2010
All Patients (N=516) Preop Assessment + OVA1

<table>
<thead>
<tr>
<th></th>
<th>OB/GYN Preop Assessment Alone</th>
<th>OB/GYN Preop Assessment + OVA1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>92.5%</td>
<td>72.2%</td>
</tr>
<tr>
<td>Specificity</td>
<td>42.8%</td>
<td></td>
</tr>
<tr>
<td>PPV</td>
<td>42.3%</td>
<td></td>
</tr>
<tr>
<td>NPV</td>
<td>92.7%</td>
<td>89.1%</td>
</tr>
</tbody>
</table>

Ovarian Cancer
Genetic Syndromes

- BRCA
- HNPCC
- Li Fraumeni
- Cowden’s Syndrome
- Ataxia Telangiectasia
- Peutz-Jeghers Syndrome

Genetic Factors

Misconceptions about family history

- “Cancer on the father’s side of the family doesn’t count.”
- “Ovarian cancer in the family history is not a factor in breast cancer risk.”
- “The most important thing in the family history is the age of women with breast cancer.”
- “Half of all women with hereditary risk inherited it from their father.”
- “Ovarian cancer is an important indicator of hereditary risk, although it is not always present.”
- “Age of onset of breast cancer is more important than the number of women with the disease.”
Ovarian Cancer
Summary

• History (SI) and Physical Exam
• Family History
• CA-125 is still King
• Combination of USG and CA-125 is the standard (NCCN)
• OVA-1 has a role in selected patients with a pelvic mass

Case 2

• 38 yo F NG LMP 2/15 for 10 days with heavy flow and clots
• Long history of infertility
• PMH: DM on oral meds, HTN
• PSH: Laparoscopy for Ovarian cysts, no endometriosis, Lap Band 6 months ago
• SH: neg, FH: neg for Cancer,
• ROS: pelvic pressure, urinary frequency and minimal incontinence

Case 2

• NI VS, BMI 33 after 80 pound weight loss
• Abdomen large, soft, no masses
• Pelvic:
  • NI external genitalia
  • NL vagina with some blood in vault
  • CX 3x3 cm nulliparous and mobile
  • Uterus 8 – 10 weeks(?)
• No adnexal masses
• Lymph: negative
Case 2
What Next?

A. Nothing
B. Ultrasound
C. Endometrial Biopsy
D. Hysteroscopy, D&C
E. MRI

ENDOMETRIAL CANCER

Risk Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity</td>
<td></td>
</tr>
<tr>
<td>&gt;30lbs</td>
<td>3.0</td>
</tr>
<tr>
<td>&gt;50lbs</td>
<td>10.0</td>
</tr>
<tr>
<td>Unopposed Estrogen</td>
<td>9.5</td>
</tr>
<tr>
<td>Complex atypical hyperplasia</td>
<td>29</td>
</tr>
<tr>
<td>Late menopause</td>
<td>2.4</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>2.0</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>2.8</td>
</tr>
<tr>
<td>HTN</td>
<td>1.5</td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>2.3</td>
</tr>
<tr>
<td>OCP use</td>
<td>0.5</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
</tr>
</tbody>
</table>
Unopposed estrogenic stimulation of the endometrium

- Increased endogenous synthesis (granulosa cell tumors, obesity)
- Decreased estrogen metabolism (hepatic disease)
- Inappropriate hormone replacement (estrogen alone)

Patients in Whom a Diagnosis of Endometrial Cancer Should be Excluded

Perimenopause: “During this time in a woman’s life, the menstrual periods should become lighter and lighter and farther apart”

Premenopause: Abnormal uterine bleeding, especially if prior history of anovulation, obesity

20-25% will be diagnosed before menopause.
5% before age 40

Endometrial Cancer in Younger Women

20%-25% diagnosed before the menopause
5% before age 40

Any woman can get endometrial cancer, including young, healthy women.
Endometrial Cancer Percent New Diagnosis by Age Group

Median Age at Diagnosis = 62


Endometrial Cancer Percent Deaths by Age Group

Median Age at Death = 71


Symptoms of Uterine Cancer

At least 90% of patients with Endometrial Cancer present with Symptoms

- Vaginal Bleeding
- Abnormal vaginal discharge
- Uterine enlargement
- Glandular cells or endometrial cells on Pap smear
Desiring Future Fertility

- FIGO I and/or AEH
  - MRI, D&C
  - Megace 80 mg/day or Progesterone IUD or Depo-Provera 200mg IM q 2 months
  - Ovulation Induction / IVF
  - Endometrial sampling q 3 months

Desiring Future Fertility

- 13 patients < 40 yo with FIGO I or AEH
  - mean time to response = 3.5 months
  - 9 children
  - 6 patients recurred (mean = 40 months)
- 5 women
  - mean time to response = 3-10 months
  - 5 pregnancies → 8 newborns

- Recommend Hysterectomy when child-bearing complete
- Risk Factors still present
- Screen for Breast and Colon Cancer

Patients in Whom a Diagnosis of Endometrial Cancer Should be Excluded

- Postmenopausal
- Bleeding
- Pyometrium

Endometrial Cells on Pap

- If morphologically abnormal endometrial cells appear on a Pap smear, 25% will have EC
Diagnostic Evaluation

- **Endometrial Bx**: False negative rate = 2-10%
- **Transvaginal Ultrasonography**: stripe > 3.0mm should undergo sampling
- **3D Ultrasonography**: sensitivity and specificity the same as 2D
- **Sonohystogram**: slightly better than USG
- **Hysteroscopy**: Direct visualization is highly sensitive and specific
- **D&C**: False negative rates of up to 10%


Endometrial Cancer

- Remember who is at risk
- Abnormal bleeding requires evaluation
- Initial evaluation should include
  - Ultrasound
  - Endometrial sampling
- AEH frequently means cancer
- Fertility sparing is possible but requires extensive evaluation and surveillance

Endometrial Hyperplasia

<table>
<thead>
<tr>
<th>Type of Hyperplasia</th>
<th>% Persisted</th>
<th>% Progressed to Carcinoma</th>
<th>Mean Year of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple Hyperplasia</td>
<td>19%</td>
<td>1%</td>
<td>15.2</td>
</tr>
<tr>
<td>Complex Hyperplasia</td>
<td>17%</td>
<td>3%</td>
<td>13.5</td>
</tr>
<tr>
<td>Simple Hyperplasia W/ Atypia</td>
<td>23%</td>
<td>8%</td>
<td>11</td>
</tr>
<tr>
<td>Complex Hyperplasia W/ Atypia</td>
<td>14%</td>
<td>29%</td>
<td>11</td>
</tr>
</tbody>
</table>

Kurman, Cancer 1985;56:403-408
### Atypical Endometrial Hyperplasia

**GOG 167**

- Community diagnosis of AEH on EMB or D&C
- “Expert” pathology review
- Poor correlation with diagnosis among pathologist, even among “experts”
- All underwent hysterectomy within 12 wks

### GOG 167

**AEH and Endometrial CA**

<table>
<thead>
<tr>
<th>Experts</th>
<th>Hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>26% EH</td>
<td>43% CA</td>
</tr>
<tr>
<td>40% AEH</td>
<td>31% Myoinvasive</td>
</tr>
<tr>
<td>29% CA</td>
<td>10% &gt; 50% invasion</td>
</tr>
</tbody>
</table>

### Case 3

- 33 yo G2P2 LMP 2/21 for 3 days on OCP
- Presents with a left breast mass that is tender for 2 months
- NSVD 3 months ago, breast feeding
- PMH, PSH: none
- OB/GYN: 11y/28d/3 – 5 d, On OCPs since 18 except when she desired pregnancy, 2 NSVDs
- SH: neg
- FH: Mother with breast at 50, PA Ovarian @ 65
Case 3

- WDWN F in NAD, VS NI, BMI 22
- L Breast: 2 x 2 tender mass in UOQ, mobile, well circumscribed
- R Breast: Fibrocystic changes
- NL abdomen and pelvis
- Nodes: negative

Case 3
What Next?

A. Antibiotics
B. FNA
C. Breast Ultrasound
D. Mammogram
E. Breast MRI

Breast Cancer

- Most common Cancer in women.
- Most women present to the Gynecologist with any breast complaints.
- Failure to recognize risk factors.
- Failure to recognize that breast cancer can occur at young age.
Breast Cancer

**RISK FACTORS**

- Sex
- Age
- Parity
- Menses
- Race
- Diet
- Weight
- ETOH

---

**RISK FACTORS**

- Dense Breasts
- Hyperplasia
- Radiation
- Hormones
  - OCP
  - DMPA
  - DES
  - HRT

---

**Risk Factors for Breast Cancer**

<table>
<thead>
<tr>
<th>Factor</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Pregnancy (&gt;30 yrs)</td>
<td>1.48</td>
</tr>
<tr>
<td>Body mass index (&gt;29.68 kg/m²)</td>
<td>1.48</td>
</tr>
<tr>
<td>College graduate</td>
<td>1.36</td>
</tr>
<tr>
<td>Alcohol use (&gt;5 g/d)</td>
<td>1.16</td>
</tr>
<tr>
<td>Delayed menopause</td>
<td>1.14 (5 yrs)</td>
</tr>
<tr>
<td>HRT (current)</td>
<td>1.12 (5 yrs)*</td>
</tr>
</tbody>
</table>
Breast Cancer Percent New Cases by Age Group

Mean Age at Diagnosis = 61


Breast Cancer Percent of Deaths by Age Group

Mean Age at Death = 68


A Model of Breast Carcinogenesis

Normal  Epithelial Hyperplasia  Atypical Hyperplasia  Cancer
Breast Cancer Risk: Benign Breast Disease

<table>
<thead>
<tr>
<th>Proliferative Breast Disease</th>
<th>CANCER RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperplasia</td>
<td>1.9</td>
</tr>
<tr>
<td>Atypical Hyperplasia</td>
<td>4.5</td>
</tr>
<tr>
<td>AH + FM HX</td>
<td>11</td>
</tr>
<tr>
<td>Cysts</td>
<td>1.5</td>
</tr>
<tr>
<td>Cysts + FM HX</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Breast Cancer
GENETIC RISK FACTORS

- BRCA 1/2
- Ataxia-Telangiectasia (ATM)
- Li-Fraumeni (p53, CHEK2)
- Cowden Syndrome (PTEN)
- Hereditary Diffuse Gastric Cancer (CDH1)
- Peutz-Jeghers Syndrome (STK11)
Genetic Factors

Misconceptions about family history

- "Cancer on the father’s side of the family is not a factor in breast cancer risk."
- "Ovarian cancer in the family history is not a factor in breast cancer risk."
- "Half of all women with hereditary risk inherited it from their father."
- "Age of onset of breast cancer is not always present."
- "Ovarian cancer is an important indicator of hereditary risk, although it is not always present."
- "The most important thing in the family history is the number of women with breast cancer."

Components of Appropriate Screening Program

- Professional Physical Examination
- Mammography
- Breast Self Examination (BSE) (?)
- Ultrasound
- MRI

Breast Cancer Risk Assessment

- Gail Model
- Claus Model
- BRCApro
- NOT intended for those at GENETIC risk
**Screening Recommendations**

<table>
<thead>
<tr>
<th>Age</th>
<th>Physical Exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 – 40 yrs</td>
<td>Every 3 years</td>
</tr>
<tr>
<td>&gt; 40 yrs</td>
<td>Annually</td>
</tr>
</tbody>
</table>

**Breast Self Exam (BSE)**

Recommended monthly for all women over the age of 20 (?)
Breast Disease
IMAGING

- MAMMOGRAPHY
  - 2 Views
  - Digital
  - 3D/Tomography
- ULTRASOUND
- MRI

Breast Cancer Mammographic Screening

<table>
<thead>
<tr>
<th>Age</th>
<th>ACS</th>
<th>NCI</th>
<th>Mortality Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 – 49</td>
<td>Q 1 yr</td>
<td>Q 1-2 yrs</td>
<td>17%</td>
</tr>
<tr>
<td>50 – 69</td>
<td>Q 1 yr</td>
<td>Q 1 yr</td>
<td>25 – 30%</td>
</tr>
<tr>
<td>70+</td>
<td>Q 1 yr</td>
<td>Q 1 yr</td>
<td>?</td>
</tr>
</tbody>
</table>

Palpable Mass:
- Cyst
- ? Cyst vs. Solid
- Solid
False Positive Enhancement
Radial scar  Fibrocystic changes

Hormonal Variability
2 weeks later

MRI-Detected Synchronous Contralateral DCIS
Clinical Evaluation and Management of Nipple Duct Discharge

Spontaneous or Expressed?

- Expressed Discharge
  - 85% of premenopausal women expressible
  - 65% of postmenopausal women expressible

- Spontaneous Discharge
  - Severity: “Does it stain your clothes?”
Single Duct or Multiple Ducts

• Single Duct Discharge
  – May suggest local breast pathology

• Multiple Duct Discharge
  – Usually physiologic
  – May suggest systemic process
    • e.g. hyperprolactinemia, hyperthyroidism

Bloody or Non-bloody

• Bloody Discharge
  – Bloody, spontaneous, single duct discharge = intraductal papilloma 99%
  – Bloody, bilateral, multiduct discharge in pregnancy is physiologic

• Non-bloody Discharge
  – white, yellow, green, dark green and brown discharges are not “pathologic”

Hemoccult testing may be helpful

Absolute Indications for Biopsy

• Any suspicious palpable lesion.
• Any suspicious lesion on imaging.
Thank You!
Medicolegal Issues with Shoulder Dystocia and Brachial Plexus Impairment

Suneet Chauhan, M.D.
Medicolegal Issues with Shoulder Dystocia and Neonatal Brachial Plexus Palsy

Suneet P. Chauhan, MD
Suneet.P.Chauhan@uth.tmc.edu
Division of Maternal Fetal Medicine
University of Texas Health Science Center at Houston

DISCLOSURE

• AABG

Case # 1

35 year WF G2P1 at 38\1/7 weeks (IVF) with BMI of 45 kg/m² non-DM, with S > D and SEFW 4,350 g. What would you do?
A. Expectant management
B. Induction
C. Primary elective cesarean
D. Consult a MFM
Case # 2

39 year WF G2P1 at 36⅓ weeks with history of shoulder dystocia, and SEFW 3,800 g. What would you do?
A. Expectant management  
B. Induction at 38⅔ weeks  
C. Primary elective cesarean  
D. Consult a MFM

Shoulder Dystocia & NBPP

Shoulder Dystocia—Definition

<table>
<thead>
<tr>
<th></th>
<th>ACOG PB</th>
<th>RCOG GG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tight shoulders</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Difficulty extracting the shoulders</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>Clinical Judgment</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>Failure of shoulder delivery after downward traction</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Requiring maneuvers, in addition to gentle downward traction on the fetal head, to affect delivery</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Time interval of ≥ 60 sec from delivery of the head to the delivery of the body</td>
<td>No</td>
</tr>
</tbody>
</table>
Shoulder Dystocia—Definition

<table>
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<tr>
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<th>ACOG PB</th>
<th>RCOG GG</th>
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<tr>
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<td>2</td>
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<tr>
<td>3</td>
<td>Clinical Judgment</td>
<td>No</td>
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<tr>
<td>4</td>
<td>Failure of shoulder delivery after downward traction</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Requiring maneuvers, in addition to gentle downward traction on the fetal head, to affect delivery</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Time interval of &gt;60 sec from delivery of the head to the delivery of the body</td>
<td>No</td>
</tr>
</tbody>
</table>

Ammons A & Chauhan SP Seminars in Perinatology 2014

Neonatal Brachial Plexus Palsy (NBPP)

- Inability to Actively Move One Upper Extremity
- Passive Range of Motion is Equal in Both Sides.
- Erb’s or Duchenne’s Palsy
  - Injury Involving C5 and C6
  - Flaccid Upper Arm, Extended and Internally Rotated Lower Arm
- Klumpke Paralysis
  - Injury to C8-T1
  - Paralysis of the Hand

Outline

- Definition
- Rate
  - ...
  - ...
  - ...
  - ...
  - ...
  - ...
<table>
<thead>
<tr>
<th></th>
<th># Pub</th>
<th>Deliveries</th>
<th>Shoulder dystocia</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total births</td>
<td>28</td>
<td>16,059,256</td>
<td>57,819</td>
<td>0.4%</td>
</tr>
<tr>
<td>Vaginal births</td>
<td>15</td>
<td>2,575,283</td>
<td>18,222</td>
<td>0.7%</td>
</tr>
<tr>
<td>Diabetes No</td>
<td>8</td>
<td>15,175</td>
<td>96%</td>
<td></td>
</tr>
<tr>
<td>Diabetes Yes</td>
<td></td>
<td></td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Operative delivery No</td>
<td>11</td>
<td>16,661</td>
<td>79%</td>
<td></td>
</tr>
<tr>
<td>Operative delivery Yes</td>
<td></td>
<td></td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>Birth weight &lt; 4,000 g</td>
<td>6</td>
<td>16,137</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>Birth weight 4,000-4,500 g</td>
<td></td>
<td></td>
<td>39%</td>
<td></td>
</tr>
<tr>
<td>Birth weight &gt; 4,500 g</td>
<td></td>
<td></td>
<td>34%</td>
<td></td>
</tr>
</tbody>
</table>
Rate—NBPP

**Total Births**

- United States
- Other Countries

**Vaginal Births**

- United States
- Other Countries

Rate—Neonatal Brachial Plexus Palsy

<table>
<thead>
<tr>
<th># Pub</th>
<th>Deliveries</th>
<th>NBPP</th>
<th>Rate /1,000</th>
</tr>
</thead>
</table>
| Total births
| USA    | 53          | 17,034,521 | 24,471 | 1.4 |
|        | 28          | 14,148,214 | 20,843 | 1.5 |
|        | 25          | 2,886,307  | 3,628  | 1.3 |
| Foreign |
|        | 29          | 1,873,330  | 3,038  | 1.6 |
|        | 18          | 1,402,740  | 2,539  | 1.8 |
|        | 11          | 470,589    | 499    | 1.1 |

Rate—NBPP Without Shoulder Dystocia
NBPP Without Shoulder Dystocia

- Rate is increasing
- Mechanistically different
- Less likely to have
  - Concomitant injury
  - Be permanent and
  - Litigated

29 reports with data of NBPP without SD
- NBPP without SD
  - 78% in the studies from US
  - 47% in the studies from other countries
- One study from US had 17,334 NBP
- Excluding this report, likelihood of NBPP without SD in US is: 45%

Permanent NBPP

- Lasting > 1 years
- Adduction contractures about the shoulder,
- Inability to externally rotate and abduct the shoulder
- Affects overall health and psychological well-being
### Rate—Permanent NBPP

<table>
<thead>
<tr>
<th></th>
<th># Pub</th>
<th>Births</th>
<th>NBPP</th>
<th>FUP ≥ 1 year</th>
<th>Perm NBPP</th>
<th>Rate /10,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>7</td>
<td>225,120</td>
<td>267</td>
<td>91%</td>
<td>10%</td>
<td>1.1</td>
</tr>
<tr>
<td>Other Countries</td>
<td>8</td>
<td>259,050</td>
<td>416</td>
<td>95%</td>
<td>19%</td>
<td>2.9</td>
</tr>
</tbody>
</table>

Chauhan SP Seminars in Perinatology 2014

### Outline

- Risk Factors
  - Prior shoulder dystocia
  - Diabetes
  - Obesity
  - Excessive weight gain
  - Postterm pregnancy
  - Prolonged 2nd stage
  - Operative VD
  - GDM
  - BW ≥ 4000 g
  - Sonographic measurements
Sonographic Estimate & Shoulder Dystocia

- Retrospective study
- At least 37 weeks, with AC or EFW ≥ 90% for GA
- Delivered within 3 weeks of SEFW
- Spartanburg, South Carolina

Chauhan SP et al. J Maternal-Fetal Medicine 2006

Sonographic Estimate & Shoulder Dystocia

- Suspected Macro (N = 225)
  - CD 47% (N = 105)
  - Vaginal Birth (N = 120)
- SD 12% No SD 88%
- 95% CI 7-20%

Chauhan SP et al. J Maternal-Fetal Medicine 2006
Sonographic Estimate & SD

<table>
<thead>
<tr>
<th>Study</th>
<th>US parameters</th>
<th>SD</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elliott JP 1982</td>
<td>CC – BPD ≥ 1.4 cm</td>
<td>4</td>
<td>75%</td>
</tr>
<tr>
<td>Cohen BF 1996</td>
<td>AD – BPD ≥ 2.6 cm</td>
<td>6</td>
<td>100%</td>
</tr>
<tr>
<td>Chauhan SP 2006</td>
<td>SEFW &gt; 4,500 g</td>
<td>15</td>
<td>0-25%</td>
</tr>
<tr>
<td>Miller RS 2007</td>
<td>AD – BPD ≥ 2.6 cm</td>
<td>23</td>
<td>25%</td>
</tr>
<tr>
<td>Rajan PV 2009</td>
<td>AD – BPD ≥ 2.6 cm</td>
<td>27</td>
<td>67%</td>
</tr>
<tr>
<td>Belfort MA 2011</td>
<td>SEFW, OFD</td>
<td>18</td>
<td>8-23%</td>
</tr>
<tr>
<td>Burkhardt T 2013</td>
<td>AD – BPD ≥ 2.6 cm; AC ≥ 350 mm; SEFW ≥ 4,000 g</td>
<td>146</td>
<td>3-7%</td>
</tr>
</tbody>
</table>

Induction for Macrosomia & Shoulder Dystocia

- Induction: 22%
- Augmentation / Spontaneous: 8%

OR 3.4 (95% CI 1.4, 8.2)

Induction Augmentation / Spontaneous

Outline

- Definition
- Rate
- Risk Factors
- Management
- Professional Liability
- Likelihood
- Minimizing Liability
- National Guidelines
Management

Fundal Pressure

- **AVOID**
- Further impacts the anterior shoulder
- Complication rate may be 77%
- Strongly associated with orthopedic and neurologic injury
- Thoracic spinal cord injury in the neonate:
  - Lower extremity motor dysfunction,
  - Urinary and rectal incontinence

Gross SJ et al AJOG 1987
Zavanelli Maneuver

- Cephalic replacement for undeliverable SD
- Consider when
  - Turtle Sign—Bilateral SD
  - Unable to complete delivery within 3-4 min
  - After Delivery of the Head
  - SD in uncommon locations—Bed, ambulance, ER

O'Leary Obstet Gynecol 1993

---

Zavanelli Maneuver

- Five Year National Registry; n = 59
- Replacement of the head within 10 min in 64%
- Delivery within 20 min in 71%
- 27% had Apgar score < 3 at 5 min

O'Leary Obstet Gynecol 1993

---

Zavanelli Maneuver

- Perm NBPP
- Seizure
- PNM

9% 8% 5%

51/1,000 births

O'Leary Obstet Gynecol 1993
Management of SD at 3 Centers

<table>
<thead>
<tr>
<th></th>
<th>Center I (N = 184)</th>
<th>Center II (N = 153)</th>
<th>Center III (N = 287)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>McRoberts'</td>
<td>98%</td>
<td>80%</td>
<td>89%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Suprapubic</td>
<td>83%</td>
<td>66%</td>
<td>54%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Woods</td>
<td>9%</td>
<td>16%</td>
<td>16%</td>
<td>0.109</td>
</tr>
<tr>
<td>Extraction of</td>
<td>3%</td>
<td>4%</td>
<td>4%</td>
<td>0.084</td>
</tr>
<tr>
<td>posterior arm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Maneuvers</td>
<td></td>
<td></td>
<td></td>
<td>0.311</td>
</tr>
<tr>
<td>&lt; 2</td>
<td>89%</td>
<td>84%</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>≥ 3</td>
<td>11%</td>
<td>16%</td>
<td>11%</td>
<td></td>
</tr>
</tbody>
</table>

Complications of SD at 3 Centers

<table>
<thead>
<tr>
<th></th>
<th>Center I (N = 184)</th>
<th>Center II (N = 153)</th>
<th>Center III (N = 287)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fractures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clavicle</td>
<td>3%</td>
<td>1%</td>
<td>4%</td>
<td>0.119</td>
</tr>
<tr>
<td>Humerus</td>
<td>3%</td>
<td>1%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>NBPP per SD</td>
<td>0</td>
<td>0</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>SD &amp; NBPP /</td>
<td>10%</td>
<td>2%</td>
<td>5%</td>
<td>0.005</td>
</tr>
<tr>
<td>1,000 vaginal</td>
<td></td>
<td></td>
<td></td>
<td>0.118</td>
</tr>
<tr>
<td>births</td>
<td>1.5</td>
<td>0.5</td>
<td>1.3</td>
<td></td>
</tr>
</tbody>
</table>
Delivery Note—Document

- Prepregnancy Weight
- Weight Gain
- EFW:
  - CEFW, SEFW, MEFW
- Induction / Aug
- Duration of Stage I & II
- Forceps / Vacuum
  - Station & # Attempts
- Maneuvers used
- Duration of Dystocia
- Umbilical Arterial pH
- Personnel Present

Delivery Note—Document

- Birth Weight
- Anterior shoulder—Right or left
- Duration of SD
- Excessive force
- Lateral traction
- NBPP, Horner’s
- Assistance Requested
- Risk Factors
- Post-partum 1 hr PG
- Recurrent Risk
- Candid Conversation

Outline

- 
- 
- 
- Professional Liability
  - Likelihood
**NBPP Over 23-Years**

<table>
<thead>
<tr>
<th></th>
<th>Rate / Mean</th>
<th>95% CI</th>
<th>1st-3rd Quartile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right sided</td>
<td>55%</td>
<td>44-66%</td>
<td>--</td>
</tr>
<tr>
<td>Duration (days)</td>
<td>21</td>
<td>--</td>
<td>3-60</td>
</tr>
<tr>
<td>Follow-up (months)</td>
<td>24</td>
<td>--</td>
<td>3.5-59.5</td>
</tr>
<tr>
<td>Permanent</td>
<td>12%</td>
<td>6-21%</td>
<td>--</td>
</tr>
<tr>
<td>Litigation</td>
<td>2%</td>
<td>0.3-8%</td>
<td>--</td>
</tr>
</tbody>
</table>

N = 85 NBPP / 89,978 births

---

**CAOG Survey**

- [Map showing data](Not Labeled, if less than 10)

---

**CAOG Survey**

- [Table showing data](Chauhan SP et al AOG 2005)
NBPP & Litigation

Retrospective Study
23 Years
89,978 Deliveries
Tertiary Center (MS)
2 Claims for NBPP

CAOG Survey
658 Respondents
17,136 Years of Practice
2,339,400 Deliveries
57 Claims for NBPP

1 Claim / 44,989 Delivery
52 Claims

1 Claim / 41,042 Delivery

2.2 Claims

Chauhan SP et al AJOG 2005
Chauhan SP et al AJOG 2005

---

NBPP & Litigation

1 NBPB per 1,000 Deliveries

1 Permanent NBPP per 10,000 Deliveries

1 NBPB Malpractice per 45,000 Deliveries

100 Deliveries

---

NBPP & Litigation

1 Year of Practice
at 150 deliveries / year

---

Chauhan SP et al AJOG 2005
Chauhan SP et al AJOG 2005

113
Outline

- Definition
- Rate
- Risk Factors
- Management
- Professional Liability
- Likelihood Minimizing Liability
- National Guidelines
ACOG

Summary of Recommendations

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Shoulder dystocia cannot be predicted or prevented because accurate methods for identifying which fetuses will experience this complication do not exist.
- Elective induction of labor or elective cesarean delivery for all women suspected of carrying a fetus with macrosomia is not appropriate.

ACOG Level B Recommendations

- Unpredictable and unpreventable
- Do NOT electively induce
- Do NOT do elective CD
ACOG

The following recommendations are based primarily on consensus and expert opinion (Level C):

- In patients with a history of shoulder dystocia, estimated fetal weight, gestational age, maternal glucose intolerance, and the severity of the prior neonatal injury should be evaluated and the risks and benefits of cesarean delivery discussed with the patient.
- Planned cesarean delivery to prevent shoulder dystocia may be considered for suspected fetal macrosomia with estimated fetal weights exceeding 5,000 g in women without diabetes and 4,500 g in women with diabetes.
- There is no evidence that any one maneuver is superior to another in releasing an impacted shoulder or reducing the chance of injury. However, performance of the McRoberts maneuver is a reasonable initial approach.

ACOG Level C Recommendations

• History of SD
  - EFW
  - DM status
  - Severity of NBPP
  - Discuss

ACOG Level C Recommendations

• No one maneuver is superior
• CD if
  - EFW > 4,500 g among DM
  - EFW > 5,000 g among non-DM
Thank YOU, All

• Not a nightmare for obstetrician

Thank YOU, All

• A nightmare for the infant, family, and ...

Case # 1

35 year WF G2P1 at 38\(\frac{1}{7}\) weeks (IVF) with BMI of 45 kg/m\(^2\) non-DM, with S > D and SEFW 4,350 g. What would you do?
A. Expectant management
B. Induction
C. Primary elective cesarean
D. Consult a MFM
Case # 2

39 year WF G2P1 at 36$^{1/7}$ weeks with history of shoulder dystocia, and SEFW 3,800 g. What would you do?

A. Expectant management
B. Induction at 38$^{1/7}$ weeks
C. Primary elective cesarean
D. Consult a MFM

Management

Management
Management
FHR Monitoring and Interpretation: Lessons Learned from Medicolegal Process

Sean Blackwell, M.D.
FHR Monitoring and Interpretation: Lessons Learned from Medicolegal Process

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Assistant Dean for Healthcare Quality in Perinatal Medicine and Women’s Health
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Sean.Blackwell@uth.tmc.edu

Disclosures

• None

Disclaimer

• This lecture represents information available at the time of presentation and is neither designed nor intended to establish an exclusive standard of perinatal care.

• Variations in practice may be warranted based on needs and unique nature of individual patient and clinical circumstances, practice setting, or practice type.
Objectives

- To discuss challenges specific to Category II tracings regarding FHR interpretation + management.
- To review key risk management issues related to allegations of medical negligence in Mx of intrapartum FHR tracings.
- To evaluate some key communication practices in cases of Category II FHR tracings.

What are realistic expectations for a FHR classification system?

3 “Realistic Expectations” of EFM

1. Identify patients who are at increased risk for intrapartum stillbirth or fetal compromise due to utero-placental insufficiency (UPI)
2. Provide information on fetal oxygenation and acid-base status at a given point in time
3. Provide some information on likelihood of FHR pattern evolution (natural history)
Not “miss” or delay Tx prevent acidemia

The right interventions at the right time

Avoid unnecessary interventions

Goldilocks Principle

Frequency of Fetal Heart Rate Categories and Short-Term Neonatal Outcome

• Collect FHR data and outcomes
  – 10 hospitals Intermountain System (Utah)
  – 28 months (2007-2009)

• Inclusion criteria: GA > 37 wks, singleton, at least 120 minutes FHR, no anomalies

Jackson et al., OG (2012)
Assessment of Intrapartum FHR Tracing

Category I

1. Reliable classification
2. Known natural history

Chill

Emergent Delivery

Category II

Prepare for Delivery + Intrauterine Resuscitative Maneuvers

If not improved, consider prompt delivery

Category III

Highly predictive of normal fetal oxygenation and acid-base status

Category I FHR

Highly predictive of abnormal fetal oxygenation and acid-base status

Category III FHR
Extremely few cases of alleged negligence involve prolonged Category III tracings.

Rare + Not Equivocal

How to Interpret Category II?

• Most cases of alleged medical negligence have Category II tracings.
• Category II remains “Indeterminate”
  - 40+ different variations
  - Unknown pattern evolution (how long to wait?)
  - Unclear optimal management (what to do with what strip?)
Category II FHR

Assessment of Intrapartum FHR Tracing

Category I
- Evaluation & Surveillance
  - Intrauterine Resuscitative Measures *
  - Continue Close Observation
  - If not improved or FHR tracing progresses to Category III, consider delivery

Category II
- Category II FHR

Category III
- Category III Management of Intrapartum Fetal Heart Rate Tracings

Management

ACOG PRACTICE BULLETIN

Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles

Management of Intrapartum Fetal Heart Rate Tracings

4th Annual Texas Two-Step Conference
February 28 - March 1, 2014
Assessment of Intrapartum FHR Tracing

**Last 2 hours**

- **Category I**
  - FHR accelerations OR moderate FHR variability
  - If not improved, consider prompt delivery

- **Category II**
  - Absent FHR accelerations AND decreased FHR variability
  - Intrauterine Resuscitative Measures *
  - If not improved or FHR tracing progresses to Category III, consider delivery

- **Category III**
  - Prepare for Delivery
  - Intrauterine Resuscitative Measures *
  - If not improved, consider prompt delivery

---

**Table 2. Intrauterine Resuscitative Measures for Category II or Category III Tracings or Both**

<table>
<thead>
<tr>
<th>Goal</th>
<th>Intrauterine Resuscitative Measures *</th>
</tr>
</thead>
<tbody>
<tr>
<td>FHR accelerations OR moderate FHR variability</td>
<td>Recurrent late decelerations, prolonged decelerations or tachycardia, maternal or absent late FHR variability</td>
</tr>
<tr>
<td>Tachycardia with Category II or III tracing</td>
<td>Recurrent variable decelerations, fetal bradycardia</td>
</tr>
<tr>
<td>Pregnant woman's desire</td>
<td>Recurrent late decelerations, fetal bradycardia, maternal or absent late FHR variability</td>
</tr>
</tbody>
</table>

---

**“ABCD” approach to electronic fetal heart rate monitoring (EFM) management**

1. **Confirm FHR and uterine activity**
2. **ABCD**
   - **A** - Assess oxygen delivery and consider other causes
   - **B** - Bag-mask or intubation
   - **C** - Continuous fetal heart rate monitoring
   - **D** - Delivery
3. **FHR Category?**
   - I, II, or III
4. **To the patient (caution)**
5. **Routine Resuscitations**
   - Antisera, antibiotics, and corticosteroids
6. **Heightened Resuscitations**
   - C-section, intubation, and resuscitative measures
7. **Electronic fetal heart rate monitoring: applying principles of patient safety**
   - Miller DA and Miller LA, AJOG (2013)
OBSSTETRICS

Intrapartum management of category II fetal heart rate tracings: towards standardization of care

There is currently no standard national approach to the management of category II fetal heart rate (FHR) patterns, yet such patterns occur in the majority of term labors. Under such circumstances, it would be difficult to demonstrate the clinical efficacy of FHR monitoring even if the technique had immense intrinsic value, since there has never been a standard hypothesis to test dealing with interpretation and management of these abnormal patterns. We present an algorithm for the management of category II FHR patterns that reflects a synthesis of available evidence and current scientific thought. Use of this algorithm represents one way for the clinician to comply with the standard of care, and may enhance our overall ability to define the benefits of intrapartum FHR monitoring.

Key words: fetal heart rate monitoring, neonatal encephalopathy, patient safety

FIGURE 1

Algorithm for management of category II fetal heart rate tracings

<table>
<thead>
<tr>
<th>Decision Point</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal tracing</td>
<td>Continue monitoring</td>
</tr>
<tr>
<td>Abnormal tracing</td>
<td>Continue monitoring</td>
</tr>
<tr>
<td>No</td>
<td>Decision Point</td>
</tr>
<tr>
<td>Yes</td>
<td>Decision Point</td>
</tr>
</tbody>
</table>

TABLE 1

Management of category II fetal heart rate patterns: clarifications for use in algorithm

1. Variability refers to parameters based on FHR patterns/peak, nadir, maximum, minimum, absent during a 5-minute evaluation period, as defined by NODP.
2. Normal tracing is considered same as moderate variability for purposes of this algorithm.
3. Significant decelerations are defined as one or more of the following.
4. Significant variability is defined as more than 50% and not exceeding a ratio more than 30% of the baseline.
5. Significant decelerations lasting longer than 60 seconds and involving a ratio less than 30% are evaluated.
6. Significant variability lasting more than 60 seconds is evaluated.
7. Any prolonged deceleration, as defined by the NODP, is abolished in this definition. Identification of a prolonged deceleration should not result in categorization of the algorithm until the deceleration is resolved.
8. Application of an algorithm as to be statistically relevant in a non-clinical setting or for commercial purposes involves the classification of patients into categories based on a pre-established hypothesis.
9. Any significant change in the patient's condition should result in reconsideration of the algorithm.
10. For category II fetal patterns or other algorithmic suggestions to be withdrawn, such therapy should ideally be evaluated within 30 minutes of initiation.
11. If any two of these factors, to be included in the algorithm, demonstrate in the category II, the algorithm no longer applies.
12. Any patient with significant variability, without significant changes is not included in the category II, unless major fluctuations are noted or if the patient is not included in the category II.
13. Algorithm may be withdrawn at any time if, after evaluation of patient, physician believes it is based on the FHR or intrauterine data.

14. Missouri State University-Warrensburg, MO.
15.owa State University College of Medicine, Stillwater, OK.
16. University of Iowa, Iowa City, IA.
17. University of Missouri, Columbia, MO.
18. University of Texas Southwestern Medical Center, Dallas, TX.
19. University of Washington, Seattle, WA.
Categories of Allegations

1. Failure to Recognize FHR pattern that requires Mx
   - Severity

2. Failure to Communicate Findings
   - Nurse-Resident
   - Nurse-Attending (or CNM)
   - CNM-physician
   - Resident-Attending

3. Failure or Delay to Intervene
   - Accurately
   - Timely

#1 Allegation
Failure to Recognize FHR tracing that requires Mx

Pattern evolution in Category II
- Which cases will progress?
  1. Persistent tachycardia
  2. Persistent minimal or absent variability
  3. Recurrent prolonged FHR decelerations

Misconception regarding Mx of Category II
- Should you wait until Category III tracing develops prior to calling cesarean or OVD for FHR indications?
  NOT TRUE !!! (several Category II FHR qualify)
#1 Allegation
Failure to Recognize FHR tracing that requires Mx

• How does this manifest?
  – Nurse does not communicate in timely fashion, until severe FHR changes and then physician engaged and activates interventions
  – Physician aware but does not come to bedside, call anesthesia, or activate surgical preparations
  – FHR progresses quickly but proceeded by “warning signs in FHR”
    – E.g. Recurrent variables or prolonged deceleration(s) prior to bradycardia and then an “emergent situation”

Many practice setting have large % of FHR tracing and labor management occurring with physician outside of hospital and FHR not visible to him/her

• FHR progresses quickly but proceeded by “warning signs in FHR”
  – Recurrent variables or prolonged deceleration(s) prior to bradycardia and then an “emergent situation”

Categories of Allegations

1. Failure to Recognize FHR pattern that requires Mx
   – Severity
2. Failure to Communicate Findings
   – Nurse-Resident
   – Nurse-Attending (or CNM)
   – CNM-physician
   – Resident-Attending
3. Failure or Delay to Intervene
   – Accurately
   – Timely
#2 Allegation
Failure to Communicate Findings

- Large % communication between nurses-physicians occur over the phone
- Always have tension between too many calls vs. appropriate information
  - Other patient commitments
  - Night time (sleep)
- Nurse is eyes-ears at bedside related to FHR interpretation and management
  - Rare for physicians to have capacity to see FHR outside hospital

When & How to communicate regarding FHR tracing

- No clear guidelines
  - Challenging to translate into written forms given complexity of clinical scenarios and settings
  - Examples:
    - Settings (how far physician from hospital)
    - Can physician do CD or need to call surgeon
    - Time to PREP for delivery
    - Risk tolerance of physician
- Often culture, experience, relationships, and local practice will drive when, how, and what

Communications

- How often & when should a nurse call?
  - Who decides?
- Does physician want to be called with every FHR change?
  - Every time in Category II?
  - Every deceleration?

Call for everything until 1 am and then only "really bad" or about to deliver
Challenges

- Physician’s perspective in retrospect after complicated case often “if only I had known of course I would have come in or called cesarean” …
- I want to know about this
- But not this

What: Communications

- Common theme in cases of alleged medical negligence is miscommunication on acuity
  - Nurse believes FHR is problematic and “something more should be done”
  - Physician hears “not normal but not an emergency”
  - Despite multiple calls & communications
  - Nurse concerned & does not want to exceed role, but also wants to “protect” own position

**Example** – Doctor X informed repetitive late decelerations and decreased variability. No other orders given.

What: Communications

- In our institutions, we work to coach bedside nurses to standardize communications + be more prescriptive
  - Category II FHR pattern
    - Type and frequency of deceleration
    - Variability
  - I am concerned and would like ...
    - You to come to hospital to evaluate FHR
    - You to come to the hospital since concerned about FHR progression
    - Dr. or Ms. X review the FHR pattern too

Nurses will often know severity of condition BUT hesitate with the strength of their feedback to physician
**What: Communications**

- If this is going to work, need physicians to NOT “rebel” against this type of approach
  - Example - complain when they have to be in hospital longer/more OR when normal outcomes OR FHR returns to Category I
  - Not push back that nurses are “over-reacting”
  - Explanation for physicians: Similar approach to appendectomy and risks ruptured appendicitis vs. removal “normal appendix”

**Categories of Allegations**

1. Failure to Recognize FHR pattern that requires Mx
   - Severity
2. Failure to Communicate Findings
   - Nurse-Resident
   - Nurse-Attending (or CNM)
   - CNM-Physician
   - Resident-Attending
3. Failure or Delay to Intervene
   - Timely

**#3 Allegation**

Failure or Delay To Intervene

- How does this allegation manifest?
  - Nurse did not take adequate steps
    - Contact physician or chain of command
    - Example “lost FHR”
  - Physician did not come to hospital
  - Did not call in OR team
  - Physician did not call cesarean or OVD in adequate time
    - Argument that 30 minute rule does not apply or that since > 30 minutes below standard
    - Rarely related to time from decision-to-delivery
#3 Failure or Delay To Intervene

- How to manage this concern?
  - Create Checklist
    - Who to contact
    - What steps to do
    - Who does what
  - Coach charge nurse/unit leaders to “ask” would you like me to prepare OR and call Dr. ... ?
  - Develop accepted processes where automatic notifications
  - On-going training/education FHR interpretation

Complex clinical situations require clinical judgment: beyond algorithms

- Patient factors
  - Gestational age, fetal growth, maternal condition, VBAC, stage of labor, prior FHR, cervical dilation, labor progress, parity, patient risk tolerance and preferences.
- Environmental factors
  - Other patients, availability OR, time of day.
- FHR assessment
  - Severity FHR, response of FHR to prior Tx, in utero resuscitation methods, which interventions and which order, delivery vs. no delivery.

Categories of Allegations

Lessons learned

1. Failure to Recognize FHR pattern that requires Mx
   - Severity

2. Failure to Communicate Findings
   - Nurse-Resident
   - Nurse-Attending (or CNM)
   - CNM-physician
   - Resident-Attending

3. Failure or Delay to Intervene
   - Timely
Summary

- 3-Tier FHR system can rapidly screen Category I and III tracings which have clear management

- Subset of Category II tracing have higher risk of progression (tachycardia, minimal/absent variability, prolonged decelerations)

- Flow diagrams do not obviate need for situational awareness in Mx Category II tracings

Management of Category II FHR

Given complexity of FHR patterns, and fluidity of patient condition, decision-making requires use of common sense beyond algorithms & expert guidance
Risk Management Issues Related to OB Triage

George Saade, M.D.
Risk Management Issues Related to OB Triage

George Saade, MD
Professor, Departments of Ob-Gyn and Cell Biology
Jeanne Sealy Smith Distinguished Chair in Obstetrics and Gynecology
Chief of Obstetrics and Maternal Fetal Medicine

OB Providers in Triage
Overall Logistics

- Better name is OB Evaluation
  - Triage vs evaluation vs observation
- Location
  - Close to labor and delivery and OR for viability
- Staffing
  - MDs or CNM or NP
- Chain of command
- Audits, debriefing, simulation, drills, near misses
- Call back patients, time studies

EMTALA

- Emergency Medical Treatment and Active Labor Act
- Federal law governs emergency medical treatment and active labor
- Applies when the absence of immediate medical attention could reasonably be expected to result or pose a threat to the health and safety of a pregnant woman or unborn child

EMTALA Mandates

- All pregnant women presenting to an ED, labor, or triage setting have a medical screening examination (MSE)
- Either
  - Medical treatment provided so that no deterioration from or during transfer
  - Delivery of child and placenta
- Violation if routine long wait so that as to leave AMA
EMTALA and Contractions

• Patient deemed stable if either
  – Infant and placenta are delivered
  – Labor contractions are gone
  – Certified to be in false labor
• Need to be assessed by a qualified medical provider (QMP)
  – CNM
  – Qualified medical person (nurses need credentialing, bylaws, and state rules)
• Requires a MSE

EMTALA and Consultants

• List of on call
• Readily available
• Clarify consultative relationship and urgency
• Documentation (should be available upon request)

Major Categories of Risk

• Assessment in a timely manner
• Appropriate and complete evaluation and documentation
• Discharge without evidence of fetal well-being
• Differentiation of false versus true labor
• Handoffs
System Potential for Errors

- Long waiting times
- Crowding
- Delays in consulting
- Medical record (including EMR)
- Handoffs

Clinical Handoffs

- Joint Commission requirement
- Best by face-to-face

Timeliness

- Acting on non-reactive NST or non-category 1 tracings
- Checking lab results
- Medications (e.g. antihypertensives)
- Recognizing active labor
Timeliness

- Triage within 5-10 min (ED standard)
- Evaluation within 30 min
  - Questions by nurse
  - On the monitor if viable
  - Additional evaluation as needed
- Disposition within 4 hours
  - Discharge
  - Admission
  - Observation

Guided Evaluation

- Prior OB history
- Medical history
- Contractions
- Fetal movement
- Vaginal bleeding or fluid
- Headache, visual symptoms, right upper quadrant pain
- Chest pain, leg pain
- Other pain
- Feverish
### Levels of Severity

<table>
<thead>
<tr>
<th>Red</th>
<th>Yellow</th>
<th>Green</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardio-respiratory</td>
<td>Contractions every 2 minutes &amp; appears</td>
<td>Nausea/vomiting/diarrhea</td>
</tr>
<tr>
<td>distress</td>
<td>uncomfortable</td>
<td>Urinary complaints</td>
</tr>
<tr>
<td>Eclampsia</td>
<td>Multipara in active labor</td>
<td>Stable gestational hypertension</td>
</tr>
<tr>
<td>Active hemorrhage/</td>
<td>Decreased fetal movement</td>
<td>Wound infection</td>
</tr>
<tr>
<td>heavy bleeding</td>
<td>Abdominal pain</td>
<td>Upper respiratory infection</td>
</tr>
<tr>
<td>Urge to push</td>
<td>Preterm labor or preterm rupture of</td>
<td>Vaginal discharge/vaginitis</td>
</tr>
<tr>
<td>Objects protruding</td>
<td>membranes</td>
<td>Wound checks</td>
</tr>
<tr>
<td>from vagina</td>
<td>Actual or potential Pre-eclampsia or</td>
<td>Staple removal</td>
</tr>
<tr>
<td>No fetal movement</td>
<td>HELLP syndrome</td>
<td>Injections, lab draws</td>
</tr>
<tr>
<td>Diabetic coma/DKA</td>
<td>Rule-out ROM</td>
<td></td>
</tr>
<tr>
<td>Other life-threatening conditions to mother or fetus</td>
<td><strong>Yellow conditions are listed in order of priority</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Actions for Levels of Severity

**Red = Emergent**

*Notify Provider Immediately*

*Move patient directly to room: OBE exam, OR, special care, or LDR room*

(Patient must be seen but will not deteriorate with slight delay in care)

**Yellow = Urgent**

*Notify provider when RN triage assessment is complete*

(Patient can wait for several hours with minimal risk of further injury)

**Green = Nonurgent**

*Notify provider when RN triage assessment is complete*

### Unit Policy & Protocol

- Patients sent to the waiting room will be re-evaluated as follows until an OBE room is available:
  - Yellow = every 30 minutes
  - Green = every hour

- RN assigned to front is responsible for completing re-evaluations and re-determining condition levels

- Documentation will be on the new “OB Evaluation Triage Note” form
<table>
<thead>
<tr>
<th>Condition Level: Red</th>
<th>Yellow</th>
<th>Green</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>Arrival Time:</td>
<td>Triage Time:</td>
</tr>
<tr>
<td>Name:</td>
<td>FMP/Sponsor:</td>
<td>SSN:</td>
</tr>
<tr>
<td>Age:</td>
<td>EDC:</td>
<td>EGA:</td>
</tr>
<tr>
<td>Height:</td>
<td>Weight:</td>
<td>G: P: T: P: A: L:</td>
</tr>
<tr>
<td>Barriers to communication:</td>
<td>□ No</td>
<td>□ Yes: □ Language □ Disability □ Other: __________</td>
</tr>
<tr>
<td>Arrival Via:</td>
<td>□ Ambulatory</td>
<td>□ Wheelchair □ Gurney □ EMS/Ambulance □ Other</td>
</tr>
<tr>
<td>Reason for Visit:</td>
<td>History of cesarean section?</td>
<td>Yes</td>
</tr>
<tr>
<td>History of/current placenta previa?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>History of/current HSV infection?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>If yes, for what complications?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergies/reaction:</td>
<td>Current Medications:</td>
<td></td>
</tr>
<tr>
<td>Location:</td>
<td>Radiation to:</td>
<td>Leaking Fluid? Yes</td>
</tr>
<tr>
<td>Contractions? Yes</td>
<td>No</td>
<td>Unsure</td>
</tr>
<tr>
<td>Regular? Yes</td>
<td>No</td>
<td>Date/time started:</td>
</tr>
<tr>
<td>Rectal pressure? Yes</td>
<td>No</td>
<td>Urge to push? Yes</td>
</tr>
<tr>
<td>Vaginal Bleeding? Yes</td>
<td>No</td>
<td>Unsure</td>
</tr>
<tr>
<td>Bloody show? Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fetal Movements? Feeling baby move like he/she normally does? Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Feeling 10 or more fetal movements in one hour without difficulty (kick counts)? Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fall risk assessment: □ Level I □ Level II □ Level III □ Side rails up □ Bed locked □ Other: __________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Domestic violence assessment: Do you feel safe at home?: Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>History of/current physical abuse? Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>History of/current sexual abuse: Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>History of/current verbal abuse: Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Psychosocial: Eye contact?: Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Affect: □ Broad □ Flat □ Blunted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mood: □ Depressed □ Labile □ Elated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hallucinations: □ Auditory □ Visual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ideations: □ Harm to self □ Harm to others</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Behavior: □ Cooperative □ Restless □ Agitated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support System: □ Lives Alone □ Family □ Friends □ Significant Others</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal exam: □ Deferred</td>
<td>Time:</td>
<td>Dil:</td>
</tr>
<tr>
<td>Provider notified:</td>
<td>Time: ____________________</td>
<td></td>
</tr>
<tr>
<td>Notes: Primary RN</td>
<td>Signature Initials Signature Initials</td>
<td></td>
</tr>
</tbody>
</table>


COMMITTEE OPINION
Number 186 • March 2014
(Replaces Connective Opinion Number 497, April 2011)
Committee on Patient Safety and Quality Improvement
This document reflects convergent consensus opinion and is subject to change. The information should not alter routine decision-making or patients' course of treatment or procedure to the Manual.
Preventing for Clinical Emergencies in Obstetrics and Gynecology

The American College of Obstetricians and Gynecologists

145
Modified Early Obstetric Warning System (MEOWS)

<table>
<thead>
<tr>
<th></th>
<th>Red trigger</th>
<th>Yellow trigger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature; °C</td>
<td>&lt; 35 or &gt; 38</td>
<td>35–36</td>
</tr>
<tr>
<td>Systolic BP; mmHg</td>
<td>&lt; 90 or &gt; 160</td>
<td>150–160 or 90–100</td>
</tr>
<tr>
<td>Diastolic BP; mmHg</td>
<td>&gt; 100</td>
<td>90–100</td>
</tr>
<tr>
<td>Heart rate; beats.min⁻¹</td>
<td>&lt; 40 or &gt; 120</td>
<td>100–120 or 40–50</td>
</tr>
<tr>
<td>Respiratory rate; breaths.min⁻¹</td>
<td>&lt; 10 or &gt; 30</td>
<td>21–30</td>
</tr>
<tr>
<td>Oxygen saturation; %</td>
<td>&lt; 95</td>
<td>–</td>
</tr>
<tr>
<td>Pain score</td>
<td>–</td>
<td>2–3</td>
</tr>
<tr>
<td>Neurological response</td>
<td>Unresponsive, pain</td>
<td>Voice</td>
</tr>
</tbody>
</table>

Finalization Before Disposition
- Review entire strip (even if presentation unrelated to fetus)
- Document findings and times
- Check all labs
- Handoff if admitted or for observation
- Instructions if discharged

Minimize Liability
- Nausea and vomiting in the third trimester is not hyperemesis
- Consider delivery after 39 weeks
- Liberal use of BPP
- Beware prior CD (particularly in obese)
Specific Conditions

Hypertension

Hypertension in Pregnancy

Report of the American College of Obstetricians and Gynecologists’ Task Force on Hypertension in Pregnancy

Specific Conditions

Hypertension

Hypertension in Pregnancy

Report of the American College of Obstetricians and Gynecologists’ Task Force on Hypertension in Pregnancy

Box E-1: Severe Features of Preeclampsia (Any of these findings)

- Systolic blood pressure of 160 mm Hg or higher, or diastolic blood pressure of 110 mm Hg or higher on two occasions at least 4 hours apart while the patient is on bed rest (unless antihypertensive therapy is initiated before this time)
- Thrombocytopenia (platelet count less than 100,000/microliter)
- Impaired liver function as indicated by abnormally elevated blood concentrations of liver enzymes (twice normal concentration), severe persistent right upper quadrant or epigastric pain unresponsive to medication and not accounted for by alternative diagnoses, or both
- Progressive renal insufficiency: serum creatinine concentration greater than 1.1 mg/dl, or a doubling of the serum creatinine concentration in the absence of other renal disease
- Pulmonary edema
- New-onset cerebral or visual disturbances
<table>
<thead>
<tr>
<th>Table 6.1: Diagnostic Criteria for Preeclampsia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Proteinuria</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>In the absence of proteinuria, nonproteinuric hypertension with the new onset of any of the following:</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
</tr>
<tr>
<td>Renal insufficiency</td>
</tr>
<tr>
<td>Hepatic dysfunction</td>
</tr>
<tr>
<td>Pulmonary edema</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

• For women with mild gestational hypertension or preeclampsia with a persistent BP of less than 160 mm Hg systolic or 110 mm Hg diastolic, it is suggested that antihypertensive medications not be administered.

  Quality of evidence: Moderate  
  Strength of recommendation: Qualified

• For women with mild gestational hypertension or preeclampsia without severe features at or beyond 37 0/7 weeks of gestation, delivery rather than continued observation is suggested.

  Quality of evidence: Moderate  
  Strength of recommendation: Qualified

• For women with preeclampsia with systolic BP of less than 160 mm Hg and a diastolic BP less than 110 mm Hg and no maternal symptoms, it is suggested that magnesium sulfate not be administered universally for the prevention of eclampsia.

  Quality of evidence: Low  
  Strength of recommendation: Qualified
Task Force Text

Although the universal use of magnesium sulfate therapy in preeclampsia without severe features is not recommended, certain signs and symptoms (headache, altered mental state, blurred vision, scotomata, clonus, and right upper quadrant abdominal pain) have traditionally been considered as premonitory to seizures and should be considered in the choice for initiation of magnesium sulfate therapy.

- For women with eclampsia, the administration of parenteral magnesium sulfate is recommended.
  
  Quality of evidence: High
  Strength of recommendation: Strong

- For women with severe preeclampsia, the administration of intrapartum-postpartum magnesium sulfate to prevent eclampsia is recommended.
  
  Quality of evidence: High
  Strength of recommendation: Strong

- For women in the postpartum period who present with new-onset hypertension associated with headaches or blurred vision or preeclampsia with severe hypertension, the parenteral administration of magnesium sulfate is suggested.
  
  Quality of evidence: Low
  Strength of recommendation: Qualified

- For women with persistent postpartum hypertension, BP of 150 mm Hg systolic or 100 mm Hg diastolic or higher, on at least two occasions that are at least 4-6 hours apart, antihypertensive therapy is suggested. Persistent BP of 160 mm Hg systolic or 110 mm Hg diastolic or higher should be treated within 1 hour.
  
  Quality of evidence: Low
  Strength of recommendation: Qualified
• For women with persistent postpartum hypertension, BP of 150 mm Hg systolic or 100 mm Hg diastolic or higher on at least two occasions that are at least 4–6 hours apart, antihypertensive therapy is suggested. Persistent BP of 160 mm Hg systolic or 110 mm Hg diastolic or higher should be treated within 1 hour.

  Quality of evidence: Low
  Strength of recommendation: Qualified

• For women with preeclampsia with severe hypertension during pregnancy (sustained systolic BP of at least 160 mm Hg or diastolic BP of at least 110 mm Hg), the use of antihypertensive therapy is recommended.

  Quality of evidence: Moderate
  Strength of recommendation: Strong

ACOG Practice Bulletin #33

Acute-onset, severe systolic (greater than or equal to 160 mm Hg) or severe diastolic (greater than or equal to 110 mm Hg) hypertension or both can occur in pregnant or postpartum women with any hypertensive disorders during pregnancy. Acute-onset, severe hypertension that is accurately measured using standard techniques and is persistent for 15 minutes or more is considered a hypertensive emergency. This occurs in the second half of gestation in patients not known to have chronic hypertension who develop sudden, severe hypertension (ie, with preeclampsia, gestational hypertension, or HELLP
ACOG Practice Bulletin #33

Antihypertensive Treatment for Preeclampsia

Hydralazine: 5–10-mg doses intravenously every 15–20 minutes until desired response is achieved* 
Labetalol: 20-mg intravenous bolus dose followed by 40 mg if not effective within 10 minutes; then, 80 mg every 10 minutes to maximum total dose of 220 mg* 


Nicardipine

• Initial infusion rate 2.5 mg/h 
• Increases by 2.5 mg/h every 5 minutes 
• Maximum dose of 15 mg/h 
• Arterial line
Hypertension in Pregnancy
Report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnancy

Executive Summary

...ation of preeclampsia as severe. Also, because fetal growth restriction is managed similarly in pregnant women with and without preeclampsia, it has been removed as a finding indicative of severe preeclampsia (Table E-1).

- If evidence of fetal growth restriction is found in women with preeclampsia, fetoplacental assessment that includes umbilical artery Doppler velocimetry as an adjunct antenatal test is recommended.

Quality of evidence: Moderate
Strength of recommendation: Strong

Task Force Text

Fetal indications for delivery
- Gestational age of 34 0/7 weeks
- Severe fetal growth restriction (ultrasonographic estimate of fetal weight less than the fifth percentile)
- Persistent oligohydramnios (maximum vertical pocket less than 2 cm)
- BPP of 4/10 or less on at least two occasions 6 hours apart
- Reversed end-diastolic flow on umbilical artery Doppler studies
- Recurrent variable or late decelerations during NST
- Fetal death
Mild Gestational Hypertension or Preeclampsia Without Severe Features

NST is nonreactive. Best practice indicates hospitalization and delivery for one or more of the following:

- 37 0/7 weeks or more of gestation
- Suspected abruption placenta
- 34 0/7 weeks or more of gestation, plus any of the following:
  - Progressive labor or rupture of membranes
  - Ultrasonographic estimate of fetal weight less than fifth percentile
  - oligohydramnios (persistent amniotic fluid index less than 5 cm)
  - Persistent BPP 6/10 or less (normal 8/10–10/10)
Specific Conditions

Fetal Heart Rate
>15 bpm if >32 wks
10 bpm if <32 wks

<2 min = acceleration
2 to <10 min = prolonged acceleration
≥10 min = baseline change

Absent variability = Amplitude range undetectable
Minimal = < 5 BPM
Moderate = 6 to 25 BPM
Marked = > 25 BPM
Early descretion
- Usually apparent early, systolic drop and recovery of the HR associated with a stable contraction.
- A gradual HR decrease is defined as from the onset to the HR nadir of 30 seconds or more.
- The HR nadir is calculated from the onset to the nadir of the deceleration.
- The nadir of the deceleration occurs at the same time as the peak of the contraction.
- In some cases, the onset, nadir, and recovery of the deceleration are coincident with the beginning, peak, and ending of the contraction, respectively.

Late descretion
- Usually apparent early, systolic drop and recovery of the HR associated with a stable contraction.
- A gradual HR decrease is defined as from the onset to the HR nadir of 30 seconds or more.
- The HR nadir is calculated from the onset to the nadir of the deceleration.
- The nadir of the deceleration is defined as the nadir occurring after the peak of the contraction.
- In most cases, the onset, nadir, and recovery of the deceleration occur after the beginning, peak, and ending of the contraction, respectively.

Variable descretion
- Usually apparent, abrupt decrease in HR.
- A sudden HR decrease is defined as from the onset of the deceleration to the beginning of the HR nadir of less than 30 seconds.
- The HR nadir is calculated from the onset to the nadir of the deceleration.
- The decrease in HR is 10 beats or more in duration or greater, lasting 15 seconds or greater, and less than 2 minutes in duration.
- Variable decelerations are associated with diastolic contractions, their onset, depth, and duration commonly varying with associated atrial contractions.
- Usually apparent, short, the variable oscillating pattern in HR baseline with a cycle frequency of 3-5 per minute which persists for 45 seconds or more.
Variable > 15 bpm

4th Annual Texas Two-Step Conference
February 28 - March 1, 2014

The American College of Obstetricians and Gynecologists
Women’s Health Care Guidelines

**Category I**
- Category I FHR tracings include all of the following:
  - Baseline rate: 110–160 beats per minute
  - Baseline FHR variability: moderate
  - Late or variable decelerations: absent
- Early decelerations: present or absent
- Accelerations: present or absent
Timely Intervention of non-Category 1

Reactivity

- Increase of 15 bpm above baseline for 15 sec (from baseline to baseline) twice in a 20 min period
- 65% of fetuses at 28 weeks are reactive by these criteria
- By 34 weeks 95% are reactive
- Same as acceleration?
- BPP if non-reactive

Specific Conditions

Preterm Labor
### Rapid Bedside fFN
**Effect on Length of Hospital Stay**
Plaut et al. *Am J Obstet Gynecol* 2003;188:1588-95

<table>
<thead>
<tr>
<th>Hours in Hospital</th>
<th>All patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8.1</td>
</tr>
<tr>
<td>5</td>
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<tr>
<td>10</td>
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<tr>
<td>35</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>

**Length of stay > 6 hours**

<table>
<thead>
<tr>
<th>Hours in Hospital</th>
<th>Length of stay &gt; 6 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>27.8</td>
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<td>5</td>
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<td>40</td>
<td></td>
</tr>
</tbody>
</table>

### fFN and Physician Behavior
**RCT**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Total (n)</th>
<th>Total (n)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate mortal</td>
<td>3 (13)</td>
<td>4 (16)</td>
<td>.44</td>
</tr>
<tr>
<td>Died</td>
<td>8 (32%)</td>
<td>9 (36%)</td>
<td>.69</td>
</tr>
<tr>
<td>Died</td>
<td>8 (32%)</td>
<td>9 (36%)</td>
<td>.68</td>
</tr>
<tr>
<td>Died</td>
<td>13 (56%)</td>
<td>11 (44%)</td>
<td>.88</td>
</tr>
<tr>
<td>Died</td>
<td>3 (13)</td>
<td>2 (9)</td>
<td>.83</td>
</tr>
<tr>
<td>Died</td>
<td>4 (17%)</td>
<td>3 (12%)</td>
<td>.88</td>
</tr>
<tr>
<td>Died</td>
<td>5 (21%)</td>
<td>4 (16%)</td>
<td>.78</td>
</tr>
<tr>
<td>Died</td>
<td>6 (26%)</td>
<td>4 (17%)</td>
<td>.42</td>
</tr>
</tbody>
</table>

*Data are presented as median (interquartile range).*
Knowledge of CL and FFN
Effect on Management of Threatened PTL - RCT

Knowledge of CL and FFN
Effect on Management of Threatened PTL - RCT

Knowledge of CL and FFN
Effect on Management of Threatened PTL - RCT
### Knowledge of CL and FFN

**Effect on Management of Threatened PTL - RCT**


<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Knowledge of FFN (%)</th>
<th>Standard (Divided)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from evaluation to discharge (min)</td>
<td>2.24 ± 1.09</td>
<td>2.49 ± 1.09</td>
<td>&gt;.14</td>
</tr>
<tr>
<td>Gestational age at delivery*</td>
<td>38.6 ± 1.1</td>
<td>37.1 ± 2.9</td>
<td>&lt;.03</td>
</tr>
<tr>
<td>PPB &lt; 37 weeks (n = 95)</td>
<td>64.6 (13.3%)</td>
<td>114/179 (65.2%)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>PPB ≥ 34 weeks (n = 95)</td>
<td>24.9 (6.6%)</td>
<td>66/241 (27.3%)</td>
<td>&gt;.20</td>
</tr>
<tr>
<td>Delivery within 7 d (n = 94)</td>
<td>1 (3.5%)</td>
<td>1/41 (2.9%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Delivery within 14 d (n = 94)</td>
<td>2 (1.1%)</td>
<td>2/41 (4.9%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Delivery within 28 d (n = 94)</td>
<td>6 (13.0%)</td>
<td>7/41 (17.1%)</td>
<td>&gt;.76</td>
</tr>
<tr>
<td>Neonatal intensive care to delivery (y)</td>
<td>60.2 ± 122</td>
<td>60/60 (100%)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Unless otherwise noted, n = 95.
**See text for two patient characteristics not listed on RCT.
***Use of 1 standard deviation.

### Labor Sx Before 34 weeks and Cx

**Dilatation < 2 cm**

Chao et al. *Obstet Gynecol* 2011;118:1301-8

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Women Without Preeclampsia</th>
<th>Comorbidity and Sudden Home Death</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women presenting labor and delivery room</td>
<td>14 (2.8%)</td>
<td>12 (2.4%)</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>Diagnosis and onset of labor and delivery</td>
<td>38 (7.3%)</td>
<td>30 (6.1%)</td>
<td>&gt;.20</td>
</tr>
<tr>
<td>Dilatation of 2 cm or less</td>
<td>61 (11.9%)</td>
<td>41 (8.1%)</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Death of 1000 g or more</td>
<td>2 (0.4%)</td>
<td>1 (0.2%)</td>
<td>&gt;.40</td>
</tr>
<tr>
<td>Death at 30 weeks or more</td>
<td>17 (3.3%)</td>
<td>15 (2.9%)</td>
<td>&lt;.20</td>
</tr>
<tr>
<td>Birth weight less than 1000 g</td>
<td>32 (6.2%)</td>
<td>21 (4.2%)</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Infant hospitalization</td>
<td>2 (0.4%)</td>
<td>1 (0.2%)</td>
<td>&gt;.70</td>
</tr>
<tr>
<td>Neonatal intensive care</td>
<td>4 (0.8%)</td>
<td>3 (0.6%)</td>
<td>&gt;.40</td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
<td>&gt;.80</td>
</tr>
<tr>
<td>Perinatal death</td>
<td>3 (0.6%)</td>
<td>2 (0.4%)</td>
<td>&gt;.80</td>
</tr>
</tbody>
</table>

*Unless otherwise noted, n = 95.
**Use of 1 standard deviation or n (%) unless otherwise specified.
### Labor Sx Before 34 weeks and Cx
### Dilatation < 2 cm

**Chao et al. Obstet Gynecol 2011;118:1301-8**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Women Without Previous Labor &amp; Birth (Diagnosis and Sent Home [n=410])</th>
<th>Comparable General Obstetric Population (n=100,000)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weeks of gestation at delivery</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>35.91±1.10</td>
<td>35.41±1.00</td>
<td></td>
</tr>
<tr>
<td>14-26</td>
<td>0.93 (20)</td>
<td>1.01 (30)</td>
<td></td>
</tr>
<tr>
<td>27-36</td>
<td>1.62 (40)</td>
<td>1.62 (40)</td>
<td></td>
</tr>
<tr>
<td>37 or more</td>
<td>3.38 (100)</td>
<td>3.20 (100)</td>
<td></td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3,249±1170</td>
<td>3,170±1599</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3,249±1170</td>
<td>3,170±1599</td>
<td></td>
</tr>
<tr>
<td>2,500-3,000</td>
<td>387 (95)</td>
<td>380 (95)</td>
<td></td>
</tr>
<tr>
<td>&gt;3,000 or more</td>
<td>387 (95)</td>
<td>380 (95)</td>
<td></td>
</tr>
<tr>
<td>Admission to intensive care</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant score of 3 or less at 5 mins</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal death</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: *an estimate/standard deviation or n (%) unless otherwise specified.

---

### Labor Sx Before 34 weeks and Cx
### Dilatation < 2 cm

**Chao et al. Obstet Gynecol 2011;118:1301-8**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Women Without Previous Labor &amp; Birth (Diagnosis and Sent Home [n=410])</th>
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<td></td>
<td></td>
</tr>
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<td>Mean</td>
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<td>35.41±1.00</td>
<td></td>
</tr>
<tr>
<td>14-26</td>
<td>0.93 (20)</td>
<td>1.01 (30)</td>
<td></td>
</tr>
<tr>
<td>27-36</td>
<td>1.62 (40)</td>
<td>1.62 (40)</td>
<td></td>
</tr>
<tr>
<td>37 or more</td>
<td>3.38 (100)</td>
<td>3.20 (100)</td>
<td></td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3,249±1170</td>
<td>3,170±1599</td>
<td></td>
</tr>
<tr>
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<td>3,249±1170</td>
<td>3,170±1599</td>
<td></td>
</tr>
<tr>
<td>2,500-3,000</td>
<td>387 (95)</td>
<td>380 (95)</td>
<td></td>
</tr>
<tr>
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<td>387 (95)</td>
<td>380 (95)</td>
<td></td>
</tr>
<tr>
<td>Admission to intensive care</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant score of 3 or less at 5 mins</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal death</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: *an estimate/standard deviation or n (%) unless otherwise specified.

---

### Labor Sx Before 34 weeks and Cx
### Dilatation < 2 cm

**Chao et al. Obstet Gynecol 2011;118:1301-8**

<table>
<thead>
<tr>
<th>Cervical Dilatation at Discharge (cm)</th>
<th>0 (n=404)</th>
<th>1 (n=76)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weeks of gestation of delivery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 24</td>
<td>9 (2)</td>
<td>0 (0)</td>
<td>&lt;0.02</td>
</tr>
<tr>
<td>24-26</td>
<td>29 (7)</td>
<td>7 (9)</td>
<td>0.05</td>
</tr>
<tr>
<td>27 or more</td>
<td>576 (90)</td>
<td>65 (48)</td>
<td>&lt;0.003</td>
</tr>
<tr>
<td>Admission to intensive care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory distress</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant score of 3 or less at 5 mins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal death</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: *an estimate/standard deviation or n (%) unless otherwise specified.
Rapid Bedside fFN
Prediction of Preterm Delivery

fFN and/or cervical dilatation > 1 cm for the predicting
delivery within 10 days in symptomatic women

<table>
<thead>
<tr>
<th></th>
<th>fFN</th>
<th>Cervix &gt; 1 cm</th>
<th>fFN pos and/or cervix &gt; 1 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>65</td>
<td>71</td>
<td>82</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>85</td>
<td>87</td>
<td>76</td>
</tr>
<tr>
<td>PPV (%)</td>
<td>41</td>
<td>46</td>
<td>36</td>
</tr>
<tr>
<td>NPV (%)</td>
<td>94</td>
<td>95</td>
<td>96</td>
</tr>
<tr>
<td>Likelihood Ratio</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>for positive test</td>
<td>4.3</td>
<td>5.5</td>
<td>3.4</td>
</tr>
<tr>
<td>for negative test</td>
<td>0.41</td>
<td>0.33</td>
<td>0.24</td>
</tr>
</tbody>
</table>

Specific Conditions
PROM
Amnisure (Aetna)

• Aetna considers the AmniSure ROM (rupture of membranes) test experimental and investigational for detecting preterm ROM and all other indications because of insufficient evidence of its clinical effectiveness over standard diagnostic methods for detecting ROM.

Last Review: 12/4/2013

Amnisure (Anthem)

• The use of the AmniSure ROM (Rupture of Membranes) test is considered investigational and not medically necessary for all indications, including detection of preterm ROM.

Last Review: 05/09/2013

Amnisure

• Use only if cannot perform clinical evaluation
• Need written policy
Specific Conditions

Magnesium for Neuroprotection

Meta-analysis of all RCT
Death or Moderate-Severe CP

<table>
<thead>
<tr>
<th>Study</th>
<th>Exposed n/R</th>
<th>Control n/R</th>
<th>RR (log scale)</th>
<th>Weight (%)</th>
<th>RR with 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEAM</td>
<td>123/1,133</td>
<td>154/1,283</td>
<td>-</td>
<td>30.00</td>
<td>0.97 (0.77–1.23)</td>
</tr>
<tr>
<td>PREMAG</td>
<td>52/647</td>
<td>66/631</td>
<td>-</td>
<td>19.00</td>
<td>0.63 (0.50–1.16)</td>
</tr>
<tr>
<td>ACTOMySOA</td>
<td>15/619</td>
<td>14/1,035</td>
<td>-</td>
<td>40.00</td>
<td>0.75 (0.6–0.94)</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>2982/2,886</td>
<td>3302/1,554</td>
<td>-</td>
<td>100</td>
<td>0.81 (0.73–0.89)</td>
</tr>
</tbody>
</table>

Meta-analysis of Neuroprotection RCT
CP or Death

<table>
<thead>
<tr>
<th>Study</th>
<th>Exposed n/R</th>
<th>Control n/R</th>
<th>RR (log scale)</th>
<th>Weight (%)</th>
<th>RR with 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEAM</td>
<td>145/1,133</td>
<td>172/1,203</td>
<td>-</td>
<td>43.00</td>
<td>0.9 (0.73–1.1)</td>
</tr>
<tr>
<td>PREMAG</td>
<td>56/547</td>
<td>67/521</td>
<td>-</td>
<td>16.00</td>
<td>0.8 (0.66–1.1)</td>
</tr>
<tr>
<td>ACTOMySOA</td>
<td>123/1,028</td>
<td>149/1,021</td>
<td>-</td>
<td>39.00</td>
<td>0.6 (0.5–1.2)</td>
</tr>
<tr>
<td>MAGNET (P)</td>
<td>500</td>
<td>1,029</td>
<td>-</td>
<td>0.00</td>
<td>4.6 (0.6–38)</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>3292/1,230</td>
<td>3892/1,194</td>
<td>-</td>
<td>100</td>
<td>0.86 (0.75–0.99)</td>
</tr>
</tbody>
</table>
The Committee on Obstetric Practice and the Society for Maternal-Fetal Medicine recognize that none of the individual studies found a benefit with regard to their primary outcome. However, the available evidence suggests that magnesium sulfate given before anticipated early preterm birth reduces the risk of cerebral palsy in surviving infants. Physicians electing to use magnesium sulfate for fetal neuroprotection should develop specific guidelines regarding inclusion criteria, treatment regimens, concurrent tocolysis, and monitoring in accordance with one of the larger trials (see Table 1) (6–8).

**Summary of Recommendations and Conclusions**

The following recommendations are based on good and consistent scientific evidence (Level A):

- Women with preterm PROM before 32 0/7 weeks of gestation who are thought to be at risk of imminent delivery should be considered candidates for fetal neuroprotective treatment with intravenous magnesium sulfate.

**Patient Safety Checklist**

**MAGNESIUM SULFATE BEFORE ANTICIPATED PRETERM BIRTH FOR NEUROPROTECTION**

Criteria (1):

- Gestational age less than or equal to 31 0/7 weeks
- Singleton or multiple pregnancy at risk for delivery within the next 30 minutes to 24 hours
- Active contractility with cervix 4–6 cm dilated or preterm premature rupture of membranes 24 hours or more
- Indicated preterm birth within the next 24 hours. (If the planned delivery is for severe preeclampsia or hemolysis, elevated liver enzymes, and low platelet count (HELLP), the full anticonvulsant magnesium sulfate regimen should be administered as routine therapy.)
UTMB Protocol

Indications

- Likely delivery within **2-24 hours** at **23-32 weeks** with patient not candidate for tocolysis.
- Examples of such cases:
  - PPROM at 23 to 32 weeks
  - Preterm labor at 24-32 weeks with cervix between 4 and 8 cm dilatation
  - Severe IUGR (with abnormal Doppler) requiring delivery
  - Abnormal Testing (Late, REDF, etc) requiring delivery within 24 hours
  - Chorioamnionitis requiring delivery

UTMB Protocol

Administration

- Dose: 6 gm loading then 2 gm/hour (40 gm of magnesium sulfate in 500 cc of NS)
- Duration of treatment: until delivery or 12 hours whichever comes first then discontinued.
- Resume treatment if still less than 32 weeks and delivery deemed likely
  - If < 6 hours since discontinuation of magnesium sulfate, restart infusion at 2 gm/hour
  - If > 6 hours since discontinuation of magnesium sulfate, load with 6 gm then 2 gm/hour
  - Do not retreat if it will delay delivery that is detrimental to mom or fetus
- Once on magnesium for neuroprotection, do not use any tocolytic agents. These patients are not candidate for tocolysis
Conclusions

• Not a tocolytic
• Use for imminent delivery (within 24 hrs) or pPROM
• Limit to less than 32 weeks (best less than 28 weeks)
• Caution

Specific Conditions

Group B Strep Prophylaxis
Corticosteroids

Specific Conditions

Asthma
Specific Conditions

Sepsis
**Definition of Systemic Inflammatory Response (SIRS)**

At least 2 of the following:

- Temperature >38°C or <36°C
- RR >20 bpm or PaCO₂ <32 mmHg
- Pulse >90 bpm
- White blood cell count >12,000/cc, or <4,000/cc, or bands >10%

**Definitions**

- Sepsis: SIRS due to infection
- Severe sepsis: end organ damage
- Septic shock: hypotension (SBP < 90 mmHg) despite volume replacement


**Initial Management of Sepsis Completed within 3 Hours**

- Measurement of lactate
- Cultures drawn before broad spectrum antibiotics
- Broad spectrum antibiotics
- Fluid bolus 30 mL/kg crystalloid for hypotension (SBP < 90 or MAP < 60-65 mmHg) or lactate ≥ 4 mmol/L
Cardiovascular Support (I)
Dellinger. Crit Care Med 2003;31:946-55

![](image)

Specific Conditions

Diabetic Ketoacidosis

What is DKA?
Biochemical Definition

- **D** - Glucose ≥ 300 mg % (180 % in pregnancy)
- **K** - Serum acetone 1:2 or greater
- **A** - HCO3 ≤ 15
  - pH ≤ 7.30
  - Anion gap [NA⁺ - (CL + HCO3)] > 12mEq/L
Treatment Priority of DKA

1. Fluid deficit ~ 100 ml/kg
2. Insulin deficit
3. K - deficit 5 - 10 mEq/kg
4. Acidosis

Treatment

Fluid deficit: 100 ml/kg (7L)
Correct deficit - 75% over 1st 24 hrs
1st hour - 1000 cc
2nd hour - 500 cc
3rd hour - 500 cc

Thereafter 250 cc/hr until 75% of deficit corrected in 24 hours

Insulin Therapy

- Wait for fluid resuscitation and K levels
- Priming dose regular insulin 0.1 units/kg IV push
- Then constant infusion 0.1 units/kg/hr
- Monitor glucose at 1-2 hours
- If glucose not decreased by 25% within 2 hours, double current insulin rate
Treatment
K+ Deficit

• Begin replacement after renal competence established

• Expect to give ~ 350 - 700 mEq during hospitalization (no more than 40 mEq/L)

• Check serum K every 2-4 hours

Specific Conditions

Thyroid Storm

Thyroid Storm

Diagnosis

• Fever
• Change in mental status
  – restless
  – nervous
  – confusion
  – seizure
  – coma

• GI symptoms
  – vomiting
  – diarrhea

• Tachycardia out of proportion
• Inciting event
Thyroid Storm
Management

• High index of suspicion
• Obtain serum FT4, FT3, and TSH prior to therapy
• Do not wait for laboratory diagnosis
• Supportive care

Thyroid Storm
Thioamides

• If oral intake possible:
  – PTU 600-800 mg oral immediately then
  – 150-200 mg oral Q4-6 hours
• If oral intake not possible:
  – Crush PTU and give by NG or
  – Methimazole suppository (120 mg/day divided Q4-6 hours)
Medical Errors in Benign Gynecology

Randa Jalloul, M.D.
Medical Errors in Benign Gynecology

Randa J. Jalloul, MD
Randa.j.jalloul@uth.tmc.edu
Assistant Professor, Department of Obstetrics and Gynecology
University of Texas Health Science Center at Houston

Disclosure

No relevant financial relationships

Learning objectives

- To review treatment options for benign tumors: ovarian, uterine
- To review risks and benefits of such options
- To discuss most common missed diagnosis and methods to avoid them
Case 1

26y.o. G0 with enlarging asymptomatic left adnexal mass, 18 cm, “likely dermoid” on CT. What would you do?

A. Expectant management  
B. Tumor markers  
C. Mini-laparotomy or laparoscopy and cystectomy  
D. Vertical incision, oophorectomy-frozen section and Gynecologic Oncology on standby

Ovarian cyst

1. Physiologic or pathologic
2. Benign or malignant
3. Risks:
   - Rupture
   - Upstaging if malignant
   - Losing an ovary if benign

Risks of rupture with laparoscopy

- Intact removal of mass is often not possible
- Rupture occurs in 12 to 25% of adnexal masses
  - Potential risk of operative spillage
  - Rapid intraabdominal dissemination via the peritoneal circulation
  - Worsening the prognosis

Leminen A. Gynecol Oncol. 1999
Risks of intraoperative rupture

- 161 women with stage I EOC were followed for 47 months:
  - Significant decrease in DFS, regardless of the presence of positive peritoneal cytology.
  - Many oncologists administer adjuvant chemotherapy.

Bakkum-Gamez JN et al Obstet Gynecol. 2009

Risks with laparoscopy

- May use a leak proof bag
  - no data on tumor dissemination
- Need for re-operation
- Consultation with Gyn Onc if staging is indicated.

Malignant vs Benign

<table>
<thead>
<tr>
<th>Malignant</th>
<th>Benign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid components seen</td>
<td>Unilocular</td>
</tr>
<tr>
<td>Nodular or Papillary excrecescences</td>
<td>Thin Walled</td>
</tr>
<tr>
<td>Septations</td>
<td>Size &lt; 10 cm</td>
</tr>
<tr>
<td>Complex components</td>
<td>Smooth regular borders</td>
</tr>
<tr>
<td>Ascites</td>
<td></td>
</tr>
<tr>
<td>Metastatic Findings</td>
<td></td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td></td>
</tr>
<tr>
<td>Omental Thickening</td>
<td></td>
</tr>
</tbody>
</table>
## Benign tumors Characteristics

<table>
<thead>
<tr>
<th>Premenopausal Simple</th>
<th>Hemorrhagic Ovarian Cyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilocular Clear Thin Wall</td>
<td>Midcycle and Unilocular Avascular Has a clot Stranding</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endometrioma</th>
<th>Teratoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed/Tender Slightly irregular cyst wall Ground glass echos Expands</td>
<td>Fat/Teeth/Bone/Sebaceous/hair Well differentiated Cystic-Solid complex Encapsulated and Mobile</td>
</tr>
</tbody>
</table>

## Simple Ovarian Cyst

<table>
<thead>
<tr>
<th>Premenopausal</th>
<th>Postmenopausal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectant + OCPs, Repeat Pelvic US in 3-6 months Remove if &gt;10 cm, persistent or symptomatic</td>
<td>Expectant, US every 3-6 months + Measure CA125 or OVA1 Remove if symptomatic or persistent</td>
</tr>
</tbody>
</table>

## Complex Ovarian Cyst?

<table>
<thead>
<tr>
<th>Premenopausal</th>
<th>Postmenopausal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure tumor markers-Serum βhCG, LDH, AFP Remove if symptomatic/persistant</td>
<td>Measure tumor markers-CA-125 or OVA 1, CEA, CA19-9 Remove if symptomatic/persistant</td>
</tr>
</tbody>
</table>
Solid Ovarian Cyst in postmenopause

Remove

CA-125

- Best predictive value at postmenopause
- Associated with other conditions:
  Endometriosis/Adenomyosis, Fibroids, CHF, PID, Diverticulosis, Pregnancy, Renal Disease, Menstruation, Lupus
- Abnormal:
  >35 u/mL: Postmenopausal
  >200 u/mL: Premenopausal


OVA-1

FDA approved (2009) when surgery is planned

<table>
<thead>
<tr>
<th>Combination of 5 markers</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA-125</td>
<td>&gt;5: Premenopausal</td>
</tr>
<tr>
<td>Transferrin</td>
<td>&gt;4.4: Postmenopausal</td>
</tr>
<tr>
<td>Prealbumen</td>
<td></td>
</tr>
<tr>
<td>Apolipoprotein AI</td>
<td></td>
</tr>
<tr>
<td>Beta 2 Microglobulin</td>
<td></td>
</tr>
</tbody>
</table>

http://www.accessdata.fda.gov/cdrh_docs/reviews/K081754.pdf
## ROMA
(Risk of malignancy assessment score)

- Includes CA 125 and HE4.
- FDA approved (2011) when surgery planned
  - Two separate logistic regression algorithms, depending on menopausal status. (SmartApp)
- Abnormal
  - Premenopause: ≥13.1%
  - Postmenopausal women: ≥27.7%


## Risk of Malignancy Index

- Multimodality approach:
  - Combines serum CA 125, pelvic ultrasound, and menopausal status, \( RMI = U \times M \times CA\,125 \)
- Primarily used in the U.K. (NIH guidelines)
- RMI version exist (RMI I through IV)


## Referral of a Newly Diagnosed Pelvic Mass to GYN ONC (SGO and ACOG)

<table>
<thead>
<tr>
<th>Premenopausal</th>
<th>Postmenopausal</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA 125 &gt;200</td>
<td>CA 125 &gt;35</td>
</tr>
<tr>
<td>Ascites</td>
<td>Ascites</td>
</tr>
<tr>
<td>Metastatic Lesions</td>
<td>Metastatic Lesions</td>
</tr>
<tr>
<td>Family History</td>
<td>Family History</td>
</tr>
</tbody>
</table>

[ACOG practice bulletin number 83](http://www.acog.org)
Case 2

• 22 YO AA G0 seeking pregnancy has multiple symptomatic uterine fibroids. She is interested in fertility.

A- Laparoscopic myomectomy
B- Open myomectomy
C- Uterine artery embolization
D- Depot Lupron followed by Robotic-assisted myomectomy

Fibroids and myomectomy

• Laparoscopy or laparotomy?
• Adequacy of repair and integrity of scar for future pregnancy/delivery?
• Multiple fibroids with menorrhagia (beware of submucous fibroids!)
• Myomectomy for multiple, multiple, multiple fibroids?

Select candidates for laparoscopy

• Location:
  – Intramural and subserosal
  – anterior and fundal
  – Not intraligamental
• Size: < 5 cm
• Number: < 3
• Surgical expertise

Sizzi G. et al, J Minim Invasive Gynecol. 2007
Laparoscopic versus open myomectomy

• Review of six randomized trials, 576 women, significant results favoring laparoscopy:
  - Decrease in blood loss (34 ml less)
  - Lower risk of complication (OR 0.47; 95% CI 0.26-0.85)
  • But...
    - Significant increase in operative duration (13 min)
    - No significant difference in the rate of recurrent myomas (up to 52 months follow ups)


Laparoscopic versus open myomectomy

• Significant results favoring laparoscopy and possibly impacting fertility:
  - Less evidence of severe adhesive disease on second look laparoscopy
  - Fewer adnexal adhesions

- Baldi et al J Am Assoc Gynecol Laparosc. 1996
- Dubuisson JB et al, Hum Reprod. 1998

Robotic-assisted myomectomy versus open

• Largest case-control study (n = 125) showed significant advantages of the Robot:
  - Decrease in blood loss (226 vs. 459 mls)
  - Improve length of hospital stay (0.5 vs. 3.3 d.),
  - Decrease number of days, regular diet (0.9 vs. 2.3 d.)
  - Decrease febrile morbidity (1.3 % vs. 38 %)
  • But...
    - Longer robotic surgical times (3.2 vs. 2.3 hours)

Ascher-Walsh CJ et al, J Minim Invasive Gynecol. 2010
Robot versus Straight stick

• Retrospective case series of 575 myomectomies
  (68.3 % open, 16.2 % laparoscopic, and 5.5 % robot)

• No significant difference between Robot (R) and laparoscopy (L) in terms of:
  - Blood loss: 150mls (R) and 100 mls (L)
  - Operative duration: 181 mn (R) and 155 mn (L)

Barakat EE et al, Obstet Gynecol. 2011

Robotic hysterectomy

• Only one report of pregnancy
• Concerns!!
  - Myometrial closure security?
  - Subsequent uterine rupture?
• Pro -“Robot use” professionals use:
  - Third operative arm instrument to hold tension
  - Barbed sutures to decrease the need to hold tension all together

J Minim Invasive Gynecol. 2008

Depot Lupron and myomectomy

• Benefits:
  - Less blood loss (P<0.01)
  - Less operative time (P<0.05)
• Risks:
  - Difficult enucleation of myomatous nodules if fibroids were hypoechoic
    (Obliterated cleavage planes)
  - Operative time is longer in low density fibroids

Case 3

23 YO G1 at 7 weeks by LMP presents to the ER with lower abdominal pain and bleeding with clots. VS stable, Cervix is closed. Labs: bHCG=2700, Hb 13 g/dl. US= no IUP, free fluid noted in the pelvis.

A. It’s a complete abortion, DC home
B. Repeat bHCG and US in 48 hours
C. It’s a non viable pregnancy, MTX IM
D. This is a pregnancy of unknown location; laparoscopy possible removal of ectopic and D&C

Pregnancy of unknown location (PUL)

• Discrimination Zone?
  ➢ One study found a 99% predicted probability of visualization of a GS was at an hCG of 3510 IU/L.

• Viability of PUL?
  ➢ Need to follow HCG levels, repeat imaging
  ➢ Consider the risk of terminating an early viable IUP

Ectopic Pregnancy

• Missing an Ectopic
• Cannot locate the ectopic gestation
• To conserve or not to conserve the fallopian tube
Ectopic Pregnancy

- Ectopic pregnancy: 1 to 2% of pregnancies
- >90-95% are located in the fallopian tube

Cornual (interstitial) ectopic

- Characteristics
  - Gestational swelling lateral to the insertion of the round
  - <5 mm from myometrium
- Rupture:
  - 20-50% of cases
- Treatment:
  - Multi-MTX dose
  - Cornuostomy
  - Resection

Cervical Ectopic versus aborting IUP

- In cervical ectopic:
  - No blood in the cavity
  - Small cavity
  - Internal os is closed
  - Positive FHT
  - GS looks normal, no debris
  - Trophoblast invades stroma
- May need to repeat US the next day or MRI.

Treatment of cervical ectopic

- Multiple Intramuscular doses of MTX
- D&E is a conservative surgical option
  - Pre Op ligation of the cervical branches of the uterine
  - Shirodkar cerclage
  - Uterine artery embolization
  - Intracervical vasopressin
  - Use of Foley, purse string sutures, Gelfoam

Ectopic in C-section scar

- Incidence:
  - 6% of ectopics
  - Does NOT increase with number of cesareans
- Treatment:
  - Surgery (laparotomy or laparoscopy): wedge resection, hysteroscopic excision, local injection of 5 mEq KCl
  - Local or systemic MTX
- Do NOT:
  - Expectant management
  - D&C is NOT an option

Case 4

- You take the patient with suspected ectopic to surgery, find 100 mls hemoperitoneum, a left tube that is slightly larger than right tube. No active bleeding.

A- Perform a diagnostic D&C and document absence/presence of villi versus Arias-stella reaction suggestive of ectopic
B- Left salpingectomy
C- Left salpingostomy and if no pregnancy tissues, follow up HCG and MTX
Salpingostomy vs Salpingectomy

• Controversial

• Same fertility outcome (cohorts)

• Higher risk of recurrent ectopics in “ostomy”

Hajenius PI et al, Cochrane Database Syst Rev. 2007

Persistent ectopic pregnancy

• Incidence
  ➢ 4 to 15%, higher after laparoscopic salpingostomy

• Clearance rate of HCG
  ➢ POD#1 levels are < 50% the preoperative value.

• Most experts
  ➢ Suggest weekly HCGs after laparoscopic salpingostomy OR
  ➢ Prophylactic one dose of MTX

Farquhar CM, Lancet. 2005

Case 5

• 60 YO G8P8 postmenopausal female presents to the emergency room with “labor-like” pelvic pain. On speculum exam you notice a 4 cm fungating mass protruding from the cervix with good uterine descensus. Your next step is:

  A- Abdominal hysterectomy
  B- Vaginal myomectomy and hysterectomy
  C- Vaginal myomectomy and interval hysterectomy
  D- Biopsy of the mass and endometrial biopsy
Red flags

- Age
- Foul smelling discharge
- Risk factors:
  - Race, Tamoxifen, pelvic irradiation, a history of childhood retinoblastoma, and Hereditary Leiomyomatosis and Renal Cell Carcinoma syndrome (HLRCC).
- Failure of response to prior therapies:
  - GnRH agonists, UAE
- Findings on MRI

Endometrial sampling should be done

Carcinosarcoma

Case 6

- 45 YO G0 obese female with 16 week size fibroid uterus on exam and pelvic ultrasound, presents with worsening menorrhagia (periods about 2 weeks long with clots), desires definitive treatment. Your next step:

A- Proceed with abdominal hysterectomy
B- Give Depot Lupron and perform a Laparoscopic hysterectomy
C- Perform an endometrial biopsy
Biopsy high risk patients

• Avoid missing endometrial cancer in patients undergoing hysterectomy for benign reasons.

• One is four cases occurs in Premenopause.

• Risk of endometrial hyperplasia and carcinoma is fairly low prior to age 45 years
  - 19 percent of cases occurs between ages 45 to 54
  - 6 percent in those aged 35 to 44 years


Guidelines to perform EMB for abnormal bleeding

• Postmenopausal:
  - Any uterine bleeding.
  - Endometrial thickness > 4 mm.

• Age 45 years to menopause
  - Intermenstrual bleeding.
  - Polymenorrhea or Menorrhagia.

• Younger than 45 years
  - Persistent,
  - Setting of a history of unopposed estrogen exposure
  - Risk factors (eg, tamoxifen therapy, Lynch syndrome...)

ACOG Practice bulletin no. 128

To Err is Human, to Err Less is Mandatory

• 1999 Institute of medicine report: 44000-98000 patient's deaths were due to preventable errors.

• Human factors:
  - Meticulous H&P, adequate use of diagnostic tools and maintenance of good medical knowledge (mentors)
  - Training and experience (surgical proctors)

• System factors:
  - Availability of adequate diagnostic tools and equipement
  - Avoiding overwork
Strategies and Solutions on How to Avoid and /or Survive Medical Malpractice Allegation

W. Russ Jones, J.D.
Strategies and Solutions on How to Avoid and/or Survive Medical Malpractice Litigation

Disclosure Statement

• I do not have relevant financial relationships with commercial interests related to the content of this presentation.
Learning Objectives

• 1. List methods for physicians to optimally communicate with patients prior to surgery and provide informed consent;
• 2. Describe steps that can be taken following an adverse event to optimally communicate and explain medical events.

Common Pathways to Medical Malpractice Litigation

• Unexpected Morbidity
• Unexpected Mortality
• Miscommunications
  – Patient-Physician
  – Physician-Family members
  – Physician-Nurse
• Patient or Family Misconceptions and/or Unrealistic Expectations

Unexpected Morbidity
Unexpected Mortality

Mrs. Kaput, a healthy wife and mother of 3, presents in active labor with her fourth son. All pre-natal screening was good, her pre-natal care was excellent, all prior births have been spontaneous vaginal deliveries without complication, and no difficulties are anticipated with this delivery...
Top Causes of Lawsuits against Ob/Gyns

Top Ob allegations
Neurologically-impaired infant (28.8%)
Stillbirth/neonatal death (14.4%)
Delay/failure to diagnose (11.1%)

Top Gyn allegations
Patient injury - major (29.1%)
Delay in or failure to diagnose (22.1%)
Patient injury - minor (20.7%)

2012 ACOG Survey on Professional Liability
(All potentially resulting in unexpected morbidity or mortality)

Miscommunications
Doctors and patients don’t agree about how well they are communicating with each other.

• 67% of the doctors thought patients knew their name, but only 18% of the patients got the doctor’s name right.
• Most doctors (77%) thought patients knew their diagnosis, but only 57% of patients actually did.
• Nearly all physicians (98%) stated that they at least sometimes discussed their patients’ fears and anxieties, compared with 54% of patients who said their physicians never did this.


Management of Expectations

“The doctor never told me that . . . .”

• A common refrain of some medical malpractice litigants
• Often the result of “mismanaged” expectations
• Requires you to walk a fine line-
  • Be confident and reassuring
  • But don’t “sugar coat” the prognosis
  • Counsel regarding avoidable risks (smoking, drinking, caffeine, OTC medications, etc.)
  • Disclose risks that could result in an adverse outcome (No one likes surprises!)
  • Document!!!
Confucius said, “A man with low expectations is seldom disappointed.”

Obstetrical Emergencies
• Consider the case of placental abruption:
  • Keep the family closely and regularly informed
  • Tell them what happened *in terms they understand, why it happened* (if no obvious cause, consider giving them the percentages of spontaneous, atraumatic occurrence), and what you are doing to treat the condition
  • Don’t “sugar coat” the prognosis- If it is dire (Hypovolemic shock, DIC, multi-organ failure), tell them so
  • Reassure them that you are doing *everything possible to save their loved ones*
  • Your *honesty, candor and compassionate concern* will maintain their trust
  • Heroes don’t always prevail, but are revered nonetheless

Let’s say we have a serious Adverse Outcome, with or without negligence. How do we best handle the situation?
The Traditional Risk Management Approach to an Adverse Outcome

• “Defend and Deny”
• Acceptance of any responsibility thought to virtually ensure litigation
• Even humane expressions of sympathy or compassion discouraged
• Patients and their family members are viewed as “opportunistic money-grabbers”, seeking financial advantage from any adverse outcome, irrespective of fault

Problems with the Traditional Approach of “Defend and Deny”

• Fails to fully understand and appreciate the real needs and motivations of Patients and their family members
• Sacrifices the physician’s greatest tool for avoiding litigation - Trust.
• Gives the impression of a “conspiracy to cover up” mistakes (If they really did nothing wrong, why won’t they TALK to me???)
• Results in multiple missed opportunities (to heal, to forgive, to move on, to regain trust, etc.)
Psychology 101
(The Psychology of Litigation Avoidance)

• The death of a loved one is one of life’s greatest psychological stressors
• The psychological stress is even greater with sudden and unexpected loss
• Remember the “Five Stages of Grief” (Denial, Anger, Bargaining, Depression and Acceptance)
• You have a unique opportunity to help the family through this process through Honesty, Candor, Transparency, and Availability
• Consider gently encouraging an autopsy

Psychology of Litigation Avoidance (cont.)

• Right after an adverse outcome resulting in unexpected morbidity or mortality, the patient and/or family will be in shock
• The will need time “to process” their loss
• They will have questions (in time)
• Well meaning “others” may plant seeds of discontent
• Encourage a “sit down” meeting to address their concerns (If you don’t, a lawyer will!)
• Make time to talk to them openly and candidly
Fed up and frustrated after receiving no answers, a bunch of double talk or excuses, the patient seeks legal advice . . . . usually just in search of answers to the questions, “Why did this happen?” or “Could this have been avoided?”

Suddenly, after not providing those answers, you find yourself “on the L Train.”

Fingers get pointed, accusations get made

Common Initial Reaction to Being Sued for Malpractice
“All studies that have attempted to determine the characteristics of patients who bring medical malpractice suits against their physicians find similar results: a clear and direct relationship between malpractice claims and communication failures between physician and patient.”

• “Patients who sue are more likely to be unhappy with the interpersonal relationship with their physician than the actual outcome of the care they received.”


“One of the most common reasons patients initiate legal proceedings is to get information when they perceive that it is purposefully being withheld or that their physician is being less than forthcoming. Following an adverse event that may or may not involve negligence, patients report greater satisfaction and are less apt to sue when they perceive the physician as communicative, caring, honest, personal, and apologetic, when appropriate.”


Why it pays to be nice to Nurses and Consultants

• Non-physician factors that increase the likelihood that a patient will sue include “recommendations by other health care workers to seek legal advice. . .”

“In general, patients who have suffered complications do not want financial compensation, but rather desire an analysis of the root causes and implementation of corrective and preventative measures.”


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Sobering Statistics

• Several studies have found that between 2 to 8% of specialists in high risk areas account for >50% of malpractice claims
• Not because of inferior skill or complicated patients
• “[Physicians at high risk] are less effective at providing meaningful communication and maintaining rapport with patients and their families, especially when a complication occurs.”


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Dale Ann Micalizzi

• Dale is a nationally renowned patient advocate and founder of “Justin’s HOPE” at the Task Force for Child Survival and Development—a calling she received after her 11 year old son died during surgery for osteomyelitis of the ankle.
• “Almost no one wants to sue their doctors, especially following the death of a child. We love docs caring for our children. But the stonewalling and lack of responsibility and accountability that can occur after a complication infuriates patients and families. They want answers and a discussion even if nothing was intentionally or accidentally done wrong. Patients and families feel the medical community owes them this. . . When they sense a lack of disclosure, the priority shifts to preventing this from happening to someone else.”
## Post Adverse Outcome Do’s & Don’ts

## Things to Avoid Saying

Table 1. Things NOT to Say to Patients or Families After a Complication

(adapted from [http://www.nurture.org/PressReleases/8618.pdf](http://www.nurture.org/PressReleases/8618.pdf))

<table>
<thead>
<tr>
<th>Do’s</th>
<th>Don’ts</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCU signed the consent for surgery and anesthesia.</td>
<td>Are you receiving counseling? You need to get over it.</td>
</tr>
<tr>
<td>These things happen and you may never know what went wrong.</td>
<td>I have no idea what happened - go see a specialist.</td>
</tr>
<tr>
<td>I guess I can squeeze you in for a meeting, but I’m very busy.</td>
<td>I don’t have to share the M&amp;M and QI investigations with you.</td>
</tr>
<tr>
<td>I didn’t tell the resident to begin surgery alone.</td>
<td>Medicine is an imperfect science - I did nothing wrong.</td>
</tr>
</tbody>
</table>
The Rise of “Medical Apology” Statutes and “Communication of Sympathy” Statutes

- Lawyers & Risk Management Professionals have long advised their clients never to apologize to patients or family members for their medical mistakes, or even give humane expressions of sympathy—for fear that such statements would be admissible at the trial of a subsequent malpractice action as an admission of liability.
- Law of Unintended Consequences: Such advice leads to increased malpractice claims.
Texas “Communication of Sympathy”
Statute
Sec. 18.061. COMMUNICATIONS OF SYMPATHY.
(a) A court in a civil action may not admit a communication that: (1) expresses sympathy or a general sense of benevolence relating to the pain, suffering, or death of an individual involved in an accident; (2) is made to the individual or a person related to the individual within the second degree by consanguinity or affinity, as determined under Subchapter B, Chapter 573, Government Code; and (3) is offered to prove liability of the communicator in relation to the individual.
Texas Civil Practice & Remedies Code, Section 18.061

2nd Degree of Consanguinity of Affinity?
• Safe to communicate sympathy to: (1) Patient; (2) Patient’s Spouse; (3) Patient’s Parents; (4) Patient’s Children; (5) Patient’s brothers and sisters; (6) Patient’s Grandparents; (7) Patient’s Grandchildren.
• Unsafe to communicate sympathy to: (1) Patient’s Great-Grandparents; (2) Patient’s Great-Grandchildren; (3) Patient’s Aunts or Uncles (or Patient’s spouses’ Aunts or Uncles); (4) Patient’s Nieces or Nephews (or Patient’s spouses’ Nieces or Nephews)

Unsafe to Communicate Sympathy to:
• Patient’s boyfriend or girlfriend
• Patient’s friends or co-workers
• Patient’s Life Partner
• Patient’s Spouse (if Marriage not recognized in Texas, e.g., a Gay Marriage or Union, though valid in another state, which is not recognized as a valid marriage in Texas)
But do it anyway because it is humane, decent and may be the one thing that keeps you from being sued for medical malpractice.
Permissible Forms of Communication

Section 18.061(b):
In this section, "communication" means:
(1) a *statement*;
(2) a *writing*; or
(3) a *gesture* that conveys a sense of compassion or commiseration emanating from humane impulses.

Exceptions to Inadmissible Statements of Sympathy

(c) Notwithstanding the provisions of Subsections (a) and (b), a communication, including an excited utterance as defined by Rule 803(2) of the Texas Rules of Evidence, which also includes a statement or statements concerning negligence or culpable conduct pertaining to an accident or event, is admissible to prove liability of the communicator.

- [AND, Communications made to someone other than the patient or family members within 2 degrees of consanguinity or affinity.]

Medical jargon is a huge barrier to effective communication.

- No one likes to admit that they are ignorant
- Even well-educated laypersons get lost in excessive medical jargon
- Lack of comprehension & understanding kills meaningful dialogue
- If the patient or her relatives cannot understand what you are telling them, they cannot ask pertinent questions, and you come across as aloof.
- Remember: “People don’t care how much you know until they know how much you care.”
10 Communication Secrets of Great Leaders by Mike Myatt, Contributor to Forbes magazine (April 2012)

1. Speak not with a forked tongue: In most cases, people just won’t open up to those they don’t trust. Trust is best created by earning it with right acting, thinking, and decision making. Keep in mind people will forgive many things where trust exists, but will rarely forgive anything where trust is absent.

2. Get personal:– think dialog not monologue. The more personal and engaging the conversation is the more effective it will be. There is great truth in the following axiom: “people don’t care how much you know until they know how much you care.”

3. Get specific: Specificity is better than ambiguity 11 times out of 10. Learn to communicate with clarity. Simple and concise is always better than complicated and confusing.
4. Focus on the leave-behinds not the take-aways: The key is to approach each interaction with a servant’s heart. When you truly focus on contributing more than receiving you will have accomplished the goal. Even though this may seem counter-intuitive, by intensely focusing on the other party’s wants, needs & desires, you’ll learn far more than you ever would by focusing on your agenda.

5. Have an open mind: A leader takes their game to a whole new level the minute they willingly seek out those who hold dissenting opinions and opposing positions with the goal not of convincing them to change their minds, but with the goal of understanding what’s on their mind. Open dialogs with those who confront you, challenge you, stretch you, and develop you. Remember that it’s not the opinion that matters, but rather the willingness to discuss it with an open mind and learn.

6. Shut-up and listen: Simply broadcasting your message ad nauseum will not have the same result as engaging in meaningful conversation, but this assumes that you understand that the greatest form of discourse takes place within a conversation, and not a lecture or a monologue. “… you begin to understand that knowledge is not gained by flapping your lips, but by removing your ear wax…
• 7. Replace ego with empathy: When candor is communicated with empathy and caring and not the prideful arrogance of an over inflated ego, good things begin to happen. Empathetic communicators display a level of authenticity and transparency that is not present with those who choose to communicate behind the carefully crafted facade propped-up by a very fragile ego. Understanding this communication principle is what helps turn anger into respect and doubt into trust.

• 8. Read between the lines: Take a moment and reflect back on any great leader that comes to mind… you’ll find they are very adept at reading between the lines. They have the uncanny ability to understand what is not said, witnessed, or heard. Being a leader should not be viewed as a license to increase the volume of rhetoric. Rather, astute leaders know that there is far more to be gained by surrendering the floor than by filibustering. In this age of instant communication, everyone seems to be in such a rush to communicate what’s on their mind that they fail to realize everything to be gained from the minds of others. Keep your eyes and ears open and your mouth shut and you’ll be amazed at how your level of awareness is raised.

• 9. When you speak, know what you’re talking about: For most people I know, fast and slick equals not credible. You’ve all heard the saying “it’s not what you say, but how you say it that matters,” and while there is surely an element of truth in that statement, I’m here to tell you that it matters very much what you say. Good communicators address both the “what” and “how” aspects of messaging so they don’t fall prey to becoming the smooth talker who leaves people with the impression of form over substance.
10. **Speak to groups as individuals:** Leaders don’t always have the luxury of speaking to individuals in an intimate setting. Great communicators can tailor a message such that they can speak to 10 people in a conference room or 10,000 people in an auditorium and have them feel as if they were speaking directly to each one of them as an individual. Knowing how to work a room and establish credibility, trust, and rapport are keys to successful interactions.

**Bottom line:** Most importantly of all, keep in mind that communication is not about you, your opinions, your positions or your circumstances. It's about helping others by meeting their needs, understanding their concerns, and adding value to their world. Do these things and you’ll drastically reduce the number of communications problems you’ll experience moving forward.

**The Art of Effective Communication requires “Active Listening”**

**Listen Twice, Speak Once**

As the old saying goes: "You have two ears and one mouth for a reason: so listen twice as much as you speak."

So while the other person is talking, give him or her your undivided attention. Don't be thinking of what you're going to say next, or you're likely to miss what the person is saying. Stay focused and absorb the information given.
The choice is entirely yours

- Characteristics of Low Risk Physicians for Malpractice claims
  - Communicative
  - Candid
  - Caring
  - Compassionate
  - Concerned

Remember: “Quam summae adepto anus”

- Characteristics of High Risk Physicians for Malpractice Claims
  - Cold
  - Callous
  - Condescending
  - Calculating
  - Cut off

THE END
THANK YOU

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