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Schedule of Events

Thursday, August 24, 2017

10:00 am – 1:30 pm  Physician Registration  Talbot
10:30 am – 1:30 pm  GOGS Board of Directors Meeting  Plaza I
1:30 – 5:00 pm  Simulation Lab Learning Activities  Talbot B/C
   *MOC Part IV Credit Awarded for Full Session*
6:00 – 7:00 pm  Opening Reception for all Guests  Ocean Front Lawn
   *(Business Casual)*

Friday, August 25, 2017

7:00 – 7:55 am  Breakfast for Physicians and Exhibitors  Talbot A-E

Clinical Sessions  Talbot F-H

8:00 am  Welcome: Cyril Spann, MD  
   GA OBGyn Society President

8:10 – 9:00 am  *ERAS and Minimally Invasive Gynecologic Surgery*  
   Fidel A. Valea, MD

9:05 – 9:50 am  *Cognitive Computing is the Future of Health*  
   Jen Novitski, RN, MBA, BSN

9:55 – 10:40 am  Break with Exhibitors  Talbot A-E

10:45 – 11:30 am  *Reducing the Primary Cesarean Rate: A Quality OB Measure*  
   Haywood L. Brown, MD
11:35 am – 12:20 pm  *Gyn Cancer and the Evolving U.S. Health Care System*  
Carol L. Brown, MD

12:20 – 1:05 pm  *What’s New in STI/STD*  
Kimberly A. Workowski, MD

1:10 pm  Adjourn

6:00 – 7:00 pm  **Reception: Physicians and Spouses/Guests**  
Courtyard

7:00 pm  Dinner on your own

**Saturday, August 26, 2017**

7:00 – 7:55 am  Gynecological Oncologists Breakfast  
Boardroom

7:00 – 7:55 am  Breakfast for Physicians and Exhibitors  
Talbot A-E

**Clinical Sessions**

7:55 am  
Moderator: **Victoria Green, MD, MBA, JD**  
Chair, GA Section ACOG

8:00 – 8:45 am  *Modern Management of Endometrial Cancer*  
Carol L. Brown, MD

8:50 – 9:35 am  *Health Outcomes for Georgia Women*  
J. Patrick O’Neal, MD

9:40 – 10:30 am  Break with Exhibitors  
Talbot A-E

10:30 – 11:15 am  *Heart Disease and Pregnancy*  
Wendy Book, MD

11:20 am – 12:05 pm  *DVT Prevention and Management*  
Fidel A. Valea, MD

12:10 – 12:45 pm  *Society Update & Business Meeting: Activities Affecting Practice in GA*  
Cyril Spann, MD, President Georgia OBGyn Society

12:50 pm  Adjourn
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>12:50 – 2:30 pm</td>
<td>Junior Fellow/Residents Luncheon &amp; Lecture</td>
<td>Amelia</td>
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<tr>
<td>6:00 – 7:00 pm</td>
<td>President’s Cocktail Reception</td>
<td>Talbot Prefunction</td>
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<tr>
<td>7:00 pm – 12:00 am</td>
<td>Annual Banquet, Awards &amp; Dancing (Black Tie optional)</td>
<td>Talbot D/E</td>
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<tr>
<td></td>
<td>Photo Booth available 6:00 – 10:00pm</td>
<td>Talbot Prefunction</td>
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</table>

**Sunday August 27, 2017**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>7:30 – 8:35 am</td>
<td>Breakfast for Physicians</td>
<td>Talbot D</td>
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<tr>
<td></td>
<td><em>Current Trends in OBGyn Litigation</em></td>
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<td></td>
<td><em>Paul Weathington, JD</em></td>
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<tr>
<td><strong>Clinical Sessions</strong></td>
<td></td>
<td>Talbot F-H</td>
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<tr>
<td>8:40 am</td>
<td>Moderator: <strong>Hugh Smith, MD</strong></td>
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<tr>
<td></td>
<td>President-Elect Georgia OBGyn Society</td>
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<tr>
<td>8:40 – 9:25 am</td>
<td><em>Redefining Postpartum Care</em></td>
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<td></td>
<td><strong>Haywood L. Brown, MD</strong></td>
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<tr>
<td>9:50 – 10:15 am</td>
<td><em>Watson for Oncology, Clinical Trials, and Genomics</em></td>
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<tr>
<td></td>
<td><strong>Jen Novitski, RN, MBA, BSN</strong></td>
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<tr>
<td>10:20 – 11:05 am</td>
<td><em>Update on Cardiovascular Guidelines: What You Need to Know</em></td>
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<tr>
<td></td>
<td><strong>Wendy Book, MD</strong></td>
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</tr>
<tr>
<td>11:10 – 11:20 am</td>
<td>Meeting Evaluation / Credit Certification</td>
<td></td>
</tr>
<tr>
<td>11:20 am</td>
<td>Adjourn</td>
<td></td>
</tr>
</tbody>
</table>
Our Distinguished Faculty

Wendy Book, MD  
Director, Emory Adult Congenital Heart Center  
Emory University School of Medicine  
Atlanta, GA

Carol L. Brown, MD  
Director, Office of Diversity Programs in Clinical Care, Research, and Training  
President-Elect, SGO  
Memorial Sloan Kettering Cancer Center  
New York City, NY

Haywood L. Brown, MD  
President, ACOG  
Roy T. Parker Professor, Chair of Obstetrics and Gynecology  
Duke University Medical Center  
Durham, NC

J. Patrick O'Neal, MD  
Commissioner  
Georgia Department of Public Health  
Atlanta, GA

Melissa Kottke, MD, MPH, MBA  
Associate Professor, Gynecology and Obstetrics  
Emory University School of Medicine  
Atlanta, GA

Jen Novitski, RN, MBA, BSN  
Clinical Solution Executive Lead  
Watson Health, IBM  
Liberty, MO

Brian Raybon, MD  
Associate Professor, Gynecology and Obstetrics  
Division Director of Maternal Fetal Medicine  
Emory University School of Medicine  
Atlanta, GA

Cyril O. Spann, MD  
President, Georgia OBGyn Society  
Gynecologic Oncology Specialists of Atlanta  
Decatur, GA

Fidel A. Valea, MD  
Chair, Obstetrics and Gynecology  
Virginia Tech Carilion, School of Medicine  
Roanoke, VA

Paul Weathington, JD  
Weathington McGrew, PC  
Atlanta, GA

Padmashree “Champa” Woodham, MD  
Director, Maternal-Fetal Medicine  
Director, Regional Perinatal Center  
The Medical Center, Navicent Health  
Mercer University School of Medicine  
Macon, GA

Kimberly A. Workowski, MD  
Professor of Medicine  
Division of Infectious Diseases  
Emory University  
Atlanta, GA
Faculty Presentations

Thursday, August 24 – Sunday, August 27, 2017
Simulation and Ultrasound Lab

Thursday, August 24, 2017
1:30 – 5:00 pm

MOC Part IV credit for full session attendance

Lab Proctors:

Padmashree “Champa” Woodham, MD
Melissa Kottke, MD, MPH, MBA
Brian Raybon, MD
Willis Lanier, MD
Hugh Smith, MD
E. Van Herrin, MD
David Byck, MD
Cyril Spann, MD
Faculty Presentations
Friday, August 25, 2017
Fidel A. Valea, MD

Friday, 8:10 – 9:00 am

ERAS and Minimally Invasive Gynecologic Surgery
Enhanced Recovery After Surgery (ERAS)

Fidel A Valea, MD
Professor and Chair, Department of Ob/Gyn
Virginia Tech Carilion School of Medicine

Disclosures

- Covidien (Medtronic) advisory board
- UpToDate author 3 sections
- Comprehensive Gynecology – Elsevier – Editor
- Gyn Onc Div member for ABOG

Objectives

- To describe the various components of the ERAS bundle.
- To highlight the various best practices surrounding perioperative care.
- To summarize the benefits of using the ERAS care bundle in your practice.
What is ERAS?

- Attenuation of pathophysiologic changes occurring after surgery
- Using alternative strategies of management
- Replace the current, traditional, but untested practices of peri-operative care
- Primary goal: to hasten recovery
- The concept dates back to 1997


Why ERAS?

- Evidence-based and best-practices
- Reduces surgical stress, maintains normal physiology, enhances mobilization
- Reduces complications
- Reduces LOS
- Cost savings

Health Care is Changing

- Moving towards Market based incentives
- Value is becoming a competitive absolute
- Patients are becoming “informed consumers”
- We are all being “rated”
- HCAHPS: started in October 2006, first reporting 2008
- Affordable Care Act 2010: HCAHPS among the measures to be used to calculate value-based incentive payments in the Hospital Value-Based Purchasing program, beginning with discharges in October 2012
- CMS in 2012 issued the Physician Fee Schedule final rule, confirming implementation of CSGCAHPS for Physician Quality Reporting System (PQRS)

GOOD OUTCOMES ARE IMPORTANT TO PATIENTS AND YOUR BOTTOM LINE
Why... LOS and Cost Improvement!

<table>
<thead>
<tr>
<th>Hospital LOS</th>
<th>ERAS (n=41)</th>
<th>Controls (n=83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean</td>
<td>6.5</td>
<td>10.6</td>
</tr>
<tr>
<td>median</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

Complex ovarian cancer debulking cohort
- $619,083 in savings for just 81 patients ($7,643 per case)
Overall ERAS cases (240) vs historic controls
- $868,732 in savings ($3,600 per case)


Transformational Change

THE KEY elements to ERAS:
1. Pt optimization
2. Euvolemia
3. Early feeding
4. Pain control

Enhanced Recovery After Surgery

Key Components

<table>
<thead>
<tr>
<th>Active Patient Involvement</th>
<th>Pre-operative</th>
<th>Intra-operative</th>
<th>Post-operative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-admission counseling</td>
<td>Active warming/hum temp</td>
<td>Early oral nutrition</td>
<td></td>
</tr>
<tr>
<td>Early discharge planning</td>
<td>Surgical techniques</td>
<td>Early ambulation</td>
<td></td>
</tr>
<tr>
<td>Reduced fasting</td>
<td>Avoid No tubes &amp; drains</td>
<td>Early catheter removal</td>
<td></td>
</tr>
<tr>
<td>Carbohydrate loading</td>
<td>Multi-modal pain management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No bowel prep</td>
<td>Multi-modal anti-emetic prophylaxis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No narcotic</td>
<td>Goal directed peri-operative fluid therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No sedative</td>
<td>Aggressive glucose control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VTE prophylaxis

Audit of compliance & outcomes
Whole Team Involvement
Pre-op Interventions – prepping for success

- Managing patient expectations—preop counseling
- Opportunity to include other essential value enhancing interventions (SSI reduction, no home shaving)
- Important for the patient to understand what is going to happen
- No solids after midnight
- Oral liquids until 2-4 hours before surgery
- Pre-op carbs
- No oral bowel prep
- Antibiotic prophylaxis
- VTE prophylaxis
- Pre-warming

Preoperative Counseling—Planning for Dismissal

- Strict Criteria for Hospital Dismissal
  - Pain controlled with oral medications
  - Tolerating solids without IV fluids
  - Independently ambulatory
  - No suspicion of complication

ASA Practice Guidelines for Preoperative Fasting

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids (e.g., water, fruit juice without pulp, carbonated beverages, carbohydrate rich nutritional drinks, clear tea or black coffee)</td>
<td>2 hours</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 hours</td>
</tr>
<tr>
<td>Infant formula and nonhuman milk</td>
<td>6 hours</td>
</tr>
<tr>
<td>Light meal (e.g., toast and clear liquids)</td>
<td>6 hours</td>
</tr>
<tr>
<td>Fried foods, fatty foods or meat</td>
<td>Additional time (e.g., 8 or more hours) may be needed</td>
</tr>
</tbody>
</table>
Preoperative Carbohydrates

Rationale: Mitigate deleterious effects of fasting (catabolism, insulin resistance)
Systematic review
- 17 RCTs, 1445 patients
- Improved insulin resistance
- Improved patient comfort indices—hunger, thirst, malaise, anxiety, nausea
- No increase in aspiration


Preoperative Carbohydrates

Cochrane review
- ≥45g carbohydrates within 4 hours of surgery
- 27 RCTs, 1976 patients
- Abdominal surgery, ortho, cardiac, thyroid
- Decreased LOS
- Increased postop peripheral insulin sensitivity
- No difference in postop complications
- No patients dx with aspiration pneumonitis

Preop carb loading options:
- 100g night before, 50g 2-3 hr preop
- Oral fluid: water, sports drink, etc.

Preop carb loading options:
- Apple juice
- Glucola
- OTC complex carb drink offerings

Bowel Prep...

- History dates back many years
- Anesthesia, antibiotics, suture material and infection rates were different
- Practice makes logical sense
- Patient satisfaction: low
- Utility has been challenged
- Several small RCTs but all are consistent!

Mechanical Prep is not needed even for colorectal surgery...
RCT: Colorectal Surgery +/- Bowel Prep

**Israel:** Zmora et al Ann Surg 2003 237(5)

- 388 pts undergoing colorectal surgery with primary anastomosis
- Randomized: no prep vs polyethylene glycol
- Results:
  - Prep
  - no prep
  - Wound infection 6.4% 5.7%
  - Anastomotic leak 3.7% 2.1%
  - Abdominal abscess 1.1% 1%
  - All infections 10.2% 8.8%
- None were significant — no prep is safe!

RCT: Colorectal Surgery +/- Bowel Prep

**Switzerland:** Bucher et al Br J Surg 2005 92(4)

- 153 pts undergoing colorectal surgery with primary anastomosis
- Randomized: no prep vs polyethylene glycol
- Results:
  - Prep
  - no prep
  - Abdominal infections 22% 8% p=0.028
  - Anastomotic leak 6% 1% p=0.2
  - Other infections 24% 11% p=0.03
  - Hosp stay 14.9 9.9 p=0.024
- No prep is safe with less complications!

Bowel Prep for Colorectal surgery

Gueraga et al Cochrane Syst Rev 2011;5(CD001544)

- 18 RCTs (5805 pts) — prep vs no prep
- Included rectal enemas with no change in results!
- Anastomotic leak: 4.4% vs 4.5% p=NS
- Wound infection: 9.6% vs 8.5% p=NS
  OR 1.16 [0.95, 1.42]
- Conclusions:
  - No evidence that patients benefit from mechanical bowel prep or rectal enemas.
  - Bowel cleansing can be safely omitted in elective colonic surgery.
Bowel Alterations Assoc with Prep
Bucher et al, Die Colon Rectum 2006;49(1)

- RCT of 50 pts undergoing elective CRS
- Looking for histologic alterations
- PEG vs no prep -> colorectal resection
- Blinded pathologist assessed morphology
- Results: bowel alterations more common after prep
  - Loss of mucosa: 96 vs 52% p<0.001
  - Loss of epithelium: 88 vs 44% p=0.01
  - Severe inflam: 50 vs 10% p=0.02

Mechanical Prep for Diverticulosis
van’t Sant et al

- 190 pts with diverticulosis had colon resections
- 103 had a bowel prep
- 87 had no bowel prep
- Anastomotic leak:
  - No prep 5.7%
  - Mech Bowel prep 7.8% p=0.79
- Conclusions: mechanical prep is not associated with lower SSI rates and has comparable anastomotic leak rates.

Most Recent Meta-analysis of Bowel prep for CRS
Dahabreh et al*

- 18 RCTs included comparing:
  - Oral prep vs enema vs nothing
  - Essentially no difference
  - Could not rule out subtle differences... Low Rectal Anastomoses
  - We need better DATA!

*Comparative Effectiveness Reviews, 2014; No. 128
What about low rectal anastomosis?

Scapini et al

- 244 patients: mech prep vs no prep
- No difference in SSI specific complication rates
- Overall infectious complications:
  - 20.0% vs 11.3% (p = .05) favoring no prep
  - Wound infections, anastomotic leaks and intra-abdominal abscess were not significantly different
- No prep is even safe in low rectal surgery!

*World Journal of Surgical Oncology 2010, 8:35

Low Rectal Surgery without Mechanical Bowel Prep

Bretagnol et al

- RCT of 178 pts with low rectal resections
- MBP group had lower overall complications
  - 44% versus 27%, P = 0.018
- MBP group had lower infectious complications
  - 34% versus 16%, P = 0.005
- No Difference in: leaks, serious morbidity
- They recommend MBP for their low rectal cases


Practical Answer for MBP in Low Rectal Cases: (not data driven)

- Colorectal surgeons have consistently ignored their own data for decades!
- Given the uncertainty in the low rectal anastomosis cases...
- consider a MBP in those select cases
Is bowel prep necessary for TLH?

- The data is just not great
- May lead to more “fluid” in bowel and distention
- In colorectal surgery associated with increase in infection?
- Conversion rate probably not related to prep
  - we need data to better understand conversions
- Not very popular with the patients

Mechanical Prep for Gyn Laparoscopy


- 162 pts randomized phosphosoda vs nothing
- Patient discomfort (vis analogue scale) was significantly less in the no prep group
- Adequacy of surgical field (5-point scale) was not compromised - surgeons were blinded
- Bowel preparation does not offer any significant advantage in visibility, operative time or conversion rate

Low Residual (Fiber) Bowel Prep

Italy RCT: Arch Gynecol Obstet 2009 Feb 20

- 83 pts with benign indications randomized
  - 42 pts <10 g fiber for 7 days
  - 41 pts mechanical prep 1 day prior
- Surgeon was blinded
- Results:
  - Overall discomfort worse in mech prep
  - No other differences including quality of surgical field
  - Low fiber prep comparable to mechanical prep
Bowel Prep for Gyn Laparoscopy:
3 Arm RCT*

- 308 pts randomized to 3 different arms
  - Just NPO at MN
  - Low residue diet for 2 days then NPO
  - Low residue diet and oral prep (Na picosulfate)
- Minimal but statistically better visualization and handling by 1 point on a 10 pt vis analogue scale
- At the expense of significantly more: HA, Thirst, weakness and tiredness!
- Conclusion: No need for prep


Mechanical Bowel Prep: Laparoscopy
Yang et al, J Minim Invasive Gynecol 2011;18(2):149-56

- 156 women randomized: (only gyn laparoscopy)
  - Oral NaP n=72 vs Enema NaP n=73
  - Surgical field: 85% v 91% p=0.43
  - Surgeons correctly predicted prep only 52%
  - Complications significantly worse in oral group
    - Bloating, weakness, dizziness, nasuea, overall discomfort
  - Conclusions: don’t use oral NaP prep

Bowel Prep in Gyn Onc Canadian Survey:
Wells et al, Int J Gynecol Can 2011;21(6):1135-1142

- 10 min survey to 110 Canadian Gyn Oncologists
  - 48% routine use of mechanical prep...77% admit no evidence to support its use
  - 43% laparotomies, 29% laparoscopies
  - Use has decreased 77%
  - Admitted use of mecha prep in other specialties even higher 53%-99%
What is the role of Oral Antibiotics?

- This used to be standard practice... Dogma!
- Anesthesia, suture and techniques were all different back in the early years
- Dissent started to grow based mostly on:
  - Patient complaints
  - Secondary infections such as C. Diff.
- The practice was abandoned based on numerous meta-analyses that did not show a benefit especially as the utility of bowel prep was challenged
- But... the tide started to turn back in 2010

---

Annals of Surgery

Preoperative oral antibiotics reduce septic complications of colon operations: results of prospective, randomized, double-blind clinical study.

J S Clarke, R E Condon, J G Bartlett, S L Gorbach, R L Nichols, and S Ochni

116 pts randomized to oral abx vs placebo, all had preps. Infections: 9 vs 33%

Ann Surg. 1977 Sep; 186(3): 251-259

---

Oral Abx for CRS with Mech Prep

- 24 Michigan Hospitals - 2011 colon resections
  - 49.6% had just mechanical prep alone
  - 36.4% had MBP and oral antibiotics
- 370 paired cases differing only on oral Abx

Pts with oral Abx:
- Less overall SSI 4.5% vs 11.8%, p = 0.0001
- Less organ space infection 1.8% vs 4.2%, p = 0.044
- Less superficial SSI 2.6% vs 7.6%, p = 0.001
- Less likely to have ileus 3.9% vs 8.6%, p = 0.011
- Similar C. Diff rates 1.3% vs 1.8%, p = 0.58

Meta-analysis: IV +/- Oral Abx
Bellows et al*

- 16 RCTs from 1979 – 2007 all RCTs
- IV + oral antibiotics: RR of SWI is 0.57, p=0.0002 compared to just IV antibiotics
- No diff in organ/space infections 0.71, p=0.2
- No diff in anastomotic leak 0.63, p=0.3
- Conclusion: oral antibiotics lower the wound infection rate!
- Oral Abx use should be encouraged!


Prevention of SSI after GI Surgery:
VA Study of Colon Resections (CRS) 2005-2009

- 112 VA Hospitals and 9940 pts having elective CRS
- No prep Yes oral antibiotics SSI 8.3%
- Yes prep Yes oral antibiotics SSI 9.2%
- Oral antibiotics alone (No prep) reduced SSI 67% (OR=0.33, 95% CI 0.21-0.50)
- Oral Abx and Prep reduced SSI 57% (OR=0.43, 95% CI 0.34-0.55)


Prevention of SSI after GI Surgery:
VA Study of Colon Resections (CRS) 2005-2009

- 112 VA Hospitals and 9940 pts having elective CRS
- No prep Yes antibiotics SSI 8.3%
- Yes prep Yes antibiotics SSI 9.2%
- No prep vs prep, SSI: 18.1% vs 20%

<table>
<thead>
<tr>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Abx only (no prep)</td>
<td>0.33</td>
</tr>
<tr>
<td>Mechanical Prep only</td>
<td>0.99</td>
</tr>
<tr>
<td>Mech prep and oral Abx</td>
<td>0.43</td>
</tr>
<tr>
<td>Timely administration of IV Abx</td>
<td>0.76</td>
</tr>
</tbody>
</table>

Oral Abx: VA Surgical Qual Improv Prog
Toneva et al*
8180 patients had CRS with no ostomy
Oral Abx pts:
- lower LOS (p<0.0001)
- Less readmissions in 30 days (OR 0.81; 95% CI, 0.68–0.97)
- Overall readmission rate: 4.9%, p=0.001
- no prep. 6.1%, mechanical 5.4%, OABP 3.9%
- shorter postoperative LOS and lower 30-day readmission rates... need mor RCTs!
*Journal of the American College of Surgeons, 2013;216:756-762

RCT: Oral Abx vs Probiotic vs Nil
Sadaivro et al*
310 pts all got bowel prep and IV antibiotics:
- Oral probiotics: SSI=18.0%
- Oral antibiotics: SSI=6.1%
- Nothing: SSI=17.9%
- Anastomotic leaks: 12.0%, 1.0%, and 7.4%
- C. Diff rates were the same!
- Conclusion oral Abx are better than probiotics or nil
*Surgery, 2014;155(3):493–503

What is more important: Oral Abx or Mech Prep?
Moms et al*
8,512 elective colectomy procedures
5,332 (62.6%) were minimally invasive (MIS)
3,179 (37.3%) were open.
3,807(44.7%) received a MBP alone
2,514(29.5%) received an OABP alone
2,191(25.7%) received no prep.
Results: Oral Abx vs Mech Prep*

- 9.8% SSI for no bowel prep
- 8.3% for MBP only
- 4.2% for OABP (p<0.001) (… a little surprising)

Conclusions:
- No prep is just as good as mechanical prep
- Oral antibiotic prep: 50% reduction in SSI rate!
- Oral antibiotics decreases SSI in both open and MIS
- Oral antibiotics associated with decreased readmission in 30 days

*Morris et al

What about Oral Abx with no Prep?

Atkinson et al*

July 2011 – July 2013
185 pts with colectomy by 4 surgeons – no prep
- 66 received oral Abx
- 119 did not receive oral Abx
- More L’scopes and Diabetes in the no Abx group
- No differene in SSI 10.9% vs 10.6%
- High EBL and steroid use associated with SSI

Conclusions: if no mechanical prep, oral Abx don’t work!

*Gastroenterol, 2014;145(5):S1055–S1057

Conclusions on Oral Abx:

- Appears to have some benefits to decrease SSIs
- Still not clear the impact of mechanical prep on oral antibiotic use
- We need more data on patients with no prep to answer the question if oral antibiotics work
- Neomycin and either metronidazole or erythromycin base
Prevention of Surgical Site Infections:
Preop showering with antiseptics*

- Fourth Up Date in this series...
- Meta-analysis of 7 RCTs evaluating antiseptic showers preop (10,157 pts.)
- 3 trials (7691 pts) chlorhexidine v placebo
  RR 0.91 (0.8 – 1.04)
- If only high quality trials: RR 0.95
- No evidence to support any reduction in SSI with preoperative antiseptic showering
- One large trial did show a benefit! (RR 0.36)

*Cochrane Database Syst Rev. 2012 Sep 12:9;CD004988.

Prevention of Surgical Site Infections:
Preop hair removal techniques*

- Meta-analysis of 14 RCTs... second update of the series
- 6 trials (972 pts) no difference between razors, clipping or depilatory creams v nothing... they were underpowered!
- No trials clipping v depilatory cream!
- 7 trials (1213 pts) shaving vs depilatory cream, No Difference! RR 1.53, 95% CI 0.73 to 3.21... also underpowered!
- 3 trials (1343 pts) shaving vs clipping with RR 2.09, 95% CI 1.15 to 3.80 in favor of clipping
- Conclusions: When hair removal is necessary, clipping is preferred over shaving. More research on depilatory creams...


Prevention of Surgical Site Infection:
RCT skin prep:

- RCT 6 centers, 4 years, 849 patients
  - 431 pts 2% chlorhexidine gluconate and 70% isopropyl alcohol
  - 466 pts 10% povidone–iodine
- SSI: 9.5% vs 16.1%, p = 0.004 favoring CHG
- RR SSI: 0.59 (95% CI 0.41 - 0.85)
- 17 pts need to be treated with CHG to prevent 1 SSI
- Caution: FLAMMABLE!!!
Prevention of surgical site infections:
Perioperative abx: ACOG Practice Bulletin 104, May 2009*

- Cefazolin: weight based ≤80 kg: 1 gm if >80 kg: 2 gm
- Consider redosing for procedures lasting > 3hrs.
- If beta-lactam allergic (all i.v. and within 1 hr of incs):
  - Alternative 1: metronidazole 500mg + gentamicin
  - Alternative 2: clindamycin 600 mg + gentamicin
  - Alternative 3: doxycycline 100mg
- Gentamicin: 1.5-2mg/kg, Obesity use adjusted weight
  ask pharmacy for assistance
- Consider quinolone or aztreonam instead of gentamicin

*Reaffirmed in 2011

Prevention of Surgical Site Infections:
Gastrointestinal Surgery

- Cefoxitin: 2gm if <100kg, 3 gm if >100kg
- If Beta-Lactam allergic similar to Hysterectomy alternatives
- Ertapenem can also be used with less SSI*:
  - Ertapenem 17.1%
  - Cefotetan 26.2%
  - More C.Diff in the ertapenem group 1.7 v 0.6% p=0.22

* tanis et al, NEJM 2006 355(25)

Temperature Regulation

- Maintenance of normothermia critical intraoperatively (>36°C).
- Hypothermia effects:
  - Impaired drug metabolism
  - Increased wound infection
  - Increased coagulopathy
  - Increased bleeding
  - Increased cardiac morbidity
Perioperative Normothermia

- 200 Colorectal Surgery pts. Randomized:
  - Standard care
  - Keep em warm
- All received prophylaxis cefamandole and metronidazole
- Final mean core temps: 34.7 v 36.6°C
- Wound infections: 19% v 6% p=0.009
- LOS prolonged 2.6 days p=0.01


Supplemental Perioperative O₂

- RCT 500 Colorectal surgery pts:
  - 30% vs 80% fIO₂ intra op and 2 hrs post op
  - Stnd anesthesia and prophylactic antibiotics
- O₂ sats were nl in both groups but partial pressure of O₂ was significantly higher in 80%:
  - 11.2% (7.3 – 15.1) vs 5.2% (2.4 – 8.0) p=0.01
- Wound infections:
  - 5.2% (2.4 – 8.0) in 80% fIO₂ group
  - 11.2% (7.3 – 15.1) in 30% fIO₂ group p=0.01


Preoxygenation is best at 25° angle

- 42 pts with BMI >40 planned L'Scope gastric band
- Randomized flat vs 25° elevation of head
- O₂ tensions: 390 vs 442 mm Hg p=0.012
- Time to desaturation: 155 vs 201 s p=0.023
- Conclusion: better safety margin with head up!

Postoperative Glucose Control

- Retrospective: 372 DM with gyn cancer
- Intensive glucose control with 24hr cont IV insulin vs SQ sliding scale
- Target glucose 90-139 mg/dl
- 35% reduction in SSI (p=0.02)
- Hypoglycemia lower: 0.7% vs 5.4% (p<0.05)

Al-Namli. Gyn Onc 2016; 155: 71-76

Fascial Closure in the Morbidly Obese Patient

- RCT 331 morbidly obese pts 1991-1998:
  - 172 continuous fascial closure
  - 159 interrupted fascial closure
- Total wound complications: 18 vs 31% p=0.021
- Deep wound complications: 5 vs 22% p=0.003
- Less operative time
- All favored continuous mass closure!


Fascial Closure: small bites vs large bites*

- 10 hospitals in the Netherlands
- 560 pts randomized
  - 284 large bites (1cm spacing)
  - 276 small bites (0.5 cm spacing)
- Small Bites:
  - Used more suture (45 v 25 p<0.0001)
  - Longer time to close (14 v 10 min p<0.0001)
  - Less incs hernias at 1 yr (13% v 21% p=0.022)
  - AVG BMI 24 with range of 22-27!

*Deenesten et al. Lancet 2015 Sep 26;386(10001):1254-60
Sub-Q Closure (Vertical Incision)?

- 225 pts with >3cm SubQ randomized:
  - Routine care
  - Closure of Camper’s Fascia
  - Closed suction drain
  - No difference in groups: 15.6 v 12.8 v 17.9%

Hoffman MS, Florica JY, Roberts WS, Grendys EC. ACOG 2008;196(2):507-514

Abdominal Closure: Subcutaneous Layer

- RCT of subcutaneous closure vs. no closure
- Cesarean section with >2cm of subcutaneous tissue:
- Subcutaneous closure is associated with:
  - Decreased incidence of seroma (5.1% vs. 17.2%)
  - Overall reduction in wound disruptions (26.6% vs. 14.5%)
  - No difference in rates of hematoma or infection


Abdominal Closure: Drains

- Cochrane Review 2004: wound drains for c/s
  - No difference in wound infections, other wound complications, febrile morbidity or endometriosis
  - Not effective for prevention of wound complications
- Multicenter RCT of c/s with >4cm of sub-Q:
  - suture closure alone vs. suture plus drain
  - No difference in wound complication rates:
  - wound dehiscence
  - seroma
  - hematoma
  - abscess
  - fascial dehiscence
  - hospital readmission

Negative Pressure Wound Therapy

- Cochrane Data Base: 5 trials 280 pts
- Not specifically an obese population
- NPWT vs any other treatment
- No clear cut benefit one way or the other
- There is a real need for RCT evaluating NPWT

J. Webster et al. Cochrane Database Sys Rev (6) 2011; updated 2012

Cost Analysis of NPWT in Gyn Onc

- Decision tree cost analysis
- NPWT cost $200
- Avg BMI 36%
- Wound Infection rate 31%

33% reduction in wound infection is required to make NPWT cost effective...

Lewis et al. Gynecol Oncol 2014 Mar;132(3):564-9

NPWT in Morbidly Obese Pts

- 317 women with BMI >40, and C/S, 1/14 – 6/16
- 2014: standard care n=107
- 2015: NPWT X 7days n=210
- All SSI: 19% vs 6% p=0.003
- All wound complications 22% vs 13% p<0.001
- In multivariate analysis: NPWT associated with 60% decrease in SSI.
- Elective C/S with no antibiotics!

Villene M et al. 37th Annual Meeting SMPM January, 2017 Las Vegas, NV
Prophylactic Anastomotic Drains
Cochrane Database: Jesus et al 2004(4)

- 6 RCTs (1140 pts) randomized
- Mortality 3% vs 4%
- Anastomatic leak 2% vs 1%
- Radiologic leak 3% vs 4%
- Wound infection 5% vs 5%
- Re-operation 6% vs 5%
- Other events 7% vs 6%

Primary Repair of Colonic Injuries:
Nelson et al Cochrane Database Syst Rev 2005(5)

- 6 RCT (705 pts) primary repair vs colostomy
- Mortality p=NS, OR 1.22 (0.4 - 3.74)
- Total complications OR 0.54 (0.39-0.76) favored primary repair
- The rest approached but didn’t reach significance
  - Infectious complications
  - Abdominal infections
  - Wound infections (dehiscence)
- All were significant if you exclude 1 trial
- Conclusions: primary repair for penetrating colonic injuries colostomy not necessary

Standard Anesthesia Protocol

- Rapid awakening from anesthesia is associated with decreased PONV and few postoperative side effects.
  - Propofol-based anesthesia preferred.
  - Avoid nitrous oxide (NO2) due to baseline high risk of PONV.
  - Decrease neostigmine dose
- Gyn Onc pts are high risk for PONV (30% / 80%)
- Multimodal approach to prevent PONV
  - at least 2-3 agents across categories
  - Dex 4mg IV and promethazine 12.5 IV at start
  - Ondansetron 4 mg IV before skin closure
  - Scopolamine patch
**Perioperative Fluid Balance**

- Colo-rectal resections randomized to zero fluid balance: fewer card/pulm complications
  - 7% vs 24%; p<0.001*
- Meta-analysis of 9 randomized trials**:
  - restrictive fluid therapy reduced morbidity
  - OR 0.41; p=0.005
- Goal is to maintain normovolemia while avoiding very restrictive or liberal fluid regimens
- Based on objective parameters such as HR, BP, UO and EBL


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**Postoperative Fluid Therapy**

- Oral fluid intake immediately post surgery is preferred.
- IVF limited to 1.2mg/kg/hr including all meds
  - Typically start at 40cc/hr
- Discontinue IV fluids within 12-24 hours of surgery.
- Oliguria as low as 20cc/hr is normal and fluid boluses should only be used within the clinical context

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**Multi-modal / Multi-phasic Analgesia**

- Goals:
  - Achieve pain control and reduce opioid consumption
  - Achieve other enhanced recovery objectives
  - Increase patient satisfaction
- Pre-op: celecoxib, acetaminophen, gabapentin
  - Pre-emptive analgesia with synergistic effects
- Avoid PCA... very important
- Post op po pain meds, use IV just for breakthrough pain
Regional Analgesia for Abdominal Surgeries

- Multiple options for regional anesthesia.
- Thoracic epidural anesthesia (TEA)
- Spinal anesthesia with low dose intrathecal morphine (ITM)
- Transversus abdominis plane blocks (TAP block)
- Continuous wound infiltration (CWI)
- Intrapertitoneal local anesthetic (IPLA)
- Local infiltration of anesthesia

Intra-thecal Morphine

- Kroon (2014): Total intravenous anesthesia with ITM vs standard general with PCA
  - Decreased time to oral intake, hospital stay, pain score
- Woodlin (2001): Spinal with ITM vs general
  - Reduced opiate use and LOS, less fatigue and pain
  - More POD on POD 0

Meta-analysis of I.V. Lidocaine*

- 16 trials comparing IV lido vs placebo
- All sorts of abdominal surgeries including L'scope
  - IV lido: 395 placebo: 369
- Findings:
  - Pain scores reduced up to 48 hrs
  - Opioid use decreased 85%
  - Earlier bowel function, flatus, LOS 1.1 days

*McCarthy... Habib. Drugs 2010;70(3):1149-63
Local Anesthesia for Laparoscopy


- 41 trials, 2794 pts, local anesthesia vs nothing
- Intraperitoneal and/or port site infiltration
- Cholecystectomy: IP infiltration improved visual analog pain score 13mm (95% CI 6-20)
- 3/8 port site infiltration showed a difference of questionable clinical significance
- All trials using mesosalpinx blocks showed a difference visual analog score 19mm (95% CI 14-25)
- IP blocks work, port site infiltration not as convincing

IP Local Anesthesia for Gyn L'scope

Anesth Analg 2000; 91:403-7

- RCT 180 pts, operative Gyn laparoscopy:
  - Bupivacaine 0.5%, Ropivacaine 0.75%, Saline
  - 20cc infused over operative site and under diaphragms

<table>
<thead>
<tr>
<th>Morphine Use at:</th>
<th>wake up</th>
<th>24 hrs</th>
<th>N/V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupiv</td>
<td>0.92 mg</td>
<td>3.08 mg</td>
<td>10%</td>
</tr>
<tr>
<td>Ropiv</td>
<td>0.25 mg</td>
<td>0.69 mg</td>
<td>15%</td>
</tr>
<tr>
<td>Saline</td>
<td>4.18 mg</td>
<td>12.93 mg</td>
<td>43%</td>
</tr>
</tbody>
</table>

Local Anesthesia for L'scopic Surgery

- Meta-analysis 26 trials, 2546 pts
- Preemptive vs postoperative infiltration of port site.
- Results:
  - Pre and post administration were both better than placebo
  - No difference between pre and post op infiltration
  - For IP use Pre was significantly better than post and placebo

**Celecoxib for Post L’scopic Pain**

- 80 pts undergoing laparoscopy randomized
  - Celecoxib 200mg Preop, BID vs Placebo for 3 days
  - Assess days 1, 2, 3, 7 and 30
- All the following were significant: (p<0.05)
  - pain, narc use and pt satisfaction
  - Bowel function 1 day earlier in celecoxib group
  - ADL 2 days earlier in celecoxib group


**Early Feeding After Gyn Surgery**

- Oral intake of food started day of surgery
- Several RCT in gyn oncology patients
  - Return of bowel function
  - Decrease length of stay
  - Greater nausea but not vomiting or NG placement
- Protein supplements can be given up to TID; typically 3-6g/100ml of protein (200-250ml).

Nelson, Gynecol Oncol 2016; 140:329-332

**Early Feeding after Gyn Onc Surgery**

- Canada 96 pts randomized LOS 4 vs 6 days (p=0.0001) safe no increase complications\(^1\)
- Italy 122 pts randomized NGT vs early feed: LOS, time to flatus and diet all improved\(^2\)
- Indiana 96 pts randomized early vs delayed feed: more emesis but less LOS p=0.008\(^3\)
- Stony Brook 200 pts randomized early feed v flatus included bowel resections (34\%)\(^4\) LOS is better
- Minig et al 143 pts randomized early feed v delay, excluded bowel resections\(^5\) LOS better by 1 full day

Early Feeding after Colorectal Resection
*Italy: Fero et al Anz J Surg 2004 74(5)*
- 100 pts randomized
- NGT until flatus
- Early feeding POD 1
- Complications: 24 v 26% p=NS
- Emesis: 14 v 32% p<0.05
- 20% needed NGT placed
- No difference in LOS, bowel function
- No NGT is safe after Colorectal surgery

Early Feeding after Colorectal Resection
*China: Zhou et al World J Gastroenterol 2006 12(15)*
- 316 pts randomized early feed vs NGT
- Flatus: 3.0 v 3.6 days p<0.001
- Stool: 4.1 v 4.8 days p<0.001
- LOS: 8.4 v 9.6 days p<0.05
- Anastomotic leak: 1.24 v 2.58% p=NS
- Wound complic: 2.48 v 1.94% p=NS
- Fever: 3.73 v 9.68% p<0.05
- Pulm infection: 0.62 v 4.52% p<0.05
- Pharyngitis: 3.11 v 23.23% p<0.001

Early Feeding after Colorectal Resection in Elderly Patients
*DiFranco et al J Am Coll Surg 2003 197(5)*
- 87 patients aged 70 or older had early feeding
- 89.6% tolerated early feeding
- 5.7% required readmission for ileus
- Mean LOS: 3.9 days
- 14.9% complications, none severe
- Conclusions: early feeding is safe and can be accomplished in an older population after colonic resection
Early Feeding after Colorectal Resection
Cochrane Database Syst Rev 2006 18(4)

- 13 RCTs (1173 patients)
- NPO vs early feeding within 24 hours
- No significant difference in any of the variables except mortality (showed a benefit)
- Conclusions: ...although non-significant results, there is no obvious advantage to keeping patients NPO. They support the notion of early feeding...

Celecoxib to Prevent Ileus?
Wattchow et al Almen Pharm Therap. 2006;32:967-998

- 210 pts major “significant” abdominal surgery
- Randomized: (all had)
  - Celecoxib 100 mg BID n=74
  - Diclofenac 50 mg BID n=69
  - Placebo n=67
- Results: (no diff in pain, complications, early feed)
  - paralytic ileus: Cele 1(1%) v Diclo 7(10%) v P 9(13%)

Final Thoughts ERAS Bundles

- The institution of ERAS bundles has decreased LOS by 2.5 days and complications by 50% in Colorectal surgery*
- Preoperative orders should be standardized to avoid omissions
- Individualized orders should be written with specific details to avoid confusion
- Prior to hospitalization patients should get very specific instructions for the 24 hours leading up to the surgery
- Smoking and alcohol should be stopped 4 weeks prior
- For 6yn Onc: Mechanical bowel prep should not be used routinely even if planning a bowel resection**
- No solid food by mouth 6 hours before surgery but clears are OK up to 2 hours prior to surgery
- Try not to pick apart each individual component, embrace the whole

Early Mobilization

- Potential benefits of early ambulation:
  - Reduced pulmonary complications
  - Decreased insulin resistance
  - Less muscle atrophy
  - Reduced length of hospital stay
  - Reduced VTE complications

Thank you... VTC School of Medicine
Jen Novitski, RN

Friday, 9:05 – 9:50 am

*Cognitive Computing is the Future of Health*
Cognitive Computing is the Future of Health

Jen Novitski MBA, BSN, RN
Clinical Solution Executive

Discussion Topics:
• Current State
• Big Data
• Evolution of Computing
• Cognitive, what is it and how can it help
• Current Cognitive Use Cases
• Future Cognitive Use Cases
• Humans + Cognitive = AI (Augmented Intelligence)
The current health system faces serious challenges.

... and vast amounts of data that can have a great impact on our health remain untapped.

The 5 Vs of Big Data

- Variety
- Veracity
- Value
- Volume
- Velocity
Cognitive Systems

Must understand
Reason with purpose
Learn at scale
And interact with humans naturally.

* Watson Health © IBM

So...

How will Cognitive Computing help?
What is a Cognitive system?

The term "cognitive system" refers to a machine learning system that is designed to learn and understand complex data, similar to how the human brain functions. These systems can process vast amounts of data and make decisions based on that data, much like how humans do.

In medicine, there’s a gap between what we know and what we do...

- 45% of medication is not evidence-based.
- It takes 17 years to translate evidence to practice.
- There’s a gap in knowledge.
- Doctors would have to read approximately 20 hours each workday to keep up with new professional insights.
- 80% of data is unstructured.

Cognitive Computing = Knowledge + Data-Driven Insights

Knowledge-driven insights
- Evidence-based guidelines
- Data from sensors, devices, devices
- Knowledge management
- Closing the transitional knowledge gap

Data-driven insights
- Electronic Medical Records
- Claims, lab, images
- Real-world evidence

Delivering real-world evidence
IBM Watson Platform for Health

Natural Language Processing: understanding text
- 200+ Health & Life-Science knowledge domains - trained ML-based annotators
- Facilitates unstructured documents, notes, patient history, lab reports...

Current Applications of Cognitive Analytic Techniques

- **Individual Empowerment**
  - Creating personalized nudges

- **Segmentation Analysis**
  - Identifying & understanding the population: targeted care delivery and policies

- **Area Insights**
  - Identifying & understanding the population: targeted care delivery and policies

- **Trade-off Analytics**
  - Personalized shared decision making
Area Insights

Tradeoff Analytics:
Optimize provider selection on service quality, proximity, license held, cost of service, and preferences

- Narrow down to the best options to meet multiple goals
- Explore visually
- Recommend based on the preferred choices

Near Future Use Cases for Cognitive

- Real World Evidence / Patient Similarity Analytics
- Precision Cohorts: dynamic identification of "patients like mine"

- EMR Analysis
- Improving workflow, "treasuring the joy to the practice of medicine"

- Mental Health and Behavioral Health
- Computational Neuroscience
Patient Similarity Analytics
Potential to create Precision Cohorts of “patients like mine”

- Identification of similar patients
- Often > 10,000 dimensions

Machine Learning automatically learn the metric from observational data and
what provides the assessment derived from data.

Care Path Flow
Potential to Visualize Care Pathways and Associated Outcomes

- Patient similarity analytics to find clinically similar patients
- Extract historical event traits and relevant patient characteristics
- Visual Summary of clinical pathways of similar patients, connected to relevant events
- Outcomes related to pathways – help inform clinical decisions with most-desirable vs. most-problematic pathway

On Being a Doctor

The Day the EHR Died

With Electronic Medical Records, Doctors Need When They Should Talk

The EMR 2010 Task Force of the American Medical Informatics Association (AMIA) has issued a series of recommendations to improve EMRs, starting with “timeliness and clarity documentation.”

According to AMIA, “important aspects of the patient’s stories can only be effectively captured by narratives” and that “with natural language processing, we might have accurate and human-readable narrative as the primary input with computer-understandable discrete data as a by-product.”
Electronic Medical Record Analysis
Reasoning to Auto-generate problem list with increased accuracy

- Auto-generate medical problem list from clinical notes
- Relate medications, labs, procedures, and clinical notes to medical problems
- Organize lists in clinical order
- Enable one-click access to raw data: notes, labs over a time line, medication history ...
- ... allergies, social history, demographics

Cognitive 'Assets' to Support Behavioral Health

Micron: facial expressions to support emotional response tracking

Wearable bio-sensors for emotional, physiological tracking

Computational Psychiatry to identify risk and changes in health
Tone Analyzer – Steve Jobs Stanford Graduation Speech

Conversational Technologies for deeper emotional & personality insights

Voice-driven analyses
- Valence (positive-negative)
- Arousal (bored-excited)
- Temper (depressive-menace-confrontational)
- Mood

Sentiment Analysis
- Opinion mining
- Customer satisfaction
Personalized Predictive Models

“Segment-of-one”

- Potential to:
  - Predict
  - Personalize
  - Prevent
  - Promote

![Diagram of personalized predictive models]

Trend: Approaching Human Accuracy

![Graph showing human error approaching zero]

Humans + Cognitive = “AI” or Augmented Intelligence

- People excel at:
  - Common sense
  - Decision making
  - Compaion
  - Imagination
  - Drawing
  - Abstraction
  - Generalization

- Cognitive systems excel at:
  - Natural language processing
  - Pattern recognition
  - Learning
  - Machine learning
  - Endless capacity
Let's Work Together

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www.ibm.com/Watson/health
Haywood L. Brown, MD

Friday 10:45 – 11:30 am

Reducing the Primary Cesarean Rate: A Quality OB Measure
The Impact of the First Cesarean on Future Pregnancy

Haywood L. Brown, MD, FACOG
President, ACOG 2017-2018
Professor of Obstetrics and Gynecology
Duke University
Durham, NC

Disclosures

- None financial
- Executive Board American College/Congress Obstetricians and Gynecologists

Objectives

Educating on the implications of primary cesarean

At the conclusion of this presentation the participants will be able to:
1. Discuss the increase in cesarean delivery over the last several decades and the primary reasons for the increase in primary cesarean.
2. Discuss provider, hospital type, liability and patient factors that contribute to rise in cesarean delivery.
3. Discuss educational strategies during the preconception and interconception periods including healthy weight, VBAC counseling and mode of practice which can potentially lead to reduction in cesarean delivery.
Cesarean Delivery

- 2014
  - 1.3 million cesarean births in the US
  - Cesarean delivery rate of 32.2%
Cesarean Delivery

- VBAC
- Total cesarean delivery

Rate per 100 live births

Year: 1999 to 2007

Cesarean in the US

- Map of the United States showing cesarean section rates by state.

Cesarean Delivery Morbidity/Mortality

- Deneaux-Tharaux et al Obstet Gynecol
  - Risk of postpartum maternal death was 3.5 times higher after cesarean than vaginal delivery (odds ratio 3.64, 95% CI 2.15-6.19)
  - Complications of anesthesia, puerperal infection, thromboembolism as leading causes of death.
- Canadian Institute for Health Information’s Discharge Abstract Database: compared 46,766 women with planned cesarean to 2,292,420 women with planned vaginal birth
  - Overall severe morbidity of 27.3/1000 compared to 9.0/1000 for cesarean vs. vaginal delivery, respectively.
  - Planned cesarean delivery increased risk for postpartum cardiac arrest (OR 5.1, 95% CI 4.1-6.3)
Cesarean delivery morbidity

- Lydon-Rochelle et al, JAMA, 2000 283:2411-2416
  - women with cesarean delivery RR of 1.8 (95% CI, 1.6-1.9) for re-hospitalization within 60 days after adjusting for maternal age
- Reasons for readmission included
  - uterine infection
  - obstetrical surgical wound complications
  - cardiopulmonary
  - thromboembolic conditions.
Barber et al OG 2011;118:29
Indications contributing to increase cesarean

- Analysis of primary and repeat cesarean
- 32,443 live births at major academic hospitals 2003-2009
- Cesarean rate increase from 26.0% to 36.5%
  - 50% increase in primary cesarean

Primary Cesarean

- Contributing factors
  - Abnormal fetal heart status
  - Arrest disorders
  - Multiple gestation
  - Macrosomia
  - Preeclampsia
- Contributing Factors
  - Provider
  - Hospital setting (private/community/university)
Cesarean Sections and Infant Mortality Over Time

Fig. 1: Extremly preterm infant mortality and cesarean delivery rates in the United States, 1999–2005.

BMI and Cesarean

Obesity and Cesarean Delivery

- Using data from the FASTER trial, assess the risk of cesarean in nulliparous patients
- Control group: 13,752 patients
- Obese BMI group: 1,473 patients
- Morbidly obese BMI Group: 877 patients
Obesity and Cesarean FASTER Trial

- Overall cesarean rate was 22.7%
- Compared to controls cesarean delivery was more common in obese and morbidly obese patients
  - Controls 20.7%
  - Obese 33.8%
  - Morbidly obese 47.4%

Extreme obesity and failed trial of labor

- Study 357 women > 275 lbs attempting trial of labor
  - Women with cesarean had greater BMI (51.6 vs 49.9 kg/m²)
  - Women with cesarean more likely to be induced (80.5% vs 57.8%) compared to those having vaginal birth
  - Multivariate analysis
    - Nulliparous women – cervical dilation at time of admission was independent predictor for cesarean
    - Every increase in BMI of 10 kg/m² associated with 3.5 increased odds for cesarean

  - Gunatilake et al. AOG 2013:209

Obesity, Weight Gain and Cesarean Birth

- Rode et al Obstet Gynecol 2007;109;1309
  - Birth weight > 4000 g increased with an increasing weight gain in underweight and normal-weight women
- Kielet al Obstet Gynecol 2007;110;752
  - Gestational weight gain for obese women < 15 lbs associated with lower risk of preeclampsia, cesarean, LGA and increase for SGA for each obesity class
Weight Gain and Outcome

Macrosomia
ACOG Practice Bulletin #22

- Cesarean Delivery and Macrosomia
  - Diagnosis of macrosomia is imprecise
  - Suspected macrosomia not an indication for induction of labor
  - Labor and vaginal delivery are not contraindicated for women with EFW up to 5000g in absence of maternal diabetes
  - Consider prophylactic cesarean for EFW > 4500g in diabetes and 5000g in nondiabetic

Sep;189(3):824-9

- Mostello D, Droll DA, Bierig SM, Cruz-Flores S, Leet T
  - women with preeclampsia at primary and secondary hospitals were more likely to be delivered by cesarean delivery
  - odds ratio 1.37; 95% CI 1.24,1.51; and odds ratio 1.16; 95% CI 1.07,1.26, respectively than at tertiary hospitals.
  - For women who were delivered at ≥17 weeks of gestation, cesarean delivery rates were 38.0%, 33.7%, and 30.0% for primary, secondary, and tertiary hospitals, respectively
Sep;189(3):824-9

- Pregnant women who have preeclampsia are more likely to avoid a cesarean delivery if they go to a hospital that offers the most specialized maternal and fetal care, according to Saint Louis University research recently published in the American Journal of Obstetrics & Gynecology.
- "Levels of expertise and staffing at tertiary hospitals may allow greater attempts and success with vaginal delivery among women with preeclampsia compared with primary or secondary hospitals," writes Erothes Mottolo, MD, assistant professor of obstetrics, gynecology and women's health at Saint Louis University School of Medicine.

Severe Preeclampsia

- Hieft et al J MFM 2001;10:301-304
  - 58 women with severe preeclampsia between 24-28 weeks
  - 14 pre-eclamptic women underwent induction of labor; 12 out of 14 of those induced required Cesarean delivery for worsening maternal condition, and the majority of infants in both groups were delivered by Cesarean section.

Multiples Monoamnionic Twins
Trends in Cesarean Delivery for Twins

Cross-sectional study from 1995 to 2008 using National Center for Health Statistics data

Over 14-year period CD rates for twins births increased steadily

Increase in CD rate higher than that which could be explained by an increase in CD for each presentation of either single presenting or normal twin


<table>
<thead>
<tr>
<th></th>
<th>1995</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertex twins</td>
<td>45.1%</td>
<td>68.2%</td>
</tr>
<tr>
<td>Breech twins</td>
<td>81.5%</td>
<td>52.1%</td>
</tr>
<tr>
<td>Overall twins</td>
<td>58.4%</td>
<td>70.9%</td>
</tr>
</tbody>
</table>

Labor Induction and Cesarean Delivery: The US Perspective

- Eubenthal, Obstet Gynecol 116:35-42
  - 7854 nulliparous women with singleton gestation 
    27-42 weeks of which
    39.9% underwent elective induction
      - 40.7% had cervical ripening (Bishop score < 6) with foley bulb
    - Induction increased odds for cesarean
    - Crude OR: 2.67, CI: 2.40-2.96
    - Adjusted OR: 1.93, CI: 1.71-2.1
    - BMI ≥ 40 kg/m² → AOR: 4.51, CI: 2.92-6.96
    - Contribution to cesarean in the cohort 20%

Cesarean Delivery

- Induction of Labor
  - Does not appear to increase cesarean when compared to expectant management
  - Risk of cesarean lower in randomized trial for those induced in cohort of women at 41 weeks gestation.
  - Defining Length of time to define failed induction leads to increased cesarean
    - No failed induction until at least 24 hours of induction attempt, or 12-18 hours of rupture of membranes
Reducing Primary Cesarean

*J Perinatology 2009;29:717* Editorial

- Clinicians can reduce primary cesarean by:
  - Offering external cephalic version for breech
  - Extending the diagnosis of active phase arrest to at least 4 hours
  - Manual rotation of the fet al occiput in the setting of persistent occiput transverse or posterior positions
  - Suppression of HSV lesion in Herpes positive
  - Incentives
  - Improve reimbursement
  - Medical/legal climate

Cesarean Delivery

- When does active labor begin?
  - Most common indication for cesarean is “arrest of labor” or cephalo-pelvic disproportion
  - Friedman’s labor curve based on 500 women published in 1954 and divided up phases of labor into latent and active phases demarcated by cervical dilation of 3 to 4 cm

Cesarean Delivery

- Redefining Active Labor
  - 95th percentile of progress in labor from 4-5 cm is 6.4 hours and from 5 to 6 cm 3.2 hours
  - Active labor may not begin until 6 cm
  - Waiting for change in active labor for at least 4 hours with adequate contractions and 6 hours without adequate contractions
  - 60% of women ultimately deliver vaginally

Cesarean Delivery

- Abnormal FHR tracings
- Second most common indication for cesarean
- Too many cesareans for Category 2 tracing
  - Challenging tracing not necessarily predictive of neonatal acidemia
  - Common during the second stage of labor
- Try resuscitative measures, **discontinue oxytocin**

Planned Vaginal Breech Delivery

Review of three randomized trials comparing planned CD for singleton breech presentation at term with planned vaginal birth.

CD occurred in 1060/1169 (91%) of those women allocated to a planned CD and 510/1227 (41%) of women allocated to a vaginal delivery protocol.

Planned CD was associated with decreased perinatal or neonatal death or serious neonatal morbidity (RR 3.33, 95% CI 1.99-5.66) and modestly increased short-term maternal morbidity (RR 1.29, 95% CI 1.03-1.53).

Jofmeyr GI and Hannah ME. Cochrane Database Syst Rev 2003;1:CD003166

Do we want to rescue this vanishing obstetric skill?

- In western world, expertise in vaginal breech deliveries has almost vanished
- Guidelines of many national societies do not encourage vaginal breech births
- Methods for instruction
  - Simulation
  - Hands-on training
Cesarean Delivery

- Not benign and not without risk!!!!

Cesarean Complications Morbidities

- Infectious
  - Endometritis
  - Wound including seromas, hematomas, etc.
- Scar dehiscence (Labor after Cesarean)
  - Silent dehiscence
  - Uterine rupture

Morbidities Associated with repeat Cesarean delivery

- Prospective cohort study 30,000 cesareans (Silver et al. Obstet Gynecol 2006;107:1126-32)
  - Cystotomy - first repeat 0.09% compared to 0.13% with initial cesarean
  - Bowel injury – first repeat 0.06% compared to 0.11% with initial cesarean
  - Each repeatcesarean associated with ~ 5 minutes longer total operative time
- Placenta invasion disorder
  - Acrreta, increta, percreta
  - Hemorrhage, hysterectomy
POSTPARTUM HEMORRHAGE
Placenta Percreta

- accreta - 73%
  - to the myometrium
- increta - 17%
  - into the myometrium
- percreta - 5%
  - through the myometrium

Placenta Accreta

C/S and Placenta Previa / Accreta

Single Layer Closure & Uterine Rupture

- Bujold, Obstet Gynecol 2010;116: 43-50
  - Multicenter, case control study of women with single TOLCD with uterine rupture during TOL
  - 96 uterine ruptures and 288 controls
  - Single layer closure
    - 30% in cases and 20% in controls (p < .01)
    - Odds of rupture with single layer 2.69 (CI: 1.37-5.28)
    - Odds of rupture with BW >3500g 2.03 (CI: 1.21-3.38)
    - Prior vaginal birth protective (OR: 0.47, CI: 0.24-0.93)
    - Single layer rupture and adverse neonatal outcome
      - OR 2.89 (CI: 1.03-8.27)

Single Layer Closure

- Bujold Obstet Gynecol 2010;115:1003-6
  - N = 1768 women with one prior low transverse cesarean incision
  - Findings associated with overt uterine rupture
    - Single layer closure
      - (OR 7.5, 95% CI – 3.2 -17.6)
      - Interdelivery interval < 18 months
        - (OR 2.8, 95% CI – 1.2 – 5.6)

Uterine Closure

  - Single v double layer closure meta-analysis of nine studies (5810 women) comparing risk of uterine rupture
    - Uterine rupture with TOL
      - OR 1.71; 95% CI 0.66-4.44 (NS)
    - Sensitivity analysis
      - Increased risk of uterine rupture with locked single layer closure (OR - 4.96; 95% CI 2.58-9.52, P, 0.001) compared to double layer but not after unlocked single layer (0.49; 95% CI 0.21-1.16)
Obstetrical Liability
Trial of Labor after Cesarean

- Common allegations
  - Failure to fully inform (DISCLOSE) patient of risks and benefits of trial of labor
  - Use of prostaglandin agents for ripening and induction leading to uterine rupture
  - Excessive doses of OXYTOCIN
  - Failure to treat rupture in timely manner
  - Failure to have appropriate personnel and equipment during trial of labor

Incidence of Cesarean SSI (2006-2008)

4.25 mil x 32.3% cesarean rate = 1.37 million cesarean sections per year

<table>
<thead>
<tr>
<th>Risk Index Category</th>
<th>Number of Hospitals</th>
<th>Number of Procedures</th>
<th>Number of SSI</th>
<th>Pooled Mean Incidence</th>
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<tbody>
<tr>
<td>0</td>
<td>59</td>
<td>20,43</td>
<td>303</td>
<td>1.46</td>
</tr>
<tr>
<td>1</td>
<td>61</td>
<td>8,595</td>
<td>219</td>
<td>2.43</td>
</tr>
<tr>
<td>2.3</td>
<td>52</td>
<td>1,256</td>
<td>48</td>
<td>3.82</td>
</tr>
</tbody>
</table>

Cesarean SSI Risk Factors

- Age
- Poor socioeconomic
- Obesity
- Diabetes
- Immuno deficiency
- Infection at remote site
- Systemic steroid use
- Nicotine use
- Inappropriate use of antimicrobial prophylaxis
- Need for transfusion
- Hair removal/Shaving
- Duration of surgery
- Surgical technique
- Prolonged ROM
- Prolonged Labor
- Chorioamnionitis
- Endometritis
Direct Cost of Cesarean SSI Per Year

$3500/event x 27,500 SSIs per year = $100,000,000

What Informed Women are Reading!!!

What every pregnancy woman needs to know about cesarean delivery
• Childbirth Connection
  • Helping women and health professionals make informed maternity care decisions
  • Childbirth Connection works to ensure that all women and babies get the best possible maternity care. We have the collective vision and we know how to get there, but we can’t do it alone
Carol L. Brown, MD

Friday, 11:35 am – 12:20 pm

**Gyn Cancer and the Evolving U.S. Health Care System**
Gyn Cancer and the Evolving U.S. Health Care System

Carol L. Brown MD, FACOG, FACS
President Elect, Society of Gynecologic Oncology
The Georgia OBGyn Society 2017 Annual Meeting

Disclosure

- I have no financial disclosures

Objectives

- Describe key elements of the 2010 Affordable Care Act (ACA) that impact OBGyn and cancer care
- Understand impact of 2017 policy and legislation on delivery of OBGyn and cancer care
- Understand how you can advocate for the ability to deliver high quality care in a dynamic health care system
Pre-ACA: Who Were the Uninsured?

- Adults without dependent children
- Low- or moderate-income families (income <400% of the poverty level)
- Working families without access to employer-sponsored insurance coverage
- Undocumented persons

Uninsured Rate Among Nonelderly Women by State, 2006-2007

Uninsured Women, Pre ACA

- Nearly 1/3 of pregnant women w/o insurance
- One in five women of childbearing age 15-44 uninsured.
  - Compared to 17.8% for all Americans under age 65
Without Insurance, Pre ACA

- Women with breast cancer were 30-50% more likely to die from the disease, 36% fewer uninsured women had a mamm in the last 2 yrs.
- Women were 3 times less likely to have had a Pap test in the last 3 years, with a 60% greater risk of late-stage cervical cancer diagnosis.
- 50% did not have a regular doctor, compared to 89% of insured women.

What are the key features of 2010 ACA?

<table>
<thead>
<tr>
<th>Insurance Reform</th>
<th>Health System Reform</th>
</tr>
</thead>
<tbody>
<tr>
<td>More people covered</td>
<td>Improved quality and efficiency</td>
</tr>
<tr>
<td>More benefits and protections</td>
<td>Stronger workforce and infrastructure</td>
</tr>
<tr>
<td>Lower costs</td>
<td>Greater focus on public health and prevention</td>
</tr>
</tbody>
</table>

How 2010 ACA covers the uninsured

- Medicaid expansion
- Health insurance marketplaces and subsidies
- Individual and employer "mandates"
- Insurance reforms
2010 ACA provisions for insurance reform

- Expands Medicaid eligibility floor to 133% FPL for childless adults
- State health care exchanges and premium tax subsidies up to 400% FPL
- Individual mandate requires penalty for taxpayers who do not purchase insurance
- Ban on pre-existing conditions, lifetime limits, gender and health rating
- Coverage of dependent children up to age 26
- Closing the Medicare part D gap

ACA provisions for Health System reform
Accountable Care Organizations

- Networks of providers that coordinate care for patient populations
  - Improve quality, control costs, improve population health
  - Bonuses for hitting quality/cost targets-penalties for not reaching targets
- Now more than 400 ACO's in the U.S.
  - Medicare Shared Savings Program
  - Medicare Pioneer Program
  - Private Insurer ACO contracts
  - Medicaid initiatives

ACA provisions for Health System reform
Patient Centered Medical Homes

- Primary Care practices receive fees to provide "whole person" enhanced care for chronic illness
- Multiple models/demonstration projects
  - Multi-payer advanced primary care practice
  - FGHC advanced primary care practice
  - HRSA Medical/Health Home initiative
  - Medicaid Health Home state plan option
  - Comprehensive Primary Care Initiative
ACA Delivery and Payment reforms

- Community-based Transitions Care program-hospital and CEO coordination to reduce readmissions
- State Innovations Models Awards-to design/test new payment delivery models
- Bundled payments for care improvement-one Medicare payment to multiple providers to encourage coordination
- Pay for Performance-Medicare payments tied to performance on outcome measures (CABI)
- Health Information Technology-electronic health records and health information exchanges

ACA Provisions supported by the AMA

- Expanding coverage for the uninsured
- Health insurance market reforms and stronger patient protections including no pre-existing condition denials
- Medicare bonus payments for primary care physicians and general surgeons
- Expanded coverage for preventive services
- Individual mandate to purchase health insurance
- Improved Medicare prescription drug coverage

Changes to ACA accomplished with AMA support

- Removal of Medicare/Medicaid enrollment fee for physicians
- Elimination of 5% Medicare payment cut for outlier physicians
- Postponement of payment penalties related to Medicare quality reporting
- Removing anti-trust barriers to physician-led ACO's
- Physician representation on health-exchanges
ACOG & ACA: Our Policy

- ACOG reluctantly opposed the Affordable Care Act in 2010
  - IPAB, No SGR Repeal, No Meaningful Medical Liability Reform
- Fully support improving the law
  - Unaffordable deductibles, narrow networks
- Fully oppose turning back the clock on women’s health

How Do OBGyns Feel about the ACA?

To what extent do you support the ACA?

![Bar chart showing support levels for the ACA](chart.png)


How Do OBGyns Feel about the ACA?

Response to the question: How has the Affordable Care Act (ACA) influenced you and your practice? (Check all that apply). N = 157. Data were collected in 2014 by the American College of Obstetricians and Gynecologists.

- 32.5%: It has had no influence on me or my practice
- 28.2%: Increased work-related stress
- 22.1%: Increased total profits in the practice
- 19.1%: Lowered my career satisfaction
- 16.0%: Other
- 14.1%: My salary is lower
- 13.6%: I provide lower quality of care because of changes due to the ACA
- 13.6%: I provide higher quality of care because of changes due to the ACA
- 13.1%: Raised my career satisfaction
- 5.5%: Increased total profits in the practice
- 3.3%: My salary is higher
- 1.2%: Decreased work-related stress


89
AHCA passed by House of Representatives on 5/4/17 by vote of 217 to 213

- Eliminates the taxes and tax increases imposed by the ACA.
- Phases out enhanced funding for the Medicaid expansion and imposes either a block grant or per capita cap on Medicaid.
- Removes the individual and employer mandate penalties.
- Increases age rating ratios from 1 to 3 to 1 to 5 in the individual and small group market and allows states to raise fees higher by waiver.
- Allows states to waive the ACA's essential health benefit requirements.
- Imposes a penalty on individuals who do not maintain continuous coverage.
- Alternatively allows states to obtain a waiver to allow insurers to health status underwrite individuals who do not maintain continuous coverage.
- Creates funds of $130 billion to assist states in dealing with high-cost enrollees and for other purposes.
- Ends the ACA's means-tested subsidies as of 2020 and substitutes for them age-adjusted fixed-dollar tax credits.

Fears if AHCA becomes law

- States drop Medicaid expansion
- Loss of Medicaid as an entitlement means major coverage losses, additional cuts in future years – sharp funding cuts force states into terrible decisions: fund mental health, or cancer care? Addiction, or asthma?
- People with serious & complex conditions locked out of affordable health coverage
- Repeal of Essential Benefits results in less access to mental health & substance use services
- Access will depend on where you live, not what you need

How replacing the ACA would affect Georgia

House: American Health Care Act (AHCA)

US Senate: Better Care Reconciliation Act (BCRA)

<table>
<thead>
<tr>
<th>Health Care Coverage</th>
<th>400,000 more uninsured</th>
</tr>
</thead>
</table>
| Hospital Inpatient | Under the AHCA, inpatient, Specialty hospitals would face a 5% increase in uncompensated care costs and services not paid for by an insurer or Medicaid. Inpatient hospitals would face a 5% increase in uncompensated care costs. Source: AHA; White Paper (July 2017). These hospitals are defined as facilities with fewer than 100 inpatient beds.
| State Revenue | $15.6 billion in federal funding potentially lost |
Medicaid Challenges

- Medicaid covers 48% of all US births, 75% of all public family planning dollars
- 80% of ob-gyns see Medicaid gyn patients
- 84% see Medicaid ob patients

Medicaid Challenges include
- Defunding PPFA and
- Changing Federal Financial Obligation: Block Grants and Per Capita Caps

“Defunding” PPFA
Annals Commentary: ACOG & NPWF

- Medicaid does not fund abortion care.
- Defunding would strip Medicaid coverage for primary and preventive care provided at PP clinics.
- Prevents 580K unintended pregnancies/yr.
- 270,000 Pap tests and 360,000 breast examinations/yr.
- CBO: 390,000 women would lose access altogether, 650,000 face reduced access within 1 year.

ACOG PRINCIPLES
Maintain Critical Benefits in All Plans

1. Maternity coverage.
   - ACOG specified insurance details
   - 8.7M women under the ACA. Only 12% of individual market plans prior.
   - $1 spent on prenatal care saves $3.38, primarily in cost of low birthweight & preterm infants.
ACOG PRINCIPLES
Maintain Critical Benefits in All Plans

2. No cost sharing for women’s preventive health services, incl contraceptives.
   - Developed under ACOG’s leadership
   - 55M women gained access to mammograms, immun, and all FDA approved contraceptives
   - Women saved $1.4B on out-of-pocket costs for contraception in 1 yr.
   - 49% of US pregnancies are unintended; cost govt $12.5B in 2008.

ACOG PRINCIPLES
Maintain Critical Benefits in All Plans

3. Ensure direct access to ob-gyn care.
   - State by State fight for 29 years. Pre ACA, no DA in 9 states, limited DA in 16. With ACA, national direct access law w no restrictions.
   - Not tied to primary care designation
   - Not limited to # of visits
   - Not limited to certain services
   - No gatekeeper, family physician medical homes etc can’t capture our pts.

ACOG PRINCIPLES
Maintain Critical Benefits in All Plans

4. Medicaid state option to expand family planning
   - $1 spent on publicly-funded family planning saves Medicaid $7.09
   - Pre-ACA: 27 states had federal waivers to provide family planning services to women with incomes above the Medicaid eligibility level, most at or near 200% of poverty
   - 75% of 2010 public family planning dollars
ACOG Principles
Maintain Insurance Industry Reforms

5. No long waiting periods.
   a. Prior to the ACA, all insurers could impose waiting periods of 9mo to 2yrs
   b. Current law:
      - Individual mkt: no waiting period
      - Employer: 3 months
      - Everyone gets coverage

ACOG Principles
Maintain Insurance Industry Reforms

6. Prohibit pre-existing condition exclusions.
   a. Under the ACA, more than 64.5 million non-elderly Americans with preexisting conditions cannot be denied insurance coverage.
   b. Prior to ACA, denial for previous C-section, domestic violence

7. Prohibit gender rating.
   a. No higher premiums for women, only age, family size, and smoking
   b. In 2008, a 25yo woman could pay 81% more than a man for identical coverage
   c. Cost women $1B/yr

8. Prohibit coverage rescissions, and annual and lifetime benefit caps.
   a. Pre ACA, health care coverage for 19.5 million insured women was subject to lifetime coverage limits, causing many with serious health issues to lose coverage mid-treatment.

ACOG PRINCIPLES
Maintain the health care safety net

9. Continue Medicaid expansion
   a. 31 States + DC
   b. 11M individuals gained access
   c. Coverage of non-pregnant low income women
   d. Pre ACA, Medicaid in most states covered low income women only while pregnant. Women lost their coverage shortly after delivery.
   e. Hospital uncompensated care costs dropped by $10.4B btw 2013-2015.
   f. Uninsured rate among women ages 18-64 fell from 19.3% to 10.8% btw 2010 and 2015
ACOG’s ACA Principles

Health reform must guarantee these fundamental principles of women’s health care:

- Maternity care coverage for all women in all plans
- No-coin coverage of evidence-based preventive care and services, defined by the Women’s Preventive Services Initiative
- Direct access to ob-gyn care
- No pre-existing condition exclusions or gender rating
- No insurance coverage annual or lifetime limits or rescissions
- No excessive waiting periods

SGO HCR Principles

1. Access to high quality, affordable care for all women with gynecologic cancer
2. Coverage of patient costs of clinical trial participation by all private and public health insurance plans
3. Public health funding for screening and prevention services for all women and children at risk for gynecologic cancer

SGO HCR Principles

4. Medical liability reform that improves patient access to specialty care and reduces health care costs
5. Cancer health equity for minority and underserved women with gynecologic cancer
6. Adequate funding and meaningful reform of Medicare and Medicaid to ensure coverage for elderly, disabled and low-income women with gynecologic cancer
ACA, AHCIA, SCFA issues covered by 500 HCR principles

1. Access to high-quality, affordable care for all women with gynecologic cancer. No existing conditions, high cost of cancer drugs, continuity of coverage, caps on coverage

3. Public health funding for screening and prevention services for all women and children at risk for gynecologic cancer. Essential Health Benefits, funding for Planned Parenthood, Prevention & Public Health Fund

6. Adequate funding and meaningful reform of Medicare and Medicaid to ensure coverage for elderly, disabled and low-income women with gynecologic cancer. Medicaid expansion and caps, QM funding

Influencing Congress*

*(yes, it can be done)

How influential are...?

[Graph showing the level of influence in various communication methods]
Health Care Reform, Organized Medicine & Me

- Joined ACOG as an Alternate delegate in 2000
- Volunteered to Chair Cancer Caucus in 2002
- Promoted to ACOG Delegate in 2004
- Vice-Chair of ACOG delegation in 2010
- Chair of ACOG delegation 2013-?
- Two meetings per calendar year for 4 days each, 1st Friday in June and November
- Why? “birds-eye” view of healthcare policy from the physician perspective and great people

Where are we with clinical trials? In crisis!

The Crisis in Gyn Cancer Clinical Trials

- Randomized clinical trials have significantly improved survival for women with gynecologic cancers, including cervical, ovarian, endometrial, and vulvar cancers

- The gynecologic cancer community has a 50yr history of developing trials, many by the Gynecologic Oncology Group (GOG) in partnership with the National Cancer Institute’s Cancer Therapy Evaluation Program (NCI CTEP).
THE CURRENT STATE: A SEVERE DECLINE IN NUMBER OF WOMEN WITH GYN CANCER ENROLLED IN TRIALS

- Women Enrolled in NCI-CTEP Gynecologic Cancer Trials
- 90% reduction in numbers of eligible patients, fewer trials

THE CURRENT STATE: A SEVERE DECLINE IN AVAILABILITY OF CLINICAL TRIALS FOR WOMEN WITH GYNECOLOGIC CANCER

- NCI-CTEP-sponsored Gynecologic Oncology Available Clinical Trials
- Numbers of trials decreasing significantly

ANALYSIS: WHY HAS THIS OCCURRED?

- National Institutes of Health Budget Reduction and Stagnation
  - 1998 NIH $14 billion
  - 2016 NIH $31 billion
  - FY2018 $24 billion
  - 18.3% Reduction
SGO Legislative/Congressional Ambassadors Continue to Expand (both number and spheres of influence)

- Education of Congressional Offices on Clinical Trials Crisis
  - 100+ SGO members are in contact with their Member of Congress offices, stressing the importance of increased support to the NCI.

- Education of Patients and Advocates
  - Expand and integrate our network, create formal coalition structure.
  - Use new technology, such as VoterVoce, that will improve efficiencies and streamline processes for patients to communicate with Congress.

#Trials4GynCancerNOW

Women with #gyncancer deserve progress. Fund trials now @realDonaldTrump
#Trials4GynCancerNow @SGO_org

How your advocacy can help achieve HealthCare System Reform

- Join your local and state medical society!
- Join the AMA!
- Volunteer for the Government Relations Committee of your Specialty Society!
- Donate to a Political Action Committee! Especially Chb-GynPACI
- Visit/call/e-mail your local and national representatives!
End women’s cancer weekend

Survivors Course, Nov. 4, 2017
5K Run/1K Walk, Nov. 5, 2017
Washington, DC
endwomenscancer.org
Kimberly A. Workowski, MD

Friday, 12:20 – 1:05 pm

What’s New in STI/STD
Sexually Transmitted Infections

Kimberly Workowski, M.D., FACP, FIDSA
Professor of Medicine, Division of Infectious Diseases, Emory University

Outline

- Changing landscape of STIs
- Emerging topics
  - Chlamydia/gonorrhea treatment, Mycoplasma genitalium, congenital syphilis
- Objectives:
  - Describe the current epidemiology of STIs
  - Explain the clinical management and treatment recommendations for common STIs
  - Discuss prevention approaches
- Disclosures
  - Research funding (HCV, HIV antiviral clinical trials): Gilead, AbbVie
  - Research funding (gonorrhea clinical trial): GSK
  - Contractor: Division of STD Prevention, CDC

Estimated New STIs (Ages 13-24 and Ages 25+)

![Graph showing estimated new STIs](image)
2015 Surveillance Report Overview
- Chlamydia: 6.9% with 1,546,408 cases reported in 2015
  - Orange by a 10.8% increase among men
  - 8.8% increase among women
- Gonorrhea: 12.1% with 201,286 cases reported in 2015
  - Orange by a 13.3% increase among men
  - 6.6% increase among women
- P. I. G. individuals: total of 551 cases reported in 2015
  - Increases seen in MSM, M&K women
  - MSM accounted for 81.7% of P. I. G. cases
  - Congenital syphilis: total of 48 cases
  - Increased from 2013-2014 with a 4% increase in 2016
  - Increase primarily seen in the West

STI Screening and Management

STD Screening for Adolescent and Young Females
- Sexually active adolescents & women < age 25:
  - Annual chlamydia and gonorrhea screening
  - HPV testing if no previous test and annual if risk
  - Syphilis serology if high community prevalence
  - Consider HIV type-specific serology if partner with genital herpes
  - No routine screening for trichomonas, BV, or HIV
- Sexually active women < age 25:
  - If increased risk: New or multiple sex partners, partner with concurrent partners, or partner with an STI
  - If increased community prevalence

www.cdc.gov/std/fq2015
Chlamydia — Rates of Reported Cases by State, United States and Outlying Areas, 2015

Chlamydia — Rates of Reported Cases in the Southern Region of the US by Age Group, 2006-2015

Chlamydia & Gonorrhea Diagnostic Tests
- Nucleic acid amplification tests (NAAT) recommended for women & men
- Optimal specimen: vaginal swabs in women and first-catch urine in men
- NAAT optimal for rectal and pharyngeal testing (MSM); not FDA approved but commercially available & validation protocols available for local labs
- Limitations: no antibiotic resistance testing with NAAT

http://www.cdc.gov/mmwr
Chlamydia Treatment

- Effectiveness of azithromycin may be less than doxycycline
  - Systematic review (Kong FY Clin Infect Dis 2013)
  - Possible small increased efficacy of up to 3% for doxycycline compared to azithromycin treatment of uncomplicated chlamydia
  - 7% increased efficacy for doxycycline for cervicitis in men
- Doxycycline delayed release 200 mg tablets
- Amoxicillin - alternative regimen in pregnancy
  - In vitro studies: bactofins induce persistent viable non-infectious chlamydia that can revert to a replicative form
  - Early amoxicillin studies in pregnancy had major limitations
-AIS (Kuchta Infect Dis Clin Pract 2001) showed higher test of cure using azithromycin vs. amoxicillin (55% vs. 85%)

Chlamydia Treatment

- Effectiveness of azithromycin c. doxycycline
- One NGU trial and several rectal infection studies

Asthomycin versus Doxycycline for Genital Chlamydia Infection in Males and Females in Youth Correctional Facilities (CY)

- Prior to Treatment
  - CT and GC test (Gen-Probe A2C)
  - Rapid GC test (AHL, CO-3)

- Study V: Treated
  - Positive CT: A2C
  - Positive GC: A2C

- Follow-up
  - 1.7% false positive rate
  - 98% false negative rate

- Study V: Ratio:
  - Positive CT: A2C
  - Positive GC: A2C

- Amoxicillin: Oral penicillin indicated
- Azithromycin: Oral penicillin indicated

Germain: NCMF 2015
**Re-infection is Common**

Re-infection with Chlamydia and Gonorrhea Among females: A Systematic Review of the Literature

- Select 3 months to 1 year
- Tools to help with
  - Patient referral
  - Contacted Partner Therapy (CPT)
  - Drugs Your Own Partner
- Effective (CPT)

In 16 studies with active follow-up, overall median proportion re-infected: 13.0%, range: 0 – 26.3%

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**Evolving Landscape of EPT: Legal Status Summary**

<table>
<thead>
<tr>
<th>Year</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
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<tr>
<td>2017</td>
<td>EPT is locally allowed</td>
</tr>
</tbody>
</table>

---

**LGV inguinal syndrome**

- C. trachomatis L1, L2, L3
- Herpetiform genital ulcers and/or papules
- Tender, fluctuant, inguinal lymphadenopathy (buboes)
LGV Proctitis
- Proctocolitis in MSM and women + rectal CT NAAAT
- PCR based genotyping
- Proctitis +/- perianal ulcers should receive presumptive tx for LGV (dox 100 mg bid x 2-3 d)
- Painful perianal ulcers or mucosal ulcers (proctoscope) presumptive therapy for HSV
- Mucosal ulcers (HSV)

2015 CDC Treatment Guidelines

Urethritis
Gonorrhea (5-20%)
Chlamydia 15-40%
M. genitalium 5-25%
Ureaplasma 0-20%
Trichomonas 5-20%
HSV 10-30%, adenovirus Enterics, Candida

Mycoplasma genitalium

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>NAAT</th>
<th>Genotyping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary</td>
<td>5-30%</td>
<td>-</td>
</tr>
<tr>
<td>Endocervix</td>
<td>2-5%</td>
<td>-</td>
</tr>
<tr>
<td>Proctitis</td>
<td>100%</td>
<td>-</td>
</tr>
</tbody>
</table>

- Mycoplasma genitalium

107
How Common is *M. genitalium*?

Diagnostics

- **Culture:** impractical; insensitive; weeks
- **Nucleic acid amplification:** None FDA cleared
  - Organism load low (<10^6 lower than C.trachomatis)
  - Male first void urine and female vaginal swab
  - RNA robust; most based on high viral genes or 16S RNA gene
  - 16S rRNA TMA RUO assay (Hologic/GP) multiple 16S RNA
  - Multiplex assays may have lower sensitivity

*M. genitalium*

- Symptomatic therapy for NGU (20%), cervicitis, PID
- Consider Mg in urethritis treatment failure
  - Doxycycline largely ineffective
  - Azithromycin 1 gram effective; resistance rapidly emerging
  - Nfxl/azithr for treatment failure (resistance emerging)
  - Investigational regimens: plakomycin, profluconazole
Gonorrhea — Rates of Reported Cases by Region, United States, 2006–2015

Estimated Proportion\(^1\) of MSM, MSW, and Women Among Gonorrhea Cases by Jurisdiction, STD Surveillance Network (SSN), 2015

CDC STD Treatment Guidelines
Uncomplicated Gonococcal Infections of Cervix, Urethra & Rectum

Ceftriaxone 250 mg as a single intramuscular dose

Ampicillin 1 g orally (preferred) or Doxycycline 100 mg twice daily for 7 days

1. Sexually transmitted pathogens:
   - Neisseria gonorrhoeae (N. gonorrhoeae)
   - Ureaplasma urealyticum
   - Mycoplasma hominis

2. Recommended treatment regimens:
   - Ceftriaxone 250 mg IM
   - Ampicillin 1 g PO
   - Doxycycline 100 mg PO
Suspect Treatment Failures

- Most treatment failure likely due to reinfection
- If treatment failure suspect, obtain culture/susceptibility test + ensure partner treatment
  - If reinfection likely (ceftriaxone/azithromycin), Rx ceftriaxone 250 mg + azithromycin 1 gram
  - If reinfection likely (ceftriaxone/azithromycin), Rx ceftriaxone 250 mg + azithromycin 2 gram
  - If treatment failure suspected, Rx gemifloxacin 320 mg + azithromycin 2 g or gentamicin 240 M + azithromycin 2 g (Gilkidy ID 2014)
- Report to local or state health department
- Test of cure 7-14 days after retreatment (culture/susceptibility test with NAAT)

Antibiotic Resistance Threats in the U.S.

Seven Threat Assessment Criteria:
- Clinical impact
- Economic impact
- Necessity
- Expected projection of incidence
- Transmissibility
- Cure rate with effective antibiotics
- Barriers to prevention

Three Urgent Threats:
- Clostridium difficile
- Carbapenem-resistant
- Enterobacteriaceae
- Drug-resistant Neisseria gonorrhoeae

Percentage of urethral *Neisseria gonorrhoeae* isolates with resistance, by drug and year, GISP, 2000-2015
Combating Antibiotic-Resistant Bacteria (CARB) and Advanced Molecular Detection (AMD)

- Strengthen surveillance (GIDR & Smini)
- Regional laboratory reference network (ARLN)
  - Maryland, Tennessee, Texas, Washington
- Strengthening U.S. response to resistant gonococcal infections (SURGID)
  - Rapid rapid detection and response capacity to rapidly identify resistant N. gonorrhoeae (Pelican Co., GA, Wilkes Co., NC)
- Epidemiological network approaches
- Economic impact of resistance

Disseminated Gonococcal Infection (DGI)

- 1-3% of gonococcal infections (monoarticular arthritis, tenosynovitis, dermatitis)
- Population-based surveillance of CDC and 10 state health departments: academic institution, health departments, infection control practitioners, other federal agencies (i.e., FDA, USDA, FDA, "4 million"
- Retrospective review of cases from 2015-2016, prospective surveillance of cases from 2017
- DGI specific case report form
- Surveillance will be among all residents from the catchment areas of 2 ABCs sites:
  - CA IDP: 3 county bay area
  - GA IDP: 20 county "MIA", metro Atlanta area, plus remaining "GOM", Georgia outside Atlanta
Genital Herpes

- Increasing proportion of orogenital infections HSV-1 (women, MSM)
- PCR is the preferred genital ulcer diagnostic test
- USPSTF (D recommendation) - suboptimal serologic test performance (SMA, VNT)
- Type specific serologic tests
  - Recurrent or initial genital symptoms with negative HSV PCR
  - Clinical diagnosis of genital herpes with lab confirmation
  - Partner with genital herpes
  - HerpeSelect HSV-2 ELSA may be false + at low index values (1.2-3.5) confirm with Blot or Western Blot
  - HerpeSelect HSV-1 ELSA insensitive for HSV-1 (80%)

2015 CDC Treatment Guidelines
HSV2 Genital Shedding

- 458 immunocompetent HSV2+
- Self collected genital swabs for 30 days

<table>
<thead>
<tr>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSV2 (%) of days</td>
<td>50%</td>
</tr>
<tr>
<td>Subclinical shedding</td>
<td>3%</td>
</tr>
<tr>
<td>HSV DNA</td>
<td>4.3 log</td>
</tr>
</tbody>
</table>

(Toledano, JAMA 2010;303(20):3443-9)


![Graph showing comparison between Placebo and Valacyclovir 500 mg once daily]

Praliflo Compared with Valacyclovir on Genital HSV Shedding

<table>
<thead>
<tr>
<th>Praliflo vs Valacyclovir on Genital HSV Shedding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Praliflo inhibits HSV replication</td>
</tr>
<tr>
<td>Mucosal HSV differences</td>
</tr>
<tr>
<td>Number of mucosal lesions</td>
</tr>
<tr>
<td>Number of active lesions</td>
</tr>
<tr>
<td>Number of young lesions</td>
</tr>
<tr>
<td>Number of large lesions</td>
</tr>
<tr>
<td>Total number of mucosal lesions</td>
</tr>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Valacyclovir 500 mg</td>
</tr>
</tbody>
</table>

(Valac, JAMA 2010)
Congenital Syphilis — Rates of Reported Cases Among Infants by Year of Birth and State, United States and Outlying Areas, 2015

<table>
<thead>
<tr>
<th>State</th>
<th>Rate per 100,000</th>
<th>Rank</th>
<th>Cases</th>
<th>State</th>
<th>Rate per 100,000</th>
<th>Rank</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>156</td>
<td>1</td>
<td>64</td>
<td>Louisiana</td>
<td>145</td>
<td>2</td>
<td>53</td>
</tr>
<tr>
<td>Louisiana</td>
<td>110</td>
<td>3</td>
<td>69</td>
<td>Texas</td>
<td>98</td>
<td>4</td>
<td>60</td>
</tr>
<tr>
<td>Texas</td>
<td>78</td>
<td>5</td>
<td>50</td>
<td>Florida</td>
<td>48</td>
<td>6</td>
<td>38</td>
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<tr>
<td>Florida</td>
<td>58</td>
<td>7</td>
<td>30</td>
<td>Illinois</td>
<td>38</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Illinois</td>
<td>38</td>
<td>9</td>
<td>23</td>
<td>Georgia</td>
<td>31</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>Georgia</td>
<td>22</td>
<td>11</td>
<td>18</td>
<td>Maryland</td>
<td>19.3</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Maryland</td>
<td>19.3</td>
<td>12</td>
<td>15</td>
<td>Nevada</td>
<td>18.1</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Nevada</td>
<td>18.1</td>
<td>13</td>
<td>12</td>
<td>Iowa</td>
<td>19.1</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Iowa</td>
<td>19.1</td>
<td>14</td>
<td>10</td>
<td>Georgia</td>
<td>18.1</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Georgia</td>
<td>18.1</td>
<td>15</td>
<td>8</td>
<td>Oregon</td>
<td>18.1</td>
<td>16</td>
<td>7</td>
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<tr>
<td>Oregon</td>
<td>18.1</td>
<td>16</td>
<td>7</td>
<td>Arizona</td>
<td>18.1</td>
<td>17</td>
<td>5</td>
</tr>
<tr>
<td>Arizona</td>
<td>18.1</td>
<td>17</td>
<td>5</td>
<td>New York</td>
<td>18.1</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>New York</td>
<td>18.1</td>
<td>18</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Congenital Syphilis — Rates per 100,000 Live Births, 2015

<table>
<thead>
<tr>
<th>State</th>
<th>Rate per 100,000</th>
<th>Rank</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>156</td>
<td>1</td>
<td>13.3</td>
</tr>
<tr>
<td>Louisiana</td>
<td>145</td>
<td>2</td>
<td>13.3</td>
</tr>
<tr>
<td>Texas</td>
<td>69</td>
<td>3</td>
<td>13.2</td>
</tr>
<tr>
<td>Florida</td>
<td>38</td>
<td>4</td>
<td>13.0</td>
</tr>
<tr>
<td>Illinois</td>
<td>50</td>
<td>5</td>
<td>12.9</td>
</tr>
<tr>
<td>Georgia</td>
<td>60</td>
<td>6</td>
<td>12.7</td>
</tr>
<tr>
<td>Maryland</td>
<td>19.3</td>
<td>7</td>
<td>12.7</td>
</tr>
<tr>
<td>Nevada</td>
<td>18.1</td>
<td>8</td>
<td>12.7</td>
</tr>
<tr>
<td>Iowa</td>
<td>19.1</td>
<td>9</td>
<td>12.7</td>
</tr>
<tr>
<td>Georgia</td>
<td>18.1</td>
<td>10</td>
<td>12.7</td>
</tr>
<tr>
<td>Oregon</td>
<td>18.1</td>
<td>11</td>
<td>12.7</td>
</tr>
<tr>
<td>Arizona</td>
<td>18.1</td>
<td>12</td>
<td>12.7</td>
</tr>
<tr>
<td>New York</td>
<td>18.1</td>
<td>13</td>
<td>12.7</td>
</tr>
<tr>
<td>New Mexico</td>
<td>18.1</td>
<td>14</td>
<td>12.7</td>
</tr>
<tr>
<td>New Jersey</td>
<td>18.1</td>
<td>15</td>
<td>12.7</td>
</tr>
<tr>
<td>North Dakota</td>
<td>18.1</td>
<td>16</td>
<td>12.7</td>
</tr>
<tr>
<td>South Dakota</td>
<td>18.1</td>
<td>17</td>
<td>12.7</td>
</tr>
<tr>
<td>West Virginia</td>
<td>18.1</td>
<td>18</td>
<td>12.7</td>
</tr>
</tbody>
</table>

Prenatal Care Status of Congenital Syphilis Cases — United States and California, 2015 (N=487)

<table>
<thead>
<tr>
<th>Did mother receive prenatal care?</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, and initiated ≥20 days PTD*</td>
<td>250</td>
<td>51%</td>
</tr>
<tr>
<td>Yes, but initiated &lt;30 days PTD</td>
<td>30</td>
<td>6%</td>
</tr>
<tr>
<td>Yes, but unknown timing</td>
<td>30</td>
<td>6%</td>
</tr>
<tr>
<td>No</td>
<td>122</td>
<td>25%</td>
</tr>
<tr>
<td>Unknown</td>
<td>42</td>
<td>19%</td>
</tr>
</tbody>
</table>

*PTD = prior to delivery
Maternal Testing and Treatment During Pregnancy
—Congenital Syphilis Cases, United States, 2015 (N=487)

<table>
<thead>
<tr>
<th>Testing/Treatment Status</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not tested in time</td>
<td>205</td>
<td>42%</td>
</tr>
<tr>
<td>Infected with syphilis during pregnancy after initial screening test</td>
<td>74</td>
<td>26%</td>
</tr>
<tr>
<td>Tested in time (and positive), but not treated in time</td>
<td>66</td>
<td>14%</td>
</tr>
<tr>
<td>Received inadequate regimen</td>
<td>15</td>
<td>3%</td>
</tr>
<tr>
<td>Other/Can’t classify based on data provided</td>
<td>135</td>
<td>28%</td>
</tr>
</tbody>
</table>

Infant Clinical Status
—Congenital Syphilis Cases, United States, 2015 (N=487)

<table>
<thead>
<tr>
<th>Clinical Status</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillborn</td>
<td>15</td>
<td>3%</td>
</tr>
<tr>
<td>Born alive, then died</td>
<td>7</td>
<td>1%</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Alive, total</td>
<td>440</td>
<td>91%</td>
</tr>
<tr>
<td>Alive, had signs/symptoms of CS</td>
<td>201</td>
<td>41%</td>
</tr>
<tr>
<td>Alive, no signs/symptoms of CS</td>
<td>248</td>
<td>51%</td>
</tr>
</tbody>
</table>

Diagnosis

- Direct detection methods (not widely available)
  - Darkfield microscopy, PCR
- Nontreponemal tests (fluoidal antigens)
  - RPR, VDRL, TRUST
- Treponemal tests (7 paliudum proteins)
  - TP-PA, EIA, CIAs, microbead immunoassays, FTA-ABS
- Point of care tests (treponemal) hiv/syphilis
Sensitivity of Serological Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Primary</th>
<th>Secondary</th>
<th>Latent</th>
<th>Tertiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>VDRL</td>
<td>76 (74-78)</td>
<td>100</td>
<td>95 (88-100)</td>
<td>71 (67-74)</td>
</tr>
<tr>
<td>RPR</td>
<td>80 (77-86)</td>
<td>100</td>
<td>70 (64-100)</td>
<td>72</td>
</tr>
<tr>
<td>FTA-ABS</td>
<td>64 (50-100)</td>
<td>100</td>
<td>100</td>
<td>96</td>
</tr>
<tr>
<td>Trepotest Agglutination*</td>
<td>75 (69-80)</td>
<td>100</td>
<td>97 (87-100)</td>
<td>94</td>
</tr>
<tr>
<td>EIA</td>
<td>83</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

*FTA-ABS and TP-PA are generally considered equally sensitive in the primary stage of disease.

Syphilis serologic screening algorithms

Traditional

Reverse sequence

Active infection, FTA, nontreponemal

Reasons for discordant test results

(i.e., EIA/TPA vs. RPR)
- Treated syphilis
  - Persistence of treponemal antibodies but seroreversion of nontreponemal antibodies
- Untreated syphilis of long duration
  - Nonreactive titers decline over time
  - Early primary syphilis
    - Treponemal antibody levels rise before nontreponemal antibody titer becomes positive
  - Prozone phenomenon
  - False-positive treponemal test result
    - Particularly with pregnant women
Discordant Syphilis Immunassay in Pregnancy: Perinatal Outcomes and Implications for Clinical Management

- More than half who were retested became DA
- Most pregnant women with discordant serology were DA/FDR/FPR
- Patients aged 35 and older more likely to be older and have a prior history of STIs

Syphilis Treatment: Primary, Secondary, Early Latent

- Penicillin treatment of choice +/- HIV
- Bicillin 2.4 million IU x1

- No 500 HIV-revealed no difference in serologic outcomes at 12 months comparing 1 x 3 doses of BPS (Kawano 2014, Ying 2014)

- Penicillin alternatives
  - Doxycycline, ceftriaxone (dose/duration)
  - Azithromycin 2 gm (A2109G, A2159 mutation)
  - MSM/MSW (05.2013)

- Do not use in MSM or pregnancy

2018 CDC STD Treatment Guidelines

Nonsexual transmission of Syphilis

- Mouth to mouth transfer of pre-chewed food
- Contaminated utensils
- Breast feeding
- Saliva applied to bottle nipples to test temperature
- Human bite

Public Health Implications

- Two epidemics
  - MSM networks
  - Social networks
- Different approaches needed for different regions: local, national, international
- Non-communicable diseases localized, non-communicable epidemic
  - Non-communicable diseases: obesity, cancer, cardiovascular disease
- Maternal health issues
  - Preterm birth, low birth weight, stillbirth, neonatal mortality
- Access to health services
  - Functional health care facilities, skilled birth attendants, antenatal care
- Public health implications
  - Disparities in health outcomes, health inequities

Association Between Genital Inflammation and HIV

- Genital inflammation associated with increased risk of HIV acquisition (OR 3.2; P = 0.04)
- Women with P. bivora were 19 times more likely to have genital inflammation and 13 times more likely to acquire HIV

Overall Vaginal Bacterial Community Diversity

- Shannon Diversity index higher in cases (median 0.9, IQR 0.4 - 2.3) vs. controls (median 0.7, IQR 0.1 - 1.4), P = 0.03
- Lower relative abundance of lactobacilli associated with vaginal health
- Gemella genus significantly associated with HIV
Bacterial Quantity and HIV Acquisition

- 5 species showed significant, concentration-dependent associations with HIV acquisition
- Associations plausibly related to the effects of these species on:
  - Vaginal mucosal immune activation
  - HIV virus-activating factors
  - Integrity of physical and chemical barriers (e.g., mucus and pH)

Can Vaginal Bacteria Interfere with Tenofovir Gel® as PrEP Efficacy?

- Tenofovir gel® highly protective against HIV with lactobacillli dominance
- TFV rapidly depleted by Gardnerella but not Lactobacillli
- Levels of TFV-45 in genital tissues and TFV in plasma are correlated to markers of bacterial vaginosis
- Vaginal microbiota may impact tenofovir uptake when applied intravaginally

Lactobacillus-Deficient Cervicovaginal Communities and HIV Risk in South African Women

- Women with high-diversity vaginal bacterial communities acquired HIV at 4x higher rates
- Activated CD4 T-cell numbers were elevated in women with most “pathologic” bacteria
- Specific bacterial taxa are associated with increased or reduced risk of HIV acquisition
- Intravaginal administration of Prokaraetia increased number of activated cervical T-cells in mice
Can Vaginal Bacteria Interfere with Oral Prep Efficacy?

- Oral Prep is protective against HIV acquisition regardless of degree of bacterial vaginosis

Additional Testing Options for Trichomonas

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDH</td>
<td>63.3%</td>
<td>98.8%</td>
</tr>
<tr>
<td>Wet prep</td>
<td>71.4%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Nucleic Acid Amplification Test (Gen-Probe)
- We use same specimen type as with CTC NAAT for females
- Will FDA cleared for use in men

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>98.2%</td>
<td>94.9%</td>
</tr>
<tr>
<td>Vaginal/anal swab</td>
<td>100%</td>
<td>96.0% to 99.6%</td>
</tr>
</tbody>
</table>

Consider a molecular test-resolved algorithm (negative wet prep followed by NAAT)

*Schwartz, JCM Micro 2011

Is single dose MTZ effective?

- Meta-analysis: 2 g single dose was 1.87x to be TV+ at test of cure (TOC) compared to 500 mg bid (Powell, STD 2017)
- RCT of HIV- women, 2g dose were 2x to have TV at TOC 500 mg bid for 7 days (Kusunger 2008)
Origin and predictors of early repeat infections among HIV negative women with *Trichomonas Vaginalis* receiving a 2 g dose of metronidazole

- Rate of TV+ at T0C among women receiving the recommended 2 g dose of MTZ.
- Crude rate at T0C was 52/70 (16.5%).
- 41 of the 52 (82%) reoccurrence did not have sexual exposure or had organism that was resistant to MTZ.
- The chances of treatment failure was, therefore, 41/50 (15.2%).
- To examine factors associated with retest positive at T0C.
- Most women had symptoms at baseline and over half had a prior TV infection, both of these characteristics were significantly more likely among women who were TV+ at T0C.

*Kremer J, GIST 2017*

---

*Trichomonas vaginalis*

- Test in women with vaginal discharge
- Consider screening in high prevalence settings
- Retesting 3 months after treatment
- Treatment: Metronidazole or Tinidazole 2 g; HIV+ 500 mg bid x 7 days
  - Management of persistent infection
    - Upto 12% at 1 month
    - Relapsification from untreated partner is common
    - Infection with MTZ-resistant strain (“A-D”)
      - Treatment resistant = Y
      - No clear relationship to clinical treatment failure
      - Susceptibility testing if resistance suspected (404-716-4141)

---

STD Prevention - The Clinicians’ Role

- Routine sexual history and risk assessment
- Screen, appropriately
  - Appropriate anatomic sites with recommended tests
  - Alcohol, drug use, tobacco, depression, intimate partner violence
- Assess appropriate vaccination status (HPV, HBV, HAV)
- Prevention messages - condoms, HIV pre- and post-exposure prophylaxis (PPTP, PEP)
- Diagnosis and treatment, partner services
- Report per state and local statutory requirements
STD Clinical Consultation Network (STDCCN)

- Provides STD clinical consultation services within 1-3 business days, depending on urgency, to healthcare providers statewide.
- Your consultation request is linked to your regional PTC's expert faculty.
- Just a click away! www.STDCCN.org
Faculty Presentations
Saturday, August 26, 2017
Carol L. Brown, MD

Saturday, 8:00 – 8:45 am

Modern Management of Endometrial Cancer
Notes on Modern Management of Endometrial Cancer:
J Patrick O’Neal, MD

Saturday, 8:50 – 9:35 am

Health Outcomes for Georgia Women
Notes on Health Outcomes for Georgia Women:
Wendy Book, MD

Saturday, 10:30 am – 11:15 am

Heart Disease and Pregnancy
Disclosures

I receive research funding from Actelion, the CDC and the NIH
No disclosures relevant to this talk

Objectives

Describe cardiovascular changes in pregnancy
Know how to manage common cardiovascular co-
morbidities during pregnancy
Recognize cardiovascular complications of pregnancy
More American Women With Heart Disease Choosing To Have Babies, Study Indicates.

HealthDay (5/22, Preidt, 21K) reports that research suggests “many more American women with heart disease are choosing to have babies.” Investigators followed approximately 61,000 women with heart disease from 2003 to 2012. The researchers found that the proportion who had babies rose 24 percent during that period. The findings were published in the American Journal of Cardiology.

Pregnancy: Hemodynamic Changes

Cardiac Output increases 30-50% above baseline
Preload increased (increased blood volume)
Afterload decreased (decreased SVR, PVR)
Heart rate increases by 15-20 bpm

High-flow, Low resistance circulation
Normal Pregnancy

<table>
<thead>
<tr>
<th>Blood Vol</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>SV</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>HR</td>
<td>↑</td>
<td>↑</td>
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</tr>
<tr>
<td>BP</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>SVR</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
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<tr>
<td>CVP</td>
<td>↓</td>
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</tbody>
</table>

Normal Pregnancy: Symptoms and Findings

- Dyspnea, fatigue, exercise intolerance, edema
- CVP remains normal, RV dilates
- Increased splitting of S2, systolic ejection murmur, third heart sound, venous hum
- S4 and diastolic murmurs uncommon

Labor & Delivery

<table>
<thead>
<tr>
<th>L&amp;D</th>
<th>SNS</th>
<th>SVR</th>
<th>CO/SV</th>
<th>Preflood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preload</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>↑20%</td>
</tr>
<tr>
<td>300-500 cc</td>
<td></td>
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</tr>
</tbody>
</table>
WHO Risk Score

<table>
<thead>
<tr>
<th>WHO Class</th>
<th>Risk</th>
<th>Eval/Management</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Low risk</td>
<td>If isolated, uncomplicated, one or two card visits</td>
<td>MVP, repaired ASO, VSD</td>
</tr>
<tr>
<td>II</td>
<td>Small Risk</td>
<td>Cardiac evaluation every trimester</td>
<td>ASD, VSD, tVSD</td>
</tr>
<tr>
<td>III</td>
<td>Signif Risk</td>
<td>Ensure counseling, multi-disciplinary team, monthly or more often with team</td>
<td>PDA, Medial Valve</td>
</tr>
<tr>
<td>IV</td>
<td>Extreme Risk</td>
<td>Contraindication-advice termination</td>
<td>PAK, CHF</td>
</tr>
</tbody>
</table>

22 year old
cr. “palpitations”
28 weeks pregnant

Ectopy Common in Normal Pregnancy

Total PVCLs, PACs/24 hrs in healthy women with palpitations during pregnancy and in the postpartum period

Evaluation
Complete FH
Rhythm disturbances requiring therapy rare
Cessation of caffeine, alcohol, nicotine
Exclude thyroid disease, anemia
Sustained tach and/or other cardiac sx = cardiac evaluation

Treatment
<table>
<thead>
<tr>
<th>Condition</th>
<th>Recurrence</th>
<th>Beta-blocker if needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAC, PVC no cardiac hx</td>
<td>Vagal Maneuvers</td>
<td>Adenosine</td>
</tr>
<tr>
<td>SVT</td>
<td>Beta-blockers, diltiazem</td>
<td>Class I anti-arrhythmic</td>
</tr>
<tr>
<td>SVT w ACHD</td>
<td>Beta-blockers</td>
<td>Cardioversion</td>
</tr>
<tr>
<td>AT/AF/Aflutter</td>
<td>Tesk, Flec, structural heart disease</td>
<td>Antiarrhythmia</td>
</tr>
<tr>
<td>VEB</td>
<td>ICD, Long QT</td>
<td>Cardioversion</td>
</tr>
<tr>
<td>Air fibrillation/flutter</td>
<td>Anti-arrhythmia, ICD</td>
<td>Permanent pacemaker if symptomatic</td>
</tr>
</tbody>
</table>

Palpitations: “Red Flags”
- History of Maternal Heart Disease
- FH sudden death, MCM, CHF, Long QT, ARVD
- Arrial fibrillation/flutter: thyroid if normal heart
- Ventricular tachycardias
- Brady-arrhythmias? Structural heart disease
24 yo with hypertension

Hypertension in Pregnancy

- Pre-existing HTN: BP >140/90mmHg before preg or before 20 weeks gestation
- Gestational HTN: >20 wks gestation, resolves by 6 wks post-partum
- De Novo HTN + Significant proteinuria (>0.3g/d)
- HTN that worsens during pregnancy + proteinuria

Non-Proteinuric Hypertension - Tight Control vs Less-Tight Control

- Target DBP < 85mmHg vs <100mmHg
- No difference in fetal, neonatal complications, or maternal complications
- Less tight associated with higher frequency severe maternal HTN
OB History of Pre-eclampsia: Marker of future CV risk

- Pre-eclampsia increases risk of future cardiovascular disease
- Ischemic Heart Disease: 2-fold increase
- HTN: 4-fold increase
- Heart Failure

Strong association with preeclampsia & PPCM

Medications for HTN in Pregnancy

<table>
<thead>
<tr>
<th>First-Line</th>
<th>Second-Line</th>
<th>Hypertensive Crisis</th>
<th>Avoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nifedipine (I)</td>
<td>Calcium Channel Blockers (C) - Nifedipine</td>
<td>Nitroglycerin (oral, sublingual, topical)</td>
<td>Acesulf (E)</td>
</tr>
<tr>
<td>Losartan (C)</td>
<td>Metoprolol (C)</td>
<td>Lisinopril (C)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>\textit{Levosimendan} (C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrochlorothiazide (C)</td>
<td></td>
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</tbody>
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Heart Failure
28 yo with heart failure

1st visit to ACHD Clinic

1. Heart failure due to congenital heart disease, low EF
2. Complete AV Block
   - i/p dual chamber pacemaker
3. Pregnancy complicated by cardiac condition
   - Currently ~9 weeks pregnant.

Management

Termination of pregnancy advised
- High maternal mortality due to poor function
- High risk of fetal death or very preterm birth and neonatal mortality
- Termination declined by patient
24 weeks

Continued decompensation
IV diuretics
Inotropes
Delivery 600g infant due to maternal decompensation

Post-partum

Cardiogenic shock
Transferred to CCU

Pre-existing Cardiomyopathy

Increase Risk:
Prior event
mod-sev LV dysfunction
FC III-IV
Events following pregnancy in women with pre-existing cardiomyopathy

Women with CM face additional risk of cardiac events post-partum.

Structural and Congenital Heart Disease

Congenital Heart - usually ‘ok’

A3D, small VSD, repaired tetralogy of Fallot

Mild MvD PS

Mild A2 gradient

*Right HF, arrhythmias may require treatment
Pregnancy Contraindicated

- PAH, Eisenmenger
- LVEF < 30%, PC II-IV
- Marfan syndrome (Ao > 45mm)
- Severe MS, Severe AS
- COA with gradient
- Cyanotic CHD (fetal risk)

Valvular Heart Disease

- Mitral & Aortic stenosis
  - Fix before pregnancy if symptomatic moderate-severe
  - MS/AS - balloon valvuloplasty during pregnancy if needed

Valvular Heart Disease

<table>
<thead>
<tr>
<th></th>
<th>No sx/Mild</th>
<th>Mod-Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Stenosis</td>
<td>exclude aortopathy, AI</td>
<td>High risk CHF, arrhythmias</td>
</tr>
<tr>
<td>Mitral Stenosis</td>
<td>exclude significant MR</td>
<td>High risk CHF, arrhythmias</td>
</tr>
<tr>
<td>Pulmonary Stenosis</td>
<td>RV size, function</td>
<td>Right Heart Failure</td>
</tr>
</tbody>
</table>
Mechanical Valves

- Hypercoagulable state + Mechanical Valve = High complication Rate
- Prevention: Choose valve type prior to pregnancy, after informed discussion

If prevention fails - Mechanical Valve: Management

<table>
<thead>
<tr>
<th>1st trimester (6-12 wks) Outcomes*</th>
<th>12-20 weeks</th>
<th>20 weeks to LAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin if dose &lt; 5mg/day</td>
<td>Warfarin</td>
<td>Change to IV heparin*</td>
</tr>
<tr>
<td>LMWH** and Xa 4-6 iu post</td>
<td>Warfarin</td>
<td>C-section if still on warfarin</td>
</tr>
<tr>
<td>dose 0.8-1.2 iu/kg</td>
<td>UFM FTT &gt; 2x control</td>
<td>Warfarin</td>
</tr>
</tbody>
</table>

*Changes in anticoagulation should occur in hospital
**Do not use LMWH unless Xa levels are strictly monitored

35 yo, late 3rd trimester
chest pressure and shortness of breath
Causes of CP and/or Dyspnea in Pregnancy

- Normal pregnancy, OERD, RAD
- Heart Failure/Cardiomyopathy
- Acute Coronary Syndrome
- CADH or Dissection
- Aortic Dissection
- Pulmonary Embolism

Cardiac “Red Flags”

- Maternal Heart Disease, Aortopathy
- Family History:
  - sudden death
  - heart failure, HCM
- New cardiac symptoms or Exam findings:
  - elevated neck veins, gallop

Peri-partum Cardiomyopathy

- Presentation:
  - Late 3rd trimester or < 5 months post-partum
  - cough, dyspnea and fatigue
- Exam: JVD, tachycardia, S3 or S4 gallop
- Evaluation:
  - echo, CXR, consider thyroid function testing
PPCM
Treatment: standard HF management
Consider Anticoagulation
In-hospital and early mortality <5%
Spontaneous recovery occurs before 6 months (about 50%)
Highest mortality in the 1st 3 months

PPCM: Future Pregnancy
AVOID subsequent pregnancies if CM persists
Risk of recurrence even with return to normal cardiac function

 Coronary Artery Disease
Atherosclerotic
Coronary Dissection
Myocardial Infarction

ECG, Troponin
PCI
Deliver if possible
Clopidogrel if stent

Aortic Disease

Changes in the aortic media and vascular compliance
Increase in aortic diameter
Aortic dissection may occur during normal pregnancy

Aortic Dissection: Risk Factors

Marfan Syndrome (>40-45mm)
Unrepaired Coarctation of Aorta
Bicuspid Aortopathy > 45-50mm
Advanced Maternal Age
Tuberous Sclerosis
Other Aortopathies
Pulmonary Embolism

- Pregnancy Hypercoagulable state (up to 12 wks PP)
- Risk factors
  - Prior VTE, PM VTE, thrombophilia, age > 35, Obesity, Smoker, Co-morbidities
- Obstetric Risk factors
  - Pre-eclampsia, multi-gestation, c-section, prolonged labor, hemorrhage
  - Immobility, infection, Surgical procedure

- High Risk
- Intermediate Risk
- Low Risk

Clinical Factor | Management
---|---
1. Prior VTE (>1) | LMWH prophylaxis + Compression stockings
2. Venous-related VTE | LMWH prophylaxis + Compression stockings
3. Thromboprophylaxis/HH + single VTE | Consider anticoagulant LMWH prophylaxis + Compression stockings
3 or more risk factors | Consider anticoagulant LMWH prophylaxis + Compression stockings
2 or more risk factors + hospital admission | Mobilize “Avoid dehydrration”
< 3 risk factors | Mobilize “Avoid dehydrration”

Take-Home Points

Risk assessment BEFORE pregnancy & AFTER Conception
Contraceptive counseling for all women of childbearing age
At-risk patients need specialty evaluation
Fidel A. Valea, MD

Saturday, 11:20 am – 12:05 pm

DVT Prevention and Management
Venous Thromboembolic Prevention and Treatment

Fidel A Valea, MD
Professor and Chair, Department of Ob/Gyn
Virginia Tech Carilion School of Medicine

Disclosures

- Covidien (Medtronic) advisory board
- UpToDate author 3 sections
- Comprehensive Gynecology – Elsevier – Editor
- Gyn Onc Div member for ABOG

Learning objectives

- To outline the various risk groups for VTE.
- To summarize the recommended prophylaxis regimens
- To explain the concept of “extended prophylaxis” in the highest risk group
Virchow’s Triad

- Rudolf Ludwig Carl Virchow—German physician
- Father of Modern Pathology
- Given credit for the etiology of pulmonary thromboembolism

Epidemiology: VTE

- Estimated 2 million DVTs in US each yr*
- 33% of DVT develop PE with 60K deaths
- Case fatality rate of approx 12% and most deaths occur within 30 minutes!
- Without prophylaxis VTE rate after major Gyn surgery is 15 – 40%**
- Risk of VTE in cancer surgery with prophylaxis about 2%***

*ACOG Task Force Bulletin 84, 2007 (reaffirmed in 2016)
**Green WD et al, Chest 2004;125(suppl):3381–3405

Armstrong Institute for Patient Safety and Quality

Estimate that 70% of hospital VTE’s can be prevented with appropriate strategies
VTE Risk Factors

- Surgery
- Trauma
- Immobility, paresis
- Malignancy
- Cancer therapy
- Previous venous thromboembolism
- Increasing age
- Pregnancy and postpartum
- Oral contraception
- Hormone therapy
- SERMs
- Acute medical illness
- Heart or respiratory failure
- Inflammatory bowel disease
- Myeloproliferative disorders
- Paroxysmal nocturnal hemoglobinuria
- Nephrotic syndrome
- Obesity
- Smoking
- Varicose veins
- Central venous catheterization
- Inherited or acquired thromophilia

Prevention Strategies

Depends on level of risk

Low Risk:
- No risk factors
- Surgery lasting less than 30 minutes
- Age less than 40
- No recommended prophylaxis except for early ambulation

ACOG Practice Bulletin 84, August 2007, Reaffirmed in 2016

Moderate Risk

- Surgery lasting <30 min and:
  - Age 40-60 with no additional risk factors
  - Risk factors
- Major surgery in pts <40 y.o and no risk factors
- Recommended prophylaxis:
  - Low dose unfractionated heparin 5000u SQ q12h
  - Low molecular weight heparin
  - Graduated compression stockings
  - Intermittent pneumatic compression device

ACOG Practice Bulletin 84, August 2007, Reaffirmed in 2016
Prevention Strategies

High Risk

- Surgery lasting <30 minutes in:
  - Inpatients over 60
  - Additional risk factors
- Major surgery in patients >40 y.o.
  - With or without other risk factors!

Prophylaxis Recommendations:

- Unfractionated heparin preop and q8h
- LMWH preop and daily
- Intermittent pneumatic compression

ACOG Practice Bulletin 84, August 2007, Reaffirmed in 2016

Prevention Strategies

Highest Risk

- Major surgery in patients over 60 y.o. plus:
  - Prior history of VTE
  - Cancer
  - Molecular hypercoagulable state:
    - Factor V Leiden
    - Antithrombin III deficiency
    - Protein C deficiency
    - Protein S deficiency
    - Prothrombin gene mutation
    - Antiphospholipid antibody
    - Acquired hyperhomocysteinemia
    - Methyleneetetrahydrofolate reductase carriers

ACOG Practice Bulletin 84, August 2007, Reaffirmed in 2016

Prevention Strategies

Recommendations for Highest Risk

- Unfractionated heparin preop and q 8 h
- LMHW preop and daily
- Intermittent pneumatic compression devices plus:
  - Unfractionated heparin or LMWH
- Consider extending prophylaxis for 2-4 weeks after discharge!
  - Based on recommendations by ACCP Conference on Antithrombotic and Thrombolytic Therapy*

ACOG Practice Bulletin 84, August 2007, Reaffirmed in 2016

Graduated Compression Stockings (GCS) for the Prevention of DVT*

- 19 RCTs involving 1681 patients
- GCS applied prior to surgery worn up until discharge or until the patients were fully mobile
- majority used radioactive $^{125}$I-uptake test for DVT
- DVT: 9% GCS vs 21% none OR 0.33 (0.26 - 0.41) p < 0.00001
- PE: 2% GCS vs 5% controls OR 0.38 (0.15 - 0.96) p=0.04
- Note: the incidence is still a little high at 9%!
- Thigh high as effective as knee high**


Intermittent Compression Devices (ICDs)

- Sometimes called pneumatic compression devices
- Medline search 1970–2002: all publication relating to mechanical prophylaxis of DVT
- Evaluated: foot / calf / calf and thigh devices
- All ICDs produce changes in femoral vein velocity
- All are effective!
- Thigh length better to prevent proximal DVT (7.2% calf-length vs 2.4% thigh-length, P < 0.05)
- Foot length effective but needs higher pressures: 130 mm Hg vs 40 mm Hg for calf devices


Intermittent Compression Devices*

- 107 patients open surgery: Duke Gyn Onc service
- Calf-high ICDs preop and for 5 days
- impedance plethysmography and $^{125}$I-fibrinogen
- Results:
  - VTE 18/52 controls 34.6%
  - VTE 7/55 pts with ICDs 12.7%, p<0.005
- ICDs are effective in reducing incidence of VTEs
- Note: the rates of VTEs are still high!

Intermittent Compression Device Compliance*

- Prospective evaluation of C/S and Benign Gyn
- 859 observations in 228 patients
- 4-month study divided in monthly segments:
  - Month 1: baseline observation of compliance
  - Month 2: structured patient education
  - Month 3: Nursing education
  - Month 4: Both PT & nursing education
- No difference in compliance: 61.3%, 54.6%, 56.0%, and 60.1% (p<0.44)
- Non-compliance increased with each day: OR: 1.18 per day, 95% CI 1.07–1.30
- C/S 52.4% vs Gyn Surgery 66.2%, p<.001


Unfractionated Heparin for VTE prevention

- Numerous studies confirming the benefit
- Starting 2 hours prior to surgery and Q 12 hours for benign surgery*

2 hours prior and Q 8 hrs for Gyn Oncology**

- 304 pts: nothing vs 2 hrs prior and Q8h vs Q8h pre and post op
- h-fibrinogen for Dx and 84% had malignancy
- DVT 18.4% controls, 9.6% vs 6.2% p<0.008
- No increase in bleeding but more wound hematomas
- If used for more than 4 days: 6% HIT***

*Seerts WS et al, Chest 2004;126(suppl):3385–4005

Low-molecular weight Heparin for DVT prophylaxis

- LMWH has greater bioavailability and once daily dosing
- Longer half-life, more predictable pharmacokinetics
- Equivalent efficacy as heparin
- More anti-factor Xa and less antithrombin activity than unfractionated heparin
- May decrease medical bleeding and hematomas
- Heparin-induced thrombocytopenia is rarely observed with LMWH
- More expensive!
- Multiple trials support its reliability for prophylaxis
Types of Heparin Recommended for VTE Prophylaxis

- Low dose unfractionated heparin 5000 u S.C.
- LMWH: currently there are two:
  - Enoxaparin 40 mg S.C. daily
  - Dalteparin 5000 u S.C. daily
- Duration of therapy:
  - At least until out of the hospital or
  - Upto 4 weeks in the highest risk group!

LMWH vs ICDs for VTE Prevention*

- Duke Gyn Oncology Service
- 211 pts over 40 years of age
- 105 LMWH vs 106 ICDs
- Post op Dopplers and 30 day interview for VTEs
- Results:
  - 1.9% VTE in heparin group
  - 0.9% VTE in ICD group
  - No difference in bleeding or other complications

*Both modalities are reasonable in this high risk group of patients!

Prospective study on VTE after Cancer Surgery

- RISTOS project using LMWH
- 2373 patients undergoing surgery
  - 1238 (52%) undergoing general
  - 685 (29%) urologic
  - 450 (19%) gynecologic surgery
- In-hospital prophylaxis given in 81.6% pts
- Post-discharge prophylaxis in 30.7% of pts
- Incidence of VTE 2% in Gyn Surgery
- 40% of events occurred more than 21 days after surgery...
  - hence the recommendation for extended prophylaxis
- 46% of deaths attributed to VTE

*Agnew et al, Am Surg 2006;243:89-95
VTE prophylaxis in Gyn Surgery
Society of Gynecologic Surgeons Systematic Review Group

- 14 RCTs: 5 benign and 9 oncology
- Overall incidence of VTE 0-2% in benign group
  - Use of ICDs decreased VTE incidence to <1%
- Overall incidence in oncology 0-14.8%
  - 34.6% VTE with no prophylaxis
- Heparin vs ICDs both superior to placebo
- Could not differentiate heparin vs ICDs
- No VTEs in prospective studies of benign laparoscopic procedures!


VTE: TAH vs MIS for Endometrial Cancer*

- Prospective cohort NSQIP database 2008–2013
- 30 day post op VTE rate
  - 9,948 pts: 61.9% MIS and 38.1% TAH
  - VTE rates: MIS 0.7% vs TAH 2.2% p<0.001
- Note: VTE in LAP 2 were similar approx 2%**
- After adjusting for age, BMI, race, OR time:
  - MIS still associated with less VTEs
  - OR 0.36 95% CI 0.24-0.53


Dual Prophylaxis

- Cochrane review* of 19 studies heparin + GCs
  - Prevented 4X more VTE than heparin alone
    - OR 4.17 (95% CI1.37-12.70)
- Separate RCT in 307 neurosurgical patients**:
  - LMWH + GCs vs GCs alone
  - 84.5% had adequate venograms
  - 17% vs 32% RR 0.52 (0.33 - 0.82) p=0.004
- No great data from RCTs in Gyn Onc
- Dual prophylaxis in the highest-risk patients, recommended by the 7th ACCP Consensus Conference in 2004

**Aquilina G et al. Nafagaheh 1998;389:80-5. (Level I)
Extended Prophylaxis*

For the highest risk group
- Patients with cancer who develop a VTE:
  - 40% will do so more than 21 days after surgery**

ENOXACAN II Trial:
- Patients undergoing cancer surgery
- LMWH prophylaxis for 1 week vs 4 weeks
- 60% reduction of VTEs with 4 weeks of therapy compared to 1 week!
- Also confirmed by U of Wisconsin in Gyn Onc

**Appel S et al. Am Surg 2006;243:89-95, (Level II)

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Summary VTE Prophylaxis

- Low risk (minor procedures no risk factors):
  - Early ambulation
- Most Gyn surgeries even with some risk:
  - Pick one: LMWH vs Heparin vs ICDs... start preop!
- Higher risk:
  - Consider dual prophylaxis vs single method
- Highest risk group:
  - Dual prophylaxis with extended prophylaxis to 4 wks!
- Spinal/Regional:
  - Hold heparin for 8-12 hrs
  - Hold LMWH for 18 hrs

ACOG Practice Bulletin 84, August 2007, Reaffirmed in 2015

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VTE Treatment Principles

- Why do we treat DVTs?
  - Prevent pulmonary embolism (PE)
  - Reduce morbidity
  - Prevent/minimize the risk of developing post-thrombotic syndrome (PTS) (20-50% of pts with DVT)

Options:
- Heparin
- LMWH
- Vit K antagonists, warfarin
- Factor Xa inhibitors
- Direct thrombin (IIa) inhibitors
- 3 months of therapy for uncomplicated DVT/PE
Vit K antagonists vs LMWH for VTE

Cochrane Database
- Traditional: LMWH/Heparin for 5 days then VitKα X 3 mo
- 16 trials with 3259 pts
- No diff in recurrent VTE: OR 0.83 (0.60 - 1.15) p = 0.27
- LMWH, less bleeding: OR 0.51 (0.32 - 0.80) p = 0.004
- No diff in mortality: OR 1.08 (0.75 - 1.56) p = 0.68

Conclusion:
- Perhaps less bleeding with LMWH
- LMWH an alternative for those that don’t want regular blood testing or with contraindications for VitKα

Andras A et al. Cochrane Database of Systematic Reviews 2017, Issue 7

Direct IIa inhibitors vs Xa inhibitors for the acute treatment of DVT*

11 RCTs of 27,945 pts.
- 3 studies with 7596 pts: evaluating DTIs (dabigatran and ximelagatran)
- 8 studies with 16,356 pts: oral factor Xa inhibitors (rivaroxaban, apixaban and edoxaban)

Results DTI vs Heparin/LMWH (no difference):
- recurrent VTE OR: 1.09 (0.80 - 1.45)
- recurrent DVT OR: 1.08 (0.74 to 1.58)
- fatal PE OR: 1.00 (0.27 - 3.70)
- non-fatal PE OR: 1.12 (0.66 - 1.90)
- associated with reduced bleeding OR: 0.68 (0.47 - 0.98)

*Robertson I et al. Cochrane Database of Systematic Reviews YR: 2015 No: 6

Direct IIa inhibitors vs Xa inhibitors for the acute treatment of DVT*

Results Xa inhib vs Heparin/LMWH (no diff)
- recurrent VTE OR: 0.89 (0.73 - 1.07)
- fatal PE OR: 1.20 (0.71 - 2.03)
- non-fatal PE OR: 0.94 (0.68 - 1.28)
- all-cause mortality OR: 0.84 (0.64 - 1.11)
- lower recurrent DVT OR: 0.75 (0.57 - 0.98) weak assoc
- Less bleeding OR: 0.57 (0.43 - 0.76)

Conclusions: New oral anticoagulants: DTIs and factor Xa inhibitors may be an effective and safe alternative to conventional anticoagulation treatment for acute DVT.

*Robertson I et al. Cochrane Database of Systematic Reviews YR: 2015 No: 6
What about Post-Thrombotic Syndrome

- 100 consecutive patients with DVT
- 39 treated with warfarin and 61 with rivaroxaban
- Assessed signs and Symptoms of PTS
- Also calculated Villalta score median 23 months
- Results:
  - Rivaroxaban: less PTS than (25% vs 49%, p=0.013)
  - Adjusted odds ratio: 3.5 (1.1-11.0, p=0.035) for warfarin
- Conclusions: Treatment of DVT with rivaroxaban might be associated with a lower risk for PTS development

Summary of VTE treatment

- Must treat at least 3 months
- There is a benefit up to 12 months
  - Duration is dependent on patient factors and it needs to be individualized
- No benefit past 12 months.
- More research is needed to figure out duration of therapy

Thank you... Dr Cyril Otis Spann, Jr and the Georgia Ob/Gyn Society
Faculty Presentations

Sunday, August 27, 2017
Paul Weathington, JD

Sunday, 7:30 – 8:35 am

Current Trends in OBGyn Litigation
Current Trends in OB/GYN Lawsuits (and How to Survive One)

BY PAUL WEATHINGTON

Intended Learning Objectives

- Top Causes of Malpractice Litigation (and What Can be Done to Reduce Risk)
- Hot Areas of Medical Liability within OB/GYN
- Tips for Providing Care with Litigation / Risk-Management in Mind
- Case Studies to Learn From / Avoidable Mistakes
Financial Disclosures

- No Disclosures

Top Five Causes of Malpractice Litigation

- Bad outcomes
- Poor communication
- Bad charting
- Poor bedside manner
- Bad responsiveness

Bad Outcomes
Poor Communication

We had failure of communication...

Bad Charting

Know Your Anatomy

Do you have pain? yes [x] no []
If answering YES to pain, complete the following:
Location of pain: back/testicles
Bad Charting

Make Timely Entries

DATE OF EXAMINATION: 06/19/2020
DATE OF DISCHARGE: 06/22/2020

We will return to the office in approximately two weeks for a final status review and a steroid course.

Slipped disc

Discharged to home.

Signature.

Signed by:

[Signature]

Bad Charting

This little piggy went to surgery....
...Or not??

Consent To Surgical, Therapeutic Or Diagnostic Procedure

Parent... (A) He/She signed and understood that the following procedure which has been performed on the patient...

[Signature]

Bad Charting

Operative Report

1. Hemostasis, fixation contractures of the right big toe.
2. Hemostasis, fixation contractures of the right big toe.
3. Hemostasis, fixation contractures of the right big toe.
4. Hemostasis, fixation contractures of the right big toe.
Bad Charting

Letter 8 months later:

As you can see, on the last office visit, the patient had no complaints at all in regard to her metatarsals from the previous surgery.

The patient’s complaint, at that point, was in regard to her big toe. The big toe was one where the patient had previous surgery, from her podiatrist, for, again, bunionectomy and osteotomy. This first ray was not touched at all in my surgery.

Bad Charting

Altered Record??

Bad Charting

The Blame Game

Appendix: The patient’s CT scan showed persisting fluid collection unchanged since previously. Therefore, it was not adequately drained. Her white count was 28,000. This did not become apparent until the following day because it was drawn at Quest Diagnostics. The patient was seen in the office and admitted for further evaluation and treatment. She was seen by the infectious disease consulted the same day. The next morning, she required admission of her pancreas, which led to a prolonged hospital course eventually resulting in death.
Bad Charting

Don’t Lie!

Discussion:
This would explain why she is not any better. I told
another doc, causing her problem and that would explain why she is no better. I would
examine the various imaging studies and get back to them on Friday. I did not tell them that
we expected on the way home. Will discuss the situation with!

... and make sure decisions as to where we go from here. There is no mention that we are going to have to go
back in on her. The question is whether the family will be willing to allow us to do that.

Bad Charting

Been there, done that.

There are some very complicating factors to this case, the first of
which is of course is that Dr. was the same doctor who had previously removed
the gallbladder that he was attempting to remove the second time in this incident with

Bad Charting

So what’s YOUR nickname?

July 3, 2002

REF. ROSE ANN

July 3, 2003

REF. ROSE ANNOYANCE

History:
Erect in hock, contin... She is again constant means poor right and hip with

... hip, which is not good, but there is still a bowel reflex in the floor, and she has

... as well as back pain from her spinal surgery.
Poor Bedside Manner

'Just shut up and take the lollipop.'

Bad Responsiveness

And he said, well, I was just giving you thumbs up that was going to be okay. She said, oh, I was just wondering because she was on life support. Jr. toured at me and he said, wait a minute. He said, do you really think I let you in?
Surviving a Swim with the Sharks—What to Expect if You’re Involved in a Lawsuit

- Common causes of malpractice litigation in perinatal cases:
  - “Bad baby” cases, shoulder dystocia, maternal issues (e.g. hemorrhage, retained products, amniotic fluid embolism)

Obstetrical Liability: An Overview

- Infant Brain Injury: A Common and Costly Allegation
  - Advances in Defending Brain Damages Claims
  - Placental Examination
  - ACOG Task Force (discussed later in presentation)

Obstetrical Liability: An Overview

- Court Opinions: Common Themes
  - Failure to Establish and Use Reporting Channels
  - Failure to Obtain Informed Consent
  - Failure to Properly Monitor
  - Failure to Provide Timely Notice to Physician
  - Failure to Supervise Nursing Personnel
Obstetrical Liability: An Overview

- Action Recommendations:
  - Develop review, and revise policies and procedures that reflect current guidelines.
  - Communicate policies to nursing and medical staff.
  - Back to basics: staff training, effective communication, documentation, adequate supervision.

Technology Overview: Obstetrics and Neonatal Care

- Apgar Monitors
- Fetal Monitors
- Birthing Beds
- Breast Pumps
- Circumcision Clamps
- Infant Incubators and Infant Transport Incubators
- Infant Scales
- Neonatal Intensive Care Ventilators
- Neonatal Physiologic Monitoring Systems
- Obstetrical Forceps
- Obstetrical Ultrasound Data Analysis Systems
- Obstetric Vacuum Extractors
- Phototherapy Units
- Radiant Warms
- Ultrasounds Fetal Heart Detectors

Fetal Monitoring

- Monitoring Techniques
  - Electronic Fetal Monitoring
  - Auscultation

- Standards and Guidelines for Fetal Monitoring
  - Method
  - Frequency
  - Documentation
Fetal Monitoring

- Interpreting Fetal Heart Rate Data
  - Baseline Rate Changes
  - Baseline Rate Variability
  - FHR Accelerations and Decelerations
  - Signs of "Nonreassuring Fetal Status"
  - Patient Management

Fetal Monitoring

- Liability Issues Related to Fetal Monitoring
  - Common Allegations:
    - Inadequate Monitoring
    - Failure to Properly Interpret FHR Data
    - Failure to Communicate to Physician
    - Failure to Supervise
    - Improper Monitoring during Oxytocin Administration

Fetal Monitoring

- Action Recommendations:
  - Make sure your nurses are adequately trained to notice EFM patterns.
  - Ensure chain of command is clearly established for prompt communication of problems to the physician.
  - When possible, ensure policies and procedures for fetal monitoring are current.
  - When possible, provide, obtain, and verify continuing education and competency in fetal monitoring.
Delaying Preterm Labor

- Background and Definitions
- Identifying Patients at Risk for Preterm Labor
- Educate Patients to Identify and Report Warning Signs
  - Genetic Factors
- Preventing Preterm Labor
  - Home Uterine Activity Monitoring
- ACOG Guidelines for Management of Preterm Labor
- Risks and Benefits of the Use of Tocolytic Agents in Preterm Labor

Delaying Preterm Labor

- Six Risk Factors Associated with Preterm Birth:
  1. Historic risk factors and demographics
  2. Stressors
  3. Inflammation
  4. Hemorrhage
  5. Pathologic distension of the uterus
  6. Maternal Illnesses

Delaying Preterm Labor

- Action Recommendations:
  - Establish objective criteria for diagnosing preterm labor.
  - Assess all pregnant patients’ risk of experiencing preterm labor.
  - Educate patients about the signs, symptoms, and significance of preterm labor.
  - Educate patients about when to notify their healthcare provider if they believe they are experiencing preterm labor.
**Placental Examinations**

- Medicolegal Defense
- Claims Statistics
- Additional Applications
- Acceptance by the Healthcare Community
  - ECRI Fax Survey
  - Standards and Guidelines
- Outsourcing and Placental Registries
- Policies and Procedures

**Placental Examinations**

- Action Recommendations:
  - Perform placental exams and retain specimens as necessary.
  - Develop an interdisciplinary protocol for placental examinations (hospital driven).
  - Develop policies and procedures for retaining placental specimens (often hospital driven).
  - Communicate clinical information to the pathologist:
    - reason for submission of specimen,
    - infant’s weight,
    - gestational age,
    - Apgar scores,
    - assessment of amniotic fluid volume,
    - any specific questions that need to be addressed,
    - name of delivering physician,
    - name of infant’s pediatrician.

**Neonatal Group B Streptococcus**

- Case Law
- Incidence and Risk Factors for GBS Disease
- 2002 and 2010 (update) CDC Guidelines
  - Threatened Preterm Delivery
  - Management of Newborns
- FDA-Approved Rapid Test for GBS
- Laboratory Issues
Neonatal Group B Streptococcus

- Action Recommendations:
  - Adopt antibiotic strategies based on the most recent guidelines and recommendations from the CDC, ACOG, AAP, and ACNM.
  - Inform pregnant women of the GBS strategy used at the hospital.
  - Facilitate timely communication of GBS results.
  - Ensure that any variances from recommended regimens and the justifications for the variances are well-documented.

Shoulder Dystocia

- Incidence Rates and Claims Statistics
  - Claims Studies

- Risk Factors and Preventability
  - Fetal Macrosomia
  - Previous Incidence for Mom
  - Others (Diabetes, etc.)

- Documentation and Consent
  - Documenting Maneuvers

- Birth Videos

- Emergency Planning

Shoulder Dystocia

- Action Recommendations:
  - Make sure clinicians are “on alert” when known risk factors are present. Be prepared for appropriate therapeutic maneuvers.
  - Consider and prepare for cesarean delivery when necessary.
  - Ensure all practitioners are prepared to manage shoulder dystocia.
  - Have a plan for emergency management of shoulder dystocia.
  - Document maneuvers, including order, degree of difficulty, and time frame.
Obstetrical Data Management Systems

- Components of an OBDMS
  - Workstations
  - Computer Network
  - Device Interfaces
  - Optical Storage Devices

- Functions of an OBDMS
  - Surveillance
  - Documentation (Charting)
  - Formats and Functions
  - Remote Information Access
  - Record Archiving

Obstetrical Data Management Systems

- Prenatal Monitoring, Testing, and Documentation
- Intrapartum Monitoring and Documentation
  - Maternal Status
  - Fetal Status
  - Progress of Labor
- Postpartum Monitoring and Documentation

Vaginal Birth after Cesarean (VBAC)

- Identifying and Assessing the Clinical Risks
- ACOG and JCAHO Accreditation Standards
  - The "Immediately Available" Recommendation
  - JCAHO Accreditation Standard
- Inducing Labor in Patients Attempting VBAC
  - Assessing Labor and Diagnosing Uterine Rupture
- Identifying the Legal Risks
  - Informed Consent
  - The Patient's Perspective
  - Documentation of Informed Consent
Vaginal Birth after Cesarean (VBAC)

- Juries' Perspectives in VBAC Malpractice Cases:
  
  $$$$$

Vaginal Birth after Cesarean (VBAC)

- Action Recommendations:
  - When possible, assess whether facility has adequate staff and equipment to meet ACOG and JCAHO standards for facilities offering VBAC.
  - Ensure that staff is trained and skilled in recognizing signs and symptoms of uterine rupture.
  - Evaluate the immediate availability of obstetricians, anesthesia, pediatrics, nursing staff, and equipment in case an emergency cesarean section is necessary.

Identifying and Managing Jaundice in Newborns

- Kernicterus on Trial: A Case Study
- Jury Verdicts and Settlements
  - Case #1
  - Case #2
  - Case #3
Identifying and Managing Jaundice in Newborns

- Action Recommendations:
  - Raise awareness of potential risks of bilirubin encephalopathy and kernicterus.
  - Ensure proper protocols are followed for nursing assessment of jaundice.
  - Educate expectant parents about neonatal jaundice.

ACOG Task Force on Neonatal Encephalopathy and Cerebral Palsy

- Mary E. D’Alton, MD, Chair of the task force / Maternal-Fetal medicine specialist at Columbia University Medical Center in New York:
  - “We know that neonatal encephalopathy is a brain disorder with a variety of causes. Metabolic disorders, infections, genetic conditions, and oxygen deprivation to the infant are all potential causes, but we don’t know how many cases are preventable. By doing a root-cause analysis, we hope to identify issues that may help prevent some cases of neonatal encephalopathy in the future.”

ACOG Task Force on Neonatal Encephalopathy and Cerebral Palsy (continued)

- In the first edition of this report, the Task Force on Neonatal Encephalopathy and Cerebral Palsy outlined criteria deemed essential to establish a causal link between intrapartum hypoxic events and cerebral palsy.
- It is now known that there are multiple potential causal pathways that lead to cerebral palsy in term infants, and the signs and symptoms of neonatal encephalopathy may range from mild to severe (depending on the nature and timing of the brain injury).
- Thus, for the current edition, the Task Force determined that a broader perspective may be more fruitful.
- This conclusion reflects the “wider recognition” that knowledge gaps still preclude a definitive test or set of markers that accurately identifies, with high sensitivity and specificity, an infant in whom neonatal encephalopathy is attributable to an acute intrapartum event.
ACOG Task Force on Neonatal Encephalopathy and Cerebral Palsy (continued)

- Neonatal Signs Consistent with an Acute Peripartum or Intrapartum Event
  - Apgar score < 5 at 5 and 10 min confer increased risk of CP
    - if Apgar at 5 min < 7, unlikely that peripartum hypoxia-ischemia played a major role in NE
  - Fetal Umbilical Artery pH < 7 (or base deficit > 12 mmol/L) or both
  - if the cord arterial gas pH levels are < 7.20, unlikely that intrapartum hypoxia played a role in NE
  - Distinct Patterns of Neuroimaging Abnormalities (obtained after first 24 hours of life) optimal taken at 30 days, with acceptable window 5-21 days will best delineate full extent of cerebral injury
  - Presence of Multi-system Organ Failure

ACOG Task Force on Neonatal Encephalopathy and Cerebral Palsy (continued)

- Type/Timing of Contributing Factors Consistent with Acute Peripartum or Intrapartum Event
  - Sentinel Hypoxic or Ischemic Event immediately before or during L&D
    - Ruptured uterus
    - Severe abruptio placentae
    - Umbilical cord prolapse
    - Amniotic fluid embolus with coincident severe and prolonged maternal hypotension and hypoxemia
    - Maternal cardiovascular collapse
    - Fetal exsanguination from vasa previa or massive fetomaternal hemorrhage

ACOG Task Force on Neonatal Encephalopathy and Cerebral Palsy (continued)

- Fetal Heart Rate Monitor Patterns Consistent with an Acute Peripartum or Intrapartum Event
  - Category I or II fetal heart rate tracing (when associated with Apgar < 7 or higher at 5 min), normal umbilical cord arterial blood, or both is not consistent with an acute hypoxic-ischemic event
  - Great distinction b/w patient presenting w/abnormal FHR pattern and one who develops abnormal FHR pattern during labor
  - Category II FHR pattern lasting 60 min or more (disturbance on initial presentation w/minimal or absent variability and lacking accelerations) is suggestive of a previously compromised or injured fetus
  - Patient who presents w/Category I FHR patterns that converts to III is suggestive of a hypoxic-ischemic event
ACOG Task Force on 
Neonatal Encephalopathy and Cerebral Palsy (continued)

- Timing and Type of Brain Injury Patterns Based on Imaging Consistent w/Etiology of Acute Peripartum or Intrapartum Event
  - Will not often reveal abnormalities in first 24-48 hours after injury
  - MRI between 24-96 hours of life proves most useful on potential timing of cerebral insult (cerebral abnormalities most prominent after 7 days from injury)
  - 2 MRIs, one b/w 24-96 hours and a 2nd at Day 10 or later, will assist with full delineation of nature and extent of cerebral injury

ACOG Task Force on 
Neonatal Encephalopathy and Cerebral Palsy (continued)

- No Evidence of Other Proximal or Distal Factors that could be Contributing Factors
  - Abnormal fetal growth, maternal infection, fetomaternal hemorrhage, neonatal sepsis, chronic placental lesions make acute intrapartum event as sole pathogenesis of NE less likely

Danger Zones— Primary areas of malpractice in obstetrics

- "Bad baby cases"—Brain injured babies— labor and delivery — EFM cases — failure to timely perform C-section, etc.
- Shoulder dystocia cases: brachial plexus injuries.
- Injuries from operative delivery: forceps, vacuum trauma type cases.
- VBAC issues: uterine rupture, etc.
- Maternal injury cases: preeclampsia, edema, hemorrhage, DIC, anesthetic fluid embolism.
- GYN issues: cervical cancer, breast cancer, etc.
- Surgical complications: laparoscopic misadventures.
Tips that will help prevent a lawsuit or strengthen your case if you are sued

- Communication issues between L&D nurses and MD.
- Communication issues between OB and anesthesia.
- Key issue is recognition and interpretation of Fetal Monitoring Strip and uterine activity by nurses, and communication to the MD.
- The nurses have the chart at their side and the MD is often “hung” by what the nurses chart if the MD does not make timely entries.

Example of vague nurse charting

- “Doctor aware of fetal heart rate pattern.”
- “Called MD. MD aware of status.”
<table>
<thead>
<tr>
<th><strong>Best Practices for avoiding or defending cases of failure to recognize a non-reassuring EFM</strong></th>
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<tbody>
<tr>
<td>• Document each and every time you are at the bedside.</td>
</tr>
<tr>
<td>• Narrative notes are best – write notations on the EFM itself if need be.</td>
</tr>
<tr>
<td>• Document interpretation of the strip, uterine activity, analysis of patient’s condition, and plan of care.</td>
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<tr>
<td>• New informed consent when plan of care changes from prior plan.</td>
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<table>
<thead>
<tr>
<th><strong>Tips for avoiding lawsuits (continued)</strong></th>
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</thead>
<tbody>
<tr>
<td>• Be aware of and comply with established protocols (Pitocin, inductions, Mag sulfate, etc.).</td>
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<tr>
<td>• Timely dictate/document op notes, discharge summaries, etc.</td>
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<tr>
<td>• Obtain cord blood and placental pathology – These results may go a long way in proving that birth injury was not from perinatal hypoxia.</td>
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<thead>
<tr>
<th><strong>Tips for avoiding lawsuits (continued)</strong></th>
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<tbody>
<tr>
<td>• Develop and maintain excellent working relationships with hospital staff, namely L&amp;D nurses; work as a team to avoid “angry charting,” etc. – Example: “Finally able to reach Dr. XXXX.”</td>
</tr>
<tr>
<td>• Have open dialogue with patient and family after adverse event– Georgia’s “apology statute” protects virtually any statement of mistake, regret, etc. from use against the MD or nurse.</td>
</tr>
<tr>
<td>• Be aware of 36 minute decision to section standard.</td>
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<tr>
<td>• Be aware of ACOG guidelines on perinatal management issues.</td>
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Poor Responsiveness

Example of a Train Wreck Case

- Factual scenario: Spanish only speaking mother – desires a VBAC – EFM shows fetal tachycardia beginning around 5 pm – MD discusses C/S a couple of times, is concerned about strip but leaves patient to go to doctors lounge while she pushes and strip deteriorates – Then, his documentation of times in his op note/discharge summary is inconsistent with documentation throughout the record.

- Result: Severely neurologically damaged baby and settlement > $2.5 million.

- Avoidable Mistakes: Document "recommendation for C/S" – not just discussion and documentation of patient refusal.
Deposition Transcript:

- Q. Okay. So you've got this patient who you're concerned because she's got a non-measuring trace, with a repeat non-measuring trace. Do you know what this means? Do you think she needs an ultrasound? Do you think she needs to have a conary section? Do you think she needs to go to the doctors lounge?
  - A. Uh-huh (affirmative).
  - Q. Okay. Do you think she's pregnant or may be pregnant soon? Is that your opinion?
  - A. Uh-huh (affirmative).
  - Q. Okay. So you think the baby may be in danger or may be in danger soon? Is that for sure?
  - A. Uh-huh (affirmative).
  - Q. Okay. So what were you doing in the doctors lounge?
  - A. I was sitting there, I don't know exactly what I was doing. They have a TV, they have a computer, or whether I was resting because, you know, it was the end of the day, and I was tired. Now, do you think she was using the computer, correct?
  - A. Any of those could be possible, yes.

Inconsistent entries

<table>
<thead>
<tr>
<th>DATE</th>
<th>FOR</th>
<th>CURRENT Activity</th>
<th>MEDICATION</th>
<th>NEW NOTE ORDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/23</td>
<td>36</td>
<td>Smaller inconsistent medical records</td>
<td>X-met - 75mg</td>
<td>Non-vaccine</td>
</tr>
<tr>
<td>12/24</td>
<td>75</td>
<td>Small inconsistent medical record</td>
<td>X-met - 75mg</td>
<td>Non-vaccine</td>
</tr>
</tbody>
</table>

[Additional information or notes related to inconsistent entries]

[Further details or comments on inconsistent entries]
Avoidable Mistakes

- Failure to document AMA or to obtain an alternate physician.
- Don’t leave the patient’s bedside if you are concerned that an emergency C-section may be necessary.
- Be careful when dictating notes to get times accurate as seconds/minutes count in these cases.
Issues in Shoulder Dystocia Cases

- Very high percentage of OB litigation is shoulder dystocia.
- Documentation of risks and consideration of same — prior SD; macrosomia; estimated fetal weight; rotation; delayed second stage; failure of descent.
- Avoidance of fundal pressure as opposed to suprapubic pressure and documentation of same.
- Documentation of maneuvers and sequence of same when SD encountered.

Maternal Injuries

- Preeclampsia/eclampsia issues: document blood pressures, edema, uric acid.
- Be aware of ACOG guidelines for classification and treatment.
- Don’t wait to look for late signs such as visual disturbance, headache, neurological change — may be too late.
- Hemorrhage — be aware of blood loss, H&H changes, risks such as vascular injuries during C-section.
- Infection — Group Strep A; necrotizing fasciitis.

General GYN Issues

- Breast/cervical cancer cases: Document abnormalities and document need for increased surveillance and proof of information to patients regarding return visits, etc.
- Importance of tickler systems for abnormal labs, missed appointments, etc.
**Tort Reform (as exists currently)**

- No Cap on damages: $350,000 cap was short lived.
- Expert witness rules tightened up: specialty of defendant is not the determining factor—overlap allowed.
- Malpractice question: is expert doctor sufficiently familiar with condition or procedure at issue?
- Joint and several liability gone: Apportionment leads to more finger pointing.
- Emergency medical care protected by “Gross Negligence standard” (at least for now): applies to Ob/Gyn care rendered immediately after patient being in ER.

**General Issues**

- Excellent documentation and communication may avoid suit even where there is a disastrous outcome, or at least make the suit more defensible.
- Knowledge of and compliance with protocols, guidelines, and evidence-based medicine decreases the likelihood of poor outcomes and provides good defense if a suit is filed.

**ABC’s of an Effective Deposition**

A. **Prepare, prepare, prepare.** Review all pertinent medical records in the case so you have a clear, chronological understanding of the case you provided. Also, review the pertinent legal documents, such as the plaintiff’s complaint, any expert affidavits, or your responses to any written questions (interrogatories) that may have been generated prior to your deposition.

B. **Tell the truth.**

C. **Never guess or speculate.** “I don’t know” and “I don’t remember” may be the best response if you are unsure of the answer.

D. **Never answer a question you do not understand; rather, make the opposing attorney repeat or restate the question.**
ABC’s of an Effective Deposition

E. Answer only the question asked. Do not volunteer information. You are not there to educate the other lawyer or persuade the other side that your case was appropriate. The time for educating others and persuading people is at trial, not in your deposition.

F. Answer the question succinctly. Even if the attorney sits and stares at you after you have finished your answer, do not feel compelled to offer any additional testimony.

G. Do not let the plaintiff’s attorney put words in your mouth. Avoid of questions that misstate your testimony or the facts of the case, and do not assent to any summary, paraphrase, or other statement by the plaintiff’s attorney that does not exactly match your testimony.

H. Pause before answering. Take your time and always think about the question being asked before you begin your answer. There are no points for speedy replies.

I. Do not think out loud.

J. Listen to your attorney’s objections. These will be cues as to whether or not you should answer. If there are any problematic areas of your personal, educational, or employment background, discuss these with your attorney before your deposition.

K. Be professional at all times. Do not express anger, joke around, or use unprofessional language during your deposition.

L. Don’t think you can speak “off the record.” Your deposition is a significant, formal proceeding even though neither the judge nor jury is present.

M. Always review the document about which you are questioned, such as a medical record, before you begin your response.

N. Dress professionally and conservatively.

O. Never show or express indifference about the patient, the lawsuit, the circumstances giving rise to the lawsuit, or the legal process.
ABC's of an Effective Deposition

P. Ask for breaks as necessary or when you need to confer with your attorney.

Q. Do not give legal conclusions; do not make statements such as "that is not relevant."

R. Do not volunteer to supply any documents requested by the plaintiff’s attorney.

S. Do not concede that any particular text or journal is authoritative.

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ABC’s of an Effective Deposition

T. Be reluctant to agree with anything the plaintiff's lawyer says. Never forget that the plaintiff's lawyer's job is to prove you were negligent.

U. Do not let the questioner interrupt your answer. Simply state that you have not finished your answer to the previous question, and then complete your answer.

V. Do not panic if you are caught in an inconsistency or backed into a corner that is not helpful to your defense. If an inconsistency comes to your attention, simply state, if asked, your present recollection and the reason for the inconsistency.

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ABC’s of an Effective Deposition

W. Remember that any hypothetical questions are really questions about the patient. The plaintiff's attorney may ask you to assume certain facts as true, and then have you give an opinion about what type of medical care should have been rendered to the hypothetical patient. Make sure you have sufficient facts to form an opinion based upon the hypothetical.

X. Summarize complicated events where possible. If you are asked a question about a complex series of events, like "what happened next?” or "tell me everything Dr. X told you,” summarize where possible. If asked "is that all?” feel free to explain that you have answered according to your present recollection.

Y. If your deposition will be videotaped, dress appropriately, turn off your cell phone, face the camera, avoid eating or drinking, and be aware of your body language.

Z. Get a good night’s sleep and be on time.
ABC's of an Effective Deposition

- Medicine is not an exact science; countless factors determine the care and treatment of each individual patient.
- You cannot “win” your deposition, so don’t feel pressured to do so.
- Remember that only you were there, and only you saw, examined, and treated the patient.

Thank you

Paul E. Weathington
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Atlanta, Georgia 30303
404-524-1500
Haywood L. Brown, MD

Sunday, 8:40 – 9:25 am

Redefining Postpartum Care
Redefining Postpartum Care

Haywood L. Brown, MD
President ACOG, 2017-2018
Professor of Obstetrics and Gynecology
Duke University
Durham, NC

Objectives

• At the conclusion of this presentation the participant should be able to:
• 1. Describe the essential elements relevant to postpartum counseling and education
• 2. Perform essential screening including for depression.
• 3. Discuss a reproductive life plan and long term health implications for this with pregnancy complications.

Redefining Postpartum Care

• Disclosures

• none
"Origin of the Postpartum Visit?"

- When Israelite women gave birth, they were considered ceremonially unclean for a time. At the end of that time, a burnt offering as a cleansing sacrifice was to be presented. All were thus reminded that imperfect, sinful life had been passed on. The infant Jesus was perfect and holy. (Luke 1:35)

Postpartum Care

- ACOG recommends that all women should attend a postpartum visit 4-6 weeks following a birth.
  - As many as 40% of women do not have postpartum follow up
  - Attendance lower for women with limited resources

Postpartum Visit

- Ramification of lack of postpartum follow-up
  - Contributes to health disparities
    - Prematurity, infant mortality
    - Pregnancy spacing
    - Early breast feeding discontinuation
  - Undiagnosed postpartum depression and anxiety disorders
Postpartum Visit

- Postpartum Care (The Fourth Trimester)
  - A time of adaption (rapid hormone changes)
  - Physical
  - Social
  - Psychological
- Challenges
  - Fatigue,
  - Breastfeeding
  - Learning to care for a newborn
  - Navigating preexisting health conditions

Postpartum Visit

- Hospital discharge planning and care coordination
  and health care navigation
- Critical for those with preexisting health conditions
  - Hypertension, diabetes, substance abuse

Why is contraception counseling at hospital discharge important!

- Many patients don’t return for their postpartum visit
- Ideally counseling about methods occurs at the prenatal visit, but should be planned at
  the time of hospital discharge following delivery
- Ideal Pregnancy Intervals
  - Recommendation to have 18 months before becoming pregnant after C-section
  and 12 months after vaginal delivery
Why is contraception important in the postpartum period?

- About 25% of women are having intercourse before their 6 week visit (by 7 weeks this jumps to 60%)
- Most first menstrual cycles are anovulatory, but not all are...
- For Bottle Feeders average menses occurs in 8 weeks with average first ovulation ~ 10 weeks. With ovulation preceding 20% of 3rd cycles but >90% 2nd cycles!

Contraception High Risk Gravida

- Special Considerations
  - Chronic diseases
  - Hypertension, diabetes, obesity
  - Contraindications to estrogen
    - Coagulation disorder, history of or high risk for thromboembolism
  - Age and Parity
    - Patient reliability (adolescence, pregnancy spacing)

Breastfeeding
Breastfeeding

- Lactational Amenorrhea – prolactin inhibits pulsatile GnRH release
- Criteria for LAM
  - Less than 6 months
  - Exclusively breastfeeding
  - No period

Long Term Health Impact: Less Obesity

- BF infants self regulate intake volume
- Early programming of self regulation
- Less adult weight gain

Liu et al. Do infants fed from bottles lack self regulation of milk intake compared with directly breastfed infants? Pediatrics 2010, 125(6)

Long Term Health Impact: Diabetes

- 30% reduction in the incidence of Type 1 DM for infant exclusively BF for at least 3 months
- 40% reduction in the incidence of Type 2 DM
  - May reflect long term positive effect of breastfeeding on weight control & self regulation
Breastfeeding Financial Benefits

- $578 million per year in federal funds is spent by the WIC programs to buy formula for babies who are not breastfeeding.
- Every 10% increase in the breastfeeding rate among WIC recipients would save WIC $750,000 per year.
- $3.6 to $7 billion excess is spent every year on conditions and diseases that are preventable by breastfeeding.

BF and Progesterone Methods

- No evidence that progesterone only methods decrease milk supply or quality and may even enhance milk production.
- Theoretically, the fall in progesterone levels triggers lactogenesis.
- The CDC recommends that these methods can be used without restriction in the immediate postpartum period.

BF and estrogen containing Methods

- Mixed data on effects on milk supply.
- May suppress milk production in the early postpartum period.
- CDC recommends waiting 30 days if no increased VTE risk.
- ACOG – 4 weeks, only if milk supply well established.
- WHO – wait 6 months.
Depo Provera
- Immediate postpartum then every 3 months
- Vaginal Dryness/Dyspareunia
  - Estrogen supplementation (vaginal cream, ring, tablets, systemic)
  - Lubricants
- Weight Gain
  - Advise on caloric intake and exercise
  - Change method
- Use as bridge immediately postpartum until LARC follow up postpartum within 6 weeks

Intrauterine Contraception

Postplacental IUD insertion
- Increased expulsion rate (24%) compared to 6-8 week postpartum (4.4%)
- One study showed that with immediate postplacental insertion (<10 minutes after placental delivery), expulsion rates lower (~11%)
- Expulsion rates decline precipitously after 4 weeks.
Nexplanon

- Implant injected under skin in arm
- Progestrone only method – MOST EFFECTIVE METHOD
- Immediate vs. 6 week delayed study ongoing at Duke
- Side effects: irregular bleeding, headaches, dizziness, weight gain, acne

Screening for Depression

A Self-Care Screening Survey for Depression Awareness

A. During the past month have you often been bothered by:
   - 1) Little interest or pleasure in doing things
   - 2) Feeling down, depressed, or hopeless?
B. If you answered yes to either 1 or 2 above complete the questionnaire on the opposite side of this sheet.

Edinburgh Postpartum Depression Scale

- 10-item questionnaire
- Effective screening tool
- Developed in Livingston and Edinburgh
- Can be completed in < 5 minutes
- Scores for each item 0-3
META-ANALYSIS
A Meta-analysis of Depression During Pregnancy and the Risk of Preterm Birth, Low Birth Weight, and Intrauterine Growth Restriction

- Included 29 prospective studies which reported data on antenatal depression and at least one adverse birth outcome
- Significant increased in relative risk of PTB by 29%, LBW by 29% and IUGR by 45%

ASSOCIATION OF DEPRESSION AND PREGNANCY RELATED HEALTH BEHAVIORS

- Depression is associated with cigarette smoking, drug abuse, and concurrent medication use
- Depressive symptoms may lead to poor weight gain during pregnancy, poor prenatal care, self-neglect, and suicide

POSTPARTUM DEPRESSION: MALE PERSPECTIVE

  - Postnatal depression and mental illness same for both sexes
  - Women's depression occurs in first 3 months and men's depression starts at ~3-9 months after birth
  - Men with depressed wives had increase risk of depression
- Postpartum Depression symptoms in me
  - Irritability, aggression, nonsocial behavior, drug abuse, low impulse control
  - Leads to jealousy toward child, feelings of alienation, change in sexual life, violence against partner
Duke Obstetrics & Gynecology
Duke University School of Medicine

Postpartum Depression

The People's Forum

Help for real trouble: Depression after childbirth.

The signers' Brief

When you still feel low after childbirth, help is there.

Association of Depression and Pregnancy Related Health Behaviors

- Depression is associated with cigarette smoking, drug abuse, and concurrent medication use.
- Depressive symptoms may lead to poor weight gain during pregnancy, poor prenatal care, self-neglect, and suicide.

Postpartum Depression

N.Y. law: Tell mothers about postpartum depression

It's not just about the baby...
Postpartum Depression

**System Recommendation**
- Ensure that all pregnant and postpartum women are screened at least once
- Optimize detection, referral and treatment
- Educate providers on risk factors and screening tools
- Preconceptional discussion of impact of pregnancy for those with pre-existing mental disorders

Sexuality

Perineal Pain

- Dyspareunia reported by 41% - 67% of women 2 - 3 months postpartum
  - Depends on severity of perineal trauma at delivery
- Perineal pain resolves by 3 months, while dyspareunia may take longer

Handa V, Semin Perinatol 2006; 30:259-266
**Practical Recommendations: Counseling on Sexuality during Pregnancy and the Postpartum**

- Engage in dialogue on emotional, mental and sexual expectations during pregnancy
- Acknowledge possible fears and guilt feelings
- Discuss normal variation/fluctuation and provide reassurance
- Give technical advice on range of sexual options:
  - Non-coital sexual activities
  - Alternative coital positions
- Provide anticipatory guidance on postpartum changes in sexual function
- Consider couple counseling/therapy postpartum

---

**Pregnancy as a Window to Women’s Health**

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**Obgyns as Women’s Health Experts**

*So what if we could predict women at high risk, change behaviors and improve health...*
The Pregnancy “Treadmill”

Pregnancy is the “physiologic stress test,” and it is the OB/GYN who has the information to facilitate changes

80-90% of women “take the test”
30-40% of women have one risk factor that can lead to long term health problems

20-30% carry a “predictor” of CVD risk!

Parity and risk of later-life maternal cardiovascular disease

Background
Prior studies relating parity with maternal cardiovascular disease (CVD) have been performed in relatively small study samples without accounting for pregnancy-related complications associated with CVD.

Methods

CVD Risk is affected by parity

- “J-shaped” Curve, with two offspring serving as the nadir
- Parity exceeding five increases the CVD risk by almost 60%
Cardiovascular Sequelae of Preeclampsia/Eclampsia: A Systematic Review and Meta-Analyses

Background
Preeclampsia, a common complication of pregnancy, is a condition characterized by hypertension and proteinuria. This condition is also associated with transient impairment of multiple organ systems and the development of eclampsia, which is a severe complication characterized by convulsions or altered mental status in women with pre-eclampsia. The coagulopathy of preeclampsia is a well-known complication of the disease and is associated with an increased risk of both maternal and fetal complications. Despite extensive research, the pathophysiology of preeclampsia remains incompletely understood, which is a major challenge in the field. Accurate understanding of the association between preeclampsia and cardiovascular complications is crucial for the development of effective preventive strategies. This review aimed to provide an overview of the current knowledge on the cardiovascular sequelae of preeclampsia and the available evidence supporting the prevention and management of these complications.

Keywords: Preeclampsia, Eclampsia, Cardiovascular sequelae, Hypertension, Proteinuria.
Hypertension
Postpartum Follow-up

Hypertensive diseases of pregnancy are common and predict cardiovascular disease

ACOG Hypertension in Pregnancy

With recurrent pre-eclampsia, preterm delivery or fetal growth restriction
  - the cardiovascular risk LATER in life is COMPARABLE to obesity or smoking
  - ACOG recommends annual blood pressure, fasting glucose, lipids and BMI


Gestational Diabetes

Impacts between 5 and 10% of all pregnancies
Type 2 Diabetes

SEVEN-FOLD risk of Type 2 diabetes later in life

Type 2 DM

- It is estimated that up to 70% of women with GDM will develop diabetes within 22–28 years after pregnancy (England 2009, O’Sullivan 1982, Kim 2002).
- Progression to type 2 diabetes may be influenced by race/ethnicity and the incidence of obesity.
- 60% of Latin-American women with GDM may develop type 2 diabetes by 5 years after the index pregnancy (Kjos 1995).

Increased Risk of Cardiovascular Disease in Young Women Following Gestational Diabetes Mellitus

Brenda S. Shah, MD, PhD(1), Rachel Rinehart, MD, MSc(2) and Gilbert L. Rees, MD, MSc(1,2)

Abstract

OBJECTIVE: To determine whether women with gestational diabetes mellitus (GDM) have an increased risk of cardiovascular disease (CVD) following pregnancy.

METHODS AND MEASUREMENTS: 8,658 women aged 14–19 years, with live births between 1994 and 2004, aged 14–19 years in Colorado, Florida, Iowa, Kansas, and Texas. Women with GDM were matched with six women without GDM and were followed for CVD.

RESULTS: The matched cohorts included 8,658 women with GDM and 43,266 women.
Long Term Health

Large population based study in Ontario, Canada looked at long term health outcomes after gestational diabetes

- acute myocardial infarction,
- coronary bypass
- coronary angioplasty
- stroke
- carotid endarterectomy

Obesity

Between 50-65% of women gain IN EXCESS of recommended weight
Obesity and Pregnancy

- Seventy-five percent of obese women gained more than the amount of weight recommended.
- The MORE they gain, the HARDER it is to lose.
- On average, women retain forty percent of their pregnancy weight gain at 6 months.

Long Term Impact!

2035 women in cohort of 7000 women examined 21 years after pregnancy.

- Women who gained excess weight during pregnancy were 2 to 4 times higher risk of being overweight or obese.

Abstract

Background: The correlation of gestational weight gain (GWG) to the development of obesity may have important implications for women in their later lives. However, whether GWG is a strong predictor of body mass index (BMI) is unclear after the index pregnancy.

Objectives: We examined the association between GWG and BMI using a community-based cohort study.

Methods: We followed a population of 2035 women from the original cohort of the third trimester weight gain in women, annual follow-up visits, and outcome. Multivariate regression models were fitted with sociodemographic, pregnancy-related, baseline, and health behaviors factors. The relationship between GWG and BMI was assessed for all participants. The relationship between BMI and GWG was assessed for all participants.

Results: In multivariable models, GWG was not associated with a change in pregnancy BMI.
Obesity and mortality: a review of the epidemiologic data

Cyril J. Salvino and Julian E. Marks

ABSTRACT
In the medical literature, obesity is defined by body mass index (BMI) in kilograms per square meter (kg/m²), with a BMI of 30 or greater considered obese. While many believe that obesity is a risk factor for mortality, the evidence for this association has been inconsistent. Recent studies have suggested that the relationship between obesity and mortality may be more complex, with other factors such as smoking, alcohol use, and physical activity also playing a role. This review will discuss the current evidence regarding the relationship between obesity and mortality, including the potential for a J-shaped curve, where individuals of normal weight may have a higher mortality rate than those who are either underweight or overweight.

Overview of the Epidemiologic Data

Mortality and cardiovascular disease

Overweight and mortality have been associated with increased risk of mortality, even among those who are not obese. This association is stronger in men than in women, and the risk appears to be more pronounced in older adults.

KEY POINTS
- Increased risk of hyperlipidemia, diabetes, hypertension, cardiovascular disease, and mortality
- Increased risk of cancer
- The concerns of a “J-curve” not born out

Weight Gain Associations

PRETERM DELIVERY
Circulation

Original Articles

Epidemiology and Prevention

Birth Characteristics and Subsequent Risks of Maternal Cardiovascular Disease

Effects of Gestational Age and Total Growth

Authors: Maria Rodrigues, M.D., Ph.D., Meirion E. Davies, M.D., Ph.D., Dana C. Cepin, M.D., Ph.D., Jana F. M. Joffre, M.D.

Author Affiliations

Correspondence to Professor Joffre, Department of Medical Epidemiology and Biostatistics, Karolinska Institute, Box 1560, 171 77 Stockholm, Sweden. E-mail: jana.joffre@ki.se

Preterm Birth

Between 6-12% of deliveries happen before 37 weeks

| First Author, Year (Reference No.) | Prevalence (per 1000) | Mean of Maternal Age | SE
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>David et al., 2008 (2)</td>
<td>2.0 (1.2, 3.4)</td>
<td>25</td>
</tr>
<tr>
<td>Spain (2004)</td>
<td>2.9 (2.1, 4.8)</td>
<td>25</td>
</tr>
<tr>
<td>China (2008)</td>
<td>2.1 (1.8, 3.0)</td>
<td>15-19</td>
</tr>
<tr>
<td>England (2006)</td>
<td>2.4 (2.0, 2.9)</td>
<td>25</td>
</tr>
<tr>
<td>Iran (2000)</td>
<td>1.3 (1.1, 1.5)</td>
<td>19-29</td>
</tr>
<tr>
<td>Taiwan (2005)</td>
<td>2.1 (1.8, 2.4)</td>
<td>19-24</td>
</tr>
<tr>
<td>China (2008)</td>
<td>2.2 (1.9, 2.5)</td>
<td>19-25</td>
</tr>
<tr>
<td>India (2000)</td>
<td>1.3 (1.0, 1.5)</td>
<td>25</td>
</tr>
<tr>
<td>China (2008)</td>
<td>1.4 (1.2, 1.6)</td>
<td>15</td>
</tr>
<tr>
<td>Russia (2001)</td>
<td>1.8 (1.5, 2.1)</td>
<td>15</td>
</tr>
<tr>
<td>India (2000)</td>
<td>1.6 (1.4, 1.8)</td>
<td>15</td>
</tr>
</tbody>
</table>
For the 8% of deliveries associated with low birth weight (<2500 g) there is a two-fold increase in cardiovascular disease and death.

...and so is birth weight!

The Intrauterine Environment

Maternal intrauterine environment and health determine the risk of preterm delivery.
Cardiovascular Disease Markers?

Are pregnancy complications such as preterm birth, preeclampsia and gestational diabetes anything more than useful early markers of subclinical CVD risk before the pregnancy started?

OR

Could pregnancy complications actually increase CVD risk by damaging vasculature or altering metabolism?

RECOMMENDATIONS

Cardiovascular risk reduction should be addressed annually through blood pressure monitoring, body mass index calculation, and lifestyle modification involving exercise and dietary changes. Age and glucose measurement should be monitored every five years.

1. For women with more than one pregnancy, the CVD increases by 5%
2. Underweight
3. Low birth weight doubles the risk of cardiovascular disease
4. Premature delivery doubles the risk of cardiovascular disease
5. Obesity
6. Two-fold risk of cardiovascular disease
7. Gestational diabetes
8. Occurred at risk of diabetes later in life and severe preeclampsia increases risk of cardiovascular disease
9. Recommendations: Repeat screening for diabetes at minimum interval of every three years; and more frequently if gestational diabetes

Hyper tension

1. Twice the risk of cardiovascular disease
2. Hypertension
3. Early assessment of blood pressure, labs, blood glucose, and body mass index
4. Medications such as aspirin, clopidogrel or extended washout
Conclusions: What’s Needed

- Re-design the Post Partum Visit
- Look at a six month “Visit” for all women with complications: Video, telephone, health promotion
- IOM and ACOG guidelines on weight gain and weight loss need to be followed
- Recreate the Guidelines of our colleagues in Internal Medicine, Cardiology, Family Practice to recognize pregnancy risk factors
- Include pregnancy risk factors in PMH

Conclusions: Postpartum Care

- Components of the postpartum plan
  - The visit
    - Timing and date and location
    - First follow up visit at 2-4 weeks
  - Infant feeding plan
  - Reproductive life plan
  - Pregnancy complications
  - Mental health
  - Postpartum problems
  - Chronic health conditions

Conclusions

- Candidates for early postpartum follow up
  - Hypertensive disorder
    - No later than 7-10 days
  - Those at risk for postpartum depression
    - Screen no later than 2 weeks
  - Cesarean delivery
  - Lactation challenges
  - Perineal wound injury and complications
  - Chronic conditions
    - Seizures, heart disease, rheumatoid disorders
Every Woman, Every Time

Who knows better than a woman’s health specialist what the long term health consequences are from pregnancy?
Jen Novitski, RN

Sunday, 9:30 – 10:15 am

Watson for Oncology, Clinical Trials, and Genomics
Discussion Topics

- Current State
- History
- Oncology & Genomics
  - Watson for Oncology
  - Watson for Clinical Trial Matching
  - Watson for Genomics

Strategic Context:
Medical knowledge sources have grown beyond human cognition...

Proliferation of medical literature is accelerating
~700K new scientific articles / year

...and vast amounts of data that can have a great impact on our health remain untapped

- 11,000 Terabytes generated per lifetime
- 6 Terabytes per lifetime
- 0.4 Terabytes per lifetime
IBM Leadership in Augmented Intelligence and Health: Over a Decade in Development

What is a Cognitive system?

Understands
Watson can read and understand text—both structured and unstructured—at a massive scale.

Reasons
Watson can search millions of pages of data and can recognize context and interpret the language of medicine.

 Learns
Watson learns from reading human medical and real world databases and continuously improves over time and experiences.

Interacts
Previously invisible data and knowledge are shared into actionable insights. Watson interacts with humans and is integrated.

Understands
Watson can read and understand text—both structured and unstructured—at a massive scale.

Reasons
Watson can search millions of pages of data and can recognize context and interpret the language of medicine.

 Learns
Watson learns from reading human medical and real world databases and continuously improves over time and experiences.

Interacts
Previously invisible data and knowledge are shared into actionable insights. Watson interacts with humans and is integrated.
In medicine, there’s a gap between what we know and what we do...

- 45% of medicine is not evidence-based
- It takes 17 years to translate science to practice

It’s humanly impossible to keep up with the knowledge and the data...

- Doctors would have to read approximately 25 hours each workday to keep up with new professional insights
- 80% of data is unstructured

Watson for Oncology

Watson's analytic algorithms in practice provide treatment options based on best evidence.
Watson for Genomics: Sixteen Early Adopters and Partners

- Ann & Robert Lurie Children’s Hospital of Chicago
- BC Cancer Agency
- City of Hope
- Cleveland Clinic
- Columbia University, Irving Cancer Center
- Dana-Farber Cancer Institute
- Fred & Pamela Buffett Cancer Center in Omaha, Nebraska
- McDonald Cancer Center at Washington University in St. Louis
- New York Genome Center
- Sanford Health
- University of Kansas Cancer Center
- University of North Carolina Lineberger Cancer Center
- University of Southern California Center for Applied Molecular Medicine
- University of Washington Medical Center
- Yale Cancer Center
- University of Tokyo

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Watson for Genomics

Client Example – UNC Lineberger Cancer Center

- Patient files analyzed: 1,022
- >98% accuracy in identifying molecular tumor board candidates
- Identified additional therapeutic options in approximately 1/4 of all cases (~335 cases)
- 255 patients are still living
- Of the living patients, 42 were identified to have "high actionability drug" potentials
- Institute researching patients for additional testing and changes to existing treatment
Wendy Book, MD

Sunday, 10:20 – 11:05 am

Update on Cardiovascular Guidelines: What You Need to Know
CARDIOVASCULAR GUIDELINES

Wendy M. Book MD

SPECIAL THANKS TO EMORY’S WOMEN’S HEART CENTER FOR PROVIDING MANY OF THESE SLIDES

Gina P Lundberg MD FACC
Clinical Director, Emory Women’s Heart Center
Assistant Professor of Medicine
Emory University School of Medicine

DISCLOSURES

- CDC – research funding
- NIH – research funding
- Actellon – research funding
Objectives

• Review new Guidelines on Blood Cholesterol, Risk Assessment, Hypertension and new information on Aspirin

Statistics for Women

• A woman dies of heart disease every minute
• 1 in 5 women has some form of heart disease; 1 in 3 after 65 years
• ~40% of all coronary events in women are fatal, most occur without prior warning

Campaigns to Increase Awareness
PREVENTABLE DEATHS FROM HEART DISEASE

Progress made in preventing heart disease and stroke deaths in those under 75, but much more can be done

[Graph showing trends in preventable deaths]

AHA/ACC Guidelines for Prevention

Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women—2011 Update

Evaluation of CVD Risk

- HISTORY: Medical family history, pregnancy
- Symptoms
- Physical examination: BF, BMI, waist size
- Laboratory tests: fasting lipoproteins, glucose
- Global risk assessment if no CVD or diabetes
“High” CVD Risk Category

- Known Coronary Artery Disease
- Cerebrovascular disease/Stroke/TIA
- Peripheral arterial disease (PAD)
- Abdominal aortic aneurysm
- Diabetes
- Chronic kidney disease
- Global 10 year risk > 10%

HTTP://WWW.CVRISKCALCULATOR.COM/

“At Risk” Women

At risk (>1 major risk factor(s))
- Cigarette smoking
- SBP >120 mm Hg, DBP >80 mm Hg, or treated HN
- Total cholesterol>200 mg/dL, HDL-C <50 mg/dL, or treated dyslipidemia
- Obesity, particularly central adiposity
- Poor diet
- Physical inactivity
- Family history of premature CVD occurring in first-degree relatives in men <55 y of age or in women <55 y of age
“At Risk” Women

At risk (≥1 major risk factor(s))
- Metabolic syndrome
- Evidence of advanced subclinical atherosclerosis (e.g., coronary calcification, carotid plaque, or thickened IMT)
- Poor exercise capacity on treadmill test and/or abnormal heart rate recovery after stopping exercise
- Systemic autoimmune collagen-vascular disease (e.g., lupus or rheumatoid arthritis)
- History of preeclampsia, gestational diabetes, or pregnancy-induced hypertension

Metabolic Syndrome

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Defining Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waist circumference</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>≥ 102 cm (&gt; 40 inches)</td>
</tr>
<tr>
<td>Women</td>
<td>≥ 88 cm (&gt; 35 inches)</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>≥ 150 mg/dL</td>
</tr>
<tr>
<td>HDL-C</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>&lt; 40 mg/dL</td>
</tr>
<tr>
<td>Women</td>
<td>&lt; 50 mg/dL</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>≥ 130 / ≥ 80 mm Hg</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>≥ 100 mg/dL</td>
</tr>
</tbody>
</table>

2011 NEW RISK FACTORS-
PREGNANCY HISTORY

- Pregnancy: unique opportunity to estimate a woman’s lifetime risk of CVD risk
- Pregnancy is a cardiovascular and metabolic stress test for each woman
- Women with preeclampsia have double the risk for subsequent ischemic heart disease, stroke and venous thromboembolic events over the 5 to 15 years after pregnancy
2011 NEW RISK FACTORS - PREGNANCY HISTORY

- Hx of Gestational DM, preeclampsia, preterm birth or low birth weight baby
- Appropriate referral postpartum by the Ob/Gyn to PCP or Cardiologist should occur for risk reduction and monitoring long term

2011 NEW RISK FACTORS - AUTOIMMUNE COLLAGEN-VASCULAR DISEASE

CV manifestations of rheumatologic diseases (ie RA, SLE):
- Vascular
- Myocardial
- Valvular
- Pericardial
- Conduction disease

2011 NEW RISK FACTORS - AUTOIMMUNE COLLAGEN-VASCULAR

- RA linked to increased risk of MI.
- RA patients experience similar rates of MI as individuals without RA who are 10 years older or have DM
"Optimal" Risk Category

- Heart healthy lifestyle
- 180 min of mod to vigorous exercise per week or more
- Ideal BP, BMI, Weight, waist < 35"
- Ideal blood glucose and lipids
- Women with no risk factors
- Less than 5% of US population

Lifestyle Recommendations for All

- Smoking cessation
- Regular physical activity (50 min 6 days/wk)
- Heart-healthy eating pattern
- Weight management (BMI and waist)
- Screen all women for depression
- Cardiac Rehab after hospitalization

Dietary Guidelines

Heart-healthy diet / Mediterranean diet

- Fruits, vegetables, grains, low-fat or nonfat dairy products, oily fish twice a week, legumes, and sources of protein low in saturated fat.
- Limit saturated fat intake to <7% of calories, limit cholesterol to <200 mg/d, and trans fatty acids should be <1% (Class I) if high risk
- Limit sodium to <2.3 g/day
**Woman “Not High Risk” of CVD**

**Implement Class I Recommendations:**
- Blood pressure control
- LDL-C-lowering therapy if \( \geq 190 \text{ mg/dL} \)

**Consider Class II Recommendations:**
- Therapy for high LDL-C, non-HDL-C and triglycerides and/or HDL-C in select women
- Aspirin

---

**History of Paroxysmal Atrial Fibrillation?**

**Implement Class I Recommendations:**
- Warfarin goal INR 2.0 to 3.0
- Aspirin, 75 to 325 mg daily, for CHADS2VASc Score < 2
- DOAC, alternative to Warfarin

---

**Table 1. Class III Interventions (Not Useful/Effective and May Be Harmful) for the Prevention of CVD in Women**

<table>
<thead>
<tr>
<th>Potential Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant Therapy</td>
</tr>
<tr>
<td>Hormone therapy and selective estrogen-receptor modulation should not be used for the primary or secondary prevention (Class II, Level of Evidence A).</td>
</tr>
<tr>
<td>Antioxidant supplements</td>
</tr>
<tr>
<td>Vitamin E, vitamin C, vitamin B6, or vitamin B12 should not be used for the primary or secondary prevention of CVD (Class II, Level of Evidence A).</td>
</tr>
<tr>
<td>Folic Acid</td>
</tr>
<tr>
<td>Folic acid, with vitamin B12 supplementation, should not be used for the primary or secondary prevention of CVD (Class II, Level of Evidence A).</td>
</tr>
</tbody>
</table>

*VOG: Vogt-Scid syndrome. M: Methylmalonic aciduria. \( * \) Folic acid supplementation should be used in the childbearing years to prevent neural tube defects.

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New Cholesterol Guidelines 2013

- High risk patients should be on high intensity statin such as high dose atorvastatin or high dose rosuvastatin.
- Moderate risk patients should be on low to moderate intensity statin such as most statins and low dose atorvastatin or low dose rosuvastatin.
- Low risk patients may not need statin therapy and should continue healthy lifestyle and monitoring.


Statin therapy for women with CAD, DM, LDL elevation over 190 or high risk by AHA pooled cohort risk assessment tool ASCVD Risk >7.5%

- Nonsatins less beneficial and less emphasis on treatment with niacin, fenofibrate, Zetia and Omega 3 Fish oils.

2013 ACC/AHA Treatment of Blood Cholesterol Guidelines

Four statin benefit groups:
- Age >21 with clinical ASCVD (acute coronary syndromes, hx of MI stable or unstable angina, coronary or other arterial revascularization, stroke, TIA or PAD)
- LDL >190 mg/dl
- DM age 40-75 and LDL 70-189 mg/dl without clinical ASCVD
- Age 40-75 and no ASCVD or DM but ASCVD Risk >7.5%
KNOWN CLINICAL ASCVD

• Age <75 should be on High-intensity statin
• Age >75 should be on Moderate-intensity statin
• It is reasonable to evaluate the potential for ASCVD risk-reduction benefits and for adverse effects, drug-drug interactions and to consider patient preferences.

DIABETES TYPE 1 OR 2

• Age 40-75 and ASCVD >7.5% should be on High-intensity statin
• Age 40-75 and ASCVD <7.5% should be on Moderate-intensity statin
ADDITIONAL CONSIDERATIONS WHEN ASCVD RISK <7.5%

• Family Hx of premature ASCVD
• LDL>160 mg/dl
• High hsCRP>=2.0 mg/dl
• CAC>300 Agatston Units or >75th percentile for age, sex, and ethnicity
• ABI <0.9
• Elevated ASCVD Lifetime Risk

INITIAL EVAL PRIOR TO STATIN INITIATION

• Fasting Lipid panel
• ALT
• HgbA1C (if DM status unknown)
• CK (if indicated)
• Consider evaluation for other secondary causes: Diet, Drugs, Diseases, and Disorders

MONITORING AND RISK ASSESSMENT

• It is reasonable to assess traditional ASCVD risk factors in adults (without ASCVD) ages 20-79 every 4-6 yrs
• The contribution of apolipoprotein B, Chronic Kidney Disease, albuminuria, and cardiorespiratory fitness is uncertain
• Careful intima-media thickness (CIMT) is not recommended for routine measurement for risk assessment
RISK DISCUSSION WITH INDIVIDUAL PATIENTS
- It is reasonable to evaluate the potential for ASCVD risk-reduction benefits and for adverse effects, drug-drug interactions and to consider patient preferences.
- Annals of Internal Medicine 5P’s: Preference, Precision, Participation, Potency & Price

CONTROVERSY: STATINS IN WOMEN AND PRIMARY PREVENTION
- Research data in Women is limited
- Statins did not prevent MI, Stroke or death in women but did have less CP and less hospitalization (fewer stents and CABG) in JUPITER (6801 Women).
- Potential risk of DM in women?
- Clear benefit with secondary prevention, less data on primary prevention.

NEW REPORTS SINCE 2011 UPDATE
- New 2013 ACC Guideline on Treatment of Blood Cholesterol
- New 2013 ACC Guideline on the Assessment CV Risk
- New 2013 HTN Guidelines
- New 2014 FDA report on Aspirin in primary prevention, 2016 USPSTF recommendation on Aspirin
An Effective Approach to High Blood Pressure Control: A Science Advisory
ACC, AHA, CDC

- Optimal BP is <140/90 mmHg for age 21-59
- For patients over age 60 with no DM or CKD, optimal BP is <150/90 mmHg
- For patients over age 60 with DM or CKD, optimal BP is <140/90 mmHg

J Am Coll Cardiol 2013;Nov 15

LIMIT SALT AND SODIUM

Too much salt!

2013 AHA/ACC GUIDELINE ON LIFESTYLE MANAGEMENT TO REDUCE CV RISK

Dietary recommendations to lower blood pressure:
- Limit sodium to no more than 2400 mg of sodium/day
- Optional goal of 1500 mg of sodium/day
- Combine DASH Diet with low sodium intake
Rx for Blood Pressure Management

- All races- Initiate ACE or ARB, alone or in combination with other drugs
- Nonblack- Initiate thiazide-type diuretic or ACE or ARB or CCB, alone or in combination
- Black- Initiate thiazide-type diuretic or CCB, alone or in combination

HTN WITH OTHER CLINICAL CONDITIONS

- Coronary artery disease/post-myocardial infarction: beta blocker (BB), angiotensin-converting enzyme inhibitor (ACEI);
- Systolic heart failure: ACEI or angiotensin-receptor blocker (ARB), BB, aldosterone antagonist, thiazide;
- Diastolic heart failure: ACEI or ARB, BB, thiazide;
- Diabetes: ACEI or ARB, thiazide, BB, calcium channel blocker;
- Kidney disease: ACE or ARB; and
- Stroke or transient ischemic attack (TIA): thiazide, ACEI.
**BLOOD PRESSURE GOALS**

- The blood pressure goal for an individual is set by utilizing a combination of factors including scientific evidence, clinical judgment, and patient tolerance.
- For most people, the goal is <140 and <90; however, lower targets may be appropriate for some populations such as African-Americans, the elderly, or patients with left ventricular hypertrophy, systolic or diastolic left ventricular dysfunction, diabetes mellitus, or chronic kidney disease.

**DIASTOLIC HTN**

- In the general population <60 years, initiate pharmacologic treatment to lower BP at DBP>90 mmHg and treatment to a goal DBP<90 mmHg
- For ages 30-59 years, Strong recommendation, Grade A
- For ages 18-29 years, Expert opinion, Grade E

**CONTROVERSIES IN HTN TX**

<table>
<thead>
<tr>
<th>Table 1: Diagnosis of hypertension</th>
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<tbody>
<tr>
<td>Seventh Joint National Committee 2003/5</td>
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<tr>
<td>Mean of two or more properly measured seated blood pressure readings of each of two or more office visits</td>
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<tr>
<td>US Preventive Services Task Force proposed 2009p</td>
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<tr>
<td>Ambulatory blood pressure monitoring to confirm high blood pressure, except when ambulatory therapy is necessary grade A recommendation</td>
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<tr>
<td>American Heart Association (2003p)</td>
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<tr>
<td>• Home blood pressure measurements if office blood pressure 90-114/50-69 mm Hg</td>
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<tr>
<td>• Ambulatory monitoring if home blood pressure is 120-129/70-79 mm Hg</td>
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<tr>
<td>Canadian (2013p)</td>
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<tr>
<td>• Office blood pressure is 140-159/90-100 mm Hg</td>
</tr>
<tr>
<td>• Ambulatory monitoring (preferred)</td>
</tr>
<tr>
<td>• Home blood pressure</td>
</tr>
<tr>
<td>• Office blood pressure in visits 2-5 daily if ambulatory monitoring and home blood pressure unavailable</td>
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SYSTOLIC BLOOD PRESSURE INTERVENTION TRIAL (SPRINT)

- 2010-2013, 9,361 participants, 50 yrs and older, syst>130 mmHg and high risk for CVD
- Regular tx: BP<140, avg 2 meds
- Intensive tx: BP<120, avg 3 meds

SPRINT

- Inclusion: over 50, one CVD risk, clinical or subclinical CVD, GFR<60
- Exclusion: CVA, DM, PCKD, CHF with EF<35%, proteinuria > 1g/d, GFR<20, adherence concerns

SPRINT

- Results:
  - Mean age 68 yrs, 28% over age 75
  - 29% stage 3 or higher CRF
  - 30% RR reduction in CVD events
  - 25% RR reduction in mortality in intensive group compared to regular group
  - Greatest benefits with CHF and CV death
2014 FDA RECOMMENDATION ON ASPIRIN

- Data do not support use of ASA for primary prevention of stroke or heart attack. And use of ASA is associated with risk of GI bleed and intracranial bleed.
- ASA for secondary prevention is still beneficial.

Summary

- CAD is the leading cause of death among American women
- New ACC/AHA guidelines need to be implemented by all physicians that care for women
- New update needs to include new CVD Risk Assessment, Cholesterol, HTN and Aspirin recommendations

Emory Women’s Heart Center

- Screen and Education Women on their individual CVD risk factors
- Educate Atlanta’s Women through Community Programs
- Educate Physicians who care for Females on the latest research and guidelines concerning the CVD health of their patients
Resident Research Abstracts
Molar Twin Pregnancy
Ashley Borgstadt, DO, MBA
Memorial University Medical Center
Savannah, Georgia

Abstract

Hydatidiform mole with coexistent fetus is a rare condition occurring in 1 in 20-80,000 pregnancies and few reported cases in the literature. Two cases of hydatidiform mole with concurrent normal fetal twin are presented here. The first case describes a complete molar pregnancy with concurrent twin pregnancy diagnosed at 18 weeks. Patient presented with symptoms consistent with thyroid storm and labs diagnostic of HELLP syndrome. Patient chose to terminate pregnancy after counseled on danger of continuing pregnancy. Lung nodules identified and patient received chemotherapy outpatient. She remained without evidence of disease for 1 year following normalization of her hCG. The second case presents a partial molar pregnancy with coexistent normal twin confirmed at 21 weeks with classic snowstorm-appearing placenta. Patient was counseled extensively on potential complications and declined termination. She had a normal antepartum course with close follow up sonographically. Patient went into spontaneous labor and delivered at 38 weeks. Normal male fetus was noted at delivery and by Neonatologist. Patient and baby discharged home in stable condition on postpartum day 2. BhCG normalized within 3 weeks of delivery. Patient was lost to follow up two months after deliver, however, she was without evidence of disease at that time. Final placental pathology confirmed ultrasound findings in both cases. Antepartum and postpartum management and surveillance recommendations are also discussed in detail.
Management of Early Endometrial cancer (EC) and Complex Atypical Hyperplasia (CAH) by levonorgestrel IUD (LIUD): A Cost and Risk Reduction Analysis

Authors:
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¹Medical College of Georgia at Augusta University, Augusta, GA,

Objectives:
Therapy with insertion of LIUD is a reasonable alternative to major surgery in patients with EC or CAH, especially in those with large body mass index (BMI) or major medical problems. This approach has potential for considerable cost savings and reduction of surgical morbidity.

Methods:
The Surgical Risk Calculator from the American College of Surgeons was used to calculate the risk for 32 patients with EC or CAH for (1) open hysterectomy with or without nodal dissection (TAH+LND), (2) laparoscopic hysterectomy + LND (TLH+LND), and (3) hysteroscopy with dilation and curettage and LIUD placement (HSC+IUD). The risks of serious complications, length of hospital stay, surgical site infection, return to operating room, and death were calculated. Demographics including age, BMI, functional status, ASA class, and comorbidities were used to individualize risk. A paired t-test was used to evaluate risk reduction. Procedural cost analysis for both commercial and government payers were performed.

Results:
Of 32 patients with EC or CAH that underwent HSC+IUD, the mean BMI and Revised Cardiac Risk Index were 49.3 kg/m² and 2.5, respectively. The clinical benefit rate of therapy as 84.6%, with 13 (50%) had complete response on subsequent endometrial biopsy, with a mean progression free survival of 3.3 years. HSC+IUD was associated with the greatest risk reduction for serious complications (mean -6.60%, -1.93%; p<0.001), return to OR (mean -0.14%, -2.75%, p=0.002), length of stay (mean -2.6 days, -0.91 days, p<0.001), surgical site infection (mean -9.90%, -1.60%, p<0.001), and death (mean -0.48%, -0.52%, p=0.012) vs. TAH+LND and TLH+LND, respectively. Total procedural charges for professional and facility fees showed a cost reduction for HSC+IUD ($9,412) vs. TAH+LND ($51,973) and TLH+LND ($33,767).

Conclusions:
LIUD is an alternative way to treat early EC or CAH in a safe and economical manner in women large BMI and significant co-morbidities who are poor surgical candidates.

Discordance between Day-3 Follicle Stimulating Hormone (FSH) and Anti-Müllerian Hormone (AMH) in women seeking fertility treatment in Georgia
Prevalence of Concurrent or Previous High-grade Cervical Intraepithelial Neoplasia in Women with High-grade Anal Intraepithelial Neoplasia and or Anal Carcinoma

Crystal Reese, MD, Evelyn Reynolds, MD, Emily Wang, MD, Michelle Uzor, BS

Department of Obstetrics and Gynecology, Morehouse School of Medicine, Atlanta, GA

INTRODUCTION
The incidence of anal carcinoma has grown 2.2% each year over the last ten years among women from the United States. 1. In a study by Coffey et al., a historical diagnosis of cervical intraepithelial neoplasia (CIN) 3 was the strongest predictor of risk of anal cancer in women aged 50 or above. 2. Human papilloma virus (HPV) infection is the major inciting factor for both CIN and anal intraepithelial neoplasia (AIN). 3. While the majority of HPV anal infections clear, persistent anal dysplasia is a precursor to anal cancer 4. There continue to be few studies in heterosexual women, even though they are more likely to be affected by anal carcinoma.

OBJECTIVES
1. Determine prevalence of previous or concurrent high-grade cervical intraepithelial lesion (CIN 2 and 3) in women diagnosed with high-grade anal intraepithelial neoplasia or anal carcinoma
2. Determine prevalence of high risk HPV positivity in women with both high-grade cervical and anal intraepithelial neoplasia or anal carcinoma

METHODS
Institutional review board approval was obtained. We conducted a chart review of patients seen in the Grady Health System from January 1, 2006-December 31, 2015. Inclusion criteria was women over the age of 18 diagnosed with AIN 2/3 or anal carcinoma. We then reviewed those records for documentation of the patient’s Pap smear history, any colposcopic procedures, and any treatment for cervical dysplasia including cervical excisional biopsy Charts without a previously documented Pap smear, colposcopy, cervical excisional biopsy for treatment of cervical dysplasia were excluded from the analysis. We also reviewed the included charts for a documented high-risk HPV test and demographic information including HIV status, age, race, and smoking status. Data analysis was completed by Morehouse School of Medicine Biostatistics Department. Descriptive statistics were used to summarize the data. Mean with standard deviation was used for continuous variables and frequency with percentage was used for categorical variables.

RESULTS
We identified 53 patients with the diagnosis of high-grade anal dysplasia or anal carcinoma during the study time period. Fifty-two patients, or 98.1%, of our study population were Black or African-American. Of the 53 patients, 16 had a previous or concurrent diagnosis of high-grade cervical dysplasia for a prevalence rate of 30.2%. We had data on high-risk HPV positivity on XX patients. The overall prevalence rate of past high risk HPV positivity in these women with high-grade cervical and anal intraepithelial neoplasia or anal carcinoma was 31.3%. Of the 16 patients with a history of cervical dysplasia, 87.5% were HIV+.
CONCLUSIONS
Currently, there are no standardized guidelines to screening for anal dysplasia or carcinoma. This may be in part because to date there no randomized clinical trials demonstrating the efficacy of any screening method. However; due to the increase in the incidence of anal carcinoma, some experts have advocated screening certain high-risk populations (such as women with prior CIN, HIV positive patients, and men who have sex with men) with anal pap smears and high-resolution anoscopy with anal pap smears or anoscopy. men who have sex with men) with anal pap smears and high-resolution anoscopy. In our study population, the majority of the women with concurrent CIN and AIN or anal cancer (87.5%) were co-infected with HIV. Thus, there is a definite role for screening HIV-positive women for both cervical and anal dysplasia. We plan to conduct a prospective study of women with high-grade cervical dysplasia and cervical cancer to determine the rates of concurrent anal dysplasia, to begin to address the question of whether all women with these diagnoses should routinely be screened.

References

This study is a retrospective chart review of the deliveries during 2010-2015 to determine the rate of rapid repeat pregnancy, most common contraceptive choice amongst the population and identify potential barriers to effective contraception.

Study design/methodology:
This is Retrospective Chart review of patients who have had deliveries at Grady Health System in the past 5 years of a sample of 500 charts of patients who delivered and have a documented plan for contraception in the postpartum period.

Results/Conclusions:
Pending final analysis
Fertility, Pregnancy, and Postpartum: A Survey of Practicing Georgia Obstetrician Gynecologists

Caitlin Martin, MD\textsuperscript{1}, Heather Hipp, MD\textsuperscript{1,2}, Lisa Haddad, MD, MPH\textsuperscript{1}, Melissa Kottke, MD, MPH\textsuperscript{1}, Jennifer Kawwass, MD\textsuperscript{1,2}

\textsuperscript{1}Emory University Department of Gynecology and Obstetrics
\textsuperscript{2}Centers for Disease Control and Prevention

Objective: To describe reproductive history and goals, infertility experiences, and birth outcomes of obstetrician gynecologists (OBGYNs) practicing in the state of Georgia.

Design: Cross-sectional study of female OBGYN providers who belong to Georgia OBGYN Society (GOGS)

Materials/Methods: An anonymous email survey was distributed to female members of GOGS. Statistics were calculated using Microsoft Excel and OpenEpi.

Results: Of 352 surveys emailed, 204 of 269 women who opened the survey agreed to participate (75.8\% response rate). There were 300 pregnancies reported among 139 women; mean age of first birth was 30.7 (SD +/− 4.2) years. Of the pregnancies, 13.3\% (n=40) reported use of fertility treatment, including controlled ovarian stimulation (n=28), intrauterine insemination (n=16), in-vitro fertilization (n=14), oocyte/embryo donor (n=1), or donor sperm (n=5). Of the pregnancies: 77\% were intended; of the viable births, 73\% delivered vaginally, and 90\% delivered ≥37 weeks. Resident mothers were more likely to report post partum depression than non-residents (29\% to 16\%, \(p<0.039\)) and a maternity leave <6 weeks (57\% to 29\%, \(p<0.0003\)); rates of exclusive breastfeeding >6 months were similar between the two groups (35\% residents vs. 41\% non-residents, \(p=0.45\)). Among those not complete with child bearing (n=63), 55\% worried about experiencing infertility, 29\% reported considering oocyte/embryo cryopreservation, and 5\% reported already using oocyte/embryo cryopreservation.

Conclusions: The average age of first live birth is four years higher (30.7 vs. 26.3\textsuperscript{1}) with a greater proportion of pregnancies that were planned (77\% vs. 55\%)\textsuperscript{2} among practicing Georgia OBGYNs compared to the general population. While use of fertility services, preterm delivery, and mode of delivery in our cohort matched nationally reported rates, increased maternal age may be associated with other complications. Awareness of increased postpartum depression among OBGYN residents may allow for improved prenatal counseling and postpartum treatment. Additionally, fertility preservation counseling may reduce anxiety among OBGYNs who desire children in the future.

\textsuperscript{1}National vital statistics reports. 2015; 64(12).
Abstract for Identification of Ureter and Prevention of Ureteral Injury using Indocyanine Green and Firefly Mode on the DaVinci XI Robot

Martha Cohen, MD, PGY2
A Al-Ansari, MD
Michael Dillon, MD
David McInotosh, MD
Hany Atalah, MD

Procedure: Robotic Assisted Trachelectomy

Objectives: Ureteral injury is a serious complication of Laparoscopic and Robotic Surgery, primarily associated with robotic assisted hysterectomy and robotic assisted trachelectomy. Approximately 3% risk of injury with benign hysterectomy. Despite current methods to prevent ureteral injury, such as palpation of non-lighted stents and placement of light stents it can still be difficult to identify the ureter and, therefore, ureteral injury inevitably occurs often during these procedures.

Case: Here we are presenting a 36 yo CF s/p subtotal hysterectomy with BSO in 2010 secondary to history of endometriosis. After having undergone routine preventive screening with her Primary OBGYN, a Pap Smear was performed and the patient was noted to have High Grade Squamous Intraepithelial Lesions on July 15, 2016. Secondary to these findings the patient was referred to Gynecology Oncology for further management of these findings as well as removal of the cervical stump. Upon evaluation, it was decided to proceed with a trachelectomy in order to remove the cervix. With there being a known history of bowel adhesions to the cervix from her prior surgery, it was decided to perform the procedure using the DaVinci XI Robot with use of Indocyanine Green and firefly scope in order to prevent potential ureteral injury.

Methods: The various treatment options were discussed with the patient the patient opted for Robotic Assisted surgery. The patient was taken to the OR and prepped and draped in a normal sterile fashion. The patient was placed in the Dorsal Lithotomy position using Allen Stirrups. A timeout was performed at which point we proceeded with the surgery. Bilateral ureteral stents were placed. The trocar ports were placed and the DaVinci XI was docked. 25 milligrams of Indocyanine Green was dissolved in 10 ml sterile water and was then injected through the stents using 10 cc syringes with approximately 7-8 cc injected into the stents bilaterally. The Da Vinci scope was changed to firefly mode. The ICG reversibly stained the inside lining of the ureter and bladder by binding to proteins on the urothelial layer. The ureter was identified in approx. 30 seconds after injecting dye into the stents bilaterally. In addition, the bladder was noted to illuminate in a fluorescent green color. The surgery lasted approximately 1.5 hours and after closing the vaginal cuff the firefly mode was entered once again and the ureters bilaterally and bladder were noted to still be illuminated proving the that injury had not occurred.

Results: The use of Indocyanine Green and the Firefly Scope with DaVinci XI proved of most excellent efficacy in order to prevent ureteral injury during a surgery such as the Trachelectomy where this is of great risk. The ureters and bladder were able to be identified and tracked in order to avoid injury with the surgical instruments. The longevity of the dye in both the ureter and bladder were also of great benefit given that this has the ability to be a long, complex procedure in which illumination would be necessary for the entirety of the procedure.

Conclusion: Intraureteral injection of indocyanine green shows promise in providing ureteral identification with high specificity during Laparoscopic and Robotic Assisted Surgery. The low dose required, rapid time to visualization, and longevity of subsequent illumination are of great benefit in preventing and identification of ureteral injury by proper identification of the ureter bilaterally, as well as the bladder.
**Fidel A. Valea, MD**  
**ERAS and Minimally Invasive Gynecologic Surgery**  
To outline the various components of an enhanced recovery after surgery protocol  
To review the data behind the major components and list the major pitfalls to implementation  
To compare some of the MIS surgical components

**DVT Prevention and Management**  
To outline the best practices surrounding the prevention of VTE after gynecologic surgery  
To review the data surrounding each of the recommended prophylaxis policies  
To review the concept of extended prophylaxis for the high-risk groups of patients

**Jen Novitski, MBA, BSN, RN**  
**Cognitive Computing is the Future of Health**  
Discuss using cognitive computing to improve health care delivery and quality  
Describe the role of cognitive computing in future healthcare  
Discuss future trends for computerized medicine

**Watson for Oncology, Clinical Trials, and Genomics**  
Discuss the historic use of computers in medicine  
Discuss how computerization is currently being used to enhance diagnosis, treatment in oncology  
Overview current clinical trials utilizing advanced computing  
Discuss how computing will be utilized within the developing field of genomics

**Padmashree “Champa” Woodham, MD**  
**Simulation Lab Ultrasound Activities**  
Identify the components of a Level 1 (Basic anatomy) ultrasound  
Utilize Color Doppler to assess umbilical artery  
Perform basic fetal cardiac assessment

**Paul Weathington, JD**  
**Current trends in OB-Gyn Litigation**  
Discuss the most current types of litigation being filed in the OBGyn community  
Review steps that can be taken to decrease the possibility of litigation

**J. Patrick O’Neal, MD**  
**Health Outcomes for Georgia Women**  
Review public health priorities for women and pregnancy  
Provide data on status current of the priorities in Georgia  
Discuss the OBGyn provider’s role in providing care based on the priorities
Kimberly A. Workowski, MD

What’s New in STI/STD
- List current guidelines for screening and treatment of gonorrhea, chlamydia and syphilis
- Define causes of recalcitrant vaginitis/cervicitis and how to manage them
- Discuss epidemiology of herpes hepatitis B and hepatitis C
- Discuss prevention, symptoms and management options

Haywood L. Brown, MD

Reducing the Primary Cesarean Rate: A Quality OB Measure
- At the conclusion of this presentation the participant should be able to:
  - Discuss the increase in cesarean delivery over the last several decades and the primary reasons for the increase in primary cesarean.
  - Discuss provider, hospital type, liability and patient factors that contribute to rise in cesarean delivery.
  - Discuss educational strategies during the preconception and interconception periods including healthy weight, VB AC counseling and mode of practice which can potentially lead to reduction in cesarean delivery.

Redefining Postpartum Care
- At the conclusion of this presentation the participant should be able to:
  - Describe the essential elements relevant to postpartum counseling and education
  - Perform essential screening including for depression.
  - Discuss a reproductive life plan and long-term health implications for this with pregnancy complications.

Carol L. Brown, MD

Modern Management of Endometrial Cancer
- At the conclusion of this talk participants will be able to:
  - Understand the changing epidemiology and genetic risk profile of endometrial cancer in the U.S.
  - Understand current treatment options including innovative surgery and fertility-sparing therapies.

Gyn Cancer and the Evolving U.S. Health Care System
- At the conclusion of this talk, participants will be able to:
  - Describe key elements of the Patient Protection and Affordable Care Act of 2010 that impact the delivery of OB/GYN and GYN cancer care
  - Understand impact of 2017 policy and legislation on delivery of OB/GYN and GYN cancer care
  - Understand how participants can advocate for the ability to deliver high-quality care in a changing health care system.

Wendy Book, MD

Heart Disease and Pregnancy
- Understand the cardiovascular physiologic changes of normal pregnancy
- Understand how these changes impact pregnant women with underlying and acquired heart disease
- Know guideline based management of common cardiovascular complications of pregnancy

Update on the Cardiovascular Guidelines: What do you need to know
- Compare and contrast the approach to lipid management in the new versus the old guidelines
- Recognize cardiovascular risk factors in women
Educational Credit

ACCME Accreditation
The American College of Obstetricians and Gynecologists is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

AMAPRA Category 1 Credit(s)™
The American College of Obstetricians and Gynecologists designates this live activity for a maximum of 16 AMAPRA Category 1 Credits.™ Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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MOC Part IV Credit
The ABOG MOC standards now allow participation in ABOG-approved Simulation Courses to meet the annual Improvement in Medical Practice (Part IV) MOC requirement. This course has been approved to meet ABOG Improvement in Medical Practice requirements for 2017.

Disclosure of Faculty and Industry Relationships
In accordance with College policy, all faculty and planning committee members have signed a conflict of interest statement in which they have disclosed any significant financial interests or other relationships with industry relative to topics they will discuss at this program. At the beginning of the program, faculty members are required to disclose any such information to participants. Such disclosure allows you to evaluate better the objectivity of the information presented in lectures. Please report on your evaluation form any undisclosed conflict of interest you perceive.
Faculty Disclosures

Conflict of Interest Disclosure: Faculty/Planning Committee Members/Reviewers

Haywood L. Brown, MD
- Executive Board American College/Congress Obstetricians and Gynecologists

Wendy Book, MD
- CDC – Research Funding
- NIH – Research Funding
- Actelion – Research Funding

Fidel A. Valea, MD
- Covidien (Medtronic) advisory board
- UpToDate author 3 sections
- Comprehensive Gynecology – Elsevier – Editor
- Gyn Onc Division member for ABOG

Kimberly A. Workowski, MD
- Research funding (HCV, HIV antiviral clinical trials)- Gilead, Abbvie
- Research funding (gonorrhea clinical trial)- GSK
- Contractor- Division of STD Prevention, CDC

Jen Novitski, RN, MBA, BSN
- IBM legal statement regarding product information