Improving Patient Safety and Reducing Liability: An Achievable Goal

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Amos Grunebaum, MD

Turkish German Gynecology Congress
April 27 – May 1, 2018
Northern Cyprus
I do not have a relationship with a commercial entity such as a pharmaceutical organization, medical device company or a communications firm.
People make mistakes
US Deaths per Year

- Heart Disease: 652,000
- Cancer: 554,000
- Strokes: 150,000
- Respiratory: 122,000
- Accidents: 112,000
- Hospital Errors: 98,000
- Diabetes: 73,000
- Alzheimer's: 66,000
- Infleunza: 60,000
- Kidney Failure: 43,000

#6 Hospital Mistakes
1999 Institute of Medicine Report

- Preventable injuries affect 3-4% of all hospitalized patients: 1+ Million patients suffering harm per year
- Over 50% of adverse events could have been prevented
- Problems mostly arrive through the System’s Errors NOT an Individual’s Errors
- The problem is not that there are bad people in health care but that good people are working in bad systems that need to be made safer.
• Tenerife airport disaster
• March 27, 1977: 583 Dead
Team Training Comes From The Airline Industry
Each Decade, U.S. Airline Safety Has Improved Markedly

Fatal Accidents per Million Aircraft Departures in Scheduled Service

- 1970-79: 0.8810
- 1980-89: 0.5050
- 1990-99: 0.2919
- 2000-09: 0.1230

Source: ATA analysis of data from the National Transportation Safety Board
Preventing Mistakes

Human errors are inevitable

Mature systems do not just try to reduce the probability of human error, they accept errors will occur and then find ways to intercept them.
Increasing Liability Premiums

In 2007 the professional liability for a physician practicing obstetrics was $235,000 per year.
19 “High Exposure Cases” at Weill Cornell

<table>
<thead>
<tr>
<th>Case Description</th>
<th>Outcome</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brachial Plexus Injury</td>
<td>Paid</td>
<td>2001</td>
</tr>
<tr>
<td>Brachial plexus injury</td>
<td>Suit</td>
<td>2002</td>
</tr>
<tr>
<td>Brachial plexus injury</td>
<td>Suit</td>
<td>2003</td>
</tr>
<tr>
<td>Infant w/ CP</td>
<td>Paid</td>
<td>2000</td>
</tr>
<tr>
<td>Maternal death; placenta accreta; contaminated platelets</td>
<td>Paid</td>
<td>2003</td>
</tr>
<tr>
<td>Anoxic brain injury</td>
<td>Paid</td>
<td>2002</td>
</tr>
<tr>
<td>Preeclampsia, Infant with brain damage</td>
<td>Suit</td>
<td>2000</td>
</tr>
<tr>
<td>Twins at 28 weeks</td>
<td>Event</td>
<td>2000</td>
</tr>
<tr>
<td>Infant with brain damage</td>
<td>Suit</td>
<td>2000</td>
</tr>
<tr>
<td>Hypoxic event 5 hours after normal delivery</td>
<td>Suit</td>
<td>2000</td>
</tr>
<tr>
<td>Term infant seizures and hypotonia</td>
<td>Event</td>
<td>2004</td>
</tr>
<tr>
<td>25 weeks preterm delivery</td>
<td>Suit</td>
<td>2001</td>
</tr>
<tr>
<td>34 weeks twins low Apgars</td>
<td>Event</td>
<td>2005</td>
</tr>
<tr>
<td>Pp eclampsia, DIC, TAH (Jehova’s witness)</td>
<td>Suit</td>
<td>2002</td>
</tr>
<tr>
<td>Triage (non Cornell patient); PROM ruled out, delivered 6 days later</td>
<td>Suit</td>
<td>2002</td>
</tr>
<tr>
<td>Twins 31 weeks, one with intrauterine demise, waited too long in triage?</td>
<td>Suit</td>
<td>2003</td>
</tr>
<tr>
<td>Twin one demise at 32 weeks</td>
<td>Event</td>
<td>2005</td>
</tr>
<tr>
<td>Fractured humerus and clavicle</td>
<td>Event</td>
<td>2005</td>
</tr>
<tr>
<td>38 weeks NR tracing; prolonged 2^{nd} stage</td>
<td>Event</td>
<td>2005</td>
</tr>
</tbody>
</table>
A $13+ Million Case

- Patient Admitted with PROM
- Oxytocin was started
- Stat C-Section done for fetal bradycardia – deceleration
- Baby Has Cerebral Palsy
PATIENT SAFETY SERIES

Effect of a comprehensive obstetric patient safety program on compensation payments and sentinel events

Amos Grunbaum, MD; Frank Chervenak, MD; Daniel Skupski, MD
Liability Premiums Obstetrics

WCM Ob Liability Premiums 2007-2017

2007: $235,000
2008: $200,262
2009: $185,509
2011: $164,081
2012: $135,032
2013: $129,150
2014: $116,236
2015: $110,422
2016: $104,901

2017: $104,901
Reduction of cesarean delivery rates after implementation of a comprehensive patient safety program

Amos Grunebaum*, Joachim Dudenhauen, Frank A. Chervenak and Daniel Skupski
Department of Obstetrics and Gynecology, New York Weill Medical College of Cornell University, New York, NY, USA

Abstract

Aims: The objective of this paper was to review our institution’s cesarean delivery rates starting in 2004 prior to the full implementation of a patient safety program including a uniform oxytocin policy until 2012 when the oxytocin policy and the safety program had been fully implemented.

Results: Cesarean delivery rates at our institution decreased incrementally from 41.6% in 2004 to 32.7% in 2012. The decrease in cesarean delivery rates was observed for each of the five age groups.

Conclusion: Concerns about an increase in cesarean delivery rates after implementation of a comprehensive patient safety program including a standardized oxytocin protocol may be unfounded. Despite the increase of US national cesarean delivery rates, our study shows that it is possible to safely lower cesarean delivery rates without concomitant concerns of litigations.

J Perinat Med. 2012 Oct
We made the decision to make significant changes to our culture on the Cornell L&D in order to make it safer to have a baby and to decrease professional liability costs
New York Weill Cornell
Obstetric Safety Program 2002 - Now

1. Team Training
2. Electronic Charting
3. Chain of Communication
4. No Misoprostol
5. Standardized Oxytocin Protocol
6. Premixed Medications
7. Templates for Documentation
8. Review of Malpractice Suits
9. Safety Nurse
10. Physician Assistants
11. Fetal Monitoring Certificate
12. Electronic Records
13. Thromboembolism Prophylaxis
14. Laborist
15. Oxytocin Checklist
The 7 deadly sins

1. Lust
2. Gluttony
3. Greed
4. Sloth
5. Wrath
6. Envy
7. Pride
Miscommunication

The 7 deadly sins

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Team Training:
A program that teaches high risk clinical departments how to function effectively as a team

• 4-8 hour course, everybody has to attend

• Check-back: Read back abnormal findings

• Two-challenge rule: Let someone know that they are making a mistake

• Call-out: Let everybody else know

• Hand Off: Signout effectively
Miscommunication

The 7 deadly sins

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NYP Labor & Delivery Team
Surviving Hurricane Sandy: October 29, 2012
Safety Nurse
Drills

- Shoulder Dystocia
- Bleeding
- Cardiac Arrest
- STAT Cesarean
Shoulder Dystocia Drills
L&D Nursing Station
Circa 2005
Electronic Board
Friday January 6, 2006
2005 Changing Labels

BEFORE

NOW
FIGURE 1
Chain of communication

Primary Nurse

Resident NP/Midwife

Charge Nurse/Nurse Manager/Supervisor

Chief Resident

Fellow (if Applicable)

Patient’s Attending

Floor Attending

Director of L&D or Director of High Risk OB or Director of OB Services

Chairman of Obstetrics & Gynecology
“Preventing Medication Errors” IOM

- “on average, a hospital patient is subject to at least one medication error per day, with considerable variation in error rates”
- There are “…enormous gaps in the knowledge base with regard to medication errors”
- A key approach for reducing medication errors is “establishing and maintaining a strong provider-patient partnership.”
OXYTOCIN AS A HIGH-ALERT MEDICATION: IMPLICATIONS FOR PERINATAL PATIENT SAFETY
In 1955, the Nobel Prize in chemistry was given to du Vigneaud for the isolation and synthesis of oxytocin, the principal agent causing contractions of the uterus and secretion of milk.
Oxytocin/”Pit”
Used to induce labor

- #1 drug on L&D
- #1 drug responsible for late decelerations
- #1 drug to injure babies and mothers

**Graph Data**

- Oxytocin: 22%
- Terbutaline: 9%
- Magnesium Sulfate: 7%
- Meperidene: 3%
- Fentanyl: 3%
2/3 of adverse outcome/liability cases were associated with Oxytocin induction or stimulation of labor.
Standardized Oxytocin Protocol

• Even though standardized and uniform practice patterns are known to have better outcomes than greater practice variations, medical practice continues to be characterized by wide variations that have no basis in clinical science.

• Oxytocin is the most frequently used intravenous medication in obstetric practice, but it is also among the drugs known to be used in many variations.
"Acceptable" ACOG Protocols for Oxytocin Stimulation of Labor

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Starting dose (mU/min)</th>
<th>Incremental Increase (mU/min)</th>
<th>Dosage Interval (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-dose</td>
<td>0.5-1</td>
<td>1</td>
<td>30-40</td>
</tr>
<tr>
<td></td>
<td>1-2</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>High-dose</td>
<td>~6</td>
<td>~6</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>6,3,1</td>
<td>20-40</td>
</tr>
</tbody>
</table>

ACOG Practice Bulletin 12/2003
Standardized Oxytocin Policy Weill Cornell

- Only Attendings can order Oxytocin
- Oxytocin Template Note
- 30 U in 500 cc by pump Buretrol minidrip
- Line must always go through pump
- Standardized dose and management: 1 mU/min q 15 min
- **Tachysystole**: Over 5 contractions in 10 min (independent of fetal heart rate)
- Nurses are empowered to decrease or stop Pitocin if tachysystole is observed – With or without FHR changes
Misoprostol/Cytotec
Used frequently for labor induction
Misoprostol/Cytotec

• Misoprostol/Cytotec has not been used at New York Weill Cornell for the last 10 years for induction of labor in a live viable fetus

• Our anesthesiologists report that our stat cesarean section rates for tachystole/fetal distress have significantly decreased
• “but without misoprostol our cesarean section rate will go sky-high.”

➤ Some of our attendings when discussing removal of misoprostol from L&D for live viable fetuses
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US Maternal Deaths: 2.8 per 10,000 Births
Why Do Pregnant Women Die?

1. Hemorrhage/Bleeding after birth
2. Pulmonary Embolism
3. Hypertension/Preeclampsia
Maternal L&D Deaths Weill Cornell Last 9-10 years (50,000+ Births)

- Expected: 14 Deaths
- Actual: No maternal L&D deaths
Saving A Life Takes A Village

- Surgery
- Medicine
- Intensive Care
- Stroke specialists
- Radiology
- Interventions
- Cardiology
- Nursing
- Pulmonary
- Hematology
- Pharmacology
- Blood Bank
- Anesthesia
- Others
Preventing Thrombembolic Events
Routine Heparin s.c. for all Post Cesarean patients
Weill Cornell: First in US based on British protocol

Routine heparin thromboprophylaxis is necessary for cesarean delivery patients
Sarah Anderson¹, Jonathan Reiss¹, Stephanie Lin¹,
Daniel Skupski², Amos Grunebaum¹
¹New York Weill Cornell Medical Center, Obstetrics and Gynecology, New York, NY, ²New York Hospital Queens, Obstetrics and Gynecology, New York, NY

OBJECTIVE: To assess our obstetric population’s risk factors for venous thromboembolism (VTE) and determine adherence to current Royal College of Obstetrics and Gynecology (RCOG) guidelines for peripartum thromboprophylaxis with low molecular weight heparin (LMWH).

STUDY DESIGN: Retrospective review of 500 consecutive births from 11/2010 to 12/2010. Patients with risk factors indicating a need for additional VTE prophylaxis with LMWH were compared with those patients who received LMWH using current RCOG criteria.

RESULTS: Thromboprophylaxis with LMWH was indicated in 266/500 (53.2%) of all of our patients, 143/159 (89.9%) of patients undergoing cesarean delivery (CD), and in 123/341 (36.1%) of patients having vaginal birth (VB). Of the women at risk for VTE, the percentage of those who received thromboprophylaxis with LMWH in these three groups was only 16/266 (6.0%), 9/143 (6.3%), and 7/123 (5.7%) respectively. Top risk factors for VTE were: age over 35, BMI > 30, elective or indicated CD, and preeclampsia (Table).

CONCLUSION: Over one-half of all deliveries (53.2%), and a majority of cesarean delivery patients (89.9%) in our population had an indication for LMWH thromboprophylaxis. Only a minority of patients (6.0% of all patients, 6.3% of CD patients and 5.7% of VB patients) actually received LMWH. A checklist-based system may provide appropriate thromboprophylaxis for many patients who are currently at risk for VTE without intervention. Given that the vast majority of our CD patients are at risk of VTE, administering universal postoperative LMWH thromboprophylaxis to all patients undergoing CD without a contraindication to LMWH would prevent missing any CD patients who are at risk.
Weill Cornell Medical Center
Labor & Delivery Central Location
Weill Cornell Medical Center
Labor & Delivery Central Location

- In the middle of the Hospital
- 7th Floor West
- Postpartum floors on same floor
- High Risk floor next to L&D
- Blood bank same building
- Laboratory same building
- Intensive care units ICUs 30-60 seconds away
- Main ORs 30-60 seconds away
- Crash/Code team 60 seconds away
- Specialists in-house
Nineteen Possible Ways To Get Sued For Ultrasound

1. Missing the sonographic finding.
2. Misinterpretation of the sonographic finding.
3. Failure to compare findings with previous ultrasound.
4. Failure to properly communicate the sonographic report to the referring physician or the patient.
5. Failure to personally examine the patient or take a proper history.
6. Incorrect sonographic approach for a specific condition.
7. Incomplete examination.
Nineteen Possible Ways To Get Sued For Ultrasound

8. Inadequate quality of films.
9. Slip and fall injuries.
10. Complications from puncture techniques under ultrasound control.
11. Failure to obtain informed consent.
12. Complications of ultrasound such as induced vaginal bleeding or abortion.
13. Equipment complications (e.g., electric shocks)
14. Failure to recommend additional sonographic or radiologic studies or biopsy.
Nineteen Possible Ways To Get Sued For Ultrasound

15. Failure to order a sonographic examination.
17. Loss of films, inadequate filing system, misplacement of films or reports.
18. Abuse of patient by sonologist or sonographer (sexual, physical, or mental).
19. Miscellaneous anxiety produced by misdiagnosis, invasion of privacy, etc.

1. Team Training
2. Electronic Eclipsys Charting
3. Added Gyn Attending 24/7
4. Safety Nurse
5. Pitocin Policy
6. Color Coded Labels for Pitocin/Magnesium Sulfate
7. Premixed IV Solutions
8. Electronic Whiteboard
9. Fetal Monitoring Certification
10. Epic Charting
11. Drills & Simulation
Total Liability Premiums WC

WCM Ob Liability Premiums 2007-2017

- 2007: $235,000
- 2008: $200,262
- 2009: $185,509
- 2011: $164,081
- 2012: $135,032
- 2013: $129,150
- 2014: $116,236
- 2015: $110,422
- 2016: $104,901
- 2017: $50,000
The Second Law of Thermodynamics

- The Entropy of the Universe tends to Increase
- The challenge to assure that entropy in obstetrics does not increase
• For centuries, medicine has been based on “individual achievements”
• This has been changing
• Teamwork is important
• Don’t just look into what’s “acceptable”
• Try finding out what’s the safest
Definition of Insanity

“Doing the same thing over and over again and expecting different results.”

Albert Einstein
Miscommunication

The 7 deadly sins

1. Lust
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4. Sloth
5. Wrath
6. Envy
7. Pride
It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change.

Charles Darwin
The New York Hospital
The New York Hospital and Lunatic Asylum
Weill Cornell

Sanity and Patient Safety on L&D
Time for Malpractice Reform in New York State?

To the Editor:

Re “A Bad Deal on Malpractice” (editorial, March 13):

New York’s medical liability system is in a crisis. New York has among the highest awards in the country, driving up costs. Premiums can reach $200,000 a year. Fewer young doctors are choosing to practice in ob-gyn. Hospitals are under severe financial stress even to provide ob-gyn services. The patients stand to suffer if we cannot bring costs under control.

Enhanced patient safety alone cannot solve the liability crisis. All physicians have an ethical responsibility to continue to improve methods of care that can increase safety and improve outcomes. But the liability problem is too large and too diverse to be resolved solely by improved patient safety. We must have meaningful liability reform.

Gov. Andrew M. Cuomo has proposed a serious set of liability reform proposals as part of the package approved by his Task Force on Medicaid Redesign. We strongly support these proposals and urge the Legislature to enact them promptly.

Frank Chervenak
Amos Grunebaum
Daniel Skupski

New York, March 14, 2011

The writers, obstetrician-gynecologists, are the authors of the study on patient safety for ob-gyn patients at NewYork-Presbyterian Hospital/Weill Cornell Medical Center cited in the editorial.
“We choose to go to the moon in this decade and do the other things, not because they are easy, but because they are hard, because that goal will serve to organize and measure the best of our energies and skills, because that challenge is one that we are willing to accept, one we are unwilling to postpone, and one which we intend to win.”

President John F. Kennedy,
September 12, 1962,
Rice University,
Houston, Texas
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