High Reliability Perinatal Units
An Approach to the Prevention of Patient Injury and Medical Malpractice Claims

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Potential Conflict of Interest: Consultant for Perigen
What has happened to the awards?

<table>
<thead>
<tr>
<th></th>
<th>1990</th>
<th>2000</th>
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<tbody>
<tr>
<td>Perinatal Asphyxia</td>
<td>$4.5-6 Million</td>
<td>$8-12 million</td>
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<tr>
<td>Permanent Erb’s Palsy</td>
<td>$250,000</td>
<td>$2 million</td>
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<tr>
<td>Fetal/Neonatal Death</td>
<td>$50,000</td>
<td>$125,000</td>
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Proposal

- Let's stop thinking about the problem in terms of obstetrical malpractice.
- Instead, let's think about the problem in terms of patient safety:
  - More positive
  - Something we can do something about
  - More important
  - Sleep better
  - Perform better
How well do hospitals do with Patient Safety?

- Institute of Medicine Report of 1999
  - No change yet in 2010
  - Approximately 100,000 patients die each year due to medical errors
  - No change since this observation was first made by Leape and colleagues in 1991
- From 2001 to 2006 there were no deaths due to airline accidents
- In the same period there were an estimated 250,000 to 500,000 preventable deaths in hospitals
  - That is the equivalent of crashing 1400 fully loaded Boeing 747’s with no survivors
- In the U.S. it is estimated that patients receive recommended practice only 50% of the time
- In an ICU the average patient requires 146 actions per day
What is the Evidence Patient Safety in Obstetrics is not Optimal

WHO IS AT GREATEST RISK FOR RECEIVING POOR-QUALITY HEALTH CARE?

58 INDICATORS EXAMINED
54.1% GOT RECOMMENDED CARE

Asch et al, NEJM 2006;354:1147-56
53% offered HIV test at first prenatal visit

44% with risk factors got glucose screen 24-28 weeks

48% with abnormal glucose screen got 3 hour GTT

33% of women undergoing cesarean got prophylactic antibiotics (65% got appropriate antibiotics)

74% of women with diagnosis of failure to progress were in the active phase of labor

42% of women with >100,000 colonies on urine culture got appropriate antibiotics

68% with 140/90 > 20 weeks had proteinuria and edema assessed
No change in the rate of cerebral palsy
No change in the rate of brachial plexus injury
No change in the rate of maternal death (actually rising)
Rising rate of prematurity but never less than when we first started keeping track
How about steroids and GBS prophylaxis?
Are there signs out there that we can do better?

- HCA
- Several studies in press from individual institutions
Hospital Corporation of America

- 220,000 deliveries annually
- 124 facilities
- 21 states, including Texas and Florida
Then we use consensus based medicine

Work Group: 120 OBs, 120 OB nurses, 120 Peds/Neos
Frequency Trends
Reported Claims Per 10,000 Births
Accident Year

HCA
HCA, ex Texas
What are the lessons and how can we learn to take these lessons to our individual hospitals?
Examples of High Reliability Complex Organizations

- Airline in flight
- Airline traffic control
- Nuclear power plants
- Banking industry
- Aircraft Carriers
- Chemical Plants
Similarities Between Obstetrical Units and High Reliability Organizations

- Perinatal systems are complex
  - Various levels of Ob and Neonatal care
  - Network of
    - Offices
    - Antenatal testing units
  - Variety of professionals
  - Diverse roles and responsibilities
  - Utilize complex technology
- Expected to operate without mistake over long periods (e.g. no preventable fetal and neonatal injury)
- Often work long shifts and/or are sleep deprived
- Good outcomes usually occur even when mistakes are made
Aircraft flight errors have decreased 400% over last 2 decades.
Commercial Aviation Worldwide Accident Rate (Boeing, 2000)
IN 2002 AND 2004 THERE WERE NO DEATHS DUE TO COMMERCIAL AVIATION ACCIDENTS ON THE PLANET EARTH

Can we say the same for preventable cerebral palsy or Erb’s palsy?
What can we learn from the airline industry?

- “Why Hospitals Should FLY” by John Nance
  - The Boeing Model 299 – 1935
    - Origin of the Check list
  - The Tenerife accident - 1977
    - There is rarely a “root cause.” Most accidents are a series of mistakes
      - Most often are due to erroneous PERCEPTION, improper ASSUMPTIONS and botched Communication
    - Hierarchy does not work
    - The “halo effect”
  - Autonomy – flight 90 – 1982
    - Airline policy now that all crew members have a say in safety issues
  - Improved communication/interactions
  - Standardized procedures
  - Restriction on amount of time flying without sleep
  - Simulators
  - Learn from near misses
Perinatal Injury is Commonly Due to Organizational Factors – Systems Problems

- System complexity
- Normalization of Deviance
- Production Pressures
- Hierarchy – Hero worship
- Sleep Deprivation*
- Harmful/abusive behavior
- Failure of trust, teamwork and effective communication
A Proposed Approach to Thinking About Patient Safety

- Errors (Defects) are inevitable – human infallibility is impossible.
- There is rarely a “root cause” multiple missed opportunities usually precede major bad outcomes.
- Errors are most often due to problems with PERCEPTION, ASSUMPTION, and POOR COMMUNICATION.
Each of these High Reliability Units share the following organizational and operational characteristics.

- **Safety is a culture**
  - Responsibility and duty of every team member
  - Everyone is considered competent
  - Everyone has an obligation to “speak up”

- **Operation is a team, not an individual, function**
  - Team interaction is collegial, not hierarchical

- **Communication is highly valued and rewarded**
  - Used to
    - orient
    - plan
    - update
    - adjust to the unexpected
    - test assumptions
    - debrief unusual or unplanned events

- **Emergencies are rehearsed and the unexpected practiced**

- **Systems are created to avoid mistakes due to complexity**

- **Continuously redefine risks by accidents that do not occur (NEAR MISSES)**
  - Unknowingly technical and professional standards degrade with time
  - Technical groups become lax because of tendency to “get away with it”
The Toxic Environment

- Examples
  - Pronovost’s OR example

- Every day Labor and Delivery interactions
  - Doctor not on site
  - Fear of reprisal
  - Concern for doctor’s sleep/busy office
  - Complex systems (fetal monitor)
  - Lack of willingness to address complications/bad outcomes as a team
  - Fatigue
  - Fear of litigation
What we need to do about it?

- Every one should be able to question and discuss
- Errors must not be viewed as human fault but system fault
- We must (as much as we hate it) begin to standardize care
  - Doesn’t matter if there is clear established best practices (although we would do well if we just standardized these)
Good outcomes are the bane of Obstetrical Safety

“Normalization of Deviance” Diane Vaughn

- Conceptually this is two things
  - Policies tend to degrade over time
  - Deviation from well proven solutions will continue as long as there is no associated bad outcome (The “O.J.”)

- I have never had a problem with that – why should I change” (The three dirty words – “In my experience”)
  - Assume an Ob does 140 deliveries per year
  - 1 permanent brachial plexus injury every 33 years
  - 1 case of CP due to intrapartum asphyxia every 48 years
  - 1 case of CP due to uterine rupture every 403 years

- We need to learn from our near misses not our mistakes
Common Organizational Features Differentiate and Characterize Highly Reliable Perinatal Units

Recognition of and Policies for Dealing with the Most Common Liability/Safety Areas
What are the key elements of a labor and delivery safety program?

- Team training – “Crew Resource Management” Seminars
- EMR – with decision support is ideal
  - Electronic access to prenatal records
- Standardized protocols (limited)
- On line Certification for EFM
- Check lists
- Drills
- Simulators
- Templates for documentation/EMR with Decision Support Systems
- Perinatal Safety Nurse
- L and D Hospitalist (Laborist)
- Debriefing and near miss events meetings
- Anonymous event reporting systems
- Safety committee – all participating health care workers
Safety is the number one purpose of our business

- Clinical safety is actively taught and constantly reinforced
  - Sign-out at change of shift for both nurses and doctors emphasize
    - What could go wrong
    - How to prevent it
  - Patients are transferred in a timely manner
    - To the OR
    - To the higher level facility
  - Simulation models must be developed and implemented
    - Shoulder dystocia
    - Forceps and vacuum
  - Drills for high risk problems must be developed and implemented
    - 30 minute CS drills are practiced unannounced
    - Shoulder dystocia drills
    - Post partum hemorrhage teams and drills
Safety is the number one purpose of our business

- Check lists for complex issues
  - Cord pH
  - Need for resuscitation team
  - Oxytocin administration
- Forms for problems where failure to document is a common theme
- OR, surgery team, anesthesia are always available – I would add an OB MD who can perform the CS
- Resuscitation team is always present for a birth when any suggestion of NRFS exists – check list established
- Recertification of nurses and doctors in complex/common problem areas
  - EFM
  - Shoulder Dystocia
- Must learn from near misses
Fetal Well Being is used as a necessary condition of:

- Maternal discharge before delivery
- Maternal medication
- Epidural anesthesia
- Oxytocin administration
- Absence of fetal well being requires
  - Written evaluation by the physician
Five common recurring clinical problems account for the majority of fetal and neonatal injuries

- Inability to recognize or respond appropriately to antepartum or intrapartum fetal distress
- Inability to timely perform a cesarean section
- Inability to appropriately resuscitate a newborn
- Inappropriate use of oxytocin
- Fetal trauma
  - Inappropriate use of forceps/vacuum
  - Shoulder dystocia
EFM and Oxytocin are the two biggest problems in Labor and Delivery.
Common Pitfalls in Intrapartum Monitoring

- Delayed response time
- No EFM in DR/OR and/or prolonged interval from D/C’ing monitor to delivery
- Failure to recognize late decelerations
  - subtle/shallow lates
  - abruptio placentae
  - premature babies with inadequate contraction monitoring
  - inadequate external tracing
- Continued oxytocin despite nonreassuring tracing
- Failure to recognize unusual tracings
  - blunted tracings
  - sinusoidal tracings
- No EFM strip in Ob evaluation area on discharged patients
- No umbilical cord pH
EFM

- Universal learning of EFM/annual certification required
  - [www.gehealthcare.com/fhr](http://www.gehealthcare.com/fhr)
- Know and use standard nomenclature
- Ongoing audits and educational sessions to review interesting cases with nurses and doctors together
- Monitor strip on all triage patients – protocol for when physician must evaluate patient
- Fetal well being is established on every admission – **any non-reactive tracing** requires immediate physician evaluation
- AFI and presentation can be evaluated by ultrasound by the nurse or in house physician – any at risk patient
- Amniotomy to r/o meconium done on at risk patients
- Internal monitors used when FHR is non-reassuring and an adequate external tracing cannot be maintained
EFM QUALITY IMPROVEMENT

- Nurse to initial strip Q 15 min
  - More important than routine documentation
  - Documentation of intervention and notification for all non-reassuring patterns
  - Define non-reassuring patterns
- P&P for when physician needs to evaluate strip
  - If the nurse thinks there is a problem, there probably is - come in and see the patient - take care of problem nurses later - education or otherwise
  - L&D Hospitalist
- Home Web based EFM review
  - EFM Company supported computer based systesm
  - Airstrip technology
- Have a good system for FHR monitor storage and retrieval
- A cord pH is done on any baby with a clinical condition which might be associated with asphyxia or a lawsuit
- Send placenta to path for any low pH, high base excess
Indications for Umbilical Cord pH
A proposed check list

- Premature delivery < 34 weeks
- Moderate or thick meconium
- Any of the following non-reassuring patterns with one hour of delivery
  - Persistent late decelerations
  - Fetal tachycardia
  - Reduced variability (<=5 bpm)
  - Severe variable decelerations
  - Recurrent prolonged decelerations
  - Bradycardia
- Intrapartum vaginal bleeding > “bloody show”
- Maternal Fever (>= 100.4 F)
- Apgar score < 7 at one and/or 5 minutes
- Unexpected fetal anomaly
- Instrumented vaginal delivery
- Shoulder dystocia
- Breech or other malpresentation delivered vaginally
- Any non-elective cesarean section
Why is Oxytocin a problem?

- Cannon fodder for plaintiff’s attys
- Oxytocin is used on about 70% of all laboring women
- Hyperstimulation is the rule
  - Six or more contractions per ten minutes
  - Contractions lasting more than two minutes
  - Contractions occurring within one minute of each other
  - Definition may or may not include the association of a non-reassuring FHR pattern
- While it is not clear that there is an association between hyperstimulation and brain damaged babies, the following arguments are made in court:
  - Dr., can oxytocin cause excess contractions?
  - Can excess contractions lead to temporary cessation of blood flow to the uterus and inadequate oxygenation?
  - Can inadequate oxygenation cause brain damage?
  - All they then have to do is show in a brain damaged baby is that Pitocin was used, there is hyperstimulation and there are associate FHR patterns which could be c/w hypoxia.
Inadequate Contraction Monitoring with Unrecognized Hyperstimulation
Oxytocin

- Check list for oxytocin use - one for induction and one for augmentation
- H&P, Physician order, pelvis clinically adequate and indication for oxytocin on chart
- EFW within past week on chart
- Physician readily or immediately available as defined locally with protocol
- One on one nursing
- EFM criteria established

  - No late decelerations within the last 30 min.
  - No variable decelerations to < 60 bpm for > 60 sec within the last 30 min.
  - Physician note required to continue oxytocin for any exception to the above

- Contraction criteria
  - Adequate recording of contractions documented or IUPC
  - UC’s not to exceed 5/10 min.
  - No two UC’s >120 sec. in 30 min.
  - If IUPC, MVU < 300 and resting tone < 25

- Protocol for dosing regimen
  - Written order and note explaining why to override
Instrumented Deliveries

- Adequate pelvis and EFW documented
- Fetal position documented
- Station documented
- Indication documented
- If for NRFS, procedure done under double set up conditions
- **Avoid vacuum followed by forceps**
- For vacuum, limit attempts to 3/20 minutes and document times for each pull, number of pulls and total duration
- Dictated delivery note or form with all required information
Shoulder Dystocia

- Risk factors identified
  - Post dates, obesity, abnormal GTT, previous large baby, large FH or Ultrasound evidence of macrosomia
- Ultrasound done in the last 3-4 weeks of pregnancy for EFW with any risk factor
- Counseling documented
- Delivery board documents “shoulder precautions”
- CS for prolonged second stage/no operative vaginal deliveries
- Shoulder dystocia team
  - Anesthesia, extra nurse or doctor, delivery doctor in early, resuscitation team
- Nurses and doctors trained in suprapubic pressure
- Know and use maneuvers: McRoberts, SP pressure, Corkscrew, extraction of posterior arm, Zavenelli
- Document time of delivery of head to remainder of baby
- Dictate note or use check list if shoulder dystocia present
Shoulder Dystocia

- 85% of cases in which money was paid over 6 years were primarily due to poor or ambiguous documentation.

- In 75% of brachial plexus impairment, an independent review could not tell if the standard of care was met or not.

Clark: HCA Data. Unpublished
Elements of Shoulder Dystocia Documentation

- List of all personnel present
- Type of delivery
  - Indication for instrumentation
  - Station and position of the head if instrumented
- Which shoulder was anterior
- Episiotomy and type
- Maneuvers performed and sequence
- Time elapsed from delivery of head to body
- Describe condition of the neonate
- Cord gases
HCA Shoulder Dystocia Delivery Note addendum

Time head delivered ________________ Time body delivered ________________

Initial Traction:
☐ Gentle attempt at traction, assisted by maternal expulsive forces

Any/all maneuvers that apply and the order in which they were utilized.

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<tr>
<th>Maneuvers utilized</th>
<th>In which order (circle)</th>
<th>By whom</th>
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<td>McRoberts</td>
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<td></td>
</tr>
<tr>
<td>Suprapubic pressure</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Episiotomy</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Episiotomy extension</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Posterior arm release</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Rubin’s Maneuver</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Woods maneuver</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
<tr>
<td>Other (list)</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
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Was fundal pressure applied by anyone after the head delivered?  ☐ No ☐ Yes:

The arm under the symphisis at the point the head was delivered was: ☐ Right ☐ Left

List other items of note ___________________________________________

_________________________________________________________________

Primary Care Provider* __________________________________________

Registered Nurse* ______________________________________________

Other Care Providers in attendance* ________________________________

Other Care Providers in attendance* ________________________________
Fetal Status/Resuscitation

- P&P
  - In what situations must team be called
  - When to call team
  - Who will resuscitate
  - Cord pH
  - Who assigns Apgars

- Equipment checks
- Resuscitation team 24/7
Many situations in Labor and Delivery compromise safety and increase liability exposure related to failure of the managing clinician to be immediately available.

L&D is an ICU
We are the last intensive care area not to have in house clinicians available to manage patients.
There are several options available to overcome this problem of not having a clinician immediately available.

- All physicians manage their patients from admission to delivery in house – **Not realistic**
- Physicians in large groups have call Dr. in house
- Physicians form large groups and keep one Dr. in house
- Hospital subsidized Dr. in house available for emergencies only
- **True Labor and Delivery Hospitalist/Laborist**
  - Manages all patients in house unless their own MD is present
  - Can bill and become self supportive
  - Does not compete for patients
  - Does a myriad of tasks not desired by Drs.
    - ER coverage
    - Drop in Deliveries
    - Administrative Duties
    - Nursing education
    - Assists in surgery
Key Elements of Changing the Culture in Labor and Deliver

- Read “Why Hospitals Should Fly (John Nance), “The Checklist Manifesto” (Atul Gawande) and “Safe Patients, Smart Hospitals (Peter Pronovost)
- Minimize the hierarchy/Create “Collegial Interactive Teams”
  - “Crew Resource Management Seminars” required
- Allow anonymous adverse event reporting
- Team rounds and/or Sign out Goals - a clear establishment of daily goals recognized by all team members
- Drills
- Simulation
- Checklists
- Standardized protocols for well established and high risk (both from a safety and medical legal perspective) clinical situations
- Recertification
- Have safety teams that work on the fly – recognize defects, problems, brainstorm and implement solutions
- Utilize an EMR with a decision support system built in.*
- Learn from your near misses – near miss teams or conferences
- Avoid sleep deprivation
How can we make these solutions happen?

- Clark – education fails, only strict enforcement succeeds
- Policies
- Strong leaderships
- Consultants
- Smart EMR’s – Decision Support Systems
What an EMR/Decision Support System can do to ensure patient safety

- Ensures documentation
- Ensures Critical Steps in Patient Care are not missed
- Educates
- Provides data
  - QA
  - Individual physician/nurse monitoring
  - Defines areas for improvement
- Reports
- Identifies events
  - Adverse outcomes
  - Near Misses
What a decision support EMR can do

We purchased PeriBirth because of its robust clinical decision support. Other than the reduction in claims (which is significant) how do we know if this tool is actually helping clinicians do the right thing? It’s a hard thing to quantify. But last week I was at McKee and the nurse manager told me about something she saw.

She was rounding on the unit and a nurse stopped her to say she had an order on her chart that she’d never seen before – “remove vaginal packing”. When they looked at the delivery report, sure enough, the physician had placed the packing due to heavy bleeding. When the doctor documented this, the system presents an alert for the physician to indicate when the packing should be removed. This was added to avoid the retained sponges on our vag deliveries. The nurse was impressed because the patient delivered 24 hours earlier and she had NOT received information in report that packing was left in.

I told the manager that was a wonderful example. She eagerly said, “Well, I’ve got another one for you”.

The anesthesiologist was in the chart shortly after the patient delivered. He received a prompt NOT to remove the epidural catheter. He started grumbling about “this stupid system” when the manager suggested he click on the explain button. The patient was scheduled for a tubal ligation the following morning and needed the epidural for that procedure. The anesthesiologist remarked that he almost did the wrong thing.

She also said the system has prompted them countless times about thrombocytopenia, a condition that needs to be carefully considered before a patient receives an epidural.

It’s pretty easy to focus on the problems with these systems and the challenges around change, but it’s nice to know that every day someone is benefitting from them. These are just a few examples from a facility that does 1,000 deliveries/year. Now do the math and you can see how often we are positively impacting patient care to the 30,000 deliveries we do every year. Impressive!
Errors do Occur

- Effective patient communication both before and after the injury
- Communicate with each other
- Debrief in calm, collegial environment after errors and near misses.
“It’s what you learn after you know it all that counts”

John Wooden