Medical Protocols
Do Protocols Improve Patient Safety & Outcome?
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Protocol - Definition
• The plan for a course of medical treatment
  — Guideline - A series of recommendations by experts
  — A compilation of the successful actions
• To achieve the same success on multiple patients
• Does not address every situation
• Is one of many strategies that can improve quality of care and patient outcome

Use of Medical Protocols
• Protocols should be defined and described in writing
• Must be readily available
• Should have an order initiating the use
• Protocol should be “individualized to the patient”
  — Ordered after an evaluation of the patient
• Monitoring parameters should be clearly stated
  — When and under what conditions is the Doctor is to be notified
• Protocol should include a timeframe for re-evaluation, for continuation, and order renewal

Medical Protocols
• For specific clinical circumstances
• Developed from evidenced based medicine
  — Exception – Psychiatry
    • Protocols based on opinion
    • No medical tests to show the conditions treated by psychiatry
• Presume its users to have certain background knowledge
  — Will not explain everything in complete detail

Protocols
• What are protocols?
• Why use protocols?
• How were the protocols developed?
• Why the recent push for medical protocols?
• Do protocols improve safety and outcome?

Proctocols
• The more skilled the person is in applying the protocol, the better the result
  — Must think about the clinical situation and the protocol
• Without protocols, treatment would be based on the skill of the practitioner and the diagnostic equipment
  — Each doctor prescribing a different course of treatment for the same medical problem
• Developed as a standard of care
Protocols – Standard of Care

- Medical malpractice has developed the standard
  - A treatment is not considered negligent if it meets the standard of the medical community
  - If all other medical practitioners follow a similar protocol

Protocols

*According to my new computerized diagnostic software, you need to upgrade your kidneys, de-fry your liver, and make a hard-up copy of your spleen.*

Why the Push for Protocols in Medicine?

- Liability
- Cost
- Quality
- Safety
  - Protocols for safety are relatively new
  - Came from reviewing medical malpractice data
- First developed by the Airline industry

Specific Protocols

May be Beneficial, But not Accepted

- Labor protocols in the United Kingdom
  - Active management of labor
  - Women are sent home if they are not in active labor (4-5 cm dilated)
- Breech deliveries
  - Breech vaginal deliveries
    - Would increase forceps delivery
  - Breech delivery – 2nd twin
    - Rupture the second sac, grab the feet, and pull the baby out before the cervix closes back down
  - Liability claims for bad outcomes of forceps or breech delivery may increase

Protocol Must be Applied Correctly

- 24 week pregnancy
  - Fetal demise
  - HELLP syndrome (uncontrolled blood pressures, elevated liver tests, platelets 20,000)
- Nurse followed the pitocin labor protocol
  - Overnight the pitocin was turned off for 2 hours because contractions were coming too often
  - Since protocol was followed, no physician was called

Previous Conventional Wisdom

Improving technology would prevent disasters
Portland, Oregon

The aircraft experienced a landing gear problem while on approach. The aircraft ran out of fuel while the crew circled in an attempt to remedy the problem.

Saudi Arabia

- Lockheed Tri-Star Riyadh to Jeddah
  - 301 persons died after a safe landing

Human Error

- Despite the improving technology, analysis of airline accidents concluded that 70% of all aviation accidents were the result of human error.
- Technology would not prevent the next accident

Major Causes of Human Error in Aircraft Accidents

Lack of Situational Awareness
Poor Decision Making
Lack of Communication
Lack of Teamwork
Lack of Resources
Lack of Knowledge
Lack of Assertiveness
Distraction
Pressure & Stress
Crew Fatigue

Herbert Heinrich’s Theory (1930’s)

- Preventing the unsafe act may prevent injury

Swiss Cheese Model of Error

- Error has a cumulative effect
  - A sequence of human failure leads to an accident or a bad outcome
- Swiss Cheese has random holes throughout a slice
  - These holes represent human error with the potential for bad outcome
  - Individual weaknesses in individual parts of a system
- Stack 15 random slices of Swiss cheese on top of one another
  - Most often you cannot see all the way through a stack of slices
    - The errors do not overlap
  - Occasionally the holes (errors) overlap and you can see all the way through the stack
    - This represents multiple errors and a bad outcome
Crew Resource Management (CRM) - 1979

- Accepted that human error occurs
  - Complex systems
  - Human limitations
  - Not all risk is foreseeable
  - Error is inevitable – The risk of failure is inherent
- The focus became - How to effectively manage error
  - Alert, well-trained teams are crucial
  - Key to safety is recognizing and managing error
    - “Stop being surprised by it, and be prepared for it”

CRM (Crew Resource management)

- Crew
  - Applies to any team (pilots, maintenance, Air Traffic Control, ICU staff, physicians, ECMO team)
- Resource
  - Other team members, equipment, procedures, systems
- Management
  - Specific behavioral skills to lead, communicate, make decisions and catch errors before they become serious or fatal
(E.g.: Pilots working with Air Traffic Control, conducting a “read back” of a new altitude clearance... or a nurse’s “read back” of verbal orders)

Maintenance Failures

Gordon Dupont’s “Dirty Dozen”
Human Performance in Maintenance Part 1 (HPIM) -1993

- Lack of Communication
- Complacency
- Lack of Knowledge
- Distraction
- Lack of Teamwork
- Fatigue
- Lack of Resources
- Pressure
- Lack of Assertiveness
- Stress
- Lack of Awareness
- Norms
Why Compare Aviation to Medicine?

- Commonalities between aviation and healthcare
  - High risk environment
  - Highly skilled professionals
  - Failures in teamwork can have deadly effects

- What aviation has learned...
  - Most crashes involve teamwork failure rather than mechanical failure
    - Miscommunication
    - Dropped communication
    - Hesitancy to question peer or “authority”
    - Written communication not accessed
  - Communication issues are evident in nearly all events or near misses

- Accident rate reduced since the introduction of CRM

Hospital Claim Allegations

- Breach of Confidentiality: 2%
- Surgical Foreign Body: 6%
- Improper Treatment: 8%
- Improper Performance: 38%
- Malpractice Error: 15%
- Other: 5%
- Diagnostic Error: 22%

The Quality of Care Problem

- Adverse events occur in 3% of all hospital admissions
- 1 to 50% attributable to preventable errors
- 10-14% result in death??
- 44,000 - 98,000 Americans die in hospitals each year as a result of errors
- Similar rates of adverse events occur in OB

Impact on Medical Malpractice

- Four ‘Never Events’ (preventable)
  - Are responsible for one out of every six medical malpractice liability claims:
    - hospital acquired infections
    - hospital acquired injuries
    - objects left in surgery
    - pressure ulcers

- These are SO preventable that many insurance companies will not reimburse for these

Aviation Human Factors Industry
News 1
Volume VIII, Issue 2, May 20, 2012

- Cause of Russian Jet Crash: Pilot Bravado
- Fatal 2010 helicopter crash likely caused by improper maintenance
- Convair 580, C–FKFY: Optical illusion blamed for Lytton, British Columbia, air tanker crash
- iPhone fire on flight caused by loose screw
- Air Canada sued for $20M over jet plunge
- Hostess plummets from Ryanair plane in Sweden
- Solving the Problem of Sleep deprived Pilots
**Unexpected Events in Obstetrics**

- Maternal death
- Fetal/neonatal death
- Fetal injury/trauma
- Unexpected NICU admission
- Apgar score <7 @ 5min
- Cord pH <7.00
- Maternal ICU admission
- Shoulder dystocia
- Postpartum hemorrhage
- Blood transfusion
- 3/4 laceration
- Uterine rupture
- Hysterectomy
- Return to OR

**O.R. Fire Safety – Training module**

- This training module will provide information that can be taken to prevent fires in areas with an oxygen enriched environment, as well as steps to take when a fire occurs.
- After reading the computer-based training module, participants will be able to:
  - Identify the components of the fire triangle (heat, air and fuel)
  - Identify the action to take if a fire occurs at Cedars-Sinai Medical Center
  - Identify proper handling of electrosurgical cautery pencil
  - Identify appropriate fire safety steps to take when performing head and neck surgery

**Cedars-Sinai – Los Angeles**

**Obstetrics**

- 4 million hospitalizations/year in US (2nd to CVD)
- Liability crisis
  - 50% of hospital risk management budget spent on OB
  - MCIC: 9% of claims, 26% of dollars paid are OB-related
  - >75% of birth related claims award >$1 million
- OB adverse outcomes have considerable impact
  - 2 patients
  - Neonatal injury results in long-term consequences
  - Financial impact
- Good outcomes are the expectation

**On fire in the OR: Hundreds are hurt every year**

- Latest data reveal about 600 people are set ablaze during surgery
- Chief focus should be on communication between the surgeon and the anesthesiologist, Bruley said, because they control two of three primary elements needed to ignite a fire in an operating room or anywhere else: heat, air and fuel.
- "If a surgeon is getting ready to use an electrosurgical pencil and he has not been informed that oxygen is flowing under the drapes, the result could be a fire," Bruley said. "Oxygen concentrations of 50 percent and higher will create a flash fire."
- About 65 percent of surgical fires occur on the upper body or inside a patient’s airway, another quarter occur elsewhere on the body and less than 10 percent actually occur inside the body cavity

**JAHCO**

- Sentinel Alert #30 (2004)
- Root cause analysis of 47 fetal deaths
  - 72% due to poor team communication (#1 cause)
  - 34% "inadequate" fetal monitoring
- Top recommendation:
  - “Team Training” to teach staff to work together and communicate more effectively
Medical Protocol

- Clinical guidelines as to how a medical practitioner should act under certain circumstances for certain patients
- Guidelines should result in the desired outcomes
- Development requires sufficient resources
  - People with a wide range of skills
  - Systematic review of the evidence available
- The practitioner should not just indiscriminately execute the guideline, but also use common sense

Medical Protocols

- Older protocols were not based on the best scientific studies
  - Outcome not safety based
- Best treatment now focused on patient safety and outcome
  - Chemotherapy for cancers
    - Medications are given that work the best and have the best safety regimen

Medical Protocol

- Clinical guidelines have potential benefits but may have unintended harm
- Because of the potential for benefit, guidelines are accepted more and more in the medical field
  - Promotion of high quality care
  - Reduction of variations in care
  - Improvement of cost efficiency

Useful Medical Protocols

- Trephining was used for treatment of intracranial and psychiatric disorders – 1500s
  - Drilling a hole in the skull let the ‘bad humors’ out of the head
- Trephined skulls have been found in France and in other parts of Europe, in northern Africa, Asia, New Guinea, Tahiti, and New Zealand – 8000 years old
More Useful Protocols

- Bloodletting drained the bad blood out
  - *Because blood was the carrier of diseases*
  - Allowed the body to produce good blood which would lead to recovery (1700s)
  - Likely caused George Washington's death (1799)
  - Also used for scurvy patients, 'lunatics' and woman in labor

- Amputation
  - The medical protocol for treating many gunshot wounds to the leg or arm in the Civil War often called for amputation of the limb (1860's)
  - Doctors did not have the ability to control infection

Protocols

- Our state of the art will likely be laughed at in the future
- We do not know how to appropriately manage many medical problems
- Current protocols are not necessarily the best way to manage
- So we must approach protocols knowing this
  - There can be unintended complications

GBS Screening & Treatment

- Desired Effect
  - Decreased GBS sepsis rates
- Unexpected Effect
  - Increased e-coli sepsis rates

Obstetric protocols

- Enhanced maternal care and antenatal health
- Induction
- Antibiotics for gestational surgery
- Assessment of fetal lung maturity
- Assessment of labor
- Intrapartum fetal surveillance
- Prevention of postpartum bleeding
- Care of the newborn in labor
- Cerebro-spinal surgery
- Complimentary emergency delivery
- Considerations for assisted reproduction
- Technology pregnancies
- Management of difficult cases
- Outpatient care of pregnant patients
- Preeclampsia
- Sepsis in labor
- Group B streptococci (GBS) preeclampsia
- Late preterm birth
- Intestinal amebiasis
- Magnesium sulfate for preeclampsia
- Magnesium sulfate for preterm labor
- Management of preterm labor and preterm delivery
- Aspiration
- Complications of tocolysis in pregnancy
- Management of complications in the newborn
- Management of antenatal labor
- Management of preeclampsia

Antenatal Steroids

- Liggins & Howie (1972)
  - Antenatal corticosteroids given to women at risk for preterm delivery reduced the incidence of RDS and neonatal mortality

- But, more must be better – So steroids were given weekly
  - Weekly steroids were associated with fetal cranial growth restriction

- Currently
  - Steroids are given one time, 2 doses, 24 hours apart
  - To women between 24 and 34 weeks gestation at risk for delivery in the next week

- Protocols must change and adapt to new information
  - Rescue dose?
  - 34 to 37 weeks?
  - Recent information – effective after 23 weeks
Surgical Site Markers: Putting Your Mark on Patient Safety


• During the NNIS reporting wrong site surgery initiative, several inquiries were received regarding the performance and sterility of surgical site marking pens.
• The majority of surgical site marking pens contain gentian violet ink, which has antifungal properties.
• Other types of marking pens used by some hospital staff to mark surgical sites are permanent ink markers and, less frequently, ballpoint pens.
• Surgical site markers are removed with skin preparation but should not be so permanent as to last weeks or months after the surgical procedure.
• Several studies describing the performance of pens or markers used to mark surgical sites were reviewed. None was conclusive in determining the best performance of marks on skin when used with skin prep solutions. Also reviewed were three studies that described the sterility of single-use surgical site marking pens and two studies that looked at cross-contamination from surgical site marking pens used on multiple patients.
• Based on the results of each sterility study, no infection or contamination was observed from single-use pens; however, the potential exists for cross-contamination from pens used on multiple patients.
• The results of the reviewed studies are not definitive as to the type of surgical site marking pen or the type of skin prep solution to use to obtain the optimal mark at the surgical site. Healthcare facilities may wish to conduct their own studies of surgical site markers and/or skin prep solutions to determine performance between markers and skin prep solutions.

Antibiotics for Cesarean Delivery

• Giving antibiotics
• Do you need to?
• Timing of antibiotics
• After cord clamp prevented sepsis work up for neonates
• Now recommendation is prior to cord clamp

Changes in Protocols With New Evidence

• We continue to learn and modify
• Some protocols previously developed need to be modified

Neonatal Resuscitation Protocol
– 2005 modified 2010
– Seven slides of changes to the protocol
Protocol Outcomes

- Protocols do not guarantee good outcome
  - Misapplied
  - Misinterpreted
  - Poor protocol
- Is there evidence that medical protocols improve outcome?

What Have Protocols Improved?

- Do protocols work?
- Depends upon what you look at
  - Cost?
  - Decreased liability?
  - Improved patient satisfaction?
  - Safety?
  - Improved patient outcomes?

Shoulder Dystocia

- Simulation training - Use of artificial pelvis
- ACOG checklist for shoulder dystocia
  - Score better on post-training exams
  - May go through more steps during an actual shoulder dystocia
  - Better documentation after delivery
- No data on improved maternal and fetal outcome

Medical Cost - Yes

- Standardized care has been shown to lower health care costs
- Adherence to protocols may reduce the costs of care up to 25%

Litigation - Yes

- Anesthesia and Obstetric physician societies
  - Reviewed closed claims from medical malpractice lawsuits to develop patient safety and treatment guidelines
  - The incidence and costs related to medical malpractice decreased and physician satisfaction improved
- Tort reform is needed, but also analyzing past medical malpractice litigation can achieve the same goals of lower costs while also promoting patient safety

Reducing obstetric litigation through alterations in practice patterns

- OBJECTIVE:
  - To estimate the extent to which obstetric malpractice claims might be reduced by adherence to a limited number of specific practice patterns.

- METHODS:
  - We examined all 289 closed perinatal claims between 2000 and 2005 from a single, large professional liability insurer. Each case was subjected to three separate analyses: 1) whether the adverse outcome was caused by substandard care, 2) what changes in practice would have avoided the adverse outcome, regardless of standard-of-care considerations, and 3) to what extent substandard documentation led to payment in cases in which there was no objective evidence of substandard care.

- RESULTS:
  - Seventy percent of claims involving obstetric practice (accounting for 79% of all costs) involved substandard care. Payments in 85% of cases involving non-vaginal birth after cesarean (VBAC) fetal monitoring, 16% of maternal injury cases, 80% of cases involving VBAC, and 54% of shoulder dystocia cases were avoidable had four specific practice and documentation patterns been followed.

- CONCLUSION:
  - Most money currently paid in conjunction with obstetric malpractice cases is a result of actual substandard care resulting in preventable injury.
  - Well more than half of hospital litigation costs might be avoided if physician practice included: 1) delivery in a facility with 24-hour in-house obstetric coverage; 2) adherence to published high-risk medication protocols; 3) a more conservative approach to VBAC.
Patient Satisfaction - Yes

- Care looks coordinated
- Patient perception of quality is higher
- Patient perception of professionalism is higher

Safety - Sometimes

- Can be harder to document
- Many reports have documented a reduction in litigation costs and therefore implied that safety is improved
- Not necessarily by direct measures
  - ’Additional research is warranted to further determine the impact of patient safety initiatives and simulation training on outcomes in the setting of obstetric hemorrhage.’

Safety - Sometimes

- STUDY - August 2007 to July 2009 - large tertiary medical center introduced:
  - (1) evidence-based protocols
  - (2) formalized team training with emphasis on communication
  - (3) standardization of electronic fetal monitoring with required documentation of competence
  - (4) a high-risk obstetrical emergency simulation program
  - (5) an integrated educational program among all healthcare providers

Safety - Maybe

Patient safety in obstetrics--the Hospital Corporation of America experience.

- Clark SL, Meyers JA, Frye DK, Perlin JA
- Hospital Corporation of America, Nashville, TN, USA.

Abstract

We report an update on obstetric patient safety efforts and results in the nation’s largest obstetric health care delivery system. The application of principles advocated by the Institute of Medicine a decade ago has resulted in reduced adverse outcomes, as reflected by claims experience. Particular progress has been made in standardization and documentation of critical processes, establishment of national quality benchmarks, reduction in elective deliveries <33 weeks’ gestation, and reduction in fatal post cesarean pulmonary embolism. Our experience provides a useful blueprint for similar progress in other health care systems.

Safety - Outcomes

- Eleven adverse outcome measures were followed prospectively
  - Adverse incidents decreased significantly from 2% to 0.8% (p<.0004)
  - Decreased birth trauma (p<.0022)
  - Decreased rates of return to the operating room (p<.018)

- Improvement in staff perceptions of safety (p<.0001)
- Improvement in patient perceptions of whether staff worked together (p<.028)
- Improved management (p<.002) and documentation (p<.0001) of abnormal fetal heart rate tracings
- Improved documentation of obstetric hemorrhage (p<.019)
Patient Outcome - Sometimes

- Little data on improved patient outcome
- Difficult to compare clinical situations
- Depends on how patient outcome is defined and evaluated
- Trend is towards better outcomes
- More research data needs to be published evaluating safety outcome

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Postpartum Hemorrhage

- Awareness of high risk patient for post partum hemorrhage
- Training in medical and surgical methods of controlling hemorrhage
- Early and coordinated use of help for a team approach
- Massive transfusion protocols

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Massive Transfusion Protocols in Obstetrics

- Am J Perinatology, 2012 Jul 26
- The Role of Massive Transfusion Protocols in Obstetrics.
- Pacheco LD, Saade GR, Costantine MM, Clark SL, Hankins GD
- Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, The University of Texas Medical Branch, Galveston, Texas.

- Obestetric hemorrhage is a leading cause of maternal mortality worldwide. New concepts involving the pathophysiology of hemorrhage have been described and include early activation of both the protein C and fibrinolytic pathways. New tendencies in hemorrhage treatment include the use of hemostatic resuscitation. Massive transfusion protocols involve the early utilization of blood products and limit the traditional approach of early massive crystalloid based resuscitation. The evidence behind hemostatic resuscitation is still limited.

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Medical Protocols

- Medical protocols will become more frequently used
- To control medical costs
- To decrease litigation costs
- To promote adherence to standard of care
- To promote quality care
- To decrease errors and provide safer care
Medical protocols

- It is not just the protocol that will improve these outcomes
- It is the staff
  - Understanding the patient’s clinical situation
  - Constantly reevaluating the patient
  - Responding in a timely manner to correct unforeseen events
  - And applying the appropriate protocol

Medical Protocols

- Unforeseen events occur
- Human error is inherent to any system
- We need to work together to prevent and correct these errors to improve outcomes
- Medical protocols are one way to do this