Conducting Reviews in Obstetric Hemorrhage

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RCA in Medicine

- Introduced by the US Department of Veteran Affairs (VA) and The Joint Commission (TJC) in the mid-90s
- Both developed their own programs
- TJC requires RCA for every sentinel event
- VA system submit RCA reports for serious adverse events to the National Center for Patient Safety
- 28 states require reporting of adverse events to state health departments

Total Reported Reviewable Sentinel Events by Year

The Joint Commission – Office of Quality Monitoring.
Sentinel Event Data: General Information, 1995 – 2Q 2014
The Joint Commission RCAs 2004 – 2Q 2014

(Events resulting in death or permanent loss of function)

<table>
<thead>
<tr>
<th></th>
<th>Maternal Events* (N = 120)</th>
<th>Perinatal Events* (N = 291)</th>
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<tr>
<td>Human Factors</td>
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<tr>
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<td>24</td>
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<tr>
<td>Anesthesia Care</td>
<td>7</td>
<td>10</td>
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</table>

* Majority of events have multiple root causes
The reporting of most sentinel events to The Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.
TJC Sentinel Event in Obstetrics

Comprehensive Accreditation Manual for Hospitals Update 2
January 1, 2015

Any intrapartum (related to the birth process) maternal death or severe maternal morbidity*

Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs), that requires the transfusion of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.
Severe Maternal Morbidity

- Define significant maternal morbidity and “near misses”

- All hospitals should identify women who:
  - Are admitted to an ICU during pregnancy (3-4 per 1000 deliveries)
  - Have been transfused with ≥4 units of blood (2 per 1000 deliveries)

- Not meant to discourage an individual site to use additional clinical criteria to define morbidity

- Cases of SMM should be reviewed for ongoing quality improvement

- ‘We believe they will serve as a good starting point’

TJC Sentinel Event Response

- Formalized team response
- Notification of hospital leadership
- Immediate investigation
- Completion of comprehensive systematic analysis
- Corrective actions
- Timeline for implementation of corrective actions
- Systemic improvement

➤ Neither necessary nor feasible for all cases of OB hemorrhage

http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf
Selecting Cases for RCA

• Culture of self-assessment needed for all cases of hemorrhage

• Screening process needed to reliably identify severe maternal morbidity and mortality (significant outcomes or near misses)

• RCA recommended when the consensus of the reviewing group is that
  – The standard of care was not met
  – The standard of care was met, but with room for improvement
Recommended Process for Obstetric Hemorrhage

DEBRIEF
- After ALL hemorrhages
- Involves ALL members of the team

Quality Assurance Review
- SMM: After transfusion of 4u PRBC or admission to ICU
- Involves QA committee

RCA
- Recommended by QA committee
- Institutional review with representative from each department involved in case
Disciplines Needed for Review of Severe Maternal Morbidity

- Obstetrics & Gynecology
- Maternal-Fetal Medicine
- Gynecologic Oncology
- Anesthesiology
- Nursing

Analysis of Hemorrhage Case

- Was the hemorrhage recognized in a timely fashion?
- Were signs of hypovolemia recognized in a timely fashion?
- Were transfusions administered in a timely fashion?
- Were appropriate interventions (e.g. medications, balloons, sutures, etc.) used?
- Were modifiable risk factors (e.g. Pitocin, induction, chorioamnionitis) managed appropriately?
- Was sufficient assistance (e.g. additional doctors, nurses, or others) requested and received?

Analysis of Hemorrhage Case

• When standards are not met or there is room for improvement, the case may be referred for RCA to determine:

  1. What happened in this case?
  2. What usually happens?
  3. Why did this outcome occur?
  4. What, if anything, can be done to prevent it from happening again?

Steps in an RCA

- Establishment of a *no blame* culture
- Identification of an event
- Formation of a multidisciplinary team
- Identification of all causes potentially associated with the outcome
- Development of targeted and measurable recommendations
- Effective communication to others in the organization about lessons learned from the RCA
Analyzing an Adverse Event

The Ishikawa diagram, also known as the “fishbone” diagram.
After these have been analyzed:

• Are there correctable things that have been identified, and what is the course of action to affect change?
• How will the effectiveness of the actions be measured and monitored?
Case Presentation: Background

• 34 yo G4P2022
  – OB history
    ▪ 2011 Term SVD
    ▪ 2012 7w SAB with D&C
    ▪ 2013 13w D&E, cystic hygroma
  – Antenatal course
    ▪ US 28w: complete placenta previa with suspicion for accreta
    ▪ MRI 29w: complete previa, no accreta
    ▪ US 35w: placental edge 2.2-2.7cm from internal os, no evidence of accreta
Case Presentation: Timeline

- **0700** Presented to triage @40w with ROM
- **1000-2232** Progressed along normal labor curve
- **2313** Delivery complicated by shoulder dystocia. EBL<500cc.
- Placenta noted to be densely adherent. Pt transferred to OR.
Case Presentation: Timeline

• **0135** OR Start time
  - Manual extraction attempted
  - Bimanual massage, pitocin, methergine, misoprostol
  - US shows retained fragment placenta
  - Sharp curettage attempted, Bakri placed
  - Brisk bleeding continues. EBL 2000cc. Gyn onc paged, blood bank notified of hysterectomy

• **0328** Hysterectomy started

• **0700** Surgery finished. EBL 4000cc. 8u PRBC, 4u FFP, 1 plt, 5300 IVF. Pt transferred to SICU.
Key Elements in Analysis of Severe Maternal Morbidity

• Was hemorrhage recognized in a timely fashion?
  ❯ Yes

• Were signs of hypovolemia recognized in a timely fashion?
  ❯ Yes

• Were transfusions administered in a timely fashion?
  ❯ Yes

• Were appropriate interventions used?
  ❯ Yes

• Was sufficient assistance requested and received?
  ❯ Yes
Key Elements in Analysis of Severe Maternal Morbidity

• Were modifiable risk factors managed appropriately?
  – Primary risk factor for hemorrhage:
    ▪ Abnormal placentation (not modifiable)
  – Imaging is not 100% effective for prenatal diagnosis of invasive placentation
    ▪ US: sensitivity 0.77, specificity 0.96
    ▪ MRI: sensitivity 0.88, specificity 1.0

➢ Yes

Warshak et al Obstet Gynecol 2006;108:573-81
Could outcome have been changed?

Severe Maternal Morbidity:

- Hysterectomy
  - Definitive management for hysterectomy
- Massive transfusion (>4u PRBC)
  - Balanced transfusion of products administered

Conclusion:

- Standard of care met

Recommendation:

- RCA not required
Case Presentation: Background

• 35yo G5P2113
  – Antenatal course
    ▪ Late transfer of care due to concern for accreta
    ▪ MRI 31w loss of placental margins consistent with placenta increta/percreta
    ▪ Planned C/D with accreta team @34w1d
      • Consented for CD/BTL/possible hysterectomy/possible bladder repair/blood transfusion
      • Anesthesia
      • 20u PRBC, 20u FFP, platelets prepared in Blood Bank

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Case Presentation: Timeline

- **9:10**: In OR, normal VS. Spinal administered by anesthesia. Normal labs

- **10:42**: Surgery start. Dense adhesions, placenta accreta with invasion into the left anterior wall of the uterus. Plan made for hysterectomy

- **10:44**: Vertical hysterotomy made to avoid placenta. Female infant delivered (Apgars 8/9)
Case Presentation: Timeline

• **10:49 to 11:25**: Intubated and transitioned to general anesthesia. Hysterotomy closed and hysterectomy completed. EBL 2500 cc. Total 7 units of PRBCs given.

Intraop labs sent:

Arterial blood gas: HCO3 17, **pH 7.19**, O2 sat 99.2, **PCO2 44**, PO2 158; Hgb 11.4, Hct 34, Ca 0.39, **K 7.1**

• **11:26**: Developed cardiac arrhythmia and subsequent cardiac arrest.
  - CPR started
  - Additional teams alerted: anesthesia, cardiology, CT surgery, perfusion, and nursing
Case Presentation: Timeline

• **11:52:** Cardiac arrest refractory to ACLS
  - CT surgery performed midline thoracotomy for internal heart massage.
  - Extracorporeal membrane oxygenation (ECMO) started.

• **15:30:** Transferred to the Cardiothoracic intensive care unit (CTICU)
  - Products received: 56 units PRBCs, 36 units FFP, 12 units platelets, 4 units cryoprecipitate
  - On 4 pressor agents
Case Presentation: Timeline

- **10/2/2010**: PRBC transfusions continued. Placed on cooling protocol in CTICU.
- **10/5/2010**: Family requested withdrawal of life support
RCA: The Four Questions

1. What happened in this case?

- Hysterectomy
- Blood product transfusion
- Cardiac arrhythmia
- Cardiac arrest
- Maternal mortality
2. What usually happens?

- Hysterectomy (expected)
- Blood product transfusion (expected)
- Arrhythmia (unexpected)
  - Response appropriate
    - ACLS initiated
    - Code called
- Mortality
  - May be as high as 3%
3. Why did this outcome occur?

- Reports and studies of severe metabolic acidosis due to hemorrhagic shock and hyperkalemia as well as hypocalcemia associated with rapid blood transfusion resulting in arrest refractory to CPR

4. What, if anything, can be done to prevent it from happening again?

- All standards of care met with room for improvement:
  - Determining location for performing CD for cases with potential need for ICU post-delivery
  - All appropriate cases scheduled for OR in main hospital rather than Labor and Delivery OR
RCA Experience

- **8276** RCAs submitted to TJC 2004-2Q 2014
- Countless more submitted to state health departments
- Experts estimate that each RCA requires 20-90 person hours to complete
- RCA frequently performed incorrectly or incompletely and do not produce usable results
- Practitioners reported barriers including
  - Lack of time, resources, data and feedback
  - Uncooperative colleagues, difficulty with teams, and inter-professional differences
  - Unsupportive management

The Joint Commission – Office of Quality Monitoring
Problems with RCA

- Formulating corrective actions (solutions) is more difficult than finding problems
- TJC and VA have not established standardized tools for action, follow-up or analysis
- Hospitals commonly experience repeated events
- No studies on the effectiveness of RCA in reducing risk or improving safety
- No evaluations of the cost or cost effectiveness

RCA: The Ideal

Errors are

✓ detected and reported
✓ subjected to root cause analysis
✓ used to design better practices, surveillance mechanisms, and systems

- RCA should be performed for every sentinel event and other selected adverse outcomes
- During a RCA each component of patient care is evaluated, and its contribution to the adverse event is assessed
- Problem solving and corrective actions then aimed at rectifying the identified key factors
Conclusions

- RCA has been widely recommended
- Although clear benefits, undercurrent of sentiment exists that this approach has limited effectiveness
- RCA processes must be evaluated for effectiveness and utility to increase usefulness
- Emphasis should be placed on understanding variations in implementation of RCA recommendations
- Represents a great area for research in obstetric hemorrhage
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