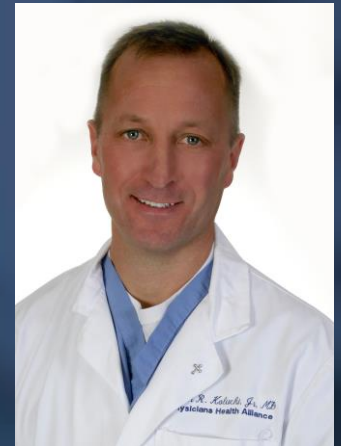




HEALTHTRUST®

November 29, 2018



Addressing the Tragedy of Maternal Mortality & Morbidity in America

A presentation for HealthTrust Members by

Frank R. Kolucki, Jr., M.D., FACOG

Chairman of the Department of Obstetrics/Gynecology, Moses Taylor Hospital

Addressing the Tragedy of Maternal Mortality & Morbidity in America: Part 1, High Reliability & Safety in Obstetrics: A Life-saving Approach

Disclosures

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Addressing the Tragedy of Maternal Mortality & Morbidity in America: Part 1, High Reliability & Safety in Obstetrics: A Life-saving Approach

Learning Objectives

- Discuss the concept of high reliability that could be replicated at any healthcare organization.
- Explain the foundations of team culture as exhibited by institutions that prioritize patient safety.
- Define the pillars upon which highly reliable clinical systems of care are built.



High Reliability & Safety in Obstetrics: A Life-saving Approach

| Maternal Mortality

An American Failure

- America is the most dangerous country in the developed world to give birth
- U.S. ranks 60th in the world regarding maternal death rate*
- Increased from 14 to 26.4 / 100,000 Births from 1990–2015

Source: *Berg CI et al Obstet Gynecol 2012*
ACOG Patient Safety and Quality Improvement

Maternal Morbidity is Extreme

- Shock
- Acute Kidney Injury
- Pulmonary Embolism
- Respiratory Distress Syndrome
- Myocardial Infarction
- Sepsis
- Increased by 45% from 2006 - 2015
- Affects 80,000 mothers per year



Sources: Callaghan, Wm et al. *Obstet, Gynecol*, 2012.


K Fingar et al *Trands and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity, 2006-2015*

| Maternal Mortality

An American Tragedy

- 40% of maternal deaths are **Preventable**
- Most maternal deaths from hemorrhage are **Preventable**

Source: Mary D'Alton, MD 51st Annual Update in OBGyn HMS 2014

The image features a blurred background of a hospital hallway with people walking. In the foreground, an IV drip is visible, hanging from a stand. The overall color scheme is a deep blue, creating a professional and clinical atmosphere.

Healthcare is a Team Sport

| Healthcare is a Team Sport

HealthTrust Team Members

- Nursing
- Pharmacy
- Laboratory Medicine
- Physicians
- Administrators

Maternal mortality and morbidity crisis cannot be fixed by obstetricians alone.

Need your help in your sphere of influence.

| Pathway 1

- Full-term pregnancy
- C/S for breech presentation (twin A)
- Two hours after delivery, increased bleeding in recovery room
- Physician called
- Medications ordered

| Pathway 1

- Continued bleeding
- Physician called again
- More medication ordered
- Continued bleeding
- Physician requested to come to hospital

| Pathway 1

- Doctor at bedside 5 hours later
- Patient in shock
- Emergency hysterectomy
- Patient coded and died on OR table

Pathway 2

- Full-term pregnancy
- C/S for breech presentation
- Bleeding in recovery room

Pathway 2

- Team assessed patient
- Nurse, obstetrician, CRNA and OR staff at bedside
- Medication given
- Continued bleeding

Pathway 2

- Patient taken to OR
- Uterine Tamponade Balloon placed
- Two units of blood given
- Patient and twins home on post-op day three

| Choice to Be Made

- Maternal death is the greatest tragedy in medicine today
- Pathway to success
- Pathway to failure

| Choice to Be Made

PATIENT SAFETY SUPERSEDES ALL

- Physician Convenience
- Nurse Convenience
- Patient Convenience

Choice to Be Made

Five Pillars Which Support High Reliability in Obstetrics

Physician Nursing
Three
Champions
Administration

MTH Family Birthing Suites



Date	OB Physicians	Births
7/2000	6	650
2004	6	1200
2005	13	2400
2007	16	2700+

| MTH Family Birthing Suites

- Level 3A Neonatal Intensive Care Unit (NICU)
- Patient catchment area extends to southern New York/Western New Jersey
- Maternal and Neonatal High Risk transfers
- 40% of patients classified as high risk

A 38-Year-Old Woman With Fetal Loss and Hysterectomy

Benjamin P. Sachs, MB, BS, Discussant

DR DELBANCO: Mrs W is a married, self-employed, healthy woman living in a community several hours from Boston. She has private health insurance. At age 38, she was admitted to the hospital for elective delivery of her first child, but the admission ended tragically with fetal loss, hysterectomy, and a prolonged hospitalization.

The pregnancy, her first, was wanted and uneventful. When seen initially by her obstetrician, Mrs W's blood pressure was 112/80 mm Hg. She showed no sign of labor at term. At 40 weeks of pregnancy, her blood pressure was 126/78 mm Hg, rising shortly thereafter to 144/85 mm Hg. She had trace proteinuria. Her creatinine level was 0.8 mg/dL (70.7 μ mol/L), and her uric acid level was 6.3 mg/dL. At 41 weeks of gestation, her obstetrician, Dr F, decided to admit her for misoprostol induction. Dr F was not on call that night.

On admission, the cervix was closed and 50% effaced, and her blood pressure was 124/90 mm Hg. She was given misoprostol (25 μ g, vaginally) and sent home that evening at 10 PM. On the way home she noted more contractions, turned around, and was admitted to the hospital at midnight in active labor. She was breathing uncomfortably with contractions, vomiting, and was hypertensive with a blood pressure of 174/104 mm Hg. The cervix was still soft and closed; the fetal heart rate was in the 130s, and no decelerations accompanied the contractions. At 1:30 AM, her membranes ruptured, and contractions were noted every 1 to 2 minutes. At 3:30 AM, her cervix was dilated to 2 cm and 90% effaced. The fetal heart rate was 120/min, with contractions every 1 to 2 minutes. She was given a test dose for epidural anesthesia (3 mL of 1%-5% lidocaine). At that point, her blood pressure dropped to 53/33 mm Hg, but it returned to 107/50 mm Hg with ephedrine. Accompanying the test dose, the fetal heart rate dropped to 80/min for 3.5 minutes, but then returned to the 130s. The epidural anesthesia was then initiated.

At 4:30 AM, the fetal heart rate was noted to have a saltatory (sawtooth pattern) with occasional late decelerations, and her cervix was dilated 4 to 5 cm. At 5:20 AM, she was fully dilated. She was having contractions every 1 to 2 minutes, and her medical record reveals that she was asked

to start pushing. Thirty minutes later the fetal heart rate was 115/min, with late decelerations. It quickly dropped to 90/min for 3 minutes, followed by further slowing for about 11 minutes. A low-forceps delivery (+2 station, right occiput anterior with caput and molding) was attempted at 6:20 AM and failed. She was rapidly transferred to the operating room; the fetal heart rate was in the 130s. An emergency cesarean delivery was performed. When the abdominal cavity was entered, the uterus was found to have ruptured in the lower segment and the placenta was in the abdomen. A stillborn male fetus, weighing 10 lb, was delivered at 6:45 AM; the fetal weight was determined after extensive efforts at resuscitation. The uterus was repaired, and Mrs W was transferred to the recovery room.

At 7:30 AM, the patient received 4 units of blood, along with misoprostol again for uterine atony. By 10 AM, a hysterectomy was performed for uterine atony unresponsive to uterine massage and intravenous pitocin, rectal misoprostol, and intramuscular 15-methyl prostaglandin F_{2 α} (Hemabate). This was followed by numerous complications, including bleeding with disseminated intravascular coagulation requiring the transfusion of 38 units of packed red blood cells, 42 units of fresh frozen plasma, 60 units of cryoprecipitate, and 111 bags of platelets. She required 3 weeks of hospital care thereafter, including 18 days in the intensive care unit. She encountered and overcame complex medical issues including prolonged disseminated intravascular coagulopathy, acute respiratory distress syndrome, sepsis, and a wound infection. She recovered steadily, was transferred to a rehabilitation hospital for further care for a few days, and then returned home where she received intensive physical therapy, occupational therapy, and other supportive care.

This conference took place at the Department of Obstetrics and Gynecology Grand Rounds at the Beth Israel Deaconess Medical Center, Boston, Mass, on May 12, 2004.

Author Affiliation: Dr Sachs is Chief, Obstetrics and Gynecology, Beth Israel Deaconess Medical Center; Harold H. Rosenfield Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School; and Professor in the Department of Society, Human Development and Health in the Faculty of Public Health, Harvard School of Public Health, Boston, Mass.

Corresponding Author: Benjamin P. Sachs, MB, BS, Department of Obstetrics and Gynecology, Beth Israel Deaconess Medical Center, 330 Brookline Ave, Boston, MA 02215 (bsachs@bidmc.harvard.edu).

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Clinical Crossroads Section Editor: Margaret A. Winkler, MD, Deputy Editor.

CME available online at www.jama.com

Beth Israel Deaconess Medical Center

- 38-year-old primigravida full-term
- Induction of labor
- Preeclampsia undiagnosed
- Fetal distress undetected
- Forceps delivery failed
- Emergency Cesarean Section
- Ruptured uterus
- Dead baby
- Hysterectomy, near maternal death

Source: JAMA August 17, 2005 Vol. 294 No. 7

| Obstetrical Catastrophe

- Reality check
- This could happen here

A blue-tinted photograph of a business meeting. In the foreground, a pair of glasses and a pen rest on a document featuring a bar chart. In the background, a person in a suit is seated at a table, holding a pen. A glass of water is visible on the left. The overall scene conveys a professional and analytical atmosphere.

High Reliability

| High Reliability

- The Right Thing
- The Right Way
- Every Time

Concept originated in the military, aviation industry and nuclear industry

Source: *ACOG Patient Safety and Quality Improvement*





Training

Audacity

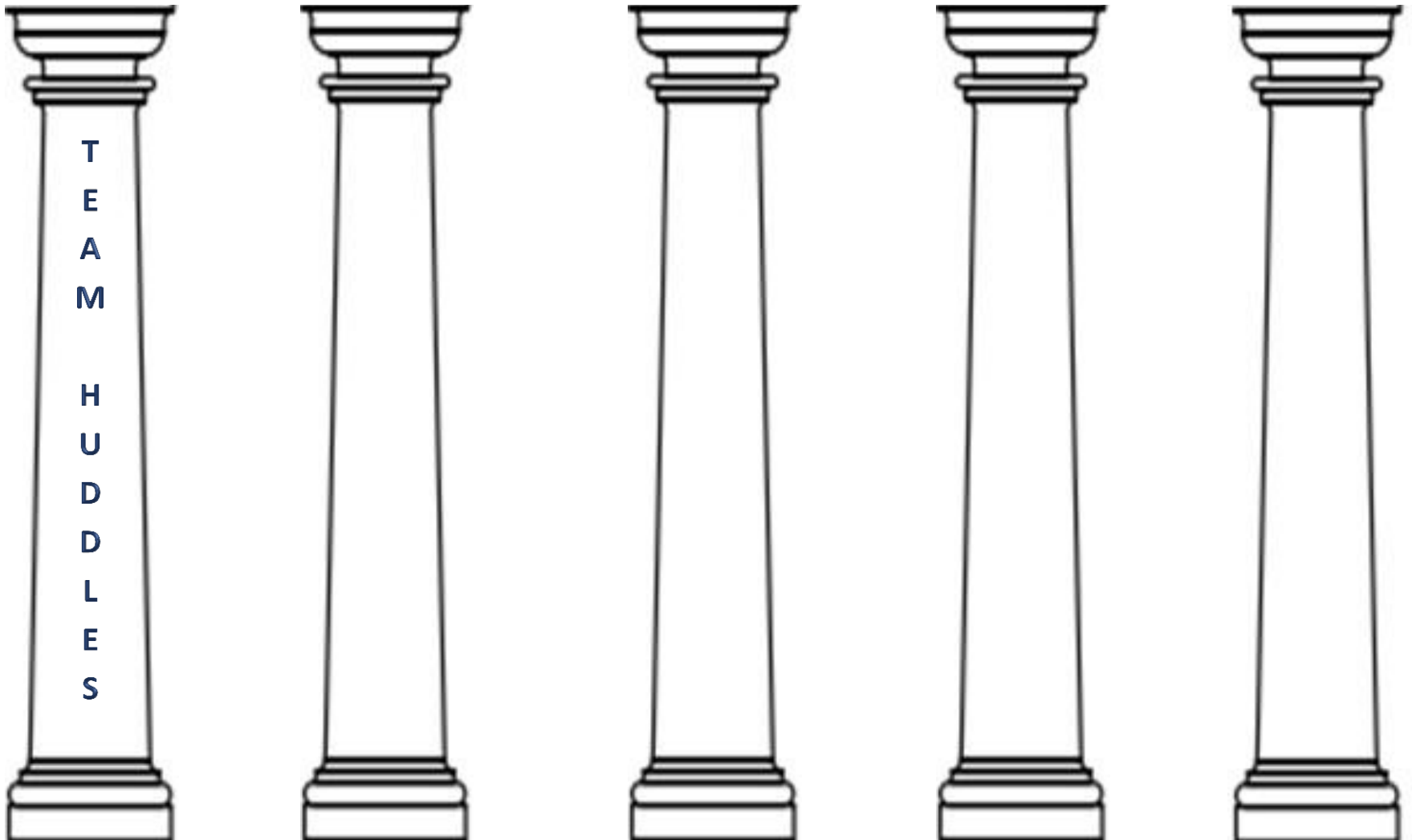


Stephen Ray Mitchell, M.D.



Stephen Pratt, M.D.

High Reliability / Safety in Obstetrics



Team Huddles 9AM, 8PM, PRN



| Team Members

- Labor Nurses
- Post-partum Staff
- NICU Staff
- Neonatologist
- Anesthesiologist
- CRNA
- Nursing Supervisor
- Secretaries
- Custodial Staff
- Labor & Birth Manager
- Director Women's/Children's Services
- OB Attending
- Chief Medical Officer
- Chief Nursing Officer
- Director of Quality & Safety
- Pharmacy Staff
- Social Work
- **Chief Executive Officer**

What Happens?

We Communicate!

- Review all patients
- Gain situational awareness
- Discuss Utilization / Allocation of Resources
- Resolve Conflicts
- Look for Potential Pitfalls

We Attempt to Outthink FATE

Source: *White AA, Pichert JW, Bledsoe SH, Irwin C, Entman SS. Obstet Gynecol. 2005;105:1031-1038.*



| Silo Mentality

My Patient

- One doctor
- One nurse
- One patient

- Tunnel vision
- Increased risk of injury

Team Culture

- Our patient
- Everyone's responsibility

- Power of collective intellect
- Injury risk mitigated

Source: *Mann Contemporary OB/Gyn January 2006*

| Change is a Loss for Someone

- Loss of hierarchical status
- Loss of power
- Loss of autonomy

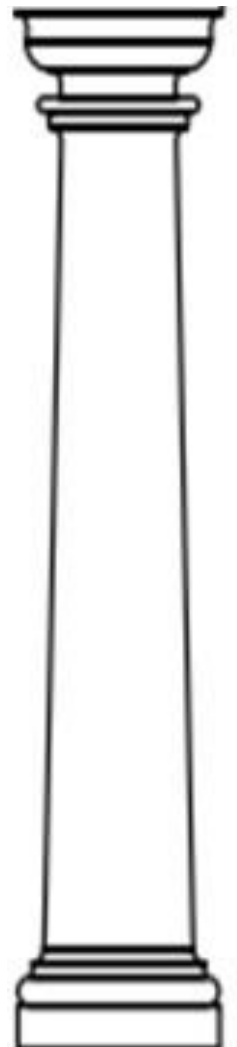
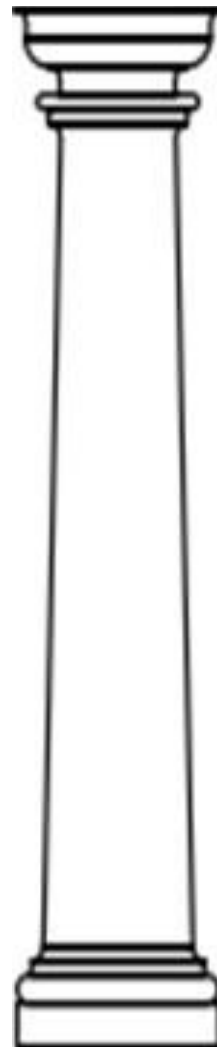
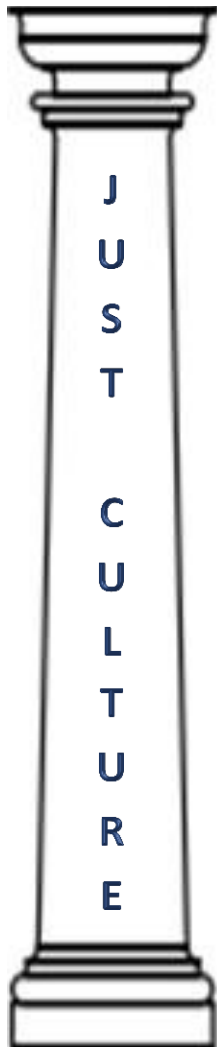
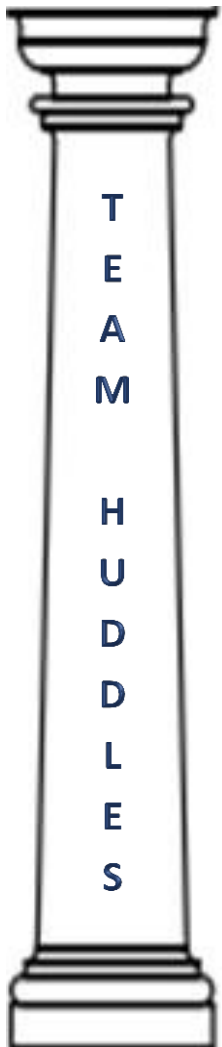
“I am tired of people telling **ME**
what to do with **MY** patient”

Change is difficult!

Change requires endurance.

Full implementation requires 12 to 24 months.

High Reliability / Safety in Obstetrics



| Just Culture

Non-negotiable Mutual Respect

Critical Components

- Lack of hierarchy
- Freedom to speak up
- Willingness to speak up
- Audacity and courage

Source: *Gardner ACOG Patient Safety & Quality Improvement 2009*

Near Miss

- Preterm labor patient on Procardia
- Super imposed preeclampsia
- Magnesium Sulfate ordered

Magnesium + Ca Channel Blocker



Synergistic Calcium Antagonism



Potential Death or Injury

| Individuals Fail

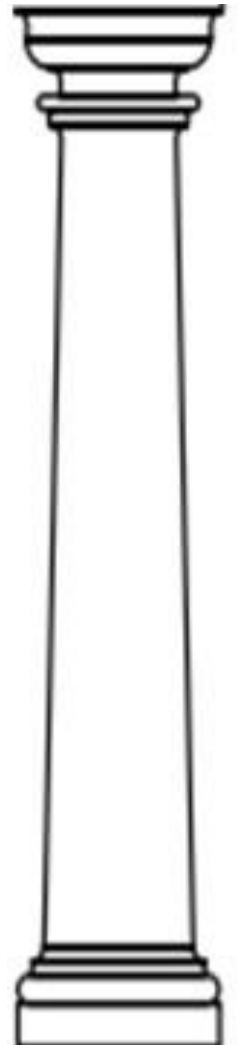
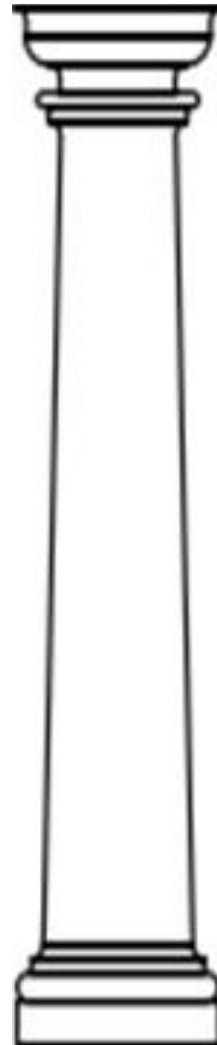
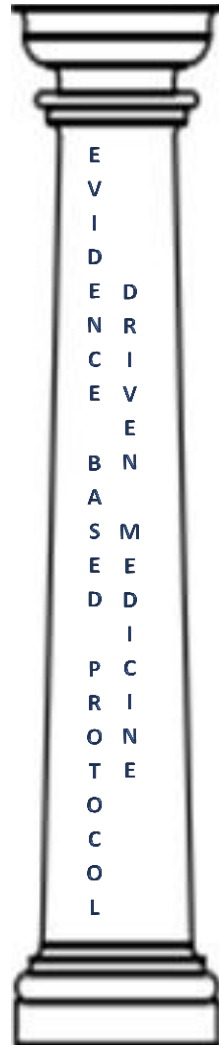
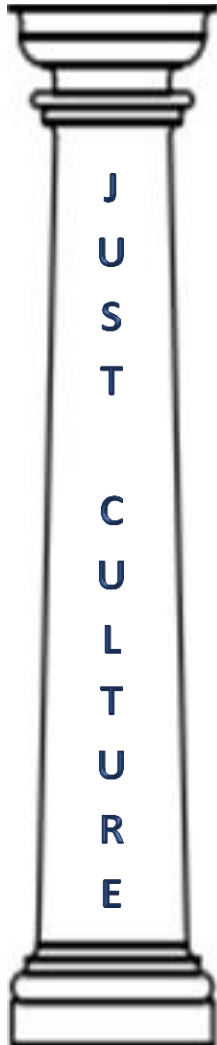
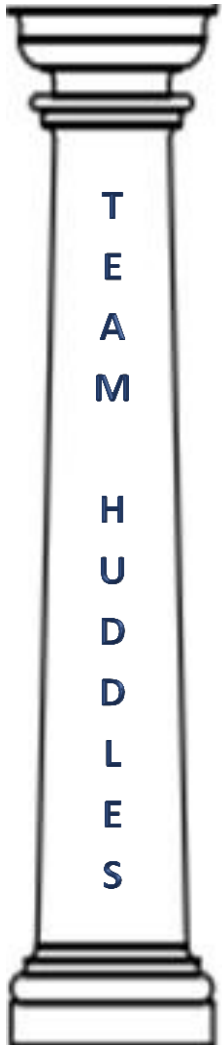
Teams Win

*“Dr. Kolucki, are you sure you want to start magnesium now?
She was just dosed with Procardia.”*

**Every member of the OB team is
required to step forward when a
process is deemed unsafe.**



High Reliability / Safety in Obstetrics



A blue-tinted photograph of a business meeting. In the foreground, a pair of glasses and a pen rest on a document with bar charts. In the background, a person in a suit is seated at a table, holding a pen. A glass of water is visible on the left. The overall scene is dimly lit, emphasizing a professional and analytical atmosphere.

The Enemy of Quality: Unsubstantiated Variation

Evidence-based Protocols / Bundles

- Preterm Labor
- Preterm Premature Rupture of Membranes
- Hypertensive Emergencies
- Eclamptic Seizure
- Amniotic Fluid Embolism / Anaphylactoid Syndrome of Pregnancy
- Maternal Cardiac Arrest
- Oxytocin Utilization Bundles
- Placenta Previa Algorithm
- Prothrombin Complex Concentrate (Kcentra) Protocol
- Factor VII Protocol
- RiaSTAP (Lyophilized Fibrinogen) protocol

Evidence-based Protocols / Bundles

- Chorioamnionitis
- Fulminant DIC Protocol
- Delayed Cord Clamping
- Fetal Death in Utero Protocol
- Emergency Uterine Relaxation
- Imminent Delivery
- Neonatal Resuscitation
- EMR – Best practice care plans

MTH Code Crimson v19

Code Crimson – Level 1

For patients with potential / actual hemorrhage

**FBS Staff- Notify Switchboard of Code Crimson (x5555) for overhead page
Switchboard will alert Laboratory, Anesthesia, Ultrasound, Interventional Radiology, Nursing Supervisor,
and Pharmacy to await further instructions**

Draw the following STAT Labs and tube specimens to Laboratory for:

Code Crimson- CBC; PT / PTT; Fibrinogen; CMBP;

Type and Screen; and Type and Cross **Three (3) Units Packed Red Blood Cells, Three (3) Units Fresh Frozen**

Plasma, and One (1) Unit Apheresed Platelets

Notify Lab (x6300) of inbound STAT Blood Work

Repeat Labwork every 60 minutes or after every completed MTP.

Ensure IV access & Patency

Confirm treatment with Tranexamic Acid 1 gm IV repeat in 30 minutes if bleeding continues

Obtain Uterine Tamponade Balloon

Prepare OR Hysterectomy pan

Notify CRNA to prepare Rapid Infuser/ Blood Warmer

Code Crimson – Level 2

For patients with a **life threatening** potential/actual hemorrhage

Notify Switchboard of Code Crimson (X5555) for overhead page and alerts

Confirm treatment with Tranexamic Acid 1 gm IV repeat in 30 minutes if bleeding continues

FBS Staff – Draw the following **STAT** Labs and tube specimens to Laboratory for:

CBC; PT / PTT; Fibrinogen; Type and Screen; CMBP, and Type and Cross

Six (6) Units Packed Red Blood Cells, Six (6) Units Fresh Frozen Plasma, One (1) Unit Apheresed Platelets, and

Ten (10) Unit Cryoprecipitate (only 1 unit plts in hospital; additional units will be procured by lab)

Notify Lab (x6300) and Blood Bank (x6361) of inbound STAT Blood Work

T/L will designate one person to be in contact with lab for blood products and to obtain when ready (blood runner).

Repeat Labwork every 60 minutes or after every completed MTP.

- Ensure two (2) large bore (#18) IV access

- Prepare OR Hyster pan/Prepare Uterine Tamponade Balloon

Ready Second MTP2 PACKAGE

- 6 Units RBCs

- 6 Units FFP

- 1 Unit Apheresed Platelets

- 10 Units Cryoprecipitate

- Administer 10 mg Vitamin K IV for 1 dose

- Calcium Gluconate 2 gm (4.65meq/ 1gm) IV

(lab will procure any additional blood products as needed)

Nursing Supervisor (x6867/6768)

Anesthesiologist

Anesthesia CRNA (x6925)

* Prepare Rapid Infuser/ Blood Warmer

**If necessary, Anesthesia will notify Cell Saver perfusionist - James Yi (H) 570-587-2510
(C) 570-815-6577**

Operating Room (x6400)

Interventional Radiology (x7306) (OB/GYN Physician or designee must speak directly with Radiologist)

If necessary, Notify Rapid Response Team (RRT)

Dial #5555, provide Switchboard Operator with Room Number / location for RRT response

Notify ICU of possible transfer (x5480)

Notify second in-house OB physician of situation

IF ANTICIPATING ONGOING BLEEDING:

• Repeat **STAT LABS- CBC; PT / PTT; Fibrinogen;**

• **CMBP**

• **INITIATE ADDITIONAL MTP2 PACKAGES with 20 Units of Cryoprecipitate**

• **Consider For Continued Life Threatening Hemorrhage**

Prothrombin Complex Concentrate (Kcentra)

Factor 7 (NovoSeven)

RiaSTAP for consumptive coagulopathy/DIC; severe hypofibrinogenemia or volume overload

Calculating Corrected Calcium Equation

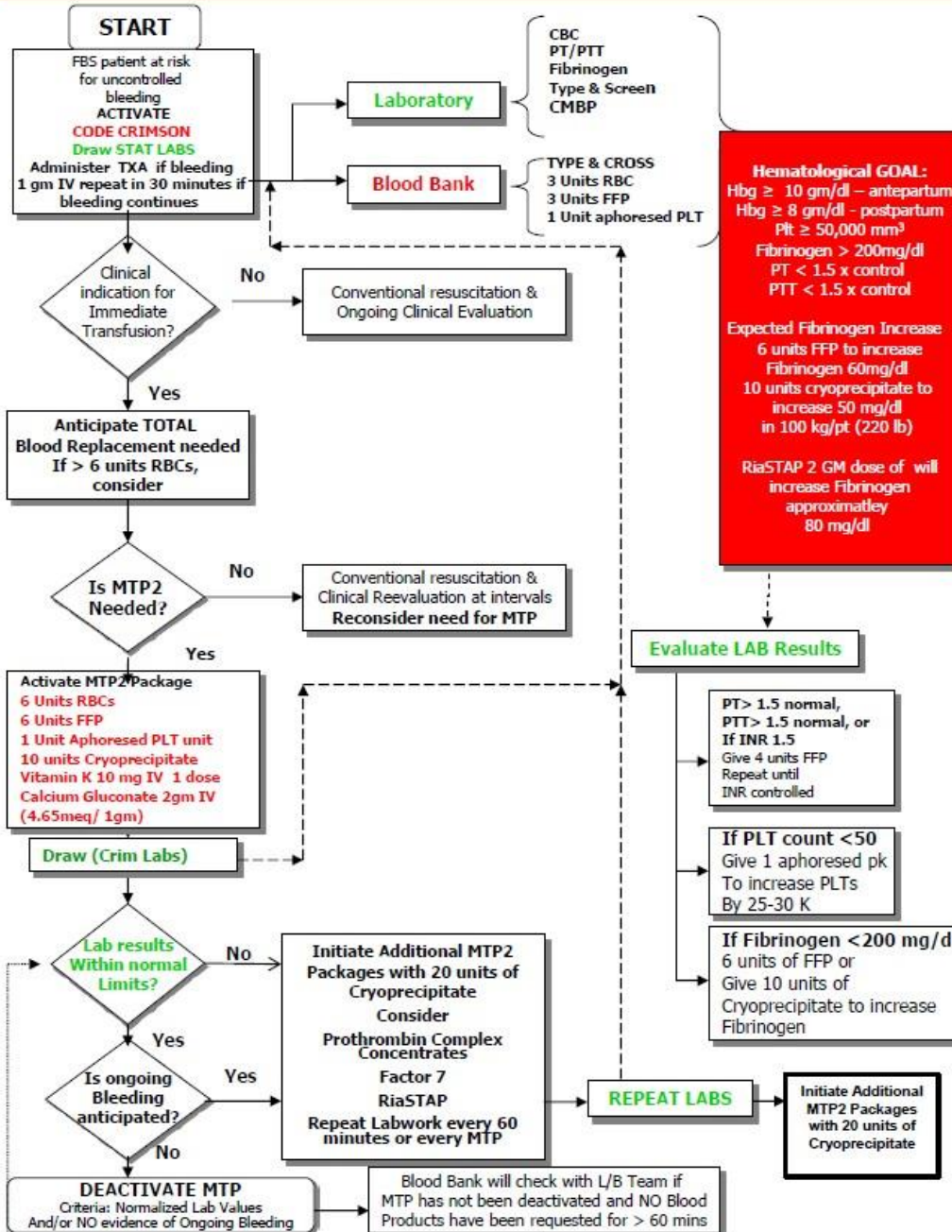
4- [(0.8 X Albumin) + serum Ca = corrected Ca

**Laboratory
may contact
the FBS-
Charge Nurse/
TL @ x6908**

*If AB plasma for
AB patient is not
available A
plasma may be
used*

MASSIVE TRANSFUSION PROTOCOL [MTP]

Updated 01./2018



Massive Transfusion Protocol: Code Crimson

Electrolytes including potassium and calcium can fluctuate wildly.

Commonwealth Health																
MASSIVE TRANSFUSION PROTOCOL CODE CRIMSON (OB)																
<small>Generic - Chemical - Therapeutic Automatic Interchange and Protocols for specific drugs as approved by the Medical Staff are permitted for implementation for all applicable orders below</small>																
Diagnosis: Post Partum HEMORRHAGE; ACTIVATE CODE CRIMSON																
<input type="checkbox"/> LEVEL 1: LABS: Draw STAT Code Crimson Lab and Massive Transfusion Package 1 [MTP1]. Notify LAB @ 6300 of inbound blood work <ul style="list-style-type: none"> <input type="checkbox"/> CBC <input type="checkbox"/> PT/INR <input type="checkbox"/> PTT <input type="checkbox"/> Fibrinogen <input type="checkbox"/> CMBP <input type="checkbox"/> D-dimer <input type="checkbox"/> Type and Screen <input type="checkbox"/> Type & Cross 3 Units Packed Red Blood Cells, 3 Units Fresh Frozen Plasma, 1 Unit Apheresed Platelets 																
<input type="checkbox"/> If ongoing bleeding, order and Prepare Massive Transfusion Package [MTP2] and 10 Units Cryoprecipitate <ul style="list-style-type: none"> <input type="checkbox"/> 8 Units Packed Red Blood Cells (RBC) <input type="checkbox"/> 8 Units Fresh Frozen Plasma (FFP) <input type="checkbox"/> 1 Unit Apheresed Platelets (PLT) <input type="checkbox"/> 10 Units Cryoprecipitate (CR10) 																
<input type="checkbox"/> LEVEL 2: LABS: Draw STAT Code Crimson Lab and Massive Transfusion Package 2 [MTP2]. Notify LAB @ 6300 of inbound blood work <ul style="list-style-type: none"> <input type="checkbox"/> CBC <input type="checkbox"/> PT/INR <input type="checkbox"/> PTT <input type="checkbox"/> Fibrinogen <input type="checkbox"/> D-dimer <input type="checkbox"/> CMBP <input type="checkbox"/> Type & Cross 8 Units Packed Red Blood Cells, 8 Units Fresh Frozen Plasma, 1 Unit Apheresed Platelets, and 10 Units Cryoprecipitate 																
<input type="checkbox"/> Insure two (2) large bore (#18) IV access																
<input type="checkbox"/> If ongoing bleeding, order additional MTP2 (8 Units Packed Red Blood Cells, 8 Units Fresh Frozen Plasma, 1 Unit Apheresed Platelets) and 20 units Cryoprecipitate CR10, CR10. Further MTP2 packs will be dictated by clinical presentation and lab work.																
Medication: <ul style="list-style-type: none"> <input type="checkbox"/> Tranexamic Acid 1 gram/ 100 ml in 0.9% NaCl; Infuse, Infuse 100 ml bag over 20 minutes (ie. 300 ml/hr) for 2 doses <input type="checkbox"/> Vitamin K 10mg in 50 mL of NSS IV once over 30 minutes <input type="checkbox"/> Calcium Gluconate 2 grams STAT after every MTP2; Administer IV Push over 10 minutes (max rate: 200mg/min) 																
Factors (SELECT ONE ONLY) <ul style="list-style-type: none"> <input type="checkbox"/> RiaSTAP (fibrinogen concentrate) 2 grams for 1 dose STAT for fibrinogen level <200mg/dl. IV infusion over 20 minutes in separate line. Rate not to exceed 5ml/min. Pharmacy to Round dose to the nearest vial size. Document lot # in Electronic Health Record (Cerner) <input type="checkbox"/> KCentra 50 units/kg based upon total body weight for 1 dose STAT, when the bleeding has not abated after administration of tranexamic acid , or immediately in a Factor Deficiency Patient or a low Fibrinogen result with cryoprecipitate or FFP administered. <ul style="list-style-type: none"> <input type="checkbox"/> Maximum Dose to be administered is 5000 units Factor IX <input type="checkbox"/> Doses will be rounded to the nearest 500 units Factor IX <input type="checkbox"/> Infuse at a rate of 0.12 mL/kg/minute (~3 units/kg/minute) in a separate line and do not mix with any other medications or blood products. Do not allow blood to enter syringe (to reduce risk of fibrin clot formation). <input type="checkbox"/> Do not exceed a rate of 8.4mL/minute (~210 units/minute) <input type="checkbox"/> Administered within 4 hours of reconstitution. <input type="checkbox"/> Document lot # in Electronic Health Record (Cerner) <input type="checkbox"/> (NovoSeven® RT) Coagulation Factor VIIa Room Temperature Stable IV Bolus over 2-5 minutes (stored in pharmacy in refrigerator or room temperature). Dose Coagulation Factor VIIa (NovoSeven® RT) based on weight below. (Dosing equals 60 mcg/kg rounded up to the nearest 1000 mcg, 2000 mcg, or 5000 mcg vial) <table border="0" style="width: 100%; font-size: small;"> <tr> <td>For patient's weight of:</td> <td><input type="checkbox"/> 50 kilograms or less, administer 3000 mcg</td> <td><input type="checkbox"/> 51-66 kilograms, administer 4000 mcg</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 67-83 kilograms, administer 5000 mcg</td> <td><input type="checkbox"/> 84-100 kilograms, administer 6000 mcg</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 101-116 kilograms, administer 7000 mcg</td> <td><input type="checkbox"/> 117-133 kilograms, administer 8000 mcg</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 134-150 kilograms, administer 9000 mcg</td> <td><input type="checkbox"/> 151-165 kilograms, administer 10,000 mcg</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 166-180 kilograms, administer 11,000 mcg</td> <td></td> </tr> </table> 		For patient's weight of:	<input type="checkbox"/> 50 kilograms or less, administer 3000 mcg	<input type="checkbox"/> 51-66 kilograms, administer 4000 mcg		<input type="checkbox"/> 67-83 kilograms, administer 5000 mcg	<input type="checkbox"/> 84-100 kilograms, administer 6000 mcg		<input type="checkbox"/> 101-116 kilograms, administer 7000 mcg	<input type="checkbox"/> 117-133 kilograms, administer 8000 mcg		<input type="checkbox"/> 134-150 kilograms, administer 9000 mcg	<input type="checkbox"/> 151-165 kilograms, administer 10,000 mcg		<input type="checkbox"/> 166-180 kilograms, administer 11,000 mcg	
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	<input type="checkbox"/> 166-180 kilograms, administer 11,000 mcg															
Physicians signature:	Date:	Time:														
Nurse Noting signature:	Date:	Time:														
Rev 1/11, 5/11, 3/12, 2/13, 4/14, 6/14, 8/14, 01/17, 01/18 0318																

Source: Luis D. Pacheco M.D., George R. Saade, M.D., Maged M. Costantine, M.D., Steven L. Clark, M.D., & Gary D.V. Hankins, M.D. An update on the use of massive transfusion protocols in obstetrics. *American Journal of Obstetrics and Gynecology*, 2016-03-01, Volume 214, Issue 3.

Massive Transfusion Protocol: Code Crimson

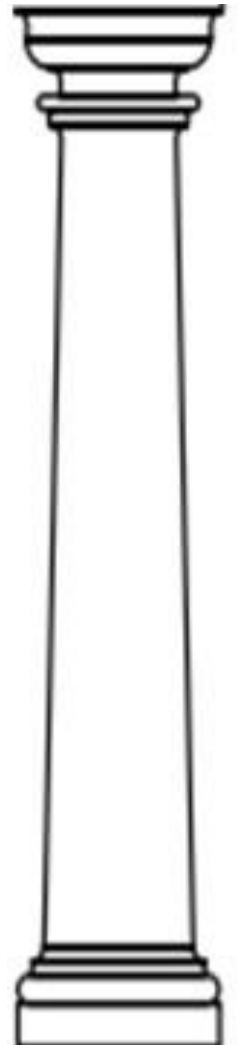
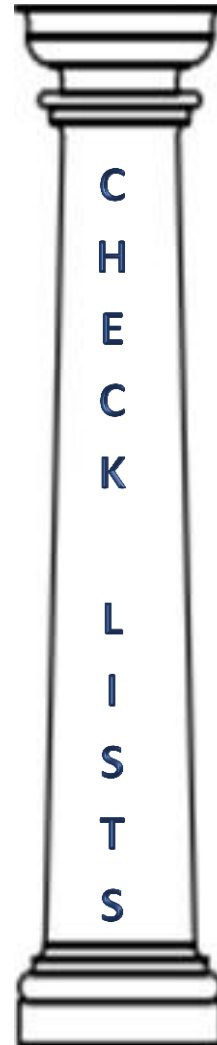
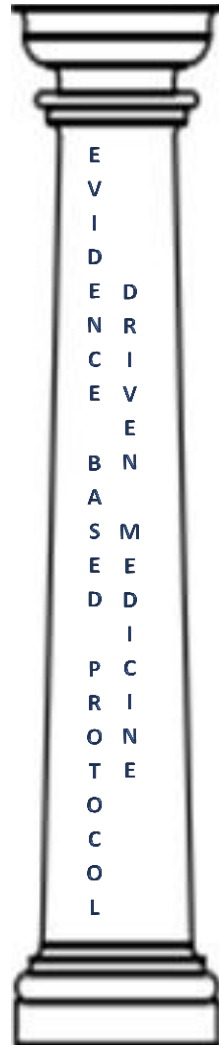
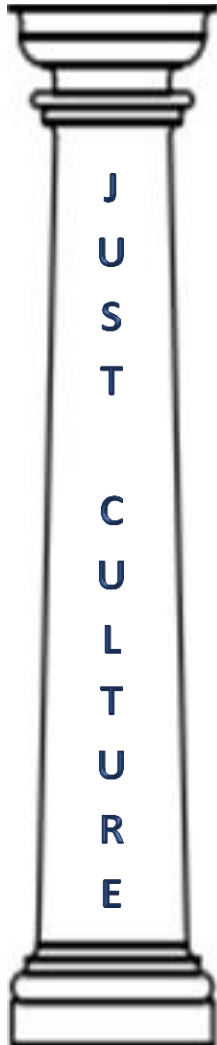
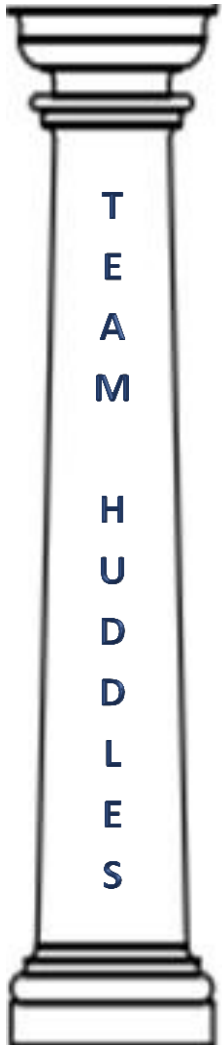
- Kcentra
- Prothrombin complex concentrate should be used as a last resort in refractory cases of hemorrhage
- More favorable safety profile than Factor 7

Source: Luis D. Pacheco M.D., George R. Saade, M.D., Maged M. Costantine, M.D., Steven L. Clark, M.D., & Gary D.V. Hankins, M.D. An update on the use of massive transfusion protocols in obstetrics. *American Journal of Obstetrics and Gynecology*, 2016-03-01, Volume 214, Issue 3.

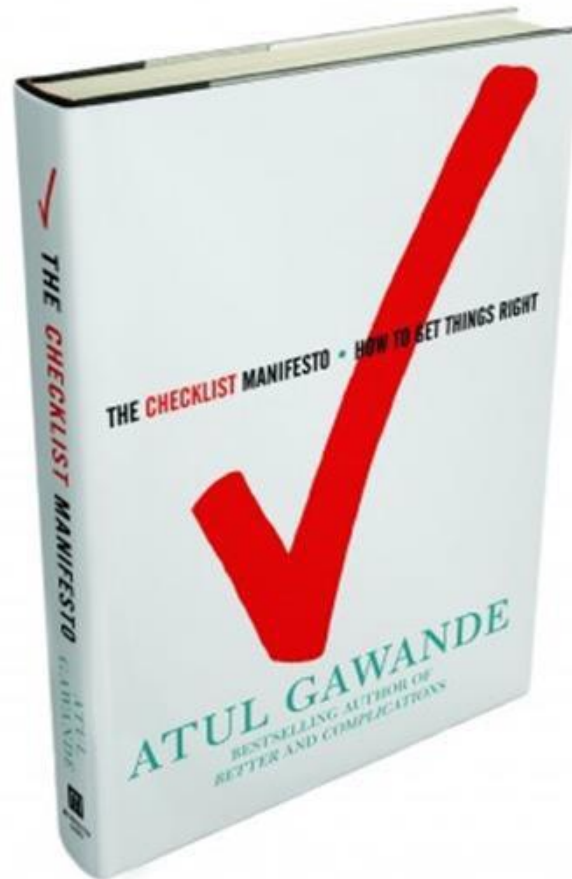
Commonwealth Health												
MASSIVE TRANSFUSION PROTOCOL CODE CRIMSON (OB)												
Generic - Chemical - Therapeutic Automatic Interchange and Protocols for specific drugs as approved by the Medical Staff are permitted for implementation for all applicable orders below.												
Diagnosis: Post Partum HEMORRHAGE; ACTIVATE CODE CRIMSON												
<input type="checkbox"/> LEVEL 1: LABS: Draw STAT Code Crimson Lab and Massive Transfusion Package 1 [MTP1]. Notify LAB @ 6300 of inbound blood work												
<ul style="list-style-type: none"> ■ CBC ■ PT/INR ■ PTT ■ Fibrinogen ■ CMBP ■ D-dimer ■ Type and Screen ■ Type & Cross 3 Units Packed Red Blood Cells, 3 Units Fresh Frozen Plasma, 1 Unit Apheresed Platelets 												
<input type="checkbox"/> If ongoing bleeding, order and Prepare Massive Transfusion Package [MTP2] and 10 Units Cryoprecipitate												
<ul style="list-style-type: none"> ■ 8 Units Packed Red Blood Cells (RBC) ■ 8 Units Fresh Frozen Plasma (FFP) ■ 1 Unit Apheresed Platelets (PLT) ■ 10 Units Cryoprecipitate (CR10) 												
<input type="checkbox"/> LEVEL 2: LABS: Draw STAT Code Crimson Lab and Massive Transfusion Package 2 [MTP2]. Notify LAB @ 6300 of inbound blood work												
<ul style="list-style-type: none"> ■ CBC ■ PT/INR ■ PTT ■ Fibrinogen ■ D-dimer ■ CMBP ■ Type & Cross 8 Units Packed Red Blood Cells, 8 Units Fresh Frozen Plasma, 1 Unit Apheresed Platelets, and 10 Units Cryoprecipitate 												
<input checked="" type="checkbox"/> Insure two (2) large bore (#18) IV access												
<input type="checkbox"/> If ongoing bleeding, order additional MTP2 (8 Units Packed Red Blood Cells, 8 Units Fresh Frozen Plasma, 1 Unit Apheresed Platelets) and 20 units Cryoprecipitate CR10, CR10. Further MTP2 packs will be dictated by clinical presentation and lab work.												
Medication:												
<input type="checkbox"/> Tranexamic Acid 1 gram/ 100 ml in 0.9% NaCl; Infuse, Infuse 100 ml bag over 20 minutes (ie. 300 ml/hr) for 2 doses												
<input type="checkbox"/> Vitamin K 10mg in 50 ml of NSS IV once over 30 minutes												
<input type="checkbox"/> Calcium Gluconate 2 grams STAT after every MTP2; Administer IV Push over 10 minutes (max rate: 200mg/min)												
Factors (SELECT ONE ONLY)												
<ul style="list-style-type: none"> ■ RiaSTAP (fibrinogen concentrate) 2 grams for 1 dose STAT for fibrinogen level <200mg/dl. IV infusion over 20 minutes in separate line. Rate not to exceed 5ml/min. Pharmacy to Round dose to the nearest vial size. Document lot # in Electronic Health Record (Cerner) 												
<input type="checkbox"/> KCentra 50 units/kg based upon total body weight for 1 dose STAT, when the bleeding has not abated after administration of tranexamic acid , or immediately in a Factor Deficiency Patient or a low Fibrinogen result with cryoprecipitate or FFP administered.												
<ul style="list-style-type: none"> ■ Maximum Dose to be administered is 5000 units Factor IX ■ Doses will be rounded to the nearest 500 units Factor IX ■ Infuse at a rate of 0.12 mL/kg/minute (~3 units/kg/minute) in a separate line and do not mix with any other medications or blood products. Do not allow blood to enter syringe (to reduce risk of fibrin clot formation). ■ Do not exceed a rate of 8.4mL/minute (~210 units/minute) ■ Administered within 4 hours of reconstitution. ■ Document lot # in Electronic Health Record (Cerner) 												
<input type="checkbox"/> (NovoSeven® RT) Coagulation Factor VIIa Room Temperature Stable IV Bolus over 2-5 minutes (stored in pharmacy in refrigerator or room temperature). Dose Coagulation Factor VIIa (NovoSeven® RT) based on weight below. (Dosing equals 60 mcg/kg rounded up to the nearest 1000 mcg, 2000 mcg, or 5000 mcg vial)												
For patient's weight of:												
<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> 50 kilograms or less, administer 3000 mcg</td> <td><input type="checkbox"/> 51-66 kilograms, administer 4000 mcg</td> </tr> <tr> <td><input type="checkbox"/> 67-83 kilograms, administer 5000 mcg</td> <td><input type="checkbox"/> 84-100 kilograms, administer 6000 mcg</td> </tr> <tr> <td><input type="checkbox"/> 101-116 kilograms, administer 7000 mcg</td> <td><input type="checkbox"/> 117-133 kilograms, administer 8000 mcg</td> </tr> <tr> <td><input type="checkbox"/> 134-150 kilograms, administer 9000 mcg</td> <td><input type="checkbox"/> 151-165 kilograms, administer 10,000 mcg</td> </tr> <tr> <td><input type="checkbox"/> 166-180 kilograms, administer 11,000 mcg</td> <td></td> </tr> </table>			<input type="checkbox"/> 50 kilograms or less, administer 3000 mcg	<input type="checkbox"/> 51-66 kilograms, administer 4000 mcg	<input type="checkbox"/> 67-83 kilograms, administer 5000 mcg	<input type="checkbox"/> 84-100 kilograms, administer 6000 mcg	<input type="checkbox"/> 101-116 kilograms, administer 7000 mcg	<input type="checkbox"/> 117-133 kilograms, administer 8000 mcg	<input type="checkbox"/> 134-150 kilograms, administer 9000 mcg	<input type="checkbox"/> 151-165 kilograms, administer 10,000 mcg	<input type="checkbox"/> 166-180 kilograms, administer 11,000 mcg	
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<input type="checkbox"/> 134-150 kilograms, administer 9000 mcg	<input type="checkbox"/> 151-165 kilograms, administer 10,000 mcg											
<input type="checkbox"/> 166-180 kilograms, administer 11,000 mcg												
Physicians signature: _____		Date: _____ Time: _____										
Nurse Noting signature: _____		Date: _____ Time: _____										

Rev 1/11, 5/11, 3/12, 2/13, 4/14, 06/14, 07/14, 12/16, 01/17, 11/17, 01/18 0318

High Reliability / Safety in Obstetrics

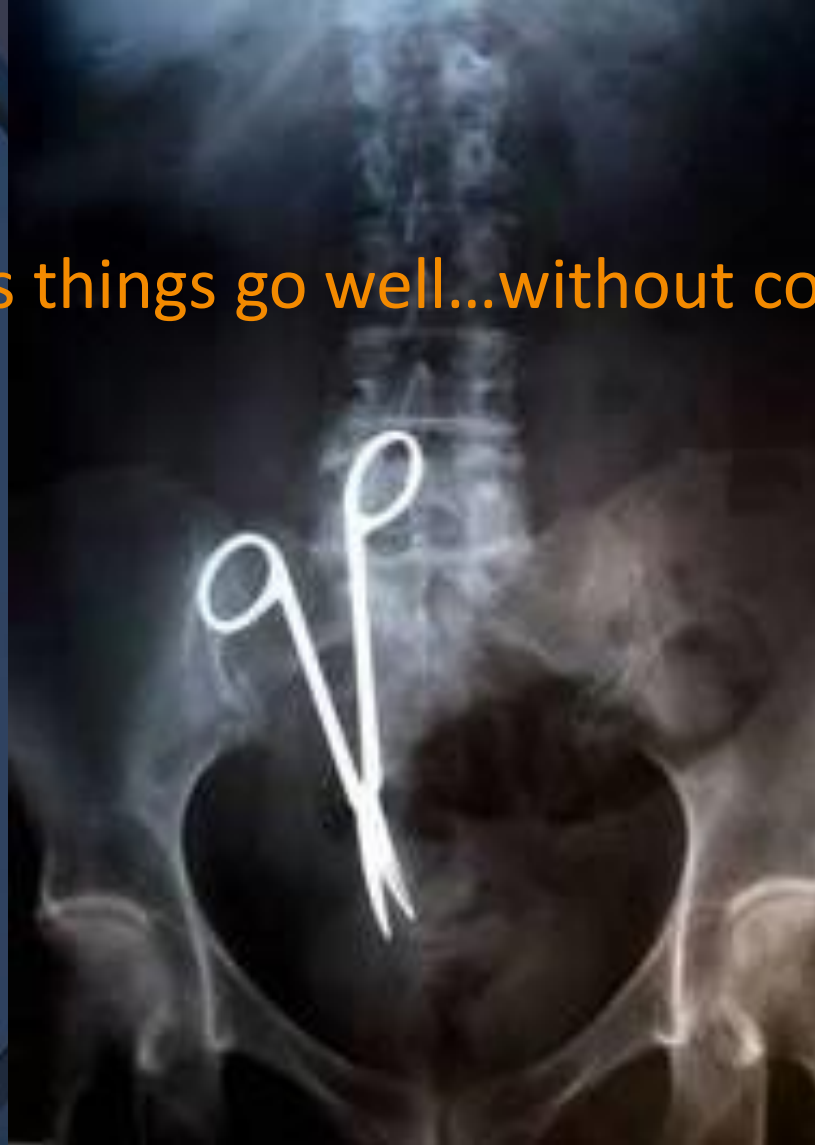


Checklists help in multistep processes where omission of any step can lead to injury



Checklists Prevent Normalization of Deviance

Most times things go well...without complication



| Checklists We Now Utilize

- Surgical Timeout
- IOL Core Measure Compliance
- Pre-oxytocin checklist
- Operative Vaginal Delivery Documentation
- Shoulder Dystocia Documentation
- Magnesium Sulfate for Neonatal Neuroprotection
- Prevention of Elective IOL to decrease C/S rate. 34% to 18%
- Peripartum Venous Thromboembolism Prophylaxis

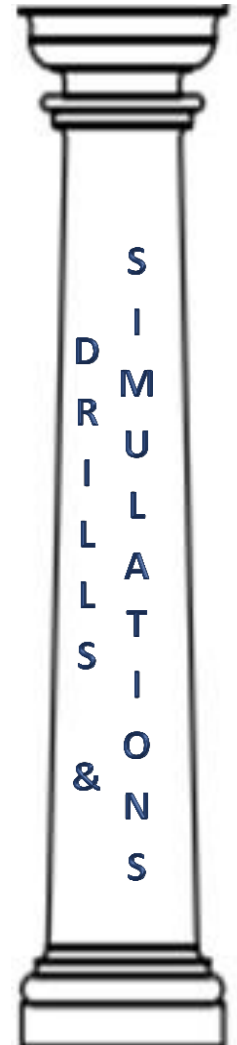
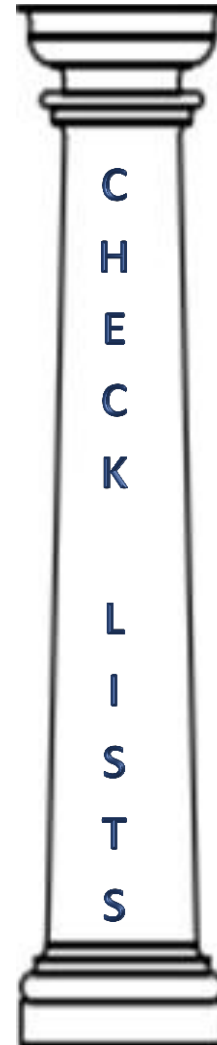
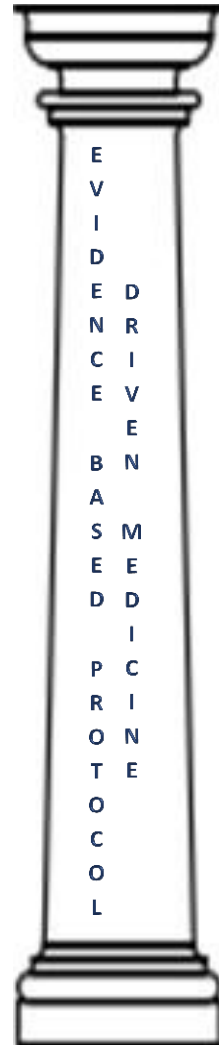
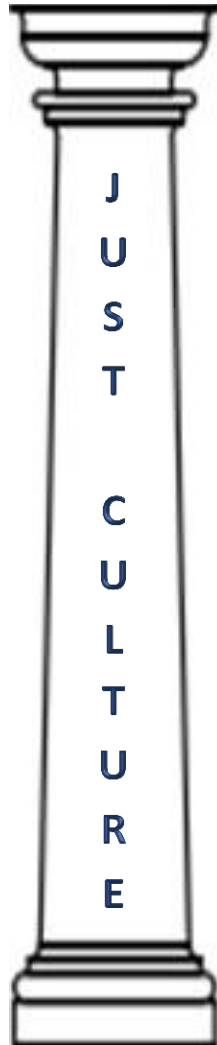
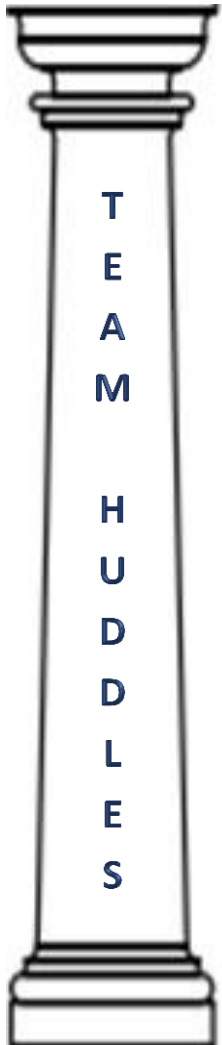


The Wisdom of Dr. Jimmy Moore

“We’ve got to get this right. She is FTD.”

“Hours of boredom punctuated with moments of sheer terror!”

High Reliability / Safety in Obstetrics



| OB Drills / Simulation

- Shoulder Dystocia
- Postpartum Hemorrhage
- Eclamptic Seizure
- Cesarean Hysterectomy
- Maternal Cardiac Arrest
- Code Stork
- Infant Abduction

A blue-tinted photograph of a business meeting. In the foreground, a pair of glasses and a pen rest on a document with bar charts. In the background, a person in a suit is seated at a table, holding a pen. A glass of water is visible on the left. The overall scene is dimly lit, emphasizing a professional and analytical atmosphere.

Types of Simulation: Formal





Types of Simulation:

- Formal
- In Situ
- Micro Sim

simulation unveils pitfalls to rapid effective care

Steven Pratt, M.D. 2013

| Peer Review / Debriefing

- The mortar that supports and repairs the pillars
- Not about blame or shame
- Focus is improving systems of care to help teams win the day
- The practice of quality medicine is not static
- It is decidedly dynamic
- Change is a constant in medicine
- Make a change for the good

| Peer Review / Debriefing

- Immediately debrief all near misses or serious adverse events
- Peer review all cases with four units PRBC or ICU admit and serious adverse events
- Lessons learned, both successes and failures are applied to quality improvement

A blue-tinted photograph of a business meeting. In the foreground, a pair of glasses and a pen rest on a document with bar charts. In the background, a person in a suit is seated at a table, holding a pen. A glass of water is visible on the left. The overall scene is dimly lit, suggesting an indoor office environment.

Do These Pillars Work?
Don't know unless you measure it.

Adverse Outcome Index

- Developed by a panel of experts and the ACOG committee on patient safety and quality improvement to assess quality in L&D units
- Cumulative outcome of 10 major indicators with clinical significance
- Each is weighted for severity adjustment

Adverse Outcome

Weight

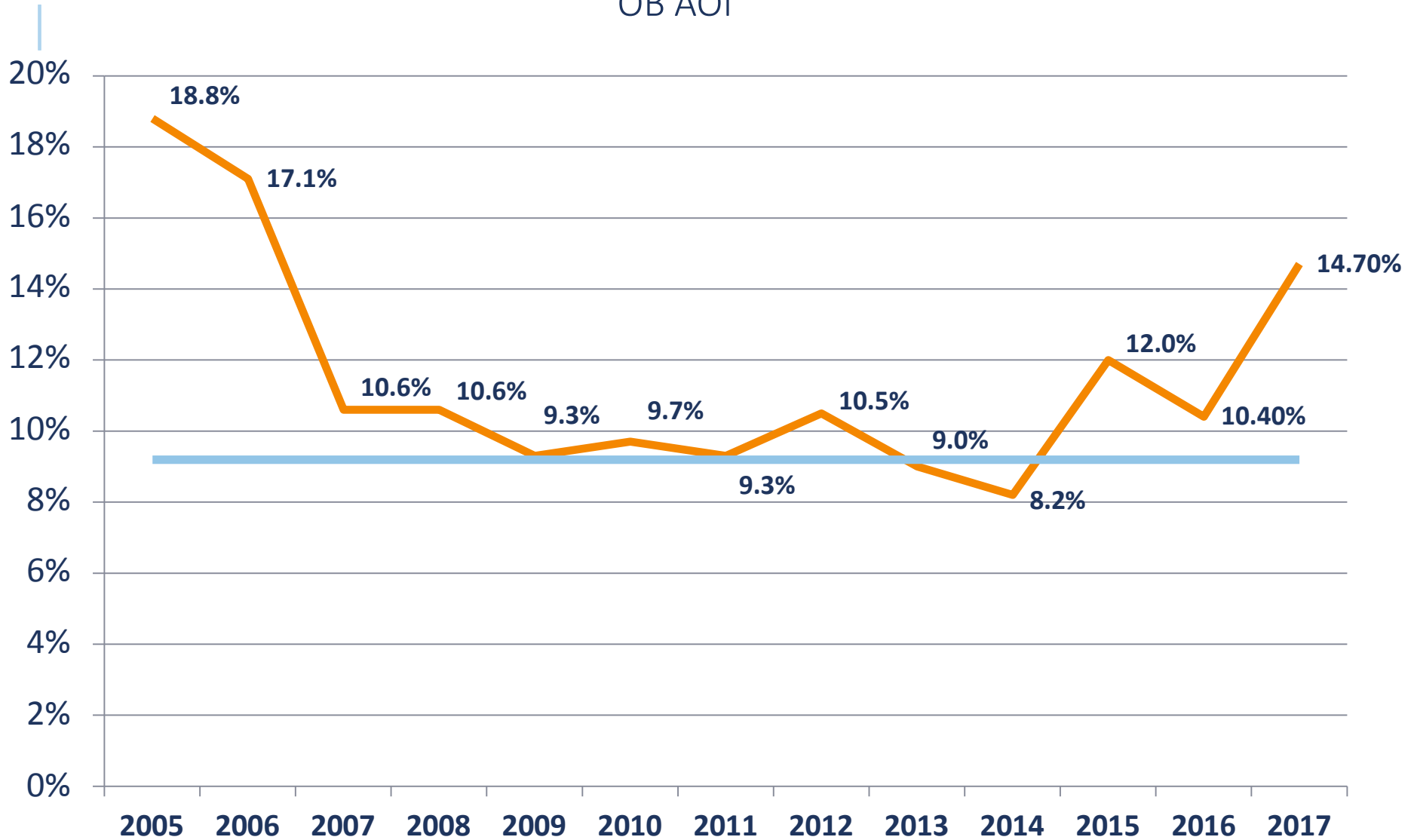
Maternal Death	750
Intrapartum or neonatal death (greater than 2500g)	400
Uterine Rupture	100
Maternal admission to ICU	65
Birth trauma	60
Return to OR/ Labor and delivery	40
Admission to NICU (greater than 2500 g for over 24 hours)	35
APGAR score <7 at 5 minutes	25
Blood transfusion	20
Third or fourth degree perineal tear	5

| AOI

Two subsets

- Weighted adverse outcome score
 - Cumulative weighted points per patient
- Severity index
 - Cumulative weighted points per patient with adverse outcome
- Utilized by many highly reliable units as their main metric

OB AOI

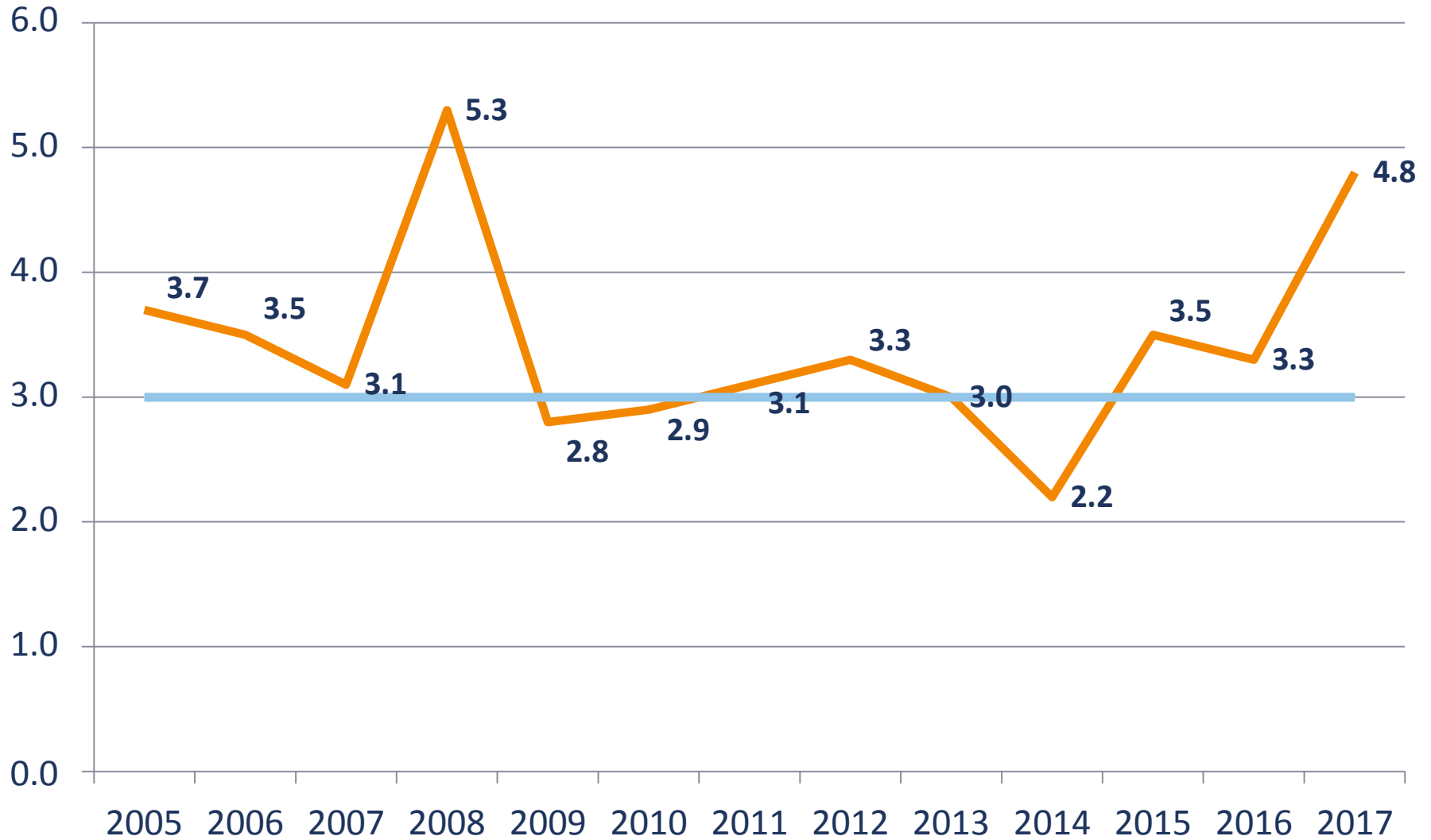


Benchmark Range
5.9 to 16.6

— Sample Hospital

— Target Rate (9.2)

Weighted Adverse Outcome Score sum of weighted points per patient



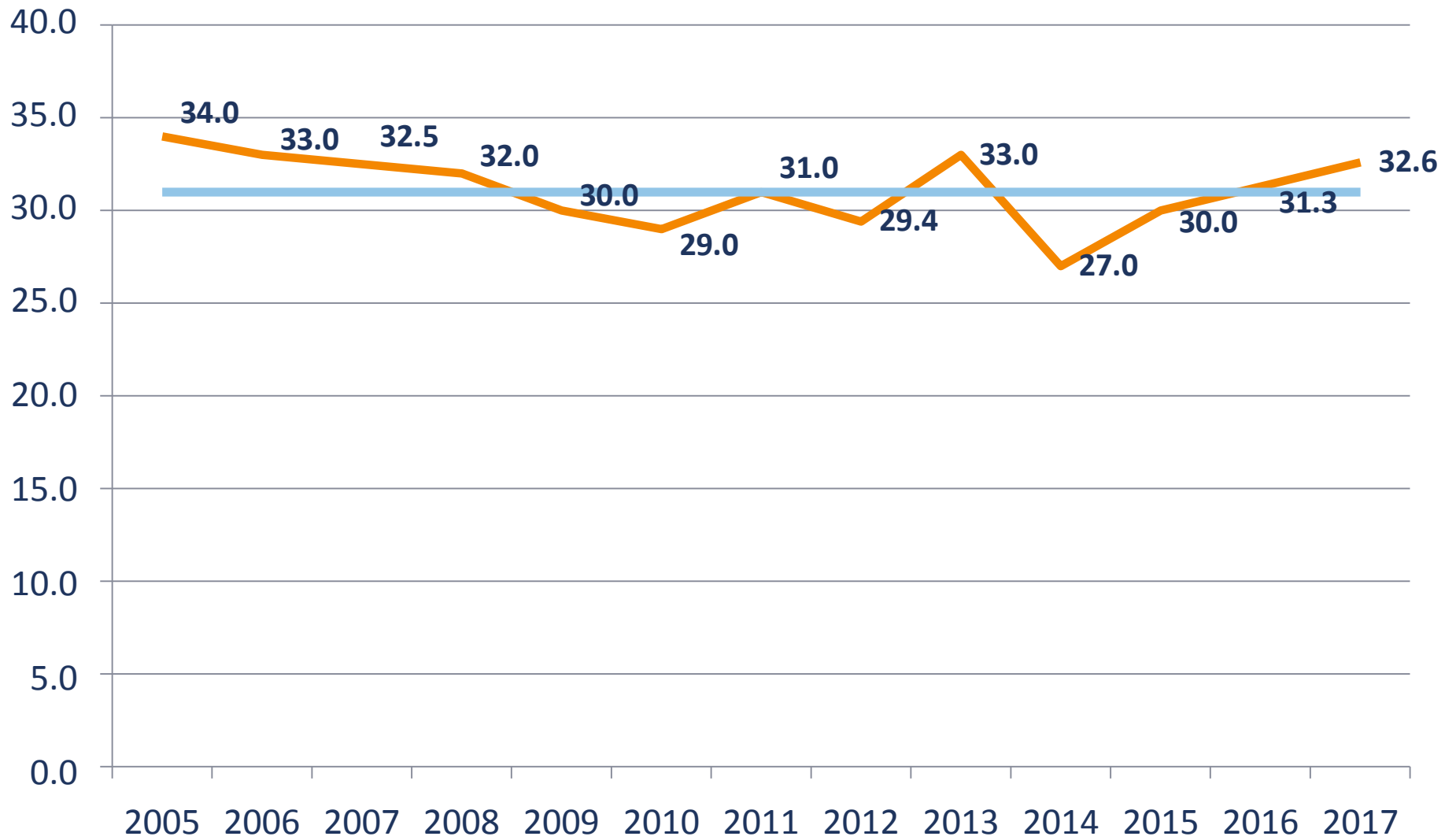
Benchmark Range
1.0 to 6.0

— Sample Hospital

— Target Rate (3)

Severity Index

sum of weighted points per patient with an adverse outcome



Benchmark Range
1.0 to 6.0

— Sample Hospital

— Average (31)

Malpractice Data

- Review of hospitals who have implemented a culture of safety has shown a significant decrease in malpractice lawsuits
- Clear Indicator of Patient Safety
- Strong Argument for Fiscal Responsibility/Stewardship

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Nation!**

**Certified in
Perinatal Care**

| Case Report, February 2008

- 25 yo G2 P1 25 Weeks Severe abdominal pain – Emergency Laparotomy
- Placenta Percreta / Ruptured Uterus Massive Hemorrhage
- Baby 650 gr / 1.1 lbs. to NICU
- Code Crimson / Massive Transfusion Protocol Ranger Rapid Transfuser
- Factor VII Hysterectomy Pelvic Packing / ICU
- Reoperation status post 48 hrs.

| Highly Reliable Collaborative Care

- 2 Patients in Extremis – 12 Liter Blood Loss
- 5 Hours of Cumulative Surgery – 54 Blood Units of Blood Component Therapy
- 41 hospital staff
- 7 specialties and sub-specialties
- **1 Mother and 1 Baby Saved**



Thank you

Frank R. Kolucki, Jr. M.D., FACOG

FKolucki@mth.org