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AHRQ's Patient Safety and Medical Liability Program

Presidential Action



On September 9, 2009, President Obama addressed a joint session of Congress to announce his proposals for health insurance reform. One component of such a plan included investing in new ways to manage medical liability claims. The President stated:

So I'm proposing that we move forward on a range of ideas about how to put patient safety first and let doctors focus on practicing medicine. I think it's a good idea, and I'm directing my Secretary of Health and Human Services to move forward on this initiative today.



Purpose of Demonstration and Planning Grants

- This initiative focused on reducing harm to patients and medical liability in health care settings
- The goals of the grants include:
 1. Put patient safety first and work to reduce preventable injuries
 2. Foster better communication between doctors and their patients
 3. Ensure that fair and timely compensation, while reducing the number of lawsuits
 4. Reduce liability premiums



Grant Awards

- Awards announced – June 2010
- \$23M for grants to States/health systems; \$2M for evaluation
 - ▶ 7 Patient Safety and Medical Liability (PSML) Demonstration Grants
 - ▶ 13 Planning Grants
- Largest Federal government investment of its kind



Preventing Harm Through Best Practices

- Two PSML demonstration projects conducted safety interventions aimed at preventing adverse events and poor health outcomes while reducing malpractice lawsuits
- One project was conducted in perinatal units and the other project in obstetrics departments



Improving Communication

- Four PSML demonstration projects addressed different forms of communication, i.e., between health care providers and patients, health care systems and providers, insurers and health care providers, and insurers and patients
 - ▶ Some of the projects implemented disclosure and resolution programs, which help physicians, risk managers, and other staff who communicate with patients to acknowledge medical injuries, implement improvements in the process of care, and in some cases, to make early offers to compensate for such injuries



AHRQ's Current Activities

- To build on promising preliminary results from its Patient Safety and Medical Liability Initiative, AHRQ moved forward to amplify and disseminate models from the following PSML demonstration projects:
 - ▶ Best practices to prevent birth trauma
 - ▶ Disclosure and early resolution
- AHRQ has designated both areas as major agency priorities



Safety Program for Perinatal Care

- The Safety Program for Perinatal Care Project is being coordinated by RTI International
- Program components include:
 - ▶ Comprehensive Unit-based Safety Program (CUSP) implementation on Labor & Delivery units
 - ▶ Teamwork and communication training
 - ▶ Use of standard procedures and checklists for common obstetrics procedures and responses to obstetric emergencies
 - ▶ *In situ* simulation



Communication and Optimal Resolution (CANDOR)

There are three elements to a Communication and Optimal Resolution Program

1. The CANDOR Process itself
2. Supporting the CANDOR Process and
3. Implementing the CANDOR Process



Communication and Resolution Toolkit

- The Communication and Optimal Resolution Toolkit was developed under a contract with Health Research and Educational Trust (HRET)
- With leadership from the relevant PSML demonstration grantees, the project developed a comprehensive toolkit to guide hospitals in implementing these principles in their own institutions
- Important advantage – this approach can be implemented without legislation



CANDOR Tool Kit

- Is available on the AHRQ website

Improved Patient Safety and Reduced Malpractice Claims

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Acknowledgements & Research Team

We wish to acknowledge funding from American Excess Insurance, Risk Retention Group (AEIX), and the Agency for Healthcare Research and Quality

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Reducing Perinatal Harm

- Labor and delivery pose substantial risks
 - Complications reported in 3-10% of deliveries (Mann et al. 2006; Nielsen et al. 2007; Kozhimannil et al. 2013; Goffman et al. 2014; New Jersey Hospital Association, 2014)
- Adverse perinatal events are caused by many factors
 - Communication breakdowns & poor teamwork associated with majority of perinatal injury (Simpson & Knox, 2003; Joint Commission 2004), increase risk of error 10-fold (Reason 1995), accounting for approximately 55 percent of all active failures in a hospital setting (Riley et al. 2010a, b, c)
- Estimated that up to 30% of Perinatal adverse events are preventable (Goffman et al. 2014)
 - Applying reliability principles may reduce unwanted variation in care processes & increase the consistency with which appropriate care is delivered
- Substantial financial impacts to providers and hospitals arising from malpractice claims and payment (AON Risk Solutions 2013; Strunk 2012; CRICO Strategies 2013)

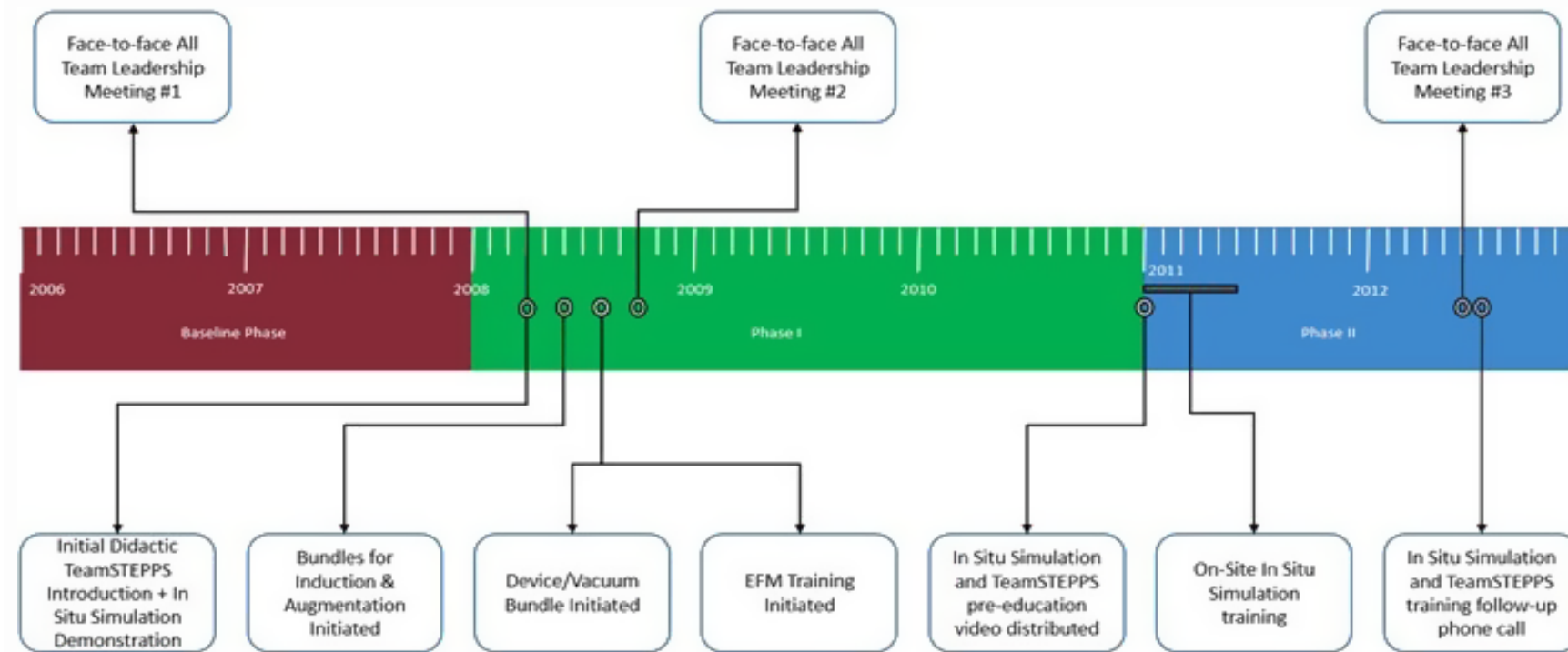
Premier Perinatal Safety Initiative (PPSI)

2006 to 2012

- Initiative to improve perinatal safety in 14 hospitals across 12 states
- 7-year prospective design using Quality Improvement Collaborative (QIC).
- Three-part intervention:
 1. Standardization of evidence-based care
 2. Interdisciplinary teamwork training
 3. Systematic performance feedback coupled with routine education

PPSI Intervention Activities & Timeline

- Baseline period (data retrospectively collected): Jan 2006 – Dec 2007
- Intervention period: Jan 2008 – Dec 2012*
- Malpractice claims analyzed:
 - Baseline: 2006-2007
 - Intervention: 2008-2009 *only*
 - Allows for claims lag



* Funding for Phase 1 (Jan 2008 – Dec 2010) from American Excess Insurance Exchange (AEIX)
Funding for Phase 2 (Jan 2011 – Dec 2012) from AHRQ

Care Standardization

- Care was standardized using three bundles
- Each hospital created an interdisciplinary team of a physician and nurse champion who directly led all interventions.
- A train-the-trainer method deployed to sequentially train a team from each hospital, which in turn trained staff in their respective perinatal units.

Table 1: Three Perinatal Care Bundles and Bundle Elements

<i>Elective Induction</i>	<i>Augmentation</i>	<i>Vacuum Extraction</i>
Gestational age ≥ 39 weeks	Documentation of estimated fetal weight	Alternative labor strategies considered
Or documented medical indication for induction if less than 39 weeks gestation	Normal fetal status	Informed consent discussed and documented
Normal fetal status prior to onset of oxytocin	Pelvic exam prior to onset of oxytocin	Estimated fetal weight, fetal position, and station known
Pelvic exam prior to onset of oxytocin	Recognition and management of tachysystole	Maximum application time and number of pop-offs predetermined
Recognition and management of tachysystole		Cesarean and resuscitation team available at delivery

Conceptual Model & Research Question

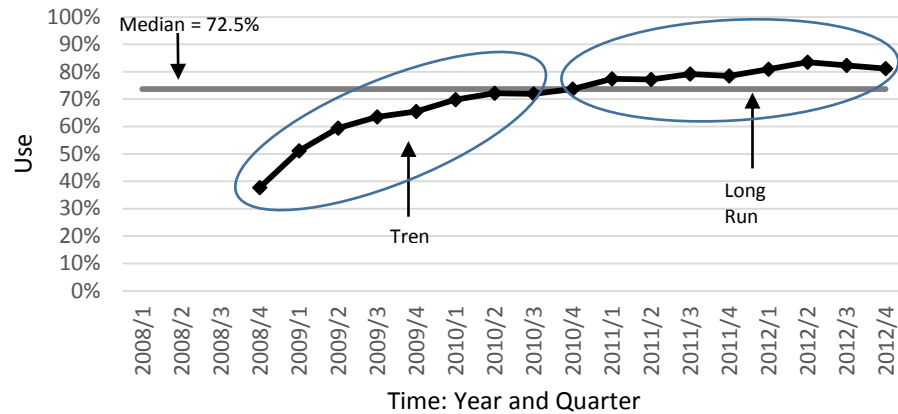
- Care Standardization and interdisciplinary Team Training → improved patient outcomes → decreased adverse events → fewer malpractice claims and payments
- Did the QIC and care bundle intervention result in lower malpractice claims and costs for the PPSI-participating hospitals?

Findings

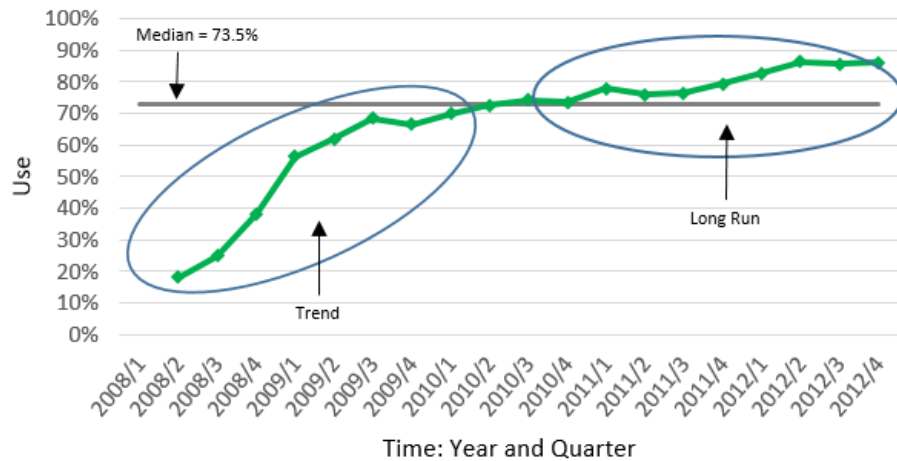
- Total 185,373 births
- Care Standardization and adverse outcomes analyzed for seven years (2006-2012)
- Malpractice claim activity analyzed for four years (2006-2009):
 - 125 perinatal malpractice claims
 - Malpractice costs: \$27,266,019
 - Indemnity: \$23,151,569
 - Legal defense: \$4,114,449

Figure 2: (a-d) Run Chart Analyses of Perinatal Care Bundles Compliance: (a) Composite, (b) Augmentation, (c) Induction, and (d) Vacuum

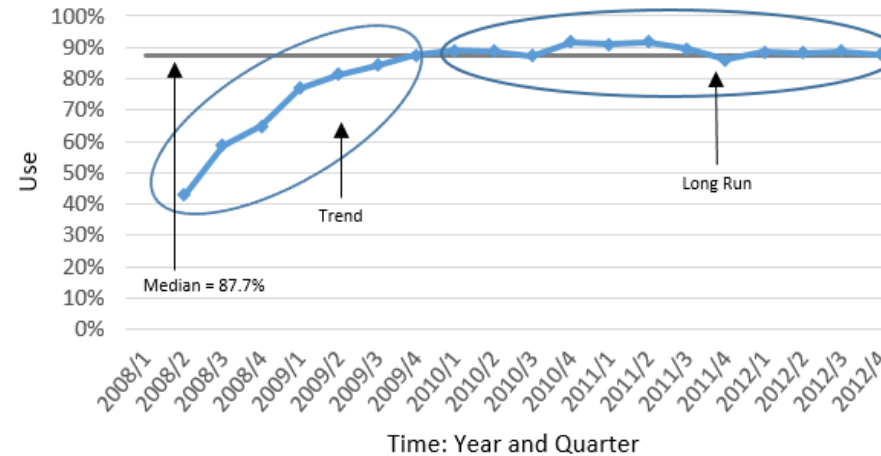
a. Overall Composite Bundle Use for 14 Hospitals from Quarter 4, 2008 through Quarter 4, 2012



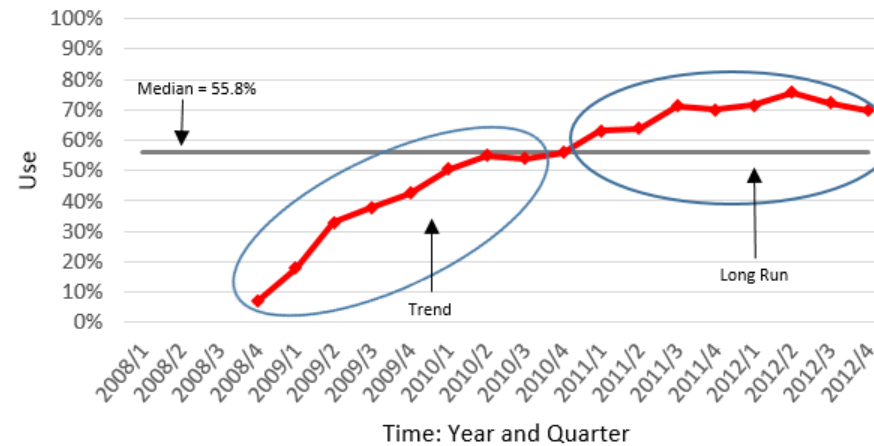
b. Overall Augmentation Bundle Use for 14 Hospitals from Quarter 2, 2008 through Quarter 4, 2012



c. Overall Induction Bundle Use for 14 Hospitals from Quarter 2, 2008 through Quarter 4, 2012



d. Overall Vacuum Bundle Use for 14 Hospitals from Quarter 4, 2008 through Quarter 4, 2012

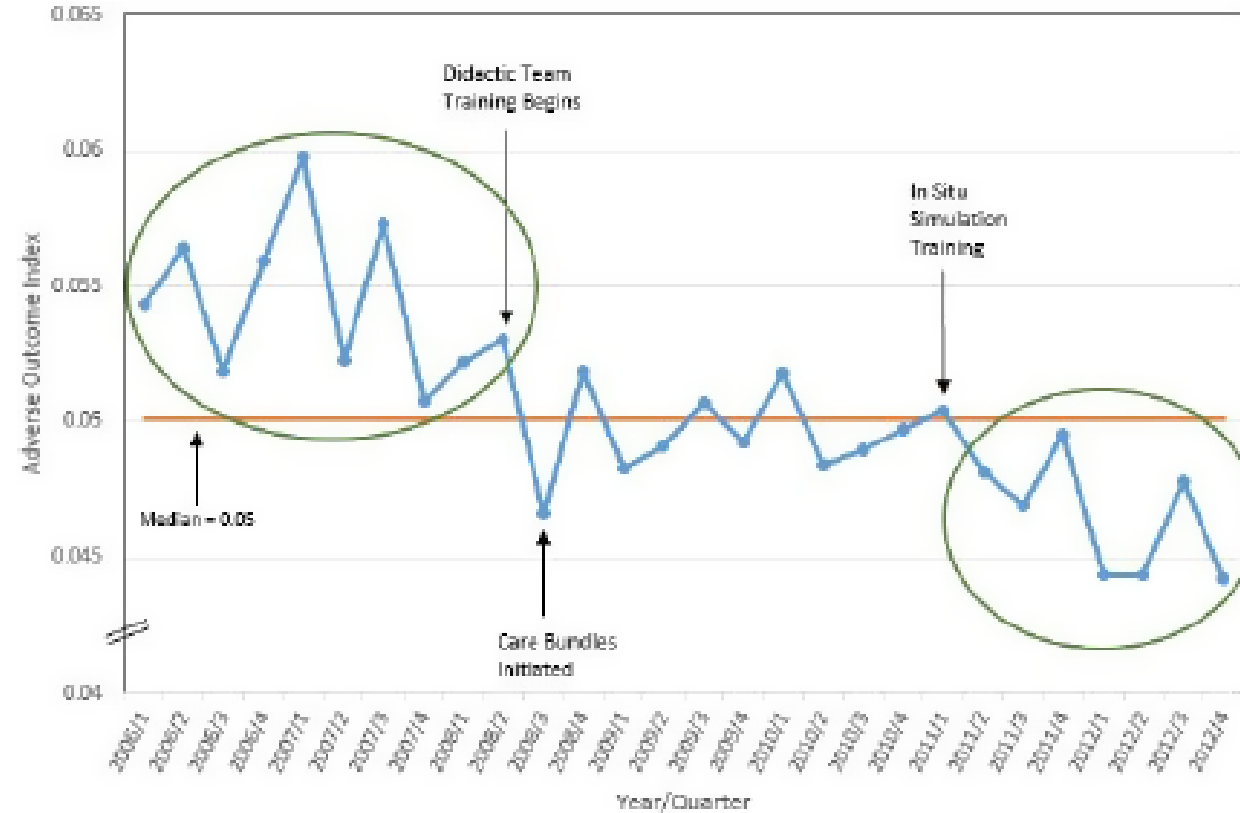


Notes. The compliance of the augmentation, vacuum, and induction standardized care bundles, as well as the composite compliance of all three bundles. Median compliance is noted in each graph, and periods of special cause are noted.

Table 2: T-tests for Composite Adverse Outcomes Index (January 2006-December 2012)

Measure	Baseline Period* (2006-2007)	Phase 2* (2011- 2012)	Change (%)	P-value
Adverse Outcome Index	0.055	0.047	-0.008 (-14.5)	0.032

Figure 3: Run Chart of the Composite Adverse Outcome Index of Fourteen Hospitals (January 2006–December 2012)



Notes. The run chart shows the effects of the interventions on the adverse outcome index. Intervention launches are indicated. Two periods of special cause are noted.

Changes in OB vs. Non-OB Malpractice Activity

- Significant declines in obstetrics claims activity:

- Number of claims paid
- Total malpractice losses paid
- Total indemnity losses paid

- No significant declines in non-obstetrics claims activity

Table 5: Changes in Baseline versus Intervention Period Malpractice Liability for Perinatal versus Nonperinatal-Related Claims at Participating Hospitals (2006–2009)

	Nonperinatal Claims				Perinatal Claims			<i>p</i> -Value for Change [†]
	Baseline: 2006–2007 (SE)	Intervention: 2008–2009 (SE)	Percent Change	<i>p</i> -Value for Change [†]	Baseline: 2006–2007 (SE)	Intervention: 2008–2009 (SE)	Percent Change	
Number of claims made (average per hospital)	43.54 (51.96)	37.00 (38.70)	–15.0%	.233	5.54 (9.73)	4.38 (7.05)	–20.9%	.214
Number of claims paid (average per hospital)	11.54 (10.78)	10.00 (7.91)	–13.3%	.219	1.23 (1.01)	0.69 (0.95)	–43.9%	.049*
Total amount of losses paid (average per hospital)	\$4,639,164 (6,809,083)	\$4,194,698 (5,849,142)	–9.6%	.367	\$1,713,296 (2,710,887)	\$384,090 (1,114,346)	–77.6%	.040*
Total amount of indemnity losses paid (average per hospital)	\$4,031,426 (6,158,116)	\$3,637,287 (5,647,905)	–9.8%	.375	\$1,527,002 (2,563,152)	\$235,888 (1,015,736)	–84.6%	.043*
Total legal defense costs (average per hospital)	\$607,738 (711,448)	\$557,411 (480,826)	–8.3%	.279	\$186,293 (213,190)	\$130,207 (231,920)	–30.1%	.153
Average amount per claim paid	\$428,349 (478,919)	\$1,260,960 (2,674,585)	194%	.149	\$1,224,246 (1,733,957)	\$175,349 (375,453)	–85.7%	.025*

Notes. [†]Significance tested using paired *t*-test.
*Significant *p*-value.

Discussion

- A number of approaches have been employed to improve perinatal safety
 - Yet there is limited empirical evidence identifying methods to improve perinatal patient safety
 - With only one exception (Grunebaum et al. 2011) there are no studies that show the relationship between improved patient safety, reduced patient injury, and reduced malpractice claims
- PPSI quality improvement collaborative used 1) standardized care bundles, 2) interdisciplinary team training and 3) systematic performance feedback. Associated with improved perinatal safety and decline in malpractice activity



Discussion & Implication

- Substantial improvement in Care Standardization, interdisciplinary Team Training, Patient Outcomes and Reduced Malpractice Activity
 - The Care Standardization and interdisciplinary Team Training are associated with significant improvement in patient safety outcomes
 - Perinatal malpractice claims and dollar amount of claim payments decreased significantly in the participating hospitals
 - No significant decrease in non-perinatal malpractice claims activity in the same hospitals
 - In perinatal units of same hospitals:
 - Mean average decrease of \$1,048,000 per perinatal claim paid.
 - Median hospital perinatal claims decrease of \$385,980 per 10,000 deliveries

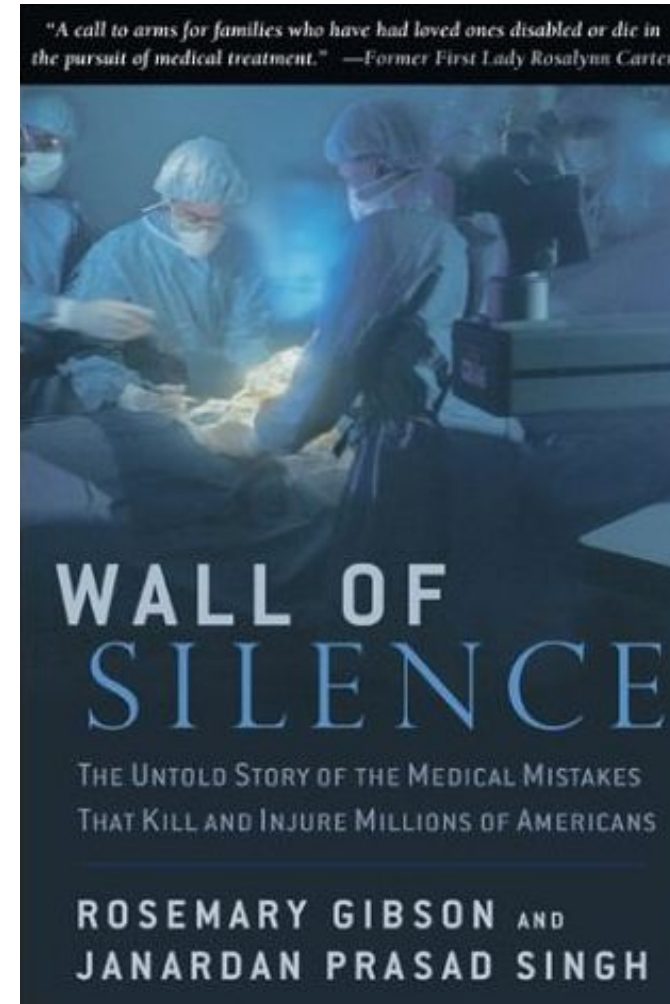
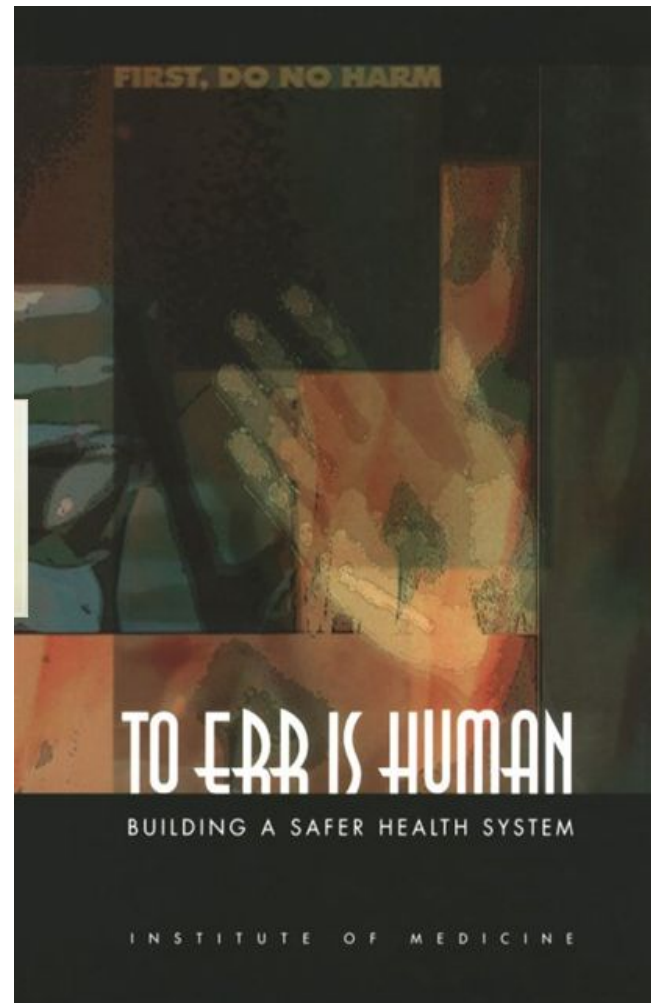
COMMUNICATION AND RESOLUTION PROGRAMS

LESSONS LEARNED FROM PSMLR PROJECTS

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The Case for CRPs



A Paradigm Shift

	Traditional Response	Communication and Optimal Resolution (CANDOR) Process
Incident reporting by clinicians	Delayed, often absent	Immediate
Communication with patient, family	Deny/defend	Transparent, ongoing
Event analysis	Physician, nurse are root cause	Focus on Just Culture, system, human factors
Quality improvement	Provider training	Drive value through system solutions, disseminated learning
Financial resolution	Only if family prevails on a malpractice claim	Proactively address patient/family needs
Care for the caregivers	None	Offered immediately
Patient, family involvement	Little to none	Extensive and ongoing

The Appeal of the CRP Approach

- It doesn't require legislative action.
- It offers something for both provider organizations and patients.
- When done right, it can produce impressive results.

History of the CRP Field

- **First wave: Pioneering Programs**
 - Veteran's Administration (VA)
 - University of Michigan (UM)
- **Second wave: Proof of concept**
 - University of Illinois (UIC)
 - Stanford University
 - Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI)
 - Oregon Patient Safety Commission (OPSC)
 - AHRQ Demonstration Projects to test and refine model
- **Third wave: Promoting spread**
 - Publication of AHRQ CANDOR toolkit
 - Collaborative for Accountability and Improvement

PSMLR CRP Projects

- New York
- UIC
- University of Texas
- Washington State
- MACRMI (planning grant)

CRP evaluation measures

- Implementation fidelity
 - Timeliness of event reporting
 - Communication elements delivered
 - Monetary remedies delivered
- Proportion of events progressing to claims and lawsuits
- Healthcare provider satisfaction

New York study: key findings

- 125 adverse events (CRP cases)
- About $\frac{3}{4}$ of events were “no liability” events
- 16% of events became claims (within 15 months)
 - Half of these were deemed “no liability” events
- Providers had low awareness of how the CRP worked, but high satisfaction with it

New York study: key findings

- Strong execution on communication elements
 - More robust disclosure practices
 - Disclosure training well received
 - CRP provided mechanism to confirm disclosure
 - More consistent feedback to families
- Improved tracking of reported events
 - More events tracked
 - Closer attention to next steps
 - Improved communication across offices
 - Greater effort to identify candidates to settle early

New York study: key findings

- Greater divergence from protocol in delivering monetary remedies
 - Few offers made where standard of care violated
 - Strong interest in settling “slam dunks”
 - Little appetite for compensating where family was not asking
- Varied experiences trying to win over surgeons
- Limited resources and heavy workload
- Variable levels of leadership support

UIC CRP

- Reported data 2002-2014 from Seven Pillars program at UIC
- CRP implemented in 2006
- CRP's impact at this hospital
 - Doubled number of incident reports
 - Halved number of claims
 - Reduced legal fees, total costs per claim
- Second analysis compared testing among patients with chest pain at UIC compared with 44 other Illinois hospitals
 - At CRP hospital, reduced growth rates in use of diagnostic testing and imaging services
- Challenging to replicate Seven Pillars at other participating hospitals

University of Texas

- Examined post tort-reform malpractice claims experience at UT System
 - Sharp drop in claim closures and associated payments
 - No change in time to resolve claims
 - Nondisclosure agreements present in 88%
- Patients as partners in learning from unexpected events
 - 72 patients and family members interviewed after adverse events
 - All identified at least one contributing factor (average was 3.7 contributing factors identified per interview)

Washington State

- Explored use of CRP in settings where multiple organizations needed to cooperate
 - Several complex barriers identified, including insurers' distance from point of care, passive rather than active leadership support, challenges with coordination, mistrust
- Innovative program developed for “certifying” CRP events in partnership with regulators
 - Seeks to mitigate physician concerns that participating in CRP could increase chances of punitive response from regulators
- PFAC-developed simulation exercise can help broad array of stakeholders understand what patients and families experience after adverse events

Lessons learned

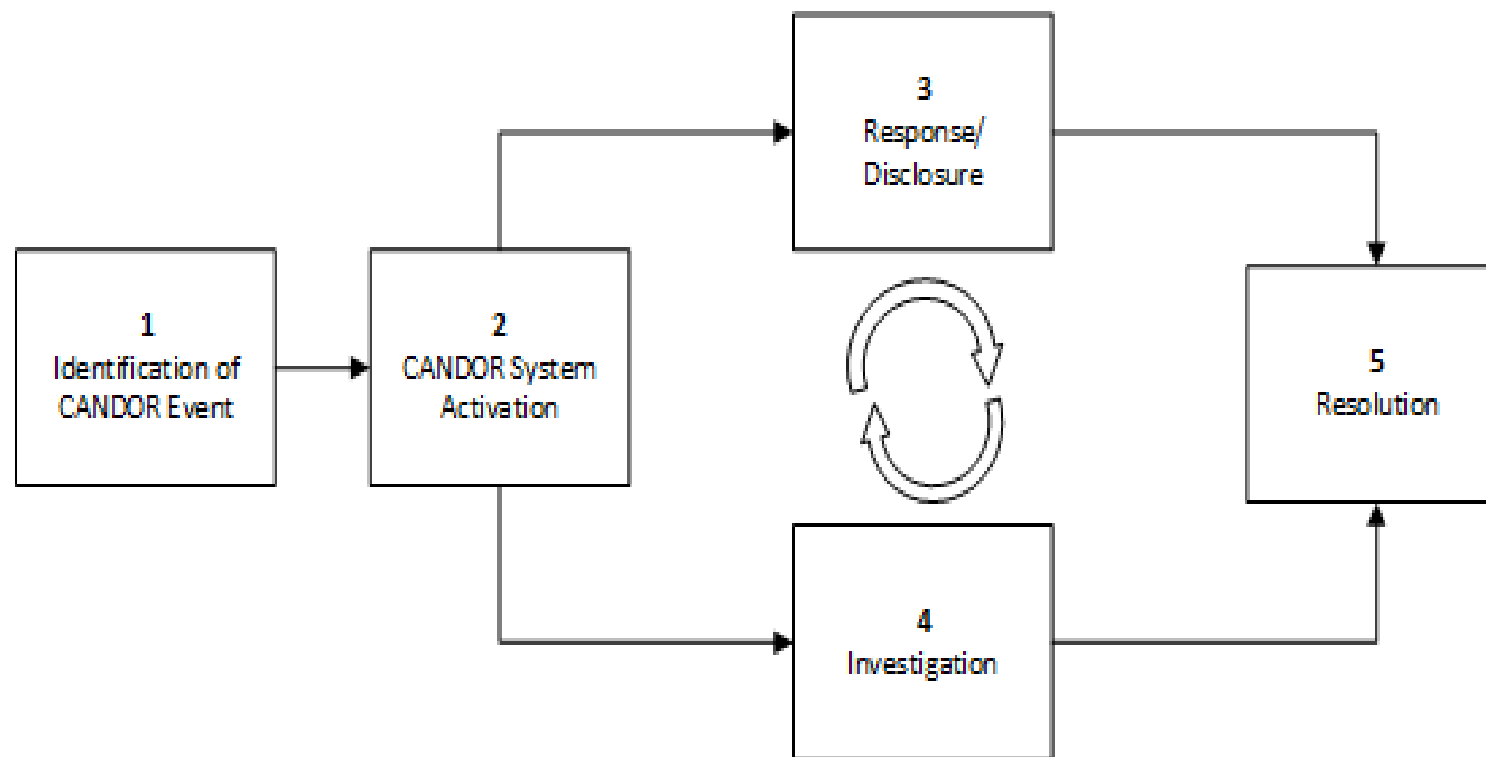
- CRPs hold promise for both improving patient safety and reducing medical malpractice liability
- Replicating and scaling pioneering CRP programs is challenging
- Longer-term research and evaluations needed
- A national surveillance system for malpractice claims could have considerable benefits

Other observations from field

- Adoption of CRPs continues to rise
- The ongoing problem of incomplete CRP implementation
 - Use of some CRP key elements but not others
 - Use of CRP for only fraction of eligible cases
- Success more likely when CRPs understood as patient safety rather than claims resolution strategy

The Communication and Optimal Resolution: CANDOR Process

- The CANDOR Process consists of five major “bundles” of activity that proceed in sequence and at times simultaneously.



Other CRP resources

- AHRQ CANDOR Toolkit
- Collaborative for Accountability and Improvement (www.communicationandresolution.org)
- Statewide CRP initiatives in Massachusetts (MACRMI), Oregon, Iowa, Washington, and others
 - MACRMI resource list: www.macrmi.info
- The Risk Authority (Stanford): <http://theriskauthority.com/advancement/webcasts/communication-and-resolution/>
- CRP work at large health systems (for example MedStar, Dignity, Trinity, Kaiser, Stanford) and insurers (Beta)

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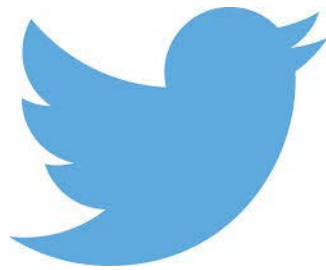
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