

The 2007 Quality Colloquium

Sanders Theater, Harvard University Campus, Boston, MA
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The Art of Patient Safety: Moving Organizations to Change

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Key elements for change

- 1. Build a shared vision of the opportunity**
 - **establish current best estimates of injury rates**
 - **anticipate and address specific barriers:**
 - > *"In my experience" this is not a problem*
(the data are wrong; this may apply to others, but it's not me)
 - > *"This is the price we must pay for the good we achieve"*
- 2. Show the way ahead**
 - **lay out a system that makes care much safer**
 - **demonstrate examples of success**
- 3. Make the business case**
 - **estimate operational costs to recover from a patient safety failure** (e.g., \$5000+ per ADE)
 - **rationalize the payment system** (new Medicare rules)

	<u>Sample size</u>	<u>Injury rate</u>	<u>% judged preventable</u>	<u>% life threatening or fatal</u>
HMPS (1984 data)	~34,000	3.7%	58%	13.6%
Utah-Colorado (1992 data)	15,000	2.9%	53%	6.6%
Australian AE (1992 data)	2,353	16.6%	69.8%	22.3%
Australian AE at LDSH		10.2% (?)		
Canada AE (2000 data)	3,745	7.5%	36.9%	20.8% (fatal)

IHI Global Trigger Tool

- ◆ LDS Hospital; random sample containing 325 patients, hospitalized during October 2004
- ◆ Record review performed March 21-22, 2005, by a team of 7 trained abstractors
- ◆ All charts, at all levels, reviewed twice

35.1% *of all admissions had at least one adverse event*

74.0% *were part of this hospital admission*

(9.1% of all hospital admissions resulted from outpatient care-associated adverse events)

<u>Rate</u>	<u>Severity Level</u>	<u>Rate</u>	<u>Source</u>
53%	E - temporary harm, required intervention	52%	medications
33%	F - temporary harm, initial or prolonged hospitalization	20%	procedure complications
3%	G - permanent harm	13%	infections
7%	H - intervention required to sustain life	8%	care issues
1%	I - patient death	3%	device failures

Unusual findings: minimal issues relating to anticoagulants, insulin, and PCA pumps, which are much bigger at other institutions (LDSH has protocols in place for these). That yields an injury rate of 82 / 1000 patient days, while most other hospitals are just above 100 injuries per thousand patient days.

Extrapolating to a full year, about 132 adverse-event-related - 'sentinel event' - deaths occurred.

Tracking patient events

Concurrent clinical (EMR-based) trigger systems

1. **Adverse drug events** (ADEs)
2. **Hospital-acquired infections**
 - post-op deep wound infections
3. **Pressure injuries**
 - **Fully automated** (EMR),
 - **semi-automated**, and
 - **manual**

Retrospective (chart review-based) trigger system

- ♦ **IHI Global Triggers** (Roger Resar)
- ♦ **QaRNS** (Australian "HMPS" system; Canadian [Peter Norton] system)
- ♦ **JCAHO Sentinel Events**
- ♦ **NQF Never Events**

Voluntary reporting

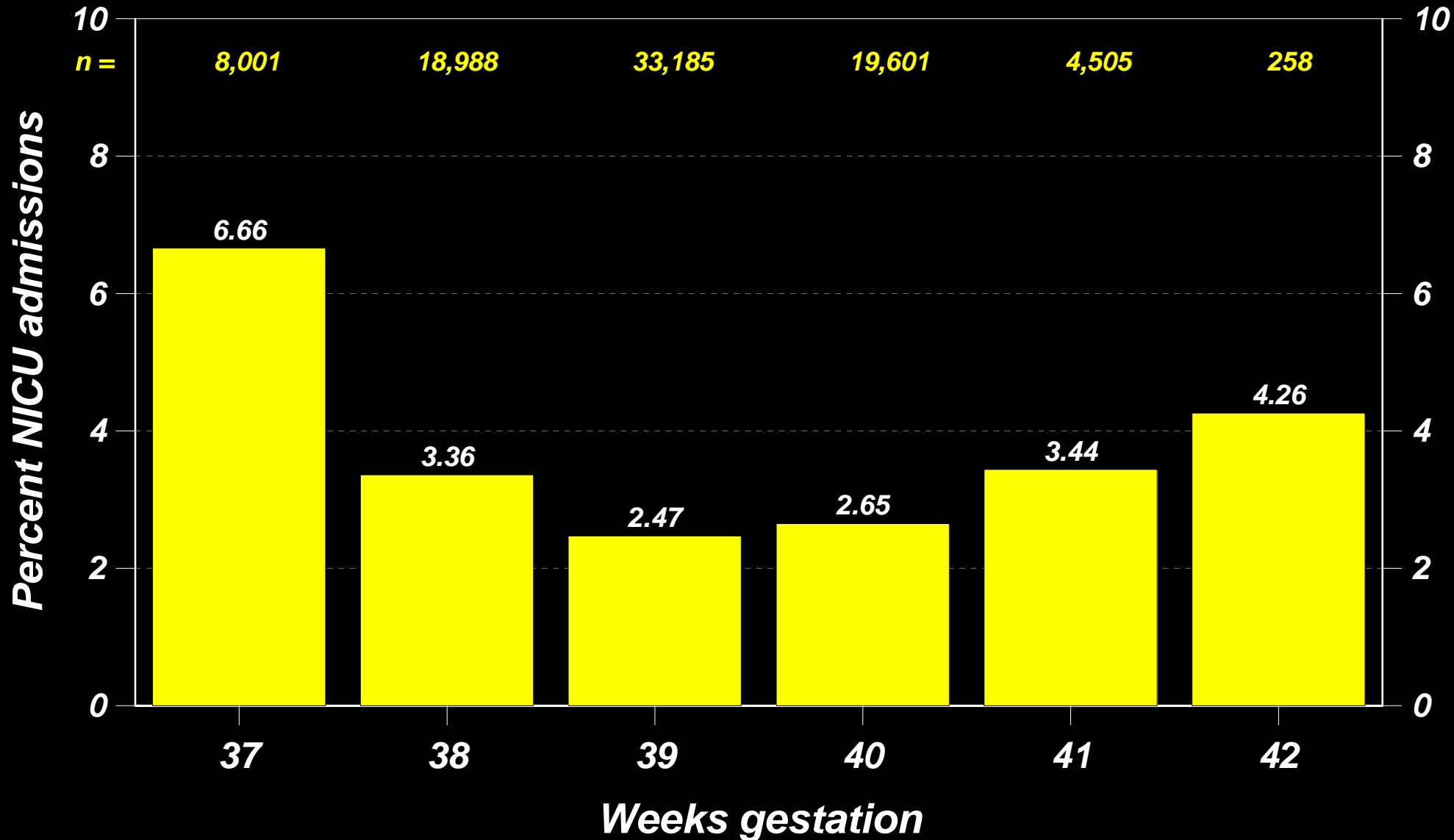
- ♦ **Culture of Safety**
- ♦ **Easy reporting**
 - multimodal
 - anonymous, if desired
 - patients and families
- ♦ **Training and rewards**

Lessons learned from injury tracking research

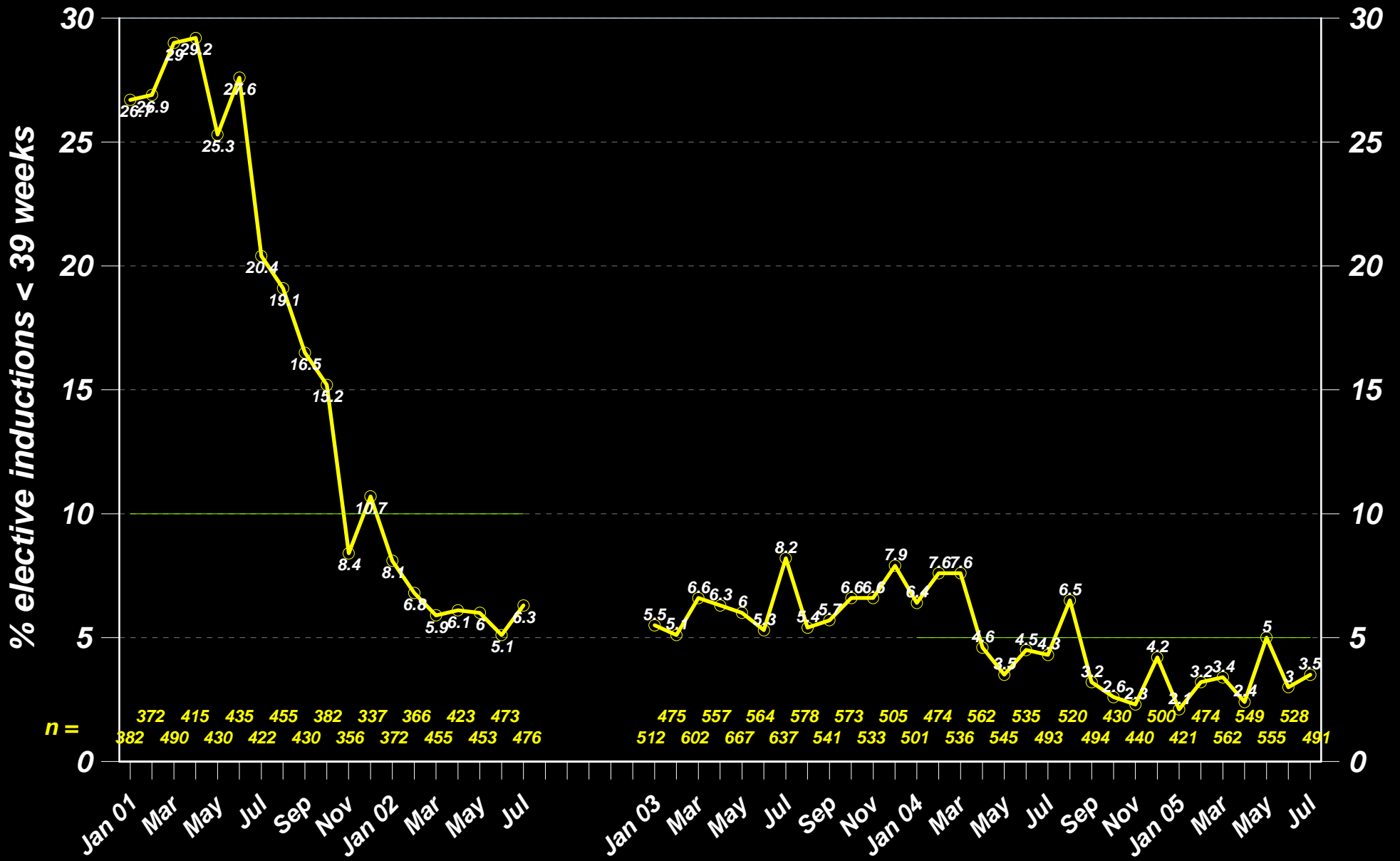
- ◆ **Current** (voluntary reporting) **systems miss the vast majority of injuries** (finding only about 1 in 100-150 injuries)
- ◆ **Most often** (e.g., > 80% of the time for ADEs), **clinical teams don't associate patient symptoms with the treatments that are causing them**
- ◆ **A more accurate perception of sources of injury can hugely change intervention strategies**
- ◆ **Think events or injuries, not errors**

NICU admits by weeks gestation

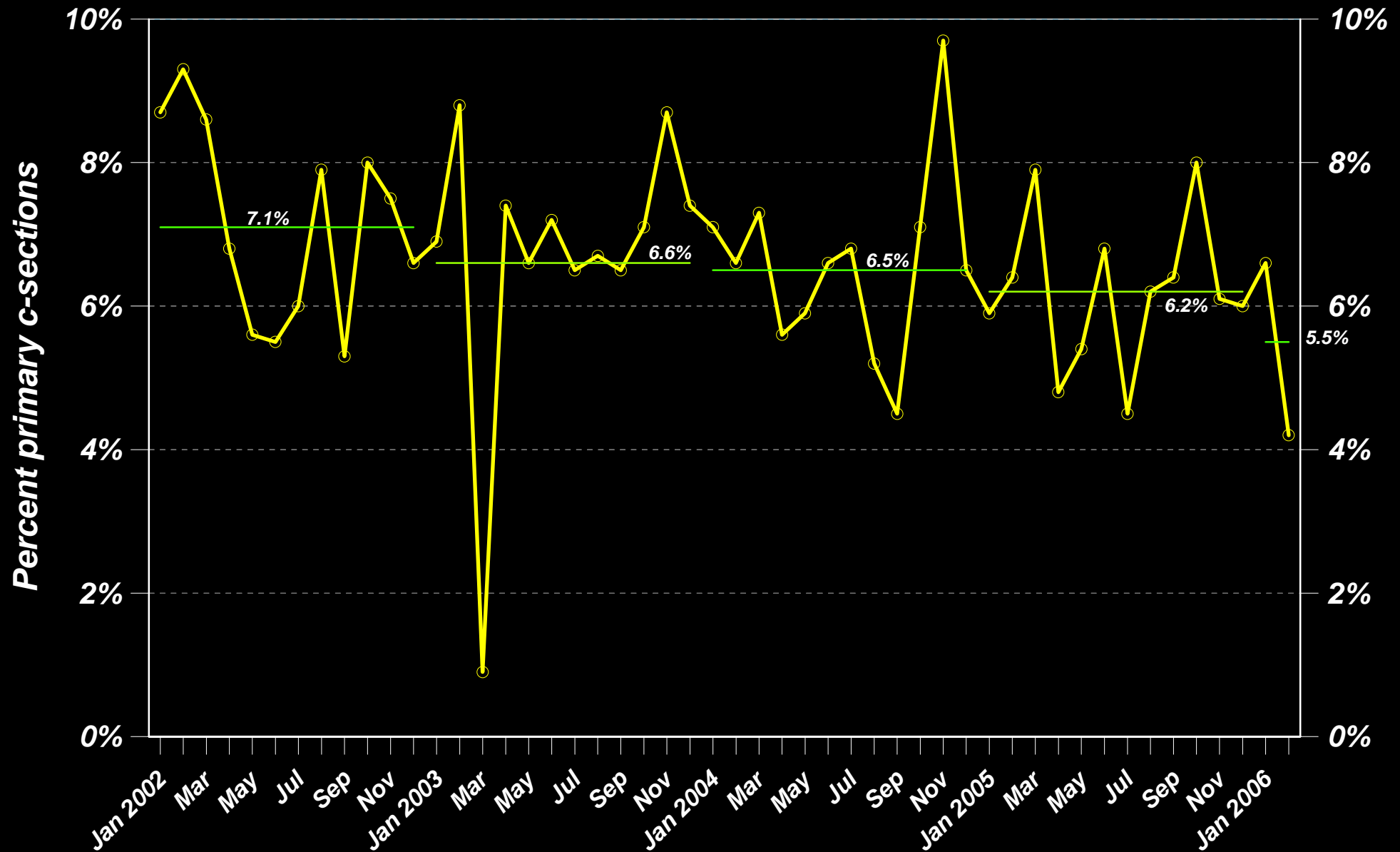
Deliveries w/o Complications, 2002 - 2003



Elective inductions < 39 weeks

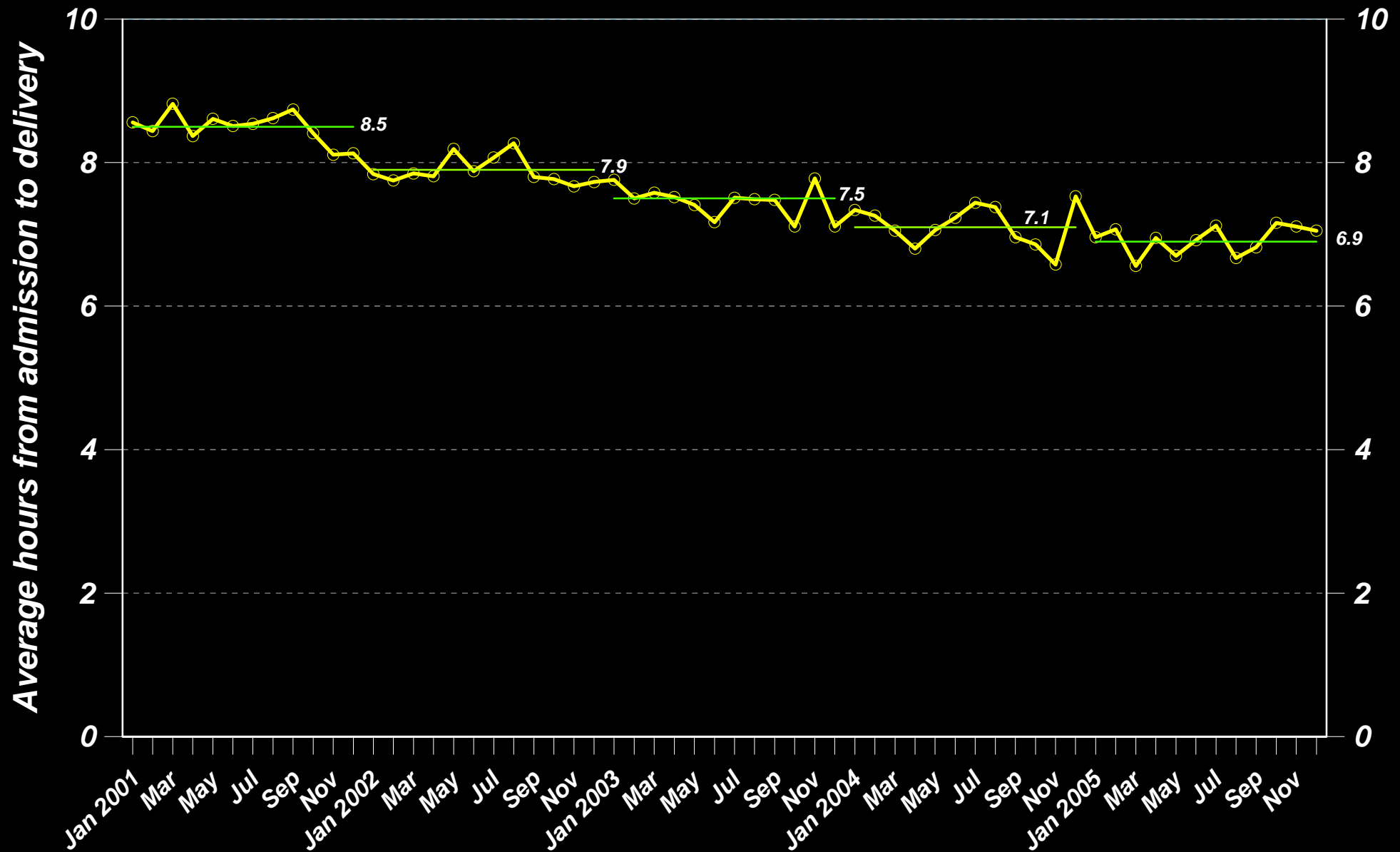


Elective induction: primary c-section



(note: includes all elective inductions; national rate has been rising)

Elective induction: length of labor



(note: includes all elective inductions)

***Medicine used to be simple,
ineffective, and relatively safe.***

***Now it is complex, effective,
and potentially dangerous.***

Sir Cyril Chantler

Neal G. Reducing risks in the practice of hospital general medicine. In *Clinical Risk Management, 2nd edition*. British Medical Journal, 2001.

Chantler, Cyril. The role and education of doctors in the delivery of health care. *Lancet* 1999; 353:1178-81.

Are most injuries unavoidable?

The price we pay

(for)

diseases of medical progress

Blendon, Robert J. *et al.* Views of practicing physicians and the public on medical errors. *N Engl J Med* 2002; 347(24):1933-40 (Dec 12).

Barr, David. Hazards of modern diagnosis and therapy - the price we pay. *JAMA* 1955; 159(115):1452-6 (Dec 10).

Moser, Robert H. Diseases of medical progress. *N Engl J Med* 1956; 255(13):606-14 (Sep 27).

A Culture of Safety is:

"... an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery."

Dr. Ken Kizer

A Culture of Safety

- ◆ *Shared beliefs and values about the health care delivery system;*
- ◆ *Recruitment and training with patient safety in mind;*
- ◆ *Organizational commitment to detect and analyze patient events and near misses;*
- ◆ *Open communication regarding patient injury results, both within and outside the organization;*
- ◆ *The establishment of a "just" culture.*

A Culture of Safety

High quality health care is predicated on safe care (IOM 1999; Kizer ?). Freedom from care-related injuries comes primarily from carefully designed health care delivery systems, with a secondary reliance upon improving the competence of professionals working within those systems (IOM 1999). In describing a context for safe care delivery practices, Kizer identified 7 features essential in a healthcare organization that can produce high-quality outcomes:

1. Continuous learning and process redesign;
2. failures readily identified and evaluated;
3. knowledge and skills actively managed;
4. performance and outcomes continuously measured and evaluated;
5. collaboration and teamwork is the norm; and
6. care is highly coordinated; needs are anticipated.

As a result, a quality healthcare delivery system can demonstrate

7. consistent and predictable (that is, reliable) performance.

A culture of safety is

“... an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery.” (Kizer ?)

High quality systems are “safe” in two ways: In order to be (1) safe for patients, the health care delivery system must design and execute safe care delivery processes. Safe processes rely upon dependable information about failures. Accurate, actionable information about failures derives from a (2) safe reporting environment for individual health care professionals.

A culture of safety thus contains the following elements (modified from Kizer ?):

1. Beliefs and values

A shared recognition by all members of a health care delivery organization, regularly and forcefully reinforced by professional and organizational leaders, that

- health care is a highly complex, error-prone, and thus high-risk undertaking; that
- failures are inevitable when humans and complex systems are involved; and that
- hazards and errors can be anticipated – processes can be designed to both prevent failures, and to prevent patient harm when a failure occurs.

2. Patient safety competence

An organizational understanding that

- knowledge and skills form an essential foundation for safe practices; that
- such competence is ephemeral and must be actively maintained; and that
- current health professional education does not address many subjects critical to a safe care delivery environment.

3. Measurement

Organizational commitment to detect as many patient injuries and near misses as possible, through

- active surveillance (based upon case-finding through real-time/interventional/prospective data based clinical triggers systems, as well as retrospective chart review driven by code-based trigger systems);
- voluntary reporting with minimum burden upon the person reporting (e.g., an independent team that completes all paperwork, a simple computerized flagging mechanism to mark possible injuries for independent review, anonymous telephone and e-mail tip lines accessible to front-line professionals, patients, and family members, “walk around” reviews conducted by internal safety experts and organizational leaders, and a system for asking front-line health professionals, as they leave work, if they experienced any unsafe conditions or observed any injuries or near misses during their just-completed work day)
- rewards and appropriate protections for individuals who report injuries and near misses.

4. Response

Organizational structure to

- prioritize events that require reporting, analysis, and action;
- rigorously analyze high-priority events, and identify possible systems-level solutions;
- verify actions taken, their effectiveness, and whether there were untoward secondary effects;
- insure leadership involvement and coordination

5. Communication

- Starts when leadership sets clear expectations regarding patient safety, reflected in organizational goals.
- Includes open sharing of patient injury results, both inside and outside the organization (i.e., with front-line professionals, boards of directors or trustees, patients and patient representatives, and health care overseers) as part of a transparent care delivery system.

Perhaps the most controversial element of a health care culture of safety is the idea of rewarding and protecting front-line health care professionals when they report injuries, errors, and near misses in which they were personally involved. Such recommendations derive from proven safety performance in other industries, such as airline transportation (NTSB), nuclear power (NRC), safe manufacturing environments (OSHA), and high-reliability military operations (U.S. Armed Forces – aircraft carriers, etc.). Those industries use a safe reporting environment to maximize discovery of injuries and near misses, which leads to effective system design that reduces injury rates in the future. All reporting is safe, with 3 exceptions:

1. criminal behavior
2. active malfeasance (repeated, knowing disregard of safety systems)
3. failure to report in a timely way (usually, within 48 hours)

Actively participate

in the **IHI 5 Million Lives Campaign**

- *state of the art measurement system*
- *learning collaborative*

"Patient Safety" Hospitals

- ◆ **Organizational infrastructure:**
 - *certified patient safety officer as part of line management;*
 - **Culture of Safety** (*organization-wide training; rewards for reporting; transparency; etc.*)
- ◆ **Measurement infrastructure:**
 - *standard concurrent and retrospective trigger systems*
 - *Culture of Safety-based voluntary reporting system*
 - *certified pharmacist (or equivalent) performing real-time ADE evaluation*
 - *certified chart reviewers (random sample or full census)*
 - *participates (sends data) to central data repository*
 - *external audits of injury detection data systems*
- ◆ **Implemented safe practices:**
 - *NQF / AHRQ evidence-based safe practices (~30, at present)*
 - *IHI 100,000 Lives campaign*

The cost of poor quality

Adverse drug events (ADEs)

- ◆ **Overdoses,**
- ◆ **allergic / idiosyncratic reactions,**
- ◆ **drug-drug interactions, or**
- ◆ **errors in route, rate, timing, or patient**

Cost (not charge) per event:

- ◆ **Moderate and severe:** **\$2,400** (1992 data)
- ◆ **Severe alone:** **\$4,700**

Classen et al. 1994

Bates et al. 1997

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