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# Shifting Patient Safety into High Gear

Boston, MA, November 16, 2012



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# PSO: History and Potential

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Shifting  
Patient  
Safety into  
High Gear

*Gregg Meyer, MD, MSc*

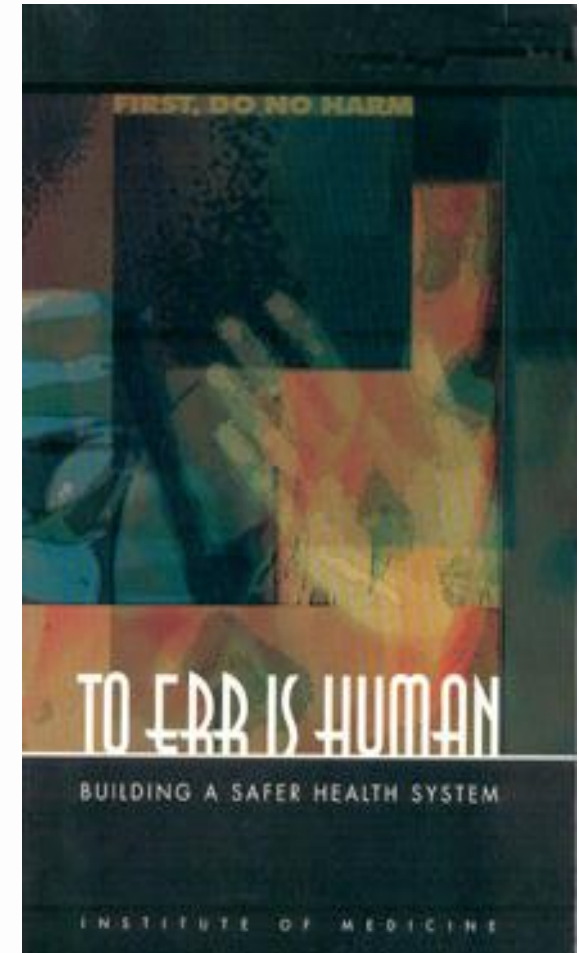
*Dartmouth-Hitchcock Medical Center*

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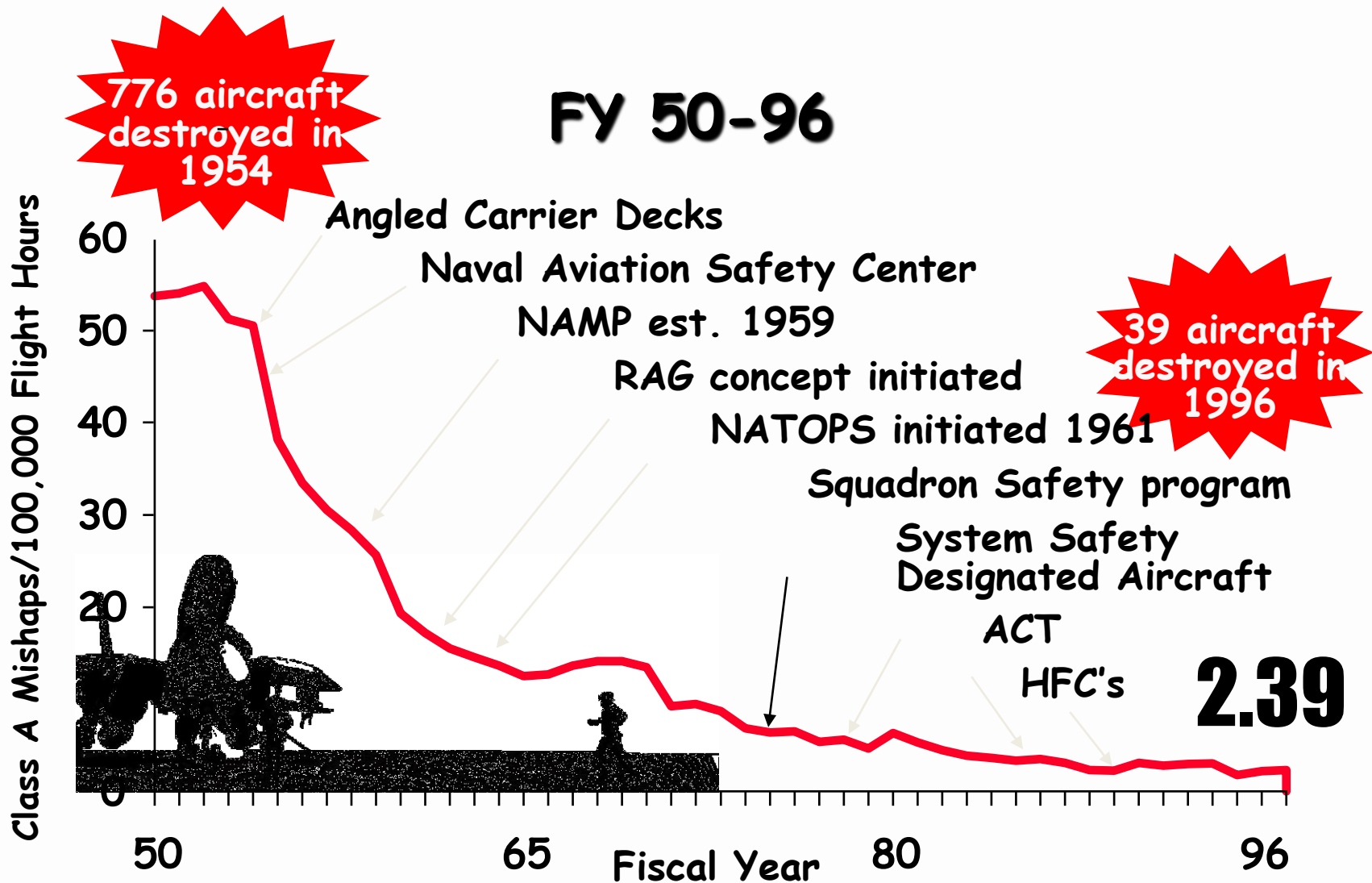
# The Context: *To Err is Human*

## Preventable medical errors

- 44,000 to 98,000 Americans die each year
- Eighth leading cause of death in the United States
- **Annual cost as much as \$29 billion annually**



# The Science of Safety



# The Response: *Doing What Counts*

- Federal Response -> QuIC
- “The QuIC supports the extension of peer review protections to facilitate reporting of errors in a blame-free environment...”
- The same document also led to the creation of the Serious Reportable Events list, Safe Practices and a \$165 Million research program

T O T H E P R E S I D E N T

February 2000

Doing  
what counts  
for patient  
safety



Report of the Quality Interagency Coordination Task Force

QuIC



# Making It Real: The Patient Safety Act of 2001

Aims to improve safety by addressing:

- Healthcare workers' fear of disclosure
- Fear of malpractice litigation
- Inadequate protection by state laws
- Inability to aggregate data on a large scale

**That sounded pretty easy...**

# The Patient Safety and Quality Improvement Act of 2005

- Creates “Patient Safety Organizations” (PSOs)
- Establishes “Network of Patient Safety Databases”
- Authorizes establishment of “Common Formats” for reporting patient safety events
- Requires reporting of findings annually in AHRQ’s National Health Quality/Disparities Reports



# Addressing the Tower of Babel: *Common Formats*

- Patient Safety and Quality Improvement Act of 2005 contains a provision authorizing the Secretary of HHS to promulgate common definitions and reporting formats (Common Formats) to support uniform reporting of quality and safety performance
- Such Common Formats allow PSOs (and other interested parties) to collect information on quality and safety that is “interoperable” and can be aggregated locally, regionally, and nationally for accelerated learning
- There is no “final” version of the Formats, which are clinical instruments; AHRQ publishes iterative versions which are updated periodically



# Patient Safety Organizations – *The Real Value*

- Enables healthcare providers to voluntarily share information related to safety and quality under **a federal grant of confidentiality and privilege (i.e. creates federal peer review protection)**
  - Unprecedented federal protection
    - ... for sharing across organizations
    - ... for collective analysis = “data hubs”
  - Rather than a patchwork of state-by-state protections, there will now be national uniform protections
  
- Allows greater understanding as to how quality and safety are being improved nationally



# What does a PSO really do?

- Keeps data safe and secure
  - Provides a fully protected legal framework: federal protection for data entered into the PSO that is a part of your patient safety evaluation system (PSES)
- Reviews data and analyzes data in order to identify risks and ways to improve patient care
- Provides opportunities for shared learning and collaboration
- Complies with the AHRQ common formats or provides alternative that is reasonable
- Submits de-identified data to National Patient Safety Data Base

# Why bother?

- Thalidomide – banned 1961
- Fen-Phen – banned 1997
- Vioxx – banned 2005



**\$58 Million Vioxx Multi-State Settlement**

**Allegations:**

- Merck knew Vioxx carried increased risk of cardiovascular side effects
- Misrepresented the safety of their product in advertisements
- Aggressively marketed directly to consumers before doctors had experience with Vioxx

**Settlement:**

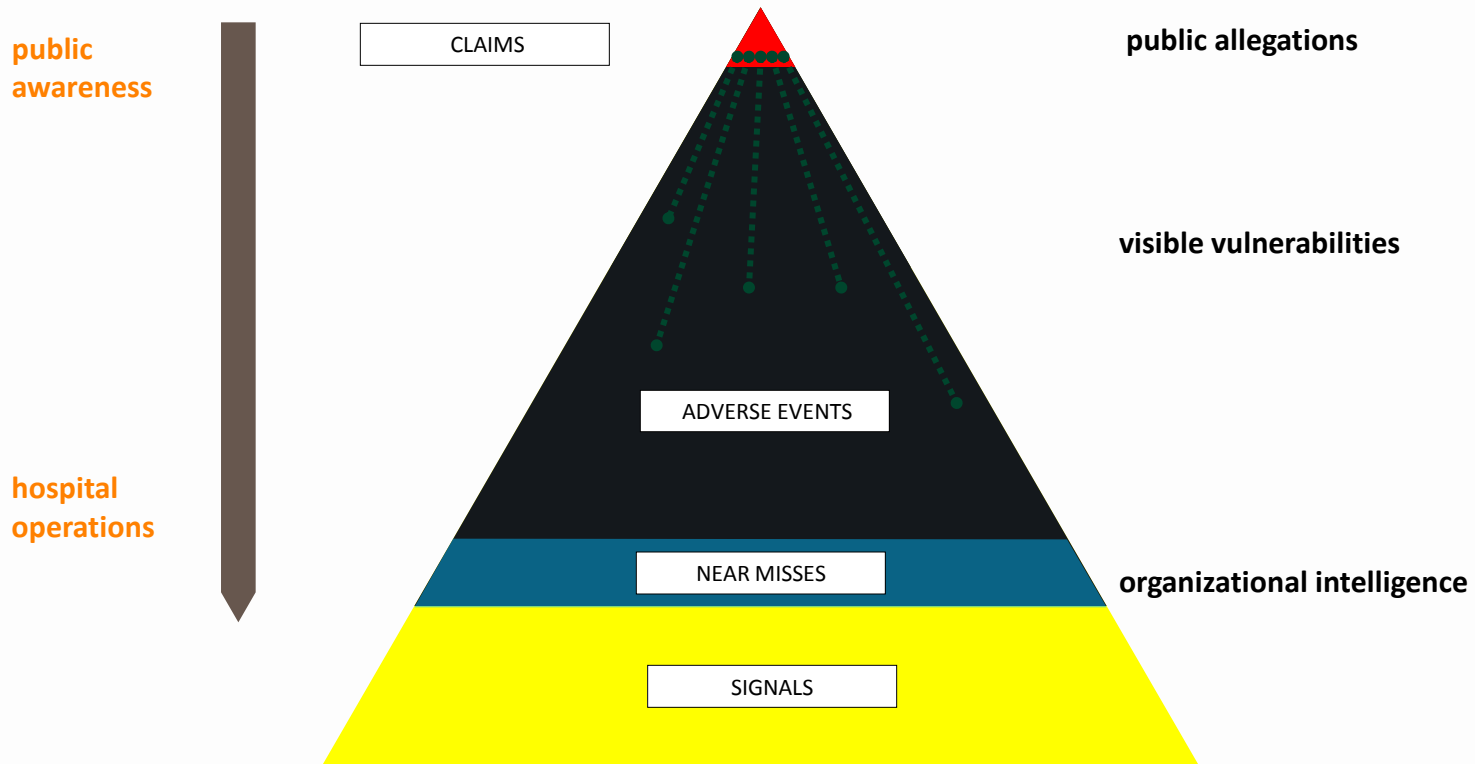
- Merck will pay \$58 million to the states involved
- Merck agrees to delay direct-to-consumer TV ads if recommended by FDA

**TOM CORBETT**  
ATTORNEY GENERAL

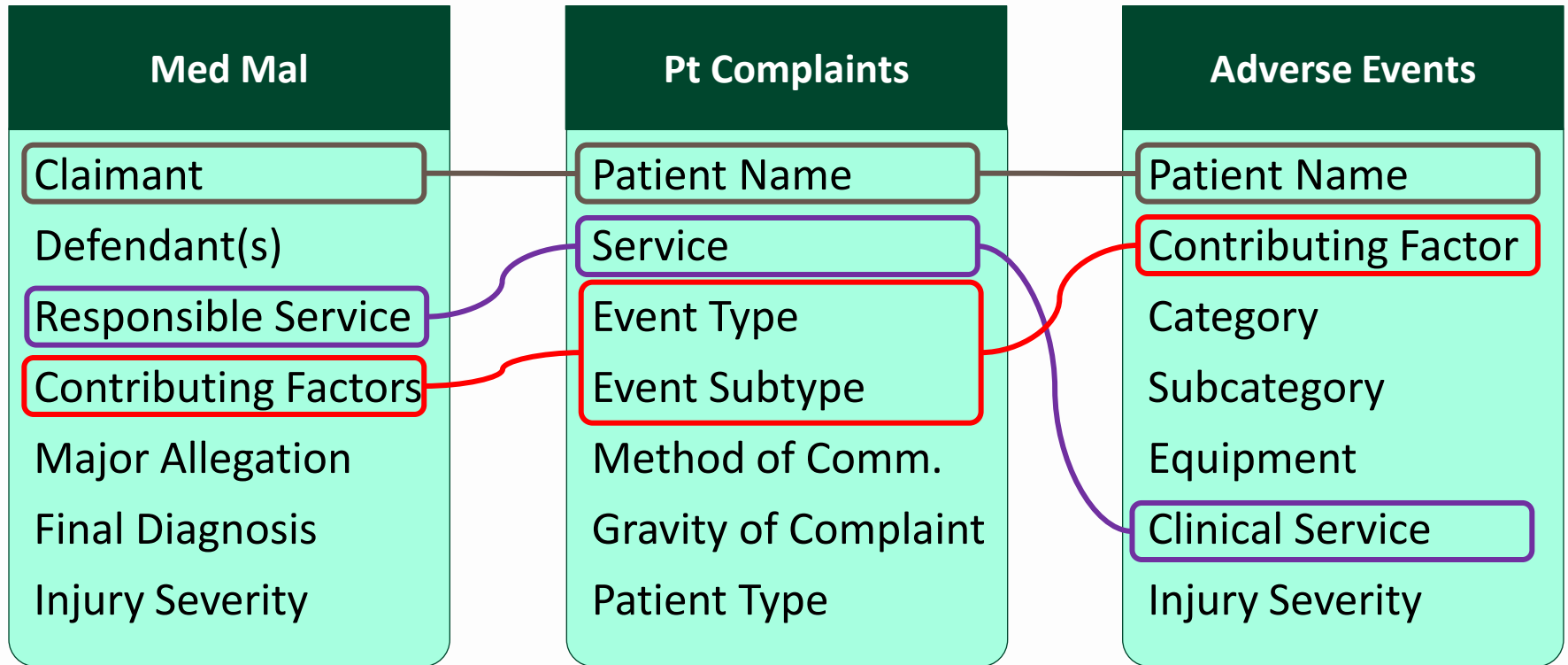
**PENNSYLVANIA**  
OFFICE OF ATTORNEY GENERAL



# Getting Below The Tip of the Iceberg...



# PSO Vision: Linking the Data Sets (aka “the mining”)



Note: The same event can be mapped to several categories or to multiple values of the same category

# Real Value Add: Expert Exchange Under Peer-Review Protection



AT THE INTERSECTION OF HEALTH, HEALTH CARE, AND POLICY

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### From the Staff

#### Comparing Treatments, Judging Health Reform Top HA Blog Most-Read List

November 8th, 2010  
by **Chris Fleming**

A look at *Health Affairs'* October issue on comparative effectiveness research tops the list of most-read *Health Affairs* Blog posts for last month. Next on the list is Tim Jost's look at the debate over the Affordable Care Act's constitutionality, followed by John Goodman's analysis of whether the new legislation will "bend the cost curve."

Here's the entire list: [Read the rest of this entry >](#)

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### Contributing Voices

#### What Is An 'Essential Benefit'?

October 29th, 2010  
by **Linda Bergthold**

A central feature of health reform is the state exchanges, through which a variety of plans will be offered. Each of those plans will be required to offer a package of "essential benefits" as defined in the *Affordable Care Act*. When most people think of benefits, they think of monthly premiums, annual deductibles and co-pays for physician or hospital services. However, essential benefits also include the definition of what services will be covered in the insurance plan and how each plan will apply those benefits to individual cases.

The Affordable Care Act itself provides relatively little guidance about what "essential" really means, other



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- John Ballard on [Conservatives Urge Aggressive Approach To Overturning Health Reform](#)
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# Convening Value: It's the meeting not the mining

- Do people show up?
- Is something done differently as a result?
- Is there an actuarial base?

It is like democracy...



# Lessons Learned

- Even with a common language combining data sources is difficult
- Discovering rare events (“big data”) is an unproven value (just potential)
- Protecting conversations that should have happened years ago is the real promise
- “What happened at your neighboring healthcare facility yesterday that is going to hurt someone in yours tomorrow?”

