

## Patient Safety and Event Reporting

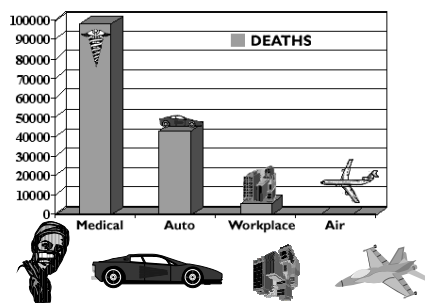
Surveillance and Using the Data  
Below the Water-Line

HS Kaplan, M.D.  
Columbia University  
AHRQ U18 Demonstration Grant



"Believe me, pal,  
the problem is DEEER on the molecular level!"

## Annual Accidental Deaths



## “To Err is Human “ Institute of Medicine Report 1999

- Identify and learn from errors through reporting systems - both mandatory and voluntary.



## Types of Analysis Means

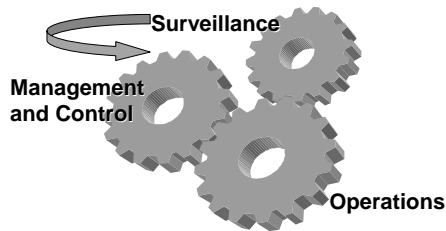
- Audit
  - Chart review
  - Observation
- Simulation
- FMEA
- Event reporting *and analysis*

## Looking Below the Waterline



- Misadventures
- Events without harm
- Near miss events
- Dangerous situations

## Management and Control of Safety of Medical Care



## Goals of the System of Management

- Prevent failure
- Make failure visible
- Prevent adverse effects of failure
- Mitigate the adverse effects

## Types of Errors/Failures

- **Active**— are errors committed by those in direct contact with the human-system interface (human error)
- **Latent**—are the delayed consequences of technical and organizational actions and decisions

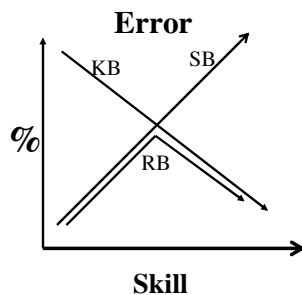
## Active Human Error Forms

- Skill Based
  - Know what you're doing
- Rule Based
  - Think you know what you're doing
- Knowledge Based
  - Know you don't know what you're doing

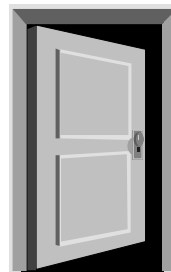
## Does Practice Make Perfect?

Skill / Error Relationship:

- Decreased errors taken as measure of increasing proficiency
- 
- But type of error is critical



## “Over-learned” Unmindful Task Performance

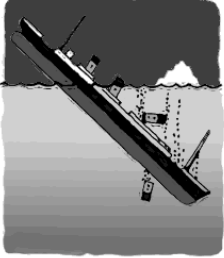


- Often performed without thought, routine, habitual
- Little attention to components of routine
- Less able to modify if interrupted or novel task elements arise

Langer, E.

### The Titanic — Latent Failures:

- Inadequate number of lifeboats
- No horizontal bulkheads
- No dry run
- Single radio channel



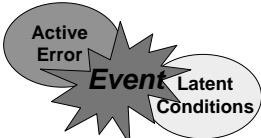
### Events Happen When:

Blunt end actions and decisions — latent underlying conditions

+


Sharp end actions and decisions — active human failure

= *Event*




### Types of Events

**MERS-TH is designed to capture all types of events.**




### Misadventures

The event actually happened and some level of harm — possibly death — occurred.




### No Harm Events

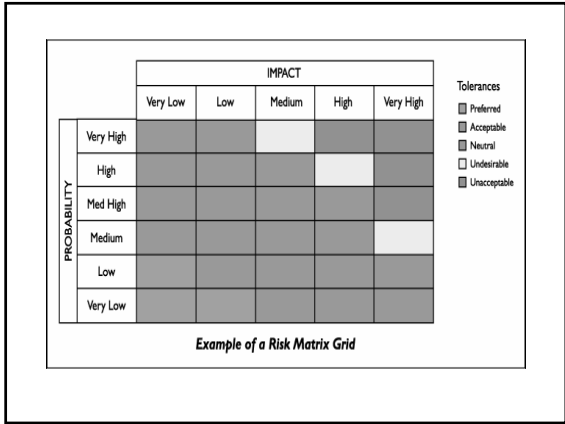
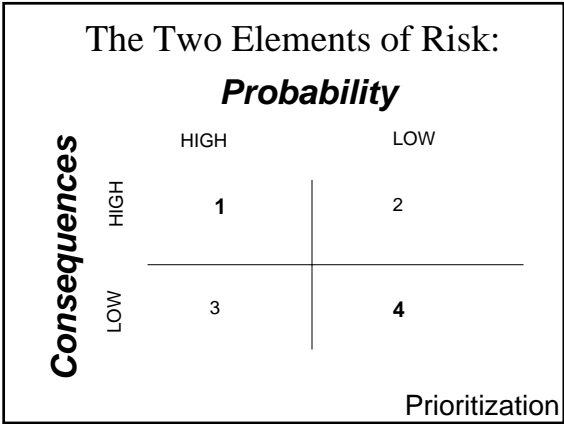
The event actually occurred but no harm was done.



### Near Miss Events

The potential for harm may have been present, but unwanted consequences were prevented because some recovery action was taken.





### A Consequence-Based Focus

- Don't focus only on what caused the event.
- Focus on factors influencing the consequences.
- Safety is all about consequences
  - Types: death, damage, dollars, disgrace ...
  - Classes: actual, expected (pipeline), potential (averted)

Modified from W. Corcoran: Firebird Forum

### Event Classification by Organizations

Event classification affects availability of information for learning:

- Organizations tend to disregard events outside classification scheme
- Classifications trigger information processing routines that channel decision maker's attention

### “Believing is Seeing”

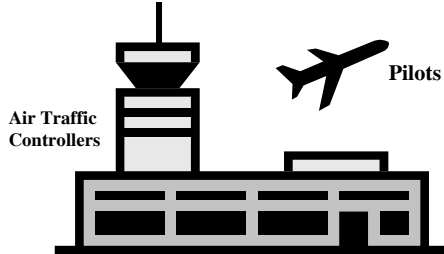
#### Event Classification by Organizations

- Organizations disregard events outside classification scheme
- Compliance sets limits of visibility



## Our Classifications Define What We See

Different definitions of NEAR MISS



## Different Definitions of Near Miss



Air Traffic Controller  
Possible Causative Factors:

- “Fanny Factor”
  - Pilot first on the scene.
- ATC: Three strikes and you’re out.

## Benefits of Near Miss Reporting

- Tell us why misadventures *didn't* happen
  - Allows for the study of recovery
- Greater number of events allows quantitative analysis
  - Near misses and no harm events: relative proportions of classes of system failures - help define risk

## Recovery – planned or unplanned

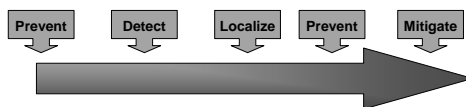
Study of recovery actions is **valuable.**

- Planned recovery
  - Built into our processes
- Unplanned recovery
  - Lucky catches



## Promoting Recovery

Current emphasis: Prevention of errors  
Actually desired: prevention of negative consequences, not errors per se.



\_\_\_\_\_ Van der Schaaf and Kanse 1999

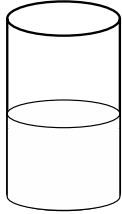
## Use of Near Miss Reports



- Portal to view potential system dangers
  - Safe lessons learned
- Exemplar cases in support of mindfulness

## Perception of Failure vs. Success

Is the glass half full - or half empty?



HRO:

- Near-miss is seen as a kind of failure revealing potential danger.

Other organizations:

- See Near-miss as evidence of success.

Karl Weick

## Conventional Wisdom?

Beware the surgeon who is very experienced in getting out of bad situations.

\_\_\_\_\_Anonymous

## Errors are Ubiquitous

- Errors are frequent in high criticality fields such as medicine and commercial aviation.
- Yet serious harm is relatively infrequent.
- Why? Error recovery is virtually continually in play.

## Errors are Ubiquitous

### Direct observation of 165 Pediatric Arterial Switch procedures at centers throughout UK:

On average 7 events / procedure from surgical team error

- 1 major (life threatening) event ,
- 6 minor events

Event recovery in majority of life threatening events

- no impact on baseline fatality risk (4-5 deaths per 100)

(de Leval 2,000)

## Reported Rates of Fatal AHTR

- |                        |   |               |
|------------------------|---|---------------|
| • Kildufe, Debakey '42 | ↓ | • 1/935       |
| • Wiener '43           | ↓ | • 1/915       |
| • Binder et al '59     | ↓ | • 1/11,625    |
| • Baker et al '69      | ↓ | • 1/8,035     |
| • Pineda et al '73     | ↓ | • 1/33,500    |
| • Myhre '80            | ↓ | • 1/500,000   |
| • Sazama '90           | ↓ | • 1/800,000   |
| • Linden 2000, HV 2002 | ↓ | • 1/1,800,000 |

## Estimated Rates of ABO Incompatibility

~1/50,000 Transfusions

Hemovigilance, SHOT, NYDOH

## Precursor Definition

“one that precedes and indicates the approach of another”

Merriam-Webster

## Secret Precursors? The Concorde Tragedy



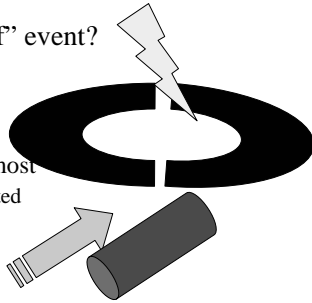
Some precursors don't indicate the approach of a misadventure

- 6 prior take-off events involved foreign objects and the Concorde
- No recognition that a foreign object could destroy the aircraft upon takeoff

## Six-Year Old Killed by Flying O<sub>2</sub> Cylinder in MRI Suite

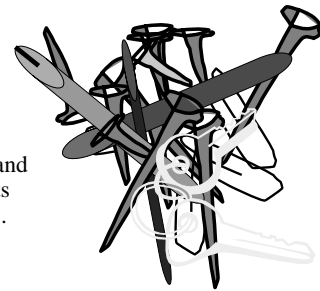
A Unique “one off” event?

- VA experience
- FDA and other reports
- Near misses - “almost unlikely to be reported”



## Near Misses Or No Harm Events With MRI

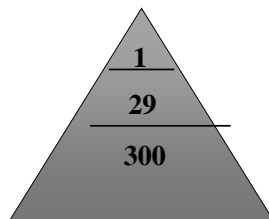
- MRI instrument dismantled at U Texas:
- Dozens of pens, paper clips, keys and other metal objects clustered inside. ...



## Heinreich's Ratio<sup>1</sup>

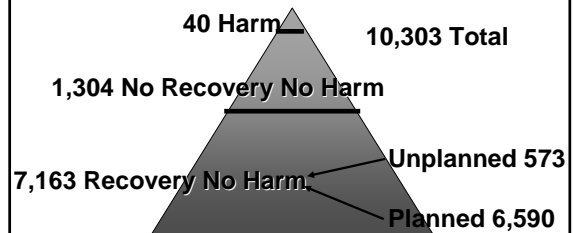
It has been proposed that reporting systems could be evaluated on the proportion of minor to more serious incidents reported<sup>2</sup>

- 1 Major injury
- 29 Minor injuries
- 300 No-injury accidents

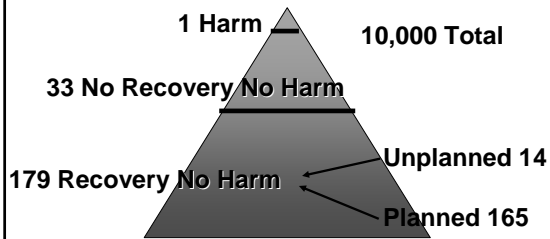


1. Heinrich HW Industrial Accident Prevention, NY And London 1941

## TM Current Data: 36 Hospitals



### TM Current Data: 36 Hospitals



### Four Major Reasons for Not Reporting

- The error was fixed before anything bad happened.
- It's easier to just fix the error than tell anyone about it.
- The error might be written in a personnel file.
- Not wanting to get themselves or anyone else in trouble.

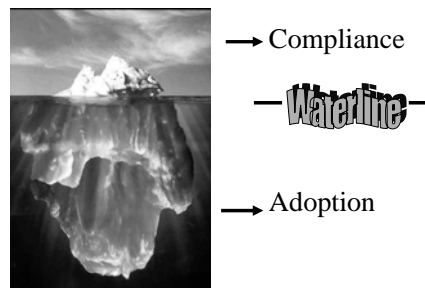
### Mail Survey to Assess Safety Culture and Event Reporting

53 Hospital Transfusion Services  
(945 employees) – 73% response

- Uncorrected mistakes, potential for patient harm - NOT always reported: 40%.
- Deviations from procedures potential for patient harm - NOT always reported: 52%.
- Mistakes self-corrected by employees - NOT always reported: 92% (73% NEVER).

Westat/MERS-TM 2000-1

### Adoption vs Compliance

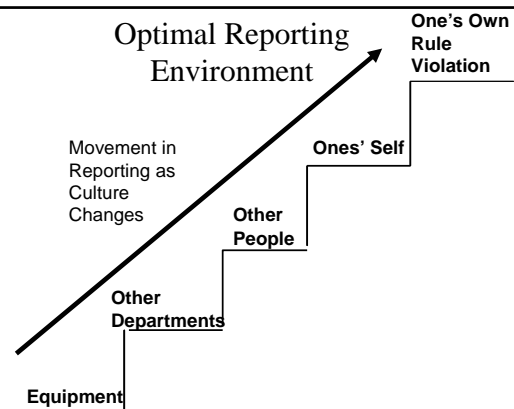


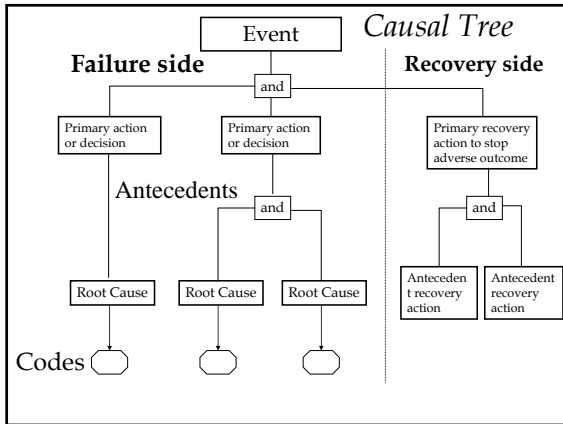
### Critical Elements of Adoption

To *adopt* event reporting rather than to simply *comply* -trust and motivation:

- Promote open communication with a “just” system of accountability.
  - Less than reckless culpability should not warrant punitive discipline
- Timely and effective *feedback* and
- Demonstrable *local usefulness*.

### Optimal Reporting Environment

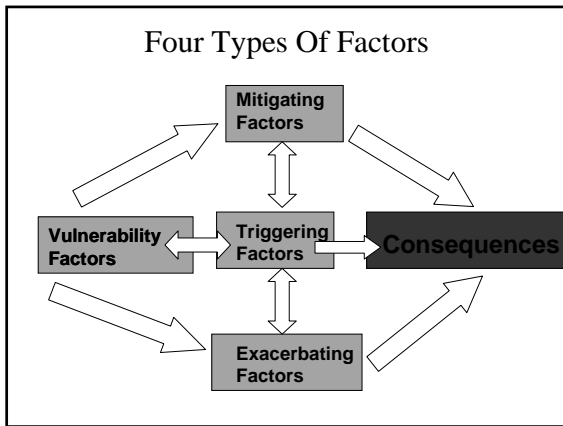




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Modified from W. Corcoran: Firebird Forum



### Eight Questions For Insight Into An Event

- **Impact:**
  - What were the consequences?
  - What is the significance?
- **Causation Factors:**
  - What set us up for it?
  - What triggered it?
  - What made it as bad as it was?
  - What kept it from being a lot worse?
- **Closeout:**
  - What should be learned from it?
  - What should be done about it?

Modified from W. Corcoran: Firebird Forum

### Surprises Most Likely to Occur at H/S Interface

3 Questions to assess where unforeseen events would surface:

- The "hands-on" question
- The "criticality" question
- The "frequency" question

James Reason

### The "Hands-on" Question:

- What activities involve the most direct human contact with the system and thus offer the greatest opportunity for human decisions or actions to have an immediate direct adverse effect on the system?

James Reason

### The “Criticality” Question:

- What activities, if performed less than adequately, pose the greatest threat to the well-being of the system ?

### The “Frequency” Question:

- How often are these activities performed in the day-to-day operations of the system as a whole?

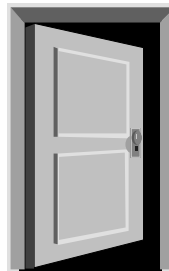
### Three Strikes and You’re Probably Out.

An activity scoring high on all three questions is more likely vulnerable to unexpected events.

Medical protocols may score high in all three

James Reason

### “Over-learned” Unmindful Task Performance



- Often performed without thought, routine, habitual
- Little attention to components of routine
- Less able to modify if interrupted or novel task elements arise

Langer, E.

Betsy Lehman, a science writer for the Boston Globe, died of a drug overdose while undergoing an experimental treatment protocol for breast cancer.

Sound Information Handling  
JG Williams  
*Toward an Electronic Patient*  
Record '96, Vol. 2, pp. 348-355.

### ***Ambiguous form: Vulnerability***

Drug manufacturer's treatment summary specified 4,000 mg in four days in a way that could have meant either 4g each day for four days or 4g total over a four-day treatment cycle.

**Error Form – Latent** (Organizational Procedure)

***10X Error in Prescribed Dose:  
Trigger***

The amount prescribed for Ms. Lehman was inconsistent with what she had received in a previous treatment cycle.

- ***Consistency-Validation Checks***

**Error Form – Active** (Rule Based error)

***Higher Credibility for Error  
Signals: Exacerbation***

Although dosage questioned by a pharmacist, the error report was overridden by the physician.

**Error Form - Active** (Rule Based error)  
**Latent** (Organizational Culture)

***Higher Credibility of Corroborated Data:  
Exacerbation***

Two other pharmacists corroborated the original error report. These reports were also dropped in favor of the original erroneous interpretation of the ambiguous treatment summary.

**Error Form - Latent** (Organizational Culture)

***Signal Detection – Classification:  
Exacerbation***

Patient reported something wrong - a very different reaction to first dose of chemotherapy than she previously experienced. Report not considered of concern for investigation in-depth .

**Error Form - Active** (Rule Based – lack of verification)

***Signal Detection – Classification:  
Exacerbation***

Laboratory results revealed an abnormal spike in administered drug levels. This did not trigger investigation for a possible antecedent error.

**Error Form - Latent** (Organizational Procedure)

***Dissemination of Lessons Learned***

Six months later, the same semantic ambiguity in daily versus treatment-cycle doses killed a cancer patient at the University of Chicago Hospital.

### “Safety Is Not Bankable”

- Safety and reliability have to be re-accomplished over and over.
- Safety and reliability are *dynamic* nonevents
- They are not static nonevents
- Weak signals do not require weak responses

Weick K, Sutcliffe K, 2001

### Barriers to Event Reporting

- Potential recriminations
  - Self image, peers and management, external agents.
- Motivational issues
  - Lack of incentive, feedback, actual discouragement
- Management commitment
  - Inconsistent, ambivalent, fearful
- Individual confusion
  - Definition, usefulness

### Near Miss Event Reporting

- Done properly, unique information about system dangers.
- Supports study of recovery
- Mindfulness - can actively counter rather than increase complacency.
- Means of engaging staff directly in patient safety.
- No direct burden of patient harm

### Thank You For Your Attention

Are there any questions?

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