Forensic Engineering and Patient Safety: Reducing the Risks of Medical Device-Related Injuries and Deaths

Presenter:
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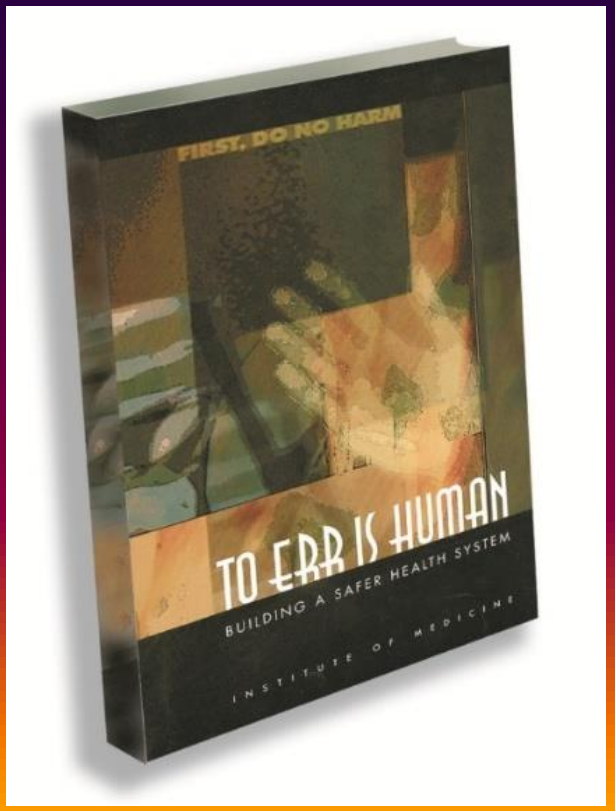
Lessons learned since . . .

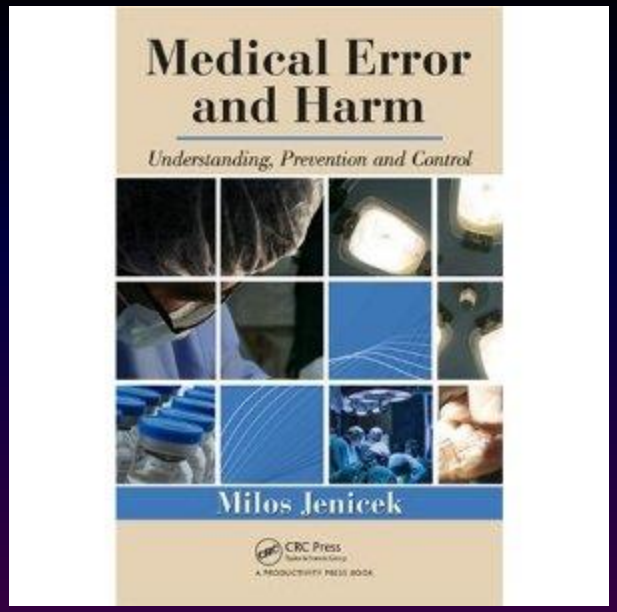
1999 Institute of Medicine Report:

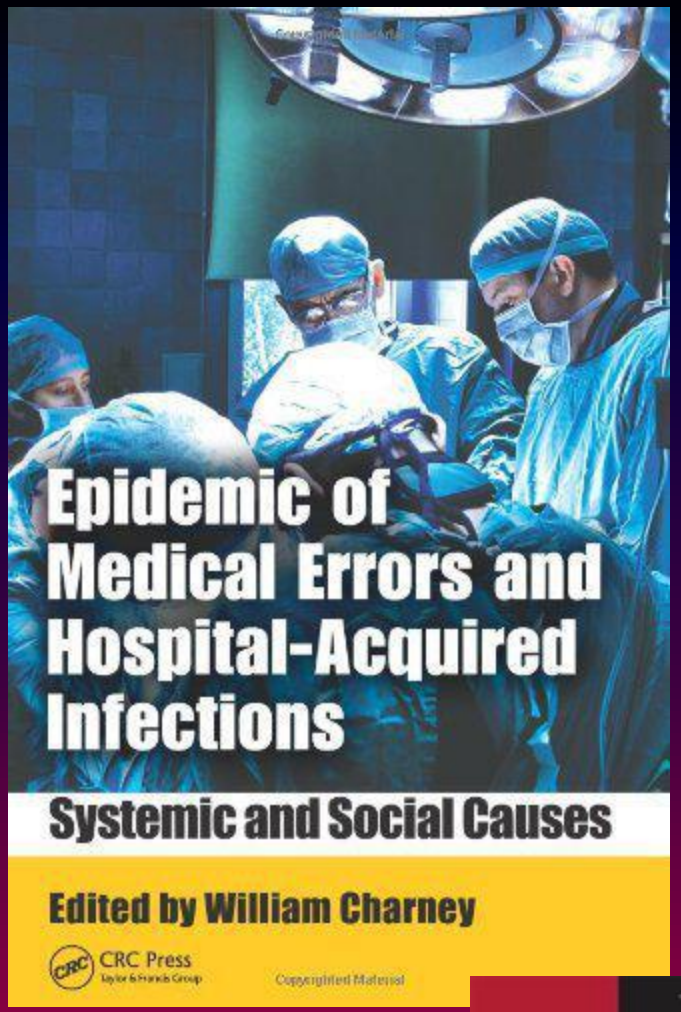
"More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them"

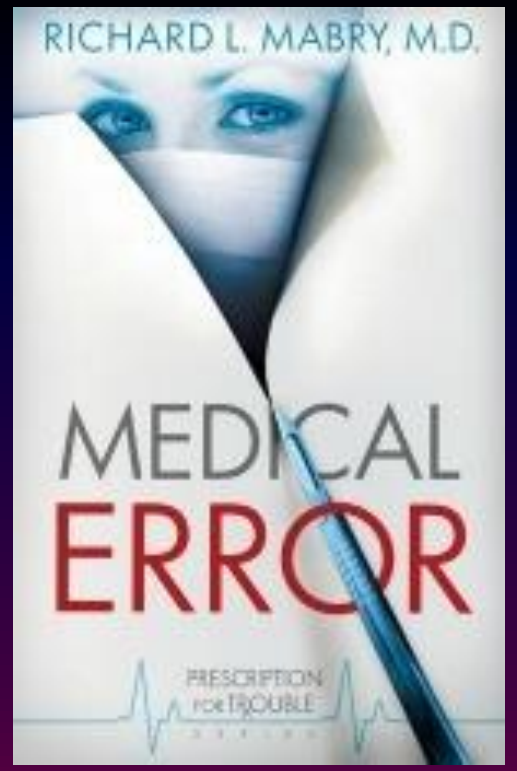


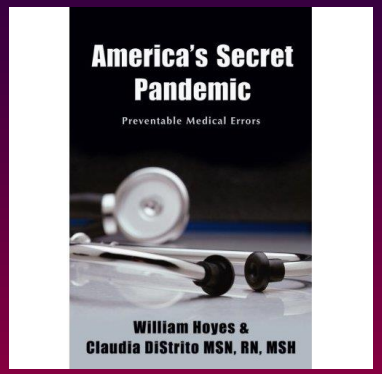
*"To Err is Human", Institute of Medicine, November 1999. National Academy Press

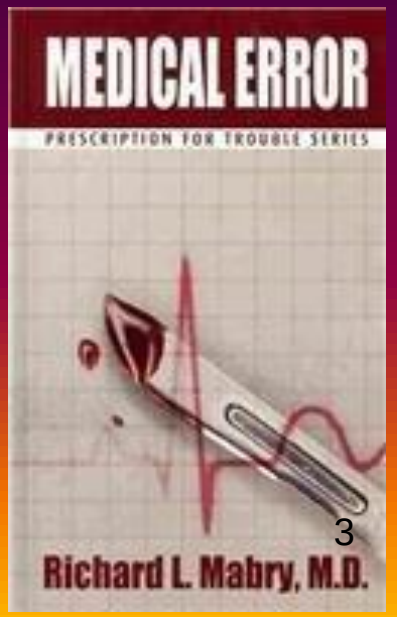
and from the continued investigation and reporting of medical device-related incidents.











Journal of Patient Safety:
September 2013 - Volume 9 - Issue 3 - p 122–128
doi: 10.1097/PTS.0b013e3182948a69
Review Article

A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

James, John T. PhD

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

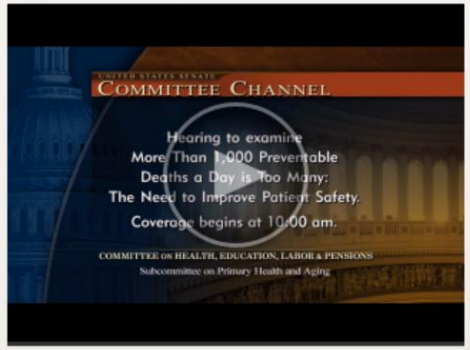
Current estimates of accidental deaths . . .

Subcommittee Hearing - More Than 1,000 Preventable Deaths a Day Is Too Many: The Need to Improve Patient Safety

Committee:
Subcommittee on Primary Health and Aging

Date:
Thursday, July 17 2014, 10:00 AM

Place:
430 Dirksen Senate Office Building



http://www.help.senate.gov/hearings/hearing/?id=478e8a35-5056-a032-52f8-a65f8bd0e5ef

Analysis of Safety-Critical Computer Failures in Medical Devices

(Abstract)
Issue No.04 - July-Aug. (2013 vol.11)
pp: 14-26
Published by the IEEE Computer Society

Homa Alemzadeh , University of Illinois at Urbana-Champaign

"Malfunctioning medical devices are one of the leading causes of serious injury and death in the U.S. Between 2006 and 2011, 5,294 recalls and approximately 1.2 million adverse events were reported to the FDA. Almost 23% of these recalls were due to computer-related failures, of which approximately 94% represented medium to high risk of severe health consequences (injuries or death) to patients".

http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=6509886

Resources . . .

Medical Device Incident Investigation Guidebook

Published by

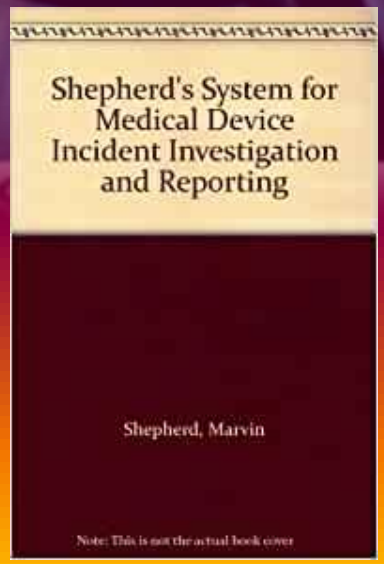
VHA Center for Engineering & Occupational Safety and Health (CEOSH)

St. Louis, Missouri

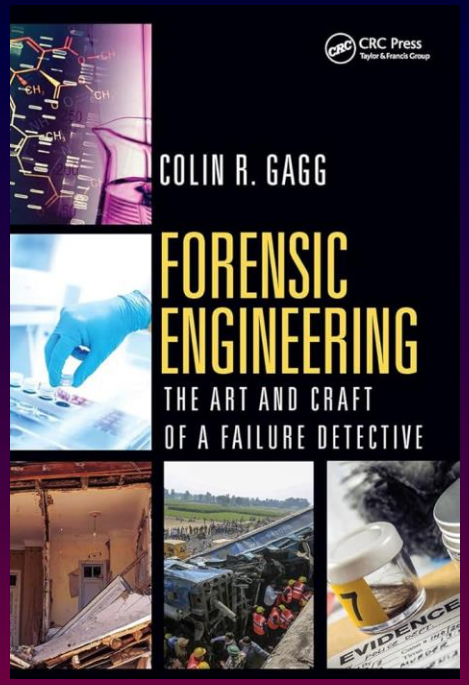
vaww.ceosh.med.va.gov

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Center for Engineering & Occupational Safety and Health

Conducting successful medical device incident investigations is an essential aspect to achieving exceptionally safe, consistently high-quality care for patients. The number of overall reported incidents is increasing dramatically, especially as health care facilities become more cognizant of system vulnerabilities and recognize the importance of reporting to correct problems. By identifying medical device safety issues, health care facilities can mitigate the risk of harm to patients.



Forensic Engineering . . .



" . . . is the investigation of materials, products, structures or components that fail or do not operate/function as intended, causing personal injury or damage to property. The consequences of failure are dealt with by the law of product liability.

. . .helps the injured party, their attorneys, judges, and juries determine the cause of accidents, injuries, or deaths." (1).

NATIONAL ACADEMY OF FORENSIC ENGINEERS

Our Mission

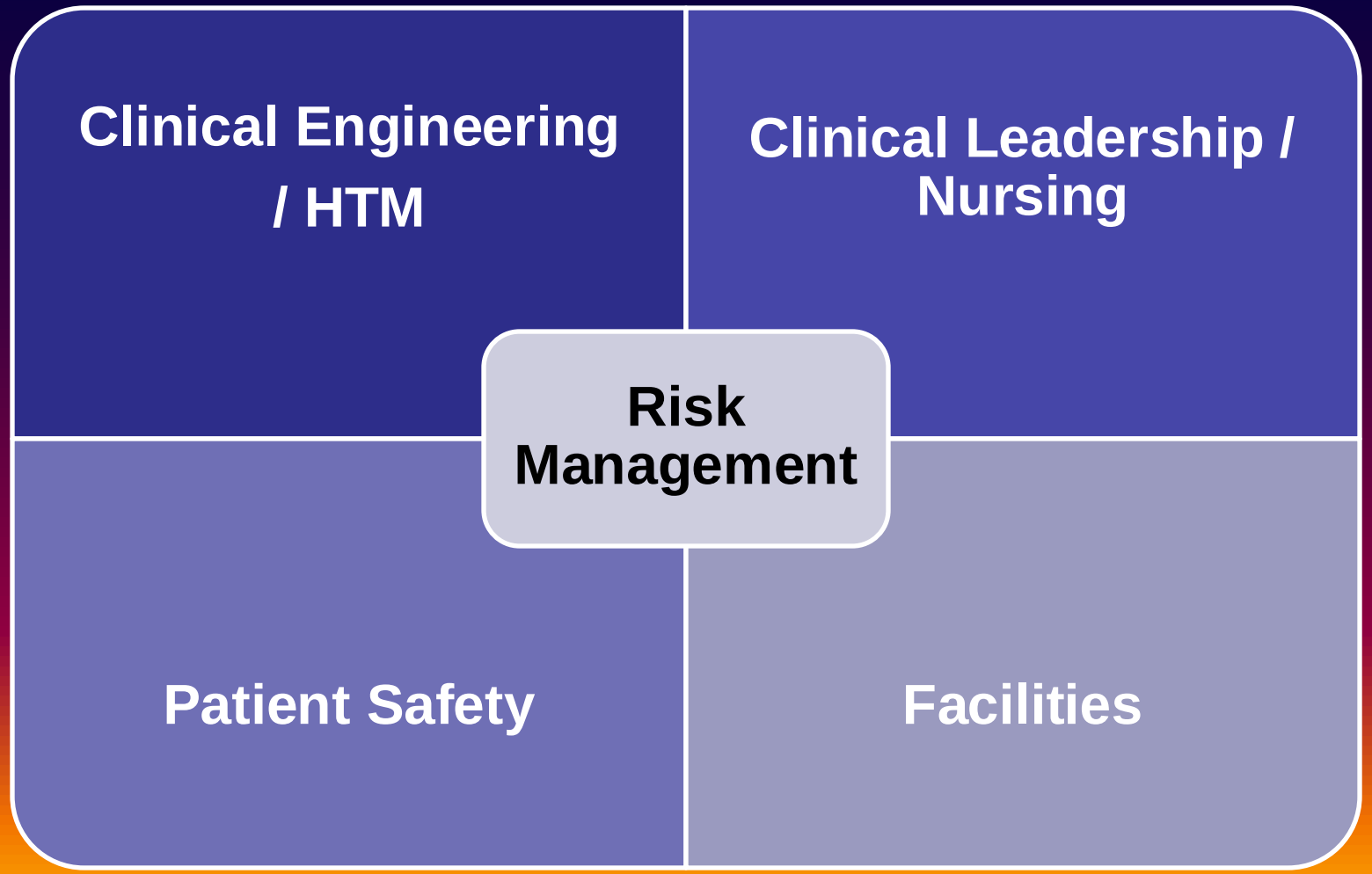
The National Academy of Forensic Engineers and its members are committed to:

- Serving the public by advancing the ethical and professional practice of forensic engineering;
- Serving the jurisprudential system by certifying individuals having achieved expertise in forensic engineering;
- Serving Academy members and furthering the development of forensic engineers through education and the publication of peer-reviewed technical literature.

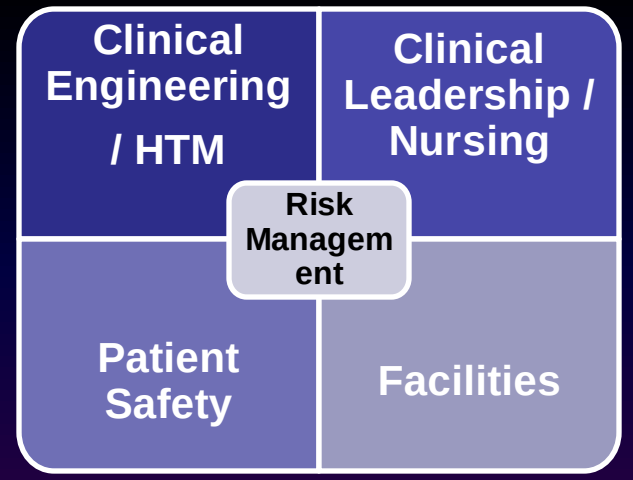
1. http://en.wikipedia.org/wiki/Forensic_engineering

https://nafe.org

Optimally,
incident investigations are a team effort

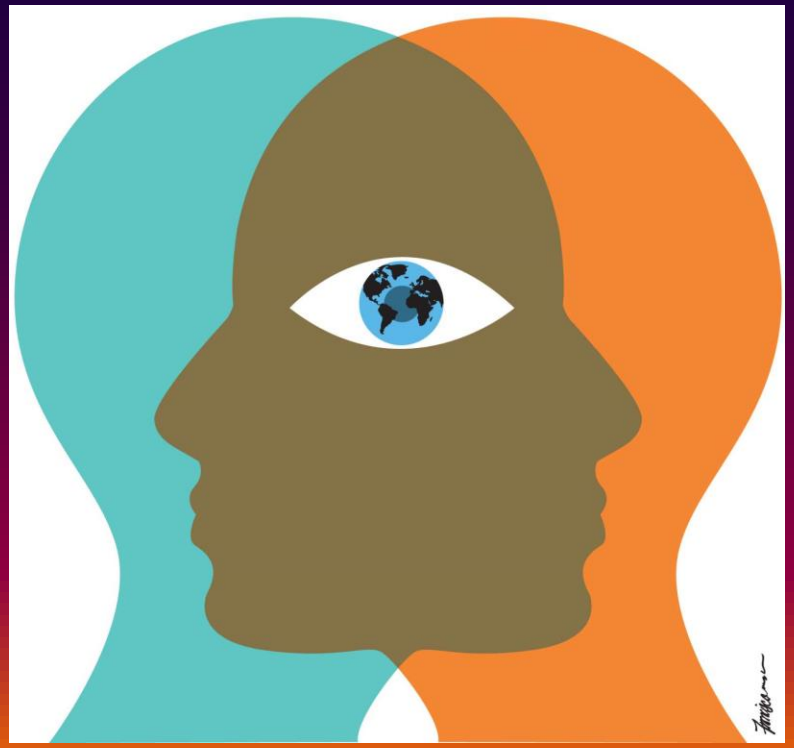


The value of an interdisciplinary response team



- Different disciplines often see, process, and interpret the same things differently.

The Good,



- Differing backgrounds and perspectives may also create communication problems, power struggles.

bad, and ugly.

The Purpose: Why we investigate incidents ?

Improved Patient Safety:

- Determine root cause(s)
- Prevent recurrence

- Adapted from: C. Schabowsky, ECRI, October, 2020.

The Purpose: Why we investigate incidents ?

For the same reason,
the NTSB exists

NTSB

An Independent
United States Federal
Government Agency

The NTSB is an independent federal agency charged by Congress with investigating every civil aviation accident in the U.S. and significant accidents in other modes of transportation-railroad, highway, marine and pipeline. more >

About the National Transportation Safety Board

Our Mission

Making transportation safer by conducting independent accident investigations, advocating safety improvements, and deciding pilots' and mariners' certification appeals.

Legislative Mandate

- Maintaining our congressionally mandated independence and objectivity;
- Conducting objective, precise accident investigations and safety studies;
- Performing fair and objective airman and mariner certification appeals;
- Advocating and promoting safety recommendation;
- Assisting victims of transportation accidents and their families.

Healthcare has much to learn from the aviation industry

NTSB
An Independent United States Federal Government Agency

The NTSB is an independent federal agency charged by Congress with
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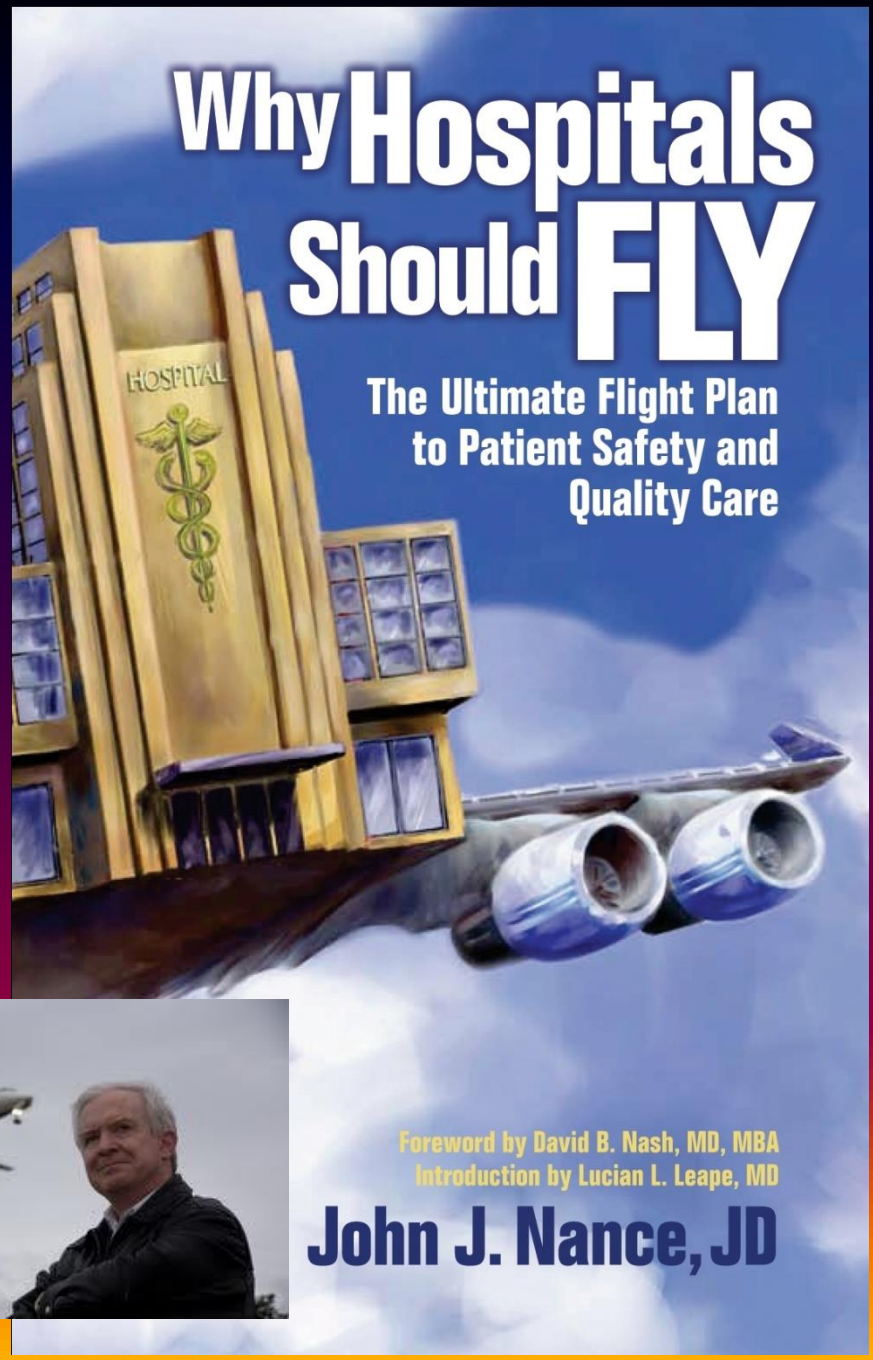
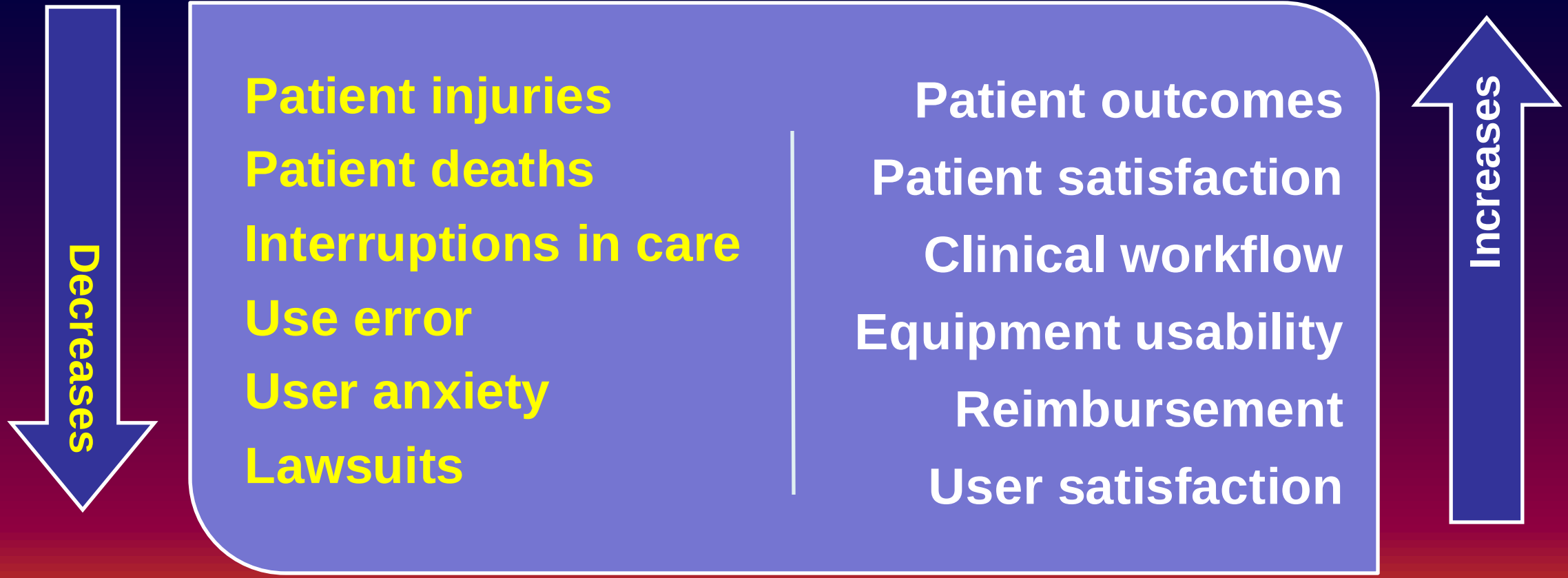


VA hospitals have borrowed and implemented many safety concepts from the aviation industry

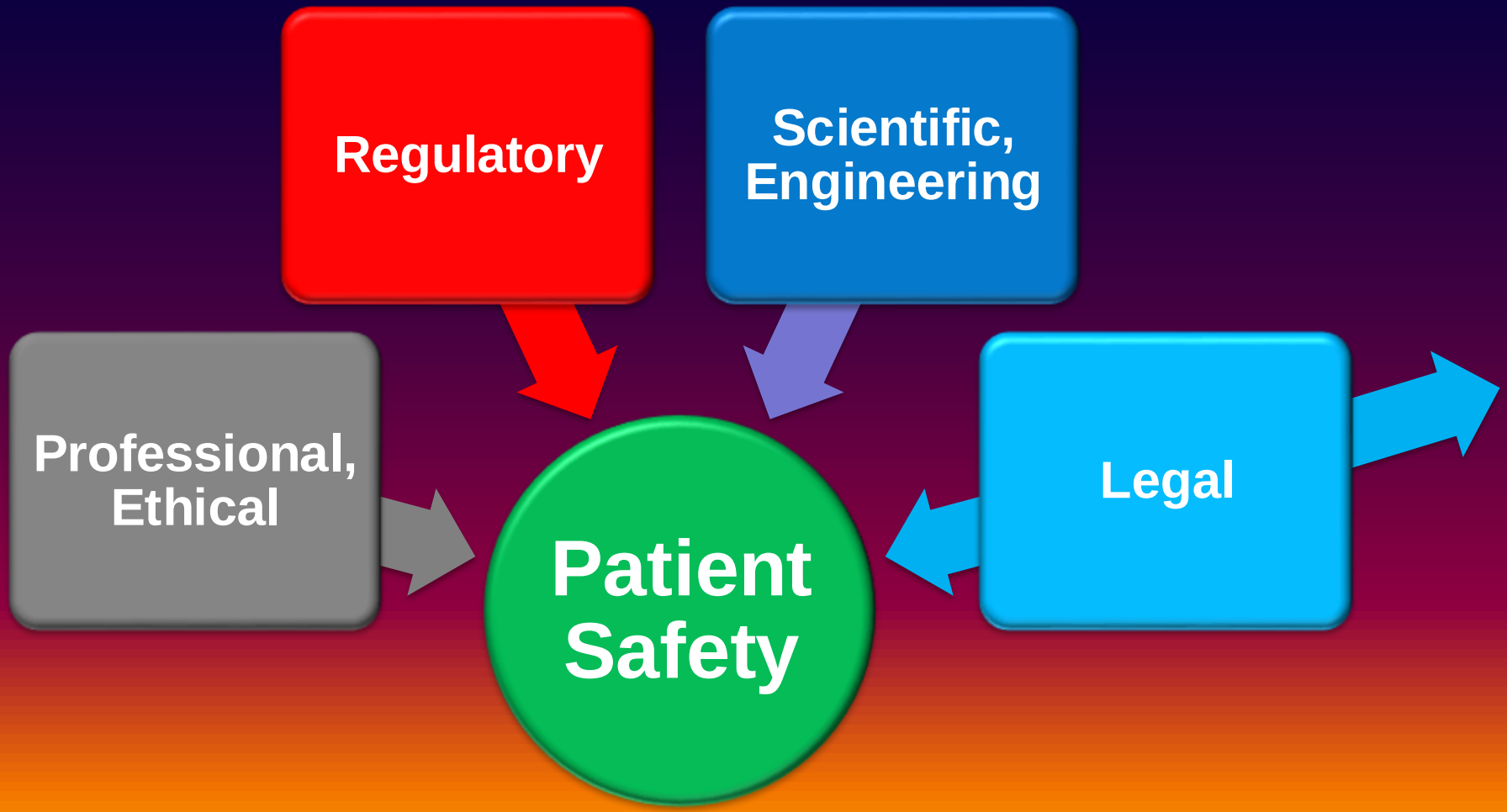
www.patientsafety.va.gov/

Improved Patient Safety . . .



The *Why* of Incident Investigations:

Complementary & Competing Perspectives



Professional, Ethical

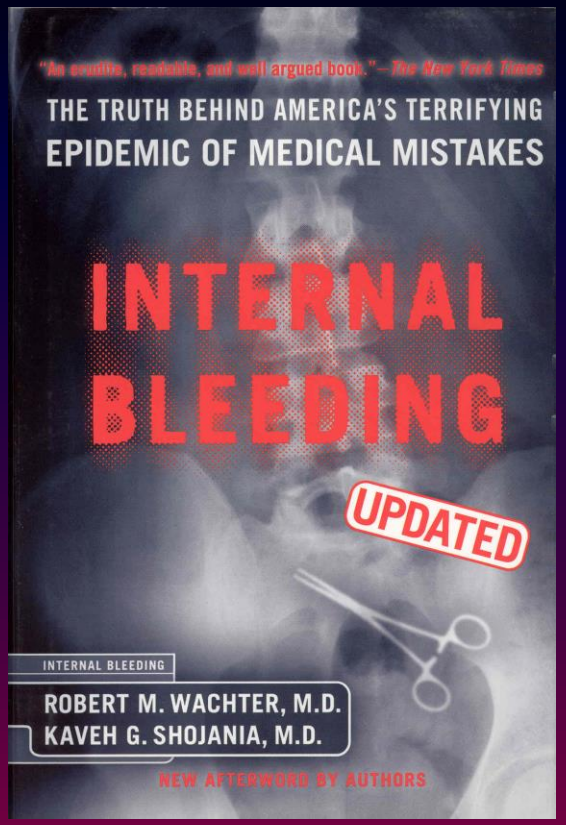
NSPE NATIONAL SOCIETY OF PROFESSIONAL ENGINEERS

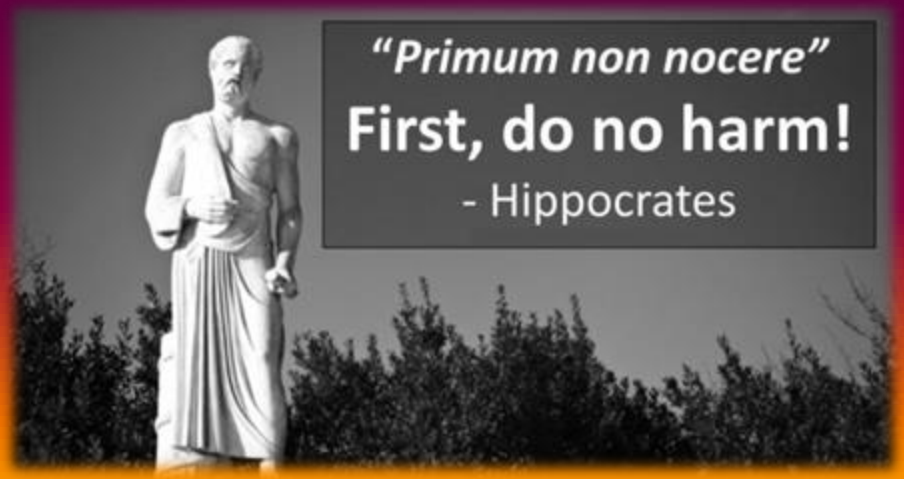
Code of Ethics for Engineers

"Engineering is an important and learned profession. As members of this profession, engineers are expected to exhibit the highest standards of honesty and integrity. Engineering has a direct and vital impact on the quality of life for all people. Accordingly, the services provided by engineers require honesty, impartiality, fairness, and equity, and must be dedicated to the protection of the public health, safety, and welfare. Engineers must perform under a standard of professional behavior that requires adherence to the highest principles of ethical conduct."

https://www.nspe.org/sites/default/files/resources/pdfs/Ethics/EthicsReferenceGuide.pdf

Professional, Ethical





"It may seem a strange principle to enunciate as the very first requirement in a Hospital - that it should do the sick no harm".

Florence Nightingale
Notes on Hospitals, 1859

Regulatory

21 CFR 803, Medical Device Reporting, provides specific MDR regulatory definitions. MDR reportable event (or reportable event) means:

- An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or,
- An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - o May have caused or contributed to a death or serious injury; or,
  - o Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

https://accenet.org/publications/Downloads/Reference%20Materials/MDII%202018%20guidebook.pdf

Regulatory

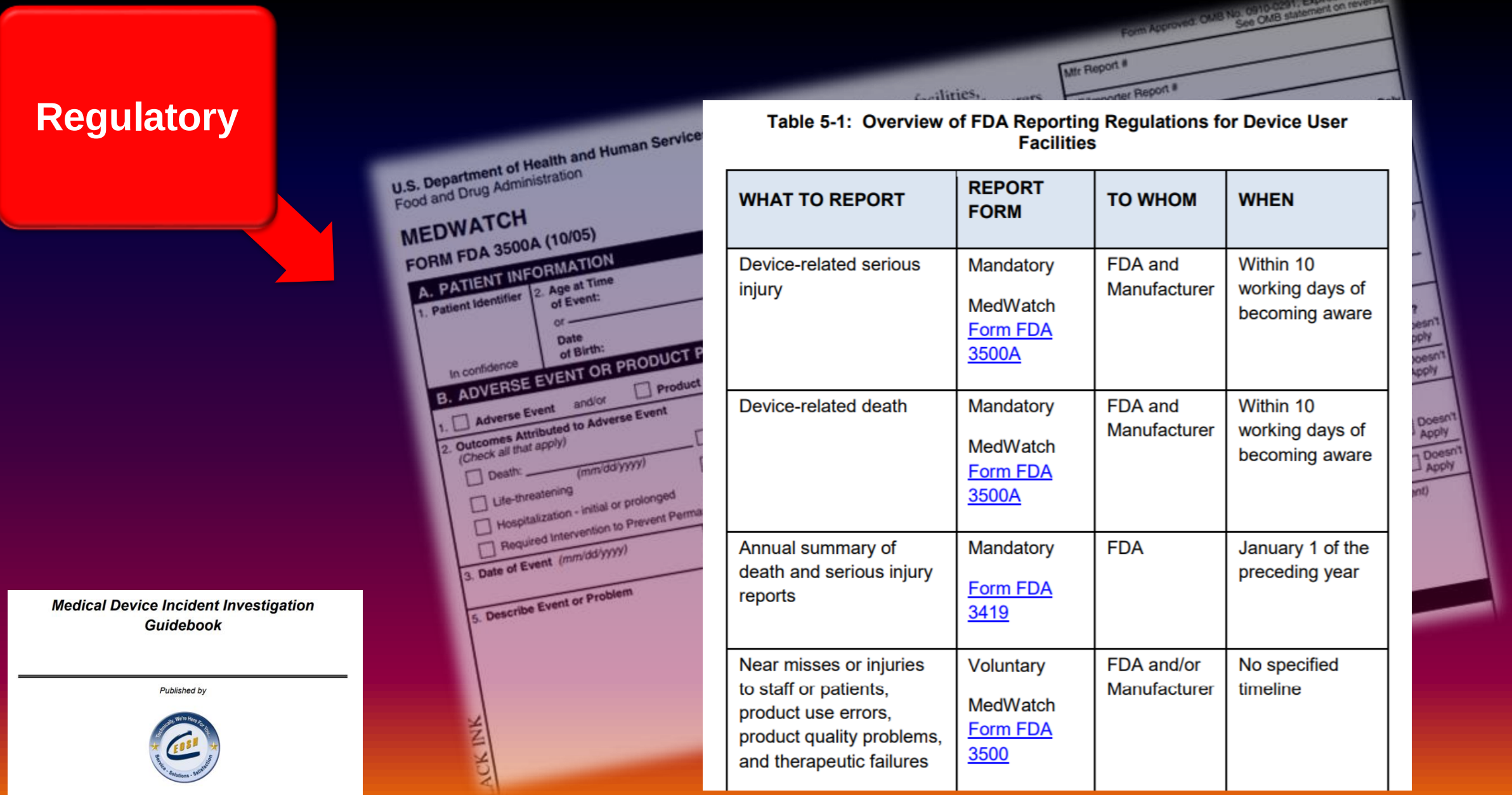


Table 5-1: Overview of FDA Reporting Regulations for Device User Facilities

WHAT TO REPORT	REPORT FORM	TO WHOM	WHEN
Device-related serious injury	Mandatory MedWatch Form FDA 3500A	FDA and Manufacturer	Within 10 working days of becoming aware
Device-related death	Mandatory MedWatch Form FDA 3500A	FDA and Manufacturer	Within 10 working days of becoming aware
Annual summary of death and serious injury reports	Mandatory Form FDA 3419	FDA	January 1 of the preceding year
Near misses or injuries to staff or patients, product use errors, product quality problems, and therapeutic failures	Voluntary MedWatch Form FDA 3500	FDA and/or Manufacturer	No specified timeline

Medical Device Incident Investigation Guidebook

Published by

VHA Center for Engineering & Occupational Safety and Health (CEOSH)

https://accenet.org/publications/Downloads/Reference%20Materials/MDII%202018%20guidebook.pdf

Regulatory

CMS issues new hospital patient safety measures

Mariah Taylor (Email) - Wednesday, August 7th, 2024

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CMS will add seven new measures to its hospital inpatient quality reporting program as part of its Hospital Inpatient Prospective Payment System final rule released Aug. 1.

The measuresare:

1. Patient safety structural measure
2. Age-friendly hospital measure
3. Catheter-associated urinary tract infection standardized infection radio statified for oncology locations
4. Central line associated bloodstream infection standarized infection ratio startified for oncology locations
5. Hospital harm-falls with injury
6. Hospital harm-postoperative respiratory failure
7. 30-day risk-standardized death rate among surgical inpatients with complications.

The patient safety measure will take effect in 2025, while the remaining six will begin in 2026.

AUG 14, 2024 • NEWS RELEASE

ECRI Supports CMS Patient Safety Structural Measure

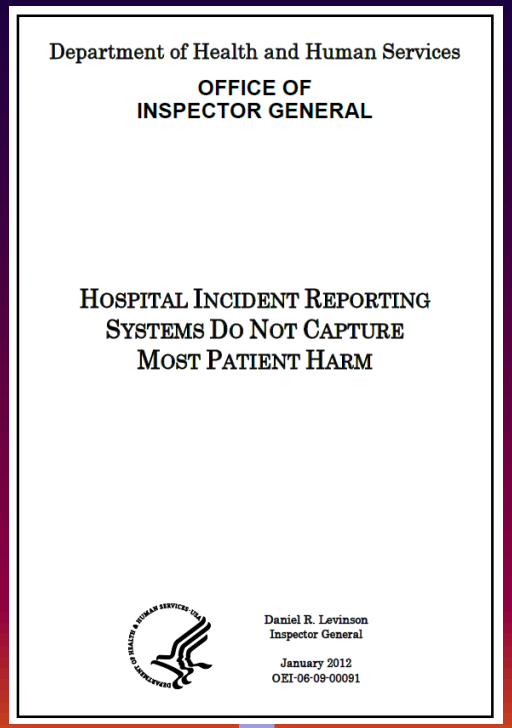
Statement from ECRI President and CEO Dr. Marcus Schabacker

On behalf of ECRI, I would like to applaud the Centers for Medicare and Medicaid Services (CMS) for approving the new Patient Safety Structural Measure as part of the update to the hospital quality reporting program. This represents a tremendous step forward in emphasizing the importance of patient and workforce safety by creating a standardized framework that will guide hospitals to practice a systems-based approach.

The patient safety structural measure assess whether hospitals have a structure and culture that prioritize safety through five domains: leadership committed to eliminating preventable harm; strategic planning and organizational policy; a culture of safety and learning; accountability and transparency; and patient and family engagement, according to a CMS final rule.

https://www.beckershospitalreview.com/quality/cms-issues-new-hospital-patient-safety-measures.html

Regulatory



Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM

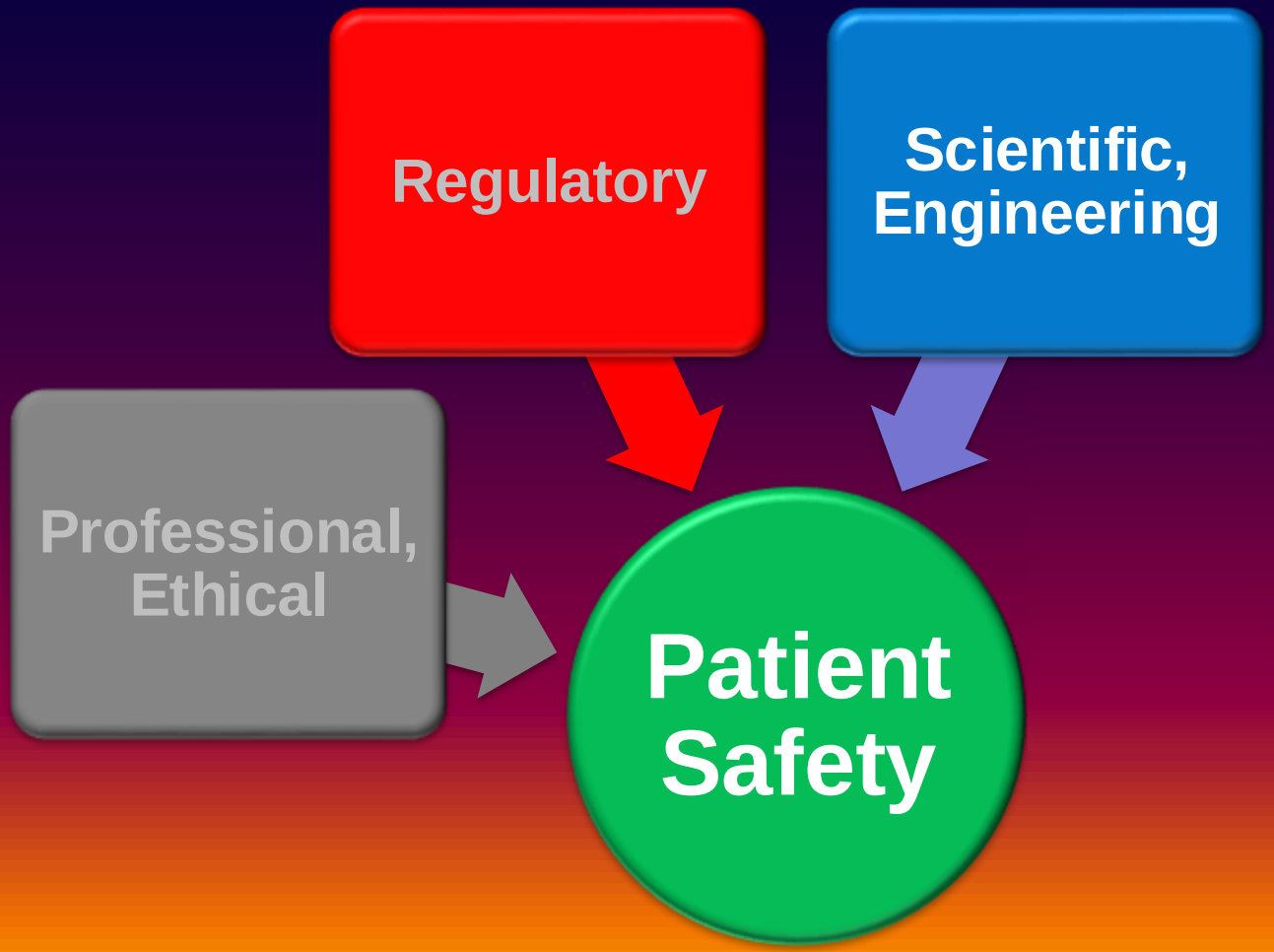
Daniel R. Levinson
Inspector General

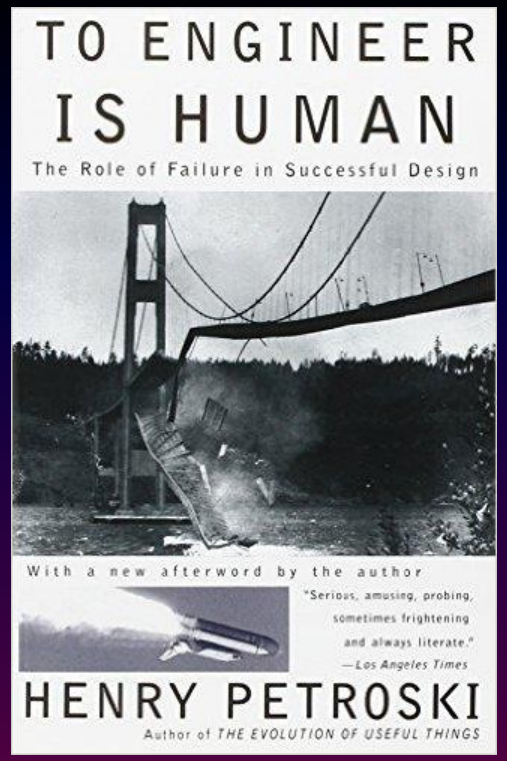
January 2012
OEI-06-09-00091

“Hospital staff did not report 86 % of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm.”

The *Why* of Incident Investigations:

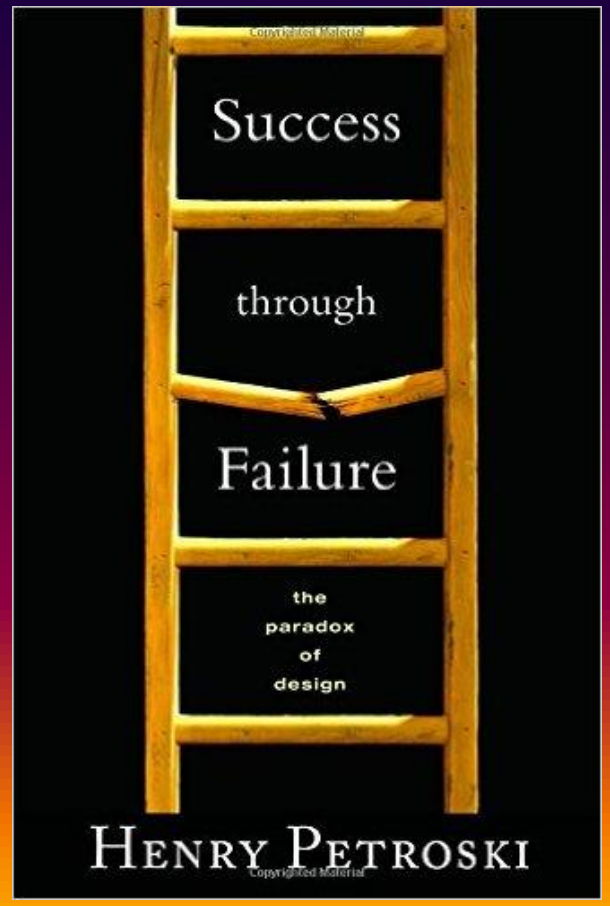
Complementary & Competing Perspectives





"Nobody wants failures. But you also don't want to let a good crisis go to waste."

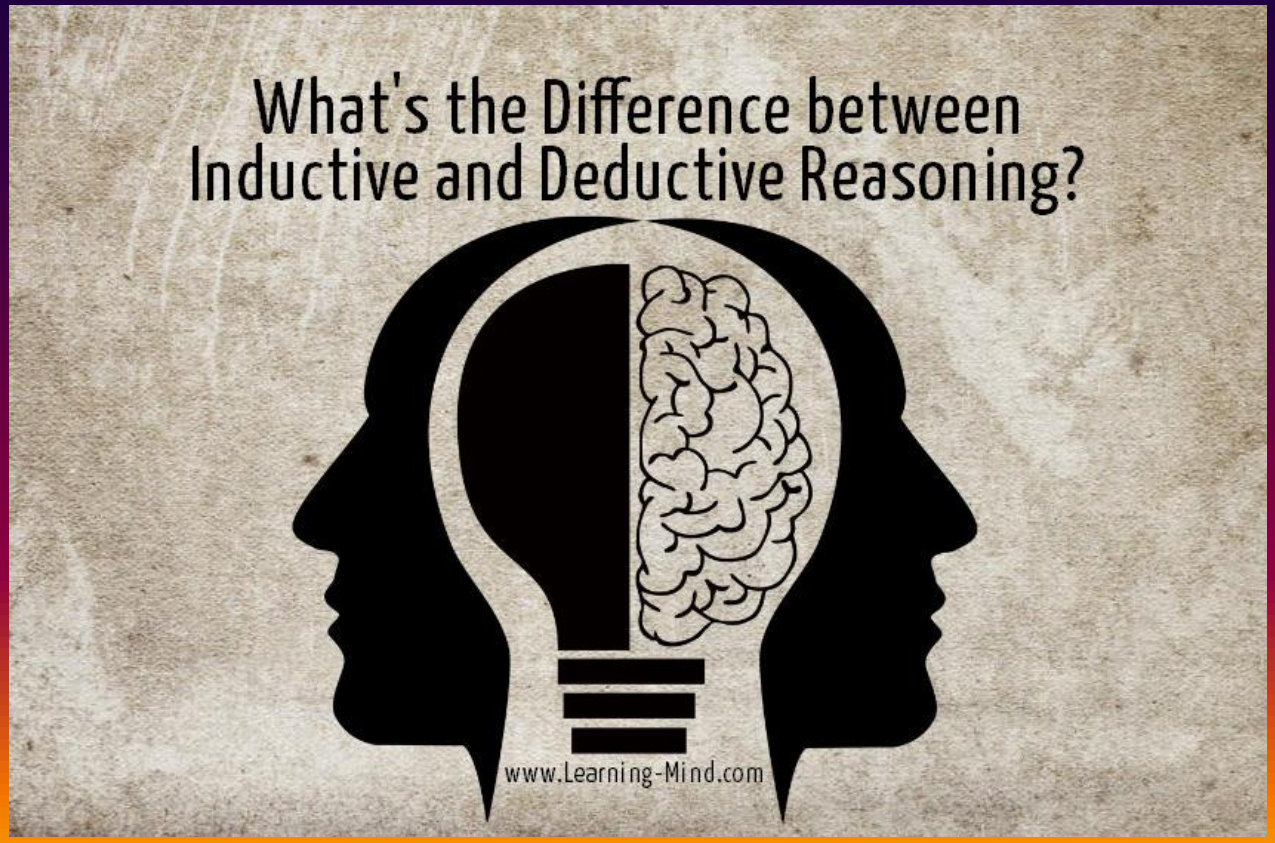
Scientific, Engineering



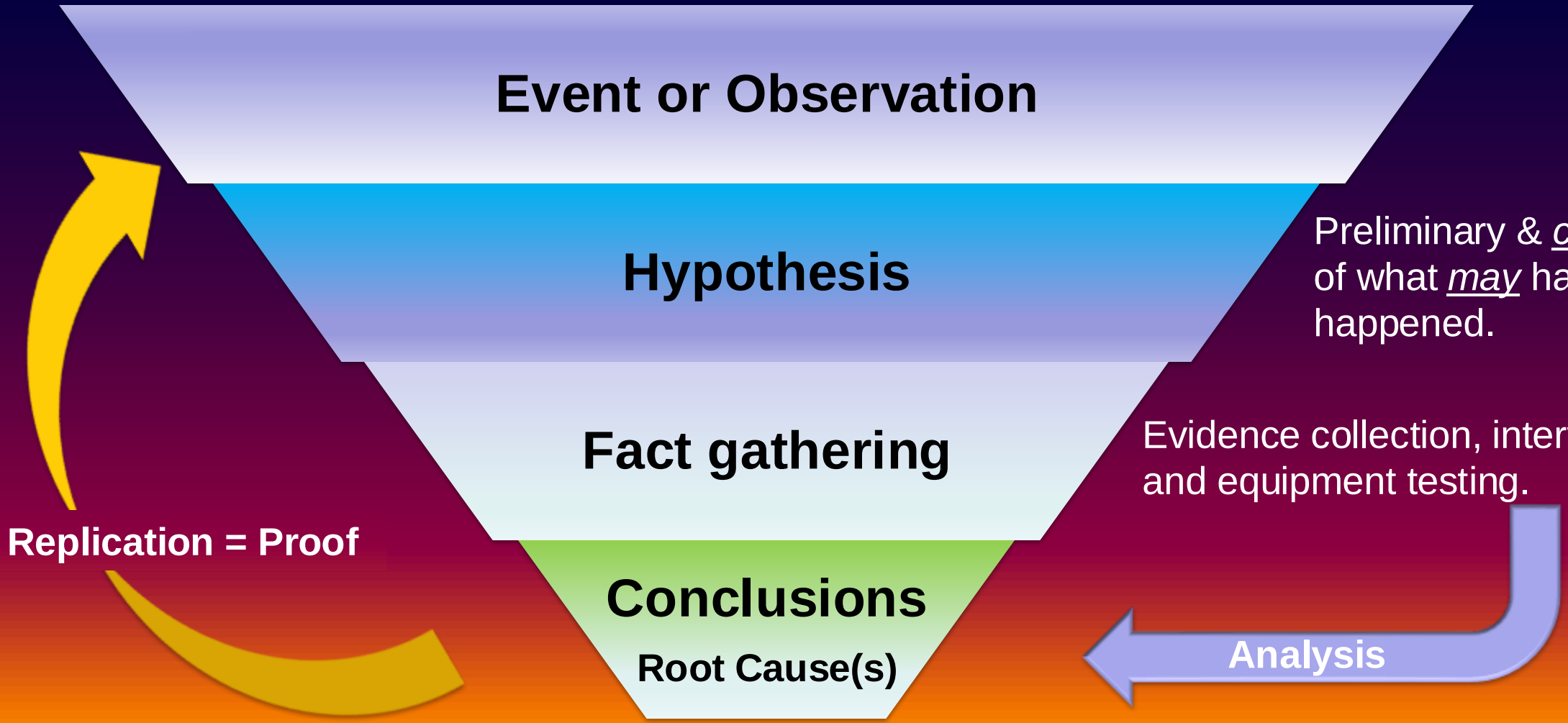
"Failures always teach us more than the success about the design of things."

A complete and thorough incident investigation and reconstruction may require a combination of reasoning skills.

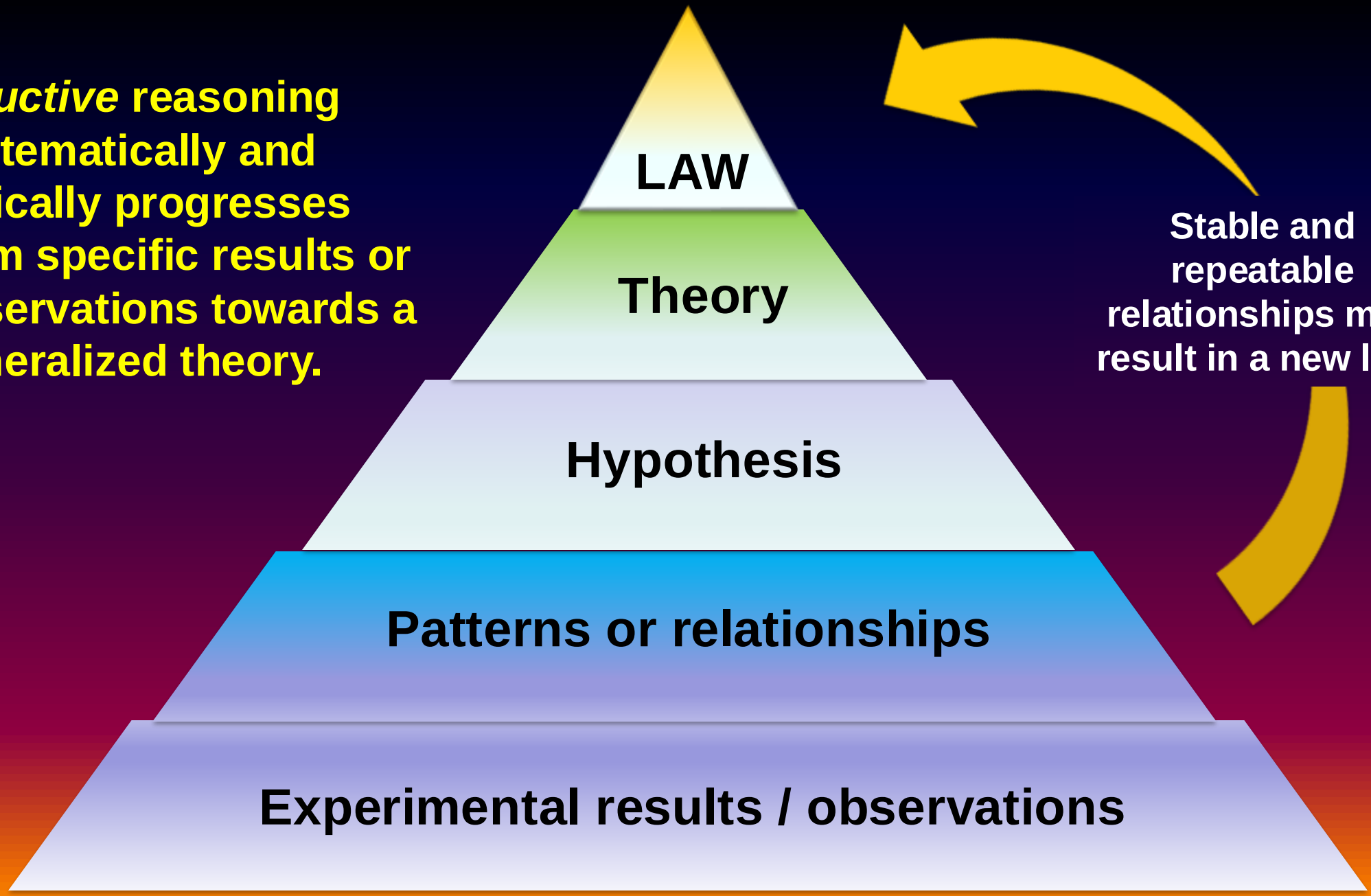
Scientific, Engineering



Deductive reasoning systematically and logically progresses from the initial event or observation to its root cause(s)



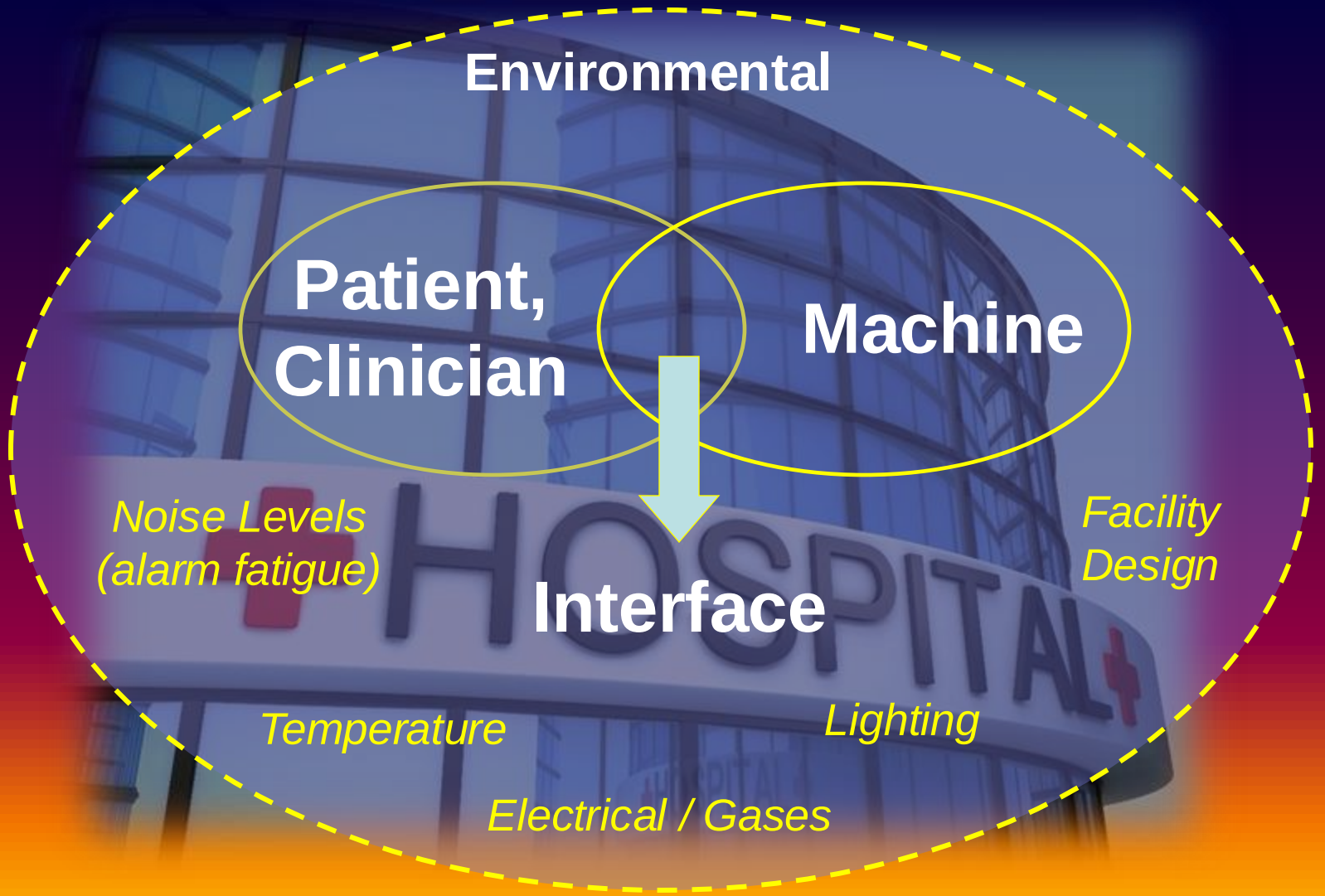
Inductive reasoning systematically and logically progresses from specific results or observations towards a generalized theory.



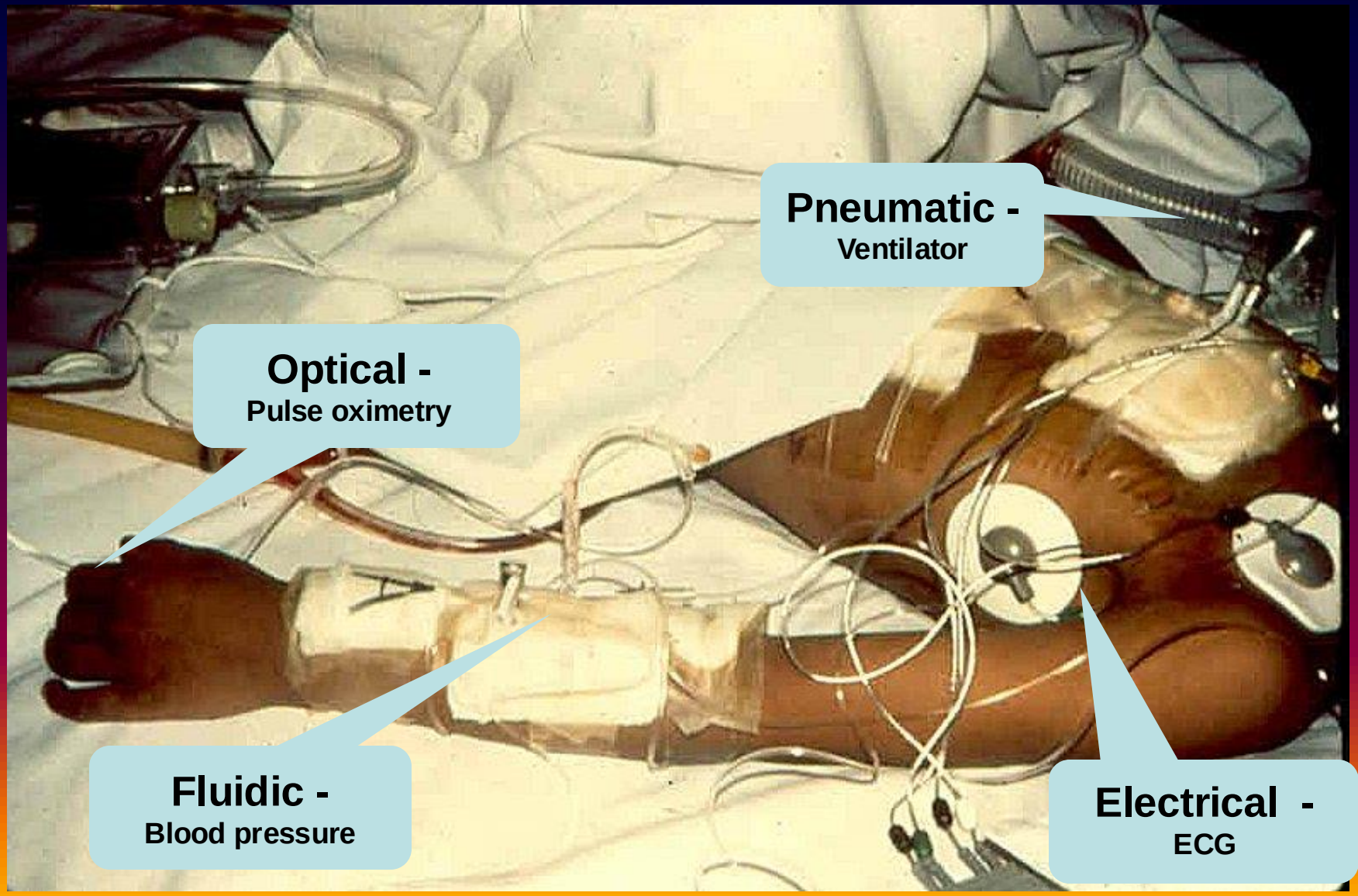
Stable and repeatable relationships may result in a new law.

Hospitals have become high-tech, high-risk, complex *systems* within *systems*

Begin each investigation from a ‘sterile’ and *systems* perspective

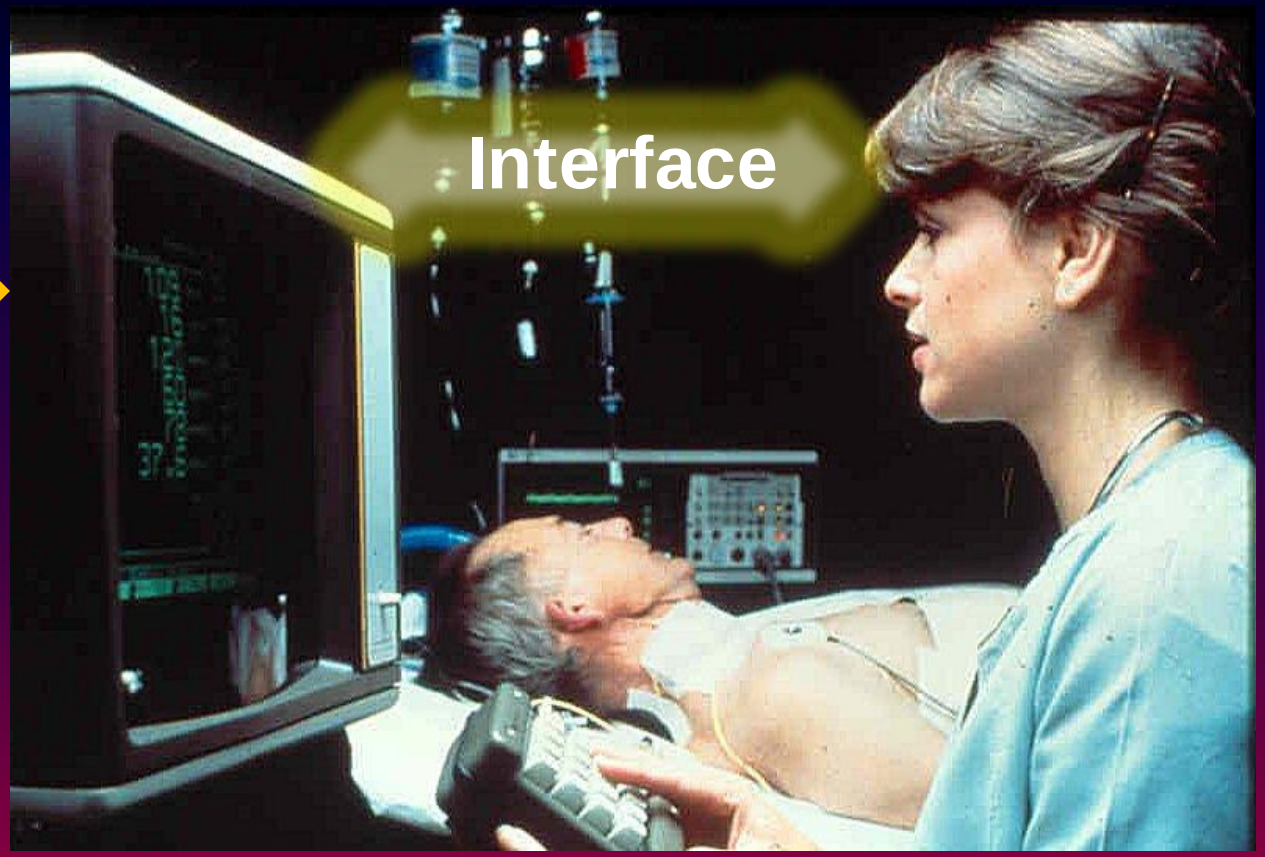


Interface complexity increases dramatically when patients become – literally – one with machines.



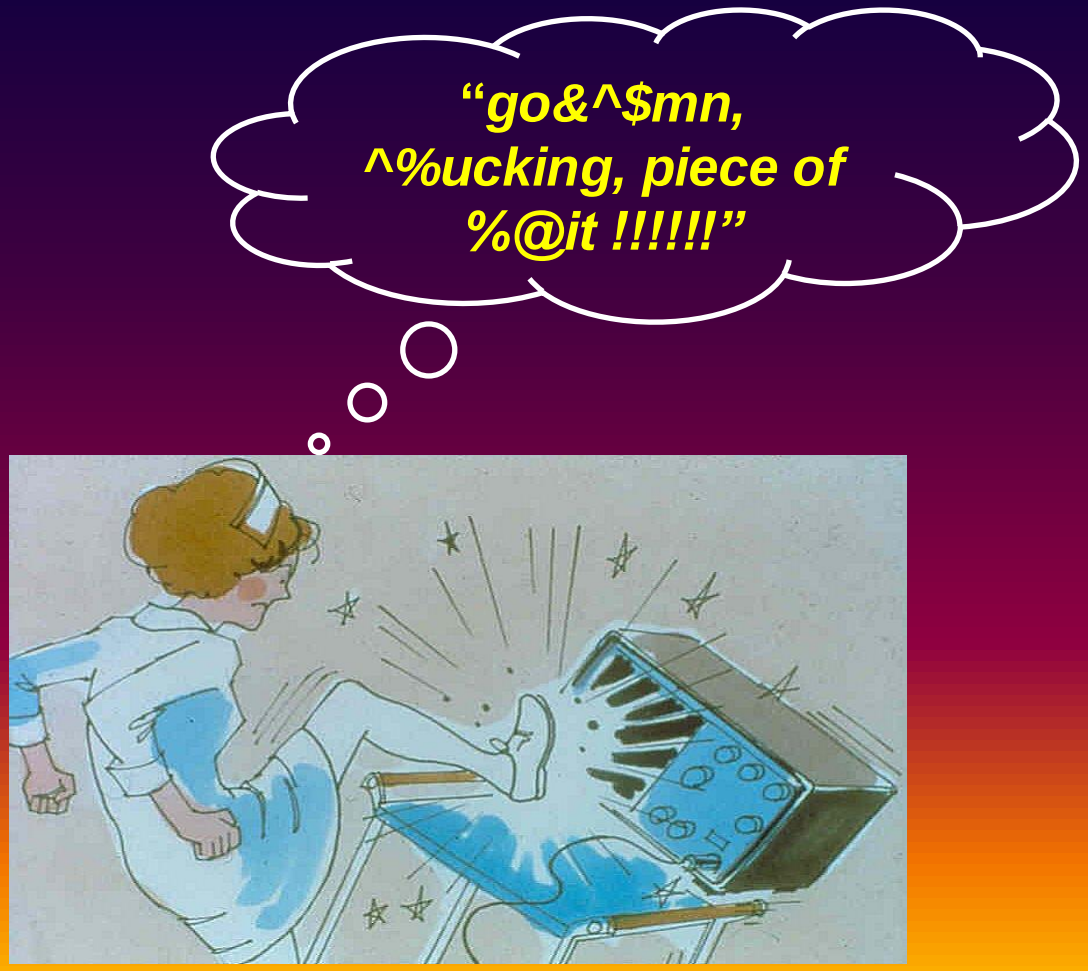
Patient / Clinician - machine interface:

Machine communicates with the clinician through display labeling, icons, waveforms, visual, and auditory alarms.



Clinician communicates with the machine via touch screens, pushbuttons, controls.

Human-machine interface remains the source of much use error and frustration

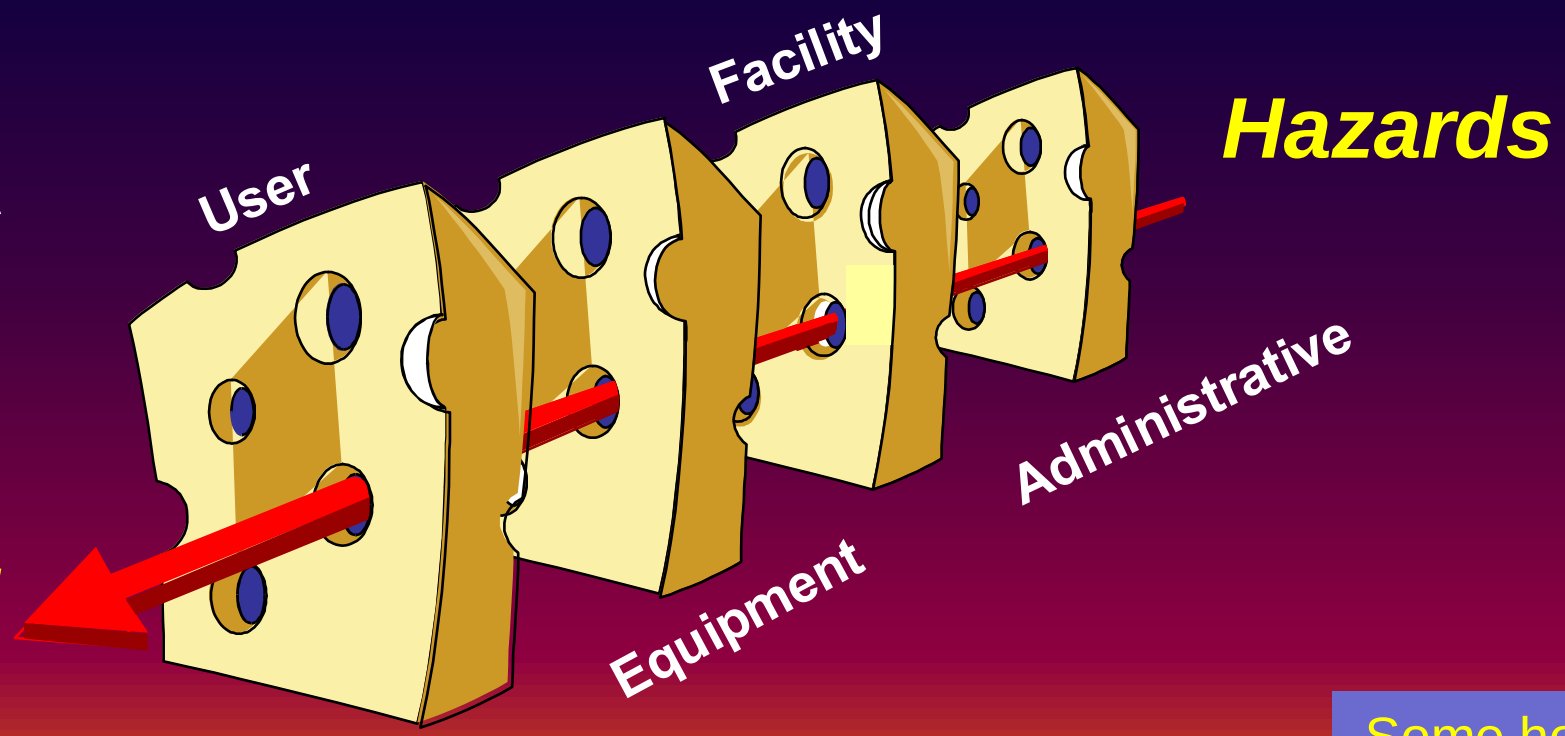


A poorly designed user interface encourages mistakes and frustration by making the user feel stupid.

Interface

Begin each investigation with a procedural framework . . .

Recognize that despite multiple protective barriers, there may be imperfections, flaws (holes) – through which intrinsic hazards may pass unimpeded – to the patient.



Some holes may be due to active failures or latent conditions.

Adapted from J. Reason. *Human Error: models and management*. British Medical Journal; 320: 768-770. 2000.

Active Failures . . .

" are the unsafe acts committed by people who are in direct contact with the patient or system. They take a variety of forms: slips, lapses, fumbles, mistakes, and procedural violations. Active failures have a direct and usually short-lived impact on the integrity of the defenses. . .

"Followers of the person {to blame] approach often look no further for the causes of an adverse event once they have identified these proximal unsafe acts."

J. Reason, Human error: models and management, British Medical J., 320:768-770, 2000

Latent conditions. . .

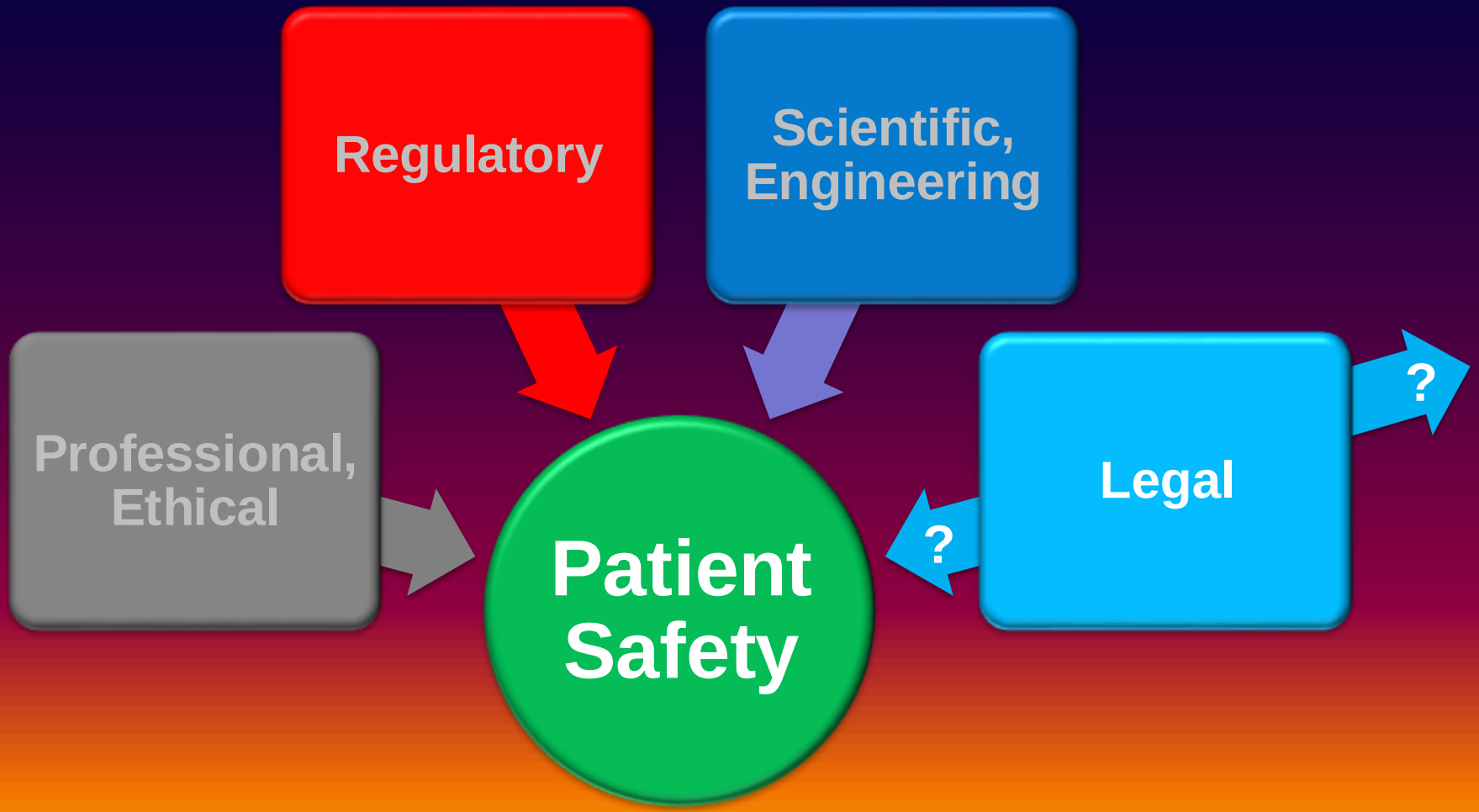
"are the inevitable 'resident pathogens' within the system. They arise from decisions made by designers, builders, procedure writers, and top-level management. Such errors typically lie dormant in the system for lengthy periods of time. . . Latent conditions have two kinds of adverse effect: they can translate into error provoking conditions within the local workplace (e.g., time pressure, understaffing, inadequate equipment, fatigue, and inexperience) and they can create long-lasting holes or weaknesses in the defenses (untrustworthy alarms and indicators, unworkable procedures, design and construction deficiencies, etc).

Unlike active failures, whose specific forms are often hard to foresee, [some] latent conditions can be identified and remedied before an adverse event occurs. Understanding this leads to proactive rather than reactive risk management."

J. Reason, Human error: models and management, British Medical J., 320:768-770, 2000

The *Why* of Incident Investigations:

Complementary & Competing Perspectives



Defendant

vs.

Plaintiff

Manufacturer

Physician / Caregiver

Hospital

Patient

Legal

(typical scenario)

If your hospital is sued, will your investigation and findings hurt or help your case ?

Review > Ann Intern Med. 1999 Dec 21;131(12):963-7.

doi: 10.7326/0003-4819-131-12-199912210-00010.

Risk management: extreme honesty may be the best policy

S S Kraman [1], G Hamm

Affiliations + expand

PMID: 10610649 DOI: 10.7326/0003-4819-131-12-199912210-00010

Free article

Abstract

This paper reviews a humanistic risk management policy that includes early injury review, steadfast maintenance of the relationship between the hospital and the patient, proactive full disclosure to patients who have been injured because of accidents or medical negligence, and fair compensation for injuries. The financial consequences of this type of policy are not yet known; however, one Veterans Affairs medical center, which has been using humanistic risk management since 1987, has had encouragingly moderate liability payments. The Department of Veterans Affairs now requires such a policy for all of its facilities; therefore, comprehensive experience may be only a few years away.

Incident Reports: How to avoid plaintiff attorneys using them against you

June 1, 2007

No Comments

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Plaintiff can use EMR charting against you

How Does a Plaintiff Attorney

Incident Reports: How to avoid plaintiff attorneys using them against you

Robert A. Bitterman, MD, JD, FACEP, Contributing Editor

Many health care providers harbor the delusion that hospital 'incident reports,' or 'occurrence screens,' are privileged and protected from discovery or admission as evidence against them in malpractice litigation. A rash of recent court decisions dispels that notion, and understanding the underpinnings of the courts' reasoning may help hospitals and emergency departments fashion procedures that circumvent the disclosure or admissibility of these materials in civil litigation.

Incident reports not protected under state peer-review statutes

Editorial > Ann Intern Med. 1999 Dec 21;131(12):970-2.

doi: 10.7326/0003-4819-131-12-199912210-00012.

Handling hospital errors: is disclosure the best defense?

A W Wu

> J Healthc Risk Manag. Fall 1997;17(4):45-8. doi: 10.1002/jhrm.5600170408.

Professional liability. Jurisdictions split on discoverability of risk management information

J C West

> AORN J. 1990 Mar;51(3):851-2, 854. doi: 10.1016/s0001-2092(07)66632-0.

Incident reports may or may not be privileged information

E K Murphy [1]

Important Legal Concepts:

Discovery:

“ is the process during which parties to a lawsuit investigate the case and during which information is revealed. Discovery is governed by *Rules 26-37 of the Federal Rules of Civil Procedure*. It often entails the collection and request for documents, the exchange of information between parties, and other activities related to the acquisition of information that is relevant to the lawsuit. Sometimes, discovery is compulsory, i.e., a party is required by law to reveal certain pieces of information relevant to a lawsuit. Discovery comprises depositions, requests for admission, request for production, and interrogatories.

Evidence:

is any object or thing that will establish or tends to establish relevant fact in a lawsuit. It may be the testimony of a witness, a map, video, recording, etc.

Interrogatory:

is a list of questions submitted to an opposing party during the discovery process that is related to the substance of the lawsuit.”

https://lawshelf.com/coursewarecontentview/discovery-and-federal-rule-of-civil-procedure-11/

Important Legal Concepts:

Spoliation of Evidence:

“ is the intentional, reckless, or negligent withholding, hiding, altering, fabricating, or destroying of evidence relevant to a legal proceeding.”

“ . . . courts have established that a person has a duty to maintain and preserve evidence if the evidence is relevant to pending, imminent, or reasonably foreseeable litigation.” But,

a Washington Court of Appeals also held that “ pre-lawsuit behavior doesn’t amount to spoliation if it is done in good faith, even it that behavior results in the destruction of evidence.”

https://www.sackstierney.com/articles/flaherty/spoliation.htm;
Black's Law Dictionary (8th ed. 2004); *Castillo v. Chief Alternative, LLC*, 140 P.3d 234, 236 (Colo. App. 2006).

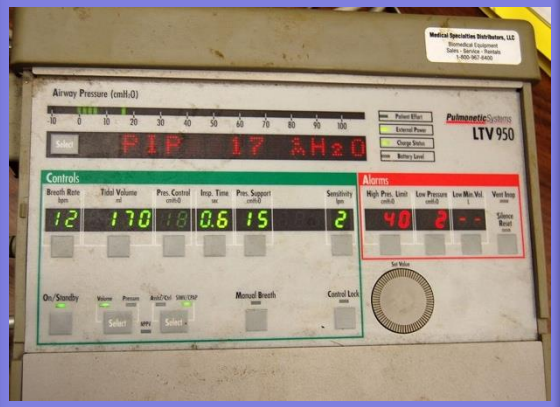
Ventilator-dependent infant died at home. Parents claiming machine just stopped and are now attempting to sue manufacturer.

Alarm limits improperly set; alarm volume set too low, or obstructed; home ambient noise levels too high; ventilator failure.

Performance testing and event log downloaded.

Conclusions

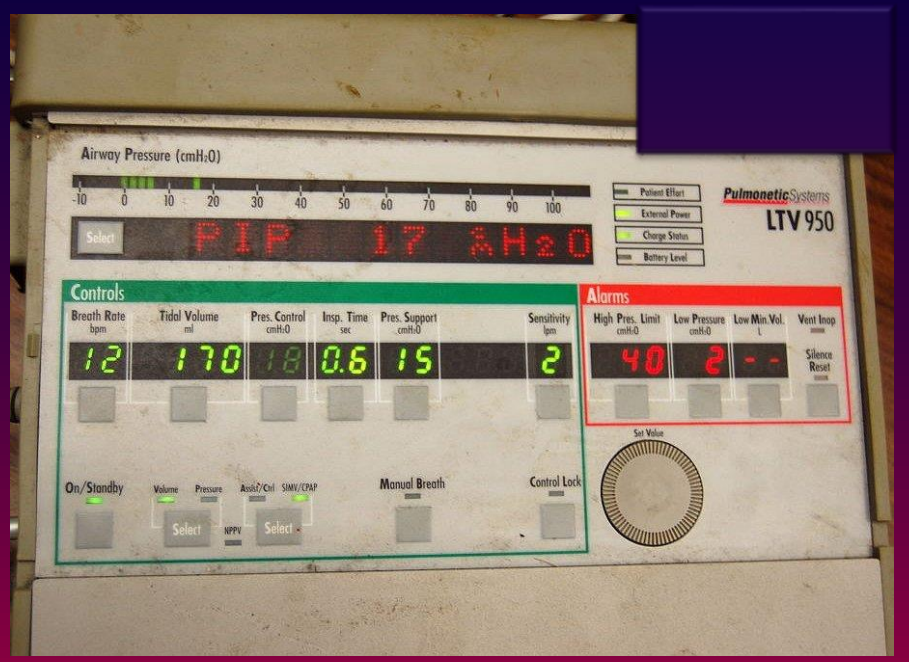
Root Cause(s)



Suspected Ventilator-Related Deaths

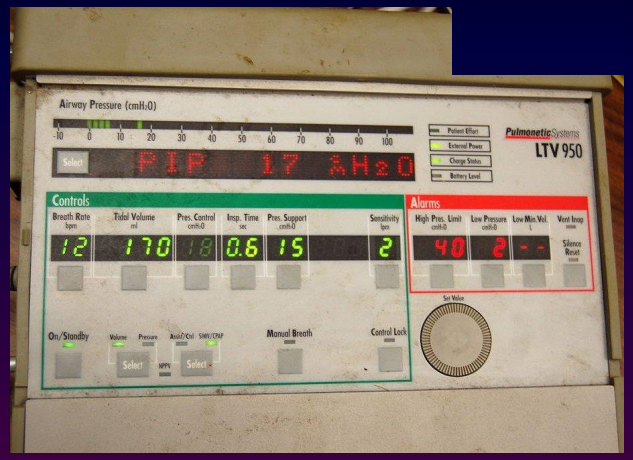
When in any doubt on how to best test and interrogate an involved device, ALWAYS test on an exemplar machine first !

Verify all testing procedures on an identical model machine first,



before testing on the actual machine involved in the incident.

Performance testing and event log downloaded.



1. Verify & document testing procedures and performance results.

Witness(es) to the Inspection:

Date:	Time:	Location:

Present	For the Plaintiff	For the Defense

Visual Inspection:

Serial No.	Mfg. Date:	Last PM Date / other:
◻ Enclosure, connectors, cables, line cord	◻ Alarm sounder port	◻ Fan filter ◻ Air f
◻ Breathing circuit (if available) ◻ PEEP valve (if present) [approx. setting ____ cmH_2O] ◻ Tubing (exhalation valve, high/low pressure sense lines)		◻ Accessories (if ava ◻ ◻ ◻

Comments:

Ventilator Power-On Self Test (w/ attached test lung):

◻ Alarm sounds, all displays illuminate, ventilator starts at pre-programmed settings
◻ Confirming audible chirp

VE (L)	I:E	Vcalc (LPM)	f PEEP (off / on)	PIP (
MAP (cmH_2O)	PEEP (cmH_2O)	f (bpm)	Vte (ml)	

Controls: **Alarms:**

Breath Rate (bpm)	Tidal Vol. (ml)	Pressure Cntrl (cmH_2O)	Insp. Time (sec)	Pressure Support (cmH_2O)	Sensitivity (lpm)		High Pressure Limit (cmH_2O)	Low Pressur Limit (cmH_2O

Vol.	Pressure	Assist / Cntrl	SIMV / CPAP	Conti

◻ Power Down – Vent Inop Alarm w/ confirming audible chirp

Comments:

Test procedures adapted from service manual.

Available Ventilator Performance Tests and Settings:

◻ VENT CHECK		◻ VENT CHECK	
◻ Alarm →	dBA @ port dBA @ 1m	◻ Alarm Op→Alarm Vol (set)	dBA
◻ Display →		◻ Apnea Int→Apnea	Sec
◻ Control → (test all controls) ◻ pass		◻ HP Delay	
◻ Leak (w/partial occlusion)		◻ LPP Alarm	
◻ Homing Valve ◻ Set Turbine		◻ High f	
◻ Pressure ◻ Flow		◻ High PEEP	cmH_2O
◻ Leak Test Fail (yes / no)		◻ PNT Assist	
◻ VENT OP			
◻ Rise Time		◻ Ver	
◻ Flow Term	% of peak	◻ Usage	Hrs
◻ Time Term	Sec	◻ Com Settings	
◻ PC Flow Term		◻ Set Date	
◻ Leak Comp		◻ Set Time	
◻ NPPV Mode		◻ Date Format	
◻ Ctrl Unlock	[easy / hard]	◻ PIP LED	
◻ Language		VHome	
◻ XDCR ZERO			
◻ AP		◻ FDw	
◻ FDb		◻ FDo	
◻ RT XDCR DATA			
◻ AP	cmH_2O	◻ FV	Lpm
◻ FDb	cmH_2O	◻ STEP	
◻ FDw	cmH_2O	◻ TS	Rpm
◻ FDo	cmH_2O	◻ BV	Vdc
◻ ETo	Lpm	◻ EV	Vdc
◻ Leak	Lpm	◻ RT	
◻ FVd	cmH_2O		

◻ Event Trace [connect laptop PC via RS232-USB cable]

◻ Event Print (store downloaded .txt file) A sample of the nature and format of the ventilator's stored events history is shown below:

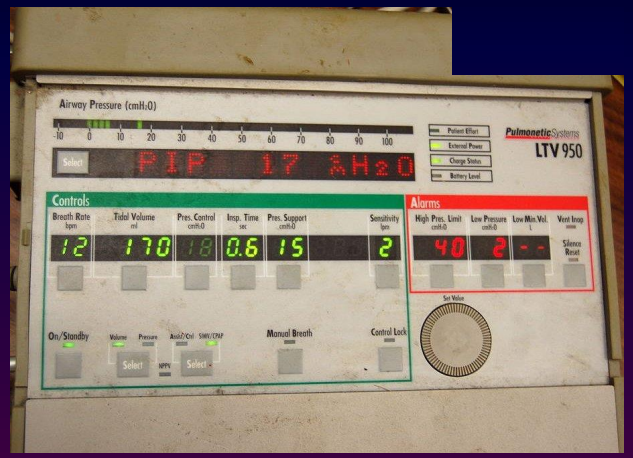
```
EVENT TRACE: 11-LOW VE 1 E 47 C  1 07/27/2004 14:24:27.745
EVENT TRACE: 12-LOW VE 0 E 48 C  1 07/27/2004 14:24:38.399
EVENT TRACE: 13-HI PRES1 E 42 C  1 07/27/2004 14:24:52.773
EVENT TRACE: 14-HI PRES0 E 43 C  1 07/27/2004 14:24:53.001
EVENT TRACE: 15-HI PRES1 E 42 C  3 07/27/2004 14:25:02.771
EVENT TRACE: 16-HI PRES0 E 43 C  3 07/27/2004 14:25:02.999
EVENT TRACE: 17-LO PRES1 E 49 C  1 07/27/2004 14:25:28.927
EVENT TRACE: 18-HIGH DIS E  8 C  1 07/27/2004 14:25:29.131 1
EVENT TRACE: 19-DISC 0   E 10 C  1 07/27/2004 14:25:29.457
EVENT TRACE: 20-HIGH DIS E  8 C  2 07/27/2004 14:25:29.655 1
```

◻ Triggered Alarm Tests

◻ High Pressure Limit	◻ Low Peak Pressure	◻ Low Minute Volume
◻ Disc/Sense Line	◻ AC Power Loss	◻

Upon agreement of all parties involved, other tests may be needed or performed depending on the above results.

Performance testing and event log downloaded.



2. Download, parse, and organize event log

Appendix E - Event Trace

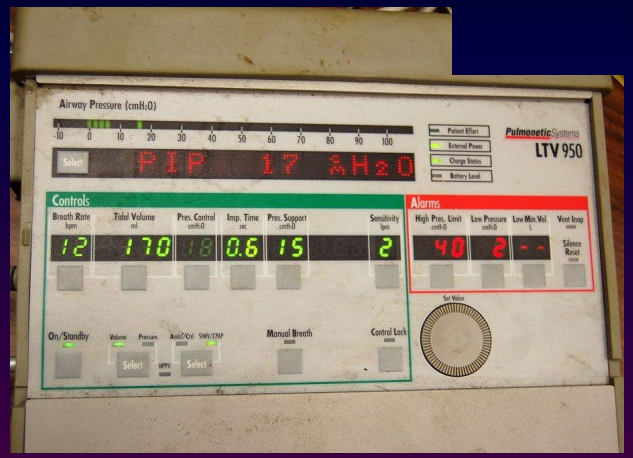
The Event Trace is a list of events recorded by the ventilator. These events may be normal conditions, such as turning the ventilator on or off, or alarm conditions such as **HW FAULT** or **HIGH PRES**.

- Initial occurrences of events are recorded the first time they occur after power up, along with the date, time and associated data, if any.
- A second occurrence of the same type of event (same event code) will be recorded as a separate line item along with the latest date, time and associated data. The quantity of occurrences is increased by one (1) (i.e. a quantity of two (2) will be displayed)).
- Additional occurrences (3rd or more) of the same type of event will update the secondary occurrence line items with the latest date, time, and associated data. The quantity of occurrences will be increased by one (1) for each additional occurrence (i.e. the quantity of 2 will be increased to 3).

EXT LST1	External power lost occurred	POWER LOST
VENT 0	Power off	None

EVENT TRACE:349:	LO PRES1	2/6/2008	10:52 AM
EVENT TRACE:350:	LO PRES0	2/6/2008	10:52 AM
EVENT TRACE:362:	LOW DIS	2/6/2008	10:52 AM
EVENT TRACE:359:	HI PRES1	2/6/2008	10:52 AM
EVENT TRACE:360:	HI PRES0	2/6/2008	10:52 AM
EVENT TRACE:371:	EXT LST0	2/6/2008	10:53 AM
EVENT TRACE:372:	EXT LOW0	2/6/2008	10:53 AM
EVENT TRACE:355:	HIGH DIS	2/6/2008	11:04 AM
EVENT TRACE:356:	DISC 0	2/6/2008	11:04 AM
EVENT TRACE:370:	EXT LST1	2/6/2008	12:23 PM
EVENT TRACE:366:	HOUR MTR	2/6/2008	12:24 PM
EVENT TRACE:373:	VENT 0	2/6/2008	12:24 PM

Performance testing and event log downloaded.



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EVENT TRACE:360:	HI PRES0	2/6/2008	10:52 AM
EVENT TRACE:371:	EXT LST0	2/6/2008	10:53 AM
EVENT TRACE:372:	EXT LOW0	2/6/2008	10:53 AM
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EVENT TRACE:356:	DISC 0	2/6/2008	11:04 AM
EVENT TRACE:370:	EXT LST1	2/6/2008	12:23 PM
EVENT TRACE:366:	HOUR MTR	2/6/2008	12:24 PM
EVENT TRACE:373:	VENT 0	2/6/2008	12:24 PM

But, 911 was not called until over two hours later . . .

Another suspicious ventilator-related infant death suggested through a downloaded event log. . .

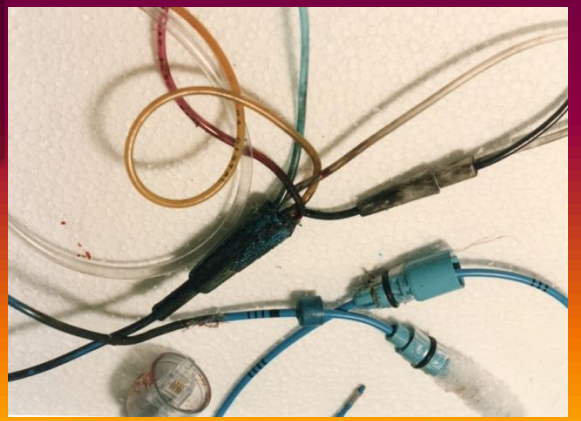
TRACE:391:LO	PEEP0	E	90C	89	6/12/2011	1:13:18 PM
TRACE:385:LO	PRES0	E	50C	28	6/12/2011	1:13:19 PM
TRACE:405:HOUR	MTR	E	3C	1	6/12/2011	1:13:21 PM
TRACE:406:VENT		0E	2C	1	6/12/2011	1:13:24 PM
TRACE:407:VENT		1E	1C	1	6/12/2011	5:08:09 PM
TRACE:408:NEW	PTNT	E	91C	1	6/12/2011	5:08:10 PM
TRACE:409:LO	PEEP1	E	89C	1	6/12/2011	5:09:26 PM
TRACE:410:LO	PEEP0	E	90C	1	6/12/2011	5:09:28 PM
TRACE:412:LO	PRES1	E	49C	1	6/12/2011	5:09:57 PM
TRACE:413:LO	PRES0	E	50C	1	6/12/2011	5:10:01 PM
TRACE:416:HI	PRES1	E	42C	1	6/12/2011	5:10:28 PM
TRACE:417:TBN	ZERO	E	45C	1	6/12/2011	5:10:29 PM
TRACE:418:HI	PRES0	E	43C	1	6/12/2011	5:10:29 PM
TRACE:422:HIGH	DIS	E	8C	1	6/12/2011	6:16:50 PM
TRACE:423:DISC		0E	10C	1	6/12/2011	6:16:51 PM

Machine is turned off here

and turned back on here

Defibrillation was attempted on patient in cardiac arrest. Upon discharge of the machine, a ball of flame engulfed the patient's head and neck.

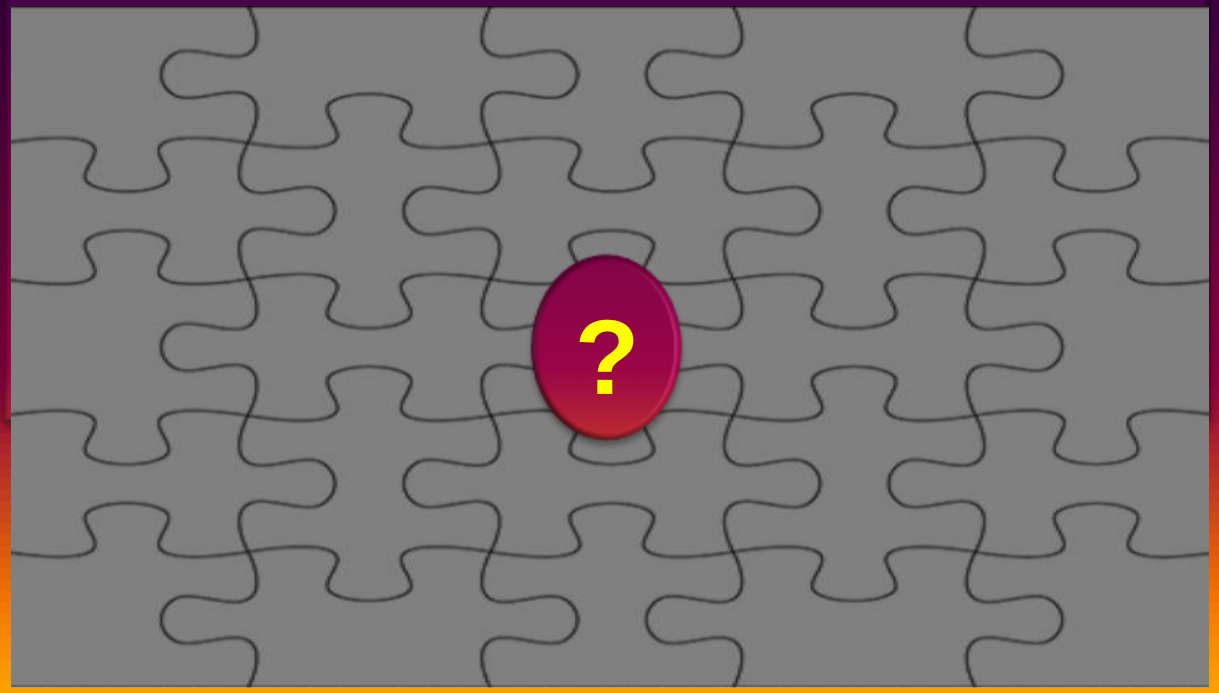
Defibrillator-Related Fire & Patient Burns



Defibrillation was attempted on patient in cardiac arrest. Upon discharge of the machine, a ball of flame engulfed the patient's head and neck.

Starting a fire requires: fuel, oxygen, and an ignition source. . .

but, how did this happen ?



Defibrillation was attempted on patient in cardiac arrest. Upon discharge of the machine, a ball of flame engulfed the patient's head and neck.

Starting a fire requires: fuel, oxygen, and an ignition source. . .

Defibrillator sequestered & tested; disposables collected; patient, bed, equipment settings, photographed.

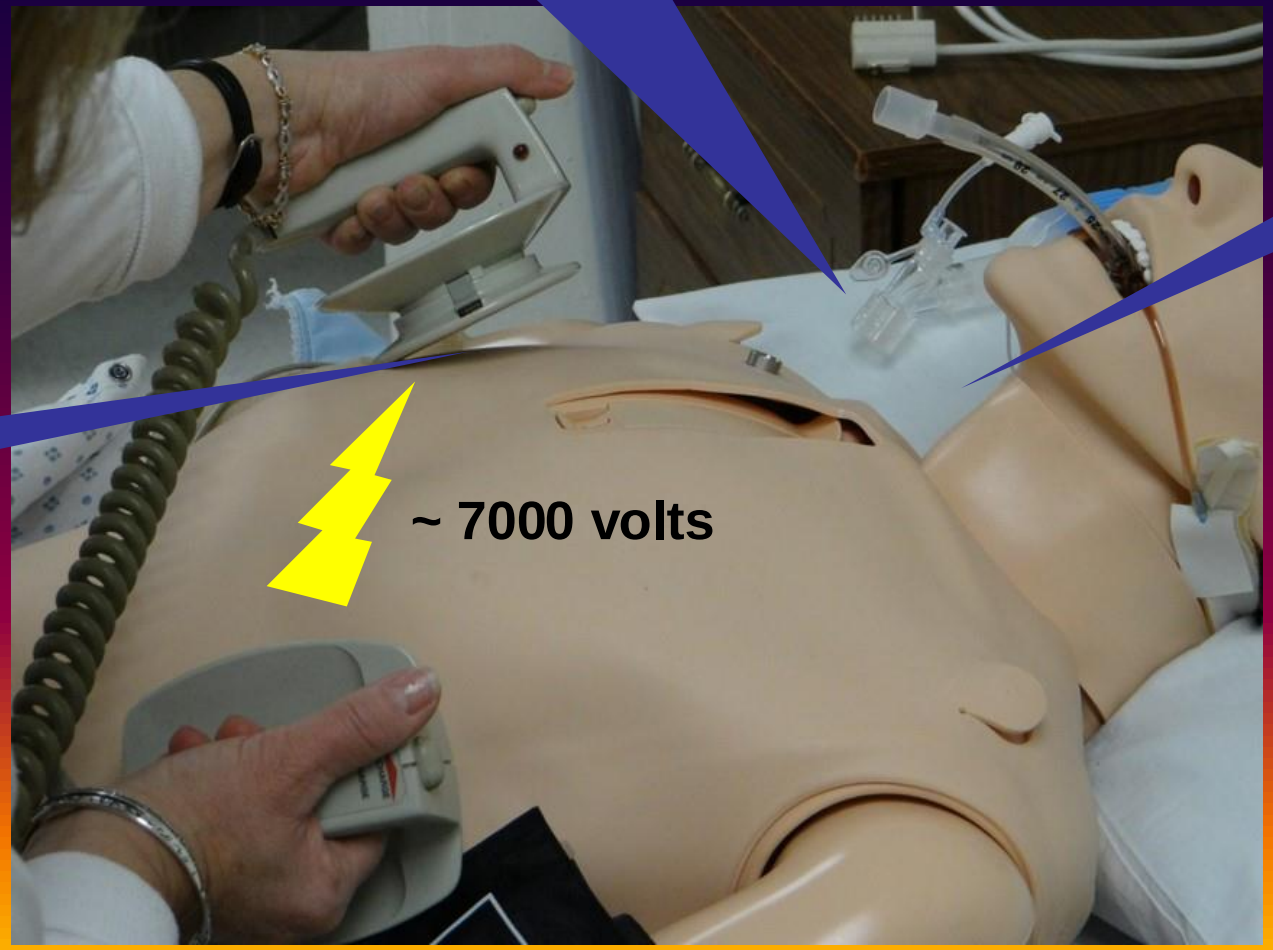
Fact gathering & staff interviews

Analysis & Conclusions Root Cause(s)

Reconstruction:

High FiO2 setting from ventilator

Proximity of disconnected breathing circuit to defib paddle

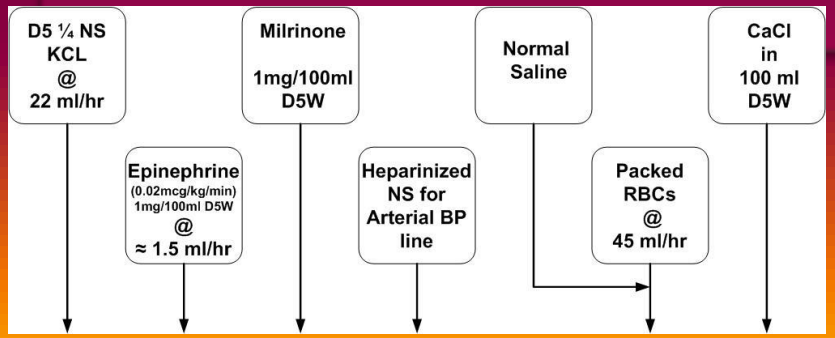


Neck dressing

Insufficient paddle contact

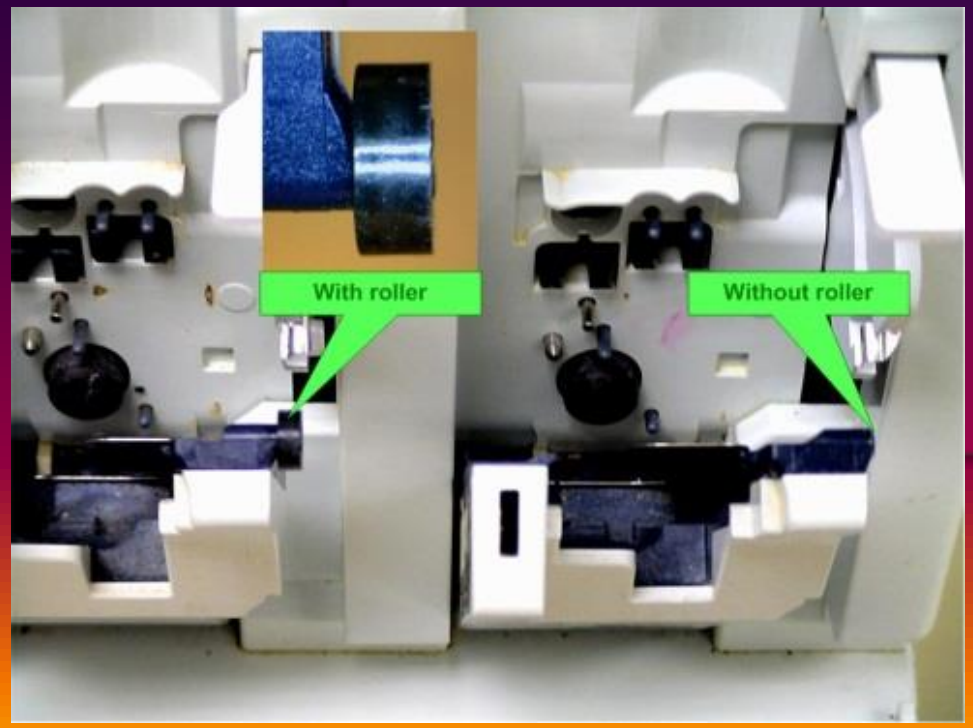
$$V_{oc} = \sqrt{\frac{2(300J)}{12\mu F}}$$

A 30-month-old PICU patient went into cardiac arrest and suffered permanent brain injury following an overdose of epinephrine from a free-flowing IV.



The hospital was claiming a defective IV pump as the cause.

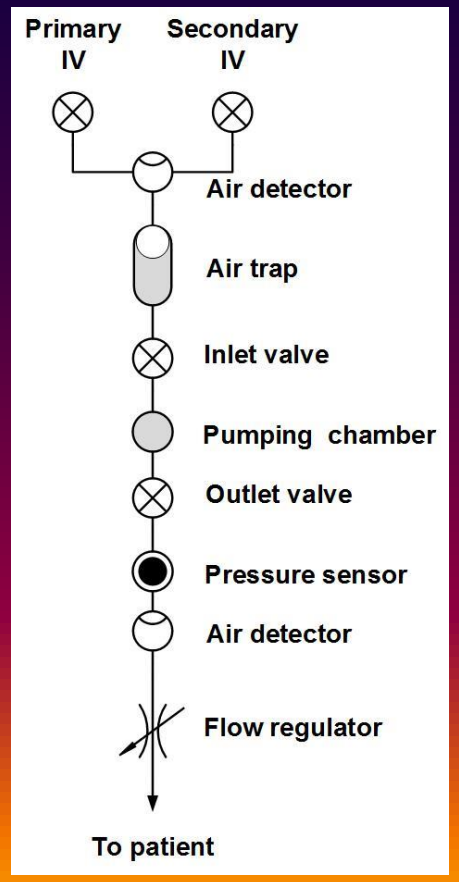
Specifically, they claimed that these pumps had a history of door roller breakage.

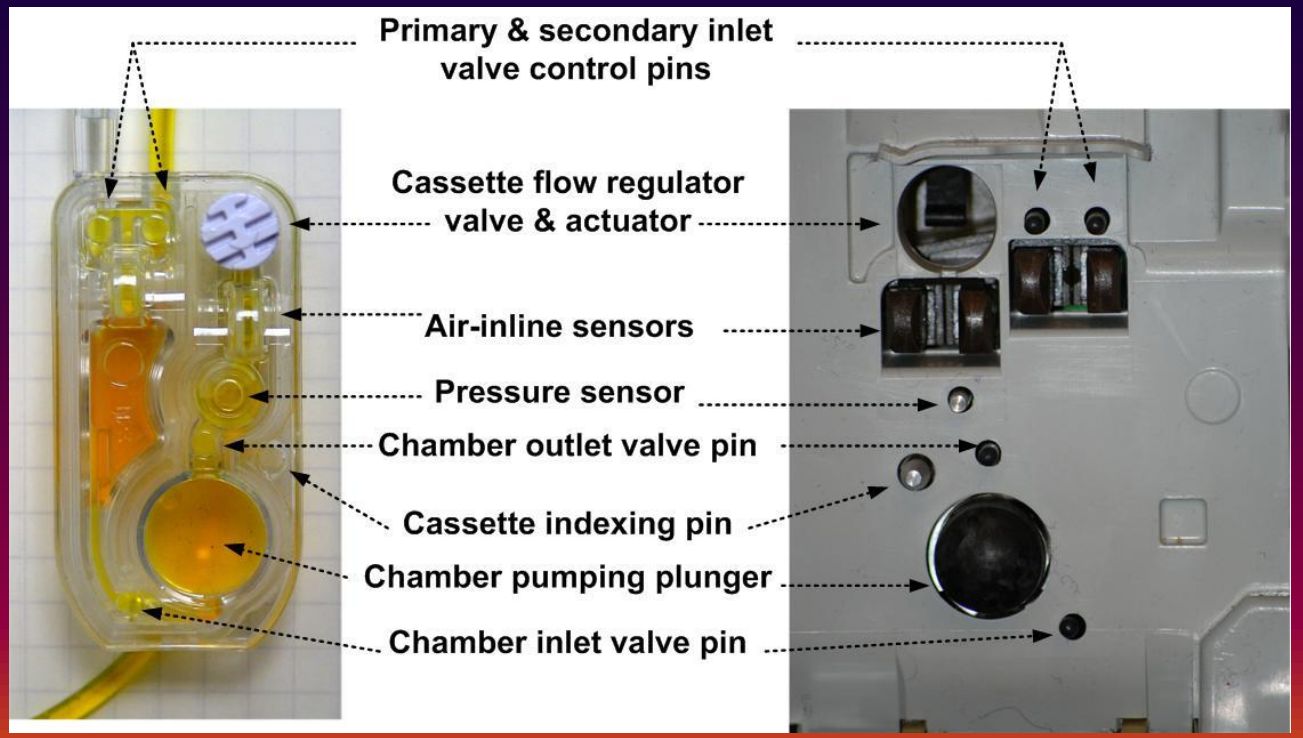


Question: would the pump even operate with a missing door roller?

Exemplar pump testing and analysis:

1. Evaluate pump design, fluid flow control features, alarms.



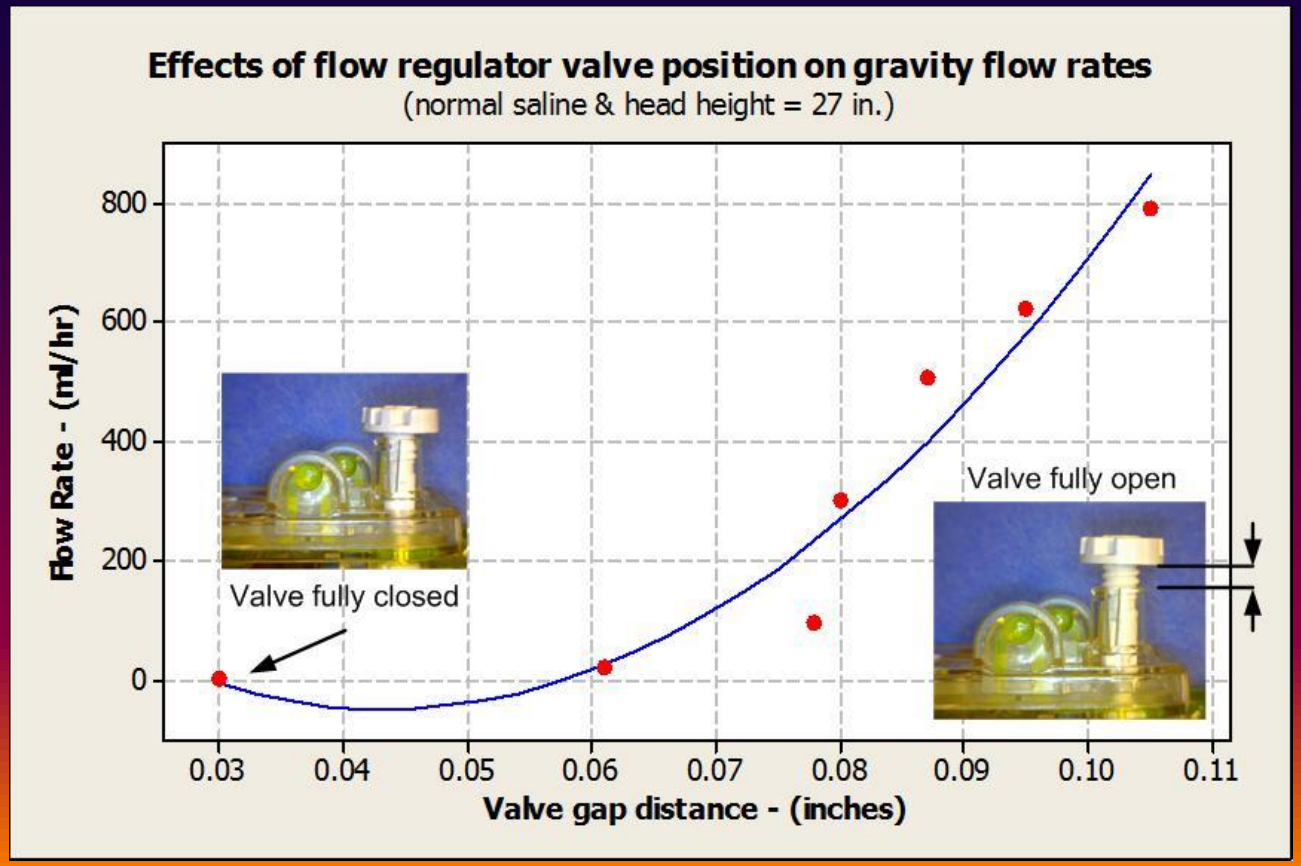


Closed door keeps cassette engaged with moving control pins.

Exemplar pump testing and analysis:

2. Characterize operation and behavior of manual cassette functions.

IV line can be initially set up and primed independent of the pump by manual control of the cassette flow regulator valve.



Valve may be manually turned or pulled to start flow.

Exemplar pump testing and analysis:

2. Characterize operation and behavior of manual cassette functions.

The pump takes over control of this flow regulator valve once the cassette is securely attached to the pump.

Exemplar pump testing and analysis:

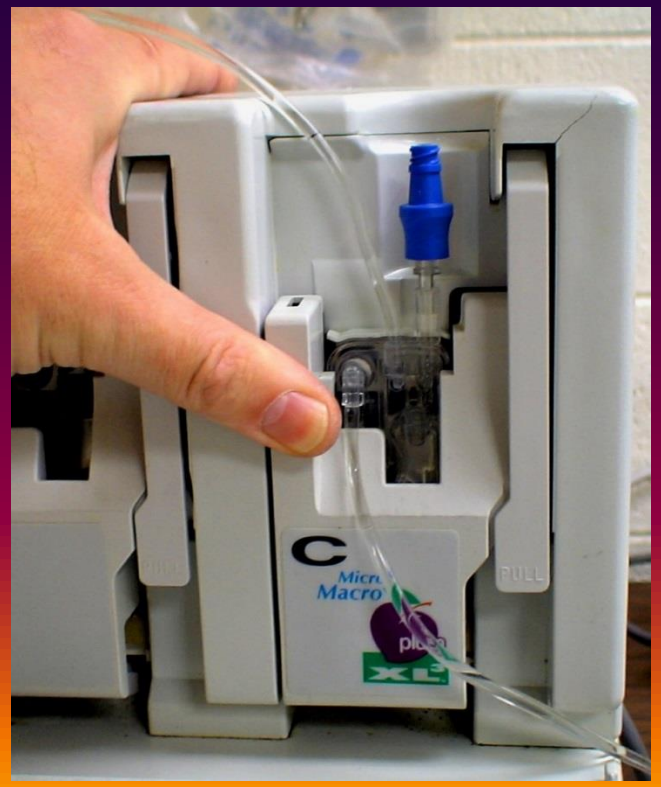
3. How can door rollers be broken?

Destructive door roller test. If the cassette is not fully seated and the door is forced close, the roller axel can be sheared off.

Exemplar pump testing and analysis:

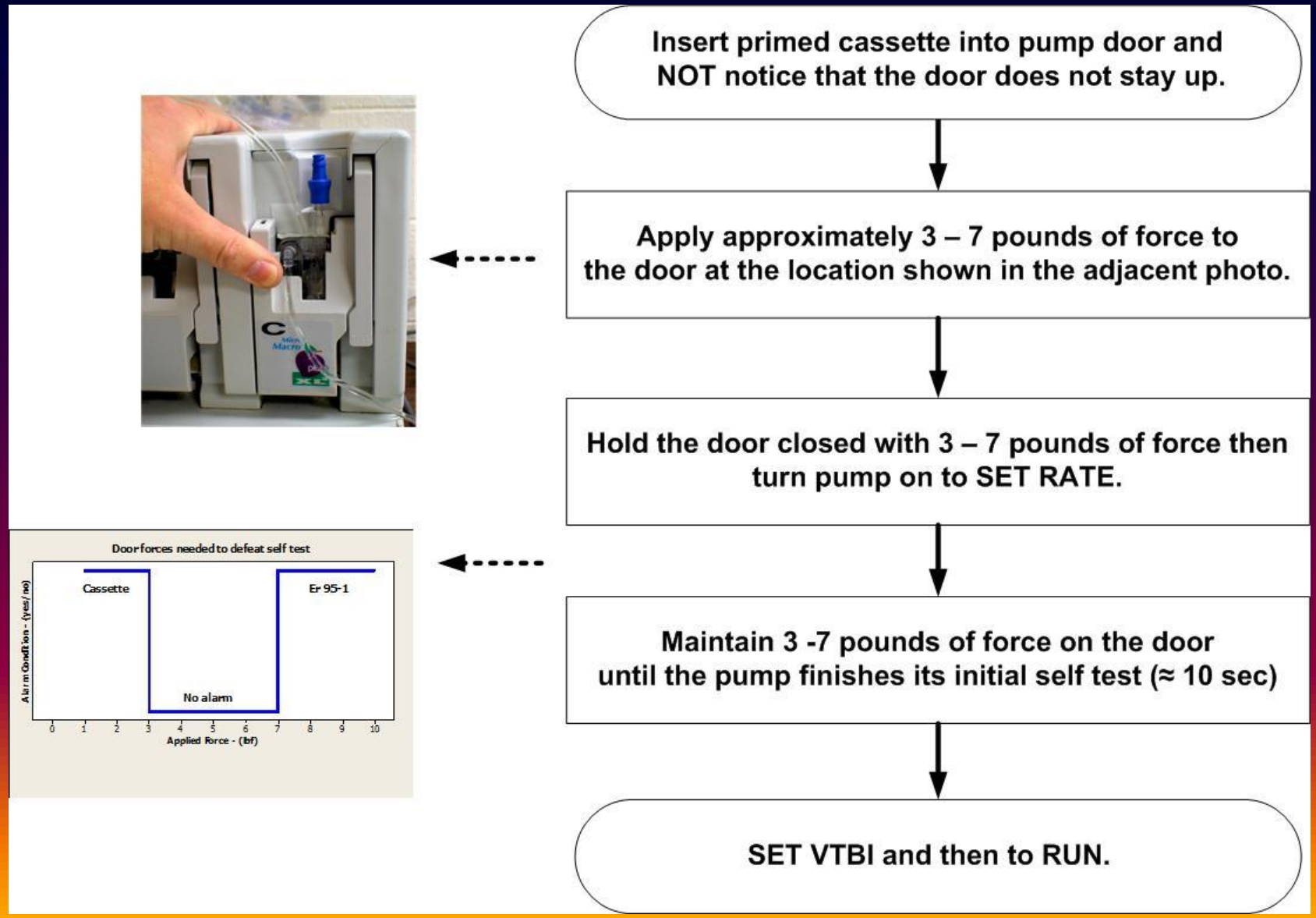
4. Could the pump even operate with a missing door roller?

Yes, a pump with a broken cassette door roller could be ‘fooled’ into passing its initial self tests and suspending any alarms if – and only if – its door was manually held closed with sufficient force during the self test.



Exemplar pump testing and analysis:

However, and specifically, it would require this sequence of events in order to defeat cassette and door alarms and allow the pump to finish its self-test:



Conclusions

Root Cause(s)

The infusion pump was not defective, did not have a broken door roller, and was operating properly with the patient upon arrival to the PICU.

In the process of discontinuing and removing the epinephrine line from the pump, the flow regulator valve on its cassette was moved to its open position.

The epinephrine line was not clamped off before being removed from the pump.

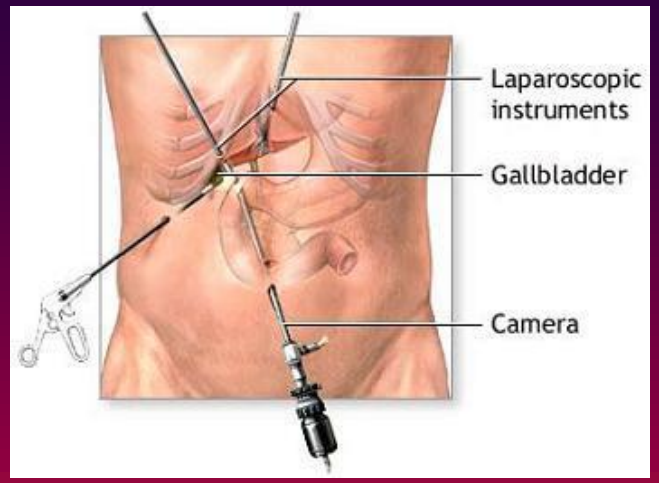
"The administration of multiple IV infusions to a single patient is a complex task with many potential associated patient safety risks".

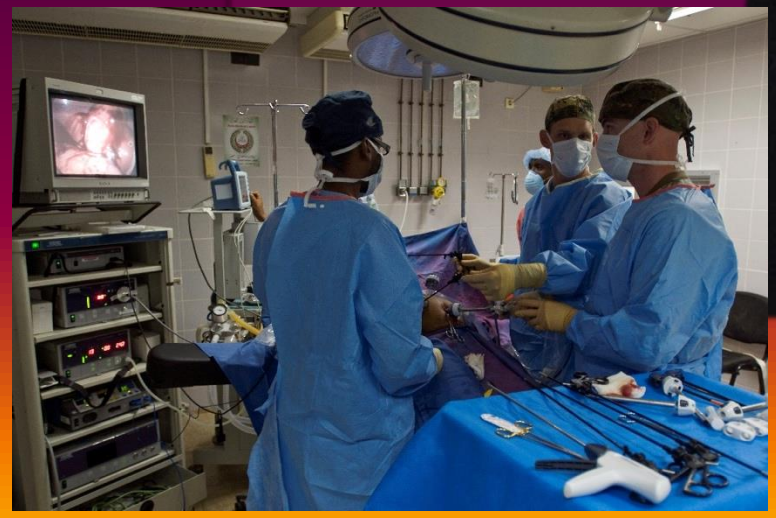
Multiple Intravenous Infusions Phase 1b: Practice and Training Scan. A. Cassano-Piche, et al. Health Technology Safety Research Team, Institute for Safe Medication Practices Canada.

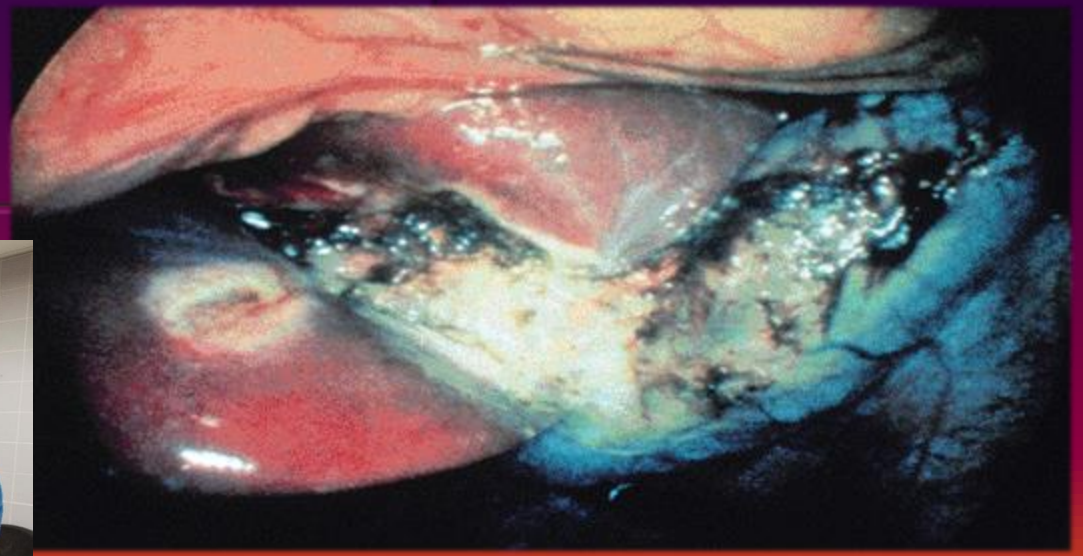
Male dies seven days after a laparoscopic removal of his gallbladder. Autopsy revealed massive peritonitis caused by a thermal burn through his stomach.

Surgical error; stray coupling of electrosurgical currents ?

Hypothesis ?







Patient & OR records; literature review

Insulation failure in laparoscopic instruments

Paul N Montero [1], Thomas N Robinson, John S Weaver, Greg V Stiegmann

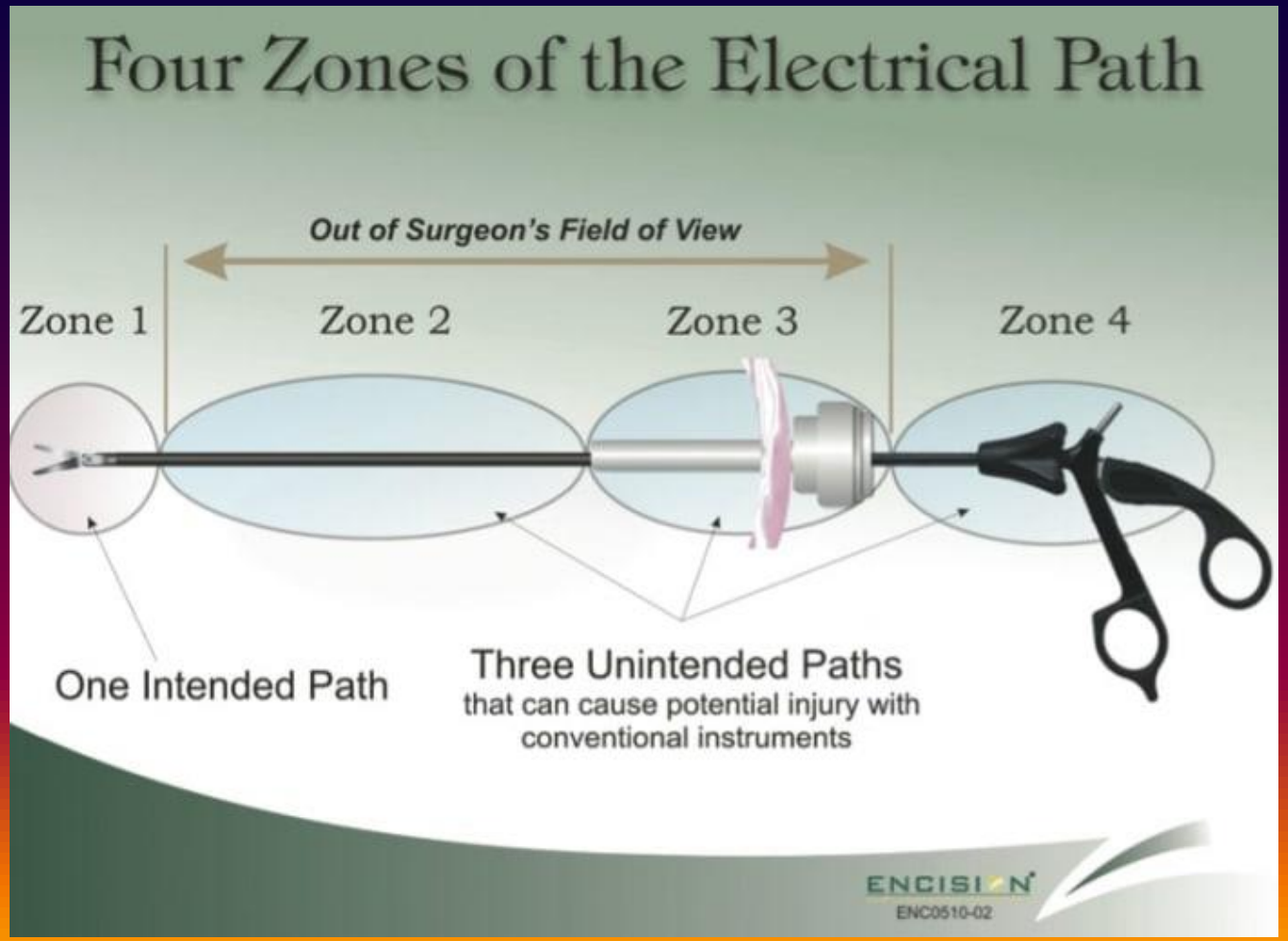
Results: Two hundred twenty-six laparoscopic instruments were tested (165 reusable). Insulation failure occurred more often in reusable (19%; 31/165) than in disposable instruments (3%; 2/61; *p < 0.01). When reusable sets were evaluated, 71% (12/17) were found to have at least one instrument with insulation failure. Insulation failure incidence in reusable instruments was similar between hospitals that routinely checked for insulation failure (19%; 25/130) and hospitals that do not routinely check for insulation failures (33%; 7/21; p = 0.16). Insulation failure was most common in the distal third of the instruments (54%; 25/46) compared to the middle or proximal third of the instruments (*p < 0.05).

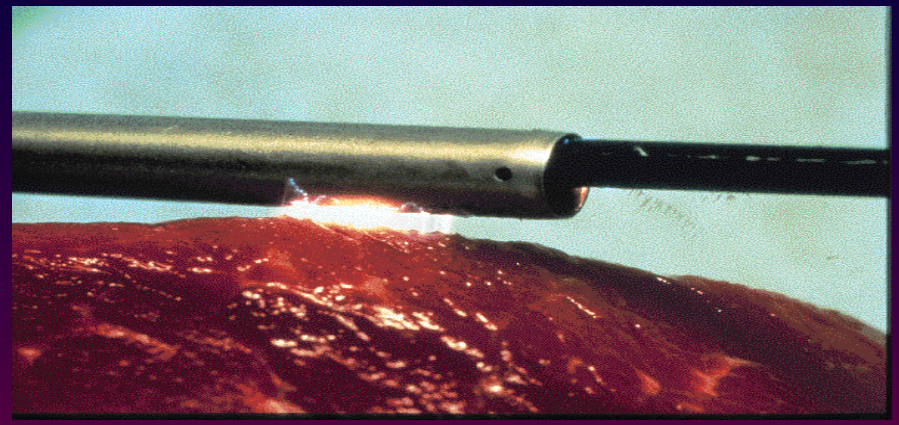
Conclusion: One in five reusable laparoscopic instruments has insulation failure; a finding that is not altered by whether the hospital routinely checks for insulation defects. Disposable instruments have a lower incidence of insulation failure. The distal third of laparoscopic instruments is the most common site of insulation failure.

APRIL 1, 2011 | ROBOTICS, AUTOMATION & CONTROL | MEDICAL | PHOTONICS/OPTICS

Method of Reducing Stray Energy Burns in Laparoscopic Surgery

Active Electrode Monitoring (AEM) instruments incorporate a "shielded and monitored" design to lower risk of injury.





https://www.medicaldesignbriefs.com/; Encision.

Conclusions

Root Cause(s)

Repeated ‘cold’ sterilization (glutaraldehyde) of laparoscopic instruments degraded insulation.

The use of available and functioning active ESU electrode monitoring technology would have prevented burns to the patient’s stomach and fatal consequences.

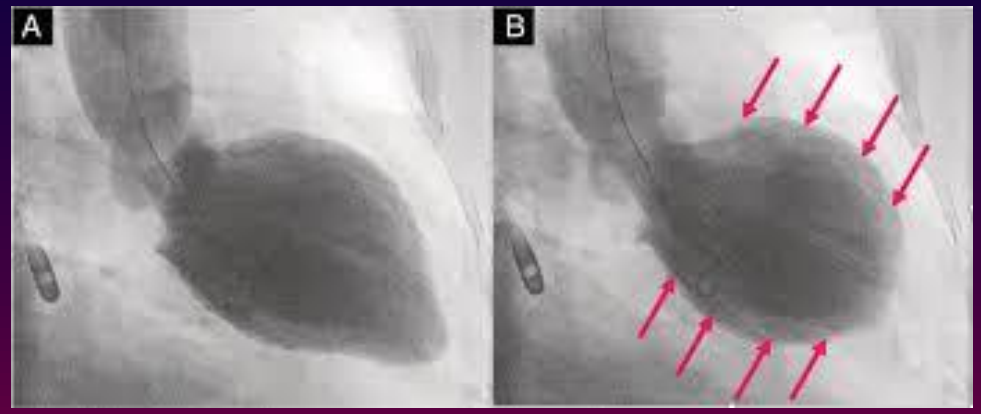
Regularly inspect and test insulation integrity of laparoscopic instruments.

Laparoscopic instrument insulation failure: The hidden hazard

“Conclusion: There is an unacceptably high prevalence of instrument insulation failure in gynecologic laparoscopic instruments. Visual inspection is not an appropriate screening mechanism for insulation failure but routine biomedical testing reduces the prevalence of defective laparoscopic instruments”.

Yazdani, A., et al. Journal of Minimally Invasive Gynecology, 14, 228-232. (2007).

A 65-year-old male was undergoing a routine cardiac angiography and ventriculography. The injector was thought to be filled with contrast agent – but was filled with air instead. Over 100 ml of air was injected into his left ventricle.



Conclusions

Root Cause(s)

Cath lab personnel (understandably) assumed the injector was correctly filled as the injector head was in its correct downward position and the syringe plunger fully retracted.

The manufacturer of this injector offered an air emboli detector for the syringe – but only as an ‘option’ and not an integral part of the design.

Is this syringe filled with clear contrast agent or air ?

ELSEVIER International Journal of Cardiology 116 (2007) 131–133 www.elsevier.com/locate/ijcard

Letter to the Editor

A serious complication of a power injector for coronary angiography

Hideaki Kaneda *, Shigeru Saito, Yusuke Miyashita, Saeko Takahashi, Takaaki Shiono, Yoshio Taketani, Hiroshi Domae

Lessons Learned:

Treat every adverse event, injury, accidental death as a precious learning opportunity . . .

Seek to identify the active failures and latent conditions - within the system – that contributed to the event.

Do not just manage the last error.

Eliminate the tendency to blame ! !

“The only real mistake is the one from which we learn nothing”.

- Henry Ford

Thanks !

fennigko@msoe.edu