

Ogden Surgical-Medical Society

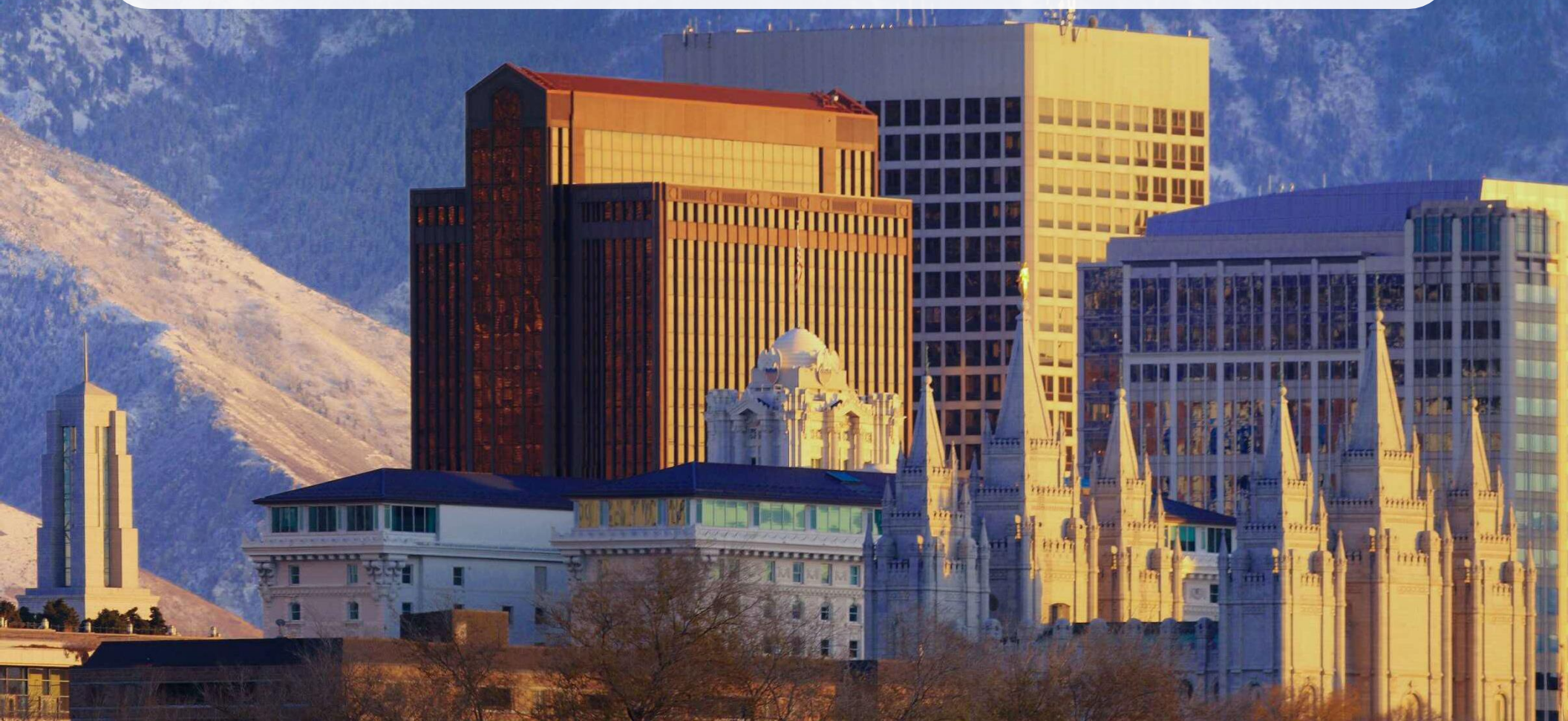
CME 2024

Weber State Univ Shepherd Union Building, 3rd Floor, 3910 W Campus Drive, Ogden, Utah
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First, Do No Harm: Reducing Care-Associated Injuries

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Disclosures

*I receive a monthly retainer as a part-time (3 days / month) senior advisor for **Health Catalyst**, and own (a small amount of) **Health Catalyst** stock.*

*I serve on the board of directors of **SaVia**, a start-up, privately-held software company that supports clinical workflow design.*

*I also serve on an advisory board for **Amplifire**, a privately-held company that provides computer-based health care education products.*

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Outline – 3 ideas

1. *Better methods for injury event detection*

2. *Injuries increase care delivery costs*

(hence, reducing avoidable injuries reduces operating expenses)

3. *Key methods to reduce injury rates*

The core value of healers *and the care system*

Primum, non nocere

(First, do no harm)

When people come to the care delivery system seeking help, they shouldn't have to worry that the care they receive will hurt them more than it helps them

While typically said to arise from Hippocrates (~470 to 360 BCE, the “pioneer of modern medicine,” from Kos, ancient Greece) or Galen (129 to 216 AD, Roman citizen living and working in modern-day Turkey), this phrase first appeared in 1860, attributed variously to Thomas Sydenham or Thomas Inman, both British physicians.

Smith, Cedric M. Origin and uses of Primum Non Nocere – Above All Do No Harm!. J Clin Pharm 2005; 45(4):371-7 (Apr)

The problem:

Anything that is powerful enough to heal can also harm

- *Health professionals walk a very thin line between help and harm; they are*
- *trying to maximize benefit, without stepping over that line.*
- *Examples:*
 - *any procedure ... things like surgery*
 - *any use of a drug – a heart medication, an antibiotic, chemotherapy*
 - *lab testing, imaging*
 - *(mis)diagnosis*

**Not all Australian
animals
will kill you.**

**Don't get me wrong,
He wants to...**

He just can't.



***All aspects of care delivery are
inherently and significantly
dangerous***

The only appropriate attitude / approach:

- *They are out to get you!!*
- *You must always be on your guard ...*

1. November 30, 1999:

The Institute of Medicine (now the National Academy of Medicine)

Committee on Quality of Health Care in America

announces its first report:

To Err is Human: Building a Safer Health System

Institute of Medicine Committee on Quality of Health Care in America. *To Err Is Human: Building a Safer Health System*. Kohn, Linda T., Corrigan, Janet M., and Donaldson, Molla, editors. Washington, DC: National Academy Press, 2000.

Care-associated injuries in hospitals

account for

***44,000 - 98,000 preventable deaths per year
in the United States***

***More people die from hospital-based preventable medical injuries
than from breast cancer or AIDS or motor vehicle accidents***

A series of studies finding that

***2 to 4% of hospitalized patients
suffer care-associated injuries***

*Injuries drive direct health care costs totaling
\$9 to 15 billion per year*

Thomas et al. 1999

Johnson et al. 1992

3 methods for finding injuries

1. *Voluntary reporting* (“*Sentinel Events*”, “*Serious Safety Events*”)

2. *Retrospective chart review*

➤ *Unstructured review (HMPS, Utah-Colorado)*

➤ **Structured review** (“triggers”; IHI GTT, Bates’ SafeCare)

➤ *Automated reuse of financial billing codes (PSI, Utah-Missouri)*

3. *Prospective expert review*

➤ *Supports prospective intervention (Evans, Bates)*

➤ *Complements retrospective chart review*

(both find events that the other method misses)

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 1 care-associated event

26.0% had at least 1 event within index 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 'sentinel event' deaths** occurred.

Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, Whittington JC, Frankel A, Seger A, James BC. 'Global Trigger Tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 2011; 30(4):581-9 (April).

Validated across multiple studies

<i>IHI GTT (2004 data)</i>	795	26.0%
DHHS OIGx2 (2010,18 data)	@800	25.0%
SafeCare* (2018 data)	2,750	23.6%

*Bates, David W., Levine, David M., Salmasian, Hojat, *et al.* The safety of inpatient health care. *N Engl J Med* 2023; 388(2):142-52 (Jan 12).

Avoidable mortality - a more accurate estimate

Conservatively (lower bound),

about **210,000 preventable deaths each year**

(upper bound :: 400,000 deaths/year)

just U.S. in hospitals

(doesn't include deaths arising from care in outpatient settings, which are probably more frequent than deaths in inpatient settings)

(U.S. COVID mortality over 3 years: ~370,000/year (1.1 million total deaths))

- **Hospitals fall somewhere between the 2nd and 4th most common cause of preventable death in the United States**; leading to
- *the idea of hospitals as a major public health problem*

James, John T. A new, evidence-base estimate of patient harms associated w hospital care.
J Patient Saf 2013; 9(3):122-8 (Sep).

Countervailing factors

- **Upside much bigger than downside** - net of patient injuries, care delivery adds 3.5 to 7 years of life expectancy on average to every person in the country
- **You are walking a thin line between help and harm** - when attempting to maximize benefit, it is almost impossible to avoid sometimes stepping over that line
- **More serious illness means more intense treatment;** more intense treatment, in turn, means higher probability of a care-associated injury event
- **Often** (as a result of the last point) **it's not years of life lost, or even months; but instead weeks or days** (but don't be too cavalier . in an end of life setting, even a few weeks can be quite important to a patient and family)

The key take-away: voluntary reporting works poorly

But it's by far the most common form of detection used across all care settings.

Also sometimes called:

- *nurse incidence reporting*
- *serious safety events (SSEs)*
- *Includes Sentinel events, JCAHO "never events"*

Compared to other methods, finds about

1 in 100 actual care-associated injury events

Done competently, with heavy emphasis:

1 in 10 actual care-associated injury events

It gets even worse:

***Voluntary reporting does not
generate a representative sample***

Better detection leads to very different

priorities / patterns / methods

for effective prevention

***You can't fix
what you can't find***

High frequency injury sources

- 1. Adverse drug events** (ADEs, ADRs)
- 2. Procedure complications**
- 3. Iatrogenic infections**
 - *post-operative deep wound infections*
 - *urinary tract infections (UTI)*
 - *lower respiratory infections (pneumonia or bronchitis)*
 - *bacteremias and septicemias*
- 4. Pressure injuries**
- 5. Mechanical device failures**
- 6. Complications of central and peripheral venous lines**
- 7. Deep venous thrombosis / pulmonary embolism** (DVT/PE)
- 8. Strength, agility, and cognition** (fall injuries, use of restraints)
- 9. Blood products**
- 10. Patient transitions** (handoff failures; mostly ADEs)

2. A case study

Detecting and reducing injuries at Common Spirit Health

CommonSpirit *(selected ~40 of 150+ U.S. based, Catholic hospitals)*

- **Automated detection, centralized nurse review**
- **~20% of inpatient admissions with 1 or more events**
 - 4 recent, major studies -- ~25% injury rate, 'state of the art' detection
 - At least 10x higher rate than that found using voluntary reporting
 - Serious/sentinel events are detected at similarly higher rates
- **On average, an event roughly doubles hospital stay, plus increases other resource consumption**
 - at CommonSpirit, **>\$4,600 in additional baseline cost per case**
 - <2% of such events result in rapid death, which avoids direct costs
- **Injury event rates fell by 20% to 60%**
 - **far better quality of care, that drove significant cost savings**
 - varied by hospital and by injury event type

3. A key background principle

Any time *(highly trained, really smart, fully committed)* **humans**
interact with complex systems,
mistakes and failures WILL happen.

Human factors engineering

System design principles based on evidence about how humans predictably fail when interacting with complex environments

**Every major example of safer care
since *Too Err Is Human* was published**

arose from designing support systems that

made it “easier to do it right.”

The human component

1. ***Skill-based performance*** (*autopilot mode*)
2. ***Rule-based performance*** (*if-then response mode*)
3. ***Knowledge-based performance*** (*"figure it out" mode*)

*Called the "Generic Error Modelling System"
Developed by James Reason and Jens Rasmussen*

Skill-based performance

- *A pattern exists in your brain*
- *developed through practice and repetition.*
- **Think “autopilot”** - *driving a car, doing the dishes, typing at a computer keyboard*
- *1 to 3 failures for every 1,000 opportunities or actions (0.1 to 0.3% failure rate)*
- *Humans will detect their own skill-based failures about 60% of the time*

Skill-based performance

Routine actions in familiar environments; little or no thought required; based on learned skills

Skill-based errors take 2 forms:

- 1) **Slips** - *the act is performed wrong (errors of commission)*
 - *misspelling a word on a slide*
 - *arriving at the grocery store when you intended to go to the dry cleaners*
 - ***misplacing a decimal point when writing a prescription (5.0 mg vs 0.5 mg)***
- 2) **Lapses** - *act not performed when required (errors of omission)*
 - *a nurse delivers a dose of medication late*

Reason divides slips and lapses into more refined categories:

- *Recognition failures (mis/non/wrong detection)*
- *Memory failures ("on the tip of my tongue")*
- *Input failures (too much information at one time)*
- *Storage failures (forgetting the plan)*
- *Retrieval failures (forgetting a name)*
- ***Attention failures (getting distracted)***

Rules

- ***Our routine, actionable knowledge of how the world works***
- ***Very common:***
 - *oil and water don't mix*
 - *what goes up, must come down*
 - *while driving, always signal (and check) before a lane change*
 - *you don't tug on Superman's cape, you don't spit into the wind, you don't pull the mask off the old Lone Ranger, and you don't mess around with Jim*
- ***Often takes the form of policies, procedures, and mandatory safe practices***

Rule-based performance

- **The brain perceives a situation,**
- **scans for a rule** *learned through training or from experience*
- **then acts to apply the rule** *(an “if-then” response)*
- **Rule-based errors take 3 forms:**
 - *wrong rule* – *the accepted rule is simply wrong (Columbus discovers America)*
 - *mis-selected a correct rule* *(spelling challenge – most/coast/boast)*
 - *decide not to follow the rule*
- *About 1 failure for every 100 opportunities (1% failure rate)*
- *Humans will detect their own rule-based failures about 20% of the time*

Creating functional rules

1. **Limited number of things that really matter– otherwise they become top heavy and unmanageable** (*max human carrying capacity: ~60 to 100*)
2. **Tested against reality – each rule actually works**
3. **Built into clinical workflow** – *so it doesn't rely on memory*
4. **Regularly reviewed and updated** – *by definition, it's a limited set ... so chose wisely*

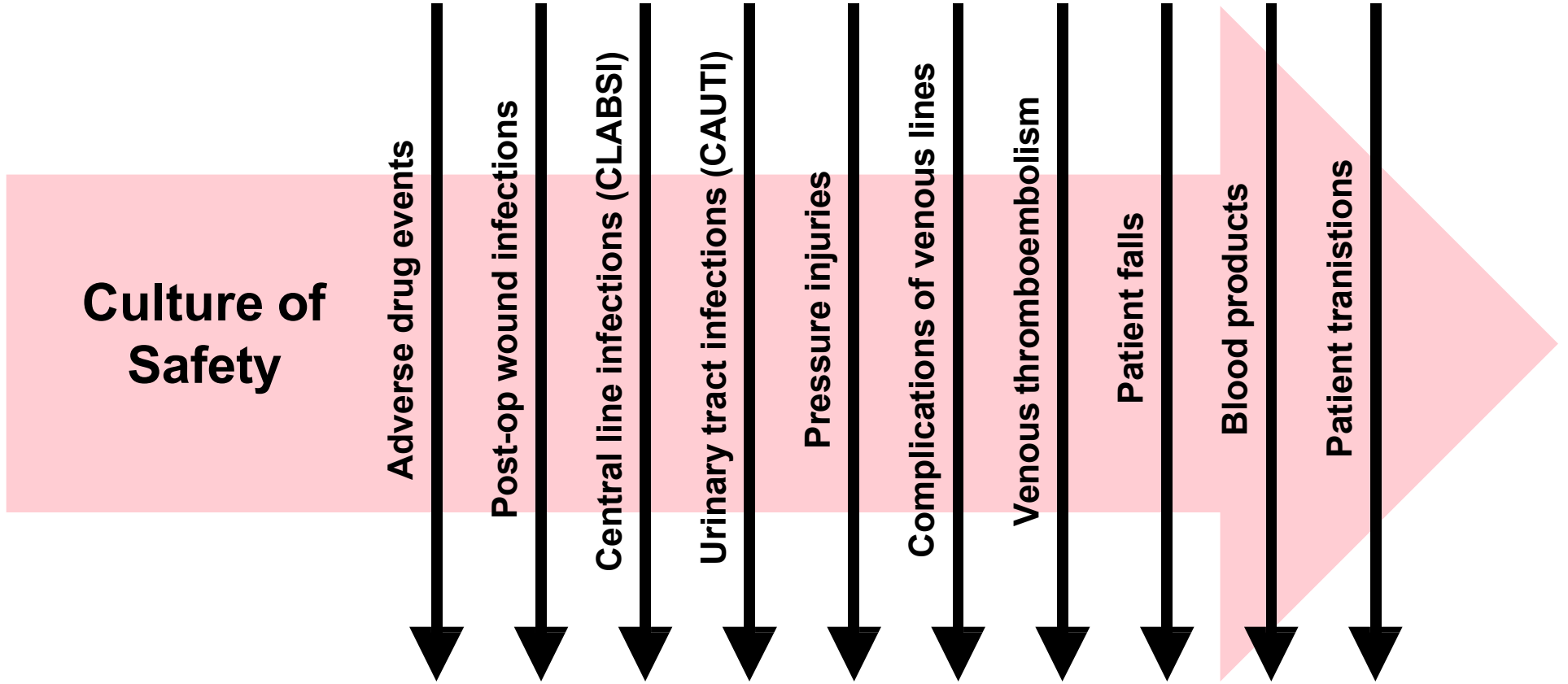
Knowledge-based performance

- ***Rules do not exist or are unknown to those doing the action***
- ***Associated with very complex problems; people working outside their areas of training and expertise, trying to “figure it out”*** (winging it)
- *“lack of knowledge” errors; sometimes called **errors of planning***
(thinking fast, thinking slow; $4+4 = ?$; area of circle 4 cm in diameter = ?)
- *3 to 6 failures for every 10 opportunities* (30-60% failure rate)
- *Humans will detect their own knowledge-based failures only about 10% of the time*

Summary

	<u>% of all injuries</u>	<u>failure rate</u>	<u>self-identify & correct rate</u>
<i>Skill-based</i>	5%	0.1 – 0.3%	60%
<i>Rule-based</i>	67%	1.0%	20%
<i>Knowledge-based</i>	27%	30 – 60%	10%

Process-based approaches *(systems)*



A culture of safety

"... 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

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–*willful and wanton* disregard)
3. failure to report in a timely way (usually, within 48 hours)

Better has no limit ...

an old Yiddish proverb

Assigning culpability for unsafe acts

(modelled from HPI's version of Reason's decision tree)

1. **Deliberate act test**

- *did the person intend the act?*
- *did the person act with malicious intent?*

(malevolent or willful misconduct – consider disciplinary action, legal action)

2. **Impairment test**

- *is there evidence of ill health or substance abuse?*
- *was the person aware of the illness or condition?*

(medical condition / substance abuse – consider health care referral, duty adjustment, leave of absence, substance abuse testing, substance abuse disciplinary action)

3. **Compliance test**

- *did the person depart from policies or generally-accepted performance?*
- *were the policies available, understandable, workable, in routine use?*
- *did the person take an unacceptable risk OR have a history of poor decisions?*
- *were there significant mitigating circumstances that support the action taken?*

(possible reckless or negligent behavior – consider disciplinary action, training, supervision)

4. **Substitution test**

- *would other individuals in the same circumstances have acted the same way?*
- *were there deficiencies in training or supervision?*

(possible unintended error – consider system and cultural redesign)

The extreme: criminal prosecution

RaDonda Vaught, Vanderbilt University Medical Center

- Dec 24, 2017, 75 year-old Charlene Murphey admitted w subdural hematoma
- Dec 26, 2017, scheduled for MRI scan; planned sedation using Versed (midazolam)
- earlier that year, computer system upgrade at Vanderbilt introduced delays; Vanderbilt instructs nurses to use automated dispensing cabinet (ADC) overrides to get medications in a timely way
- Nurse Vaught attempts to get Versed from an ADC, via 2 digit search code – “VE”
- Vaught forced to override – a very common nursing action, at that point; Investigation found that “Overriding was something we did as part of our practice every day. You couldn’t <even> get a bag of <IV> fluids for a patient without using an override function.”
- ADC finds and releases vecuronium, a paralytic agent
- Vaught administers the vecuronium; patient goes into cardiac arrest; resuscitated
- **Vaught immediately reports the error**
- patient taken off life support the next day, dies
- Vanderbilt initially classifies death as due to “natural causes,” does not mention the vecuronium, fails to report the event to federal and State regulators, as required by law
- January, 2018, Vanderbilt investigates then fires Vaught
- Vanderbilt settles with Murphey’s family; includes non-disclosure clause in settlement
- in 2018, an anonymous whistle blower reports the death; CMS investigates
- later in 2018, Tennessee DoH Board of Nursing investigates, takes no disciplinary action; in 2019 the Board reopens the case; in 2021, revokes Vaught’s nursing license, fines her \$3,000, and requires that she pay up to \$60,000 in “prosecution costs”
- Mar 25, 2022, RaDonda Vaught convicted at jury trial of “gross neglect of an impaired adult and negligent homicide”; sentenced to 3 years’ probation