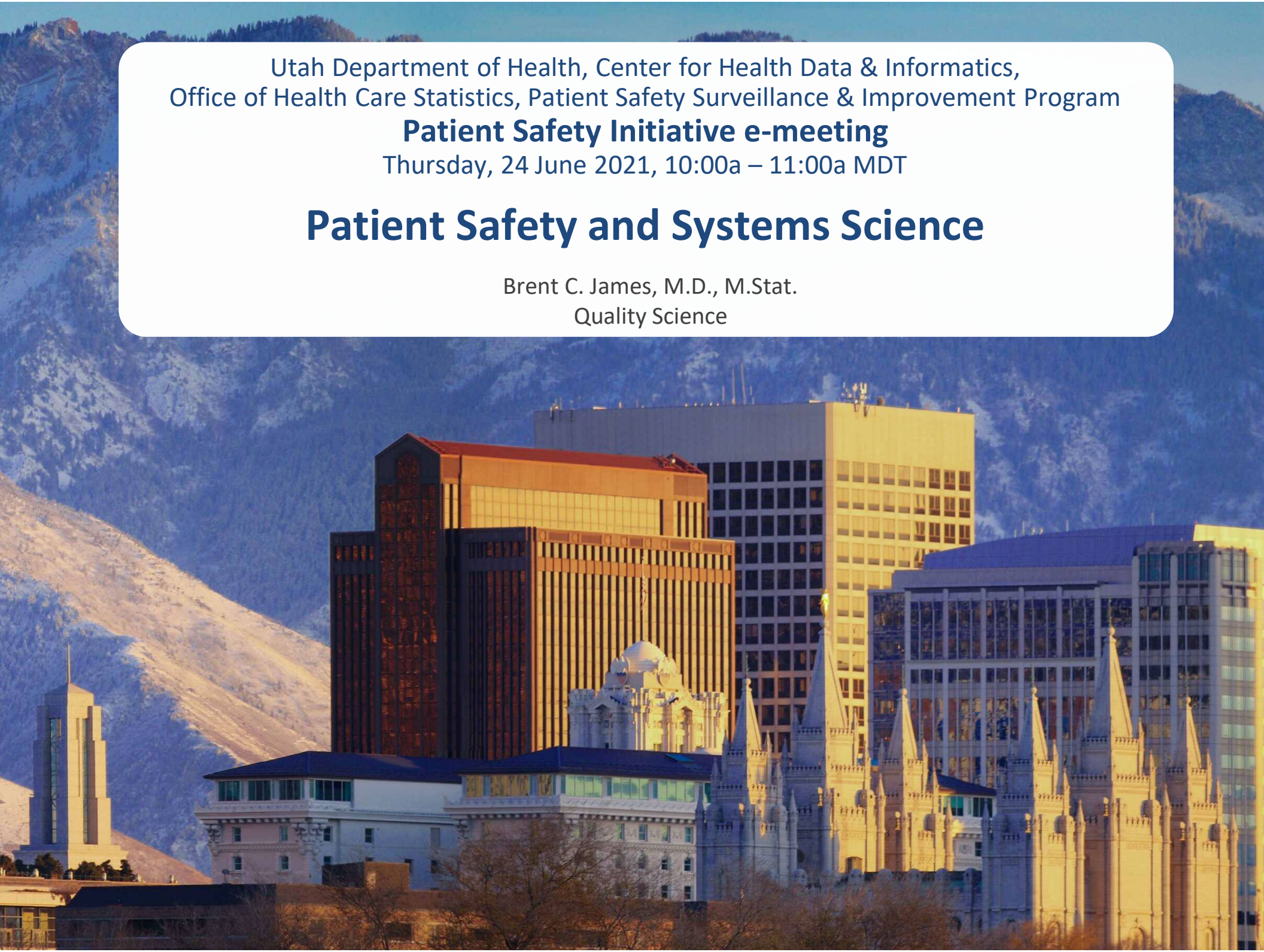


Utah Department of Health, Center for Health Data & Informatics,
Office of Health Care Statistics, Patient Safety Surveillance & Improvement Program

Patient Safety Initiative e-meeting

Thursday, 24 June 2021, 10:00a – 11:00a MDT

Patient Safety and Systems Science

Brent C. James, M.D., M.Stat.
Quality Science

Disclosures

*I receive a monthly retainer as a part time (3 days / month) senior advisor for **Health Catalyst**.*
I also own (a small amount of) Health Catalyst stock.
*I serve on an advisory board for **Amplifire**,*
a privately-held company that provides computer-based health care education products.

Other than that, neither I nor any family members have any relevant financial relationships to be directly or indirectly discussed, referred to or illustrated within the presentation, with or without recognition.

Outline

1. ***Detecting care-associated injuries***

2. ***When humans interact with complex systems***

3. ***Some design ideas for safety systems***

Part 1:

Detecting care-associated injuries:

You can't fix what you can't find

November 30, 1999:

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

Committee on Quality of Health Care in America

releases 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 to 98,000 preventable deaths each year

in the United States

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

Injuries drive direct health care costs totaling

$9 to 15 billion per year

Thomas et al. *1999*
Johnson et al. *1992*

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.

When preparing *To Err Is Human*, we knew we were being conservative

Two areas of further research:

1. ***Structured chart review***

2. ***Real-time detection of injuries***
   - *examine treatment patterns, as care happens*
   - *allows on-the-fly intervention, interrupting worse injury*

Estimates of hospital injury rates

	Charts reviewed	Injury rate	% judged preventable	Projected avoidable deaths
HMPS (1984 data)	~34,000	3.7%	58%	98,000
Utah-Colorado (1992 data) (Dr. Eric Thomas)	15,000	2.9%	53%	44,000
Australian AE (1992 data)	14,179	16.6%	51.2%	
Australian AE (corrected)		8.5% (Dr. Eric Thomas)		
Australian AE at LDSH		10.2%	(??!! ~2.0% in Utah-Colorado!)	
Canada AE (2000 data)	3,745	7.5%	36.9%	

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 during index admission*** *(max = 7)*

Rate	Severity Level
53%	E - temporary harm, required intervention
33%	F - temporary harm, initial or prolonged hospitalization
3%	G - permanent harm
7%	H - intervention required to sustain life
1%	I - patient death

Rate	Source
52%	medications
20%	procedure complications
13%	infections
8%	care issues
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.

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).

At one "gold standard" hospital *(LDSH)*

Number of SSEs reported in entire State** (73 hospitals)**:** **36

***Number of SSEs reported in "gold standard" hospital:** **9** (6.7%)*

Number of SSEs that actually occurred in that hospital:** **134

9.1% of all hospital admissions
arose from injuries associated w outpatient care

R. Scott Evans, PhD *(LDSH)*

- ***Based in Dept of Infectious Disease***
- ***Tasked to assess adverse drug events*** *(antibiotics, mostly)*
- ***Conclusion: Most ADEs were not reported*** *within the SSE system*
- ***Possible drivers: fear, administrative burden***

- ***Major insight:***

Even if the clinical team did not report the event,
they almost certainly still treated the patient's symptoms …

- ***Might it be possible to***

detect potential injuries but evaluating treatments patterns?

Tx patterns for detecting ADEs

	Detection criterion	Location	True Positive Rate (%)	% of All ADEs Detected	Cumulative Total (%)
1.	use of **naloxone**	pharmacy	21.9	28.3	28.3
2.	use of **benadryl**	pharmacy	21.0	20.8	49.1
3.	use of **inapsine**	pharmacy	39.2	20.4	69.5
4.	use of **lomotil**	pharmacy	26.8	8.5	77.0
5.	nurse reports of **rash/itching**	nurse reporting	17.9	5.1	82.1
6.	use of **loperamide**	pharmacy	22.3	3.4	85.5
7.	**test for c. deficile toxin**	clinical lab	24.3	3.1	88.6
8.	**digoxin level > 2**	clinical lab	2.3	2.2	90.8
9.	**abrupt med stop or reduction**	pharmacy	48.0	1.0	91.8
10.	use of **vitamin K**	pharmacy	4.8	0.9	92.7
11.	**doubling of blood creatinine**	clinical lab	0.4	0.8	93.5
12.	use of **kaopectate**	pharmacy	21.8	0.7	94.2
13.	use of **paregoric**	pharmacy	9.8	0.7	95.0
14.	use of **flumazenil**	pharmacy	77.3	0.7	**95.7**

Source: Dr. Samuel Henz, Zurich, Switzerland.

Detecting Adverse Drug Events

# of ADEs / % (# per annum)	Nurse Incidence Reporting	"Enhanced" Reporting	HELP System
Total ADEs	9 / 0.025% (6)	91 / 0.25% (60)	731 / 2.0% (487)
Moderate and severe ADEs			701 / 1.9% (467)

3 methods to detect injury events

1. ***Voluntary reporting*** *(a.k.a. "Sentinel Event reporting")*
   - *the traditional method that pretty much everybody routinely uses*

2. ***Retrospective chart review***
   - *uses structured "trigger" elements found in the post-discharge chart*
   - *finds more than **10x** more events than voluntary reporting*
   - *"after the fact" – no chance to intervene in real time*

3. ***Prospective treatment-based review triggers***
   - *uses real-time treatment patterns to detect possible events*
   - *finds more than **10x** more events than voluntary reporting*
   - *allows real-time intervention, reducing injury impact / severity*
   - *complements structured chart review – each finds things that the other misses*

Overall, voluntary** (sentinel event) **reporting finds only about 1 in 100 of all actual injury events

Institute of Medicine Committee on Data Standards for Patient Safety. *Patient Safety: Achieving a New Standard of Care.* Aspden, Philip, Corrigan, Janet M., Wolcott, Julie, and Erickson, Shari M., editors. Washington, DC: National Academy Press, 2001 (Nov 20).

Traditional voluntary injury detection systems

under-detect by a factor of 10-150;

the main element that drives under-reporting is

~~***fear***~~

failure to link patient symptoms to treatment

(fear is #2)

Key findings from these studies

- ***Voluntary reporting*** *(SSEs)*

  grossly under-detects

- ***With better detection systems,***

  very different

  safety improvement priorities emerge

- ***The Patient Safety Indicator (PSI) system***

  fails completely

In a "gold standard" evaluation,

- *true positive rate = 5.8%*
- *false positive rate ≈ 50%*
- *PSIs were not built for these purposes (Dr. Gregg Meyer, while at AHRQ)*
- *better system are available*
- *PSIs should not be used for national reporting or comparisons*

The real preventable death rate

about ***210,000 preventable deaths each year***
just in hospitals

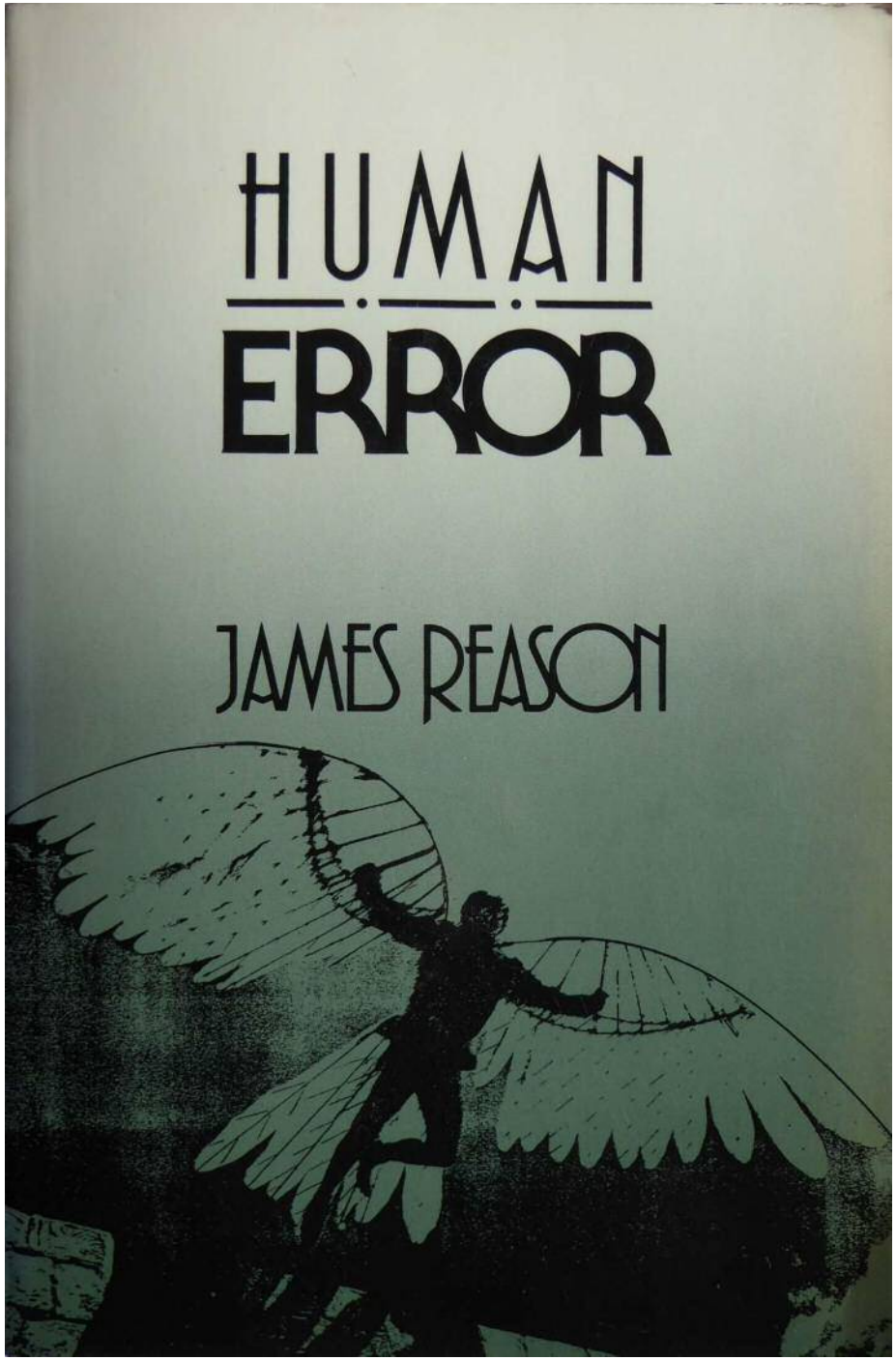
(doesn't include deaths arising from care in outpatient settings, which are probably more frequent than deaths in inpatient settings)

- *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).

Part 2:

Errors versus systems



Complex systems and humans

Core premises:

- ***Anytime*** *really smart, well-trained, extremely careful, deeply dedicated, highly motivated, well-rested,* ***human beings interact with complex systems,***

failures will occur.

- ***Such failures have detectable patterns.***
- ***It is possible to redesign the system, anticipating failure patterns; and thus***

greatly reduce failure *(harm)* ***rates.***

Human factors engineering

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

What does “error” mean?

The intuitive viewpoint *– someone messed up; they made an avoidable mistake* *(inherently pejorative; think bad apple, malpractice actions)*

versus

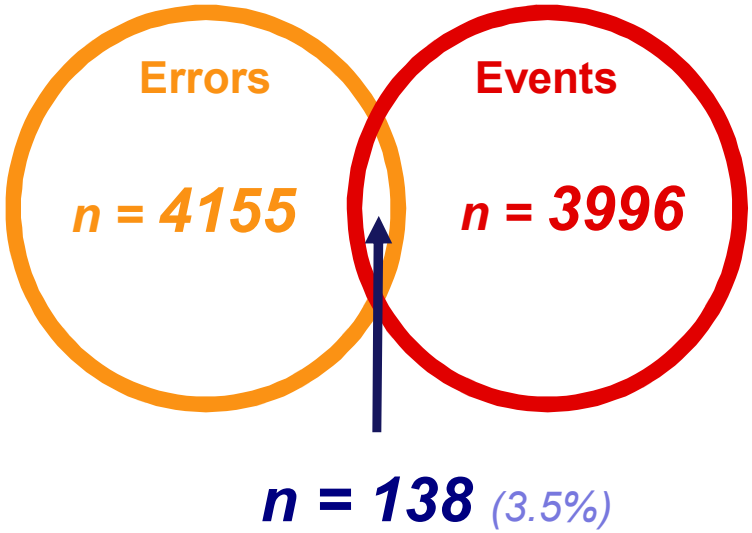
A rigorous technical definition

Causes of Adverse Drug Events

Class	%	Description	Avoidable?
Pharm Expected	28.0	Known drug reactions	?
Physio Renal	23.0	Failure to adjust for decreased renal function	Yes
Physio Age	14.2	Failure to adjust for patient age	Yes
Physio Weight	5.7	Failure to adjust for patient body mass	Yes
Order Dosage	5.0	Error in dosage on order	Yes
Physio Hemal	4.6	Failure to adjust for known hematologic factors	Yes
Total preventable	**66.2**		

Sources of injuries

Prospective daily surveillance of 202,222 inpatients for the occurrence of medication errors and adverse drug events



n = 138 *(3.5%)*

Definition of medication errors: Assumes that the physician orders correctly, but that the pharmacist then prepares the medication incorrectly, or that the nurse delivers it incorrectly. Specifically, (1) wrong preparation, (2) wrong dose, (3) wrong route of delivery, (4) wrong rate of delivery, and/or (5) wrong patient.

Key findings in *To Err Is Human*:

- ***Injuries occur because of system failures***
- ***Preventing injuries means designing safer systems of care***
- ***Organizations*** *(think senior administrators), not individual physicians, nurses, or other health professionals,* ***control those systems of care***

Committee on Quality of Health Care in America. *To Err is Human.* Institute of Medicine, 1999.

You must choose

Is your main purpose to (1) find common patterns of failure, then build robust systems that anticipate and prevent injuries (a "patient first" strategy);

or to

(2) identify and punish "negligent" professionals?

*All major improvements in patient safety, over the past 20+ years, have come from the **first** method.*

If you want to reduce harm,

think "injuries," not "errors"

Merely using the term "error" will subconsciously push you down the wrong path …

(in the vast majority of instances) you will harm the innocent, and you will not make care safer.

(There are "bad apple" clinicians out there, but they are quite rare. When we do find them, leadership has an obligation to appropriately respond. However, helping good people perform better has a dramatically bigger overall impact than removing the bad apples. Do both, but with most of your effort directed toward understanding failure patterns, then building safer systems of care.)

Part 3:

Some timely system design ideas

The human component *(Reason's technical defn of "error")*

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)*
- *Input failures (too much information at one time)*
- *Retrieval failures (forgetting a name)*
- *Memory failures ("on the tip of my tongue")*
- *Storage failures (forgetting the plan)*
- *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*
- ***In health care, usually takes the form of policies, procedures, and mandatory safe practices***
- ***Benefit from built-in structures; for example, can take the form of things like checklists***

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*

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

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

For skill-based performance

Training *(and a commitment to personal excellence)* ***counts …***

If you haven't already, review Denver-based computerized training system ***Amplifire****'s approach*

For rule-based performance …

How many rules can a human being remember and properly apply at one time?

generously, perhaps 60 to 100

How many rules does a typical health system have "in play" at any given point in time?

1,000+

Creating functional rules

1. ***Limited number of rules, only for things that really matter*** *– otherwise, they become unmanageable*

2. ***Tested against reality – each rule actually works***

3. ***Built into clinical workflow*** *– so they don't rely on human memory to call them forth and correctly include all necessary steps*

4. ***Regularly curated, reviewed and updated*** *– by definition, it's a limited set … so choose wisely*

To return to our earlier case study

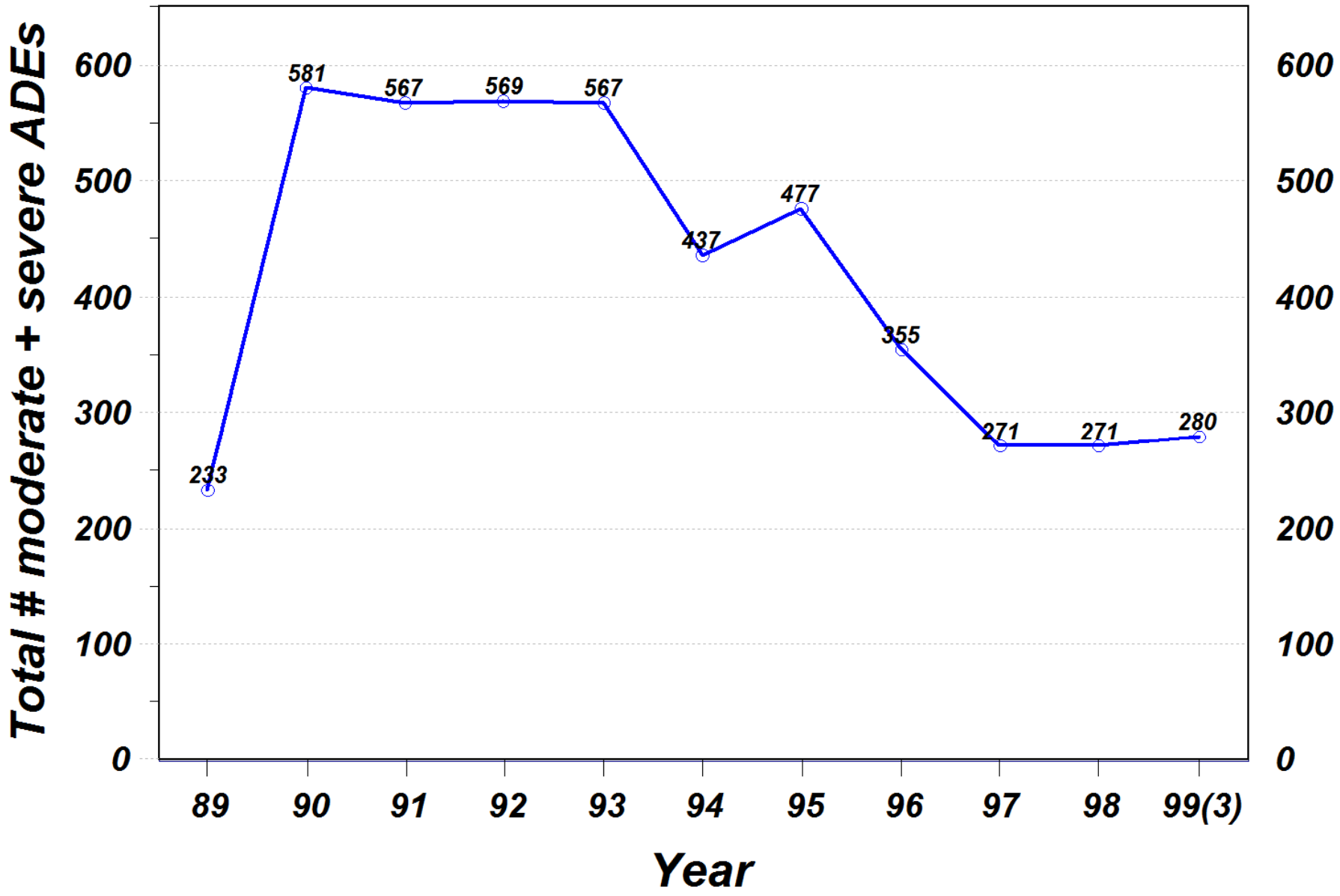
1. ***The LDSH team built a computer application***

2. ***It tested every dose of every drug, before it was given*** *– some things considered: age, gender, known allergies, allergenicity, body mass, estimates of kidney function, estimates of liver function, other blood chemistry values, etc.*

3. ***As appropriate, recommended alternative medications, dosing, etc.***

These sorts of systems have since become quite common …

ADEs at LDS Hospital



One last idea …

A question:

What is the single most important factor that determines

- *clinical quality of care / patient experience of care*
- *perceptions in the community* (*"back door" advertising – dramatically more effective than any other modality in driving patient volume and market share)*
- *productivity*
- *long-term financial performance?*

The answer:

Medical staff and workforce engagement / morale

Prominent thought leader: Dr. Stephen J. Swensen

- *recently retired from Mayo Clinic* (*Mayo's Chief Quality Officer, then head of Leadership Development)*
- *now lives in Heber, Utah* (*avid Nordic skier)*
- *his new book on the topic came out on 7 February 2020 –* Mayo Clinic Strategies to Reduce Burnout

Another possible resource: Jill Green, COO, Mission Health, North Carolina
(*c/o Health Catalyst)*

Better has no limit ...

an old Yiddish proverb