The Quality Colloquium
on the Campus of Harvard University
Annenberg Hall, Harvard University, Cambridge, Massachusetts
Monday, 23 August 2004 -- 9:00a - 9:45a

An Overview of the Quality Challenge

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The emergence of modern medicine

~1860 - 1910:

- ***new high standards for clinical education***
- ***strict requirements for professional licensing***
- ***clinical practice founded on scientific research***
- ***new internal organization for hospitals***

1912 : The 'Great Divide'

"... for the first time in human history, a random patient with a random disease consulting a doctor chosen at random stands a better than 50/50 chance of benefitting from the encounter."

Harvard Professor L. Henderson

(Harris, Richard. *A Sacred Trust*. New York, NY: New American Library, 1966)

Current health care

is the best the world has ever seen

A few simple examples:

- ***From 1900 to 2000, average life expectancy at birth increased from only 49 years to almost 80 years.***
- ***Since 1960, age-adjusted mortality from heart disease (#1) has decreased by 56%; and*** *(from 307.4 to 134.6 deaths / 100,000)*
- ***Since 1950, age-adjusted mortality from stroke (#3) has decreased by 70%.*** *(from 88.8 to 26.5 deaths / 100,000)*

Initial life expectancy gains almost all resulted from public health initiatives -- clean water, safe food, and (especially) widespread control of epidemic infectious disease. But since about 1960, direct disease treatment has make increasingly large contributions.

Centers for Disease Control. Decline in deaths from heart disease and stroke--United States, 1900-1999. *JAMA* 1999; 282(8):724-6 (Aug 25).

National Center for Health Statistics. *Health, United States, 2000 with Adolescent Health Chartbook.* Hyattsville, MD: U.S. Dept. of Health and Human Services, Center for Disease Control and Prevention, 2000; pg. 7 (DHHS Publication No. (PHS) 2000-1232-1).

U.S. Department of Health and Human Services, Public Health Service. *Healthy People 2000: National Health Promotion and Disease Prevention Objectives.* Washington, DC: U.S. Goverment Printing Office, 1991 (DHHS Publication No. (PHS) 91-50212).

Dr. John Wennberg

- ★ ***Geography is destiny*** *("Who you see is what you get" *)*
- ★ ***There is no health care "system"***
- ★ ***Supplier-induced demand:***
  - ◆ *Field of Dreams approach: Build it and they will come*
  - ◆ *James T. Kirk: Do something, Bones! She's dying!*
  - ◆ *Eddy: More is better -- if it might work, do it*
  - ◆ *Chassin: Enthusiasm for unproven methods*
  - ◆ *Boston City / Boston University Hospital, 1998:*
    - ▸ *Same housestaff on both services*
    - ▸ *More beds / easier access to resources on Boston University service*
    - ▸ *Boston University readmit rate ~50% higher*

* *Richard Deyo, MD, MPH - in: Cherken, Deyo, Wheeler and Ciol. Physician variation in diagnostic testing for low back pain.* Arth & Rheum *1994; 37(1):15-22 (Jan).*

November 30, 1999:

The Institute of Medicine

Committee on Quality of Health Care in America

announces its first report:

To Err is Human: ***Building a Safer Health System***

Medical injuries

Account for

44,000 - 98,000 deaths per year

in the United States

More people die from medical errors than from breast cancer or AIDS or motor vehicle accidents

Brennan et al. *New Engl J Med 1991*
Thomas et al. *1999*

Direct health care costs totaling

$9-15 billion per year

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

November 20, 2003:

The Institute of Medicine

Committee on Patient Safety Data Standards

announces a major follow-on report:

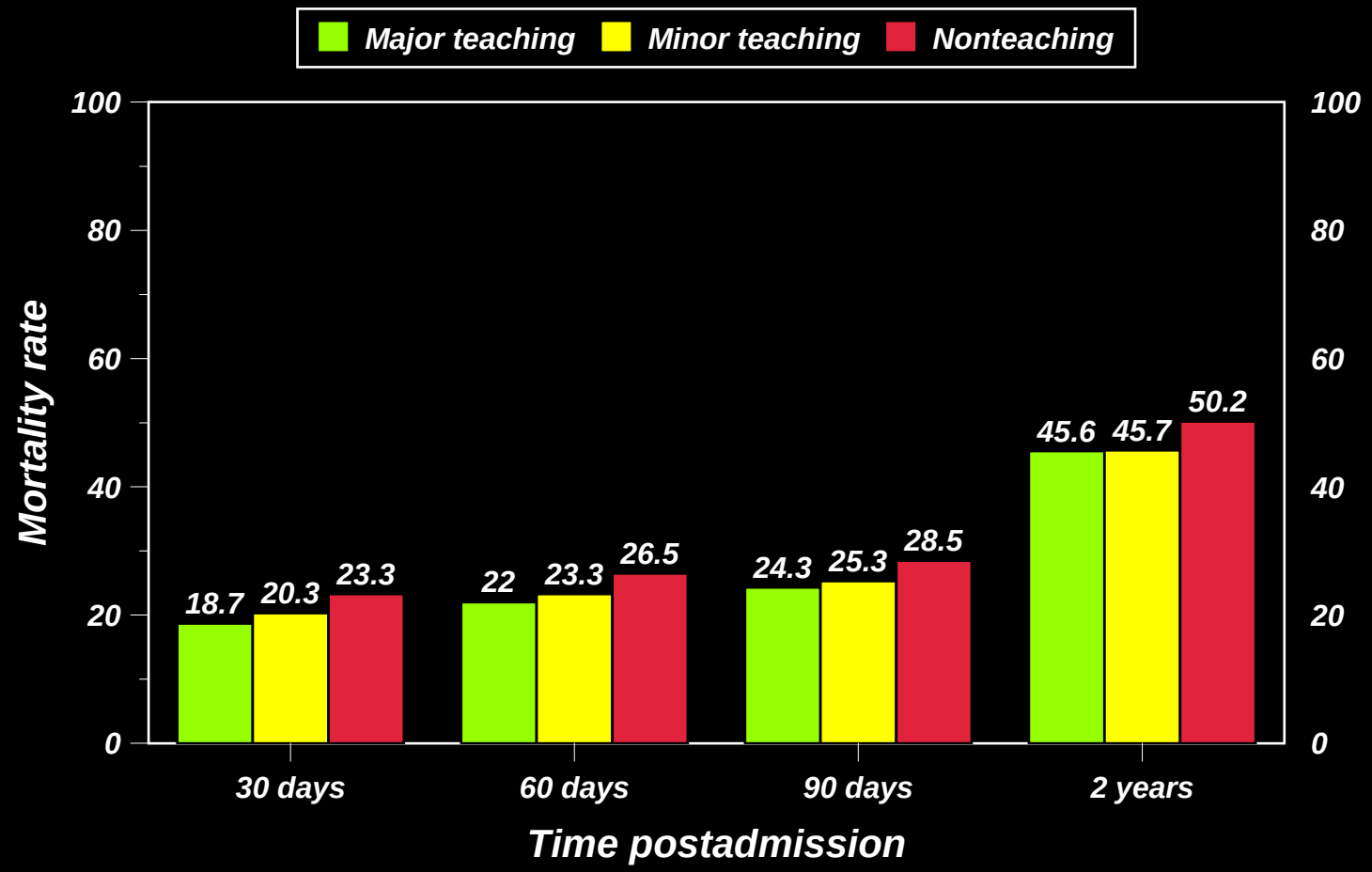
Patient Safety: ***Achieving a New Standard for Care***

Injuries of commission

versus

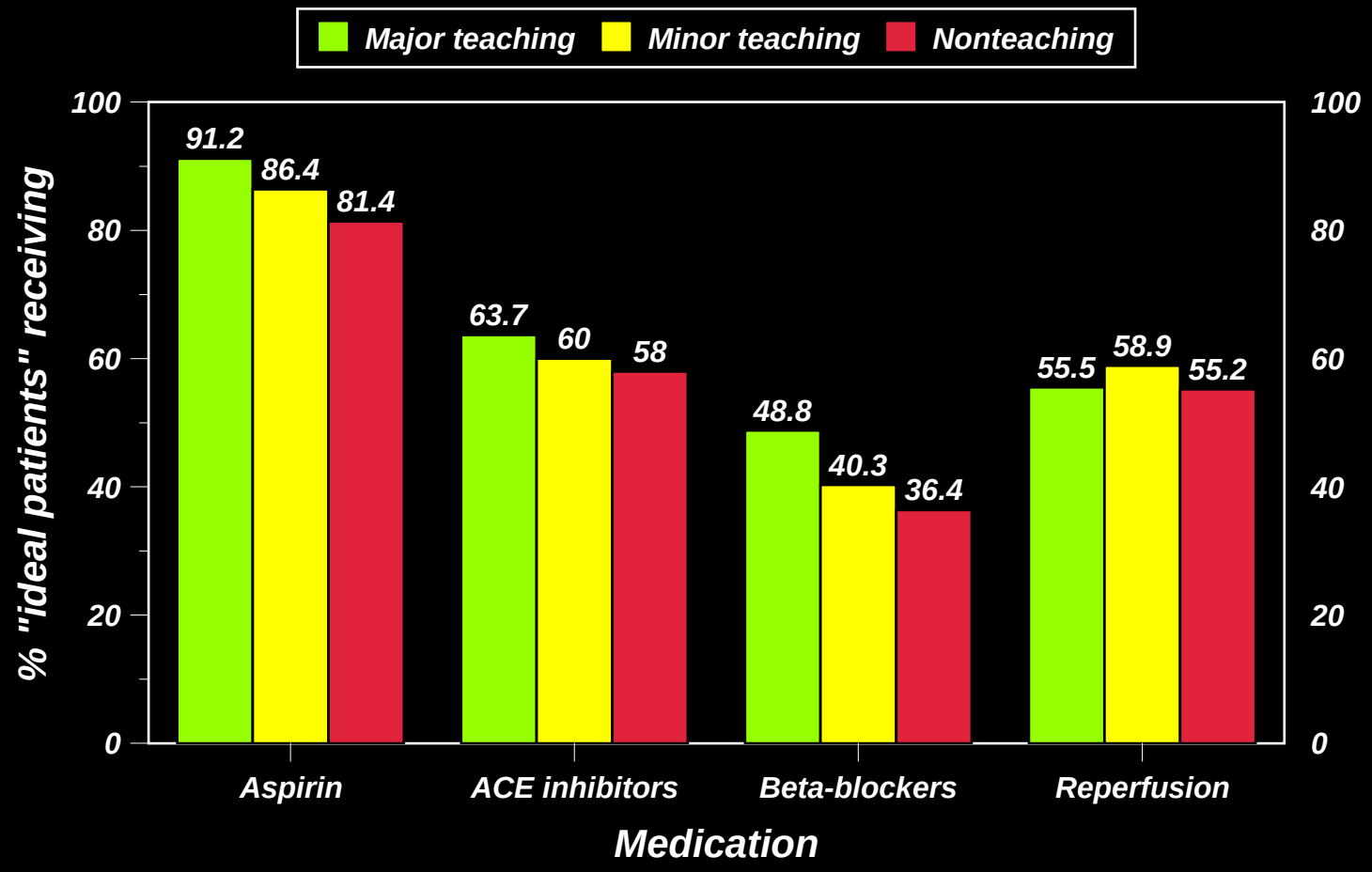
Injuries of omission

How good is American health care?



Allison JJ *et al*. Relationship of hospital teaching with quality of care and mortality for Medicare patients with acute MI. *JAMA* 2000; 284(10):1256-62 (Sep 13).

How good is American health care?



Allison JJ *et al*. Relationship of hospital teaching with quality of care and mortality for Medicare patients with acute MI. *JAMA* 2000; 284(10):1256-62 (Sep 13).

American health care
"gets it right"
54.9%
of the time.

McGlynn EA, Asch SM, Adams J, *et al*. The quality of health care delivered to adults in the United States. *N Engl J Med* 2003; 348(26):2635-45 (June 26).

Are most injuries unavoidable?

The price we pay

(for)

diseases of medical progress

Barr, David. Hazards of modern diagnosis and therapy - the price we pay. *JAMA* 1955; 159(115):1452-6 (Dec 10)
Moser, Robert H. Diseases of medical progress. *N Engl J Med* 1956; 255(13):606-14 (Sep 27)

High frequency injuries sources

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

Detecting Adverse Drug Events

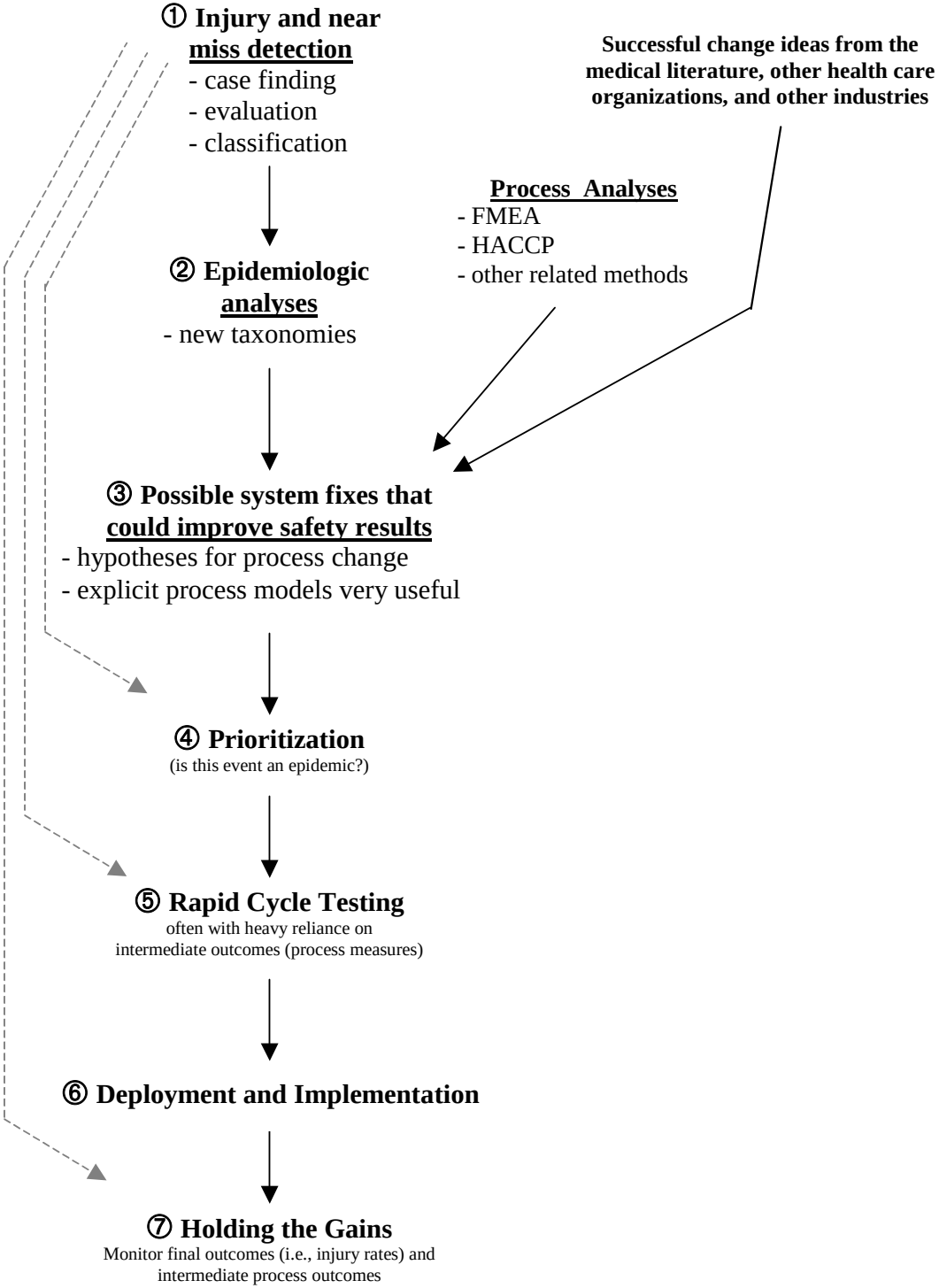
# of ADEs / % (# per annum)	Nurse Incidence Reporting	"Enhanced" Reporting	HELP System
Total ADEs	9 / 0.025% (6)	91 / 0.25% (60)	731 / 2.0% (487)
Moderate and severe ADEs			701 / 1.9% (467)

Simple criteria 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

Tracking injuries

- ***Current** (voluntary reporting) **systems miss the vast majority of injuries** (finding only 1 in 100-150 injuries)*
- ***Most often** (e.g., > 80% of the time for ADEs)**, clinical teams don't associate patient symptoms with the treatments that are causing them***
- ***A more accurate perception of sources of injury can hugely change intervention strategies***


① Injury and near miss detection
- case finding
- evaluation
- classification
Successful change ideas from the medical literature, other health care organizations, and other industries
Process Analyses
- FMEA
- HACCP
- other related methods
② Epidemiologic analyses
- new taxonomies
③ Possible system fixes that could improve safety results
- hypotheses for process change
- explicit process models very useful
④ Prioritization
(is this event an epidemic?)
⑤ Rapid Cycle Testing
often with heavy reliance on intermediate outcomes (process measures)
⑥ Deployment and Implementation
⑦ Holding the Gains
Monitor final outcomes (i.e., injury rates) and intermediate process outcomes

Detecting patient safety events

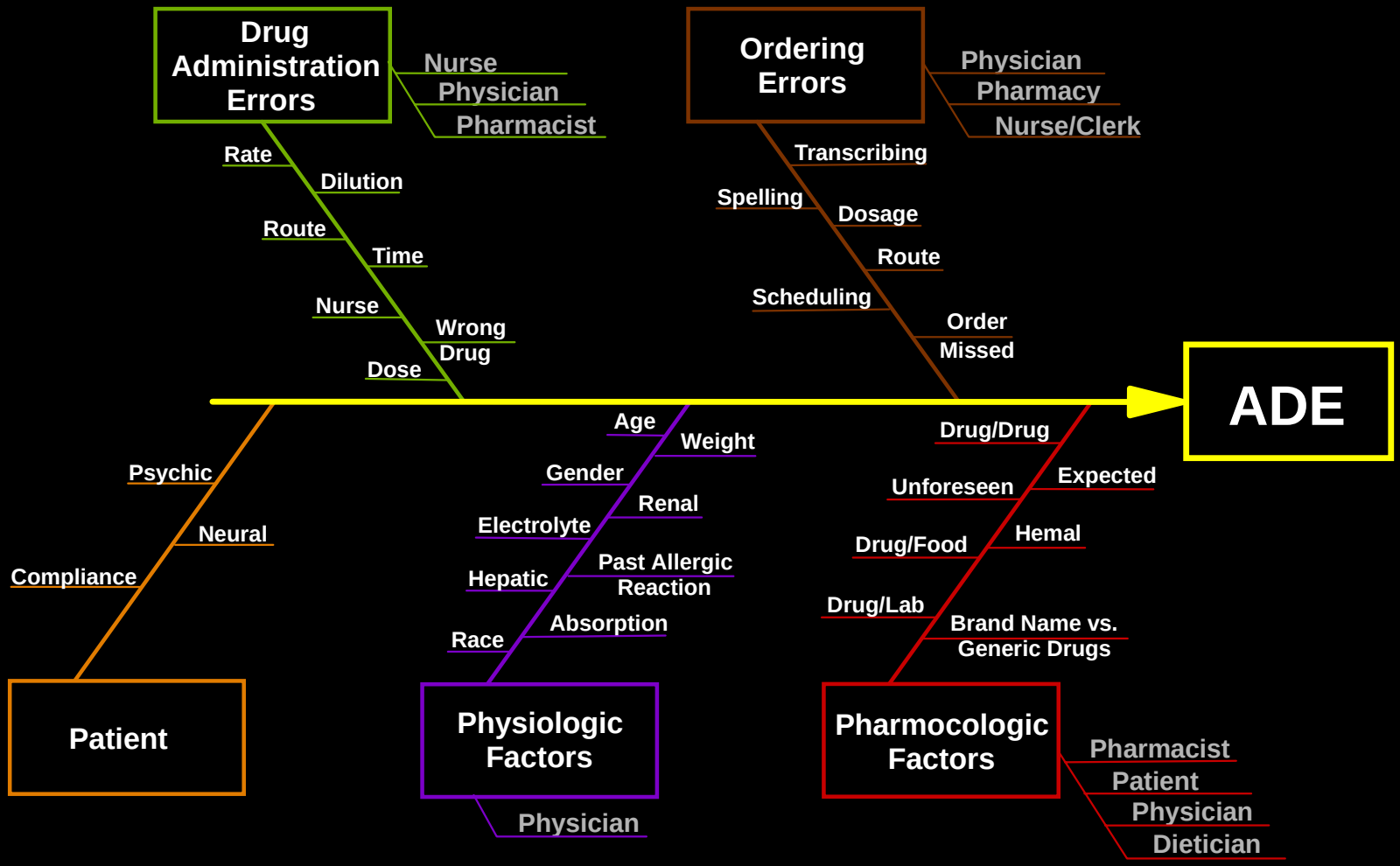
External
data system
audit

1. ***Case finding*** *(based on explicit criteria)*
2. ***Evaluation*** *(based on explicit criteria)*
3. ***Classification*** *(based on explicit criteria)*

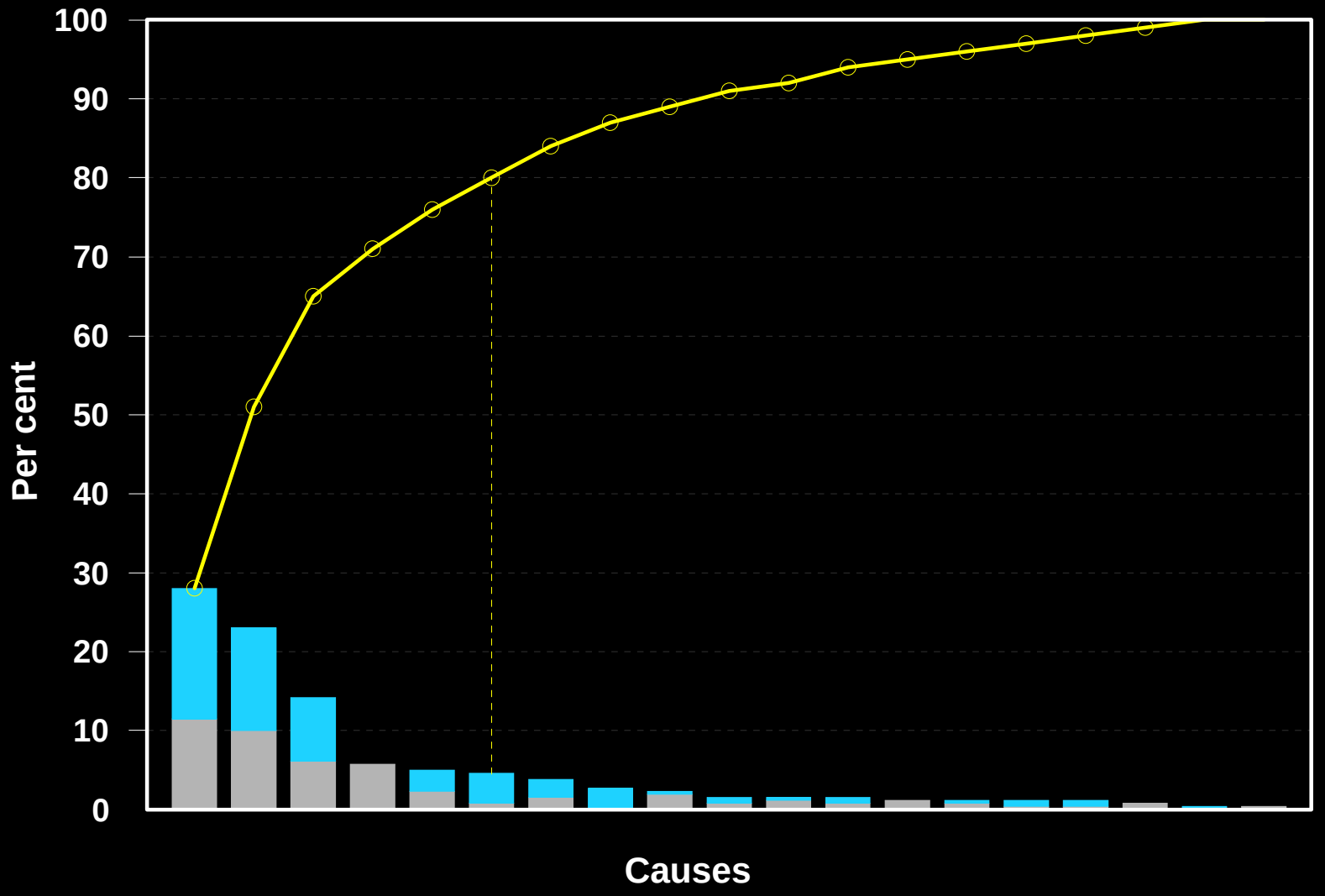
Case finding

Common events	Prospective data-based trigger systems	Retrospective data-based trigger systems	Criteria-based chart review (e.g, QaRNS, JCAHO SE, NQF "Never Events")	Voluntary reporting (in a Culture of Safety)
Adverse drug events	LDSH / B&W	Utah-Missouri (AHRQ)	Relatively poor event detection rates	Relatively poor event detection rates
Iatrogenic infections	CDC infection control	x		
Pressure injury	x	x		
Mechanical device failures	LDSH	LDSH		
Venous lines	x	x		
VTE	x	x		
Transfusions	x	x		
Patient falls	B&W	x		
Patient transitions	x	x		
Rare events				
"Wrong" surgery	X	X	Current most effective method	Current most effective method
Kidnapping				
Suicide				
- etc. -				

Preventable causes of ADEs



Causes of Adverse Drug Events

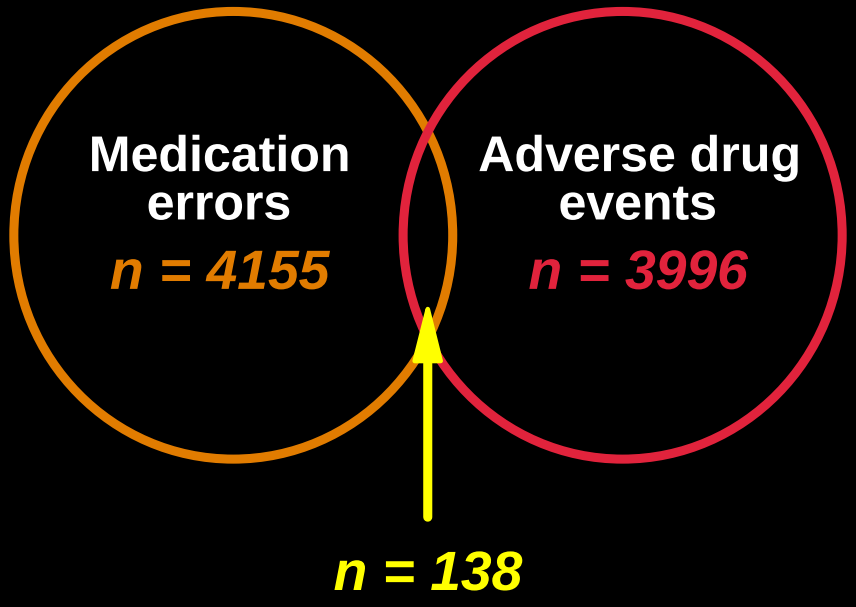


Causes of Adverse Drug Events

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**		

Medication errors vs. ADEs

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



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.

Attack injuries, not errors

What is classified as an "error"
derives from what is judged to "preventable;"

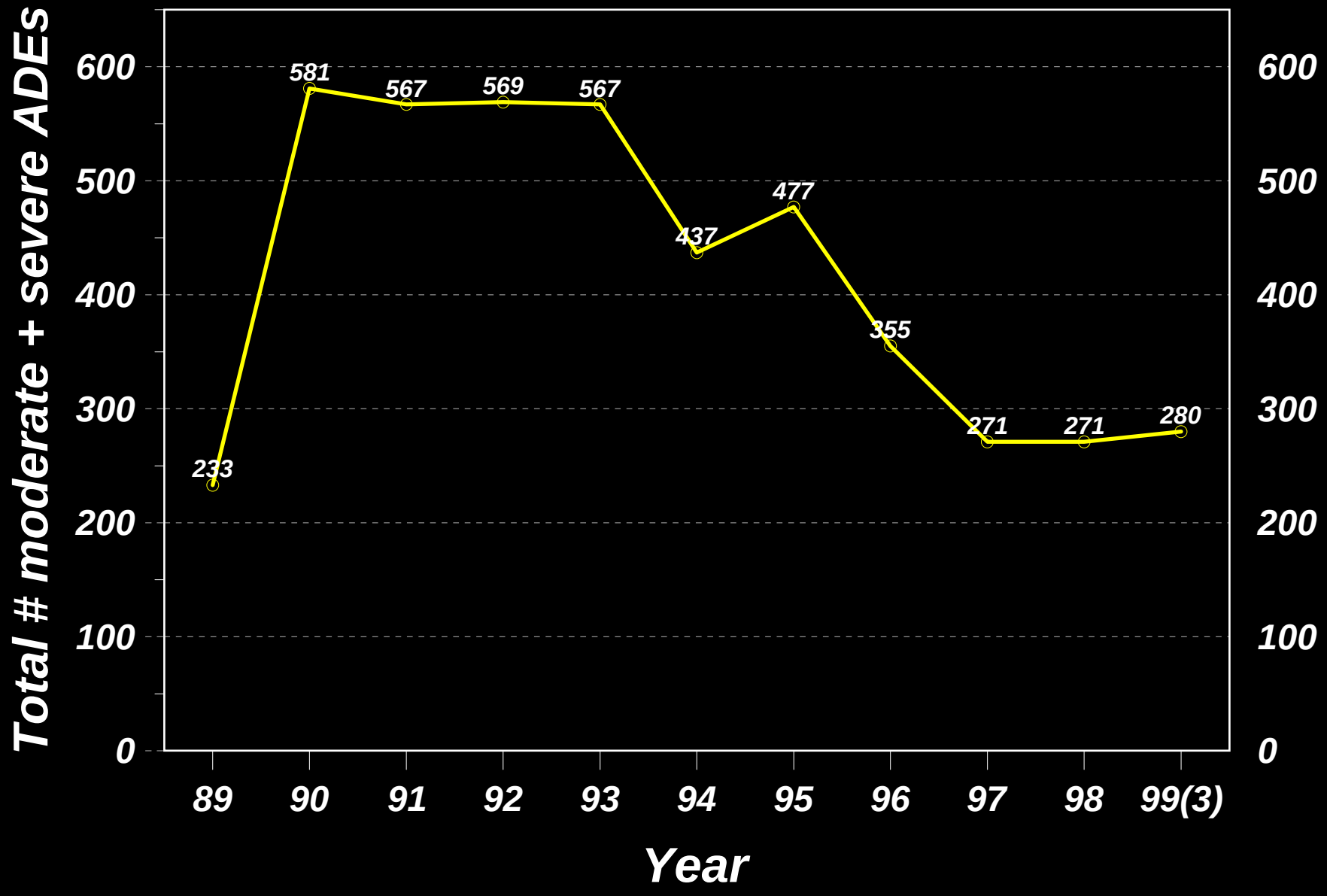
but, at this stage, those (subjective) judgments may be perverted by the "name, shame, and blame game," and seriously misinformed.

It is more useful to think in terms of "medical injuries" rather than "errors."

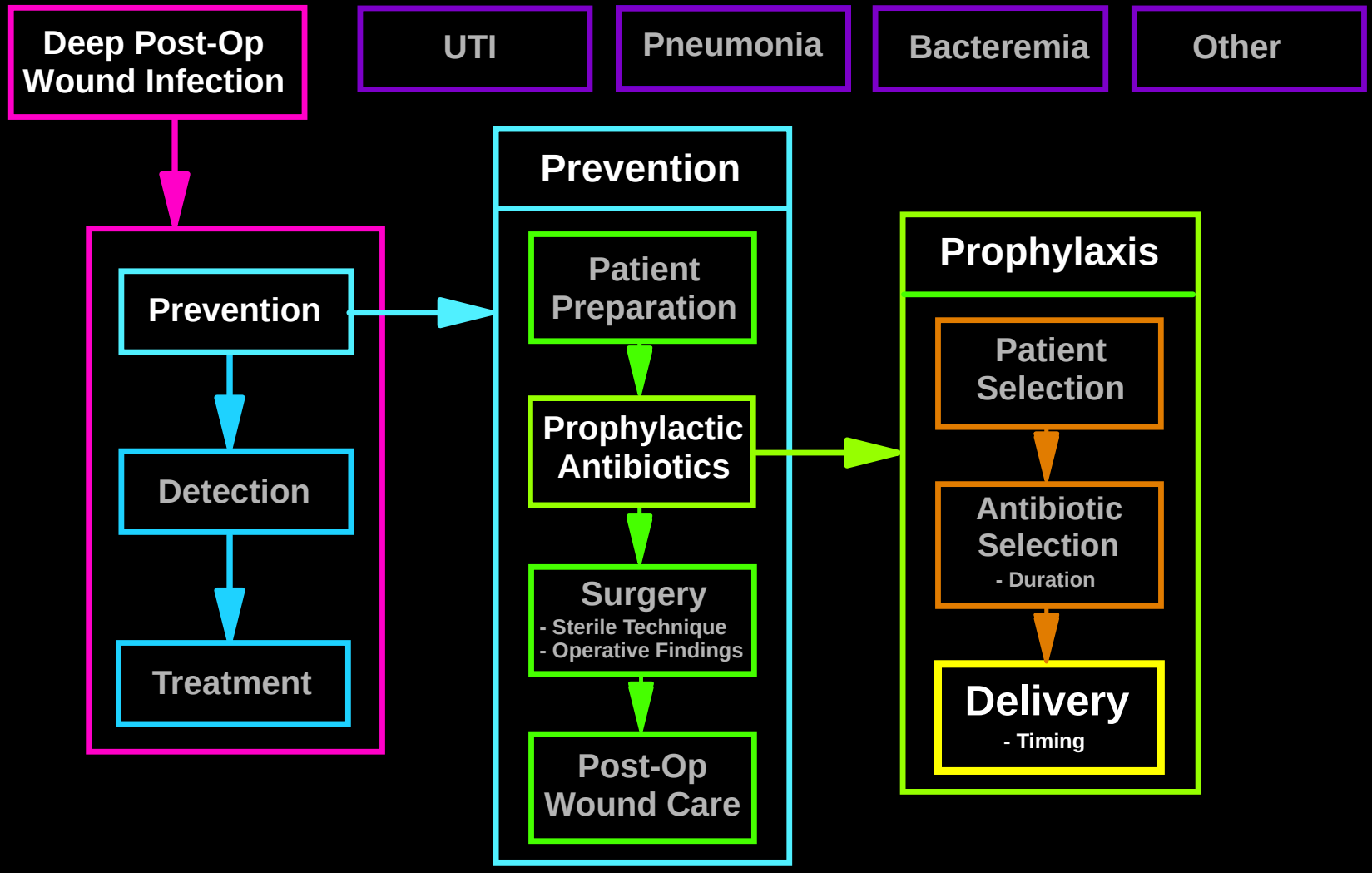
A Culture of Safety

- *Shared beliefs and values about the health care delivery system;*
- *Recruitment and training with patient safety in mind;*
- *Organizational commitment to detecting and analyzing patient injuries and near misses;*
- *Open communication regarding patient injury results, both within and outside the organization;*
- *The establishment of a "just" culture.*

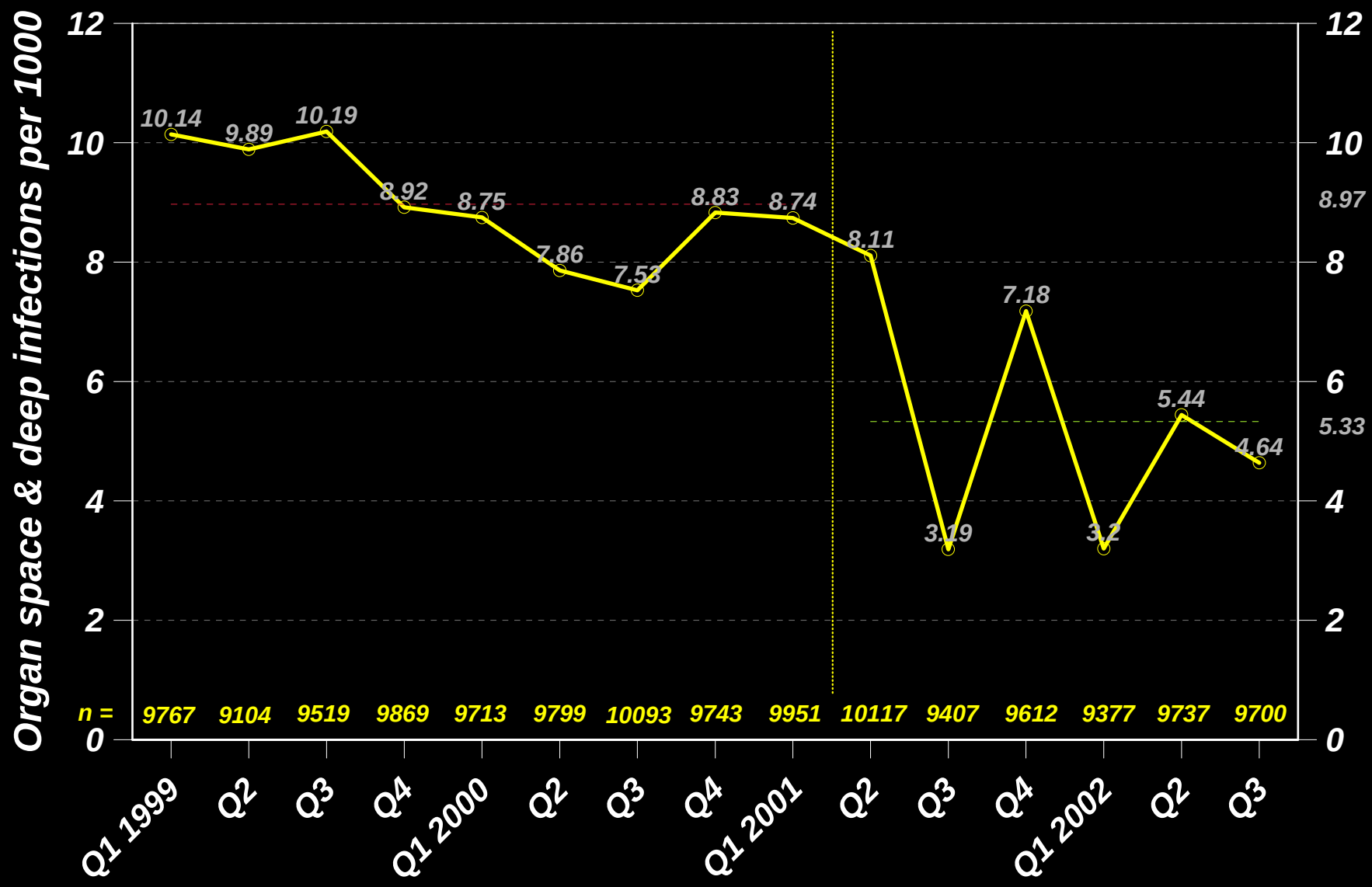
ADEs at LDS Hospital



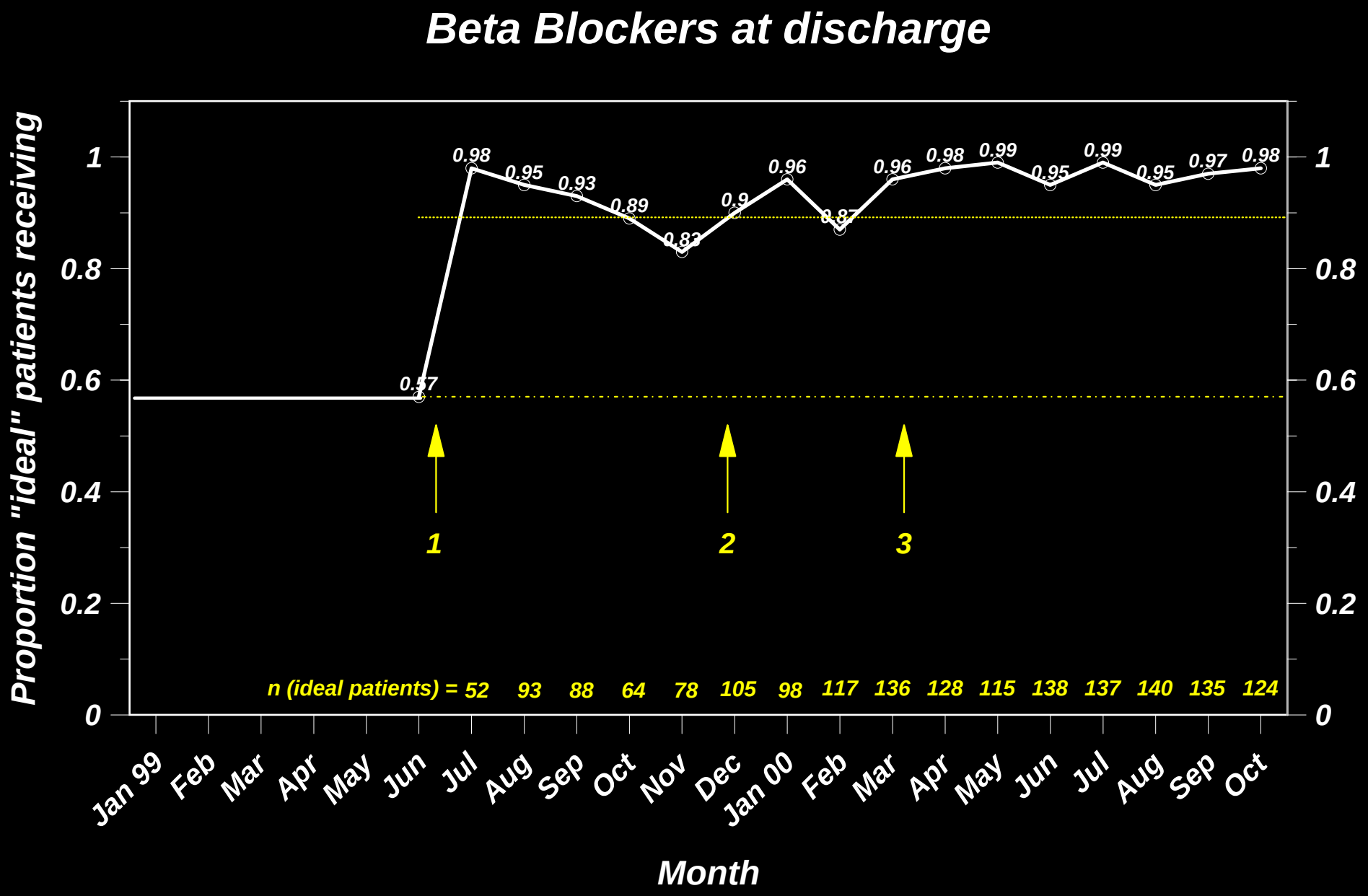
Nosocomial infections



Prophylactic antibiotics on time



Beta blockers at discharge



Cardiac discharge meds

	Before	After	National 2000
Beta blockers	57%	97%	41%
ACE / ARB inhibitors	63%	95%	62%
Statins	75%	91%	37%
Antiplatelet	42%	98%	70%
Wafarin (chronic AFib)	10%	92%	<10%

	Mortality at 1 year			Readmissions w/ in 1 year		
	Before	After		Before	After	
CHF (n = 19,083)	22.7%	17.8%	331	46.5%	38.5%	551
IHD (n = 43,841)	4.5%	3.5%	124	20.4%	17.7%	336
Total			455			887

Reasons for practice variation

Clinical uncertainty:

- **Complexity**
  - How many factors can the human mind simultaneously balance to optimize an outcome?-- Alan Morris, MD
  - "The complexity of modern American medicine exceeds the capacity of the unaided human mind" -- David Eddy, MD
- **Lack of valid clinical knowledge** (poor evidence)
- **Reliance on subjective judgment**
  - Subjective evaluation is notoriously poor across groups or over time

- ***Enthusiam for unproven methods ...*** Mark Chassin, MD
- ***If it might work, do it ...*** David Eddy, MD, PhD
- ***Quality = spare no expense ...*** Brent James, MD, MStat

Medicine used to be simple, ineffective, and relatively safe.

Now it is complex, effective, and potentially dangerous.

C. Chantler

Neal G. Reducing risks in the practice of hospital general medicine. In *Clinical Risk Management, 2nd edition*. British Medical Journal, 2001.

Today's problems
are often
yesterday's solutions.

(We can't solve problems using the same kind of thinking we used when we created them)

(It works better if you plug it in)

Albert Einstein

He that will not apply new remedies must expect new evils; for time is the greatest innovator.

Francis Bacon (1561 - 1626); in **Essays** *(1625),* **Of Innovations**

The caring professions are changing

From craft-based practice

- *individual physicians, working alone (housestaff ::= apprentices)*
- *handcraft a customized solution for each patient*
- *based on a core ethical commitment to the patient and*
- *vast personal knowledge gained from training and experience*

To profession-based practice

- *groups of peers, treating similar patients in a shared setting*
- *plan coordinated care delivery processes (e.g., standing order sets)*
- *which individual clinicians adapt to specific patient needs*
- *early experience shows*
  - *less expensive (facility can staff, train, supply an organize to a single core process)*
  - *less complex (which means fewer mistakes and dropped handoffs, less conflict)*
  - *better patient outcomes*

Protocols can improve care

A multidisciplinary team of health professionals -

1. ***Select a high priority care process***
2. ***Generate an evidence-based "best practice" guideline***
3. ***Blend the guideline into the flow of clinical work***
   - *staffing*
   - *training*
   - *supplies*
   - *physical layout*
   - *measurement / information flow*
   - *educational materials*
4. ***Use the guideline as a shared baseline, with clinicians free to vary based on individual patient needs***
5. ***Measure, learn from, and (over time) eliminate variation arising from professionals; retain variation arising from patients*** *("mass customization")*

Why "profession-based" practice?

1. *It produces better outcomes for our patients*

2. *It eliminates waste, reduces costs, and increases available resources for patient care*

3. *It puts the caring professions back in control of care delivery*

4. *It is the foundation for useful shared electronic data -- an important next step in care delivery improvement*

Four main ideas

1. *Current American health care is very good, but ...*

   there is compelling evidence that health outcomes could be <u>much</u> better.

2. *Experience shows that*

   it is possible to close the quality gap.

3. *Better care can be cheaper care*

   clinical quality drives financial performance.

4. *Better care is (mostly) a systems feature:*

   Make it easy to do it right.