

# Safety as a System Property

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# Crossing the Quality Chasm

6 aims for the 21<sup>st</sup> century:

1. Effective
2. Safe
3. Equitable
4. Patient-centered
5. Timely
6. Efficient

# Simple Rules for the 21<sup>st</sup> Century

## Current Approach:

- Care is based upon visits.
- Professional autonomy drives variability.
- Professionals control care.
- Information is a record.

## New Rule:

- Care based on continuous healing relationships.
- Care customized based on patient needs & values.
- The patient is the source of control.
- Knowledge is shared and information flows freely.

# Simple Rules for the 21<sup>st</sup> Century

## Current Approach:

- Decisions are based on training & experience.
- Do no harm a personal responsibility.
- Secrecy is necessary.
- System reacts to needs.

## New Rule:

- Decision making is evidence-based.
- Safety is a system property.
- Transparency is needed.
- Needs are anticipated.

# Simple Rules for the 21<sup>st</sup> Century

## Current Approach:

- Cost reduction is sought.
- Preference given to professional roles over the system.

## New Rule:

- Waste is continuously decreased.
- Cooperation among clinicians is a priority.

## Overriding Tenet:

Medical accidents are usually the result of complex systems failure. Although incompetent and malfeasant staff exist, adverse outcomes are more commonly the result of systems problems. As safety in the aviation industry improved only after its leaders adopted this tenet, safety in medicine will not improve unless its complex systems are redesigned.

# Definitions

- Adverse Event: an injury related to medical care. May or may not be due to error.

# Definitions

- Adverse Reaction: any untoward effect that occurs during normal and correct medical care. Not related to error.

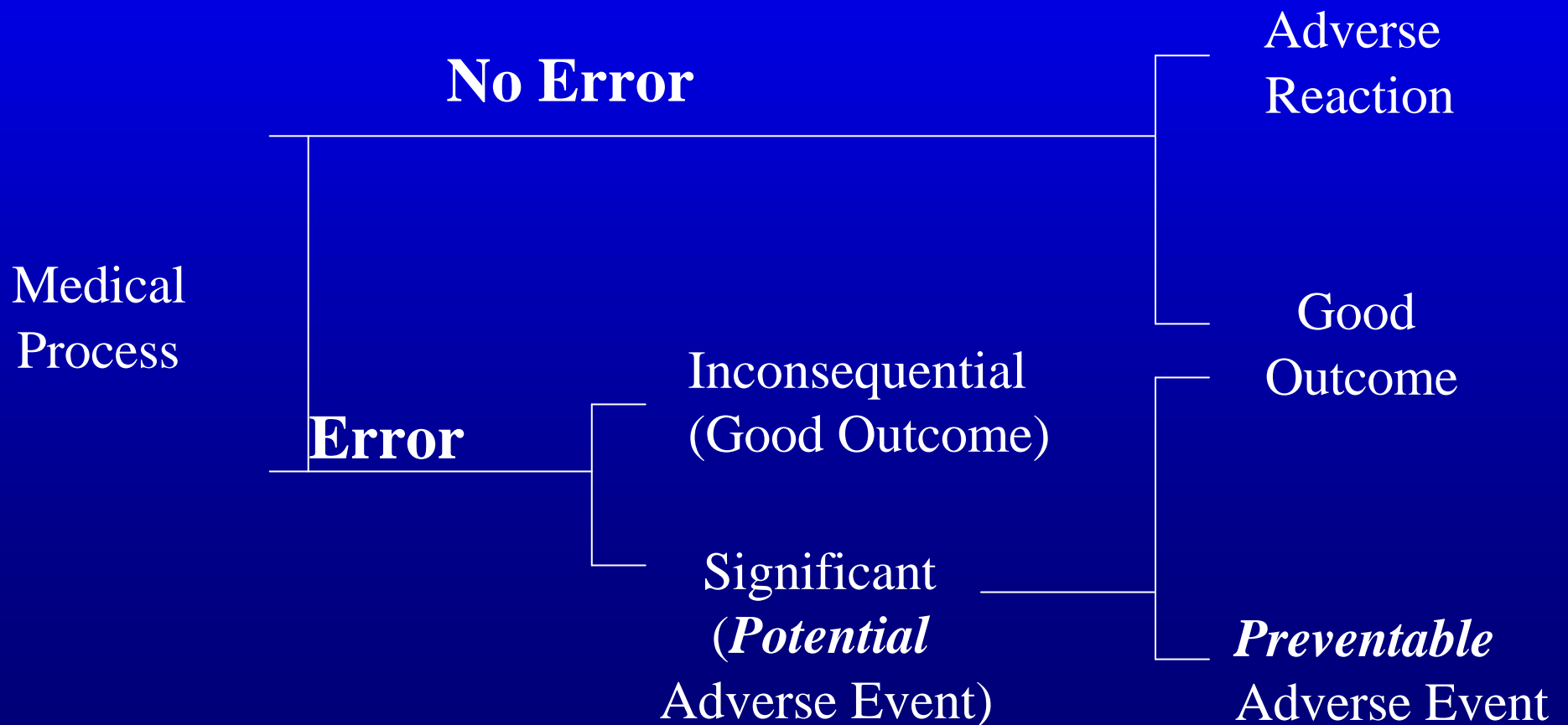
# Definitions

- Potential Adverse Event: a medical error with the potential to cause an adverse event, but does not do so, either because of good fortune, or because it was intercepted.

# Definitions

- Error: failure to carry out a plan as intended or the use of an incorrect plan of care.

# Outcomes of the Medical Process



# Error vs. Harm

# Adverse Drug Events: Facts

- 4% hospitalized patients suffer adverse event
- extrapolates to 1,000,000 injuries/yr
- 180,000 deaths/yr (45,000 deaths from auto accidents)
- 69% due to an error in management
- medications = 19.4% of all adverse events
- medications lead to 35,000 deaths/yr (96/day)

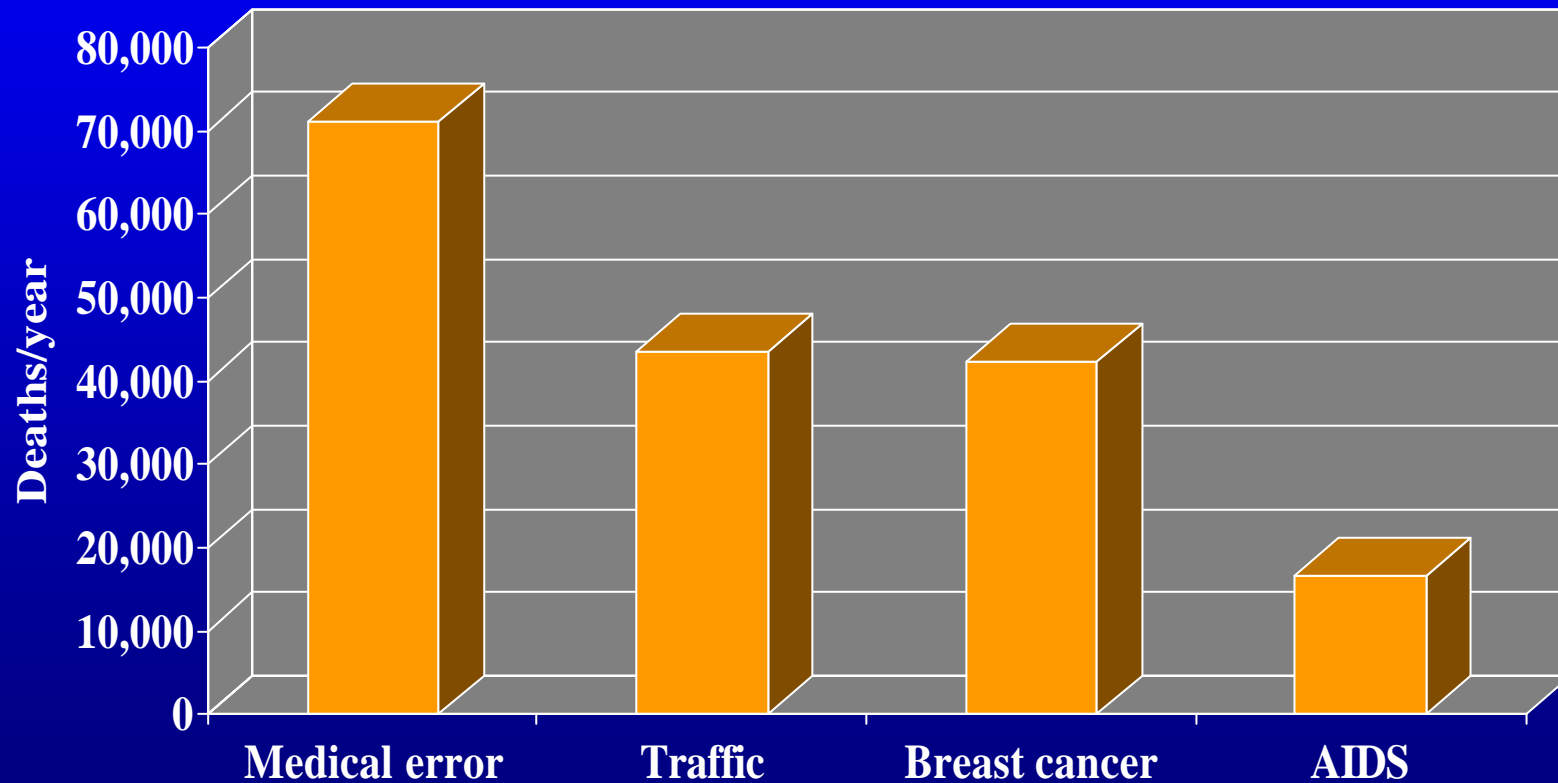
# Adverse Drug Events: Facts

- 6.5 ADE/100 non-obstetrical admissions
- 5.5 potential ADE (intercepted)/100 non-ob admits
- severity:
  - fatal: 1%
  - life-threatening: 12%
  - serious: 30%
  - significant: 57%

# 1999 Institute of Medicine Report

- Rate of adverse events in hospitals:
  - Colorado/Utah study: 2.9% (8.8% fatal)
  - New York study: 3.7% (13.6% fatal)
  - Over half were preventable
- Extrapolates to 44,000 – 98,000 deaths/year
- Total national costs of preventable adverse events = \$17 – 29 billion, half of which are health care costs

# 1999 Institute of Medicine Report



**\$9 billion in annual costs**

# 1999 Institute of Medicine Report

- Medication errors result in 7,000 deaths/year. This compares with 6,000 deaths/year from workplace injuries.
- Hospital costs of preventable adverse drug events = \$ 2 billion.

# Adverse Events in British Hospitals

- 10.8% frequency
  - 34% serious
  - 6% resulted in permanent injury
  - 8% contributed to death
  - 53% preventable (5% frequency)
- extrapolates to 850,000 injuries and £1 billion/year

# IHI Idealized Design of the Medication Process Trigger Study

- Uses triggers to identify potential harm
- Sample 10 charts/week
- 8 hospitals, over 500 charts
- Harm rate = 25%

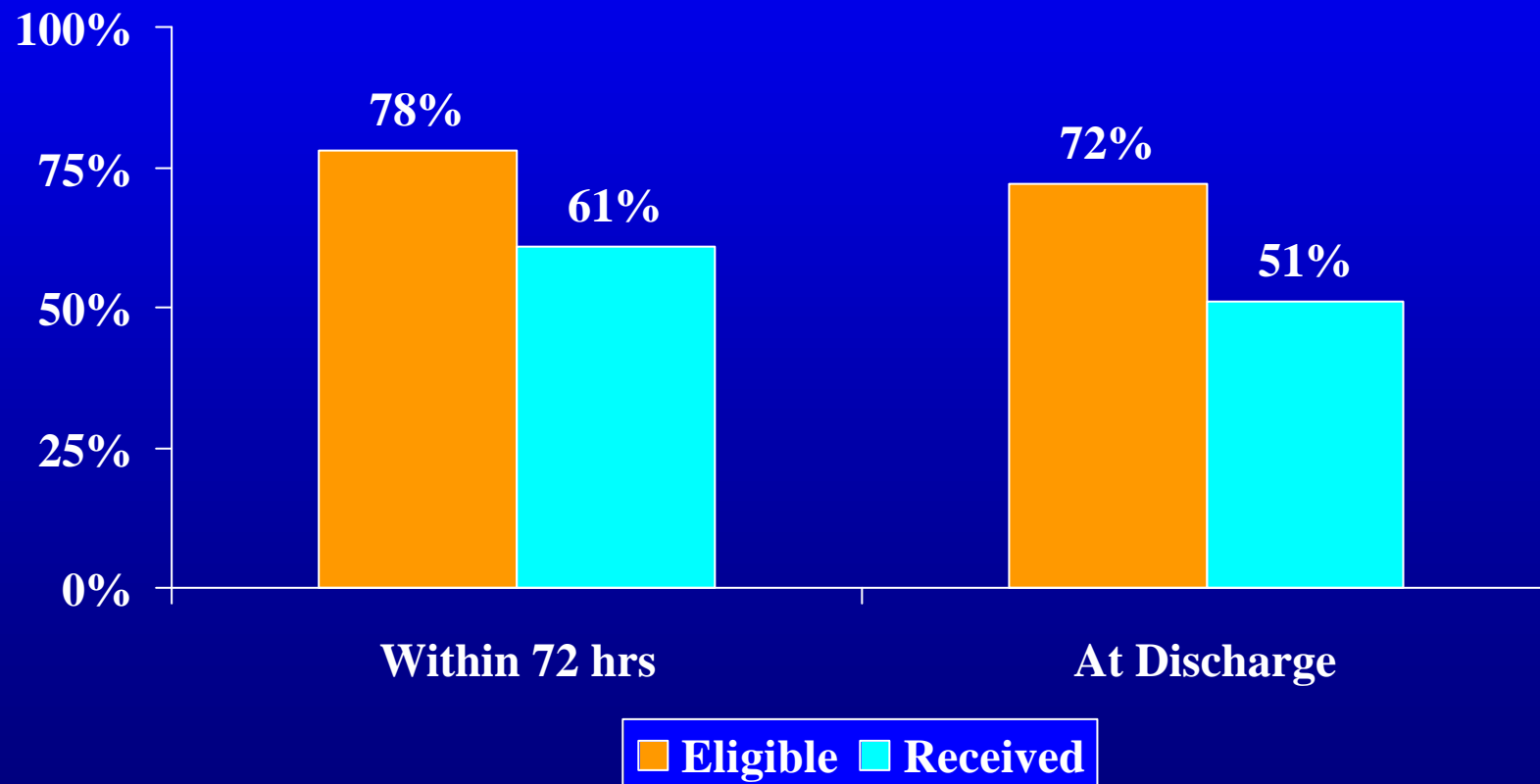
# Errors in Outpatient Clinics: Study of 385 Prescriptions

- 64 errors (17%)
- 15 adverse events (4%)
- Errors more likely on new vs refilled prescriptions (24% vs 10%)
- Errors less likely with computerized prescribing (4% vs 34%)
  - these errors were unrelated to handwriting

# Living with 99.9%

- 84 unsafe landings/day
- 1 major plane crash every 3 days
- 16,000 items of lost mail/hr
- 37,000 bank transaction errors/hr
- 12 babies given to the wrong mother every day
- 2 million documents lost at the IRS/year

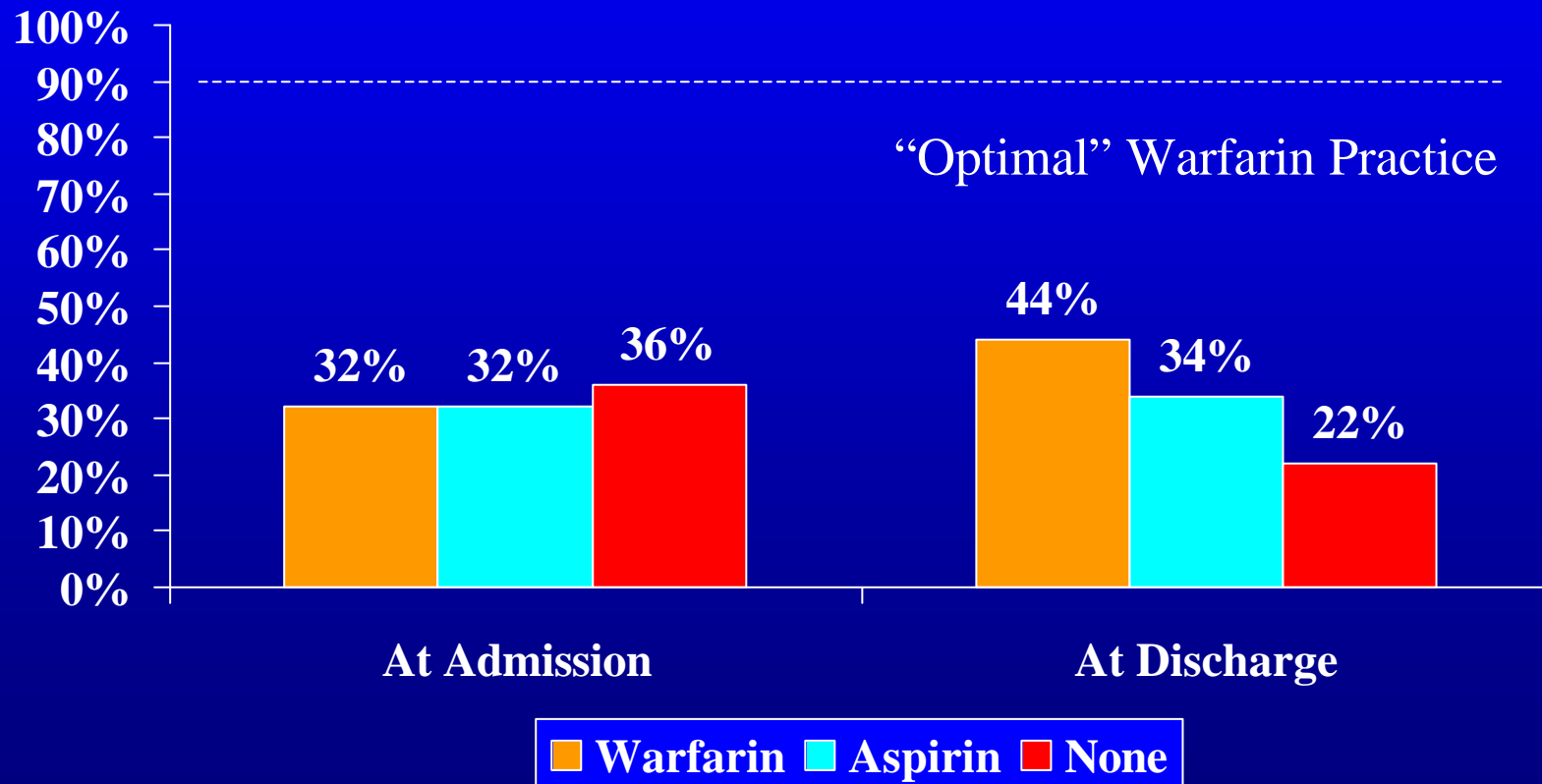
# Beta Blocker Use for MI



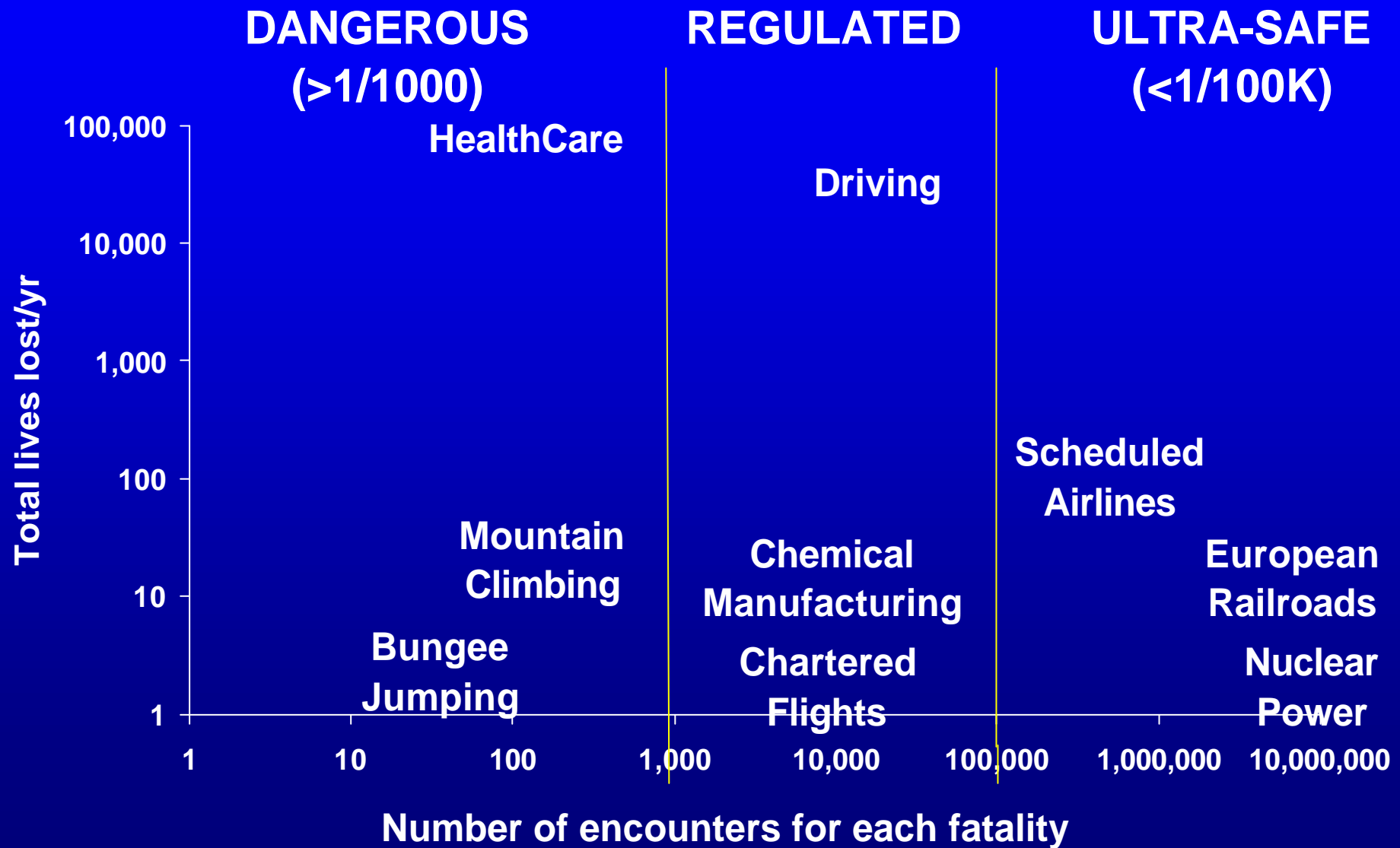
Am Heart J May 1996:872.

Data confirmed in Ann Intern Med 1999;131:648

# Anticoagulation Therapy for Atrial Fibrillation



# How Hazardous Is Health Care?



## U.S. Deaths from Infectious Transmissions in Blood Transfusions: 1999

- Transfusion units: 16,000,000
- Deaths: 20
- Safety rate: 99.99987%
- CDC is working to reduce this error rate to zero

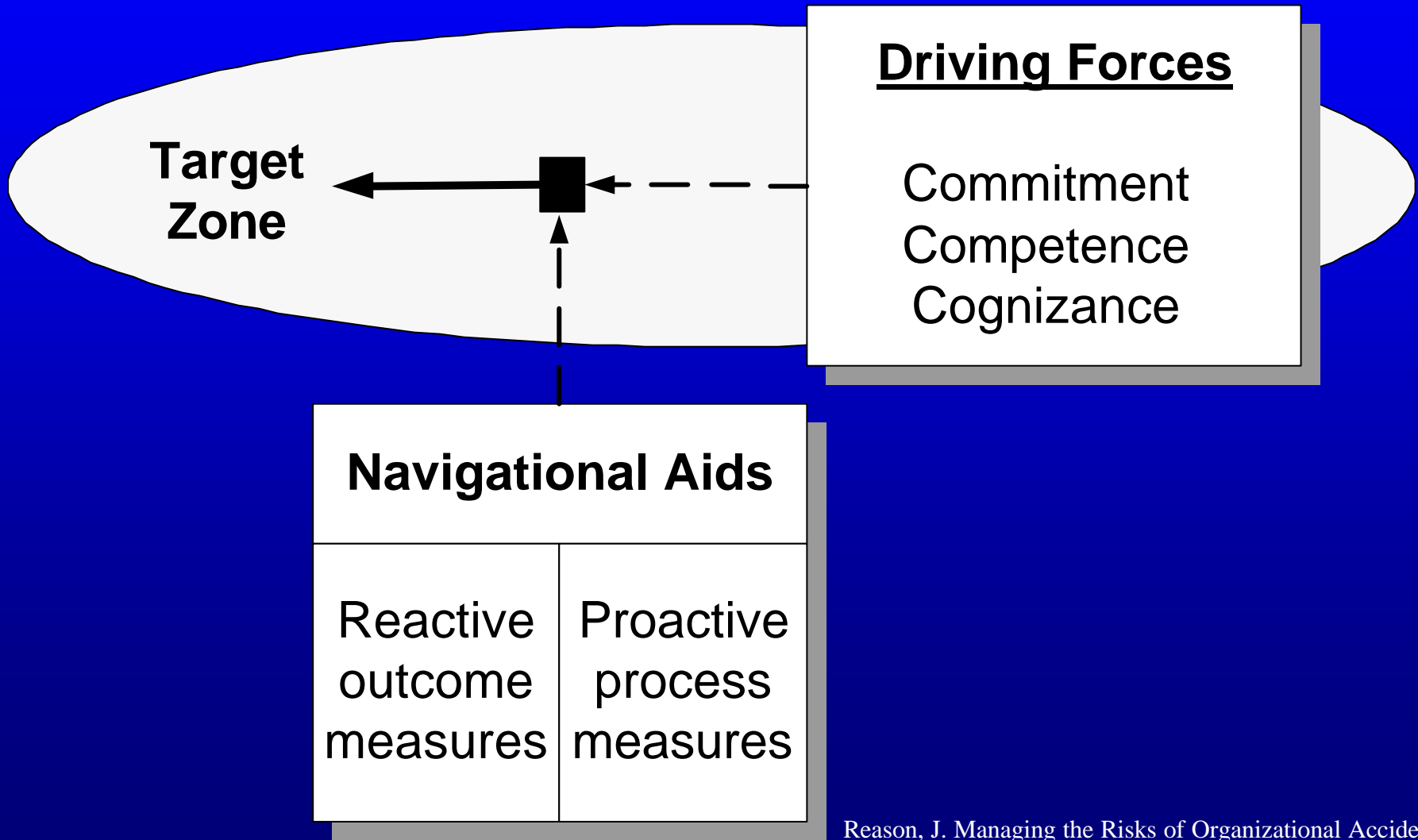
# Elements of Safe Systems

- Leadership
- Culture
- Technology
- Process
- External environment

The single most important marker of safety is the commitment by the organization's leadership. While front line staff can positively influence processes and culture, only leadership can set expectations and provide the resources necessary for fundamental change.

# Principle factors involved in navigating the safety space

← Increasing Resistance     Increasing Vulnerability →



# Leadership's Responsibility

- Ensures that safety & error reduction
  - part of strategic & quality plans
  - part of every job description & performance review
- Routine, open reports to broad audiences
- Budget for error reduction
- Sets expectations
- Constant reinforcement
- Leadership walkarounds

# Culture of Safety

- Culture: the set of shared attitudes, values, goals, and practices that characterizes a company or corporation

WWWebster Dictionary 1998

- Safety: freedom from accidental injury

– IOM report 1999

*What can your health system  
promise your patients?*

Joanne Lynne

# Culture of Safety: Characteristics

- Non-punitive error reporting
- Error-proofing new products, programs, and services
- Training and organizing in teams
- Direct communication
- Fatigue management

No one makes an error on  
purpose.

Lucian Leape

Everyone makes dumb mistakes  
every day.

Fear of punishment is not  
irrational.

No one admits an error if you  
punish them for it.

What do we mean when we say  
“Non-Punitive”?

*and*

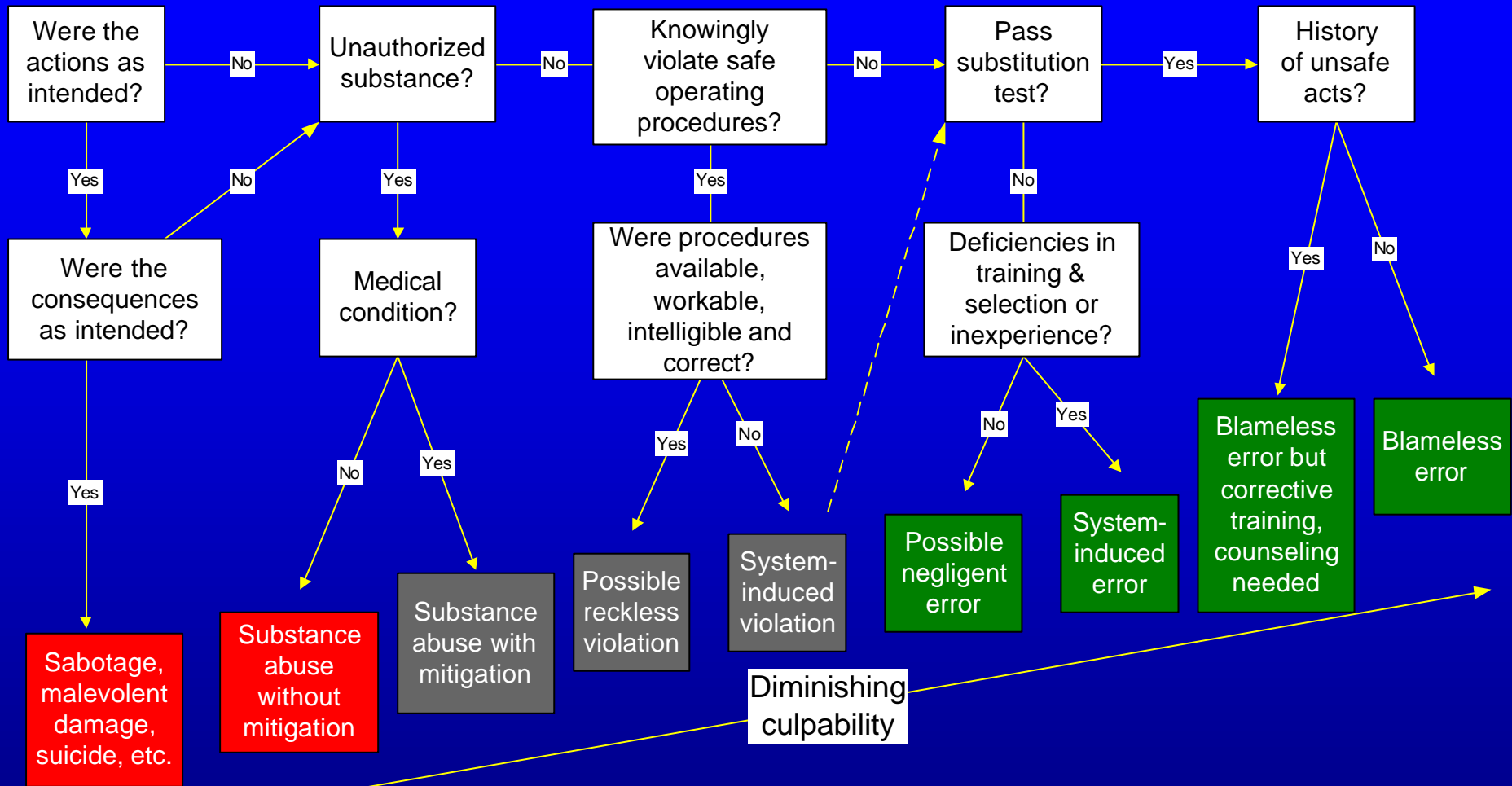
What don't we mean?

# What don't we mean?

- Abandonment of professional accountability
- Anonymity
- Ignoring
  - gross incompetence
  - gross procedural violations
  - gross insubordination
  - illegal activity
  - practicing under the influence
- Lack of disciplinary action for the failure to report

## What do we mean?

A system in which it's difficult to blame individuals for intangible system failures.



# Decision Tree for Determining Culpability of Unsafe Acts

# Vocabulary Changes

human error	→	accident/failure
root cause	→	multicausal
investigation	→	analysis/study
judgement	→	learning
blame/fault	→	accountable
isolated event	→	system
punitive/retaliatory	→	blameless

# Principles of Error Management

- The best people can make the worst errors.
- Short-lived mental states, such as forgetfulness or inattention, are the last & least manageable part of an error sequence.
- People will always make errors & commit violations.
- Blaming people for their errors will have no effect on their future fallibility.

# Principles of Error Management

- Errors are unintentional. Management cannot control what people did not intend to do in the first place.
- Errors arise from informational problems and are best tackled by improving the quality of information.

# Principles of Error Management

- Violations are social & motivational problems. They are best addressed by changing people's norms, beliefs, attitudes, & culture as well as improving the credibility, applicability, availability, and accuracy of the procedures.

# Technology and Safety

# Available Medication Technology

- Pharmacy computer systems
- Automated dispensing cabinets
- Bar coded drug selection
- Bar coded patient identification
- Computer-generated or electronic medication administration records
- Electronic drug information

## Substantial published data proving the benefits of technology:

- Computerized physician order entry
- Ambulatory prescribing
- Bar coded drug administration

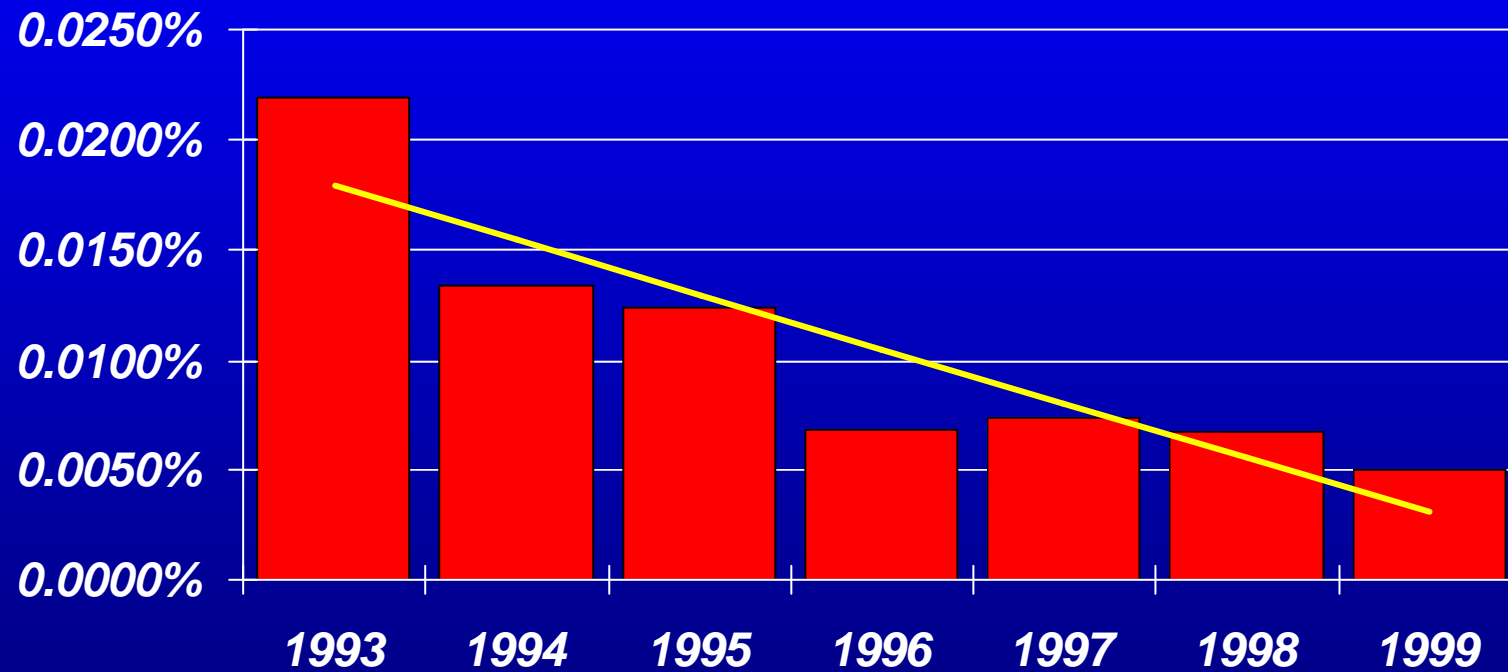
# Computerized Physician Order Entry Reduces:

- Serious medication errors 55%
- Prescribing errors 19%
- Transcription errors 84%
- Dispensing errors 68%
- Administration errors 59%
- Preventable ADE's 17%
- Non-intercepted potential ADE's 84%

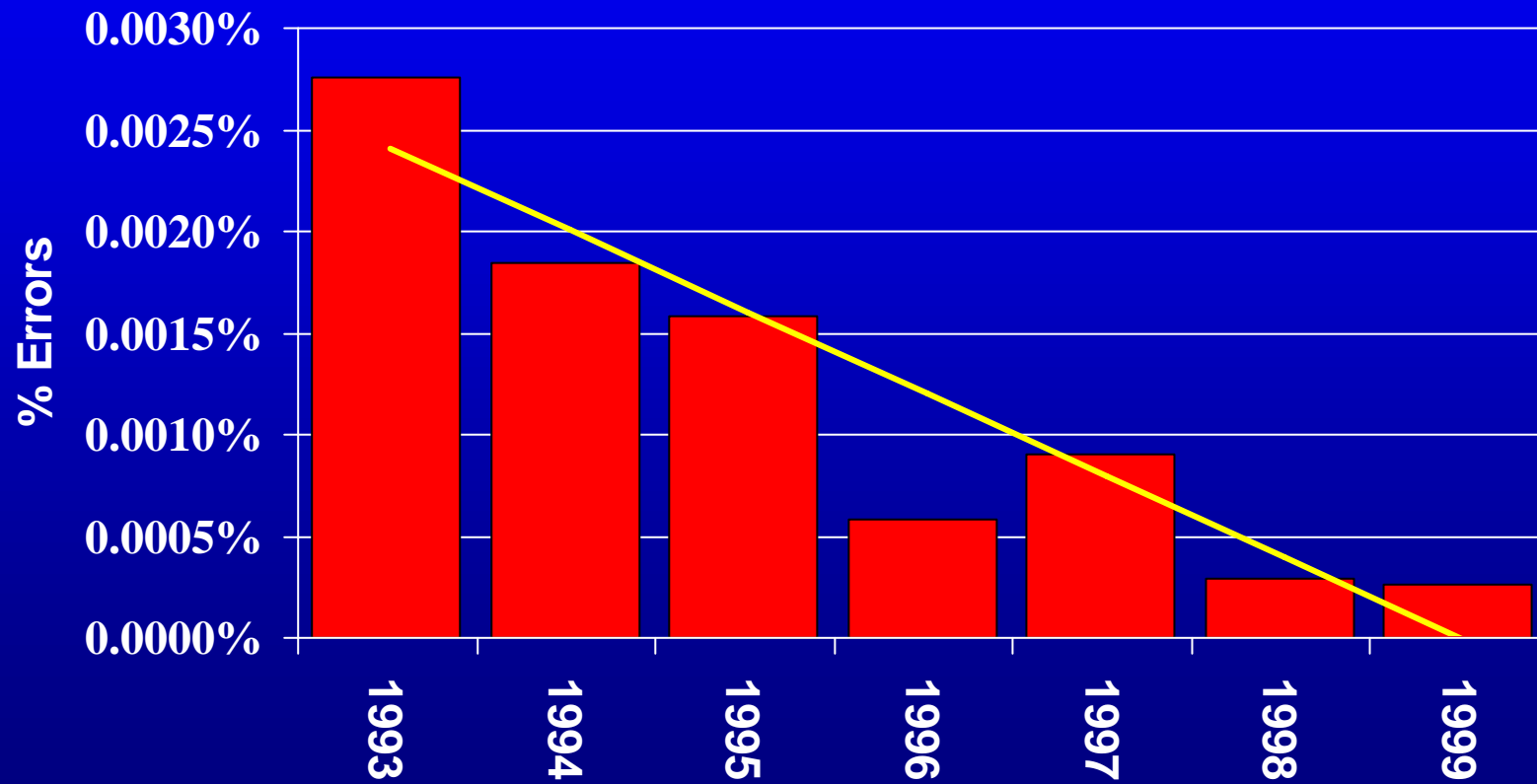
# Automated Prescribing

- Hand-held device (Palm, Jornada)
- Connected to office system
- Daily download of formulary information and preferred drugs
- Doses, routes, and frequencies pre-built
- Automatic check for drug interactions, incorrect doses, allergies
- Will print a prescription or electronically send it to a retail pharmacy

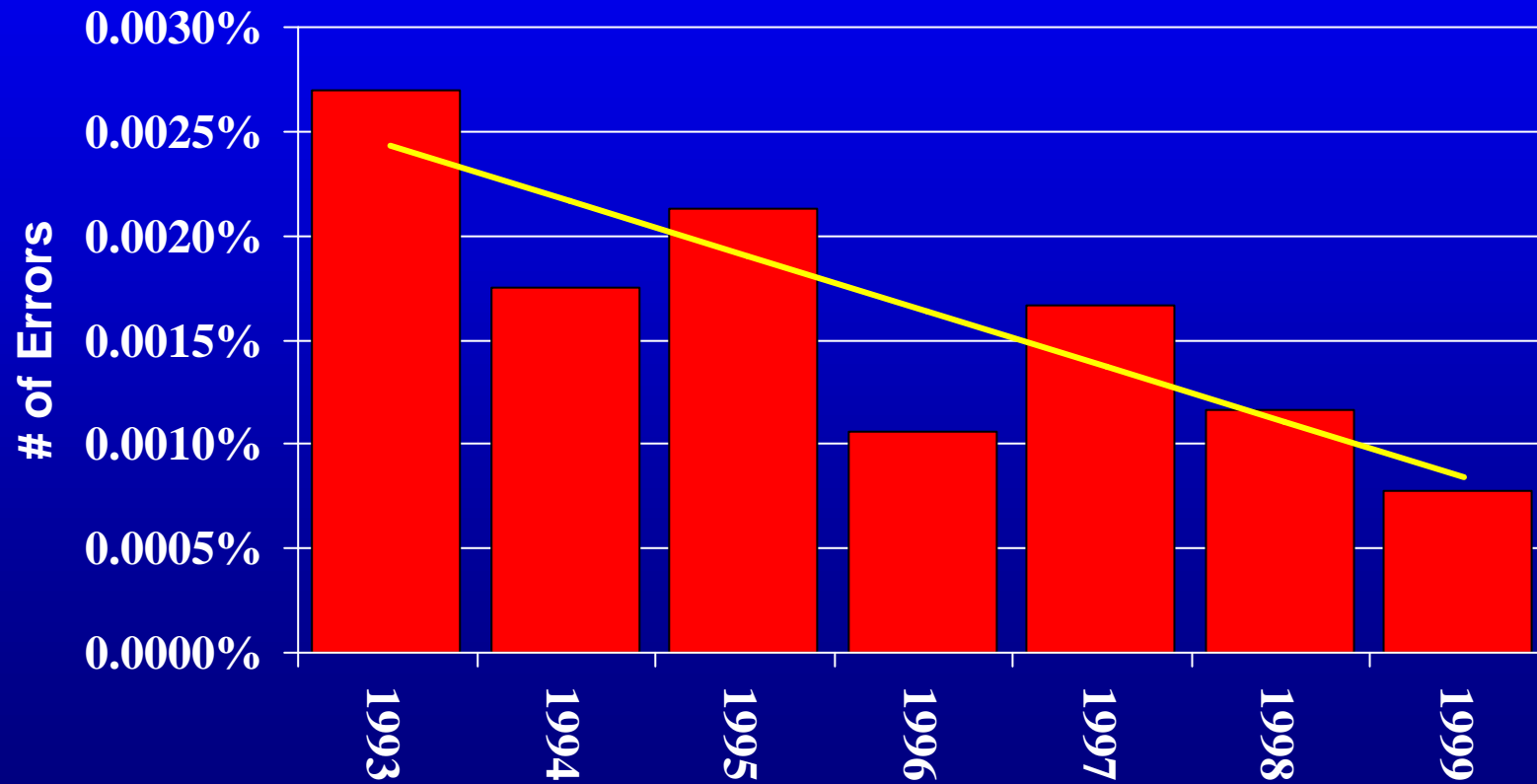
# Error Rate Trends By Year



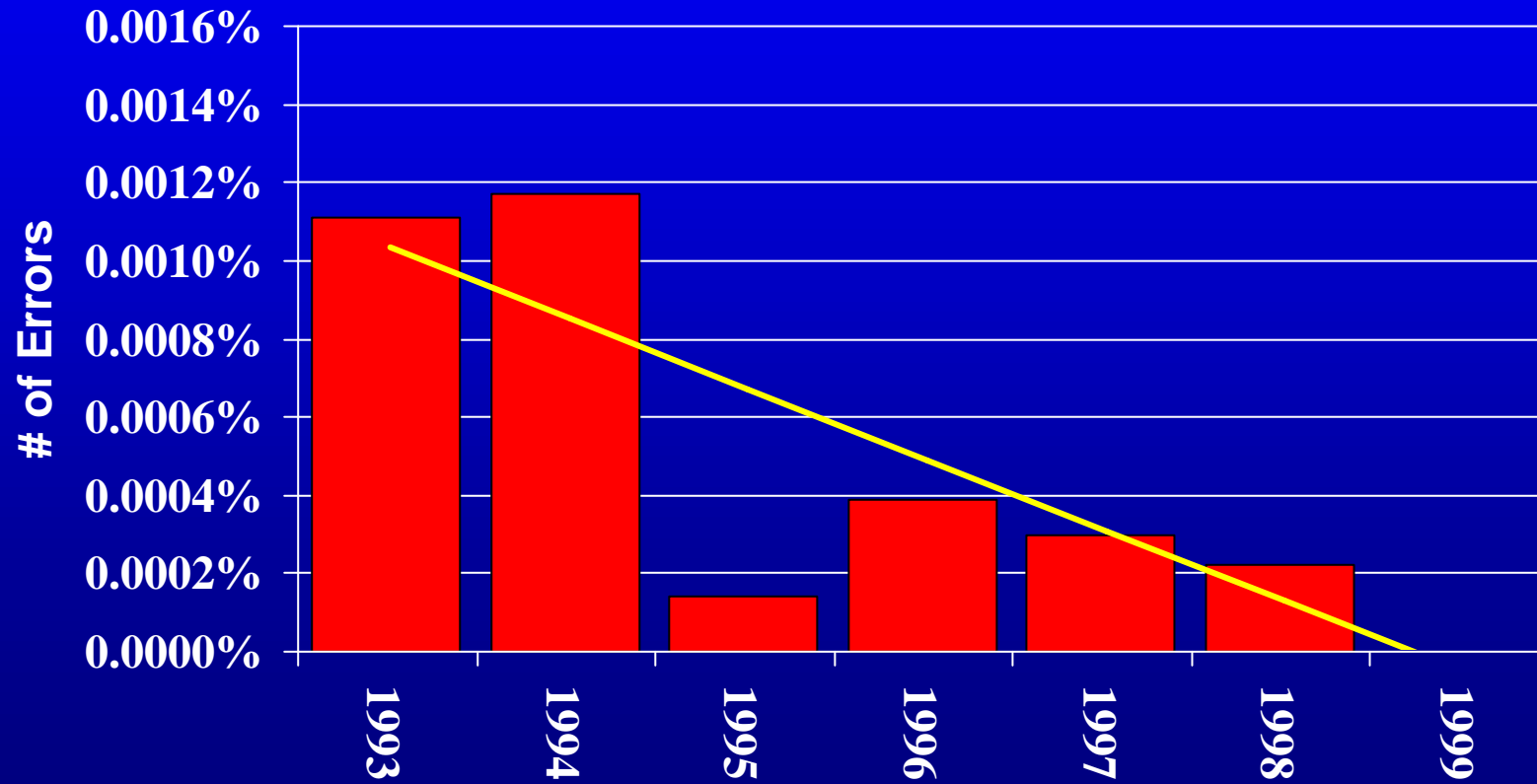
# Wrong Medication Errors



# Wrong Dose Errors



# Wrong Patient Errors



# Technology has become a preferred solution by many groups:

- IOM report
- Insurers
- JCAHO
- HCFA (Medicare)
- Media

# Global problems with automation

- Over reliance can instill a false sense of security
- Belief that the immediate effects of automation alone will ensure safety
- Major infrastructure changes necessary
- Lack of clinical information systems staff

# Global problems with automation

- Barriers that lead to circumventing the automation
  - overrides on automated dispensing cabinet
- Ineffective leadership to move automation forward

# Global problems with automation

- Placing automation on top of problematic systems (automation does little to enhance medication systems already plagued with problems)

# Improving Processes

# Three Design Principles for Safety

- Design systems to prevent errors.
- Design procedures to make errors visible.
- Design procedures that can mitigate harm from errors.

Nolan T. BMJ 2000; 320:771

# Process Improvement Key Change Concepts

- Standardization
- Simplification
- Constraints & forcing functions
- Assigning clear accountability
- Improving communication

# Complex Systems: Probability of Performing Perfectly

## Probability of Error, Each Step

<u># Steps</u>	0.05	0.01	0.001	0.0001
1	0.05	0.01	0.001	0.0001
25	0.33	0.05	0.005	0.0002
50	0.92	0.39	0.05	0.005
100	0.99	0.63	0.10	0.01

# Managing the External Environment

- Regulators
- Purchasers & Insurers
- Manufacturers
- Educators
- Labor market
- Media

A system that values stories & story-telling is potentially more reliable because people know more about their system, know more of the potential errors that might occur, and they are more confident that they can handle these errors because they know others have handled similar errors.

Karl Weick

There are no final victories in the  
safety war.

James Reason