Quality and Patient Safety

ACPE
Executive Leadership Series
April 2002
Presented by Ray Fabius MD, CPE, FACPE

Quality and Patient Safety

- Evolution of Quality Theory in Healthcare
- Types of Dysquality
- Magnitude
- Costs (Direct and Indirect)
- Focus on Inpatient and Rx
- What are we doing presently?
- Challenges

Quality and Patient Safety

- Definitions
- Moving to a more responsible system
  - Treasuring Mistakes
- A look at other industries
- A glimpse at what one payer is doing
- The future contribution of eHealth
  - Plug future Webcast
- The IOM Recommendations

Three Quotes

- Hippocrates " First do no harm"
- Don Berwick " Many anecdotes is not data"
- Emo Philips " Some days it isn't worth gnawing through the leather straps "

The Evolution of Quality in Health Care
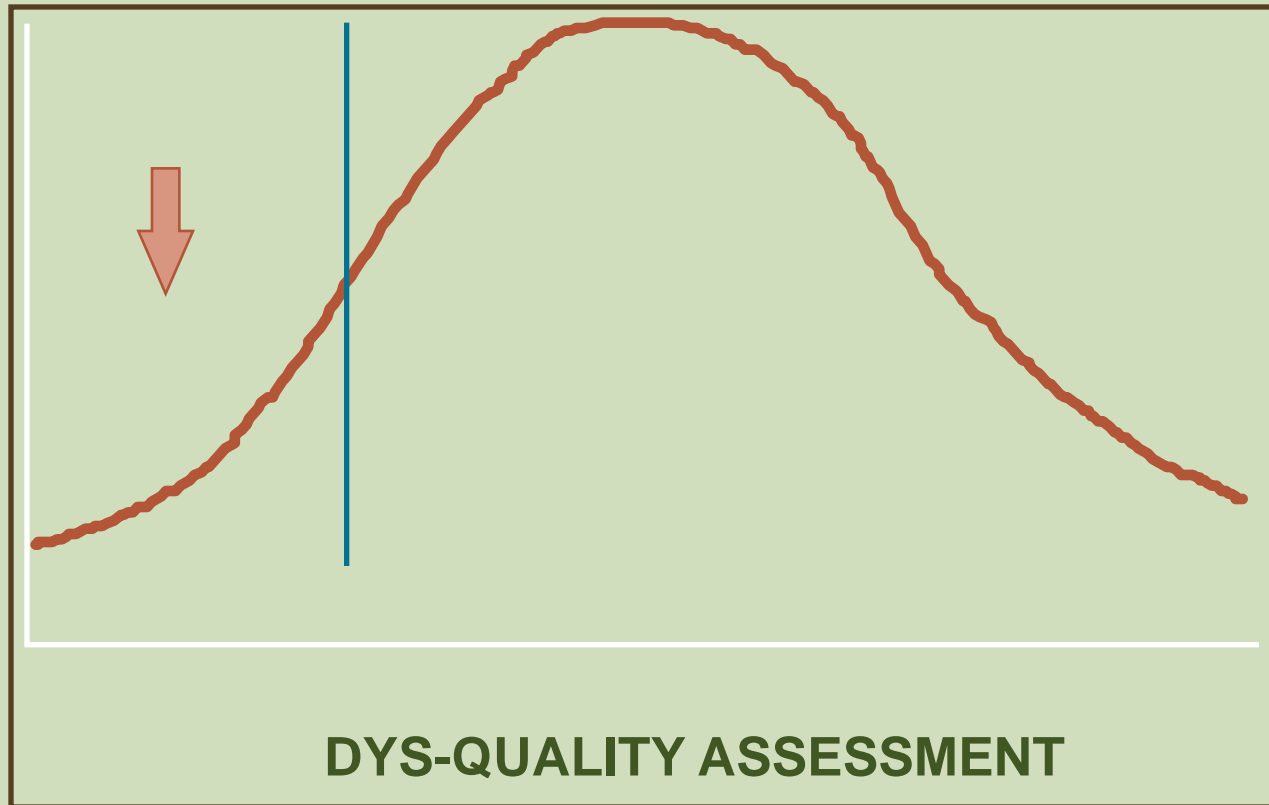
Framework of Quality Assessment
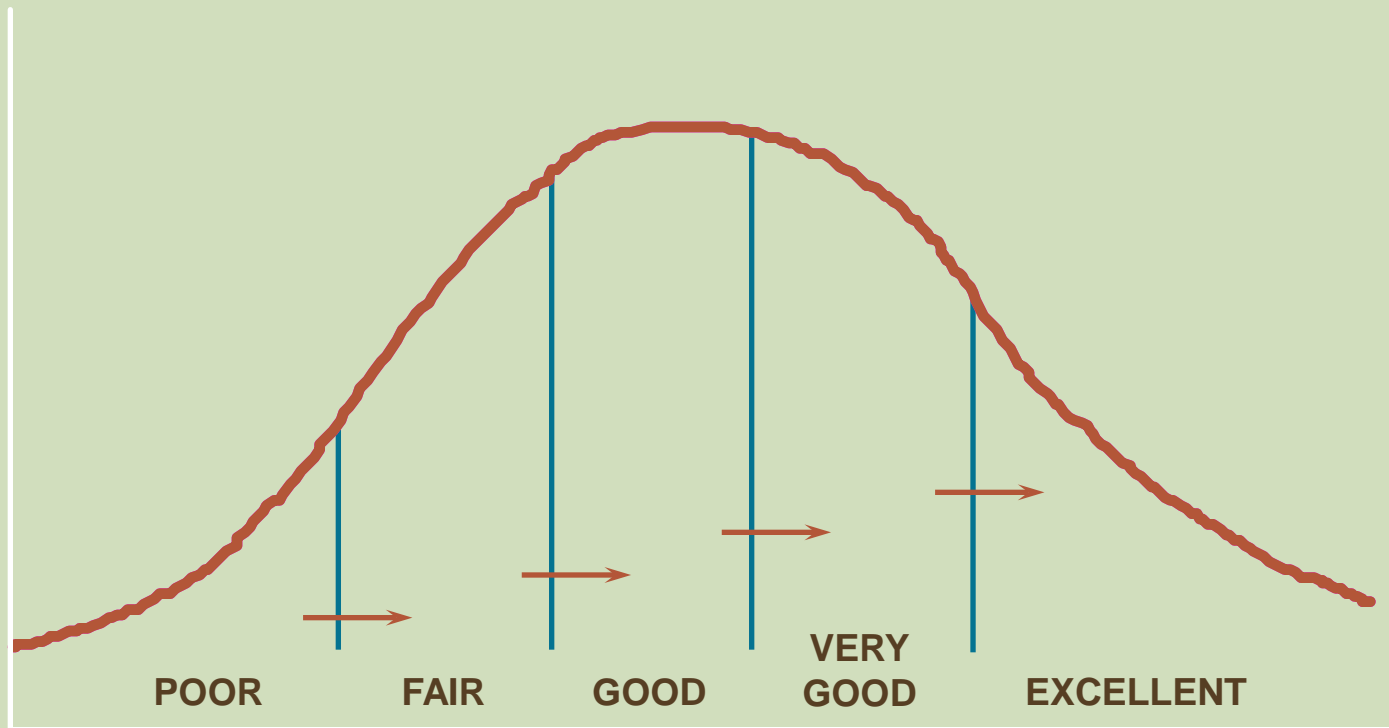
STRUCTURE / *Systems*

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PROCESS / *Operations*

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OUTCOME / *Results*
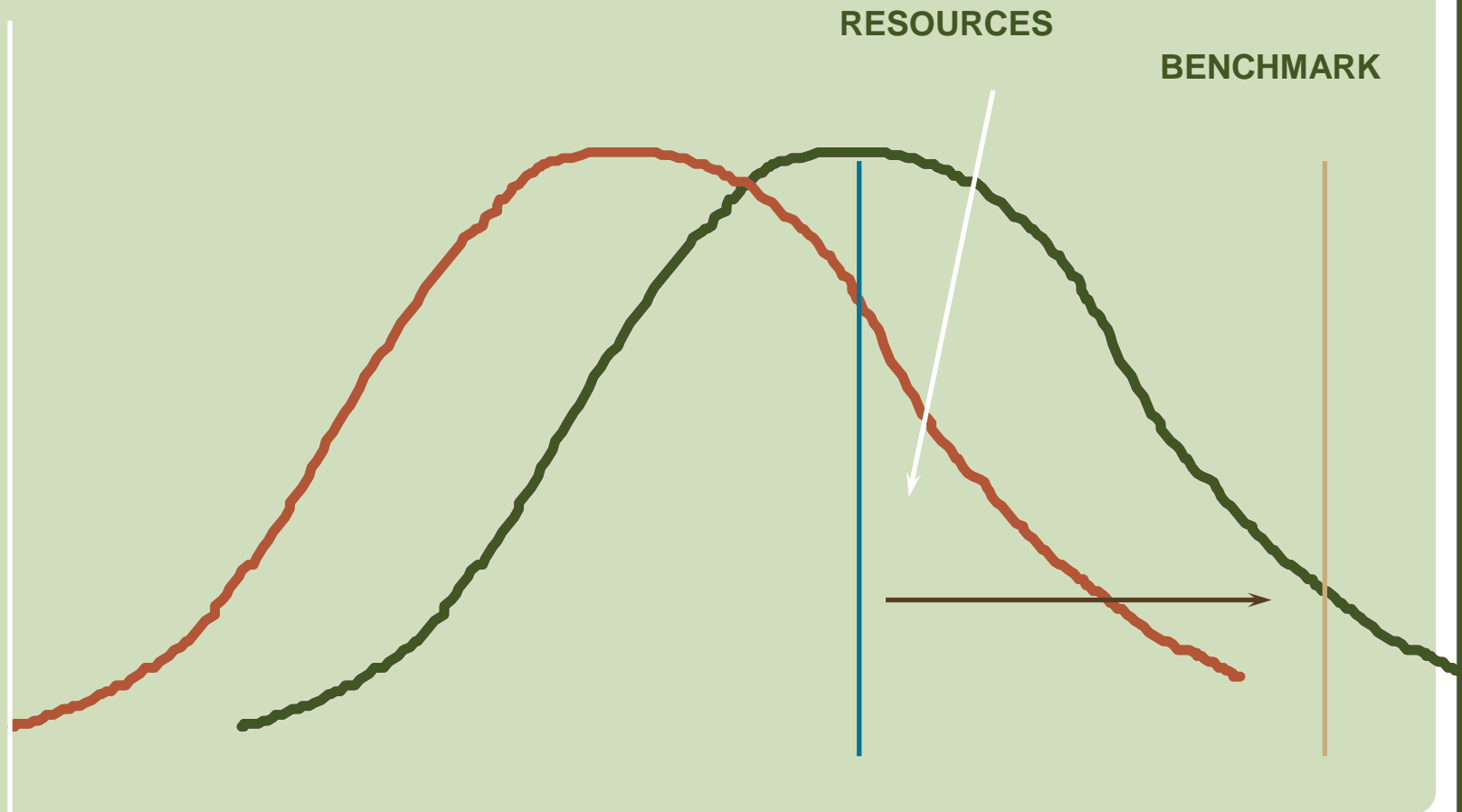
1970s Approach to Quality Assurance

DYS-QUALITY ASSESSMENT

1980s Approach to Quality Improvement

POOR   FAIR   GOOD   VERY GOOD   EXCELLENT
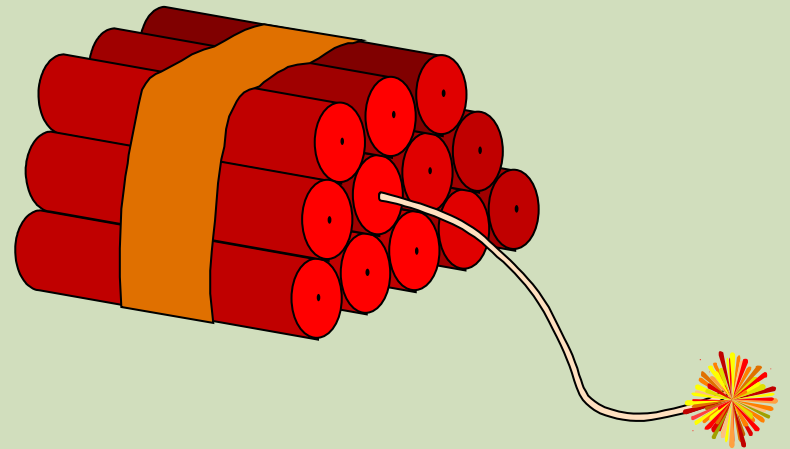
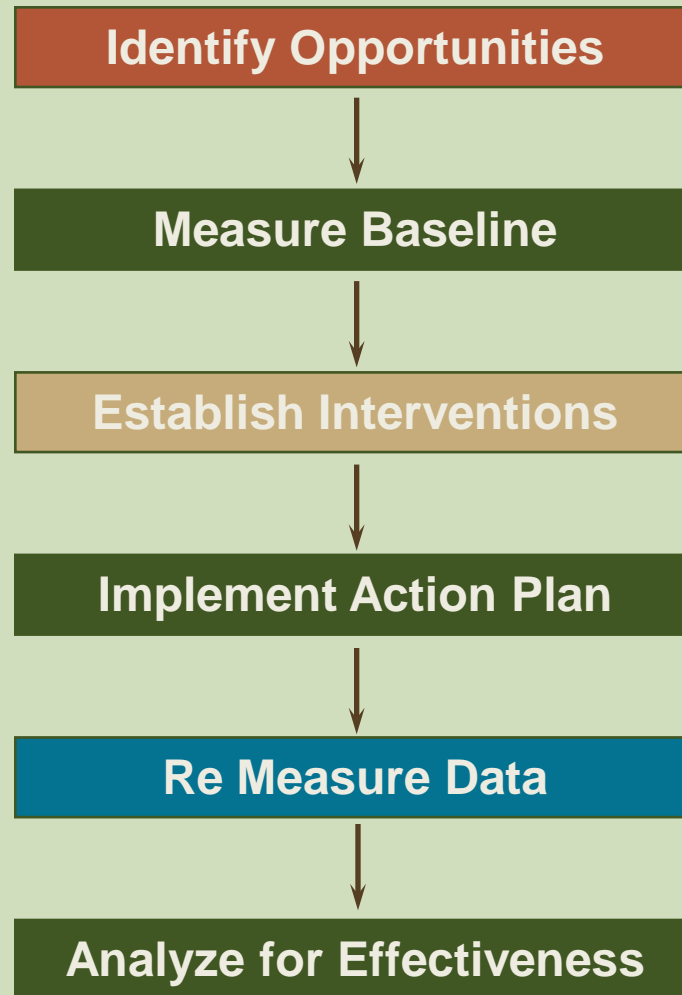**TOTAL QUALITY MANAGEMENT**

1990s Striving for Excellence

BENCHMARKING

What is Next? -Reengineering

- What if we were starting from scratch?
- Retrograde Interference
- Stakeholders
- Fantasy Island
- Consultation
- Expensive

Effectiveness Pathway

Identify Opportunities

↓

Measure Baseline

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Establish Interventions

↓

Implement Action Plan

↓

Re Measure Data

↓

Analyze for Effectiveness

What are the Components of Quality Health Care?

- Nearly error free
- Achieves positive outcomes
- Easily accessible
- Promotes functional status or wellness
- Relies on "shared decision making"
- Applies "state of the art" technology efficiently
- Documents and measures care delivered
- Continuously improves
- Value driven

Categories of Quality Pursuit

- Underuse
  - Access and Availability
  - Patient Activation and Compliance
- Overuse
  - More is Better
  - Perverse Incentives
- Misuse
  - Missed Opportunities
  - Mistreatment

Mistreatment Categorization

- Testing Errors
- Diagnostic Errors
- Treatment Errors
  - Medications
  - Procedures
  - Therapies
  - DME
  - Disposable Medical Supplies

Categories of Indirect Cost

- Loss of Trust
- Diminished Satisfaction
- Morale of Health Professional
- Reduced School Attendance
- Duplicate Testing
- Malpractice / Liability Cost
- Lost Worker Productivity
- Lost Prosperity

What is a Patient Error?

- Error - Failure of a planned action to be error of execution) or completed as intended (e.g. use of a wrong plan to achieve an aim (error of planning).
- Error - The failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance.

The Issue of Intention

- Two Kinds of Failure
  - Correct actions do not go as intended
    - Slip
      - Observable - Turning the wrong knob
    - Lapse
      - Hidden - Not being able to recall something
  - Intended action is not the correct one
    - Mistake
      - Assessed Incorrectly
      - Lack of Knowledge of a Situation
      - Failure of planning

Definitions

- **Error in Planning** - Use of Wrong Plan to Achieve an Aim
  - Preventive Services
  - Diagnostic Testing
  - Treatment

- **Error in Execution** - Failure of Planned Action to be Completed as Intended
  - Preventive Services
  - Diagnostic Testing
  - Treatment

Definitions

- Adverse Event - An injury due to medical intervention

- Preventable Adverse Event - An injury due to a medical error

Predisposition for Errors

- Technology
  - Increased Complexity
  - "Opaque"-Worker Removed from Process
  - Operator Monitors Automated System for Rare Abnormal Events
  - Automated Processes
    - Poorly prepared to handle response or solution
      - Automated Cell Phone Numbers
  - Lack of Standardization

Human Factors

- Anesthesia study found that human error was involved in 82% of preventable incidences.
- Corrective Actions
  - labeling and packaging strategies
  - workspace changes
- Improving the Human-System Interface
  - training issues
  - work-rest cycles
  - relief and replacement processes
  - equipment improvements

Human Factors

- Naturalistic Decision making
  - Study the actual setting
    - time pressure
    - noise
    - other distractions
    - insufficient information
    - competing goals
  - Researchers go out with workers in various fields
    - Simulator

Human Factors

- Reporting
  - Incident Reports
- Investigation
  - Analysis of Incidents and Trends
- Innovation
  - Suggested Changes & Improvements
- Dissemination
  - Implementation

David Woods, Ohio State University

Understanding Errors

- Active Errors
  - ◦ Frontline Operator
  - ◦ Immediate
- Latent Errors
  - ◦ Removed from direct control of the operator
    - • Poor Design
    - • Incorrect Installation
    - • Faulty Maintenance
    - • Bad Management Decisions
    - • Poorly Structured Organizations

Latent Errors

- Offer greatest opportunity to build safer systems
- Often Unrecognized
- Pose greatest threat to safety
- Exponential Impact
- Normalization of Deviance
  - Deviant events become acceptable
    - Signals are overlooked or misinterpreted and accumulate without being noticed.

Magnitudes of Errors-Inpatient

- Colorado & Utah - adverse event rate 2.9% of hospitalizations leading to death in 6.6% of cases
- New York - adverse event rate 3.7% of hospitalizations leading to death in 13.6% of cases both studies over half
- In of these adverse events resulted from medical errors and could have been prevented!

Magnitudes of Errors-Inpatient

- Extrapolation of these studies over 33.6 million admissions in 1997 implies that between 44,000 and 98,000 deaths occur annually in America's hospitals due to preventable medical errors

- This suggests that the health care system is the 8th leading cause of death in America ahead of MVA (43,458), breast cancer (42,297) and AIDS (16,516)

Leape, Lucian L. et al, N Engl J Med. 324: 370-384,1991
Harvard Medical Practice Study I & II

Magnitudes of Errors-Cost

- Health Care Costs (over half)
- Lost Income
- Lost Productivity
- Disability
- Estimated to be between 17 - 29 Billion

Thomas, Eric J et al *Inquiry* 36:255-264 1999

Medication Error at Hospital Level

- 2 of every 100 hospital stays experience preventable adverse drug event
- average increase cost for these admissions is $4700
- $2.8 Million increase cost annually / hospital
- Extrapolated to all U.S. Hospitals implies $2Billion Cost Annually

Bates, David W. et al *JAMA* 277: 307-311, 1997

Pharmacy Issues

- In 1998 alone, FDA approved:
    - 90 new drugs
    - 30 new molecular entities
    - 124 new or expanded uses of already-approved drugs
    - 344 generic drugs
    - 8 over-the-counter drugs
    - 9 orphan drugs

- Approximately 48% of all prescription on the market today became available only since 1990.

- An average of 11 prescriptions per person is written in the United States annually.

FDA, "Improving Public Health through Human Drugs," CDER, 1998 Report to the Nation.
Shatin, Deborah, et al. Letter. JAMA 281(4):319-320, 1999.
Friedman, Michael A., et al. JAMA, 281(18)1728-1934, 1999.

Pharmacy Issues

- Creation of the Office of Post-Marketing Drug Risk Assessment (OPDRA)
    - Adverse Effects of Drugs Becomes Clear only after Approval and Wide Use
- Five drugs were removed from the market between September, 1997 and September, 1998 after 20 million people were exposed to their risks.
- Human Factor - Sound-alikes/Look-alikes
    - "Celebrex" (arthritis) - "Cerebyx" (seizures) - "Celexa" (depression)

Patient Safety in Other Health Settings is Largely Unstudied!

- Rehabilitation
- Skilled Nursing
- Nursing Homes
- Ambulatory Surgical Centers
- Ambulatory Care Facilities
- Home Care
- Physician Offices
- Self Care

Health Care Vs Workplace Errors

- 6000 deaths per year in the Workplace
- 7000 deaths per year from medication errors in the hospital setting alone

Phillips, David P. et al *The Lancet* 351:643-644, 1998

Categories of Indirect Cost

- Loss of Trust
- Diminished Satisfaction
- Morale of Health Professional
- Reduced School Attendance
- Duplicate Testing
- Malpractice / Liability Cost
- Lost Worker Productivity
- Lost Prosperity

What is Patient Safety?

- Who coined the term?
  - In 1983, The Anesthesia Society of America's Committee on Patient Safety and Risk Management under the leadership of Ellison C. Pierce, Jr., MD (www.asahq.org/NEWSLETTERS/2001/8_01/stoeting.htm)
- The National Patient Safety Foundation
  - Patient Safety is the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare. (www.ama-assn.org/med-sci/npsf/research/research.htm)

What is Patient Safety?

- Maximizing Therapeutic Benefit
- Reducing Risk
- Eliminating Harm
- Weighing Alternative Treatments
- Systematic Approach
- Continuous Improvement
- Increasing Reliability

"Safety is defined as freedom from accidental injury."

Understanding Safety

- Perrow's Normal Accident Theory
  - Accidents are inevitable and normal
- Reliable Systems and Industries
  - Military Aircraft Carriers
  - Chemical Processing
- Characteristics of Highly Reliable Industries
  - Organizational Commitment to Safety
  - High Levels of Redundancy in Personnel & Safety Measures
  - Continuous Learning
  - Willingness to Change

Tipping the Scale

Documentation
Non-Punitive
Active Learning
Change Agent
Technology
Training
Feedback

Leadership
Resources
Awareness
Guidelines
Collaboration
Standardization
Simplification

Errors

Safety

Healthcare Delivery

38

Conditions that Prevent Errors

- Good Managerial Decisions
- Right Equipment
- Maintenance of Equipment
- Skilled & Knowledgeable Workforce
- Reasonable Workload & Schedule
- Well-Designed Jobs
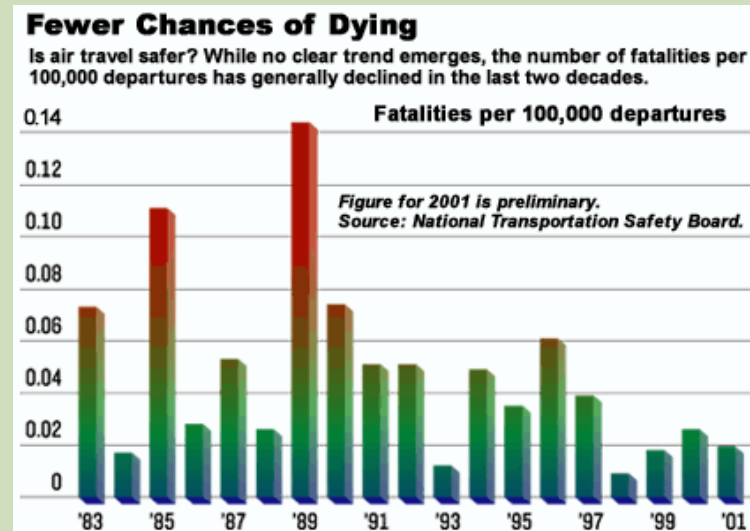- Clear Guidance on Desired & Undesired Performance

Safety Efforts in Other High Risk Industries

- Oil Drilling
- Construction
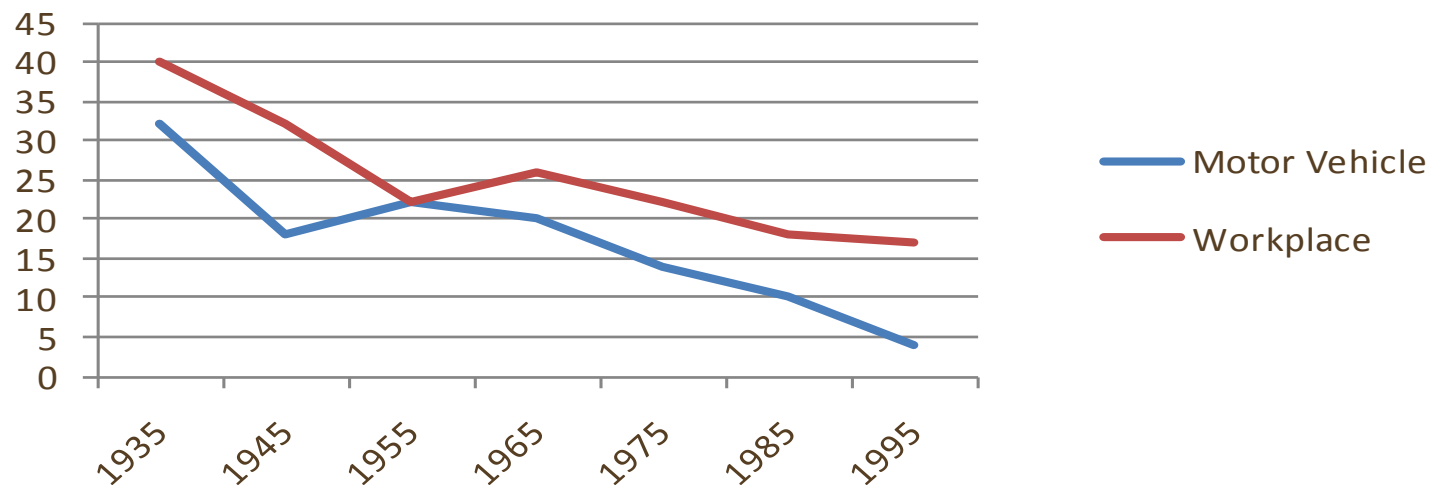- Automobiles
- Aviation
- Food

Best Practice *Aviation*

- Between 1967 and 1976, risk of dying in a domestic jet flight was 1:2,000,000.
- By the 1990's, the risk declined to 1:8,000,000.

Fewer Chances of Dying

Is air travel safer? While no clear trend emerges, the number of fatalities per 100,000 departures has generally declined in the last two decades.

0.14   **Fatalities per 100,000 departures**

Figure for 2001 is preliminary.
Source: National Transportation Safety Board.

0.12
0.10
0.08
0.06
0.04
0.02
0

'83   '85   '87   '89   '91   '93   '95   '97   '99   '01

Forbes, 4.01.02, Mark Tatge.

"the Aviation Safety System," www.faa.gov/publicinfo.htm

US Vehicle & Workplace Death Rates

Motor Vehicle

Workplace

Common Sense at Work, www.osha-slc.gov/OshDoc/OSHFacts/OSHAFacts.html

Occupational Health vs. Motor Vehicle

Lessons Learned

- Growing Awareness
- Comprehensive Strategies
- Intolerance with Errors
- National Focal Point for Leadership
- Dissemination of Information
- Regulatory Responsibility
- Research
- Expanding Knowledge Base
- Substantial Resources

Key Safety Design Concepts

- Make things <u>visible</u> and <u>obvious</u>
- <u>Simplify</u> the structure of tasks
- Affordances and natural mapping
  - An <u>affordance</u> is a characteristic of equipment or workspace that communicates how it is being used.
    - Telephone head set that is uncomfortable to use in any position to use, but the correct one.
  - <u>Natural Mapping</u> refers to the relationship between a control & its movement.
    - In steering a car to the right, one turns the wheel right.

- Use of <u>constraints</u> or <u>forcing functions</u>
  - A <u>constraint</u> makes it difficult to do the wrong thing.
  - A <u>forcing function</u> makes it impossible.
    - One cannot start a car that is in gear.
- Assume errors will occur and design plans for recovery by making it easy to <u>reverse</u> operations and hard to carry out non-reversible ones.
  - Is user really interested in deleting this file?

Key Safety Design Concepts

Changing the Health Care Environment

- Purchasers pay for performance
- Payers pay for performance
- Providers utilize technology at POC
- Patients select care based on data
- Investors back new technology and knowledge management
- Regulatory / Legislative Alignment
- Supplier / Consultant / Leadership participation

Challenges to Patient Safety

- Fragmentation
- Lack of Accountability
- Weak Purchasing Pressure
- Few Rewards
- Lack of Awareness

Present Processes to Promote Patient Safety

- Credentialing
- Licensure
- Certification
- Accreditation
- Medical Liability System

Setting Standards in Healthcare

- Healthcare Organizations
- Hospital Licensure
- Pharmaceutical Industry
- Physician's Office
- Ambulatory Facilities
- Nurse Practitioners
- Physicians

- NCQA and URAC
- JCAHO
- FDA
- AMAP
- AAAHC
- ANCC
- State and Professional Boards

Present - Bad Apple Approach

- Error Identified
- Witch Hunt Begins
- Blame Storming
- Revoking Privileges
- Removal of licensure
- Sue the Quack
- "Criminalize" the Situation

Future Hope - A Responsible System

- Error Tracking
- Error Trending
- Error Analysis
- Active Learning
- Improved Processes
- Error Reduction

- Motivation of Health Professional
- Ethics
- Technology
- Application of error reduction knowledge and tools
- Strong Leadership
- Legislative and Regulatory Initiatives

Forces to Exert Change

- Purchaser pressure
- Consumer demand and participation
- Active Learning from Errors
- Disseminate Best Practices in Patient safety

Forces to Exert Change

Change Agents

- Leadership
- Awareness
- Attention
- Investment

Changes Required to Improve Patient Safety

- Create Awareness
- Align Payment System
- Align Liability System
- Training and Education
- Create a Culture of Safety

Benjamin Zander - Conductor of Boston Symphony
Response to uncovering an error - "How Wonderful"

- Establish Center for Patient Safety
  - Set national goals
  - Issue annual report
  - Develop research agenda
  - Communicate best efforts
  - Positioned under Agency for Healthcare Research and Quality AHRQ

Institute of Medicine Recommendations

- Identify and Learn From Errors
  - Report, track, trend
  - CQI identify-analyze-act-measure
  - Mandatory Reporting of serious preventable medical errors with public disclosure
    - States report to National Forum for Healthcare Quality Measurement and Reporting
  - Voluntary & Confidential reporting of less serious preventable adverse errors
    - Encouraged by Center for Patient Safety

Institute of Medicine Recommendations

- Set Performance Standards
  - minimum levels for licensure
- Set Expectations
  - Through standards development
  - Require meaningful patient safety programs
  - Purchasers need to create incentives to demonstrate CQI in patient safety

Institute of Medicine Recommendations

- Health Professional Licensing Bodies
  - Re-examine / Re-license with a new focus on patient safety
  - Credentialing / Certification programs need to better identify unsafe providers and take action

Institute of Medicine Recommendations

- Professional Societies
  - Learn from Anesthesia
  - Develop curriculum
  - Disseminate information
  - Build patient safety into clinical guidelines
  - Work with Center for Patient Safety
  - Collaborate with other professional societies on patient safety

Institute of Medicine Recommendations

- FDA
  - packaging and labeling
  - test sound alike and look alike in pilots
  - coordinate post marketing surveillance actions

Institute of Medicine Recommendations

- Implement Safety Systems
  - Executive Responsibility (Alcoa story)
  - Visible Attention to Patient Safety
  - Non-Punitive Reporting and Analyzing
  - Standardize and Simplify
  - Training and Stimulation
  - Interdisciplinary Approach

Institute of Medicine Recommendations

- Member of The Leapfrog Group (as an employer to safeguard the health and well-being of its employees and their families   April 2001
- Letter to participating hospitals encouraging support for The Leapfrog Group's initiatives   October 2001
- Link to The LeapFrogGroup on DocFind
- Established an Internal Patient Safety Workgroup
- Drug-to-drug and drug-to-disease pharmacy programs that integrate medical and pharmacy data to alert pharmacists to potential interactions or contraindications at dispensing time for 10 Million Beneficiaries

Aetna Actions

- Aetna Foundation research grants to 5 leading academic institutions to study reduction of medical errors, improve surgical safety and improve infection control in long term care facilities
- Leadership role in The Coalition for Affordable Quality Healthcare, which supports patient safety by using health plan data to identify best practices.
- Point of care prescribing to reduce the amount od adverse drug events
- Hospital Quality Review: Uses administrative data to demonstrate what happens during and after hospitalization to identify quality improvement opportunities
- PCP Clinical Pharmacy Report : Feedback on prescribing habits
- Vaccine Storage Initiative: Promotes safe refrigeration and storage of vaccines.
- Drug Safety for Seniors Project: Poly-pharmacy review
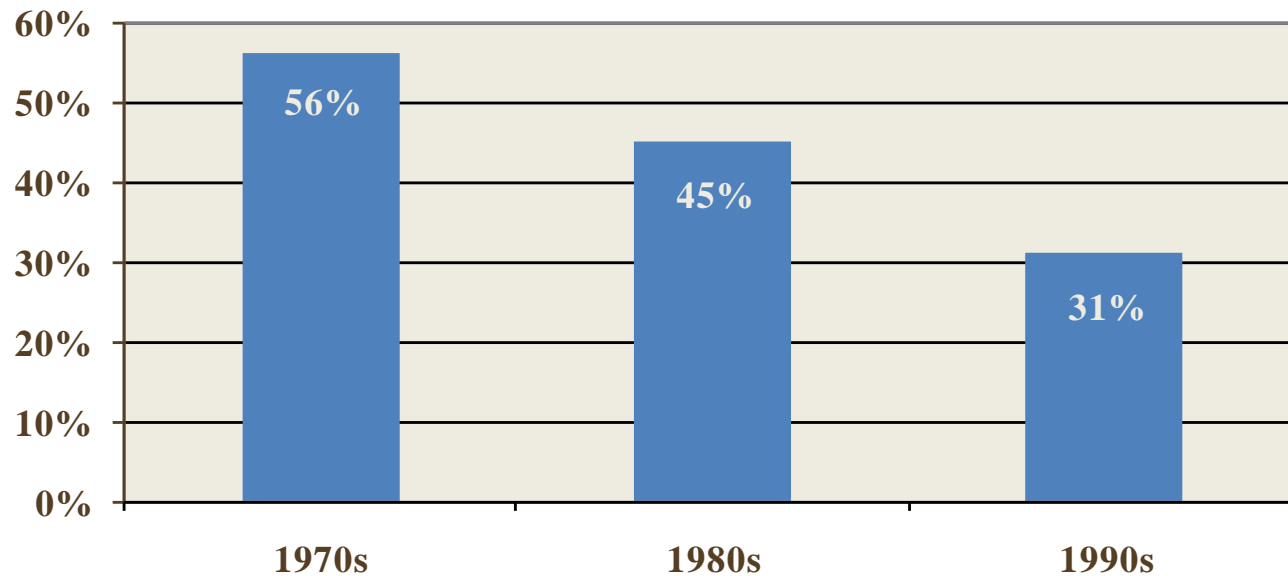
Aetna Actions (continued)

- Responding to rising malpractice premiums in the mid-1980's
- Identified issues - long operations, rapid problem evaluation and decision making, variation in design of anesthesia devices, fatigue and sleep deprivation, competing institutional, professional and patient care priorities.

Anesthesiology as a Benchmark

- Successfully reduced mortality rates from two deaths per 10,000 anesthetics administered to one death per 200,000-300,000 anesthetics administered.
- Accomplished through
  - Technical Changes (new monitoring equipment and standardization of equipment
  - Information-based Strategies & Guidelines and standards
  - Application of Human Factors - Simulators for training
  - Non physician anesthesia providers be supervised by a physician
  - Formation of the Anesthesia Patient Safety Foundation
  - Leadership

Anesthesiology as a Benchmark

Insurance Claims for Death or Permanent Brain Damage

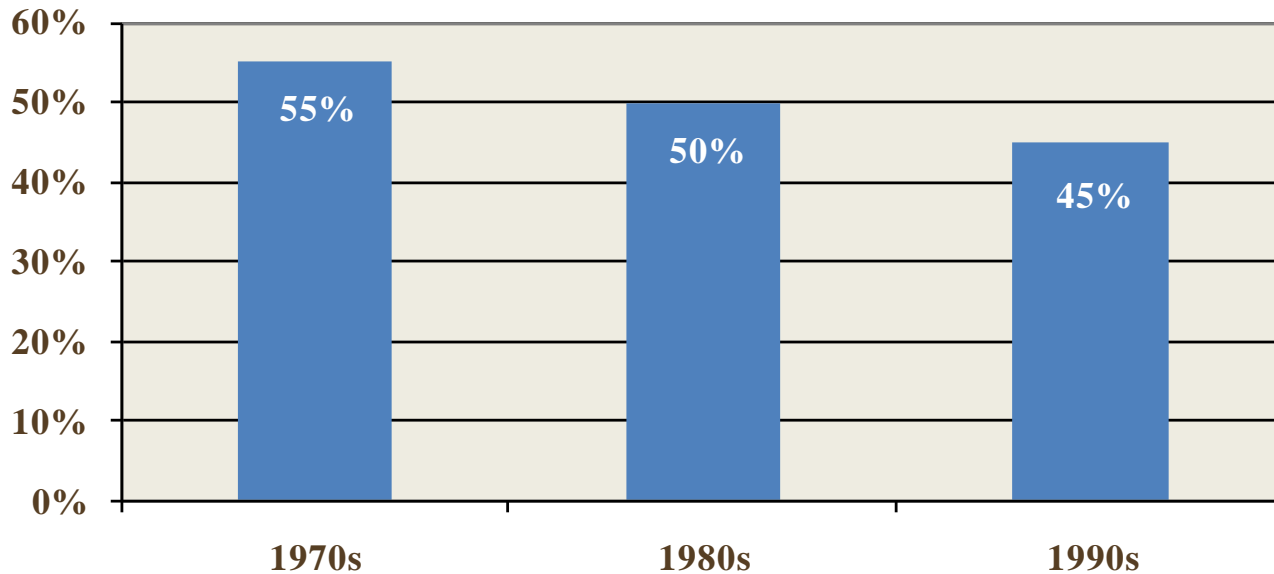|	1970s	1980s	1990s
	56%	45%	31%

Anesthesia Profession (ASA) Patient Safety Contributions

Source: ASA Committee on Professional Liability's Closed Claims Project

Claims for Death and Brain Damage Caused by Respiratory System Events

P<0.05compaired to 1975-79

Decade	Percentage
1970s	55%
1980s	50%
1990s	45%

Anesthesia Profession (ASA) Patient Safety Contributions
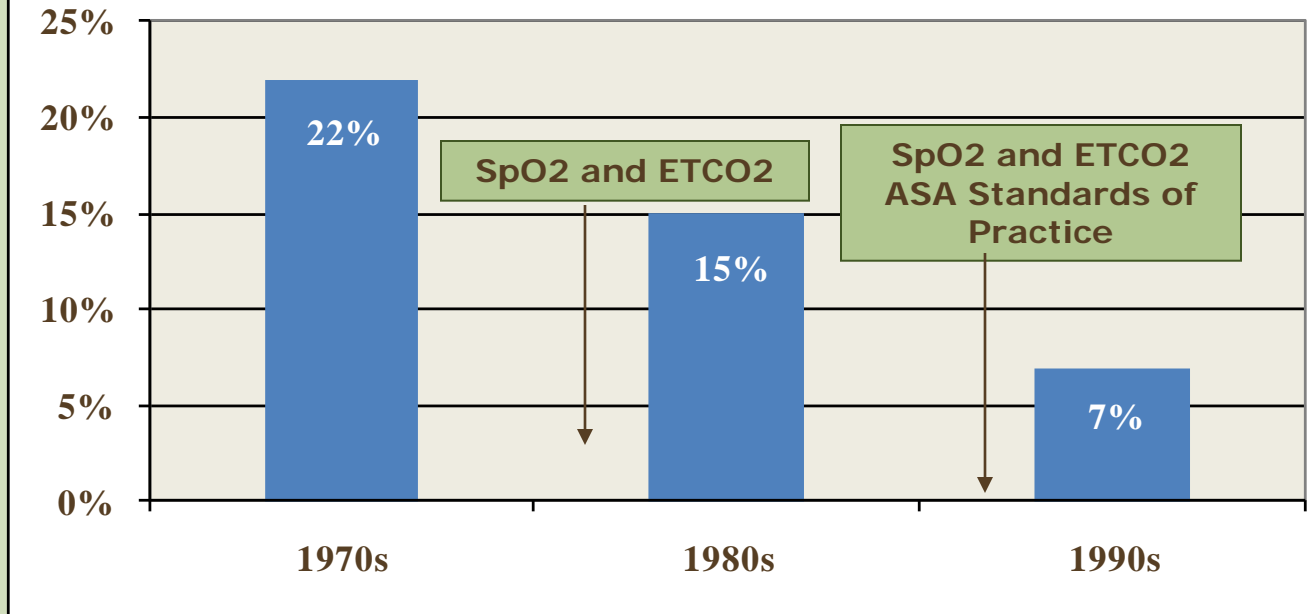
Source: ASA Committee on Professional Liability's Closed Claims Project

Three Most Common Respiratory System Damaging
Events Causing Death or Brain Damage

- Inadequate Ventilation
- Esophageal Intubation
- Difficult Intubation

Anesthesia Profession (ASA) Patient Safety Contributions

Inadequate Ventilation as a Cause of Death or Brain Damage

Anesthesia Profession (ASA) Patient Safety Contributions

Source: ASA Committee on Professional Liability's Closed Claims Project

Still more…

- Anesthesia Patient Safety Foundation (APSF) (1985) (raise awareness of anesthesia related safety issues through research and publication of patient safety materials).
- Develops anesthesia-related practice parameters, minimum clinical practice standards, and evidence-based practice guidelines
- Develops patient safety educational video tapes for use in anesthesiology residency programs and for continuing education

Anesthesia Profession (ASA) Patient Safety Contributions

- Health Risk Appraisals
  - General & Condition Related
  - WellMed
- Electronic Medical Records
  - Clinical vs. Personal
  - Medicalogic
- Practice Guideline Tools
  - Consumer in parallel with physician
  - EBMSolutions

The Promise of eHealth

- Disease Trackers
  - To promote self care and case management
  - PDHI
- Pharmacy Directories
  - Pill identifiers, drug interaction, side effects
  - Micromedix
- Solution-based Health Consumer Content
  - Prescription Information
  - Healthwise

The Promise of eHealth

- Secure Doctor-to-Doctor and Doctor-to-Patient Messaging
  - eVisits
  - Healinx
- Physician and Hospital Selectors
  - Doc Find
- Health Plan Reporting
  - NCQA Accreditation
  - HEDIS
- Patient Safety Guidance
  - Linked to common procedures
  - Doctorquality.com

The Promise of eHealth

Quality and Patient Safety

- Dysquality, CQI, Benchmarking, Re-engineering
- Under use, Overuse, MISUSE
- Preventable errors kill many patients
- Costs (Direct and Indirect) 17-29 Billion
- Focused on Inpatient and Rx
- Presented where we are now
- Described the Challenges

Quality and Patient Safety

- Universal definitions are needed
- Moving to a more responsible system
  - Treasuring Mistakes
- Took a look at other industries
- A glimpse at what one payer is doing
- Suggested the future contribution of eHealth
  - Plug future Webcast again
- Reviewed the IOM Recommendations