Medical Reliability and Safety

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Mishaps

What Do You Fear Most?

- Flying
- Driving
- Medical care
- Nuclear power
- **.....**

Is Fear Based On?

- Data
- Statistics
- Knowledge
- Perceptions
- Experience

Some Mishaps Are Impersonal

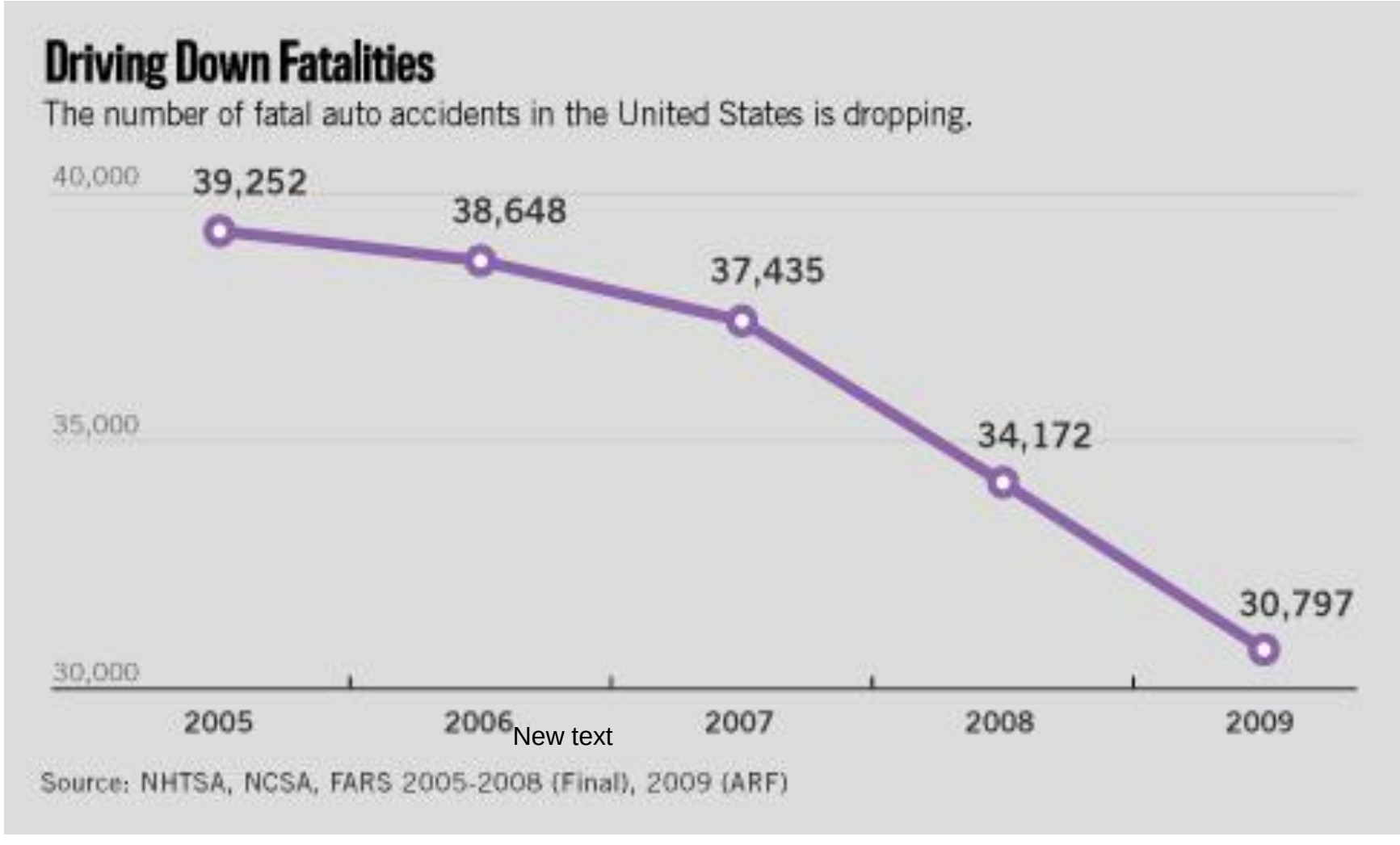
Some mishaps receive a lot of media attention (mass events)

It won't happen to me!

Some Mishaps Are Very Personal

- Typically medical mishaps receive little media attention
- Single events; one at a time; invisible to the public concern
- The expectation is no errors or mistakes

Auto Accidents

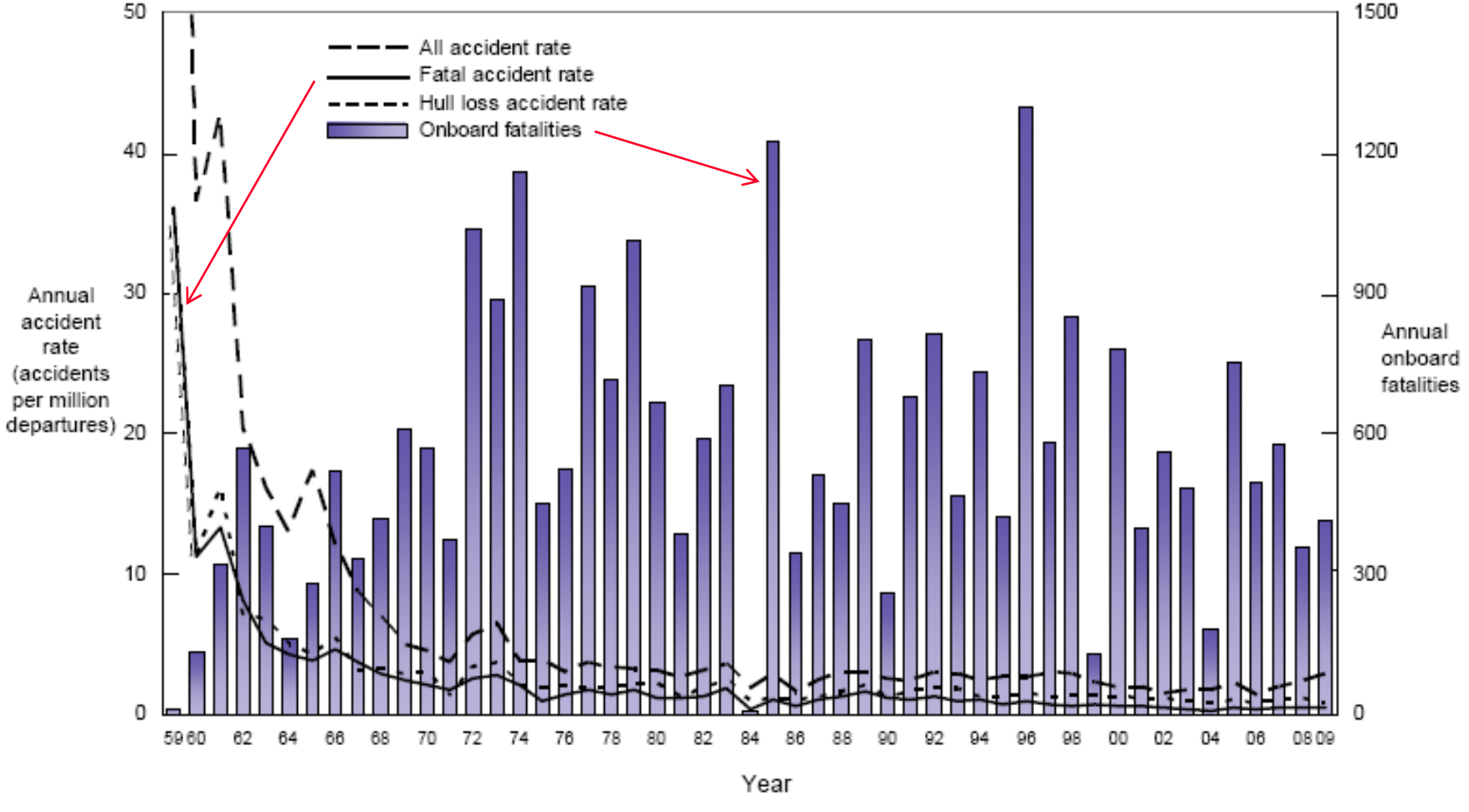


http://www.usnews.com/opinion/articles/2010/09/28/fatal-auto-accidents-declining-in-united-states

Commercial Aircraft Accidents

Accident Rates and Onboard Fatalities by Year

Worldwide Commercial Jet Fleet – 1959 Through 2009



http://www.boeing.com/news/techissues/pdf/statsum.pdf

BOEING

Comparisons

- Mortality rates:
  - Commercial aircraft – 400 deaths worldwide (yr 2009)
  - Automobile – 30,979 death in U.S. (yr 2009)
  - Heart Disease 652,091 (yr 2005)
  - Cancer 559,312 (yr 2005)
  - Medical error 800,000 (yr 2009)
- Medical error is killing as many people as disease
- "Death by Medicine" is becoming a leading cause of death in the U.S.

Null, G., *Death by Medicine,* 2010, Praktikos Books, Mount Jackson, VA

Data Now Withheld from Public

- According to Dr. Marty Makary, a surgeon at The Johns Hopkins Hospital and author of the book *Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Healthcare,* eliminating medical errors must become a national priority.
- But rather than tackling the issue, the US federal government has quietly decided to "solve" the problem by burying it and shielding it from scrutiny... *USA Today (Aug 6, 2014)* recently reported that:
  - *"The federal government this month quietly stopped publicly reporting when hospitals leave foreign objects in patients' bodies or make a host of other life-threatening mistakes.*
  - *The change, which the Centers for Medicare and Medicaid Services (CMS) denied last year that it was making, means people are out of luck if they want to search which hospitals cause high rates of problems such as air embolisms... or giving people the wrong blood type.*
  - *CMS removed data on eight of these avoidable 'hospital acquired conditions' (HACs) on its hospital comparison site last summer but kept it on a public spreadsheet that could be accessed by quality researchers, patient-safety advocates and consumers savvy enough to translate it. As of this month, it's gone. Now researchers have to calculate their own rates using claims data."*

http://articles.mercola.com/sites/articles/archive/2014/08/20/medical-errors-public-disclosure.aspx

August 20, 2014

http://articles.mercola.com/sites/articles/archive/2013/03/24/modern-medical-errors.aspx

Medical Errors (2003)

Condition	Deaths
Adverse Drug Reactions	106,000
Medical error	98,000
Bedsores	115,000
Infection	88,000
Malnutrition	108,800
Outpatients	199,000
Unnecessary Procedures	37,136
Surgery-Related	32,000
TOTAL	783,936

Null, G., *Death by Medicine,* 2010, Praktikos Books, Mount Jackson, VA

Example Mishaps

1984	18-year-old girl dies from medical error, partly due to lax resident supervision
1994	Woman dies from chemotherapy overdose
1995	Diabetic man has wrong leg amputated
1999	Healthy volunteer dies while participating in research study
2001	Healthy volunteer dies while participating in research study
2001	18-month-old girl dies from dehydration
2001	17-year-old girl dies after receiving heart-lung transplant of wrong blood type

Understanding Patient Safety, R. M. Wachter, MD, McGraw-Hill, 2008

Therac-25

- Computerized radiation therapy machine (linear accelerator 25 MeV)
- Derived from Therac-6 (mid 1970s) and Therac-20 (early 1980s)
- Resulted in 8 Major Accidents between June 1985 and Jan 1987
  - Two deaths (severe radiation overdose; burns)
  - Six serious injuries (radiation overdose; burns)
- Transition from hardware system to computer controlled system
  - Some software reuse from earlier versions (Therac-6 and Therac-20)
  - Replaced hardware safety interlock with software interlock
  - Errors not detected and reported
  - Software race conditions resulted in erroneous settings
  - Embedded software design by one engineer
    - Inadequate software engineering practices
    - Inadequate/flawed fault analysis and safety analysis
- Company/industry failed to react aggressively to initial reports of problems

Error Perspective

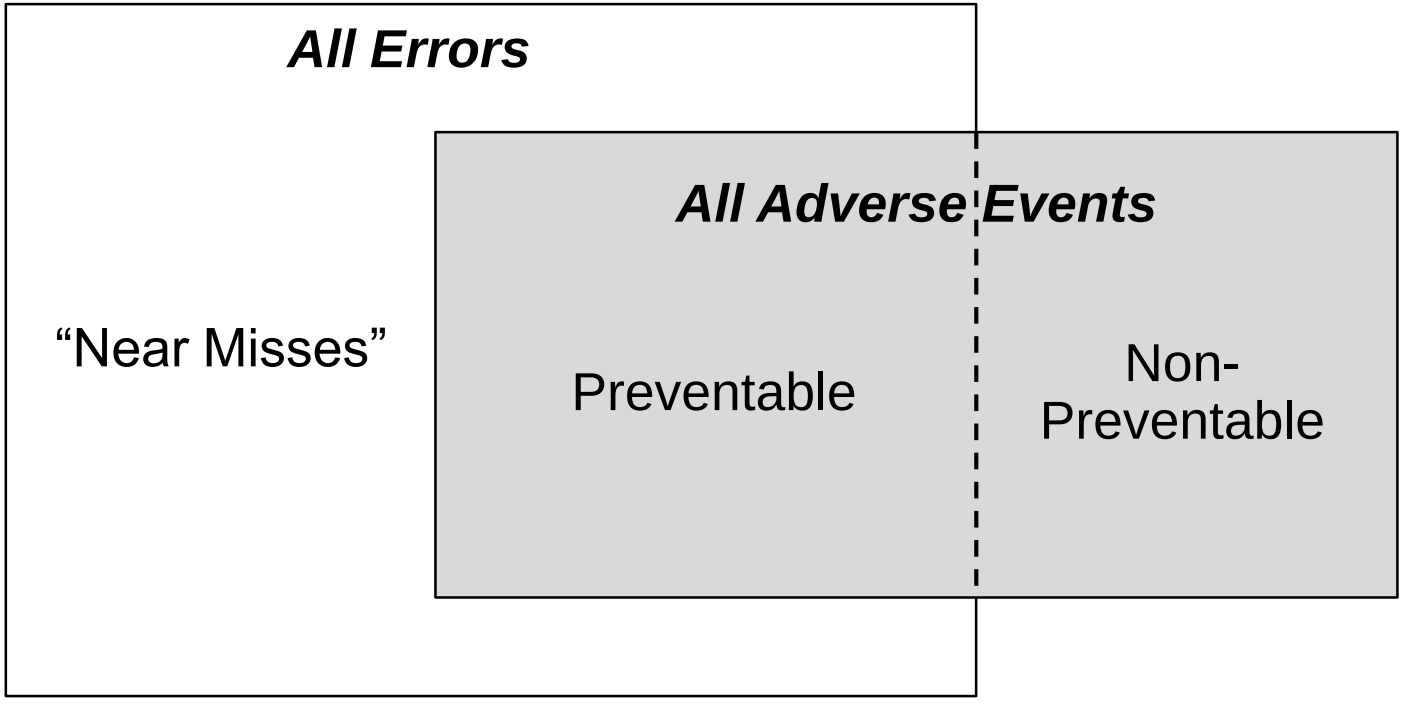
- Dr. Lucian L. Leape opened medicine's Pandora's box in his 1994 JAMA paper, "Error in Medicine”
- ICU patient had an average of 178 *activities* a day
  - Of which 1.7 were errors
  - 1% failure rate (FR)
- Perspective (given 0.1% FR)
  - Two unsafe plane landings per day at O'Hare airport
  - 16,000 pieces of lost mail every hour (U.S. mail)
  - 32,000 bank checks deducted from the wrong bank account every hour (banking)

What is Death by Medicine?

- Medical Error
  - Death as a result of practicing medicine
  - Iatrogenic event (or adverse event) – induced by physician

- Example of medical errors
  - Amputation of wrong leg
  - Surgical procedure error
  - Chemo overdose
  - Radiation burning
  - Anesthesia error
  - Wrong drugs given
  - Wrong diagnosis
  - Chemical fire burning patient
  - Damage during surgery

Patient Safety Terminology



Adverse Event – injury or harm resulting from medical care.
Iatrogenic – adverse effect of medical care rather than underlying disease.
Sentinel Event – adverse event resulting in death or serious harm.

Contributing Factors

- It's an invisible problem; it does not receive attention like an airplane crash
- Archaic dysfunctional medical system
  - Dr. is master and commander
    - Has total control & decision making
    - Cannot be questioned
    - Doctor makes more money the more surgeries he performs
  - No direct and immediate supervisory oversight
  - Insurance companies drive many decisions
  - Fear of reporting errors – liability
- Doctors on BODs of drug companies – conflict of interest for use & recommendations
- Fatigue
- Inadequate staff training

Contributing Factors (cont'd)

- Doctors are rewarded for their efforts, not their results
- It appears that only a fraction of medical errors are reported
  - Protection from lawsuits
  - Job security
  - Results in low visibility
- Medical school – does not teach safety
- Human error is not adequately addressed

- Human error is natural & inevitable, BUT, it can be controlled

Classification of Medical Errors

- Human Factors
  - Fatigue
  - Depression
  - Burn-out
  - Diverse patients
  - Time pressures
  - Variations in training and experience
  - Failure to accept the prevalence of errors

Human error is considered a major factor

- Medical complexity
  - Complicated technologies
  - Powerful new drugs
  - Intensive care
  - Prolonged hospital stays

Classification of Medical Errors (cont'd)

- System failures
  - Poor communication
  - Unclear lines of authority between physicians, nurses, and others
  - Complications increase as patient to nurse staffing ratio increases
  - Disconnected reporting system
  - Drug names that look alike or sound alike
  - The impression that action is being taken by other groups
  - Reliance on automated systems to prevent errors
  - Cost-cutting measures without analysis
  - Irrelevant or frequent warnings from machines
  - Unsafe facilities or environnants

Types of Human Error

- Omission
- Commission
- Sequence error
- Timing error
- Understanding
- Communication
- Perception

- The study of human error is a technical discipline
  - Understanding
  - Prediction
  - Control
  - Reliability

Comparisons - FAA and Medical

Medical Issues	Aviation	Medicine
Type training and check before use of new technology	Always	No
Recurrent training in simulator for skill maintenance	Twice a year	No
Competency checks in simulator	Twice a year	No
Emergency training	Every year	No
Extensive use of checklists	Yes	Some
Duty time limitations and fatigue management	Yes	No
Risk assessment before novel operation	Yes	No
Standard procedure for tasks	Yes	No

Patient Safety: A Human Factors Approach, S. Dekker, CRC Press, 2011, p4

Root Cause Factors

- Funding
- Training
- Lack of knowledge
- Medical schools
- Doctors
- Lack of consistent safety standards & control
- Some aspects of medicine are an art
- Archaic dysfunctional system

Current Actions

- Little has been done to improve – studies & miniscule efforts
- Checklist similar to commercial aircraft checklists (Gawande)
- Pay 4 performance
  - Reward success and quality
  - Undermined by insurance companies
    - Will not pay for new things to reduce errors
    - Will pay for additional procedures due to errors
- 2000 study by the Institute of Medicine
  - Report titled – To Err is Human: Building a Safer Healthcare System
  - Brought the problem into view
  - Recommended 25 solutions to implement – only 4 were adopted
  - Called for a 50% reduction in 5 years, instead the problem has increased

Simple Truths About Medical Errors

There is a well-established body of research about errors in medicine, and most experts agree on the following:

1. Errors will happen. Since no human is infallible, errors are bound to happen, and this includes physicians and their staffs working in the delivery of health care services.

2. Since errors can be expected, systems must be designed to prevent and absorb them.

3. Errors are not synonymous with negligence. Medicine's ethos of infallibility leads, wrongly, to a culture that sees mistakes as an individual problem and remedies them with blame and punishment instead of looking for root causes and fixing problems by improving systems.

4. Creating a culture supportive of error reporting is the starting point in reducing future medical errors.

Medical Errors And Patient Safety: A Curriculum Guide For Teaching Medical Students And Family Practice Residents, New York Medical College, 2003

Simple Truths About Medical Errors

- While errors are a part of every day practice, many errors are the direct result of overly complex processes and are preventable.
- Error rate is significant:
  - As Becher and Chassin write, "If each step in a ten-step process can be performed with 99 percent reliability, that system functions error-free 90 percent of the time.
  - A similar process with fifty steps functions error-free only 61 percent of the time

Medical Errors And Patient Safety: A Curriculum Guide For Teaching Medical Students And Family Practice Residents, New York Medical College, 2003

Medical Safety Goals

- First do no harm
- Prevent the Cure from Being Worse than the Disease
- Make the medical system safe and reliable
- Apply system safety and reliability engineering to medical systems
- Patient Safety – the avoidance, prevention and amelioration of adverse events stemming from the process of healthcare
  - Design for Reliability
  - Design for Safety

Breakthrough !???!

The modern approach to patient safety hinges on "systems thinking" – a recognition that most errors are made by compete tent, careful and caring providers, and preventing these errors often involves embedding the providers in a system that anticipates glitches and catches them before they do harm. (2008)

Understanding Patient Safety, R. M. Wachter, MD, McGraw-Hill, 2008

Reliability and System Safety Engineering have understood this for 40 years

What Can Be Done?

- Application of reliability & safety engineering
  - Processes
  - Tools
  - Equipment
  - Safety culture

- Legislation
- Guidelines
- FDA Requirements
- Reliability/Safety specialists part of hospital staff
- Federal Medical Safety Administration (like FAA)

Past Recommendations

- “Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety”.

- Recommendations:
  - Congress should create and fund a patient safety agency
  - A nationwide mandatory reporting system should be established (analyze, share, report)
  - Establish performance standards
  - Improve drug packaging and naming
  - Implement improved medication safety practices
  -
  -

Recommended 25 solutions – only 4 were adopted

To Error is Human; Building a Safer Health System, Institute of Medicine, Editors: L. Kohn, J. Corrigan and M. Donaldson, Institute of Medicine, National Academy Press, 2000

FDA -- Infusion Pumps

- FDA has seen an increase in the number and severity of infusion pump recalls. Analyses of MDRs have revealed device problems that appear to be a result of faulty design. Between34 January 1, 2005 and December 31, 2009, FDA received over 56,000 MDRs associated with the use of infusion pumps. Of these reports, approximately 1% were reported as deaths, 34% were reported as serious injuries, and 62% were reported as malfunctions. (MDR – Medical Device Recall)
- The most frequently reported infusion pump device problems are: software error messages, human factors (which include, but are not limited to, use error), broken components, battery failure, alarm failure, over infusion and under infusion. In some reports, the manufacturer was unable to determine or identify the problem and reported the problem as “unknown.” Subsequent root cause analyses revealed that many of these design problems were foreseeable and, therefore, preventable.

Guidance for Industry and FDA Staff – Infusion Pumps (Apr 23, 2010); UCM209337.pdf

FDA -- Infusion Pumps

- New FDA document, primarily for design safety and reliability
- The FDA guideline requires:
  - Reliability Program
  - Hazard Analysis
  - Risk Management
  - Safety Case
- A Safety Case is required to show that system hazards are mitigated to an acceptable level of risk

Medical equipment safety is improving

Guidance for Industry and FDA Staff – Infusion Pumps (Apr 23, 2010); UCM209337.pdf

Hazard Categories From FDA Document

- Operational Hazards
- Environmental Hazards
- Electrical Hazards
- Hardware Hazards
- Software Hazards
- Mechanical Hazards
- Biological and Chemical Hazards
- Use Hazards

Hazard coverage

- A Safety Case is required to show that these hazards are mitigated to an acceptable level of risk
  - Safety claim
  - Argument
  - Evidence

Guidance for Industry and FDA Staff – Infusion Pumps (Apr 23, 2010); UCM209337.pdf

Use Hazards From FDA Document

Hazard	Corresponding Risks to Health	Potential Causes
The pump is programmed incorrectly	• Overdose • Underdose • Delay of therapy • Incorrect therapy	• User believes “piggy back” is accounted for in set up but it is not. • The instructions for use are confusing for the user. • The user specifies incorrect configuration parameters (blood glucose reading, drug concentration, etc.). • The user accidentally touches the pump console, presses the wrong key or key “bounces” when hit, changing or mistakenly programming pump settings.
Wrong medication or concentration is delivered	• Incorrect therapy • Delay of therapy	• User selects and sets up pump with incorrect medication or incorrect concentration. • Medication is correct but user selects incorrect concentration or delivery rate for that medication.

Pump delivers overdose because:

a) Failure / malfunction
b) Programmed incorrectly → why? → design error, operator training, etc.
c) Computer fault
d) Software error

Guidance for Industry and FDA Staff – Infusion Pumps (Apr 23, 2010); UCM209337.pdf

Reliability & Safety Tools

- Failure Modes and Effects Analysis (FMEA)
  - Evaluate the effect of potential failure modes
  - Covers HW, SW, HE, processes, procedures
  - Provides component failure rates
- Fault Tree Analysis (FTA)
  - Identifies all causal factors leading to an undesired event
  - Covers HW, SW, HE, processes, procedures
  - Provides a Probabilistic Risk Assessment (PRA)
- Hazard Analysis (HA)
  - Identifies hazards, causal factors and risk
  - Covers HW, SW, HE, processes, procedures
  - Types – PHA, SHA, O&SHA, HHA

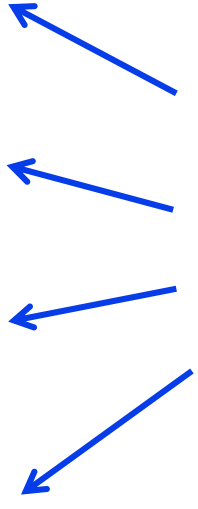
Refer to reference 4 for methodology detail

Tools for Medical Problems

Medical Issues	FMEA	FTA	HA
Surgical errors	X	X	X
Medication errors	X	X	X
Diagnostic errors	X	X	X
Machine use errors	X	X	X
Transition/handoff errors	X	X	X
Teamwork/comm errors	X	X	X
Infection control errors	X	X	X
Records errors	X	X	X
Facility errors/failures	X	X	X
Device failure/error	X	X	X

Safety & Reliability Coverage

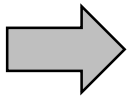
Systems	Problems	Tools
Medical Devices	• HW Failures • Human Errors • SW errors • HW False Alerts	• FMEA • FTA • Hazard Analysis • Reliability Analysis • HRA • PRA • HTS
Surgery	• Failures • Human Errors • False Alerts	
Hospital Support	• Records • Drugs • Sanitation	
Environment	• Infections • Power • Radiation • Storms	



Infusion Pump Hazard Considerations

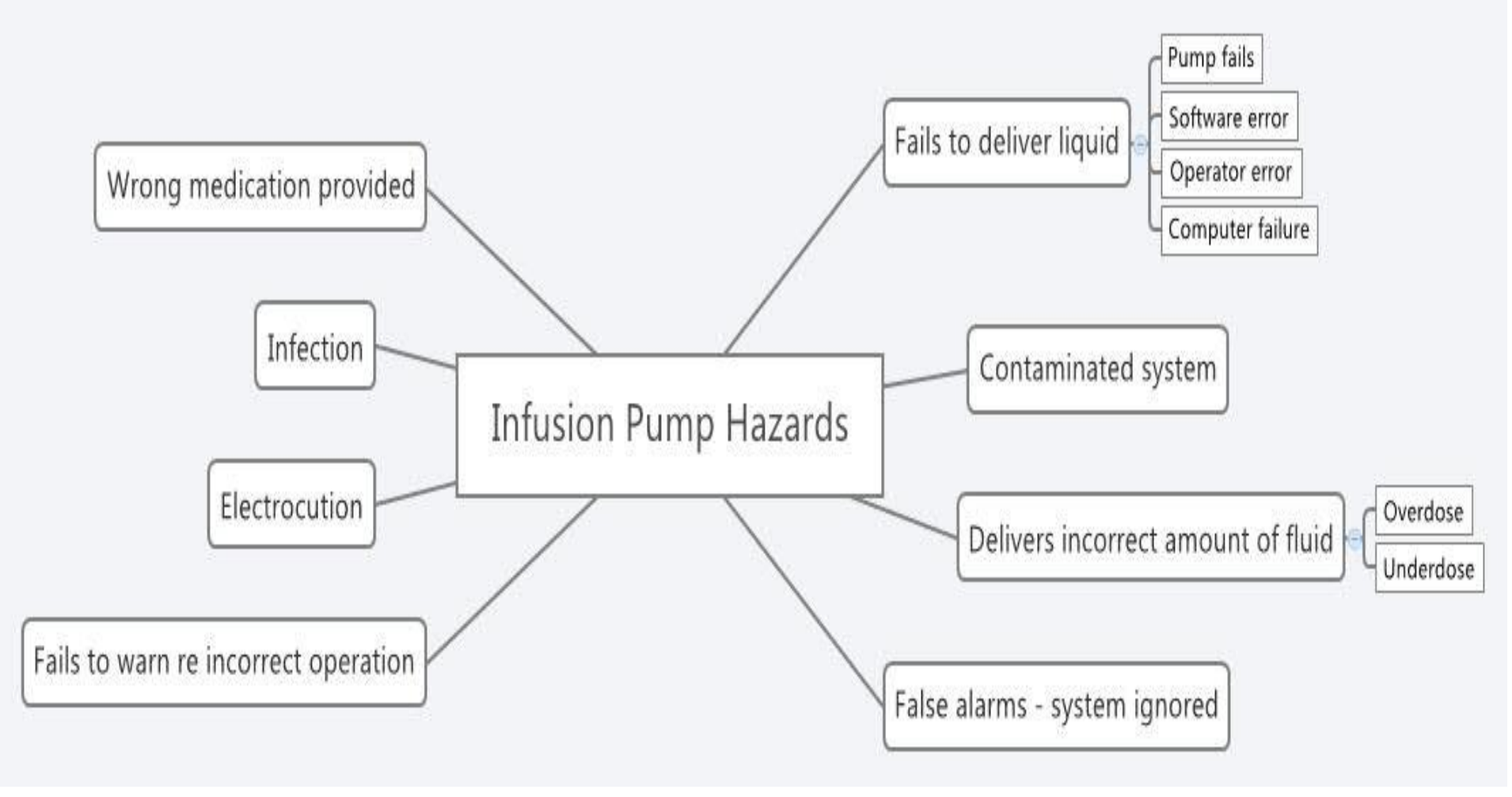
System Components:
- Processor
- Software
- Pump
- Pump Driver
- Warning Subsystem
- Fluid Sensor #1
- ADC Converter #1
- Fluid Sensor #2
- ADC Converter #2
- Touch Screen Control
- Power Input
- Backup Battery
- Wireless Interface
- Memory

System Functions:
- Deliver liquid med
- Shutoff liquid flow
- Control flow amount/time
- Detect abnormal conditions
- Provide warning
- Fail safe



What Happens If:
- Fails to operate
- Unable to control
- Operates incorrectly/erroneously
- Operates prematurely/inadvertently
- Operates out of sequence
- Operates in degraded mode
- Unable to stop
- Sends erroneous data
- Receives erroneous data
- Displays erroneous data
- Causes operator confusion
- Erroneous operator input
- Too too slow
- Too far; too short
- Too much; too little
- Too early; too late; omission
- Wrong direction

SMM for Infusion Pump



SMM-System Mishap Model

Infusion Pump Example HA

Hazard	Effect	Cause	I-Risk	Design Safety Feature	F-Risk
Pump delivers overdose to patient due to pump failure	Patient dies	Pump part *XX* fails	1C	High reliability components.	1E
Pump delivers overdose to patient because pump is incorrectly programmed	Patient dies	• Design of setup is confusing. • Poor operator training. • Software error.	1C	System checks parameters, provides warning.	1E

Conclusion

- A medical healthcare problem exists
  - Patient Safety is not receiving sufficient attention or action
    - Too many iatrogenic deaths / injuries
  - Medical industry is where the airline industry was 40 years ago
  - Reliability and safety are of concern but not taught; randomly implemented
  - No safety oversight at a Federal level
- Recommendations
  - Human error and risk can be controlled through Reliability and System Safety engineering techniques
  - Paradigm shift – change from medicine being an art to medicine as a functionally controlled system (e.g., FAA)
- To err is human, but to allow errors to kill is not acceptable…it is preventable (i.e., the medical system can do better)
- Chapanis – the root of every human error is a design error (1986)

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