Fear Factors
Human Factors
Health Care Reform
There is no pill for the depression caused by a “pandemic of fear”
Outline

• Science of Fear
• Association of Fear and Human Factors
  – Medical errors
• Fear, Human Factors and Health Care Reform
The Science of Fear
The Science of Fear
On September 12, 2001

- We all had to go back to the routine of daily living
- The residual images were visceral
- Flying felt strange and dangerous
- Politicians, pundits and experts weighed in
Flying

• Air travel dropped and car travel surged despite the facts about safety of flying
  – If you fly once a month, you have a 1/135,000 chance of being killed assuming one passenger jet per week is hijacked and all aboard are killed
  – The annual odds of being killed in a car crash-1/6000
• The point is….in the one year following 9/11, 1,595 more Americans were killed in car crashes as a result of switching from flying to driving
  • according to a calculations of a psychologist at the Max Planck Institute in Berlin
The Science of Fear is Not New

• “Let me assert my firm belief that the only thing we have to fear is fear itself—nameless, unreasoning, unjustified terror which paralyzes needed efforts to convert retreat into advance”
  » Franklin Delano Roosevelt

• Three and a half centuries ago:
  – “the thing I fear most is fear”
  » Michel de Montaigne
Recent Epidemic of Fear

- Terrorists
- Internet stalkers
- Drugs
- Infections: Avian flu, SARS, West Nile Virus, Mad Cow, Flesh eating bacteria
- Contaminated food
- Obesity
- Global warming
Why Have We Become a Culture Manipulated By Fear?

• Fear is a great marketing tool
• Fear works quickly
• Fear sells
• Calm and rational often requires time to think things through
Who Benefits From Fear?

• Government sponsored scientists
  – No problems, no funding
• Media
  – Stories of mortal peril get your attention
• Politicians
  – Promise to slay the “wolf at the door” if you elect them
Fear

- Dependent on Cultural values
- Confirmation bias
  - Once a belief is in place, we screen what we see and hear in a biased way that ensures that our beliefs are proven correct
- Group polarization
  - People in groups share beliefs and become more convinced their beliefs are right and become more extreme in their views
- Culture, confirmation bias and group polarization significantly influence what we fear
Body of Science Regarding Fear

• System 1-Feeling/Gut
  – Appearance equals reality rule
  – Works fast through “availability” heuristics and automatic settings
  – May generate irrational conclusions
  – Intuitive, quick and emotional

• System 2-Reason/Conscious Thought
  – Our best bet for accurate results
    • Has its limitations
  – Needs to be educated
  – Often works very slowly
So Now that We Have Everyone Afraid, Let’s Tell Them How Medical Professionals Are Killing People
Medical Errors/Human Factors
IOM Recommends Looking at Aviation As An Example of What Human Factors Principles Can Do

- risk of dying in a domestic jet flight between 1967 and 1976 was 1 in 2 million
- by 1990’s the risk declined to 1 in 8 million
- 1950’s-military aviation safety centers
- 1954-Flight Safety Foundation
- 1960-USC began first advanced safety management program with human factor emphasis
General Principles Gleaned From Aviation

- developed systems approaches to compensate for human propensity to err
- automation
- simplification
- standardization of functions and equipment
- guidelines or protocols
- teamwork checks and balances
  - Not a perfect system but works well especially in procedure oriented specialties
Aviation Safety
Separation of Roles

• FAA (in Dept. of Transportation) has regulatory oversight of the industry and explicit charge of ensuring safety

• NTSB is an independent federal agency that conducts accident investigations and issues recommendations to the FAA but has no regulatory or enforcement power
NASA ASRS (Aviation Safety Reporting System) is a confidential incident reporting system

- incident defined as an occurrence associated with the operation of an aircraft that affects or could affect the safety of operations
What if there was an Airline Run with the Policies and Procedures in Medicine?

• Schedules
  – Each of our captains uses his professional judgment as to when the plane should leave, where it should go, how fast it should fly and when it should arrive

• Aircraft type
  – that is really the kind of technical decision we feel is best left to the pilot; after all he is the one who has to fly it
AMA Airlines

• Fares
  – the pilot, copilot and navigator each charge each individual passenger what they feel they’re professional services are worth and a third party will decide what they will get paid

• Safety oversight
  – pilots and planes are certified by the FAA
  – if there are any questions about safety, the pilots are ethically obligated to discuss the matter confidentially among their peers and then take the necessary corrective action
Why Are Human Factors Important In Aviation?
REMEMBER, QUALITY IS OUR TOP PRIORITY.

QUESTION: IS IT MORE IMPORTANT THAN SAFETY?

OOH...I FORGOT ABOUT THAT ONE.

QUESTION: IS QUALITY MORE IMPORTANT THAN OBEDYING THE LAW?

WELL, PROBABLY NOT.

IF WE COULD MAXIMIZE SHAREHOLDER VALUE BY SELLING LOWER QUALITY ITEMS...

...WOULDN'T WE HAVE A FIDUCIARY RESPONSIBILITY TO DO IT?

I'M SURE IT'S IN THE TOP FOUR.

WHAT IF WE HAD TO LIE TO ACHIEVE QUALITY?
Wally, I discovered a deadly safety flaw in our product. Who should I inform?

No one. The stock would plunge and we'd have massive layoffs. Your career would be ruined.

But my negligence could cause the deaths of a dozen customers. The first dozen is always the hardest.
Human Factors

- Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimize human well-being and overall system performance.
Human Factors Engineering

• **Use error**, and not device failure, is the most important cause of injury associated with medical device use.

• Human factors engineering (HFE) is the most reliable method of reducing the risk of device use error.

• Recent international standards now establish the HFE processes and tools essential to safe device design.
Human Factors Analysis

• “About 44% of manufactured recalls are due to design problems. A case-by-case examination of those recalls indicates the prevalence of design-in errors, or errors induced by bad design.”

Dick Sawyer
- Human Factors Scientist
  Center for Devices & Radiological Health
Trend Internationally

**International ISO/IEC Standards**

- ISO/IEC 62366 – Medical devices: Application of usability engineering to medical devices
  - Extends IEC 60601-1-6 to **all** medical devices, not just electrical medical devices
Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern. Many of the MEDICAL DEVICES developed without applying a USABILITY ENGINEERING PROCESS are non-intuitive, difficult to learn and to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. In simpler times, the USER of a MEDICAL DEVICE might be able to cope with an ambiguous, difficult-to-use USER INTERFACE. The design of a usable MEDICAL DEVICE is a challenging endeavor, yet many organizations treat it as if it were just “common sense”. The design of the USER INTERFACE to achieve adequate (safe) USABILITY requires a very different skill set than that of the technical implementation of that interface.

ISO/IEC 62366
Human Factors Design Cycle

Figure D-1 in ISO/IEC 62366
## Sample of design flaws and associated use errors

<table>
<thead>
<tr>
<th>Example of design flaw</th>
<th>Possible resultant use error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Push-buttons on a control panel are too closely spaced</td>
<td>Operator presses the wrong button</td>
</tr>
<tr>
<td>Two icons on a software screen look too similar</td>
<td>Operator misinterprets the icon and selects the wrong function</td>
</tr>
<tr>
<td>A UI requires a complex, lengthy, and arbitrary sequence of button pushes to initiate an infusion</td>
<td>Operator enters incorrect sequence and fails to initiate infusion</td>
</tr>
<tr>
<td>Infusion pump displays misleading “Open Door-Reset” message when there is air in the infusion line</td>
<td>Operator repeatedly opens the door and presses the reset key instead of clearing air from the infusion line</td>
</tr>
<tr>
<td>Operator-adjusted high and low alarm limits on a heart-rate monitor are not continuously displayed</td>
<td>Operator fails to detect a dangerous increase in heart rate because alarm limit is set too high and operator is over-reliant on alarm system</td>
</tr>
<tr>
<td>Typical operator-applied force exceeds breaking strength of catheter connector</td>
<td>Operator cracks catheter connector when tightening</td>
</tr>
</tbody>
</table>
FDA has initiated regulations to help eliminate human factors flaws

- A manufacturer who lacks evidence of device usability, which relates directly to safety, runs the risk of not receiving FDA clearance to bring its product to market
  - Must conduct human factors related design studies which include performing usability tests that demonstrate that a device is suitable for use
True Tales of Design, Technology and Human Error

- 33 y.o. man positioned beneath a State-of-the-Art Therac-25 Radiation Therapy Machine
- Two keys: pinpoint accuracy and ability to separate treatments
- DEC VT 100 Terminal connected to a PDP11 computer controlled the radiotherapy accelerator
- Two modes of operation:
  - X key: High power x-ray (full 25 million electron volt capacity)
  - E key: low power electron beam mode (200 rad burst)
Some Human Factors Highlights Involving cognition

• All humans, not just old ones, have a tendency to forget, so functions that depend on memory are bound to have some failures
• Failures are predictable because they result from brain functions known to be intrinsically weak
• Short term memory is fallible and medicine requires lots of remembering…. a unit of information or remembering to do something
• More likely to occur when interruptions or distractions
• We tend to “pay attention” to some activities subconsciously… but we are easily distracted
  – Like walking into a room and then forgetting why we are there
Make Critical Information Legible and Readable

• Not all medical information has equal value
  – Vital sign values and alarm messages
• Easy to mistake a 7 for 1; 8 for 3
• Large
• Sharp Contrasts
• Color coding
Present Information in Usable Form

• Converting information from one form to another introduces the opportunity for error

• Initial presentation should be usable form
  – Conversion of units is undesirable
  – Alarms, failure codes and cryptic abbreviations or acronyms can be misinterpreted

• Need to take the cognitive workload out of the displays
Simplify and Ensure Proper Connections

• Sorting through the “malignant spaghetti” of cables, wires and tubes often causes loss of precious minutes or sometimes “fatal” misconnections.
Use of Tactile Coding

- Multitasking of clinicians often use a device without looking at it
- Surgeons watch monitors while doing surgery by “feel”
- Tactile feelings of force to actuate switch
- Distance the switch travels
- Audible cues when switch travels
Prevention of Disabling Critical Alarms

• “Casino syndrome”
  – Caregivers want control over alarms
  – Opponents say safety factor outweighs nuisance factor

• Safest approach
  – prevent the disabling of
  – make alarms smarter
    • smarter devices allow users to silence, but not disable alarms for a predetermined period of time
Automatic Checks

• As microprocessors become smarter, adding software routines that detect possible use errors becomes more feasible

• Alert users to unusual or potentially dangerous settings
  – extension of the device’s alarm system (alerts)
Environment of Use

• Where used, shipped and stored
  – Assists engineers in developing appropriate design input and verification test criteria for a device and packaging configuration
  – Eg. oxygen sensors that are altitude dependent and might be used with life-flight operations
Guard Critical Controls

• Prevent accidental and unauthorized actuation
  – Pressing and holding a power key
  – Recessed push buttons
  – Lever interlocks requiring actuation of a release mechanism (like pressing brake before putting a car into drive)
  – Software interface requiring a password
Do Not Permit Settings to Change Automatically

• Devices resetting themselves or unexpectedly changing their operational state without the user knowing
  – Highly frustrating
• Need to boldly indicate any changes that were not initiated by the user
• Users should have full control of important settings under all conditions
Reduce Potential for Negative Transfer

• User applies experience from using one device to another device even though they do not function the same way
  – Use of arrows with a confirming button versus use of arrows without a confirming button

• Even minor differences invite the user to confuse the operation of the two devices
Is there a pill we can take to make the fear and depression go away?
Psychological Pandemic of Fear

- People are in a kind of suspended alarm state
- Waiting for the future to unfold and not expecting it to be good
- The world we know is receding
- “The dread is chronic”
- We are worried about a way of life and the loss of the upward trajectory
Psychological Pandemic of Fear

• Leaders thought to be selfish and dishonest
• Institutions thought to be incompetent and undependable
• People feel unled and overwhelmed and feel the situation is unsalvageable
• The moment we are living now is a strange one, a disquieting one, a time that seems full of endings
  – There is no pill for that.
The Pill is:
Stimulus Package
Can you feel the tingle?
If one wishes to be a true scientist-an explorer not in search of what one desires to be true but rather in search of whatever truth there is-then one must be willing to accept, to engage, even to pursue further the most unwelcome and confounding data. One must be willing to make discoveries that shatter one’s most deeply held beliefs. Maybe it turns out that the Earth is not the center of the universe.”

Rivka Galchen
Conventional Wisdom

• Often masks unwelcome and confounding data
• Extrinsic incentives (financial compensation) often conflicts with intrinsic incentives (the moral command to do one’s duty)
• Ask the question- Will financial incentives result in desired human behavior?
The Hidden Forces That Shape Our Decisions

DAN ARIELY
Reform plan broken down into three parts saying that it builds “upon the strengths of the U.S. health care system.”

• 1. Quality, Affordability and Portability
• 2. Lower Costs & Improve Quality
• 3. Prevention & Public Health
New Administration’s Plan

• Promote patient safety
  – Requirement to report preventable medical errors

• Align incentives for excellence
  – Providers who see patients in the National Health Insurance Exchange, Medicare and FEHBP rewarded for achieving performance thresholds on outcome measures
New Administration

- Relies on the evidence from research that pulls heavily from reports by the Commonwealth Fund and the Institute of Medicine
- The nonprofit Commonwealth Fund has published studies showing that moving from paper medical records and prescribing to electronic technology can save money
- Health information technology is the cornerstone of the new healthcare reform plan
Highlights

• Health information technology investment is aimed at reducing unnecessary spending that results from preventable errors and inefficient paper billing systems.
• Improving prevention and management of chronic conditions.
The Doctor of the Future

Now with Turbo Clogs

Whiz-Bang gadgets

That will change the way you practice!
The Five Core Elements of Personalised Medicine

The Digital Health Care System
EMR/EHR
What Are the EMR Companies Promising?

• Fast implementation times
• Reasonable pricing
• Integration with existing software
  – Pre-loaded software demonstrations aren’t the same as real use conditions;
Joint Commission’s Position on Where EHRs Might Add Value

- Improve Accuracy of Patient ID
- Improve Effectiveness of Communication Among Caregivers
- Improve Safety of Using Medications
- Improve Effectiveness of Clinical Alarm Systems
So Why Am I Skeptical?

Beside the fact that EHRs have been around for about 50 years and have a low adoption rate
Magical Thinking
Skeptical

- Systems are often implemented with much fanfare and expense but rarely fulfill their promise or realized the anticipated cost savings.
- The implementation process is usually too constrained and doom the projects to failure.
Misalignment of Incentives

• Why in an environment characterized by major regulatory and reimbursement challenges, should the doctor be asked to invest in medical record systems whose primary beneficiaries are elsewhere?
History of EHR Failure

• About 50% of all EHR installations fail
  – Some are abandoned and some just get less than optimal use

• Many are only partially implemented
  – If only one person keeps paper charts, you lose much of the efficiency and effectiveness of the EHR
Failures

• Many vendors have products that are not ready for “prime time”
• Many physicians who buy EHRs don’t have the time, patience or know how to build the templates required
• WORKFLOW issues are grossly underestimated!
  – Need to rethink every process
Other Reasons for Failure

• Fragmented US Health System results in local decision making on IT investment
• Few professionals trained to work at the intersection of biomedicine and IT
  – Result
    • Elegant systems that have unrealistic workflows
Change is VERY Difficult

• EHRs can support, extend and enhance what the clinician does….but they will also CHANGE what the physician does
• Not trivial…humans react to change in a number of ways….may be counter to:
  – Organizational goals
  – Improved patient care
  – Expectations of the physician
Culture eats a good idea for breakfast every morning

• My paper system is just fine
  – no relative advantage
• It won’t work in my practice
  – incompatible with existing workflow
• It takes too much time and will be disruptive
What Will Be The Innovations That Might Work?
Everyone Has An Opinion
“The significant problems we face today cannot be solved at the same level of thinking we were at when we created them”-Einstein

- Sustaining technologies usually incrementally improve performance
- Disruptive technologies often result in worse performance but offer some fringe advantages
  - cheaper, smaller, simpler and often more convenient
Sustaining Innovation

• Risk missing less complex, more convenient and affordable innovations designed for simpler, less demanding needs

• The innovation usually outstrips customer’s ability to utilize the new features
  – Overshoots the needs of less demanding customers

• Capabilities eventually become disabilities
Disruptive Innovation

- Technologically simplistic but functionally appropriate
- Often unattractive or ignored by industry leaders
- Do not require existing customers to change but expands to meet needs of new ones
- Gives capability to less costly, less skilled staff to perform work formerly done by expensive, less-accessible specialists
Disruptive Innovations

• In any industry, a disruptive innovation sneaks in from below

• Dominant players are focusing on improving their products or services to the point where the average consumer gets overwhelmed
  – they miss the low end of the market

• Over time, the simpler offerings get better
Disruptive Innovation

• **Disruptive** technologies have caused many of history's best companies to plunge into crisis and ultimately fail.

• This phenomenon of overshooting the needs of average customers and creating the potential for disruption quite accurately describes the **healthcare** industry.
Disruptive Innovations

• Many of the most powerful innovations that disrupted other industries did so by
  – enabling a larger population of less skilled people to do more in a convenient, less expensive setting

• Opportunity for health care
  – Doing things that historically could be performed only by expensive specialists in centralized, inconvenient locations.
Innovator’s Prescription

• Hospitals-workshops within which physicians are trained and practice their intuitive craft

• Complex cases are solved and unanticipated emergencies and complications are resolved with as much certainty as possible
Hospital Business Model

• Do everything for everybody
  – Not a viable value proposition for any successful business

• Could the model be broken into 2 parts?
  – Defining the problem, what is causing it and what can be done to correct it
  – Fix the problem effectively, affordably and conveniently
Two different business models within the same operating unit

- “If not for the tangled web of subsidies, administered prices and regulations that constrain competition, today’s general hospitals would not be economically or competitively viable”
- Answer might be Solution Shop Hospitals and Value Adding Process Hospitals
Solution Shops

- Solution shops—essentially diagnostic activities
  - Centralized labs and imaging departments filled with most advanced technologies
  - Those who assemble and interpret the results are schooled in the arts of intuitive medicine
  - If the finest can’t definitively diagnose the problem, they have the resources to test and refine hypotheses
Value Adding Process Hospitals

• Addresses the jobs-to-be-done
  – Fix the problems after the diagnosis is made

• Surgeries, interventional radiology

• A lot like a manufacturing plant
Why Might Disruptive Innovations Fail?

- Most innovations generally fail in the marketplace
  - health care providers find failure too risky
- Two psychological principles key in understanding resistance to change (or willingness to try new things) include:
  - Habit toward an existing practice or behavior
  - Perceived risks associated with innovation adoption
Is Dr. Google in the House?

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CVS
Dispensing Drugs-And Health Reform

• CVS/Caremark is one of the 20 biggest companies in America

• Tom Ryan, CEO
  – Wants to transform Health Care System using
    • CVS’s vast prescription database
    • Burgeoning network of in-store clinics
      – Treat chronic disease
      – Keep patients out of hospital
  – Drive compliance
Convenient and Accessible
CVS/Caremark

• Combination of a national drug chain and a PBM
  – essentially adversaries
  – May depend on new administrations support of managing chronic diseases

• Banking on greater use of IT and attacking chronic disease (sound familiar?)

• Example: a PBM patient gets a call from a pharmacist because he stopped ordering drugs—may drive home the medical and economic importance of compliance
In-Store Medical Care

• 500 Minute Clinics
• Over 100 million visits for mostly low acuity conditions
• Some clinics now on premises of Caremark’s corporate clients such as AT&T
  – Believed to reduce absenteeism and overall health care costs
• New model-Maintenance Choice
  – Savings of mail-order prescription with pick-up convenience at local CVS Stores
Disruptive Innovation
What Might Work?

• Target undemanding applications where patients will be delighted to have simpler, more accessible care

• Allow patients to access treatment formerly only available in inconvenient and centralized settings

• Start simple and inexpensive
  – Incrementally add value
Brainstorming

A mild sprinkling of free association quickly turned into a brain storm.
Thank You