
Good
Morning

Medical Errors

How Your healthcare May Be Harming You

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Plan for the Course

- Session 1: Introduction and Definitions
- Session 2: Diagnostic Errors
- Session 3: Medication Errors, Surgical Errors
- Session 4: Communication Errors
- Session 5: US Healthcare System/Industry
- Session 6: Science and Technology
- Session 7: Comparison with Other Countries
- Session 8: Solutions, Reduction, Prevention

OLLI Fall 2023 Semester
September 7, 2023

SESSION 1
INTRODUCTION and DEFINITIONS

Plan for the Session

- Definitions: Medical Error, Iatrogenesis
- Background studies
- IOM 1999 *To Err is Human* report
- Healthcare system errors
- Medical error deaths = daily jumbo jet crash
- Healthcare errors and negative outcomes
- IOM 4-Part Action Plan and Recommendations

Medical Errors

- Preventable adverse effects of medical care, whether or not harmful to the patient.
- Mostly associated with new procedures, extremes of age, urgency, and the severity of the medical condition.
- Serious consequences most likely to occur in:
  - intensive care units (ICUs)
  - operating rooms (ORs)
  - emergency departments/emergency rooms (EDs/ERs)

Iatrogenesis

- From the Greek *iatros* (physician) and *genesis* (origin).
- Through miscalculated risk, error or negligence, the physician becomes a causal agent of harm instead of healing,
- Injury from clinician's actions includes side effects and risks associated with medical intervention.

Iatrogenesis

- Causation of disease, harmful complication, or other ill effect by any medical activity, including diagnosis, intervention, error, or negligence.
- It includes mental suffering via practitioner's actions or statements.
- In a 2013 estimate, about 20 M negative effects from treatment had occurred globally, and an estimated 142K persons died from adverse effects of medical treatment (up from an estimated 94K in 1990).

INITIAL REPORTS
Before ***TO ERR IS HUMAN***

Initial Reports

Before *To Err is Human*

- In 1964 Schimmel reported that 20% of patients admitted to a university hospital medical service suffered iatrogenic injury and that 20% of those injuries were serious or fatal.

- Steel in 1981 found that 36% of patients admitted to a university hospital medical service suffered an iatrogenic event, of which 25% were serious or life-threatening, and more than ½ of the injuries were related to medication.

- In 1991 Bedell analyzed cardiac arrests at a teaching hospital, and found that 64% were preventable, and that medication use was the leading cause of the events.

Harvard Medical Practice Study

(HMPS)

- HMPS reported a study of iatrogenic injury among the 2,671,863 patients discharged from the state of New York hospitals in 1984:
  - 98,609 (4%) patients had adverse events with an injury that prolonged their hospital stay or resulted in serious disability
  - 13, 806 (14%) of these injuries were fatal
  - 27,179 (27.5%) adverse events involved negligence.

- Author Lucian Leape said: "If these rates are typical of the US, then 180K people die each year partly as a result of iatrogenic injury, *the equivalent of 3 jumbo-jet crashes every 2 days."*

- *By March of 1995, Newsweek had* slightly altered it, dropping the *"three-every-two"* formulation to just *"a jumbo-jet crash every day."*

Harvard Medical Practice Study

(HMPS)

- Examined adverse events in healthcare organizations.
- Established measuring standards for those events.
- Laid the basis for policy discussions on patient safety.

The methods used were based on the 1977 California medical insurance feasibility study applied to a random sample of patients and hospitals, and gave one of the 1st large sample estimates of adverse events.

Harvard Medical Practice Study
(HMPS)

- HMPS method for identifying adverse events is based on a two-stage retrospective chart review.

- In the 1st stage, nurses screen patient records that are likely to include an adverse event.

- In the 2nd stage, physicians review selected charts in more detail to confirm adverse events and to assess how much they indicate substandard care.

INSTITUTE of MEDICINE (IOM)
1999 REPORT

To Err is Human

TEIH

- Quality of Health Care in America project was initiated by the IOM in June, 1998.
- Charge was to develop a strategy that would produce a threshold improvement in healthcare quality over the next 10 years.
- *To Err is Human,* published in 1999 is the 1st in a series of reports to be produced by the project.

To Err is Human

TEIH

- Examines how the forces of legislation, regulation, and market activity influence the quality of care provided by healthcare organizations, and how they handle medical mistakes.

- Reveals the statistics of medical error and the disparity between incidence and the public perception of them.

- Many patients' expectations are that their healthcare always performs perfectly.

Objectives of TEIH Report

- Identify Errors in Healthcare
- Frame a comprehensive approach to improving patient safety.
- Describe how and why healthcare errors happen.
- Build leadership and knowledge for patient safety.
- Analyze error reporting systems.
- Protect voluntary reporting systems from legal discovery.
- Set performance standards and expectations for patient safety.
- Create safety systems in healthcare organizations.

To Err is Human

TEIH

- Two large studies found that adverse events occurred in 2.9 % and 3.7 % of hospitalizations.
- In Colorado and Utah hospitals, 6.6 % of adverse events led to death, while in New York hospitals, it was 13.6%.
- In both studies, > 50% of these adverse events resulted from preventable medical errors.

Consequences of Medical Errors

- When extrapolated to the >33.6 M admissions to U.S. hospitals in 1997, the Colorado and Utah studies imply that 44K patients die each year from medical errors.

- The results of the New York Study suggest the number may be as high as 98K per year.

- If true, more people would die in any year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

To Err is Human

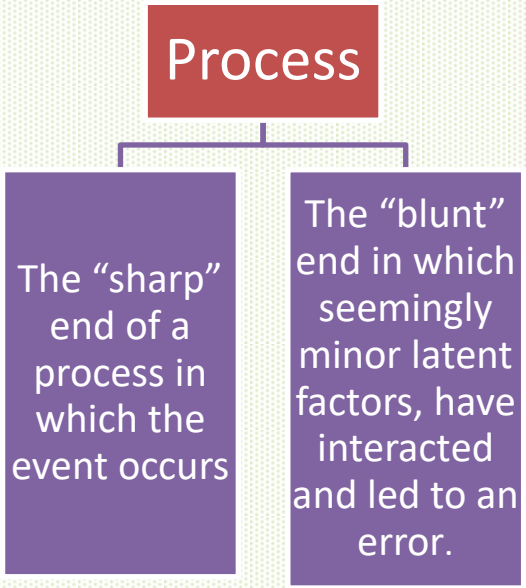
TEIH

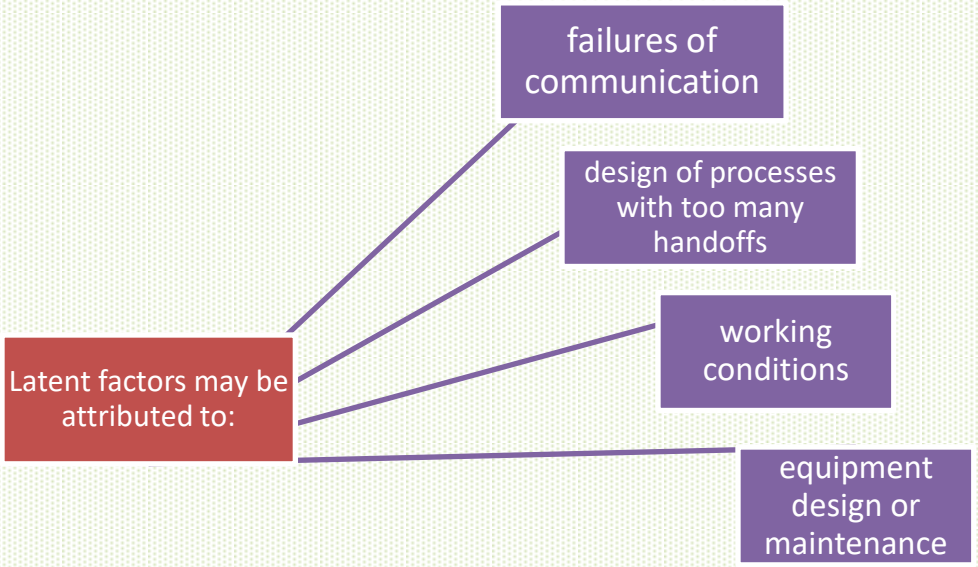
- *TEIH* asserts that the problem is not bad people in health care: it is that good people are working in bad systems that need to be safer.

- This report offers a clear, comprehensive and straightforward prescription for raising the level of patient safety in American healthcare.

- It also explains how patients can influence the quality of care that they receive in a hospital.

Adverse Event Factors





To Err is Human

TEIH

- Systems should make it hard for people to do the wrong thing and easy to do the right thing.
- Healthcare systems should design processes to keep patients safe from accidental injury.
- The goal is to create sufficient pressure to make errors costly to health care organizations and providers, so they improve safety.

To Err is Human

TEIH

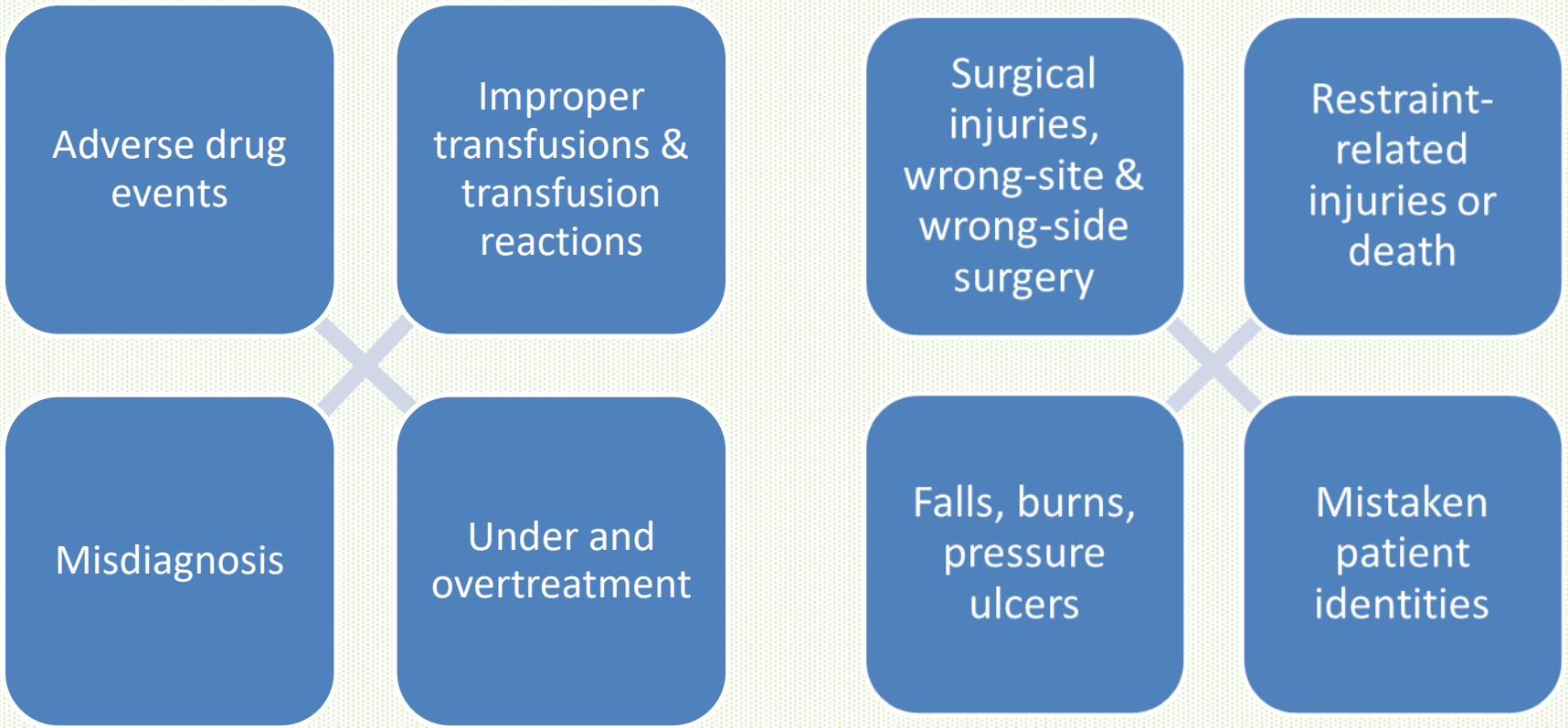
- Unsafe care is the price we pay for having disorganized systems of care without clear accountability lines.
- It's unacceptable that patients are harmed by the same healthcare system that is supposed to offer them healing and comfort.
- After agreeing to a treatment, patients should be assured that it will proceed correctly and safely to achieve the desired outcome.

Cost of Medical Errors

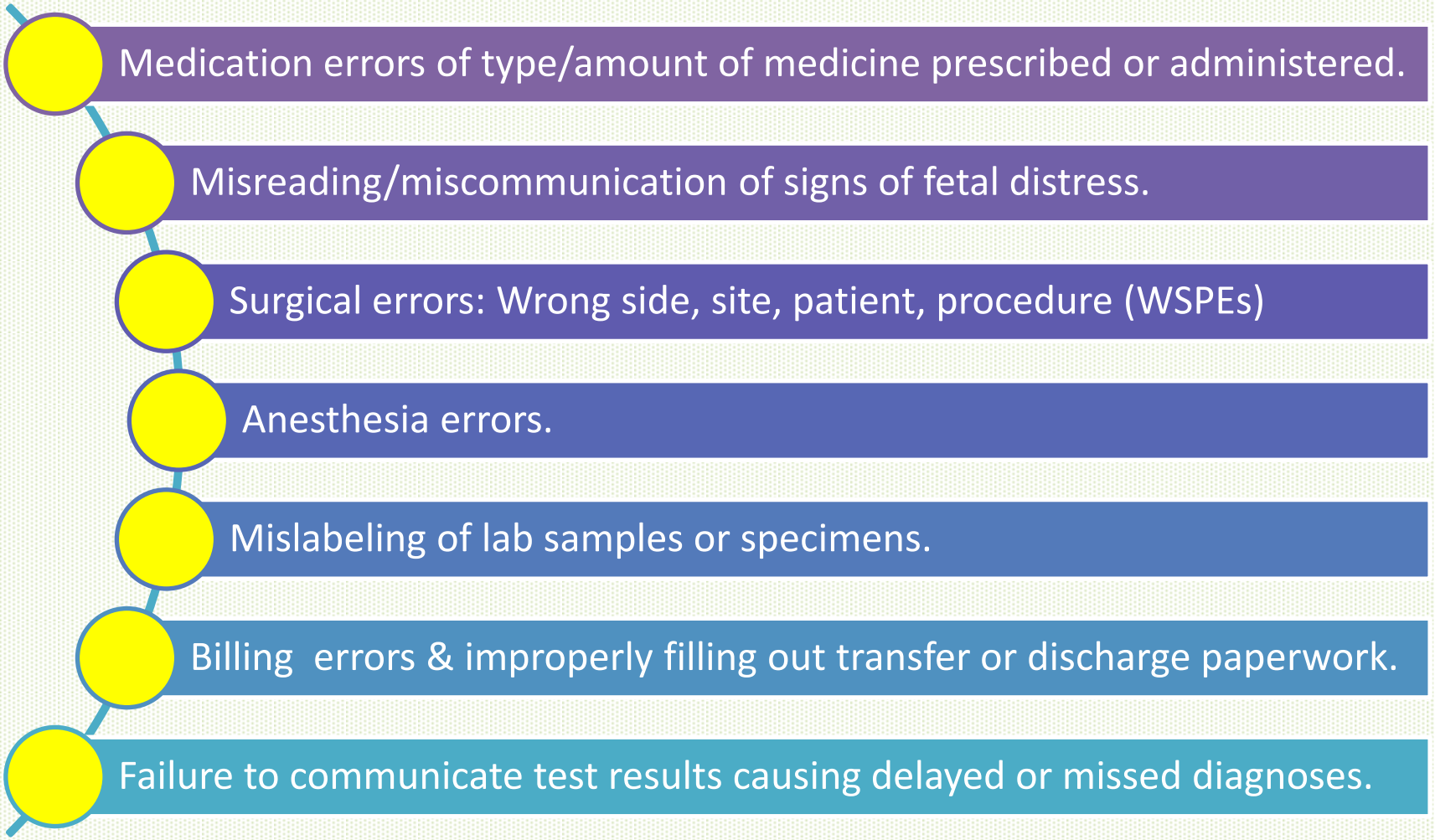
- Total national costs of preventable medical errors resulting in injury are estimated to be between $17 B and $29 B, of which health care costs represent over 50%.

- Medication errors, in or out of the hospital, are estimated to cause >7K deaths annually.

Common Medical/System Errors



Healthcare System Errors



Billing Errors

- Patients are charged for procedures they did not receive, or for staying longer at a facility than they actually did, or when correct procedures or stays are coded incorrectly.
- Medical billing errors cost Americans around $210 B annually.
- Around 80 % of medical bills contain some type of error, rarely in favor of the patient.

Major Medical Complications in US

- Central line-associated bloodstream infection (CLABSI)
- Surgical site infections (SSI),
- Catheter-associated urinary tract infection (CAUTI)
- Ventilator-associated pneumonia (VAP)

- Obstetrical adverse events
- Injury from falls
- Injury from burns
- Injury from immobility
  - Pressure ulcers
  - Venous thrombosis (blood clots)
  - Restraints injury

NEJM 1991

5 Most Diagnosed Conditions

- Cancer related issues
- Neurological related issues
- Cardiac-related issues
- Urological related issues
- Complications in surgery and post-op

BMJ 2016 AND 2019 STUDIES

The 2016 BMJ Study

(3rd Leading Cause of Death)

- In 2016, Johns Hopkins patient safety experts examined 4 separate studies that analyzed mean death rate data from 2000 to 2008, and calculated that >250 K deaths per year are due to medical error in the U.S.

- Using 2013 hospital admission rates, they extrapolated that of 35,416,020 total hospitalizations, 251,454 deaths (9.5 %) each year in the US were caused by a medical error.

- The CDC's 3rd leading cause of death is respiratory disease, with 150K deaths/year, so medical error became the 3rd cause.

The 2016 BMJ Study

Problems and Criticism

- Mistakenly extrapolates an observation found in one population sample to a different type of entire population.
- If we look at everyone hospitalized in the United States, 1 out of 10 patients is there to deliver a baby.
- Taking death statistics from a sample of Medicare patients and extrapolating it to all hospitalized patients is like turning apples into oranges.

Medical Error 3rd Leading Cause of Death

Fake News

- In 2019, a video released by the NRA used this myth to claim that medical malpractice was deadlier than guns, because deaths from medical errors were 500X higher than deaths from accidental gun incidents

- The claim has also been weaponized by believers in alternative medicine to paint conventional medicine as dangerous while touting the alleged safety of their favorite pseudo-medical practices.

The 3rd Leading Cause of Death?

Problems and Criticisms

- The BMJ Article analyzes studies that were never meant to look at deaths caused by medical errors.
- They combined and reported in a crude way a very small number of deaths from populations that are not generalizable to the whole of the US.
- The BMJ's higher estimate of 440K preventable patients deaths/year due to medical error, would equal 62% of all hospital deaths!

The 2016 BMJ Study

Problems and Criticisms

- Based on studies whose data was never meant to be generalized to the entire U.S. hospitalized population.
- One of these studies was conducted in Medicare patients, 65 or older, with disabilities or ESRD.
- The authors counted the deaths in their sample linked to medical errors, and then used it in the analysis to extrapolate to all U.S. hospitalizations.

Other Studies

- A study from the UK showed that 3.6% of hospital deaths were due to preventable medical error
- A similar study out of Norway reported 4.2%
- A meta-analysis (BMJ, 2019) concluded that 5% of patients were affected by preventable harm, and 12% suffered from permanent disability or death because of this harm.

BMJ 2019 Meta-Analysis

- 70 (from a total 7,313) reports involving 337,025 patients in the UK were included in the meta-analysis.
- 28,150 patients (8%)had harmful incidents and 15,419 (4.5%)had preventable harmful incidents
- A total of 47,148 harmful incidents were found in the sample, with 25,977 (55%) being preventable.

Preventable Patient Harm

PPH

- The result of an identifiable, modifiable, preventable cause for an event whose recurrence can be avoided by adaptation to a process or adhering to guidelines

- Developing and implementing evidence-based mitigation strategies specifically for PPH could lead to major cost-effective service quality improvements in care.

BMJ 2019 Meta-Analysis

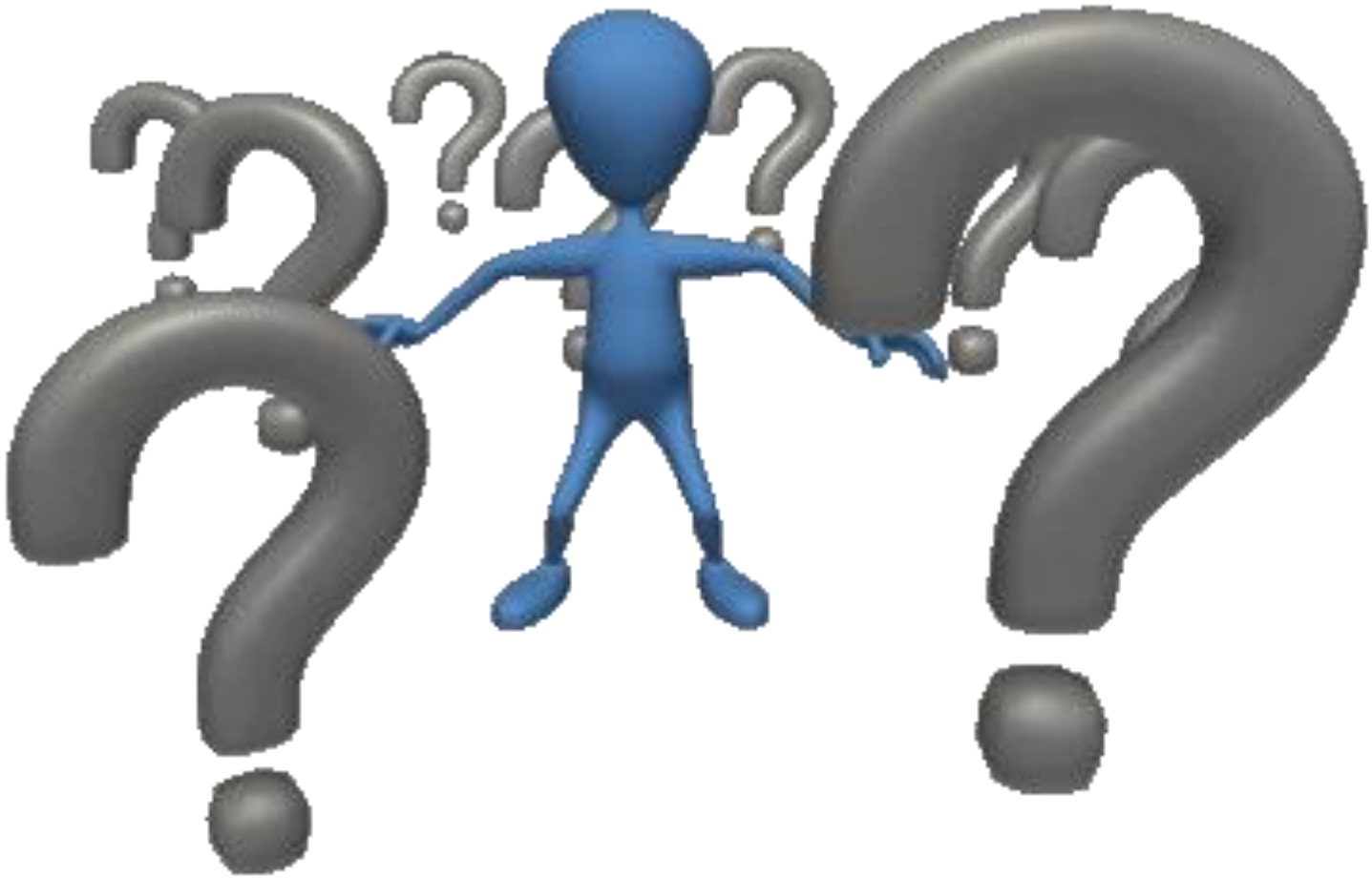
- Preventable patient harm was 6%, with drugs (25%) and other treatments (24%) accounting for the largest proportion of them.
- Studies varied considerably, and It was hard to determine if a particular patient harm was preventable or not.
- 33 studies (47%) were conducted in the US, 27 (39%) in Europe, and 10 (14%) elsewhere.

BMJ 2019 Meta-analysis

A study reported that the doctors who review hospital medical files to make the assessment of Preventable Patient Harm (PPH) often disagree:

- If 1 reviewer decided that a death was preventable, there was only a 16% chance that a 2nd reviewer would agree.
- Also, there was a 15% chance that a 2nd reviewer would clearly disagree.

Questions? (1)



MEDICAL ERRORS

Medical Errors Fake News

- If you constantly read in popular medical papers and reports that:
  - more Americans are killed in U.S. hospitals every 6 months than died in the entire Vietnam War
  - medical errors kill the equivalent of 3 fully loaded jumbo jets crashing every other day
  - these errors and injuries are borne of a cult of silent denial

- Re-read carefully and think!

- It's an imperfect system requiring active striving for improvements, but problems in aircraft design should not encourage us to see if carpets can fly.

Medical Errors

- Consensus protocols that streamline the delivery of care and reduce variability can improve quality and lower costs in healthcare.

- Regarding medical errors, it has been said that you can’t manage what you can’t measure; but using incredible numbers borne out of unreliable calculations cannot be the solution.

Medical Errors

Medical errors are underestimated because:

- studies tend to focus exclusively on hospitals and not on the rest of the healthcare system
- some errors may have debilitating effects only years down the road, and are thus harder to trace
- reporting these errors may not be encouraged by the medical culture

International Classification of Diseases
Clinical Modification (ICD10-CM)

- The coding system used in US was designed to maximize billing for physician services, not to collect national health statistics.

- Medicare & Medicaid use ICD10-CM codes to determine the amount of payment for health care services given to beneficiaries.

ICD10-CM

- There are around 70K diagnosis codes that can be used, and around 71K procedure codes available.

- For many years, diagnostic errors and medical mistakes resulting in a person's death were under-codified and unintentionally excluded from health statistics.

IOM Findings

- National Roundtable on Health Care Quality described how variable the quality of health care is in the US and highlighted the urgent need for improving it.

- National Cancer Policy Board report concluded that there is a wide gulf between ideal cancer care and the reality that many Americans experience with cancer care.

Who Loses?

Everybody!

Patients lose trust in the system and they and health professionals have diminished satisfaction.

Patients have longer hospital stay or disability as a result of errors and pay with physical and psychological discomfort.

Healthcare professionals pay with loss of morale and frustration at not being able to provide the best care possible.

Employers and society lose worker productivity, have reduced school attendance, and lower levels of population health.

Adverse Event
Near-Miss Event
Swiss Cheese Model
Sentinel Event
Never Event

HEALTHCARE ERRORS and NEGATIVE EVENTS

Healthcare Error

- The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

- Errors depend on 2 types of failures:
  - Planning error: the original intended action is incorrect
  - Execution error: the action does not proceed as intended

JT Reason 1993

- Errors can happen in all stages in the process of care, from diagnosis, to treatment, to recovery, rehab and preventive care.

Adverse Event

Preventable Adverse Event (PAE)

- Preventable or unpreventable injury resulting from medical management, and usually not related to the patient's underlying condition.
- All adverse events result from failure in medical management, but not all adverse events can be attributed to errors.
- The injury sustained due to the adverse event does not meet the standard of a sentinel event.

Adverse Events & Errors

- Adverse events may be due to medical errors, in which case they are preventable, or to factors that are not preventable.
- An error may or may not cause an adverse event.
- Adverse events result from a medical intervention and are responsible for harm to the patient:
  - life-threatening illness
  - prolongation of the hospital stay
  - disability at the time of discharge
  - bankruptcy
  - death

Sentinel Event

("Red Flag")

- A significant negative outcome that shows underlying weaknesses in the system or process, as a result of compound errors.

- An unexpected occurrence involving risk of serious physical/psychological injury, and which is debilitating to the patients and health care providers.

- When properly analyzed and addressed, may provide important keys to strengthening the system and preventing future adverse events or outcomes.

Sentinel Event

- An unexpected, preventable event that leads to severe psychological or physical harm, loss of limb or death and which requires immediate investigation.

- Sentinel events include:
  - Wrong Side, Procedure, Patient, Site (WSPEs) errors
  - Post- surgical and post-procedural retained objects
  - Administration of incompatible blood products
  - Incorrect medication administration
  - Treatment-related errors resulting in death

Root Cause

- The fundamental reason or underlying factor for the occurrence of an undesired outcome.
- It's the core issue that sets in motion a chain of events that leads to the undesirable outcome
- Common root causes of sentinel events include but are not limited to human factors and poor communication and leadership.

Root Cause Analysis
(RCA)

- Problem-solving method used for identifying the origins of faults or problems, widely used in medicine and the healthcare industry.

- It is a form of inductive and deductive inference with 4 clear steps:
  - Identify and describe the problem clearly.
  - Establish a timeline from normal state until the problem occurred.
  - Distinguish between the root cause and other causal factors.
  - Establish a causal graph between the root cause and the problem.

- Is input to remediation with corrective actions to prevent recurrence.

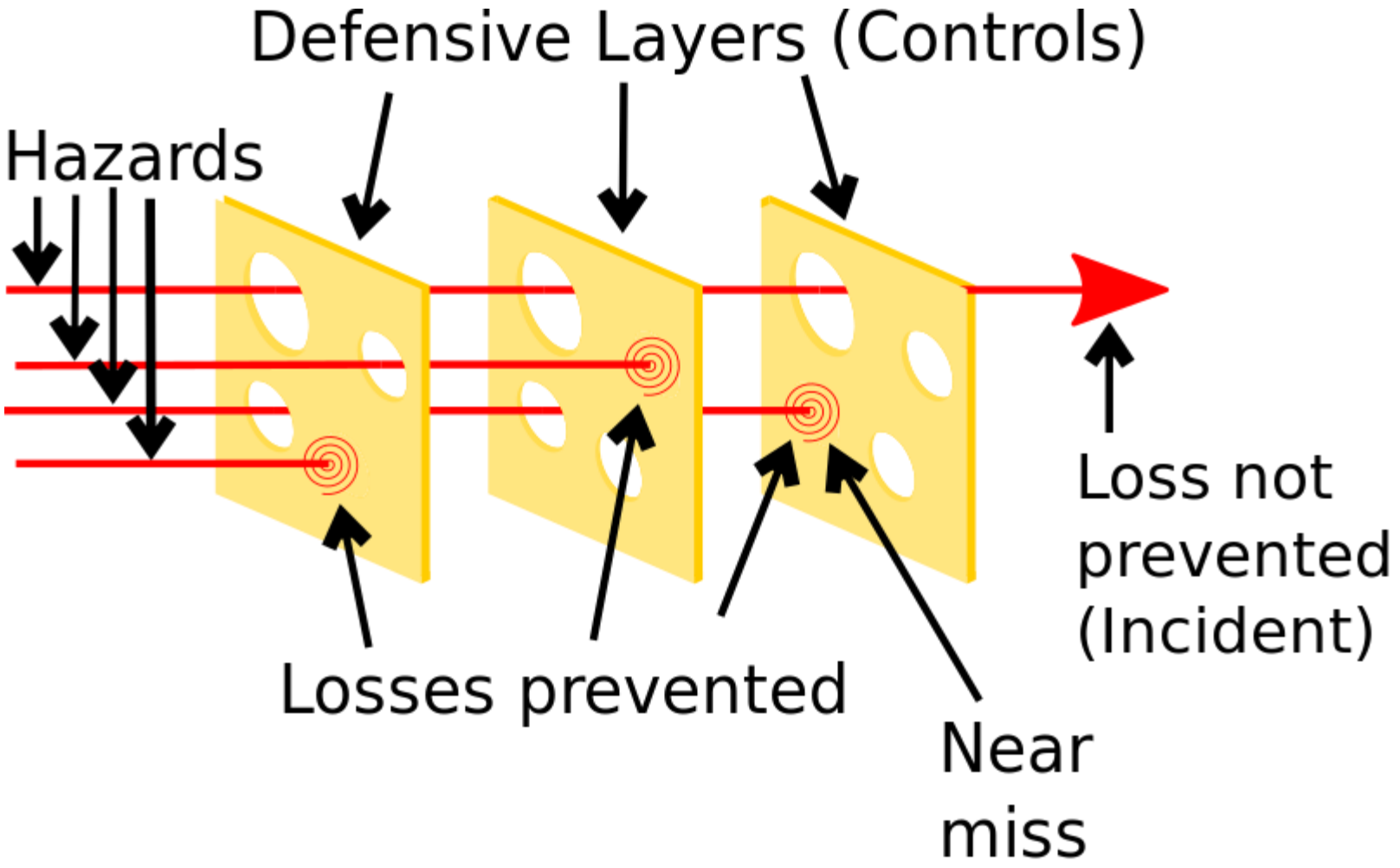
Near-Miss Event

- An unplanned event that almost occurred and had the potential to result in patient harm.
- An act of commission or omission that could have hurt the patient but did not cause harm, as a result of chance, prevention, or mitigation (IOM).
- A near-miss analysis enables healthcare systems to identify and modify protocols before patient harm occurs.

Swiss Cheese Model

- Originally proposed by James T. Reason of the University of Manchester in 1990.
- Lapses and weaknesses in one defense do not allow a risk to materialize since other defenses also exist to prevent a single point of failure.
- Disaster occurs when a hole in each slice in the stack aligns with holes in all other slices.

Swiss Cheese Model



Never Event

"Serious reportable event" (SRE)

- Originally defined a particularly shocking medical error, such as wrong-site surgery, that should never occur.
- The term has expanded to signify adverse events that are:
  - unambiguous (clearly identifiable and measurable)
  - serious (resulting in death or significant disability)
  - usually preventable
- The name identifies issues in the care provided that negatively affect the credibility of a healthcare facility.

Never Events

The list now consists of 29 *serious reportable events* (SRE's) grouped into 7 categories:

- Surgical or procedural events
- Product or device events
- Patient protection events
- Care management events
- Environmental events
- Radiologic events
- Criminal events

Negative Events in Healthcare

Event Type	Risk	Harm/Injury	Preventable or Identifiable
Adverse (PAE)	Moderate to High	Yes, Variable	May be unpreventable
Near-Miss (NME)	High	Potential	Yes
Sentinel (SE)	High	Yes, Severe Physiological & Psychological	Yes, but Unexpected
Never (SRE)	Very High	Severe	Yes

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Reasons for Errors

- Ineptitude
  - Existent knowledge incorrectly applied
  - Incompetence in performing a task
  - Lack of “eptitude”
- Negligence: Medical care that fails to meet the standard of care.
- Ignorance
  - Of existent knowledge
  - Of unknown knowledge

Rumsfeld

- *Known knowns*: things we know that we know.
- *Known unknowns*: things we know that we do not know.
- *Unknown unknowns*: things we don't know that we don't know.

Healthcare Practitioners

- Rapid identification and corrective action of unsafe practitioners are important to a comprehensive safety program.
- Licensing, certification and accreditation processes for health professionals should place greater attention on patient safety and clinical performance skills.
- Boards responsible for monitoring continuing medical education (CME) and clinical skills do not communicate or coordinate with each other.

Healthcare Practitioners

- Professional societies and groups should become active leaders in encouraging and demanding improvements in patient safety.

- Tools that contribute to a culture of safety:
  - setting standards
  - communicating with members about safety
  - incorporating patient safety into training programs
  - collaborating across disciplines

Questions? (2)

IOM 4-PART ACTION PLAN and RECOMMENDATIONS

Part 1

National Center for Patient Safety

- IOM recommended the creation of a National Center for Patient Safety in the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ).

- This center would also serve as a clearinghouse and source of effective practices to be shared broadly.

- Healthcare is a decade or more behind other high-risk industries in its attention to:
  - ensuring basic safety
  - establishing national safety goals
  - tracking progress in meeting them
  - investing in research to learn more about preventing mistakes

Part 2

Reporting Systems

- IOM recommended establishing a nationwide, mandatory public reporting system, with Federal legislation to protect the confidentiality of medical mistakes without serious consequences.

- The intent was to encourage the growth of voluntary, confidential reporting systems so that practitioners and health care organizations could learn about and correct problems before serious harm occurs.

Part 3

Role of Consumers, Professionals & Certifying Groups

- Pressure and incentives from many public and private purchasers of health care, regulators, and licensing and certifying groups.

- The Joint Commission issued new standards, and the National Quality Forum issued *Safe Practices for Better Health Care,* in 2003 as a set of evidence-based practices that can reduce the occurrence of adverse health care events and improve patient outcomes.

- The *Safe Practices* were updated in 2006, 2009, and 2010 to reflect new evidence and implementation strategies. The latest version includes 34 practices.

Part 4

Building a Culture of Safety

- The IOM urged organizations to create an environment in which safety becomes a top priority, and urged adoption of safety principles from other industries.

- This report stressed the need for leadership by executives and clinicians and for accountability by boards of trustees.

- Stressed medication safety because medication errors are so frequent and because many evidenced-based practices were already known and needed wider adoption.

Improving Patient Safety

IOM SAFETY OPPORTUNITIES in HEALTHCARE

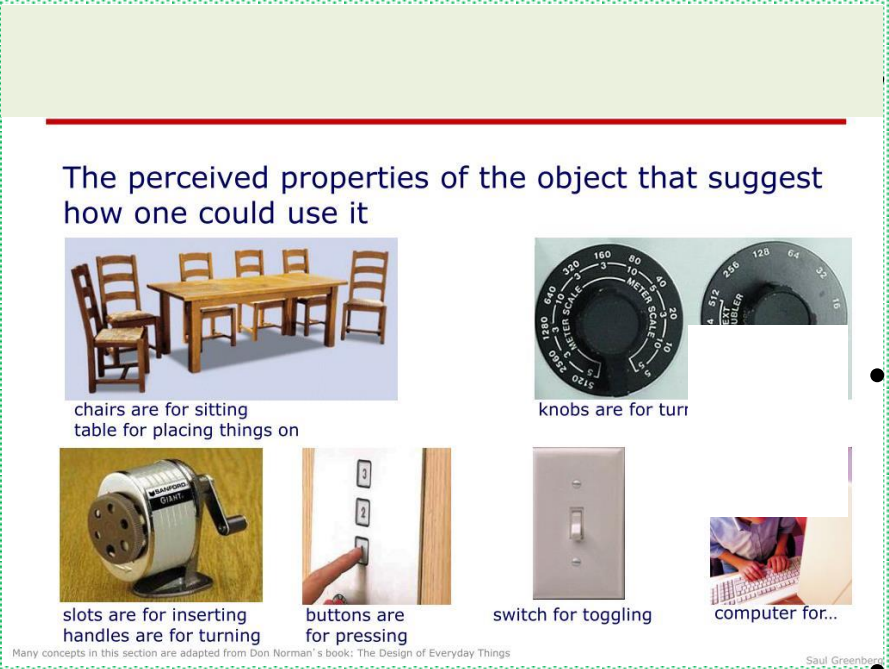
Improving Patient Safety
(IOM Opportunity Categories)

1. User-Centered Design:

- Make things visible so that the user can see how to return to an earlier step, change a setting, and see what would happen if a step is skipped.

- Incorporate into healthcare:
  - affordances
  - natural mappings
  - constraints
  - forcing functions

Improving Patient Safety
(User-Centered Design)



Affordance is a characteristic of equipment or workspace that communicates how it is to be used.

- Natural mapping is the relationship between a control and its movement, sound or brightness.
- A constraint makes it hard to do the wrong thing.
- Forcing functions make it impossible to do the wrong thing.

Improving Patient Safety
(IOM Opportunity Categories)

2. Avoid Reliance on Memory:

- Standardize processes and equipment.
- Use protocols and checklists to enhance safety.
- Simplify key processes by reducing the number of steps or handoffs that are needed.

Improving Patient Safety
(IOM Opportunity Categories)

3. Attend to Work Safety:

- work hours
- workloads
- staffing ratios
- sources of distraction
- shift changes (circadian rhythm)

4. Avoid Reliance on person's Vigilance

- use checklists & require use at regular intervals
- limit long shifts
- rotate staff
- Use equipment that automates some functions
- use reliable visual and auditory alarms

Improving Patient Safety

(IOM Opportunity Categories)

5. Train Concepts for Teams

- Whenever possible, training programs and hospitals should establish interdisciplinary team training.
- Effective interdisciplinary team members come to trust one another's judgments and expertise and deal with one another's safety concerns.
- Examples are labor and delivery teams, and hospital rapid response teams.

Improving Patient Safety

(IOM Opportunity Categories)

6. Involve Patients in Their Care

- Safety improves when patients and their families know their condition and the treatments, medications, and technologies that are used in their care:
  - At discharge, patients should receive a list of their medications, doses, schedules, interactions, side effects, & activities to avoid.
  - Also clear written information about follow-up visits and a contact person.

- Give special attention to family caregivers in terms of their ability to:
  - provide safe care
  - manage devices and medication
  - safely respond to patient needs

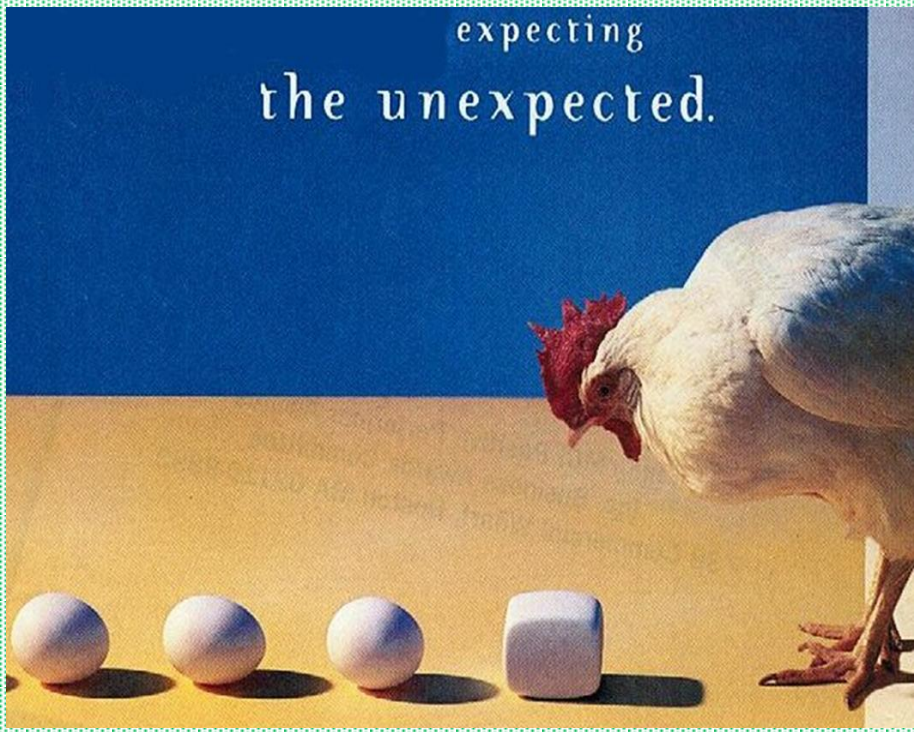
Health Literacy

Give attention to problems resulting from lack of patient and family health literacy:

- information may be too complex to absorb or in a language unfamiliar and frightening
- rapid and incomplete instructions about home care of catheters or devices
- warnings and dosage information on medication bottles may be not understood

Improving Patient Safety
(IOM Opportunity Categories)

7. Anticipate the Unexpected



- The likelihood of error increases with reorganization, mergers, and other organization-wide changes.
- Technologies, such as computerized physician order entry systems (CPOE), are engineered to prevent error, but despite the best intentions, all technology introduces new errors.
- Health care professionals should adopt automation cautiously before widespread implementation.

Improving Patient Safety
(IOM Opportunity Categories)

8. Design for Recovery

- Assume that errors will occur, and design and plan for recovery by making it easy to reverse operations and hard to carry out nonreversible ones.
- Have standardized, well- rehearsed procedures in place for responding quickly to adverse events.
- Use simulation training to practice tasks, rescues, and processes in life-like circumstances using models or virtual reality.

Improving Patient Safety
(IOM Opportunity Categories)

9. Access to Accurate, Timely Information:

- Information for decision-making should be available at the point of patient care.
- Information should be coordinated over time and across settings.
- The greatest challenge we all face is to learn, use, and share better information about how to prevent harm to patients.

Unbalanced Results

- The attention-grabbing focus on medical error initially appeared as if it might work too well.
- Little interest was left over for quality problems that could not be cast as medical errors.
- Recently, there has been substantial interest in the optimal management of:
  - chronic illnesses
  - equitable access to healthcare
  - patient-centeredness
  - pressing need to eliminate wasteful practices
  - other important quality problems

Improving Patient Safety

- In Session 8 we will discuss the current efforts to increase patient safety and eliminate errors.
- We will explore advances and blocks.
- We will mention unintended consequences:
  - benefits
  - drawbacks
  - perverse results

Final Questions?

Session 2: Diagnostic Errors

September 14th, 2023

- How Doctors are Taught to Think (or NOT)
- The Diagnostic Process
- Underdiagnosis and Overdiagnosis
- Common “Laws”
- Cognitive Biases
- “Cookbook” Medicine and Diagnostic Pathways


THANK YOU
THANK YOU
THANK YOU
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