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TALK SERIES

Why My Next Career Step is Forensic Engineering?

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Adverse drug event detection using natural language processing: A scoping review of supervised learning methods

Rachel M. MurphyI, Joanna E. Klopotowska, Nicolette F. de Keizer, Kitty J. Jager, Jan Hendrik Leopold, Dave A. Dongelmans, Ameen Abu-Hanna, Martijn C. SchutID, Amsterdam, The Netherland

To reduce adverse drug events (ADEs), **hospitals need a system to support them in monitoring ADE occurrence routinely, rapidly, and at scale**. Natural language processing (NLP), a computerized approach to analyze text data, has shown promising results for the purpose of ADE detection in the context of pharmacovigilance. However, **a detailed qualitative assessment and critical appraisal of NLP methods for ADE detection in the context of ADE monitoring in hospitals is lacking**.

Therefore, we have conducted a scoping review to close this knowledge gap, and to provide directions for future research and practice. We included articles where NLP was applied to detect ADEs in clinical narratives within electronic health records of inpatients. Quantitative and qualitative data items relating to NLP methods were extracted and critically appraised. Out of 1,065 articles screened for eligibility, 29 articles met the inclusion criteria.

Trends in adverse events over time: why are we not improving?

With widespread interest and investments in patient safety in the 13 years following the US Institute of Medicine report *To Err is Human*, the question has understandably arisen: have we decreased medical harm? One widely cited study showed no significant reductions in either the overall rate of harm or the rate of preventable harm in 10 US hospitals chosen on the basis of patient safety activities. A second US study, though not focused on temporal trends, reported that one-third of patients suffered harm from their medical care at three tertiary care hospitals recognized for their efforts in improving patient safety. Given that previous major studies reported adverse event rates in the range of 3–16%, progress seems sorely lacking.

Adding to this distressing picture, Baines *et al* report in this issue of the journal that the adverse event rate among hospitalized patients in the Netherlands increased from 4.1% in 2004 to 6.2% in 2008. Somewhat reassuringly, the preventable adverse rate did not change. The increase in non-preventable adverse rates may reflect better documentation in medical records as a result of interest in patient safety, with the stable rate of preventable events suggesting that safety has not actually worsened. Nonetheless, the main message of this study and the two previous ones, remains: sustained attention to patient safety has failed to produce widespread reductions in rates of harm medical care.

Trends in adverse events over time: why are we not improving? | BMJ Quality & Safety

Why has patient safety not improved?

First, while patient safety and healthcare quality have certainly received substantial attention for more than 10 years now, the ==actual investments in patient safety still pale== beside investments in traditional biomedical research. While some striking successes have occurred, the ==overall death rate from cancer has decreased only 5% since 1950.==

This disappointingly small impact has occurred over a much longer time than the patient safety era and with orders of magnitude greater financial investments. Moreover, the war on cancer had a tremendous head start, with decades of relevant research and a large scientific workforce. **Patient safety began with nothing like the existing research base in physiology and molecular biology, nor anything like the number of people with the expertise (or interest) to develop and test patient safety interventions**. That we have made little progress in a relatively short period of time, with modest resources by the standards of most major biomedical endeavors, and fewer people working on the problem should thus come as no surprise. **We get what we pay for.**

Second, showing ==progress in patient safety requires== three achievements to have occurred:
- Identification of interventions that reduce common types of adverse events.
- Dissemination of (some of) these effective interventions into routine practice.
- Development of a tool to measure improvements in patient safety problems.

Unfortunately, none has occurred. **We have few effective patient safety interventions**. Those that may be effective have not been widely adopted (or not adopted in an effective form). And the gold standard instrument for measuring patient safety problems is probably too blunt to detect changes over time.

Trends in adverse events over time: why are we not improving? | BMJ Quality & Safety

A failure in the medication delivery system –
how disclosure and systems investigation improve patient safety

Medical errors that receive widespread media attention frequently spur health systems to reexamine their own culture and practices to prevent similar errors. This commentary describes one health system's effort to identify and improve the system factors (systems, processes, technology) involved in the error. The action plan proposed by this project includes ensuring a just culture so staff feel empowered to report errors and near-misses; regularly review and improve medication delivery systems; build resilient medication delivery systems; and establish methods of investigations.

Outline

- Change Forces in Healthcare Delivery

- Healthcare is Local, but Technology is Global

- The Scope and Purpose of the Forensic Engineering Field

- How Forensic Engineering Professionals Apply their Skills in Healthcare

- Understanding the Methodology for Conducting Forensic Engineering Investigation

- Case Studies in Forensic Engineering Field

- Is it Worth it?

"The significant problems we face cannot be solved at the same level of thinking we were at when we created them."

Albert Einstein
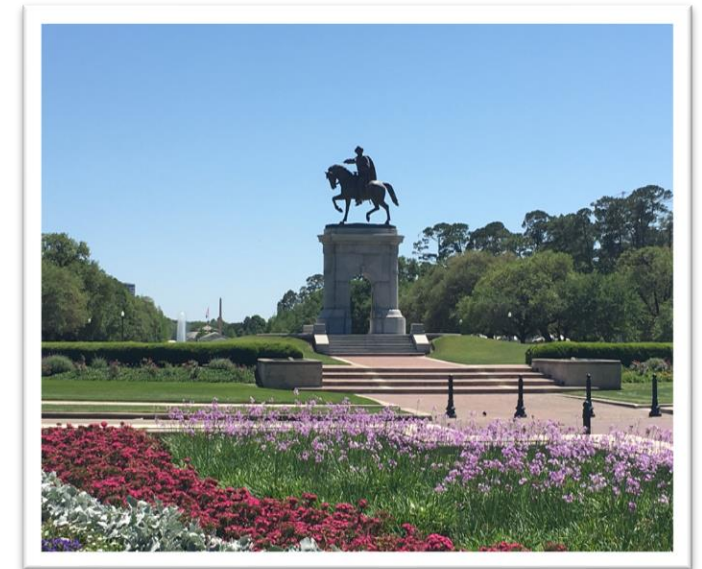
Healthcare Environment

The **Dependency of Healthcare services on technology** for the delivery of its services as at all time high. This growth trend is expected to continue.

Expanding environments of care delivery such as assisted living, homecare, virtual care (telehealth, eHealth, mHealth), and rehabilitation programs are examples of improving access to services across the Globe but not without **challenges.** The recent one is medical networks' Cybersecurity.

Healthcare delivery is facing capacity issues amid ongoing staffing shortages, fatigue, and lack of availability **to sustain training.**

This raises issues of **who is competent** to guide, to integrate, **and manage** these systems. Also **how to insure** public mandate of **quality outcomes, "do no harm" pledge, and improve efficiency,** is **met.**

Is there sufficient exchange of evidence on best systems' strategy and on engineering management of the technology life-cycle (Emerging & legacy, regulated & COTS)?

MEDICAL DEVICES MARKET

Technology is Global

Global Medical Devices Market (US$ Bn), 2017 to 2025

2025
2023
602.1
2021
2019
397.5
2017

Global Medical Devices Market

North America Medical Devices Market, 2017

$ 159.0 Billion

North America

Europe

Asia Pacific

XX

XX

XX

The Middle East & Africa

XX

Latin America

Global healthcare IT market projected to reach USD 829.2 billion by 2026 from USD 319.2 billion in 2021, at a CAGR of 21%

https://www.googleadservices.com/pagead/aclk?sa=L&ai=DChcSEwj8iLXgss3zAhVIbG8EHZ9nBIcYABABGgJqZg&ae=2&ohost=www.google.com&cid=CAESQOD2QTnRIT_0XB9NtGQxS49fQhUh9CrjGA6JLZbZkRbih4qa3u-h3Sgy0BwgM_YyE9DlINLpe_Y8z2AvXdhY-3U&sig=AOD64_3dzsGrCCevoxpBbpG-HZeC54KSRQ&q&adurl&ved=2ahUKEwjBmangss3zAhXHlmoFHahMAfoQ0Qx6BAgFEAE

BECKER'S
HEALTH IT & CIO REPORT

Amazon, Google, Apple to drive life sciences market to $1.5T by 2022, report says

Written by Jessica Kim Cohen | July 11, 2018 | Print | Email

Partnerships between healthcare organizations and technology giants will propel the global life sciences market to $1.5 trillion by 2022, according to a Frost & Sullivan report.

Advancements in healthcare digitization, healthcare consumerism, big data analytics and value-based care reimbursement models will help push the industry toward the $1.5 trillion milestone, according to the market research company.

Many of these trends sit at the intersection of healthcare and technology, with pharmaceutical researchers deploying artificial intelligence and cloud technologies, pathology labs adopting health analytics, and research labs increasing their spending on "smart" genomics.
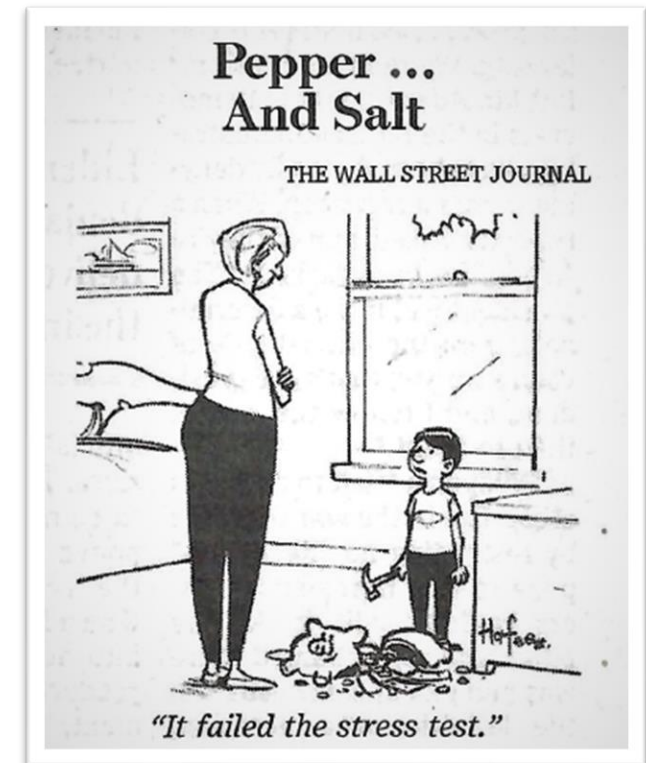
Standards, guidelines, and regulations

FDA- 21CFR Part 820

ANSI/AAMI – 14155 Clinical investigation of devices for human subjects

ASTM Standards

- Medical/Surgical Instruments
- Arthroplasty
- Biocompatibility Test Methods
- Cardiovascular Standards
- Cells and Tissue Engineered Constructs for TEMI
- Classification and Terminology for TEMPs
- Editorial and Terminology
- Human Clinical Trials
- Material Test Methods
- Neurosurgical Standards
- Plastic and Reconstructive Surgery
- Spinal Devices

- Adventitious Agents Safety
- Assessment for TEMPs
- Biomaterials and Biomolecules for TEMPs
- Cell Signaling
- Ceramic Materials
- Computer Assisted Orthopaedic Surgical Systems
- GI Applications
- Implantable Hearing Devices (IHDs)
- Metallurgical Materials
- Osteosynthesis
- Polymeric Materials
- Urological Materials and Devices

Pepper ... And Salt
THE WALL STREET JOURNAL

"It failed the stress test."

NFPA 99 – Health Care Facilities Code
NFPA 115 – Laser safety

ISO 13485 - medical device quality management
ISO 9001 -   general quality management
ISO 11607 – medical devices packaging

IEC 60601 – Family of Standards
IEC 62304 - Software life cycle
IEC 62494 - Radiography
IEC 80001 - Risk management networks
IEC 14971 – Risk management medical devices

The Scope and Purpose of Forensic Engineering Field

- the application of engineering principles and scientific methodology to investigate causes of unintended outcomes (such as the adverse event of machine, structure, component, material, clinical care, etc.) - ranging from service ability to catastrophic - which may lead to legal activity, including both civil and criminal

- The field also includes the investigation methodology of intellectual property infringement and/or validity

- Many times, these findings are used in litigation to help settle a case or a claim. When this happens, the engineer will be deposed to offer testimony as to why the failure occurred.

- Improve overall systemic safety level when technology used for the delivery of healthcare services

Why Do We Perform Unintended Outcomes event Investigations?

- **Prevention** – Do no harm! Most patients can not defend themselves

- **Mitigation** – Risk containment, Tort law & Professional liability

  - Negligence, breach of warranty, misrepresentation, strict liability

- **Ethical** – Public commitment to the protection

- **Compliance** – Regulations, standards, and accreditation

- **Understanding** – Determine the reasons, Facilitate better design, and/or use discontinuation or improvements

Investigation components in the clinical setting

- Determine the sequence of events that led to the unintended outcome

- Had the event could have been detected prior to the adversity

- Deploy validated engineering testing methodologies that explain how factors led to the outcome

- Offer alternative or corrective action recommendations to prevent the recurrence of such adverse event

Who should conduct the investigation?

Competent experts

- Qualified investigator

If internal to the hospital -

- Supervisor of the affected employee
- Safety committee representative for the area
- Safety officer
- Affected employee(s)
- Quarantine and preserve the evidence

Who qualifies as an expert?

Federal Rule of Evidence 702 ensures that any and all scientific testimony or evidence admitted is not only relevant but reliable." 509 U.S. 579, 589 (1993)

"If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

The Court identified worthwhile considerations when analyzing scientific opinion testimony:

- **Whether the theory or technique can be (and has been) tested;**
- **Whether the theory or technique has been subjected to peer review and publication;**
- **Whether there is a known or potential rate of error of the particular technique or theory;**
- **Whether the theory or technique is "generally accepted."**

The Key Issues

- What happened?

- Why did it happen?

- What do we need to do to prevent it from happening again here?

- What do we need to do to prevent it from happening again elsewhere?

Gathering the Evidence

- Begin at the Beginning; The Unusual Occurrence Form

- Why Not Begin Interviews Now?

- Examination of the Device

- Examination of the Scene

- Examination of Patient Records

- Examination of Maintenance Records

- Examination of National Databases

- NOW Perform the Interviews – learn the technique/listen

Analyzing the Evidence

- What Was the Administrative Cause of the Accident?
- What Can We Do to Prevent It From Happening Again?
- Is This a Reportable Event Under SMDA?
- Review all information
- Clarify the facts
- Analyze information
- Examine contributing factors
- List all possible causes
- Identify the cause

Do not jump to conclusions

Institute of Medicine Report

"To Err is Human" Principles for the Design of Safety Systems

- "**Create a learning environment**"

- "**Implement mechanisms of feedback and learning from error**"

- **Safety training must be integrated into every stakeholder curriculum**.
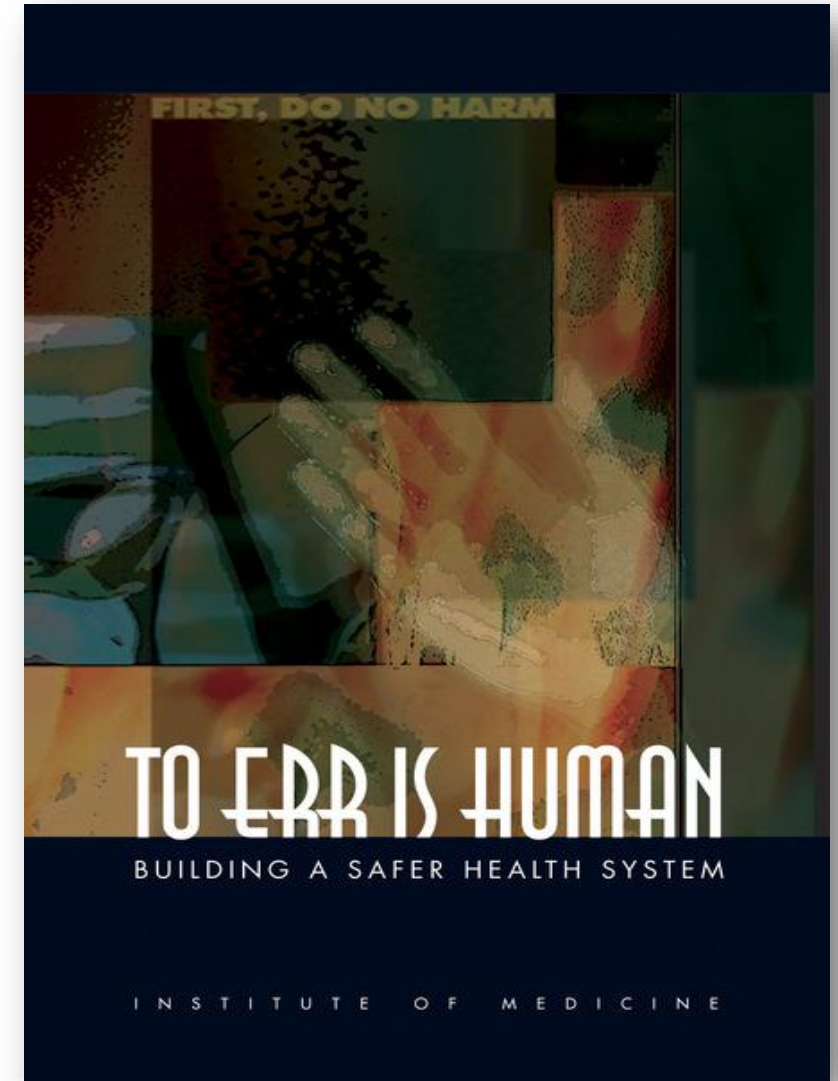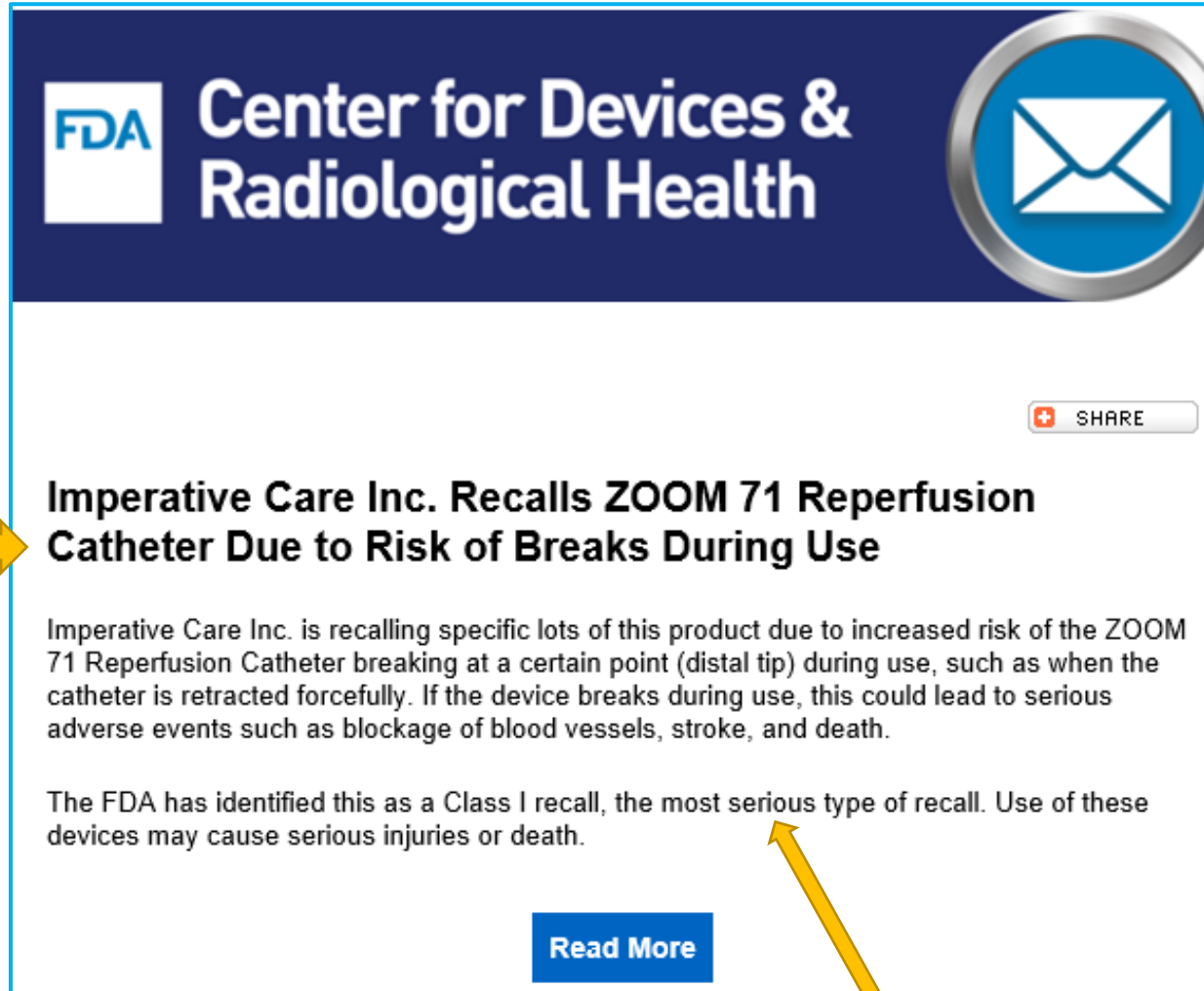
https://nap.nationalacademies.org/catalog/9728/to-err-is-human-building-a-safer-health-system , 2000

- Yadin David's Disclaimer:

Products shown or mentioned are for educational purposes only. Opinions expressed are solely my own. I am using my clinical engineering career experiences at various institutions in this presentation, however, no institution or myself endorse, recommend, nor exclude certain products and do not take any responsibilities nor liabilities for the content of this presentation.

Recently, the FDA posted this…

FDA Center for Devices & Radiological Health

SHARE

Imperative Care Inc. Recalls ZOOM 71 Reperfusion Catheter Due to Risk of Breaks During Use

Imperative Care Inc. is recalling specific lots of this product due to increased risk of the ZOOM 71 Reperfusion Catheter breaking at a certain point (distal tip) during use, such as when the catheter is retracted forcefully. If the device breaks during use, this could lead to serious adverse events such as blockage of blood vessels, stroke, and death.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Read More

The Hazards

- Hazards associated with everything we do in our lives but at various levels.

- For the average consumer, drugs and technology, can be highly sophisticated to manage on their own. In addition, there are times and conditions when they are consumed/administered but the consumer is not able to defend for her/himself (e.g., during surgery). Situation of learned care provider and passive consumer.

- In healthcare, similar to laws in transportation safety (aviation, vehicles, trains), the safety of drug, technology, cosmetics and of foods are controlled by governments. In the U.S., the FDA is the agency that responsible for excluding unsafe and ineffective technology from reaching the market and to protect the public.
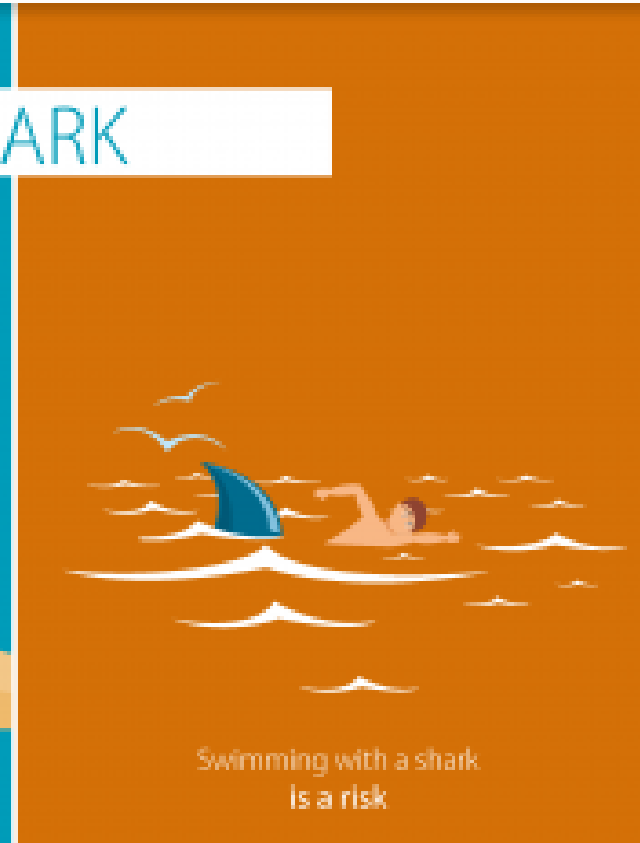
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Hazard, Risk & Safety

Error – failure to complete a planned action as intended, or the use of a wrong means or methods to complete it.

Hazard – the potential to cause harm, damage or loss.

Risk - the possibility of suffering harm, damage or loss **=**

Probability of the Event (committing error) **+**

Severity of the Event +

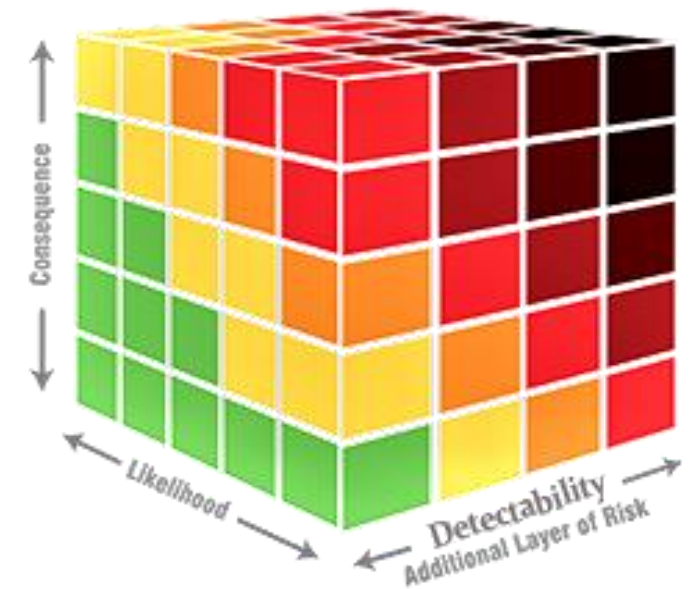**Discoverability** of the event

What is Safety?
that level of risk that you are **willing to accept** or the **absence of unacceptable risk.**

If risk goes up safety goes down, If risk goes down safety goes up
Risk is measured in numbers; **safety** is subjective
Safety is that level of risk you (organization) are willing to accept

Risk management Program concerned with patient care experience, the protection of human, physical, financial and information resources as well as with the general credibility of the institution, and the professionals who work there.

Grades of Hazards

Types of technology

- Commercially Of the Shelf (COS) products (e.g., smart phone) governed by for example NHTSA or
United States Consumer Product Safety Commission

- Regulated products (Medical device) (e.g., smart phone that diagnose ECG) governed by (FDA)
United States Food and Drug Administration

- Software, middleware, services or combination of these (process vs. display images) by Both agencies
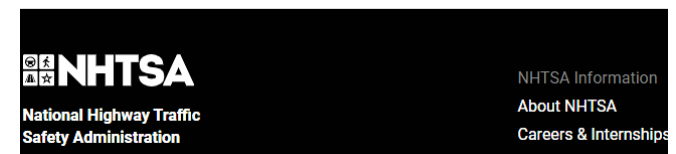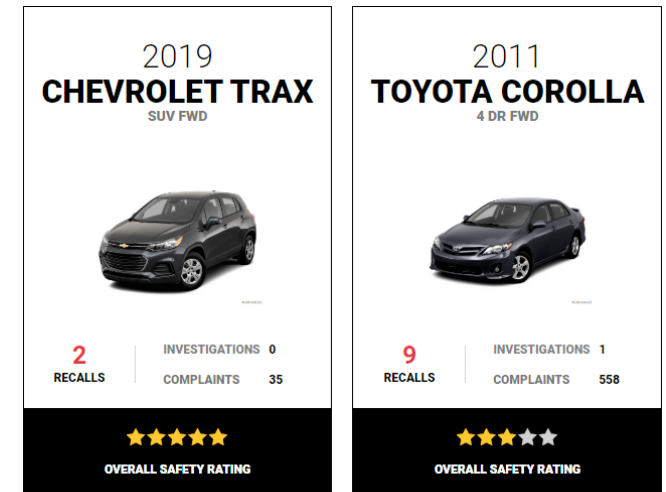
A Medical Device is

"...an **instrument, apparatus**, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, **intended for use** in the **diagnosis** of disease or other conditions, or in **the cure**, mitigation, **treatment**, or **prevention** of disease, in **man** or other animals, or intended to affect the structure or any function of the body of man or other animals, and which **does not achieve any of it's primary intended purposes through chemical action** within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

A Medical device is a product

➢ Whose primary mechanism of action is physical, not chemical, e.g., vascular stent

➢ Intended to affect any structure or function of the body, e.g., seal leaking cardiac blood vessel

➢ Claimed to diagnose, treat, or prevent medical conditions in man or other animals, e.g., help prevent heart attack

Includes: Software as a Medical Device

Its all about the **Intended Use**

Where should **Technology Life Cycle** be subject to control?

From acquisition and/or donation acceptance to obsolesce and replacement

CONCEPT

PROTOTYPE

PRECLINICAL

CLINICAL

MANUFACTURING

MARKETING

COMMERCIAL USE

OBSOLESCENCE

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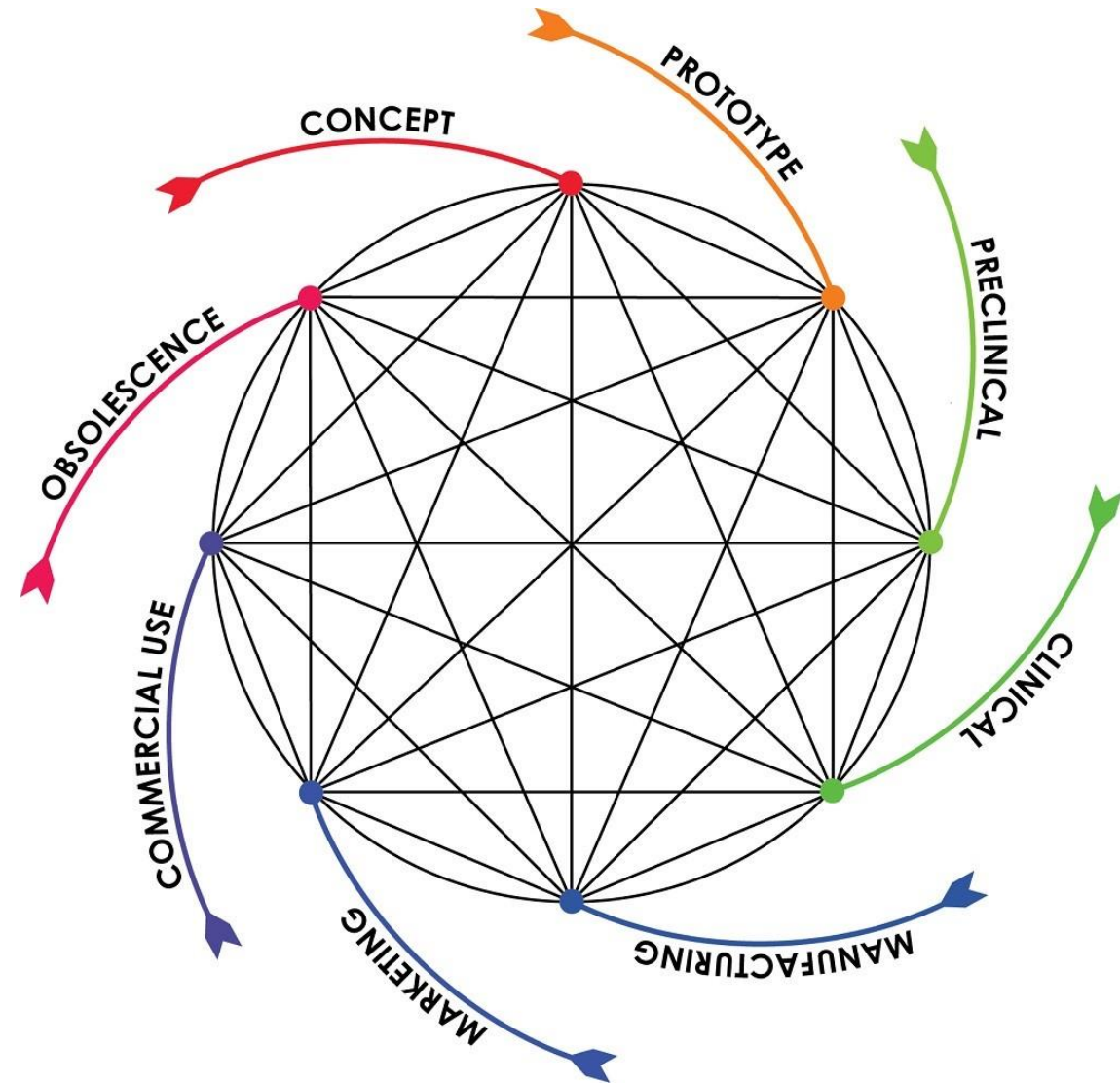
FDA Mission Statement

"protecting consumers and enhancing public health by **maximizing compliance** of FDA regulated products and **minimizing risk** associated with those products."

FDA, India Halt 500 Illicit Drug, Device Shipments to U.S.

Effort is the first bilateral enforcement operation with India.

U.S. Food and Drug Administration   02.19.20
https://www.mpo-mag.com/contents/view_breaking-news/2020-02-19/fda-india-halt-500-illicit-drug-device-shipments-to-us/

Vision Statement

"all food is safe; **all medical products are safe and effective**; and the public health is advanced and protected."

In general, FDA regulates:

- **Foods, including:**
  - dietary supplements, bottled water, food additives, infant formulas, other food products (although the U.S. Department of Agriculture plays a lead role in regulating aspects of some meat, poultry, and egg products)

- **Drugs, including:**
  - prescription drugs (both brand-name and generic), non-prescription (over-the-counter) drugs, **Biologics**, including**:** vaccines for humans, blood and blood products, cellular and gene therapy products, tissue and tissue products, allergenics

- **Medical Devices, including:**
  - simple items like tongue depressors and bedpans, complex technologies such as heart pacemakers, dental devices, surgical implants and prosthetics, **Electronic Products that give off radiation,** including microwave ovens, x-ray equipment, laser products, ultrasonic therapy equipment, mercury vapor lamps, sunlamps

- **Cosmetics, including:**
  - color additives found in makeup and other personal care products, skin moisturizers and cleansers, nail polish and perfume

- **Veterinary Products, including:**
  - livestock feeds, pet foods, veterinary drugs and devices

- **Tobacco Products, including:**
  - Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco

FDA authority

- US Congress on May 28, 1976, gave the FDA the authority to begin regulating all medical devices - *The Medical Devices Act*.

- FDA Rules are posted in the Federal Register and once finalized published in the Code of federal Regulations, Title 21, Parts 800-1299.

- FDA has established medical devices classification system.

- All medical devices are classified into either Class I, Class II, and Class III.

- The classification system is based on the product's risk:

  - **Class I** devices are low risk (about 780 types)

  - **Class II** devices moderate risk require general controls (about 800 types)

  - **Class III** devices highest risk require general control and PMA approval

  (about 120 types mostly life supporting/sustaining)

# Emergency Use Authorizations (EUAs) for Medical Devices

- The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) contains legal authorities to sustain and strengthen our Nation's preparedness for public health emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, as well as emerging infectious disease threats.

- The law has provisions that further FDA's mission of fostering the development and availability of medical products, including drugs, vaccines, and devices, for use in these emergencies, also referred to as medical countermeasures (MCMs).

- Provided clearer authority for FDA to issue EUAs--before a CBRN emergency occurs--to enable stakeholders to prepare for use of unapproved medical products, or unapproved uses of approved products, if certain criteria are met.

- HHS has subsequently declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19 (February 4, 2020), personal respiratory protective devices (March 24, 2020) for use during the COVID-19 outbreak pursuant to section 564 of the Act and subject to the terms of any authorization issued under that section.

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices

How products get on the market legally

- Be on the market prior to May 28, 1976

- Be exempt from 510(k) requirements – very low risk & established technology (e.g., tongue blade)

- Obtain 510(k) clearance

- Obtain PMA Approval
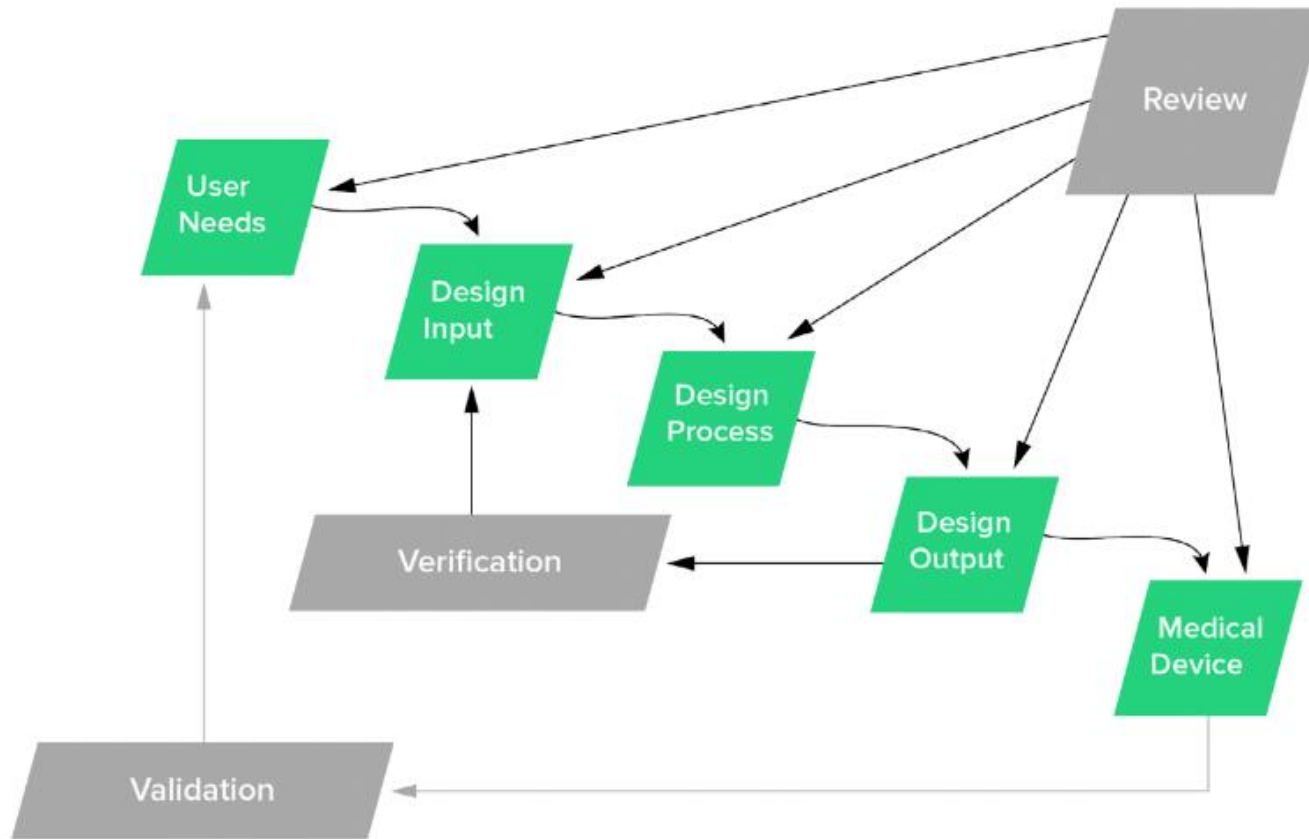
FDA Waterfall Diagram
Design control guidance for medical devices

The FDA does not conduct tests but rather depends on the industry to validate and verify safety and efficacy of their product through compliance with design and manufacturing systems controls and with post-market surveillance.

* FDA recognizes some Consensus Standards: IEC 60601, ISO 13485, IEC 62304, ANSI 14971

Challenging the FDA processes

REPORT BRIEF · JULY 2011

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Medical Devices and the Public's Health
The FDA 510(k) Clearance Process at 35 Years

MEDICAL DEVICES AND THE PUBLIC'S HEALTH
THE FDA 510(k) CLEARANCE PROCESS AT 35 YEARS

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Medical devices play a critical role in the health care of Americans. They can range from simple tools, such as tongue depressors and bandages, to complex or life-saving equipment, such as pacemakers, magnetic resonance imaging machines, and heart–lung machines. Devices are used in healthcare facilities—such as hospitals, physicians' offices, and nursing homes—and at home.

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires a "reasonable assurance of safety and effectiveness" before a device can be marketed. The U.S. Food and Drug Administration (FDA) is responsible for enforcing this requirement. Devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the 510(k) process, named for Section 510(k) of the FFDCA. Devices that are subject to the 510(k) process include such devices as blood pressure cuffs as well as some types of contact lenses and pacemakers. The FDA received about 4,000 510(k) submissions in 2009.

Some policymakers and patients have expressed concern about the ability of the 510(k) process to ensure that medical devices on the market are safe and effective. Other policymakers and patients, as well as the medical-device industry, have asserted that the process has become too burdensome and time-consuming and that it is delaying important new medical devices from entering the market.

Medical Errors

Estimated 8-12% of patients admitted to the hospital experience adverse events while receiving healthcare. Adverse events include:

The Fourth Global Ministerial Summit on Patient Safety

2–3 March 2019, Jeddah, Kingdom of Saudi Arabia

Patient Safety
4th Global Ministerial Summit 2019
القمة الوزارية العالمية لسلامة المرضى 2019

World Health Organization

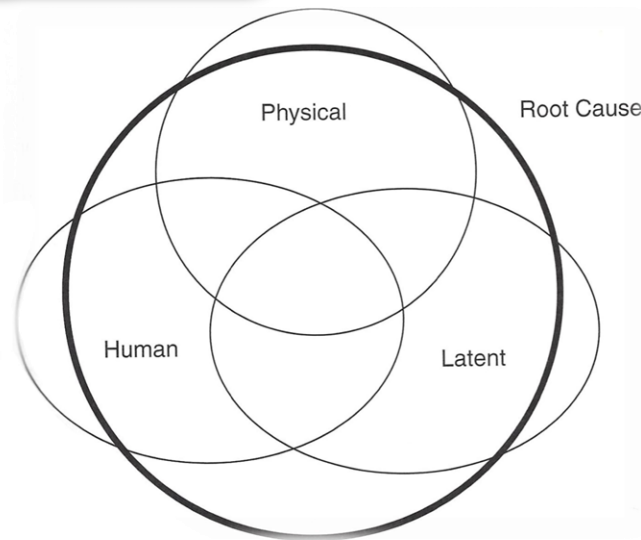| Magnitude	Incidence	Medications
1 in 4	**134 million**	**$42 billion**
As many as 1 in 4 patients are harmed whilst receiving primary and ambulatory health care	134 million adverse events occur each year in hospitals in LMICs, contributing to 2.6 million deaths annually due to unsafe care	Medication errors cost an estimated 42 billion USD annually

People, Structure, and Technology

>600,000 **medical device** reports per year received by the FDA

- More than 1/3 involve use errors
- Use error often linked to design flaws

44% of medical device recalls due to **design problems***

From How to Organize and Run Failure Investigation
Daniel Dennies

* Reported by the FDA Recall Study

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Guide to risk management

Mitigation of risk (risk control) is critical factor for obtaining clearance or approval to get product on the market. You can do this by:

➢ Removal of the product from the market

➢ Limit the intended use

➢ Design change

➢ Communicate contra-indications

➢ Add warnings

➢ Inform/Educate & Train

WHO compendium of innovative health technologies for low-resource settings

2021

COVID-19 and other health priorities

World Health Organization

	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	LOW	MEDIUM	HIGH	HIGH	HIGH
Probable	LOW	MEDIUM	MEDIUM	HIGH	HIGH
Occasional	LOW	LOW	MEDIUM	MEDIUM	HIGH
Remote	LOW	LOW	LOW	MEDIUM	HIGH
Improbable	LOW	LOW	LOW	LOW	MEDIUM
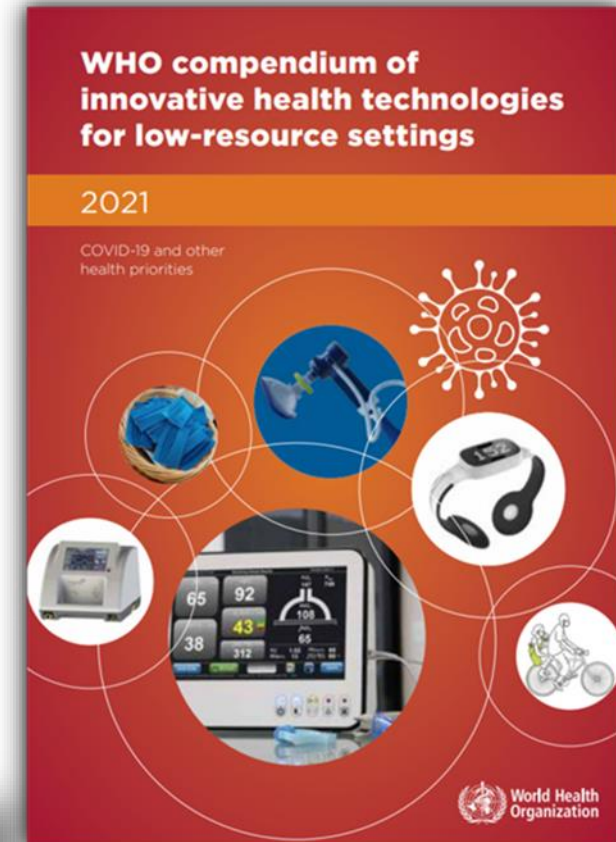
Is the oversight system for safe and effective products, after 42 years, flawed?

March 18, 2019

KHN
KAISER HEALTH NEWS

HEALTH LAW | AGING | INDUSTRY | PHARMA | INVESTIGATIONS

BOTCHED OPERATION

Death By 1,000 Clicks: Where Electronic Health Records Went Wrong

The NEW ENGLAND JOURNAL of MEDICINE

HOME | ARTICLES & MULTIMEDIA ˅ | ISSUES ˅ | SPECIALTIES & TOPICS ˅ | FOR AUTHORS ˅ | CME ˃

SPECIAL ARTICLE

The Nature of Adverse Events in Hospitalized Patients — Results of the Harvard Medical Practice Study II

Lucian L. Leape, M.D.., Troyen A. Brennan, M.D., J.D., M.P.H., Nan Laird, Ph.D., Ann G. Lawthers, Sc.D., A. Russell Localio, J.D., M.P.H., Benjamin A. Barnes, M.D.., Liesi Hebert, Sc.D., Joseph P. Newhouse, Ph.D., Paul C. Weiler, LL.M., and Howard Hiatt, M.D..

N Engl J Med 1991; 324:377-384 | February 7, 1991 | DOI: 10.1056/NEJM199102073240605

July 24/31, 2002

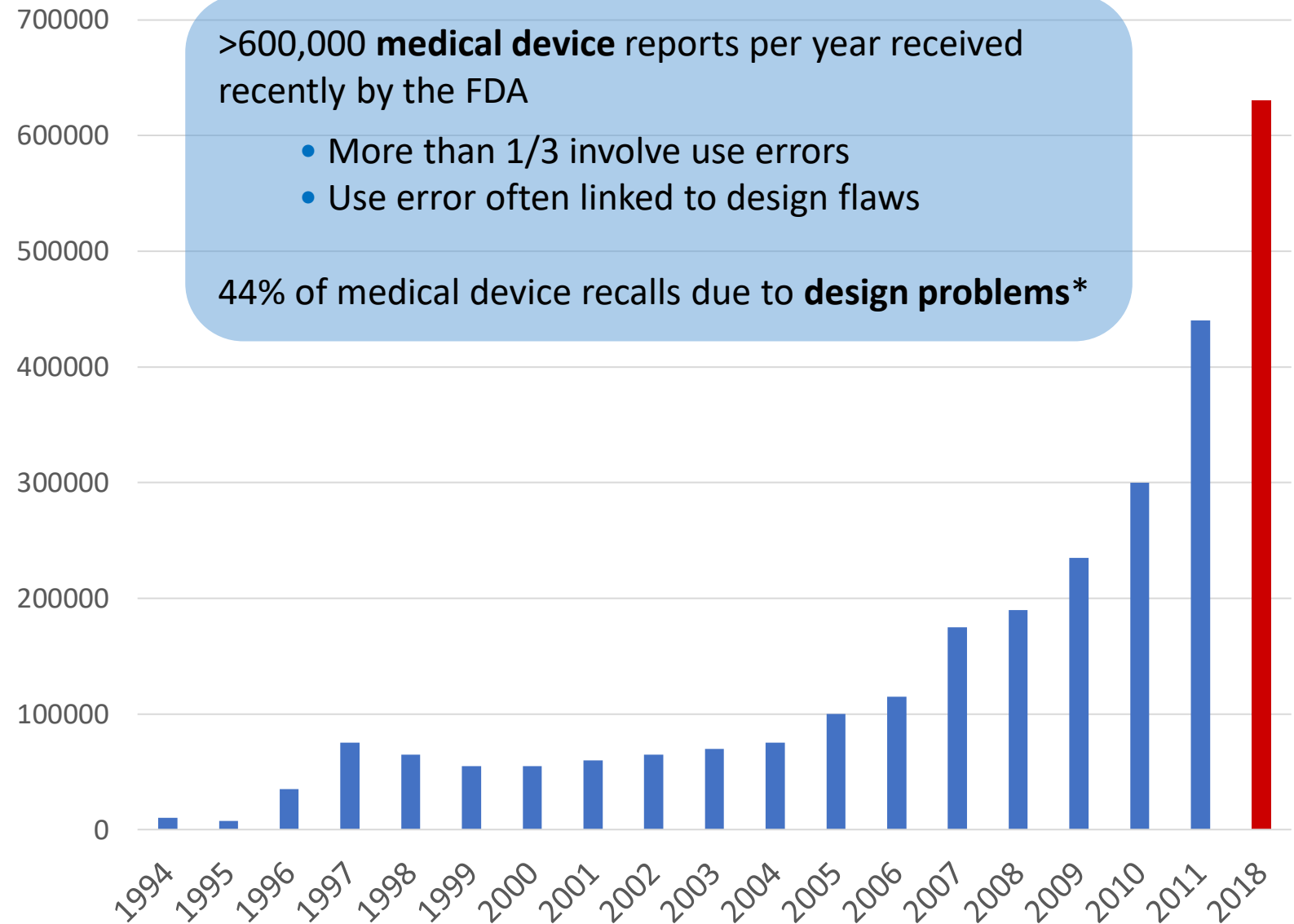### Safe but Sound
Patient Safety Meets Evidence-Based Medicine

Kaveh G. Shojania, MD; Bradford W. Duncan, MD; Kathryn M. McDonald, MM; et al

˃ Author Affiliations

JAMA. 2002;288(4):508-513. doi:10.1001/jama.288.4.508

Adverse Events report received by FDA

- **Malfunctions** reported in 63% of database
- **Injury** events ≈ 35%
- **Death** events ≈ 2%/year of reported database

>600,000 **medical device** reports per year received recently by the FDA
- More than 1/3 involve use errors
- Use error often linked to design flaws

44% of medical device recalls due to **design problems***

People + Structure + Technology

Near Miss incident without adverse event

Usually Poorly Reported

Adverse event – an injury/death caused by medical management and that prolong hospitalization, produced disability, or both.

If a nurse catches a medication mistake at the bedside, before it reaches the patient, what does it tell you about the hospital's efforts to prevent medication errors?

Answers:
1. System is working (?);
2. System is not working (?);
3. both (?)

Near Miss Reporting

- If a near miss is a sign the system is working, there is no incentive to question the process and learn from the event.

- True or False
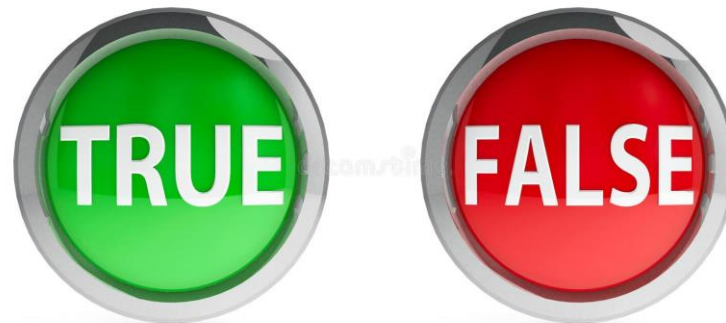
What should be investigated?

- All incidents that cause
  - Injury
  - Illness
  - Death
  - Lost time
  - Property damage
  - Clinical error
+ All near-miss incidents

Case Studies: Human Factors

- The science of understanding the properties of human capability.

- The application of this understanding to the design, development and deployment of systems and services (Human Factors Engineering).

- The art of ensuring successful application of Human Factors Engineering to a program (referred to as Human Factors Integration). It can also be called ergonomics.

Whose Fault is Use Error?

Who besides the user could be at fault?

The manufacturer/designer ?
The salesman?
The service technician?
The facility ?
Other staff member?
The patient ?

Case Studies

- Surgical instruments dirty/oil
- Misconnection
- Anesthesia machine life cycle maintenance
- Humidifier alarm
- The Icepack
- Monitor connection
- Audiometer hearing loss
- Port catheter separation
- Tubal ligation
- Cardiac Cath. Lab fire
- Rotating bed setup
- Infant warmer servicing
- Surgical stapler mechanism
- Laser, surgeon, and eye loss
- Radiation exposure

Conclusions

Organizations react swiftly and positively to incidents; their actions reaffirm their commitment to their mission of delivering the safety and well-being of their patients and employees.

Forensic Engineer is a competent professional who is experienced in health technology, and its governing rules, understands the clinical use environment, and knows how to -

- Conduct an incident investigation
- Find the facts and not place blame
- Find the cause of an incident
- Complete an incident investigation report
- Recommends resolution

Knowing that your expertise contributed to improvement in

patient safety when technology is deployed – Priceless!