Confronting the Risks of Implementing new technologies: From Artificial Intelligence to Biomedical Devices to Health Services

Stavanger, June 12 , 2019

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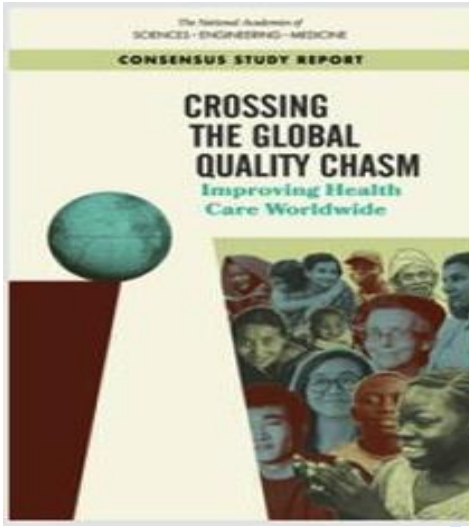
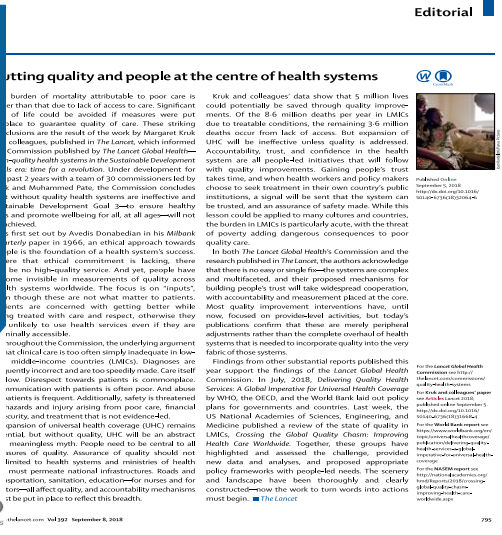
Global Quality Status 2018

- 1 in 10 patients harmed in hospital care/ betwe en 5.7 and 8.4 m deaths occurring annually fro m poor quality care in LMICs,
- 14 out of every 100 patients affected by HAI
- 2% patients subject to surgical complications f or the 234 million surgical operations performe d every year
- 20-40% health spending wasted due to poor q uality

  of care and safety failures

- 15% of hospital costs being due to patient har ms caused by adverse event,





Is/will Future technology in medicine be helpful or could it be harmful? or both?

The Code of Hammurabi is a well-preserved Babylonian c ode of law of ancient Mesopo tamia, dated back to about 17 54 BC

“We are all like the bright moon,

we still have our darker side.”

Kahlil Gibran

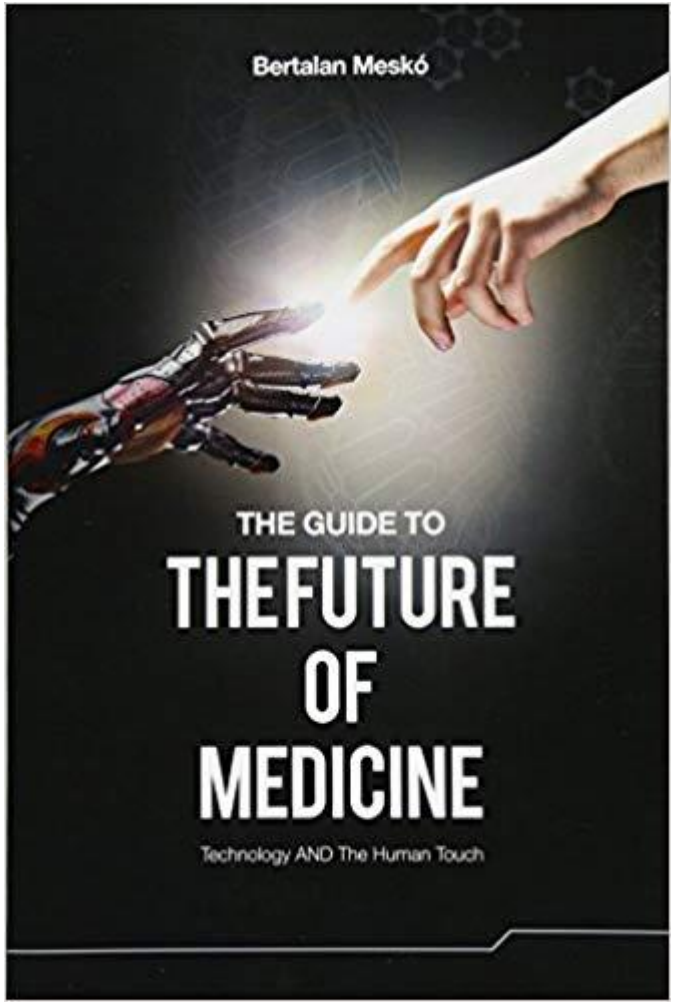
The Future of Medicine

- Without being prepared .. all stakeholders will come across human treats, ethical issues
  and serious problems.

- We can still prepare for the amazing yet uncertain future of medicine.

- What is definitely needed, among others things such as new skills, is a robust **Public Discussions** now.

Bertralan Mesko



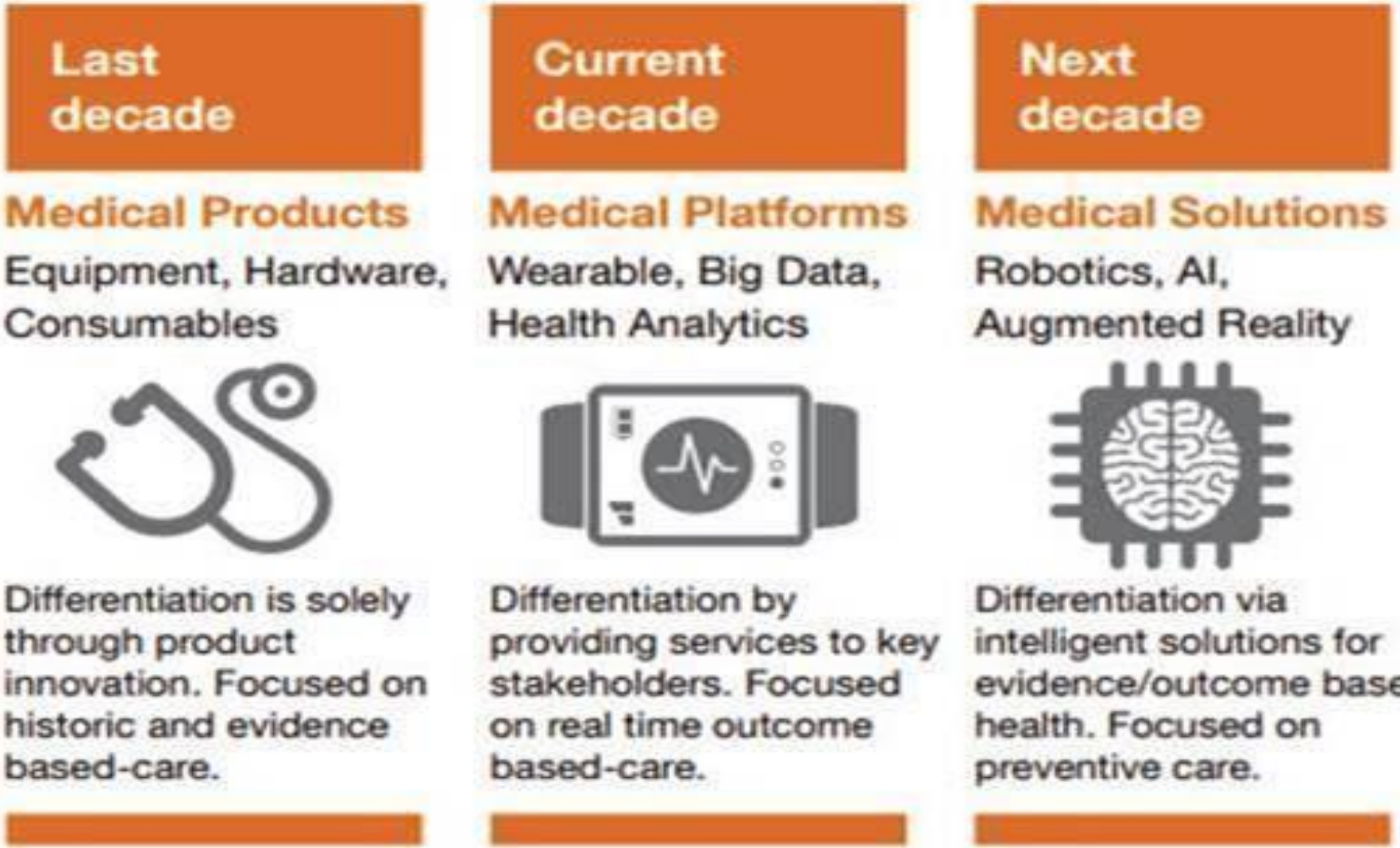


FIGURE 3-2 Trends in health care technology throughout the decades.
SOURCE: PwC, 2017.

Lost in Translation-EPIC in Denmark

- A consultant says the group from Denmark "went to Epic and fell in love" in being overly influenced by its campus
- Doctors and nurses dispense medications directly rather than pharmacists and Epic won't allow nurses to prescribe in emergencies as is done in hospitals there, leading to workflow problems.
- Medical terminologies had to be translated using Google Translate, creating problems such as when surgeons were offered two choices for the leg they intended to amputate: "left" or "correct."
- An anesthesiologist working on the project says the first hospital that went live was in "indescribable, total chaos" as Epic recommended going live with no pilot sites, which he describes as "worse than amateurish" when doctors and nurses were forced to use a system they hadn't seen, after which they were "weeping openly for days."
- The regional health administrator admits that he was overzealous in trying to get Epic implemented quickly to avoid t he cost and integration challenges of running it alongside the old system.
- Eighty percent of patients in Denmark move casually from hospital to home or other care setting and back over long periods, creating problems for clinicians who are forced to follow the American standard of re-entering diagnoses and medications each time using different screens for inpatient and outpatient.
- Discharge letters to doctors include "nonsense that's a copy-paste of everything in the patient record … five pages of gibberish [in which] there are five lines the doctor probably should read but doesn't." The government hired a cons ultant to use AI to extract the useful inormation.
- Physician satisfaction with Epic is at 12%, and the country's physician association said of Epic's offer to let them r un its system free in their offices, "You couldn't give us enough money to install Epic. We've seen how it works."
- The rest of Denmark decided not to follow the Copenhagen's region's lead, selecting Systematic over Epic, leading s ome politicians to call for Epic's replacement in Copenhagen, but the Health Ministry's digital director says Epic is "too big to fail" after they have spent $500 million on it.

Powerful head of the Electronics Department Atomenergikomissionens Forsøgsanlæg Risø / Risø National Laboratory

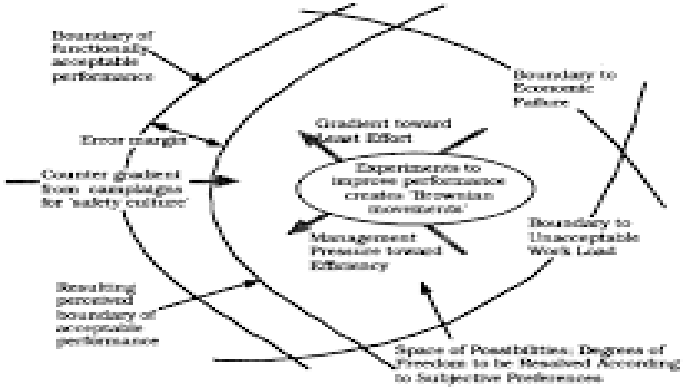


Fig. 3. Under the presence of strong gradients behaviour will very likely migrate toward the boundary of acceptable performance.

> 1,000 citations

Rasmussen, J. (1986). *Information Processing and Human-Machine Interaction: An Approach to Cognitive Engineering. Amsterdam: North Holland.*

Rasmussen, J. (1983). Skills, rules and knowledge; signals, signs and symbols and other distinctions in human performance models. *IEEE Transactions on Systems, Man, and Cybernetics, 13(3), 257 - 266.*

Rasmussen, J., Pejtersen, A. M., & Goodstein, L. P. (1994). *Cognitive Systems Engineering. New York: John Wiley & Sons, Inc.*

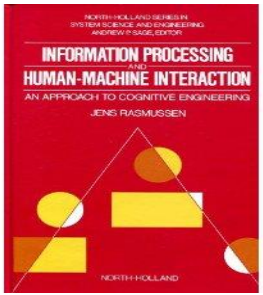
Rasmussen, J. (1997). Risk management in a dynamic society: a modelling problem. *Safety Science, 27(2/3), 183 - 213.*

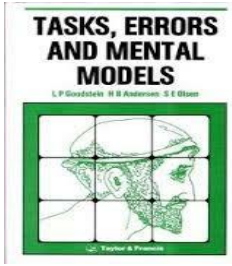
2,952

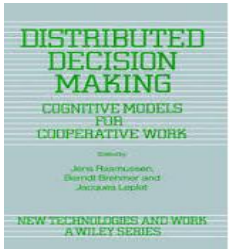
2,435

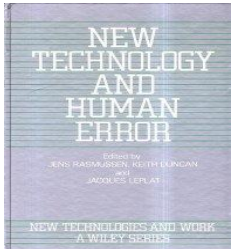
1,430

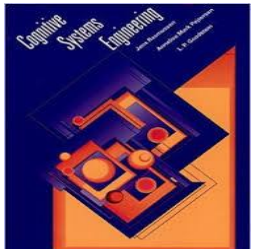
1,116





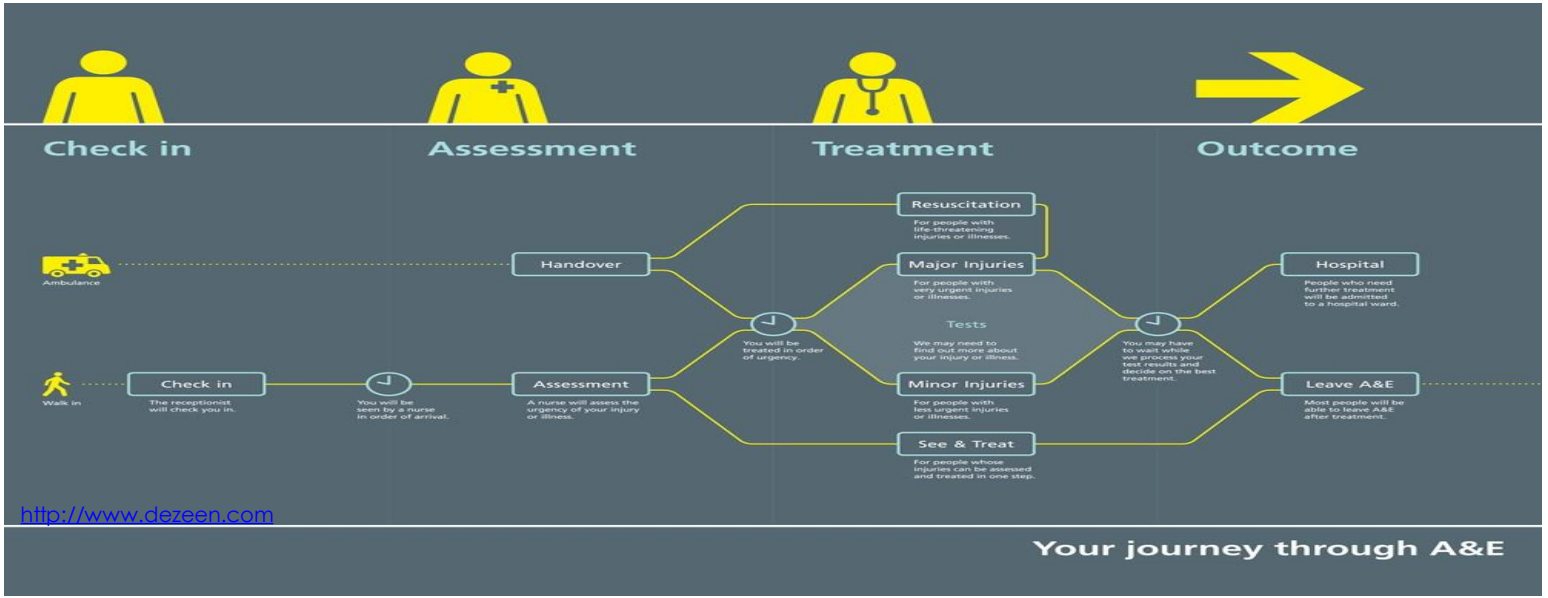




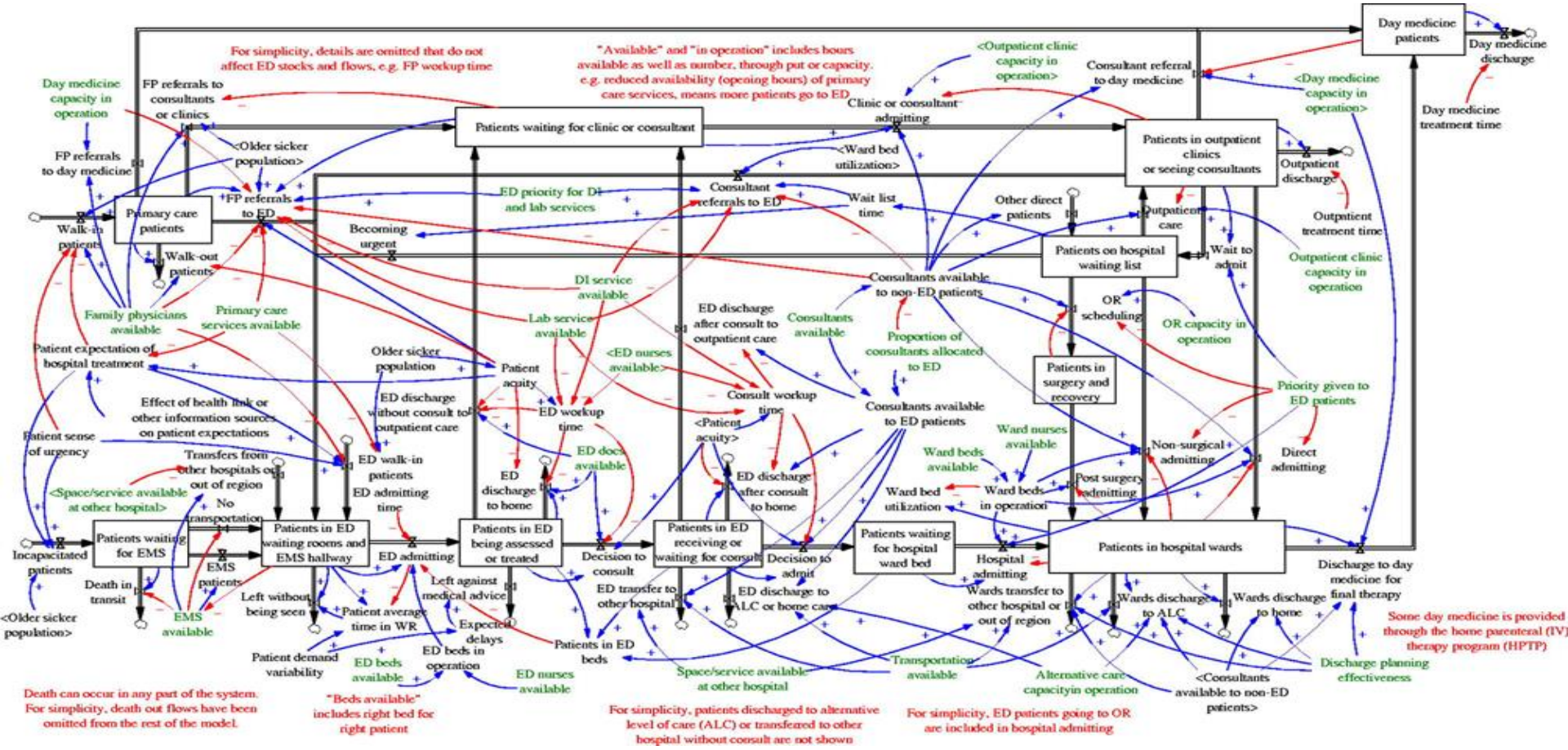



FAIL

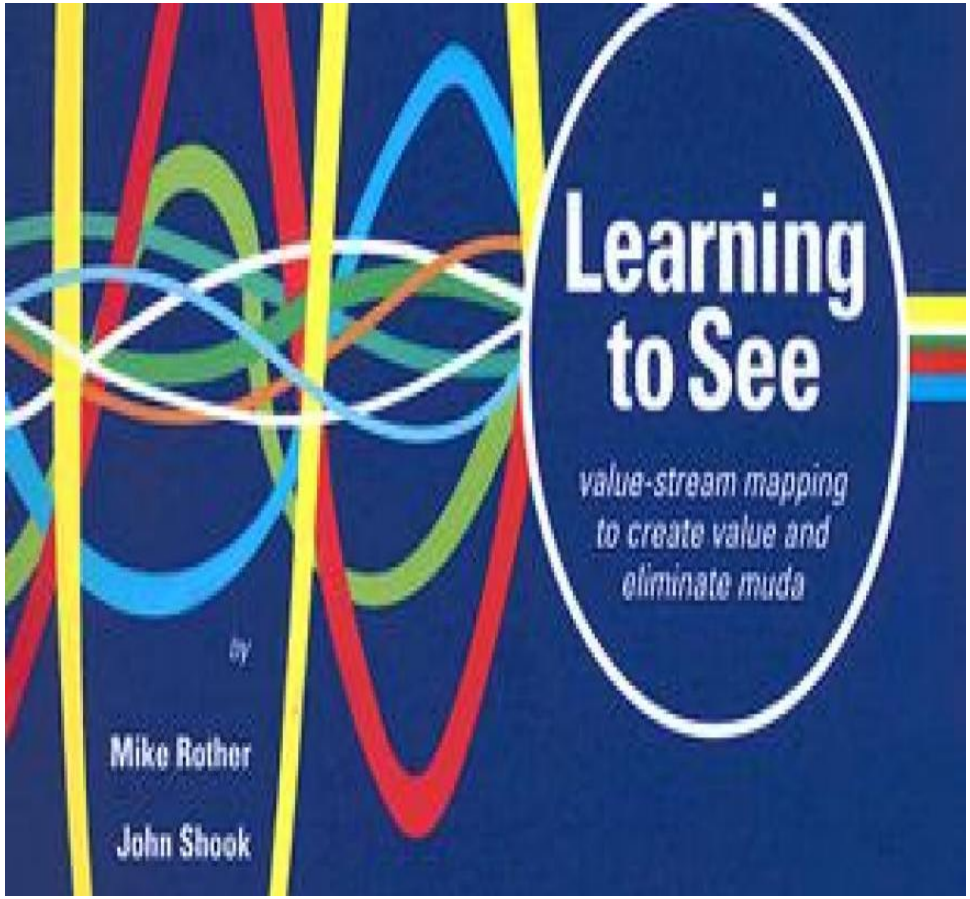
Work as Imagined



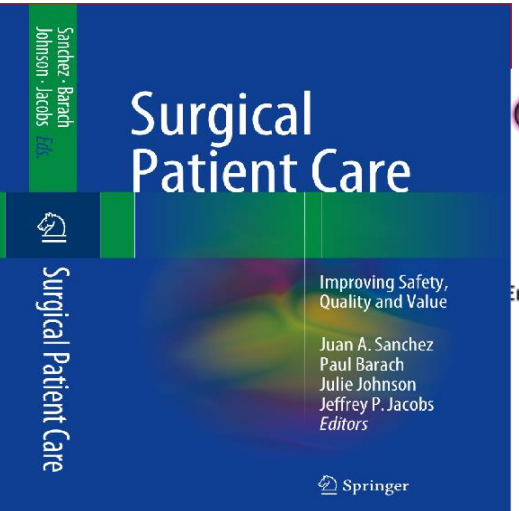
It is the system, stupid..my father's flow through the hospital…



Learning to See



A Social-Technical Model to Improve Safety



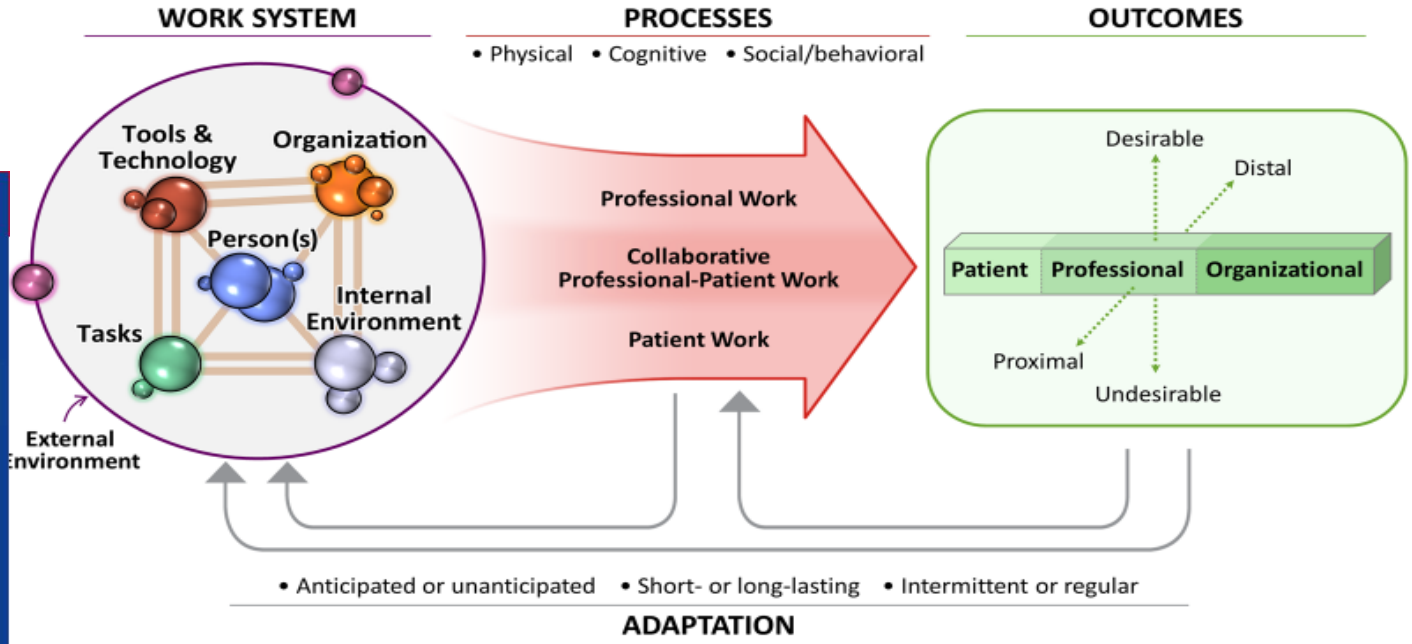
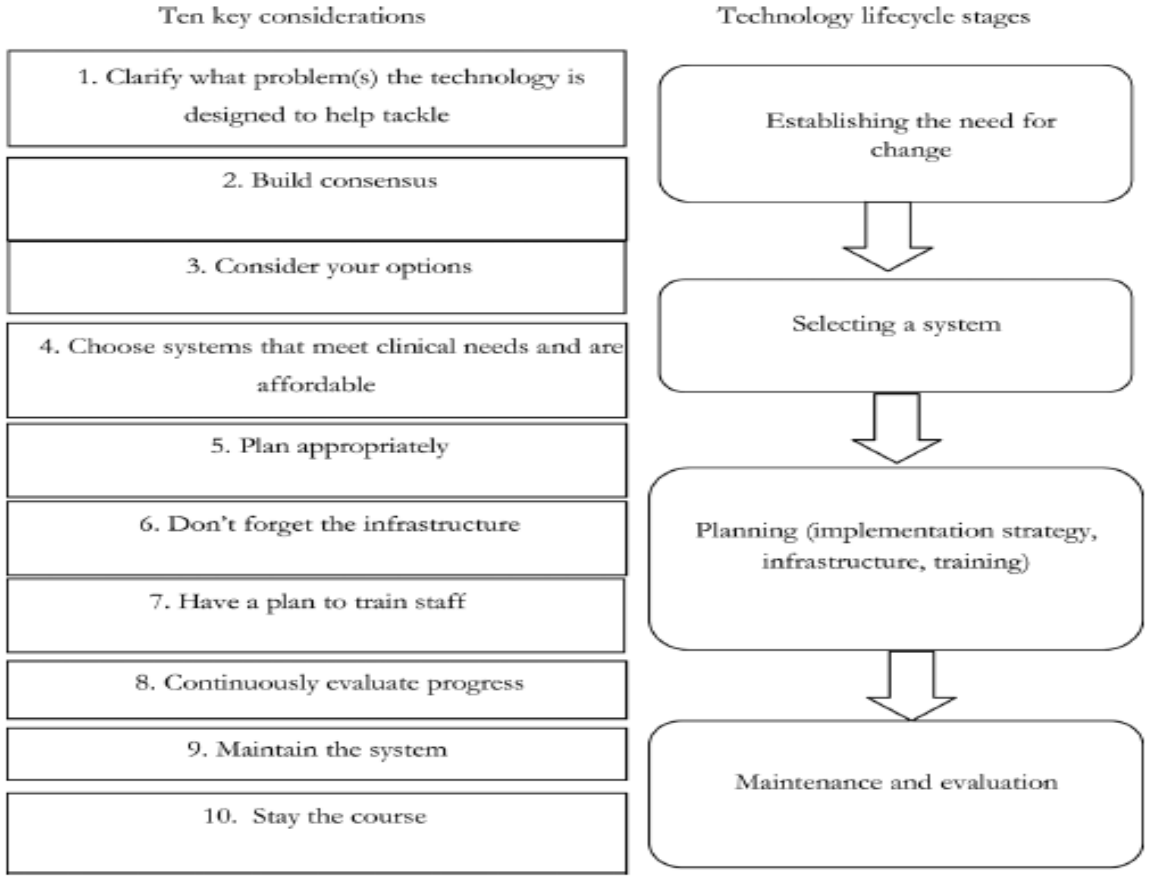


Figure 1 Summary of the lifecycle stages of health information technology and the ten key considerations.



Box 1 Factors associated with effective implementation identified in the literature[5–51]

Technical: usability, system performance, integration and interoperability, stability and reliability, adaptability and flexibility, cost, accessibility and adaptability of hardware

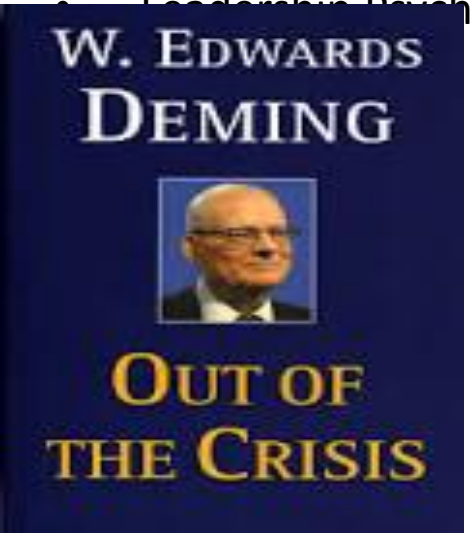
Social: attitudes and concerns, resistance and workarounds, expectations, benefits/values and motivations, engagement and user input in design, training and support, champions, integration with existing work practices

Organizational: getting the organization ready for change, planning, leadership and management, realistic expectations, user ownership, teamwork and communication, learning and evaluation

Wider socio-political: other healthcare organizations, industry, policy, professional groups, independent bodies, the wider economic environment, international developments

Dr. W. Edwards Deming:
System of Profound Knowledge (and Learning)

- Appreciation for a System
- Understanding Variation as the main cause for proce ss and outcome failures
- Theory of Change Knowledge
- Leadership Psychology



Mindfulness and Safety in HRO's

1. Preoccupation with failure

   Regarding small, inconsequential errors as a symptom that something is wrong; finding the half-event

2. Sensitivity to operations

   Paying attention to what's happening on the front line at the shop floor

3. Reluctance to simplify

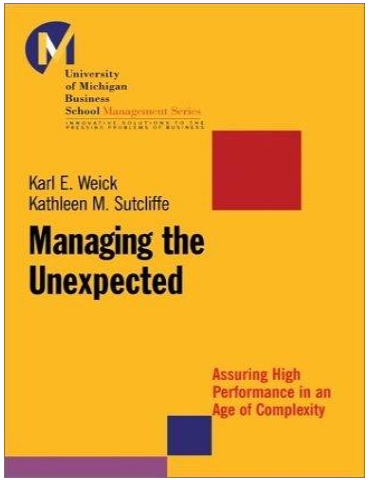
   Encouraging diversity in experience, perspective, and opinion

4. Commitment to resilience

   Developing capabilities to detect, contain, and bounce-back from events that do occur

5. Deference to expertise

   Pushing decision making down to the person with the most related knowledge and expertise



Hacking Medical Devices

- It has already been proven that pacemakers and insulin pumps can be hacked.

- Security experts have warned that someone would be murdered through these methods any time soon.

- How can we prevent wearable devices that are connected to our physiological system from being hacked and controlled from a distance?

Defending Privacy

- We share much more information about ourselves.
  Check mypermissions.org to see.

- What if using augmented reality contact lenses (see Minority Report) and system get information about people immediately?
- (https://www.youtube.com/watch?v=8deYjcgVgm8)

- **While such big data could significantly improve healthcare, how to prevent companies and governments from using these?**

Biological Differences by Digital Divide

- Today, societies struggle to fight gender and financial inequality.
- But from the time technology can truly augment human capabilities, people will get smarter, healthier and faster only by being able to **afford** them.

- **How do we prepare society for a time when financial differences lead to biological ones?**

Technological Developments vs. Evidence Based Medicine

Huge Discrepancy!

- Technological advances become so fast, and hard to keep track of them.
- Evidence based medicine (EBM) shapes how we deliver healthcare.
- EBM is a fundamentally long process and could never be as fast as technological developments.
- Seeing the amazing innovations not being accessible to them in the everyday care, how will people react and how will it transform the practice of medicine?

Artificial Intelligence in Medicine Raises Ethical Questions

- Algorithms can contain **bias** that is reflected in the secretive algorithms and in the clinical recommendations they generate.

- Also, algorithms might be designed to skew results, depending on who's developing them. Physicians and policy makers must adequately understand how algorithms are created, understand how the models function against becoming overly dependent on them.

- Data becomes part of the "collective knowledge" of published literature and information and without regard for clinical experience and the human aspect of patient care.

- Machine-learning-based clinical guidance may introduce a third-party "actor" into the physician-patient relationship, challenging the **dynamics of responsibility AND accountability** in the relationship and the expectation of confidentiality.

David Magnus

Sources of Bias

human bias;
bias that is introduced by design;
bias in the ways health care systems use the data

"The algorithms being built into the health care system might be reflective of different values, and clear conflicting interests"

A Very Important Thing That Sentient Beings have...

"The one thing people can do that machines can't do is step aside from our ideas and evaluate them critically."

Could Data Become The Doctor? No!!

- What physicians learn from the data needs to be heavily weighted against what they know from their own **clinical experience and the value of putting the patient at the center of their decision making.**

- For example, if clinicians always withdraw care in patients with certain diagnoses, such as extreme prematurity or brain injury or carcinomatosis of GI cancer, machine-learning systems may learn that such diagnoses are always fatal.

Competing Organizational and Financial Priorities

Conflicting Interests

- "The perpetual **tension** and the lack of transparency between the goals of improving health and generating profits … since the builders and purchasers of machine-learning systems are unlikely to be the same people delivering bedside care"

Responsibility and Challenges on Health Care Professionals

- Physicians who use machine-learning systems can become more educated about their construction, the data sets they are built on and their limitations.
- Remaining ignorant about the construction of machine-learning systems or allowing them to be constructed as black boxes will lead to ethically problematic outcomes."

New Pressure to Make Everything Available

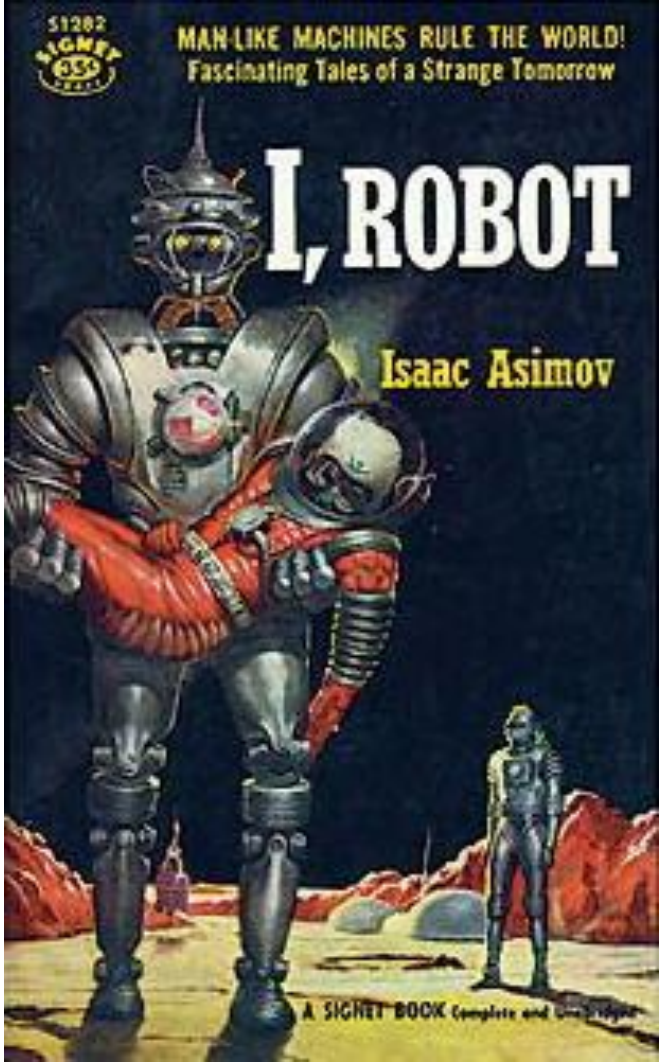
“Once machine-learning-based decision support is integrated into clinical care, withholding information from electronic records will become increasingly difficult, since patients whose data aren’t recorded can’t benefit from machine-learning analyses,”

Ethical Issues Created by AI in Healthcare

- The potential for AI to make **erroneous** decisions.
- Who is **responsible** when AI is used to support decision-making?
- Difficulties in **validating** the outputs of AI systems.
- The risk of **inherent bias** in the data used to train AI systems.
- Ensuring the **security** and **privacy** of potentially sensitive data.
- Securing **public trust** in the development and use of AI technology.
- Effects on people's sense of **dignity** and **social isolation** in care situations.
- Effects on the roles and skill-requirements of healthcare professionals.
- The potential for AI to be used for malicious purposes.

The Crucial Challenge to AI and Robotics

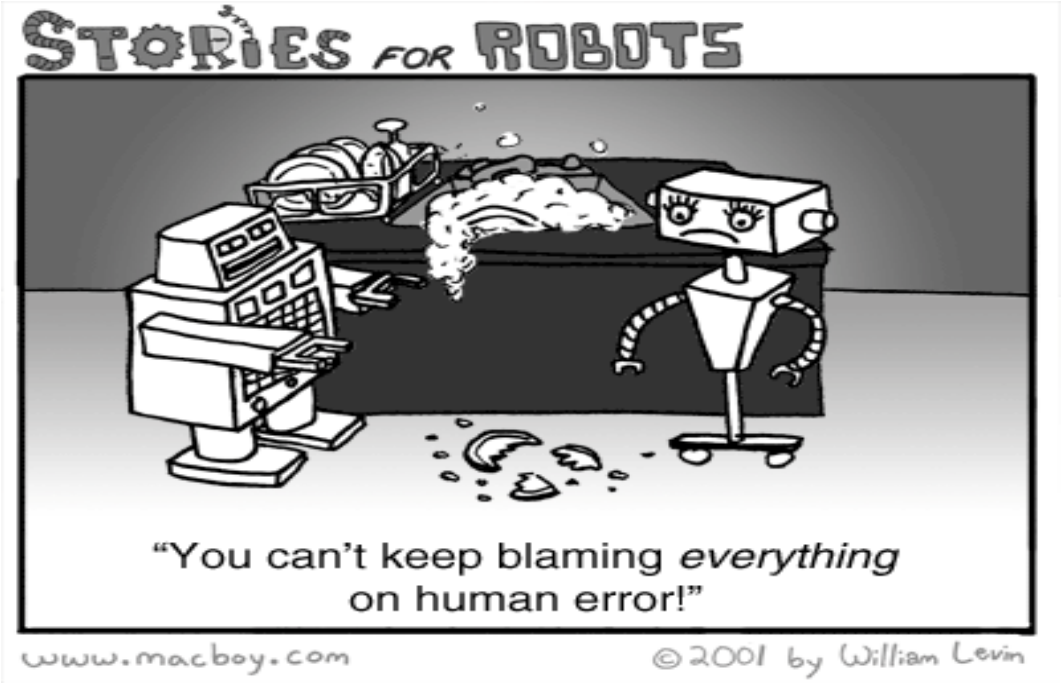
"To ensure that innovation in AI is developed and used in a ways that are **transparent**, that address **societal** needs, and that are **consistent** with public values."



WHY ASIMOV PUT THE THREE LAWS OF ROBOTICS IN THE ORDER HE DID:

POSSIBLE ORDERING	CONSEQUENCES	
1. (1) DON'T HARM HUMANS 2. (2) OBEY ORDERS 3. (3) PROTECT YOURSELF	[SEE ASIMOV'S STORIES]	BALANCED WORLD
1. (1) DON'T HARM HUMANS 2. (3) PROTECT YOURSELF 3. (2) OBEY ORDERS	EXPLORE MARS! HAHA, NO. IT'S COLD AND I'D DIE.	FRUSTRATI WORLD
1. (2) OBEY ORDERS 2. (1) DON'T HARM HUMANS 3. (3) PROTECT YOURSELF		KILLBOT HELLSCAP
1. (2) OBEY ORDERS 2. (3) PROTECT YOURSELF 3. (1) DON'T HARM HUMANS		KILLBOT HELLSCAP
1. (3) PROTECT YOURSELF 2. (1) DON'T HARM HUMANS 3. (2) OBEY ORDERS	I'LL MAKE CARS FOR YOU, BUT TRY TO UNPLUG ME AND I'LL VAPORIZE YOU.	TERRIFYIN STANDOFF
1. (3) PROTECT YOURSELF 2. (2) OBEY ORDERS 3. (1) DON'T HARM HUMANS		KILLBOT HELLSCAP

Stop blaming everything on “human error”!



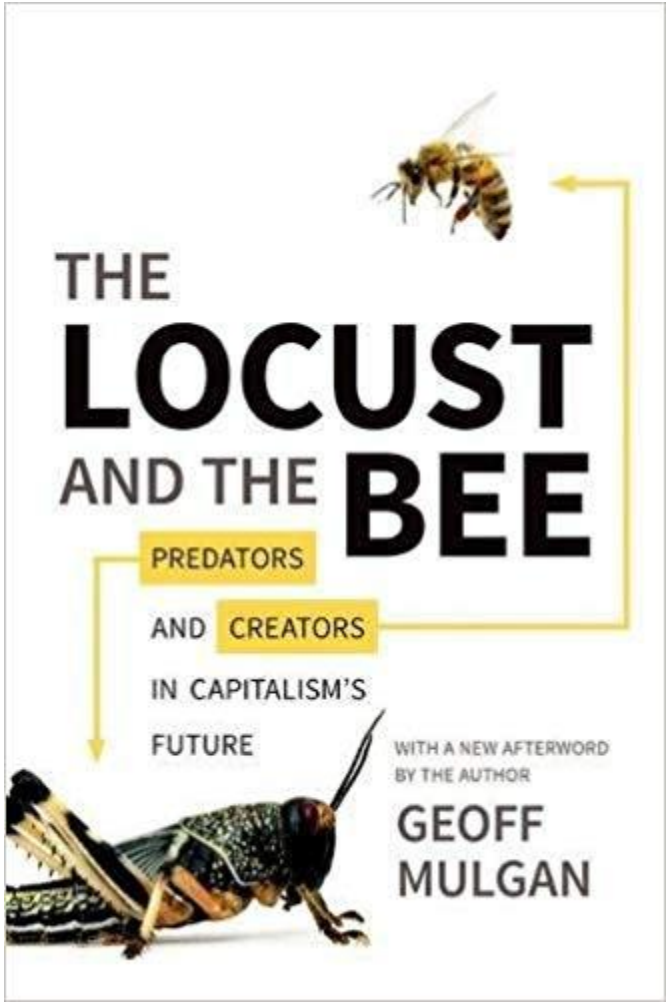
"If an error is possible, someone will make it. The designer must assume th at all possible errors will occur and de sign so as to minimize the chance of t he error in the first place, or its effect s once it gets made"

Norman, The Design of Everyday Thi ngs, 2001

Greed, Secrecy and Lack of Peer Review

Theranos calls it quits after scandal

- The Silicone biotech company built its reputation on the promise to revolutionize blood testing. Th e firm claimed its technology could use one drop of an individual's blood to test for a variety of di seases at a lower cost. The company, thanks to this revolutionary technology, was once valued at $ 9 billion.
- The company began to unravel after a *Wall Street* lished an investigation alleging Theranos' devices
- The *WSJ* article prompted regulatory and quality c stigations lead to federal fraud charges against Th -CEO of the company, and Theranos' former presi
- Holmes settled the fraud charges brought against investors with the Securities and Exchange Comm fine of $500,000 and agreed not to serve as a dir
- Ms. Holmes and Mr. Balwani both face criminal ch
- Theranos declared bankruptcy and in default on a



Geoff Mulgan

2013

How do we get beyond this state of “technology will save me” and “technological determinism”?

A System that Promotes Innovation

- Should comprehend people who desperately confront problems
- Should have a mechanism to encourage collaboration to resolve society problems
- Should have efficient pathways to make things realized in the real world
- Should have **connectivity** and more than just gathering
- Should be about continuous learning and improvement

A System Ahead of Ethics

“Machine can devour the world because it evolves so fast”

(So, is it too late to consider ethics after technological development?)

To make a Neotopia not a Utopia:

“The Place people can grow and is ready to adapt”

Don’t forget human resilience

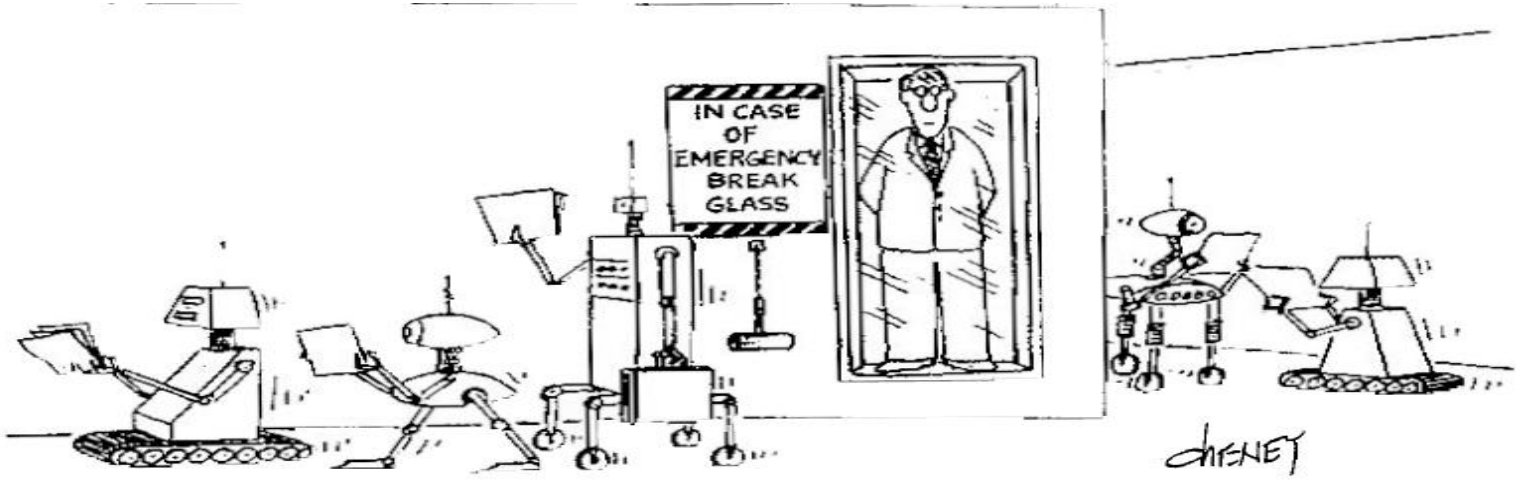


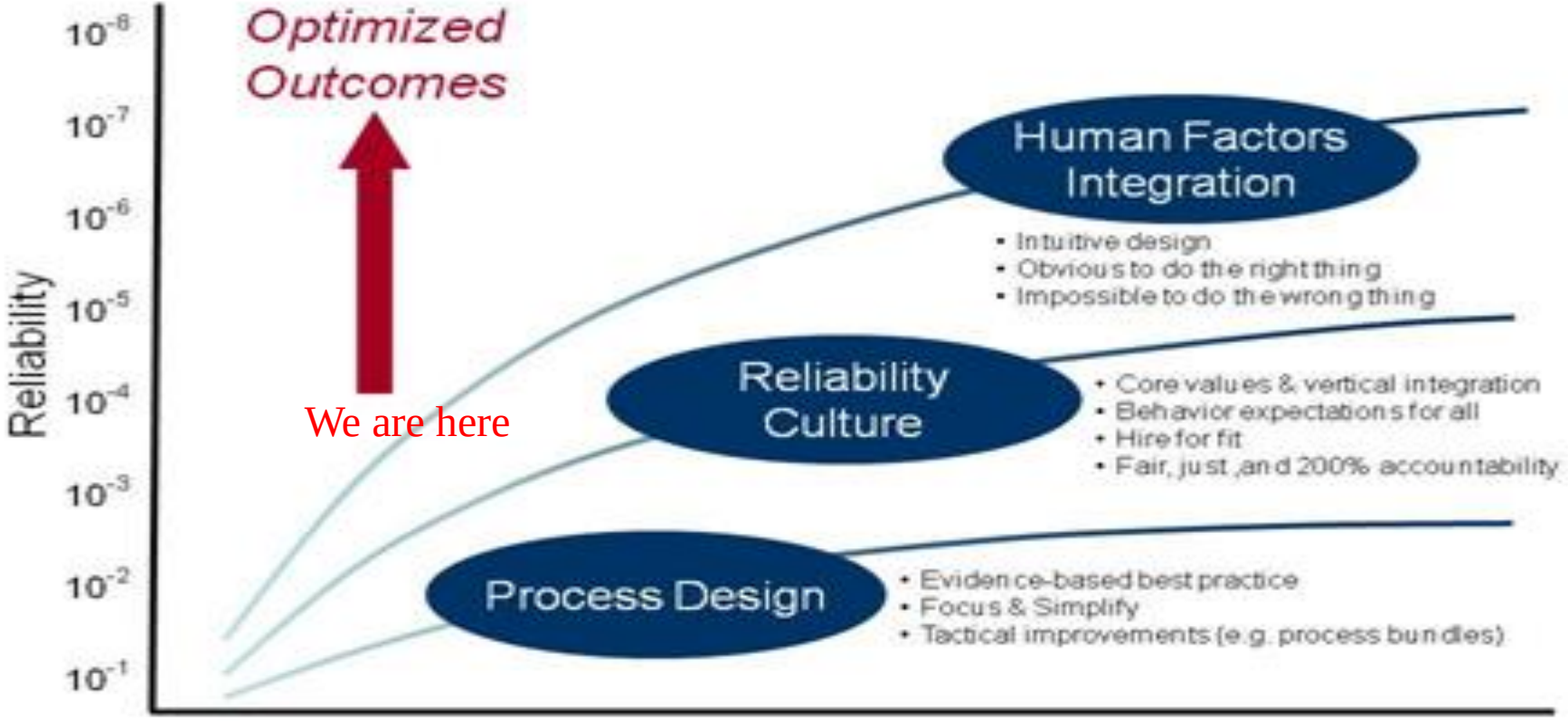
FIGURE 3.5
Ultimate functional allocation when using a “capability” criterion. (*Source:* Cheney, 1989. New Yorker Magazine, Inc.)

Four Essential Directions to Consider

1. Expose and be transparent in inefficiency and failures
2. Redefine conflicts of interest by disorganizing interests group
3. Change points of view and frame of thinking
4. Promote connection and authentic relationships to support alternative

All of them are needed, and don’t depend on fixed ideas or legacy opinions!!

Journey to Reliability – The Next Zero



New Solutions to Overcome

Ethical Considerations
Technological Limitations
Medicolegal Issues
Regulatory Approval
Healthcare Costs
Philosophical Issues

Healthcare Innovation Platform

“Seoul Declaration for Ethical Medical Technology”

- We need a paradigm shift of healthcare innovation for the welfare of people all over the world.
- A pledge to support ethical medical technologies.
- Support collaborative, ethical and transparent biomedical design methodologies working with industry in transparent manner for global health concerns.
- Call on our governments to fund and support development of new technical standards, international registries for medical technologies and applications, and open-access e-infrastructures for global action
- Strive for harmonization of medical devices regulations, directives and accessible standards.
- We must instigate new conversations as currently we have inadequate

Taylor & Francis

Minimally Invasive Therapy & Allied Technologies

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The Seoul Declaration: A Manifesto for Ethical Medical Technology

Young-Woo Kim, Paul Barach & Andreas Melzer

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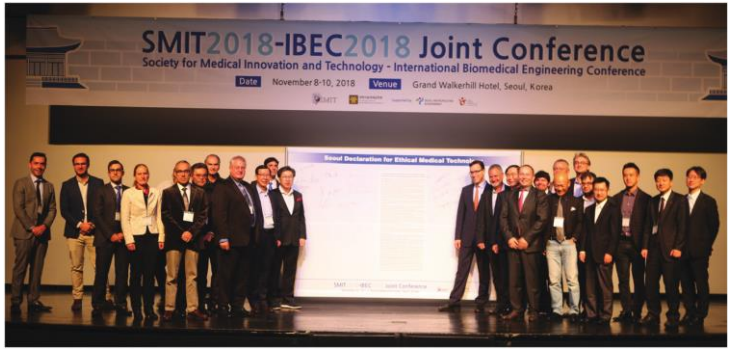

Figure 1. Declaration singed by the attendees of iSMIT 30th international conference, Seoul, South Korea. 9th November 2018.

improved service delivery and improved safety and quality;

Recognizing the role of engaging and empowering patients and families in the design and implementation of medical technologies that help deliver safe and quality care and in all aspects in health care - policy development, organizational level, decision making, health literacy and self-care.

We declare that we will:

Pledge to support ethical medical technologies with the goal of "*Primum non nocere*"
Enable health care institutions, both public and private, from the level of primary care through to referral level care, to implement changes in an ethical and transparent manner, in terms of conflict of interest in systems and practices to improve patient safety and human values using new medical technologies, while contributing to achieving UHC and SDGs;

Support collaborative, ethical and transparent biomedical design methodologies working with industry for global health concerns. Collaboration is essential for successful engineering of complex projects and the biomedical engineering field stands out for the need of multidisciplinary teams capable of systematically addressing the development of medical devices considering medical, social, economical, technical, safety and regulatory issues.

Call on our governments to fund and support development of new technical standards and open-access e-infrastructures for global action. The development and employment of adequate data management strategies and of methodologies for improved information sharing is intimately connected to the construction of healthy, sustainable, creative, effective and efficient collaborative design environments. Developing user-friendly, versatile, stable and safe open-access e-infrastructures, for supporting these online interactions in the collaborative development of biomedical devices, and following FAIR (findable, accessible, interoperable and reusable) data principles as the right direction for achieving global action towards the democratization of medical technology.

Strive for harmonization of medical devices directives and accessible standards. Construct a framework for enabling medical technologies to reach everyone and everywhere relies on the use of common design practices and on the fulfillment of broadly accepted regulations that must warrant patients' safety and improving human values that should allow for a compliant device to be commercialized and applied worldwide. Establish clinical follow up, post market surveillance and registries of the use of medical devices, if needed in addition to loco regional regulatory demands.

Sign and assume the present manifesto, as a symbol of commitment and deep respect for future collaboration. We will pursue the aims highlighted in this document, supporting our partners, promoting collaboration with significant stakeholders (from patients, patients' associations, medical professionals and biomedical engineers, to educators, policy makers, manufacturers and companies), working towards universally accessible, intrinsically safe and high-quality medical technologies and solving unforeseen issues with a balance between pragmatism and idealism (pedes *in terra ad sidera visus).*

Conclusions

- Healthcare professionals should co/lead/ and create the future direction based on “ethical” values. ---**Involve clinical staff from the get-go!**
- Understand the difference between implementation and adoption—**hire expertise in improvement and implementation sciences.**
- Select the right leader for the “crawl, walk, run” journey
- Find the right technology partner
- The goal is not just for better healthcare but to make the world a better and prosperous and not to ruin it by technology!

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Stavanger, June 12 , 2019

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