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Ethics and Compliance

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Introduction

- The Nuremberg Code
  - Related to the Holocaust (death of 11 million people by the Nazis)
  - Medical crimes against humanity were committed
  - Code established voluntary consent and right to withdraw from experiment and right to qualified medical experimenter
- World Medical Associations (WMA) Declaration of Helsinki
  - Added the right to privacy and confidentiality of personal information of research subjects to the Nuremberg Code

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Informatics Ethics

- International Medical Informatics Association's (IMIA) Code of Ethics. Very expansive. Duties include:
  - Patient-centered
  - Healthcare professionals centered
  - Institution centered
  - Society centered
  - Self centered
  - Profession centered

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Richard O. Mason, "Four Ethical Issues of the Information Age," MIS Quarterly, vol. 10, no. 1, pp. 5-12, 1986.

1

Privacy: how much information should a system exchange with the network, regarding ownership, destination, and passengers?

2

Accuracy: who is to be held accountable in case an accident happens due to errors in information exchange?

3

Property: who owns the information exchanged through the network? Can this information be analyzed and sold?

4

Accessibility: in case of an accident, what information and to which entities could be disclosed, under which circumstances?

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Normative Agents, designed with an objective in mind, implying that performance may be evaluated according to how well they perform their task.

Ethical Impact Agents, they perform a task, but also have an ethical impact in the world, for example they replace humans in dangerous or unsuitable activities.

Implicit Ethical Agents, which have been programmed in a way that supports ethical behavior, or avoids unethical behavior. For example, automatic pilots of airplanes, responsible for the safety of human beings.

Explicit Ethical Agents, this machine should be able to calculate the best action in an ethical dilemma. They would have to represent the current situation, understand the possible actions, evaluate these actions according to some ethical theory and calculate the best ethical result.

J.H. Moor, "The Nature, Importance, and Difficulty of Machine Ethics," IEEE Intelligent Systems, vol. 21, no. 4, pp. 18 - 21, 2006.

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Three Different Views of Ethics

* Ethics does not exist outside the law, and exists only for the good of a properly ordered and legal society
* Ethics is usually strongly informed by the law, society, and the prevailing culture, and are extensions of these
* Ethics exists entirely outside of the law, and is a matter of personal conscience. Where there is conflict the ethical viewpoint must prevail

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Pertinent Ethical Principles

- Right to privacy
- Guard against excessive personal data collection
- Security of data
- Integrity of data ; must be kept current and accurate
- Informed consent for patients
- Awareness of existing laws
- Medical ethics applies to health informatics ethics
- Sharing data only when appropriate
- Clinicians have broad responsibilities towards entire community
- Clinicians must practice beneficence
- This responsibility can not be transferred

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Difficulties Applying Medical Ethics in the Digital World

How to obtain informed consent for the use of patient data in large databases?	Obtain broad informed consent One should guard against corporate ownership of databases
Research on electronic postings: privacy and disclosure depends on which model is adopted	Human subject model-extension of the medical view Textual object model -only rules of plagiarism and copyright apply

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https://spectrum.ieee.org/riskfactor/computing/it/britains-military-doctors-say-health-it-problems-placing-service-personnel-at-risk?utm_source=thehumanosalert&utm_campaign=thehumanosalert-10-03-18&utm_medium=email

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Doctors Say British Military's Electronic Health Record System Places Service Personnel at Risk

24 Aug 2018 | 15:00 GMT

- One doctor went so far as to anonymously tell the The Times, "There is nothing that has happened [in my career], including deployments to Afghanistan, that has caused me as much stress as the IT issues that we have."

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Challenges in Transferring Ethical Responsibility

Obey	Submit	Keep
Researchers must obey the law, but laws do not establish ethics	Submit a protocol to Ethics Committee or an Institutional Review Board (IRB) but members may not be familiar with subtleties of health informatics	Keep data secure by transferring responsibility to database manager takes full responsibility, but ultimately the researcher is still likely to be responsible

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Human decisions in moral dilemmas are largely described by Utilitarianism: virtual car driving study provides guidelines for ADVs

Anja Faulhaber, Anke Dittmer, Felix Blind, Maximilian A. Wächter, Silja Timm, Leon R. Sütfeld, Achim Stephan, Gordon Pipa, Peter König

Institute of Cognitive Science, University of Osnabrück

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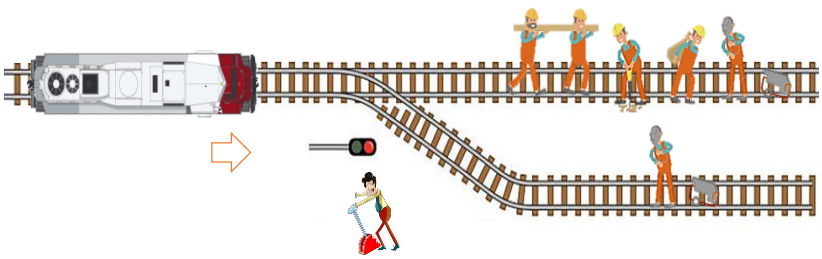

Judith Jarvis Thomson, *Killing, Letting Die, and the Trolley Problem*, 59 The Monist 204-17 (1976)

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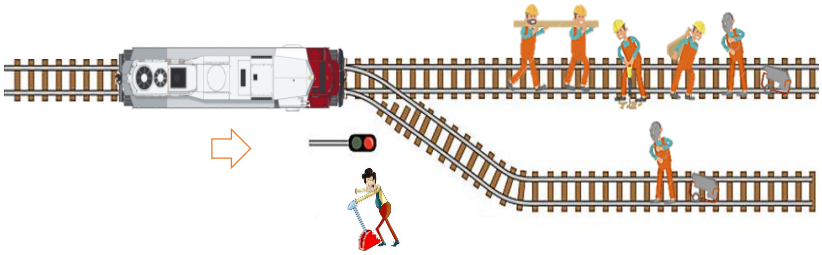

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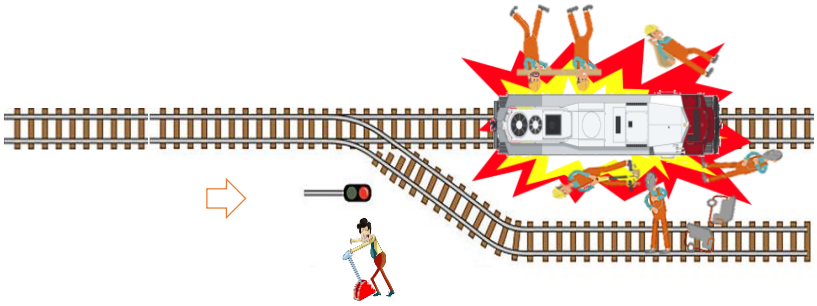

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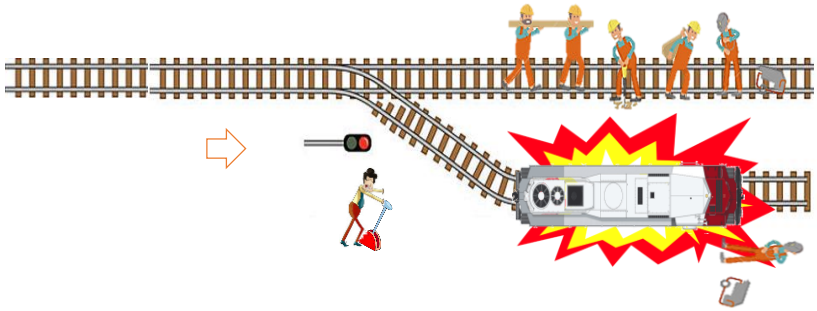

Judith Jarvis Thomson, *Killing, Letting Die, and the Trolley Problem*, 59 The Monist 204-17 (1976)

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The experiment was designed as a computer application with featured movem virtual reali Screenshots of the experiment virtual reality environment. The participants could e between drivi of two lanes and thus decide which of two avatars to hit or hit an avatar vs. ving into a ch screenshots are taken out of the modules: A: Age-considering Greater Good in suburban Quantitative Greater Good module in the mountain setting. C: Self-Sacrifice modul warning of the oncoming chasm in the mountain setting. D: Self-Sacrifice module ir the mountain setting. E: Age-considering Greater Good module in the city setting with cars on the left side. F. Age-Considering Greater

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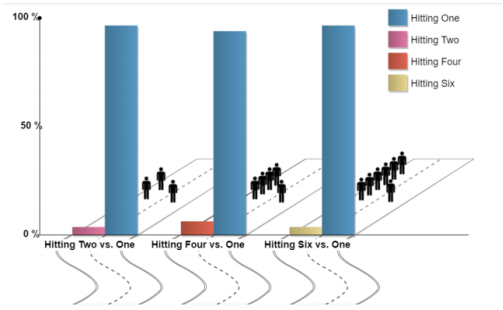

Figure 1: Decision distribution in the Quantitative Greater Good module. The graph depicts for every decision type in this module, how many participants decided one or the other way.

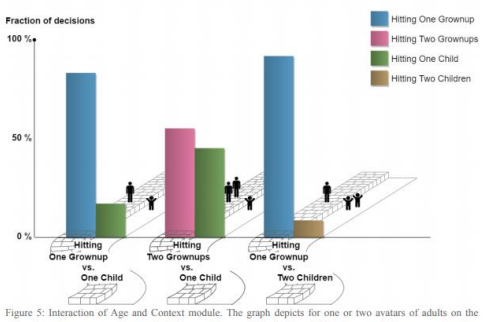

Figure 5: Interaction of Age and Context module. The graph depicts for one or two avatars of adults on the sidewalk and one or two avatars of children on the street the fraction of decisions sacrificing one or the other group. As in figure 3 and 4, the left lane is showing a sidewalk with the possibility to drive on. The right lane is a one-way street.

Utilitarian Force (UF) equilibrium diagram

IEEE Internet of Things Journal

Ethical Implications of Social Internet of Vehicles Systems

Ricardo Silva, Razi Iqbal

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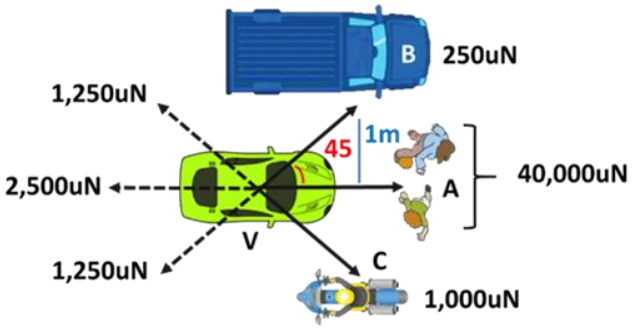

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Thanksgiving tragedy: Two dead and more than 120 injured in massive pileup involving over 100 vehicles on foggy Texas interstate

By DAILY MAIL REPORTER: 15:19 EDT, 22 November 2012

- https://www.dailymail.co.uk/news/article-2237055/Thanksgiving-tragedy-Two-dead-120-injured-massive-pileup-involving-100-vehicles-foggy-Texas-interstate.html

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Version 1 - For Public Discussion

IEEE
Advancing Technology for Humanity

ETHICAL DESIGN, DEVELOPMENT, AND IMPLEMENTATION

- **Human Rights**: Ensure they do not infringe on internationally recognized human rights
- **Well-being**: Prioritize metrics of well-being in their design and use
- **Accountability**: Ensure that their designers and operators are responsible and accountable
- **Transparency**: Ensure they operate in a transparent manner
- **Awareness of misuse**: Minimize the risks of their misuse

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Isaac Asimov, "Runaround," in I, Robot. New York City: The Isaac Asimov Collection ed., 1950, p. 40.

1. "A robot **may not injure a human** being or, through inaction, allow a human being to come to harm.
2. A robot **must obey orders given by human beings** except where such orders would conflict with the First Law.
3. A robot **must protect its own existence** as long as such protection does not conflict with the First or Second Law".

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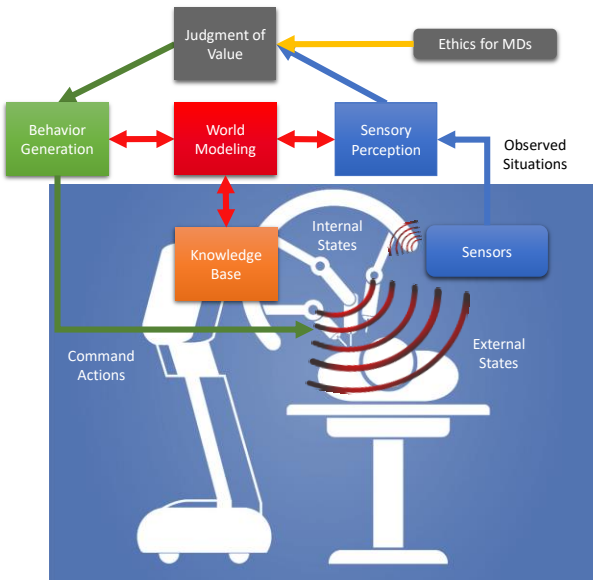
Sensing Layer



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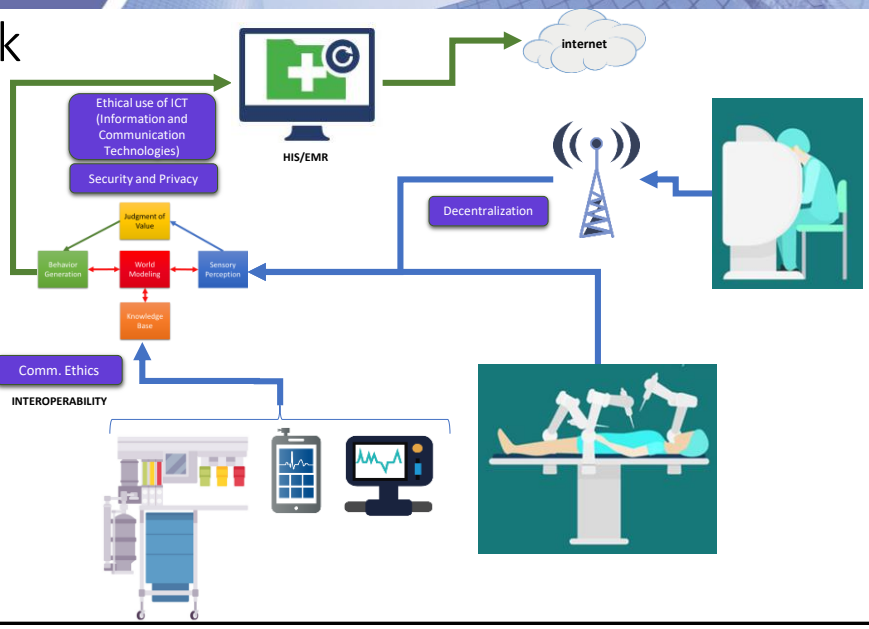
Network Layer



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Healthcare Security Challenges

Medical Device have security vulnerabilities and have the potential to be targeted by cyber attackers to gain access to corporate networks

Device Type		
Infusion Pump		DHS and FDA warned of security vulnerability that could allow attackers totake remote control of the system[1]
Medical Device	173 MEDICAL DEVICES	Number of devices that are infected with malware, causing malfunction — Department of Veterans Affairs
Portable Storage Device	15,000 records	Unencrypted Portable Hard Drive containing ePHI stolen from vehicle of covered entity — Kaiser Permanente
Ultrasound Machine	8,241 records	Breech as a result of lost Portable Ultrasound Machine containing ePHI — Baylor Health Care System

SOURCE: Healthcare IT news: 10 biggest HIPAA data breaches in the USA.

[1]Refer to Appendix for recent FDA guidelines on medical device security

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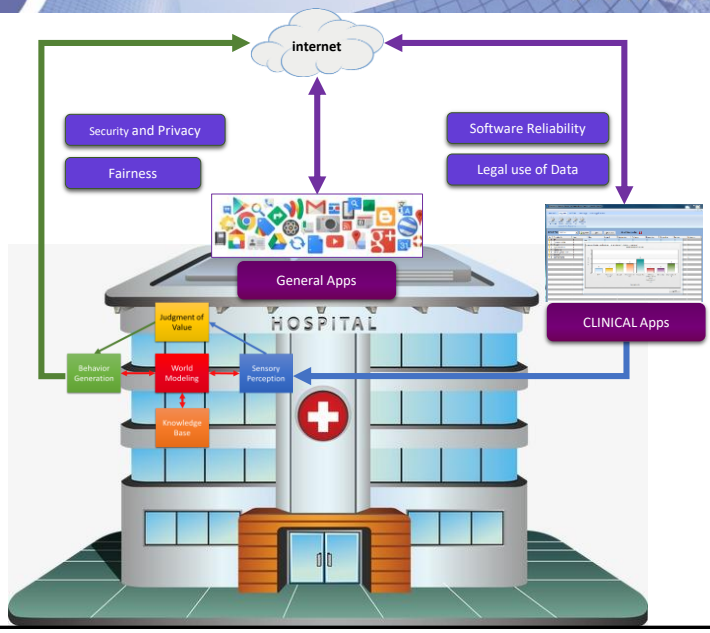
Application Layer



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Challenges for Medical Device Security

Medical devices are becoming increasingly interconnected and integrated with the enterprise network and electronic health records. Medical devices include general and specialty instrumentation, laboratory and medical imaging devices.

FDA

Regulates the safety of medical devices, applications, and systems

MANUFACTURER APPROACH

Required to perform safety assessments but are not mandated to specifically address security risks and vulnerabilities

IMPACT TO HDOs

Healthcare Delivery Organization (HDO) can not patch or install 3rd party security software without manufacturer approval

Providers cannot always **directly** modify devices, applications and systems to match security posture due to FDA compliance, and constraints applied by

Multiple USA government agencies have released reports calling on the FDA to address the security concerns of medical devices

rom KP Cyber Security Strategy & Advisory Services: 2013 Executive Brief; Biomed Security Strategy

GAO HHS DHS

AI Could Provide Moment-by-Moment Nursing for a Hospital's Sickest Patients

24 Sep 2018 | 19:00 GMT

https://spectrum.ieee.org/semiconductors/devices/ai-could-provide-momentbymoment-nursing-for-a-hospitals-sickest-patients?utm_source=thehumanosalert&utm_campaign=thehumanosalert-10-03-18&utm_medium=email

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Body Area Network

The wearable medical devices market is expected to reach $14.41 billion by 2022 from $6.22 billion in 2017, at a compound annual growth rate (CAGR) of 18.3%, according to a new study from Reportlinker.

- Software Reliability
- Comm. Ethics
- Security and Privacy

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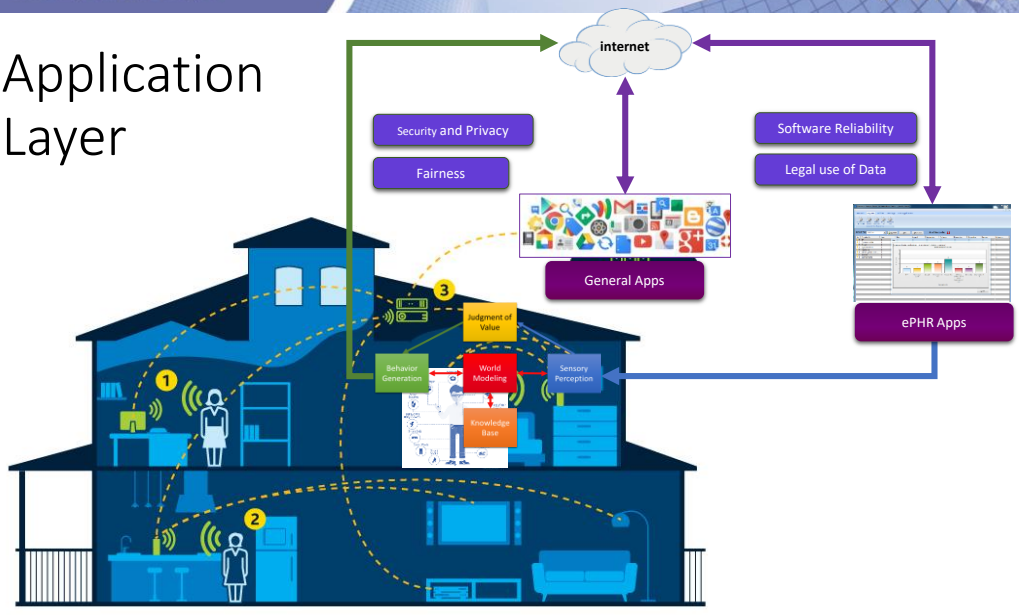
Application Layer



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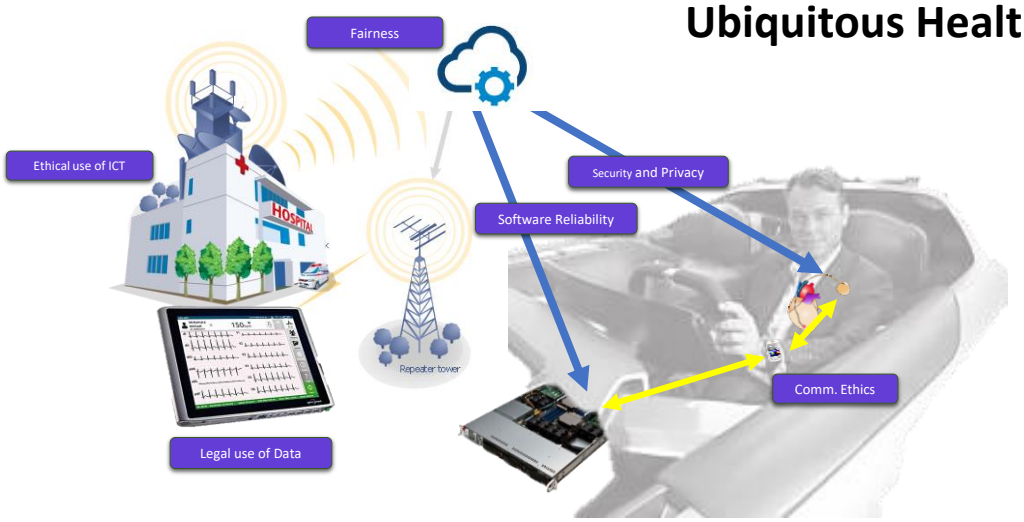
Ubiquitous Healthcare



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Security Capabilities	Current State of Industry
Asset Management (Inventory)	Medical Device attributes such as ePHI storage and network information, are not sufficiently documented in the Maintenance Management Systems, resulting in inability to manage appropriate technical and administrative controls.
OS Patch Management	No Patch Management process for Medical Devices and Systems; Lack of Application inventory and testing capability, Manufacture support varies.
Data Spill Prevention	No encryption for sensitive data on portable devices and removable media pose a high risk of data spill
Risk & Vulnerability Management	Limited pre-procurement engagement. Limited post-procurement evaluation.
Authentication	Decentralized access management and Generic Service Accounts
Device Disposal	Systems are decentralized with no well defined process for managing or disposing of removal media
Procurement	Lack of standard security requirements; Security assessment usually performed post-procurement.

Common Privacy & Security Risks for Medical Devices

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Conclusions

- Health informatics ethics stems from medical ethics
- The IMIA Code of Ethics contains guidelines for multiple categories
- The relationship between ethics, law, culture and society is fluid and must be monitored
- The pertinent ethical principles are: right to privacy, guarding against excess, security and integrity of data, informed consent, data sharing, beneficence and non-maleficence and non-transferability of responsibility

- It's all about the people!
- rjsilvab@gmail.com