Ethics in Informatics

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Learning Objectives

- What are legal issues in informatics?
- What are ethical issues in informatics?
  - Four prinicples in understanding Ethical Cases
- Case Study 1: Therac 25
- Case Study 2: Medical Students using Google Calendar
- Genomic Information and Ethics

Reading

McGonigle: Ethical Applications in Informatics.

Context: Patient Rights

- Access to Care
- Respect and Dignity
- Privacy and Confidentiality
- Personal Safety and Security
- Information
- Consent

UHS Patient Rights and Responsibilities

Legal protections for patients

- Health Information Privacy and Accountability Act (HIPAA)
- Genetic Information Nondiscrimination Act (GINA)

HIPAA

Health Information Privacy and Accountability Act (HIPAA)

Patients have the right to

- Access their information in EHRs
- Send their information to third parties
- Have their privacy protected
    - Information needs to be de-identified

GINA

Genetic Information Nondiscrimination Act

Not only DNA! Also protects family history

Discrimination is prohibited by clinics and insurance companies on

- Family History
- Genetic Tests
  - including consumer testing

However

- Many people and stakeholders are involved in patient care
  - Patient, Family, Nurses, Physicians, Insurance Companies
- There are many grey areas which there are no legal protections
- We still have to make decisions about these
- Need to think about ethical frameworks for these cases

Care Ethics

- Responsiveness to needs of patients
  - Provide care, prevent harm, maintain relationships
- Focus is on needs of others and how to provide for those needs

Ethics and System Design

What does informatics have to do with ethics?

- http://ethicalsystems.org/tags/ethical-systems-design
- Nudge encourage people to do the right thing by default
  - example: opt out organ donation for drivers licenses

Four main principles

Beauchamp & Childress outline four main principles for evaluating an ethical decision:

Beneficience

- Does our decision do good for our patient?

Nonmaleficence

- Does our decision do no harm to our patient?

Autonomy

- Does our decision affect patient independence?

Justice

- Is our decision fair and equitable to our patient?

Patient Rights in terms of principles

- Access to Care (Justice)
- Respect and Dignity (Autonomy)
- Privacy and Confidentiality (Autonomy/Non-maleficence)
- Personal Safety and Security (Beneficence/Non-maleficence)
- Information (Autonomy/Justice)
- Consent (Autonomy)

UHS Patient Rights and Responsibilities

Analysing Ethical Cases

1. List stakeholders and their needs/goals
2. List the relevant facts and outcomes
3. What are the underlying problems that they were trying to address?
4. What went wrong?
5. Were the actions in accord with the principles? Were there any conflicts?
6. What were the alternative actions? Were they in line with principles?

Therac-25: Facts

- Therac-25: Medical Device and Software from AECL of Canada to give radiation treatment
- Potentially revolutionary treatement
- Due to software bugs and design, some patients received massive radiation overdoses
  - 100 x the recommended dose
  - 4 patients died
  - 2 lived with lifelong complications

Therac-25: Root Causes of Failure

- Investigation on deaths started
- Software had bugs that caused fatal errors
  - Error codes were uninterpretable, just numbers
  - "Malfunction 54" - operators were "typing too fast"
- Design: controlling computer was responsible for everything
  - No hardware interlocks or failsafes

Killed by a machine

Clinician Use of Therac 25

- Malfunction would happen on the machine
  - Errors were code numbers
  - Clinicians would try to override/reset

Therac-25: Stakeholders

- Patients
- AECL
- Software/Hardware Engineers
- Clinicians delivering treatment

Therac 25: Facts and Outcomes

- Patient radiation overdoses
- Patient Death and Disability

Therac-25: What went wrong?

- Code from previous instrument used with the new hardware
- System design conflicted with clinician usage
- Error codes were cryptic
- Failsafes were not implemented
- Software was not rigorously tested

Therac-25: Principles involved

- Non-maleficence
  - intention by clinicians to do no harm
  - system design prevented them from doing so
- Beneficence
  - clinicians wanted to deliver correct dosage
  - in conflict with system design & usage
- Autonomy?
- Justice?

Therac-25: What was the response?

- Denial that software was the issue
- Initially, AECL suggested bandaid fixes
  - "Remove the up arrow key"
  - After a treatment, "pause"
- Consequence: Device was still on the market with bugs
- Consequence: Patient product liability lawsuits

Therac-25

Therac-25: Response part 2

- FDA and consumers demanded a larger response
  - Recall of Device required
  - Medical Device/Software Standard IEC 62304
- This action was in line with principles
  - ensured non-maleficence
- Consequences of part 2 response: better medical devices/software
  - rigorous testing cycles required

Your turn

Medical Students at a University used Google Calendar to schedule their patients, including relevant clinical information.

As a response, University Administration made the use of a secure calendaring system and email program mandatory across the university.

Look at this from the issues of patient privacy. Were patient rights violated because of these actions?

Combo Form

See link in D2L.

Ground Rules

- Work together on the assignment
- Discuss each principle and how it relates to the case
- Everyone must be heard and contribute
- Be respectful of each other's opinions and viewpoints
- Don't be afraid to ask me questions

The Ethics of Genomic Information

- How Data Brokers Make Money off your Medical Information
- Balancing Health, Research, and Patient Privacy in the Genomics Era

Burlington Northern Santa Fe Railroad

- Obtained blood samples from employees who were seeking disability compensation as a result of carpal tunnel syndrome
- Employees were not told the purpose of the tests (and therefore did not consent), which was to perform genetic testing for a mutation on Chromosome 17 that had been associated with hereditary neuropathy with liability to pressure palsies
- Workers were threatened with discharge if they did not provide the sample

What happened?

- Lewin T. Commission sues railroad to end genetic testing in work injury cases. New York Times. February 10, 2001:A7. => violation of the Americans With Disabilities Act
- Girion L. Railroad Settles Suit Over Genetic Testing. LA Times. May 9, 2002. => Workers paid between $5,900 to $75,000, depending on whether they were tested

SNPs make you identifiable

It has been estimated that only about 30-100 single nucleotide polymorphisms (SNP) are required to distinguish an individual's DNA record.

What does that mean?

Genomic Information Implications

- Need for protection of patient genomic information!
  - Opt-in for research studies: understand the risks
- Be careful with consumer genomics (23andMe)
  - Understand how your data will be used

References

- Ethical Applications in Informatics
- Models and Resources for Decision-Making
- Balancing Health, Research, and Patient Privacy in the Genomics Era
- http://ethicalsystems.org/tags/ethical-systems-design
- Therac-25