Part 5

Lecture 2 Data Ownership and Privacy

Who I am…

Pascal Tyrrell, PhD *Associate Professor*

Department of Medical Imaging, Faculty of Medicine

Institute of Medical Science, Faculty of Medicine

Department of Statistical Sciences, Faculty of Arts and Science

Overview

- □ Ethics
  - □ Accountability
  - □ Value Alignment
  - □ Explainability
- □ Fairness
- □ Data Ownership
- □ Regulatory Implications

Data Ownership

Who Owns the Data?

- ❑ Under U.S law, there is no property in mere facts

- ❑ Much of the discussion surrounding the use of medical research data is grounded in notions of individual privacy:

  - ❑ Medical data is personal and should thus be utilized only with the consent of the individual

Data Privacy

Country	Privacy Laws
Canada	•Privacy Act (public sector) •PIPEDA - Personal Information Protection and Electronic Documents Act (private sector) Every province and territory has its own laws that apply to handling of PII and PHI (e.g., Personal Information Protection Act (PIPA), Health Information Act (HIA), and Freedom of Information and Protection of Privacy Act (FIPPA) in Alberta).
Costa Rica	•Personal Data Protection Act (Law No. 8968)
European Union	•GDPR - General Data Protection Regulation
United States	•FTC Act - Federal Trade Commission Act •HIPAA - Health Insurance Portability and Accountability Act •GINA - Genetic Information Nondiscrimination Act There are many laws at the state level that regulate the collection and use of personal data, and the number grows each year (e.g., California health and medical privacy laws).

Bill C-27

An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts

Still being reviewed in the house of commons...

How will digital health companies (specifically utilizing data for AI and ML) be affected by this regulatory action?

PIPEDA: Fair Information Principles

- ❑ Accountability
- ❑ Identifying Purposes
- ❑ Consent
- ❑ Limiting Collection
- ❑ Limiting Use, Disclosure, and Retention
- ❑ Accuracy
- ❑ Safeguards
- ❑ Openness
- ❑ Individual Access
- ❑ Challenging Compliance

Privacy

- ❑ Privacy regulations currently permit data-based research to be conducted without the need for individual informed consent

- ❑ But these regulations have little impact on common law rights and duties of researchers or research participants.

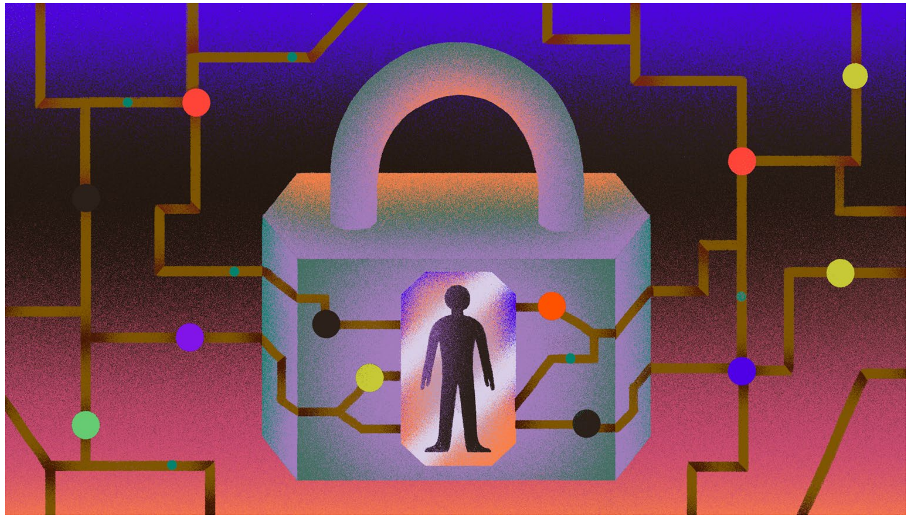
Ownership

- □ Can too much individual control over personal health information hinder socially valuable biomedical research?

The Data Use Agreement

❑ The DUA should include provisions addressing data quality, integrity, privacy, security, and patient control, must necessarily be patient-centered

❑ DUAs can also be tailored to patient preferences. For example, to contribute data for secondary uses



User Data Rights

- ❑ AI should be designed to protect user data and preserve the user’s power over access and uses

- ❑ Users should have control over interactions and the AI.

User Data Rights

❑ The European Commission found that 71% of EU citizens find it unacceptable for companies to share information about them without their permission

❑ These percentages will rise as AI is further used to either amplify our privacy or undermine it. (IBM Watson Everyday Ethics)

Patient Data has 2 Owners…

In Canada…

1) The patient themselves or the POA (Power of Attorney)
2) The Provincial Government

Is this fair? How will companies gain consent for medical information

How It's done in every other sector: **Terms and Agreements**

User Data Rights: How to Resolve This Ethical Concern

❑ Users should maintain control over what data is being used and in what context

  ❑Be able to deny access to personal data that they may find unfit for AI

❑ Users' data must be protected from theft, misuse, or data corruption

❑ Provide full disclosure on how the personal information is being used or shared

User Data Rights: How to Resolve This Ethical Concern

- ❑ Allow users to deny service or data by having the AI ask for permission before an interaction or providing the option during an interaction
  - ❑ Privacy settings and permissions should be clear

- ❑ Other companies should not be using data without permission when creating a new AI service

- ❑ Recognize and follow national and international laws and rights when using AI

Regulatory Implications and Algorithm Limitations Going Forward

Currently…

❑ Difficult to regulate because there are no universal approval guidelines currently exist

❑ AI developers do not all study medicine, they need to learn some medicine in order to create specific algorithms that suit it

❑ Lack of exposure in the clinical setting inevitably results in a degree of mistrust

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Ethics in Action!

❑ IEEE global initiative on ethics of autonomous and intelligent systems from IBM group

  ❑ Focuses on autonomous and intelligent systems ethics

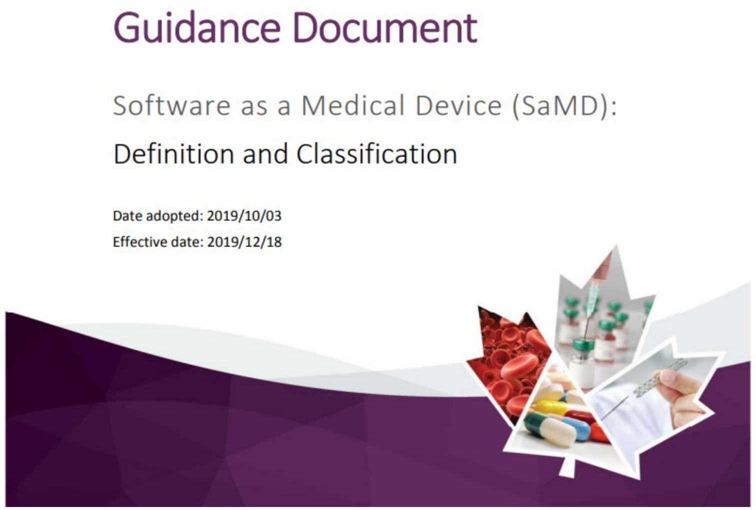
❑ The criteria and metrics for ethical AI systems will ultimately depend on the industry and use case they operate within

❑ FDA has strict acceptance criteria

  ❑ FDA has approved some assistive algorithms

SaMD – Software as a Medical Device

- ❑ Health Canada and the FDA recognize SaMD as a legitimate concern with the rise of AI
- ❑ Guidelines are derived from frameworks derived from 2019 in regard to use of software in medical diagnostics
- ❑ Similar in Health Canada…Guidance Document



Guidance Document

Software as a Medical Device (SaMD):

Definition and Classification

Date adopted: 2019/10/03

Effective date: 2019/12/18

End of Lecture 2

Next up Part 6 Lecture 1: Wrap-up!

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