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Ethical issues raised by big data and real world evidence projects

Digital Ethics Lab

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What is real world evidence and big data?

- Real world evidence is evidence that is generated from health data coming from sources besides clinical trials.
  - National registries, health care registries.
  - Electronic medical records, and data from hospitals and GPs.
  - Longitudinal cohort studies and biobanks.
  - Non-medical sources, such as social media applications, personal health monitoring technologies (e.g. home sensors, wearables)
- Real world evidence is varied and complex.
- Can be considered part of the broader big data phenomenon
  - large, rich datasets for research
  - Useful for decision-making across healthcare

What is novel about real world evidence and big data?

- Complexity
  - Different types of data
  - Different sources of data
- Size
  - Aggregation (longer)
  - Linkage (wider)

These features can create challenges for existing norms and ethical, social and legal processes.

Ethical issues

- Within ROADMAP we have reviewed was is already known about ethical issues raised by a real world evidence approach.

Key concepts

- Informed consent
  - What do people need to be told to be informed about the ways their data may be used?
  - What kind of consent is needed for the various uses of people's data?

- Autonomy and participation
  - How to engage with participants, so they can exercise meaningful choices about their participation?

Ethical issues

Key concepts

- Transparency
  - What account needs to be given of how data is collected, stored, handled and shared in order to foster trust?
- Privacy and discrimination
  - What governance policies and, what technical processes, need to be in place to protect participant's privacy and avoid discrimination?

Ethical issues

Key concepts

- Ownership
  - Who has a say in how data is used?
  - Who has a say in how benefits generated from the data are used?
- Data provenance
  - What is required to curate data in an ethically responsible way, to maintain quality and utility?

Ethical issues

- Ethical frameworks and codes of practice have been designed to help navigate these issues in a principled way.
- Many share a common set of key values
  - Protection of participants
  - Accountable governance
  - Scientific quality
  - Engagement and dialogue
- But what does this look like in practice?

Consent

Different data sources may use different types of consent

- Specific and informed consent
  - Informed consent for *specific researchers* to use data for a *specific research question*.
  - E.g. Specific research studies
- Broad consent
  - Broad consent *to allow a data access committee* to decide *which researchers* can use which data for *which research questions*.
  - E.g. Biobanking or longitudinal studies.
- Implied consent
  - Implied consent for members of *the healthcare team* to use data for *your care*.
  - E.g. Routine care.

Ethical issues raised by specific or implied consent

- A key issue is re-use
  - Is it permissible for *other researchers* to use data for a *different research question*?

- Ways to address this include
  - For new studies:
    - Dynamic consent
    - Tiered consent
  - For existing studies:
    - Anonymisation and privacy-protecting analysis techniques

Ethical issues raised by broad consent

- A key issue is governance
  - How should decisions be made about who gets to use data and for what purposes?

- Ways to address this include
  - Transparent, accountable and streamlined procedures.
  - Engagement methods that help to build and maintain trust, and ensure study's activities are aligned with participant's interests.

Responsible research and innovation

- Creating larger and richer datasets real world evidence raises ethical, social and legal issues.
- Issues need to be addressed as well as raised.
- In practice this requires innovative and flexible ways to embed these principles in the design of new systems and platforms

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