Supporting Health Data Needs for Community-Driven Change

Sharona Hoffman

Case Western Reserve University School of Law

The Common Good

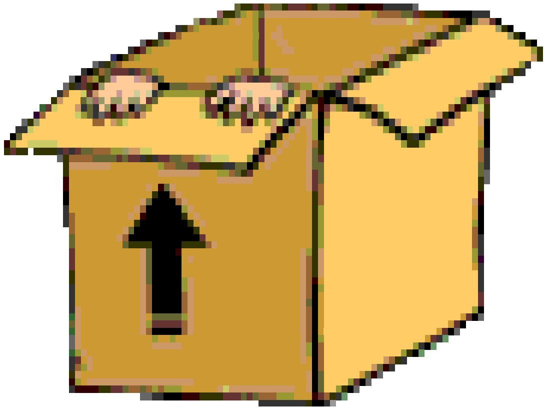
- Should be prevailing value in context of non-interventional research
- Free-rider problem: all community members benefit from research advances
- Public health precedents

Public buy-in depends on privacy protection

- Continue to improve data security
- Identity concealment techniques
- Regulatory interventions
  - HIPAA Security Rule must cover research database operators

De-identification

- Large databases of de-identified data
- HIPAA’s 18 identifiers
- Concern about re-identification
- .01-.25% risk if certain publicly available information used



Secure statistical analysis of distributed databases

- Institutions maintain control of records
- Distributed queries made through standard web service
- Trusted aggregators used to run query service
- Researchers receive summary statistics but not individually identifiable data
- FDA Sentinel health data network

Informed Consent

- Historically, primary concern is abusive experimental interventions
  - Nazi experimentation
  - Tuskegee
- Nuremberg Code, Declaration of Helsinki, Belmont Report language

Data Ownership

- Patients own health data
- Providers own medical records
- No constitutional right to control medical records
  - NASA v. Nelson, 131 S.Ct. 746 (2011)

Trouble with Consent

- Selection bias
- Cost & burden

OTHER DATA & ANALYSIS PROBLEMS THAT CAN AFFECT COMMUNITIES

Data Quality Problems

- EHR databases can be deficient:
  - Data entry errors
  - Fragmented or incomplete records
  - No interoperability
  - Coding problems
- Data collected for billing & clinical purposes, not research / public health

Making Sense Out of Data

- Selection bias
- Measurement bias
- Confounding bias
    - Causal inference problems