Ethical Use of Administrative Data for Research Purposes

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Charge for Paper

• **Focus**: An overview of the ethical considerations and issues associated with the maintenance, integration, and use of administrative data for research purposes.

• **Primary Audiences**: policy makers and administrators in public agencies

• **Length**: About 30 pages doubled spaced, excluding references.

• **Process**: Outline of proposed paper approved in Fall 2010, peer/expert review in early to mid 2011, conference in November 2011, final version by early 2012.
Approach to Paper

• Provide an overview of ethical issues associated with using administrative data for research purposes
• Readable by multiple stakeholders
  – Comprehensive, but not deep scholarly discussion
• Incorporate the concept of due diligence (how to)
• Structure of paper
  – General Introduction and Concepts
  – Ethical Considerations for Data Owners/Custodians
  – Ethical Considerations for Data Users/Researchers
• Disclosure
Context

- Rapidly increasing capacity to collect, store, integrate, and analyze data
- Shift in use of these data from primarily managing agency programs and performing audits to conducting research and informing policy; purposes are broader in scope and depart from the original intent for which these data were collected
- Ease of access to these data has often outpaced our consideration of the legal and ethical issues
Introduction

• Historical Perspective & Core Principles
  • Nuremberg Code
    • voluntary informed consent
  • Belmont Report
    • Respect for Persons
    • Beneficence
    • Justice
Introduction

• Availability of Administrative Data
  • Increased availability
  • Increased use for secondary purposes
    • Issues:
      • People whose information is in the database
      • Data owners/custodians
      • Scientific merit of secondary use
    • Challenges:
      • Poor secondary data quality
      • Statistical significance without meaningfulness
      • Multiple use of statistical tests
Introduction

• Legal Landscape Governing Access to Administrative Data
  • Freedom of Information Act (FOIA)
  • Federal Education Rights and Privacy Act (FERPA)
  • Health Insurance Portability and Accountability Act (HIPAA)
  • Other (local, state, foreign)

• Definitions of Key Concepts
  • Data Owners/Custodians
  • Data Users
  • Due Diligence
  • Ethics and Research Ethics
Considerations/Framework

• Development of Considerations
• Framework of Principles
  – Data Security
    • Training (expertise)
    • Policies (processes)
    • Technology (tools)
  – Confidentiality of Information
  – Disclosure Permissions
  – Appropriate Use
Ethical Use of Administrative Data

Data Owner/Custodian
- Recent attempts to ID best ethical practices for data protection & management from data owner perspective
  - Mason (1986)
  - AMIA (2007)
  - Stiles et al (2011)

Data User/Researcher
- Similar concerns as data owners, however some important differences in emphasis (many data users are also data owners)
- Need well developed internal and external connections to ensure data integrity/security as well as valid analyses
# Principle #1: Data Security

<table>
<thead>
<tr>
<th>Data Owner/Custodian</th>
<th>Data User/Researcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Need to secure and protect data against inappropriate disclosure</td>
<td>• Provide as good or better security than data owner</td>
</tr>
<tr>
<td>• Standards are readily available online, but balance in 3 areas are recommended:</td>
<td>• Similar considerations in areas of:</td>
</tr>
<tr>
<td>– Training (expertise)</td>
<td>– Training</td>
</tr>
<tr>
<td>– Policies (processes)</td>
<td>– Policies and processes</td>
</tr>
<tr>
<td>– Technology (tools)</td>
<td>– Technological security</td>
</tr>
<tr>
<td>• Need to be careful not to lose vigilance with security concerns</td>
<td>• Need to be careful not to lose vigilance with security concerns</td>
</tr>
</tbody>
</table>
Principle #2: Confidentiality

**Data Owner/Custodian**
- Conceptual foundations
  - Trust
  - Autonomy and privacy
- Need to clarify processes for deidentification, encryption, etc
- Federal law (e.g., HIPAA)
- Integrating data and creating new information
  - Reidentification

**Data User/Researcher**
- Document and follow confidentiality processes (e.g., encryption, auto-logouts, deidentification)
- Federal laws
- Special considerations when combining data sets
Principle #3: Disclosure Permissions

**Data Owner/Custodian**
- Need to secure permissions to provide and allow use of data at 2 levels:
  - Institutional
  - Individual
- Document in agreement:
  - that data were obtained and provided appropriately
  - that adequate permission was secured to use data for the intended research purposes

**Data User/Researcher**
- Provide formal and detailed data request
- Data agreement should clarify terms of data possession and use
- Third party requests for the data should be referred back to data owner
Principle #4: Appropriate Use

**Data Owner/Custodian**
- Confirm capacity of data requestor to store/use data
- Be available to provide intelligence about data and interpretation
- Monitor (ask for updates about use) to ensure appropriate use of data

**Data User/Researcher**
- Critical yet often overlooked area of consideration
- Researcher should ensure:
  - He/she has adequate capacity to use the data
  - That data received are valid and useful for research
  - That the research team has adequate understanding of the data
Conclusions

• Data owners and users have a overarching responsibility for ensuring due diligence.

• We offer this four principle framework for assessing ethical responsibilities of data custodians and the researchers who use these data.
Questions

• Is the level of detail in the paper appropriate for policy makers and administrators in public agencies?

• Are there ethical issues included in the paper that should be removed or any issues that should be added?

• How can we improve the structure and/or format of the paper?