Data Sharing to Advance Global Public Health: Ethical Challenges and a Principled Way Forward

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Consider

- Data from cancer and human studies are least likely to be shared
- Researchers with the most experience in the field are less likely to share data
- Data sharing in well-funded studies remains low despite explicit requirements from funders

“data is least available in areas where it could make the biggest impact”

(Piwowar, PLoS One 2011)
Case: Polio

- Researchers have limited access to polio specific data needed for modeling transmission risk and new eradication strategies (e.g. AFP, immunization status, LQAs, genetic sequence data)
- WHO is reluctant to share country data
- MOUs must be negotiated with each country → laborious, time-intensive, not always successful
- 800 hrs to access and construct datasets on where and when polio campaigns took place: a duplication of efforts!
Data sharing

• making data available to others for use in research or other analytic activities

• involves the transfer of data between two or more parties or distribution into the public domain

• can take several forms, e.g. sharing raw data, metadata, models

• also referred to as ‘data access’
Data sharing is not new

• The Royal Society, 1660

• Open Access movement began in 1960s, gained prominence in 1990s

• The Bermuda Principles, 1996

• Common in some research domains, e.g. genomic and geophysical sciences

• Funders of health research have data sharing policies: CIHR (2007, revised 2013); Genome Canada (2005, revised 2008); NIH (2003); Wellcome Trust (2007, revised 2010); Bill & Melinda Gates Foundation (2011)
Data sharing is widely promoted

Meeting the Demand for Results and Accountability: A Call for Action on Health Data from Eight Global Health Agencies

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Sharing research data to improve public health: full joint statement by funders of health research
Data sharing remains a challenge for global health

• Limited culture of data sharing in public health

• Ethical and practical barriers along the data management lifecycle
  
  collection ▶ access ▶ use ▶ disclosure ▶ retention ▶ disposal

• Reconciling different socio-cultural norms, e.g. DNA as embodied knowledge; Maori and Amerindians view body and soul as an integrated whole

• Data sovereignty: data ownership tied to cultural identity → exportation restrictions, e.g. India, Malawi, Mexico

• Insufficient guidance in international ethical codes to address issues relating to data sharing
Ethical challenges

- individuals / communities
- informed consent
- privacy / confidentiality
- risks vs benefits
- investigators / organizations / countries
- loss of ownership / control
- inequity; exploitation
- reciprocity
- disclosure risks
- trust
- benefit-sharing
- investigators / organizations / countries
- stewardship
- disclosure risks
- justice
- distrust / mistrust
- benefit-sharing
- loss of ownership / control

LMICs

HICs

asymmetrical collaborations

Ethical Issues
Case: Polio

• **Data ownership**: WHO will not share data from member states without express consent

• **Loss of control / distrust**: concerns about misuse and misrepresentation of data, e.g. GEO data, sub-national boundaries

• **Disclosure risks**: potentially damaging or stigmatizing facts revealed, e.g. poor immunization record; impact on trade and tourism resulting in economic harm, legal liability

• **Inequity / Exploitation**: researchers will benefit from publication and career advancement, while data producers receive no benefit; lack of infrastructure and capacity in endemic countries permits exploitation
Needed: a principled approach

Principles

• express common values and capture the goals that underlie motivation for data sharing
• emphasize moral duty and common purpose
• provide a common framework for policy development
• ‘anchor the actionables’: principles remain consistent though conventions differ
• Adjudicate between competing ethical requirements
Case: Global Health Data Access Principles of the Gates Foundation

Global Health Data Access Principles

- Promotion of the Common Good
- Reciprocity
- Respect
- Accountability
- Proportionality
- Stewardship
Why these principles?

- Elaborate values of global health, paying special attention to the goal of reducing inequities
- Are responsive to the ethical challenges
- Interoperability: capture the norms articulated by data sharing policies of other major health funders
Development of the principles

- Comprehensive literature review, with a view to identifying trends, challenges, and best practices in data sharing
- Review and analysis of data sharing policies, statements and guidelines from developed and developing countries, selecting from a broad range of agencies, funders and disciplines (n=26)
- Distillation of principles, followed by an internal and external expert review
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<thead>
<tr>
<th>Document</th>
<th>Country / Region</th>
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<tbody>
<tr>
<td>1. BIOTA AFRICA Data Sharing Policy</td>
<td>Africa</td>
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<tr>
<td>2. NSS Practice Guide to Sharing Your Data With Others</td>
<td>Australia</td>
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<tr>
<td>3. LBA Data Sharing and Publication Policy</td>
<td>Brazil</td>
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<td>4. Universities Service Centre of China Studies DCS Data Sharing Policy</td>
<td>China</td>
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<td>5. CARTaGENE Samples and Data Access Policy</td>
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<td>6. CIHR Access to Research Outputs Policy</td>
<td>Canada</td>
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<td>7. Genome Canada Data Release and Resource Sharing Policy</td>
<td>Canada</td>
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<td>8. Guidelines of the National DNA Bank</td>
<td>Gambia</td>
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<tr>
<td>9. Ethical Guidelines for Social Science Research in Health</td>
<td>India</td>
</tr>
<tr>
<td>10. Data Sharing Policy of Nairobi Convention Clearinghouse and Information Sharing System</td>
<td>Kenya</td>
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<td>11. Kenya National Spatial Data Infrastructure Policy</td>
<td>Kenya</td>
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<tr>
<td>12. CODATA Principles for Dissemination of Scientific Data</td>
<td>International</td>
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<td>13. HUGO Ethics Committee Statement on Human Genomic Databases</td>
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<td>14. OECD Principles and Guidelines for Access to Research Data from Public Funding</td>
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<td>15. P3G Charter of Fundamental Principles</td>
<td>International</td>
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<td>17. BBSRC Data Sharing Policy</td>
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<td>18. MalariaGEN Data Release Policy</td>
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<td>19. MRC Funded Research Data Policy</td>
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<td>20. Wellcome Trust Data Management and Sharing Policy</td>
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<tr>
<td>21. American College of Epidemiology Policy Statement on Sharing Data from Epidemiological Studies</td>
<td>USA</td>
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<tr>
<td>22. Gordon and Betty Moore Foundation Data Sharing Philosophy and Plan</td>
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<td>23. ICPSR Access Policy Framework</td>
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<td>24. NIH Data Sharing Policy</td>
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<td>25. NIH Policy for Genome Wide Association Studies</td>
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<tr>
<td>26. NSF Dissemination and Sharing of Research Results</td>
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The Principles

• Not hierarchical

• Logically and internally consistent
  → each principle is compatible with the others, and failure to satisfy one principle impacts the others

• Pay special attention to promoting equity and fair-benefit sharing
# Promotion of the Common Good

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<th>Statement</th>
<th>Rationale</th>
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| Promotion of the Common Good     | Data will be shared as broadly and as promptly as possible to optimize prospects for the translation of findings into life-saving solutions. Data access should enhance the value of research and program effectiveness. | • The ‘all-encompassing’, over-arching principle  
• Appeals to our common humanity: the ‘common good’ (not the ‘public good’ or the ‘global good’) represents the fundamental good that is common for all human beings: to be alive and healthy. |
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| Respect  | Respect must be given to matters of identity, privacy, and confidentiality as they pertain to the individuals and communities from or about whom data are collected. Respect must also be given to matters of attribution as they pertain to researchers, evaluators, and their collaborators. | • Respect is fundamental to interactions between all stakeholders  
• Respect between researchers and collaborators is highlighted, since this is a critical aspect of data sharing that is often overlooked owing to the tendency to focus solely on respect for research subjects. |
## Accountability

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<td>All processes and procedures for data access will be transparent, clear, and consistent with data management standards that ensure quality data, appropriate security, and equitable access.</td>
<td>- Captures both senses of accountability that are important for data sharing: 1) one is accountable for making data accessible, and 2) one is accountable for the processes that make data accessible, e.g., quality, security</td>
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## Stewardship

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| Stewardship | All who produce, share, and use data are stewards of those data. They share responsibility for ensuring that data are collected, accessed, and used in appropriate ways, consistent with applicable laws, regulations, and international standards of ethical research conduct. | • Replaces the idea of ‘ownership’ which can lead to conflict and disputes in data sharing  
• Captures the notion of responsibility commonly articulated in data sharing policies of other major health research funders, e.g. NIH, Wellcome Trust  
• Recognizes the ‘data trail’ and the continuing responsibility that is passed on from one steward to another  
• Makes explicit that ethical data sharing begins with legitimate acquisition of data |
## Reciprocity

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| Reciprocity | The aim of benefiting the individuals and communities who enable and support inquiry should be furthered to the extent possible and is of particular importance when involving individuals and communities from developing countries. | • Recognizes the need ‘to give something back’ to those that make R&D possible, mitigates the risk of exploitation  
• Acknowledges the asymmetry in researcher-participant relationships, and North-South relationships  
• An important principle to attend to in collaborations involving developing countries by recognizing the unacceptability of research practices that yield nothing of benefit to source communities |
Lessons from the pilot year

• Principles were formally adopted in June 2011

• An audit of 40 Data Access Plans (DAPs) was conducted to evaluate application of the principles. Results showed:
  • Researchers were largely supportive of data sharing, but were ill-equipped to see it through → faced with ‘conceptual’, political, and structural challenges
  • Researchers needed additional guidance to operationalize principles in their data sharing practices
  • Principles had the most traction in data sharing agreements involving organizations that collect public health data
Lingering questions

• Is there an ethical obligation to share data in the interest of public health?

• Should there be a standardized approach to international data sharing for public health?
Summary

• Ethical issues present barriers to sharing public health data
• Issues of inequity and exploitation are of particular concern in data sharing arrangements involving LMICs and HICs
• Principles that are responsive to the ethical issues can serve as a starting point for policy development to facilitate data sharing
Wisdom alone is true ambition’s aim, wisdom is the source of virtue and of fame; obtained with labour, for mankind employed, and then, when most you share it, best enjoyed.

- A.N. Whitehead
Thank you!

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