Participants' perspectives and the evolution of genomic data sharing policies

Mary Majumder, JD, PhD
Overview

1. Setting the stage
2. Findings from research
3. Implications?
Overview

Public

Patients

Serious, options-limited condition

Research participants
While the majority often expressed support for broad consent when that was the only choice offered, only a minority of respondents favored broad consent when other options, such as tiered or study-by-study consent, were offered... Willingness to give broad consent increased if data were de-identified. While individuals were generally willing for data or biospecimens to be shared with other academic researchers, individuals were less willing for their data to be shared in federal databases or with commercial enterprises.

Nonetheless, questions remain about the ethical and practical desirability and acceptability of broad consent for research and data sharing. Approaches to obtain permission for use of genomic samples and data include no consent, opt-out, opt-in, case-by-case, tiered or categorical, and broad or blanket consent. Many have argued that blanket consent for unanticipated future research uses is unethical or unworkable, whereas others argue that such consent is acceptable as long as additional protections are in place, especially since broad data sharing...
BACKGROUND
Sharing of participant-level clinical trial data has potential benefits, but concerns about potential harms to research participants have led some pharmaceutical sponsors and investigators to urge caution. Little is known about clinical trial participants' perceptions of the risks of data sharing.

METHODS
We conducted a structured survey of 771 current and recent participants from a diverse sample of clinical trials at three academic medical centers in the United States. Surveys were distributed by mail (350 completed surveys) and in clinic waiting rooms (421 completed surveys) (overall response rate, 79%).

RESULTS
Less than 8% of respondents felt that the potential negative consequences of data sharing outweighed the benefits. A total of 93% were very or somewhat likely to allow their own data to be shared with university scientists, and 82% were very or somewhat likely to share with scientists in for-profit companies. Willingness to share data did not vary appreciably with the purpose for which the data would be used, with the exception that fewer participants were willing to share their data for use in litigation. The respondents' greatest concerns were that data sharing might make others less willing to enroll in clinical trials (37% very or somewhat concerned), that data would be used for marketing purposes (34%), or that data could be stolen (30%). Less concern was expressed about discrimination (22%) and exploitation of data for profit (20%).

CONCLUSIONS
In our study, few clinical trial participants had strong concerns about the risks of data sharing. Provided that adequate security safeguards were in place, most participants were willing to share their data for a wide range of uses. (Funded by the Greenwall Foundation.)

ABSTRACT
Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing
Michelle M. Mello, J.D., Ph.D., Van Lieou, B.S., and Steven N. Goodman, M.D., Ph.D.
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Your DNA, Your Say

Global Public Perceptions of Genomic Data Sharing: What Shapes the Willingness to Donate DNA and Health Data?

Anna Middleton,1,2,a Richard Milne,1,3,a Mohamed A. Almarri,3 Shamim Anwer,6 Jerome Auitornu,1 Elena E. Baranova,9 Paul Bevan,7 María Cerero,7 Yali Cong,6 Christine Critchley,5,10 Josipine Fernow,11 Peter Goodhand,12 Quarratulain Hasan,13,14 Aiko Hibino,15 Gry Houeland,16 Heidi C. Howard,11,16 S. Zakir Hussain,14 Charlotta Ingvarsdottir Malmgren,16,17 Vera L. Izhevskaya,18 Aleksandra Jedrzejak,19 Cao Jiuhong,20 Moeumi Kimura,21 Erik Kleiderman,22 Branki Leach,23 Keving Liu,22,b

Percentage willing to donate

Country

Recipient Doctors Non-profit For-profit

\[ \text{Percentage willing to donate} \]

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vennity, Aarhus 53206, Germany; 16Italian University Murers School of Law, Buntington, IN 47405, USA; 17Work Research Institute (WRI), Oslo Metropolis University, Oslo 0130, Norway; 18Institute of Psychiatry, Psychology & Neuroscience, King’s College London, London SE5 8AF, UK; 19Centre for Epidemiology and Biostatistics, Melbourne School of Global and Population Health, The University of Melbourne, Melbourne, VIC 3010, Australia; 20Medical Ethics, Lund University, Lund SE-221 00, Sweden

Correspondence: anna@smc在当地区名.com

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Table 2

**Deliberant Hopes and Concerns**

<table>
<thead>
<tr>
<th>Hopes</th>
<th>Concerns</th>
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<tbody>
<tr>
<td>Benefit future generations</td>
<td>Breaches of data security and inability to protect individuals’ privacy</td>
</tr>
<tr>
<td>Lead to ground-breaking medical advances (e.g. cure for cancer)</td>
<td>Accuracy and completeness of EHR data</td>
</tr>
<tr>
<td>Represent the public’s interests</td>
<td>Breaches of data security and inability to protect individuals’ privacy</td>
</tr>
<tr>
<td>Offer direct benefits/incentives to deliberants when possible</td>
<td>People would be charmed into donating their information</td>
</tr>
</tbody>
</table>

1. No involvement
2. Feedback through surveys
3. Community advisory board
4. Participants on governing board
5. Participant-run with experts hired when needed
Implications?

**Concerns/Consent**
- Data hoarding violates the expectations and wishes of many participants.
- Most participants prefer to be given choices, have reservations about sharing with for-profits, government.
- But in practice, most willing to consent to broad data sharing.
- Not accommodating all consent preferences ≠ violating rights.

**Context**
- Steps can be taken to increase comfort/trust, demonstrate respect, and establish trustworthiness (e.g., return of value, care re access rules and other aspects of governance, vigilance re privacy and security).
- Especially important if aiming for more representative data resources.

**Cautions**
- Groups with cause for concern, sensitive research: special measures to involve and protect participants warranted.