Data Sharing and Embedded Research Guiding Principles

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Why?

- Public health
- Maximizing investment
- Accelerate learning
- Foster collaboration (pay it forward)

Ultimately...transparency, reproducibility, secondary use of medical research, are good for society
Recently .....
A Revival: Gathering of Data Sharing Evangelists
## Carrots & Sticks: Author Incentives

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Authors</th>
<th>Manuscript DOIs</th>
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<tbody>
<tr>
<td>1</td>
<td>Primary authors generate data set and designate “data authors,” DOI is assigned, and primary publication occurs</td>
<td>3</td>
<td>1 Manuscript DOI: MS 1 DOI</td>
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<td>2</td>
<td>Secondary analysis by members of primary group</td>
<td>2</td>
<td>2 Authors (A, C) 1 New Manuscript DOI: MS 2 DOI</td>
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<td>3</td>
<td>Secondary analysis with collaborator</td>
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<td>4</td>
<td>Secondary analysis by independent investigator</td>
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<td>1 Author (E) 1 New Manuscript DOI: MS 4 DOI</td>
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<td>5</td>
<td>Combination of data set with other data for new analysis by independent investigator</td>
<td>1</td>
<td>1 Author (F) 3 Data authors: Data set 1 DOI (A, B) Data set 2 DOI (F)</td>
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[be bierer et al. n engl j med 2017; 1684-1687]
Carrots & Sticks: Industry Data Sharing

Study sponsors

This section of the site provides information on study sponsor's criteria for listing studies and other relevant sponsor specific information.

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Contentious issues: data sharing...and comparisons
Ethical Considerations

• The ethical responsibility to share data generated by publicly funded research must be balanced against the need to protect patient privacy and scientific integrity.
Principles

• Patient privacy: Essential obligation
Principles

• Patient privacy: Essential obligation
• Health system privacy: Sometimes necessary
The Balance of Benefits & Risks
Collaboratory Trials Policy

• Data sets will be structured to maximize future scientific value while protecting patient and health system privacy.
• Data should not include any of the 18 HIPAA-specified direct identifiers.
• Investigators may make more detailed data available through a more “restrictive” data sharing option.
Structures and tools (from least to most restrictive)

- Public archive – send data to any user
- Private archive – send data to approved users
  - For any purpose
  - For approved purposes only (e.g. governed by DUA)
- Public enclave – any user may send questions to data
- Private enclave – some users may send questions to data
  - Automatically executed
  - Moderated (either queries or results)
Summary

- Data sharing is a societal good
- Like healthcare, health systems are complex
- Collaboratory should lead the way
Thank You