Ethics & current guidelines on data sharing …and a research agenda

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Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk. In January, 2016, we published a proposal aimed at helping to create an environment in which the sharing of de-identified individual participant data becomes the norm.[1] In response to our request for feedback we received many comments from individuals and groups. Some applauded the proposals, while others expressed disappointment they did not more quickly create a commitment to data sharing. Many raised valid concerns regarding the feasibility of the proposed requirements, the necessary resources, the real or perceived risks to trial participants, and the need to protect the interests of patients and researchers.

It is encouraging that data sharing is already occurring in some settings. Over the past year, however, we have learned that the challenges are substantial and the requisite mechanisms are not in place to mandate universal data sharing at this time. Although many issues must be addressed for data sharing to become the norm, we remain committed to this goal.

Therefore, the ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

1 As of July 1, 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.
2 Clinical trials that begin enrolling participants on or after Jan 1, 2019, must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained on the ICMJE website.

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For **ICMJE's website** see www.icmje.org

For **ICMJE's policy regarding trial registration** see www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Should individual level health-research data be shared widely?

What do you think?

Why and why not?

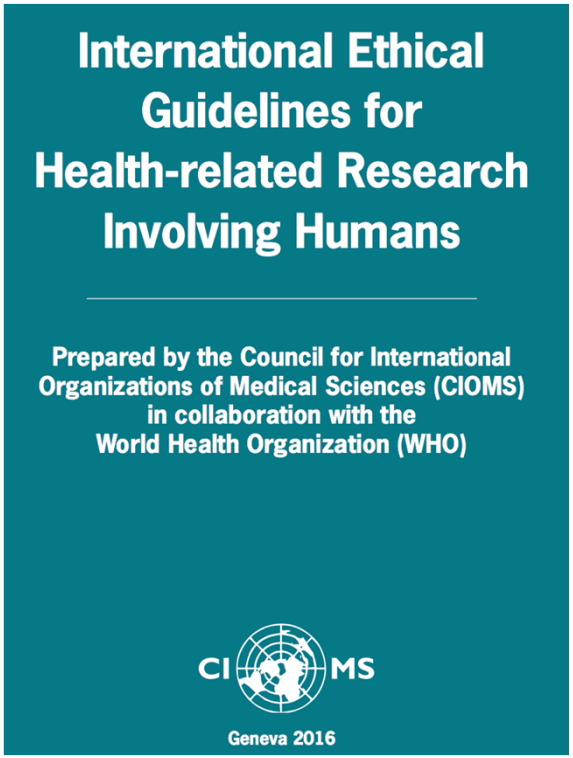
- Transparency & openness
- Reanalysis –confirm results
- New analysis, new findings
- Bigger more powerful datasets
- Different statistical methods
- Cost effective
- For teaching
- Improve science
- Improve health

- Confidentiality
- Group harms
- Data quality
- Data curation & management is expensive
- "Rogue analysis", cherry picking
- Misuse?
- Exacerbates inequality
- Primary researchers
- Data ownership issues
- Authorship? Data author?
- Consent issues – specific, broad?

Bull, Cheah et al. J Empir Res Hum Res Ethics 2015;
Cheah, Tangseefa et al. J Empir Res Hum Res Ethics 2015 etc

Broad consent

- When data are collected and stored for research purposes, either specific informed consent for a particular use or broad informed consent for unspecified future use must be obtained from the person from whom the data were originally obtained.
- ***Is broad consent "informed consent"?***



CIOMS 2016, Guideline 12 - Data Sharing

Broad consent

Informed consent = information, understanding, voluntary

<u>Proponents</u>
Broad consent *IS* informed consent. Allowing others to decide, a consent to governance (Sheehan, 2011; CIOMS 2016)

<u>Opponents</u>
Broad consent is *NOT* informed consent – “unspecified future use” does not fulfill the ”information” criteria for informed consent

Our experience

- Data sharing policy and Data Access Committee since 2016
- I am the DAC coordinator
- 17 applications

http://www.tropmedres.ac/data-sharing

Data access committee – reviews

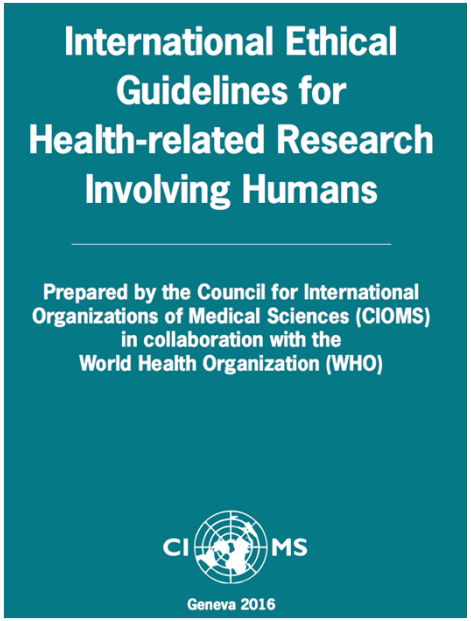
- Who is applying?
- What will the data be used for?
- How would the primary investigators be credited?
- Any potential for group harms
- Any potential for breach of confidentiality
- Data access agreement

REAL practical & ethical challenges

- Resource implications
  - Data management
  - Protocol, information sheet, consent form
  - Data access committee
  - Contracts team
  - Track what happens to data?
- Consent
  - No prior consent

Cheah & Day. Lancet 2017
Cheah, Day et al. Asian Bioethics Review 2017

- Applicants
  - All from high income settings
  - Pharma



- Data access committee
  - CIOMS 2016 suggests that governance structures should have “representation of the original setting”

I have many research questions

- Is data sharing *really* beneficial?
- Could data sharing *really* be harmful?
- What do you need to set up infrastructure for data sharing?
- How much does it cost?
- What are the training needs?
- How to incentivise data sharing?
- How to appropriately get consent for data sharing?

How do we plan to it?

- Track datasets & impact, benefits or harms – publication, policy changes, improvement in health?
- Track costs & resources needed
- Track – who applies for data, what were the objectives, who got approval, who didn't and why? What were the DAC worried about?
- Gap analysis – where we want to be vs where we are now
- Interviews with researchers and data requesters who have shared/requested for data
- Large quantitative survey

We are hiring!

THANK YOU

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