

# Imposing Risk: Ethical Challenges in Data Sharing

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# Outline

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- 2. What is a 'risk imposition'?
- 3. Case: whole genome sequencing for TB surveillance and drug sensitivity testing
- 4. Conclusions

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

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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 deidentified individual participant data becomes the norm. In response to our request for feedback we received many comments from individuals and groups.<sup>1</sup> 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, ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

- i) 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.
- ii) Clinical trials that begin enrolling participants on or after January 1, 2019 must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained at [www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html). If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (e.g. study protocol, statistical analysis plan, etc.); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses and by what mechanism). Illustrative examples of data sharing statements that would meet these requirements are in the Table 1.

These initial requirements do not yet mandate data sharing, but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions. These minimum requirements are intended to move the research enterprise closer to fulfilling our ethical obligation to participants. Some ICMJE member journals already maintain, or may choose to adopt, more stringent requirements for data sharing.

Sharing clinical trial data is one step in the process articulated by the World Health Organization (WHO) and other professional organizations as best practice for clinical trials: universal prospective registration; public disclosure of results from all clinical trials (including through journal publication); and data sharing. Although universal compliance with the requirement to prospectively register clinical trials has not yet been achieved and requires continued emphasis, we must work towards fulfilling the other steps of best practice as well—including data sharing.

As we move forward into this new norm where data are shared, greater understanding and collaboration among funders, ethics committees, journals, trialists, data analysts, participants, and others will be required. We are currently working with members of the research community to facilitate

<sup>a</sup> *Annals of Internal Medicine*, American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106, United States of America (USA).

<sup>b</sup> World Association of Medical Editors, All India Institute of Medical Sciences, New Delhi, India.

<sup>c</sup> *Ugeskrift for Læger (Danish Medical Journal)*, Hvidovre, Denmark.

<sup>d</sup> PLOS Medicine, San Francisco, USA.

<sup>e</sup> *The Lancet*, London, England.

<sup>f</sup> *Journal of Korean Medical Science*, Seoul, Republic of Korea.

<sup>g</sup> *Ethiopian Journal of Health Sciences*, Jimma, Ethiopia.

<sup>h</sup> *Bulletin of the World Health Organization*, Geneva, Switzerland.

<sup>i</sup> *The British Medical Journal*, London, England.

<sup>j</sup> *New Zealand Medical Journal*, Wellington, New Zealand.

<sup>k</sup> *Revista Médica de Chile (Medical Journal of Chile)*, Santiago, Chile.

<sup>l</sup> *New England Journal of Medicine*, Boston, USA.

<sup>m</sup> *Journal of the American Medical Association*, Chicago, USA.

<sup>n</sup> *Deutsches Ärzteblatt (German Medical Journal)*, Cologne, Germany.

<sup>o</sup> Library Operations, National Library of Medicine, Bethesda, USA.

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ed a total of 107 public draft GDS Policy. submitted by organizations, and entities academic institutions, scientific societies, advocacy groups, unions, industry and organizations, tribal and public health organizations, tribal and public health organizations have been posted on the GDS Web site.<sup>10</sup> Comments on the principles of advance research. There are a number of concerns and calls for more specific aspects of a summary of the Policy, is provided

### ability

commenters stated that the Policy is unclear with regard to the technology to which the Policy applies. Some commenters expressed concern that the Policy might not apply to array-based or high-throughput technologies) and focus on determining the scope of the Policy. They

Allergy and Infectious Diseases Data Sharing and Release Guidelines<sup>12</sup>) or program requirements. In addition, definitions of key terms used in the Policy (e.g., aggregate data) have been included and other terms have been clarified.

The statement of scope remains intentionally general enough to accommodate the evolving nature of genomic technologies and the broad range of research that generates genomic data. It also allows for the possibility that individual NIH Institutes or Centers (IC) may choose on a case-by-case basis to apply the Policy to projects generating data on a smaller scale depending on the state of the science, the needs of the research community, and the programmatic priorities of the IC. The Policy applies to research funded in part or in total by the NIH if the NIH funding supports the generation of the genomic data. Investigators with questions about whether the Policy applies to their current or proposed research should consult the relevant Program Official or Program Officer or the IC's Genomic Program Administrator (GPA). Names and contact information for GPAs are available through the NIH GDS Web site.<sup>13</sup>

clearly defined protocols, and should in any event be made available for use on the least restrictive basis possible.

# Preamble

Where we've been:

- Data sharing key to modern scientific research & clinical trials research
- Key issues to consider
  - Privacy and confidentiality
  - Security of data
  - Location of cloud
  - Academic pressures to publish
  - HIC profiting from LMIC
  - Stewardship & governance
- Principles to adopt and apply
  - Trust
  - Transparency
  - Self-determination & autonomy
  - Patient or community consent
  - Access (e.g., to medical products)
  - Obligations to future generations
  - Data as a public good

# Preamble

Where we're going

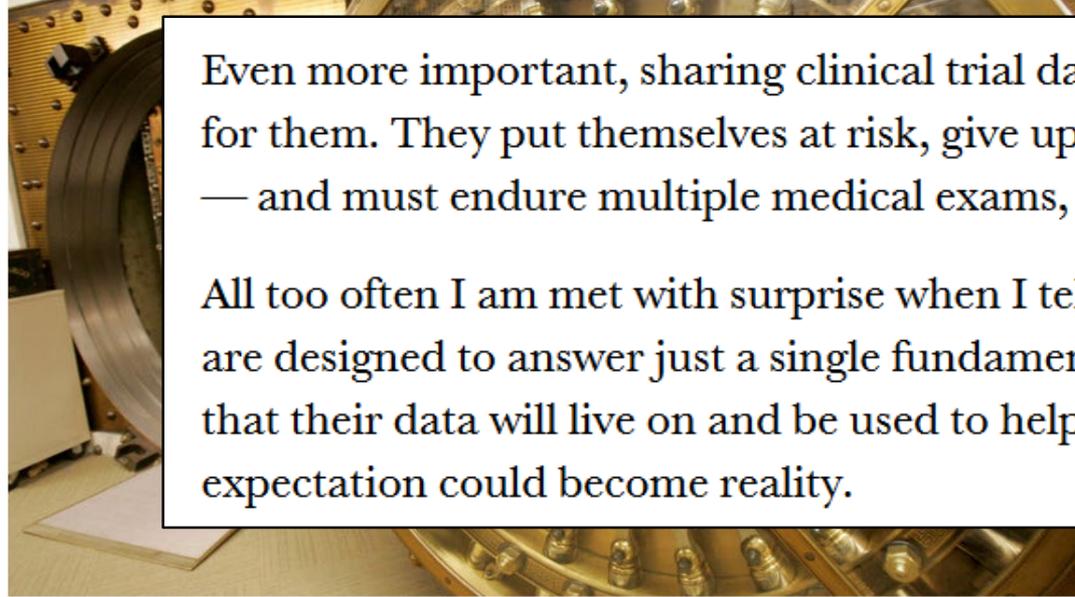
- How do we account for data gathered via machine learning?
- What 'data' are we sharing in 2019 and onward?
- Is anonymity possible in 2019? If so, what does it look like?
- How can one's data be used malevolently?
  - What responsibility do we have to prevent this?

# The ethics of risk

## FIRST OPINION

## Move clinical trial data sharing from an option to an imperative

By REBECCA LI / FEBRUARY 19, 2019



JEFF CHIU/AP

Even more important, sharing clinical trial data honors the people who volunteer for them. They put themselves at risk, give up precious time — sometimes years — and must endure multiple medical exams, blood draws, scans, and more.

All too often I am met with surprise when I tell patient groups that clinical trials are designed to answer just a single fundamental question. They rightfully expect that their data will live on and be used to help solve future problems. Now this expectation could become reality.

Data from clinical trials have long been locked away, some in this principal investigator's computer bank, some in that pharmaceutical company's cloud. For years we have been talking about opening up those vaults and freeing these data. The key has finally turned: Data sharing is becoming the new reality.

From Jan. 1, 2019, onward, the world's leading medical journals, including [the New England Journal of Medicine](#), [the Lancet](#), [Annals of Internal Medicine](#), [BMJ](#), and [thousands more](#) require authors to disclose whether and how they plan to [share deidentified raw data](#) from individual participants in their clinical trials.

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### FDA Statement

## Statement by FDA Commissioner Scott Gottlieb, M.D., on new strategies to modernize clinical trials to advance precision medicine, patient

But these opportunities can be delayed or [stymied](#) by a clinical research enterprise that is often extraordinarily complex and expensive. Efforts to streamline medical product development based on advancing science can be frustrated by legacy business models that discourage collaboration and data sharing, and the adoption of disruptive technologies that make clinical research more effective. Without a more agile clinical research enterprise capable of testing more therapies or combinations of therapies against an expanding array of targets more efficiently and at lower total cost, important therapeutic opportunities may be delayed or discarded because we can't afford to run trials needed to validate them.

the agency can make a positive approval decision, patients can gain earlier access to important new therapeutic options. To take advantage of these innovations, the agency is also seeking new ways to modernize its approaches to accommodate these novel opportunities.

The FDA isn't alone. The advent of precision medicine is challenging the entire medical research ecosystem to develop more efficient approaches to testing and developing diagnostics and therapeutics, to harness the full potential of science to reduce the suffering, death, and disability caused by complex human illnesses. The agency is committed to developing a regulatory framework for precision medicine that generates robust evidence of product safety and efficacy as efficiently as possible, including frameworks that are more carefully suited to the kinds of precision technologies that underpin new treatments.

But these opportunities can be delayed or [stymied](#) by a clinical research

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# Risk

What are the risks associated **with sharing** clinical data for the development of drugs and therapeutics?

What are the risks associated **with not sharing** clinical data for the development of drugs and therapeutics?

# 1. What is 'risk' to a bioethicist?

- Interested in arresting future harms, not compensating for past harms
  - Tort law, e.g., *Palsgraf v. Long Island R. Co.*, 248 N.Y. 339, 162 N.E. 99 (1928)
- Risk of *harm* (or hazard)
  - Physicalist
  - Non-physicalist
- Risk of harm = (the good of  $x$  – the bad of  $x$ ) + probability of  $x$  occurring (See: Joel Feinberg)
  - Consider:
    - Throwing a large rock off a highway overpass
    - Dying from a firearm
    - Dying from motor vehicle accidents

# 1. What is 'risk' to a bioethicist?

- Risk-benefit ratio or analysis
  - Maximize benefits, minimize risks
  - Impartial as to the distribution of benefits and risks
- Objections
  - Determining value of the benefit  $x$
  - Who bears the brunt of the risk?
  - Who's imposing the risk?

## 2. What is a ‘risk imposition’?

“In addition to the concept of hazard and risk we need , in at least some cases, to take a third element into account: the risk imposer, or the process by which the risk is created.”

“Blame attaches itself not to the hazard or the probability but to the cause of the hazard. Hence, it appears, the cause of the hazard must appear as an independent variable if we are to model public concerns about risk. Cause concerns how a hazard is created or sustained, and in consequence whether it can be viewed as a matter of culpable human action or inaction, especially the culpable action of those supposed to have a special responsibility.”

Jonathan Wolff (2006)

## 2. What is 'risk imposition'?

- Impossible not to place other in position of risk
- One ought to consider who's imposing risk onto whom and how
- Red flag: the same persons or groups of people at risk for the sake of others
- Red flag: the benefits of a risky activity are not equally distributed
- Red flag: certain risky options seem 'irresistible' only to some persons or group of people

## 2. What is 'risk imposition'?

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### Dust, TB and HIV: the ugly face of mining in South Africa

The Wellcome Trust and Gates Foundation fund health centres in the country, but remain invested in fossil fuel companies whose mining operations, it is claimed, have a profound impact on the health of local communities



Zululand Anthracite Colliery is owned by Rio Tinto, a mining company invested in by the Gates Foundation and the Wellcome Trust. Photographs: Khaya Ngwenya/Demotix/for the Guardian

David Smith in Mtubatuba and Damian Carrington in London

Tuesday 26 May 2015 15:00 AEST

**W**orried that his eyes and urine were turning a deep yellow, Gednezar Dladla made his way to a local clinic and was referred to a district hospital, where he was x-rayed, diagnosed with gallstones, and admitted for the night. Both institutions receive funding from the Wellcome Trust and the Bill & Melinda Gates Foundation.

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## 2. What is 'risk imposition'?

“Each side takes the position of the man who was arrested for swinging his arms and hitting another in the nose, and asked the judge if he did not have a right to swing his arms in a free country. ‘Your right to swing your arms ends just where the other man’s nose begins.’” Zechariah Chafee, Jr.

- Your freedom and autonomy must coexist with the freedom and autonomy of others.
- Reciprocal notion of freedom, reciprocal notion of risk

# Risk

What are the risks associated **with sharing** clinical data for the development of drugs and therapeutics?

What are the risks associated **with not sharing** clinical data for the development of drugs and therapeutics?

## 2. What is 'risk imposition'?

Risk imposition, data sharing, and clinical drug trials

- Would you be willing to participate in data sharing in clinical drug trials?
- Who are the persons or populations we're asking to entrust us with their data?
- Have we meaningfully engaged with local communities whose data we want to share?
- How can we ensure that the data we're using from others was obtained in an ethical manner?
- For those directing academic institutions, are you removing barriers to data sharing (lessening professional risk for faculty)?
- Are we reciprocating the professional respect we would want with colleagues in LMICs?
- Other questions I'm sure I'm missing?

## 2. What is 'risk imposition'?

To what extent are current business models for development of drugs and diagnostics antithetical to discussions of ethics, risk, and data sharing?

What are the risks associated with the *status quo* of not sharing (or hesitatingly sharing) clinical trials data?

# 3. Case: whole genome sequencing for TB surveillance and drug sensitivity testing

TB - airborne pathogen

- ~ 10mil infected in 2017
- ~ 2mil deaths
- ~500,000 M/XDR-TB cases, less than 50% treatment success
- Unequal burden abroad and at home
- Surveillance key public health tool

Whole Genome Sequencing

- Read complete *M. tuberculosis* genome from each case in an outbreak
- Identify mutations shared between different people
- People with shared mutations may have transmitted disease to each other.
- Helps us to identify potential person-to-person transmission events
- Need for other data inputs
- Helps us identify drug resistant strains
- Can answer: how TB entered a community how and why is TB spreading in that community, city, or region, which individuals are contributing the most to transmission.

### 3. Case: whole genome sequencing for TB surveillance and drug sensitivity testing

- Project: Ethical issues in use of whole genome sequencing for TB surveillance and diagnostics
- Qualitative interviews + philosophical/ethical analysis
- Twenty-three interview with gov. officials, clinicians, and laboratory staff
  - Representing Canada, USA, UK, International Org.
  - No direct LMIC representation
- Empirical paper under peer-review; policy paper being drafted

Funded by:  **Genome**  
British Columbia

# 3. Case: whole genome sequencing for TB surveillance and drug sensitivity testing

Two key lessons

- Trust of the public, trust between staff
  - The ‘black box’ of whole genome sequencing
  - Time to include lab folks as direct part of care teams?
- Risk and risk imposition
  - Not just cost-benefit of potential use of data science technology  $x$
  - Utility of patient-level metadata vs. potential data breaches and identifiability
  - Who will bear the risk? Who’s imposing the risk? Who gets to accept or reject risk?

*They're [researchers in LMICs] pretty hesitant and what has been done in the past is that if they have volunteered to provide data that companies can come in, identify potential mutations that would be of relevance and make a diagnostic and then sell it back to the country. So the country is a little bit concerned that what may happen is that a company can basically make money off of their data that they're providing for free.*

*(Interview #1, Lab)*

*So we've put a huge amount of thought into that [data sharing], because that's one of these things where these projects can die. So the most important thing is really having solid relationships across – between the science, and particular in the hub-and-spoke model that we have between us and all the other participants. If you haven't got trust, then nothing works, and to do that, you need face-to-face meetings, and a lot of nurturing of relationships early on.*

*(Interview #16, Lab)*

*But we still have to go through our privacy before we can deposit information and one thing that still seems to be a sticking point, not necessarily just with us, I think with other institutions is any associated metadata. (Interview #9, Lab)*

*So what does it mean if we start, you know, that slippery slope, well what happens if we start sharing like well let's just share gender now, oh let's share country of origin now. (Interview #7, Public Health).*

# Conclusions

- Risk-benefit calculations ought to take into account risk and risk imposition
  - Including risks associated to not sharing data
- Assuming profit and ethics aren't antithetical, what are we willing to do to minimize risks associated with data sharing?
- What challenges do you face with regards to data sharing?