Ethical Challenges for Sharing Data from Pragmatic Clinical Trials

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Notice of Special Interest: Administrative Supplement for Research and Capacity Building Efforts Related to Bioethical Issues (Admin Supp Clinical Trial Optional)

Notice Number:

NOT-OD-21-020

Key Dates

Release Date:	November 17, 2020
First Available Due Date:	December 16, 2020
Expiration Date:	March 06, 2021

Project Motivations

IDEAS AND OPINIONS

Annals of Internal Medicine

Data Sharing and Embedded Research

Gregory E. Simon, MD, MPH; Gloria Coronado, PhD; Lynn L. DeBar, PhD, MPH; Laura M. Dember, MD; Beverly B. Green, MD, MPH; Susan S. Huang, MD, MPH; Jeffrey G. Jarvik, MD, MPH; Vincent Mor, PhD; Joakim Ramsberg, PhD; Edward J. Septimus, MD; Karen L. Staman, MS; Miguel A. Vazquez, MD; William M. Vollmer, PhD; Douglas Zatzick, MD; Adrian F. Hernandez, MD, MHS; and Richard Platt, MD, MS

NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Statement by Individual Leaders and Investigators Involved in Pragmatic Clinical Trials Embedded in Healthcare Systems

Why PCT Data Sharing “Different”

- PCTs often embedded into health systems
  - Potential risks not only for patients, but also for providers/institutions
  - Use of EHR data, rather than data newly collected for purposes of research
- Often use waivers/alterations of informed consent
- Potential inability to control sensitive data populated in an EHR
  - repercussions for meeting obligations of CoCs

Need for future work to

> "[e]xamine…the unique data sharing concerns of other stakeholders, including secondary subjects, who may include health care providers or organizations delivering care to research participants…"

Supplement Overview

- Identify the specific features of the pragmatic clinical trial (PCT) context that may alter the risk-benefit calculus for data sharing, as compared to explanatory trials & other settings with ethically relevant similarities.
- Explore trade-offs presented by data sharing in PCTs, as understood by those responsible for the oversight, generation, dissemination, & future use of PCT data
- Evaluate extent to which existing & proposed policies/guidance to promote data sharing are responsive to PCT-specific risks & benefits

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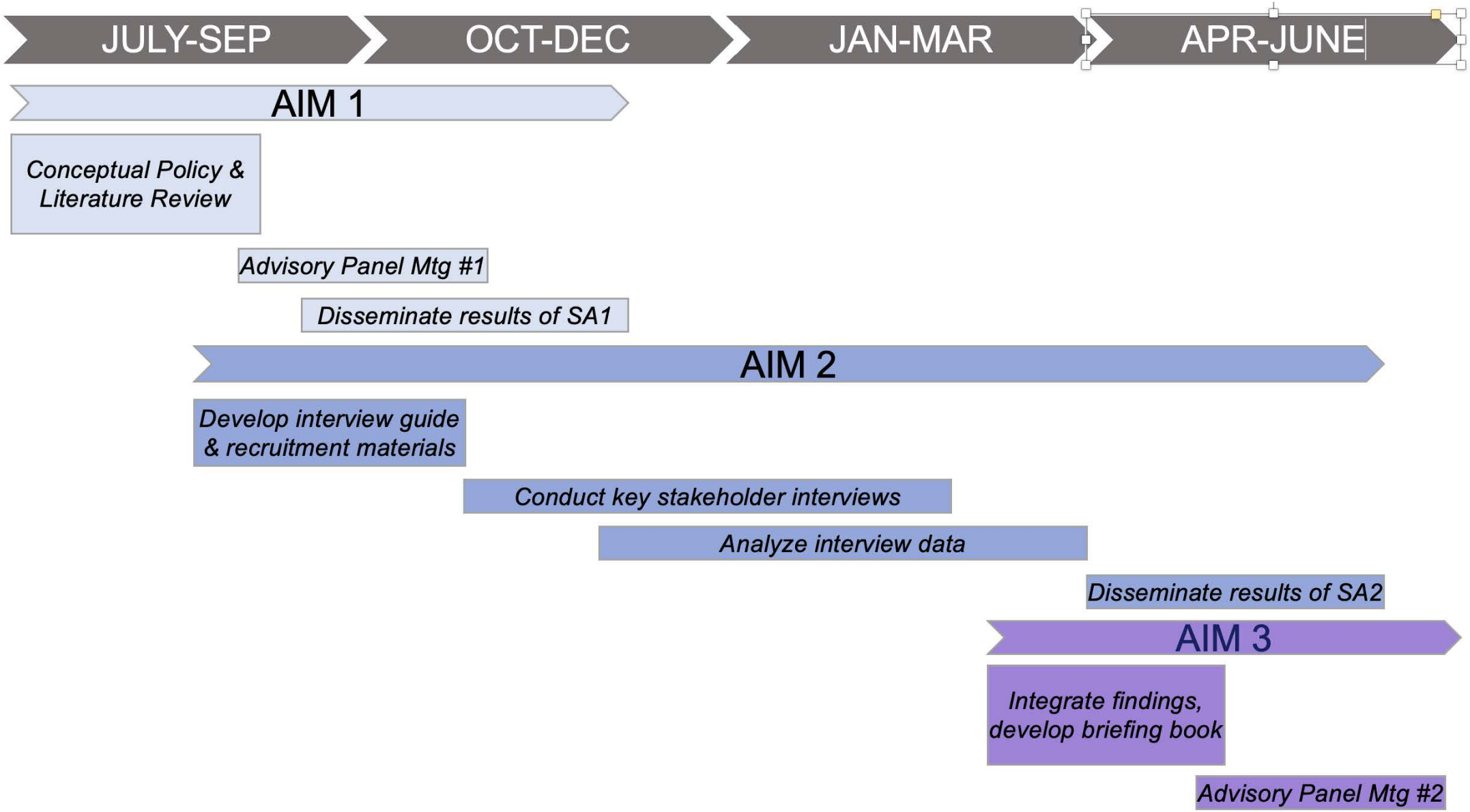
Completed (Paper 1)

Underway


JULY-SEP
OCT-DEC
JAN-MAR
APR-JUNE
AIM 1
Conceptual Policy & Literature Review
Advisory Panel Mtg #1
Disseminate results of SA1
AIM 2
Develop interview guide & recruitment materials
Conduct key stakeholder interviews
Analyze interview data
Disseminate results of SA2
AIM 3
Integrate findings, develop briefing book
Advisory Panel Mtg #2


BABYBJÖRN

Aim 1

What are the ethical challenges in sharing data from PCTs? (Paper 1)

- Uses of waivers/alterations of informed consent
- Risks for health systems & clinicians
- Sharing of EHR data
- Confusion (& conflicts?) with new CoC policy

Waivers/Alterations of Informed Consent & PCT Data Sharing

Traditionally…

- data sharing presented as honoring the preferences of trial participants

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

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.

"most clinical trial participants…believed that the benefits of data sharing outweighed the potential negative aspects and were willing to share their data"

Compiled Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance

Guide Notice Number: NOT-OD-20-013

November 06, 2019 – January 10, 2020

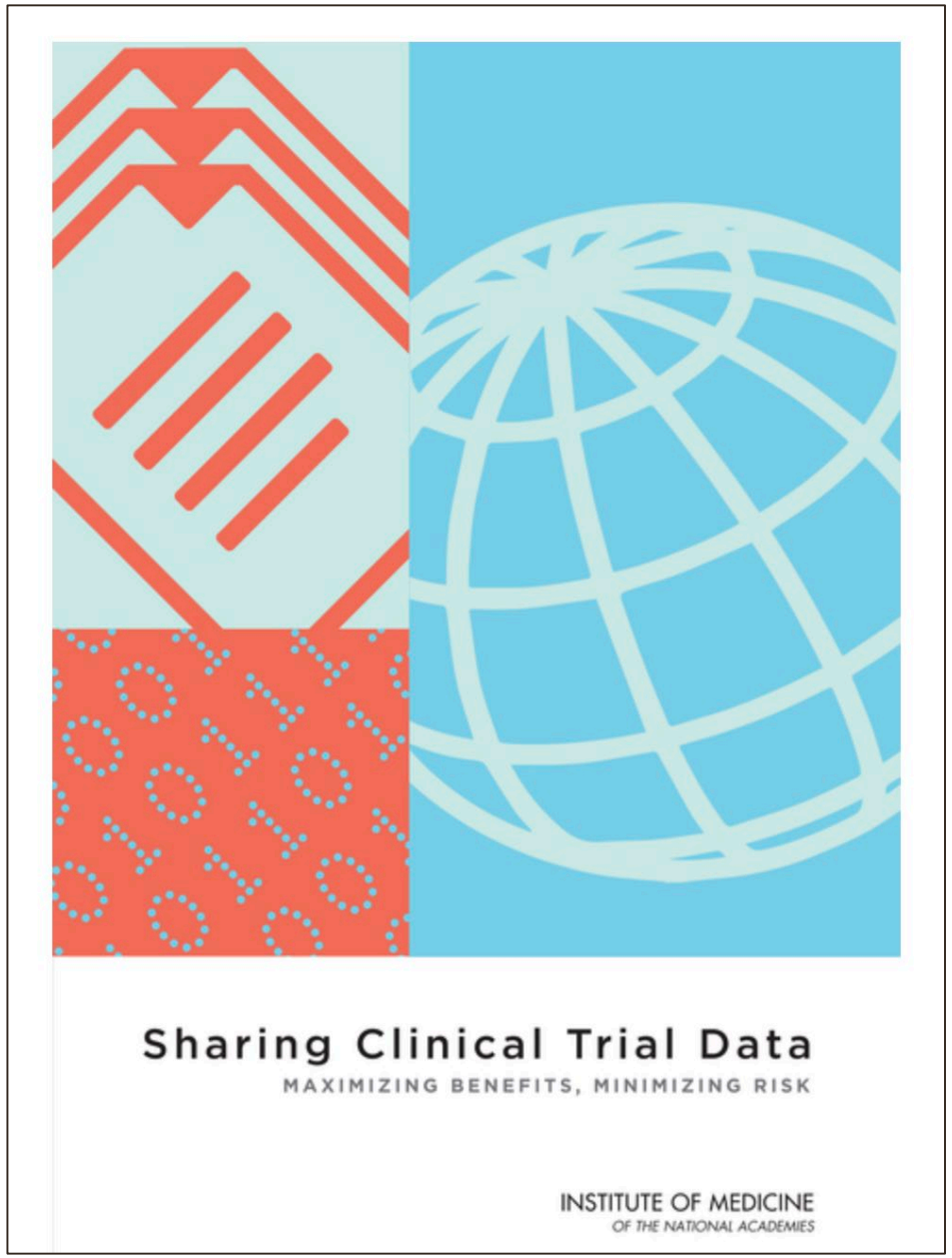
"It is especially worth considering that many human participants expect their data from their participation will be shared with other qualified researchers."

"Moreover, clinical trial data sharing also respects trial participants' assumption of personal risk to contribute to science by maximizing the value of their contributions."

Waivers/Alterations of Informed Consent & PCT Data Sharing

Traditionally…

- data sharing presented as honoring the preferences of trial participants
- heavy emphasis on role of informed consent to fulfill the ethical obligation to respect those whose data are shared



"for most prospective trials…the informed consent process provides an opportunity to obtain participants' approval for planned data sharing and to be transparent about potential future data sharing"

Implications of Waivers/Alterations for PCTs

- Cannot assume sharing data is consistent with preferences of patient-subjects
- Cannot rely on informed consent to fulfill ethical obligation of respect

What does it mean to *respect* PCT patient-subjects with respect to data sharing?

Burdens/Risks for Health Systems & Clinicians

- Data may include proprietary business information
- Naïve/poorly executed comparisons from secondary analyses might misrepresent the quality of certain providers and/or institutions

How should we understand clinician/staff obligations to participate in PCTs, and, subsequently, to have data about them shared beyond their respective institutions?

Overall Risk/Benefit Analysis of PCT Data Sharing

- “Benefits” of data sharing requires data will, once shared, be used
- Early experience of sharing data for explanatory trials support proof-of-concept for sharing, but contribution to social value still uncertain

Data Sharing — Is the Juice Worth the Squeeze?

Brian L. Strom, M.D., M.P.H., Marc E. Buyse, Sc.D., John Hughes, B.Sc., and Bartha M. Knoppers, Ph.D.

EDITORIAL

Data Sharing—The Time Has (Not Yet?) Come

Clyde W. Yancy, MD, MSc; Robert A. Harrington, MD; Robert O. Bonow, MD, MS

Overall Risk/Benefit Analysis of PCT Data Sharing

What is “demand” for PCT data?

Aim 2

Open Questions: Key Stakeholder Interviews

- How do gatekeepers weigh protecting patient privacy versus promoting socially valuable knowledge through data sharing?
- Are some types of data viewed by institutions as more/less sensitive or prone to biased/misleading conclusions?
- What is demand for PCT data? Are some types of studies more/less likely to generate subsequent social value?

Approach: Key Stakeholder Interviews

- N=40 (recruitment underway)
- Purposive sampling, targeting:
  - PCT researchers
  - health system leaders
  - data governance experts
  - journal editors
  - research sponsors
  - secondary data analysts


We want
YOU

Looking Ahead

- Additional key questions for stakeholder interviews?
- Additional stakeholder groups?

Future Research Priorities

- What is “uptake” of shared PCT data?
  - Replication? Secondary analyses? Commercialization?
- What are patient/public attitudes regarding sharing PCT data?
  - Views on tradeoff between prioritizing autonomy v. promoting generation of socially valuable knowledge via data sharing?
  - How to weigh those views in policy decision-making about data sharing?

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