NATIONAL ACADEMY OF MEDICINE

CLINICAL EFFECTIVENESS RESEARCH INNOVATION COLLABORATIVE (CERIC) MEETING

JANUARY 25, 2018 MEETING HIGHLIGHTS

MEETING FOCUS: Oversight practices for learning activities embedded in health systems and plans that aim to provide evidence for care improvement.

Meeting Objectives:

1. *Aim:* Consider regulatory barriers to embedding continuous learning activities that are important to care improvement within health systems, practices, and health plans, and approaches to addressing those barriers.
2. *Decisions:* Discuss the kinds of system-level care improvement decisions that health systems, practices, and health plans make and the type of evidence needed to support those decisions.
3. *Considerations:* Review considerations relevant to determining appropriate levels of oversight and consent for embedded learning activities.
4. *Case examples*: Discuss approaches institutions are taking to oversight and consent and how to facilitate cross-institutional adoption of effective practices.

Outcomes Intended: Identify opportunities for streamlining institutional oversight and consent for learning activities that can effect system-wide care improvement.

REPRESENTATIVE OBSERVATIONS

- Barriers to a continuously learning health system are both cultural and structural. The regulatory environment contributes to structural challenges and creates significant frustration and delays. (WD)
- Institutions are developing processes for evaluating systems interventions that aim to improve health care quality. Examples include the Business Innovation, Learning, and Dissemination (BuILD) Framework at University of Pittsburgh Medical Center (UPMC) and the Clinical Pathways Program at the Children's Hospital of Philadelphia (CHOP). These programs generally rely on quasi-experimental designs to evaluate systems changes. (DH & RK)
  - At CHOP, publishing results is encouraged; staff either decide that evaluations do not constitute human subjects research or seek an IRB exemption.
- Criteria used by Baylor Scott & White Health to select improvement initiatives are: magnitude of impact, strength of evidence, ability of interventions to impact outcomes, system change capacity, and program opportunity costs. IRB review is sought when the goal is to create generalizable knowledge. (AM)
- The federal regulations governing human subjects research use ambiguous terms including generalizable knowledge and practicability, which has led to varying interpretations of when oversight by an IRB and/or informed consent is required. (TL, DA, & BI) Risks of harms to individuals may be a better marker for the need for oversight.
- A consequence of the federal regulations is that, fearing decisions of IRBs related to informed consent, some investigators propose less valuable approaches to evaluating system-level interventions. Arguably, there should be a lower tolerance for deploying interventions without an evaluation. (DA)
- While oversight can be burdensome, it is important to remember that its purpose is to stand between investigators and patients because investigators, and even institutions, can have biases that do not align with patient interests. (DA, HFL, SJ, & ND)
- Institutions have established various processes for determining which evaluation activities require IRB oversight and for overseeing QI activities.
  - UPMC has a quality research committee that is separate from the institutional review board (IRB) to review quality improvement (QI) activities. (DH)
  - Kaiser Permanente Northern California established a research determination process overseen by a trained research determination official. (TL)
  - Intermountain Healthcare has a privacy board that oversees QI projects using detect controls. QI activities are defined as those that deploy evidence-based interventions, do not compare interventions, and allow clinicians to vary practice based on patient needs. (BI)
- With respect to the federal regulations, the implementation of the changes to the Common Rule has been delayed until July 2018 and potentially longer. The changes will have no or minimal impact on QI activities. (JM & HFL)
  - Some changes suggested in the notice of proposed rulemaking related to program improvement and quality assurance activities did not appear in the final rule largely due to concerns from QI investigators. (JM)
- Provisions in the final rule that QI investigators may want to review include those related to secondary research and demonstration projects. (JS)
- The Common Rule was not designed to address evaluations of system-level interventions. A problem for people doing this type of research is that there is no consensus on what a good outcome from an oversight process is or how to measure it. (JL) Potential markers might be increased rigor of QI projects, reduced variability in review, and shorten time for review. (DA)
- A Transportation Security Administration (TSA) model, where each institution has a first level of oversight before any evaluation activity is undertaken, just like each airport requires passengers to undergo an initial security screening, may be a valuable approach. (PO)
- In all systems, policies should be transparent and patients should be engaged to ensure that policies are consistent with their values and interests. (BPL)

COLLABORATIVE ACTIVITIES FOR CONSIDERATION

Based on the discussion, the following ideas are particularly noteworthy for ongoing collaborative actions:

- *Collect case studies of system-level improvement activities that challenge oversight policies and practices:* The goal would be to develop an understanding of how different institutions are overseeing these types of activities and to promote greater consistency across organizations. Another possibility would be to refine the case examples in the briefing book prepared for this meeting and circulate those to a greater number of organizations.
- *Collate examples of institutional oversight policies and practices:* The goal would be to understand the variety of approaches institutions have adopted to oversee QI activities and to make decisions about which activities require IRB oversight, as well as the pros and cons of each approach.
- *Revising the Belmont Report:* To account for changes in the clinical research, clinical practice, and cultural landscape, it may be useful to revisit the principles reflected in the Belmont Report. A report recommending changes was recently published by the Community Campus Partnerships for Health. (BPL)
- *Articulate models for engaging patients in conversations about continuous learning and oversight:* Transparency, trust, and patient buy-in are critical to continous improvement. Understanding successful approaches to engaging patients in discussions about institutional policies is necessary for advancing progress.

THE LEARNING HEALTH SYSTEM SERIES

Participants

Rick Kuntz (Medtronic), Rich Platt (Harvard University) – co-chairs, Melissa Abraham (Harvard University), David Asch (Penn Medicine Center for Health Care Innovation), David Atkins (U.S. Department of Veterans Affairs), Carlos Blanco (National Institute on Drug Abuse), Francis Chesley (Agency for Healthcare Research and Quality), Jennifer B. Christian (IQVIA), Wyatt Decker (Mayo Clinic), Neal Dickert (Emory University School of Medicine), Jonathan Finkelstein (Boston Children's Hospital), Sarah Greene (Health Care Systems Research Network), Claudia Grossmann (PCORI), Diane Holder (UPMC Health Plan), Brent James (Former, Intermountain Healthcare, Inc.), Steven Joffe (University of Pennsylvania), Ron Keren (Children's Hospital of Philadelphia), Laurie Kunches (Harvard Pilgrim IRB), John Lantos (Children's Mercy Hospital), Emily Largent (University of Pennsylvania), Lisa Soleymani Lehmann (U.S. Department of Veterans Affairs), Susan Levy (Children's Hospital of Philadelphia), Tracy Lieu (Kaiser Permanente Northern California), Holly Fernandez Lynch (University of Pennsylvania), Andrew Masica (Baylor Scott & White), Ross McKinney (Association of American Medical Colleges), Devi Mehta (HHS Office for Civil Rights), Jerry A. Menikoff (HHS Office for Human Research Protections), David Meyers (Agency for Healthcare Research and Quality), Catherine Meyers (National Institute of Health), Alexander Ommaya (Association of American Medical Colleges), Pearl O'Rourke (Partners HealthCare System), Bray Patrick-Lake (Duke Clinical Research Institute), Jodyn E. Platt (University of Michigan Medical School), Kevin A. Prohaska (U.S. Food and Drug Administration), Joshua C. Rubin (University of Michigan), Holly Schachner (Sanofi), Mark Schreiner (Children's Hospital of Philadelphia), Jeremy Sugarman (Johns Hopkins Berman Institute of Bioethics), Roger Veronique (Mayo Clinic), David Vulcano (Hospital Corporation of America), Joel Weissman (Brigham and Women's Hospital), Charlotte Yeh (AARP Services, Inc.), Maryan Zirkle (PCORI)

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Participating Organizations

AAMC
AstraZeneca
AHIP
AHA
Baylor Scott & White
Blue Cross and Blue Shield
Brigham and Women's
Bristol-Myers Squibb
Brookings Institution
Cedars-Sinai Medical Center
CMTP
Christiana Care
Duke University
Epic Systems
Georgetown University
Harvard University
ICER
Institute Hlthcre Imprvmnt
Intermountain Healthcare
Temple University
Johnson & Johnson
Kaiser Permanente
Mayo Clinic
Montefiore Medical Center
Mount Sinai Health System
Outcome Sciences Inc.
Optum Labs
Partners HealthCare
PCORI
Tufts University
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Federal agencies:
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– AHRQ
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