Meeting Focus: Peer reviewed journal publication frameworks that promote dissemination of evidence developed by learning health systems.

A premise of the learning health system is that data developed during the delivery of care will contribute evidence about the comparative effectiveness of preventive and therapeutic policies, treatments, and procedures. The expectation is that this information will be useful to delivery system leaders who make many decisions based on analyses of routinely collected health information in enterprise data warehouses or commercially available data, data from registries, or secondary analysis of clinical trial data. This approach to decision-making is sometimes at odds with some journals’ requirements for prior specification of testable hypotheses, and criteria for assessing the statistical significance of analyses of hypotheses that are specified after data are available to investigators who collected the data, and, increasingly, to the public.

Motivating questions:

1. **Key Issues:** How should health system based investigations be designed, conducted, and reported to maximize their credibility? Ideally, this advice should recognize that these evaluations are often designed to provide actionable information in the shortest possible time. Does different guidance apply to prospective and retrospective analyses? When is it appropriate to adjust for multiple hypothesis testing? What role should prior registration play, for instance in ClinicalTrials.gov?

2. **Barriers:** What are the current barriers to publishing results of health system based assessments in peer reviewed journals? What are appropriate approaches for addressing these barriers?

3. **Strategies:** How can researchers, journal editors, and decision-makers work together to develop standards to promote analysis and publication that maximizes the value of data from both randomized controlled trials and observational studies that are embedded in delivery systems?

Outcomes anticipated: Identification of best practices for publishing data from health system based research.
8:30 am  Coffee and light breakfast available

9:00 am  Welcome, introductions & meeting overview

Welcome from the National Academy of Medicine

Michael McGinnis, National Academy of Medicine

Opening remarks and meeting overview by Collaborative Chairs

9:30 am  Case examples: challenges of publishing results of analyses that are specified after data are available to promote continuous learning and improvement

During this session, participants will hear from researchers who experienced difficulties publishing results of health system based analyses in peer reviewed journals, including the types of feedback they received from reviewers and editors. During the discussion, decision makers will be asked to comment on the utility of the results from these analyses for promoting continuous learning and improvement.

Confirmed speakers:
Susan Huang, University of California, Irvine
Nilay Shah, Mayo Clinic
Tracy Wang, Duke University

Q&A and open discussion

10:45 am  Break

11:00 am  Journal editor perspectives: current publication practices

During this session, participants will hear about the review and editorial processes for manuscripts describing results from health system based analyses. The discussion will focus on strengths and limitations of current practices.

Confirmed speakers:
Stephen Fihn, University of Washington
Joseph Ross, Yale School of Medicine
Elizabeth Loder, Harvard Medical School
Joyce Backus, National Library of Medicine

Q&A and open discussion

12:15 pm  Pick up LUNCH
During the lunch session, stakeholders responsible for using results from health system based analyses to guide their decisions will comment on what they look for when evaluating evidence from peer reviewed journal articles. Specific topics will include 1) whether and to what extent decision makers value and/or rely on peer-reviewed publications to guide decision making, 2) health system leaders’ interest in publication of studies that do not meet the standard, and arbitrary, $P<=.05$ cutoff, particularly when the effect size is relatively large, and 3) the need to clarify standards for reporting non-inferiority results.

Confirmed speakers:
Donna Keyser, UPMC
Sanjay Doddamani, CMMI
Rebekah Angove, Patient Advocate Foundation

Q&A and open discussion

This session will build on the discussions from earlier in the day to consider best practices for reporting results of analyses of existing data to promote the dissemination of knowledge generated by learning health systems.

Confirmed speakers:
Steven Asch, Stanford University
Lucy Savitz, Kaiser Permanente Center for Health Research
Jerry Sheehan, National Library of Medicine
Paul Tang, IBM

Q&A and open discussion

This session will feature comments from the co-chairs on themes from the day’s discussion and next steps.

Adjourn