NIH Health Care Systems Research Collaboratory

Stakeholder Engagement Core

Sean Tunis, MD, MSc
Center for Medical Technology Policy
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## SE Core Workgroup Members

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<tr>
<td>Sally Retecki</td>
<td>Strategies and Opportunities to Stop Colon Cancer in Priority Populations</td>
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<td>Jerry Jarvik</td>
<td>A Pragmatic Trial of Lumbar Image Reporting with Epidemiology (LIRE)</td>
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<td>Katie James</td>
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<td>Lynn DeBar</td>
<td>Collaborative Care for Chronic Pain in Primary Care</td>
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<td>Carmit McCullen</td>
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<td>Mark Vander Weg</td>
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<td>Alfred Cheung</td>
<td>Pragmatic Trials in Maintenance Hemodialysis</td>
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<td>Greg Simon</td>
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<td>Susan Huang</td>
<td>Decreasing Bioburden to Reduce Healthcare-Associated Infections and Readmissions</td>
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<td>Ed Septimus</td>
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<td>Sean Tunis</td>
<td>CMTP / SE Core Staff</td>
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<td>Rachael Moloney</td>
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<td>Ellen Tambor</td>
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<td>Tammy Reece</td>
<td>Duke Coordinating Center</td>
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<td>Russ Glasgow</td>
<td>NIH Representatives to the SE Core</td>
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<td>David Chambers</td>
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OVERVIEW

• What are stakeholders?
• What is stakeholder engagement?
• Why engage stakeholders in CER?
• Why engage stakeholders in the Collaboratory?
• SE Core progress to date
  – Identification of high priority issues
  – SAG recruitment
• Discussion
STAKEHOLDER ENGAGEMENT

- A process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interests in a particular issue, for the dual purposes of:

1) Creating a shared understanding;
2) Making relevant, transparent, and effective decisions.

WHY ENGAGE STAKEHOLDERS IN CER

• Gaps in evidence will be reduced with greater collaboration between decision makers, researchers and other stakeholders in:
  – Priority setting
  – Defining research questions
  – Designing and reviewing study protocols
  – Implementing studies
  – Disseminating / implementing results
Methods of combining evidence

- Meta-criteria
- Trust
- Respect
- Accountability
- Legitimacy
- Fairness
- Competence

- Change in Knowledge/attitudes

- Change in CER project decisions (e.g. choice of interventions, study design, funding priorities)

CER

- More useful evidence for clinical and health policy decision making
- More efficient use of healthcare resources
- Improved health outcomes.
WHY ENGAGE STAKEHOLDERS IN THE COLLABORATORY?

(other than it being the fashionable thing to do)
COLLABORATORY GOALS

• “...to strengthen the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations as research partners.”

• “...to provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research.”
FROM VISION TO REALITY

• Many barriers to metamorphosis from health care delivery system to research partner
• Health systems and research community don’t have all necessary authority, resources, insights
  – Optimal “implementation methods and best practices” may require actions by other agents
• Stakeholder Engagement Core provides forum to engage broader healthcare community
  – Shared understanding and decisions / actions
STATEMENT OF PURPOSE

- The Stakeholder Engagement (SE) Core will provide the forum within which a broad range of stakeholders can discuss how best to deploy their authorities, resources and insights to support the Collaboratory goal of transforming healthcare delivery organizations into research partners.

- The dialogue will also require us to clarify why this transformation is important for these organizations, their employees and the patients they serve.
SE Core Work to Date

- Develop initial statement of purpose
  - Feedback from Collaboratory Steering Committee
- Identify potential issues for Stakeholder Advisory Group (SAG)
- Identify and recruit SAG members, based on issues and stakeholder categories
  - 16 confirmed; target size 20-25
  - Scheduled first in person mtg of SAG on May 9
- Discussion with broader Collaboratory community (today)
IDENTIFYING TOPICS FOR SAG DISCUSSION

- Conducted interviews with representatives from each of the 7 demonstration projects to:
  - Identify generalizable challenges best addressed at a higher level, in a broad stakeholder discussion
  - Elicit suggestions for stakeholder groups or organizations relevant to challenges/issues
- Developed preliminary list of discussion topics
- Feedback from Collaboratory Steering Group and Stakeholder Engagement workgroup
SUGGESTED TOPICS FOR SAG

- Regulatory oversight and human subjects protections
- Reimbursement for services
- Clinician and patient incentives
- Optimizing adoption of results at the local, system, national levels
- Data & EHR Capabilities

In coordination with:

- Ethics/Regulatory Core
- HCS Interaction Core
- HIT Core, PRO core
Informed Consent and IRB Review

1. Barriers related to informed consent in healthcare systems research
   a) Individual consent in cluster RCTs and other PCTs
   b) Consent for use of clinical and administrative data generated through routine clinical care
   c) Differences in and potential standardization of “minimal risk” definitions

2. Mechanisms to encourage greater reliance on central IRBs
Reimbursement

1. Payment for routine clinical services that are being evaluated in the trial
   a. “Investigational” vs. “experimental” confusion
2. Implications of Medicare clinical trials policy
3. Coverage for new interventions that are a combination of existing covered services
4. Willingness of delivery system or payers to support innovative care delivery models after positive trial results
CLINICIAN AND PATIENT INCENTIVES

• For some demo projects, participation in research is low priority for clinicians
• Patient recruitment challenges also noted
• Potential role for “behavioral economics”
• Existing payment rules, quality reporting requirements can be disincentive to participate
OTHER POTENTIAL ISSUES

• Competition for attention to research during ACA-driven delivery and payment reform

• How to most efficiently align HCS research with other data-intensive activities
  – Quality improvement programs, quality measurement and reporting, clinical registries...

• How and when best to plan for practice and policy changes indicated by study results
CRITERIA FOR SAG MEMBERS

- Organizations and individuals who are likely to have authorities, resources, insights related to one or more of the key issues
- Special emphasis on those not already engaged in healthcare systems research
- Broad range of relevant professional experience
**STAKEHOLDER ADVISORY GROUP (SAG): CONFIRMED MEMBERS**

**Patients/Consumers/Advocates**

**Marc Boutin, JD**  
Executive VP & Chief Operating Officer  
National Health Council

**Pam Wescott, MPP**  
Director of Patient Perspectives  
Informed Medical Decisions Foundation

**Donna Cryer, JD (liver patient)**  
Chief Executive Officer  
Cryer Health

**Deborah Collyar (cancer survivor)**  
Co-Chair, Committee on Advocacy, Research Communications, Ethics, & Underserved Populations  
National Breast Cancer Coalition

**Regulatory/Ethics**

**Susan Kornetsky, MPH**  
Director of Clinical Research Compliance  
Children’s Hospital, Boston

**Alex Capron, LLB**  
Chair, Board of Directors  
Public Responsibility in Medicine and Research (PRIM&R)

**Clinical care providers**

**Lyle Fagnan, MD**  
Professor, Family Medicine  
Oregon Rural Practice-based Research Network  
Oregon Health & Science University

**Robert Chow, MD, MBA, FACP**  
Program Director, Internal Medicine Residency Training Program and Vice-Chair of Medicine, Good Samaritan Hospital of Maryland
SAG MEMBERS (CONT’D)

Thought leaders in QI, practice incentives, and innovative care delivery

Scott Halpern, MD, PhD, MBE
Deputy Director
Center for Health Incentives and Behavioral Economics
Penn Leonard Davis Institute

Peggy O’Kane, MHA
President
National Committee for Quality Assurance

Kavita Patel, MD, MS
Managing Director for Clinical Transformation and Delivery, Engelberg Center for Health Care Reform, Brookings Institution

Public payers

Patrick Conway, MD, MSc
Director and CMS Chief Medical Officer
Office of Clinical Standards and Quality

Jeff Schiff, MD, MBA
Medical Director
Minnesota Healthcare Programs

Private payers

Derek van Amerongen, MD, MS
Chief Medical Officer
Humana of Ohio

Elizabeth Malko, MD, MEng, FAAFP
Executive VP and Chief Medical Officer
Fallon Community Health Plan
SAG MEMBERS (CONT’D)

Patient Centered Outcomes Research Institute (PCORI)

*Rachael Fleurence, PhD*
Acting Director, Accelerating PCOR Methods Program, PCORI

Health IT

*Kelly Cronin*
Healthcare Reform Coordinator
Office of the National Coordinator for HIT

Healthcare System Administrators

TBD, (Recruiting)

Life Sciences Industry

*TBD (Recruiting)*
MAXIMIZING VALUE OF SAG

• Demonstration projects, other workgroups are “living laboratories” to identify critical topics for SAG attention

• Active input and direction from Collaboratory participants essential to focusing SAG attention on most critical issues
QUESTIONS / SUGGESTIONS