NIH Health Care Systems Research Collaboratory

Stakeholder Engagement Core

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Center for Medical Technology Policy
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SE Core Workgroup Members

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

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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

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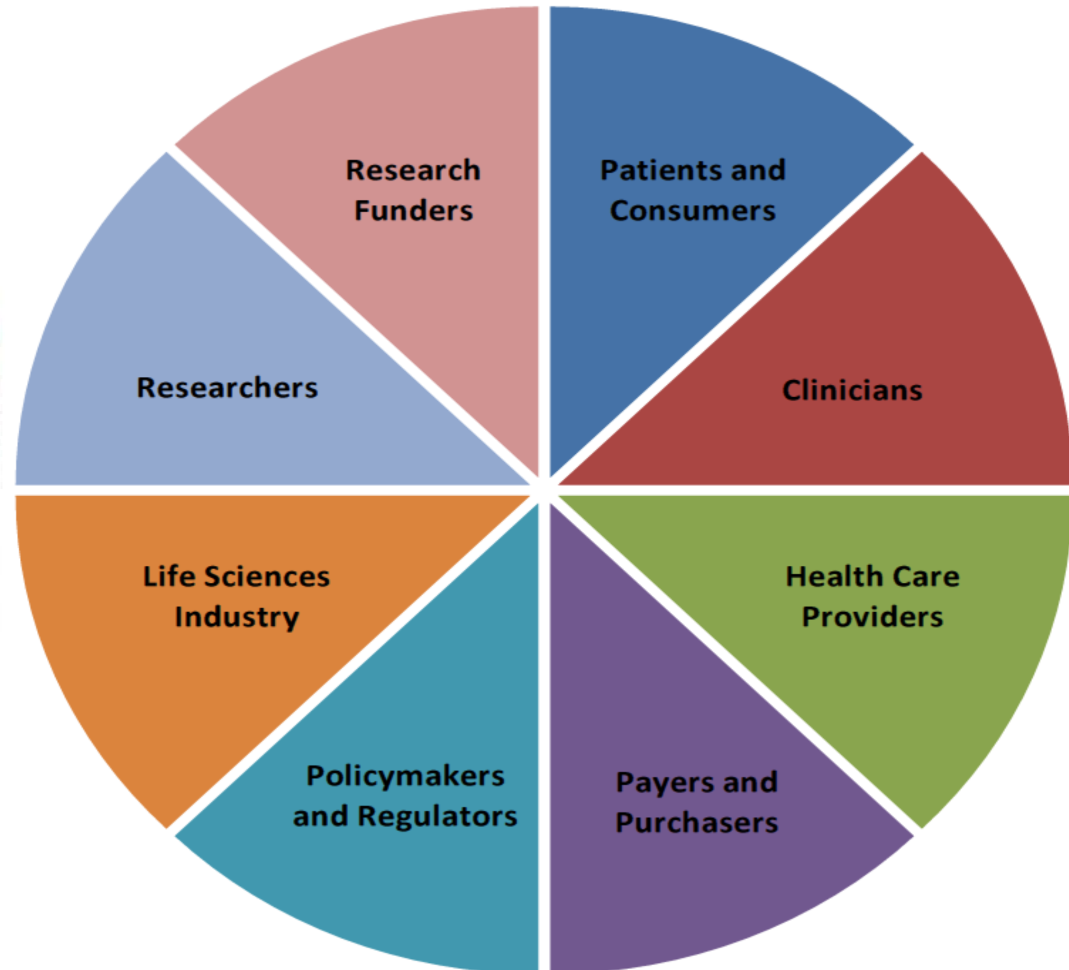
Stakeholder Categories



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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.

Deverka, Lavallee, Desai, et al. Stakeholder participation in CER: defining a framework for effective engagement. J Compar Effect Res 2012;2:181-94.

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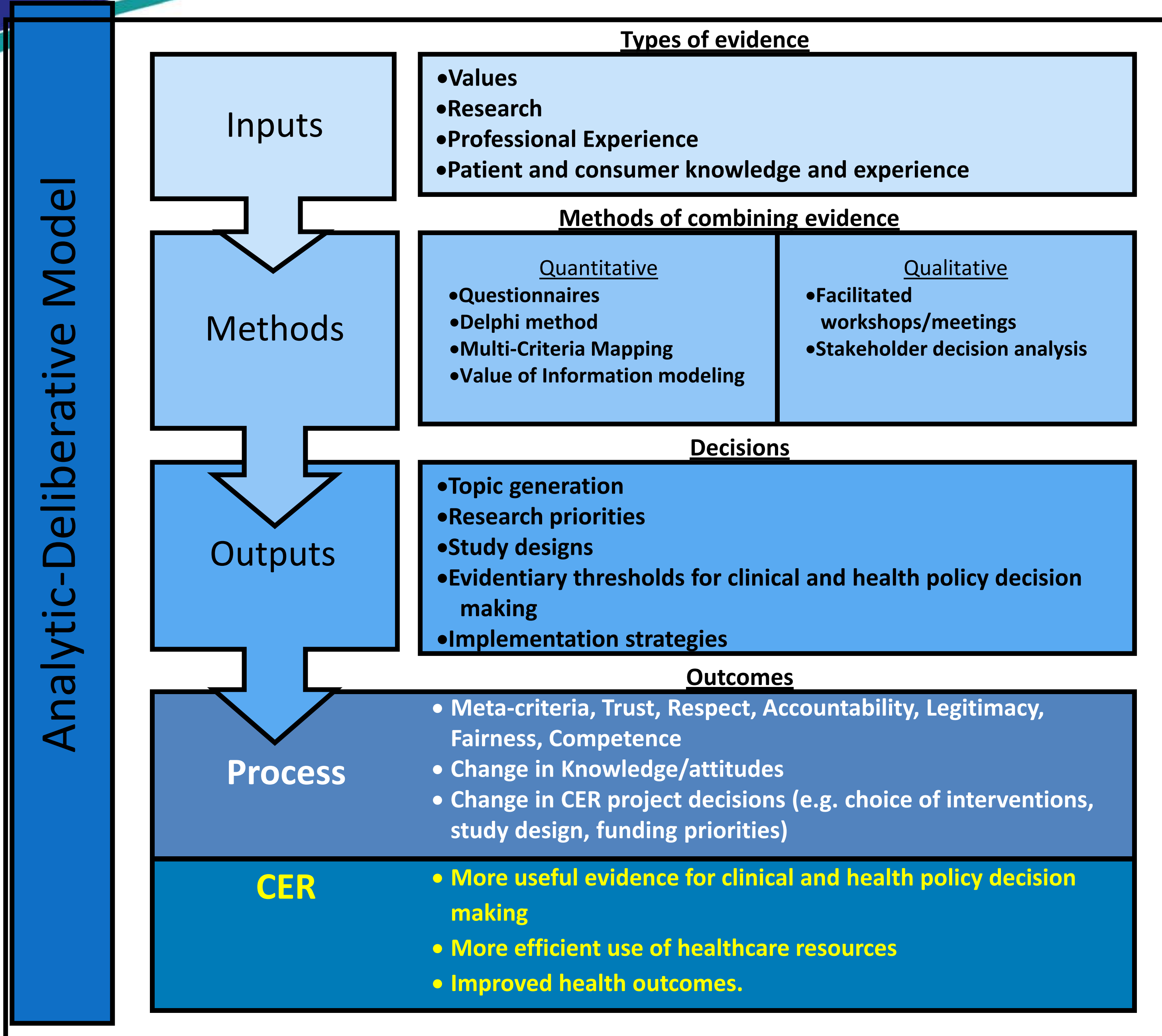
Why Engage Stakeholders in CER

- 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*

CONCEPTUAL MODEL



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WHY ENGAGE STAKEHOLDERS IN THE COLLABORATORY?

(other than it being the fashionable thing to do)

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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

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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.

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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)

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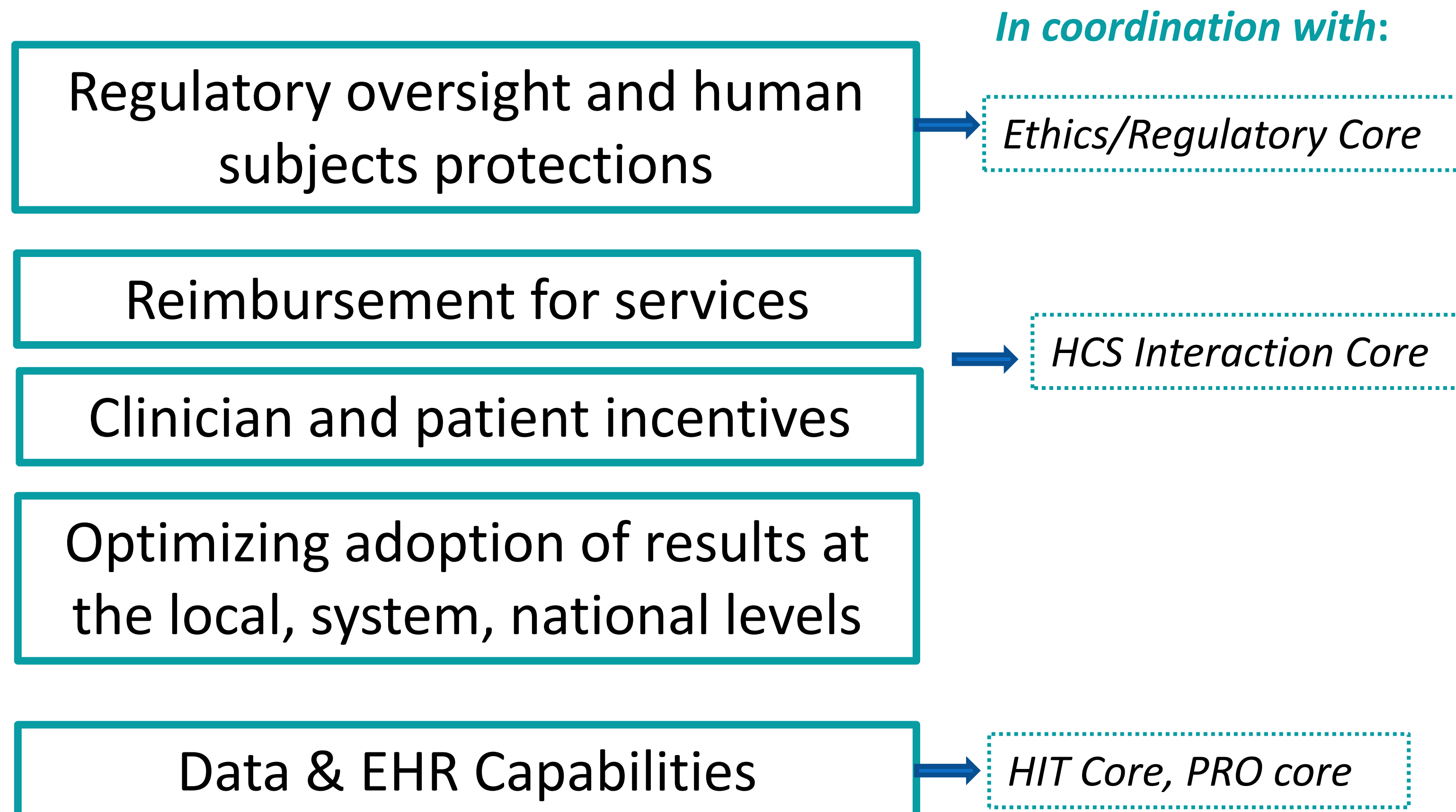
Identifying Topics For SAG Discussion

- 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



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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

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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

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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

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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

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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

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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

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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)

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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

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QUESTIONS / SUGGESTIONS