



Health Care Systems Research Collaboratory

## Stakeholder Engagement Core Lessons Learned , Update and Plans

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**Center for Medical Technology Policy**

**Collaboratory Steering Committee Meeting  
February 25, 2014**



Rethinking Clinical Trials

# Presentation Overview

- Review of Stakeholder Engagement Core
- Year 1 Lessons Learned
- Year 2 focus / June 2014 SAG meeting
- Restocking the SAG
- Year 1 and 2 Deliverables

# Stakeholder Engagement Core

## Statement of Purpose:

The **Stakeholder Engagement (SE) Core** provides the forum within which a wide range of stakeholders can bring their different perspectives and expertise to the work of overcoming barriers to the transformation to a learning health care system.

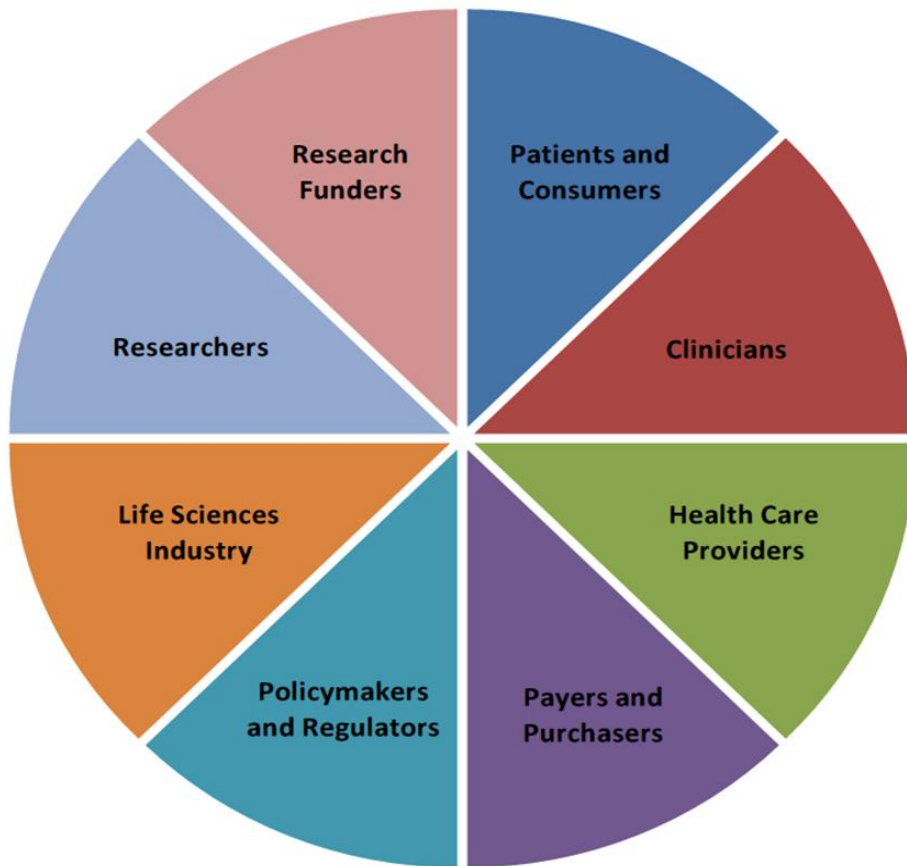
Through dialogue with stakeholders we will also clarify why this transformation is important for these organizations, their employees and the patients they serve.

→ Primary focus is to identify strategies to promote long term success of Collaboratory.

# Why Engage Stakeholders?

- Wide range of barriers to metamorphosis from health care delivery system to research partner
  - Technical, operational, regulatory, financial, cultural
- Health systems and research community don't have all necessary expertise, 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
- **Sustainable infrastructure depends on compelling business case for patients, clinicians, health systems**

## Stakeholder Categories



# Organizations Represented on SAG

- National Health Council
- Patient Advocates in Research
- American Liver Foundation
- Informed Medical Decisions Foundation
- Public Responsibility in Medicine & Research
- Patient Centered Outcomes Research Institute
- Office of the National Coordinator for Health Information Technology
- Centers for Medicare & Medicaid Services
- Minnesota Healthcare Programs
- Humana of Ohio
- Evolent Health
- Veterans Health Administration
- HCA America
- Good Samaritan Hospital of Maryland
- Cincinnati Children's Hospital
- Children's Hospital of Boston
- National Committee for Quality Assurance
- Engelberg Center for Health Care Reform, Brookings Institution
- Oregon Health & Science University
- Leonard Davis Institute of Health Economics, UPenn
- Boston College Connell School of Nursing
- Medtronic, Inc.
- Pfizer

# Year 1 Activity Review

- Stakeholder Advisory Group – 24 members recruited
- Topic Identification with SE workgroup and demo PIs
- SAG Orientation to HCS Collab - Webinar (April 24<sup>th</sup>)
- SAG In-person Meeting - May 9<sup>th</sup>, 2013 (Baltimore, MD)
- Meeting Summary White Paper completed - August 2013



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## Stakeholder Advisory Group

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### Meeting Summary

Engaging Health Care Systems as Partners in Research:  
Moving Toward a Sustainable Partnership

May 9th, 2013  
World Trade Center Baltimore



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# Knowledge and Attitudes about LHS

- There is a lot of public education needed to build greater support for the necessity of more efficient learning
  - Uncertainty and risks in clinical care
  - Risk of overprotection/under-protection with current approach
- Many people believe their own clinicians provide good care, but can appreciate that they can only know what is known
- Understanding clinical trials and randomization is complicated
- **Easy to underestimate patient/public fears that research results will be used to limit care**

# SAG Views on Oversight of HCS Research

- The notion that learning will lead to better patient care is not in itself sufficient justification for major reductions in research oversight or regulation.
- Modified consent: Greater disclosure/explanation may be viable alternative to more extensive standard consent for selected experimental studies
  - Not limited to “fully-loaded” consent vs none
- Acceptance of alternative methods varies based on trust
  - Extent to which the provider/system upholds commitments to patients that “learning” is translated into practice
  - Results not used to restrict patient/clinician treatment options



# Year 2 Focus for SE Core / SAG

- Ethical & regulatory issues
  - Support Coord Center Ethics Supplement
- **Incentives for patients, clinicians and health systems to partner in LHS**
  - Value proposition / business case for each
  - Key to potential for sustainability

# The Business Case for Learning

- *Healthcare systems* must perceive that there is a reasonable and sustainable business-case to allocate organizational resources to serve as active partners for Collaboratory researchers and future learning efforts
- *Clinicians* must perceive sufficient monetary or nonmonetary benefits to justify adding extra responsibilities to their already substantial workloads (and the workloads of their nurses and staff)
- *Patients* must be activated as agents of change – to *insist* on conducting more clinical research quickly and efficiently
  - Requires understanding the benefits of research and risks of *not* doing research
  - Requires trust that such research is appropriately regulated, safe, ethical, and beneficial to their own healthcare in addition to society as a whole

# Work Plan – Business Case for LHS

- **White paper** in collaboration with the Health Systems Interactions Core: *Toward a sustainable learning health system: roadmap for building health system, clinician and patient support*
- **In-person SAG meeting** in May/June to allow for in-depth dialogue of the issues discussed in the draft white paper
- **Manuscript** based on background research and meeting
- Work will be coordinated with two PCORI-funded IOM workshops on the value proposition of integrating care and research
  - Targeted to Health System Leaders



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# Extra Slides



# Stakeholder Advisory Group

## *Patients/Consumers/Patient Advocates*

***Marc Boutin, JD***

Executive VP & Chief Operating Officer  
National Health Council

***Deborah Collyar***

Co-chair, Committee on Advocacy, Research Communications, Ethics & Underserved Populations; Founder, Patient Advocates in Research (PAIR)

***Donna Cryer, JD***

President & CEO  
American Liver Foundation

***Pam Wescott, MPP***

Director of Patient Perspectives  
Informed Medical Decisions Foundation

## *Regulatory and Ethics Stakeholders*

***Alex Capron, LLB***

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

***Susan Kornetsky, MPH***

Director of Clinical Research Compliance  
Children's Hospital, Boston

## *Life Sciences Industry*

***Alexandra Clyde, MS***

Vice President, Health Policy and Payment  
Medtronic, Inc.

***Eleanor Perfetto, PhD, MS***

Professor, Pharmaceutical Health Services Research, University of Maryland (Previous: Senior Director, Reimbursement & Regulatory Affairs, Federal Government Relations, Pfizer)

# Stakeholder Advisory Group

## *Physician / Researcher*

### ***LJ Fagnan, MD***

Professor, Family Medicine  
Oregon Rural PBRN  
Oregon Health & Science University

### ***Robert Chow, MD, MBA***

Program Director, Internal Medicine  
Residency Program & Vice-Chair, Medicine  
Director of General Internal Medicine  
Good Samaritan Hospital of Maryland

## *Healthcare System Administrators*

### ***Ann Latstetter***

Division VP, Quality  
HCA America, Capital Division

### ***Joe Francis, MD, MPH***

Chief Quality and Performance Officer  
Veterans Health Administration

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## *Private Payers*

### ***Elizabeth Malko, MD, MEng***

Senior VP Clinical Delivery and Operations,  
Evolent Health; (Previous: Executive VP and  
CMO, Fallon Community Health Plan)

### ***Derek van Amerongen, MD, MS***

Chief Medical Officer  
Humana of Ohio

## *Nursing*

### ***Tam Ngyuen, PhD, MSN, MPH***

Assistant Professor  
Boston College  
William F. Connell School of Nursing

## *Health IT experts*

### ***Kelly Cronin***

Healthcare Reform Coordinator  
Office of the National Coordinator for HIT

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# Stakeholder Advisory Group

## ***Public Payers***

***Jeff Schiff, MD, MBA***

Medical Director

Minnesota Healthcare Programs

***Shari Ling, MD***

Deputy Chief Medical Officer

CMS Center for Clinical Standards & Quality

***William Shrank, MD, MSHS***

SVP, CMO and CSO, Provider Innovation & Analytics, CVS Caremark; (Prev: Director, Rapid Cycle Evaluation Group, CMMI)

## ***PCORI***

***Rachael Fleurence, PhD***

Acting Director, Accelerating PCOR Methods Program, Patient-centered Outcomes Research Institute

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## ***Thought leaders in QI, practice***

***incentives & innovative care delivery***

***Scott Halpern, MD, PhD, MBE***

Deputy Director

Center for Health Incentives and Behavioral Economics, Penn Leonard Davis Institute

***Mary Barton, MD, MPP***

VP for Performance Measurement

National Committee for Quality Assurance

***Kavita Patel, MD, MS***

Managing Director for Clinical

Transformation and Delivery,

Engelberg Center for Health Care Reform, Brookings Institution

***Michael Seid, PhD***

Director, Health Outcomes and Quality Care Research, Cincinnati Children's Hospital Medical Center

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# SE Workgroup Members

- Sean Tunis
- Ellen Tambor
- Rachael Moloney
- Mark Vander Weg
- Sally Retecki
- Alfred Cheung
- Kathryn James
- Carmit McCullen
- Ed Septimus
- Jerry Jarvik
- Lynn DeBar
- Gregory Simon
- Susan Huang
- David Chambers
- Jerry Suls