

NIH Collaboratory

Health Care Systems Research Collaboratory

Stakeholder Engagement Core Overview and Progress Report

Steering Committee Meeting

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Rethinking Clinical Trials



Stakeholder Engagement Core

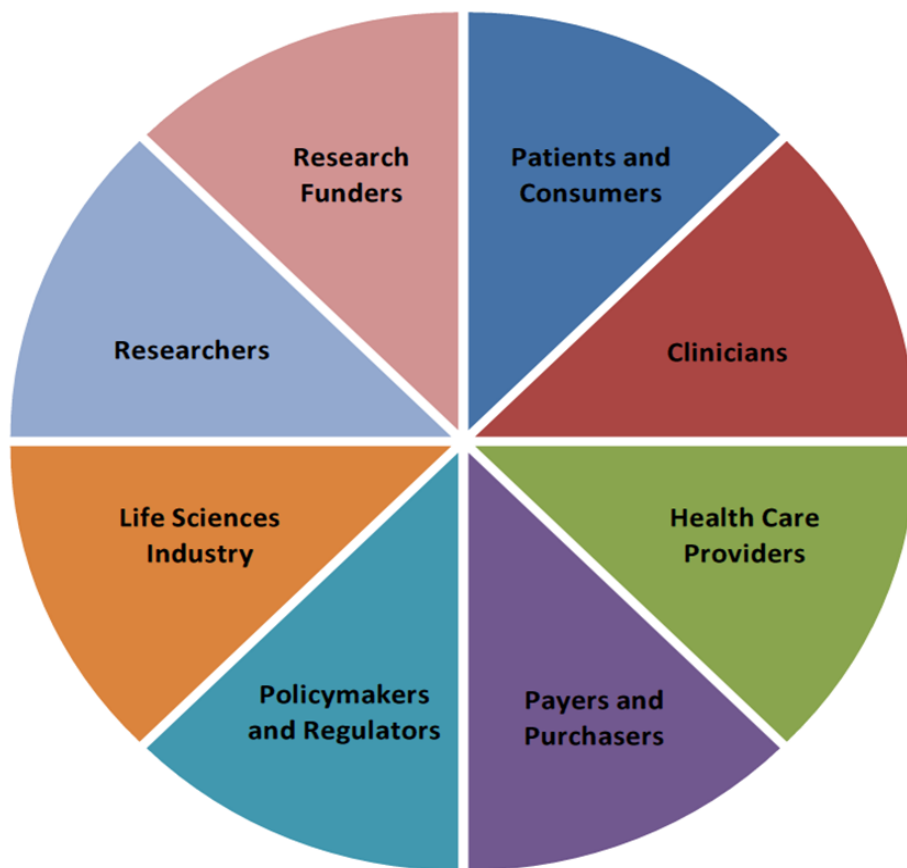
Statement of Purpose:

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.

Stakeholder Categories





Stakeholder Advisory Group (SAG)

Organizations Represented

- ☐ Alliance of Chicago Community Health Services
- ☐ Boston College Connell School of Nursing
- ☐ Centers for Medicare & Medicaid Services
- ☐ Children's Hospital of Boston
- ☐ Cincinnati Children's Hospital
- ☐ Clinical Directors Network
- ☐ COPD Foundation
- ☐ Distributed Ambulatory Research in Therapeutics Network (DARTNet) Institute
- ☐ Engelberg Center for Health Care Reform, Brookings Institution
- ☐ Evergreen Health Co-op
- ☐ Evolent Health
- ☐ Fletcher Allen Health Care
- ☐ National Health Council
- ☐ Patient Advocates in Research
- ☐ Global Liver Institute
- ☐ Good Samaritan Hospital of Maryland
- ☐ HCA America
- ☐ Healthwise (formerly Informed Medical Decisions Foundation)
- ☐ Humana of Ohio
- ☐ Institute of Medicine
- ☐ Johns Hopkins Healthcare, LLC
- ☐ Leonard Davis Institute of Health Economics, UPenn
- ☐ Medtronic, Inc.
- ☐ Merck and Company
- ☐ Minnesota Healthcare Programs
- ☐ National Committee for Quality Assurance
- ☐ Office of the National Coordinator for Health Information Technology
- ☐ Oregon Health & Science University
- ☐ Patient Centered Outcomes Research Institute
- ☐ Public Responsibility in Medicine & Research (PRIM&R)
- ☐ Veterans Health Administration



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
- **Sustainable infrastructure depends on compelling business case for patients, clinicians, health systems**



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Stakeholder Advisory Group

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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A New Ethical Framework for a Learning Healthcare System

7 Obligations of the New Ethics Framework

1. Respect the rights and dignity of patients and families
2. Respect the judgment of clinicians
3. Provide each patient optimal clinical care
4. Avoid imposing non-clinical risks and burdens
5. Address unjust health inequalities
6. Conduct continuous learning activities (clinicians, health care institutions, payers)
7. Contribute to the common purpose of improving the quality and value of clinical care (patients and families)

Faden RR, Kass NE, et al. An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. Hastings Cent Rep. 2013 Jan-Feb;SpecNo:S16-27.



Stakeholder Feedback on Hopkins Model - 1

- Framework emphasizes how much uncertainty exists in clinical care.
- While patients / consumers may recognize this generally, not easily accepted in context of ongoing clinical care.
 - “May apply generally, but my doctor knows what she is doing.”
- Patients / consumers also have limited awareness of how much personal data is already collected in health care.
 - Emphasizes need to better educate public that LHS aims to make better use of data, much of which is already being collected



Stakeholder Feedback on the Overall Goals of the Collaboratory and Learning Healthcare Systems

- The notion that a learning will lead to better patient care in not in itself sufficient justification for major reductions in research oversight or regulation.
 - Sense of group: in the rush to learn more quickly, we must also remain respectful of rights to be fully informed, and protected from potential harms.
 - SAG feedback provided good reality check on degree to which reduced oversight would be acceptable.



Thoughts on the Path Forward

- Understanding clinical trials and randomization is really complicated.
- Progress is possible within current regulatory environment
 - But regulatory changes may be necessary
- 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
 - Potential harms of not learning



Health Care Systems Research Collaboratory

Strengthening the Business Case for Learning in Health Care

Stakeholder Advisory Group Discussion

Hosted by:

The Center for Medical Technology Policy

May 28, 2014



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Meeting Objective

- To promote the sustainability of infrastructure for learning/ research within health care delivery systems, we need to better understand the value proposition of learning/ research to these systems and other key stakeholders (e.g. patients and clinicians).
- In particular, we hope to better understand the business case for deploying this data collection infrastructure to support hypothesis driven research that is integrated with the delivery of care.



High Level Framing for Discussion

- The business case for integrating learning into health care delivery is reasonably strong for quality improvement (QI) / process improvement
- It appears weak, at best, for “hypothesis driven research”
- Our goal is not to craft a more compelling sales pitch to persuade health systems of ROI...
- ...Instead, our goal is to determine: What actions can be taken, and by whom, that will shift the value proposition to a net positive?



Concerns Raised about ROI for Hypothesis-Driven Research

- Not a response to the “burning platform” in healthcare
 - “System Transformation” is essential, urgent activity
- No bandwidth for “nice to have” learning
 - 2/3 of hospitals lose money or break even
 - Upfront costs for downstream payoff not attractive
 - “Almost free” is not good enough
- There is plenty of evidence we don’t apply
 - Prefer to focus on learning to use what we know already
- What researchers like to do is often not what health systems most need



Encouraging Observations

- Some places are doing full range of learning – really well!
- A number of key thought-leaders are convinced of viability
- Infrastructure necessary for QI is same/similar to what is needed for research...
 - marginal costs of research may be small
- A portfolio of learning, weighted to QI, may be attractive
 - Especially if external resources help build, expand and sustain infrastructure that is also useful for process improvement.
- There are overlapping priorities between health system needs and researcher interests.



Insights from May 28th SAG Discussion

- 1. First, figure out how to do the short-term, immediate payoff research much faster, more efficiently, and at lower cost than we do now**
 - ❖ Drive down costs by expanding an infrastructure that is yet under-developed, informed by highly functional models that exist in some systems.
- 2. Second, try to minimize incremental costs for doing hypothesis-driven research**
 - ❖ With clear understanding that it will cost systems more than not doing the research, but that our ultimate goal is to reduce those research costs by an order of magnitude.
- 3. Third, acknowledge that incremental costs for hypothesis-driven research will generally not be absorbed by the health systems**
 - ❖ Funding may come from traditional researchers at much lower projects costs that is currently the case in the absence of extensive infrastructure.



Critical Need for Patient Leadership

- Patient and Consumer community support is essential to our shared goals of embedding research in care delivery
- Consumer demand may be essential for a viable business case for health systems
- Reforms to human subjects and privacy policy are unlikely to be successfully led by any other stakeholder group
- Major emphasis on public education is essential, can complex
 - How to overcome assumption that most care is currently evidence-based and that health systems are already learning



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