



# NIH Collaboratory

Health Care Systems Research Collaboratory

## Collaboratory Stakeholder Advisory Group Insights From First In Person Meeting

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Center for Medical Technology Policy

**Collaboratory Grand Rounds**

**July 12, 2013**



Rethinking Clinical Trials



# Presentation Overview

- Refresher on Stakeholder Engagement Core
- May 9<sup>th</sup> SAG mtg agenda/participants
- General impressions of SAG
- Feedback on human subjects oversight
- Potential Next Steps



# Stakeholder Engagement Core: Statement of Purpose

The **Stakeholder Engagement (SE) Core** provides a Collaboratory 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.

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



# Stakeholder Advisory Group (SAG) Meeting

*May 9, 2013 – Baltimore, MD*



# SAG Meeting Overview

- Introductions and Collaboratory Overview
- Discuss two key challenges to the success of the Collaboratory
  - a) Optimal approaches to collecting PRO data (Amy Abernathy)
  - b) Behavioral and financial incentives to promote participation of patients, providers, and health systems in research (Scott Halpern)
    1. Regulatory and ethical oversight of learning activities
      1. Ruth Faden, Nancy Kass, Rich Platt, Jeremy Sugarman, Jerry Menikoff



# 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

***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***

Senior Director, Reimbursement & Regulatory  
Affairs, Federal Government Relations, Pfizer

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# Stakeholder Advisory Group

## ***Physician / Researcher***

### ***Lyle 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***

Executive VP and Chief Medical Officer  
Fallon Community Health Plan

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

Chief Medical Officer  
Humana of Ohio

## ***Nursing***

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

Faculty Research Associate  
Center of Excellence for Cardiovascular  
Health of Vulnerable Populations  
Johns Hopkins University

## ***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

***Patrick Conway, MD, MSc***

Director and CMS Chief Medical Officer  
Office of Clinical Standards and Quality

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

Director, Rapid Cycle Evaluation Group  
Center for Medicare & Medicaid Innovation

## ***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

***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

***Michael Seid, PhD***

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

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# Collaborators and Guests

- Amy Abernathy - Duke
- Rich Platt - Harvard
- Rob Califf – Duke
- Eric Larson – Group Health
- Jeremy Sugarman - JHU
- Christina Brackna – NCCAM
- Catherine Myers – NCCAM
- Jerry Menikoff - OHRP
- Ruth Faden - JHU
- Nancy Kass – JHU



# Impressions of SAG

- Broadly-informed
- Highly engaged
- Supportive of Collaboratory goals
- Constructive suggestions
- Intelligent challenges
- Diversity of views generates helpful insights



# 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 Hopkins Model - 2

- Informed consent options are not limited to “fully-loaded” approach vs. no consent. **Explanations** could play a key role.
  - SAG commented on approach in which everyone gets *some level* of explanation regardless of the risk involved.
- Distinction drawn between decisions that patients would typically address with their clinician and those they would not
  - E.g. decisions about hospital staffing don’t solicit patient input.



# Hand Hygiene Learning Case Study (Rich Platt)

## Case Study 1: SoftClean – A New Hand Hygiene Product

<b>Scenario</b>	Three hospitals are adopting a new FDA approved, commercially available hand hygiene product (SoftClean) that is advertised to be easy on the skin AND antimicrobial
<b>Approach</b>	<p><b>Hospital A:</b> A few months after introducing SoftClean, the hospital's infection preventionist surveys personnel about usability and reviews patients' infection experience</p> <p><b>Hospital B:</b> Infection preventionist polls members of her professional association. 50 work in hospitals that have adopted SoftClean and 50 work in hospitals that haven't. They combine their user polls and infection data.</p> <p><b>Hospital C:</b> Infection preventionist polls members of her professional association and 100 hospitals are contemplating adopting SoftClean. They agree that 50 randomly selected hospitals will adopt it immediately and the other 50 will wait a few months. They develop standard survey and reporting forms</p>
<b>Results</b>	<p><b>A:</b> Personnel report more skin problems, possibly because the product was introduced in winter. A few more patients acquired infections than had done so before. Can't tell if the increase is clinically meaningful since power is limited</p> <p><b>B:</b> Personnel preferences not comparable because of different survey forms. Patients in SoftClean hospitals had more infections, but these were hospitals with sicker patients</p> <p><b>C:</b> SoftClean users had fewer skin problems. Patients in SoftClean hospitals acquired fewer infections.</p>



# Reactions to Case Study 1

- While SAG members understood that the third approach was most likely to provide accurate answer, and that risks to patients was minimal, they never converged on a view that IRB review and individual consent should not be required, despite lengthy discussion.
- Also understood that requirement for individual consent might mean that the best option is not pursued, and that clinical care is actually worse with first two options
- Bottom line: If people are going to part of a formal study, they want to be informed, and have a choice about whether or not to participate





# Thoughts on the Path Forward

- 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
  - Risk of overprotection/under-protection with current approach
- Understanding clinical trials and randomization is really complicated.
  - Need the best materials possibly to explain these concepts using multiple media.
- Progress is possible within current regulatory environment
  - Use cases; adopting best current practices across IRBs
- Modified consent: Greater disclosure/explanation may be viable alternative to standard consent for selected experimental studies
- Acceptance of alternative methods of consent may vary based on the extent to which the provider/system upholds commitments to patients that “learning” will actually translate into improved care.



# Longer Term Regulatory Changes

- Ultimately, efficient approach to human subjects oversight in Collaboratory and LHS will require some regulatory change
- Future discussions on this issue with SAG will explore nature of changes that might gain broad support
- SAG members and organizations may be helpful in securing level of support necessary to motivate reconsideration of current regs
- SE core is in the process of developing an updated plan for SAG and SE workgroup, beyond human subjects issues
  - Open to suggestions!!

# Questions?



# 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
- Fallon Community Health Plan
- 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
- Johns Hopkins School of Nursing
- Medtronic, Inc.
- Pfizer



# 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.



# Feedback on Collaboratory Goals and LHS

- Need to further raise public awareness that healthcare systems are not currently learning systems
  - Note that even those who recognize gaps in knowledge often don't think this is true of their own providers
- Stakeholders support of learning activities depends heavily on being convinced of commitment to use evidence to change