

Attitudes about the Ethics of Research on Medical Practices (RoMP)

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Spectrum

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Research on Medical Practices

- An intentional framing to convey that these activities are “research”
- Labeling it research does not presume that a specific approach to risk, consent, or oversight is appropriate

Study Aims

Objective: To better understand how patients, their surrogates, the general public, and IRB members view ethical implications of randomization within usual clinical practices.

Aim 1: Assess and compare attitudes of potential research subjects towards risks and benefits of, and towards informed consent for participation in, research on medical practices.

1a) Adults and parents of children who are active health care users

1b) A nationally representative population sample.

1c) Determine the factors, such as perceived health status, health care utilization, trust, parental status, education, or socioeconomic status, that are associated with attitudes about the acceptability and expectations related to research on medical practices.

Aim 2: Assess attitudes of IRB members towards risks and benefits of, and towards informed consent for participation in, research on medical practices.

Research Questions

- How do these stakeholders value and weigh tradeoffs between autonomy, risks, quality of care, and other characteristics of this specific class of clinical research?
- How do these stakeholders view different approaches to notifying, informing, and engaging patients and communities about the design of, and informed consent for, such research?



Approach

- NCATS award to Stanford(SPECTRUM) and Seattle (ITHS) CTSA
- Development of videos and illustrations to convey
 - Influences on practice variation
 - Approaches to Research on Medical Practices
 - Information disclosure and agreement



	Focus Groups	Survey	Interviews
IRB Members	3	500	60
Regular health care users	8	500	60
General public		3000	

Study Team

COLLABORATORS

Stanford

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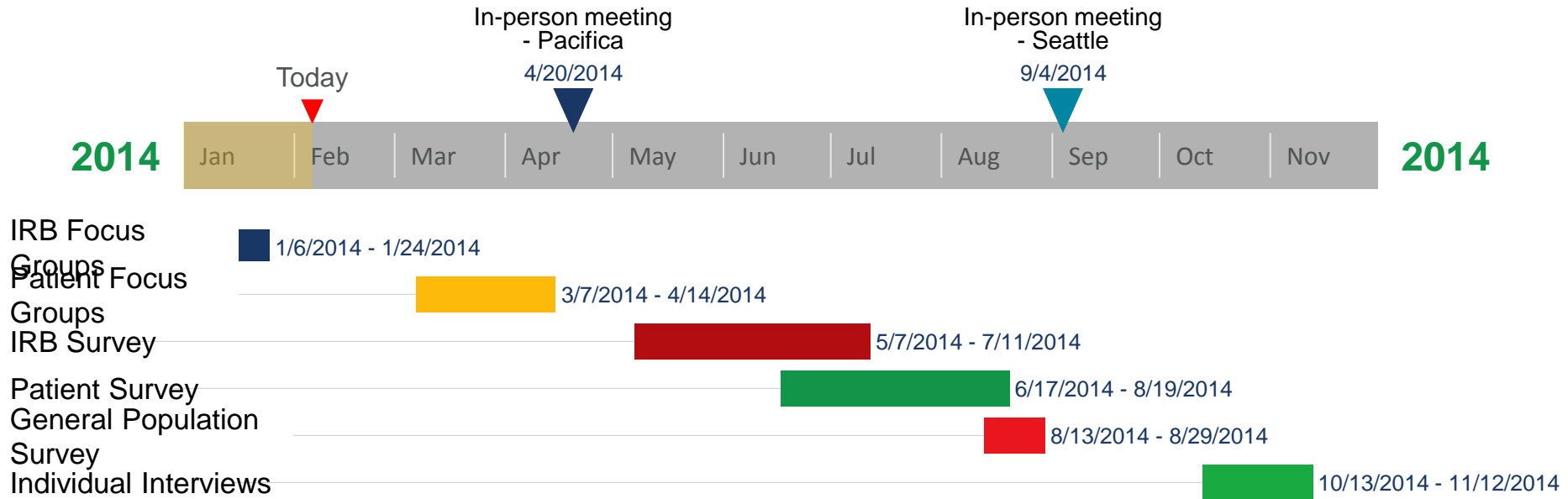
Mildred Cho, PhD (Stanford)

Consultants

Alex Capron, LLB (USC)

Steve Joffe, MD, MPH (U Penn)

Timeline for Data Collection



IRB Focus Group Findings (Preliminary)

- Defining Research on Medical Practice
 - Significant confusion about QI/research distinctions
 - Recognized ambiguity about adequacy of current regulatory framework
- Identifying Risks
 - See randomization as a significant issue less about risks more related to restricting the choices of:
 - Physicians to make recommendations to patients about choices of treatment
 - Patients about treatment
- Consent and waivers
 - Range of view about waivers of consent and effectiveness of notification
- Oversight measures
 - Lack of current oversight of those activities not labeled as research
 - Concerns about the feasibility of community engagement

Assessing public attitudes can be challenging

- Public may lack understanding of how physicians make choices and how individualized and evidenced based those decisions are
- Attitudes can depend on framing of questions
- Public attitudes play a role but don't determine policy

Videos and Illustrations

- 3 short videos (2-3 min) with accompanying illustrations using hypertension medications as example.

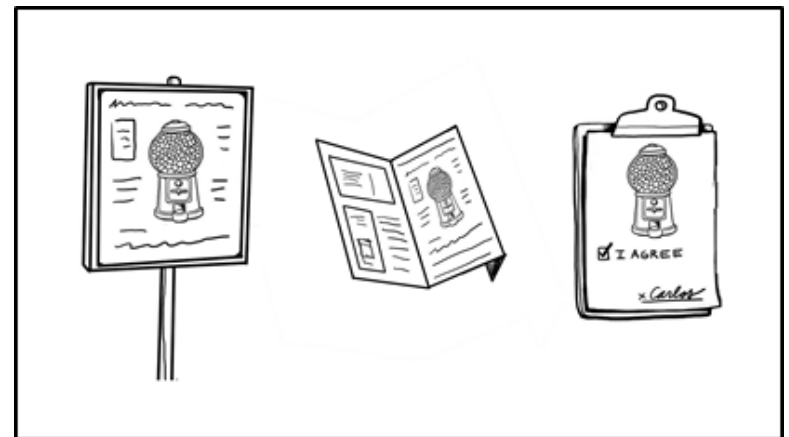
1. Influences on variation in usual medical practices

2. Research on medical practices

- Observation (typical variation or standardized approaches)
- Randomization (Point of Care and Cluster)

3. Alternative approaches to patient engagement

- General Information
- Specific Information
- Specific Agreement



Patient and Parent Focus Groups: March/April 2014

- 8 focus groups of cardiology and nephrology patients/parents at sites in Seattle and Stanford
 - Recruitment at clinic visits
 - Population: Return patients seen within 12 months
- Videos and illustrations to help illustrate concepts during focus groups (and provide feedback on the videos)
- Questions:
 - Influence on practices variation
 - Research on medical practice and randomization
 - Notification and Consent
 - Oversight
- Results of focus groups used to drive patient and general population survey content

Influences on Practice Variation Questions

- 1) What do you think leads a doctor to prescribe a particular drug for a patient? Let's say in this case, to help manage high blood pressure?

Show video

- 1) Did the video change your impression of how doctors make treatment decisions in everyday practice?
- 2) Does the general issue of how doctors decide what is best, raise any concerns for you?

Research on Medical Practice Questions

- (1) What do you see as the potential advantages and disadvantages, or risks and benefits of research on medical practice?
- (2) What would you think and feel about your doctor deciding which blood pressure medication to use based on randomization?
- (3) Research using randomization may affect an individual doctor's ability to make specific treatment decisions for individual patients, since patients are assigned randomly to treatment options. Do you have any concerns about this?
- (4) Research on Medical Practice—using observation or randomization—can go even faster when doctors at different clinics share with other clinics health information about how their patients respond to different treatments. Do you have any concerns about having your health information shared across doctors or hospitals?

Notification and Consent Questions

- 1) What information would you like to be told about any of these activities related to research on medical practice?
- 2) Would you want your health care provider to provide specific information about research on medical practices to you, as opposed to just receiving general information that the hospital is engaged in research on medical practice?
- 3) In addition to information about the research, would you want your health care provider to ask for your consent—that is, agreement to participate in research on medical practices?
- 4) Do you think you would agree if you were asked to participate in research on medical practice? What factors would play into your decision?

IRB Survey (n=500)

- Recruitment through letter from PRIM&R
- Link to Online survey using Redcap
- Opportunity to explore broad range of attitudes about risk, consent, oversight or range of research approaches

Public Surveys in Summer 2014

- Patient Survey (n=500)
 - Recruitment in clinics
 - Return patients seen within 12 months
 - Survey administered on tablets while waiting for visit
- General Population Survey (n =3000)
 - Representative Sample from Zoomerang
 - Email link

Interviews in Fall 2014

- Patient interviews (n=60)
- IRB interviews (n=60)



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