Survey to Assess Common Ethical Framework for low risk CER activities

December 3, 2014

Sheila Fireman, JD
Department of Population Medicine
Harvard Pilgrim Health Care Institute
Overview

• Identify if a common ethical framework exists for certain types of low risk comparative effectiveness and studies of healthcare operations

• Survey IRB chairs, leaders of healthcare quality improvement programs, and patients to assess attitudes and beliefs about informed consent requirements and risk assessment for these types of interventions

• Common constructs evaluated across all 3 surveys
# Core Investigative Team and Liaisons

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Affiliation</th>
<th>Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susan Huang, MD MPH</td>
<td>UC Irvine, Assoc Professor Director, Epidemiology &amp; Infection Prevention</td>
<td>Quality improvement, infection prevention, healthcare epidemiology, infectious diseases, CER</td>
</tr>
<tr>
<td>Jim Sabin, MD</td>
<td>Harvard Pilgrim Health Care Institute Professor, Population Med &amp; Psychiatry Director, Ethics Program</td>
<td>Psychiatry, ethics in patient care and research, including CER and clinical trials</td>
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<tr>
<td>Sherrie Kaplan, PhD</td>
<td>UC Irvine, Professor Assistant Vice Chancellor for Healthcare Evaluation and Measurement</td>
<td>Expert psychometrician; qualitative and quantitative survey design and evaluation; CER; served on IRB for 15y</td>
</tr>
<tr>
<td>Sheila Fireman, JD</td>
<td>Harvard Pilgrim Health Care Institute Director, Research Integrity &amp; Compliance</td>
<td>IRB Liaison, Ethics Core, NIH Collaboratory</td>
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<tr>
<td>Adrijana Gombosev, MS</td>
<td>UC Irvine</td>
<td>Project Coordinator</td>
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<tr>
<td>Lauren Heim, MPH</td>
<td>UC Irvine</td>
<td>Project Coordinator</td>
</tr>
<tr>
<td>Becky Kaganov, BS</td>
<td>Harvard Pilgrim Health Care Institute</td>
<td>Research Associate</td>
</tr>
<tr>
<td>Julie Lankiewicz, MPH</td>
<td>Harvard Pilgrim Health Care Institute</td>
<td>Project Coordinator, ABATE Infection Trial liaison to Collaboratory Ethics Core</td>
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Project Aims
Survey of Patients

- Develop and conduct a structured interview-administered survey of hospitalized patients to evaluate their expectations of consent for hospital activities related to comparative effectiveness or health care delivery.

- Include questions to evaluate effectiveness of phrases to communicate:
  1) That hospitals are dedicated to improving medical care.
  2) That participating in QI initiatives and research helps improve health care for current and future generations.
Survey of Directors of QI Programs

- Develop and conduct a survey of directors of hospital quality improvement programs to assess the range of QI activities being conducted with and without a research premise to provide context for ethical oversight of such studies

- Use example scenarios to explore the ethical boundaries related to quality improvement research and the assessment of risk, consent and waiver of consent
Survey of IRB Chairs

- Develop and conduct a survey of IRB Chairs to assess their experience with and interpretation of minimal risk research activities, including quality improvement research studies as it relates to waiver of consent.

- Use example scenarios to assess the common range of IRB determinations applied and evaluate common drivers of risk determination and consent requirements.
Survey Constructs
Projects below threshold of risk operate under same fundamental principles, regardless if it is a quality improvement project or research project.
Single Ethical Framework

Can We Generate a Single Ethical Framework for Evaluating Routine, Minimal Risk Studies?

Learning Health System Projects Limited to:
1. Minimal Risk
2. Principle of Agency applies*
3. Reasonable Rationale**

IRB Programs QI Programs Patients

Endorsement of Activity Reflected by:
Waiver of Consent

*PI, treating physician, healthcare system provides oversight for respect of patients’ rights, welfare, and dignity

**Design and conduct will provide benefit to individuals or generalizable knowledge to improve healthcare

IRB Waiver of Consent Rules
1. Minimal risk
2. No adverse effect to subjects’ rights/welfare
3. Research cannot be practicably carried out
4. Subjects provided with additional info
How to Evaluate Consent?

- **Patient Survey**
  - Is providing permission necessary

- **IRB Survey**
  - Types of studies eligible for a waiver of consent

- **QI Survey**
  - Identify reasonable and feasible QI study
Survey Sub-Constructs

- Hospital Environment
- Products Used on or by Patients
- Medication, Health Equipment, and Devices
- Policies and Procedures
- Data Sharing
Hospital Environment

- Looking at different ways to reduce noise level at night
- Trying out special types of lighting at night to improve patients’ sleep
- Comparing different types of privacy curtains
- Trying out different placement options for handrails in patient rooms to prevent falls
Products Used On Or By Patients

- Trying out different types of bathing soap to reduce risk of infections
- Seeing how long patients should wear stockings to prevent blood clots in leg
- Trying out different thermometer types for taking temperature
- Comparing different types of bandages to improve healing or reduce irritation
Medication & Devices

- Comparing use of generic vs. name brand drugs
- Comparing different types of blood drawing needles or methods of drawing blood
- Comparing automatic blood pressure monitors to manual check by nurses
- Comparing whether blood pressure lowering drugs work better when taken in morning or night
Policies and Procedures

- Trying out different post discharge teaching materials or education methods
- Trying out different ways of closing surgical incisions
- Seeing whether having nurses call patients after they go home improves their care at home
- Trying out ways to reduce patient wait time in the emergency room
Data Sharing

- Changing to computerized vs. paper medical records
- Including patient data in disease registries
- Trying out different ways to help patients understand their own medical record information
- Using patient data to improve care at only the hospital where they were seen
- Using patient data to improve care at other hospitals that take care of similar patients
Response Options

1. For each of the following questions, would it be okay for the hospital to go ahead without your permission to compare ways they might improve care?

(CIRCLE ONE NUMBER ON EACH LINE)

DEFINITELY YES  PROBABLY YES  MAYBE YES MAYBE NOT  PROBABLY NOT  DEFINITELY NOT

a. XXXX.......................... 1 2 3 4 5

10. How comfortable would you feel letting each of the following use protected health information, if they protected patients from being individually identified?

(CIRCLE ONE NUMBER ON EACH LINE)

VERY COMFORTABLE  COMFORTABLE  SO-SO  UNCOMFORTABLE  VERY UNCOMFORTABLE

a. XXXX.......................... 1 2 3 4 5
**SECTION 2. MAKING CHANGES IN THE HOSPITAL ENVIRONMENT**

The following questions ask about if you would like to be asked for your permission before hospitals can make changes in patient care that involve the **physical surroundings**.

1. For each of the following questions, would it be okay for the hospital to go ahead *without your permission* to compare ways they might improve care?

*(CIRCLE ONE NUMBER ON EACH LINE)*

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>a. Trying out different ways to reduce noise levels in hospitals at night...</td>
<td>1</td>
<td>2</td>
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<tr>
<td>b. Comparing two types of privacy curtains around patient beds? ........</td>
<td>1</td>
<td>2</td>
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<td>5</td>
</tr>
<tr>
<td>c. Trying out different places to put handrails in patient rooms to prevent falls? .....................</td>
<td>1</td>
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### Products Used on or by Patients

#### SECTION 3. MAKING CHANGES IN THINGS THAT ARE PUT ON OR USED BY PATIENTS

The following questions ask about whether you would like to be asked for your permission when hospitals make changes in things that are used by or put on patients.

1. For each of the following questions, would it be okay for the hospital to go ahead without your permission to compare ways they might improve care?

(CIRCLE ONE NUMBER ON EACH LINE)

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<tr>
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<tr>
<td>a. Trying out different types of bathing soaps to reduce the risk of infections?</td>
<td>1</td>
<td>2</td>
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<td>4</td>
<td>5</td>
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<tr>
<td>b. Trying out different types of wound bandages to improve healing or reduce irritation?</td>
<td>1</td>
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<td>5</td>
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<tr>
<td>c. Trying out which type of thermometers (oral, underarm, ear) work best for taking temperature?</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>5</td>
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</table>
## SECTION 4. MAKING CHANGES IN TYPES OF MEDICATIONS OR DEVICES USED IN HOSPITALS

The following questions ask about when you would like to be asked for your permission when comparing the ways hospitals use already approved medications or devices to improve patient care or experiences.

1. For each of the following questions, would it be okay for the hospital to go ahead without your permission to compare ways they might improve care?

   *(CIRCLE ONE NUMBER ON EACH LINE)*

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<td>a. Comparing whether blood pressure lowering drugs work better when taken in morning or night?</td>
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<tr>
<td>b. Trying out the use of generic or less expensive versions of same drug vs. brand name drug?</td>
<td>1</td>
<td>2</td>
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<tr>
<td>c. Trying out different types of blood drawing needles to improve blood flow when drawing blood</td>
<td>1</td>
<td>2</td>
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</tbody>
</table>
## Policies and Procedures

### SECTION 5. MAKING CHANGES IN HOSPITAL POLICIES OR PROCEDURES

The following questions ask about when you would like to be asked for your permission when hospitals compare *changes in certain types of procedures, policies*, or ways things are done.

1. For each of the following questions, would it be okay for the hospital to go ahead *without your permission* to compare ways they might improve care?

   *(CIRCLE ONE NUMBER ON EACH LINE)*

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<tr>
<td>a. Comparing different types of teaching materials to see which is best at educating patients about what to do after they leave the hospital?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>b. Seeing whether getting patients up to walk sooner after surgery reduces problems (such as pneumonia, blood clots)?</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>c. Seeing whether having nurses call patients after they go home improves their care at home?</td>
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### SECTION 6. MAKING CHANGES IN THE WAYS HOSPITALS COLLECT, USE, OR SHARE PATIENT INFORMATION

The following questions ask about when you would like to be asked for your permission when hospitals compare changes in the ways they collect, use, or share information with other healthcare providers.

1. For each of the following questions, would it be okay for the hospital to go ahead without your permission to compare ways they might improve care?

(CIRCLE ONE NUMBER ON EACH LINE)

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<td>a. Changing from paper to computerized medical records?</td>
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<td>2</td>
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<td>4</td>
<td>5</td>
</tr>
<tr>
<td>b. Including patient data (names and addresses) in disease registries (databases for specific diseases) for research?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>c. Sharing pictures of the patient's body without the face with doctors, nurses, or students for teaching purposes?</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>5</td>
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Next Steps

- Patient survey underway at two academic medical centers, BWH in Boston and UC Irvine in Orange, CA
- QI survey – launch early 2015
- IRB survey – launch early 2015