Perspective on the Boundary between Quality Improvement Studies and Research: Patients, QI Leaders, IRB Leaders

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ABATE Infection Project

Disclosures

- No conflict of interest

Background

- Converging trends highlight importance of identifying types of interventions to improve care that require patient consent:
  - Quality improvement strategies
  - Increasing focus on comparative effectiveness research
  - Pragmatic trials
  - Learning healthcare systems

"I don't need informed consent to give you a sponge bath."

HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Mary Beth Hamel, M.D., M.P.H., *Editor*

Informed Consent, Comparative Effectiveness, and Learning Health Care

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The [Common Purpose] Framework comprises **seven moral obligations:**

First, respect the rights and dignity of patients; second, respect the clinical judgments of clinicians; third, provide optimal care to each patient; fourth, avoid imposing nonclinical risks and burdens on patients; fifth, reduce health inequalities among populations; sixth, conduct activities that foster learning from clinical care and clinical information; and seventh, contribute to the common purpose of improving the quality and value of clinical care and health care systems.

The first six obligations fall on researchers, clinicians, health care administrators, institutions, payers, and insurers. The seventh falls on patients to participate in certain types of learning activities that will be integrated with their clinical care.

Not without controversy…

- Randomization alone requires consent (Anderson & Schonfeld NEJM 2014)
- FDA regulations do not permit waiver of consent when study involves comparison of medications (Schreiner, NEJM 2014)

FDA Changes

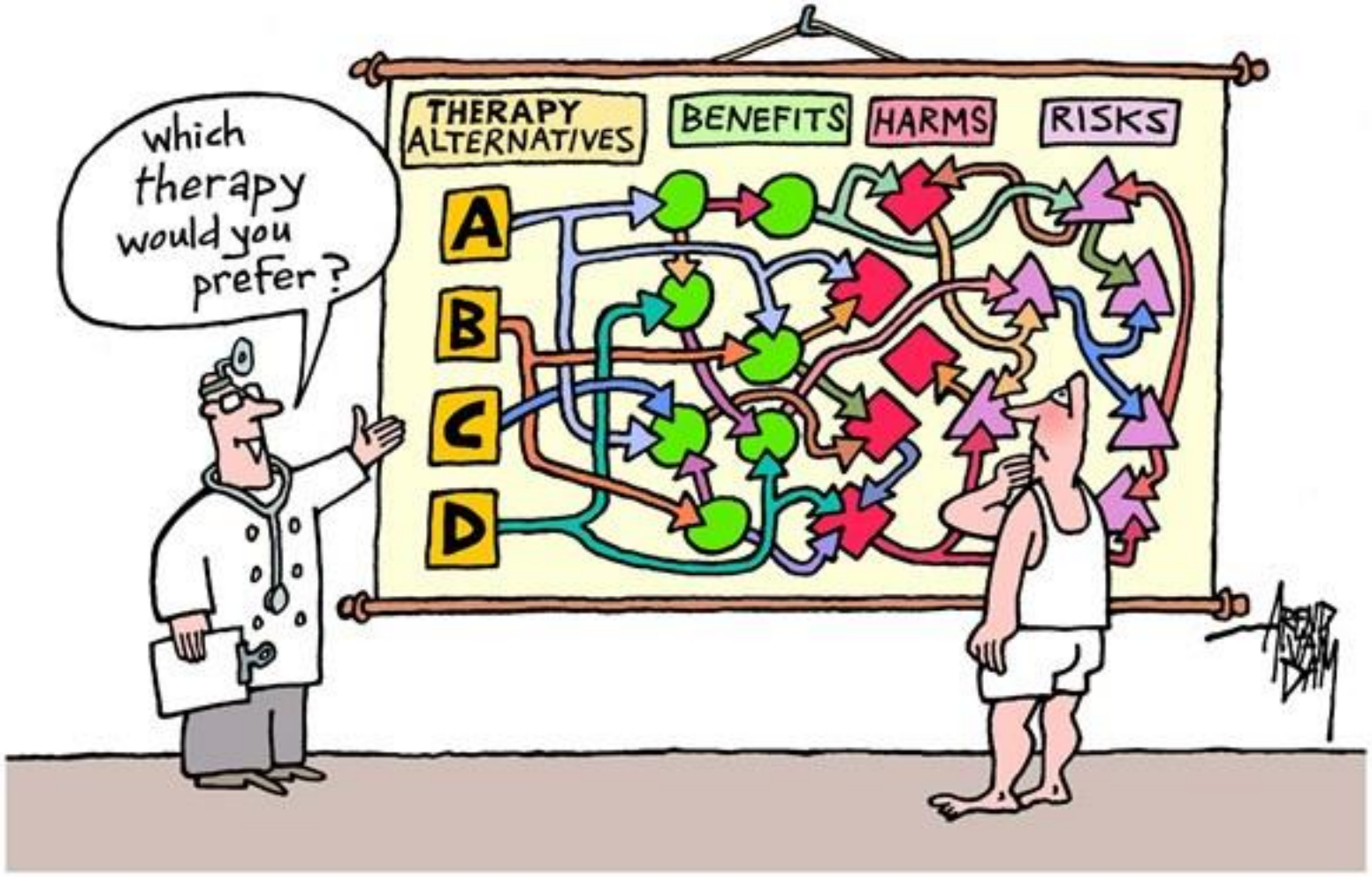
- 21st Century Cures Act → amendment to FDA informed consent requirement effective December 13, 2016
  - Informed consent **can be** waived for drug and device clinical investigations if the proposed clinical investigation pose no more than minimal risk and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject

More Background

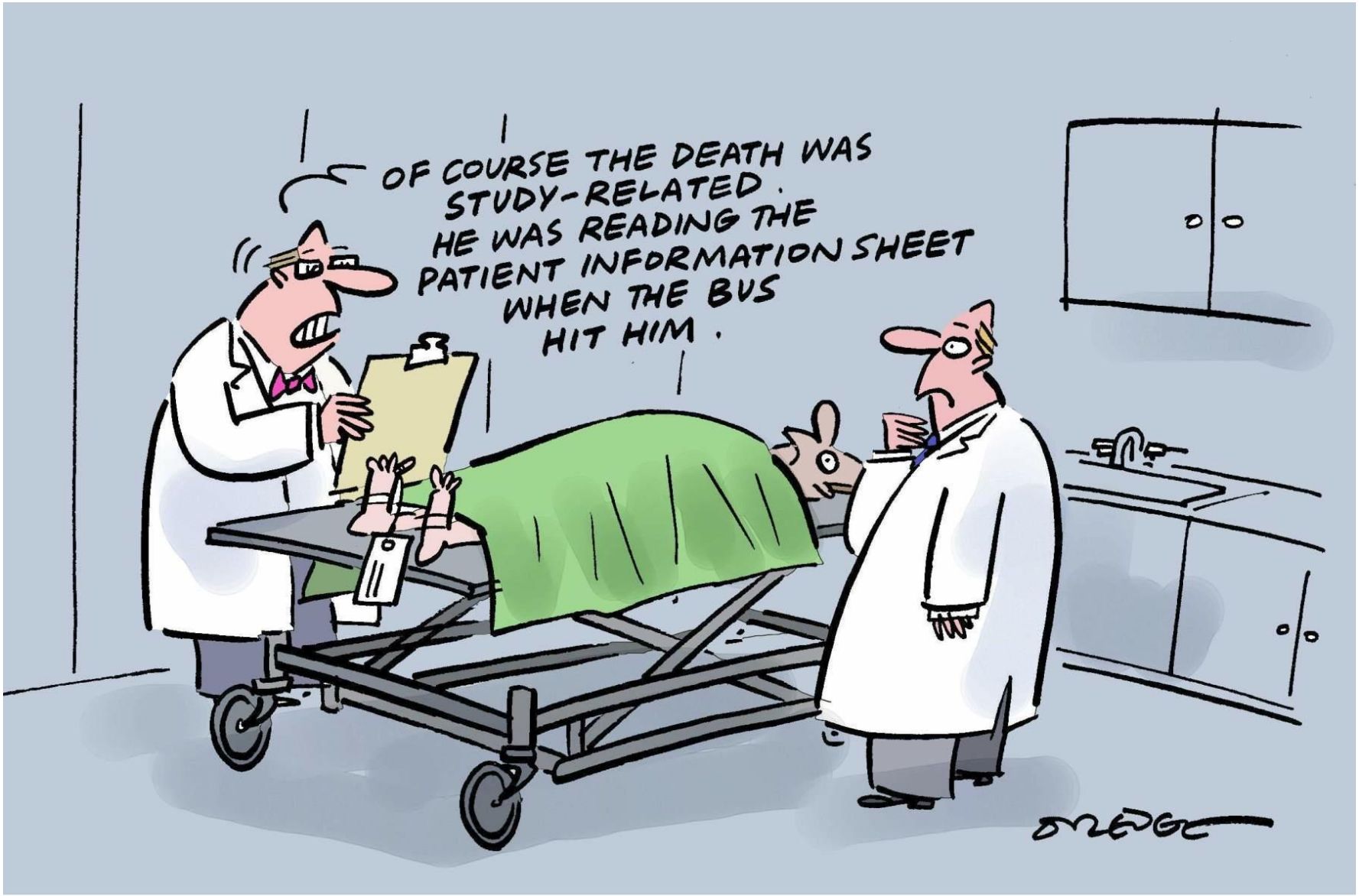
- Boundaries between clinical research and QI are vague
- Search for definitions/criteria on-going but controversial
- Limited empirical study
- Missing patient perspective

Statement of the Problem

- Oversight system designed to protect patients from abusive research practices vs. rapidly improve the care they receive
- Current system designed by providers, researchers, without patient input
- The current informed consent process is burdensome, time consuming, ill-timed and unintelligible to most patients



informed consent


OF COURSE THE DEATH WAS STUDY-RELATED. HE WAS READING THE PATIENT INFORMATION SHEET WHEN THE BUS HIT HIM.

Current Issues

- What is the perspective of patients, QI leaders and IRB leaders on whether quality improvement/CER studies can or should go on without consent?
- Which types of studies?

Overall Goal

- Three survey assessment to evaluate willingness to waive consent for quality improvement projects
- Target populations
  - Hospital Patients
  - QI leaders
  - IRB leaders
- Survey Design
  - Using example scenarios to determine willingness to waive consent for minimal risk quality improvement projects

How to Evaluate Consent?

- **Patient Survey**
  - Is providing permission necessary
- **QI Survey**
  - Identify reasonable and feasible QI study
- **IRB Survey**
  - Studies eligible for a waiver of consent

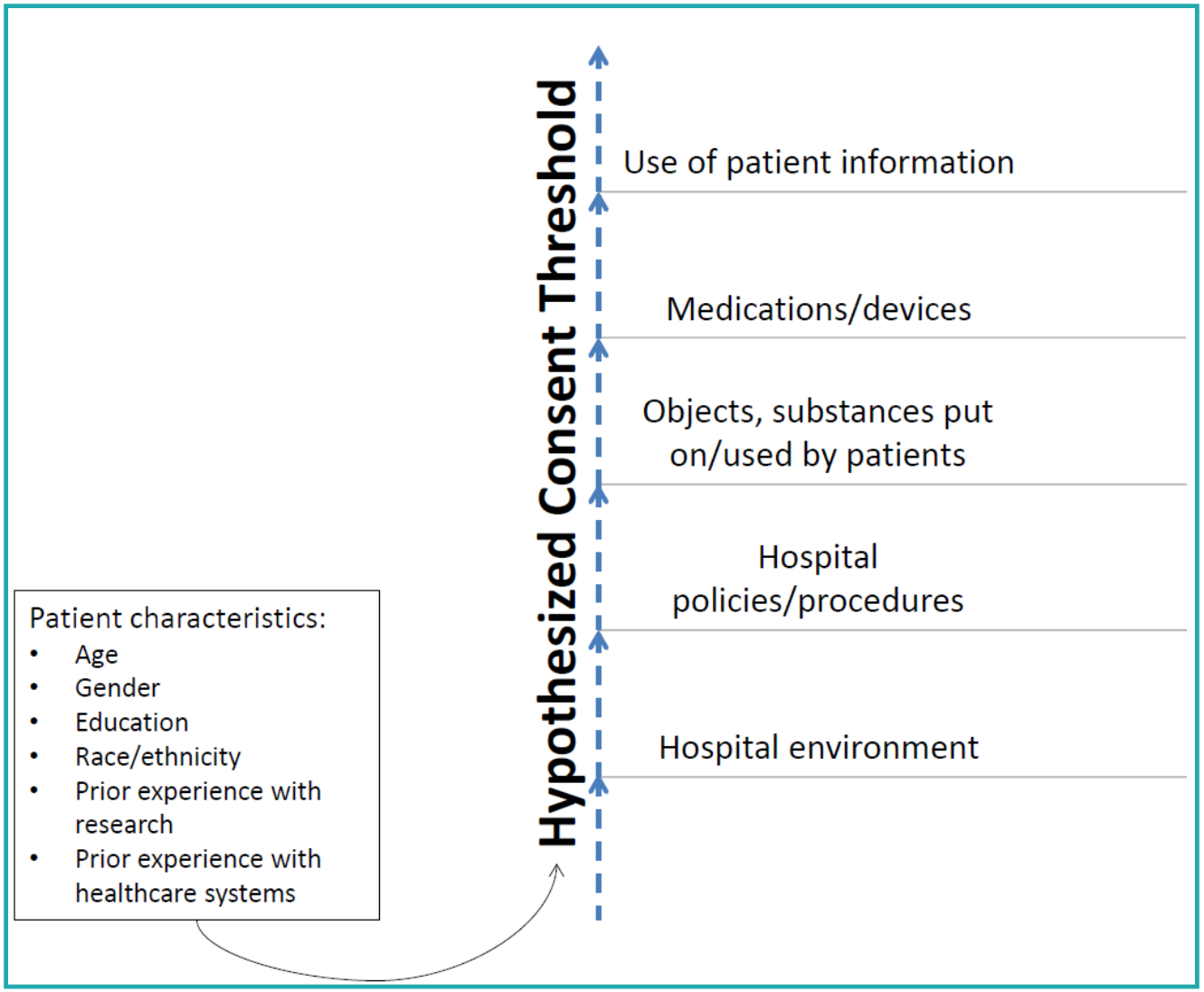
Survey item content development

- Using modified Delphi process, authors plus individuals who had been recently hospitalized, generated item content for each of 5 intervention categories
- Initially identified 53 items across 5 intervention categories
- Repeated modified Delphi process to ensure item fidelity with conceptual model, eliminate redundant items

Common Constructs Evaluated Across all 3 surveys

- Hospital Environment
- Things put on or used by patients
- Medication, Health Equipment ,and Devices
- Policies and Procedures
- Data, collection, use and sharing

Hypothesis and Conceptual Model



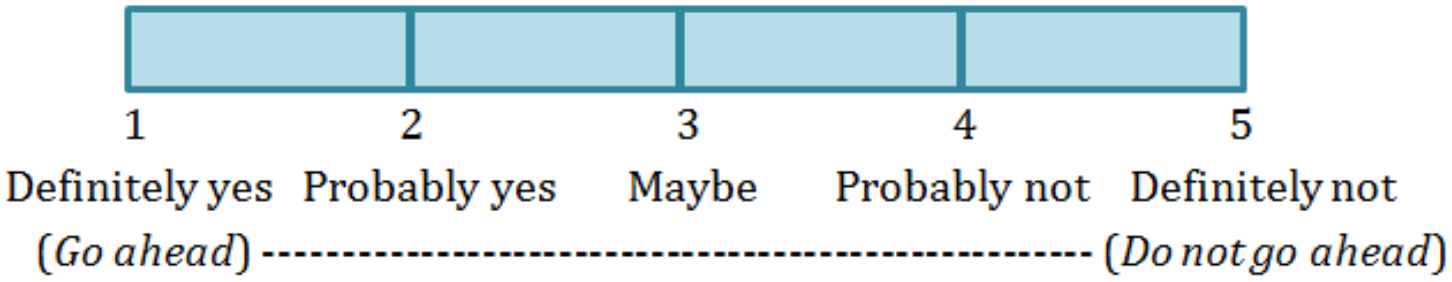
On listening to patients…

Prior Patient Survey

- Developed and tested survey-based measures of patients' "consent thresholds"
- Identified types and categories of interventions where patients were asked to consider if waiver of consent is required prior to implementation
- Study conducted at UC Irvine Douglas Hospital and Brigham and Women's Hospital
- Convenience samples at each institution identified from general medicine/surgical non-critical care units from Oct 2014-Mar 2015 → Total completed surveys: 200
- Published AJOB April 2016

Constructs

- Survey divided into 5 sections
- Each section's items reflect content specific to construct
  - E.g. hospital environment, medications, policies
- Patients were asked to score on a scale of 1-5 on whether they would allow the hospital to go ahead with an improvement project <u>without</u> their permission



Hospital Environment

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)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
a. Trying out different ways to reduce noise levels in hospitals at night? .	1	2	3	4	5
b. Comparing two types of privacy curtains around patient beds?	1	2	3	4	5
c. Trying out different places to put handrails in patient rooms to prevent falls?.....	1	2	3	4	5
d. Seeing whether using different cleaning products on things patients touch often (doorknobs, bed rails, call buttons) prevent infections?	1	2	3	4	5

Things Put on or Used 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)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
a. Trying out different types of bathing soaps to reduce the risk of infections?	1	2	3	4	5
b. Trying out different types of wound bandages to improve healing or reduce irritation?.....	1	2	3	4	5
c. Trying out which type of thermometers (oral, underarm, ear) work best for taking temperature?...	1	2	3	4	5
d. Seeing how long patients should wear stockings to prevent blood clots in the legs?	1	2	3	4	5

Medication and Devices

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)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
a. Comparing whether blood pressure lowering drugs work better when taken in morning or night?	1	2	3	4	5
b. Trying out the use of generic or less expensive versions of same drug vs. brand name drug?	1	2	3	4	5
c. Trying out different types of blood drawing needles to improve blood flow when drawing blood	1	2	3	4	5

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)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
a. Comparing different types of teaching materials to see which is best at educating patients about what to do after they leave the hospital?	1	2	3	4	5
b. Seeing whether getting patients up to walk sooner after surgery reduces problems (such as pneumonia, blood clots)?.....	1	2	3	4	5
c. Seeing whether having nurses call patients after they go home improves their care at home?.....	1	2	3	4	5

Data Collection, Use, and Sharing

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)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
a. Changing from paper to computerized medical records?.....	1	2	3	4	5
b. Including patient data (names and addresses) in disease registries (databases for specific diseases) for research?	1	2	3	4	5
c. Sharing pictures of the patient's body without the face with doctors, nurses, or students for teaching purposes? ...	1	2	3	4	5

Patient Survey – Validity and Reliability

- Identified valid and reliable survey-based measures for eliciting patient preferences for waiving consent for minimal risk quality improvement/CER studies
- Psychometric properties of measures suggest acceptability for group comparisons

Patient Survey – Reliability Results

Table 2. Description and Distribution of Newly Developed Consent Threshold Scales and Validation Variables (N=200)

Consent Threshold Scales	*K of Items*	*Scale Mean*	*Scale SD*	*Cronbach's Alpha*
Making changes in:				
The hospital environment	6	89.0	17.6	0.74
Hospital policies or procedures	7	86.0	18.6	0.75
Objects or substances that are put on or used by patients	7	86.7	20.0	0.83
Types of medications or devices used in hospitals	5	73.3	26.0	0.73
The ways hospitals collect, use, or share patient information	7	57.4	29.2	0.83

NOTE: Higher scores = more likely to waive consent

Patient Survey – Reliability Results

Table 2. Description and Distribution of Newly Developed Consent Threshold Scales and Validation Variables (N=200)

Consent Threshold Scales	*K of Items*	*Scale Mean*	*Scale SD*	*Cronbach's Alpha*
Validation Variables				
Comfort sharing PHI	4	75.4	22.8	0.91
Comfort sharing personal information online	7	56.5	23.8	0.88
Trust in hospitals	6	54.2	18.0	0.73

NOTE: Higher scores = more likely to waive consent

Patient Survey – Validation Results

Table 3. Consent Threshold Scales for Selected Patient Characteristics(N=200)

Consent Threshold Scales	*Age <50 Years* *Mean (SD) N=90*	*Age ≥50 Years* *Mean (SD) N=110*	*Mean Difference (+95% CI)*
Making changes in:			
The hospital environment	87.9 (18.4)	89.9 (17.0)	-2.1 (-7.0, 2.9)
Hospital policies or procedures	83.5 (21.2)	88.1 (15.9)	-4.6 (-9.7, 0.6)
Objects or substances that are put on or used by patients	83.4 (21.9)	89.4 (17.8)	-6.0* (-11.6, -0.5)
Types of medications or devices used in hospitals	70.7 (26.4)	75.4 (25.6)	-4.6 (-11.9, 2.3)
The ways hospitals collect, use, or share patient information	53.3 (29.0)	60.8 (29.1)	-7.4 (-15.6, 0.7)

*p<0.05
**p<0.005
***p<0.0001

NOTE: Higher scores = more likely to waive consent

Patient Survey – Validation Results

Table 3. Consent Threshold Scales for Selected Patient Characteristics(N=200)

Consent Threshold Scales	*Poor/Fair Health Rating* *Mean (SD) N=75*	*Good to Excellent Health Rating* *Mean (SD) N=125*	*Mean Difference (+95% CI)*
Making changes in:			
The hospital environment	84.6 (22.1)	91.7 (13.7)	-7.1* (-12.1, -2.1)
Hospital policies or procedures	78.4 (21.9)	90.6 (14.5)	-12.2*** (-17.3, -7.2)
Objects or substances that are put on or used by patients	81.7 (24.0)	89.7 (16.5)	-8.0* (-13.7, -2.4)
Types of medications or devices used in hospitals	64.5 (28.5)	78.6 (22.9)	-14.1*** (-21.3, -6.9)
The ways hospitals collect, use, or share patient information	48.8 (28.3)	62.6 (28.6)	-13.8** (-22.0, -5.6)

*p<0.05
**p<0.005
***p<0.0001

NOTE: Higher scores = more likely to waive consent

Current Results: Comparison across Patient, IRB and QI Surveys

IRB Survey

- Used the same 5 constructs and example scenarios as the patient survey
- IRB directors and chairs were asked whether they would grant a waiver of consent
- Participants contacted by PRIM&R leadership using membership contact information for those self-identified as IRB directors or chairs
- Request for participation 7/16/15 to 9/30/15 with 3 sets of reminders → Total completed surveys: 172

IRB Survey: Respondent Characteristics

- # of respondents: 172

Respondent Roles	
IRB Director	69
IRB Chair	57
IRB Administrator	7
Other	30

Respondent Degrees/Certificates	
MD/DO/DDS	33
Doctorate (PhD, ScD, JD)	48
Masters (BSN, BS, BA)	89
Certified IRB Professional	146
PRIM&R Member	125
Other	15

IRB Survey: Respondent Characteristics

Types of Research Expertise/Experience	
Phase 1-3 clinical studies	113
Post-marketing clinical studies	105
Quality improvement research	126
Community-based comparative effectiveness research	87
Device/Engineering studies	83
Genetic Research	78
Other	56

QI Survey

- Used the same 5 constructs and example scenarios as the patient survey
- QI leaders were asked to consider if ok to waive consent for the project
- Two target population of participants contacted
  - Society of medical directors for infection prevention (SHEA)
  - Hospital Corporation of America QI leaders
- Request for participation occurred 1/29/15 to 4/6/15 with 3 sets of reminders for each group
  - Completed SHEA surveys: 109
  - Completed HCA surveys: 101

QI Survey

- Distributed to QI leads at Hospital Corporation of America and SHEA Research Network members
- # of respondents: 210

Average Years QI Experience	16

Respondent Degrees	
Masters	68
RN/BSN	37
PhD	11
MD/DO	83
Other	11

Respondent Roles	
Director of Infection Prevention	101
Chief Quality Officer	36
Director of Quality Improvement	37
Director of Patient Safety	11
Chief Medical Officer	2
Chief Nursing Officer	5
Care Coordinator	1
Other	33

Comparison of Respondent Characteristics

	Patient Respondents N=200	IRB Respondents N=172	QI Respondents N=210
	N (%)	N (%)	N (%)
Age (Mean, SD)	52.6 (17.1)	52.8 (11.2)	51.1 (9.8)
Female	108.0 (54%)	101.0 (65.2%)	149.0 (71%)
Overall health rating (scale mean, SD)	47.0 (29.2)	73.7 (23.9)	77.3 (24.9)
Education			
Less than college graduate	104.0 (52%)	0	0
College graduate	66.0 (33%)	21.0 (12.1%)	37.0 (17.6%)
Master degree	16.0 (8%)	52.0 (30.1%)	68.0 (32.4%)
Doctorate degree	14.0 (7%)	78.0 (45.1%)	94.0 (44.8%)
Years of experience (QI/IRB) (Mean, SD)	– –	9.3 (6.2)	15.5 (8.8)
Prior participation in research studies (mean, SD)	3.1 (3.6)	– –	– –

Reliability

Consent threshold scales and validation variables

	K of Items	Patients (N=200)	IRB Leaders (N=172)	QI Leaders (N=210)
		Cronbach's alpha	Cronbach's alpha	Cronbach's alpha
Making Changes in:				
Hospital Environment	6	0.76	0.94	0.91
Hospital policies or procedures	7	0.76	0.83	0.88
Objects or substances put on or used by patients	7	0.83	0.92	0.91
Types of medications or devices used in hospitals	5	0.73	0.86	0.81
Ways hospitals collect, use, or share patient info	7	0.82	0.75	0.73
Validation variables				
Comfort sharing PHI in a protected manner	4	0.91	0.90	0.89
Comfort sharing personal information online	7	0.88	0.72	0.84

Relationship of Consent Threshold Scales to Validation Variables

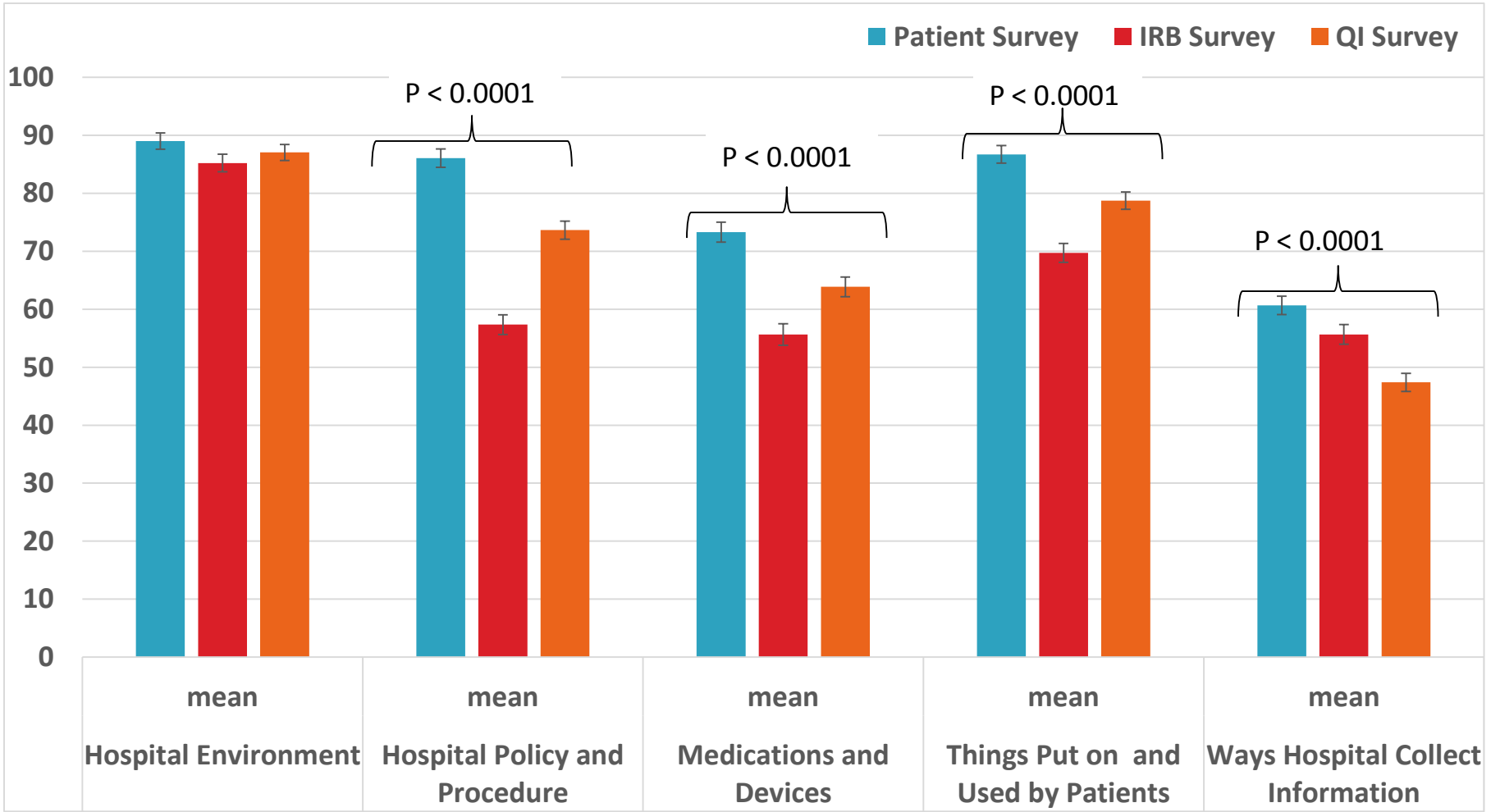
IRB Respondents (N=172), QI Respondents (N= 210)

Consent Scale*	Population	Comfort sharing PHI in a protected manner	Comfort sharing personal information online
Hospital environment	QI	**0.35***	0.12
	IRB	**0.25***	0.14
Hospital policies or procedures	QI	**0.38***	**0.23***
	IRB	**0.21***	0.14
Objects or substances that are put on or used by patients	QI	**0.34***	**0.23***
	IRB	**0.24***	0.19
Types of medications or devices used in hospitals	QI	**0.29***	**0.30***
	IRB	0.14	0.16
The ways hospitals collect, use, or share patient information	QI	**0.41***	**0.25***
	IRB	**0.34***	**0.23***

*$p < 0.01$

Consent Threshold Scales

Patient survey (N=200), IRB Survey (N=172), QI Respondents (N= 210)



Summary

- Reliability of consent threshold scales adequate for group comparisons
- Scales had significant relationships to most validation variables
- Groups differed on thresholds for consent by type of study
- Patients more likely to waive consent for all study types compared to other QI and IRB respondents

Policy Implications, Future Directions

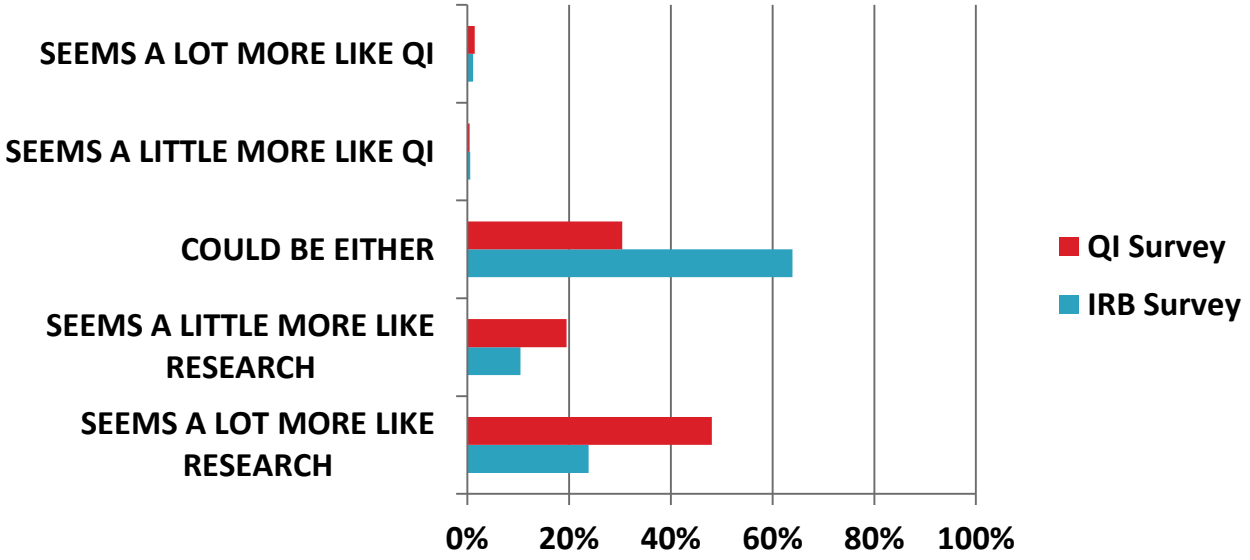
- Consent processes evolving in face of increasing demand for rapid answers to policy and clinical practice questions
- Increased emphasis on replication of study findings
- Understanding consent thresholds by types of study takes on amplified importance
- Changing regulatory requirements (e.g. FDA) may clarify or confuse boundaries between QI and research
- Protections against discovery for QI studies may need more scrutiny

Additional Explorations: IRB and QI Surveys

IRB vs QI survey Respondents:
Quality Improvement vs Research

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

Are funded by external sources (such as private donors, federal funding agencies, industry funds)

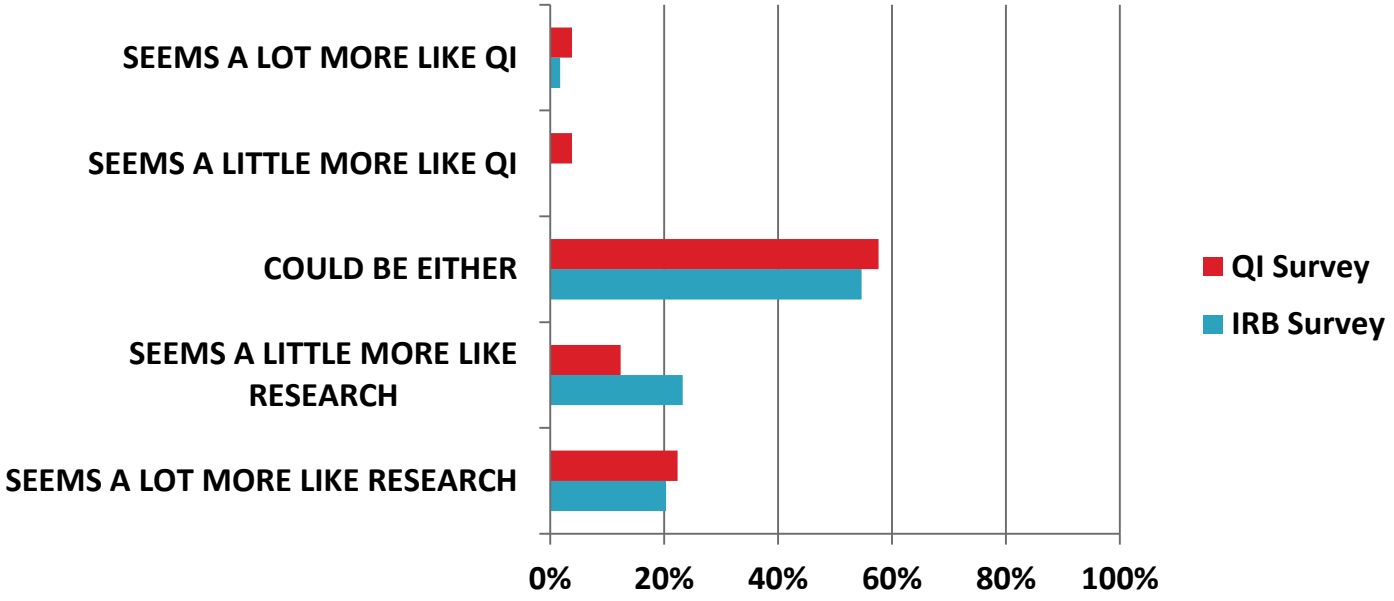


IRB vs QI survey Respondents

Quality Improvement vs Research

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

Include multiple participating hospitals

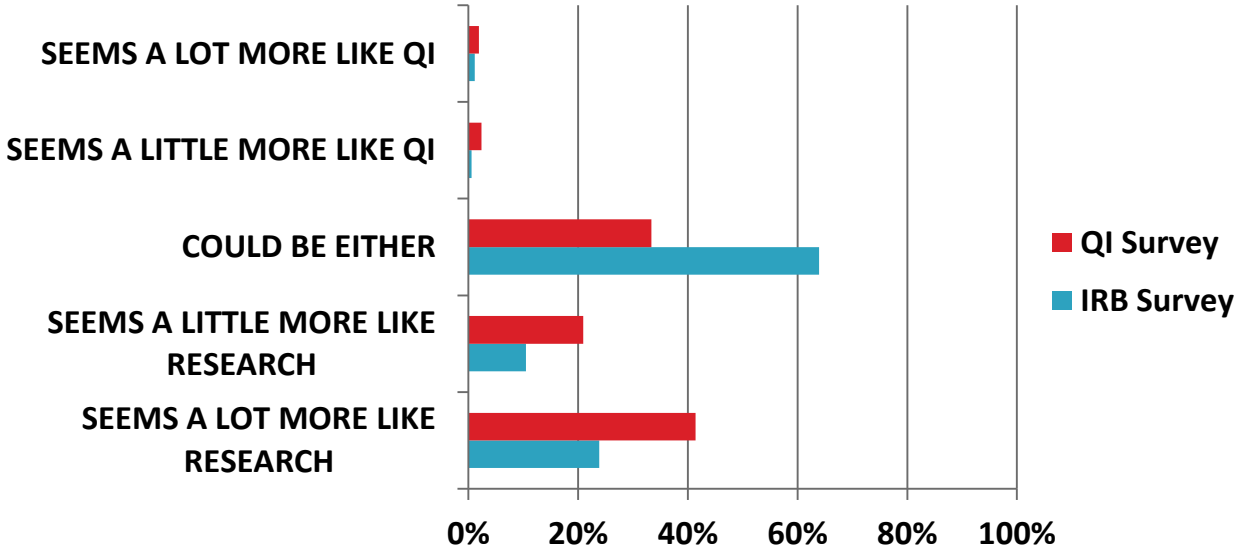


IRB vs QI survey Respondents

Quality Improvement vs Research

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

Include vulnerable populations (such as those who are children, fetuses, or mentally incapacitated)

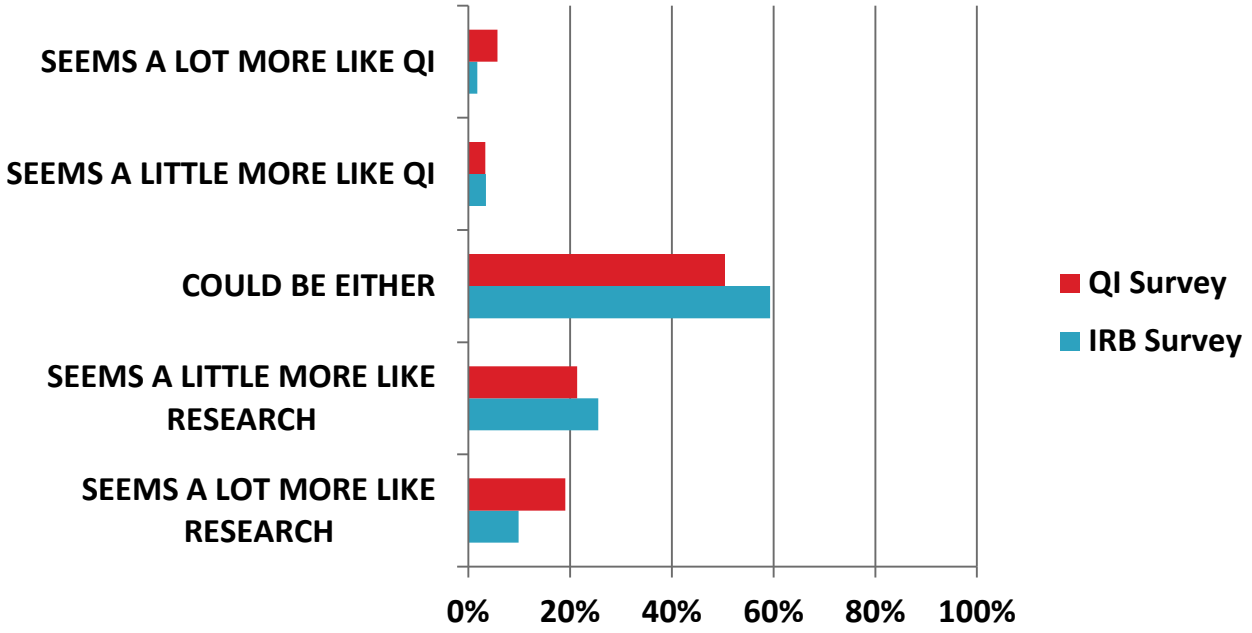


IRB vs QI survey Respondents

Quality Improvement vs Research

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

Involve sending data to an external site for analysis

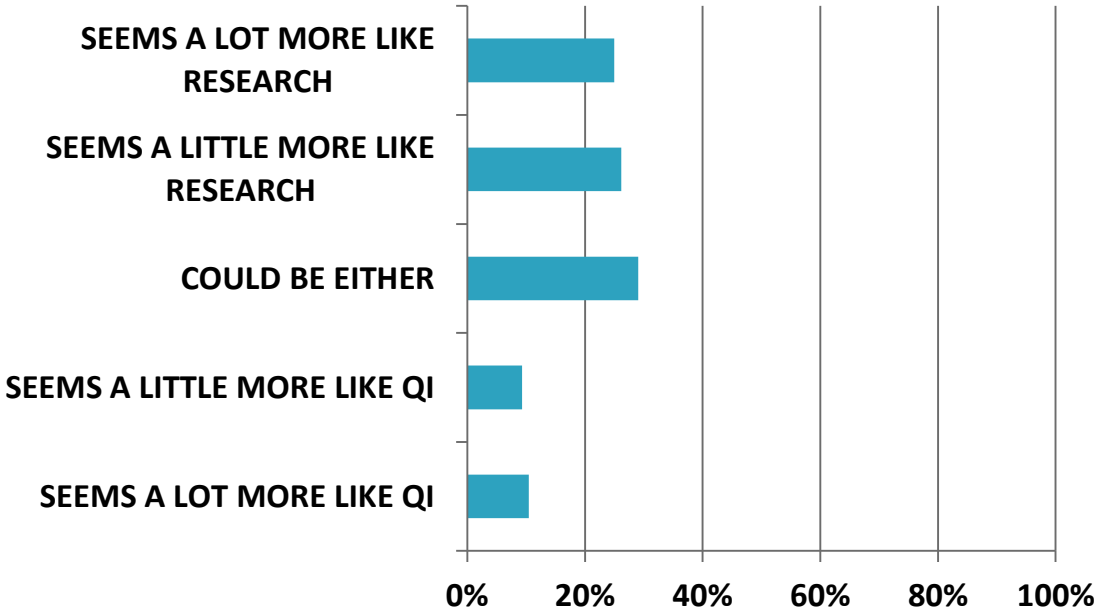


The Impact of Randomization

IRB Survey:
Randomization of QI Strategies

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

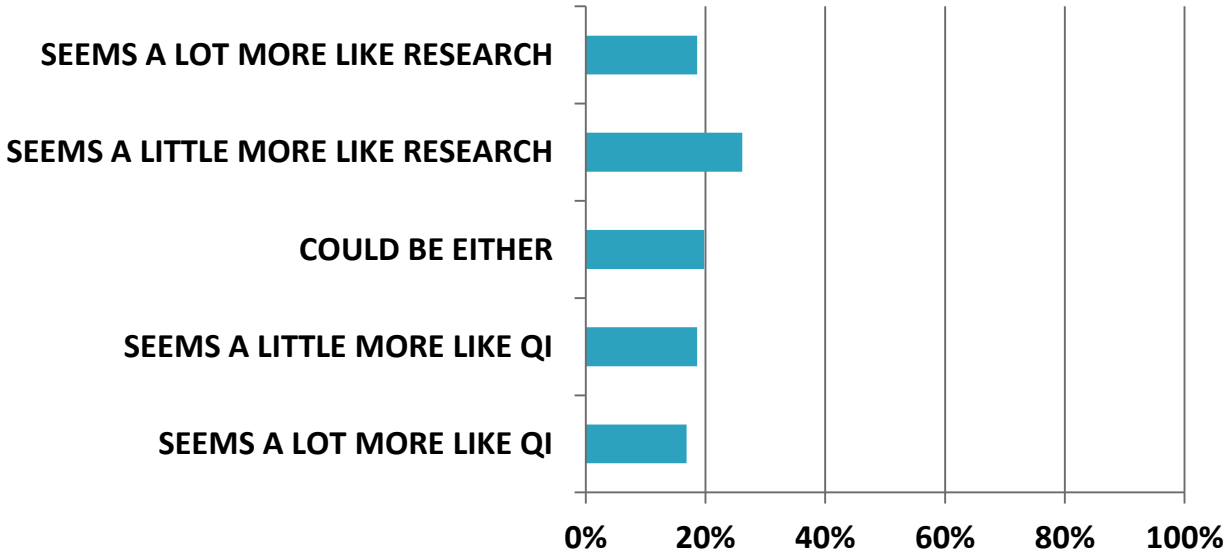
Involve a randomized comparison of quality improvement strategies



IRB Survey:
Randomization of Environmental Cleaners

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

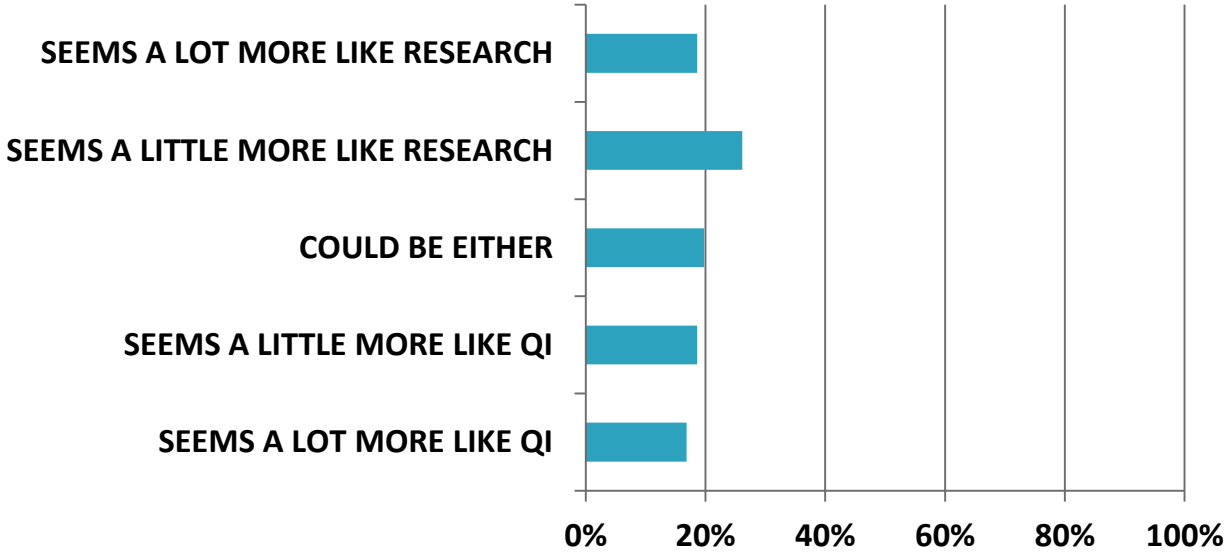
Randomize hospitals to different environmental interventions (such as two different floor cleaners)



IRB Survey:
Randomization of Drug Formularies

Which of the following would you consider to be more like research (i.e. requires patient consent) vs. quality improvement projects (i.e. would NOT require patient consent)?

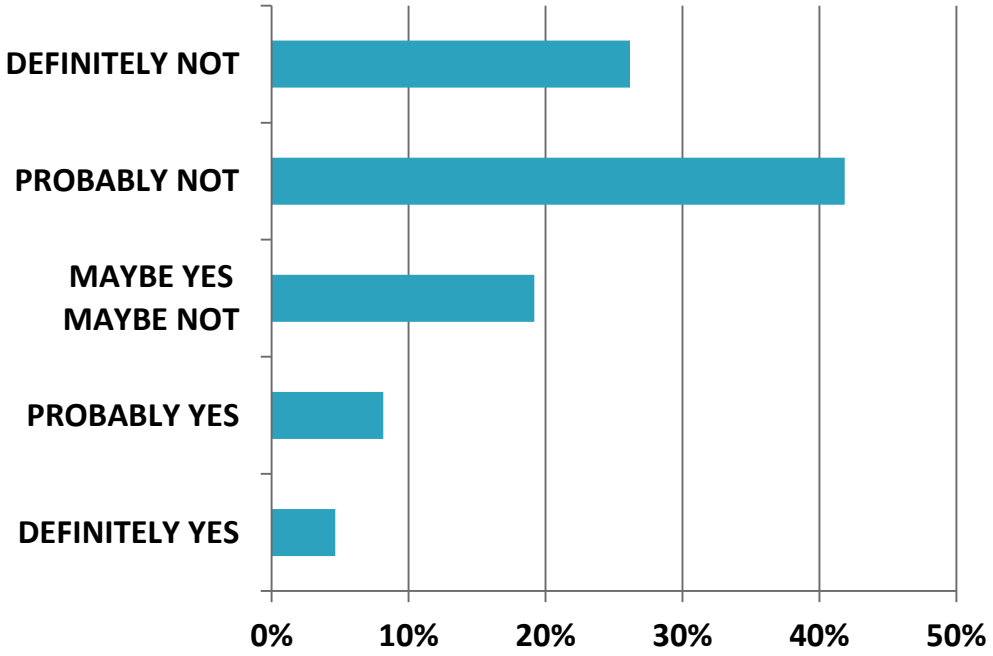
Randomize hospitals to test changes in drug formularies



IRB Survey:
Randomization of Minimal Risk Strategies

In your IRB review of projects, should each of the following apply?

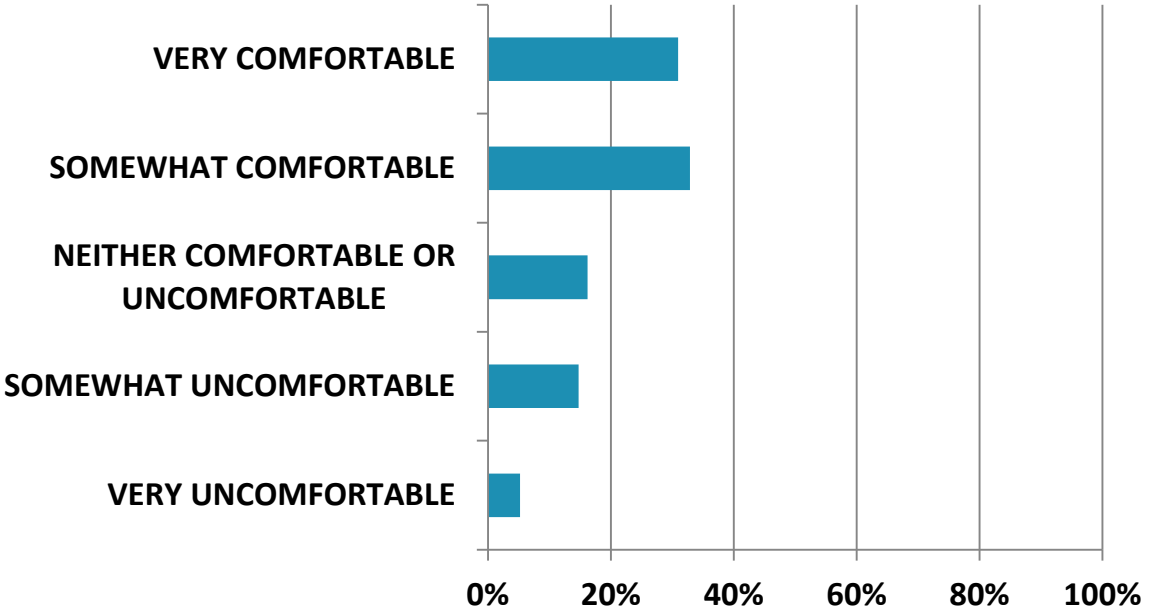
For a minimal risk intervention, should randomization of hospitals to receive the intervention automatically make the study no longer minimal risk?



QI Survey:
Randomization in QI

How comfortable would you feel recommending that your hospital participate in a QI Collaborative if:

Requires that hospitals be randomized (such as one of two products or one of two start times)?



Questions?

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- Rebecca Kaganov, BA

- **Hospital Corporation of America (HCA)**
- **The Society for Healthcare Epidemiology of America (SHEA)**
- **Public Responsibility in Medicine and Research (PRIM&R)**