UNIVERSITY OF CALIFORNIA,
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Understanding the Patient Perspective in the Ethical Gray Space between Research and Quality Improvement

THESIS

submitted in partial satisfaction of the requirements
for the degree of

MASTER OF SCIENCE

in Biomedical and Translational Science

by

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Thesis Committee:
Professor Susan Huang, Chair
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DEDICATION

To

my parents, sister, family, and friends.

Your enduring love is what drives me to succeed and your compelling support is what makes it happen.

“You have brains in your head.
You have feet in your shoes.
You can steer yourself any direction you choose.
You're on your own. And you know what you know.
And YOU are the one who'll decide where to go...”
— Dr. Seuss, Oh, The Places You'll Go!

What you get by achieving your goals is not as important as what you become by achieving your goals.
— Henry David Thoreau

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ABSTRACT OF THE THESIS

Understanding the Patient Perspective in the Ethical Gray Space
between Research and Quality Improvement

By

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Master of Science in Biomedical and Translational Science

University of California, Irvine, 2014

Professor Susan Huang, Chair

Quality improvement (QI) projects and clinical research projects both contribute to the body of evidence that furthers clinical practice. With a recent shift in making research more pragmatic, the lines between QI and research can be blurred. The purpose of this study was to develop a survey aimed at understanding the patient's perspective on being part of QI and research projects in a hospital or health care system (HCS). The goal is to identify if a common ethical framework exists for the implementation of minimal risk projects. Additionally, we wanted to understand the drivers of patient's decisions pertaining to projects aimed at improving patient care. In order to assess this, we developed constructs, or subjects of measurement, of sequential examples that assess these concepts.
Patients were asked to select a response ranging from definitely yes to definitely not (Likert scale) on a number of questions related to their comfort level of providing their permission for hospitals to implement these projects. The surveys will allow us to better understand the patient perspective when it comes to improving patient care in a minimal risk setting. Their responses will enable us to establish when permission would be needed

to carry out certain activities intended to improve patient care. Additionally, the surveys may allow us to assess potential linkages between attitudes and actions and the strength of that association across various scenarios. Further data collection is needed to obtain a more concrete understanding of patient's comfort level in participating in patient care improvement projects.

CHAPTER 1: Introduction

Quality Improvement and Research Projects in Health Care

Improvement project in health care can generally fall into two groups, one is quality improvement (QI) projects and the other is research projects. However, despite their common conception between their differences, there are many more growing similarities between them. The distinction between QI and research is blurring with the increasing movement towards pragmatic trials and due to the nation's direction towards learning health systems (LHS). We aim to develop a survey that will enable us to better understand how patients view improvement projects in hospitals and what aspects would require them to provide their consent.

QI has been defined as "systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings". [1] This means that when a hospital wants to improve their policies for operational reasons they do so under the definition of a QI project. These projects are directly tied to local operations and are carried out by health care workers (e.g., nurse, physician, infection preventionist) under the lead of a quality director or hospital administration. The goal of QI projects is to identify opportunities for improvement as well as deficits in performance and to implement improved practices. [2, 3] Common examples of QI projects include revising health care worker training to improve nursing performance, allowing computerized orders for certain drugs so patients do not have to wait for a physician to sign off, or comparing two different protocols to see which better identifies patients with pneumonia.

The Office for Human Research Protections (OHRP) defines research projects as intending to contribute to generalizable knowledge.[4] Research can include such projects as surveying nursing home residents about their admission process to the nursing home, enrolling patients into a randomized trial comparing two types of drugs used to treat depression, or reviewing patient charts to assess the frequency of hospital-associated infections to see if a change in protocol is needed. These projects are conducted by trained investigators and study coordinators who have received IRB approval to implement the research in order to improve health care by sharing their findings with the medical community.

Pragmatic Clinical Trials and Learning Health Systems

Pragmatic trials aim to evaluate the effectiveness of interventions in routine practice conditions [5] They allow researchers to be more inclusive in their subject populations (not exclude certain populations) making the findings more generalizable. Findings of pragmatic trials are more likely to be able to be applied to real world settings inside of health care systems. An example of a pragmatic trial is the REDUCE MRSA Trial, which randomized ICUs within a hospital to one of three QI strategies aimed at reducing rates of methicillin-resistant Staphylococcus aureus (MRSA). The QI interventions were implemented as part of the hospital's standard care procedures and therefore included entire ICU populations across all randomized hospitals.

A learning healthcare system (LHS) is designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety,

and value in health care.[6] There are several aspects to a LHS, one it encourages hospitals to work together to implement best practice guidelines, it also integrates research into practice.[7] Furthermore, LHS enable us to learn more, faster, and broader while contributing to generalizable knowledge.

Overlap Between QI and Research

An ethical conflict exists since QI and research project can be very similar, especially when focusing on minimal risk research, where "the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".[8] The distinction between QI and research is decreasing even further with research moving towards a learning health system (LHS), which contributes to generalizable knowledge.

Furthermore, with organizations such as the National Quality Forum (NQF) aiming to improve performance measures within U.S. hospitals, the importance of understanding the similarities between QI projects and research projects is critical.[9] Recent concepts of a learning health system [10] have raised awareness of the inefficiencies of limiting advancements to research projects and have advanced the important notion of "learning while doing," whereby healthcare facilities and providers group day-to-day data, knowledge, and experience to continually and more rapidly inform best practice. A LHS allows hospitals to use existing infrastructures and tailor them in a way that hospitals can learn as they go about their day-to-day activities.

While overlap between QI and research is common, they do hold two different governing bodies. QI projects are overseen by hospital operations and quality improvement teams while research projects are governed by an Institutional Review Board (IRB).[11] However, other than the issue of the intent of the project, the projects that can be pursued under research and QI can be similar if not identical. Such an example can be the use of chlorhexidine (CHG) bathing. Findings of the benefits of CHG bathing have been published as both QI project results[12] as well as research findings. [13] Due to these similarities, we set out to create a survey to understand how patients view providing their consent for projects aimed at improving their quality of care.

Ethical Framework of QI and Research Projects

The practical implementation of a learning health system requires thoughtful attention to the ethical boundaries of research and quality improvement.[14-19] This increasing overlap and merging of the two projects is why we believe that QI and minimal risk research studies should have a single ethical framework aimed at evaluating the project based on what it entails rather than stratifying it to either be labeled as QI or research. However, more work is needed to understand key stakeholder's views (i.e., IRB directors/chairs, QI managers, and patients) on creating a single ethical framework for implementing these type of studies.

CHAPTER 2: Background

Project Background

This project is part of the NIH Health Care Systems Research Collaboratory, which aims to improve the way clinical trials are conducted by creating a new infrastructure for collaborative research.[20] In addition, the collaboratory has invested greatly in pragmatic clinical trials such as the ABATE Infection Project, which is the parent trial of this supplemental project. The ABATE Infection Project works with a health care system to enroll 50+ hospitals into a pragmatic trial aimed at preventing infections in non-critical care units. The study waives consent and uses existing infrastructures to implement the intervention and routine care arms, making it a pragmatic study. Studies like this are becoming more common, which makes having a better understanding of viewpoints towards patient improvement studies even more important.

The Collaboratory provided us with supplemental funding as part of their ethics/regulatory core to implement a project aimed at addressing ethical dilemmas in research. In our proposal, we wanted to add to address the viewpoints of various stakeholders when it came to implementing patient care improvement projects. These stakeholders include IRB chairs and directors, QI managers and directors, as well as hospitalized patients. We selected these stakeholders as they all are invested in making improvements in patient care. To quantify stakeholders' viewpoints, we proposed to develop three linked surveys, the first aimed at patients, the second at QI managers, and

the third at IRB directors or chairs. These surveys would allow us obtain a better understanding on stakeholder's opinion on minimal risk studies.

Grant Goal

The patient survey used for this thesis is part of a larger grant funded by the National Institutes of Health (NIH) as an ethical supplement. The grant highlights and addresses the ethical gray space related to the interface of research and quality improvement studies, as they would ideally be applied to LHS. The goal of the grant is to provide valuable insight into the modifications needed to make ethical and regulatory standards pragmatic and relevant to research studies in LHS. This will include insight into the regulation of population-based research designs, the ethics of randomization, multi-center oversight, consent for research involving quality improvement initiatives, and other key controversial issues. We will administer three separate but linked surveys to key stakeholders – IRB directors/chairs, QI leaders, and hospitalized patients – to inform the discussion of how to integrate their ethical frameworks into a consistent guidance structure for research involving quality improvement strategies. This project is currently in progress with the patient survey data collection ongoing. We anticipate starting data collection for the QI and IRB surveys in early 2015. The combined responses from all three surveys will allow us to identify if a common ethical framework exists for the implementation of minimal risk projects.

Patient's Perspective

It is imperative to include patients in understanding their perspective since they are part of making improvements in the hospital. The surveys will allow us to better understand the patient perspective when it comes to improving patient care in a minimal risk setting. Their responses will allow us to establish when permission would be needed to carry out certain activities intended to improve patient care. We should be able to assess the frequency with which certain elements were required and assess the attitudes that may drive specific actions (e.g., patient participation in a research project). Additionally, the surveys may allow us to assess potential linkages between attitudes and actions and the strength of that association across various scenarios.

Furthermore, being able to understanding patients' expectations of either unknowingly being part of a QI project or knowingly being part of a research project (provide their permission) offers important insight into this dilemma. When do they perceive their potential benefits outweigh any potential harms? What hospital procedures can be changed? What data can be shared without their knowledge and/or without their consent? Patients' responses can provide us with valuable insight into the modifications needed to make ethical and regulatory standards pragmatic and relevant to research studies in LHS. Finally, the survey responses provided us with an innovative assessment of communication elements that influence patient understanding of QI initiatives and research projects and improve trust and willingness to participate in studies intended to improve patient health and safety.

Filling the Gap

In years past, medical-care improvement was generally an informal, fragmented activity, largely the work of individual practitioners. In recent years, however, as both public and professional pressure for improvement has grown, medical QI has become increasingly planned and organized, involves large numbers of participants, and requires the collection and analysis of data, thus, superficially at least, coming to resemble clinical research.[21] The patient surveys may provide some insight into which factors drive patients to require giving their permission for QI initiatives and research projects aimed at improving best practice within a learning health system or hospital. This in turn may allow us to create better guidance for implementing QI projects along with minimal risk research projects as part of a single ethical framework.

Purpose of Patient Survey

The purpose of the survey was to understand what factors affect patients when allowing changes in hospitals to take place. The patient survey we implemented allowed us to compare and contrast critical elements of QI initiatives devoid of research intentions and research that focuses on QI targets. Our intent is to explore areas where a double standard may exist for the conduct of similar studies and to attempt to resolve these discrepancies in favor of ethical consistency and guidance that will enable development of a LHS combined with appropriate ethical and regulatory oversight.

> While professionals and organizations have an ethical responsibility toward patients and an obligation to meet certain expectations of quality and care, the suggestion that patients are also morally obligated to participate in

> improving the quality of care is somewhat novel. The argument in support of this is that an individual seeking care from a healthcare organization cannot refuse to at least minimally cooperate in activities to improve care without thwarting the very (quality) benefit she or he seeks from that organization.[22]

This type of overlap can make research projects gear towards a QI initiative. Especially since the Common Rule requires research to be reviewed and approved by an IRB. However, QI projects do not have the same requirement as they are considered part of hospital policy. We set out to understand the ethical construct of research versus quality improvement projects.

Conceptual Model

The development of our conceptual model for this survey started out with the overlap in research and QI projects. We wanted to address the projects that fall within the research/QI intersection and understand if we can generate a single ethical framework for them. We hypothesized that the conceptual framework would be a reflective model, where our related measures reflect the underlying constructs.

Thesis Focus

The focus of this thesis is the assessment of consent in minimal risk studies focused on hospital improvement. While the problem in understanding the differences between QI and research is large, we focused on minimal risk research in order to be able to compare the types of interventions being implemented to QI projects. The reason we chose to sample from an inpatient population is because they can experience both QI projects and

research projects while being in the hospital. Therefore, they would be able to provide their opinion pertaining to implementation of these projects. This would allow us to understand patients' ethical disposition in the issue of consent for hospital improvement projects. We developed a survey that allows us to assess whether patient consent is based on the type of project that is being implemented (i.e., research vs. QI) and what factors they perceive as risk.

CHAPTER 3: Methods

Study Design

The primary goal of this thesis was survey development. We developed a survey using published survey methods to understand patients' personal perceptions of the boundary between QI and research regarding their need to provide their consent to proceed with hospital improvement projects. The targeted survey population was I served as the project coordinator of the survey development team, hospitalized patients at the University of California Irvine Medical Center, Orange, CA and Brigham and Women's Hospital (BWH), Boston, MA. The finalized survey was approved by the UC Irvine Office of Research IRB (HS# 2013-9843) as well as by the BWH IRB (protocol# 2013P002629/BWH).

SURVEY DEVELOPMENT

Survey Development Team

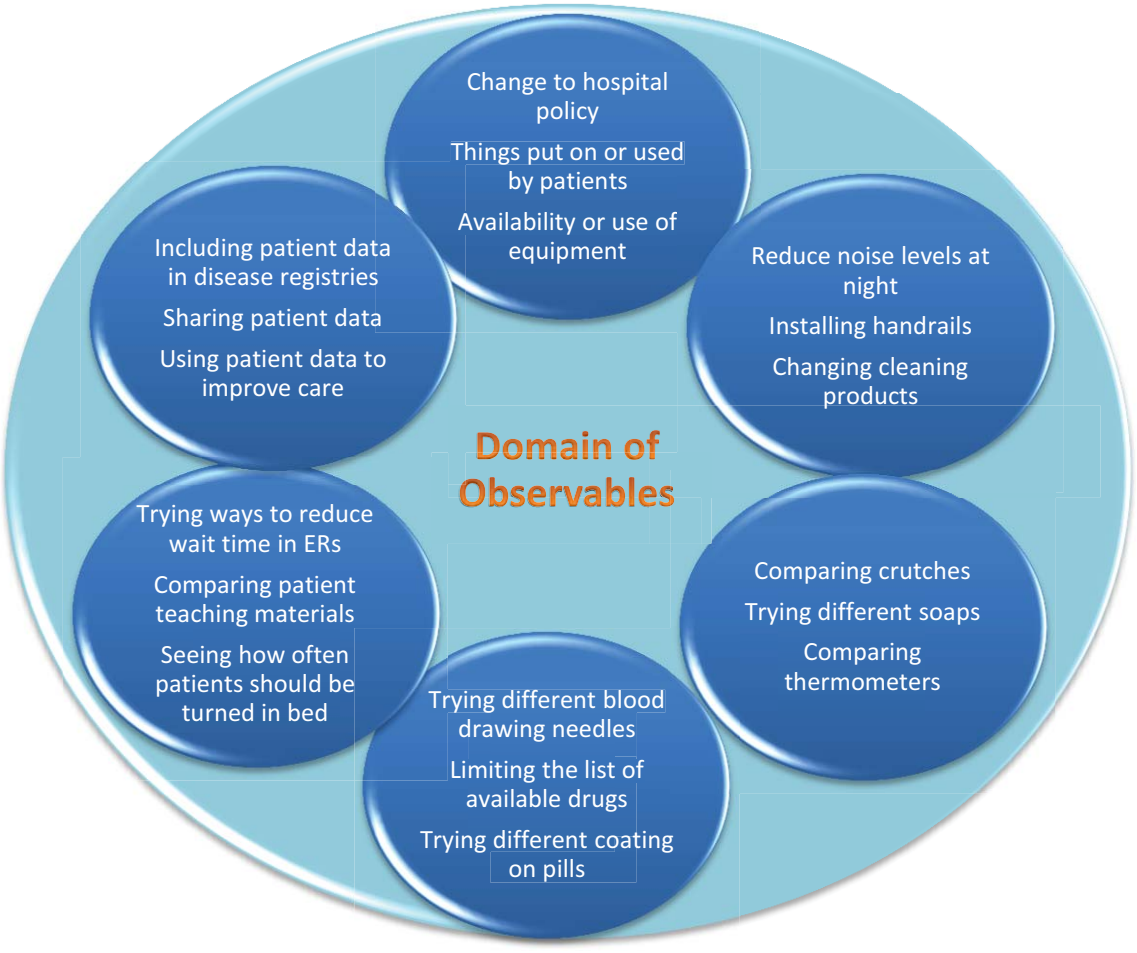
I served as the project coordinator of the survey development team, which included Susan Huang, MD MPH, Professor of Medicine and Director, Epidemiology and Infection Prevention at UC Irvine, Jim Sabin, MD, Professor of Population Medicine and Psychiatry, Director, Ethics Program at Harvard Pilgrim Health Care Institute, and Sherrie Kaplan, PhD Professor of Medicine, Assistant Vice Chancellor for Healthcare Evaluation and Measurement at UC Irvine. Additionally, guidance was provided by Sheila Fireman, JD, Director, IRB at Harvard Pilgrim Health Care Institute, David Vulcano, Associate VP of Clinical Research, Hospital Corporation of America (HCA), as well as the NIH Collaboratory Ethics Core Working Group and Steering Committee. Since our survey development team

included experts from various fields, we were able to work together with them to ensure the content of the survey was appropriate (i.e., the stems were credible, common, and addressed the questions we wanted to answer), rather than vetting the survey by experts after the survey was drafted.

Domain of Observables

We initially sampled from a large pool to obtain an exhaustive list of item development. Our domain of observables focused on projects aimed at improving patient care in hospitals or LHS.

Figure 1. Domain of Observables



Survey Constructs and Item Development

Our goal was to create a survey that would allow us to measure a patient's comfort level in providing their consent for various patient care improvement methods. We wanted to understand the drivers of patient's decisions pertaining to projects aimed at improving patient care. In order to assess this, we developed constructs, or subjects of measurement, of sequential examples that assess these concepts.

We started our draft survey outline by discussing various avenues pertaining to patient improvement projects. Construct development included classifications such as interruption of care to understand when patients would allow for their medical care to be interrupted in order to provide their consent for a patient care improvement project. Additionally, we wanted to understand if a difference exists in patients' perception as to who is implementing the project (e.g., nurse, physician, researcher). In order to measure these responses, we decided to draft the response options on a Likert scale. Finally, we included validation questions such as "In general, how would you rate the ways hospitals use patient experiences to improve the care they give?" which enabled us to ensure our concepts were well established throughout he survey.

Once we limited our focus, we were able to develop our constructs, which aimed to understand patient's comfort level in providing their consent for various types of studies that address changes to improve patient care. Below are the sample categories of studies we used to ensure we were able to measure our constructs.

1) Hospital Care
    - Questions about the patient's general opinion for hospital improvement projects
2) Hospital Environment
    - Questions about when the patient would like to be asked for their permission before hospitals can make changes in patient care that involve the physical surroundings
3) Things Put on or Used by Patients
    - Questions about when the patient would like to be asked for their permission when hospitals make changes in things that are used by or put on patients
4) Medications or Devices
    - Questions about when the patient would like to be asked for their permission when comparing the ways hospitals use already approved medications or devices to improve patient care or experiences
5) Policies and Procedures
    - Questions about when the patient would like to be asked for their permission when hospitals compare changes in certain types of procedures, policies, or ways things are done
6) Data Collection and Sharing
    - Questions about when the patient would like to be asked for their permission when hospitals compare changes in the ways they collect, use, or share information with other healthcare providers

Pilot Testing and Cognitive Interviews

To ensure our response options to the items in question were clear, we initially conducted cognitive interviews with four patients to confirm our response options and questions were indeed answering the questions we want to understand. We then revised the survey based on the feedback from our interviewees and piloted the survey (after IRB approval) to six patients at UC Irvine Medical Center. During the pilot phase we timed each survey to ensure it would take 15-20 minutes to complete, we also wrote down any questions the patients asked during the survey where further clarification of a survey question was needed.

Inclusion Criteria

1) Admitted patients (in non-critical care units) at UC Irvine Medical Center, Orange, CA and/or Brigham and Women's Hospital, Boston, MA
2) Adults (≥18 years old)
3) Able to speak and understand English
4) Medically and mentally well enough to provide responses

Exclusion criteria were applied by unit charge nurses who were asked to provide a line list of patients who fit the requirements for survey administration for each collection period.

SURVEY COLLECTION

Setting and Sample

Surveys were administered to hospitalized patients at the University of California Irvine Medical Center in Orange, CA and Brigham and Women's Hospital in Boston, MA. The

survey was administered in person by trained research coordinators and entered into REDCap, which is a secure, web-based application for building and managing online surveys and databases. Study data were collected and managed using REDCap electronic data capture tools hosted at UC Irvine.[23] REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Data were collected for a two-month period (October-November 2014) in non-critical care units at both hospitals.

Data Collection

Once an eligible patient was selected based on the charge nurses recommendation, a trained research coordinator would provide them with a brief introduction to the survey (IRB approved study information sheet) and explain what it entailed. All research coordinators were trained and provided with a survey script to ensure the data collection procedures were uniform across coordinators and both sites. Upon introduction of the survey and verbal agreement from the patient to participate, an example question was provided along with the core response options. Additionally, patients were provided with the opportunity to have printouts of survey response options available should they like to reference them throughout the survey process. Research coordinators entered the data into a central data warehouse (REDCap) which allowed for a seamless export into Excel and SPSS for analysis. Furthermore, REDCap had an internal quality check, where an alert

would pop up if data was missing as it was being entered (in real time) during the survey process. This allowed us to ensure data was complete and no variables were missing.

Scoring System

The survey centered around questions pertaining to various types of QI and research projects. Patients were asked to select a response ranging from definitely yes to definitely not on a number of questions related to their comfort level of providing their permission for hospitals to implement these projects. The responses were scored on a Likert scale from one to five, one indicating definitely yes (go ahead without my permission) and five indicating definitely not (do not go ahead without my permission) as indicated in figure 2.

Figure 2: Scoring System

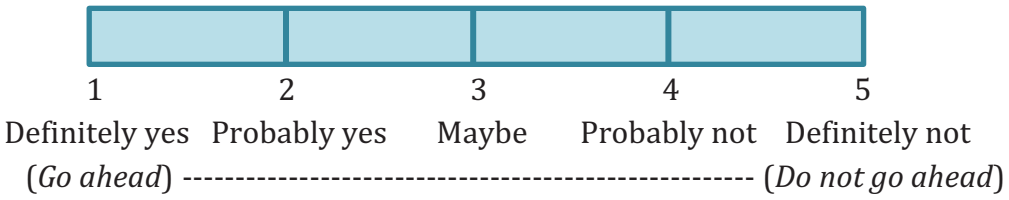
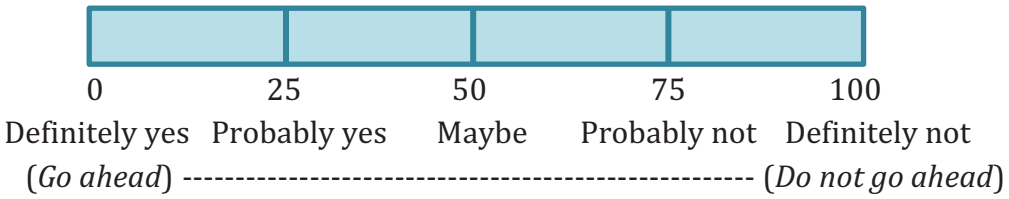


Figure 3: Transformed Scoring System



To make the results easier to interpret, the scores were transformed to a scale of 1-100 (figure 3). The scores to each response were then aggregated and averaged across each section. The lower the score the more comfortable the patients were with allowing the hospital to implement a project without their permission. The inverse is also true, the

higher the score the less likely the patients would allow hospitals to move ahead with a project without their permission.

Statistical Analysis

We ran a non-parametric correlation (Pearson's correlation) to asses for validity across the survey sections. Reliability was assessed with Cronbach's alpha, which was used to assess internal consistency.

CHAPTER 4: Results

LESSONS LEARNED FROM SURVEY DEVELOPMENT

Sampling from the Domain of Observables and Creating Constructs

Sampling form the domain of observables allowed us to better understand the constructs we wanted to test. The domain of observables reflected on what we wanted to measure, which is patient's comfort level in providing their consent for projects pertaining to improving patient care in hospitals or LHS. Our constructs focused on the drivers of patient's decisions pertaining to projects aimed at improving patient care.

Drafting Response Options and Question Stems

During the process of question development, we learned how to properly word questions to get the correct response. Below are some common concepts that we implemented in the survey draft stage.

- Stems have to be short and concise
- Stems cannot include the word "or" as you will not know what the response you receive is pertaining to
- Including examples within the stems makes the concept come across clearer
- You have to limit the number of stems and ensure they fall within the domain you want responses to

Pilot Testing and Cognitive Interview Findings

To ensure our response options to the items in question were clear, we conducted cognitive interviews with four patients. Their feedback allowed us to better focus the response options and revise the survey. We changed our main response options to the below:

NEITHER INFORM NOR ASK PATIENT PERMISSION	INFORM BUT NOT ASK PATIENT PERMISSION	INFORM AND GET VERBAL PERMISSION	INFORM AND GET WRITTEN PERMISSION
GO AHEAD	POST	ASK ME	SIGNATURE

The survey was then piloted with the revised response options to six patients at UC Irvine Medical Center. During the pilot phase we timed each survey to ensure it would take 15-20 minutes to complete, we also wrote down any questions the patients asked during the survey where further clarification of a survey question was needed. The pilot survey results showed us that our response options had to be revised to make the survey more understandable to our patient population. We shortened our busy response options to definitely yes, probably yes, maybe, probably not, and definitely not. These were much easier to interpret than our previous response options.

DEFINITELY YES	PROBABLY YES	MAYBE	PROBABLY NOT	DEFINITELY NOT

Assessing Construct Validity

We ran a non-parametric correlation (Pearson's correlation) to asses for validity across the sections. Tables 1-7 provide the correlation coefficient for each construct to ensure validity across the survey questions.

Table 1. Validity Testing: Section 1: Hospital Care

	Q1.A	Q1.B	Q1.C	Q1. D	Q1.E
Hospital Care	.955**	.816**	.907**	.931**	.784**
Hospital Environment	.533**	.216	.504**	.513**	.357**
Things Put on or Used by Patients	.611**	.471**	.608**	.567**	.370**
Medications or Devices	.491**	.325*	.470**	.461**	.454**
Policies and Procedures	.273*	.117	.430**	.243	.145
Data Collection and Sharing	.621**	.564**	.636**	.611**	.545**

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Table 2. Validity Testing: Section 2: Hospital Environment

	Q2.A	Q2.B	Q2.C	Q2.D	Q2.E	Q2.F	Q2.G
Hospital Care	.471**	.427**	.496**	.421**	.324*	.218	.224
Hospital Environment	.835**	.735**	.889**	.850**	.784**	.759**	.412**
Things Put on or Used by Patients	.267*	.249	.409**	.350**	.222	.243	.207
Medications or Devices	.253	.316*	.466**	.365**	.207	.262*	.079
Policies and Procedures	.366**	.293*	.550**	.509**	.407**	.379**	.189
Data Collection and Sharing	.228	.247	.369**	.335**	.239	.295*	.350**

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Table 3. Validity Testing: Section 3: Things Put on or Used by Patients

	Q3.A	Q3.B	Q3.C	Q3.D	Q3.E	Q3.F	Q3.G
Hospital Care	.449**	.562**	.523**	.505**	.533**	.602**	.488**
Hospital Environment	.321*	.412**	.161	.328*	.371**	.419**	.183
Things Put on or Used by Patients	.842**	.945**	.880**	.875**	.836**	.956**	.836**
Medications or Devices	.586**	.623**	.573**	.586**	.528**	.624**	.471**
Policies and Procedures	.550**	.607**	.375**	.564**	.453**	.583**	.324*
Data Collection and Sharing	.452**	.462**	.414**	.400**	.333**	.451**	.430**

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Table 4. Validity Testing: Section 4: Medications or Devices

	Q4.A	Q4.B	Q4.C	Q4.D	Q4.E
Hospital Care	.320*	.253	.571**	.488**	.335**
Hospital Environment	.059	.205	.457**	.424**	.269*
Things Put on or Used by Patients	.401**	.316*	.763**	.647**	.407**
Medications or Devices	.739**	.751**	.736**	.788**	.728**
Policies and Procedures	.303*	.279*	.602**	.512**	.328*
Data Collection and Sharing	.408**	.376**	.467**	.562**	.392**

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Table 5. Validity Testing: Section 5: Policies and Procedures

	Q5.A	Q5.B	Q5.C	Q5.D	Q5.E	Q5.F	Q5.G
Hospital Care	.286*	.188	-.002	.392**	.139	.282*	.216
Hospital Environment	.283*	.382**	.181	.532**	.275*	.479**	.466**
Things Put on or Used by Patients	.505**	.388**	.165	.523**	.366**	.549**	.477**
Medications or Devices	.511**	.456**	.007	.365**	.447**	.444**	.473**
Policies and Procedures	.533**	.841**	.526**	.834**	.814**	.728**	.717**
Data Collection and Sharing	.270*	.270*	.037	.305*	.251	.143	.271*

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Table 6. Validity Testing: Section 6: Data Collection and Sharing

	Q6.A	Q6.B	Q6.C	Q6.D	Q6.E	Q6.F	Q6.G	Q6.H
Hospital Care	.557**	.428**	.491**	.558**	.473**	.575**	.539**	.398**
Hospital Environment	.308*	.299*	.402**	.347**	.233	.329*	.314*	.050
Things Put on or Used by Patients	.452**	.296*	.375**	.423**	.291*	.419**	.363**	.206
Medications or Devices	.356**	.511**	.466**	.449**	.442**	.490**	.375**	.343**
Policies and Procedures	.080	.211	.239	.416**	.255*	.262*	.344**	-.022
Data Collection and Sharing	.613**	.785**	.709**	.765**	.826**	.819**	.656**	.732**

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Table 7. Validity Testing: Section 7

	Q7.10 A-D	Q7.11 A-G	Q7.12 A-E
Hospital Care	.516**	.325*	.085
Hospital Environment	.516**	.341**	.033
Things Put on or Used by Patients	.366**	.315*	.091
Medications or Devices	.437**	.298*	.245
Policies and Procedures	.258*	.436**	.177
Data Collection and Sharing	.443**	.293*	.255*

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Reliability

The below table provides the scale mean, scale standard deviation, and Cronbach's alpha, which was used to assess internal consistency. The higher the scale mean the less likely that patients would allow hospitals or health care systems to implement a QI project without their permission.

Table 8. Sample Item Content Scale

Construct	K of Items	Scale Mean*	Scale SD	Cronbach's Alpha
Hospital Care	5	20.50	28.78	0.922
Hospital Environment	7	10.36	15.91	0.865
Things Put on or Used by Patients	7	14.58	22.45	0.950
Medications or Devices	5	24.92	20.82	0.792
Policies and Procedures	7	13.15	15.87	0.835
Data Collection and Sharing	8	41.88	26.47	0.881

*High score indicates that patients are more likely to require providing their permission before hospitals can make changes

INTERIM DATA ANALYSIS OF 60 PATIENTS

Patient Characteristics

The data collection period started October 2014 and lasted one month, before ending in November 2014. We collected data (surveys) for 60 patients. Our sample consisted of 51 patients from UCI and 9 patients from BWH. Patient characteristics are shown in Table 9. The mean age of surveyed patients was 48 years, (range: 22-89), with 50% (N=30) being male. The majority (58%) of the population was white (N=35) and 17% (N=10) was of Hispanic ethnicity. Furthermore, 60% (36) had commercial insurance, 27% (N=16) had Medicare, 25% (N=15) had Medicaid, and 2% (N=1) had no insurance. Of those surveyed 28% (N=17) had previously participated in research studies requiring signing a consent form. The age distribution was skewed to favor younger ages with the median age=49 and the mode=29. Generally, hospitalized patients are considerably older. Study findings may therefore not generalize to the larger hospitalized patient population.

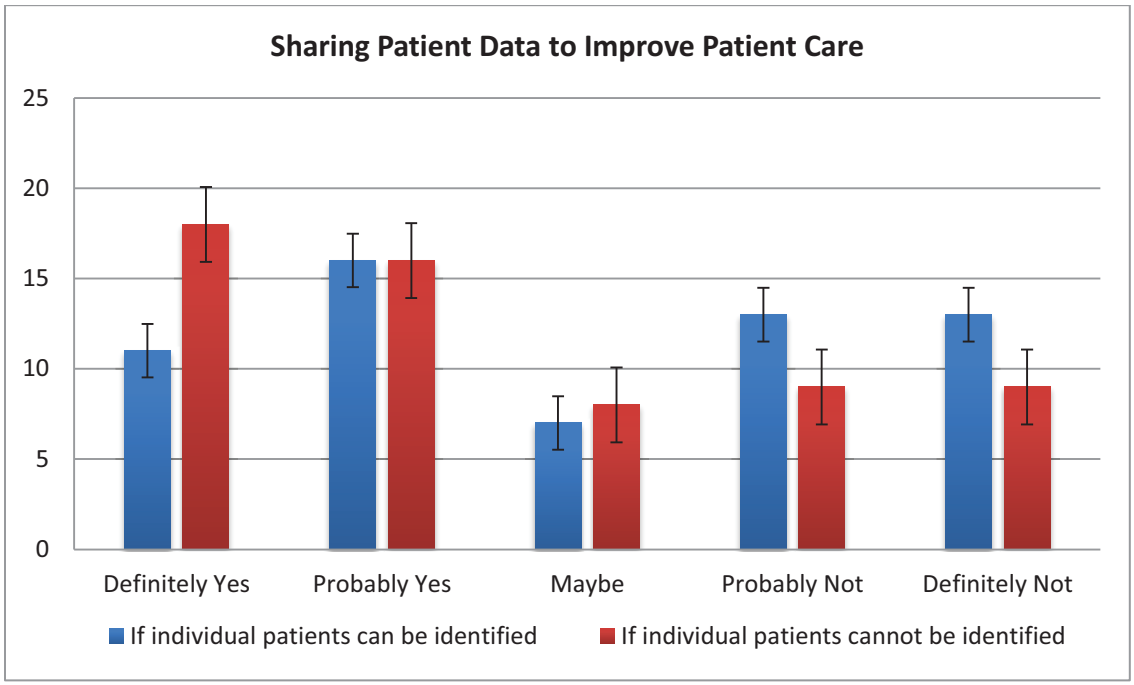
Table 9. Demographics

Age (years)	N	Percent
18-39	21	35%
40-64	32	53%
65+	7	12%
Mean (SD)	48 (14)	
Median (IQF)	49 (23)	
Sex	**N**	**Percent**
Male	30	50%
Race	**N**	**Percent**
American Indian or Alaskan Native	1	2%
Asian	5	8%
Black or African American	6	10%
Native Hawaiian or Pacific Islander	2	3%
White or Caucasian	35	58%
Mixed Race	6	10%
Unknown	5	8%
Ethnicity	**N**	**Percent**
Hispanic	10	17%
Education	**N**	**Percent**
Less than High School	4	7%
High School/GED	6	10%
Associate Degree/Some College	27	45%
Bachelors	16	27%
Masters	6	10%
Doctorate	1	2%
Insurance Type	**N**	**Percent**
Commercial	36	60%
Medicare	16	27%
Medicaid	15	25%
None	1	2%
Number of admissions in last year	**N**	**Percent**
1	35	58%
2-5	22	37%
6-9	2	3%
≥10	1	2%
Participated in research studies	**N**	**Percent**
Yes	17	28%

Sharing PHI to Improve Patient Care

Next, we analyzed the difference in either sharing identifiable patient data vs. unidentifiable patient data. As expected, patients were more comfortable sharing their data if it meant they could not be identified, as is shown in figure 4. The standard error bars indicate that the "probably yes" and "maybe" responses are not statistically significant.

Figure 4: Data Sharing: Identified vs. Unidentified



Overall, patients feel comfortable allowing access to their PHI if they are protected from being individually identified as displayed in the figure 5a. To further showcase patients comfort level with sharing their PHI, we grouped the categories "very comfortable" and "comfortable" into one category labeled "comfortable" and the "very uncomfortable" and "uncomfortable" categories into one labeled "uncomfortable". Figure 5b presents this distribution making it evident that patients are more comfortable with sharing their PHI.

Figure 5a: Using PHI if Patients Cannot be Individually Identified

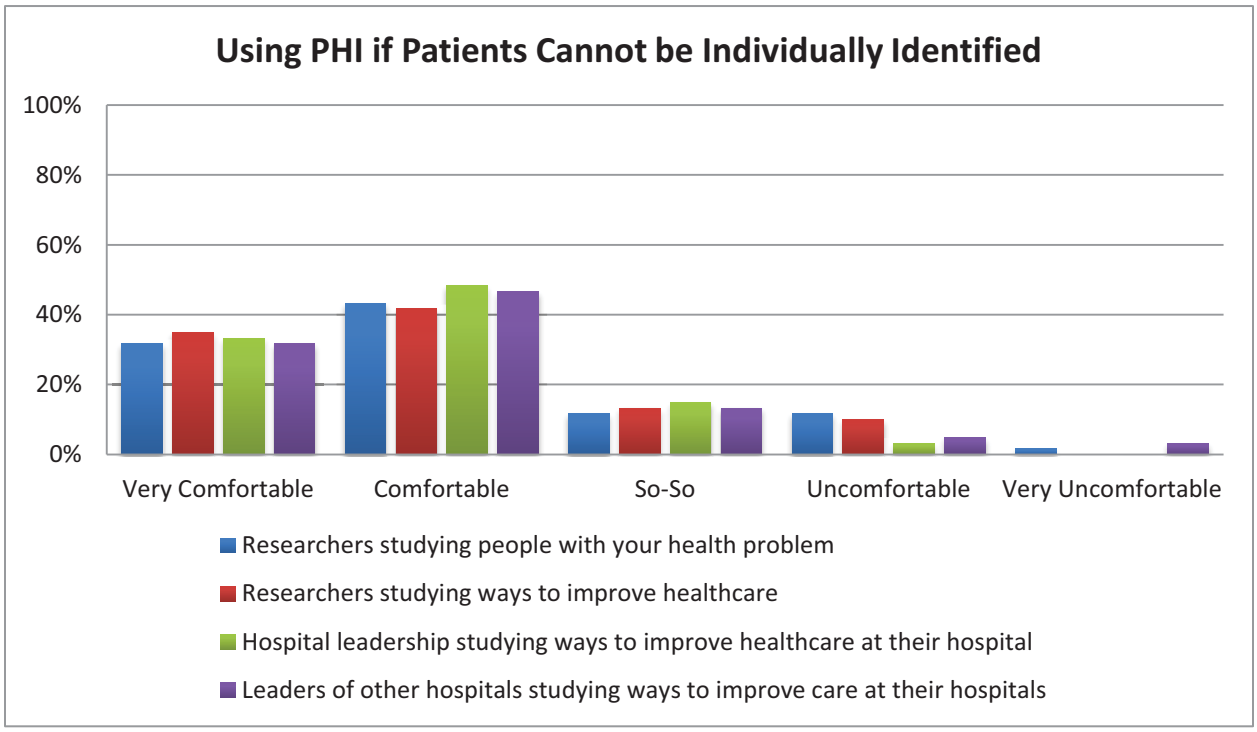
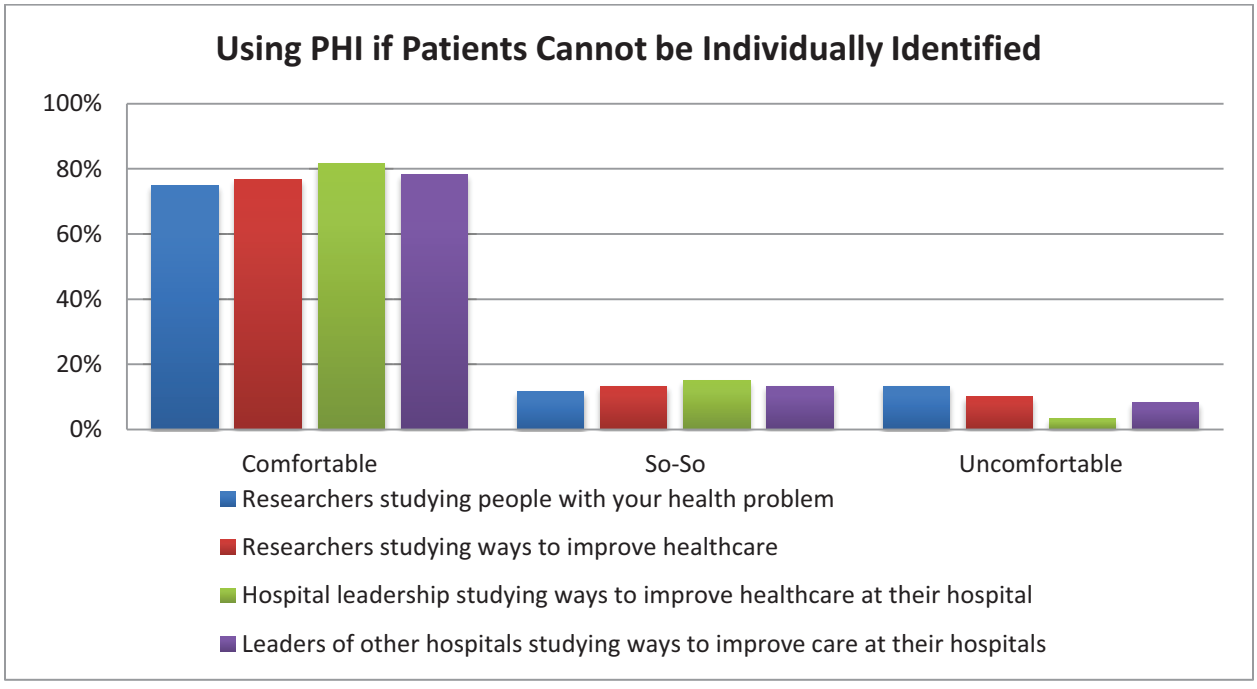


Figure 5b: Using PHI if Patients Cannot be Individually Identified Merged Responses



CHAPTER 5: Discussion

Survey Goal

The patient survey was developed as part of a trio of surveys aimed at identifying questions pertaining to patient perspective for implementing QI or research projects to improve patient care. The responses will allow us to inform dialogue pertaining to processes aimed at patient care improvement. Furthermore, it will provide us with an understanding of whether research and QI projects should be treated the same under one ethical framework versus having their own ethical governing bodies. The goal is to compare the patient responses to other stakeholders (i.e., IRB directors and QI managers) to provide a comprehensive representation of the implementation of patient care improvement projects.

Changes in the Field

The research field is heading into a direction where research is becoming more pragmatic, where the effectiveness of interventions can be evaluated in routine practice conditions. [5] Additionally, LHS, which the Institute of Medicine describes as a health system "in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care"[24] are also expanding. With this expansion it becomes even more important to understand patient's willingness to be part of QI and research studies. The shift in research to be part of LHS will require a congruent shift in the current IRB guidelines as well.

Organizations such as the National Quality Forum are working on improving health care by endorsing evidence-based measures as gold standard to be implemented in hospitals and health care systems. Furthermore, LHS are implementing research projects in hopes to advance the findings and results of research and make it more pragmatic in implementation. However, boundaries still exist when it comes to identifying QI projects vs. research projects. It is evident that more needs to be done to create a more efficient assessment of potential projects. As Platt et al, write:

> In brief, we believe that rigorous, systematic evaluation of clinical practice should become the norm. Evaluation requires institutional oversight using existing mechanisms and full compliance with the privacy provisions of HIPAA that apply to treatment and operations. But evaluation of minimal-risk, approved care should not require IRB involvement, nor should it require consent from patients beyond that required for normal medical care (or from health care workers beyond the norms of employer-employee relationships). IRBs provide essential protections for patients participating in greater-than-minimal-risk research, but they can impede progress when the risk is no greater than is typical of accepted clinical practice.[25]

Patients' Comfort Level

The questions in this survey allowed us to assess a preliminary cohort of 60 patients' comfort level in providing (or not providing) their permission for hospitals or health care systems to implement QI projects or minimal risk research projects. The data suggest that patients generally feel comfortable allowing hospitals to implement projects to improve

patient care such as comparing different types of thermometers for monitoring temperature. The distinction to the patients does not lie in whether the project is QI or research, but whether their PHI will be used and shared making them individually identifiable.

We initially anticipated seeing a variation between the survey constructs not pertaining to data use (hospital care, hospital environment, things put on or used by patients, medications or devices, policies and procedures); however, their scale means were not significantly higher when compared to each other. This indicated that the distinction between research projects and QI projects seems irrelevant to patients. Further surveys or studies are needed to engage patients to better understand when they would like to be notified of an ongoing project vs. asked to provide their formal consent in order to participate.

The patient survey data collection is still in process as we anticipate recruiting a total of 200 patients. We conducted a few interim analyses of 60 patients to assess findings related to patients' opinions about sharing their PHI and participation in QI and research projects. We look forward to conducting a comprehensive analysis of the complete patient sample as well as including the patient results in the overall analysis of the three surveys. The goal of the findings of all three surveys will bridge the ethical gap between QI and research projects.

Project Limitations

There are several limitations to this project. First, the survey target population consists of admitted patients at UC Irvine Medical Center in Orange, CA and Brigham and Women's Hospital in Boston, MA. We used a convenience sample that was drawn from the larger population that was available and/or accessible to us at the time of data collection. Second, our inclusion criteria were provided to the charge nurse who was then asked to provide us with a list of approachable patients for each data collection visit. The patient identification process was at the discretion of the charge nurse, therefore if there was a patient we could have approached but they were not included on the charge nurse's list, it would present a missed opportunity. Third, the survey was only written in English and therefore respondents would have to be English-speaking in order to participate.

Additional Surveys

While the findings of this survey shed some insight into how a small sample of patients feel about giving their permission for improvement projects and sharing their data, it does not provide us with an overall understanding of the ethical gray space between minimal risk research projects and QI projects. The patient survey is the first of three surveys to be implemented for this project. As previously discussed, we will also survey QI managers and IRB directors/chairs to obtain their assessment of QI vs. minimal risk research.

REFERENCES

1. Lynn J. The Ethics of Using Quality Improvement Methods in Health Care. Annals of Internal Medicine 2007;146(9):666.
2. Jennings B, Baily MA, Bottrell M, Lynn J. Health Care Quality Improvement: Ethical and Regulatory Issues. Hastings Cent Rep 2007.
3. Jencks SF, Wilensky GR. The health care quality improvement initiative. A new approach to quality assurance in Medicare JAMA. 1992 Aug 19;268(7):900-3.
4. Department of Health and Human Services, "Code of Federal Regulations: Protection of Human Subjects," 102, section 46.102(d). http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102 Accessed September 6, 2014.
5. Patsopoulos NA. A Pragmatic View on Pragmatic Trials. Dialogues Clin Neurosci. Jun 2011; 13(2): 217–224. Dialogues Clin Neurosci. Jun 2011; 13(2): 217–224.
6. Faden RR, Beauchamp TL, Kass NE. Informed consent, comparative effectiveness, and learning health care. N Engl J Med 2014;340:766-768.
7. Faden RR, Kass NE, Goodman SN, Pronovost P, Tunis S, Beauchamp TL. An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. Hastings Cent Rep 2013;Spec No:S16–27.
8. Office for Human Research Protections. Institutional Review Board Guidebook. http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm Accessed September 3, 2014.

9. Measuring performance. National Quality Forum. http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx Accessed August 14, 2014.
10. The Learning Health System Series. Workshop Summary. Institute of Medicine (US) Roundtable on Value and Science-Driven Health Care. Washington (DC): National Academies Press (US); 2012.
11. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report (Washington, DC: U.S. Government Printing Office, 1979).
12. Popp JA, Layon AJ, Nappo R, Richards WT, Mozingo DW. Hospital-acquired infections and thermally injured patients: chlorhexidine gluconate baths work. Am J Infect Control. 2014 Feb;42(2):129-32.
13. Huang SS, Septimus E, Kleinman K, Moody J, Hickok J, Avery TR, Lankiewicz J, Gombosev A, Terpstra L, Hartford F, Hayden MK, Jernigan JA, Weinstein RA, Fraser VJ, Haffenreffer K, Cm E, Kaganov RE, Lolans K, Perlin JB, Plait R; CDC Prevention Epicenters Program; AHRQ DECIDE Network and Healthcare-Associated Infections Program. Targeted versus universal decolonization to prevent ICU infection. New England Journal of Medicine. 2013 June 13;368(24):2255-65.
14. Baily MA, Bottrell M, Lynn J, Jennings B, Hastings Center. The ethics of using QI methods to improve health care quality and safety. Hastings Cent Rep. 2006;36(4):S1-40.
15. Lynn J, Baily MA, Bottrell M, Jennings B, Levine RJ, Davidoff F, Casarett D, Corrigan J, Fox E, Wynia MK, Agich GJ, O'Kane M, Speroff T, Schyve P, Batalden P, Tunis S,

Berlinger N, Cronenwett L, Fitzmaurice JM, Dubler NN, James B. The ethics of using quality improvement methods in health care. Ann Intern Med. 2007;146(9):666-73. Epub 2007 Apr 16.

16. Ethical Oversight of Learning Health Care Systems. Hastings Center Report. 2013; S1-S44.
17. Mazor KM, Sabin JE, Boudreau D, Goodman MJ, Gurwitz JH, Herrinton LJ, Raebel MA, Roblin D, Smith DH, Meterko V, Platt R. Cluster randomized trials: opportunities and barriers identified by leaders of eight health plans. Med Care. 2007 Oct;45(10 Supl 2):S29-37.
18. Sabin JE. Comparative effectiveness research, informed consent, and research regulation in a Learning Healthcare System. ACRP Monitor. 2010;45-49.
19. Faden RR, Kass NE, Goodman SN, Pronovost P, Tunis S, Beauchamp TL. An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. Hastings Cent Rep 2013;Spec No:S16–27.
20. NIH Collaboratory. Rethinking Clinical Trials. Health Care Systems Resarch Collaboratory. Accessed December 3, 2014. https://www.nihcollaboratory.org/Pages/default.aspx.
21. Berwick DM. Escape Fire. Designs for the Future of Health Care (San Francisco, CA: Jossey-Bass, 2004.
22. Mitty E. *J Nurs Care Qual*. Hastings Center special report: the ethics of using QI methods to improve health care quality and safety. 2007 Apr-Jun;22(2):97-101.
23. Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven

methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

24. Institute of Medicine, IOM Roundtable on Evidence-Based Medicine, The Learning Healthcare System, Olsen, Aisner, and McGinnis, eds.
25. Platt R, Grossmann C, Selker HP. Evaluation as part of operations: reconciling the common rule and continuous improvement. Commentary. Hastings Cent Rep 2013;Spec No:S37–9.

Making Improvements in Hospital Care Survey

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About this Study

Hospitals regularly look to make changes to improve the care they provide to patients. Some of these changes may seem minor and may not need permission from patients before they are made. Other changes may seem more important and need written permission from patients. “Written permission” would require that patients read and sign a document agreeing that they will participate in the evaluating of possible changes.

We are conducting this study to find out how patients feel about being asked for their permission when hospitals look to make changes to policies, procedures, practices, and the physical environment to improve patient care. We are especially interested in your ideas about when you would like to be asked for your **permission** where different types of changes in the delivery of care are being studied. There are **no right or wrong answers**. We are only interested in your opinions.

Instructions

- Please complete the entire questionnaire as carefully as you can.
- There are no right or wrong answers. We are interested in your opinions and experiences, whatever those may be.
- Please answer every question.
- If you have comments on any question or the questionnaire in general, we have provided a space at the end for comments and suggestions.
- Some questions may seem repetitive. There are small but important differences among the questions so it is very important to answer each one.
- All of your responses will only be shared with the study team. If you have any questions about this study or this questionnaire, please call Adrijana Gombosev at (949) 824-0670 or email at agombose@uci.edu.

SECTION 1. MAKING IMPROVEMENTS IN HOSPITAL CARE

The following questions ask about your **general opinion** for hospital improvement projects.

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. Changes in the hospital setting that do not directly touch patients (such as reducing noise levels at night, location of handrails to reduce falls, etc.)?.....	1	2	3	4	5
b. Changes in things put on or used by patients (such as different bandages, leg compression stockings, bathing soaps, etc.)?……..	1	2	3	4	5
c. Changes in the availability or use of equipment (such as different types of crutches, exercise equipment, heart rate monitors, etc.)?……	1	2	3	4	5

(*CIRCLE ONE NUMBER ON EACH LINE*)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
d. Changes in hospital <u>policies</u> or the ways things are done (such as different methods for educating patients after they leave the hospital, ways to remind patients about appointments, ways to shorten emergency room wait time, etc.)?….	1	2	3	4	5
e. Changes in the ways hospitals <u>use or share patient information</u> (such as changing to computerized medical records, sharing patient information to improve care, ways to give patients their own information, etc.)?……	1	2	3	4	5

2. **In general, how would you rate the ways hospitals use patient experiences to improve the care they give?**

(***CIRCLE ONE***)

EXCELLENT..... 1

VERY GOOD 2

GOOD..... 3

FAIR 4

POOR..... 5

---

3. **In general, how often should hospitals ask for patients' permission to make changes in the ways they take care of patients?**

(***CIRCLE ONE***)

ALWAYS..... 1

USUALLY..... 2

SOMETIMES..... 3

RARELY..... 4

NEVER..... 5

---

4. Should patients be included on committees in hospitals that are responsible for keeping track of and improving the quality of patient care?

(***CIRCLE ONE***)

YES, DEFINITELY 1

YES, PROBABLY 2

MAYBE 3

NO, PROBABLY NOT 4

NO, DEFINITELY NOT 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)

	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

(CIRCLE ONE NUMBER ON EACH LINE)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
e. Trying out the use of calming music in places where patients are especially stressed (such as the recovery room or intensive care unit) to relax them? ……..……	1	2	3	4	5
f. Trying out different types of lighting at night to improve patients' sleep?	1	2	3	4	5
g. Trying out different styles of artwork to improve hospital appearance? …	1	2	3	4	5

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

(CIRCLE ONE NUMBER ON EACH LINE)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
e. Comparing different types of blood pressure monitors that automatically take blood pressure instead of having it checked by nurses? ……	1	2	3	4	5
f. Comparing different types of crutches or walkers for patients who need them? ……	1	2	3	4	5
g. Comparing different activity monitors (such as pedometers) to see which one is better at measuring patients' activity while in the hospital? ..……	1	2	3	4	5

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

(CIRCLE ONE NUMBER ON EACH LINE)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
d. Trying different coatings on pills to make them easier to swallow? …….	1	2	3	4	5
e. Limiting the list of drugs available at the hospital to those that do the same job but cost less?..……..	1	2	3	4	5

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

(CIRCLE ONE NUMBER ON EACH LINE)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
d. Trying out ways to reduce patient wait time in the emergency room (such as electronic check in, displaying estimated waiting time)?.....	1	2	3	4	5
e. Trying out different ways of closing surgical incisions (such as stitches, staples, or certain glues)? ……..	1	2	3	4	5
f. Trying out different ways of getting written permission for treatment from patients (such as videos, reading consent forms)? …….....	1	2	3	4	5
g. Seeing how often patients should be turned in their bed to prevent bedsores? ……	1	2	3	4	5

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

(CIRCLE ONE NUMBER ON EACH LINE)

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
d. Comparing different ways to give patients access to their medical record information in the hospital (such as in-room electronic record access)?.....	1	2	3	4	5
e. Sharing patient data with hospital partners to figure out better ways to take care of patients, if individual patients <u>can</u> be identified?……...	1	2	3	4	5
f. Sharing patient data with hospital partners to figure out better ways to take care of patients, if individual patients <u>cannot</u> be identified?.....…	1	2	3	4	5
g. Using patient data that can identify the patient to improve care at <u>only the hospital where they were seen</u>?	1	2	3	4	5
h. Using patient data that identify the patient to improve care <u>at other hospitals that take care of similar patients</u>?…….	1	2	3	4	5

SECTION 7. ABOUT YOU

The following questions ask about your personal characteristics and experiences with hospitals.

1. What was your age at your last birthday? …… ☐☐ **[*ENTER NUMBER*]**

---

2. What is your gender? **(*CIRCLE ONE*)**

a. MALE ……..…….. 1

b. FEMALE ……..…….. 2

---

3. Please specify your race. (***CIRCLE ONE***)

a. AMERICAN INDIAN OR ALASKAN NATIVE 1

b. ASIAN 2

c. BLACK OR AFRICAN AMERICAN 3

d. NATIVE HAWAIIAN OR PACIFIC ISLANDER 4

e. WHITE OR CAUCASIAN 5

f. MIXED RACE 6

g. UNKNOWN 7

---

4. Please specify your ethnicity. (***CIRCLE ONE***)

a. HISPANIC OR LATINO 1

b. NOT HISPANIC OR LATINO 2

---

5. What is the highest grade level of school you completed? (***CIRCLE ONE***)

LESS THAN HIGH SCHOOL	1
HIGH SCHOOL GRADUATE/GED	2
SOME COLLEGE	3
ASSOCIATE DEGREE (AA, AS)	4
BACHELOR'S DEGREE (BA, BS)	5
MASTER'S DEGREE (MA, MS, MBA, MPH)	6
PROFESSIONAL DEGREE (MD, DDS, JD)	7
DOCTORATE DEGREE (PhD, EdD)	8

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6. What insurance do you have? **(CHECK YES OR NO)**

a. COMMERCIAL INSURANCE (BLUE SHIELD, KAISER)	☐ YES	☐ NO
b. MEDICARE	☐ YES	☐ NO
c. MEDICAID	☐ YES	☐ NO
d. NONE	☐ YES	☐ NO

---

7. **How many times <u>in the past year</u> have you been a patient in a hospital <u>overnight</u>?**

☐☐ **[*ENTER NUMBER*]**

---

8. **Have you <u>ever</u> been asked for your written permission to take part in a research study (such as a study of new treatments, new tests, new patient education programs)? ("Written permission", means that you read and signed a document agreeing to be part of the study.)**

[*CHECK ONE*]

NO ☐ YES ☐ → **1a. How many studies have you ever been <u>asked</u> to take part in?**

☐☐ **[*ENTER NUMBER*]**

1b. How many studies did you <u>agree</u> to take part in?

☐☐ **[*ENTER NUMBER*]**

Go to question #5

---

9. In general, how would you rate your current overall health?

(*CIRCLE ONE*)

EXCELLENT..... 1

VERY GOOD 2

GOOD..... 3

FAIR 4

POOR..... 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. Researchers studying people with your health problem?	1	2	3	4	5
b. Researchers studying ways to improve healthcare?…….……	1	2	3	4	5
c. Hospital leadership studying ways to improve healthcare at their hospital? ……	1	2	3	4	5
d. Leaders of other hospitals also studying ways to improve care at their hospitals for patients like you? ……	1	2	3	4	5

11. How comfortable do you or would you feel sharing your personal information in the following ways?

(*CIRCLE ONE NUMBER ON EACH LINE*)

	VERY COMFORTABLE	COMFORTABLE	SO-SO	UNCOMFORTABLE	VERY UNCOMFORTABLE
a. Shopping online……..	1	2	3	4	5
b. Emailing your physician ...	1	2	3	4	5
c. Taking part in an online support group…….	1	2	3	4	5
d. Emailing with friends ….	1	2	3	4	5
e. Completing patient forms online……...	1	2	3	4	5
f. Posting a photo online (for example, Facebook, Twitter)…….……	1	2	3	4	5
g. Checking lab results online …….	1	2	3	4	5

12. Indicate how strongly you agree or disagree with the following statements.

(***CIRCLE ONE NUMBER ON EACH LINE***)

	STRONGLY AGREE	**AGREE**	**SO-SO**	**DISAGREE**	**STRONGLY DISAGREE**
a. All things considered, patients can trust hospitals completely……..	1	2	3	4	5
b. The care hospitals give is often influenced by how much money they can make ……	1	2	3	4	5
c. Patients can always trust hospitals to provide the highest quality medical care....	1	2	3	4	5
d. Hospitals do whatever it takes to make sure patients get all the care they need……..	1	2	3	4	5
e. Hospitals care more about costs than quality of care ……..……..	1	2	3	4	5

Thank You!

We greatly appreciate your help with this survey! Thank you for providing us with critical information on improving patient care. Your responses will be kept confidential and will only be shared with the study team.

If you complete the survey on your own, please call Adrijana Gombosev at (949) 824-0670 or email at agombose@uci.edu for pick up.

Please provide any comments, questions, or concerns that you would like to share with the study investigators:

Making Improvements in Hospital Care Survey

• Please complete the entire questionnaire as carefully as you can.

There are no right or wrong answers. We are interested in your opinions and experiences, whatever those may be.

Please answer every question.

If you have comments on any question or the questionnaire in general, we have provided a space at the end for comments and suggestions.

Some questions may seem repetitive. There are small but important differences among the questions so it is very important to answer each one.

All of your responses will only be shared with the study team. If you have any questions about this study or this questionnaire, please call Adrijana Gombosev at (949) 824-0670 or email at agombose@uci.edu

Thank you!

About this Study

Hospitals regularly look to make changes to improve the care they provide to patients. Some of these changes may seem minor and may not need permission from patients before they are made. Other changes may seem more important and need written permission from patients. "Written permission" would require that patients read and sign a document agreeing that they will participate in the evaluating of possible changes.

We are conducting this study to find out how patients feel about being asked for their permission when hospitals look to make changes to policies, procedures, practices, and the physical environment to improve patient care. We are especially interested in your ideas about when you would like to be asked for your permission where different types of changes in the delivery of care are being studied. There are no right or wrong answers. We are only interested in your opinions.

Instructions

- Please complete the entire questionnaire as carefully as you can.
- There are no right or wrong answers. We are interested in your opinions and experiences, whatever those may be.
- Please answer every question.
- If you have comments on any question or the questionnaire in general, we have provided a space at the end for comments and suggestions.
- Some questions may seem repetitive. There are small but important differences among the questions so it is very important to answer each one.
- All of your responses will only be shared with the study team. If you have any questions about this study or this questionnaire, please call Adrijana Gombosev at (949) 824-0670 or email at agombose@uci.edu.

SECTION 1. MAKING IMPROVEMENTS IN HOSPITAL CARE

The following questions ask about your general opinion for hospital improvement projects.

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?

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
1.1a Changes in the hospital setting that do not directly touch patients (such as reducing noise levels at night, location of handrails to reduce falls, etc.)?	☐	☐	☐	☐	☐
1.1b Changes in things put on or used by patients (such as different bandages, leg compression stockings, bathing soaps, etc.)?	☐	☐	☐	☐	☐
1.1c Changes in the availability or use of equipment (such as different types of crutches, exercise equipment, heart rate monitors, etc.)?	☐	☐	☐	☐	☐
1.1d Changes in hospital policies or the ways things are done (such as different methods for educating patients after they leave the hospital, ways to remind patients about appointments, ways to shorten emergency room wait time, etc.)?	☐	☐	☐	☐	☐
1.1e Changes in the ways hospitals use or share patient information (such as changing to computerized medical records, sharing patient information to improve care, ways to give patients their own information, etc.)?	☐	☐	☐	☐	☐

1.2 In general, how would you rate the ways hospitals use patient experiences to improve the care they give?

- ☐ EXCELLENT
- ☐ VERY GOOD
- ☐ GOOD
- ☐ FAIR
- ☐ POOR

1.3 In general, how often should hospitals ask for patients' permission to make changes in the ways they take care of patients?

- ☐ ALWAYS
- ☐ USUALLY
- ☐ SOMETIMES
- ☐ RARELY
- ☐ NEVER

1.4 Should patients be included on committees in hospitals that are responsible for keeping track of and improving the quality of patient care?

- ☐ YES, DEFINITELY
- ☐ YES, PROBABLY
- ☐ MAYBE
- ☐ NO, PROBABLY NOT
- ☐ NO, DEFINITELY NOT

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.

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?

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
2.1a Trying out different ways to reduce noise levels in hospitals at night?	☐	☐	☐	☐	☐
2.1b Comparing two types of privacy curtains around patient beds?	☐	☐	☐	☐	☐
2.1c Trying out different places to put handrails in patient rooms to prevent falls?	☐	☐	☐	☐	☐
2.1d Seeing whether using different cleaning products on things patients touch often (doorknobs, bed rails, call buttons) prevent infections?	☐	☐	☐	☐	☐
2.1e Trying out the use of calming music in places where patients are especially stressed (such as the recovery room or intensive care unit) to relax them?	☐	☐	☐	☐	☐
2.1f Trying out different types of lighting at night to improve patients' sleep?	☐	☐	☐	☐	☐
2.1g Trying out different styles of artwork to improve hospital appearance?	☐	☐	☐	☐	☐

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.

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?

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
3.1a Trying out different types of bathing soaps to reduce the risk of infections?	☐	☐	☐	☐	☐
3.1b Trying out different types of wound bandages to improve healing or reduce irritation?	☐	☐	☐	☐	☐
3.1c Trying out which type of thermometers (oral, underarm, ear) work best for taking temperature?	☐	☐	☐	☐	☐
3.1d Seeing how long patients should wear stockings to prevent blood clots in the legs?	☐	☐	☐	☐	☐
3.1e Comparing different types of blood pressure monitors that automatically take blood pressure instead of having it checked by nurses?	☐	☐	☐	☐	☐
3.1f Comparing different types of crutches or walkers for patients who need them?	☐	☐	☐	☐	☐
3.1g Comparing different activity monitors (such as pedometers) to see which one is better at measuring patients' activity while in the hospital?	☐	☐	☐	☐	☐

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.

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?

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
4.1a Comparing whether blood pressure lowering drugs work better when taken in morning or night?	☐	☐	☐	☐	☐
4.1b Trying out the use of generic or less expensive versions of same drug vs. brand name drug?	☐	☐	☐	☐	☐
4.1c Trying out different types of blood drawing needles to improve blood flow when drawing blood?	☐	☐	☐	☐	☐
4.1d Trying different coatings on pills to make them easier to swallow?	☐	☐	☐	☐	☐
4.1e Limiting the list of drugs available at the hospital to those that do the same job but cost less?	☐	☐	☐	☐	☐

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.

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?

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
5.1a Comparing different types of teaching materials to see which is best at educating patients about what to do after they leave the hospital?	☐	☐	☐	☐	☐
5.1b Seeing whether getting patients up to walk sooner after surgery reduces problems (such as pneumonia, blood clots)?	☐	☐	☐	☐	☐
5.1c Seeing whether having nurses call patients after they go home improves their care at home?	☐	☐	☐	☐	☐
5.1d Trying out ways to reduce patient wait time in the emergency room (such as electronic check in, displaying estimated waiting time)?	☐	☐	☐	☐	☐
5.1e Trying out different ways of closing surgical incisions (such as stitches, staples, or certain glues)?	☐	☐	☐	☐	☐
5.1f Trying out different ways of getting written permission for treatment from patients (such as videos, reading consent forms)?	☐	☐	☐	☐	☐
5.1g Seeing how often patients should be turned in their bed to prevent bedsores?	☐	☐	☐	☐	☐

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.

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?

	DEFINITELY YES	PROBABLY YES	MAYBE YES MAYBE NOT	PROBABLY NOT	DEFINITELY NOT
6.1a Changing from paper to computerized medical records?	☐	☐	☐	☐	☐
6.1b Including patient data (names and addresses) in disease registries (databases for specific diseases) for research?	☐	☐	☐	☐	☐
6.1c Sharing pictures of the patient's body without the face with doctors, nurses, or students for teaching purposes?	☐	☐	☐	☐	☐
6.1d Comparing different ways to give patients access to their medical record information in the hospital (such as in-room electronic record access)?	☐	☐	☐	☐	☐
6.1e Sharing patient data with hospital partners to figure out better ways to take care of patients, if individual patients can be identified?	☐	☐	☐	☐	☐
6.1f Sharing patient data with hospital partners to figure out better ways to take care of patients, if individual patients cannot be identified?	☐	☐	☐	☐	☐
6.1g Using patient data that can identify the patient to improve care at only the hospital where they were seen?	☐	☐	☐	☐	☐
6.1h Using patient data that can identify the patient to improve care at other hospitals that take care of similar patients?	☐	☐	☐	☐	☐

SECTION 7. ABOUT YOU

The following questions ask about your personal characteristics and experiences with hospitals.

7.1 What was your age at your last birthday? _____

7.2 What is your gender?
- ☐ MALE
- ☐ FEMALE

7.3 Please specify your race.
- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Pacific Islander
- ☐ White or Caucasian
- ☐ Mixed Race
- ☐ Unknown

7.4 Please specify your ethnicity.
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

7.5 What is the highest grade level of school you completed?
- ☐ Less than high school
- ☐ High school graduate/GED
- ☐ Some college
- ☐ Associate degree (AA, AS)
- ☐ Bachelor's degree (BA, BS)
- ☐ Master's degree (MA, MS, MBA, MPH)
- ☐ Professional degree (MD, DDS, JD)
- ☐ Doctorate degree (PhD, EdD)

What insurance do you have? Select all that apply.

	Yes	No
7.6a Commercial insurance (Blue Shield, Kaiser, Harvard Pilgrim Health Care)	☐	☐
7.6b Medicare	☐	☐
7.6c Medicaid	☐	☐
7.6d None	☐	☐

7.7 How many times in the past year have you been a patient in a hospital overnight, including current stay? _____

7.8 Have you ever been asked for your written permission to take part in a research study (such as a study of new treatments, new tests, new patient education programs)? ("Written permission", means that you read and signed a document agreeing to be part of the study.)
- ☐ Yes
- ☐ No

7.8.1a If yes, how many studies have you ever been asked to take part in? _____

7.8.1b If yes, how many studies did you agree to take part in? _____

7.9 In general, how would you rate your current overall health?

- ☐ EXCELLENT
- ☐ VERY GOOD
- ☐ GOOD
- ☐ FAIR
- ☐ POOR

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

		VERY COMFORTABLE	COMFORTABLE	SO-SO	UNCOMFORTABLE	VERY UNCOMFORTABLE
7.10a	Researchers studying people with your health problem?	☐	☐	☐	☐	☐
7.10b	Researchers studying ways to improve healthcare?	☐	☐	☐	☐	☐
7.10d	Hospital leadership studying ways to improve healthcare at their hospital?	☐	☐	☐	☐	☐
7.10d	Leaders of other hospitals also studying ways to improve care at their hospitals for patients like you?	☐	☐	☐	☐	☐

How comfortable do you or would you feel sharing your personal information in the following ways?

		VERY COMFORTABLE	COMFORTABLE	SO-SO	UNCOMFORTABLE	VERY UNCOMFORTABLE
7.11a	Shopping online	☐	☐	☐	☐	☐
7.11b	Emailing your physician	☐	☐	☐	☐	☐
7.11c	Taking part in an online support group	☐	☐	☐	☐	☐
7.11d	Emailing with friends	☐	☐	☐	☐	☐
7.11e	Completing patient forms online	☐	☐	☐	☐	☐
7.11f	Posting a photo online (for example, Facebook, Twitter)	☐	☐	☐	☐	☐
7.11g	Checking lab results online	☐	☐	☐	☐	☐

Indicate how strongly you agree or disagree with the following statements.

		STRONGLY AGREE	AGREE	SO-SO	DISAGREE	STRONGLY DISAGREE
7.12a	All things considered, patients can trust hospitals completely	☐	☐	☐	☐	☐
7.12b	The care hospitals give is often influenced by how much money they can make	☐	☐	☐	☐	☐
7.12c	Patients can always trust hospitals to provide the highest quality medical care	☐	☐	☐	☐	☐
7.12d	Hospitals do whatever it takes to make sure patients get all the care they need	☐	☐	☐	☐	☐
7.12e	Hospitals care more about costs than quality of care	☐	☐	☐	☐	☐

7.13 Where was this survey completed?

☐ UCI
☐ BWH

Thank You! We greatly appreciate your help with this survey! Thank you for providing us with critical information on improving patient care. Your responses will be kept confidential and will only be shared with the study team. If you complete the survey on your own, please call Adrijana Gombosev at (949) 824-0670 or email at agombose@uci.edu for pick up. Please provide any comments, questions, or concerns that you would like to share with the study investigators:

_____