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ARTICLE

The patient's perspective on the need for informed consent for minimal risk studies: Development of a survey-based measure

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ABSTRACT

Background: Recent efforts to study quality improvement (QI) efforts to improve the effectiveness and efficiency of healthcare have raised important questions about ethical boundaries for waiving informed consent. Confusion exists because similar projects can be undertaken for research or QI purposes, a distinction currently used to define Institutional Review Board oversight. However, patients are not aware of such distinctions. We sought to evaluate patients' views of waiving consent for non-invasive projects to improve healthcare quality and delivery. **Methods:** We developed a 32-item measure of patient thresholds for waiving consent for different types of QI interventions, including those involving changes to: 1) the hospital environment; 2) hospital policies or procedures; 3) objects used by patients; 4) medications or devices; and 5) use of patient information. In a sample of 200 hospitalized patients, we tested and confirmed the reliability and validity of subscales representing each of the 5 intervention types. **Results:** For each of the five consent threshold scales, all items in each scale had substantial item-to-total correlations with the other items in that scale taken together. All five internal consistency reliability coefficients exceeded .70 for the total sample. Means for all 5 scales indicated general patient support for waiving consent across all categories of interventions studied. However, patients were significantly less comfortable foregoing consent for interventions involving medications or devices, or sharing of patient information. **Conclusion:** We developed and tested a survey instrument to contribute to the understanding of patient preferences for consent in QI assessment activities. Measures were found to be reliable and valid. Findings indicated general patient support for waiving consent across all minimal risk categories studied. However, more work is needed to reassure and protect patients during minimal risk studies involving medications or devices, or the sharing of patient information.

KEYWORDS

quality improvement studies; informed consent; waiver of consent; survey; clinical research

The convergence of a number of trends aimed at delivering increasingly effective and efficient health care has called into question the boundaries between traditional clinical research with clear requirements for patient consent and studies related to quality improvement where those requirements are less clear (Kass et al. 2013; Bellin and Dubler 2001). Recent innovations include the concept of the "learning healthcare system" (Olsen, Aisner, and McGinnis 2007) in which medical research is embedded in routine care delivered by health systems to enable "learning while doing," leading to rapid improvements in medical care (Solomon and Bonham 2013), often without the requirement for informed consent. The expansion of comparative effectiveness research (CER) and implementation science (Bonham and Solomon 2010) to find generalizable improvements in the quality of clinical care has spurred the call for "pragmatic trials" and the development of clinical trial "collaboratories," which represent networks of institutions dedicated to identifying and implementing best practice strategies in routine health care (National Institutes of Health [NIH] Collaboratory 2015; Joseph and Fu 2015; Huang et al. 2013; Harris et al. 2013; Climo et al. 2013; Derde et al. 2014). These pragmatic trials are embedded in routine care for which explicit informed consent may not typically be sought and which may make previous patient consent policies unnecessary and impractical (Faden, Beauchamp, and Kass 2014; Capron 2013).

The distinction and potential overlap between traditional clinical research and quality improvement studies have sparked considerable controversy in the medical ethics and clinical research communities, resulting in a push to define better criteria for when informed consent is required and clearer boundaries between quality improvement and research endeavors (Kass et al. 2008; Faden 2014; Kim and Miller 2014; Pletcher, Lo, and Grady 2014; Lynn et al. 2007). While a number of such criteria have been put forward (Ogrinc et al. 2013; Faden et al. 2013; Kass et al. 2008; Lynn et al. 2007; Bellin and Dubler 2001), to date the debate has largely been dominated by ethicists and researchers with limited empirical data. In particular, the patient's perspective is rarely represented. While some have deemed "consultation with patients and other stakeholders" necessary to specify the nature of this divide and its

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implications for oversight (Faden, Beauchamp, and Kass 2014), few studies to date have directly queried patients, providers, leadership of institutional review boards (IRBs), or health care administrators for their opinions about these boundaries.

While ethicists, researchers, and quality improvement experts are concerned about distinguishing between quality improvement and research, patients are often unaware of such distinctions. Patients may, for example, be unaware that for many quality improvement studies their consent is not required, and that more of these studies, particularly those involving multiple institutions, are now being published (Joseph and Fu 2015; Huang et al. 2013; Harris et al. 2013; Climo et al. 2013; Derde et al. 2014).

Without a better understanding of the values and preferences of key stakeholders about the boundaries defining when explicit informed consent should be required, the debate cannot be resolved. As a step toward providing the missing stakeholder input, we initiated a study to examine the categories of interventions that three groups of respondents (patients, IRB leaders, and leaders of quality improvement programs) would consider as requiring consent and those that could be conducted or performed without consent. We developed separate survey instruments for each of these three groups to evaluate the characteristics of health care delivery interventions (from the hospital environment to the use of personal health information) that might inform individuals' perspectives on whether consent should be required for the intervention category. Our intent was to develop measures that together could be used to identify respondents' "consent thresholds," or the categories of interventions for which they thought patient consent should be required. We describe here the development and testing of the patient version of these survey measures.

Methods

Measure development

Conceptual model. After careful review of the literature on the evaluation of hospital-based improvements in clinical care that could help define the thresholds perceived as requiring patient consent, we developed a conceptual model with five categories of interventions, all of which could be considered noninvasive or minimally intrusive. Since our focus was not to distinguish between quality improvement and research, we selected interventions that could be used in either research studies or quality improvement projects with the goal of assessing patient views on whether they would waive their informed consent for those efforts. These intervention categories included those representing changes made in the hospital environment; hospital policies or procedures; objects or substances put on or used by patients; medications or devices (all with existing Food and Drug Administration [FDA] approval); and collection, use, or sharing of patient information by hospitals. We developed these intervention categories to represent a hierarchy of interventions that progressively affect or "touch" patients, from changes in the hospital environment to changes related to medications or use of patient information. Each of these five intervention categories represented a "consent threshold construct" by which to evaluate characteristics that influence the determination for requiring or waiving consent. We hypothesized that respondents would be more restrictive in their willingness to waive consent for interventions involving direct patient care or use of identifiable patient information. Based on the literature (McGuire et al. 2011; Damschroder et al. 2007; Riordan et al. 2015; Willison et al. 2009; Whitddet et al. 2006; Damery et al. 2011), we also expected that patients who were more willing to waive consent would have certain sociodemographic characteristics (e.g., would be less well educated); would be more comfortable in general sharing of personal health information, using the Internet and social media in personally identifiable ways; and would be more trusting of health care providers. The measurement model we used to support measure development was intended as reflective rather than formative (Edwards and Bagozzi 2000). Reflective models assume that the measured items reflect or are caused *by* the underlying or latent construct, in this case an intervention "consent threshold," while formative models assume that measured items cause the underlying construct. That is, we hypothesized that individuals have a sense of intervention categories for which patient consent should be sought and that the measured items would reflect that 'consent threshold'.

Item generation and selection. We identified twelve individuals who were collaborators or contacts of collaborators in an ongoing national study (Active Bathing to Eliminate Infection [ABATE Infection] Trial 2015) and had content expertise in informed consent, experience with quality improvement or clinical research, or a background in clinical ethics, or had recently been in the hospital as a patient. These individuals assisted in the initial development of item content within each of the five consent threshold constructs. Although we did not use formal grounded theory methods (Glaser 1998), we used a review of the relevant literature and a modified Delphi approach to ask each member of the group involved in item generation a series of questions with probes to formulate item content and ensure adequate representation (rather than theoretical saturation) of each of the constructs. We then had conference calls to discuss group member input. Written summaries of the call content were then circulated iteratively to all group members for further comment and revision. Initial response options for all items were to be scored on 5-point Likert scales ranging from "always" to "never" requiring written permission before initiating the interventions specified in the item. Group members recommended changing the response options to whether it was "definitely yes" to "definitely not" appropriate to proceed without patient consent for each intervention.

Using this process, we initially identified 53 items across the five constructs. Item content was then reviewed by project leadership (SK, SF, JS, SH) for fidelity with the conceptual model and each of the constructs. After this review, using a modified Delphi process, thirty two items were retained, distributed over the five consent threshold constructs as Hospital Environment (six items); Hospital Procedures or Policies (seven items); Things Put On or Used by Patients (seven items); Medications or Devices (five items); and Hospital Collection, Use or Sharing of Patient Information (seven items).

Preliminary testing. To assess patients' perceptions about consent, we targeted currently hospitalized patients as a group who

would be engaged in care at the time of the survey, and therefore attentive to the potential need for consent for hospital-based interventions. We asked a convenience sample of 10 hospitalized patients to complete and comment on the survey, using cognitive interviewing techniques (Willis 2006).

All patients met the inclusion criteria specified in the following. We asked respondents not only about appropriateness of survey content, but also about survey format, time required to completion, and whether hospitalized patients could understand and provide well-reasoned responses. Based on responses by these patients, we made changes in survey instructions, in format (e.g., provision of large-type scale response options), and in ordering of response options. The modified survey (see Appendix A) was used in the following further evaluation.

Measure evaluation

Sample and settings. A convenience sample of subjects was identified from patients of general medicine/surgical non-critical care units at each of two academic medical centers in the United States, one on the East Coast and one on the West Coast, from October 2014 through March 2015. Subjects were identified by inpatient rosters and were excluded if they were <18 years of age, did not speak or read English, were cognitively impaired, combative, or psychologically unstable, or were not available for interview during business hours. Patients admitted to dedicated oncology and peripartum units were excluded. In total, 243 subjects were identified as eligible, of whom 200 completed surveys (82.3%); data collection continued until 100 patients completed surveys at each institution. This study was approved by the institutional review boards at each participating hospital.

Specification of validity variables. To assess construct validity, we also included single-item summary ratings where respondents gave overall ratings on a 5-point Likert scale (from "definitely yes" to "definitely not" appropriate to proceed without patient consent) for each of the five intervention categories. To assess discriminant validity, we used selected patient demographic characteristics, health status, comfort sharing health and other types of information, and trust of the health care system. Based on previous research (O'Malley et al. 2005; Fenton et al. 2012), we expected that three demographic characteristics would distinguish patients with higher (more permissive) from those with lower (less permissive) consent thresholds for all intervention categories: age, level of education, and race/ethnicity. We also anticipated that patients' health status and prior participation in research studies would influence their threshold for waiving consent for all intervention categories (Campbell 2013 et al.; Gonzalez-de Paz et al. 2015).

We further expected that more permissive consent thresholds would be associated with greater comfort sharing personal health information, greater comfort sharing personal information on the Internet, and greater trust in hospitals (Hill et al. 2015). We thus developed a four-item scale to represent comfort sharing personal health information (Egede and Ellis 2008), developed a new seven-item scale representing comfort sharing personal information online, and created a five-item trust in hospital scale modified from a multidimensional trust in researchers scale (Hall et al. 2006).

Scale development and scoring. Multi-item scales were developed within each of the five consent threshold constructs (hospital environment, hospital policies and procedures, objects or substances used by patients, medications and devices, and data sharing), using simple algebraic sums of the Likert-scaled items for that construct. Composite scales for each construct were then transformed to range from 0 to 100 by subtracting scale means from theoretical scale minimums and dividing the result by the theoretical scale maximum from minimum and multiplying that result by 100. High scale scores indicated more permissive consent thresholds.

Reliability and validity testing. The sample size ($n = 200$) was not adequate to conduct cluster analyses (e.g., factor analysis) to assess item-construct alignment (Nunnally and Bernstein 1994; Segall 1994; Charter 1999; MacCallum et al. 2001). Therefore, we conducted two separate internal consistency reliability analyses on data from each of the study sites to assess both the reliability of the composite scale and the relative contributions of items to the total variance of each scale (i.e., item-to-total correlation coefficients). Furthermore, we eliminated two items based on poor item-to-total correlation and on improved Cronbach's alpha if these items were eliminated from their respective scales. We then combined the samples and repeated the internal consistency reliability analysis.

As preliminary evidence of validity, we assessed the association between each of the five consent threshold scales (CTSs) and single-item measures of that scale using Pearson product-moment correlation coefficients. Discriminant validity was assessed using separate analyses of variance for the five CTSs and the patient demographic characteristics (age, education, and race/ethnicity). Convergent validity between single-item summary ratings of each of the five consent threshold constructs and their corresponding multi-item scales was assessed using Pearson product-moment correlation coefficients. Using separate analyses of variance, we assessed the relationship of each of the five CTSs to the scales representing patient comfort sharing personal health information, comfort sharing personal information online, and trust in hospitals. In separate multiple linear regressions, we assessed the relative contribution of the three convergent validity variables to each of the five CTSs, adjusting for the patient demographic characteristics.

Results

The study sample was middle aged (mean age = 53 years, SD 17.1), majority female, roughly two-thirds non-Hispanic white, and more than three-quarters had completed more than a high school education (see Table 1). More than one-third of the patients surveyed had been hospitalized three or more times in the prior year, more than one-third had previously participated in research studies, and the mean self-reported overall health rating was 47.0 (SD 29.2) (see Table 1), with 37.5% reporting their health as "fair" or "poor."

For each of the CTSs, all items in each scale had substantial item-to-total correlations with the other items in that scale

Table 1. Characteristics of the patient sample ($N = 200$)[1].

Characteristics	Mean/%
Mean age	53 [17.1]
Female (%)	54
Non-Hispanic white (%)	62.5
Hispanic[2] (%)	13.5
More than high school education (%)	78.5
Three or more hospital admissions in prior year (%)	36
Any prior participation in research studies (% yes)	36.5
Overall health rating[3]	47 [29.2]

[1]Table entries based on self-reported survey information; data are means with standard deviations reported in parentheses below or percentages as indicated.
[2]Proportion of patients reporting Hispanic ethnicity, independent of race.
[3]Based on 5-point scale ranging from "excellent" to "poor", transformed to range from 0 to 100 by subtracting scale mean from theoretical minimum, dividing result by theoretical minimum minus maximum, and multiplying result by 100.

taken together (see Appendix B). All internal consistency reliability coefficients for each of the five CTSs and for the three multi-item validation scales exceeded .70 for the total sample (see Table 2), a value considered adequate for group comparisons in the early stages of measure development (Nunnally and Bernstein 1994). Coefficients were not significantly different for each of the site-specific subsamples (data not shown).

Scale means for all five CTSs indicated general patient support for waiving consent across all categories of interventions studied. However, the observed higher scale means for certain CTSs indicated that patients were more comfortable foregoing consent for interventions involving changes to the hospital environment or policies and procedures, and for minimally intrusive components of care (such as pedometers, compression stockings, bathing soaps), compared to interventions involving medications or devices, or sharing patient information, for which scale scores indicated less comfort waiving consent (see Table 2).

While the three considered sociodemographic characteristics (age, race, and educational level) had mean differences associated with higher versus lower consent threshold scale values in the anticipated directions, there were only two p values $<.05$ for these variables, which did not reach statistical significance after Bonferroni correction (see Table 3).

We found that patients who had previously participated in research were significantly less permissive than those who had not in waiving consent, but only for interventions involving the use or sharing of information (see Table 3). Those in poorer health were also significantly less permissive than those in better health for all five CTSs. This finding was similar for patients with more experience with the health care system, as measured by number of hospitalizations in the prior year (data not shown).

As evidence of convergent validity, we correlated the multi-item CTSs with single-item ratings of each of the respective constructs. All Pearson product-moment correlation coefficients were statistically significant: Multi-item Hospital Environment CTS $\approx$ single item $= .25$; multi-item Hospital Policies/Procedures CTS $\approx$ single item $= .33$; multi-item Components of Care CTS $\approx$ single item $= .33$; multi-item Medications/Devices CTS

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[2]
Making changes in:		*Would it be okay for the hospital to go ahead without your permission to:*			
The hospital environment	6	Try out different places to put handrails in patient rooms to prevent falls. (Response options: definitely yes to definitely not).	89.0	17.6	0.74
Hospital policies or procedures	7	See how often patients should be turned in their bed to prevent bedsores. (Response options: definitely yes to definitely not).	86.0	18.6	0.75
Objects or substances that are put on or used by patients	7	Compare different activity monitors (such as pedometers) to see which one is better at measuring patients' activity while in the hospital. (Response options: definitely yes to definitely not).	86.7	20.0	0.83
Types of medications or devices used in hospitals	5	Try different coatings on pills to make them easier to swallow. (Response options: definitely yes to definitely not).	73.3	26.0	0.73
The ways hospitals collect, use, or share patient information	7	Share patient data with hospital partners to figure out better ways to take care of patients, if individual patients cannot be identified. (Response options: definitely yes to definitely not).	57.4	29.2	0.83
Validation variables					
Comfort sharing PHI[3]	4	How comfortable would you feel letting researchers studying ways to improve healthcare use protected health information, if they protected patients from being individually identified. (Response options: very comfortable to very uncomfortable).	75.4	22.8	0.91
Comfort sharing personal information online[4]	7	How comfortable do you or would you feel sharing your personal information when shopping online(Response options: very comfortable to very uncomfortable).	56.5	23.8	0.88
Trust in hospitals[5]	6	How strongly you agree or disagree with the statement that the care hospitals give is often influenced by how much money they can make. (Response options: strongly agree to strongly disagree).	54.2	18.0	0.73

[1]Table entries are self-reported survey-based measures; all Consent Threshold Scales were reported on 5-point Likert scales ranging from "definitely yes" to "definitely not" in response to the overall item stem: "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?"; scale means were transformed to range from 0 to 100 by subtracting scale mean from theoretical minimum, dividing result by theoretical minimum minus maximum and multiplying result by 100. A higher score indicates that the patient is more comfortable with allowing the hospital to make changes without their permission.
[2]Internal consistency reliability coefficient (ref: Cronbach)
[3]Protected Health Information (PHI) includes name, date, diagnosis, lab results, etc. Adapted from Hall et al. (2006).
[4]Online refers to the Web in general, such as sharing on social media, e-mail, online shopping.
[5]Adapted from LE Egede LE and C Ellis, Development and testing of the Multidimensional Trust in Health Care Systems Scale, J Gen Intern Med. 2008 Jun;23(6):808-15.

Table 3. Consent threshold scales for selected patient characteristics ($N = 200$).

Consent Threshold Scales	Age <50 years[2] Mean (SD)	Age ≥50 years[2] Mean (SD)	Mean difference	Race White[3] Mean (SD)	Race non-White[3] Mean (SD)	Mean difference	Education ≤high school[4] Mean (SD)	Education >high school[4] Mean (SD)	Mean difference	Participated in research[5] Mean (SD)	Did not participate in research[5] Mean (SD)	Mean difference	Poor/fair health rating[6] Mean (SD)	Good to excellent health rating[6] Mean (SD)	Mean d ifference
Making changes in:	$N = 90$	$N = 110$	(± 95% CI)[7]	$N = 140$	$N = 60$	(± 95% CI)[7]	$N = 43$	$N = 157$	(± 95% CI)[7]	$N = 73$	$N = 127$	(± 95% CI)[7]	$N = 75$	$N = 125$	(± 95% CI)[7]
The hospital environment	87.9	89.9	−2.1	89.8	87.1	2.7	86.7	89.6	−2.9	87.2	90.1	−2.9	84.6	91.7	−7.1*
	(18.4)	(17.0)	(−7.0, 2.9)	(17.0)	(19.1)	(−2.6, 8.1)	(19.0)	(17.3)	(−8.9, 3.1)	(19.0)	(16.8)	(−8.0, 2.2)	(22.1)	(13.7)	(−12.1, −2.1)
Hospital policies or procedures	83.5	88.1	−4.6	86.7	84.4	2.3	87.8	85.6	2.2	86.1	86.0	0.1	78.4	90.6	−12.2***
	(21.2)	(15.9)	(−9.7, 0.6)	(17.6)	(20.8)	(−3.3, 8.0)	(16.7)	(19.1)	(−4.1, 8.6)	(20.8)	(17.3)	(−5.3, 5.5)	(21.9)	(14.5)	(−17.3, −7.2)
Objects or substances that are put on or used by patients	83.4	89.4	−6.0*	87.6	84.6	2.90	80.7	88.3	−7.6*	85.7	87.3	−1.6	81.7	89.7	−8.0*
	(21.9)	(17.8)	(−11.6, −0.5)	(19.3)	(21.4)	(−3.1, 9.0)	(27.2)	(17.2)	(−14.3, −0.9)	(22.4)	(18.5)	(−9.6, 5.5)	(24.0)	(16.5)	(−13.7, −2.4)
Types of medications or devices used in hospitals	70.7	75.4	−4.6	75.1	68.9	6.2	72.4	73.5	−1.1	72.0	74.0	−2.0	64.5	78.6	−14.1***
	(26.4)	(25.6)	(−11.9, 2.3)	(20.0)	(30.0)	(−1.7, 14.1)	(30.6)	(24.7)	(−9.9, 7.8)	(27.3)	(25.3)	(−7.4, 4.2)	(28.5)	(22.9)	(−21.3, −6.9)
The ways hospitals collect, use, or share patient information	53.3	60.8	−7.4	60.0	51.3	8.7	60.2	56.6	3.6	50.9	61.2	−10.3*	48.8	62.6	−13.8**
	(29.0)	(29.1)	(−15.6, 0.7)	(28.1)	(31.0)	(−0.1, 17.6)	(30.0)	(29.0)	(−6.4, 13.5)	(31.0)	(27.5)	(−18.6, −1.9)	(28.3)	(28.6)	(−22.0, −5.6)

*p < .05. **p < .005. ***p < .001.

[1]Table entries are unadjusted mean differences with standard deviations in parentheses below, based on separate analyses of variance. All Consent Threshold Scales were reported on 5-point Likert scales ranging from "definitely yes" to "definitely not" in response to the overall item stem: "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?"; scale means were transformed to range from 0-100 by subtracting scale mean from theoretical minimum, dividing result by theoretical minimum minus maximum and multiplying result by 100. A higher score indicates that the patient is more comfortable with allowing the hospital to make changes without their permission.

[2]Age was based on self-reported survey information.

[3]Any race other than white or Caucasian was considered non-white. Hispanic ethnicity falls within both categories, as it depends on the patient's identification of self.

[4]Education was based on self-reported survey information.

[5]Participation in research was based on self-reported survey information, inquiring if the patient had ever participated in research.

[6]Health rating was based on self-reported survey information ranging from poor to excellent health.

[7]The response options were scored on a scale from one to five, one indicating definitely not (do not go ahead without my permission) and five indicating definitely yes (go ahead without my permission). Ninety-five percent confidence intervals around mean difference were calculated using two-tailed-tests.

≈ single item = .33; and multi-item Sharing of Patient Data CTS ≈ single item = .51. To evaluate convergent validity further, we correlated each of the CTSs with patient-reported comfort sharing personal health information, comfort sharing personal information online, and trust in hospitals. All correlation coefficients showed a modest positive relationship between the CTSs and validity variables, and only one correlation (Hospital Environment CTS ≈ Trust in Hospitals) did not reach statistical significance (see Table 4).

To examine the magnitude of differences in each CTS for each of the validation constructs, we dichotomized comfort sharing personal health information, comfort sharing information online, and trust in hospital scale scores at the median and computed scores for each of the CTSs. Results from multiple linear regression adjusting for patient demographic characteristics did not alter results; unadjusted values are presented in Figures 1a–1c. There were substantial and statistically significant differences between those with low versus high scale scores on the three validation constructs for each of the CTSs, all in the expected direction. Patients with greater comfort sharing personal health information, greater comfort sharing personal information online, and those with greater trust in hospitals were also more comfortable waiving consent for all of the categories of interventions represented in the five CTSs.

Discussion

The boundaries between interventions that require patient consent and those that do not are increasingly being called into question. A recent editorial in the *New York Times* underscored the broader relevance of this concern for interventions being undertaken in other industries beyond health care (Meyer and Chabris 2015). Improvements in the way health care is delivered are undertaken regularly by clinics and hospitals, generally without formal study or notification of patients. These efforts to improve quality are often deemed to be of minimal risk to patients and target efficiencies in care delivery, implementing policies for selecting or enforcing care "pathways," adopting newly approved products or monitoring systems, and developing "smart tool" applications to support or augment electronic health information systems or other interventions to improve effectiveness of care.

Until recently, these quality improvement strategies or interventions were rarely empirically studied for their relative value or benefit over current practices. Now, such studies are routinely conducted to support recommendations for best clinical practices as encouraged by scientific, clinical, and quality improvement societies, and are proliferating in the published literature (Joseph and Fu 2015; Huang et al. 2013; Harris et al. 2013; Climo et al. 2013; Derde et al. 2014). Pragmatic clinical trials evaluating these strategies, such as the use of protocols to prevent health care-associated infections and other patient safety strategies, frequently include comparisons of different clinical practices. The proliferation of these types of studies elevates the importance of redefining the boundaries between research and quality improvement studies, specifically the characteristics of studies that require patient consent.

Most of the published debate on these boundaries has been engaged primarily by researchers and ethicists (Kass et al. 2008; Faden, Beauchamp, and Kass 2014; Kim and Miller 2014; Pletcher, Lo, and Grady 2014; Lynn et al. 2007); however, some have called for input by patients and other stakeholders (Faden, Beauchamp, and Kass 2014). This study was designed to address the gap in patient stakeholder input into the characteristics of studies that, from their perspective, would require informed consent. We developed and completed initial testing of a measure of patients' level of comfort for waiving consent for different types of minimal risk interventions being undertaken by hospitals to improve care.

We found support for the reliability and construct validity of five separate multi-item CTSs, each representing categories of minimal risk interventions. Overall, we found that patients were generally comfortable waiving consent for certain categories of interventions. However, we also found a consistent gradient of decreasing comfort as these interventions progressed from having a less direct impact on patients (such as changes to the hospital environment or changes in minimally intrusive or unpleasant components of care, e.g., pedometers, bathing soaps) to a more direct impact (e.g., medication timing, or use and sharing of personal health information). In particular, approximately half of the patients surveyed were concerned

Table 4. Relationship of Consent Threshold Scales to validation variables ($N = 200$).

Consent Threshold Scales	Comfort sharing PHI[2]	Comfort sharing personal information online[3]	Trust in hospitals[4]
Making changes in:			
The hospital environment	0.31***	0.15*	0.13
Hospital policies or procedures	0.19*	0.16*	0.26***
Objects or substances that are put on or used by patients	0.35***	0.14*	0.15*
Types of medications or devices used in hospitals	0.25***	0.21**	0.22**
The ways hospitals collect, use, or share patient information	0.30***	0.16*	0.34***

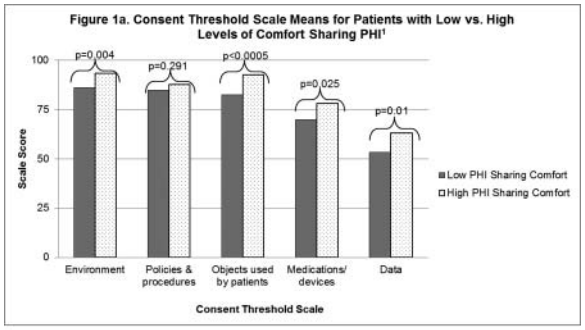
*p < .05. **p < .005. ***p < .001.

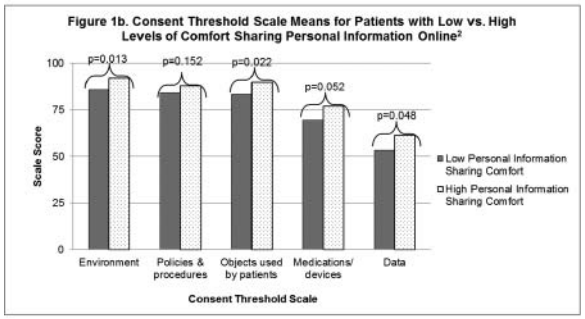
[1]Table entries are Pearson Product-Moment Correlation coefficients. All Consent Threshold Scales were reported on 5-point Likert scales ranging from "definitely yes" to "definitely not" in response to the overall item stem: "For each of the following questions, would it be okay for the hospital to go ahead without your permission to compare ways they might improve care?"; scale means were transformed to range from 0-100 by subtracting scale mean from theoretical minimum, dividing result by theoretical minimum minus maximum and multiplying result by 100. A higher score indicates that the patient is more comfortable with allowing the hospital to make changes without their permission.

[2]Protected Health Information (PHI) includes name, date, diagnosis, lab results, etc. Adapted from Hall et al. (2006).

[3]Online refers to the web in general, such as sharing on social media, email, online shopping.

[4]Adapted from Egede and Ellis (2008).





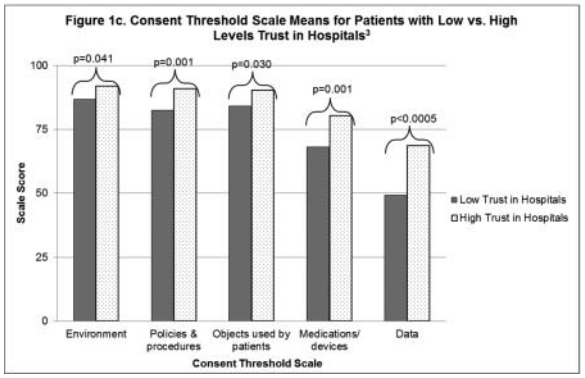


Figure 1. Figure entries are unadjusted mean scale scores, dichotomized at the median, with standard deviations in parentheses below. All Consent Threshold Scales were reported on 5-point Likert scales ranging from "definitely yes" to "definitely not" in response to the overall item stem: "For each of the following questions, would it be okay for the hospital to go ahead without your permission to compare ways they might improve care?"; scale means were transformed to range from 0-100 by subtracting scale mean from theoretical minimum, dividing result by theoretical minimum minus maximum and multiplying result by 100. A higher score indicates that the patient is more comfortable with allowing the hospital to make changes without their permission. 1. Protected Health Information (PHI) includes name, date, diagnosis, lab results, etc. Adapted from MA Hall et al., Measuring trust in Medical Researchers, Med Care. 2006 Nov;44(11):1048-53. 2. Online refers to the web in general, such as sharing on social media, email, online shopping. 3. Adapted from LE Egede LE and C Ellis, Development and testing of the Multidimensional Trust in Health Care Systems Scale, J Gen Intern Med. 2008 Jun;23(6):808-15.

about the use of identified personal health information for the purposes of improving quality of care. This finding paralleled another study showing a gradient in willingness to waive consent by the level of invasiveness of the intervention under study (Abboud et al. 2006).

We found that patients who were waiving consent for all five categories of interventions were also more comfortable sharing personal health information, were more comfortable sharing personal information online, and had greater trust in hospitals. Each of the multi-item CTSs was significantly correlated in the expected direction with the single-item measure of that construct, and with the three validation measures. These findings lend support for the construct validity of these scales. However, further testing is needed to assess, for example, whether patients with greater comfort waiving consent would also be more likely to participate in effectiveness research, be more active in accessing their medical record information when available (Walker et al. 2011; Vodicka et al. 2013), and be more willing to share information to improve their health care (Zulman et al. 2011).

We were surprised by the lack of association of the CTSs with patient characteristics, particularly age and education. Previous studies have shown that older patients, minority patients, and those with lower levels of education may be less comfortable waiving consent (Gaylin et al. 2011). However, there were no significant relationships between any of the sociodemographics studied and the CTSs. Different from the participants in the previous surveys by Gaylin et al. (2011) and those of a recent survey using three vignettes to assess attitudes toward informed consent (Cho et al. 2015), respondents for this study were hospitalized patients, who were older, in poorer health, and more likely to have previously participated in research studies.

Interestingly, we found that patients with more experience with the health care system (i.e., those in poorer health status, those with more hospitalizations in the prior year, and those with prior participation in research) were less comfortable waiving consent. Because this was a cross-sectional study, further research is needed to determine, for example, whether the realities of declining health and active experience with health care may make patients more concerned rather than more comfortable about waiving consent.

Limitations. This study has important limitations. First, the study sample was not representative. Subjects were hospitalized patients recruited from two academic medical centers on the East and West Coasts, with exclusions that limit generalizability (e.g., non-English-speaking patients). Second, the small sample size did not allow for certain analyses, for example, confirmatory analysis of factor structure to assess discriminant validity of the five CTS. Third, the cross-sectional design did not allow causal modeling that could have informed the relationship between lower versus higher consent thresholds and future behavior such as active participation in clinical effectiveness or quality improvement studies.

Conclusions

In a sample of patients actively under treatment, we have begun the development of measures to identify the categories of interventions for which patients would feel comfortable waiving consent, as opposed to those for which they would not. We found initial support for the reliability and validity of these measures and the feasibility of their use in healthcare settings. Further, our findings supported a gradient in the categories of minimal risk quality improvement studies that patients perceived could be undertaken without patient consent. More work is needed to understand the reasons for concern among those who would not waive consent for improving healthcare processes and treatment through interventions involving medications or devices, or the sharing of patient health information

for these purposes. As efforts to improve care and accelerate the implementation of effective interventions continue to challenge the understanding and practical boundaries of informed consent, in addition to ethical analysis, more careful studies of understanding patients' and other stakeholders' perspectives on these boundaries are needed in order to develop appropriate policies.

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Author contributions

SK, SH, SF, JM, AG, LH, LS, and RK contributed to the conception and design of the article. SK, SH, AG, LH, LS, and RK contributed to data collection. All authors (SK, AG, SF, JM, LH, LS, RK, KO, TT, and SH) contributed to the drafting of the article.

Conflicts of interest

The authors disclose no conflict of interest relevant to the subject matter discussed in this article. In the interest of disclosure, the following authors are conducting clinical studies in which participating health care facilities are receiving contributed product from Sage Products (SH, AG, LH, RK, LS, TT), Molnlycke SH, AG, LH, RK, LS), 3M (SH, AG, LH, TT), and Clorox (SH, AG, LH, TT).

Ethical approval

This study was approved by the institutional review boards at UC Regents (University of California Irvine Health) and Partners Human Research Committee (Brigham and Women's Hospital).

References

Abboud, P. A., K. Heard, A. A. Al-Marshad, and S. R. Lowenstein. 2006. What determines whether patients are willing to participate in resuscitation studies requiring exception from informed consent? *Journal of Medical Ethics* 32(8): 468–72.

Active Bathing to Eliminate Infection (ABATE Infection) Trial. 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT02063867 (accessed January 2, 2015).

Bellin, E., and N. N. Dubler. 2001. The quality improvement–research divide and the need for external oversight. *American Journal of Public Health* 91(9), 1512–17.

Bonham, A. C., and M. Z. Solomon. 2010. Moving comparative effectiveness research into practice: implementation science and the role of academic medicine. *Health Affairs* 29(10): 1901–5.

Campbell, B., H. Thomson, J. Slater, C. Coward, K. Wyatt, and K. Sweeney. 2007. Extracting information from hospital records: what patients think about consent. *Quality and Safety Health Care* 16(6): 404–8.

Capron, A. M. 2013. The real problem is consent for treatment, not consent for research. *American Journal of Bioethics* 13(12): 27–29.

Charter, R. A. 1999. Sample size requirements for precise estimates of reliability, generalizability, and validity coefficients. *Journal of Clinical and Experimental Neuropsychology* 21: 559–66.

Cho, M. K., D. Magnus, M. Constantine, et al. 2015. Attitudes toward risk and informed consent for research on medical practices: A cross-sectional survey. *Annals of Internal Medicine* 162(10): 690–96.

Climo, M. W., D. S. Yokoe, D. K. Warren, et al. 2013. Effect of daily chlorhexidine bathing on hospital-acquired infection. *New England Journal of Medicine* 368(6): 533–42.

Damery, S., R. Ryan, R. J. McManus, S. Warmington, H. Draper, S. Wilson; Improving Colorectal Outcomes (ICOS) Group. 2011. The effect of seeking consent on the representativeness of patient cohorts: Iron-deficiency anaemia and colorectal cancer. *Colorectal Disease* 13(11): e366–73.

Damschroder, L. J., J. L. Pritts, M. A. Neblo, R. J. Kalarickal, J. W. Creswell, and R. A. Hayward. 2007. Patients, privacy and trust: Patients' willingness to allow researchers to access their medical records. *Social Science & Medicine* 64(1): 223–35.

Derde, L. P., B. S. Cooper, H. Goossens, et al.; MOSAR WP3 Study Team. 2014. Interventions to reduce colonisation and transmission of antimicrobial-resistant bacteria in intensive care units: An interrupted time series study and cluster randomised trial. *Lancet Infectious Diseases* 14 (1): 31–39.

Edwards, J. R., and R. P. Bagozzi. 2000. On the nature and direction of relationships between constructs and measures. *Psychological Methods* 5 (2): 155–74.

Egede, L. E., and C. Ellis. 2008. Development and testing of the multidimensional trust in health care systems scale. *Journal of General Internal Medicine* 23(6): 808–15.

Faden, R. R., N. E. Kass, S. N. Goodman, P. Pronovost, S. Tunis, and T. L. Beauchamp. 2013. An ethics framework for a learning health care system: A departure from traditional research ethics and clinical ethics. *Hastings Center Report* 43(s1): S1627.

Faden, R. R., T. L. Beauchamp, and N. E. Kass. 2014. Informed consent, comparative effectiveness, and learning health care. *New England Journal of Medicine* 370: 766–68.

Fenton, J. J., A. F. Jerant, K. D. Bertakis, and P. Franks. 2012. The cost of satisfaction: A national study of patient satisfaction, health care utilization, expenditures, and mortality. *Archives of Internal Medicine* 172(5): 405–11.

Finkelstein, J. A., A. L. Brickman, A. Capron, et al. 2015. Oversight on the borderline: Quality improvement and pragmatic research. *Clinical Trials* 12(5): 457–66.

Gaylin, D. S., A. Moiduddin, S. Mohamoud, K. Lundeen, and J. A. Kelly. 2011. Public attitudes about health information technology, and its relationship to health care quality, costs, and privacy. *Health Services Research* 46(3): 920–38.

Glaser, B. G. 1998. *Doing grounded theory: Issues and discussions*. Mill Valley, CA: Sociology Press.

González-de Paz, L., B. Kostov, P. Solans-Julian, M. D. Navarro-Rubio, and A. Sisó-Almirall. 2015. Do patients and health care professionals view the communication processes of clinical research differently? A Rasch analysis from a survey. *Journal of Evaluation in Clinical Practice* 21(5): 790–7.

Hall, M. A., F. Camacho, J. S. Lawlor, V. Depuy, J. Sugarman, and K. Weinfurt. 2006. Measuring trust in medical researchers. *Medical Care* 44 (11): 1048–53.

Harris, A. D., L. Pineles, B. Belton, et al. 2013. Universal glove and gown use and acquisition of antibiotic-resistant bacteria in the ICU: A randomized trial. *Journal of the American Medical Association* 310(15): 1571–80.

Hill, E. M., E. L. Turner, R. M. Martin, and J. L. Donovan. 2013. "Let's get the best quality research we can": Public awareness and acceptance of consent to use existing data in health research: A systematic review and qualitative study. *BMC Medical Research Methodology* 13(1): 72.

Huang, S. S., E. Septimus, K. Kleinman, et al.; CDC Prevention Epicenters Program; AHRQ DECIDE Network and Healthcare-Associated Infections Program. 2013. Targeted versus universal decolonization to prevent ICU infection. *New England Journal of Medicine* 368(24): 2255–65.

Joseph, A., and S. Fu. 2015. Proactive outreach strategies to connect smokers with tobacco cessation treatment. *JAMA Internal Medicine* 175(2): 226–27.

Kass, N., P. J. Pronovost, J. Sugarman, C. A. Goeschel, L. H. Lubomski, and R. Faden. 2008. Controversy and quality improvement: Lingering questions about ethics, oversight, and patient safety research. *Joint Commission Journal on Quality and Patient Safety* 34(6): 349–53.

Kass, N. E., R. R. Faden, S. N. Goodman, P. Pronovost, S. Tunis, and T. L. Beauchamp. 2013. The research–treatment distinction: A problematic

approach for determining which activities should have ethical oversight. *Hastings Center Report* 43(s1): S4–15.

Kim, S. Y. H., and F. G. Miller. 2014. Informed consent for pragmatic trials: The integrated consent model. *New England Journal of Medicine* 370: 769–72.

Lynn, J., M. A. Baily, M. Bottrell, et al. 2007. The ethics of using quality improvement methods in health care. *Annals of Internal Medicine* 146(9): 666–73.

MacCallum, R. C., K. F. Widaman, K. J. Preacher, and S. Hong. 2001. Sample size in factor analysis: The role of model error. *Multivariate Behavioral Research* 36: 611–37.

McGuire, A. L., M. Basford, L. G. Dressler, et al. 2011. Ethical and practical challenges of sharing data from genome-wide association studies: The eMERGE Consortium experience. *Genome Research* 21(7): 1001–7.

Meyer, M. N., and C. F. Chabris. 2015. Please, corporations, experiment on us. *New York Times*, June 19. Available at: http://www.nytimes.com/2015/06/21/opinion/sunday/please-corporations-experiment-on-us.html (accessed June 21, 2015).

National Institutes of Health [NIH], the NIH Health Care Systems Research Collaboratory. 2015. Available at: https://www.nihcollaboratory.org/Pages/default.aspx (accessed June 11, 2015).

Nunnally, J. C., and I. H. Bernstein. 1994. *Psychometric theory* (3rd ed.). New York, NY: McGraw-Hill.

Ogrinc, G., W. A. Nelson, S. M. Adams, and A. E. O'Hara. 2013. An instrument to differentiate between clinical research and quality improvement. *IRB Ethics and Human Research* 35(5): 1–8.

Olsen, L. A., D. Aisner, and J. M. McGinnis. 2007. *The learning healthcare system*: W*orkshop summary*. Institute of Medicine of the National Academies Roundtable on Evidence-Based Medicine. Available at: http://www.ncbi.nlm.nih.gov/books/NBK53494/

O'Malley, A. J., A. M. Zaslavsky, M. N. Elliott, L. Zaborski, and P. D. Cleary. 2005. Case-mix adjustment of the CAHPS hospital survey. *Health Services Research* 40: 2162–81.

Pletcher, M. J., B. Lo, and D. Grady. 2014. Informed consent in randomized quality improvement trials: A critical barrier for learning health systems. *JAMA Internal Medicine* 174(5): 668–70.

Riordan, F., C. Papoutsi, J. E. Reed, C. Marston, D. Bell, and A. Majeed. 2015. Patient and public attitudes towards informed consent models and levels of awareness of Electronic Health Records in the UK. *International Journal of Medical Informatics* 84(4): 237–47.

Segall, D. O. 1994. The reliability of linearly equated tests. *Psychometrika*. 59: 361–75.

Solomon, M. Z., and A. C. Bonham. 2013. Ethical oversight of research on patient care. *Hastings Center Report* 43(s1): S2–S3.

Vodicka, E., R. Mejilla, S. G. Leveille, et al. 2013. Online access to doctors' notes: Patient concerns about privacy. *Journal of Medical Internet Research* 15(9): e208.

Walker, J., S. G. Leveille, L. Ngo, et al. 2011. Inviting patients to read their doctors' notes: Patients and doctors look ahead: Patient and physician surveys. *Annals of Internal Medicine* 155(12): 811–19.

Whiddett, R., I. Hunter, J. Engelbrecht, and J. Handy. 2006. Patients' attitudes towards sharing their health information. *International Journal of Medical Informatics* 75(7): 530–41.

Willis, G. B. 2006. Cognitive interviewing: A tool for improving questionnaire design. *Quality of Life Research* 15(3): 571–73.

Willison, D. J., V. Steeves, C. Charles, et al. 2009. Consent for use of personal information for health research: Do people with potentially stigmatizing health conditions and the general public differ in their opinions? *BMC Medical Ethics* 10(1): 10.

Zulman, D. M., K. M. Nazi, C. L Turvey, T. H. Wagner, S. S. Woods, and L. C. An. 2011. Patient interest in sharing personal health record information: A Web-based survey. *Annals of Internal Medicine* 155(12): 805–10.