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Patients' Views Concerning Research on Medical Practices: Implications for Consent

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Abstract

Background—Comparative effectiveness research (CER) and pragmatic clinical trials commonly test interventions that are in routine use and pose minimal incremental risk or burdens to patients who participate in this research. The objective of this study was to elicit the range of patients' views and opinions regarding a variety of different types of research on usual medical practices, especially notification and authorization for them.

Methods—We conducted twelve focus groups with adults in five U.S. cities—six focus groups addressing CER ("CER groups") and six groups addressing research involving hospital operations and clinician interventions ("Operations groups"). Participants discussed hypothetical research studies and potential methods of notifying patients and obtaining their authorization to participate. Group discussions were recorded, transcribed, and coded to identify patients' views related to research on standard medical practice.

Results—A total of ninety six people participated. Twelve key themes emerged from participants' discussions of the hypothetical research studies; these themes were then grouped into four general categories: clinical care; notification and authorization; communication; and conduct and design of research. The desire to be actively notified and asked was more prominent with regard to CER studies than with regard to Operations studies.

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ETHICAL APPROVAL: This study was approved by the institutional review boards at Duke University Medical Center and Johns Hopkins University.

Conclusions—Our data suggest that effective policy and guidance will involve balancing different patients' interests and potentially different sets of interests for different types of research studies on usual medical practices.

Keywords

comparative effectiveness research; pragmatic clinical trials; ethics; research ethics; focus groups; policy

Introduction

Comparative effectiveness research (CER) and pragmatic clinical trials (PCTs) commonly test interventions that are in routine use and pose minimal incremental risk or burdens to patients who participate in this research. CER has been defined as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care" (Committee on Comparative Effectiveness Research Prioritization). As such, CER is a type of PCT. While PCTs have been defined in a variety of ways, it has been suggested that there are "three key attributes of PCTs: (1) an intent to inform decision-makers (patients, clinicians, administrators, and policy makers), as opposed to elucidating a biological or social mechanism; (2) an intent to enroll a population relevant to the decision in practice and representative of the patients/populations and clinical settings for whom the decision is relevant; and (3) either an intent to (a) streamline procedures and data collection so that the trial can focus on adequate power for informing the clinical and policy decisions targeted by the trial or (b) measure a broad range of outcomes" (Califf and Sugarman 2015). Accordingly, CER and PCTs may be quite diverse and can include an evaluation of a therapeutic intervention (e.g., randomization to one drug versus another used to treat the same condition, to assess their comparative effectiveness) as well as interventions at the level of a medical center's operations (e.g., using different schedules for bathing inpatients or educating staff).

Research that compares different medical practices has been accompanied by an array of ethical and regulatory challenges. Perhaps most strikingly are the vigorous debates about the SUPPORT study, a trial that examined higher and lower levels of oxygen saturation targets in the treatment of premature infants. The debates about the trial, including arguments about the level and disclosure of risk, as well as whether the interventions tested could be considered accepted medical practices, have included disputes in the academic literature (Buchanan 2013; Drazen, Solomon, and Greene 2013; Hudson, Guttmacher, and Collins 2013; Macklin and Shepherd 2013; Macklin et al. 2013; Magnus and Caplan 2013; Wilfond 2013; Wilfond et al. 2013), a public hearing (OHRP 2013), controversial proposed guidance for this type of research (OHRP 2014; IOM 2014), and attempted legal action (First Amended Complaint and Demand for Jury Trial, *Looney v. Moore*, No. 2:13-cv-00733-UNAS-KOB (N.D. Ala. filed May 20, 2013)). In addition, projects within the National Institutes of Health's Health Care Systems Research Collaboratory, which is an initiative that conducts PCTs involving an array of conditions, have encountered difficult ethical and regulatory issues (Sugarman and Califf 2014). These issues included questions about what

constitutes minimal risk, whether consent requirements can and should be altered or waived, whether and how FDA regulations apply, the adequacy of privacy protections, and the most appropriate means of monitoring the research for safety and efficacy (NIH 2015).

While conceptual work on these topics has started to address some of these complex issues (Anderson, Califf, and Sugarman 2015; Faden, Beauchamp, and Kass 2014; Feudtner, Schreiner, and Lantos 2013; Macklin and Shepherd 2013; McKinney 2013; Wendler 2013; Wilfond 2013), there remains a dearth of empirical data to further inform and contextualize these discussions. Moreover, policies and practices designed to protect the rights, interests, and welfare of those who participate in all types of research should reflect careful consideration of multiple stakeholder perspectives, particularly those of prospective participants. Because policies and practices for research oversight are intended to protect and serve participants and the integrity of the research process, policymakers would benefit from a more nuanced understanding of patients' perspectives in the context of research on medical practices. Recent studies using focus groups (Kelley et al. 2015), surveys (Cho et al. 2015), and deliberative democracy methods (Fabi et al. 2015) have begun to identify important patient perspectives about research comparing different therapeutic approaches for individual patients. These studies found widespread support for research, a preference for being notified and asked permission by their doctor to be enrolled in the research, and a concern about how research would impact their care. However, less is known about how people's views differ depending upon the type of research study; for example, individual therapeutic interventions versus those involving medical center operations.

The objective of this study was to elicit the range of patients' views and opinions regarding a wide variety of different types of research on medical practices, including research notification and authorization.

Methods

Twelve focus groups were conducted between June and December 2014. They were designed to capture the public's views and opinions regarding three different kinds of research on medical practice: CER involving pharmacotherapies, research involving hospital operations, and research examining clinician education/support interventions. To ensure sufficient time for discussion, six focus groups were devoted exclusively to CER research ("CER groups") and six groups concentrated on research involving hospital operations and clinician interventions ("Operations groups"). The institutional review boards of the Duke University Health System and Johns Hopkins School of Medicine approved this research.

Focus Group Moderator Guide Design

Separate focus group discussion guides were developed for the CER and Operations groups. Each guide was circulated to team members for revision and iteratively refined based on the findings from pilot focus group discussions. Seven pilot groups (three CER groups and four Operations groups) were conducted between April and July 2014. In these pilot focus groups, we encountered significant challenges in ensuring that the participants had a good understanding of the nature of research on medical practices, especially in comparison to traditional clinical trials. Final moderator guides were supplemented with a standardized

multimedia video describing research on medical practices that substantially facilitated participants' understanding (available by request). With permission, the video was based upon earlier videos developed for a related project (see: http://spectrum.stanford.edu/romp-videos).

Participant Recruitment

In an attempt to collect opinions from people from a number of geographic locations and broad demographic characteristics, focus groups were conducted in Baltimore, MD; Chicago, IL; Durham, NC; San Francisco, CA; and Washington, DC. Participants were recruited for focus groups in Baltimore, Durham, and Washington, DC, using Craigslist (https://www.craigslist.org/about/sites). To be eligible for participation in a focus group, participants must have seen a doctor or been hospitalized in the past year and must have been able to speak English. Individuals working in health care-related fields or the pharmaceutical industry were excluded. Participants were recruited for the focus groups in Chicago and San Francisco by Fieldwork (http://www.fieldwork.com/), with Fieldwork's proprietary database using the same criteria described above.

Focus Groups

Demographic information was obtained from participants during screening. Participants provided oral (groups in Durham, NC) or written informed consent (all other locations). All participants received an incentive ranging between $75 and $125, based on local standard practice. All focus groups were moderated by one of two research team members (KW or JB) and at least one additional team member observed each group and took notes. Each focus group lasted approximately two hours and was audio-recorded.

The CER groups began with an educational video that provided a basic overview of CER, using an example that compared three commonly prescribed medications to treat the same condition. Following the video, the moderator asked participants their views on the problem of uncertainty about the best treatments in use for many medical conditions and the potential for research on medical practices to reduce this certainty. The moderator then described two scenarios in which a patient visits a doctor seeking treatment for back pain. In the first scenario, the physician examines the patient, conducts necessary testing, and determines that there are two drugs approved by the FDA for back pain that could be prescribed to treat the patient. The physician explains that no one knows with certainty which drug is best for someone like the patient; thus, the physician chooses a drug to prescribe and instructs the patient to call the physician's office to switch drugs if it has not worked. The second scenario begins identically, but after explaining that no one knows with certainty which drug is best, the physician tells the patient that the health care center is doing a study that randomly assigns patients to receive one of the two drugs and measures their outcomes to help learn whether one drug is better than the other. The physician explains that the patient can still switch drugs if desired and that the patient will be contacted in a week to follow up. Each focus group talked through the similarities and differences between the two scenarios to ensure understanding and then discussed the pros and cons of four methods by which patients could be notified or could authorize agreement to participate in the research scenario: general notification, oral consent, oral consent with an information sheet, and

written consent (see Appendix A for descriptions presented to participants and Appendix B1 for the moderator's discussion guide).

The Operations groups discussed three hypothetical research studies that compared two policies, interventions, or training methods to determine which, if either, is more effective. The first study compared infection rates at hospitals using hand soap alone versus hospitals using either hand soap or hand sanitizing gel. The second study involved testing whether the use of a computer pop-up alert would reduce the rate of negative drug interactions. The third study compared two different methods for training surgeons to perform laparoscopic surgery. Each group discussed the value of conducting each research study, whether or not patients need to be notified about it, and whether and how they needed to authorize their participation (see Appendix B2).

Analysis

Focus group audio recordings were transcribed and personal identifiers removed from the transcripts. Each redacted transcript was reviewed and summarized by the note taker who observed the group, creating a two-three page narrative summary. Each summary described the demographic characteristics of the participants, overall impressions (including nonverbal aspects, tone, talkativeness, etc.), and a chronological summary of the group's discussion. Narrative summaries were then checked for accuracy by the second team member who was present at the group and audited against the transcript by a third team member who was not present at the group. We used narrative summaries for our primary qualitative coding. (For another example of this approach, see Maxwell 2012.)

Members of the study team reviewed the narrative summaries and coded them with respect to patients' general views of research on medical practices. Findings reported here emerged primarily from parts of the narrative summaries related to the pros and cons of each notification/authorization model in the CER groups (see Appendix C) and discussions about participants' reasons for preferring particular notification/authorization methods in the Operations groups, although some relevant findings emerged from other parts of narrative summaries. Four team members (JB, TC, RT, and KW) independently assigned content codes to each narrative summary. The four coders, along with an additional investigator with expertise in qualitative research methods (KB), met to resolve disagreements and iteratively revised the codes and their definitions. Original transcripts were consulted to clarify ambiguities in the narrative summaries and to identify exemplary quotes for specific views. We identified the final list of codes after four rounds of revisions.

Results

Sample Characteristics

A total of ninety six participants took part in the focus groups across the five sites. The sample had slightly more women than men, reflected a wide age range, and had a varied make up in terms of race/ethnicity and education (see Table 1).

Conduct of the Groups

In the CER groups, participants had few questions following the educational video, indicated that the information presented in the video was clear, and—in comparison to the pilot groups—seldom expressed a misunderstanding about the nature of the research studies under discussion. However, some participants still required occasional reminders throughout the discussion that (1) the drugs being compared were approved by the FDA for this particular indication and had been in use for several years (i.e., none were "experimental"), and (2) that all aspects of care would be the same as in a regular clinical encounter, aside from the random allocation of the particular medication they would receive and the planned follow-up call at one week following the encounter. In the Operations groups, people had fewer concerns about notification/authorization than people in the CER groups and were more interested in discussing the motivation for conducting the hypothetical studies and how they might be redesigned.

Participants' Perspectives on Research

During the course of discussing the scenarios, twelve key themes emerged from participants' discussions of the hypothetical research studies; these themes were then grouped into four general categories: A) clinical care; B) notification and authorization; C) communication; and D) conduct and design of research (see Table 2).

A. Clinical Care—This category includes: 1) certainty about the effectiveness of medical care and 2) prioritization of personal medical care.

A1. Certainty about the effectiveness of medical care: This was expressed in every CER group and manifested in two main ways: First, when discussing the existence of multiple treatments approved by the FDA for the same medical condition, participants agreed that it was important to determine which was the best—in general and for specific types of patients—and that research should be done to find this out. As one participant noted:

> It does seem like they already know that it's not gonna be a one pill fits all, so … to me it feels a little reassuring, like we're trying to narrow the gap of how to do better in selecting what we do. (Durham CER 2).

Second, participants were disconcerted by the idea that their doctor might not know which of several treatments was best for them. One participant expressed this concern as follows:

> I might be a little naive but when I go to my doctor I want some more definitive answers than "I don't know which one works best." I rely on him [the doctor], that medical expertise. For me, knowing my personal history and everything, what is going to work best for me? (Washington, DC CER)

The degree of trust people had in clinicians was a major consideration in how they reacted to a doctor's disclosure of uncertainty about the best treatment in the scenarios. That is, participants were generally more willing to accept that the disclosure of uncertainty reflected a true lack of knowledge in the medical field if it was coming from a clinician they trusted. On the other hand, many participants reported that if they did not trust a particular clinician,

they would interpret the admission of uncertainty as a shortcoming of that particular clinician. This is exemplified in the following quote:

> I think it depends on your relationship with the doctor. Like if it's a doctor that you trust, that almost gives me a little bit more confidence in them that they're willing to say, like, you know, if I trust that doctor it's going to be OK that he says that and he's honest with me. But if it's a doctor that I don't know and that hasn't, like, maybe been good to me in the past, just because I haven't had experience with that doctor, then maybe I would take that as a sign of like, you know lack of staying informed, I guess. (Durham CER 1)

A2. Prioritization of personal clinical care: This refers to people's desire for their doctor to give priority to caring for them as individuals over the requirements of a research study. In four of the six CER groups some participants expressed concern about whether and how the doctor's role in the research might compromise his or her ability to provide effective, individualized care. As stated by one participant:

> It's not the traditional role that a doctor…he's not in there to do clinical trials. And so going along with [Participant 2]'s concern is that, yeah I don't want him to be doing clinical trials, I want to be treating me the patient. Not to get my input so that they can use it for study. Because clinical trials do that, not in a doctor's office setting. (Washington, DC CER)

B. Notification and Authorization—This category captures the range of approaches to notification and authorization for research on usual medical practices including: 1) not notified; 2) passively notified; and 3) actively notified and invited.

B1. Not notified: There were participants in all of the Operations groups, but none in the CER groups, who said they did not need to be notified in any way. As one participant remarked:

> [E]specially with this where there's no … [pause] there's no downside really, you're not getting worse care by being part of the other … the control group or whatever it is, because you're getting the care that you always would've gotten. There's no difference. (Chicago Operations)

Other participants in the Operations groups said that passive notification (discussed below) would be beneficial, but was not necessary. Also, several participants in the Operations groups indicated that, while they were comfortable with passive or no notification, they would feel differently if they later found out that serious adverse events occurred during the research. For these participants, serious adverse events would indicate that the true risks of the study were nontrivial and so more active notification and authorization should have occurred.

B2. Passively notified: This refers to wanting information about the research study to be made available in the form of posters in waiting rooms, announcements on the institution's website, and other methods of general notification. Participants expressed this desire in four of the six CER groups and all of the Operations groups. As an example, one participant in an

Operations group described how general notification might take place by disclosing only the least specific "layer of knowledge" about research participation:

> I think they should disclose it somehow…. they don't need to advertise and say, guess what? We're doing a study and you're participating. But they can say, this is a hospital that is a research hospital or whatever, and conducts studies, and if you want to know more, click on this link, or something. And then that way at least they could like avoid somebody saying, hey, I didn't know they were doing that. I didn't want to be a guinea pig for this. (San Francisco Operations)

B3. Actively notified and invited: This refers to being given information about research, being explicitly approached about the possibility of participating in it, and authorizing their agreement to do so. This could be accomplished via oral consent, oral consent with an information sheet, or written consent. Some participants in all of the CER groups and two of the six Operations groups said that this approach was appropriate. In this illustrative quote from a CER group participant, general notification is contrasted with more active forms of notification and authorization:

> In the same way that it's somewhat of a benefit to the hospital to do that [general notification] because it makes it more cost effective, it's a negative to the patient themselves because to me if it's going to be a study it should be done formally. There should be something signed [so that consent has been given]… It should not be the assumption that someone has seen whatever literature you posted somewhere. (Baltimore CER)

B.4. Pros and cons of different methods for notification and authorization: Some of the preceding findings were based on discussions in the CER groups around the pros and cons of four different approaches to notification/authorization: 1) general notification; 2) oral consent; 3) oral consent plus information sheet; and 4) written consent (See Appendix C). Table 3 summarizes the general advantages and disadvantages for each method, which were identified by three or more of the groups. It is noteworthy that the use of oral consent plus an information sheet was the method for which no cons were cited by three or more of the groups. Also, while several pros were identified for written consent, there were also a host of cons dealing with risks of poorer understanding about the study (including overestimating the degree of risk), difficulty recruiting, and greater costs.

C. Communication—Views related to communication about research on medical practices included desires for: 1) easy access to study information; 2) eliminating information that is not important to patients; 3) clear communication of information; and 4) accurate view of risks.

C1. Easy access to study information: Some participants in all of the CER groups said that it would be an advantage to have convenient access to information about the research study, including information about whom to contact for additional information. None of the participants in the Operations groups voiced this view. Easy access to information was usually cited as a reason some participants liked having an information sheet or a formal consent document they could take home. Some participants who initially said they would

want to be asked to provide written informed consent later said that oral consent with an information sheet would achieve the same goal of providing easily accessible information. As an example, one participant in a CER group said:

> I like the fact that now I have something in my hand [a 1-page information sheet] along with you telling me what's going on in the study. Now I have something that I can actually read. In my hand. (Baltimore CER).

C2. Eliminate information that is not important: This refers to the desire to reduce the burden of the consent process on potential research participants by removing extraneous information from communications about the research. Participants in five of the six CER groups expressed the view that this was important. In particular, they highlighted lengthy consent documents as a chief source of unnecessary burden. This exchange from a CER group illustrates this need:

> Participant 3: One of the pluses *[of oral consent with an information sheet is]* that you are getting a one-pager with the frequently asked questions.
>
> Participant 4: I think efficient without being like excessive.
>
> Moderator: What do you mean by not excessive? What does that mean?
>
> Participant 4: It means it's not a twenty-page … the whole IRB proposal or something like that. It's just like the one-pager, here's everything you really probably need to know about without the medical jargon or anything else that … (Chicago CER)

C3. Clear communication of information: This refers to the desire for communication about the research study that is easily understandable. Participants in all of the CER groups and one of the Operations groups expressed this concern. Participants cited the importance of reducing jargon and boilerplate language in consent documents that can interfere with understanding important information about a study. One participant referred to written consent forms, saying: "*I think it's confusing to get through all that. The way they word some of it is hard to understand*" (**Durham CER 2**). Participants also expressed concerns that information should be understandable to those who do not speak English or are sight- or vision-impaired.

C4. Accurate view of risks: This refers to having an accurate view of the potential risks of participating in the research. This was a priority for almost all of the groups (10 out of 12). Interestingly, it was often expressed in the form of concern that more active methods of notification/authorization (e.g., written consent) might make patients overestimate the risk associated with the research. As one participant observed: "*The more and more involved it [the consent process] is, the more that people perceive that there is the potential for something bad to happen"* (**Durham CER 1**). Similarly, in the following quote, a participant is saying that a written informed consent document would make her think that the study is *more* risky than it really is, and that oral consent would be more appropriate.

> It's gonna start bringing up things of, you know, what am I signing for? Why am I doing this? Why, you know. This is new - must be [a] new medication that's

> coming up, that they want to test. Not that it's been around and is safe and effective. I'm gonna start thinking, questioning the safety and effectiveness of these medications and that's not what I'm doing. I'm actually just signing do I want the computer, do I want the doctor to make that choice… But all that's blurred now because we've just had this discussion with them giving me this long thing [consent form]. I've been in medical studies before when I've got the thing, and I've consented to all that and everything. That's for that kind of study. That's what's gonna be in my mind. I'm testing. I'm the guinea pig for this, I'm whatever. Versus somebody saying, oh let me just tell you about this, instead of me choosing, it's a computer. Yes or no. That's all I need. (Durham CER 2)

D. Conduct and Design of Research—This category relates to the conduct and design of research including: 1) responsibility for roles with respect to research; 2) study designs that generate valid information; and 3) privacy.

D1. Responsibility for roles with respect to research: This refers to the extent to which health care institutions, clinicians, and patients take responsibility for their roles with respect to research studies. This view surfaced in five of six CER groups and one Operations group, and manifested itself in two ways. First is the idea that signing a consent document would help patients to take their decision about research participation more seriously. As one participant in a CER group said: "*To me I feel like because I'm gonna sign it, I grasp it better. I put more energy into knowing what's what.*" (**Durham CER 2**). Second is the notion that clinicians and health care institutions should honor their commitments. Paradoxically, written informed consent forms were cited both as a facilitator and a barrier to clinicians and institutions living up to their responsibilities. Some felt that having a signed consent form would, like a contract, make the people conducting the research more accountable and thus more responsible in discharging their duties. On the other hand, others felt that consent documents serve to provide legal cover for clinicians and institutions, making it difficult to hold them accountable for not treating research participants as they should, as indicated by this participant:

> I mean you can't, you or your family can't sue, I mean, God forbid it causes you liver malfunction, you know liver problem, kidney damage or death [laughs]. I mean you've given your consent. (Durham CER 2)

D2. Study designs that generate valid information: This refers to having research studies be designed and conducted so that they would provide useful information about which health care practices are best. This was evidenced in all but one group and was expressed most frequently as a concern that some methods of notification/authorization might threaten the scientific validity of the study, e.g., by scaring people away from participating or by altering the behavior of the participants who are participating. One participant from an Operations group expressed the latter example in this way:

> It [notifying the public] would be nice, but it would change the study. It's exactly the same as if you are testing … how efficient teachers are at teaching. You tell the students your grades on this test are going to be used to measure how well your

> teacher does and the student is like, “I hate this teacher, I’m gonna fail every question so that my teacher gets dinged.” It’s a different study.…They shouldn’t be notified. (Durham Operations 2)

D3. Privacy: This refers to what protections would be in place to protect participants’ private health information. Concerns about privacy were expressed in four of six CER groups and one of the Operations groups. For example, when asked what information they would want to know about participating in the hypothetical CER study, one focus group participant observed: “*Nowadays some companies are hiring based on what they find out medically about that person. So I’d want the privacy issue to hold up there*” (**San Francisco CER**).

Discussion

We conducted focus groups to understand people’s views and opinions with respect to the conduct of randomized studies comparing interventions that are considered usual medical practices. Strengths of this study included multiple pilot focus groups to develop an effective approach for communicating about these types of research studies, as well as a diverse sample drawn from five cities around the US. Our data speak to several important issues.

First, we found that people’s views regarding notification and authorization differed depending upon the type of research study being considered. Prior work (Cho et al. 2015; Kelley et al. 2015) focused on research to test therapeutic interventions, whereas our study also included research on medical center operations. The desire to be actively notified and asked was more prominent with regard to CER studies than regarding Operations studies. Whether this difference was due to the type of intervention (individual-level therapeutic versus medical center operations) or some other feature of the studies (e.g., individual versus cluster randomization) will need to be clarified in future research. Nevertheless, our findings suggest that policy makers should consider whether different kinds of research on usual medical practices require different approaches to notification and authorization.

Second, our findings make clear that prospective research participants have a variety of interests that should be respected when crafting policies and practices for human subjects protections. In addition to interests traditionally considered under obligations to respect autonomy and privacy, we also heard significant concerns about personal well-being (or beneficence-based considerations), such as the desire for clinicians to be certain about which treatment would be best for them. Despite the relatively weak evidence base for many medical practices, a lot of participants were reluctant to believe that their doctor would somehow not know what is best for them (see Kelley et al. 2015 for similar findings). Nevertheless, participants’ views were similar to those in two recent studies (Cho et al. 2015; Kelley et al. 2015) in endorsing the goal of conducting research to answer questions about which treatment is best. Similarly, participants also wanted to ensure that research studies on medical practices were methodologically sound. Participants were especially concerned that research not suffer from slower (or impossible) enrollment, poor generalizability, or inadvertently cause patients to change their normal behavior—all things that participants indicated were more likely to occur with more intensive forms of

notification and authorization. Accordingly, policy makers should consider the effects of current and future policies in light of the range of patients' views we heard, including their strong interest in having medical practices based on solid research findings.

Participants in the CER groups, and to some extent those in the Operations groups, expressed several important concerns regarding communication that have implications for the design of disclosure and authorization processes for research on medical practices. For example, participants wanted convenient access to information about the study. Initially, this desire for access to information was cited as a motive for wanting written informed consent by some who later said that simply receiving an information sheet would achieve the same goal. This initial desire for traditional written consent voiced by some participants may be due to the commonality of such consent processes for research and the lack of familiarity with other approaches to disclosure and authorization. In addition to having access to information, participants wanted communications to be effective and easy to process, citing obfuscating language and long consent documents as barriers to good communication. Finally, and perhaps most importantly, participants in the CER groups wanted to ensure that a written consent process did not artificially inflate prospective participants' perceptions of risk. In the CER groups, a multipage consent form in particular was cited by participants as connoting more risk than was actually present. In the Operations groups, some were concerned that any kind of active informing might cause unnecessary alarm. Thus, processes for letting patients know about these studies and, when appropriate, getting their explicit agreement to participate, should be clear, simple, and proportional to the level of actual risk in this type of research.

These findings should be interpreted with several limitations in mind. First, similar to the experiences of Kelley et al. (2015), it took considerable effort during our pilot phase to make clear how the research we were describing differed from both usual clinical care and from experimental trials of new therapeutics. While we made efforts to query participants about their understanding during the focus groups, we cannot be certain that all participants did understand these important distinctions. This in itself is an important finding—that educating people about research on medical practices can be quite challenging. Second, as mentioned earlier, our study was not designed to identify specific aspects of study design beyond those tested here (individual randomization to individual therapeutic interventions versus cluster-randomization to medical center operations). Third, our design did not allow us to assess how the same participants would view CER versus Operations types of studies. Finally, our experience conducting these groups highlighted the powerful role of language and framing in eliciting people's reactions. We made every effort to use neutral language and multiple framings within a single group. However, it is impossible to escape the fact that all of the participants' reactions were conditioned by the conversational frame, and that alternative framings might have led to different conclusions. Our group has initiated a large national survey that will address these last two limitations by permitting finer discriminations among study types and explicitly manipulating alternative framings.

Conclusion

Research comparing medical practices promises to improve the quality of health care (Tunis, Stryer, and Clancy 2003). Conducting such research may involve special considerations for protecting the rights, interests and welfare of research participants. Those involved in crafting and interpreting policies regarding human subjects protections must be sensitive to the full range of people's needs and interests regarding research on medical practices, including the importance of methodologically sound studies that can help determine which treatments will be most beneficial for them. Based on our data, policy makers should expect that effective policy and guidance in this arena will involve balancing different patient interests and potentially different sets of interests for different types of research studies on medical practices.

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Appendix A. Description of Notification/Authorization Methods Used in CER Groups

General Notification

Under general notification, there will be posters at the clinic entrance, flyers in the waiting rooms, and information on the hospital's web site telling you that the hospital does studies on different conditions and you might be randomly assigned a prescription if you have one of those conditions. You would need to tell your doctor if you don't want to participate. Otherwise, it is assumed that simply by going to this hospital, you agree to participate in studies that are appropriate for your condition.

Verbal Explanation from Doctor

Verbal explanation means you and your doctor have a conversation about the study. Your doctor will explain the study to you, answer your questions, and make sure you are OK with participating. If so, the computer will randomly assign a prescription.

Verbal Explanation + Simple Information Sheet

Just like verbal explanation, your doctor will explain the study to you and answer your questions. Under this option, you will also receive a 1-page information sheet that outlines the study and how it works. If you are OK with participating, the computer will randomly assign a prescription.

Verbal Explanation + Full Consent Form

Under this option, your doctor will explain the study to you and answer your questions, and you will also receive a consent form several pages long that describes the study in detail. You must sign the consent form in order to participate in the study, and then the computer will randomly assign a prescription.

Appendix

Appendix B1. CER Groups Moderator Guide

INTRODUCTION

- Welcome participants, thank them for participating
- Introduce yourself
- You have been invited to participated because each of you responded to our ad on Craigslist and because each of you has seen a doctor or been to the hospital in the past year
- We are conducting several focus groups to hear people's thoughts about different situations that might take place at a doctor's office.
- My role is to listen to what you have to say and report it back to the researchers.
- There are no right or wrong answers, only opinions
- Please feel free to share your ideas and opinions, even if they differ from what others have said. It's helpful to hear different points of view
- We'd like to hear from all of you equally
- Also, feel free to talk to each other as well as to me. If at any time during our discussion you don't feel comfortable answering a question you don't have to.
- We are audio recording our discussion to make sure we get all of your comments. Summarized as group data only
- Everything you say will be confidential, nothing will be linked to your name
- Be respectful of others' privacy and remember that what is said in this room, stays in this room
- Because we have limited time together, I may, for the sake of time, jump in and move the discussion forward
- If you have any questions about our research or how your feedback will be used, please feel free to speak with me after the session.
- Finally, please turn off any cellular phones, pagers, or other electronic devices for the duration of our discussion.

- Feel free to get up and get more snacks or drinks and to use the bathroom. We will not be stopping for a break.

PARTICIPANT WARM-UP

To get started, I would like to go around the room and have everyone introduce himself/herself. When you introduce yourself, please tell us your first name and, just for fun, if you had a free airline ticket, where would you go?

EDUCATIONAL COMPONENT

[NARRATED SLIDESHOW]

Many people see a doctor when they are having a health problem. Sometimes, the doctor will prescribe a medicine or drug to help the person feel better.

Often, there is more than one drug that has been approved as safe and effective to treat a particular condition. So, when patients go to the doctor about a health problem, there might be several drugs the doctor can pick from that are commonly used for that condition.

For example, let's imagine Bob goes to see the doctor for a problem he's having. The doctor does a thorough physical exam, looks at Bob's medical history, and asks Bob questions in order to understand the problem. The doctor thinks Bob needs a medication to treat his condition, and there are several drugs on the market the doctor could prescribe. Before choosing one to prescribe, the doctor reviews Bob's medical record and asks Bob questions to find out if he has any drug allergies, what other medications he is taking, and whether he has taken any of the available drugs in the past.

Based on all of this information, the doctor determines that there are three medications currently available – let's call them Drug A, Drug B, and Drug C – that Bob could take. All three drugs are considered safe and effective, and all are commonly used by physicians to treat conditions like Bob's. However, there are no studies that compare the drugs to one another, so doctors don't know if one of the drugs might be *better* for people like Bob.

So how do doctors decide what to do in a situation like this? Well, as Bob's doctor did, they think about the patient's personal medical history and make sure not to pick one that they know the patient is allergic to, or that wouldn't interact well with other drugs the patient takes. After that, it pretty much depends on each doctor's habits and experiences. For example:

- Dr. Armstrong always prescribes Drug A for patients like Bob because Drug A is the one she first learned about earlier in her career
- Dr. Baker has been prescribing Drug B for patients like Bob since returning from a conference where he heard a pharmaceutical representative talking about Drug B

- Dr. Carey recently switched to prescribing Drug C for patients like Bob after a colleague told her about one patient who especially liked Drug C

None of these doctors are wrong – Drugs A, B, and C all *work* for people with Bob's condition. The problem is that there is no information to show which would be *best*.

Discussion

1 In just a few moments we are going to ask you for your thoughts and reactions to this information, but right now, is there anything that was confusing or that we could clarify before we continue?

2 As the video described, oftentimes there are several drugs approved as safe and effective and that doctors currently use to treat a particular condition, but there isn't enough information comparing the treatments for doctors to know which, if one may be *better*.

Does everyone know what effective means?

Does this sound like something that actually happens in medical care?

- *[If yes]* For those of you who think this does ring true, tell me more.
- *[If no]* For those of you who think this does not ring true, tell me more.

[CONTINUE SLIDESHOW]

One way to figure out whether one drug is better than the others for treating a particular condition would be to do studies comparing the drugs to each other. The best way to do these comparisons is by randomly assigning which drug people will get, and then carefully following everyone to see how they do.

When we say "randomly assign," what do we mean by "randomly"? Let's look at an example. Imagine a gumball machine. You put in a quarter, and a gumball comes out. You don't get to choose the color of the gumball, because it's decided by chance. You will randomly get a red gumball, a green gumball, or a blue gumball.

So in the situation we've been talking about, where doctors don't know which currently available drug is best, one way to find out would be to randomly assign each patient to one of the drugs. By chance, some will be assigned to get Drug A, some will be assigned to Drug B, and some will be assigned to Drug C. No matter which one they get, they will know it is one that is approved as safe and effective for their condition.

In medical research, randomly assigning patients to a treatment is considered the best way for making comparisons. This is because randomization 'evens out' any differences between the groups so that researchers can be sure that any differences in the results would be due to the drug.

But doctors will follow up closely to find out how each patient is doing, and by looking at all the patients in the study, see if they can find out whether one drug is better than the others. They could find out that, although all of the drugs work, one drug seems to work better for nearly everyone, or that one drug is better for certain kinds of patients.

Discussion

3 In just a few moments we are going to ask you for your thoughts and reactions to this information, but right now, is there anything that was confusing or that we could clarify before we continue?

4 In situations where no one knows which drug is better, do you think it is a good idea to do studies to find out which one is best?

- *[If yes]* For those of you who think it is a good idea, can you tell why you think this would be a good thing?
- *[If unsure]* For those of you who are unsure whether it is a good idea – can you tell me more?
- *[If no]* For those of you who think it is not a good idea, can you tell me more about why not?

CLINICAL SCENARIO

OK, let's take a look at our first scenario

SCENARIO 1 [HANDOUT]: You visit your doctor, Dr. Lee, because you have had lower back pain for over a week. Dr. Lee asks all about your symptoms, does a physical exam, and takes an X-ray. Dr. Lee tells you, "Based on all that we've done today and your personal medical history, there are two pain medications I can prescribe – one is called Thoradex and one is called Infradone. They are both approved to treat pain and have been in use for several years. Unfortunately, no one knows which one actually works best for people like you. So I'm just going to start you off with a prescription for Thoradex and, if that doesn't seem to work for you after about a week, give my office a call and we'll get you a prescription for Infradone."

Discussion

5 Thinking about this scenario, what questions would you have for the doctor?

- What would be important to you about knowing that information?
- Probe (if needed): Would you want information about Infradone (the drug that was *not* prescribed)?

Moderator note:

- Butcher paper

- *Examples (if needed):*
  - Side effects
  - Cost
  - Duration (how many days to take the medication)
  - Frequency (how many times/day to take the medication)

6 What is your reaction to the doctor in this scenario saying "No one knows which is best"?

- Does this ring true for you – do you think a doctor *would* say "No one knows which is best" – or just give you a prescription without mentioning it?
- If a doctor *did* say to you "No one knows which is best", how would that affect your view of the doctor (if at all)?

RESEARCH SCENARIO

SCENARIO 2 [HANDOUT]: You visit your doctor, Dr. Lee, because you have had lower back pain for over a week. Dr. Lee asks all about your symptoms, does a physical exam, and takes an X-ray. Dr. Lee tells you, "Based on all that we've done today and your personal medical history, there are two pain medications I can prescribe – one is called Thoradex and one is called Infradone. They are both approved to treat pain and have been in use for several years. Unfortunately, no one knows which one actually works best for people like you. So our hospital is doing a study to try to find out which one is better, and we are using a computer program to randomly assign one treatment or the other. We'll start you off with a prescription for whichever one the computer tells us. You can call us if you are having any problems – otherwise, my office will call you in a week to collect information about how you are doing. If the drug you were assigned isn't working for you, we can switch you to the other one. We will also use the information about how you are doing, combined with information from other patients in the study, to help researchers learn which drug works best."

Note: emphasize randomization can be done using hat, coin, a gumball machine, or in this case a computer program.

Discussion

7 Let's compare this scenario to the previous one.

- Similarities between Scenario 1 and Scenario 2:
  - Doctor asks about symptoms, does exam, x-rays, etc.

- Doctor rules out any drugs you should *not* take based on medical history
- The drugs you might get are the same (both safe, effective, and commonly used)

- Differences between Scenario 1 and Scenario 2:
  - Computer randomly assigns drug (rather than doctor arbitrarily picking)
  - Doctor will call you to follow up (rather than you calling if problems)
  - Researchers will look at data from all people in the study to try to learn which drug is best (rather than continuing with no one knowing)

> *Moderator note*:
>
> Walk people through the similarities and differences and make sure they understand, rather than asking them to identify these themselves

8 Thinking about Scenario 2, what questions would you have for the doctor? In particular, compared to Scenario 1, would you have:

- The same questions?
- Different questions?
- Additional questions?

> *Moderator note*:
>
> Butcher paper

9 In Scenario 2, the doctor says “Our hospital is doing a study, so the prescription you get will be the one the computer randomly assigns.” However, in real life, there are a couple of different ways this information could be communicated to patients and to be sure you are OK with it.

PASS OUT HANDOUT

[HANDOUT] Let me tell you briefly about each one:

1. **General notification:** Under general notification, there will be posters at the clinic entrance, flyers in the waiting rooms, and information on the hospital’s web site telling you that the hospital does studies on different conditions and you might be randomly assigned a prescription if you have one of those conditions. You would need to tell your doctor if you don’t want to participate. Otherwise, it is assumed that simply by going to this

hospital, you agree to participate in studies that are appropriate for your condition.

2. **Verbal explanation from doctor (like Scenario 2):** Verbal explanation means you and your doctor have a conversation about the study. Your doctor will explain the study to you, answer your questions, and make sure you are OK with participating. If so, the computer will randomly assign a prescription.

3. **Verbal explanation + simple information sheet:** Just like verbal explanation, your doctor will explain the study to you and answer your questions. Under this option, you will also receive a 1-page information sheet that outlines the study and how it works. If you are OK with participating, the computer will randomly assign a prescription.

4. **Verbal explanation + full consent form:** Under this option, your doctor will explain the study to you and answer your questions, and you will also receive a consent form several pages long that describes the study in detail. You must sign the consent form in order to participate in the study, and then the computer will randomly assign a prescription.

   In just a few moments we are going to ask you for your thoughts and reactions to each of these, but right now, is there anything that was confusing or that we could clarify before we continue?

10 Now I would like to get your thoughts on each one of these ways of letting patients know about a study. As a reminder:

- Your doctor will always consider your personal medical history before prescribing any drug.
- The only kind of study we are talking about today is one where you will always get a drug that has already been approved as safe and effective for your condition. The reason for the study is to learn whether one drug works better than another.
- You will take the prescription for the drug you are assigned to your pharmacy and will get drug information sheet from pharmacist, just like you would for a regular clinic visit.

Let’s start with the first approach, general notification.

a. What advantages or positive things can you think of about using [this approach]?

b. What disadvantages or negative things can you think of about using [this approach]?

[Repeat for each of the 4 approaches]

Moderator note:

- Butcher paper to write pros/cons for each of the 4 approaches
- *As appropriate:*
  - Compare/contrast the pros and cons of each one as you go along
  - Compare/contrast to expectations in clinical scenario
- If people want full consent mainly so their decision is documented, remind them, "Your decision about participating in the study will always be documented in your medical record—that is how your doctor will know to call you to collect the follow-up information for the study."

11 We have been discussing different ways of letting patients know about a study—the pros and cons of each, and why certain things might be important to you.

Some of the things people said would be important if there was a study *[fill in with examples from prior discussion, e.g., getting written information, signing a consent form]* did not seem as important when we were talking about the first "Clinical Scenario".

So in the situation where no one knows which of two approved drugs is best, help me understand what you see as the difference between a doctor just picking one vs. being randomly assigned one?

Probes:

- What are the risks you are seeing in the second "Research Scenario"?
- Is the Research Scenario more or less risky than the Clinical Scenario?
- What are the big differences for you?

Moderator note:

If possible, interweave discussion of Risks and comparison to Clinical Scenario with discussion of the 4 approaches; otherwise, be sure to bring up as a separate question

➔ ASK PARTICIPANTS TO COMPLETE WORKSHEET ON ACCEPTABILITY OF EACH APPROACH

12 What is your overall reaction to Scenario 2?

a. Positive or negative (and why?)

- Probe (if time): In Scenario 2, the doctor says her office will follow up with you to gather information for the study about how you are doing. How do you feel about this (compared to Scenario 1, where the doctor does not actively follow up)? Why?

b. Would you participate in the study, or tell the doctor that you do not want to participate (and why?)

Appendix B2. Operations Groups Moderator Guide

INTRODUCTION

- Welcome participants, thank them for participating
- Introduce yourself
- You have been invited to participated because each of you has seen a doctor or been to the hospital in the past year
- We want to hear people's thoughts about different kinds of projects that might be done to improve how health care is delivered. Today we are going to give you four specific examples of health care delivery and then we want to get your opinions about what would be the best way to do those projects. My role is to listen to what you have to say and report it back to the researchers.
- There are no right or wrong answers, only opinions
- Please feel free to share your ideas and opinions, even if they differ from what others have said. It's helpful to hear different points of view
- We'd like to hear from all of you equally
- Also, feel free to talk to each other as well as to me. If at any time during our discussion you don't feel comfortable answering a question that is fine
- We are audio recording our discussion to make sure we get all of your comments. Summarized as group data only
- Everything you say will be confidential, nothing will be linked to your name
- Be respectful of others' privacy and remember that what is said in this room, stays in this room
- Because we have limited time together, I may, for the sake of time, jump in and move the discussion forward
- If you have any questions about our research or how your feedback will be used, please feel free to speak with me after the session.

- Finally, please turn off any cellular phones, pagers, or other electronic devices for the duration of our discussion.

PARTICIPANT WARM-UP

When you introduce yourself, please tell us your first name and, just for fun, where you would go on vacation if money were not a factor.

INTRODUCTION TO SCENARIOS

We want to hear your thoughts about four types of projects that might be done to improve health care for patients. I will describe an example, and then I'll ask some questions so I can get your opinions about how the project could be done.

HAND WASHING SCENARIO

[PASS OUT SCENARIO 1]

- Hand washing can prevent disease spread, but only works if people do it
- Soap and water great, but time consuming; sanitizer faster, convenient
- Both soap and water and the gel are safe to use, both are known to reduce the spread of infection, and both have been in wide use for years.
- Hospitals consider two hand washing policies to lower infection rates

Policy 1. Encourage providers to use soap and water to wash their hands before seeing every patient.

- Sink-stations with soap and water available in every patient exam room, as well as in bathrooms, cafeterias, and other public areas.
- Hand sanitizer available in public areas, but would not be in patient exam rooms.

Policy 2. Encourage providers to use either soap and water *or* hand sanitizer before seeing each patient

- Sink stations with soap and water available in all patient exam rooms and public areas,
- Hand sanitizer dispensers also be available in every patient exam room and all public areas.

- Compare infection rates at hospitals using the two different types of hand washing policies by randomly assigning hospitals to one policy or the other
- What does this mean? (Imagine 20 hospitals, hat with 20 sheets of paper), emphasize chance over choice

- After period of time, compare infection rates to see if one policy is better

Discussion

1. We will talk about this scenario more in a few minutes, but first, does anyone have any questions? Is there anything confusing?
2. Could someone explain back to the group what this project is about? Why do you think a project like this would be done?
3. What do you think of this type of project?
4. And if hospitals decide to take part, do you think they should make this information public? Why or why not?
   a. If yes, how should they make the information available? (web site, admission forms, notices posted in the hospital, blanket notification)
5. Is there anything else patients should know about this project?

POP-UP NOTIFICATION SCENARIO

Now let's move on to another scenario. This second example relates to how to improve health care when doctors prescribe medications.

[PASS OUT SCENARIO 2]

- Many patients need to take several medications every day
- Patients can have bad reactions if two meds don't work well together
- If bad reaction possible, doctor will choose a different medicine
- Safeguards to prevent bad interactions (doctor checks, pharmacy)
- Sometimes doctor doesn't check for interactions or misses something
  - Patient forgets to tell doctor about a medication
  - Patient and doctor move on to other topics, forget to go back
- To minimize mistakes, some people started putting an "alert" in computer system – pops-up when interaction, reminds doctor
- Unclear whether this system works
  - Too many alerts might be ignored
  - Doctors might become dependent (miss something not in system)
  - Very costly to change system, could be waste of time/ resources
- To see if system works, randomly assign some docs to get alert, others not (use example of hat with 20 slips of paper)

- After period of time, compare groups to see if number of drug interactions lower in one group or another
- Find out whether the alert system helps, hurts, or makes no difference

Discussion

1. We will talk about this scenario more in a few minutes, but first, does anyone have any questions? Is there anything confusing?
2. Could someone explain back to the group what this project is about? Why do you think a project like this would be done?
3. Does anyone know what it means to randomize doctors like this? Can someone try to explain that to the group? Why would it be done this way?
4. And if hospitals decide to take part, do you think they should make this information public? Why or why not?
   a. If yes, how should they make the information available? (web site, admission forms, notices posted in the hospital, blanket notification)
5. Is there anything else patients should know about this project?

LAPAROSCOPIC SURGERY SCENARIO

Now let's move on to a third scenario. This example has to do with training doctors on how to use new things. Because medicine is advancing rapidly, doctors require ongoing education and training to stay up-to-date on the latest advances in medicine. But we need more information on which ways of educating doctors work best, or whether they actually work the same and are all equally good.

[PASS OUT SCENARIO 3]

- Laparoscopic surgery – use really small cuts to do abdominal surgeries
- One small cut is made to put a thin tube with a camera into the body
- Another small cut is made to insert surgical instruments
- Doctor views pictures from the camera on a TV monitor and performs surgery
- Two different training approaches
  - Observe an experienced surgeon doing the training in person
  - Complete online training and modules of experienced surgeons conducting the surgeries
- For both methods,

- The surgeons who are learning laparoscopic surgery are already practicing surgeons. They are simply learning a new technique
- The doctor being trained is watching experienced surgeons do these types of procedures.
- Regardless of training method, the doctor in training would perform first 10 surgeries with another experienced surgeon in the room.

- Healthcare professionals want to learn if one way is better than other
- Randomly assign healthcare centers. Doctors trained in one way or other
- Compare patient outcomes at centers using different training techniques

Advantages of online modules:

- Pause, rewind, watch multiple times
- Can see surgery from multiple angles
- Developed by experts with intention of training and education
- Accessibility (rural locations, can complete at any time)

Discussion

1. We will talk about this scenario more in a few minutes, but first, does anyone have any questions? Is there anything confusing?
2. Could someone explain back to the group what this project is about? Why do you think a project like this would be done?
3. Does anyone know what it means to randomize doctors like this? Can someone try to explain that to the group? [Discuss randomization] Why would it be done this way?
4. And if hospitals decide to take part, do you think they should make this information public? Why or why not?
   a. If yes, how should they make the information available?
      i. Probes: web site? Admission forms? Notices posted in the hospital? Blanket notification?

MEDICAL RECORDS SCENARIO

Let’s talk about a project that is looking at two different drugs designed to lower high blood pressure

[PASS OUT SCENARIO 4]

- As you probably know, there are many, many different medications used to treat various conditions, and often there are multiple medicines that have been approved as safe and effective to treat the same medical problem.
- So when patients go to a doctor about a health problem, there might be several drugs the doctor can pick from that are commonly used. All of the drugs that the doctor might use are proven to be safe and effective.
- Sometimes we don't have information about which drug works best, or whether they actually work the same. Everyone agrees that the drugs are safe and effective, but no one knows if one is better than another.
- Imagine there are two drugs designed to lower high blood pressure. Some doctors prescribe Drug A and some prescribe Drug B.
- Healthcare professionals want to know if one drug is better than another. Maybe Drug A is slightly better at lowering blood pressure.
- One way to find this out is through medical record review.
- Doctors would prescribe their patients Drug A or Drug B as they normally would, and patients would have a normal follow up visit with their doctor to see if the drug was working.
- Researchers would look at patients' medical records to observe the changes in patients' blood pressure between their initial doctor's visits and their follow up visits.
- The researchers themselves would not take patients' blood pressure and patients wouldn't have any additional appointments.
- Researchers would compare the changes in blood pressure for patients who took Drug A and those who took Drug B to see if one was more effective than the other at lowering high blood pressure. They would also note if patients changed medications.

1. Can someone summarize this project for the group? How would it work and what is it trying to do?

2. What do people think about this project? Does it sound like a good idea?

- I want to tell you a few more things about how medical records are typically used in usual care:
  - In the course of usual medical care many people have access to a person's medical record for a variety of reasons: some people

need to look at them for billing purposes. Other people might look at them for quality control.

- Those who have access to people's medical records have undergone training about privacy and confidentiality.
- There are also laws about privacy of medical information, such as HIPAA.

3. Does that affect how you view the project? Do you think it's a good idea to do projects like this?
4. Probes:
   a. a. Would your view of the study change if the data was de-identified? What if it was not de-identified?
   b. b. Are there any sensitive areas of someone's medical record which you think they might not want researchers to see? (i.e. sexual orientation, medications, stigmatized conditions)

Discussion

1. We will talk about this scenario more in a few minutes, but first, does anyone have any questions? Is there anything confusing?
2. Could someone explain back to the group what this project is about? Why do you think a project like this would be done?
3. And if hospitals decide to take part, do you think they should make this information public? Why or why not?
   a. If yes, how should they make the information available?
      i. Probes: web site? Admission forms? Notices posted in the hospital? Blanket notification?
4. Do you think hospitals or researchers doing a project like this should be required to get permission or consent from every patient for it? Why or why not?

Conclusion

- Given what we've talked about today, would you be willing to participate in projects like this? Why or why not?

Appendix C. Participants' Perceptions of Pros and Cons for Different Approaches to Notification and Authorization for a Hypothetical CER Study

Method	Pros		Cons	
	Theme	No. of Groups	Theme	No. of Groups
General Notification	Less time intensive	2	Places burden on patients to be informed about study; people may not know they're in a study; opt out model assumes everyone wants to participate	6
	More accurate study results (ensures a valid sample)	2	May not notify individuals who are not English speakers or who are illiterate	5
	Greater participation rate	2	Poorly timed, as patients may be in pain, distracted, or may not be able to think properly	3
	Alerts patients so they can discuss with doctor if they have questions	2	If people find out after the fact they will be upset they weren't notified	2
	Covers hospital liability, meets legal requirements	2	If only on the website, won't reach individuals without internet access	1
	Increases awareness of the study	2	Unclear who to contact with questions about the study (if no handout)	1
	Low cost	1	Informal (because no signature or consent form)	1
	Minimal demands on staff	1	fails to protect patients	1
	People can make informed decisions about where to seek their care (can decide to seek treatment from non-participating institutions)	1	Lacks detail, is incomplete	1
	Evidence of institution's commitment to advancing knowledge, providing high quality care	1	Is impersonal	1
	Provides reading material while waiting for doctor	1	Feels more like patients are guinea pigs	1
	Less formal way of notifying people	1		
	Casts a large net, is available for everyone to see	1		
	Won't scare patients with bureaucratic language and explanations	1		
	Simple way of informing patients	1		
Oral Consent	Gives patients the opportunity to ask questions	5	No reference sheet to take home; people may have difficulty remembering details. A "one shot deal,"	6

			especially for patients who are in pain or distracted.	
	Ensures patients are informed; better chance of understanding	4	Patients might not get full details of the study (especially if doctor forgets, omits, or is in a rush)	5
	More personal	3	No way to prove individuals gave consent to be in the study	2
	Individuals are able to be engaged in direct communication	3	People with hearing or language difficulties might not understand	2
	Builds trust between patient and clinician; shows value and respect for patients	2	Doctor may “bully” patients into participating	1
	Offers a more detailed explanation of the study and motivation for doing the study	2	Some patients may be uncomfortable asking the doctor questions	1
	Can pick up on nonverbal cues from provider	1	Very reliant on doctor’s interpersonal cues and mannerisms in presenting study info	1
	Feels more legitimate than general notification	1	Presumes a trusting relationship between patient and doctor	1
	A preferred mode of notification when personal information is involved (sensitive to personal info)	1	Is time consuming and will increase wait times	1
			More bureaucratic	1
			Some people learn better non-verbally	1
			May hurt the doctor’s credibility when he/she has to explain that he/she doesn’t know which drug is best	1
Oral Consent plus Information Sheet	Information sheet provides reference materials, information about the study that individuals can refer to later; more information	6	No proof of consent because there is no signed form	1
	Information sheet has standardized information in case the provider forgets something	2	Greater legal risk for hospital (more patients can sue)	1
	Appropriate amount of information, less scary language (compared to lengthy consent form)	2	Higher cost than general notification	1
	May help patients to think of more questions	2	Information sheet is just an outline, doesn’t have all the information	1
	Can direct patients to outside resources or give contact information	2	Doctor might spend less time explaining the study, rely too heavily on the information sheet, or omit details	1

	Two different ways of communicating allow for different learning styles	1	Patients might ignore the doctor's explanation and become overly reliant on the info sheet	1
	Leaves participants more room to sue if something goes wrong because they didn't actually give written consent	1	Information sheet might be distracting	1
	If information sheet is in several languages, it will be more accessible and complementary to the oral explanation (for second language learners)	1	May take more time than other notification methods	1
	Takes pressure off the conversation with the doctor	1	Might make people anxious	1
	Doesn't assume that patients want to participate (more active; indicates that hospitals are doing their part to ensure patients are informed)	1	Patients may be distracted or in pain and unable to process the information	1
	Will save time in the appointment	1		
Written Consent	"Full disclosure," formal, official, comprehensive; feels appropriate for participating in research	4	Consent form might be too long and result in information overload; too much to read and understand, especially when patients are in pain or distracted	6
	Provides more opportunities for patients to say no; allows patients to give permission (active); clearly indicates that patients are opting in. No ambiguity.	3	Lengthy forms might lead people to overestimate the risk of the study; reading through and having to sign might make patients anxious	3
	Signature protects both the institution and the participant	2	Loss of accuracy in study results because of patients who will opt out because they are worried about risks	3
	Signature gives proof of agreement	2	Requires too much time, effort, and/or bureaucracy	2
	Provides more options for understanding the study/ processing information	2	Signing only protects the hospital and puts the legal burden on patients; if they agree to whatever is in the consent forms, they will be held accountable	2
	Signature feels like a contract or agreement	1	Will increase costs	1
	Signature helps people read carefully, pay attention, and retain information	1	Patients may feel pressured into participating	1
			No recourse for patients once they have signed	1
			Takes away from clinician/patient time	1

			Takes away from doctor's professionalism (focus should be on care, not research)	1
			People will ignore the boilerplate language	1

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Table 1

Demographic Characteristics of Focus Group Participants (N = 96)

Characteristic	No. (%)
Location	
Baltimore, MD	6 (6)
Chicago, IL	17 (18)
Durham, NC	33 (34)
San Francisco, CA	20 (21)
Washington, DC	20 (21)
Topic of Focus Group	
CER	50 (52)
Operations	46 (48)
Sex	
Female	52 (54)
Male	44 (46)
Median age, years (interquartile range)	48 (34–56)
Minimum age	20
Maximum age	81
Race/Ethnicity	
African-American	30 (31)
White, non-Hispanic	53 (55)
Hispanic	8 (8)
Asian	2 (2)
Other	3 (3)
Education	
High school or Graduate Equivalent Degree	10 (10)
Some college	28 (29)
Bachelor’s degree	34 (35)
Post-graduate degree	21 (22)
Not provided	3 (3)

Table 2

Views Regarding Research on Medical Practices by Type of Focus Group

Theme	No. of CER Groups (n= 6)	No. of Operations Groups (n=6)
A. Clinical Care		
A1. Certainty about the effectiveness of medical care	6	__*
A2. Prioritization of personal clinical care	4	0
B. Notification and Authorization		
B1. Not notified	0	6
B2. Passively notified	4	6
B3. Actively notified and invited	6	2
C. Communication		
C1. Easy access to study information	6	0
C2. Eliminate information that is not important	5	0
C3. Clear communication of information	6	1
C4. Accurate view of risks	5	5
D. Conduct and Design of Research		
D1. Responsibility for roles with respect to research	5	1
D2. Study designs that generate valid information	5	6
D3. Privacy	4	1

* The Operations groups did not include explicit querying about the uncertainty about which treatments for patients were the best.

Table 3

Summary of Most Frequent Pros and Cons for Different Approaches to Notification and Authorization for a Hypothetical CER Study.

Method	Pros	Cons
General Notification	• Simple and efficient • Better participation/sample • Informs patients	• Requires greater patient initiative • Some patients may not see or be able to understand the notification
Oral Consent	• Opportunity for patients to ask questions • More personal and effective communication	• No information sheet to take home • Patient might not be told all necessary information
Oral Consent plus Information Sheet	• Information sheet provides standardized information and is accessible to patient after appointment • More effective communication is possible	(No cons mentioned in ≥3 groups)
Written Consent	• Feels more formal and comprehensive • Clear choice is provided to patient • Signature provides proof of agreement to patient and institution	• Consent form might be too long to read and understand • Consent form might lead people to overestimate the risk of the study and become anxious • Could lead to poorer participation that compromises validity of study sample • Requires increased resources

Note: This table includes findings that were common in 3 or more focus groups. See Appendix C for all findings.