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Patient Perspectives on the Learning Health System: the Importance of Trust and Shared Decision Making

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Abstract

We conducted focus groups to assess patient attitudes towards research on medical practices in the context of usual care. We found that patients focus on the implications of this research for their relationship with and trust in their physicians. Patients view research on medical practices as separate from usual care, demanding dissemination of information and in most cases, individual consent. Patients expect information about this research to come through their physician, whom they rely on to identify and filter associated risks. In general, patients support this research, but worry that participation in research involving randomization may undermine individualized care that acknowledges their unique medical histories. These findings suggest the need for public education on variation in practice among physicians and the need for a collaborative approach to

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the governance of research on medical practices that addresses core values of trust, transparency and partnership.

Background

Clinical research within the range of usual medical practice in health care settings is important. An emerging view holds that health care institutions have obligations to patients to improve the safety and efficacy of care. This approach has been referred to as one of learning health systems "in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience." (IOM 2007; 2012) This view is in part based on the appreciation that much of medical care is not evidence-based and that a shift is needed to improve both its quality and value.

With increasing calls to improve the efficiency and quality of day-to-day care, routine collection of data in health care practice settings increasingly blurs the lines between research and practice. (Faden et al. 2013; Kass et al. 2013; Kass et al. 2008; Altman et al. 2013) Patients, however, may not appreciate this rationale or the extent to which research activities are conducted in the clinical space. (Fiore et al. 2011; Largent et al. 2011) Yet research on medical practices (ROMP)—including medical record reviews, comparative effectiveness research, quality improvement interventions, and point-of-care randomization—is critically important to improving medical care, reducing risks to patients, and decreasing costs. (Faden et al. 2013)

Current approaches to oversight, risk assessment, and informed consent are poorly suited to research on medical practices potentially making much of this research prohibitively expensive or logistically impossible. (Whitney 2012; Tarini et al. 2008) In addition, such research raises significant ethical questions about risk and risk communication to participants. (Joffe & Miller 2008) What are the risks of the research itself, as opposed to the risks of clinical care, and which are ethically relevant? How should risks of randomization between usual practices be understood? What should informed consent standards be for this type of research?

Despite recognition of the inadequacy of risk assessment and informed consent for this type of research, there is not yet consensus about what appropriate approaches should be. The routine use and sharing of health status, care utilization, and clinical outcomes within and among health care institutions has become both commonplace and widely accepted for the purposes of quality improvement. We do not fully understand, however, how much the public appreciates the potential benefits of such activities for their medical care. (National Academies 2011)

Studies on patient and public attitudes towards research with stored samples, patient records (Hull et al. 2008), and attitudes towards emergency research consent waivers (Dickert & Kass 2009), suggest that although people typically want to be aware of such activities, at least some are willing to forego the traditional approaches to informed consent.

The Office for Human Research Protections (OHRP) has issued draft guidance for IRBs and researchers about research that takes place within the context of medical practice. (OHRP 2014) To inform this policy debate we sought to better understand how patients view the ethical implications of studying clinical outcomes through randomization within usual practice. Our study assesses patients' perspectives about the relationship between medical practices and research on medical practices. We examined how patients value and weigh tradeoffs between autonomy, risk, quality of care, and other characteristics of research within usual care. We also assessed how they view different approaches to informing and engaging patients and communities about research on medical practices.

Because of the centrality of the physician-patient relationship throughout our data, we grounded our analysis in the principles of trust and Shared Decision-Making (SDM). SDM incorporates the patient's perspective by respecting patient values and preferences and by supporting decision-making through the provision of high-quality, accessible information. (Barry & Edgman-Levitan 2012) SDM is rooted in the ethical obligations that arise between patients and physicians in relationship to one another. As such, this model helps guide our approaches to informed consent and randomization in designing research studies within standard medical practices. We propose an approach that promotes engagement grounded in the principle of respect for persons, either as patients or as research participants, and that builds on the physician-patient relationship within the learning health systems.

Methods

This qualitative study was designed to inform development of a national survey on patient attitudes toward research on medical practice. (Cho et al. 2015) We conducted a series of 8 focus groups at Stanford Medical Center, University of Washington Medical Center, and Seattle Children's Hospital. These discussions included cohorts of adult patients and parents of pediatric patients. In addition, two small group interviews are included in the dataset. These two groups were planned as focus groups, however due to last minute cancellations by participants, consisted of two participants each. The format and questions of these discussions were the same as the focus groups. The same analytic techniques were used for all transcripts. Both adults and pediatric (parent) populations were targeted to capture potential variation in experiences and attitudes between adult participants and parental decisions and attitudes on behalf of pediatric participants. We used a combination of in-person and email approaches to recruit from adult and pediatric cardiology and nephrology clinics as convenience samples of patients likely to have sufficient experience with ongoing hospital care to discuss the issues. In addition, patients were recruited through the Stanford University's Research Registry. We emailed 526 patient addresses; 53 invitees ultimately enrolled. (Table 1)

A focus group methodology was chosen for concept elicitation, and an open-ended, semi-structured interview guide was used to generate discussion among focus group members (Bloor et al. 2001; Stewart et al. 2007). Interview focus group guides were developed by the investigator team, based on the literature and study objectives through an iterative process of discussion and revision. The guides were then piloted at each site for patient understanding of directions and questions, then revised for further clarity. All groups were conducted in

English. Each focus group and interview was moderated by a senior research team member with at least one additional team member present for observation and note-taking. Moderators at both sites used the same semi-structured focus group guides. (Appendix A). To support robust discussion among the patient cohort, we also developed and screened a set of three short animated videos during patient focus groups and interviews. We developed the videos to explain the major concepts addressed in the focus group guide [https://rompethics.iths.org/].

The focus groups and interviews were audio-recorded and transcribed. All data were uploaded to the qualitative data analysis software Dedoose. Initial codes were first generated inductively through a collaborative reading and analysis of a subset of interviews and then finalized through successive iterations into categories and codes. At least one primary and one secondary coder independently coded each transcript. Differences were reconciled through consensus coding. We relied upon modified grounded theory to analyze our data and used a combination of *a priori* coding based on concepts derived from the literature and *in vivo* substantive coding based on inductive concepts that emerge from the dataset for hypothesis generation (Ryan & Bernard 2003; Glaser & Strauss 1967).

The study was approved by Stanford University School of Medicine and University of Washington institutional review boards. Participants provided oral consent for participation in the study.

Results

The objective of this study was to better understand patients' attitudes and expectations regarding research activities within medical practice. Within the context of this overarching goal, our findings clustered around six themes (Table 2). The first three themes represent the dominant, cross-cutting values: the tension between duties arising from the personal and population view, physician-patient autonomy, and trust within the physician-patient relationship. The remaining themes reflect the significance of these relational values for different approaches to consent, study design, and community engagement.

1. Support for Research vs. Desire for Individualized Care

There was a central tension and some concern among patients regarding the trade-offs of participating in research within medical practices. Although most patients appreciated the value of practice improvements through this type of research at the population level, most also expressed concern and uncertainty regarding its impact on individualized care. There was, however, some indication that these concerns might shift with greater understanding of research within usual care and with reassurances that the physician would retain control over decision-making for the particular patient's health.

General support for research—In general, patients expressed support for research and appreciated the benefits of sharing health information for the purpose of improving practice:

> *I think it's necessary for medicine to be successful and for teaching people the different stuff. I mean the whole idea of sharing with other people, the more people*

know I think is absolutely phenomenal because I would be very upset if one thing was held and only studied in one place and nobody else knew about it. (FG1)

It makes me feel secure that they're studying these practices to determine how to improve, so you know these practices are under an umbrella of constantly [asking]-how can we make these better? (FG5)

Some patients readily acknowledged that they or family members had benefited from prior research, and this motivated them to consider contributing their own data for the benefit of others:

I'd love to benefit from it, but I'd be okay with just finding out, whether good or bad, if it affected me better because somebody else down the line will benefit from it, so ultimately that's where I'm looking at it. Someone prior to me actually went through a study and that's the only reason that I'm on the treatment that I'm on now so I see the benefit of that. (FG8)

Parents of children with serious medical conditions were especially aware of how past research efforts had helped their children:

My son is 16 and we've had 16 years' worth of improved care because of other people taking the steps and doing the research and improved options for him, and so I wanted to be able to give back to that. (FG1)

Concerns about the impact of research on individualized care—Despite widespread recognition of the societal benefits of research, there was also a pervasive assumption that physicians know what is best for each individual patient—by virtue of knowing their individual health histories and being able to respond quickly to symptoms or reactions to certain treatments. Some articulated this view of individualized care as an emotional connection—the physician cares for them personally in a way a researcher who does not know them may not. The general concern was that if a research design did not leave room for physician discretion over their personal care, they might be worse off by participating in such research. For example, one patient acknowledged that randomization is a valuable research tool but felt that his unique medical status required individualized decision-making that would be incompatible with participation in a randomized study:

I think I prefer observation if observation means I get the prescription… and then a researcher came back and said, what were [my] outcomes? Because I'd like to feel the doctor chose what he thought was the best one for me and then there's seeing what the results were, versus one where he was just forced to assign something to me without the benefit of personalization…. (FG5)

Other patients were torn between the recognized benefits of learning from research on medical practice and the perception that some forms of participation (particularly randomization) might mean foregoing individualized care for themselves or their child:

I…feel like it's the chicken and the egg, randomization. The only way for doctors to feel comfortable to prescribe something is by reading the research and the information that is on the other drugs, and that really can only be done in a larger scale randomization. I don't know if I would feel comfortable with it for my own

child, but I do understand that that type of information, data collected with that type of method is probably a lot better and more specific than one doctor deciding on their own what they think would be better. I'm really torn, I guess. (FG4)

When you're dealing with the emotion, I mean you really want to have your kid be the one that helps the next five or 500 or 5000, but I don't think your heart allows you to do that. (FG1)

2. Patients Value Shared Physician-Patient Autonomy

Patients' desire for individualized care was closely related to the value they vested in the relationship with their physician. For many patients, this value centered on two senses of physician-patient autonomy: physician choice and physician-patient collaboration. These two aspects of physician-patient autonomy influenced how patients made decisions not just about clinical care, but also about participating in research on medical practices.

Physician choice—Many patients noted the importance of knowing that their physicians were free to make appropriate medical decisions on their behalf. Patients viewed this aspect of shared decision-making as essential to receiving individualized, tailored care from their physician and reluctant about situations where their physicians' choices or judgments would be limited. For some patients, protecting physicians' ability to make choices was a foundational aspect of the trusting relationship with one's physician:

It would be realizing that my doctor isn't really in charge of making choices about my health that I thought he or she was. That would be a breach of trust in my eyes. (FG6)

Physician-patient collaboration—Patients also emphasized the collaborative nature of the physician-patient relationship. Many patients felt that open and honest conversations with their physicians were critical for making medical decisions. Others highlighted how a longstanding physician-patient relationship, strengthened by a collaborative decision-making process, can lead to better health outcomes:

There's a certain level of comfort in knowing your doctor and knowing your doctor knows you and your history, and what medications therefore are more likely to be beneficial to you or have fewer side effects. And whenever you don't have that situation, I think there's a little bit more risk. I wouldn't say it's huge amounts obviously, but I would say there's a little more risk. Hopefully on both sides there's a vested interest in a personal relationship that's developed over the months and years that leads everybody into a greater sense of comfort and health, overall health. (FG6)

One patient described the importance of taking an active, responsible role in reporting side effects and communicating with one's physician, again, echoing the belief in the value of individualized care:

By me being a minority, a Black male, I know that there are different medications that will help me more so say than say an Asian or Caucasian, and I ask… 'Have there been any studies done on this particular blood pressure medication that's

geared towards minorities?' and he said 'Yes.' I said 'Well which one do you think will work best for me?' So I say we as patients, we have to ask, and if we ask, … then we'll have the knowledge and we'll be able to say 'That's not working.' (FG3)

Patients felt that transparency and collaboration were essential aspects of shared decision-making that, if preserved, would foster comfort with the idea of participating in research:

I would feel better about the situation if I knew that you and your partner/doctor were collaborating, and because he's got all the knowledge on B, you've got all the knowledge on A, I would feel much more comfortable if I knew you were both watching what was going on, 'cause you're bringing your expertise on the two medicines, and at that point, sure, I would definitely participate in that. (FG4)

3. The Importance of Patient Trust in Physicians and Institutions

Participants emphasized the significant role that trust in both a physician/team and hospital would play when considering whether or not to participate in research on medical practice.

Nearly all patients in our focus groups expressed trust in their physicians, medical teams, and hospitals and, if asked to participate in research to improve practice, would largely defer to their physicians. This deference, however, was not absolute and most saw themselves taking active roles as patients, asking questions to ensure their individual interests remained central.

Once a doctor comes to me and says 'Okay, this is what we want to do. We want you to take A, B, or C.' After I've asked the questions and after I've been satisfied with the answers that he's given me as to why he's prescribing this medication for me, I feel comfortable with his decision because I understand that he's a part of the team, and if he's prescribing this medication to me… I know that … they have done the research and that he is intelligent enough and wise enough to make a tangible decision… to choose the right drug in conjunction with me, choose the right medication for me. (FG3)

Patients pointed to a trusting relationship with physicians and transparency within that relationship as central to their willingness to participate in research.

The relationship with your physician, the questions they ask you, what they know about you, what you share with them, I think is a very important relationship and knowing the full extent of that relationship, developing that trust, is something that's very important and that if things are happening without your knowledge, like you're being put into a study without your knowledge or a random drug study without your knowledge, then I would object to that. (FG6)

Patients underscored the importance of a physician knowing them or their child in making the best treatment decisions and were more skeptical that a researcher, lacking such ties, could have a vested interest in providing the best care.

Participant 1: They know our child. They know us. We've been in the trenches with him. …And Robert [Name of researcher in video] is just … some guy off the street in a [Hospital] trial, or you know what I mean, but it's like there's no vested interest

for Robert to convey anything. He's just a very neutral, very great person, whereas the doctor is…

Participant 2:Trusted. (FG4)

Patients also expressed trust in the institutions where they or their child receives care and attributed a willingness to participate in research within a learning health system to that broader trust in the medical center or hospital.

… I'm not kidding you. I passed [Hospital 1] and I passed [Hospital 2]. I passed good hospitals to come here because the fact that I trust them…. (FG4)

4. Significance of Shared Decision-Making for Study Design

When asked about attitudes toward different approaches to study design, such as randomization, participants consistently looked to their physician as a guide to evaluating potential risks and benefits. Patients wanted assurances that their physician's judgment about treatments or changes in the course of treatment would not be affected by participation in research within usual care.

Randomization—Patients preferred standard clinical care with treatment based on physician judgment over being randomized to care, unless reassured that their physician would remain in charge of particular decisions over their health. Randomization was widely perceived as a process that precludes personal attention, individualized evaluation of risks and benefits, and emotional reassurance.

In this discussion we've been considering two scenarios. One is the doctor I know very well and trust, and who listens to what I say, and the other is this ultra impersonal randomized situation where you feel defensive immediately because of a lack of personal connection …I think you want a system where there's confidence in a person and then that gives you a basis…for being maybe flexible on some of the other things, but if it's a choice between the two…that's a stark kind of situation. (FG8)

Again, in the context of scenarios describing randomization, many participants expressed concern that decisions would not be made based on their individual history and symptoms. They were concerned that randomization might undermine medical judgment, explaining that usual care incorporates unique characteristics of the patient that randomization might overlook:

I'd say 'Can you tell me what are some of the factors, based on all the other things I take or my symptoms?' That's when I would want his input knowing me as a patient. I get it that he's going on 'A and C work', but then that's when I would want the personal input, test, feedback, 'cause that becomes critical. Then it's not just random. (FG3)

If … my doctor said 'This would be good for your son because this medication has all these specific things that might help him.' 'Well yeah, but we might not get that,' and so I don't want to be randomized. (T)hrough observation my doctor knows my son and what's best for him, and his progress has been observed

throughout the year on these different medications, and I want it tailored to him, not randomized. (FG4)

Some participants asserted that randomization could lead to a patient being assigned a treatment different than what his or her physician would normally have prescribed based on the patient's unique history. As this participant noted, assignment to a randomized study may not incorporate existing medication combinations or other symptoms that could have unintended side-effects not taken into account by the research protocol:

I…wonder if it interferes with their judgment, …if everyone's in this randomization, 'cause there could be side effects. There could be other medications that could interfere and that could cause problems. So it kind of makes me wonder if doctors are actually paying attention to it or just saying 'Oh this person's in the randomization. Let's just give it to them,' not looking at the person's background and history with other medications, 'cause then that could cause problems. (FG2)

Randomization was generally considered acceptable if the physician genuinely did not know which treatment would be optimal for the patient and remained free to make a judgment about whether participation in a randomized study is appropriate:

The only time I see the benefit of the [loss of] physician control is if the physician himself or herself is unsure which one is the best one. So the physician doesn't know which- A, B or C- is best. Then they might say, "Well, you know what, we'll just assign you one at random and we'll monitor the outcome." So that's where I see it, but generally my expectation is that the doctor knows what should be best for me and that's why they should be recommending it. So one situation is a physician really isn't sure which medication would work better so that's where randomization could work. (FG5)

Ensuring that the physician remained as gatekeeper was not only important during enrollment but throughout the length of the study. As one participant explained, there should be opportunity to change treatment should new information or study results become available:

…but as soon as the doctor knows that A will be better than B for this particular patient then I, irrespective of any sort of study, I would want the doctor to prescribe me A" (FG9)

Medical Record Review and Data Sharing—In contrast to randomization, participants appreciated that medical record review allowed for the physician judgment and personalized care that they felt should be a standard. Overall, participants were comfortable with the idea of data sharing, as long as a standard of anonymity was maintained.

I don't think people should have a right to make their files private, because something in their chart could help somebody else. (FG1)

The theme of data sharing as an altruistic means to advance medical progress was repeatedly cited, with one participant noting, "*I might have a piece of the puzzle that believe it or not the doctors don't have" (FG9).* Another patient again referred to the trust established in the physician-patient relationship:

If there's somebody who can benefit from my data, fine with me no matter what because I'm sure that the physician does what is best and he has experience or should have at least, and that is enough for me. (FG10)

5. Significance of Shared Decision-Making for Informed Consent and Notification

Consistent with the overall theme of the physician-patient relationship as a central value, participants' attitudes toward different approaches to consent and notification were largely informed by the role a physician might play in sharing information about the potential benefits and risks of research on medical practice.

Physician-Patient Relationship Central to Consent and Notification—Most participants indicated that the physician-patient relationship affects a participant's overall comfort level with research and likelihood to participate. One participant noted that a mutually communicative relationship was central to whether s/he would feel comfortable opting out of treatment:

When my doctor asked me and he said 'I think this would be good for your son to be in this specific medication study,' I really put a lot of value on it because he told me but in thinking of my own things and my son and my family, I decided against it and I had no problem expressing to him that 'At this point, I don't think it'd be good, but if something else comes up later, I'm open to it.' (FG4)

Patients Rely on Physicians as Guides in Assessing Risks—Multiple participants stated a strong preference for consent or notification to occur through a conversation directly with a physician, as opposed to a researcher or other clinical staff. Participants again emphasized the value of physicians playing a gatekeeper role in assessing the potential risk of research activities specific to their own clinical history and experiences:

I think it has to go through the physician because if you're volunteering to participate … your physician would know best whether that's a risk to you or not, and just going through a research coordinator, who doesn't know me, is a risk, I would say definitely through the physician. (FG9)

Participants cited several reasons for this preference, including the belief that having an opportunity for personal interaction with one's physician is an indication of quality care. As one participant explained, having such conversations about research with their physician could positively impact both the relationship and the likelihood for research participation.

If they have a conversation with you and then ask for your consent, then it's more personal… It just seems like they care more. …[R]ather than 'Oh hey, this is going on and, by the way, you're a part of this.' It's just kind of like 'Oh, you know you're just another number. We don't really care about you. We're just putting you in this.' "So…it's more beneficial for the consent" (FG2)

Another participant emphasized a similar idea: if a physician takes the time to talk with the patient about the research and its importance, the more empathetic nature of the physician-patient relationship might lead patients to pay more attention to the information:

> *[I]f it's important enough for your doctor to actually sit down and discuss it with you, then you listen up. That's when people pay attention, especially if their doctor is empathetic and tuned in and willing to understand that a lot of people kind of glaze over and they're able to provide the information in such a way that makes it comprehensible to their patient.* (FG8)

For some participants, the physician-patient relationship serves as an important screen for studies requiring consent versus notification. As one participant explained, a trusted physician taking the time to describe the research could be sufficient for taking the physician's recommendation to participate:

> *I really, really trust him, so I feel like he has really good conversations with me and really educates me. So him coming to me saying 'This is what I'm gonna do and this is the way,' I don't need to sign anything. I have a really great relationship and trust with him. That would be enough.* (FG4)

Even when it is generally known that a hospital is engaged in research or is 'a learning health system,' some patients still preferred individual consent or personal notification from their physician. For nearly all of the participants in our study, general knowledge that one's health system is engaged in QI research is not sufficient for their willing participation.

> *Yeah. I mean I go to the [hospital] and it's a research hospital, so I know I'm walking through the doors knowing that pretty much everybody associated there is involved in research of some sort, but I still want to be approached by a doctor about 'Do you want to participate? This is what we're doing,' specifically. Definitely would prefer that.* (FG2)

6. Significance of Shared Decision-Making for Oversight and Community Engagement

In general, patients acknowledged the potential value of oversight, however they struggled with articulating the specific goals of oversight and the process by which these goals might be achieved. Participants believed that representation of an oversight body warranted careful consideration and a balance of stakeholders would be important.

Others shared the concern that patients may be too close to the issues and may be too "compromised" to provide unbiased oversight. Respondents identified potential bias and its implications for the research as a serious challenge to identifying appropriate individuals for oversight:

> *I would be careful in that you want the oversight committee to be non-biased and very independent. It need not be patients. It could be patients. It could be anybody, general public, but you need to be very selective of who the oversight committee is without bias.* (FG7)

Others suggested that patients might not have sufficient expertise to assess decisions related to research. One participant expressed her concern stating that, "*patients are not scientists*." (FG7) Another worried, *"I think there's too great a risk of people bringing non medical issues into the fore, and that would inappropriately impact research."* (FG9)

This concern about research expertise was identified as a barrier to participants' own likelihood to engage in an oversight process. This assessment of research or medical expertise further influenced whether they would trust those contributing to oversight decisions:

> *I only know my personal experience and what I would want for myself, for my child or other people, but I'm not a doctor. I don't know if I'm qualified. So I want to be able to put my trust in someone, but that's tough, 'cause I don't know if they're qualified.* (FG4)

Participants did express that an institutional reputation for oversight impacted their perception of and trust in research conducted at that institution. As one participant explained:

> *I feel really comfortable with how [Medical Center] does Institutional Review Board approvals because it's a strict, stringent challenging process, right, you just can't get human subjects…things through the system very easily unless you have a comprehensive detailed research plan, and so I have confidence in that.* (FG9)

Generally, participants identified anonymization of data and the return of research results to study participants as two key areas for oversight. As one participant further explained, his trust in the oversight process and perception of whether patient input was required was based on trust in his own physician. In this way the physician-patient relationship influenced patient involvement not only in a research study, but in broader oversight as well:

> *T)he thing I'd like to know is that my data will be anonymized so…I'm not too concerned about who's doing the research. I'm assuming my doctor is ethical and knows who's doing the research and so on. To me it's more important that the general data is anonymized, but I have access to the outcome information. So was it successful- the study I participated in- was it successful? Was it not? Was there something better that came out of it?* (FG5)

Discussion

Debate over the ethics of research on medical practice and recent OHRP guidance have focused primarily on identifying the relevant added risks and managing these risks through informed consent. (Magnus & Wilfond 2015) Our study reveals that what patients care most about is how risks and consent are managed and communicated within the physician-patient relationship. This suggests a need for greater focus on the conditions for maintaining open communication and trust in shared decision-making with patients who receive care within learning health systems. The centrality of the physician-patient relationship is evident in our major findings and has a number of important implications for key issues in this debate, including: (1) although some have called for rejecting the research-practice distinction, patients in our cohorts perceived research on medical practices as distinct activities from usual clinical care, expecting sharing of research information and in most cases, individual verbal notification or consent; (2) patients expected information about research on medical practices to come through their physician and rely on their physician to identify and manage any risks from participation; (3) although patients generally supported the collection of

patient data to improve clinical outcomes, they worried that participation in randomized research may undermine their ability to receive individualized care wherein physicians take into account each patient's unique characteristics and histories; and (4) education about the rationale for research on medical practices is needed to address what many patients may not appreciate, namely, the degree to which there is variation in practice, not always rooted in evidence, between different physicians. These findings suggest the need for a collaborative approach to the governance of research on medical practices that addresses core values of trust, transparency and partnership.

The Centrality of the Physician-Patient Relationship to the Management of Risk

In addressing the potential for risk from research on medical practice, patients identified their relationships with their physicians as the central conduit for disclosure, decision-making and management of risk. Importantly, our results suggest that patients were less concerned with the distinctions between *disclosure* versus *consent* per se, and were much more attuned to the relational context in which information about research would be offered and decisions made. They expect their physicians to help assess and navigate potential risks of research participation within usual care and assume that their physicians would only approach them when they believe their participation would be beneficial on balance. In so far as risk was a concern among patients, it was a general concern; patients looked to their physicians to identify, evaluate and filter research that might present undue risk.

IRBs and researchers need clear and consistent criteria for evaluating risk in ROMP. However patients identified trust as a core value that motivated their views on how research risk should be managed, suggesting that perceptions of minimal risk may vary depending on the trusting nature of the physician-patient relationships. While it is possible that our population sample reflected a higher baseline trust in physicians and hospitals than the general population and, in particular, than disadvantaged populations, the importance of trust or lack of trust would seem equally if not more important for participants lacking trust in physicians and institutions. In the latter case, being mindful of how best to *build* trust may be a key consideration for this type of research. While from the patients' perspective, trust is a way to navigate risk, it is only a successful strategy when trusted persons or institutions uphold expectations. (Resnik et al. 2011) In this way, strong patient-physician relationships enable patients to navigate sensitive, "riskier" situations—minority patients, for example, may regard clinical research with heightened degrees of distrust unless physicians can adequately demonstrate sensitivity to their concerns. (Durant et al. 2011) Patients also identified transparency as a core value in conveying mutual respect between individual and institutional actors. The simple act of "being asked" bolstered a sense of trust. They wanted the opportunity to ask questions and discuss research activities with their physicians, recognizing that physicians are pressed for time, and that engaging patients individually is more time consuming than general notification or signing a consent form. Given our findings, taking this time will be essential for ensuring support for research in medical practice by addressing what is most important for many patients—conversations with their physicians.

Patients as Partners: Insights from Shared Decision Making

In light of patients' concerns that the physician-patient relationship can freely function in the context of research on medical practices, we suggest that shared decision-making (SDM) can serve as a valuable model for managing disclosure, consent, randomization, and data sharing. Originally developed in the context of clinical decision-making, in SDM the physician is usually the person who engages the patient (and the patient's family as appropriate) in the decision making process. In particular, SDM has been recommended as a way to encourage patient-physician conversations regarding uncertainty in treatment options, making it particularly relevant to comparative effectiveness research. (Politi et al. 2013) For research questions aimed at determining treatments when there is limited high-quality, clinical evidence, SDM can support collaborative physician-patient decision-making that addresses uncertainty and bridges the power gap between patient and physician knowledge while promoting transparency and trust. (Braddock 2013)

Existing SDM models could address some of the limitations of standard approaches to informed consent (King & Moulton 2006), depending on whether the decision is basic (e.g., a lab test), intermediate (e.g., a change in medication or dosage), or complex (e.g., a cancer screening test) (Braddock et al. 1999). SDM might also offer a way to assist patients in assessing research risk by recognizing that patient values and preferences greatly influence the perception of harms and benefits and could vary across patients. (O'Connor et al. 2004; Elwyn et al. 2013) In addition, according to a recently published update to a Cochrane Database Study, decision aids supporting SDM conversations resulted in more realistic patient perceptions of risk (Stacey et al. 2014), a finding highly relevant to learning health systems research.

Patients Value and Expect Individualized Care

As the adoption of learning health systems expands, it will be important to proactively address potential misunderstandings held by patients. Patients in our study generally support research activities and recognize the potential value for improved clinical care through research. However, our findings underscore that research activities such as point-of-care randomization are new to patients and challenge expectations about clinical care. Tensions around the perceived tradeoff between individualized care and the goals of using research to develop standardized clinical approaches represent a particular challenge. As one patient explained, "what my own physician thinks is best for *me,*" dictates optimal treatment. There was a general worry that standardized practices might undermine their physician's medical discretion and ability to tailor care to meet the patient's specific health needs.

These concerns seemed more pronounced when participants considered the healthcare needs of their children and other relatives, as they worried that a standardized approach may not be "best" in light of their individual patient history and experience. Although patients appreciated the need for and benefits of comparisons across larger populations for clinical practice, they worried that the best outcomes for the "average patient" would fail to take into account their unique characteristics. Those who identified themselves as heavier users of the healthcare system also identified this concern, perhaps because of their more intense relationships with their physicians and their complicated medical histories. For these

patients, the physician-patient relationship and the key role of the physician as a critical guide in navigating potential benefit and risk of using research findings to guide clinical care loomed large.

Although the tension that patients perceived between individual obligation and population benefit is not unique to research on medical practice, addressing this concern will be critical to public acceptance of research on medical practice as a public good. Influential proposals (Faden et al. 2013) posit obligations to participate in learning health systems for the benefit of all, but do not adequately consider the conflict and tension this implies for the physician-patient relationship. It will be important to communicate more realistically with patients about the limitations of physician knowledge and explain that research may prove beneficial when physicians truly do not know the best clinical approach. At the same time, we will need to reassure patients that physicians remain free to intervene on patients' behalf when they would be better served with an alternative therapy. Given patient concerns, addressing issues of physician-patient autonomy and discretion head on will be important in framing research on medical practice to the public. In particular, our findings suggest a need for models for shared decision making that enable open lines of communication, involve patients in priority-setting, and yet counter the problem of "over protection" that can stunt research.

Greater focus on the physician-patient relationship can help guide patient engagement for ROMP in settings where the lines between clinical care and research are increasingly blurred. Such a shift in thinking is not without challenges given genuine concerns about physicians having undue influence in research recruitment. But our data do support placing less emphasis on the *content* of consent and pre-determination of risks and more emphasis on ensuring that the physician acts as a filter/conduit for information and assessment of risks and benefits. If this is of utmost importance to patients, it is worth taking seriously.

Limitations and Questions for Further Research

The primary goal of our qualitative data collection was to inform the design of a national public survey (Cho et al. 2015). As such, this study was not designed to achieve saturation on all issues, but rather to identify issues for survey development. For example, we were unable to distinguish potentially interesting differences and nuances between high users of health care and low or naïve users, and adult versus parents of pediatric patients. While we included both adult patients and parents of pediatric patients in our focus groups, our numbers were insufficient to tease out differences between these two populations. Although our data identify important emergent themes, additional empirical data will help clarify our observations and confirm more widely held attitudes. The data did, however, generate a number of interesting questions for further research in this emerging area of research ethics. For example: How much does baseline trust matter—for things like acceptance of broad notification? How do models of trust-building mitigate the perception of risk associated with research methodologies among diverse populations? How does trust influence research-related issues such as return of results and data sharing activities? How are potential role conflicts managed with the increased participation of physicians in research consent and disclosure? Ongoing studies are currently addressing these and other related questions.

To facilitate discussion in our patient groups, our study relied on short videos, explaining the concept of research on medical practice and related ethical concepts to increase the meaningfulness of participant responses. While this helped patients understand the idea, two potential confusions persisted. First, it was clear that few patients appreciated the level of uncertainty that exists in clinical decision-making; most seemed to take for granted that physicians generally know what is best *for them* and such judgments are based on sufficient evidence from clinical trials. This suggests that the very rationale of research within usual care needs to be conveyed as part of an education effort in hospitals conducting ROMP. For this reason some participant responses seemed in part based on knowledge and impressions of clinical research trials, suggesting some conflation of traditional clinical research and research within usual care.

Finally, we acknowledge that our recommendations for relying on SDM in the research context raise potential challenges related to conflicts of interest. If we honor patients' expectations for physicians as the conduit of information, whether notification or full individual consent, as well as allowing a strong role for physicians in assessing risks and benefits, this represents a departure from the usual model that advocates that those charged with obtaining consent are not primarily responsible for patients' clinical care. (Morin et al. 2002) However, our findings strongly suggest that patients look to physicians for guidance when considering research in the context of usual clinical practice, and that this relationship is key to maintaining and building trust in these research activities. Furthermore, it could be argued that the basis for the conflicting interests in typical clinical research does not exist in the particular context of research that compares treatments that are already known to meet minimum standards of safety and efficacy. That is, the clinician is not necessarily faced with a conflict between the best interests of the patient and the interests of the research in studies of research on standard medical practices. Future work is needed to balance these concerns.

We also recognize that maintaining the centrality of the physician-patient relationship as the main conduit for information presents challenges as a scalable long-term solution. The emergence of the learning health system as an infrastructure for research within usual care may require a period for building and evaluating effective models of engagement, such as that offered by SDM within the context of clinical decision making. Although trust-building in this context cannot be left solely to physicians, our results suggest that the quality of care-based relationships developed between physicians and patients is nonetheless an important starting point for fostering mutual respect, credibility, and demonstrated care as research is integrated systematically into the clinical environment.

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Table 1

Characteristics of Focus Group Participants (n=53)	
Gender	
Female	26 (49%)
Male	27 (51%)
Age (years)	
Mean	49.7
Range	18–78
25th–75th percentile	40–61.25
No response	1 (2%)
Race	
American Indian or Alaska Native	0 (0%)
Asian	11 (21%)
Black or African-American	4 (8%)
Native Hawaiian or Other Pacific Islander	0 (0%)
White	38 (72%)
More than one race	0 (0%)
Prefer not to disclose	0 (0%)
Ethnicity	
Hispanic or Latino	1 (2%)
Not Hispanic or Latino	48 (91%)
Prefer not to disclose/unknown/no response	4 (8%)
Have you/has your child been hospitalized in the past calendar year?	
No	36 (68%)
Yes	17 (32%)
Recruitment method	
Adult cardiology/nephrology clinic	15 (28%)
Pediatric cardiology/nephrology clinic	10 (19%)
Research registry	28 (53%)

Table 2

	Theme	Representative Quote
1	**Support for Research and Desire for individualized Care**	*I think the way it's said is very important, the relationship you have with your doctor, but also research is just very, very important, which I'm sure is why we're all here. Research is very important.* (FG4)
2	**Patients Value Physician-Patient Autonomy**	*We have a game plan, what to do and stuff, but it never works just doctors alone. You have to be informed. The consumer, just like any other thing, you have to know your condition of the body when it is the one type of the medication, how it works at stuff.* (FG6)
3	**The Importance of Patient Trust in Physicians and Institutions**	*When you go to the doc, you put all your faith and trust in him, but I think it's also incumbent upon us as patients to learn as much as we possibly can so as we move forward, we will have the knowledge. We know how our bodies feel.* (FG3)
4	**Significance of Shared Decision Making for Study Design**	*Randomization is great to figure out what's safe and what's not safe because then you can use controls and you can do the studies. But I think for a unique individual like my particular situation, I prefer observation if observation means okay, I get the prescription, so my doctor prescribed the medication and then a researcher came back and said okay, what were [my] outcomes? Because I'd like to feel the doctor chose what he thought was the best one for me …versus one where he was just forced to assign something to me without the benefit of personalization and then we just looked at the outcome.* (FG 1)
5	**Significance of Shared Decision Making for Informed Consent and Notification**	*You can post things. You can hand people sheets of paper. If it's important enough for your doctor who has you in and out in limited period of time, if it's important enough for your doctor to actually sit down and discuss it with you, then you listen up. That's when people pay attention, especially if their doctor is empathetic and tuned in and willing to understand that a lot of people kind of glaze over and they're able to provide the information in such a way that makes it comprehensible to their patient.* (FG2)
6	**Significance of Shared Decision Making for Oversight and Community Engagement**	*I guess that as long as the oversight is comprised of not just the doctors, but also family members and things like that then, yeah, I would like to have an oversight, but the oversight cannot be just unilateral. It has to be bilateral. It has to be everybody.* (FG1)