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The Role of Patient Perspectives in Clinical Research Ethics and Policy: Response to Open Peer Commentaries on “Patient Perspectives on the Learning Health System”

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We appreciate the very thoughtful commentaries on our empirical ethics study, “Patient Perspectives on the Learning Health System: The Importance of Trust and Shared Decision Making” and are encouraged by the liveliness of the debate on this topic. As we note at the end of our paper, and as several of the commentaries demonstrate, significant gaps remain in the empirical work on the ethics of research on medical practices. This qualitative data was part of a larger mixed-methods study aimed at understanding US national attitudes among patients and IRBs. (Cho et al. 2015; Lee et al 2015) Not surprisingly, disagreement surrounding both our qualitative and quantitative data has focused on our interpretation of the data and to what extent patient attitudes should inform ethical and policy arguments. In our response we will address substantive questions related to the role of trust and shared decision making (SDM) in research on medical practices in light of the research-care

distinction. We will also clarify methodological misunderstandings about our qualitative analysis and the degree to which we were making any strong policy recommendations based on that analysis.

Trust and Trustworthiness

The trust that patients place in physicians to make the best decision about their care was a central theme in our data. On the whole patients cared most about preserving the relationship with their physicians and the ability to make decisions together about the best care or treatment plan. We agree with Largent that the research-care distinction remains important to patients and that their favorable attitudes toward the value of research on medical practices likely depend upon the presence of trusting relationships with their physicians and hospital.

We did not, however, probe patients on the conditions that create trust and noted this in the limitations of the study. Future work on the sources of trust needed to support participation in learning health systems will be critical. Salloch et al. and D'Angio note the important difference between trustworthiness and trust. Trustworthiness better captures how health care systems and health care providers earn trust over time, and how certain trustworthy practices affect patients' assessment of risk and the potential benefits of research on medical practices. Future empirical work on the ethics of research on medical practices as well as public engagement about new policies should further examine how physicians and health care institutions earn and retain deserved trust in the context of learning health systems.

Conflicts of Interest and Shared Decision-Making in Research

We have suggested that shared decision making (SDM) as a model for ethical decision making in clinical medicine offers insights for taking into account patients' expressed concerns that research within usual care (particularly randomization) might alter the physician-patient relationship. We do not recommend the wholesale adoption of SDM in the clinical research context and note the challenges needing further consideration. D'Angio, Dubljevic and Sugarman argue that SDM is the wrong analytic frame for any research context in part given the concerns about introducing or exacerbating conflicts of interest.

There are well established approaches to mitigating conflicts of interest, including, as D'Angio suggests, open and transparent communication between physicians and their patients about potential dual roles in research on medical practices. In fact, various approaches to shared decision-making arose in part within clinical ethics as a response to managing conflicts of interest and paternalism in clinical decision-making. (Salzberg 2011) Involving patients openly in learning health systems and making patients more aware of the blurred roles of physicians or hospitals engaged in research on medical practices might diminish the types of concerns raised by these critiques. Furthermore, when RoMP delivers the same care to patients that they would ordinarily receive, worries about therapeutic misconception—a major concern arising from clinician-investigators' dual roles—are markedly diminished.

In our research, we identified key issues, concepts, and themes by which our data could be examined and referenced. This was carried out by drawing on *a priori* issues and questions derived from the aims and objectives of the overall study as well as issues raised directly by our participants and views or experiences that recur in the data. Dubljevic and Sugarman both object to our analysis and interpretation of the data. Sugarman suggests that we offer the data free from analytic framing. This suggestion reveals a misunderstanding of robust approaches to qualitative analysis that introduce theoretical constructs to offer possible explanation of the themes that emerge descriptively. SDM was not an analytic frame which we foisted upon the data, rather, it was suggested by the data. The construct offered a flexible and dynamic way of thinking about the meaning and implications of the data and was introduced in the discussion to make sense of the strong emergent themes regarding patients' focus on the physician-patient relationship. This methodological approach aims to provide an analytic roadmap for empirical work to directly address key issues for policy. We remained appropriately circumspect about what ought to be done in practice or policy following these findings and instead used our data to identify research questions for future empirical and conceptual work. We encourage further rigorous normative debate on exactly the questions raised by Sugarman and Dubljevic.

Why Patient Perspectives Matter When Informing Health Policy

Goodman and Flory raise concerns about the right way to respond to patient preferences. In all areas, not only health care, considering context for the implementation of policy is important for successful and meaningful uptake in the relevant setting. In the specific case of developing policy for research on medical practices, the reasons for understanding patients' attitudes extend beyond the pragmatic concerns of effective implementation. Genuinely inquiring into patients' own views, concerns, and even potential misunderstandings demonstrates a respectful and inclusive approach to policy making. Certainly, to the degree that some patients' attitudes might rest on misunderstandings about aspects of clinical care or research within medical practice—such as a strong belief in the ideal of personalized medicine—these findings demonstrate a need for further patient engagement and education. We acknowledge this in our paper and argue that an approach that emphasizes the need for transparency and open dialogue about the uncertainty of clinical decision-making would improve patients' understanding of the need for research on medical practices and clarify their values around future participation in these activities.

However, we disagree that many of our findings were due to participant misunderstanding—the study was designed with the use of educational videos that explained the rationale for research within medical practices and the key concepts needed to discuss attitudes in a meaningful way. One of the biggest challenges in engaging patients on their perspectives and ethical concerns about research on medical practices is that we might not like what they have to say or be able to accommodate all preferences. (Lantos 2015) In our related survey (Cho et al 2015), we presented patients with the trade-off between requiring individual informed consent or being forced to abandon the research. Most respondents were willing to accept alternative approaches to consent that were less burdensome, such as notification and opt-out, if necessary to allow the research to move forward. To dismiss patients' attitudes and concerns regarding the ethics of research within medical practice would be to ignore a

critical aspect of the context in which such research occurs and is evaluated. More deeply, however, we share the concern that what patients want or are willing to accept might not be consistent with ethical guidance meant to protect patients and participants regardless of their preferences. In this case, revealing a gap between patients' attitudes and more stringent protections driven by normative or other empirical considerations warrants a vigorous debate about whether human subjects protections for clinical trials are out of sync with patients' acceptance of clinical risks in research on medical practices.

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