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Is Shared Decision Making an Appropriate Analytic Frame for Research on Medical Practices?

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Large scale efforts are now being directed towards research on medical practices, which includes the conduct of pragmatic clinical trials, comparative effectiveness research, and analyses of data collected for clinical purpose. Such efforts promise to inform clinical practice and policy. Unlike much conventional, hypothesis-driven research that involves testing new agents for safety and efficacy, research on medical practices tends to evaluate available and familiar interventions already in use to determine which is best. In addition, in contrast to conventional research that usually involves extra burdens associated with data collection, data for research on medical practices may be harvested from existing sources such as electronic medical records. Thus, research on medical practices typically poses minimal incremental inconvenience and risk to patients compared to standard medical practice. Regardless, such streamlined research efforts may be currently unfamiliar to both regular clinical practice and research. Nevertheless, as an ethical and regulatory matter it is critical to ensure that the rights, interests and welfare of patients who participate in research on medical practices are protected. While at first glance meeting these obligations would seem relatively straightforward given the nature of the research, a perhaps surprising amount of debate has ensued at least in part because of different views on the nature of research on medical practices and clinical practice itself, interpretations of risk and provisions of current regulatory structures, and limited information about the perspectives of patients concerning this type of research. (Sugarman and Califf 2014) Empirical data promise to inform some of these debates.

Toward this goal, Sandra Soo-Jin Lee and her colleagues provide data from focus groups conducted to facilitate the development of a quantitative survey in their article, “Patient Perspectives on the Learning Health System: the Importance of Trust and Shared Decision Making”. (Lee et al, 2015) While the term “learning health system” does not appear in their focus group guide, it is clear from the examples used that the authors intended to capture relevant attitudes for research on medical practices. At the outset, the authors describe that:

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"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)." While their findings regarding the physician-patient relationship and the inherent trust related to it are critical, it is important to consider the appropriateness of using SDM as the analytic frame in this setting and the relevance of the conclusions regarding the interpretation of risk and treating clinicians that follow from doing so in informing debates about appropriate policies and practices.

Shared Decision-Making

SDM is quite relevant for many aspects of clinical practice, where it has emerged as a means of honoring patients' preferences and values while determining a course of clinical action aimed at enhancing their welfare. (Frosch and Kaplan 1999; Whitney 2003) SDM emphasizes the importance of providing information about alternative clinical approaches and then eliciting patient's preferences regarding them, guided by clinicians' knowledge and expertise. In the language of ethical principles, SDM is a process that seeks to align the requirements of the principles of respect for autonomy and of beneficence. While SDM is in many ways similar to informed consent, there are some important differences, especially in the research setting. In research, unlike clinical care, the primary goal is not to benefit patients; rather, research is directed primarily at generating information. While there are of course obligations of beneficence in research that include minimizing risks and maximizing benefits to participants, and patients' values can and should be incorporated into research designs and procedures, a SDM model arguably doesn't seem to find a ready place in the setting of most research on medical practices unless of course the distinction between research and clinical practice is fully abandoned. However, as the authors observed, "although some have called for rejecting the research-practice distinction, patients in our cohorts perceived research on medical practices as distinct activities from usual care, expecting sharing of research information and in most cases verbal notification or consent." (Lee et al, 2015) Thus, we should be cautious about simply adopting a particular approach to clinical decision making, namely SDM, in this context since the primary aims and characteristics of clinical care and research are different. As such, adopting this SDM frame can suggest some potentially odd conclusions in regard to risk and the physician-patient relationship in research on medical practices.

Risk

The authors found that patients want to have physicians be mediators of risk in research on medical practices. For example, "what patients care most about is how risks and consent are managed and communicated within the physician-patient relationship." (Lee et al, 2015) In addition, "[i]n 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." (Lee et al, 2015) However, unlike some conventional translational research the risks in much research on medical practices are minimal, making it difficult to understand the relevance of this finding in informing ethics and policy discussions. The authors offer a potential clue to this finding in that "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." (Lee et al, 2015) If participants were interpreting research on medical practices in this way, it is not at all surprising that they would want to be meaningfully engaged with a clinician who could help them navigate this decision that may plausibly involve different risks.

Physician-Patient Relationship

The "centrality of the physician-patient relationship throughout the data" also warrants mention. (Lee et al, 2015) The "results suggest that patients were less concerned with distinctions between *disclosure* and *consent* per se, and were much more attuned to the relational context in which information about research would be offered and decisions made." (Lee et al, 2015) For patients without traditional clinical research experience, and perhaps even some of those with it, it is quite plausible that the most familiar model for information related to clinical practice would be a physician. Focus group participants "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." While this is an understandable desire, it is unclear if it is realistic in the setting of much research on medical practices for a variety of reasons. For example, aside from ensuring that a particular patient should not be included in a particular research project, frontline clinicians are unlikely to be meaningfully involved in any particular research on medical practice project, making them ill-prepared to discuss and describe the particular features of the research such as data security. Rather, they are expected to primarily continue to meet their clinical obligations to patients regardless of the research activity. In addition, the notion of a dyadic physician-patient relationship that appears to be assumed in the findings may be anachronistic except for those with complex illnesses or substantial resources.

Informing Debates

While Lee and colleagues took efforts to inform focus group participants about research on medical practices, including the use of accessible videos, their findings suggest that all did not grasp some of the essential characteristics of this research. Accordingly, they seem right to call for greater education about research on medical practices. While it is perfectly conceivable that even with greater education patients may still desire for clinicians to be meaningfully engaged in decision-making, as described earlier it does not follow that the correct conceptual model to apply is SDM. Although good arguments can be made that some types of research on medical practice are akin to clinical care, this is not always the case, especially when the types of interventions being evaluated differ in important qualitative ways (e.g., medical and surgical approaches to the same clinical problem) where express consent is clearly required. (Faden, Beuachamp and Kass, 2014) On the other hand, it also does not follow that the current approach to research oversight should be adopted wholesale for all research on medical practices. In contrast, there seems to be a need for a hybrid approach that captures the fundamental importance of transparency, disclosure, and often authorization for such research activities. Towards this end, it would be useful to consider analyzing the data without a particular clinical or research decision making frame

to see if relevant findings emerge. This should also be relevant for other concurrent efforts that are generating data regarding research on medical practices.

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