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## POLICY FORUM

### **Research on Medical Practices and the Patient-Physician Relationship: What Can Regulators Learn from Patients?**

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The practice of medicine is markedly improving due to increasing availability of health care data. Systems-level efforts to continually evaluate clinical practices [1] and prospective randomized studies that compare the efficacy of different medications and procedures used routinely in clinical practice provide physicians with critical information for making evidence-based treatment decisions. These activities, which we term “research on medical practices” (ROMP) [2], have the potential to improve patient care by determining which standard practices are most effective.

Physicians who engage in ROMP face a professional and ethical challenge, however. This research takes place in the context of ordinary clinical care, blurring the boundary between research and practice. A physician’s primary obligation is to act as a fiduciary toward her patients, whereas a researcher’s duty is to benefit society at large by producing generalizable knowledge. Having physicians serve both roles simultaneously is considered by some to be cause for concern due to potential conflicts of interest [3]. Yet others have argued that these two roles can be aligned, even in clinical trials, when physicians are knowledgeable about their patients’ preferences and the research protocol [4]. Indeed, when research is integrated into clinical practice, physicians might be best situated to discuss the research with their patients and to obtain consent.

One approach for physicians to take in conversations with patients about potential participation in ROMP is the “integrated consent model” [5]. This approach integrates research consent into the same model as consent for treatment: the physician and patient discuss the research, including its rationale, risks, benefits, and alternatives, and the physician documents the conversation and the patient’s decision in the patient’s medical record. The integrated consent model accomplishes two things: first, it allows patients the opportunity to discuss the proposed research and its implications with their physicians, just as they would with any clinical decision. Second, it streamlines the consent process in cases in which waiving documentation or other elements of informed consent is appropriate from both a research design and an ethical viewpoint [6].

From a patient perspective, the integrated consent model can accommodate a patient’s desire to discuss research participation with her physician. A national survey on attitudes

about ROMP [7] (the “ROMP survey”) found that three-quarters of US respondents prefer to have conversations about participating in randomized or retrospective medical record studies with their physicians rather than with researchers. These survey data are supported by findings from focus groups with patients [8], which show that patients desire and expect information about ROMP to come from their physicians. When research takes place in the setting of clinical care, patients prioritize the maintenance of the patient-physician relationship and, in fact, rely on their physicians to advise them and offer recommendations about the research—because they trust that their physicians will only propose that they participate in studies that are safe and worthwhile [8]. This trust highlights the need for physicians to be careful and deliberate about how they present the possibility of research participation to their patients.

Although the integrated consent model has not been studied in practice, these studies on patient preferences suggest that it could be a favorable approach that meets the needs of individual patients and promotes the conduct of valuable research. For example, although many patients would prefer to have their consent documented in the traditional manner of a signed form [7, 9], more than two-thirds of respondents in the ROMP survey were comfortable with using an alternate approach to a written consent form if the research could not otherwise take place [7]. By using the integrated consent model and altering the elements of consent, physicians can focus on the most critical questions that patients need to consider in making decisions [5]. Weiss and Joffe, for example, have recently proposed reframing research oversight to focus on four key topics—the purpose of the study, alternatives to participation, risks and potential benefits of the study agents, and any other risks or discomforts of participation [10]—rather than including all of the elements required for traditional research consent [11] and documentation [12]. Simplified approaches can allow physicians to engage in straightforward consent processes and more clearly convey information to patients. This could also include innovative approaches such as mobile applications and videos.

Yet the Office for Human Research Protections (OHRP) has issued draft regulatory guidance [13] that, if finalized, would prohibit the use of [nontraditional informed consent models](#) and effectively forestall the possibility of pursuing the integrated consent model. The draft guidance, which is intended to help local institutional review boards apply federal research regulations to ROMP, asserts that, if a prospective study is designed with the goal of assessing a risk, for regulatory purposes that risk is categorized as a risk *of the research itself*—even when that same risk also exists in ordinary clinical care. By categorizing the risks of the clinical treatments as research risks, the draft guidance characterizes most randomized ROMP as carrying more than minimal risk to participants; this means it cannot, under federal regulations, qualify for a [waiver](#) of written documentation of consent [12].

This characterization has serious implications for the future of ROMP. First, nearly all randomized ROMP would require documentation of informed consent in a signed, written form, thus precluding patient-friendly alternate proposals such as the integrated consent model. A second undesirable consequence of the OHRP draft guidance is that it could discourage some potential participants by making ROMP sound riskier than ordinary clinical care, which might not be accurate. Specifically, by reframing clinical uncertainty as a research risk, the draft guidance could lead those obtaining consent from patients to misattribute the source of the risk, giving patients the impression that participating in this kind of research is significantly riskier than getting their usual clinical care [2, 14]. As a result, some patients who otherwise would have been interested in participating in research might hesitate to do so. The vast majority of ROMP survey respondents, however, strongly support using ROMP to improve medical practices [7], and many focus group participants view participation in ROMP as a chance to contribute to the medical system in recognition of the medical advances from which they have personally benefited [8]. Thus, respecting patient values might mean not only obtaining patients' informed consent, but also working to ensure that patients have the opportunity to support and participate in valuable research.

The OHRP draft guidance could also reinforce the popular myth that physicians are typically confident in their treatment choices in everyday practice. In reality, there is great clinical uncertainty in many areas of medicine about which treatments are best for patients. This is precisely the reason for the national efforts to support systems-level learning and evidence-based medicine. The OHRP draft guidance, however, implies that the potential for harm associated with clinical uncertainty only exists when patients are randomized by research protocols, not in everyday practice. In the ROMP survey, nearly all respondents said that, in order to maintain their trust, it is at least moderately important that their physicians tell them when they are uncertain about which treatment is best, including more than 80 percent who said that disclosure of uncertainty is very important [7]. So, not only could the OHRP draft guidance result in physicians overstating the risks of research to patients, but it could also foster mistrust between physicians and patients. Trust and transparency in the process of informed consent are critical for the preservation of the ongoing patient-physician relationship [8]; if these two criteria are not fulfilled, there could be implications for the patient's continuing medical care that go far beyond a particular research protocol.

A growing body of literature on patient preferences about ROMP has raised questions about whether the OHRP draft guidance really protects the values that are most important to patients [15]. The studies cited here show that patients value ROMP, are sometimes willing to forgo written documentation of informed consent, and place a high value on their relationships with their physicians. These preferences should be integrated into regulatory oversight in a nuanced way that achieves the goals that are meaningful to patients and allows them a voice as stakeholders in the improvement of

medical care at the systems level. As written, the OHRP draft guidance could preclude opportunities to streamline informed consent processes in ways that fit with patients' values about research and the patient-physician relationship.

As systems-level learning increasingly informs medical practice and as new regulatory guidance goes into effect, physicians will play a critical role in overcoming challenges to the incorporation of ROMP into clinical settings. Physicians can provide a bridge between their patients and the greater medical and research communities, and they are therefore uniquely situated to guide and support their patients throughout their everyday care, in their decisions about research participation, and as potential beneficiaries of the future medical advances that ROMP can help bring about.

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**The Research on Medical Practices Group** at the University of Washington's Institute of Translational Health Sciences (ITHS) and the Stanford Center for Clinical and Translational Research and Education (Spectrum) were jointly established in October of 2013 to conduct empirical research as a basis for informed policy recommendations on the ethical conduct of research on medical practices and communicating with patients about such research.

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