



## AN INTERVIEW WITH **ELLEN S. TAMBOR**

**Member of the NIH Collaboratory Stakeholder  
Engagement Core**

Interviewed by Liz Wing, MA, Coordinating Center Staff Writer

**At the May 2017 NIH Collaboratory Steering Committee meeting in Bethesda, MD, we sat down with Ellen Tambor and asked her to reflect on the first 5 years of the Core as well as on the challenges ahead.**

### **What are some key things you've learned about making pragmatic trials successful?**

Stakeholder engagement is a core aspect of pragmatic trials and comparative effectiveness research in general. Pragmatic trials take stakeholder engagement to a new level of importance in terms of both the scope of engagement and the array of potential stakeholders. For example, stakeholder engagement has traditionally focused on picking the right question to make sure it will be of interest to everyone involved in the research. Engagement happens primarily at the beginning and end of the trial, and in the middle everything runs its course. But as we've been hearing consistently from the investigators of the Collaboratory's pragmatic trials, engagement of stakeholders is essential all the way to trial completion. This is due to the very nature of trials that are conducted within clinical settings of healthcare systems. We've learned that we rightly need to focus early engagement on system leadership in order to reach agreement about conducting a trial in their system—but we cannot stop at that level. When actually implementing the trial, engagement requires the cooperation of very busy doctors, nurses, and

other clinic staff. Pragmatic trials require engagement not only at the top but all the way through the system down to the frontline providers. This has been the most important revelation about stakeholder engagement in our experience.

### **How can one go about making sure the right people are involved throughout pragmatic research?**

There are two guiding questions about this. The first is, Who is going to use the evidence that results from the study? Because the definition of a stakeholder is someone who will use the evidence to make decisions, or someone who will be affected by the decisions, such as patients, clinicians, and policymakers. The other question is, Who will help ensure that the study is implemented as seamlessly as possible? We need to think about everyone who is touched by the study protocol in any way, from beginning to end. It can take an army at the clinical site level because there are so many people who may be indirectly involved. For example, the office administrator who checks patients in will inevitably

get questions about the trial. Any member of the site staff who might in some way contribute to the trial or need to answer questions about it should know about the trial. For pragmatic trials, the right stakeholders will always include healthcare system leaders, patients, caregivers, patient advocates, and providers—and depending on the trial might also include payers, policymakers, and industry representatives.

### What questions remain to be answered?

I think we've only touched the surface of the importance of patient engagement. Engaging patients in one isolated pragmatic trial is one thing, but scaling up to a learning healthcare system is the underlying vision—and that will take a tremendous increase in awareness about what these trials are and why they're important. For example, many patients don't know that a lot of the decisions being made in healthcare are not directly evidence-based. If we are to move toward a learning healthcare system that involves patients and their clinicians contributing to the evidence, then more work needs to be done to raise the level of awareness about how critical these new forms of evidence are.

Another area for future work is developing a more comprehensive framework about how best to engage with frontline clinicians and staff. This remains a complicated area with many barriers and types of incentives.

Last, while the work of the Stakeholder Engagement Core has more recently focused on the specific challenges of the Demonstration Projects, we will need to return to a broader view for stakeholders as we discuss dissemination and implementation and building a learning healthcare system.

“Pragmatic trials require engagement all the way through the system down to the frontline providers.”

– *Tambor*

