

## Giving research participants their voice: assessing comprehension in the informed consent process

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In 1966, Henry Beecher, one of our research ethics heroes, after uncovering numerous consent violations, found it necessary to write: “Most codes dealing with human experimentation start out with the bland assumption that consent is ours for the asking. This is a myth. The reality is that informed consent is often exceedingly difficult to obtain in any complete sense... Nevertheless, it remains a goal toward which one must strive for sociological, ethical, and legal reasons” [1].

Now, nearly 50 years later, the language we use when we begin the enrollment process indicates that we have not yet shed this assumption. We tend to say that we are ‘going to consent the patient,’ as though this is something we do to the prospective participant just like drawing blood or administering a vaccination. We assume we will walk out of the encounter with a signed consent form. But how do we ensure that the consent is valid, that the signature on the document represents a truly informed study participant? We are responsible for educating patients about the research, helping them review their options and to be sure that they understand the purpose of the research, the risks and benefits of participation and what is expected of them. If they do not understand those things then their signature on the consent form cannot be considered valid. We are always told that ‘informed consent is a process not a form,’ but many people who are obtaining consent for research have never been trained on how to have an effective

consent discussion that results in a valid consent. An effective process needs to include an assessment of understanding. We usually do that by asking two questions:

- Do you understand?
- Do you have any questions?

This is not adequate. We need to do better.

In 2009, when the US FDA published the “Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects” they stated that when delegating tasks investigators “should ensure that there is adequate training for all staff participating in the conduct of the study” and that the staff “are competent to perform or have been trained to perform the tasks they are delegated.” During inspections, the FDA has identified instances where informed consent, a frequently delegated task, was being performed by people lacking adequate training and supervision [2].

In response to this guidance document, The Dartmouth Hitchcock Medical Center’s Clinical Trials Office and our IRB, The Committee for the Protection of Human Subjects, convened a group of people interested in improving the informed consent process for the purpose of developing an enhanced education program for investigators and study coordinators. We chose to focus our program around using the teach back technique to assess understanding of the consent form. The teach back technique has been widely used in



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clinical settings but rarely in the research setting. In teach back, the prospective research participant is asked to ‘teach back’ to the person obtaining consent the important information in the consent form. A signature is obtained only if the patient has demonstrated adequate understanding of the study. Some studies use tests or quizzes to do this. Tests and quizzes tend to put the responsibility for understanding on the patient. What distinguishes teach back from a test or quiz is that it puts the onus on us, the investigator or study coordinator, and not the patient. If the patient is unable to teach back the information correctly, then it is because we did not do a good enough job of explaining it.

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Our project, the Valid Informed Consent Education Program, or VoICE, was awarded a Quality Improvement Grant from Dartmouth Hitchcock Medical Center in 2010 to create and pilot test the program in our institution. As a quality improvement project, we were exempt from IRB review. Sixteen study coordinators volunteered to participate (we invited PIs as well but none attended). Our goal was to see if we could effectively teach people how to use teach back in the consent process. Our pilot program included observation of the participants having a consent discussion with a standardized patient before they attended the education session, and 1 week and 3 months after. Each person had the same consent form to work with, one that had been adapted from a real study. At the end we held a focus group with several of the participants for feedback on our education session and suggestions for improving it. Even though our sample size was small, we demonstrated that we could engage the study coordinators that we were able to teach the technique, and that in the test setting, the study coordinators used more teach back questions in both post-test observations than they had before the education session. We also learned that the study coordinators were hungry for this type of training.

We recognize that putting a valid informed consent process into practice is not without challenges but it needs to be done. As of this writing, the FDA has a draft guidance for informed consent that recommends the need to assess understanding of the research in the consent process [3]. Time constraints, pressure from sponsors and PIs to meet enrollment goals and the persistence of the therapeutic misconception are all factors. One of the biggest and largely unrecognized

challenges is patients with limited literacy and health literacy skills. There are more people in this category than many of us realize and consent forms continue to get longer and more complex.

The concept of health literacy is the basic rationale for using teach back, both clinically and for research. The Institute of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions” [4]. In the United States, 42% of the adult population has low literacy skills [4]. According to UNESCO, 84% of the worldwide population is illiterate [5]. Even people with proficient literacy skills can become functionally illiterate when in pain or confronted with a new diagnosis of a serious disease.

We cannot count on patients telling us whether or not they can read, so we cannot rely on paper forms alone. It is less important that someone read the form than it is that they understand what is in it. We need to take the informed consent mantra ‘It’s a process, not a form’ very seriously. So what is a good process that results in valid consent? Researchers and prospective participants need to sit down together and have a conversation. Yes or no questions do not encourage a give and take exchange between the study coordinator and the prospective research participant. Most consent forms, above the signature line, say “I have had the study explained to me and had all my questions answered.” A lot of patients will say they do not have any questions which may be because they do not know what questions to ask. All of us at one time or another run into situations we know so little about that we do not know what to ask, such as signing mortgage papers for the first time.

When we initiate a conversation at the beginning of a consent discussion, we give voice to even the shyest of patients. We begin by finding out what they already know about the study. We let them know that as we go through the consent form together that we will pause now and then to have them explain back in their own words what we have just said because it is our job to explain things in a way they can understand and we need to make sure we are doing that. If a person is unable to teach the information back to us, we will say something like: “Let me see if I can do a better job explaining that to you.” Be creative about how you present the information. Perhaps someone is visual learner so drawing a diagram might help. This process is repeated until the person shows understanding and if several attempts do not work, you will not be able to get valid consent and should not enroll the patient.

We teach people to focus on the parts of the consent form that provide information that is likely to impact their decision to participate or not. We recommend creating a 'Master Consent' for teach back by selecting the most important things the person must understand and embed teach back questions to ask after explaining that section. An example of a question to ask is: "When you go home tonight and your spouse asks you what the study is about, what will you say?" The technique is simple and straightforward but it can be awkward at first and takes practice.

Since our pilot project, a VoICE module has become a regular part of our institution's semi-annual orientation class for study coordinators. We have also traveled to other sites to conduct teach back education sessions and consistently received enthusiastic positive feedback. It is evident that people want the opportunity to develop techniques to improve their consent process, and in turn offering their patients a stronger voice and fuller understanding when making decisions about research participation.

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