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What Patients Expect, Need, and Want to Know about Clinical Research



Diane Simmons and Kenneth Getz

Continuous education is the missing link in building a community that takes pride in playing a role in advancing medical science and improving public health. To be effective, education provided before, during, and after trials must reflect what patients and potential volunteers expect, need, and want to know about clinical research.

When the public's primary source of information about the clinical research enterprise is the media, the communication they hear tends to focus on sensationalistic accounts of human error, concealment, fraud, and corruption. More than two thirds (69%) of Americans are exposed to information on clinical research studies through television, radio, print media, and via Internet advertising. Only one in seven adult Americans is exposed to information about clinical research studies from their primary or specialty care physician. In a recent survey,¹ the public expressed great interest in receiving information about clinical trials from their pharmacist, but survey respondents reported

reluctance in requesting it and thought it highly unlikely that they would receive it. Pharmacy-directed educational strategies, in addition to education provided by medical professionals, are crucial in building and sustaining public understanding of the clinical research process.

Last year, the nonprofit Center for Information and Study on Clinical Research Participation (CISCRP) led a series of focus groups among study volunteers to probe for factors that most inform and educate clinical research participants. These focus groups revealed core motivations of all study volunteers, regardless of age and socioeconomic status, which can serve as a blueprint for continuous patient and public education. First and foremost, study volunteers want to know that their participation will make a difference. They want to develop personal relations with study staff and feel that they are taking control of their medical condition and well-being.

Pre-Trial Educational Message

Typical perceptions of clinical research participation must shift away from the "guinea pig" image before

people can take part proudly and comfortably in a research community.

The *Medical Heroes* public service campaign developed by CISCRP with *pro-bono* support from the international advertising agency Ogilvy HealthWorld and with growing usage by sponsors, CROs, patient advocacy groups, and research sites, is aiding in educating and winning over the public about the importance of clinical research participation. *Medical Heroes* provides easy-to-remember messaging and acknowledgement of ordinary people's contributions to public health. The TV, radio, and print advertisements are lauded for their "humanity and emotional appeal," as viewers declare, "These people are heroes in their own way," "They've done something great for all of us," and "I see the benefit of clinical research to society."

When research sites reinforce this public service campaign's message and invite potential volunteers to begin conversations, the relationship grows into lasting commitments to the center and its staff. The lesson

here is that pre-trial educational interventions need to incorporate acknowledgements of potential volunteers as human beings, whose concern for their own and others' welfare makes them an important part of medical research. Research site staff should emphasize the nonmaterial benefits of volunteering and give clear, consistent explanations of the key elements of participation—not only the research procedures, but the volunteer's vital role.

Communicating During the Trial for Improved Retention

At a time when recruitment and retention strategies and tactics tend to marginalize the role of the study staff, the results of CISCRP's focus groups² strongly suggest the need to more effectively engage these professionals as real assets in the clinical trial process. Warm and caring interactions make it easier for patients to feel comfortable enough to ask questions without the fear of being bothersome. These interactions also provide the opportunity for clinicians to give more information about the clinical trial process and the importance of participation.

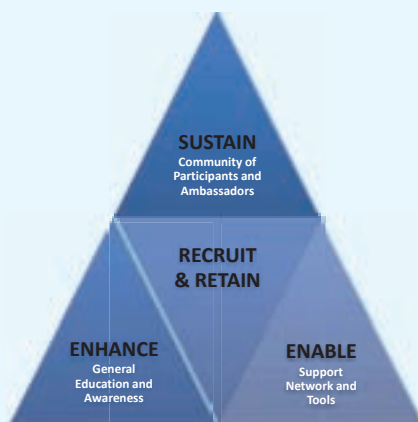


Figure 1. CISCRP's model for providing participants the education, enthusiasm and support they need to become ambassadors of the clinical research process

Education extends initial connections between volunteers and the center to ensure their overall satisfaction and to encourage their sustained involvement as trial participants. Labels like “research subject” turn participants into passive recipients of investigational drugs and procedures. As “volunteers,” they become active participants, aware of the risks and benefits involved in their decision to remain in a trial. In the CISCRP focus group, one person reported that she “didn’t want to be...my own guinea pig...in terms of not being aware of what was going [on] every day.” As a self-aware research volunteer, the participant can claim an active role in his or her wellness, and find a level of control that might otherwise be out of reach.

Even when a face-to-face informed consent process is established, participants can still lack basic comprehension of the concepts that define many trial protocols. In the same CISCRP focus groups, for example, some volunteers did not have a good grasp of study-defining words like “placebo-controlled,” and could offer only hazy speculations on the scientific purpose driving their particular study. Many admitted to skimming over the “legalese” in informed consent documents, but still wanted to know the information the pages contained. While it is not necessary to explain every technicality of a research proposal to study volunteers, it is essential to make sure they understand what to expect during their trial, the basic principles guiding the study, and why their participation is essential to reaching an identifiable research goal.

The Necessity of Post-trial Communication

The post-trial follow-up period is a pivotal time when research centers

can reinforce the relationships built before and during the study volunteer's enrollment period. Education provided after a trial's conclusion will benefit the growing population of volunteers clamoring for information, while strengthening the research center's backbone of satisfied, active participants.

Following their participation, the majority of volunteers want to receive the results of their clinical trial when they are available.³ Medical research reports often involve as many technical terms, abbreviations and symbols as the detailed protocols outlined in informed consent documents. On the tail end of a trial, however, participants typically no longer have the benefit of an attentive study staff to guide them through unfamiliar jargon. Therefore, post-trial education needs to include relevant study results and consistent interactions to ensure volunteers continue to feel valued even after their last site visit.

CISCRP and Pfizer collaborated to test a new process for routinely communicating clinical trial results to study volunteers after their participation has ended. Between June and December 2009, trial results for Celebrex/Celecoxib and Sutent/Sunitinib malate were translated into lay language by a team of consumer, science, and medical writers and published in print, web, and audio formats. The pilot test results demonstrate that a process for preparing and disseminating trial results summaries to patients following their participation in clinical trials is feasible. Moreover, patients reacted very positively to the variety of formats and showed marked improvement in their comprehension of their clinical trial

findings. The next step, initiated by CISC RP and Pfizer in first quarter 2010, is a larger-scale expansion as a beta test.

In summary, as shown in Figure 1, if general education and awareness of the clinical research process are enhanced, and if patients are enabled to participate because of the support network and educational tools provided to them, then issues with recruitment and retention in trials will improve. A sustained commitment to education will result in an ever-growing community of volunteers who will ultimately become the ambassadors of the clinical research process. ■

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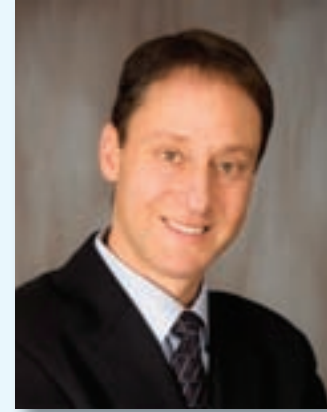
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