

# A Look at Clinical Trials From the Participant's Perspective.

*By Deborah Collyar*

Clinical trials are totally foreign to most people who get a life-threatening disease, no matter what socioeconomic group or culture they come from. Current enrollment rates for cancer clinical trials remain historically low—around 3-5% of all cancer patients.<sup>1</sup> Many in the healthcare community bemoan this situation and focus efforts on increasing awareness and accrual. Unfortunately, the clinical trial path is fraught with many conflicting interests, systematic problems and policies that make it difficult for patients to consider or to participate in clinical trials. Thus, it is critical that we develop policy-based approaches to address myriad issues, such as limited access to information and a system unable to handle an influx of patients, if we truly expect to conquer the diseases of our modern age.

Clinical trials exist because people get diseases and we have vested interest in improving available treatments. Clinical trials can help identify new advances in treatment, care, and prevention that are desperately needed by thousands of people. Simplistic approaches to increasing accrual rarely address the real needs of most patients. It is time we look at how patients view the medical system and the clinical trial process.

## Getting back to patient-focused medicine

Prior to a diagnosis, most people know very little about a given illness and rarely understand the latest cures touted in the media. Interpreting articles on risk factors, research abuses, or problems with newly approved drugs can be overwhelming. They may enter an illness assuming that the medical system will provide good care with what is an established 'best treatment.'

This attitude may not be shared, however, when health disparities are present. Ethnic, rural and other underserved communities often feel disenfranchised by medical systems that do not consider cultural differences, geography, and traditional beliefs.<sup>2</sup> Their trust is further challenged when they realize that they are not referred to specialists or hospitals as much, and do not receive the same level of health screening as white patients.<sup>3</sup> Cultural competence education for healthcare workers is part of the answer, but must be addressed in more systematic ways to ensure that all people receive comparable health care.

## Clinical trial issues

The majority of patients may never learn about clinical trials because (a) they go to doctors who do not support or are unfamiliar with them, (b) they are not offered the option due to assumptions regarding higher treatment costs by health providers,<sup>4</sup> (c) they have comorbidities<sup>5</sup>, or (d) the referring doctor is afraid of "losing" the patient to the physician leading the study.<sup>6</sup> As a result, many patients, especially from underserved groups such as African Americans, Hispanics/Latinos, older

patients, or those with low income, do not know about promising advances that could be important for them to consider as they decide what to do.

While all cancer patients face the issues mentioned above, additional problems exist for people from communities that have dealt with health disparities historically. However, it is important to emphasize that patients from underserved communities have less access to health care in general, may be predisposed to certain comorbidities, and may have significant distrust due to a history of abuse in their communities by researchers. We must also be mindful of special issues, such as the coercive effect of compensation for participation in a clinical trial, that are particularly salient in underserved communities that are poor.<sup>7</sup>

Despite these challenges, some people look favorably toward research, either after learning of past improvements that were developed or to get new agents that are not yet available commercially. Rather than deterring patients, trials may also attract them because they have a better chance of receiving innovative treatment.

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## Helping patients make an informed, personal choice

Fortunately, there are many ethical rules that must be followed that make sure that patients are informed before entering a clinical trial. Participants must sign a written informed consent form to confirm that the study and any associated risks have been explained and to ensure that they know they are taking part in the study.

Regulations that govern informed consent forms exist to ensure that clinical trials are conducted in an ethical manner and that patients receive required information. Since ethics covers many gray areas, however, the ethics community, researchers, and patients can differ in their opinions on how to describe clinical trials. HIPAA has also added challenging dimensions to this already complex process, with overly-cautious interpretation by some institutions and inconsistent application across the U.S. remaining troublesome for both researchers and patients.<sup>8</sup>

For a patient, the informed consent forms can be confusing or unavailable in his/her native language. These issues complicate a situation that is already quite stressful for the patient. Thus, a discussion about a clinical trial may be blurred by the patient's emotional duress after receiving a serious diagnosis. Upon receiving such news, a person may go into shock, making it difficult to hear or comprehend what is being said. Something called a clinical trial may come up in a discussion about treatment options. However the term may be scary or alienating, as

‘clinical’ can sound sterile and a ‘trial’ is a synonym for ‘problem’ or ‘struggle.’

If a patient agrees to participate, the informed consent process, which involves several steps, can help a potential participant and her/his family understand what risks and benefits may apply. Giving appropriate information in a context that each person can understand is critical, especially when working with people from different cultures and backgrounds. Clinicians and staff who learn to deal with the emotional aspects of decision-making can help their patients weigh key factors much more effectively.

Once in a trial, most participants remain committed to the project and like the planned care they receive. They also feel that they receive more information, since there is little assurance that they will be told of side effects and other ramifications that exist with standard treatments. They may also feel fortunate to be involved in a clinical trial if they perceive they derive personal benefit from doing so.

### **Some steps toward solutions**

Healthcare providers who learn the stages of how people cope with a diagnosis can help their patients through this traumatic time and can better explain options like clinical trials. This is why some patient advocates create materials or presentations that explain how family, job, insurance, and other issues can influence a person’s decisions. The more competent providers become at explaining these concerns and the more seamless the process becomes, the easier it is for each patient to make a decision and to consider a clinical trial as a viable alternative.

To ensure that each clinical trial has a chance to succeed, accrual plans should be designed to address needs and issues faced by each patient population and to build appropriate collaborations with referral sites. They must also include culturally appropriate strategies to describe the clinical trial and to the patient has.

Hundreds of cancer patient advocates currently collaborate with scientists. However, more will be needed to ensure that barriers are not built into clinical trials from the outset. Patient advocates will continue to help during protocol development, approval, accrual, adherence, and review to ensure that successful results translate quickly into better answers for people. Sharing clinical trial results will also become imperative, as more community support and word of mouth will be incorporated into enrollment efforts.

### **Key discussion points to consider for health disparities**

Although many health disparities have been caused by past discrimination and prejudice, there are some important questions for each community to consider when the subject of research or a clinical trial comes up.

### *Pharmacogenetics and pharmacogenomics*

The possibility of customized treatment for each patient is quickly evolving with the advent of the new sciences of pharmacogenetics and pharmacogenomics. Patients who understand the purpose of these fields of research seem willing to participate at the same levels of enrollment as other kinds of clinical trials.<sup>9</sup> Thus, to have more informed patients, it is critical that the medical and research communities include community representatives in the research process. All subsets of the population must participate in these clinical trials or else risk their communities being left out on important advances. Active engagement of community members in all phases of the research process – including design – may also help alleviate fears about privacy and of discrimination.

### *An era of chronic disease*

Another area that draws controversy is the new era of chronic illness. Modern biomedicine, with its technological breakthroughs, has eradicated many of the acute diseases and left us with long-term, debilitating and demoralizing illnesses. This often exacerbates health disparities as some drugs that are used long-term (i.e. Avastin)<sup>10</sup> offer modest benefits for a premium price, often adding ~\$50,000 to the cost of treatment. Efforts by insurers, hospitals, clinics, and patients to control costs will have a disproportionate effect on groups that already deal with health disparities, and cause further imbalance.

### *Finding solutions*

There are no easy answers, for every policy solution has a cost associated with it. The real solution is balancing the pros and cons of medical research, while taking each person’s situation into account. More patient advocates who represent communities of color and those with health disparities are needed to ensure that clinical trial policies are appropriate to disparate communities and to help alleviate health disparities. As with others who work in the healthcare community, patient advocates should also be guided by policies and ethical standards that protect the patients they serve. This will help ensure that they focus on the needs of the group over the individual, stay current by continually talking with newly diagnosed patients; and disclose associations they have with various organizations, companies, and institutions that may present a conflict of interest.

Over the past fifteen years patient advocates have helped the research system fix problems before they impact patients, helped patients learn about and consider clinical trials, and educated the scientific community, patients, and their families. If we don’t continue to challenge and improve the system, we will continue to face the same problems. Now is the time to work together for a better future. ●

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