

Editorial

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Research Volunteers are Heroes!

In this month's editorial, I want to talk a little about clinical research and how it fits into the larger picture of modern medical practice. My thoughts on this topic were stimulated when I was asked recently to give a brief pep talk to a group of prospective volunteers for clinical research trials.

I accepted the assignment rather casually, as I believed it would be fairly straightforward to summarize the many positive experiences that research volunteers have while participating in clinical trials. Typically, volunteers receive considerably more clinical attention than patients who don't volunteer because the research staff serves as clinical advocates to help volunteers navigate the complicated health care system. Volunteers also receive additional laboratory and radiologic studies, which occasionally reveal findings of true clinical importance. Sometimes they really hit the jackpot and receive therapies currently unavailable to the general public that could significantly improve their underlying medical condition.

As I continued thinking about my upcoming talk, it began to dawn on me just how critical these brave souls are to medical progress. Without such gallant individuals, willing to take a chance on a brand new therapy, we would never find out which therapies work and which don't. Oh, I know that we learn a fair amount about how certain treatments work by studying them in animal models. Some would say that animal trials are more than enough, but deep down I think we all recognize that there are significant limitations to the information we can extrapolate from studies in mice or rabbits, no matter how

encouraging the results may be. It is necessary to try these new therapies out with human volunteers, who are truly noble in what they do to advance the scientific enterprise.

We certainly have rigorous protections in place through institutional review boards and other organizations, but the reality is that unexpected negative consequences of new therapies sometimes are revealed in clinical trials. That's why we're doing the trials in the first place: to define more precisely the risks, as well as the benefits, of proposed new therapies.

When I finally went to make my presentation, it fortuitously turned out that there was one gentleman who had come with his own agenda. He was unfailingly polite, but nonetheless very persistent in his pointed

hat and dismiss his herbal therapies out of hand. But then a light bulb went on in my head, and I realized that he had inadvertently handed me a golden opportunity to clarify the true importance of clinical research.

I pointed out to the crowd that there was clearly a major disconnect between what this gentleman believed about the herbal remedies he had taken and the skepticism of his physicians. How could such conflicting views be reconciled? The obvious answer is that clinical trials need to be conducted to test the herbal therapies that our gentleman was advocating. He's not necessarily wrong to believe in them, since they may well have healing powers that have not yet been demonstrated formally. But that's the key here: Rigorous clinical trials are

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questions about herbal therapies. He asked repeatedly why the medical community was so resistant to acknowledge the wonderful benefits of herbal remedies and insisted upon describing how his own chronic liver disease had responded extremely well to these over-the-counter therapies. But his physicians had been skeptical and sometimes downright hostile about the treatments that had helped him so much. Initially, I was sorely tempted to put on my academic high

absolutely necessary to determine whether his enthusiasm is justified. Our gentleman has jumped the gun in declaring these therapies to be very useful. But his physicians also have jumped the gun in rejecting them, although their skepticism is more consistent with the scientific principle of insisting upon proof before widely applying new treatments.

Fortunately the crowd, which had been getting a bit annoyed with the man's efforts to monopolize the

discussion, was very receptive to this teachable moment. They accepted my point that this fellow was not necessarily wrong in his herbal enthusiasm but that he was definitely premature in advocating their widespread use. I think I left with a greater understanding of how essential and how laudable the role of the research volunteer really is. The volunteer offers himself or herself as a true pioneer willing to test the unknown, in order to allow medicine to separate the wheat from the chaff.

I was reminded, too, of how dependent we all are upon the goodwill and bravery of our clinical research

volunteers who help us on our journey to greater scientific certainty. So if you encounter a research volunteer in the course of your clinical activities, be sure to give him or her a very hearty thanks for all they are doing to advance medical science. ●

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