



GUESTWORDS: Rethinking Clinical Trials

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April 3, 2013

A diagnosis of cancer leads to many complex and life-altering decisions for the patient and family. Treatment choices, family role disruption, and quality-of-life issues are among the challenges faced by the patient almost immediately. They come at a time when the psychological trauma of accepting the knowledge of a chronic, life-threatening disease is faced — usually unexpectedly and in addition to the challenges of maintaining a healthy lifestyle and coping with growing old.

The current status of the modern, scientifically based medical specialty of oncology affords the patient a wide variety of treatment methods, including active surveillance, suppression or control of the disease, palliative care, and end-of-life (hospice) care. The problem for the patient may lay more in the choice of treatment (or forgoing treatment), as well as the prominent issues of the side effects of aggressive treatment interfering with the quality of life in a dramatic and sometimes irreversible manner.

Among the difficult decisions the patient must make is the possibility of volunteering for a clinical research trial. A clinical trial is by definition the testing of a new, unproven, possibly risky, but hopefully effective treatment. The decision must therefore be carefully considered, with help from professional medical and mental health resources as well as family members.

One prevailing negative myth about clinical trials is that the person must enter some sort of experiment and play the role of a guinea pig. While there is truth to the notion that the trial is experimental, the negative connotations of being used as a test subject with no benefit to the individual is a fear-driven and gross distortion of the reality of the benefits and safeguards of clinical trials. In contrast to alternative methods of treatment that may have long histories of use in certain cultures, the clinical trial is performed under close scrutiny in the scientific community.

A clinical trial is a treatment option in which some new approach to prevention, screening, or treatment of cancer is being tested in a carefully controlled and monitored scientific setting. It is a form of medical research that is usually proposed to test a new drug, but other means of intervention are also included, with the goal of destroying, slowing, or preventing the growth of human cancer cells. Some form of either laboratory or animal testing usually precedes a trial with people. Trial scientists base their research on an established theory or evidence that the method will work and will consequently stand up to the high standards of scientific scrutiny that test for safety, efficacy, and tolerance.

Before enrolling in a trial, all patients are provided with informed-consent information and documents about the intent, possible side effects, costs, and length of time. While undergoing a trial, the patient may remain in treatment or in consultation with his or her regular doctors, who should also be informed about the trial. Some of the built-in safeguards of a trial are guidelines that it will be terminated if serious side effects occur at any time, or if treatment gains are judged to be negligible or less than those that standard treatment can provide.

The general public usually expresses some concern over being assigned to the control or placebo group, which does not receive the new and more promising drug. Scientifically controlled studies in which all forms of bias are minimized or eliminated and an objective measure of outcome is provided require random assignment to comparative groups of patients. Placebos, or fake

pills, are rarely used alone these days. Cutting-edge study designs will compare treatment effects among patients receiving an alternate form of preapproved, standard drug, which is compared to the test drug. In some cases of slow-growing cancer, no ordinary medical treatment is available and active surveillance is considered an acceptable option to use as a comparable group. In addition, if a new drug is found to be highly effective, the trial may be terminated and all patients will be afforded treatment with the new drug.

Clinical trials are by no means the treatment of last resort. Trials fitting the categories of screening, preventive interventions, establishing diagnostic clarity, as well as preventing reoccurrence are certainly not designed to assist a dying patient. In this regard, a clinical trial may be considered an ancillary or additional treatment. Some trials are meant to explore enhancing or strengthening the effects of standard treatment. The trial might also provide follow-up or extra services in dealing with side effects of concurrent treatment. There may also be cases of high risk for cancer as predicted by family history or genetics. In these cases, a trial may provide knowledge of lifestyle interventions or medication to avoid or suppress pathological genetic trajectory.

Having multiple options to treat a very serious, life-threatening disease may contribute to sustaining a healthy coping or a mentally stable attitude. The most frequent psychological reactions to cancer are described as “stressor or distress conditions.” Clinically, the reactions are labeled diagnostically and related to acute or chronic anxiety or depressive states. Because of the life-threatening and existential crises raised by cancer, the condition known today as post-traumatic stress disorder may readily apply to any cancer patient.

Cancer counselors are well aware of these mental barriers to living with or coping with cancer and facing the loss of a previously healthy body and mind. Empirically based mental health interventions draw upon decades of methods for treating these conditions, which universally include elements of instillation

of hope, taking control, and actively participating in one's treatment plan. Clinical trials are one possible means to enhancing corrective emotional experiences to better cope with the physical disease.

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