Dying for Access

Ideally, all patients with advanced cancers would be in clinical trials. Until then, the right to try is an option we all should have.

March 12, 2018 By Kelly Shanahan (METUP)

We're dying to participate in clinical trials.

This was the message METUP delivered at the 2017 San Antonio Breast Cancer Symposium. Access to clinical trials must be an option for all people with advanced and metastatic cancers. Until then, Right to Try (RTT) legislation gives us another option.

At a time when only 3 to 5 percent of eligible cancer patients enroll in clinical trials—and some trials are unable to get off the ground because of low accrual—reform of the clinical trial process is imperative.

For far too long, oncology trials have sought what we like to call "Olympians": the healthiest of the dying. These include patients who haven't undergone multiple prior lines of therapy, those who don't have brain metastases and those who don't have comorbidities, like diabetes, high blood pressure or HIV.

Major players in the cancer research game are beginning to recognize that change is necessary. The American Society of Clinical Oncology (ASCO), Friends of Cancer Research and the Food and Drug Administration (FDA) recently examined eligibility requirements for clinical trials and made recommendations to facilitate enrollment of people who are more representative of the population that needs a new drug.

These recommendations include allowing patients with stable treated brain metastases—and even patients with active brain mets—if there is either rationale for benefit or if brain metastases are common in the intended population. They also allow inclusion of people with kidney or liver disease if the drug is not toxic to those organs, as well as patients with prior or concurrent cancers if this is unlikely to compromise the safety or efficacy of the study drug.

In addition, trials should include patients in the age groups most affected by the cancer and work harder to enroll people of all races, ethnicities and socioeconomic statuses. And breast cancer trials should include men as well as women.

In addition to restrictive eligibility requirements, there are logistical and financial barriers to

participation in clinical trials. Although the majority of cancer patients in the United States are treated in community hospitals, the majority of trials are conducted at big city academic centers. I recently talked to a woman in a trial who drove six hours round-trip for a five-minute blood draw at a major center!

Trials should begin to move away from the brick-and-mortar mother-institution model and accept outside imaging and lab tests. When specialty labs are required, samples can be drawn locally and shipped to the research center. If FedEx can get the best seller I ordered from Amazon.com to me in a day, then certainly a local lab can get blood to a research center in a timely manner.

While working to expand clinical trial eligibility, passing federal RTT legislation is another way to expand access to experimental therapies. Currently, 38 states have RTT laws on their books, which allow patients to access promising treatments before they are FDA approved.

Opponents of pending RTT legislation claim that the FDA's compassionate use program is adequate and that RTT weakens safety standards. However, any medication considered for RTT must have already been proved safe in Phase I clinical trials. Unlike compassionate use—which requires a patient to have exhausted all other options and be unable to enroll in a clinical trial—RTT requires only that an individual has considered all currently available options. This may allow patients to try a promising new drug when they are experiencing rapid disease progression but are not yet on death's doorstep.

Another distinction between RTT and compassionate use is that RTT does not require Institutional Review Board (IRB) approval, allowing patients who are treated in small oncology practices not affiliated with a hospital—and therefore without an IRB—the opportunity to access potentially life-extending medications.

Neither right to try nor compassionate use is perfect. Neither of them requires drug companies to supply the medication or insurance companies to pay for it. Ideally, all patients with advanced and metastatic cancers would be enrolled in clinical trials. But until then, the right to try is an option we all should have.

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