Boosting Trial Entry

Cancer organizations and the Food and Drug Administration want to broaden eligibility criteria for cancer clinical trials.

March 18, 2019 By Liz Highleyman

Overly restrictive entry criteria may be keeping out many people with cancer who could benefit from clinical trials—but researchers and patient advocates are working to change that.

Clinical trials can be a good way to gain access to promising new treatments, but entry restrictions often exclude older people, patients with more advanced disease and those with other illnesses or conditions.

People with coexisting conditions, such as hypertension, asthma or a prior cancer, are less likely to talk to their doctor about trials, less likely to be offered a chance to participate and, ultimately, less likely to enroll, according to a study from SWOG, an international cancer clinical trials network.

The American Society of Clinical Oncology, Friends of Cancer Research and the Food and Drug Administration recently recommended that trial eligibility be expanded to include people with certain coexisting conditions, including HIV, kidney or liver impairment, and brain metastasis (cancer that has spread to the brain).

The SWOG study, published in JAMA Oncology, found that implementing these changes would enable 6,317 more people to join trials and receive experimental treatments that could potentially extend or improve their lives. Removing all comorbidity restrictions could allow nearly 12,000 more people to join.

“Cancer clinical trials provide high-quality, guideline-based care for cancer patients,” says Joseph Unger, PhD, a health services researcher for SWOG at the Fred Hutchinson Cancer Research Center in Seattle. “Allowing people with manageable comorbidities to join trials would increase treatment opportunities for several thousand patients.”

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