

Select few cancer patients enroll in potentially life-extending clinical trials

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Patient enrollment in clinical trials as the first course of treatment after cancer diagnosis is low, despite the fact that enrollment may increase life expectancy, according to researchers at Penn State. They also found that white males with private health insurance and metastatic cancers treated at academic medical centers are more likely than other groups to enroll

in clinical trials.

Dr. Nicholas G. Zaorsky, an assistant professor of radiation oncology at Penn State College of Medicine, led a team of Penn State Cancer Institute researchers who analyzed data from more than 12 million patients with 46 different types of [cancer](#) between 2004 and 2015 in the National Cancer Database. They found that only 11,576 (0.1 percent) of those patients were enrolled in [clinical trials](#) as their first course of therapy following diagnosis.

According to Dr. Niraj J. Gusani, professor of surgery at the College of Medicine and senior author of the study published in the Journal of the National Comprehensive Cancer Network, the low enrollment is troubling because clinical trials may be beneficial for patients.

"Major advances in cancer treatment have been supported by clinical trials," Gusani said. "By volunteering to participate in a trial, patients may help further the field of research and gain access to new treatments."

Zaorsky, Gusani and their team found that patients with cancer treated in clinical trials, when matched and compared to similar patients not treated on trials, lived longer. They report that patients with cancer in clinical trials at the first course of therapy had a median survival of seven and half months more than those not enrolled in a trial.

According to Zaorsky, previous evaluations of whether clinical trials improved survival compared patients who were enrolled in trials against those not enrolled in trials— but didn't account for factors like age, race, gender and cancer type.

The researchers performed a stratified analysis in which they matched each patient who participated in a clinical trial with another patient who

was not enrolled in a trial that had ten similar characteristics—including cancer type, age, race, insurance type, disease stage, and whether or not surgery or chemotherapy were part of the treatment plan.

"If you're going to evaluate whether clinical trial enrollment is beneficial for patients, you have to try and match each patient to someone who has a similar cancer and sociodemographic profile," Zaorsky said.

"Otherwise, it is like comparing apples to oranges."

While the survival trend was evident across cancer types, the researchers said that this may not necessarily be true for the general population. In their analysis, they determined that the patients who enrolled in clinical trials at first course of therapy tended to be white males with private insurance, metastatic disease, who had no other chronic medical conditions and were treated at [academic medical centers](#).

"If clinical trials are going to be used to determine standards of care for the general population, then the study participants need to be representative of the [general population](#)—and this study shows that often this isn't the case," Gusani said.

According to Zaorsky, increasing patient enrollment in clinical trials cannot happen without first improving the infrastructure of clinical trial design and management. Patients may not live close to locations where clinical trials are offered. Even if they are in [close proximity](#) to a center offering clinical trials, the trials may not be for their type or stage of cancer.

Gusani suggests that the biggest barrier to clinical trial enrollment is the stigma around them. Patients may feel they are "guinea pigs" in experiments and that they are receiving substandard care. In reality, trials emphasize patient safety at every stage and are carefully regulated and monitored by institutional review boards.

"The increased level of quality control in clinical [trials](#) may be beneficial for patients," Zaorsky said. "Patients who go onto a clinical trial must be treated per protocol, meaning that there are many quality measures that must be met, and that there are many other health care providers looking over the patient's care."

Provided by Pennsylvania State University

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