

Insurance approval rates for clinical trial participation rose under Affordable Care Act

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Approval rates for privately insured patients seeking to enroll in oncology clinical trials increased after the passage of the Affordable Care Act.

The study is published by *Clinical Cancer Research*, a journal of the American Association for Cancer Research, by David S. Hong, MD, deputy chair and associate professor in the Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, at The University of Texas MD Anderson Cancer Center in Houston; and Kenneth L. Kehl, MD, a member of MD Anderson's Division of Cancer Medicine.

Previous studies explained that since 2000, publicly funded Medicare has covered the routine costs of clinical trial participation. Patients who were covered by private insurance often faced a patchwork of coverage options, with different insurers and different states determining whether participation in a clinical trial would be covered.

In 2010, the passage of the Patient Protection and Affordable Care Act (ACA) mandated that [private insurers](#) cover "standard of care" costs of clinical trial participation, effective Jan. 1, 2014. Hong, who oversees phase I clinical [trials](#) at MD Anderson, said that after the ACA mandate took effect, he perceived that patients in his practice were experiencing fewer delays in being approved for clinical trials, and undertook the study to see whether his observation was true on a larger scale.

Hong and colleagues analyzed 2,404 referrals from the departmental

database of the Clinical Center for Targeted Therapy at MD Anderson, comparing rates of insurance clearance and the time to clearance in three separate time periods: July 2012-June 2013; July 2013-December 2013; and January 2014-June 2015.

The study showed that approval rates climbed steadily for privately insured patients, from about 85 percent prior to the ACA mandate to approximately 95 percent after the mandate. Also, the privately insured patients experienced fewer delays in being cleared for participation.

Among patients with Medicare or Medicaid coverage, there was no significant association between the referral time period or insurance clearance rate.

Hong explained that timely approvals are crucial for patients who want to participate in clinical trials. He said the fact that the privately insured patients experienced fewer delays indicates that the ACA provision that requires private insurers to cover clinical trial participation had a direct benefit for those patients.

"In a phase I trial, many patients are in a state of advanced disease, so a single day can matter a great deal to them," he said. "We are in a golden era of new drugs, but the only way to get them approved and available to patients is to get more people into clinical trials," Hong said.

The ACA is in a state of flux, as President Donald Trump has vowed to repeal it and a replacement bill crafted by the U.S. Senate has stalled. Hong said that his study's findings indicate that any replacement for the ACA should include provisions to ensure patient access to [clinical trials](#).

"Clinical trials are crucially important in helping get drugs to the patients that need them," Hong said. "This study is one piece of evidence that the ACA is helping more [patients](#) get access to these trials."

Provided by American Association for Cancer Research

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