

Medicaid policies can increase diverse participation in cancer clinical trials

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Two Medicaid policies can interact to increase oncology clinical trial enrollment among Black and Hispanic patients, according to a new study by investigators at Weill Cornell Medicine, the University of



Pennsylvania, and Medidata AI. Black and Hispanic patients are historically underrepresented in cancer clinical trials; equitable enrollment helps ensure the knowledge gained from trials generalizes to the entire population and promotes equitable patient access to the latest treatment options.

The study, <u>published</u> July 25 in the *Journal of Clinical Oncology*, examined the effect of the interaction between two Medicaid policies on the rates of enrollment for Black or Hispanic adults in cancer clinical trials in the United States: Medicaid expansion under the Affordable Care Act (ACA), which extended Medicaid eligibility to more than 20 million residents, leading to greatly improved coverage for people with low income; and pre-existing state-level mandates requiring Medicaid coverage of the routine costs of clinical trial participation.

The study team analyzed deidentified national enrollment data for nearly 50,000 participants in cancer clinical trials from 2012 to 2019 from Medidata's Rave electronic data capture archives. During the study period, only 12 states and the District of Columbia mandated Medicaid coverage of clinical trial costs.

"We found that Medicaid expansion under the ACA was associated with about a 5-percentage-point increase in Black or Hispanic patient enrollment in <u>oncology</u> clinical trials in states that had these coverage mandates," said co-lead author Dr. William L. Schpero, assistant professor of population health sciences at Weill Cornell Medicine. "We consider this strong evidence that Medicaid is an important policy lever for improving equity in clinical trials in the United States."

The study revealed that Medicaid expansion under the ACA alone was not associated with a statistically significant increase in oncology clinical trial enrollment among Black or Hispanic patients.



"The headline here is that Medicaid expansion by itself did not improve cancer clinical trial diversity; we only saw improvement in those states that already mandated coverage of the routine costs of clinical trial participation," said co-lead author Dr. Samuel U. Takvorian, an assistant professor of hematology-oncology in the Perelman School of Medicine at the University of Pennsylvania. "What we learned, in essence, is that both access and coverage are important for improving accruals of historically underrepresented groups to cancer clinical trials."

In oncology clinical trials, the cost of the study drug is generally covered by <u>pharmaceutical companies</u>, but the "routine costs of care"—for example, the cost of administering a new chemotherapeutic agent—are generally not. Federal law has required coverage of these costs in Medicare since 2000 and in most commercial markets since 2014. It was not until 2022 that all state Medicaid programs were federally mandated to cover the costs as part of the Clinical Treatment Act of 2020.

"One of the biggest factors that determines whether a patient enrolls in a cancer clinical trial is whether their physician recommends it," said Dr. Schpero, who is also co-associate director of the Cornell Center for Health Equity. "Increasing physician awareness of the 2022 federal coverage mandate could help boost enrollment of underrepresented populations in clinical trials."

More information: William L. Schpero et al, Association Between State Medicaid Policies and Accrual of Black or Hispanic Patients to Cancer Clinical Trials, *Journal of Clinical Oncology* (2024). DOI: 10.1200/JCO.23.01149

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