Policy Change Alone Won't Achieve Equity in Clinical Trial Participation

By Deborah Borfitz

August 8, 2024 | A federal mandate that all state Medicaid programs cover the routine costs of participation in clinical trials could have a "meaningful impact" on equity in study participation, according to William L. Schpero, Ph.D., assistant professor of population health sciences at Weill Cornell Medicine. Up until 2022, Medicaid was the only healthcare payer not already doing so nationwide.

The focus should now be on ensuring states collaborate with frontline clinicians to ensure they are aware of the latest Medicaid policy change, and that those who "disproportionately treat patients from minoritized communities are plugged into relevant trial networks and able to refer patients to [applicable] trials," he says. Provided those conditions are met, Schpero is optimistic that cancer clinical trial diversity will improve.

Hope stems from findings of a recent study, published in the *Journal of Clinical Oncology* (DOI: 10.1200/JCO.2023.41.16_suppl.1510), where progress was seen in states mandating coverage of the routine costs of clinical trial participation in Medicaid on their own prior to 2022, when the federal mandate from the Clinical Treatment Act of 2020 went into effect. In those states only, Medicaid expansion under the Affordable Care Act (ACA) was associated with about a 5-percentage-point increase in Black or Hispanic patient enrollment in oncology clinical trials.

The study was co-led by Schpero and Samuel Takvorian, M.D., an assistant professor of hematology-oncology in the Perelman School of Medicine at the University of Pennsylvania. It 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 and provides "strong evidence that Medicaid is an important policy lever for improving equity in clinical trials in the United States," Schpero says.

Minoritized groups are disproportionately enrolled in Medicaid, he notes. Among non-elderly adults, about 35% of Blacks are enrolled in the joint federal and state program, despite accounting for about 12% of the U.S. population per the 2020 census. About 31% of Hispanics are similarly enrolled although their proportion in the general population is just under 19%.

'Natural Experiment'

Variation in how Medicaid is structured from state to state enables innovation in how services or benefits are provided, but also creates inequalities based on where a beneficiary happens to live, Schpero says.

While Medicare has been covering the routine cost of clinical trial participation since 2000 and most commercial plans were required to do so after the ACA was signed into law in 2010, there was no federal mandate in Medicaid until the Clinical Treatment Act (part of the 2020 omnibus spending bill passed by Congress) went into effect in 2022. Since a subset of states had by then created their own mandates, "that created a natural experiment to look at whether [that]... might improve equity in trial participation," he says. At the time of the study, only 12 states and the District of Columbia mandated Medicaid coverage of clinical trial costs (by 2021, 16 states had explicit mandates).

Since good data didn't exist to study the introduction of those state mandates directly, investigators instead decided to do so indirectly in the context of the expansion of Medicaid eligibility under the ACA, explains Schpero. The first question was whether the ACA improved access to trials and

disparities in participation and the second if that differed based on whether states had coverage mandates.

“In some ways our hypothesis was born out and, in some ways, it was not,” Schpero says, referencing the key finding that the impact was seen only in states that had independently enacted the coverage mandates.

Wraparound Costs

In oncology clinical trials today, the cost of the study drug is generally covered by pharmaceutical companies, with public and private healthcare payers reimbursing clinicians for routine, trial-related costs (e.g., administering a new chemotherapeutic agent), Schpero says. Under Medicaid, physicians are not allowed to bill a patient for the difference between the amount charged and the amount approved for reimbursement.

But this does nothing to erase the substantial indirect costs incurred by participants in these studies. These might include travel, lodging, and time missed from work by participants or their caregivers and “manifest across all forms of insurance,” says Schpero. Numerous studies have cited financial barriers among the top factors limiting access to trial participation.

When the federal mandate first went into effect guaranteeing coverage of routine costs associated with study participation, Schpero and Takvorian penned a perspective piece on Medicaid’s role in supporting equitable access to clinical trials (*New England Journal of Medicine*, DOI: 10.1056/NEJMp2101627). The article highlighted that Medicaid is uniquely positioned to help mitigate some of the cost burden on participants, in part because it reimburses for non-emergency transportation.

Another step that states might take is to use Medicaid funding to set up patient navigation programs to help people negotiate the complex trial participation process, they suggest. Moreover, they write, stronger accountability measures are needed to ensure standardized reporting and enhanced transparency regarding participation of marginalized populations in clinical trials.

One cited study found that among trials leading to FDA approvals of oncology drugs, only 63% reported data on participants’ race and in that subset of trials Black and Hispanic patients were consistently underrepresented relative to distributions of people with cancer in the U.S.

There is certainly a role for state Medicaid agencies, as well as advocacy organizations such as the American Cancer Society (ACS), in ensuring that community oncologists are aware of the federal policy change, Schpero says. “The ACS historically was a major advocate for the federal mandate and... in a position help clinicians act on [the legislation] in how they refer patients to participate in trials.”

The latest study finding an association between state Medicaid policies and the accrual of Black and Hispanic patients to cancer clinical trials represents one of the first pieces of evidence pointing to the role of federal- and state-level interventions in improving access, Schpero notes. Up to now, efforts have primarily focused on what cancer centers and health systems can do in the way of outreach to minoritized communities and reducing barriers to trial access and participation.

Moving forward, state and federal policymakers might also want to start thinking of ways to use their regulatory authority to negate some of the ancillary costs currently being born by participants in oncology clinical trials, he adds. These indirect costs run an average of $600 per month, or $7,200 per year, based on a 2015 analysis (*Oncologist*, DOI: 10.1634/theoncologist.2015-0068). A more recent analysis specific to early-phase clinical trials finds that nearly half of all enrolled patients face monthly out-of-pocket costs of at least $1,000 (*Oncologist*, DOI: 10.1002/onco.13767).