Improving Representation in Clinical Trials and Research

Building Research Equity for Women and Underrepresented Groups

The National Academies of Sciences, Engineering, and Medicine (the National Academies) undertook the most comprehensive examination to date of the representation of women and underrepresented populations in clinical trials in research. This included a review of the health and economic impact this lack of inclusion has on the United States, a review of factors that prevent full inclusion, and facilitators to broaden representation in clinical trials and research in the United States.

The study committee found that while progress has been made with representation of white women in clinical trials and clinical research, there has been little progress in the last three decades to increase participation of racial and ethnic minority population groups. This underrepresentation is compounding health disparities, with serious consequences for underrepresented groups and for the nation.

The report emphasizes the urgency needed to address this issue, as failure to do so will only prove more costly over time and will prevent meaningful reductions in disparities in chronic conditions. However, improving representation in clinical trials and research requires an investment of time, money, and effort. Building trust with local communities requires a sustained commitment and presence and investing in systems and technologies to reduce barriers to participation takes resources. This investment is the responsibility of everyone involved in the clinical research landscape, which is complex and involves multiple stakeholders. However, we must *all* make this a priority to drive change on a systems level.

The role that the Centers for Medicare and Medicaid Services (CMS) plays in insuring that clinical trials are diverse is especially important. First, CMS is critical for reimbursing participants for the costs associated with participating in clinical trials. While costs of routine care to participants in trials are usually covered by Medicare and Medicaid, many costs, such as transportation, time away from work, and other ancillary costs are still borne by the participants, decreasing participation especially among financially disadvantaged patients. The committee was also not aware of any studies that examined the impact that Medicare and Medicaid reimbursement policies had on participant recruitment and retention and the barriers to accessing these coverage options.

CMS also plays a critical role in diversifying clinical trials as a provider of health insurance and prescription drug coverage. In 2014, CMS released an updated guidance that allows CMS to determine coverage of an item or service only in the context of a clinical study, called Coverage with Evidence Development (CED). For example, in its coverage with evidence development for transcatheter mitral valve repair, CMS explicitly noted, “study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial”. Such requirements by CMS have the potential to change the landscape of clinical trial representation because millions of Americans served by Medicare who have been traditionally underrepresented in clinical trials could now be recognized and actively recruited.

RECOMMENDATION 7

The CMS should amend its guidance for coverage with evidence development to require that study protocols include a plan for recruiting and retaining participants that are representative of the affected beneficiary population and a plan for monitoring achievement of representativeness, including a process for remediation if CED studies are not meeting these goals.

RECOMMENDATION 9

The CMS should expedite coverage decisions for drugs and devices that have been approved based on clinical development programs that are representative of the populations most affected by the treatable condition.

RECOMMENDATION 10

The CMS should incentivize community providers to enroll and retain participants in clinical trials by reimbursing for the time and infrastructure that is required. Through the creation of new payment codes, CMS should reimburse activities associated with clinical trial participation, including but not limited to data collection and personnel (e.g., community health workers, patient navigators) to support research education and recruitment.

RECOMMENDATION 11

The Government Accountability Office (GAO) should assess the impact of reimbursing routine care costs associated with clinical trial participation for both Medicare (enacted in 2000) and Medicaid (enacted in 2020). The assessment should include an analysis of whether there is timely and complete reimbursement, any implications for innovation and care delivery to underrepresented populations, and any challenges to implementation.

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For additional information regarding the consensus study, visit http://www.nationalacademies.org/cwsem.

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