Highlights of GAO-23-105245, a report to congressional committees

Why GAO Did This Study

Diverse representation in clinical trials is important to ensure the safety and efficacy of treatments for the patient population likely to use the treatment being studied. It is also important from an equity perspective as these trials often represent the best available health care. Despite more than 3 decades of government policies intended to improve clinical trial diversity, certain groups remain consistently underrepresented in cancer clinical trials. Those groups include certain racial and ethnic groups, adolescents and young adults, older adults, women, low-income individuals, and individuals from rural communities.

The Henrietta Lacks Enhancing
Cancer Research Act of 2019 and
House Appropriations Report 116-450
each included a provision that GAO
study diverse representation of
patients in cancer clinical trials. This
report describes (1) actions federal
agencies have taken to facilitate
enrollment of patients from diverse
backgrounds in cancer clinical trials
and (2) practices used by selected
non-federal cancer centers to facilitate
enrollment of patients from diverse
backgrounds in cancer clinical trials.

GAO interviewed officials and reviewed documents from federal agencies that fund or conduct cancer clinical trials. GAO also identified 17 cancer centers with a history of enrolling diverse populations in cancer clinical trials and asked them to describe relevant practices that facilitated such enrollment. GAO identified practices facilitating diverse enrollment that were described by or about these centers.

View GAO-23-105245. For more information, contact John E. Dicken 202-512-7114, dickenj@gao.gov

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CANCER CLINICAL TRIALS

Federal Actions and Selected Non-Federal Practices to Facilitate Diversity of Patients

What GAO Found

GAO found that both federal agencies and selected non-federal cancer centers took actions to facilitate participation of patients from diverse backgrounds in cancer clinical trials. Generally, these actions addressed a variety of barriers to participation that are often cited in the literature.

The Department of Health and Human Services, Department of Defense, and Department of Veterans Affairs took actions that have the goal of increasing the proportion of patients from diverse backgrounds enrolled in federally funded cancer clinical trials. These efforts are focused on developing research collaborations, modifying research practices, reducing barriers to patient participation, and collecting and sharing data.

Federal Actions to Facilitate Diversity in Cancer Clinical Trials

Research collaborations



Federal agencies have created networks of community-based research sites that bring cancer clinical trials to their own communities. Research practices

Federal agencies have included minimum enrollment requirements, broadened patient eligibility criteria, and promoted development of enrollment strategies.

Reducing barriers to patient participation



Federal agencies have implemented practices to reduce financial, logistical, and linguistic and cultural barriers to participation.

Data standardization



Federal agencies have implemented processes to standardize data collection for more effective analysis of subgroup data.

Source: GAO analysis of information from the Department of Defense, Department of Health and Human Services, and Department of Veterans Affairs. | GAO-23-105245

The 17 non-federal cancer centers in GAO's review implemented practices to facilitate the enrollment of patients from diverse backgrounds that were focused on four areas: organization, community, workforce, and patients. Fifteen of the centers implemented practices in at least three of these four areas.

Selected Cancer Center Practices to Facilitate Diversity in Cancer Clinical Trials

Organization-level practices



Cancer centers have adopted an institutional commitment to serving diverse populations or have partnerships with other organizations to help increase access for diverse populations.

Community-level practices

Cancer centers have used community ambassadors—lay representatives of the community—to increase awareness of clinical trials.

Workforce-level practices



Cancer centers have provided training to better communicate clinical trial opportunities to patients and have implemented efforts to increase the diversity of the workforce.

Patient-level practices

Cancer centers have used clinical trial education, used culturally and linguistically tailored information, used patient navigators, and provided financial and logistical support.

Source: GAO analysis of information about the 17 selected cancer centers. | GAO-23-105245