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New recommendations aim to eliminate racial bias in myeloma trials

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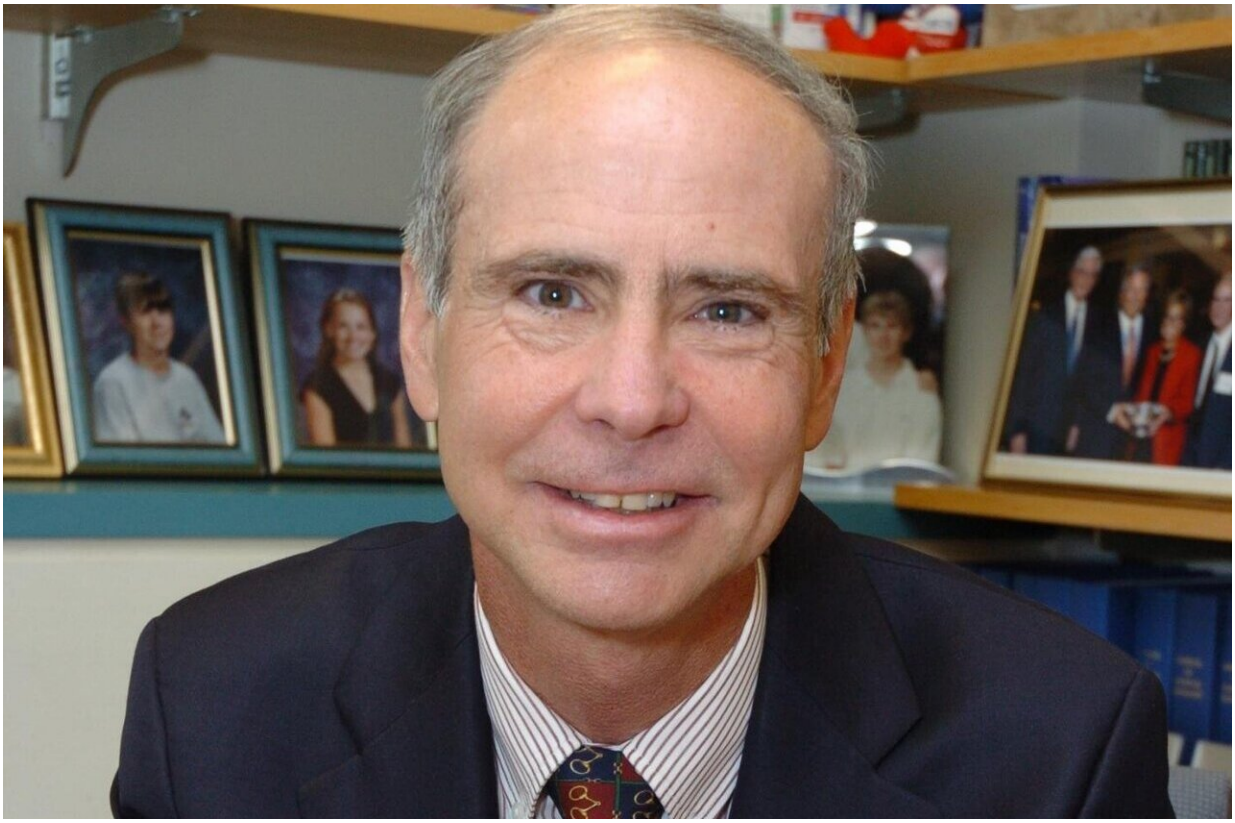

Ken Anderson, MD. Credit: Dana-Farber Cancer Institute

Researchers from Dana-Farber Cancer Institute, the U.S. Food and Drug Administration (FDA) and the American Association for Cancer Research (AACR) are releasing recommendations designed to address

the under-representation of African Americans in clinical trials for multiple myeloma (MM), a blood cancer that is twice as deadly in this demographic as in whites.

The initiative, publishing today in the AACR journal *Blood Cancer Discovery*, is a "road map" for designing myeloma clinical trials to eliminate racial bias by including more African American patients, as well as gathering "real-world" data from health records about the effects of drugs in African American patients. Through this joint workshop initiated by the FDA and AACR, a cohort of researchers, physicians, patients, statisticians, the pharmaceutical industry and regulators reviewed existing issues with the goal of improving effectiveness of MM therapies in African Americans.

Multiple myeloma is diagnosed in about 30,000 people in the United States annually, resulting in more than 12,500 deaths. African Americans are more than twice as likely as whites to be diagnosed with myeloma—15.9 vs 7.5 cases per 100,000 population—and to die from the disease—5.6 vs 2.4 myeloma deaths per 100,000 for African Americans compared with whites.

Although the disease is not presently curable, an array of new treatments in recent years has generally improved outcomes for myeloma patients. It is concerning, however, that data from large multiple myeloma clinical trials shows a decrease in enrollment of African Americans by 3.5% over a recent 10-year period, and even more critically, most racial and ethnic minority patients participated in trials that did not involve novel agents."There hasn't been as much progress in African Americans as there has been in other groups," says Dana-Farber Cancer Institute's Kenneth C. Anderson, MD, the corresponding author of the study and program director of the Lebow Institute for Myeloma Therapeutics and the Jerome Lipper Multiple Myeloma Center. "The number of African Americans enrolled in clinical trials of novel agents or treatments of

multiple myeloma has been tragically low. When they have enrolled, their outcome to treatment with novel therapies has been the same or even better than other patients," he said.

African Americans comprise 20% of people diagnosed with myeloma, but between 2003 and 2017 only 4.5% of patients in new drug and biological license applications for myeloma were African American. This disparity has raised concerns that the findings of therapeutic clinical trials may not be entirely valid for African Americans, due to underlying genetic and biological differences that have been discovered between African American and white myeloma patients.

The new recommendations emerged from a February 2020 workshop in Washington D.C. which was co-chaired by Nicole Gormley, MD and Lola Fashoyin-Aje MD, MPH from the FDA, as well as Anderson, who heads the Regulatory Science and Policy Subcommittee of the AACR. The group recommended a number of changes to the design of clinical trials of drugs for which manufacturers are seeking approval. They included:

- Broadening eligibility criteria whenever possible. For example, study criteria that reject patients with conditions like high blood pressure and kidney disease may disproportionately exclude African Americans. Including such patients may allow researchers to collect more data in racial and ethnic subpopulations.
- Requiring trial sponsors to complete a diversity study plan that sets targets for enrolling diverse participants.
- Appointing a diversity officer to assist with trial design and recruitment. Trial design should encompass disease subtypes and features most commonly seen in African Americans. Patients and patient advocates involved in the workshop strongly supported the recommendation of a diversity officer "to define strategies

> that support African American participation in clinical trials." The presence of a diversity officer "will hold researchers and industry accountable to conduct more inclusive and patient-centric trials," the recommendations stressed.

Other recommendations concerned gathering clinical trial data in the post-approval period. Studies conducted after the drug has entered clinical use could identify differences among racial and ethnic subpopulations with regard to safety and efficacy.

The recommendations also seek to increase diversity by directing stakeholders to devise strategies to overcome clinical, social, and socioeconomic impediments to trial access.

Anderson emphasized the importance of myeloma patients' participation in the workshop that formulated the recommendations.

"Our patients are truly the inspiration and heroes of this collaborative effort to eliminate the glaring issue of racial disparities in clinical trials," he said. "If we can make clinical trials more inclusive and representative of real-world patients, we may not only enhance participation of African American patients, but also provide a paradigm for new drug development more broadly."

More information: *Cancer Discovery* (2021). bloodcancerdiscov.aacrjournals … 643-3230.BCD-20-0123

Provided by Dana-Farber Cancer Institute