

News in Review

COMMENTARY AND PERSPECTIVE

DEIA

Staff Diversity Improves Study Participation

A LACK OF DIVERSITY AMONG PARTICIPANTS in clinical studies is a persistent problem in medicine. Researchers at Boston Medical Center (BMC) report that one way to address this deficit is to increase the diversity of the clinical research staff who directly work with patients enrolled in studies.¹

Study details. For their retrospective study, the BMC researchers examined screening log information collected on 1,380 eye clinic patients from an urban, academic hospital who were approached to participate in any of 10 prospective ophthalmic clinical studies between January 2015 and December 2021. The screening logs included information such as each patient's decision to participate or decline, basic demographic information, and the research staff member who approached the patient. The average patient age was 58 years old—43.5% were Black, 25.1% were Latino or Hispanic, 28.6% were White, and 2.8% identified as being part of another race or ethnicity. Another 5.8% declined to provide demographic information.

Results. The investigators discovered that if a research staff member was of the same race or ethnicity as the patient, 65.1% of patients consented to study participation compared to 39.9% who consented when approached by a staff person of a different race or ethnicity.



STUDY RECRUITMENT. *If a research staff member is of the same race or ethnicity as the patient, patient participation in the study is more likely, new research suggests.*

Black, Hispanic, and Latino patients were less likely to consent to participate in studies compared to White peers. Those who were of a lower socioeconomic status were also less likely to be part of clinical studies. When clinical staff were of an ethnic or racial identity similar to prospective participants, the odds of participant consent increased by a factor of nearly 3.

Unexpected finding. Lead author Manju L. Subramanian, MD, FACS, at BMC and Boston University Chobanian & Avedisian School of Medicine, said she was struck by the fact that communicating with patients in their primary language was not associated with higher odds of consent in a clinical study. But, she said, “It’s possible that our inability to detect this association was due to having a smaller sample size of languages other than English.”

Pursuing health equity. Previous research shows that there are racial and ethnic differences in the prevalence of some diseases and that specific patient groups respond differently to the same treatments, Dr. Subramanian said.

“Achieving health equity means that treatments need to work equally well for all patients, therefore clinical trials need to enroll patient cohorts that match the demographics of the disease burden,” Dr. Subramanian said, noting that racial and ethnic minorities participate in clinical studies at significantly lower rates across all medical specialties.

There is a need to develop novel strategies to increase enrollment of racial and ethnic minorities into clinical studies, she said. “Our study shows that the odds of affirmative consent are increased when there is racial concordance between research staff and the patient being approached to participate in a clinical study,” she said, but it will require a concerted effort from the medical community at large and especially from investigators and study sponsors.

“I think the medical research community can consider this one strategy to improve participant enrollment, but I don’t believe this is the only strategy. Other interventions may include reducing the burden of time and travel cost,

community outreach, and promoting community support.”

—*Brian Mastroianni*

1 Bains A et al. *JAMA Ophthalmol.* 2023;141(11):1037-1044.

Relevant financial disclosures: Dr. Subramanian—None.

NEURO-OPHTHALMOLOGY

GCA Does Not Appear to Be a Seasonal Disease

GIANT CELL ARTERITIS (GCA) IS NOT tied to a particular season, suggests new research. Until now, it has been unclear whether there is a relationship between month of year and incidence of GCA, a potentially blinding disease and always an ophthalmic emergency. Analyzing data from the Academy IRIS Registry, researchers found that across the United States, time of year does not appear to correlate to an increased likelihood of developing GCA.¹

“Clinicians must be wary of giant cell arteritis throughout the year,” said lead author Edward J. Wladis, MD, at Albany Medical College, in Albany, N.Y. He and colleagues undertook the study after he saw a seasonal trend in his clinical practice. “I noticed that the warmer months were associated with the uptick. In particular, the number of biopsies performed in my practice was higher in the summer,” said Dr. Wladis. He turned to the literature and discovered that some studies demonstrated a clear seasonal impact while others showed no association.

The power of numbers. Hoping to draw more meaningful conclusions, Dr. Wladis and colleagues harnessed the IRIS Registry to explore the impact of season on new diagnoses of GCA. The IRIS Registry, which includes data on more than 72 million patients, yielded 27,339 eyes nationwide with a new diagnosis of GCA between 2013 and 2021. By contrast, the largest cohort in previous studies consisted of 3,928 patients.

The data revealed that winter, spring, summer, and fall accounted for 6,892,

6,920, 6,716, and 6,811 GCA cases, respectively. A subgroup analysis showed that the finding of no seasonal connection remained true across each geographical region of the United States.

Surprise finding. Dr. Wladis expected that season would have some impact and that the data might reveal some regional differences, but he said the data were very clear. “The Academy has developed a massive database with the IRIS Registry, and harnessing such a meaningful tool enables clinicians to really understand disease in new and exciting ways,” Dr. Wladis said.

Limitations. The authors acknowledged that the IRIS Registry does not offer direct insights as to how a GCA diagnosis was reached or about the specific location in which the patient resides. Despite these concerns, they said the trends uncovered in this analysis are relevant.

Takeaway. Dr. Wladis advised clinicians to be vigilant for GCA regardless of the season. “Giant cell arteritis is a devastating, vision-threatening, potentially life-threatening illness, so it’s a diagnosis that clinicians must not miss. The time of year cannot be used to alter the comprehensive diagnostic testing required to determine whether a patient’s symptoms may be attributed to GCA.” —*Miriam Karmel*

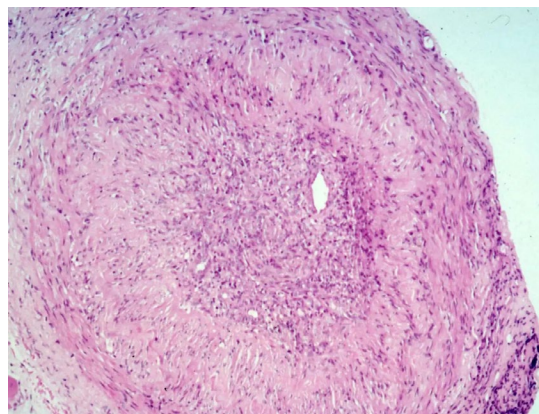
1 Wladis EJ et al. *Graefes Arch Clin Exp Ophthalmol.* Published online Oct. 11, 2023.

Relevant financial disclosures—Dr. Wladis: American Academy of Ophthalmology: S.

RETINA

Biennial Screening May Delay DR Treatment

THE UK NATIONAL SCREENING committee recommends biennial eye screening for people living with diabetes who are considered “low risk” for



GCA. A positive temporal artery biopsy indicates narrowing of the arterial lumen, thickening of the arterial wall, and absence of the internal elastic lamina. Multiple giant cells are present.

diabetic retinopathy (DR). But a large U.K. study that compared annual eye screening for DR with screening every two years for DR suggests that biennial screening may cause treatment delays and possible vision loss for a proportion of those deemed low risk. Delays may also disproportionately affect some patient populations.¹

Background. The U.K. National Health Service introduced the Diabetic Eye Screening Programme in 2003, recommending annual eye screenings for people ages 12 and up with type 1 and type 2 diabetes. The goal was early detection and treatment of DR. In 2016, the recommendation for low-risk individuals with diabetes changed from annual to every-other-year screening and was supported by evidence of safety, cost-effectiveness, and the potential to reduce the number of appointments and workload (implementation of this recommendation nationally in England was delayed).

“When we started the study, two-year recall for diabetes eye screening was a proposed change, but it was not enacted,” said corresponding author John Anderson, MD, at Homerton Healthcare NHS Foundation Trust, in London, where he and colleagues run a large diabetes eye screening program. “There was limited data in peer-reviewed journals on whether this would mean a delay in the discovery of sight-threatening eye disease in some people.”

Objectives and methodology. To

learn more about the impact of biennial versus annual screening for the detection of sight-threatening diabetic retinopathy and proliferative diabetic retinopathy, Dr. Anderson and colleagues used 2012-2021 data from one of the largest most ethnically diverse diabetic screening programs in North East London. They tracked the eye health of 82,782 people with diabetes who had no diabetic eye disease in either eye on two previous consecutive screens.

“We did not know what the findings might be, but we felt that real-life data should be used to find out,” Dr. Anderson said.

Findings. Biennial screening was shown to potentially delay diagnosis by one year in 56.5% of those with sight-threatening diabetic retinopathy and in 44% of those with proliferative diabetic retinopathy.

“The study showed that in a proportion of people who met the proposed criteria for two-year recall, the iden-

tification of sight-threatening disease would be delayed by a year,” Dr. Anderson said.

Projected diagnostic delays disproportionately impacted Black and South Asian individuals living with diabetes, as well as those living with diabetes who were younger than 45 and those who were older than 65 years. The results suggest significant differences in sight-threatening diabetic retinopathy rates across different ethnicities and age groups.

Disease. The highest sight-threatening diabetic retinopathy rates were seen in people living with diabetes who were of Black and South Asian ethnicity; the rates were 121% and 54% higher than in White people living with diabetes, respectively.

Progression to sight-threatening diabetic retinopathy was higher in the youngest and oldest age groups. Sight-threatening diabetic retinopathy rates were also found to be higher in those with type 1 diabetes compared

to people with type 2 and in females compared with males.

Health equity. The findings suggest that a biennial screening interval could negatively and disproportionately affect certain ethnic and age groups. “Different groups within the very diverse London population would be affected unequally by the introduction of a two-year recall,” said Dr. Anderson.

Moving forward, the criteria that determines which people with diabetes should be reexamined more often to minimize age- and ethnicity-linked health inequalities needs to be reevaluated, said Dr. Anderson.

“We hope that our findings will be used to personalize screening pathways for population subgroups to prevent unequal health outcomes,” he said.

—Patricia Weiser, PharmD

1 Olvera-Barrios A et al. *Br J Ophthalmol.* 2023; 107(12):1839-1845.

Relevant financial disclosures—Dr. Anderson: None.

See the financial disclosure key, page 9. For full disclosures, including category descriptions, view this News in Review at aao.org/eyenet.



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