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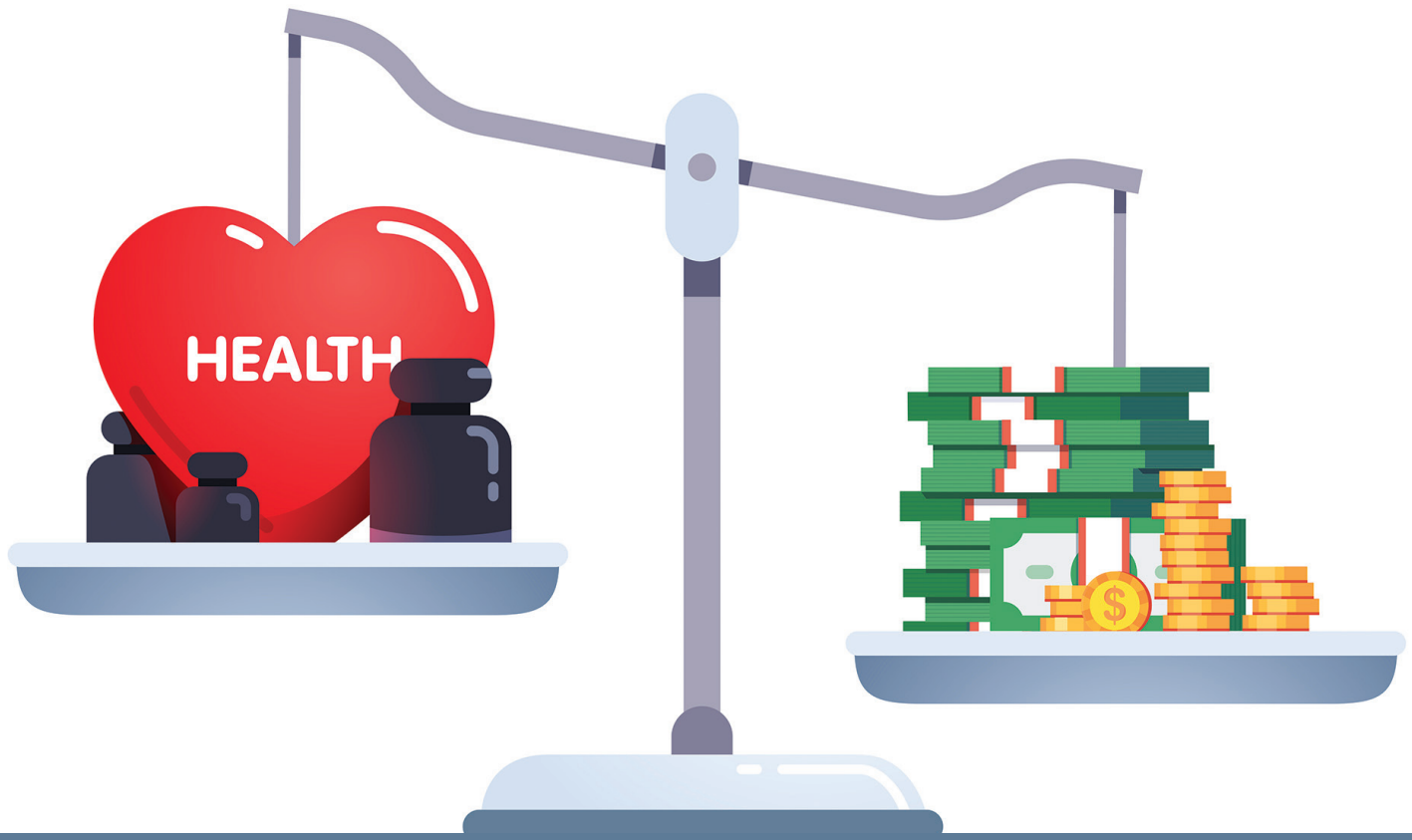
HEALTH CARE DISPARITIES:

Increasing Awareness and Searching for Solutions in Retina



JUDY E. KIM, MD, FARVO, FASRS
PROGRAM CHAIR

ADRIENNE W. SCOTT, MD, FASRS

RISHI P. SINGH, MD

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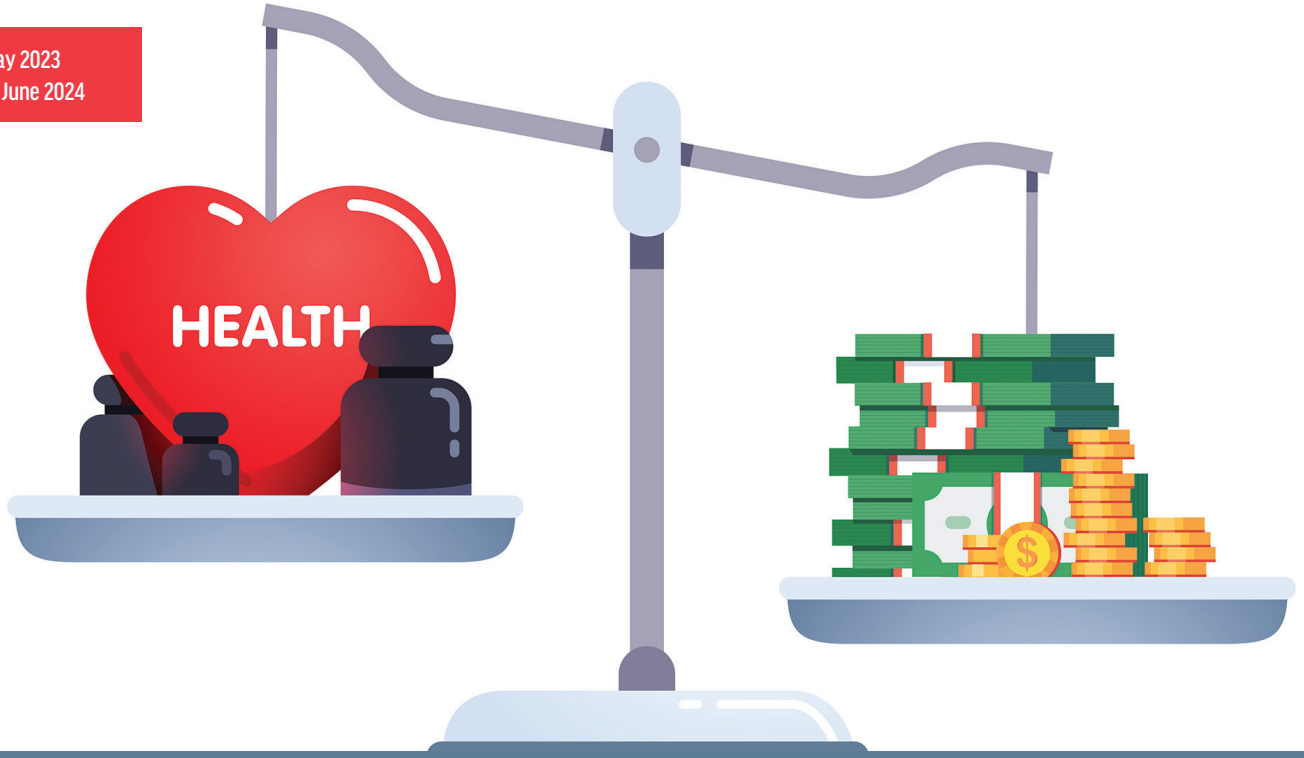

HEALTH CARE DISPARITIES:
Increasing Awareness and Searching for Solutions in Retina

Judy E. Kim, MD, FARVO, FASRS
Program Chair
Professor, Ophthalmology and Visual Sciences
Professor, Graduate School of Biomedical Sciences
Director, Teleophthalmology and Research
Medical College of Wisconsin
Milwaukee, WI

Adrienne W. Scott, MD, FASRS
Chief, Wilmer Eye Institute - Bel Air
Associate Professor of Ophthalmology
Johns Hopkins University School of Medicine
Baltimore & Bel Air, MD

Rishi P. Singh, MD
Staff Physician and President
Cleveland Clinic Martin Hospitals
Stuart, FL
Professor of Ophthalmology
Cleveland Clinic
Lerner College of Medicine
Cleveland, OH

Content Source

This continuing medical education (CME) activity captures content from a live-virtual symposium.

Activity Description

This supplement summarizes a panel discussion on disparities in retinal disease awareness, screening, and access to care among patients with the highest risk factors, as well as barriers to treatment, including patient noncompliance. The faculty also share their experience with these issues and potential solutions through case studies.

Target Audience

This certified CME activity is designed for ophthalmologists who care for patients with retinal disease.

Learning Objectives

Upon completion of this activity, the participant should be able to:

- **Discuss** how race and socioeconomic status impact screening, access to care, and outcomes in retinal diseases
- **Identify** factors within ophthalmology that may be driving health inequities
- **Evaluate** data on the utilization of standard-of-care treatments and clinical trial enrollment in historically marginalized populations
- **Develop** strategies to reduce care disparities in historically marginalized patients with retinal diseases

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PRETEST QUESTIONS

Please complete prior to accessing the material and submit with Posttest/Activity Evaluation/Satisfaction Measures for credit.

1. **Please rate your confidence in your ability to develop strategies to reduce care disparities among historically marginalized patients with retinal diseases (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).**
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

2. **On a scale of 1 to 5 (with 1 being never and 5 being always), please rate how often you see in your practice the ways in which race and socioeconomic status impact screening, access to care, and outcomes in retinal diseases.**
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

3. **All of the following represent disparities in adult vision health in the United States EXCEPT:**
   a. Vision loss and vision impairment are common with age
   b. Women at greater risk of vision loss than men
   c. Lower socioeconomic status associated with underutilization of eye care
   d. Men at greater risk of vision loss than women

4. **All of the following statements about DME and racial disparities are true EXCEPT:**
   a. The baseline VA between Black and White patients with DME is not significantly different
   b. After treatment, Black patients had better VA following anti-VEGF injections
   c. The White patients on average received a greater number of injections over a 1-year period compared to the Black cohort
   d. After treatment, White patients had better VA following anti-VEGF injections

5. **You are seeing a 45-year-old native Spanish speaker for evaluation in your office. She has a history of diabetes, hypertension, hyperlipidemia, coronary artery disease, peripheral vascular disease, and obstructive sleep apnea. You note bilateral proliferative diabetic retinopathy and recommend prompt treatment. The patient lives far from your clinic but agrees to the prescribed treatment. All of the following represent risk factors for this patient being lost to follow-up EXCEPT:**
   a. Primary language other than English
   b. Age <55 years
   c. Living <20 miles from clinic
   d. Having more than five comorbidities

6. **A 53-year-old patient presents to your office for evaluation. On examination, you note bilateral proliferative diabetic retinopathy with diabetic macular edema (DME) and recommend starting monthly anti-VEGF injections. She has no insurance and worries about her ability to pay for her visit today as well as future visits. Which of the following is a step you can take to help this patient?**
   a. Discuss with the patient that observation of this disease may be in her best interest
   b. Screen the patient for any clinical trials of anti-VEGFs to see if she may qualify
   c. Referral to another retina specialist
   d. Only inject one eye

7. **A 45-year-old Hispanic woman presents to your office for evaluation of blurry vision. You note bilateral DME and recommend treatment. According to health care disparity research, which of the following is TRUE?**
   a. This patient is more likely to be treated with bevacizumab
   b. This patient is more likely to be treated with aflibercept
   c. This patient is more likely to be treated with ranibizumab
   d. This patient is more likely to be treated with faricimab

Health Care Disparities: Increasing Awareness and Searching for Solutions in Retina

For decades, reports in the literature note racial, socioeconomic, and gender disparities in the treatment of major retinal diseases including diabetic retinopathy (DR), diabetic macular edema (DME), and age-related macular degeneration (AMD).[1] Health inequality exists; the relationship between socioeconomic position and morbidity/mortality has long been demonstrated. It is well established that major retinal diseases, such as diabetic eye disease, do not affect all patient populations equally. Nearly 600 million people worldwide are expected to be living with diabetes by 2035, and racial and ethnic minorities are disproportionally affected.[2-5] What factors are driving these inequities? The following roundtable discussion includes topics such as how race and socioeconomic status impact screening, access to care, and outcomes in the treatment of retinal diseases, as well as strategies to reduce care disparities in historically marginalized patients.

—Judy E. Kim, MD, FARVO, FASRS, Program Chair

DEFINING HEALTH DISPARITY

Dr. Kim: What do we mean by "health disparity?" Health disparity is a health difference based on one or more health outcomes that adversely affects defined disadvantaged populations.[6] Health disparities can come from number of areas. It can be due to race, ethnicity, gender, sex, disability, geography, income, or immigrant status. Health disparity populations designated by the National Institutes of Health (NIH) are detailed in Table 1. Dr. Scott, how do we define health equity?

Adrienne W. Scott, MD, FASRS: Health equity is an important concept. Health equity exists when all people—regardless of race, gender, sexual orientation, disability, socioeconomic status, geographic location, or other societal constructs—have fair and just access, opportunity, and resources to achieve their highest potential for health.[7] Unfortunately, social and political determinants of health may negatively affect entire communities and the ability of those living there to lead healthy lives. Let's review additional definitions in these concepts.

TABLE 1. NATIONAL INSTITUTES OF HEALTH-DESIGNATED DISPARITY POPULATIONS

Racial and ethnic minority groups: Native Americans Alaska Natives Asian Americans Black Americans African Americans Hispanic Americans/Latinos Native Hawaiians Other Pacific Islanders
Sexual and gender minorities
Socioeconomically disadvantaged populations
Underserved rural populations

Political determinants of health involve the systemic structuring of relationships, distribution of resources, and power administration that operate in ways to mutually reinforce or influence other concepts to shape health equity or exacerbate health inequities.[8] Social determinants of health are the conditions and environments in which we learn work, play, worship, and age that affect health function and quality of life.[7,9] To understand health equity in the context of ophthalmology, we must understand disparities and demographics in eye care. Globally, there is evidence of disparities in eye care that have been linked to region, education, income, sex, and ethnicity.[10,11]

How might these and other factors affect DME and DR care in the United States? We know from published literature that disparities in adult vision health are present. We know that vision loss and vision impairment are more common with age and more common in women. That may be because women live longer on average than men, and therefore are at a greater risk of vision loss. It is well documented that lower socioeconomic status is associated with the underutilization of eye care and worse health outcomes in eye care.[12,13] Diabetes is particularly important and influenced by socioeconomic and educational factors.[14,15]

Additionally, adults with low socioeconomic factors are disproportionately affected by diabetes. Education level and risk of diabetes exist on a relative gradient; patients with the least

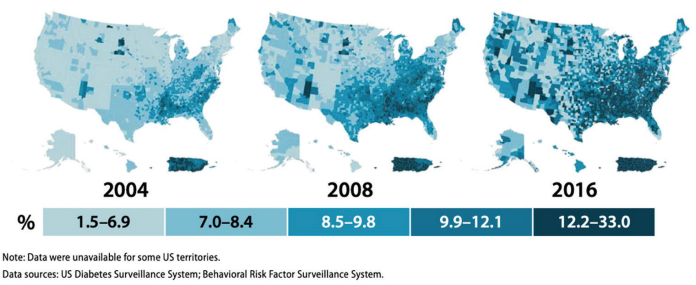

Figure 1. Prevalence of Diabetes in the United States by Region from 2004-2016.[16]

educational status have the highest risk of diabetic eye disease. We also know that diabetes in the United States is increasing. Figure 1 shows the increased percentage of individuals affected by diabetes in the United States from 2004 to 2016.[16]

What does it mean to be underrepresented in a particular population and a particular disease state? The percentage of individuals with diabetes by race and ethnicity are illustrated in Table 2.

Of note, 16.4% of Black (non-Hispanic) Americans are affected with diabetes, but in the raw population, this comprises only 5.2 million Americans with diabetes.[3,16] Also of note, the Hispanic population disproportionately represents the number of individuals affected with diabetes. DR disproportionately affects Black Americans more than White Americans (32.2 per 1,000 vs 24.1 per 1,000). The prevalence of DME in Black Americans is 3 times greater than White Americans, and race tends to be more of a factor even than hemoglobin A1C levels in determining development and incidents of DME.[17]

Importantly, the natural history of DME depends on multiple interrelated factors such as social determinants of health including (+ distance to specialty care clinic + geographic location + transportation + trust of physicians + health literacy/education), health care access (transportation + health literacy + health insurance), and disease burden (nephrology, endocrinology, and ophthalmology appointments). These factors influence individuals having varying abilities to achieve their best health equity.

TABLE 2. PREVALENCE OF DIABETES IN THE UNITED STATES BY RACE[3,16]

Race/Ethnicity	Percentage with Diabetes	Raw Population with Diabetes
Black, non-Hispanic	16.4%	5.2 million
Asian, non-Hispanic	14.9%	2.3 million
Hispanic	14.7%	6.4 million
White, non-Hispanic	11.9%	19.5 million

Q | Dr. Kim: When we are looking for solutions to problems, we first must define the problem to get to the root cause. As you stated, non-Whites have higher incidence of diabetes. What are some contributing factors?

Dr. Scott: That's a complex topic with multiple contributing factors. There's a higher rate of insulin resistance in Black and Hispanic populations in the United States; therefore, some genetic component is at play.[18,19] But these social and political determinants of health certainly influence health access. Is there a Whole Foods in your neighborhood or more fast food options? How far do you have to travel to purchase healthy foods? Body mass index (BMI) unfortunately is also affected disproportionately in United States, with Black and Hispanic populations tending to have a higher BMI.[20] This might also harken back to socioeconomics and to lack of resources or the distance that one has to travel for healthy and affordable food.[21,22] There are also dietary traditions that may predispose to diabetes and hypertension in certain cultures. There's a complex interplay of these factors that I think do play a role.

REAL-WORLD EVIDENCE OF CARE DISPARITIES

Q | Dr. Kim: Dr. Singh, can you address the real-world evidence we have of health care disparities in eye care?

Rishi P. Singh, MD: It's a pleasure to share some of the data we've published and presented during the past couple of years. A study from 2021 by Osathanugrah et al assessed the impact of race on short-term treatment response to bevacizumab in DME.[23] The researchers found that the percentage of patients who experienced visual acuity (VA) improvement with one injection of bevacizumab was much lower in the Black population than it was in Hispanic and White populations (27% vs 39% and 50%, respectively). They defined VA improvement as a 2-line gain in vision. These numbers improved after the study population received three injections of bevacizumab, but still the Black populations lag behind the Hispanic and White populations (34% vs 55% and 59%, respectively). The differences in VA improvement between Hispanic and White populations were not statistically significant at either time point. Further, the differences in central macular thickness (CMT) reduction were not different among the groups at either timepoint. Essentially, while the retinopathy or CMT may be better in all groups, unfortunately, the vision each group achieves is very different. There's a disconnect between OCT and vision in the diabetic population. It may be that there's another underlying condition that might explain some of these differences.

This has led to a lot of different insights. First and foremost, we see that more Black individuals with advanced retinopathy conditions. A phenotype they might present with is one without features of retinopathy, so they develop ischemia more often than other individuals without overt signs of proliferation. There's a variety of different phenotypical things that may explain these differences. For that matter, sometimes there are health care disparities within a community such as access to eye care providers. Certainly, views on injections and the opportunity to come to appointments may be different for different populations.

It's difficult to separate these factors individually because they have a lot of interplay on each other. You have socioeconomic factors, racial differences, ethnicity differences between Hispanic and non-Hispanic individuals, access issues, and insurance differences. It's multifactorial. I want to be cautious to say that this truly is not

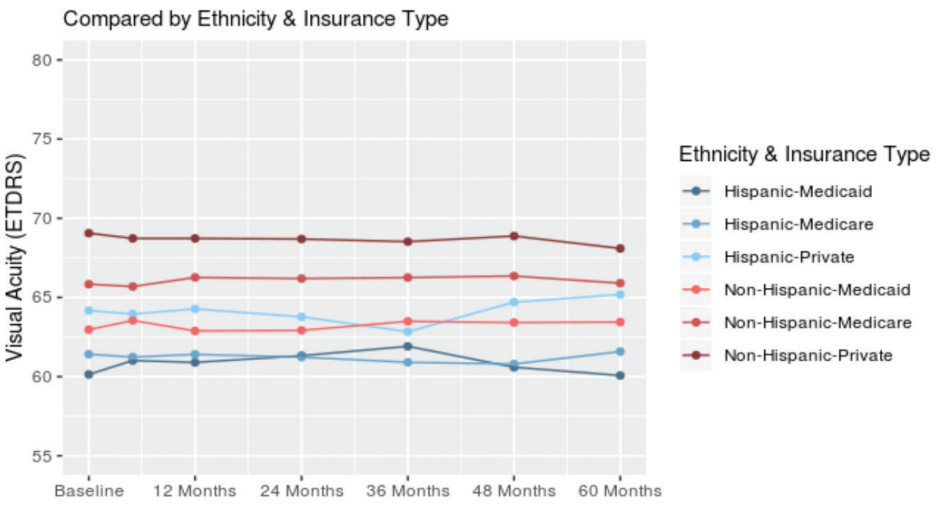

Figure 2. Visual acuity by ethnicity and insurance type.[24]

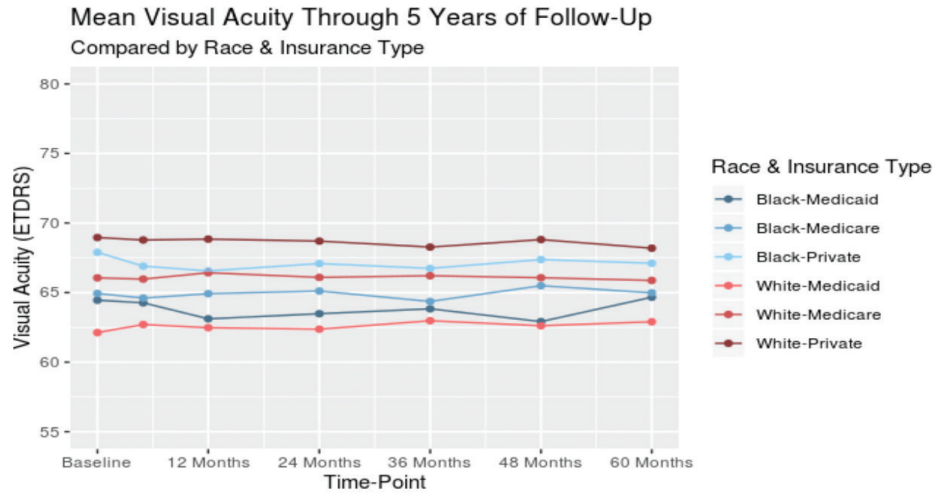

Figure 3. Mean visual acuity at 5 years compared by race and insurance type.[24]

just a race issue; it's related to many of these underlying conditions.

I was a coauthor on a study that characterized how racial and socioeconomic factors affected the use of anti-VEGF treatment and outcomes for patients with DME in Northeast Ohio.[24] The study looked at zip codes and census data to see the income levels. We looked at 5 years of ongoing therapy for anti-VEGFs and assessed the differences in the racial and ethnic groups as well as for those based upon insurance. First and foremost, there were differences in the baseline VA of patients who entered the study. Hispanic patients were most likely to have the worst VA upon entry compared to non-Hispanic individuals (Figure 2).

There was no difference in the VA of these individual patients both with race and with ethnicity and with the insurance type (Figure 3). These are all existing functions of what impacts the patient. This is the concerning part, right? Not only do they present with different vision levels, despite our interventions they stay in their respective lanes not achieving the same visual results.

Baseline VA between Black and White patients with DME was not significantly different ($P = .1453$). However, White patients had better VA after anti-VEGF treatment (68.38 ± 14.92 vs 63.78 ± 17.65; $P = .0136$) and, on average, received a greater number of injections during a 1-year period compared to Black patients (4.93 ± 3.14 vs 3.20 ± 2.43; $P < .0001$) Areas below the poverty line had the highest rates of cancelled appointments and no shows. Those living three times above the poverty line had the fewest no shows and attended most appointments.

On average, Americans with DME receive two to three, maybe four, anti-VEGF injections a year. But patients in the highest socioeconomic category receive an average of five anti-VEGF injections a year. These trends make sense, right? Patients who have good economic status can potentially take off time from work, which likely gives them paid leave. This may also correlate to some of the differences we just discussed regarding baseline vision and outcomes. More injections were given to the White population versus the Black population, and there were better outcomes within the White population than the Black population.

Our study was done in Cleveland, but there are data from abroad that reflect this as well. A study from Singapore looked at the link between DR outcomes and a person's socioeconomic status, education, income, and housing type.[25] They found that lower income was associated with increased risk of DR and visual impairment. In looking at the area-level socioeconomic status and not within a certain region or province of Singapore, they were associated with greater incidence of DR, diabetic progression, and visual impairment in these patient populations.

Another study I coauthored characterized the association of risk factors including race, ethnicity, and insurance status with presenting VA and DR severity in patients initiating treatment with anti-VEGF therapy for DME using the IRIS Registry database. We found that patients on Medicare and private insurance presented with higher baseline VA compared with patients on Medicaid (median of 2.31 and 4.17 greater ETDRS letters, respectively $P < .01$).[26] Therefore, not only do we have all of the things we discussed regarding ethnicity and race, but we also have insurance status disparities.

Q | Dr. Kim: These are important findings. Why do you think we have these differences?

Dr. Singh: Copays are a significant part of medical care. The way that people take on insurances drastically changed after the Affordable Care Act, but even within that umbrella there

are certain people who have high and low deductibles based on where they are in the insurance cycle. That can change how patients perceive or accept care. For example, if they have a large deductible, they're not necessarily willing to fill the deductible. However, once they hit their deductible, many of them are willing to undergo therapy. If their copays are low, they're more likely to receive care.

Brian VanderBeek, MD, MPH, MSCE, from the University of Pennsylvania studied this in detail, looking at claims data in 6,220 patients with newly diagnosed DME.[27] He found that in this patient population, 3,010 (48.4%) underwent a follow-up examination within 90 days of diagnosis, and of those, 1,453 patients (48.3%) received treatment in the observation window. Having any type of copay lowered the odds of receiving treatment (odds ratio = 0.60; 95% CI, 0.51-0.71; $P < .001$), but interestingly, having an insurance plan and a high deductible were unrelated to initiating therapy.

We also know that geographic variety can determine treatment patterns. His study characterized treatments by areas in the United States, finding that the Northeast had greater likelihood of receiving branded versus nonbranded anti-VEGF. He found that areas in the Southern Midwest had higher odds of receiving any anti-VEGF or even focal laser than any part of the country. In the South Atlantic states, any anti-VEGF was the most likely choice and they're highly unlikely to receive any type of laser treatment.

Even within our microcosm of the United States, there's differences in treatment patterns. Making this milieu even more complicated is step therapy. A study from DRCR.net essentially validated step therapy more or less for the treatment of DME, finding that first-line bevacizumab was a reasonable approach.[28]

Dr. Kim: Please comment further on the role of step therapy in our management of patients with DME.

Dr. Singh: What has transpired since Protocol AC from DRCR.net was published is that Medicare Advantage plans now have the choice of implementing step therapy to manage Part B drugs (as of January 1, 2019), which are really expensive to the Medicare population. Currently, there are more than 20 million beneficiaries enrolled in Medicare Advantage plans. Several plans but not all have attempted to implement this change. There is no clear definition of "failure," although some commercial plans have tried defining it with strict, nonpatient care–focused definitions. The biggest problem in all of this is the Medicare Advantage plans have extrapolated these data to all disease states, not just diabetes, but to AMD, retinal vein occlusion (RVO), and other areas where they've said, "Yes, we think bevacizumab is a reasonable place to start therapy." But they don't know the difference between DME, RVO, and AMD or the treatment nuances required. It's up to us to educate them.

I think the other thing that complicates this is that in Protocol AC, "real failure" was defined and determined by both anatomy and vision.[28] Unfortunately, most of these plans don't include the definition for failure. Therefore, it's up to the physician to determine failure and have to implement that step therapy in their practices as a result of it.

There are many issues with fail-first policies.[29-31] Your best chance of improving vision is in the first 3 to 6 months, especially in DME. Missing that opportunity because of delayed care, copays, or nonresponse to therapy, really impacts outcomes a year or even 2 years out. In the ideal scenario, patients are treated monthly, but that doesn't align with real-world practice. When you look at these fail-first policies and compare to the real-world outcomes, that doesn't look as rosy with regard to its ability to have the same VA outcome if you have a lower therapy there as well. These policies have been detrimental in some way, shape, or form. In a clinical trial setting, it probably works fine, but in the real world it does not have the same effect in my opinion.

Dr. Kim: I agree with you that what we find in clinical trials may not always translate to the real world. Any additional comments?

Dr. Singh: I want to discuss loss to follow-up (LTFU), which is important. Green at al conducted a study at Boston University Medical Center, which is the free-care hospital for Boston, looking at patients with proliferative diabetes who were LTFU. Many private hospitals pay into Boston University Medical Center so not to absorb those free-care patients. LTFU will be the highest in a facility like this because it has the lowest socioeconomic status and highest potential population diversity. Green et al found that among patients being treated for PDR, the risk factors for LTFU were primary language other than English, age older than 55 years, living less than 20 miles from clinic, and having more than five comorbidities. Sometimes you have to think about what barriers or safety nets you can put up for preventing new people from being LTFU over time.

STRATEGIES TO REDUCE CARE DISPARITIES

Dr. Kim: Thank you, Dr. Singh. Those were all excellent points. Now, let's discuss strategies for reducing care disparities. I'm going to concentrate this section on clinical trials, because we get our drugs approved through clinical trials. If drugs are not tested in the right population, or adequate numbers of diverse population, findings from the clinical trials may not be generalizable to all.

Berkowitz et al looked at clinical trials for FDA-drug approval during a 20-year period (2000-2020) for glaucoma, AMD, and DR.[32] Among the 31 clinical trials that tested 13 drugs in more than 18,000 participants, the study found there was an increase in Asian and Hispanic/Latino patient enrollment for AMD ($P < .001$) and DR ($P < .001$), but there was a decrease in enrollment of Black patients for DR ($P < .001$). There was an increase in the enrollment of Black and Hispanic/Latino patient enrollment for glaucoma. The study found significant underrepresentation of minorities by disease burden per the National Eye Institute and US Census.

How underrepresented are patient enrollment in clinical trials compared to the patient population in the real-world? Bowe et al looked at the racial, ethnic, and gender disparities in DME clinical trials.[33] It included 10 clinical research and industry-sponsored

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—Judy E. Kim, MD, FARVO, FASRS

DME trials of more than 4,000 people compared to IRIS Registry database that included more than 200,000 people. The study found there were more White and more male patients enrolled in clinical trials compared to the percentage in the IRIS Registry data. This is important because if we are not looking at the same type of population, the clinical trial results may not be widely applicable. For instance, the drug may not work as well on some underrepresented populations.

Kaakour et al looked at DME and RVO trials between 2004 and 2020 compared with 2010 US Census data.[34] Of the 23 trials included, 15 on DME and eight on RVO, White patients were more frequently overrepresented and Hispanic patients were most frequently underrepresented. Sanjiv et al looked at race and ethnic representation in 25 NIH- and industry-sponsored United States DME and DR trials between 2001 and 2020.[35] Black patients were underrepresented by 3-fold in NIH trials and 4.5-fold in a DME trials sponsored by industry. In industry-funded DR trials, there was a 2.1-fold disparity compared to the disease burden. For equality's sake, we need to look at the patient distribution and enroll more underrepresented minorities in our clinical trials.

Finally, it's important to note that disparities exist not only in our clinical trial participants, but also within ophthalmology itself. There is a huge disparity among the ophthalmology workforce. Ophthalmology departments across the United States are some of the least diverse departments in medicine.[36-38] We ranked at the bottom when the number of departments analyzed in terms of diversity in race as well as female gender among departmental faculty. Therefore, we must diversify ophthalmology trainees as well as the workforce, the technicians, and so forth.[39,40] Why? Because studies have shown that workforce diversity improves patient adherence.[41-44] Studies have shown that racial concordance between the physician and the patient improve the trust from the patients. It improves communication and patient satisfaction, thus increasing odds of adherence to therapy and better visual outcome.

I have heard patients say they would rather risk acquiring COVID-19 by coming to the doctor's office for an intravitreal injection and maintain vision than to stay home because of fearing COVID-19 and go blind from not getting the treatment. We know patients fear blindness as much as a cancer diagnosis. Vision is important to everyone, every race, every gender. Eye health disparities are present among all ophthalmic subspecialties. We need to do better. As for retina specifically, we need to detect disease earlier because we know that earlier detection and timely treatment are more likely to result in better final VA. We need to improve screening as well. We should all consider the effects of systemic racism, social determinants of health, and implicit and explicit biases. We can do that by better educating ourselves and activities like this are a good first step.

We should strive for equity in clinical trials. We must diversify research teams and plan for recruitment and retention in clinical trials. Finally, we must improve community engagement. All of us should work together.

CASE 1: PATIENT WITH TYPE 2 DIABETES AND NO VISION INSURANCE

Dr. Kim: Our first case is a 58-year-old Hispanic man with a history of type 2 diabetes who was referred for an eye exam by his new primary care physician because his previous primary care physician did not address that. His most recent HbA1C was 12.3%, and his BMI is 33 kg/m^2. Obviously, we need to discuss better glycemic control. A BMI of 33 kg/m^2 is very common among patients enrolled in DME and DR clinical trials. In addition to type 2 diabetes, he has hypertension, which is controlled with medication.

His last eye examination was 3 years ago, and he does not know whether his eyes were dilated. This is very common. Many patients don't know if they've had a dilated eye exam and think going for a glasses eye exam is the same thing as a retinal examination for DR. We need to educate our primary care physicians and our patients.

Furthermore, this patient did not feel that annual eye examination was necessary because he sees well enough to do daily activities, including driving and working. When we saw him, his VA was 20/25 in the right eye and 20/60 in the left eye. His IOP was 15 mm Hg in both eyes. He had an early cataract and moderate nonproliferative diabetic retinopathy (NPDR) in the right eye and severe NPDR with center-involving DME in the left eye. Figure 4 shows his OCT in his left eye.

The map on the top and the B scan on the bottom shows he has center-involved DME with a significant amount of intraretinal fluid. Dr. Singh, how would you take care of this patient?

Dr. Singh: What is his insurance status?

Dr. Kim: He has medical insurance but not vision insurance. He does not have secondary insurance. He's 58 years old, so he does not have Medicare.

Dr. Singh: In this case, I would be forced to start with bevacizumab. Protocol AC did give some credence to that.[28] However, I would file an authorization for the other drug in case I want it to use it at some point. I don't need it right away, but I need to know if we can get it eventually. I also think it's worthwhile to do an angiogram to make sure he doesn't have peripheral proliferation.

Dr. Kim: If insurance and money are issues, what do you do about the angiogram? Sometimes patients decline tests because they're worried about the expense.

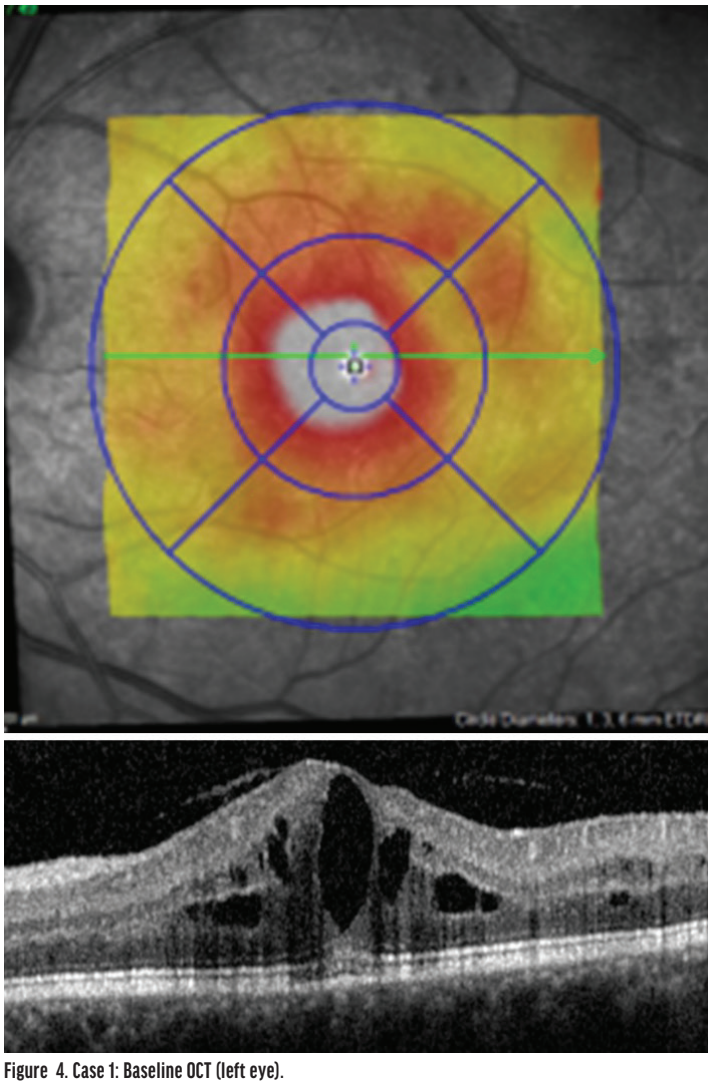

Figure 4. Case 1: Baseline OCT (left eye).

Dr. Singh: I don't think people necessarily refuse the medical-related issues per se because they don't think about it that much. We have to provide some billing ahead of the patient's visit. There's a new act, Requirements Related to Surprise Billing, that allows patients to know what exactly we're going to be charging them prior to their office visits. It's brand new, so we're going to have to figure out what that looks like. But right now, patients don't often ask about the cost. I think it's reasonable to do the angiogram knowing that it is covered by most medical insurances and will go toward the patient's deductible.

Dr. Kim: Bevacizumab may not work as well for non-White patients with DME after one to three injections, as shown in the study. Does that come into play?

Dr. Singh: It does, but this is a real-world patient and Protocol AC was a study with coordinators and lots of follow-up. You don't necessarily have that in the real world. Bevacizumab is not my first choice, but I may be forced to use it because of this patient's specific situation.

"I like to use ultra-widefield imaging for a baseline evaluation."

– Adrienne W. Scott, MD, FASRS

Dr. Kim: Protocol T from DRCR.net showed that in patients with less than 20/40 VA, aflibercept worked best.[45,46] Then DRCR.net did Protocol AC, which looked at potential cost savings as well as whether there was any harm by starting with bevacizumab, the less expensive medication. Protocol AC found that at year 2, the group started with bevacizumab and switched to aflibercept had equivalent VA compared with aflibercept monotherapy based on VA and OCT criteria.[28] But you have made an important point; it was in a clinical trial in which they were seen monthly and had an average of 22 visits and a mean of 14 injections in 24 months, which is a lot more than what we do in the real world. Therefore, I'm concerned if Protocol AC is truly applicable and generalizable to real-world populations. What do you think?

Dr. Singh: I agree. That's the problem with many of these idealistic studies; they can't emulate real-world treatment patterns. For example, in Protocol T we had almost as-needed, prn treatment for those patients. We don't do that in clinical practice per se, but it's a much better correlation with what we do in real-world clinical practice.

Dr. Kim: We started this patient on bevacizumab because of his insurance status. He then went on a patient access program for aflibercept so he didn't have to pay for the drug. He actually did quite well following treatment and regained VA. If we start the treatment early in eyes with DME, the response tends to be favorable. Also, once retina becomes dry, the follow-up interval can be extended rapidly and the number of intravitreal injections often decrease significantly, even to the point of only needing observation. I advise my patients with DME that we may have to work hard together with frequent injections initially, but unlike other conditions such as neovascular AMD, patients with DME do not need injections forever.

CASE 2: THE IMPORTANCE OF ULTRA WIDEFIELD IMAGING

Dr. Singh: Our next case is a 49-year-old African-American man who was referred to me. He has had type 2 diabetes for 7 years. His HbA1C is 8.9%, which is better than our last case but still has room for improvement. His IOP is 21 mm Hg. The optometrist who performed the dilated eye exam said the OCT was normal. Figure 5 shows the OCT. They showed me the OCT and asked for a second opinion. What do you all think? Does this look normal?

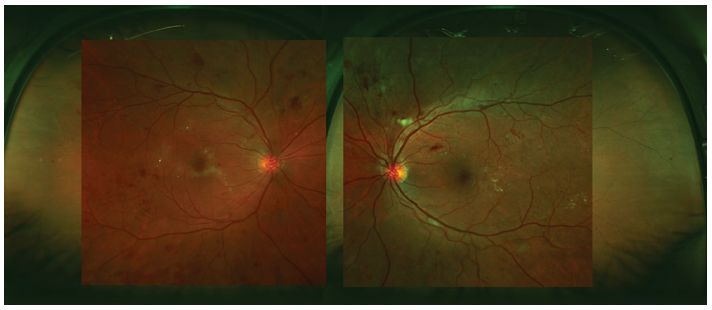

Figure 5. Case 2: Baseline OCT.

Dr. Scott: I like to use ultra-widefield imaging for a baseline evaluation. We know that this person is at high risk for retinal ischemia, and in these cases I like to obtain fluorescein angiography. I'm not certain if there's neovascularization, but I wouldn't be surprised. There's peripheral ischemia, and we know from Protocol AA that peripheral ischemia does predispose PDR development.[47] This person likely has peripheral retinal ischemia and possibly neovascularization.

Dr. Singh: The optometrist recommended a 6-month follow-up, but this patient actually returned within 6 weeks with decreased vision in both eyes. He was seen by optometry. His VA was 20/20 in both eyes, but his IOP was now 43 mm Hg in his right eye and 35 mm Hg in his left. The patient was referred to me on the same day and was found to have peripheral nonperfusion, as you can see at the top of Figure 6, and neovascularization of the disc in the right eye. There's no true PDR present. Certainly, this patient has proliferative disease in the right eye, which may explain the pressure issues.

There are many different treatment options for this patient, including panretinal laser and anti-VEGF therapy. You can start the patient on IOP-lowering drops. Thankfully, the patient was started on two IOP-lowering medications and bilateral anti-VEGF therapy. His VA remained 20/20 and the IOP decreased to 15 mm Hg. The patient had an impressive response after a single injection, but this patient needs laser treatment. Figure 7 shows all those areas of peripheral nonperfusion that are very clearly visible now that the hemorrhages are gone.

You can see those ischemic vessels, which really means there is active disease. Figure 8 shows the OCT over a couple of visits during a 3-month period. Even though the right eye initially looked normal by the OCT, when you see patterns on the enface image where it looks scalloped in nature, you really have to look for proliferative disease in these cases because it's a good sign that you have something else going on that's more significant. That's usually a marker for inner retinal ischemia, which again goes along with the idea that you have advancing diabetic disease as well.

Dr. Kim: We recently learned that ultra-widefield fluorescein angiogram can give us some prognosis 4 years down the line. The more nonperfusion present at baseline, the more likely the condition will worsen.[48] I think doing some of this imaging at baseline will be helpful in managing our patients. He most likely had neovascular glaucoma in the left eye, too, because pressure was high

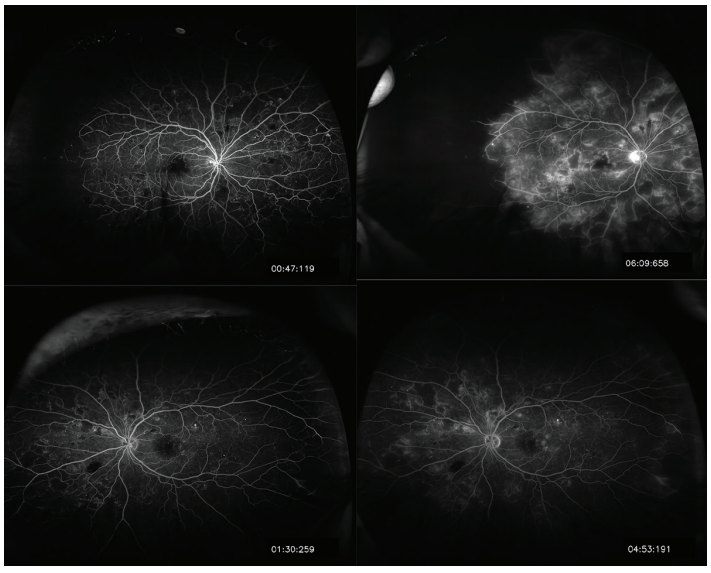

Figure 6. Case 2: Imaging after retinal referral.

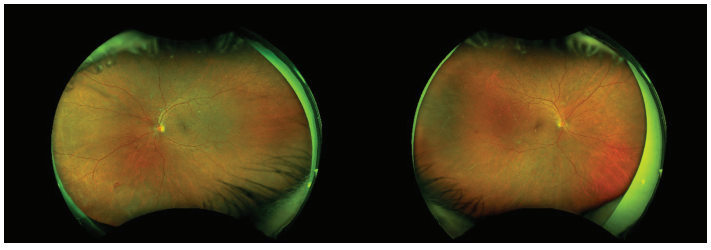

Figure 7. Case 2: Imaging after anti-VEGF injection.

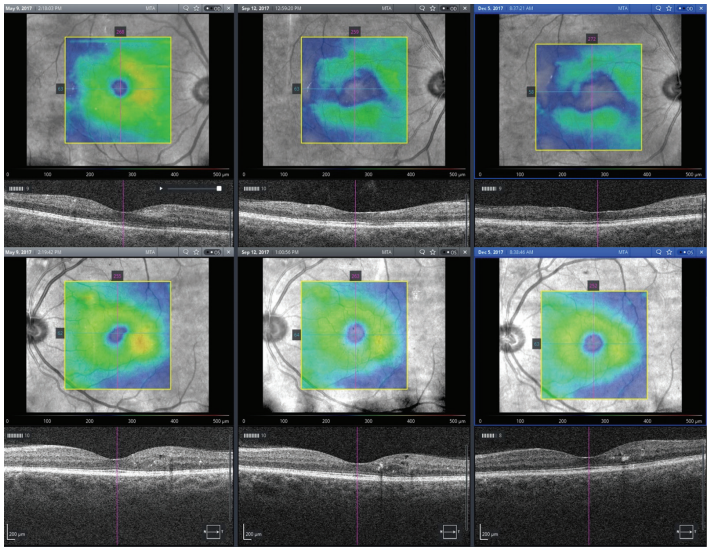

Figure 8. Case 2: OCT imaging over 3 months.

and he responded well to anti-VEGF. I wonder if gonioscopy had been performed prior to dilation. Ultimately, both eyes will need panretinal photocoagulation for durability of treatment; otherwise, you may have to keep injecting with anti-VEGF.

CASE 3: DIABETIC PATIENT LTFU

Dr. Scott: This case was shared with me by a colleague who

treated the patient previously. This is a 37-year-old Black woman with type 2 diabetes. She has elevated HbA1C upwards of 11% and 20/20 VA in both eyes. She presented to the retina specialist and was diagnosed with nonhigh-risk proliferative diabetic retinopathy (PDR). Close observation was advised with a 3-month follow-up. The patient returned 6 months later, and she had progressed to neovascularization elsewhere (NVE) in both eyes. She was advised to undergo PRP in both eyes in 2 weeks. Financial authorization needed to be obtained for the procedure, and the patient wanted to come back when she had a driver present.

She returned 2 months later, and PRP was initiated in the right eye with the left eye scheduled in 2 weeks. The patient returned 10 months later. At that point, PRP was initiated in the left eye and further progression of NVE was noted. The patient continued to progress, and anti-VEGF was recommended. A 4-week follow-up was recommended, and the patient came back 2 months later. She was advised to have bilateral bevacizumab injections, and that was pending the financial authorization. She received a single bevacizumab injection in both eyes with a recommended follow-up in a month. The patient didn't return for 2 years, which is when I met her.

Keep in mind all this while there's a global pandemic happening, which certainly did not help the case for adherence to follow-up recommendations. Figure 9A/B shows the imaging for her left and right eyes, respectively.

In the left eye, you can see a complete PRP pattern. There's some progression of the fibrovascular proliferation, perhaps the hyaloid adherence, just temporal to the macula there, but a retained foveal contour. She's maintaining 20/30 VA. However, in her right eye, her VA has decreased to 20/400 and she's developing a sensory exotropia. You can see subretinal fluid through the macula and extensive fibrous proliferation despite laser.

These patients need close follow-up despite PRP placement because of the risk of progression. How do you manage treatments requiring authorization and other factors preventing same-day treatment? How do you manage care when patients are unable to maintain their follow-up schedule?

Dr. Kim: Even in patients with insurance, sometimes they don't show up because there are other life issues and comorbidities.

Dr. Singh: Prior authorization is a complicated scenario, especially given the landscape in which we take care of patients. Authorizations are a real burden on a practice, so we've had to centralize those things. It still requires paperwork, unfortunately, because many of these insurance companies don't have electronic authorization systems.

CASE 4: PATIENT WITHOUT INSURANCE AND SUDDEN VISION LOSS

Dr. Kim: Our final case involves a 47-year-old Black woman who has had poorly controlled type 2 diabetes for 12 years. Her HbA1C is 14%. She works two part-time jobs but has no medical insurance. It is difficult for her to afford her medications. Her last retinal exam was 3 years ago at her primary care office, but it was

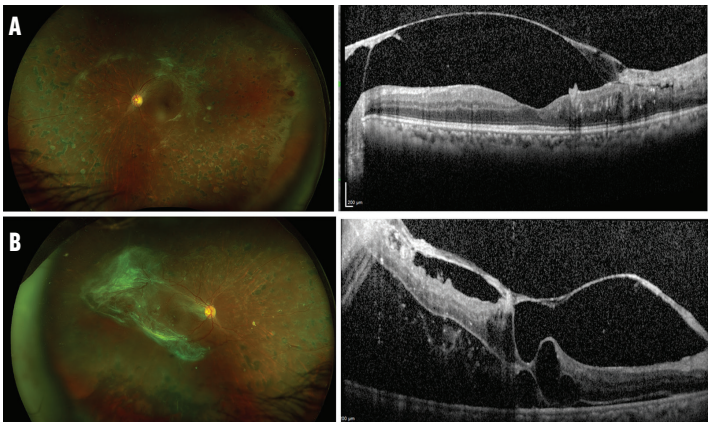

Figure 9 A/B. Case 3: Imaging 2 years lost to follow-up (left and right eyes, respectively).

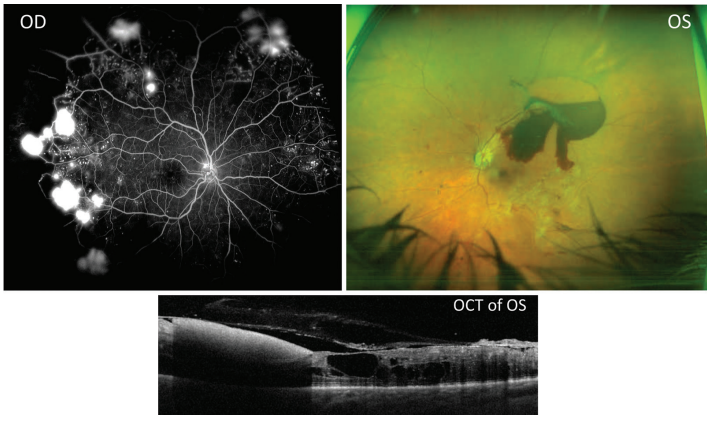

Figure 10. Case 4: Baseline ultra-widefield fluorescein angiogram (right and left eyes, respectively).

with a direct ophthalmoscope. She came in for an exam because she was experiencing gradual decline in vision in the right eye and thought she needed glasses. But then she had sudden loss of vision in her left eye with floaters. When we saw her, her VA was 20/25 in her right eye and 20/100 in her left. Figure 10 shows her ultra-widefield fluorescein angiogram.

You see there are proliferative changes. There is a subhyaloid hemorrhage and some vitreous hemorrhage as well, which is why her vision decreased in her left eye suddenly and she saw floaters. This patient has bilateral PDR. How should we treat this patient when we are worried about follow-up and adherence?

Dr. Scott: Anti-VEGF has been shown to be noninferior to PRP, but if I'm worried the patient will be LTFU, I will initiate prompt PRP. It's the most durable, cost-effective way to keep the patient from progressing. The patient could still progress on PRP, but given the barriers to appointment adherence, PRP should be considered in patients with these issues.

Dr. Kim: Do you try to do the PRP the same day when you see the patient, or do you schedule it?

Dr. Scott: We schedule it. It's reasonable to give the patient time to wrap their head around the procedure and what you've told them, and to make arrangements for a driver. But I think we need

a better system to monitor these patients who could potentially be LTFU. How many times have we seen a patient and recommend they come back in 2 weeks only to realize a year later that they've slipped through the cracks? There is some opportunity to catch these patients who are LTFU by proactively reaching out to them.

Dr. Singh: I don't perform PRP on the same day as the patient visit because it becomes too complicated. I want the patient to think about what we're doing. Anti-VEGF is a good option for temporizing them, at least for the initial parts. Then if they're truly nonadherent therapy, I'll do laser.

Dr. Kim: How do you manage patients without insurance if they want to come to see you?

Dr. Singh: It's tough. We do have patient assistance programs, and there are places we can refer them to. We have copay assistance programs, which do help. The problem with those is they run out as the year goes on. Ultimately, we encourage them to acquire insurance through the Affordable Care Act. It's available to everyone.

Dr. Kim: How do we stress the importance of early screening for DR to our primary care doctors, endocrinologists, or nurses? How do we best communicate this to people of color?

Dr. Scott: We haven't touched much on health literacy, but that is a factor. We need a good, efficient system in place where primary care and family practice doctors can easily refer these patients. Telehealth can help streamline screening and education to get patients in front of us sooner.

Dr. Singh: In the future we are planning on scheduling patients on Saturday and Sunday so a technician can do the photographs and OCT, and then call the patient back with a virtual appointment on Monday. It's a way to use our offices 7 days a week and give people flexibility to come in on a weekend and not interrupt their work week, which is a problem for many of these patients.

Dr. Kim: Many people with diabetes have part-time jobs or are working several jobs. Giving them the flexibility to see an eye doctor on evenings and weekends is important.

CLOSING REMARKS

Dr. Kim: Thank you, Dr. Scott and Dr. Singh, for your knowledge, insights, and for having this important discussion and highlighting salient points. We encourage everyone to continue the good fight in reducing health disparities so all patients regardless of race, color, and gender can see for a lifetime.

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HEALTH CARE DISPARITIES: INCREASING AWARENESS AND SEARCHING FOR SOLUTIONS IN RETINA

Release Date: May 2023
Expiration Date: June 2024

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DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
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___ NP
___ Nurse/APN
___ PA
___ Other

Years in Practice
___ >20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this educational activity)
___ 0
___ 1-15
___ 16-30
___ 31-50
____ >50

Region
___ Midwest
___ Northeast
___ Northwest
___ Southeast
___ Southwest

LEARNING OBJECTIVES

Did the program meet the following educational objectives?	Agree	Neutral	Disagree
Discuss how race and socioeconomic status impact screening, access to care, and outcomes in retinal diseases	_____	_____	_____
Identify factors within ophthalmology that may be driving health inequities	_____	_____	_____
Evaluate data on the utilization of standard-of-care treatments and clinical trial enrollment in historically marginalized populations	_____	_____	_____
Develop strategies to reduce care disparities in historically marginalized patients with retinal diseases	_____	_____	_____

POSTTEST QUESTIONS

Please complete at the conclusion of the program.

1. Based on this activity, please rate your confidence in your ability to develop strategies to reduce care disparities among historically marginalized patients with retinal diseases (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

2. Based on this activity, on a scale of 1 to 5 (with 1 being never and 5 being always), please rate how often you see in your practice the ways in which race and socioeconomic status impact screening, access to care, and outcomes in retinal diseases.
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

3. All of the following represent disparities in adult vision health in the United States EXCEPT:
   a. Vision loss and vision impairment are common with age
   b. Women at greater risk of vision loss than men
   c. Lower socioeconomic status associated with underutilization of eye care
   d. Men at greater risk of vision loss than women

4. All of the following statements about diabetic macular edema (DME) and racial disparities are true EXCEPT:
   a. The baseline VA between Black and White patients with DME is not significantly different
   b. After treatment, Black patients had better VA following anti-VEGF injections
   c. The White patients on average received a greater number of injections over a 1-year period compared to the Black cohort
   d. After treatment, White patients had better VA following anti-VEGF injections

5. You are seeing a 45-year-old native Spanish speaker for evaluation in your office. She has a history of diabetes, hypertension, hyperlipidemia, coronary artery disease, peripheral vascular disease, and obstructive sleep apnea. You note bilateral proliferative diabetic retinopathy and recommend prompt treatment. The patient lives far from your clinic but agrees to the prescribed treatment. All of the following represent risk factors for this patient being lost to follow-up EXCEPT:
   a. Primary language other than English
   b. Age <55 years
   c. Living <20 miles from clinic
   d. Having more than five comorbidities

6. A 53-year-old patient presents to your office for evaluation. On examination, you note bilateral proliferative diabetic retinopathy with DME and recommend starting monthly anti-VEGF injections. She has no insurance and worries about her ability to pay for her visit today as well as future visits. Which of the following is a step you can take to help this patient?
   a. Discuss with the patient that observation of this disease may be in her best interest
   b. Screen the patient for any clinical trials of anti-VEGFs to see if she may qualify
   c. Referral to another retina specialist
   d. Only inject one eye

7. A 45-year-old Hispanic woman presents to your office for evaluation of blurry vision. You note bilateral DME and recommend treatment. According to health care disparity research, which of the following is TRUE?
   a. This patient is more likely to be treated with bevacizumab
   b. This patient is more likely to be treated with aflibercept
   c. This patient is more likely to be treated with ranibizumab
   d. This patient is more likely to be treated with faricimab

ACTIVITY EVALUATION

Your responses to the questions below will help us evaluate this activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low____

This activity improved my competence in managing patients with this disease/condition/symptom. ____ Yes ____No

Probability of changing practice behavior based on this activity: ____High ____ Low ____No change needed

If you plan to change your practice behavior, what type of changes do you plan to implement? (check all that apply)

Change in pharmaceutical therapy ____
Change in nonpharmaceutical therapy ____
Change in diagnostic testing ____
Choice of treatment/management approach ____
Change in current practice for referral ____
Change in differential diagnosis ____
My practice has been reinforced ____
I do not plan to implement any new changes in practice ____

Please identify any barriers to change (check all that apply):

____ Cost
____ Lack of consensus or professional guidelines
____ Lack of administrative support
____Lack of experience
____ Lack of time to assess/counsel patients
____ Lack of opportunity (patients)
____ Reimbursement/insurance issues
____ Lack of resources (equipment)
____ Patient compliance issues
____ No barriers
____ Other. Please specify: _____

The design of the program was effective for the content conveyed	___ Yes	___ No
The content supported the identified learning objectives	___ Yes	___ No
The content was free of commercial bias	___ Yes	___ No
The content was relative to your practice	___ Yes	___ No
The faculty was effective	___ Yes	___ No
You were satisfied overall with the activity	___ Yes	___ No
You would you recommend this program to your colleagues	___ Yes	___ No

Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced through your participation in this activity:

____ Patient Care
____ Practice-Based Learning and Improvement
____ Professionalism
____ Medical Knowledge
____ Interpersonal and Communication Skills
____ System-Based Practice

Additional comments:

_____

This information will help evaluate this activity. May we contact you by email in 3 months to inquire if you have made these changes? If so, please provide your email address below.

_____

_____