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RT Retina Today

BREAKING BARRIERS TO CARE: RETINAL DISEASE IN AT-RISK POPULATIONS

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Breaking Barriers to Care: Retinal Disease in At-Risk Populations

CONTENT SOURCE

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

ACTIVITY DESCRIPTION

This supplement focuses on timely issues related to race and socioeconomics and how they affect patient care. The faculty discuss access to care, disease awareness among patients with the highest risk factors and treatment noncompliance.

TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists.

LEARNING OBJECTIVES

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

- **Discuss** how demographics and socioeconomics impacts patient awareness of the ocular complications of diabetes
- **Explain** the efficacy of current treatment options in specific populations
- **Develop** individualized plans for patients with diabetic eye disease who may be at higher risk for progression due to nonadherence
- **Apply** case study examples to clinical settings

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PRETEST QUESTIONS

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

1. Please rate your confidence in your ability to describe how ethnicity and socioeconomics impact patient awareness of the ocular complications of diabetes (based on a scale of 1 to 5, with 1 = "Not at all confident" and 5= "Very confident").

a. 1
b. 2
c. 3
d. 4
e. 5

2. What percentage of adults at least 40 years old have diabetic retinopathy (DR)?

a. ~10%
b. ~20%
c. ~ 30%
d. ~40%

3. Which of the following statements about the relationship between DR and socioeconomic status is TRUE?

a. Low personal-level socioeconomic status was associated with increased risk of DR and visual impairment.
b. Low personal-level socioeconomic status was associated with decreased risk of DR and visual impairment.
c. Low area-level socioeconomic status was associated with decreased DR incidence.
d. Low area-level socioeconomic status was associated with decreased DR progression.

4. According to real-world evidence on loss to follow-up in diabetic eye disease, which of the following is TRUE?

a. Government insurance holders are less likely than self-pay patients to be lost to follow-up at 6 months.
b. Self-pay patients are less likely than government holders to be lost to follow-up at 6 months.
c. There was no correlation between insurance status and loss to follow-up.
d. Government insurance holders and self-pay patients are equally likely to be lost to follow-up at 6 months.

5. All of the following are risk factors for being lost to follow-up in patients being treated for proliferative DR, EXCEPT:

a. Primary language other than English
b. Age < 55 years
c. Age > 55 years
d. Having > 5 comorbidities

6. Which factor says the most about your health?

a. Insurance status
b. Education level
c. Zip code
d. Health literacy level

7. The prevalence of diabetes is increasing everywhere, but particularly in what part of the United States?

a. Northwest
b. Northeast
c. Midwest
d. South

8. What do many insurance companies now require that prevents timely treatment of diabetic macular edema with anti-VEGF agents that physicians may be recommending?

a. Step therapy
b. Inability to treat the same day as the exam
c. Preauthorization
d. All of the above

9. What therapy has evidence of improved outcomes in patients with DME and 20/50 or worse VA?

a. Panretinal photocoagulation
b. Bevacizumab
c. Aflibercept
d. Ranibizumab

10. One reason Black patients are underrepresented in clinical trials is_____.

a. Lack of interest
b. Lack of insurance
c. Lack of transportation
d. Lack of access

Breaking Barriers to Care: Retinal Disease in At-Risk Populations

Diabetic eye disease is the leading cause of new cases of blindness in adults aged 18 to 64, with nearly 12% of patients with diabetes having some form of visual dysfunction. Nearly 28% of diabetic adults older than age 40 have diabetic retinopathy (DR), and 60% to 70% of people with diabetes have nervous system damage.[1] In the United States alone, 13% of adults have diabetes. Even more alarming, 21% of US adults with diabetes are unaware that they have it.[2] Diabetes and diabetic eye disease does not affect the population equally; socioeconomic variables play a large role in disease prevalence.[3] We also know that there is a relationship between education level and diabetes risk.[4] In the following roundtable, thought leaders in the diabetic eye disease space present cases that illustrate these disparities and discuss the challenges and potential solutions to providing equitable care to all patients.

—Ankoor Shah, MD, Moderator

DISPARITIES IN DIABETES, DIABETIC EYE DISEASE, AND OUTCOMES

Dr. Shah: Diabetes is associated with many serious comorbidities such as stroke (16% of patients with diabetes age 65 and older), diabetic neuropathy (44% of patients with diabetes), and heart disease (6% of patients with diabetes age 65 years and older).[1] Underdiagnosis of diabetes is a real challenge, with many diagnosed during their first visit to the retinal office.

Wherever you live in the United States, the prevalence of diabetes is increasing, but it is particularly high in the Southern states.[2] Diabetes is about 17% more prevalent in rural areas than urban ones, but 62% of rural counties do not have diabetes self-management education and support services.[5,6] When broken out by race, the highest overall percentage among the Black population at 16.4% (Table 1). However, the raw population data indicates that White, non-Hispanic people have the highest diabetic population at 6.4 million.[2] Looking across all minority populations, the Hispanic community has the highest number of patients with diabetes.

There are factors outside of ethnicity that are contributing to differences in outcomes. Globally, evidence of disparities in eye care have been linked to region, education, income, sex, and ethnicity. This has been shown time and again.[7] The question is, how might these factors affect patient care for diabetic macular edema (DME), and more generally, DR in the United States?

In evaluating the recent literature, stunning facts emerge. First, DR disproportionately affects Black Americans more than White Americans (32.2 per 1,000 vs 24.1 per 1,000).[8] The prevalence of DME among Black Americans is three-times greater than White Americans. Race is more of a factor than HbA1c levels for determining DME development.[9] These are interesting findings that tie-in with a real-world study by Osathanugrah et al, which evaluated at the impact of race and ethnicity on efficacy of intravitreal bevacizumab for DME in anti-VEGF treatment-naive patients.[10] They looked at visual acuity improvement after one injection when sorted by race versus after three injections. The top-line takeaway was that Black patients with DME are less likely to experience visual acuity improvements after bevacizumab therapy compared to White and Hispanic patients. Digging into those numbers a little bit, what they found specifically was that Black patients experienced lower odds of visual acuity improvement compared with White and Hispanic patients after one injection (odds 0.480, 95% CI [0.284-0.814]; $P = .006$) and three injections (odds 0.342, 95% CI [0.149-0.782]; $P = .008$) while controlling for age, sex, baseline HbA1c, baseline central macular thickness, baseline VA, laser history, injection time course, and follow-up delay (Table 2).

TABLE 1. PREVALENCE OF DIABETES IN THE UNITED STATES, POPULATION DATA[2]

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

TABLE 2. ENROLLMENT IN RANDOMIZED CONTROLLED TRIALS FOR DIABETIC MACULAR EDEMA[11-13]

Race	Share of US Population1	Share of Populationin VISTA2*	Share of Population in RISE/RIDE3^
White	76%	82%	79%
Black	13%	11%	12%
Asian	6%	2%	4%

*Study only enrolled US patients.
^Studies enrolled US and ex-US patients.

Q | How do you incorporate these types of real-world data into the clinic setting?

Yoshihiro Yonekawa, MD: This is a really fantastic paper from a safety-net hospital—Boston Medical Center—that takes care of

"Black, White, and Asian patients make up 13%, 76%, and 6% of the US population, respectively. However, when we break down by race the populations of major randomized controlled trials for DME, Black and Asian patients are underrepresented."

—Ankoor Shah, MD

a lot of patients with diabetes. In this paper, they control for many variables, but there's always a limit to how much you can use statistics to control for complex diseases such as diabetes. There are several other factors at play also that were not included in the study, including education level, insurance status, and number of comorbidities. An important comorbidity in particular is kidney disease. This is an informative study and a great representation of the Boston Medical Center experience. Whether these data can be extrapolated to the general population is still to be seen, but the authors provide a great launching pad to this complex question.

John Kitchens, MD: I agree that this is an interesting study. I think the critical question is whether there is a different mechanism of disease in Black patients that may make bevacizumab not the best choice? Perhaps they have more inflammatory mediators or perhaps they need a more durable anti-VEGF with a higher binding affinity. It's difficult to say. What this does point to though is that Black patients have suboptimal outcomes when we treat them exactly the same as we treat White or Hispanic patients. We need to clearly state this point to insurance companies. Black patients are more likely to receive bevacizumab because they're more likely to be on Medicaid or to be uninsured. We need to look at this and determine if it is something we can pivot on and find a better way to treat these patients. Then we must leverage that with insurance companies and explain that in order to do the best job possible, they must provide us with the tools; in this case, an alternative anti-VEGF agent.

Dr. Shah: Black, White, and Asian patients make up 13%, 76%, and 6% of the US population, respectively.[11] However, when we break down by race the populations of major randomized controlled trials for DME, Black and Asian patients are underrepresented. For example, White patients made up 82% and 79% of the VISTA and RISE/RIDE populations, respectively. Black patients made up 11% and 12% of those populations, respectively, and Asian patients made up 2% and 4%, respectively.[12,13] Dr. Holekamp, do these disparities in clinical trial demographics impact our ability to apply clinical trial data across all populations?

Nancy Holekamp, MD: Black patients are traditionally underrepresented in our large randomized clinical trials, which is where we obtain our best data about drugs for treating disease. There could be many reasons for this, but one is access to care and to the types of institutions that are doing the clinical trials. I agree we should pursue these data further because it's really a wake-up call. I applaud the authors for doing this real-world analysis because, for me as a single practitioner, I would never have detected this was happening in my own patients.

Dr. Shah: Let's discuss DME outcomes in light of various factors. Malhotra et al recently presented an interesting study during the Association for Research in Vision and Ophthalmology 2021 Annual Meeting.[14] This retrospective cohort study compared anti-VEGF injection use and outcomes for DME among minority groups and patients of various socioeconomic statuses. They found that baseline visual acuity between Black and White patients with DME was similar, however, White patients had better visual acuity after anti-VEGF treatment in that study (68.38 ± 14.92 vs 63.78 ± 17.65; $P = .0136$). The White patients on average also received a greater number of injections during a 1-year period compared to the Black cohort (4.93 ± 3.14 vs 3.20 ± 2.43; $P < .0001$) and had fewer no-show appointments (1.39 ± 2.08 vs 3.23 ± 3.39; $P < .0001$). There was also a correlation between living in communities with lower average incomes and receiving fewer anti-VEGF injections ($P = .0051$) and having more no-show appointments ($P = .0105$).

It's hard to say what those discrepancies are related to, whether it's insurance or other factors, but it is certainly of interest that this has happened. Does this possibly provide some of the answers as to why the outcomes were not as effective? Maybe it's not just the medicine; maybe it's how it's delivered and the frequency of delivery?

Dr. Holekamp: We've done real-world analyses that show the number of injections is certainly tied to visual acuity outcomes. If you receive fewer injections, you're going to have a worse visual acuity outcome.[15] The data on White patients having more injections during a 1-year period with a *P* value of 0.001 is striking. That *P* value is remarkable, and I think it's incumbent upon us as physicians to watch that "no-show" rate and follow-up with the patients who miss their appointments and who aren't receiving a necessary number of injections. This study echoes the study from Boston University. These racial disparities exist, and it's up to us to understand the reasons why.

Dr. Yonekawa: I think this study shows that DR is not just DR; it's a social and economic condition with a wide spectrum of

"One variable I pay particular attention to in my clinic is the zip code. Where you live plays a huge role in your outcomes because your address is generally tied to income level, health literacy, educational level, and family support."

—Yoshihiro Yonekawa, MD

nonophthalmic/nonmedical variables. Such variables in DR seem to play more of a role than they do in other common diseases like age-related macular degeneration. One variable I pay particular attention to in my clinic is the zip code. Where you live plays a huge role in your outcomes because your address is generally tied to income level, health literacy, educational level, and family support. Most retina specialists travel to different offices, and each office has its own unique patient population with different rates and severities of DR. Zip code impacts this and is something to keep an eye on.

Dr. Holekamp: In my practices, the initial visual acuity changes dramatically depending on where the office is located. A DME patient in one zip code comes in doing well initially and then a DME patient in a different zip code is counting fingers with a vitreous hemorrhage. You've probably heard the sound bite that your zip code says more about your health than your genetic code. That's true in multiple diseases, including diabetic eye disease.

Dr. Kitchens: Every Wednesday, I travel 2.5 hours to Eastern Kentucky into Appalachia and treat low-income White patients with severe DR. They do tend to make their appointments, but they have terrible disease. Eastern Kentucky is a completely different world than Lexington, Kentucky, where I practice; the patients have a completely different level of disease and level of control of their diabetes.

Dr. Shah: To your point, socioeconomics can really change the population you truly treat, and this finding can be seen on an international scale. A 2021 study out of Singapore examined links between DR outcomes and person-level socioeconomic status (including education, income, and housing type), and area-level socioeconomic status (including the socioeconomic disadvantage index).[16] This study showed that, as you would expect, low income was associated with increased DR. Worse area-level scores were also associated with greater incidents of DR.

INSURANCE STATUS CONTRIBUTES TO DISPARITIES IN DIABETIC EYE DISEASE

Dr. Shah: Perhaps more interestingly, a 2020 study of the Ontario Health Insurance Program (OHIP) records found high rates of diabetic patients who were unscreened for DR; 37% of patients in the OHIP system with diabetes hadn't been screened for DR. Toronto had the highest density of unscreened DR patients, and low income was linked with unscreened status in that city.[17] These studies validate what we are experiencing on a day-to-day level in the clinic. Many patients with lower socioeconomic status have difficulty getting DR screening.

Dr. Kitchens: In the United States, this conversation is often framed as an insurance issue, where these patients are deemed uninsured or underinsured. However, we are seeing similar trends in Canada, where they have universal health care, regarding lack of screening and poor outcomes with lower socioeconomic status. What do you make of that?

Dr. Shah: Canada has a public system with some combination of a private component. They do have a separate private system for supplemental insurance covering dentistry, mental health costs, and outpatient medications, but the vast majority exclusively use the public system. It honestly isn't clear to me why they would see this discrepancy.

However in the United States, I do think insurance status plays a role. In fact, a study recently looked at racial, ethnic, and insurance-based disparities upon initiation of anti-VEGF treatment for DME in the United States.[18] The investigators found that DME patients had higher baseline visual acuity if they were in Medicare and private insurance plans compared to Medicaid plans. I think that's something we often experience in our clinics, and it's one that's surprising.

Dr. Yonekawa: Insurance status does predict how patients present. It also directly affects what interventions we can employ.

Dr. Shah: That is a critical point. Insurance companies play a role in step therapy and what we can and cannot do.

Dr. Kitchens: It's a vicious cycle. You have patients who don't receive effective therapy, and they're going to be less likely to come back because they don't see the benefit. We need to leverage these data and explain to the insurance companies that our treatment recommendations are justified because we're doing what's best for our patients.

Dr. Holekamp: We all went to medical school thinking we would diagnose DME, we would know the clinical trial results, and we would initiate the correct therapy. What we're realizing is that there are a lot of extra factors that impact treatment decisions, such as insurance. It's critical for us as physicians to understand the external factors affecting our patient care.

Dr. Shah: Copays and location affect our initial treatment choice for DME. In 2020, a retrospective cohort study using administrative medical claims data identified 6,220 newly diagnosed DME patients.[19] They found that 48% of those patients underwent a follow-up examination within 90 days, and 48% of patients who had a follow-up examination received treatment. Having any type of copay significantly lowered the odds of receiving treatment of any kind. This is sad and unfortunately reinforces some of the negative things we think about with copays.

And while it's disappointing, it's what we would expect. For patients, copays add an extra barrier to accessing care. I completely understand that insurance companies want some cost-sharing, so the system isn't misused, but it prevents patients from seeking care. Interestingly in this study, and perhaps surprisingly, having a high deductible plan, had no impact in terms of initiating treatment.

Taking all this into consideration, I would also like to say that I take these big data studies with a grain of salt because it's hard to apply it in an individual practice setting, but these are interesting data to see.

Dr. Holekamp: When I read this paper, what struck me is how they positioned these data. They position it as patient choice, because patients themselves have a choice to have a high deductible or not and to have a copay or not. They made this a patient variable. I find that patients who chose a high deductible often tend to not seek necessary care. I think there's way more here than we can process in our busy clinics, but it is interesting.

Dr. Shah: The regional variables in the study were also interesting. When the investigators looked at the various geographies, they found that in the Northeast patients have a greater likelihood of receiving aflibercept or ranibizumab compared with bevacizumab when initiating therapy, but overall low odds of receiving anti-VEGF as initial treatment. In the Southern Midwest region, there were higher odds of any anti-VEGF agent or focal laser treatment, and in the South Atlantic, any anti-VEGF agent was the most likely choice. We see differences in terms of focal laser versus anti-VEGF, as well as what type of anti-VEGF, depending on the part of the country you were in.[19]

Q | In my practice, anti-VEGF has replaced focal laser as the primary initial therapy. Focal laser is perhaps supplemental, more of an adjuvant in select cases. What are your thoughts on these regional treatment differences?

Dr. Kitchens: I try to treat all patients with DME with aflibercept as a first-line therapy. If it's good enough for the worst patients, it should be good enough for all patients. It's shocking how often we run into a tiered therapy situation. Tiered therapy and prior authorizations are our biggest barriers to treatment. About 50% of patients with DME come back for their follow-up visit. Well, if they have a prior authorization, that is their follow-up visit. So if someone has challenges with transportation or getting off work, having this prior authorization requirement in place is a deterrent. We also try to treat patients the day they come in for an initial evaluation. Try not to delay their treatment a week or 2 because that's when you end up with high no-show rates.

Dr. Holekamp: I thought these data were shocking. Of those 6,220 patients, only a quarter were actually being treated. There are likely many reasons for this. If you can't treat them the same day, they never make it back. Many people have fear and anxiety about injections and don't want to come back. Many people don't want to pay their copay again to come back and be treated. There are many barriers to unpack here, and Dr. Kitchens has highlighted some significant areas.

Dr. Shah: Let's look at how Medicare advantage plans have changed in terms of implementing their step-therapy policies. Sometimes you have this tiered policy where you need to go through the motions and start with something you wouldn't have otherwise selected. These plans add barriers, but not insurmountable ones. The initial barrier is that having step-therapy components does add an extra hurdle for patients to receive FDA-approved medications. However, in Texas, I have been fortunate that the reasons we can provide for needing to step up to FDA approved therapy have been pretty open. Many times you have to show that the disease is not responding as well, the fluid is not going away to your satisfaction, or you're not treating at the frequency needed. You want to go longer between treatments and patients don't want to come every month. In Texas, not only are these reasons medically valid, but all of these reasons currently appear to be acceptable to insurers. I take this as a moderate positive, because they could be more stringent in their review.

Q | What have your experiences been with step therapy?

Dr. Yonekawa: Step therapy is all too common and quite frankly, very silly. We have treatments available that we know are safe and effective; why aren't we using them? Why are we going through these motions? Unfortunately, our hands are usually tied. We can move on to medications we feel are best for patients eventually, but it can take several months.

Dr. Shah: Fail-first policies create a barrier between the physician and the patient, which adds another challenge. You're saying to the patient, "I would like to do this for you, but I'm not going to do it for you." You must ally yourself with your patients and say, "I'm eventually going to get you onto the medication you need, but you're going to have to stick with me through these steps." It's an added barrier. It takes extra explaining in an already busy clinic. Fail-first policies may affect patient outcomes, lead to patient nonadherence, and have clear clinical and ethical issues.[20,21]

We all know that loss to follow-up (LTFU) is a significant challenge in diabetic eye disease. Reasons for LTFU in the literature

may be counterintuitive or contradictory. There are many studies on this, so I'll highlight one. In 2020, Green et al looked at risk factors for LTFU among patients being treated for proliferative diabetic retinopathy (PDR) and identified the following risk factors: primary language being anything other than English, age greater than 55, living less than 20 miles from a clinic, and having more than five comorbidities I can personally attest that I see these challenges in some of our satellite clinics, especially among patients with multiple comorbidities. Being in the hospital for other conditions keeps you out of the outpatient setting. Is there anything that you would add to this list?

Dr. Holekamp: This study focused on PDR, but there was a great study a few years ago looking at patients with DME.[23] They found that patients with DME on average had 25 doctor visits a year. Think about having to go to the doctor 25 times a year; that's twice a month. Now imagine adding anti-VEGF injections with every-other-month visits on that list. It's not just the PDR patients;

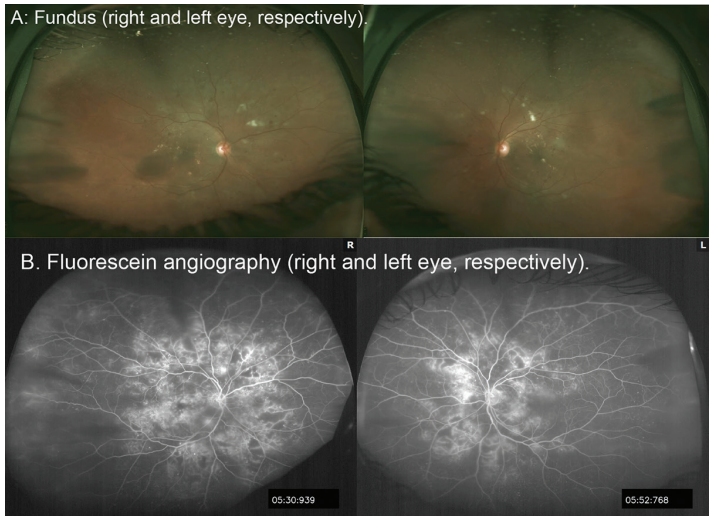

Figure 1. Case 1: Baseline fundus and fluorescein angiography.

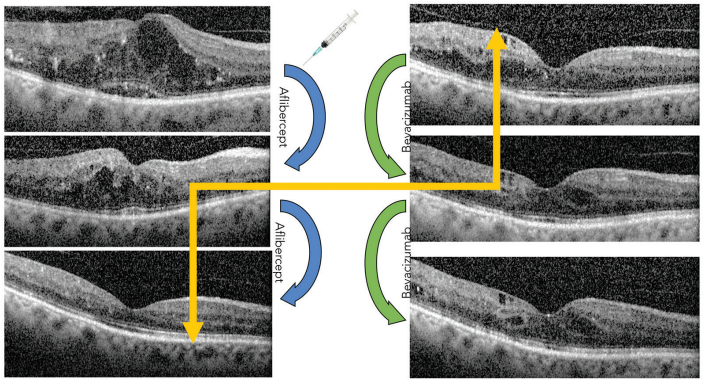

Figure 2. Case 1: Optical coherence tomography on aflibercept versus bevacizumab. OCT images of the right eye over time with anti-VEGF therapy. Initial presentation (top left) with evidence of DME, hard exudates, and subretinal fluid. Progressive improvement is noted with ongoing aflibercept therapy (middle left and bottom left). Medication is switched due to insurance changes to bevacizumab (top right) and maintained on the same anti-VEGF therapy for two additional monthly treatments (middle and bottom right respectively).

DME patients have a horrendous burden with their comorbidities and their other doctor's visits. This is a very real problem.

CASE 1: THE ETHICS OF INSURANCE REQUIRING LESS-EFFECTIVE THERAPY

Dr. Shah: Our first case is a patient of mine who was 64 years old when she first came to see me and she turned 65 as the case progressed. She is an African American female with a history of noninsulin dependent diabetes whose VA was 20/200 and 20/70 in the right and left eyes, respectively. Figure 1a shows her color photos at baseline, which reveal about what you'd expect: hard exudates, some DME, dot-blots, and cotton wool spots in both eyes. Figure 1b shows the fluorescein angiography (FA). There's a lot of leakage that can be seen throughout the right eye with less leakage in the left, without clear evidence of neovascularization. The optical coherence tomography (OCT) shows some DME, some hard exudates, and subretinal fluid.

I initiated therapy with aflibercept based on Protocol T data. Protocol T was the first trial to compare the efficacy and safety of ranibizumab, bevacizumab, and aflibercept. Visual acuity improvement was seen with all three agents, but improvement was greatest with aflibercept, particularly in patients with 20/50 or worse vision.[24] Her insurance approved aflibercept therapy.

We continued with treatment, and then she turned 65. At that time, her insurance switched to a Medicare Advantage plan. Unfortunately, she's a new patient to that Medicare Advantage plan, so I have to start over with bevacizumab even though we've had success with aflibercept. Figure 2 shows her OCT images while on aflibercept versus the OCT while on bevacizumab. She's doing okay on bevacizumab, but there is still persistent DME; it's not completely resolved. She's clearly doing worse on bevacizumab than she was on aflibercept. Fortunately, we are in the process of switching her back to aflibercept.

Q | Does anyone have an ethical dilemma with this? We know that 6 months of chronic edema leads to irreversible vision loss.

Dr. Kitchens: It depends if the patient is symptomatic. If the patient notices the difference in edema because their visual acuity declines, then I do worry they may require more frequent treatment. Protocol V was a multicenter trial across 91 sites in the United States and Canada that enrolled 702 patients with center-involved DME.[25] To be included on the trial, patients had to have a VA of 20/25 or better. They were randomly assigned to one of three management strategies: initial treatment with aflibercept every 4 weeks (n = 226), laser photocoagulation, (n = 240), or observation (n = 236). Patients in the laser and observation arms were followed at 8 and 16 weeks and were switched to aflibercept if they experienced a decrease in 2 or more lines of vision at any visit or 1 line of vision in two consecutive visits.

Although 20 and 30% of patients on observation and on laser, respectively, did receive injections by the end of the 2-year study

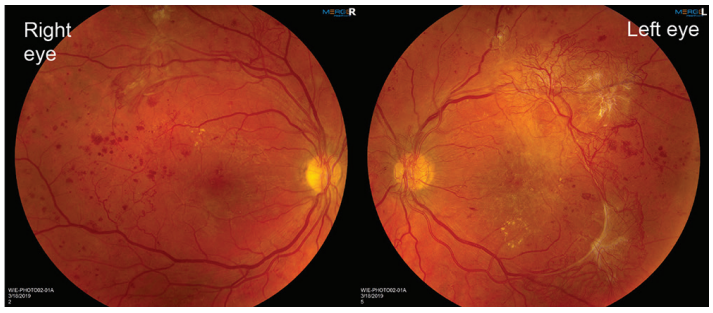

Figure 3. Case 2: Baseline fundus photographs for 33-year-old woman with type 1 diabetes.

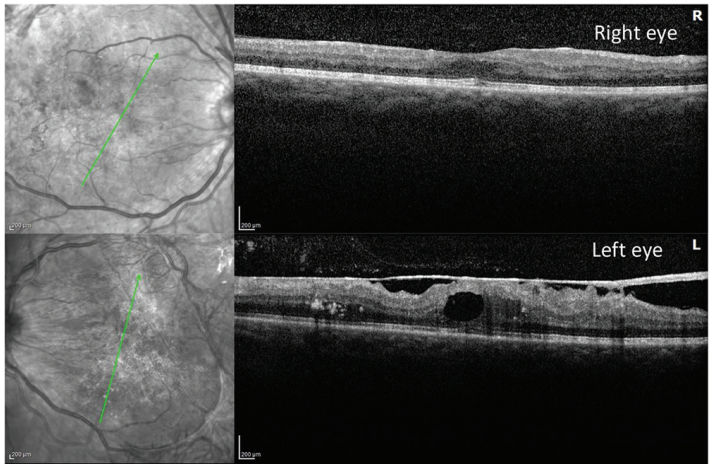

Figure 4. Case 2: Baseline optical coherence tomography.

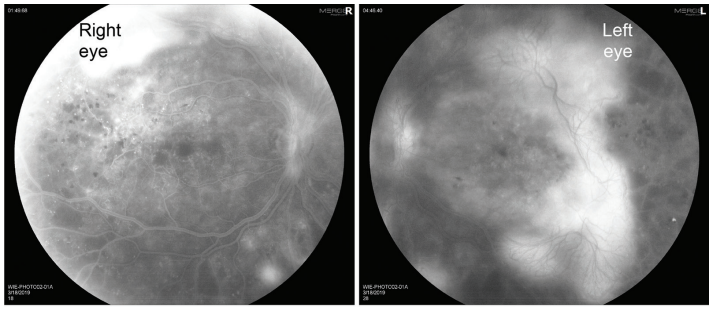

Figure 5. Case 2: Baseline fluorescein angiography.

period, the number of patients who lost 5 or more letters did not significantly differ between groups. The average VA was 20/20, just as it was at baseline. We know from these data if the patient has good vision without symptoms with this amount of edema, we can ride out the 3-month requirement before switching them back. It's only an ethical decision if you're the one who must make it. If the insurance provider is making the decision for you, there's not much you can do. I try to push the patient to talk to their insurance company directly. It may or may not work, but at least they tried.

CASE 2: TYPE 1 DIABETIC WITH PDR LOST TO FOLLOW-UP

Dr. Yonekawa: Our next case is a 33-year-old woman with type 1 diabetes from Philadelphia. Her color fundus photographs show a lot of neovascularization in both eyes, but especially in the left

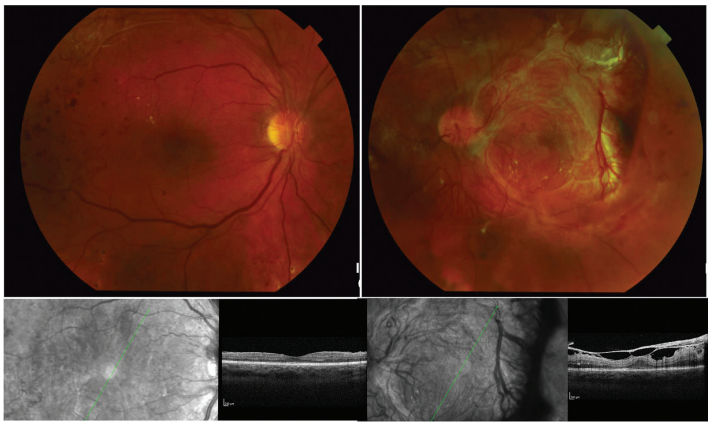

Figure 6. Case 2: Imaging after 6 months lost to follow-up. The right eye is shown on the left.

(Figure 3), in addition to the exudates, hemorrhages, and aneurysms. Her VA is 20/40 OU. She doesn't know her HbA1c, which alone may be a risk factor for delayed presentations and poor outcomes. She is on a Medicaid plan. The macular OCT of her right eye looks good overall, but there is some thinning and neuronal loss in the left eye (Figure 4). There is more edema, and a tractional retinal detachment from the contractile posterior hyaloid.

The FA shows a lot of leakage (Figure 5). We started her with sample injections of aflibercept. Thankfully, we had samples because her insurance required a specialty pharmacy order that would require medication to be shipped to us, which could take some time to set up and thus significantly delay treatment. We followed the injections with panretinal photocoagulation (PRP) in both eyes. However, she missed multiple appointments shortly after.

She returned 6 months later. Her right eye was doing well, but the neovascularization and traction was worsening in her left eye (Figure 6). Her VA was 20/60, but it is declining, and the images reveal the eye is approaching the tipping point of very poor outcomes. Her widefield imaging showed the tractional retinal detachment in the left eye is progressing and her right eye has persistent neovascularization. She told us she lost her health insurance, assumed she couldn't do anything, and didn't answer our calls. She is currently undergoing surgical treatment. Loss of health insurance is a big reason why patients miss appointments, especially during the past 2 years. Many people were laid off from their jobs during the COVID-19 pandemic and lost health insurance. Fears of COVID infection caused massive numbers of patients to delay care. Many were also hospitalized from COVID-19 and related complications. LTFU is a major problem right now.

CASE 3: TYPE 2 DIABETIC EXPERIENCING HOMELESSNESS WHO NOW LIVES IN A NURSING HOME

Dr. Holekamp: Our next case is a 53-year-old White female who presented on a referral from her nursing home. Your antenna should be up right away. She's 53, in a nursing home, and the chief complaint isn't that *she* says she's not seeing well, the folks at the nursing home say that she's not seeing well. She was found sleep-

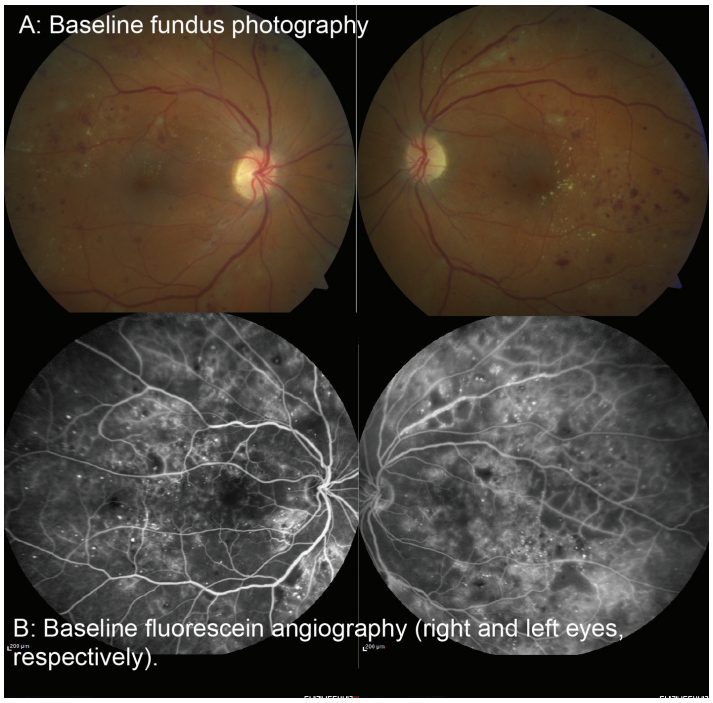

Figure 7. Case 3: Baseline imaging for a patient with type 2 diabetes and no access to health care.

ing on a park bench in Texas, so she's experiencing homelessness. She was brought to Missouri to live with her estranged son and, at the time, she was found to have a uterine mass. Her gynecologist helped her acquire Medicaid coverage so he could do surgery. The tumor was, thankfully, benign. While she was hospitalized, she was diagnosed with diabetes.

Clearly, she's had diabetes for some time, but she had no access to health care. She was recovering from her surgery in the nursing home, had Medicaid, and the plan was for her to live there long-term because otherwise she was homeless. She presented with VA of 20/400 in the right eye, 20/80 in the left eye, and significant cataract. We removed her cataracts, put in standard lenses, and now her VA is 20/63 and 20/80. Figure 7 shows her baseline imaging. She has a moderately severe to severe nonproliferative DR, a lot of lipid exudates, a lot of venous dilation, and even some intraretinal microvascular abnormalities. She also has a lot of areas of nonperfusion and diffuse leakage, but she's not proliferative yet. Remarkably she has no DME, but as we all know from the PANORAMA study, her risk for severe vision loss is about 50% during the next 12 months.[26] I'm very worried about this patient.

As I'm sure you all know, treating a patient with Medicaid or Medicare who is in a nursing home is tricky and fraught with complicated paperwork. We were able to enroll the patient in a clinical trial, and the study will pay for treatments in her fellow eye, if needed. I now have a way to give her free care for both eyes, and the study provides transportation to all study visits. The study will actually pay her $100 per visit. She has no other income. The study goes for 2 years, plus an extension trial. I feel extremely fortunate that we were able to find an avenue to protect and preserve the vision for this patient who had very few additional resources.

Dr. Shah: Kudos to you, Dr. Holekamp, for thinking out of the box and coming up with a solution. This is a clever solution that contributes to research and gives her the best possible outcome.

Dr. Kitchens: We enroll some patients who are uninsured or underinsured into clinical trials. Interestingly, they make most—if not all—their appointments.

Dr. Holekamp: They never miss.

Dr. Kitchens: There's a disconnect here. It may be transportation,

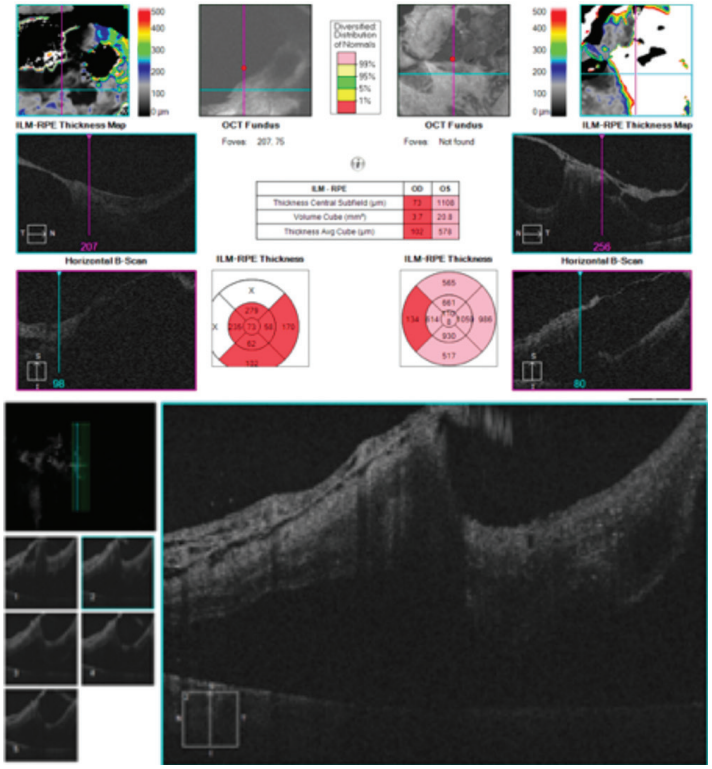

Figure 8. Case 4: Baseline imaging of patient with Moyamoya disease and history of drug abuse.

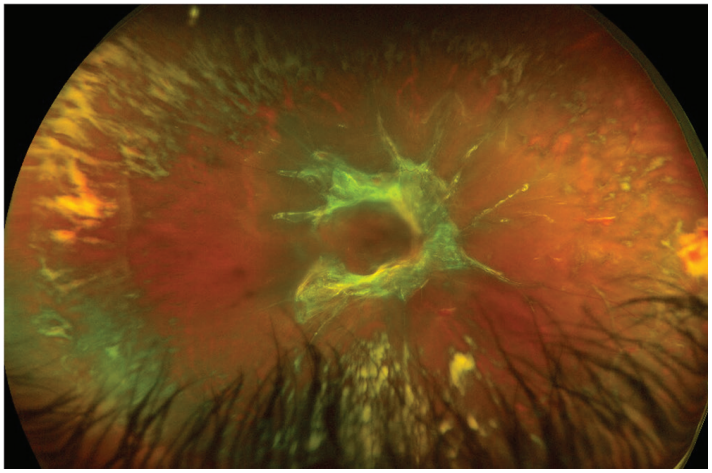

Figure 9. Case 4: Fundus photography of right eye.

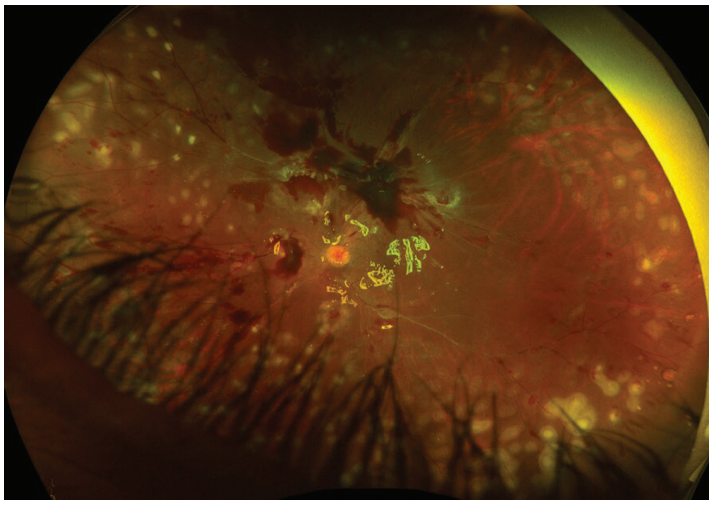

Figure 10. Case 4: Postoperative fundus photography (left eye).

because those patients are the best at following up on trials and not missing those appointments.

Dr. Holekamp: I agree 100%, Dr. Kitchens.

CASE 4: PATIENT WITH MOYAMOYA DISEASE AND HISTORY OF DRUG ABUSE

Dr. Kitchens: Our next case is a patient with a cruel combination of factors. The patient is a 38-year-old African American man with well-controlled diabetes, and an HbA1c of 6.3%. He was recently diagnosed with Moyamoya disease and has a history of methamphetamine use. The combination of diabetes and drug abuse, especially methamphetamines or cocaine, is terrible. His VA is 3/200 and 21/50. Figure 8 shows his OCT prior to surgery. He presented with bilateral macula-off detachment. Figure 9 shows his right eye at a postoperative follow-up visit for his left eye. He had one of the worst diabetic tractional detachments/vascular retinal detachments that I've tackled in quite a while. Fortunately, we gave him anti-VEGF therapy before surgery, which is absolutely essential for our patients who have these acute presentations. There's so much difference made by giving an anti-VEGF injection prior to surgery that it cannot be emphasized enough. We were able to repair his retinal detachment with surgery, and put the patient under silicone oil. With silicone oil, if the patient bleeds after surgery, it tends to be isolated under the oil. As long as that hemorrhage is not over the macula, the patient will have decent vision. Figure 10 shows the patient's left eye postoperatively.

Interestingly, the patient returned, and his VA was 20/400 from 3/200. He was very happy. A week after his surgery, he had a stroke. It's such a tragedy. He's now in a long-term treatment facility. It's a heartbreaking story.

CASE 5: PATIENT WITH UNCONTROLLED DIABETES AND SUDDEN VISION LOSS

Dr. Kitchens: Our next patient case is a brighter story. This is a 41-year-old patient with an HbA1c of 14%. She's a smoker. She

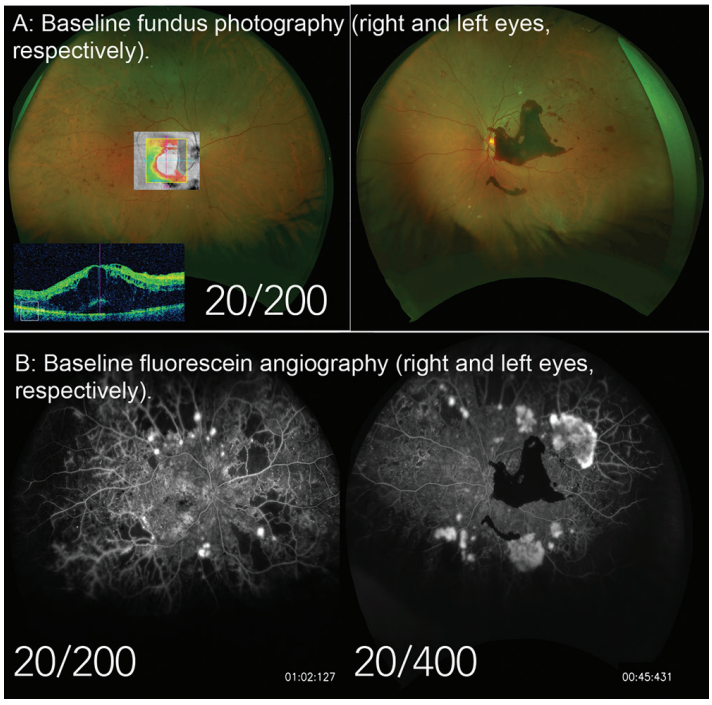

Figure 11. Case 5: Baseline imaging for 41-year-old patient with 14% HbA1c.

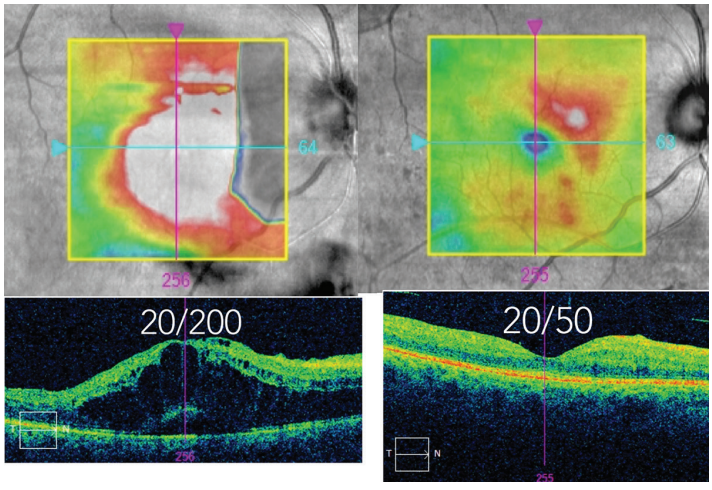

Figure 12. Case 5: Right eye after anti-VEGF and panretinal photocoagulation treatment.

only came in to see me because she had a sudden loss of vision in her left eye. She had a gradual loss of vision in her right eye and figured she needed glasses, but "didn't have time for that." Figure 11 shows her baseline imaging. There are areas of neovascularization and nonperfusion. Prior to anti-VEGF therapy, there is zero doubt her left eye was going to need surgery, but with a combination of anti-VEGF therapy and PRP laser treatment, we were able to improve her vision in the right eye and stabilize the left eye without surgery. The OCTs of her right eye show just how dramatic her improvement was (Figure 12). Her VA was 20/200, and we started her on bevacizumab. We were able to switch her to ranibizumab and then later to aflibercept, which allowed us to extend her visits.

The VA in her right eye changed from 20/200 to 20/40, then worsened to 20/50 before eventually improving to 20/25. The VA in her left eye was around 20/70 with some macular atrophy from nonperfusion, with treatment. What is really remarkable is that after PRP and anti-VEGF, her left eye did not need surgery. The biggest impact on her life is what she was able to do outside of her eyes. She said, "I was finally able to see how this was affecting me." She is not an educated person, but she's an intelligent person and she had great insight into the gravity of her disease at the point that she lost her vision.

Her HbA1c now is rarely above 7%. She's lost 100 pounds and stopped smoking. She said, "I wouldn't be alive if it wasn't for my eyes going bad," because it was that wake-up call she needed. She rarely, if ever, misses an appointment. I see several of her family members now because most of them have diabetes and eye problems and she's educated them about their diabetes and their eyes. She's become an advocate in her community. She's an amazing person and still has struggles, but fortunately is still alive and making a big difference for others.

Dr. Shah: These are great cases. Your point about anti-VEGF therapy prior to surgery is critical. It totally changes the game. Under this pretreatment therapy, broad sheets of neovascularization can contract and the connections to the retinal vasculature condense to small pegs that are substantially easier to peel during surgery and significantly less likely to bleed. It makes a remarkable difference on surgical intensity and outcomes.

Our last case is a reminder of the amazing things we can do with our armamentarium of current therapy. It really is a privilege to take care of these patients. With that in mind, I want to thank you all for joining me to discuss this important topic. ■

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INSTRUCTIONS FOR CME CREDIT

To receive credit, you must complete the attached Pretest/Posttest/Activity Evaluation/Satisfaction Measures Form and mail or fax to Evolve Medical Education LLC; 353 West Lancaster Avenue, Second Floor, Wayne, PA 19087; Fax: (215) 933-3950. To answer these questions online and receive real-time results, please go to http://evolvemeded.com/online-courses/2123-supplement. If you experience problems with the online test, please email us at info@evolvemeded.com. Certificates are issued electronically, therefore, please provide your email address below.

Please type or print clearly, or we will be unable to issue your certificate.

Full Name_____

Phone (required) _____ Email (required) _____

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City _____ State/Country____ Zip/Postal Code_____

License Number _____ OE Tracker Number _____

DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ OD
___ 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 activity)
___ 0
___ 1-15
___ 16-30
___ 31-50
___ >50

Region
___ Northeast
___ Northwest
___ Midwest
___ Southeast
___ Southwest

Setting
___ Solo Practice
___ Community Hospital
___ Government or VA
___ Group Practice
___ Other
___ I do not actively practice

Models of Care
___ Fee for Service
___ ACO
___ Patient-Centered Medical Home
___ Capitation
___ Bundled Payments
___ Other

LEARNING OBJECTIVES

Did the program meet the following educational objectives?	Agree	Neutral	Disagree
Discuss how demographics and socioeconomics impacts patient awareness of the ocular complications of diabetes	_____	_____	_____
Explain the efficacy of current treatment options in specific populations	_____	_____	_____
Develop individualized plans for patients with diabetic eye disease who may be at higher risk for progression due to nonadherence	_____	_____	_____
Apply case study examples to clinical settings	_____	_____	_____

POSTTEST QUESTIONS

Please complete at the conclusion of the program.

1. Based on this activity, please rate your confidence in your ability to describe how ethnicity and socioeconomics impact patient awareness of the ocular complications of diabetes (based on a scale of 1 to 5, with 1 = "Not at all confident" and 5= "Very confident").

a. 1
b. 2
c. 3
d. 4
e. 5

2. What percentage of adults at least 40 years old have diabetic retinopathy (DR)?

a. ~10%
b. ~20%
c. ~ 30%
d. ~40%

3. Which of the following statements about the relationship between DR and socioeconomic status is TRUE?

a. Low personal-level socioeconomic status was associated with increased risk of DR and visual impairment.
b. Low personal-level socioeconomic status was associated with decreased risk of DR and visual impairment.
c. Low area-level socioeconomic status was associated with decreased DR incidence.
d. Low area-level socioeconomic status was associated with decreased DR progression.

4. According to real-world evidence on loss to follow-up in diabetic eye disease, which of the following is TRUE?

a. Government insurance holders are less likely than self-pay patients to be lost to follow-up at 6 months.
b. Self-pay patients are less likely than government holders to be lost to follow-up at 6 months.
c. There was no correlation between insurance status and loss to follow-up.
d. Government insurance holders and self-pay patients are equally likely to be lost to follow-up at 6 months.

5. All of the following are risk factors for being lost to follow-up in patients being treated for proliferative DR, EXCEPT:

a. Primary language other than English
b. Age < 55 years
c. Age > 55 years
d. Having > 5 comorbidities

6. Which factor says the most about your health?

a. Insurance status
b. Education level
c. Zip code
d. Health literacy level

7. The prevalence of diabetes is increasing everywhere, but particularly in what part of the United States?

a. Northwest
b. Northeast
c. Midwest
d. South

8. What do many insurance companies now require that prevents timely treatment of diabetic macular edema with anti-VEGF agents that physicians may be recommending?

a. Step therapy
b. Inability to treat the same day as the exam
c. Preauthorization
d. All of the above

9. What therapy has evidence of improved outcomes in patients with DME and 20/50 or worse VA?

a. Panretinal photocoagulation
b. Bevacizumab
c. Aflibercept
d. Ranibizumab

10. One reason Black patients are underrepresented in clinical trials is_____.

a. Lack of interest
b. Lack of insurance
c. Lack of transportation
d. Lack of access

ACTIVITY EVALUATION

Your responses to the questions below will help us evaluate this CME 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

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:

_____

_____ I certify that I have participated in this entire activity.

This information will help evaluate this CME activity; may we contact you by email in 3 months to see if you have made this change? If so, please provide your email address: _____

_____