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NAVIGATING THE WORLD OF RETINA:

Updates for the Newer Retina Specialist

Dean Eliott, MD
SriniVas Sadda, MD
Gaurav K. Shah, MD

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Updates for the Newer Retina Specialist

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FACULTY

DEAN ELIOTT, MD
Director, Retina Service
Massachusetts Eye and Ear
Stelios Evangelos Gragoudas Professor
Harvard Medical School
Boston, Massachusetts

SRINIVAS SADDA, MD
President, Doheny Eye Institute
Professor of Ophthalmology
Department of Ophthalmology
David Geffen School of Medicine at UCLA
Los Angeles, California

GAURAV K. SHAH, MD
Partner, The Retina Institute
St. Louis, Missouri

CONTENT SOURCE

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

ACTIVITY DESCRIPTION

Retinal disorders, including age-related macular degeneration (AMD) and diabetic macular edema (DME), can result in vision loss if not treated early and—in most cases—continuously. The need for newer retina specialists to be fully educated on the various treatment options remains crucial to delivering the best patient care. In addition, retina specialists new to practice must also navigate the business aspects of their clinics.

TARGET AUDIENCE

This certified CME activity is designed for newer retina specialists involved in the medical management of patients with retinal disorders.

LEARNING OBJECTIVES

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

- **Summarize** the most recent clinical study evidence using available therapies for AMD and DME.
- **Identify** treatments under investigation for AMD and DME.
- **Develop** individualized treatment plans for patients with retinal disorders that use a combination of imaging, treat-and-extend, or treat-and-observe approaches.
- **Evaluate** practice flow to determine the most efficient patient experience.
- **Establish** and **Implement** plans to reduce reimbursement denials.

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1. Rate your level of confidence in your ability to determine when to treat a patient with diabetic macular edema (DME).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very confident

2. Rate your level of confidence in your ability to determine when to extend a patient being treated with anti-VEGF therapy for neovascular age-related macular degeneration.

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very confident

3. After performing an intravitreal injection, how often do you tell patients to contact the office for any pain, decreased vision, pus, or discharge (on a scale of 1-5, where 1=never and 5=always)?

a. 1 (Never)
b. 2
c. 3
d. 4
e. 5 (Always)

4. Which of the following is NOT true?

a. Failure to diagnose a condition (such as retinal detachment) is the most common claim in ophthalmology.
b. Regarding intravitreal injections, delay in the diagnosis and treatment of endophthalmitis is the most common claim.
c. Regarding intravitreal injections, there have been no claims of drug choice (bevacizumab, ranibizumab, aflibercept) and no claims of floaters due to silicone oil droplets from compounded bevacizumab.
d. Retinopathy of prematurity claims have the highest payments to plaintiffs.

5. The FLUID study demonstrated that in treatment of neovascular age-related macular degeneration with anti-VEGF therapy:

a. Zero tolerance of any fluid is essential to achieve optimal visual outcomes.
b. Intraretinal fluid is associated with better visual outcomes than sub-retinal fluid.
c. Interval between injections can be extended when mild amounts of subretinal fluid are present.
d. Monthly therapy should be continued until pigment epithelial detachments are flattened.

6. Does EBITDA refer to the evaluation done for private equity deals to obtain a multiplier?

a. Yes
b. No

7. According to the DRCR.net Protocol V clinical trial, _____ is a reasonable approach for managing an asymptomatic patient with good vision and center-involved DME.

a. Monthly aflibercept injections
b. Observation
c. Focal laser treatment
d. Steroid injections

8. What is the most critical step an ophthalmologist can take in order to avoid a lawsuit?

a. Document every interaction with and test on the patient
b. Have consistent, frequent communication with the patient
c. Do not appear rushed during an appointment
d. Know and practice the standard of care

9. The Centers for Medicare & Medicaid Services is planning on reimbursement cuts to which retinal procedures?

a. Vitrectomy
b. Laser panretinal photocoagulation
c. Intravitreal injections
d. A and B
e. B and C
f. A and C

10. The period of time before a lawsuit is filed is called _____.

a. Discovery
b. Malpractice
c. Intent to file suit
d. Plaintiff

Navigating the World of Retina: Updates for the Newer Retina Specialist

Retinal disorders, including age-related macular degeneration (AMD), diabetic retinopathy (DR), and diabetic macular edema (DME), can result in vision loss if not treated early and—in most cases—continuously.[1-3] Significant challenges lie ahead in addressing these patients' needs, as providers are being tasked with treating an increasing number of patients due to the aging population and growing prevalence of diabetes.[4-6]

Early-career retina specialists must also navigate the business aspects of their clinics to make educated decisions on selling a practice or joining a practice that may be sold to a private equity firm. Further, in today's increasingly litigious society, it's vital for physicians to understand how to protect themselves from a lawsuit; ophthalmologists are no exception.[7]

The following discussion brings together thought leaders in the treatment of retinal disorders to review how to treat commonly seen cases. Panelists also provide business and malpractice advice invaluable to any early-career ophthalmologist.

— SriniVas Sadda, MD, Moderator

MANAGING DIABETIC PATIENTS IN THE REAL WORLD

By 2035, it is estimated that about 600 million people worldwide will be living with diabetes, a significant increase from the 382 million in 2013.[8] DR is the most common ocular complication of diabetes and leads to more than 10,000 new cases of blindness in the United States each year.[9] Approximately 33% of diabetic patients will develop DR.[6]

There are two types of DR: nonproliferative and proliferative. Nonproliferative DR (NPDR) will advance to proliferative diabetic retinopathy (PDR) if not properly managed.[10] Up to 10% of patients with mild NPDR will progress within a year.[11] Once a patient has severe or very severe NPDR, progression to PDR is very likely within a year at 50% and 75%, respectively.[12]

Approximately 11% of patients with diabetes will develop DME.[6] For many years, the standard of care for DME treatment was laser photocoagulation.[13] However, anti-VEGF agents are now considered the first-line therapy for center-involved DME (CI-DME) based off the strength of multiple clinical trials.[14-17] The American Academy of Ophthalmology's (AAO) guidelines note laser photocoagulation is still the preferred treatment for non-center-involving DME.[18]

The cornerstone of successful DR and DME management is yearly eye exams, at minimum, and proper glycemic control. Loss to follow-up remains a significant issue with these patients. The AAO found that upwards of 40% of people with diabetes forego annual eye appointments to screen for ophthalmic complications.[18] Gao et al found that one in four patients with NPDR didn't return for follow-up after their first anti-VEGF injection.[19]

The following cases provide real-world examples of common clinical scenarios early-career retina specialists can expect to face when managing patients with diabetes.

Case 1: Mild NPDR With Good Vision

SRINIVAS SADDA, MD: Our first case is a 64-year-old patient with mild NPDR who has been diabetic for some time. Until recently, her NPDR was well controlled. During her annual follow-up exam, I noticed that her vision was down slightly to 20/25 in her right eye, but she hadn't noticed visual changes. Her exam showed mild NPDR and edema that had just creeped into the center, which presumably explains her vision loss. At this point we have four courses of action for this patient: observation only, anti-VEGF therapy, steroids, or focal laser treatment. Which would you pick and why?

GAURAV K. SHAH, MD: Given that the patient is asymptomatic, I'd select observation. I think clinical practice and studies have shown that observation is quite appropriate for these patients. I don't like to treat patients who are asymptomatic and have good vision.

DEAN ELIOTT, MD: I would also observe. This was the subject of a recent DRCR.net study, and observation was a reasonable approach.

DR. SADDA: What does the literature tell us about how to treat this patient? The DRCR.net Protocol V clinical trial specifically looked at how to treat patients with CI-DME and very good vision.[20]

The trial was conducted at 91 sites in the United States and Canada and included 702 adults with type 1 or type 2 diabetes. Patients were randomly assigned to 2.0 mg of aflibercept (n = 226) every 4 weeks, focal/grid laser photocoagulation (n = 240), or observation (n = 236). The primary outcome was at least a 5-letter visual acuity (VA) decrease from baseline at 2 years. At 2 years, 16%, 17%, and 19% of eyes had at least a 5-letter VA decrease in the aflibercept, laser photocoagulation, and observation groups, respectively (Figure 1). Further, 27%, 25%, and 21% of patients had at least 5-letter gain at 2 years with aflibercept, laser photocoagulation, and observation, respectively (Figure 2). Very few patients lost even a line of vision regardless of the treatment strategy. Given that there

Figure 1. DRCR.net Protocol V clinical trial primary outcome data: letter loss experienced with aflibercept versus laser versus observation.

Figure 2. DRCR.net Protocol V clinical trial secondary outcome data: letter gain achieved with aflibercept versus laser versus observation.

was no significant difference in vision loss between the groups, the researchers concluded that observation without treatment may be a reasonable strategy unless VA worsens.

DR. ELIOTT: This is assuming the patient comes back for follow-up exams.

DR. SADDA: That's a fair point. If you choose to observe the patient, you'll only know if they progress if they come in for follow-up exams. Presumably patients who progress will also have vision loss. That could trigger them to come in, but there's no guarantee. If you suspect a patient will not return for follow-up, that may impact your approach. There are classic considerations that impact our management of diabetic patients. It makes a difference if they're poorly compliant, have poor systemic control, will need cataract surgery soon, or have concomitant, more severe retinopathy.

That said, I'd argue that a single anti-VEGF injection won't have a long-term impact anyway; you'd need to consider laser treatment. The takeaway message is that a relatively low percentage of patients will progress and need treatment. What does this mean for nonfoveal macular edema? Does anyone laser for this situation currently?

DR. SHAH: Sometimes. I laser those patients occasionally prior to having cataract surgery. Depending on the follow-up of the patients, if compliance is not great, focal laser might be appropriate for a small, select few where microaneurysms are noted in the extrafoveal region.

DR. ELIOTT: I very rarely use focal laser. I agree with Dr. Shah that focal laser is a reasonable approach for the few patients who have microaneurysms within an area of extrafoveal edema and may have difficulty with compliance.

Case 2: Very Severe NPDR Treated With Anti-VEGF

DR. SADDA: Our second case is of a 51-year-old Latino male who has had diabetes for 5 years. He presented with blurry vision in the right eye and also had very severe NPDR in addition to CI-DME. The patient was treated with anti-VEGF therapy, which resolved the DME and improved the retinopathy within 4 months. Should treatment continue? What are the next steps?

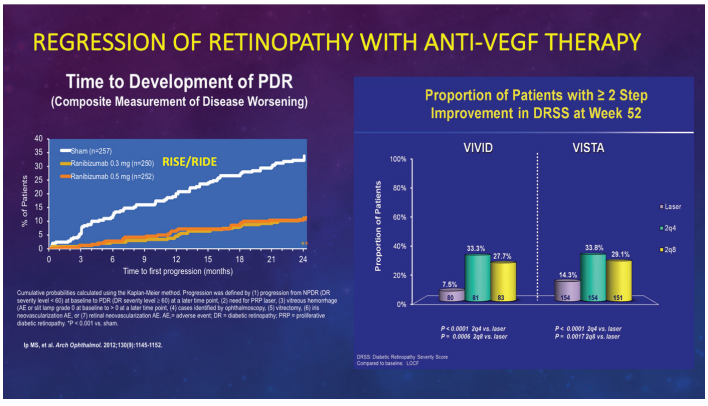

Figure 3. Key RISE/RIDE clinical trial data.

DR. SHAH: I've found it difficult to convince asymptomatic patients to continue with injections. I'm not sure I would continue to treat this patient if they're totally asymptomatic. Now, if you do wide-angle angiography and you find large areas of nonprofusion, then you know there's a potential that the retinopathy will worsen.[21]

DR. SADDA: The RISE/RIDE trials showed that intravitreal ranibizumab reduced the risk of DR progression in eyes with DME, and many ranibizumab-treated eyes experienced improvement in DR severity (Figure 3).[22] Post-hoc analyses showed at least a 2-step improvement with ranibizumab 0.3 mg at month 24. For patients with baseline moderate to severe NPDR levels, ranibizumab reduced the chance of a new PDR event at month 36 by three times compared with sham treatment.[22] After 36 months, 500 of 582 patients rolled over to the open-label extension of RISE/RIDE and were treated with pro re nata (PRN) ranibizumab 0.5 mg based on predefined DME retreatment criteria. Between month 36 and 48, 24% did not require ranibizumab. Diabetic Retinopathy Severity Score (DRSS) improvements with ranibizumab were maintained in more than 70% of open-label extension patients after switching to a PRN dosing regimen.[23]

Patients in RISE/RIDE were treated almost monthly for 3 years, and then they could transition to PRN. To me, the bottom line is that a significant proportion of patients who required additional therapy were treated very infrequently, yet the majority still had DRSS improvements. There seemed to be some actual disease

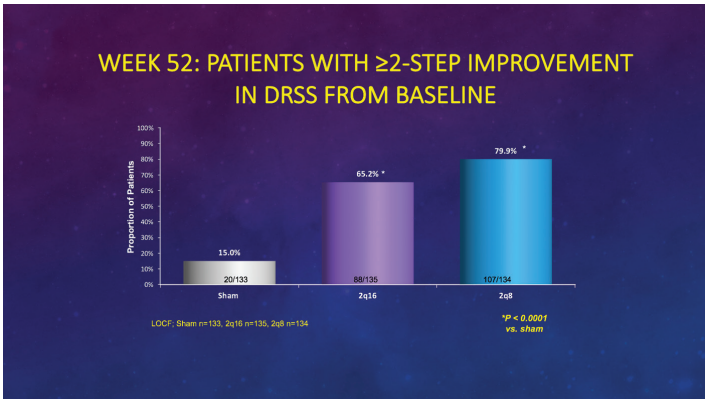

Figure 4. PANORAMA clinical trial data: aflibercept every 8 weeks versus aflibercept every 16 weeks.

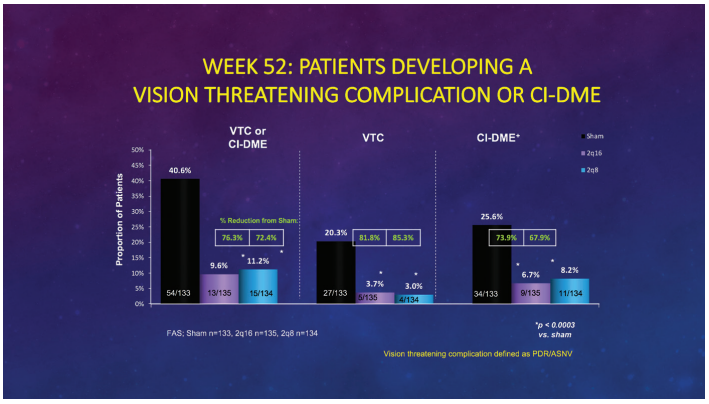

Figure 5. Vision-threatening complications in PANORAMA.

modification, at least to the visible retinopathy. Given that DRSS improvements can be maintained with less frequent PRN therapy, this may warrant consideration of earlier intervention, especially in patients with moderately severe and severe NPDR or higher.

DR. ELIOTT: The other thing you have to recognize is that in diabetic patients, sometimes their vascular status improves; their hypertension gets better and their kidney function improves. It's not your anti-VEGF injections that are doing it, it's really their systemic diseases that are improving. As they come into the office, they become more aware of how to take care of themselves. RIDE/RISE had patients who were consistently coming in for follow-up exams and treatment. Compliant study patients are very different from the patients we see every day.

DR. SADDA: You're right; that is an important caveat. Another point to consider is that DRSS assessment was a post-hoc analysis of the RIDE/RISE trials data. We do, however, have a randomized trial—PANORAMA—that studied this question.

PANORAMA was a phase 3, double-masked, randomized study that examined at the safety and efficacy of intravitreal aflibercept for moderately severe to severe NPDR. A total of 402 patients were randomly assigned to one of three groups: sham (n = 133), aflibercept every 16 weeks (n = 135), or aflibercept every 8 weeks (n = 134). The primary endpoint was at least a 2-step improvement on DRSS score from baseline.[24]

The results were profound. The proportion of patients with at least a 2-step improvement in DRSS was significantly greater with aflibercept; 80% of patients who received aflibercept every 8 weeks and 65% of patients who received aflibercept every 16 weeks met the primary endpoint compared with only 15% of patients in the sham group (Figure 4). Importantly, the proportion of patients who developed a vision-threatening complication was significant in the sham group, and that was defined as being either PDR or anterior segment. Furthermore, vision-threatening complications and CI-DME occurred in a substantially greater proportion of sham patients (Figure 5). Based on these data, aflibercept was approved for this indication in May 2019. Two-year data are pending.

The bottom line is a substantial proportion of patients, just like in RISE/RIDE, had an improvement in their retinopathy score. This, of course, doesn't address the issue of compliance. But I think aflibercept treatment is worth discussing with your patients.

AMD: MANAGING PERSISTENT FLUID AND ANTI-VEGF NONRESPONDERS

By 2040, it is estimated about 228 million people worldwide will be diagnosed with AMD. If left untreated, more than 40% of patients with neovascular AMD (nAMD) may lose 6 lines of vision (or more) within 3 years.[25] Anti-VEGF treatment been shown to improve vision by 6 to 10 letters, and extension studies have found between 33% and 38% gaining at least 15 letters from baseline.[26-28] Anti-VEGF agents (ranibizumab, aflibercept, and bevacizumab) are considered the standard of care for AMD treatment.

That said, about 10% of patients won't respond to treatment, and more than half won't significantly improve.[29] The PAT Survey found about 78% of all respondents consider three to six injections sufficient to determine adequate patient response, and lacking optimal responses, most physicians would consider switching agents.[30] Although switching can reduce fluid,[31,32] it's unclear if switching will improve visual outcomes; clinical trials have found that visual gains could not be maintained long term.[33,34]

The next cases provide real-world examples of common clinical scenarios early-career retina specialists will face when treating AMD patients.

Case 1: Persistent Fluid in AMD

DR. SADDA: Our first case is a patient with 20/40 vision and AMD who had persistent fluid after monthly aflibercept therapy. I switched him to ranibizumab, and initially thought there was less fluid. However, after multiple ranibizumab injections, I still couldn't get him dry. I went back to aflibercept, and it was the same situation; I initially thought they were getting better, but realized the disease state was the same.

After more than 25 monthly injections and no extension, he still has fluid but good vision. What do you do about the persistent fluid?

DR. SHAH: I'd like to see them back, but sometimes you can't get

rid of all the fluid. I've had some patients whose vision actually worsened after the fluid has gone away. Patients care about their vision, not about what's on the OCT. If you give them anti-VEGF therapy 2 weeks later and the fluid is exactly the same, then maybe the drugs we have aren't going to work on their disease.

DR. SADDA: Dr. Shah brings up a great point. Anytime I have a patient who doesn't seem to be responding to therapy, I will do a 2-week test to see if there is a reduction in fluid at 2 weeks. If there's no change in 2 weeks, then you have to question if the disease process is responsive to VEGF and consider a confounding diagnosis. For example, sometimes these patients have polypoidal choroidal vasculopathy (PCV), central serous chorioretinopathy (CSCR), or CNV complicating CSR, and you're not sure which is the contributor to the fluid. Is it the CNV? Sometimes it's not because we know CNVs can be quiescent, but it's actually the CSR.

DR. SHAH: The drugs we have don't address all the problems in that lesion, and that's okay. If you bring them back in 2 weeks and they aren't worse, then you know it's not a persistent problem either. This is a way to judge really what's going on when drugs are given since intervals are quite long otherwise.

Case 2: Ongoing Subretinal Fluid in AMD

DR. SADDA: We're now going to look at patients who we think are VEGF-responsive, but also need frequent anti-VEGF treatment. Our next patient has 20/20 vision and has had subretinal fluid for the last 2.5 years. It's remained stable without treatment (Figure 6). The treating ophthalmologist suspected CNV, but the patient improved on their own. That happens in patients with fluctuating fluid; we've all seen cases like that. These patients need frequent follow-up. Tolerating fluid is a controversial topic, and the FLUID study attempted to answer the question of if we can tolerate some fluid in our treatment protocols.

FLUID was a phase 4, randomized, controlled, single-masked study that investigated the efficacy and safety of ranibizumab treat-and-extend using an intensive retinal fluid retreatment regimen compared to a relaxed retinal fluid retreatment regimen in patients with AMD.[35,36] A total of 349 patients with one treatment-naive eye were randomly assigned 1:1 to either intensive or relaxed fluid management. The full study design is outlined in Figure 7.

Patients received three doses of ranibizumab, and then they went into a treat-and-extend regimen. The investigators set 200 µm of subretinal fluid as the cutoff—if at any time the patient had more than 200 µm of fluid, they were treated. The vision outcomes were the same. Patients treated with a relaxed treat-and-extend protocol that tolerated some fluid achieved similar VA but with much fewer injections to those patients who underwent an intensive treatment regimen that sought to resolve the fluid completely (Figure 8).

The clinical implication is that some residual subretinal fluid may be tolerated in the short-term. That said, I have some issues with this study. First, the visional gains in the study were not very good at only 3 letters. In addition, intraretinal fluid was tolerated if it was thought to be due to degenerative cysts, but it may not be easy to distinguish degenerative from active cysts. We also don't have adequate long-term data of what happens if you don't treat activity in patients with CNV—there could be significant negative consequences later on.

I treat to dry, but if I can't get the patient dry, then I'm not losing sleep over it. The important thing is you can't let the lesion get out of hand, and you still need to treat these patients.

DR. SHAH: There are patients who I observe more frequently than others. There are some patients who will never be completely dry, despite responding to treatment. Not all fluid needs to be treated, and if fluid is persistent despite therapy, maybe they have disease that is not anti-VEGF mediated.

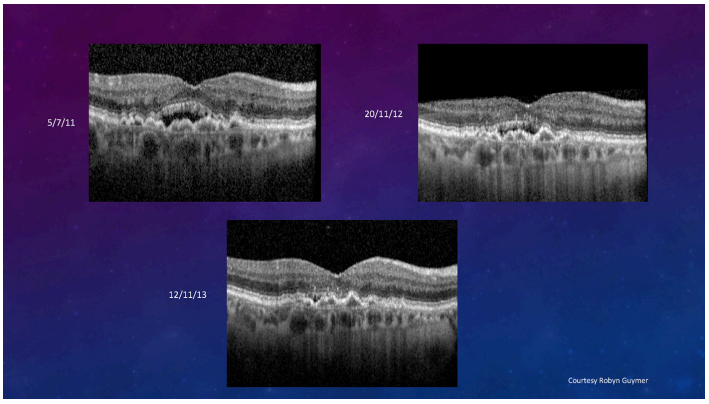

Figure 6. Patient with stable subretinal fluid without treatment.

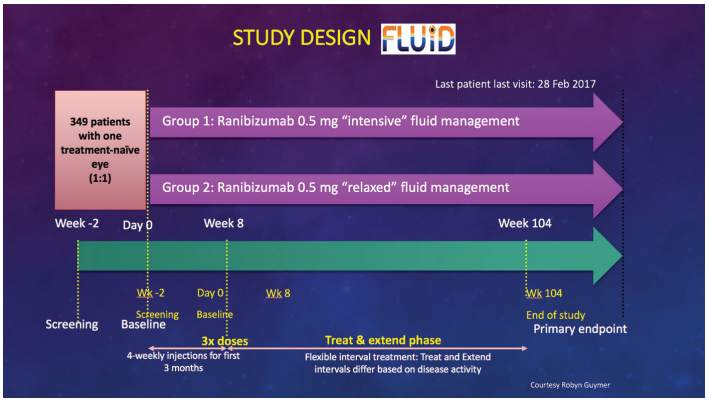

Figure 7. FLUID study design.

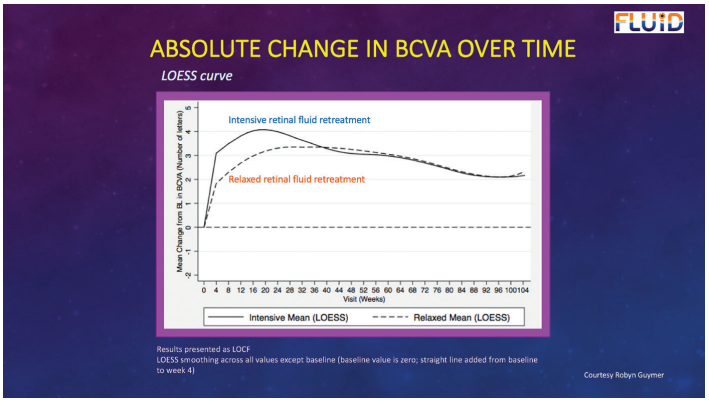

Figure 8. FLUID outcome data.

PRIVATE EQUITY FIRMS IN OPHTHALMOLOGY

In recent years, there's been an increase in the number of ophthalmology practices bought by private equity firms.[37] These business partnerships have significant financial ramifications on the practice and physicians, as well as the care patients receive. Private equity buy-outs come with many pros and cons. The ultimate goal is to increase the value of the practice. A sale provides practice owners with a large sum of money and/or stock upfront, but they no longer maintain control over the practice. A sale can help offset physician debt and fund infrastructure improvements, but workforce morale and patient care may suffer. Further, early-career physicians who aren't yet partners may find themselves locked into a contract at a low salary. Before joining a practice that has been sold or may soon be sold, due diligence is needed.

DR. SADDA: What is a private equity firm, and why are ophthalmology practices so attractive to them?

DR. SHAH: Private equity is an asset class that consists of equity securities and debt in companies that are not publicly traded. Simply stated, private equity is an investment in a private company.

It's critical to understand what a private equity firm is because they are becoming increasingly important in ophthalmology. Ophthalmology is appealing to private equity firms because of the aging population, limited providers, and a lack of competition with health care systems. Ophthalmology is a growing field and has additional income streams such as optical shops and ambulatory surgery centers.

Demographics make the ophthalmology sector appealing to investors as well. The AAO estimates that more than 24.4 million Americans over age 40 have cataracts, including half of those older than 75 years.[38] About 50 million Americans will have cataracts by 2050, spurring increased demand for cataract surgery.[39] Elective laser surgery and new intraocular lens technology are also growing in popularity.

DR. SADDA: How does private equity compare as an asset class to public equity?

DR. SHAH: Private equity is a short-term investment of typically 3 to 5 years. Private equity firms have no regulatory oversights, and the goal is to achieve 2 to 4 times the invested capital. Public equity, on the other hand, can be either short- or long-term investments, but typically only see single-digit returns that are tied to the stock market. They are also highly regulated.

There are different types of private equity including venture capital and angel investing. Private equity firms are often confused with venture capital firms because both look to invest in companies and exit later by selling those investments. The key here is exit. They acquire a mature company to increase its overall value in order to produce a significant return for investors. The Table below provides a breakdown of differences between the private equity types.

DR. SADDA: What are the main private equity firms in ophthalmology, and how do they profit?

DR. SHAH: The largest private equity firms currently are the Blackstone Group, the Carlyle Group, KKR & Co. Inc., and Apollo Global Management. Currently, Blackstone owns more anesthesia companies or anesthesia doctors than any other group. A private equity firm has limited partners, and everyone gets a percentage fee. Say, for example, Blackstone closes a deal for $500 million. One percent of $500 million is a lot of money. These firms aren't

TABLE. DIFFERENT TYPES OF PRIVATE EQUITY.

	Private Equity	Venture Capital	Angel Investing
Target Investment	Mature companies often underperforming or undervalued	Startups, early-stage companies, usually prerevenue	Startups, very early stage, prerevenue
Target Industry	All industries, usually with an established market for the product/service	High-growth industries like technology, biomedical, alternative energy	All Industries
Returns	Average returns of 10.64%	The vast majority are failures, with some solid returns, and a few spectacular successes	Vast majorities are failures, with some solid returns, and a few spectacular successes
Risk Level	Moderate	High	Very High
Investment Size	Traditionally at least $1M	Less than $10M	Less than $1M
Structure	Ownership equity	Ownership equity	Convertible debt or ownership equity

typically interested in a $5 million deal—they are looking for $50 million, $500 million.

Private equity firms make money by buying companies cheaply. The average price-to-earnings paid for a private company in 2015 was 7.1. The historical average price-to-earnings ratio is between 15 and 25 for a public firm (www.multpl.com/s-p-500-pe-ratio/table/by-year). Relative to their earnings, private companies are bought at half to one-third the price of what would be paid for the same company if it were public, which creates a huge return potential in the case of a liquidity event.

DR. SADDA: How can a physician in private practice assess the practice value to inform their decision to sell?

DR. SHAH: As a business owner, it's very important to know how profitable your practice is and how to read a balance sheet. No one will look at your money like you will; you have to do it yourself. To evaluate the profitability of your practice, use EBITDA: Earnings Before Interest, Tax, Depreciation, and Amortization.

EBITDA focuses on operating decisions. It is capital structure neutral, meaning it is not affected by debt and excludes noncash expenses like depreciation, which may or may not reflect your practices ability to generate cash that it can pay back as a dividend to its owners. It excludes non-operating decisions, such as interest expenses, which is a financing decision, tax rates, depreciation are tangible assets and amortizations are intangible assets.

DR. SADDA: Under what circumstances would a physician in private practice want to sell their business?

DR. SHAH: Selling a practice makes perfect sense for doctors nearing retirement. The payout from the sale will generally dwarf the earning potential of 5 to 7 more years practicing and comes with the relief of not having to worry about the minutiae of day-to-day practice management.

It can also be beneficial for early- to mid-career physician-owners as well. Although there are significant benefits to maintaining control, selling your practice can be a shrewd fiscal decision under the right circumstances.

Generally, you will be compensated in cash and stock in the management company. Receiving a sizable cash windfall presents an opportunity to invest and grow that money more than a standard income, which is spread out over many years and possibly subject to fee reductions. Investing this large sum early in your career may afford you the opportunity to develop an impressive nest egg and possibly cut back your hours or retire early down the line.

Equity in the management company or the original practice will ideally continue to appreciate as well. For some young owners, the idea of practicing medicine without the burden of management concerns may also be appealing. Moreover, groups with a large number of subspecialists need a wide referral base, and consolidation can add referral practices to the "mothership" practice. This is especially relevant if local competing practices have been acquired by other management companies and are looking to add to their own referral base.

DR. SADDA: What do early-career physicians need to know about private equity firms before joining a practice?

DR. ELIOTT: If you're thinking of joining a practice, it's critical to know if they're contemplating selling to it to a private equity firm. You could get burned if you join a practice and they sell 1 year into your employment; you're not a partner, you're an employee, and you've lost a lot of the upside income potential.

DR. SHAH: If you're looking for a job, there are scenarios you need to consider before joining a practice that has been or soon will be acquired by a private equity firm. Let's walk through a few different situations. Say a fellow signs a contract, and then the group sells and joins a private equity firm shortly thereafter. If private equity was not what you signed up for, you can get out of the contract. You'll have to get lawyers involved, but it's within your right.

This gets trickier if you're already a practice associate 3 to 5 years into the partnership. The original contract you signed is no longer valid. Private equity firms typically offer a new contract and pay physicians with a bonus that's now determined by the board. You will most likely not be eligible for any of the initial money. You'll need to ask how your employment contract will change, and how the pay will change with the new structure.

Some questions to ask include:

- Are management functions going to be centralized, decentralized, extreme decentralized, or something in between?
- How controlling is the acquiring management company?
- What does the acquiring company offer employees?
- What happens to restrictive covenant?
- How will the staffing change?
- How will the benefits change?

Remember, the goal of consolidation is to maximize profits. There is always a possibility that this profit-centered attitude will affect staff treatment, quality of new employees, investment in future equipment needs and practice infrastructure, and, most importantly, patient care.

You also have to know how long you're required to stay with the new group once you sign the contract. The new contract may come with a higher salary, but it's going to come with some baggage like a minimum number of years you're required to stay.

DR. ELIOTT: You also have to remember that you're now working for other people. You'll have a boss, and you'll lose all the advantages of a private practice, where you make a lot of money and you're your own boss. This is something to be aware of.

DR. SHAH: It's difficult to predict the future of consolidation in ophthalmology. The main question is whether the boom in acquisition of ophthalmology practices will continue to grow or plateau in coming years. Regardless of whether acquisitions continue or level off, there is significant opportunity outside of private practice for younger doctors. With proper research and forethought, it is possible for early- to mid-career physicians to maintain a stable lifestyle and even profit from the present flux in practice ownership.

MITIGATING MALPRACTICE RISK

A retrospective analysis of closed malpractice claims against ophthalmologists in the United States found that 24% of closed claims resulted in payment; two-thirds were dropped, withdrawn, or dismissed.[40] Fifty percent of claims stemmed from cataract and cornea surgeries. Although ophthalmology has a lower number of malpractice claims when compared to other health care specialties, ophthalmologists still need to understand how to protect themselves in the event of a lawsuit.

DR. SADDA: What are some common terms early-career ophthalmologists should know regarding malpractice lawsuits?

DR. ELIOTT: Malpractice is negligence plus causation. The plaintiff is the patient, and the defendant is the doctor who is getting sued. An expert witness is a doctor in the same specialty who can testify on standards of care. You're not really a witness, as you didn't observe anything directly, but that's what it is called.

An intent to file suit means the period of time before a suit is filed. This varies from state to state, and it's actually a positive to be in a state that has intent to file suit timeframes because you'll know you have a 6-month period before the suit gets filed.

Discovery is the period of time where people are gathering information. If you are sued, it may seem like the suit is moving slowly, but a lot is happening behind the scenes. For example, your lawyer may tell you to expect to be deposed. The deposition is when you have to go under oath and the plaintiff's lawyers ask you about your care for the particular patient. The discovery period can take months.

DR. SADDA: How do you prevent a lawsuit?

DR. ELIOTT: First and foremost, you must know the standard of care, which is what a reasonable doctor would do in a reasonably similar situation. You have to know what your colleagues are doing. That means attending meetings and continuing with your medical education because the standard of care evolves with time. The AAO Subspecialty Day is a great meeting to attend to keep up with the standard of care.

You also have to read the journals, such as the *American Journal of Ophthalmology*, *Ophthalmology*, and *JAMA Ophthalmology*. You should also read the specialty-specific journals, such as *Ophthalmology Retina*, and the trade publications. They're easily readable and give you a lot of good, practical information. Also pay attention to the American Society of Retinal Specialists' Preferences and Trends (PAT) Survey to see what your colleagues are doing. It will help you know if you're in the mainstream or not regarding standard of care. Finally, it's important for early-career ophthalmologists to have a group of colleagues you stay in touch with and in whom you can call on to discuss complicated cases. Communication is critical.

The other way to avoid a lawsuit is through documentation. Document the patient's history, the exam, test results, and try to have thorough chart information. If you don't have documentation, you can't protect yourself in the event of a lawsuit.

Good communication with your patients and their companions is also critical. Acknowledge the people who accompanied them to their office visit. Look the patient in the eye when you're talking to them. It's also important to listen and acknowledge their situation. Have a positive attitude. All of these things determine your relationship with the patient. The less you look at them, the more they're going to think you're cold and uncaring. If something happens, you're more likely to get sued. Explain test results to the patient. Show them the OCT. Ask if they have questions. The most important thing is to demonstrate compassion; show the patient that you're a human being and that you care about them.

"Demonstrating compassion is an important point. You never want to abandon your patients. If you abandon your patients, they will abandon you."

—Gaurav K. Shah, MD

DR. SHAH: Demonstrating compassion is an important point. You never want to abandon your patients. If you abandon your patients, they will abandon you.

DR. ELIOTT: Yes, exactly. Don't be a robot. If your patient comes in with a retinal detachment, instead of spouting off facts about their condition, tell them you're so sorry this happened. Explain that it can happen spontaneously, and they did nothing to cause it. Try to demonstrate that you're more than a doctor giving data, and try to maintain a positive outlook.

DR. SADDA: How can physicians prevent a lawsuit in the event of an adverse outcome?

DR. ELIOTT: Adverse outcomes happen, and there are a few things you can do to prevent a lawsuit in those situations. As is the case with all patient interactions, document your findings, communicate effectively with the patient, and demonstrate compassion. In the event of an adverse outcome, in order to demonstrate compassion, you have to spend extra time with the patient. You should also suggest they get a second opinion. If I have an unhappy patient, I'll refer them to one of my colleagues. If you do that, it's a good idea to

send them to somebody a little bit older than yourself who's more experienced. That way it looks like they're getting someone with a little more wisdom who can help them through this difficult situation, and it shows that you care about them.

DR. SADDA: Are there certain patients who are at higher risk for bringing a lawsuit than others?

DR. ELIOTT: Yes, absolutely. These include patients who are uninsured and those who are noncompliant. Noncompliant patients are of particular concern, especially if they need a test. Let's say you suspect ocular involvement from syphilis, and you order a fluorescent treponemal antibody (FTA) and rapid plasmin regain (RPR). The patient disappears for 5 years and it turns out they had a positive FTA, but you weren't aware of that because you were planning on checking the result when they returned for their 2 week follow-up. No one checked the test results because the patient didn't come back in a timely fashion. You have to check all the test results regardless of whether that person has followed up as they were supposed to.

DR. SHAH: You not only have to check the test, you have to close the loop. If the patient needs a referral, you need to provide it and document that you provided it. If they don't show up for the appointment, document that as well. You need to make every attempt to reach them.

DR. ELIOTT: Lawyers also tend to be problematic patients, especially litigation attorneys. Patients who live elsewhere (for example, patients who are on vacation in your town/city when you see them) are concerning as well, because they may not continue to engage with you when they return home. Distance can make communication more difficult, and you won't see them as often as the typical local patient. Patients with systemic comorbidities, like diabetes, are also concerning, as they are more likely to have severe problems with anesthesia—this may include an increased risk of death.

DR. SADDA: If you have a high-risk patient, what are some strategies?

DR. ELIOTT: If you have a high-risk patient, recommend observation if they're looking for an elective procedure. If it's a necessary, but not urgent procedure, bring them back another time and get to know them a little better. You want to establish a trusted rapport before surgery. If it's an urgent procedure, like a retinal detachment, spend a little more time talking to them preoperatively. If they're sick, make sure they're cleared by anesthesia prior to surgery, document everything, and then spend a little bit of extra time with them postoperatively as well. The bottom line is people usually don't sue people they like. High-risk patients will like you if you show that you care about them.

Early-career physicians should be especially wary if they don't know the diagnosis and don't know what to recommend for a given patient. In those situations, repeat and refer. I recommend bringing the patient back in a week or so and repeating the exam. Maybe the repeat exam and/or scans will show you something you didn't think of before. A week between appointments will also give you time to discuss the potential diagnosis with friends and colleagues. Colleagues can provide a fresh perspective.

DR. SADDA: What are some common lawsuit scenarios in ophthalmology?

DR. ELIOTT: Failure to diagnose a condition is the most common claim in ophthalmology. For general ophthalmologists, it's usually a missed retinal detachment that brings about a claim. For retina specialists doing intravitreal injections, the most common claim is delay in the diagnosis and treatment of endophthalmitis.

You also must communicate potential complications to the patient after every injection. Remind them that if they have any pain, decreased vision, pus, or discharge, that they should contact the office immediately. Their eyes may feel uncomfortable for a day, but it should feel normal after that. Say it over and over, after every treatment. And if a patient calls after an injection saying they have blurry vision, bring them in for an exam.

So far, there hasn't been a claim over intravitreal drug choices, but there have been claims regarding floaters due to silicone oil droplets from compounded bevacizumab. Make sure your compounder does not have this problem.

DR. SADDA: If you are sued, what steps should you take to mitigate the damage?

DR. ELIOTT: If you know you made a serious mistake that harmed the patient, attempt to settle the case so it's not on your record. If you settle, you can negotiate. The patient will receive compensation and you can hopefully learn from the unfortunate experience and not make the same mistake again. That said, if you did not commit malpractice, you have to aggressively attempt to get the case dropped.

In medical school, they teach you to let the lawsuit play out. I disagree with this. Don't be passive. Gather all the data, get a good defense expert witness, and attempt to discredit the plaintiff's expert witness. Is he board certified? Does he actually specialize in the area of expertise needed? Does he currently treat patients with the condition in question or perform the procedure? Oftentimes the plaintiff's expert doesn't specialize in the issue at hand; they are simply hired guns trying to make money. You've got to be on offense.

We're all going to make mistakes. The important thing is preventing a lawsuit by a commitment to continued learning, providing the standard of care, knowing your limitations, demonstrating compassion for your patients, treating your patients with respect, and having your patients like you. Patients need to realize you're a human being, a nice person, and that you care about them. Remember, that will go a long way in preventing lawsuits.

OPTIMIZING OFFICE WORKFLOW

As more and more patients put demands on medical retina services, wait times in the office are likely to increase and/or patients cannot be scheduled in a timely manner to receive monthly evaluations and (when necessary) the proper injections.[41] This, in turn, can lead to patient dissatisfaction with the overall treatment process and may be a contributing factor to poor patient compliance and adherence to a monitoring schedule.

Further adding to the strain on retina clinics is Centers for Medicare & Medicaid Services, which is planning on reimbursement cuts from 33.6% for procedures such as vitrectomy to 68% cuts for laser panretinal photocoagulation.[42] In order to maintain profitability, retina clinics need to evaluate and treat more patients without sacrificing efficiency or patient care.

DR. SADDA: I think a critical aspect is having a good image management or a picture archiving and communication system that integrates all of your imaging devices under one common viewing platform. This picture archiving and communication system should also be directly tied into your electronic medical record. We really don't have time in a busy practice to be running back and forth to your imaging devices. I have found that this has had a big impact on our practice efficiency.

DR. ELIOTT: The doctor is the rate limiting step in office workflow. Because the doctor can only see one patient at a time, it is important the doctor does not spend time doing tasks that can be performed by other office personnel. A strong team of friendly, skilled, and dedicated people are essential to keep the doctor moving at an efficient pace. ■

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NAVIGATING THE WORLD OF RETINA:
Updates for the Newer Retina Specialist

Release Date: January 2020
Expiration Date: January 2021

INSTRUCTIONS FOR CREDIT

To receive credit, you must complete the attached 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 visit evolvemeded.com and click https://evolvemeded.com/ online-courses/1923-supplement. If you are experiencing problems with the online test, please email us at info@evolvemeded.com. Certificates are issued electronically; please be certain to provide your email address below.

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

Name _____ ❑ MD/DO participant ❑ OD ❑ non-MD participant

Phone (required) _____ ❑ Email (required) _____

Address _____

City _____ State _____ Zip _____

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 educational 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
Summarize the most recent clinical study evidence using available therapies for AMD and DME.	_____	_____	_____
Identify treatments under investigation for AMD and DME.	_____	_____	_____
Develop individualized treatment plans for patients with retinal disorders that use a combination of imaging, treat-and-extend, or treat-and-observe approaches.	_____	_____	_____
Evaluate practice flow to determine the most efficient patient experience.	_____	_____	_____
Establish and Implement plans to reduce reimbursement denials.	_____	_____	_____

POSTTEST QUESTIONS

Please complete at the conclusion of the program.

1. Based on this activity, please rate your level of confidence in your ability to determine when to treat a patient with diabetic macular edema.

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very confident

2. Based on this activity, please your level of confidence in your ability to determine when to extend a patient being treated with anti-VEGF therapy for neovascular AMD.

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very confident

3. After performing an intravitreal injection, how often do you tell patients to contact the office for any pain, decreased vision, pus, or discharge (on a scale of 1 to 5, where 1=never and 5=always)?

a. 1 (Never)
b. 2
c. 3
d. 4
e. 5 (Always)

4. Which of the following is NOT true?

a. Failure to diagnose a condition (such as retinal detachment) is the most common claim in ophthalmology.
b. Regarding intravitreal injections, delay in the diagnosis and treatment of endophthalmitis is the most common claim.
c. Regarding intravitreal injections, there have been no claims of drug choice (bevacizumab, ranibizumab, aflibercept) and no claims of floaters due to silicone oil droplets from compounded bevacizumab.
d. Retinopathy of prematurity claims have the highest payments to plaintiffs.

5. The FLUID study demonstrated that in treatment of neovascular AMD with anti-VEGF therapy:

a. Zero tolerance of any fluid is essential to achieve optimal visual outcomes.
b. Intraretinal fluid is associated with better visual outcomes than sub-retinal fluid.
c. Interval between injections can be extended when mild amounts of subretinal fluid are present.
d. Monthly therapy should be continued until pigment epithelial detachments are flattened.

6. Does EBITDA refer to the evaluation done for private equity deals to obtain a multiplier?

a. Yes
b. No

7. According to the DRCR.net Protocol V clinical trial, _____ is a reasonable approach for managing an asymptomatic patient with good vision and center-involved DME.

a. Monthly aflibercept injections
b. Observation
c. Focal laser treatment
d. Steroid injections

8. What is the most critical step an ophthalmologist can take in order to avoid a lawsuit?

a. Document every interaction with and test on the patient
b. Have consistent, frequent communication with the patient
c. Do not appear rushed during an appointment
d. Know and practice the standard of care

9. The Centers for Medicare & Medicaid Services is planning on reimbursement cuts to which retinal procedures?

a. Vitrectomy
b. Laser panretinal photocoagulation
c. Intravitreal injections
d. A and B
e. B and C
f. A and C

10. The period of time before a lawsuit is filed is called _____.

a. Discovery
b. Malpractice
c. Intent to file suit
d. Plaintiff

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

I plan to make changes to my practice based on this activity. _____ Yes _____ No

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 below.

_____