What Could She See This Year?

EYLEA® (aflibercept) Injection
For Intravitreal Injection

Inspired by a real patient with DME.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
• EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS
• Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
• Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
• There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.


EYELA is a registered trademark of Regeneron Pharmaceuticals, Inc.

REGENERON

Implications of the data presented are based on exploratory endpoints that were not controlled for multiplicity. The analyses of these exploratory endpoints were not multiplicity protected and are descriptive only.

EYLEA ACHIEVED RAPID, SUSTAINED OUTCOMES IN DME

Mean change in BCVA (ETDRS letters) at Year 1 from baseline 1-5, *

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (n=151)</td>
<td>35.5</td>
<td>+10.7</td>
<td>+10.3</td>
<td>+9.3</td>
</tr>
<tr>
<td>EYLEA Q8 (n=154)</td>
<td>32.7</td>
<td>+14.6</td>
<td>+10.3</td>
<td>+10.4</td>
</tr>
<tr>
<td>EYLEA Q4 (n=154)</td>
<td>32.2</td>
<td>+13.6</td>
<td>+10.4</td>
<td>+10.3</td>
</tr>
</tbody>
</table>

Footnotes:
5. Year 2 data was consistent with results seen in Year 1.

EYLEA ACHIEVED RAPID, SUSTAINED OUTCOMES IN DME

Demonstrated efficacy outcomes in VISTA and VIVID, phase 3 anti-VEGF trials in DME (N=862)1

Mean change in BCVA (ETDRS letters) at Year 1 from baseline

<table>
<thead>
<tr>
<th></th>
<th>VISTA</th>
<th>VIVID</th>
<th>VISTA</th>
<th>VIVID</th>
<th>VISTA</th>
<th>VIVID</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Gains (Month 5)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EYLEA Q4</td>
<td>+10.3</td>
<td>(n=154)</td>
<td>+9.3</td>
<td>(n=136)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EYLEA Q8†</td>
<td>+9.9</td>
<td>(n=154)</td>
<td>+9.3</td>
<td>(n=135)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>+1.8</td>
<td>(n=154)</td>
<td>+1.8</td>
<td>(n=132)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary Endpoint (Year 1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EYLEA Q4</td>
<td>+12.5</td>
<td>(n=154)</td>
<td>+10.5</td>
<td>(n=136)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EYLEA Q8†</td>
<td>+10.7</td>
<td>(n=151)</td>
<td>+10.7</td>
<td>(n=135)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>+0.2</td>
<td>(n=154)</td>
<td>+1.2</td>
<td>(n=132)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prespecified Exploratory Endpoint (Year 3)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EYLEA Q4</td>
<td>+10.4</td>
<td>(n=154)</td>
<td>+10.3</td>
<td>(n=136)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EYLEA Q8†</td>
<td>+10.5</td>
<td>(n=151)</td>
<td>+11.7</td>
<td>(n=135)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>+1.4</td>
<td>(n=154)</td>
<td>+1.6</td>
<td>(n=132)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P<0.01 vs control at Year 1.

The analyses of these exploratory endpoints were not multiplicity protected and are descriptive only.

Year 2 data was consistent with results seen in Year 1.3

VISTA and VIVID study designs: Two randomized, multicenter, double-masked, controlled clinical studies in which patients with DME (N=862; age range: 23-87 years, with a mean of 63 years) were randomized and received: 1) EYLEA 2 mg Q8 following 5 initial monthly doses; 2) EYLEA 2 mg Q4; or 3) macular laser photocoagulation (control) at baseline and then as needed. From Week 100, laser control patients who had not received EYLEA rescue treatment received EYLEA as needed per re-treatment criteria. Protocol-specified visits occurred every 28 (±7) days.1

In both clinical studies, the primary efficacy endpoint was the mean change from baseline in BCVA at Week 52, as measured by ETDRS letter score.1

*Last observation carried forward; full analysis set.
†Following 5 initial monthly doses.

SEE WHAT EYLEA COULD DO FOR YOUR PATIENTS WITH DME AT HCP.EYLEA.US

anti-VEGF, anti-vascular endothelial growth factor; BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; Q4, every 4 weeks; Q8, every 8 weeks.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (aflibercept) Injection 2 mg (0.05 mL) is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).


Please see Brief Summary of Prescribing Information on the following page.
<table>
<thead>
<tr>
<th>Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Reactions</strong></td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
</tr>
<tr>
<td>Intraocular pressure increased</td>
</tr>
<tr>
<td>Retinal hemorrhage</td>
</tr>
<tr>
<td>Ocular hypertension</td>
</tr>
<tr>
<td>Retinal edema</td>
</tr>
<tr>
<td>Retinal detachment</td>
</tr>
<tr>
<td>Eyelid edema</td>
</tr>
<tr>
<td>Vision blurred</td>
</tr>
<tr>
<td>Ocular pain</td>
</tr>
<tr>
<td>Retinal hemorrhage</td>
</tr>
<tr>
<td>Intraocular pressure increased</td>
</tr>
<tr>
<td>Retinal detachment</td>
</tr>
<tr>
<td>Eyelid edema</td>
</tr>
</tbody>
</table>

Less common adverse reactions reported in <1% of the patients treated with EYLEA were: visual disturbances, retinal tear, and endophthalmitis.

**Macular Edema Following Retinal Vein Occlusion (RVO)**

The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 595 patients treated with a 2-mdose, in 2 double-masked, controlled clinical studies (WE2001 and HEW202) for 24 months (with a mean follow-up of 12 months).

Safety data observed in 289 patients with nonproliferative diabetic retinopathy (NPDR) throughout week 52 in the PANTORA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 2 above).

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

**Risk Summary**

Adverse effects observed in pregnant women with EYLEA have been reported in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including uterine, visceral, and skeletal malformations. A total of 1265 pregnant patients were treated with EYLEA. Approximately 2% (25/1265) of patients had a reported adverse event related to pregnancy. Aflibercept produced fetal malformations in rabbits at all doses assessed in rabbits. Aflibercept is contraindicated in pregnant women. Aflibercept produces fetal malformations at all doses assessed in rabbits and the total NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects (1 mg/kg), systemic exposure (AUC) of aflibercept was approximately 30 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg/kg), systemic exposure (AUC) of aflibercept was approximately 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal injection of 2 mg.

**Risk Evaluation**

All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-3% and 15%-20%, respectively.

**Data**

Aflibercept-induced effects included increased incidences of retinal detachment, dense vitreous hemorrhage, choroidal neovascularization, and endophthalmitis, which are considered serious adverse reactions that may result in permanent vision loss. There was no evidence of an association between aflibercept-induced effects and the frequency of adverse events that may result in permanent vision loss. The incidence of endophthalmitis observed with aflibercept in the phase 3 trials was similar to that observed with other anti-VEGF agents. The incidence of endophthalmitis was lower than the incidence of endophthalmitis observed with anti-VEGF agents in patients with diabetic retinopathy. The incidence of endophthalmitis was lower than the incidence of endophthalmitis observed with other anti-VEGF agents in patients with diabetic retinopathy. The incidence of endophthalmitis was lower than the incidence of endophthalmitis observed with other anti-VEGF agents in patients with diabetic retinopathy. The incidence of endophthalmitis was lower than the incidence of endophthalmitis observed with other anti-VEGF agents in patients with diabetic retinopathy.
No one likes to waste time or money, especially in a busy retina practice. But sometimes, because you are busy, it’s hard to identify inefficiencies clogging up the workflow. Maybe staff members are spending extra time searching for patient charts or digging around in the supply closet. Maybe they are walking from one end of the office to the other to fetch patients from the waiting room … and then walking all the way back to notify the doctor when the patient is ready. These seemingly small inefficiencies could make a 1-hour appointment take twice as long and make patients cranky and staff members tired.

This is where a lean business strategy can help. Broadly speaking, the lean philosophy focuses on value as seen from the eyes of the patient. Bottom line: Whatever doesn’t contribute to effective delivery of care gets tossed out the window. That’s what Austin Retina Associates did, and, reportedly, they couldn’t be happier. A handful of lean analyses helped the practice leaders there realize that technicians were tramping around the office to the tune of 6 miles each day! By embracing a lean office design and investing in some new equipment, they cut that distance by more than half.

This month’s featured article details the impressive changes that a lean strategy brought to Austin Retina Associates—and lays out how you can achieve similar efficiencies in your office. Who knows, you might even have a little fun taking a waste walk with your technicians or creating a spaghetti map of patient movements. You might be surprised by what you find.

If you aren’t ready for lean, this month’s Practice Management column offers key pointers to help you think, not just plan, strategically when considering practice changes.

Elsewhere in this issue, you will find tips for implementing a cash balance plan to boost your retirement savings and a fun Q&A on coding modifiers. No matter what help you may need to improve your practice, the articles in this issue are not going to waste your time.
Mastery of modifiers can lead to clean claims and prompt reimbursement for your practice. The converse is also true: Lack of mastery can lead to trouble. In a review of common denial reasons reported by insurance payers, inappropriate modifiers and a lack of modifiers consistently top the list of reasons for rejections.

There are common scenarios in the retina practice that require consideration of modifier use. Here’s a pop quiz. Can you name the appropriate modifier?

Question: A patient receives focal laser treatment for diabetic macular edema. During the postoperative period, the retina specialist performs an intravitreal injection in the same eye. What modifier should be appended to the CPT code 67028?

Answer: As outlined in Table 1, modifier -58 has three definitions for use. An injection performed in the global period of a major surgery would meet the definition of therapy following a diagnostic surgical procedure. Submit 67028 -58 and the appropriate eye modifier for this case.

Question: During the global period of panretinal photocoagulation of the left eye for proliferative diabetic retinopathy, the patient presents with complaints of significant visual disturbance in the right eye. The diagnosis is mild nonproliferative diabetic retinopathy with macular edema. Which modifier should be appended to the exam code?

Answer: Bill the appropriate level of Evaluation and Management (E/M) or Eye visit code appended with modifier -24 linked to the ICD-10-CM code for nonproliferative diabetic retinopathy with macular edema, with laterality. This modifier should be used when billing for an unrelated examination in the postoperative period, as in this case when performed in the fellow eye. See Table 2 for more coding tips for modifier -24.

Question: During the global period of cataract surgery in the right eye, the patient is evaluated for and diagnosed with cystoid macular edema. Can the exam be billed with modifier -24?

Answer: If the patient was referred by an outside practice, the retina specialist should bill the examination with no modifier, because this would not be considered postoperative. If referred from within the same practice, the global period applies—and the diagnosis of cystoid macular edema is related to the cataract surgery. In this case, modifier -24 is not appropriate to use, and the office visit is not billable. Any medically necessary testing performed is billable without a modifier.
Question: During the preoperative administration of medication at our ambulatory surgery center, the patient’s blood pressure is extremely elevated. The surgery is then canceled, and the patient is sent to the emergency department. How should the facility and surgeon bill for this case?

Answer: The ambulatory surgery center can bill with the applicable modifier specific for outpatient facilities:

- Modifier -73 when surgery is discontinued before administration of anesthesia.
- Modifier -74 after administration of anesthesia.
- Because the procedure is not initiated, the surgeon has nothing to bill.

Question: An office visit was recently denied by Medicare because the patient is receiving hospice care. What is the correct coding?

Answer: When patients elect hospice coverage, they waive all rights to Medicare Part B payment for professional services related to the treatment and management of their illness while in hospice care. If the reason for the encounter is not related to the illness, append modifier -GW, service unrelated to hospice care.

Question: During an encounter for a Medicare Part B patient accompanied by her son, the son mentions that his mother is residing in a skilled nursing facility (SNF). Fluorescein angiography and fundus photography are performed. How should this be coded?

Answer: When a patient is residing in a SNF, there are three services not covered by Medicare Part B, and the SNF is responsible for payment of the following:

- The technical component of testing services,
- The drugs injected, and
- Postoperative cataract glasses (durable medical equipment).

The retina specialist should bill Medicare for the professional component of the test and should bill the SNF for the technical component of the test. The retina specialist should submit:

- 92235-26 and 92250-26 to Medicare Part B and
- 92235-TC and 92250-TC to the SNF.

Question: During the global period of a complex repair of retinal detachment (CPT code 67113) in the left eye, the patient is taken to the OR for additional surgery for recurrent retinal detachment in the same eye secondary to proliferative vitreoretinopathy in association with a giant tear. What is appropriate coding for the second surgery?

Answer: Modifier -78, unplanned return to the OR by the same physician for a related procedure during the postoperative period is correct. Code as 67113-78-LT.

When modifier -78 is used, the following are true:

- Only the intraoperative portion of the surgery is paid, at 70% of the fee schedule.
- A new postoperative period does not begin; the 90-day postoperative period is completed on the 91st day following the original procedure.

Question: Which modifier should be appended to an exam conducted on the same day as a laser procedure to repair a retinal detachment (CPT code 67105)?

Answer: As of 2017, the global period for CPT code 67105 changed from 90 days to 10 days. Because this is a minor procedure, modifier -25 would be appended to the exam, if the definition for use was met: a significant, separately identifiable E/M service on the same day as a minor surgery. Review your chart documentation and apply this statement: Although it is medically necessary, if the exam is performed solely to confirm the need for the minor procedure, the exam is not separately billable.

If the laser in this example was CPT code 67210, destruction of localized lesion of retina, which has a 90-day global period, modifier -57 would be appended to the exam to indicate the decision for major surgery. See Table 3.

**Table 2. Coding Tips for Modifier -24**

<table>
<thead>
<tr>
<th>Modifier -24</th>
<th>Coding Tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrelated evaluation and management service by the same physician during the postoperative period</td>
<td>• Management of a problem unrelated to the surgery or in the unoperated eye&lt;br&gt;• Generally requires a diagnosis code different from the surgical diagnosis code&lt;br&gt;• Physicians in the same group practice share the same global period</td>
</tr>
</tbody>
</table>

**Table 3. Comparison of Modifiers -25 and -57**

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Definition</th>
<th>Coding Tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modifier -25</td>
<td>Significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service</td>
<td>• Append to evaluation and management or E/M visit codes the same day as a minor surgery when the definition is met&lt;br&gt;• Minor surgery is defined as one with a 0- or 10-day global period</td>
</tr>
<tr>
<td>Modifier -57</td>
<td>Decision for surgery, major procedure</td>
<td>• Append to E/M or Eye visit codes the same day as a major surgery&lt;br&gt;• Major surgery is defined as one with a 90-day global period</td>
</tr>
</tbody>
</table>

**MORE TESTING**

Test your coding competence with the AAO’s 100-question Ophthalmic Coding Specialist Retina examination. Unique to retina, the test is available at aao.org/ocs.

JOY WOODKE, COE, DCS, OCSR

- Coding and Practice Management Executive, American Academy of Ophthalmology, San Francisco
- jwoodke@aao.org
- Financial disclosure: None
Feature Story

Implementing a Lean Approach in the Retina Practice

This business strategy can help you overcome clinic inefficiencies and reduce patient wait times.

By Aneesh Suneja, MBA; Jose Agustin Martinez, MD; and Stephanie Collins Mangham, MBA

All retina practices want a healthy staff. But within the hustle and bustle of a busy clinic, many practice owners may not realize that staff members are spending hours of their time simply walking around the clinic, with high patient wait times, low satisfaction, bottlenecks, and low morale as the results.

Five years ago, it became apparent that Austin Retina Associates (ARA) was growing quickly, and with that growth, patients were experiencing longer wait times. To overcome this, one of the authors (Stephanie Collins Mangham), brought in FlowOne Lean Consulting to implement lean process improvements and to help increase efficiencies and reduce patient wait times.

After implementing several lean tools such as spaghetti mapping and a waste walk, the leaders at ARA realized that staff members were walking an average of 6 miles a day in the clinic (Figure 1). That translated to approximately 2 hours of pay—just for walking.

In an effort to reduce the mileage and increase efficiency, ARA created smaller work areas, or pods, for each physician (Figure 2). Each pod included exam rooms, workup lanes, and diagnostic equipment such as OCT and fluorescein angiography. Each doctor was assigned a core group of technicians who grew to know exactly how that particular physician preferred to run their clinic, which led to further efficiencies that reduced waste.
Each doctor-team could also test smaller efficiency changes through small-scale trials. If a trial worked, it could be expanded to other doctor-teams to improve the patient experience throughout the practice.

When ARA moved, added equipment, and retrofitted the office into pods, the practice not only reduced the distance staff walked from 10,000 to 3,000 steps each day (a time saving of 70 minutes or 3.5 miles per day), it also reduced bottlenecks and flow redundancies by purchasing more equipment, improving visual lines of communication, and becoming paperless.

Using the lean philosophy, the practice reduced both wait times and visit time by 50% in 3 months. Patients were now spending an average of 55 minutes in the clinic rather than 1 hour and 50 minutes. In addition, patient satisfaction scores jumped from 8 to 9.5 or 10 out of 10, and staff satisfaction went from 6 to 9 out of 10.

Reducing wait times elevated the mood in the practice. Doctors no longer had to apologize to patients throughout the day for the long wait. Patients started complimenting the staff for the kind and efficient care, which elevated the

**AT A GLANCE**

- Lean is an operating philosophy that views value from the patient’s eyes, and any part of the patient experience that does not directly contribute to the effective delivery of care is an area for improvement.
- Using the lean philosophy, Austin Retina Associates reduced the distance staff walked by 3.5 miles a day and minimized bottlenecks and flow redundancies.
- A lean architectural design for Retina Specialists of Michigan led to a 15% increase in patient and staff satisfaction, a 30- to 45-minute increase in productivity per clinic, a 50% reduction in staff walking distance, and a 74% reduction in patient wait times.
staff’s mood and created a positive clinic environment. Doctors could now stay focused on patient care rather than dealing with negative patient moods resulting from long wait times.

Lean also resulted in a major culture change; the front-line staff was now empowered to make workflow decisions to increase efficiencies and problem-solve to find solutions. The level of teamwork, collaboration, and increased engagement among the health care personnel changed the culture of the entire practice, which was, and still is, a huge benefit that leadership never anticipated.

ARA no longer uses a top-down approach imposing processes from above because the front-line staff is empowered to make daily decisions and improvements around workflow, as they are closer to the issues that arise in the daily operations in the clinic.

**Figure 2. The pods—highlighted in blue, pink, and green—helped to create efficiencies within the office, which cut staff walking time by more than half and improved patient wait times.**

**LEAN TOOLS DEFINED**

**Spaghetti Diagram:** A visual representation of the clinic flow, using a continuous colored line, tracing the movement of the patients, the staff, and the physicians in the clinic. The diagram can be drawn on an office floor plan or sketched on a blank piece of paper.

**Waste Walk:** A clinic flow observation activity, for a planned period of time, to identify real-life examples of seven types of lean wastes in the doctor's office: motion, transportation, inventory, waiting, defects, over-processing, and over-production.
LEAN INTO DESIGN

When the practice leaders at Retina Specialists of Michigan discovered that they had an inefficient workspace, they collaborated with AMDG Architects and FlowOne Lean Consulting to design new lean facility that addressed the inefficient way patients and staff moved within their old space.

“If you add lean principles when you are shaping a new space in architecture and design, it yields a more powerful solution,” said Peter Baldwin, President of AMDG Architects. “When designing spaces, the challenge is that people tend to ask for the things with which they are familiar. Lean encourages them to think differently so they can gain new insights and implement better solutions and ways of doing things.” Retina Specialists of Michigan also used staff input throughout the design.

SEEING THROUGH A LEAN LENS

Why is lean so effective? This operating philosophy views value from the eyes of the patient, and any part of the experience that does not contribute to the effective delivery of care is an area for improvement. For example, time spent by a physician or other team member consulting with a patient is an added value, whereas time spent looking for supplies or other team members is waste. Ultimately, lean identifies waste and works to create a revised clinic flow that is calm and efficient.

Lean process analysis uses value stream mapping, which analyzes where in the clinic a patient interacts with staff, waits, or moves, and assigns a time to these activities. For example, during a patient visit that took 88 minutes, the process time (value-added time with staff or the physician) might be 41 minutes and the wasted patient time (waiting or moving through the office) might be 47 minutes. Using this information, the practice can reduce or eliminate waste by focusing on the non-value-added moments and identifying opportunities to improve that flow.

To reduce wasted patient wait time, lean design examines factors such as these:

- **Front desk efficiencies.** Are there potential delay factors at check-in, including whether the front desk staff is moving around to access printers, forms, or other information?
- **Supply location.** Are supplies located in easy-to-access areas, such as top drawers or wall-mounted shelving, to reduce unnecessary search time?
- **Screening and testing processes.** Are patients moving back and forth to waiting rooms or the lobby before getting to the physician’s examination room? The whole process can be reengineered for efficiency by using examination and tech rooms interchangeably, so patients don’t need to move unnecessarily.
- **Staff location.** Are physicians, scribes, and technicians located close to each other for easy communication?

- **Patient flow technology.** Use of HIPAA-compliant lean software such as eSynchrony (FlowOne Lean Consulting) allows staff members to capture real-time patient visit data and wait times. This facilitates improvement based on unbiased data.

A LEAN ADVOCATE

ARA values lean principles so much, it now employs a full-time lean advocate who deploys lean techniques in all areas of the office, educates new staff members, and assists staff members with metrics and trials to help the practice make continuous improvements.

The biggest benefit ARA has gained from lean is that it has empowered the staff and changed the culture to one that encourages everyone to openly discuss and implement changes together to improve the practice.

STEPHANIE COLLINS MANGHAM, MBA
- Chief Executive Officer, Austin Retina Associates, Texas
- scollins@austinretina.com
- Financial disclosure: None

JOSE AGUSTIN MARTINEZ, MD
- President, Austin Retina Associates, Texas
- Affiliate Faculty, Ophthalmology, University of Texas at Austin Dell Medical School, Austin, Texas
- jmartinez@austinretina.com
- Financial disclosure: None

ANEESH SUNEJA, MBA
- President, FlowOne Lean Consulting, LLC, Menomonee Falls, Wisconsin
- Coauthor, Synchrony and Lean Doctors
- Developer, patient flow software platform
- asuneja@flowone.com
- Financial disclosure: Employee (FlowOne Lean Consulting)
Strategic planning for your practice should not be handled by external consultants; it shouldn’t be boiled down to an annual PowerPoint presentation either. Instead, strategic planning should be a way of thinking—continuous critical analysis that is ingrained in the business model and the minds of your practice’s physician leaders. This mode of strategic thinking should be communicated consistently to every member of your team.

In ophthalmology, strategic thinking should focus on improving the patient experience while maintaining a healthy work environment and excellent patient care. This will ultimately improve the bottom line because, when the revenue cycle is operating efficiently and money is collected effectively, the entire patient experience is better, and the physicians and staff members are happier.

Practices should start their strategic thinking with two analyses, best outlined by the acronyms PEST and SWOT.

**PEST Analysis**

This type of analysis looks at the Political, Economic, Sociocultural, and Technological factors that affect a practice. These external forces define the environment within which a business sets a strategy. Leadership must understand these forces and stay abreast of any changes.

**Political Factors**

Decisions made by CMS can have a profound impact on ophthalmology, and on retina practices in particular. For example, at the end of 2020, the concept of the most favored nation drug pricing model threatened to change the revenue structure for Part B drugs and biologics profoundly. At the same time, CMS has proposed dramatic reductions in the conversion factor and changes to relative value units within the Medicare Physician Fee Schedule.

Thankfully, lobbying efforts by the AAO, the American Society of Ophthalmic Administrators, and other medical specialty societies stopped the most favored nation proposal and reduced the conversion factor impact—for now. Prior authorization requirements and step therapy programs in the Medicare Advantage world, however, have not ended.

**COVID-19 relief programs have been complicated, but they have enabled many practices to survive. Practices that carefully evaluate the potential revenue impact of political changes such as these are better positioned to endure.**

**Economic Factors**

The impact of COVID-19 on the entire US economy has been felt equally in health care. As many businesses were forced to close, patients lost their jobs and, often, their health insurance. Thus, there are now more people enrolled in Medicaid or commercial plans with ever-increasing coinsurance and deductibles. We must anticipate how these changes will affect the net collection rates of practices.

**Sociocultural Factors**

Ophthalmology continues to benefit from the aging of the population, which creates a robust demand for services. Practices must think about how they will meet that demand moving forward.

Due to the pandemic, consumer attitudes have changed dramatically toward what used to be standard health care scenarios. Patients never liked to sit in waiting rooms, but they now understand that doing so is dangerous. This mindset is likely to persist, even after the pandemic, affecting your patient loads and flow.

Patients have been deferring visits altogether to avoid exposure to COVID-19, leaving gaps in your schedule and building a backlog for the future. In addition, they may be more comfortable receiving services in a small office with limited personal interactions, and they may want procedures performed in an ambulatory surgery center rather than a hospital setting with a higher risk of exposure. These attitude shifts should be considered in your strategic thinking.

**Technological Factors**

Technological changes have accelerated during COVID-19. New telemedicine platforms allow physicians to remain connected to their patients even when they cannot see them in person. New technologies have also facilitated a hybrid visit model in which patient and physician exposure is minimized.
The shift to remote work has required practices to expand their IT capacity and make technology changes. In addition, ophthalmic equipment has required retrofitting with personal protection—not necessarily a cheap endeavor. Assessing and setting a course to adapt to these changes is critical.

**SWOT Analysis**

An analysis of Strengths, Weaknesses, Opportunities, and Threats (SWOT) can help leaders design an internal response to the external factors identified in the PEST analysis.

**Strengths**

These are the tools or resources that will help your practice respond to the external factors within your PEST analysis. They can include anything from state-of-the-art equipment to access to capital, from leadership and staff skills and flexibility to a strong practice culture. Once you identify your practice’s strengths, maintaining them is key.

**Weaknesses**

These are tools or resources you lack, whose presence could help your practice respond to external factors. The pandemic has exacerbated several common weaknesses:

- Many practices struggled or were forced to close when they lacked access to capital that was highly leveraged.
- Practices that had resisted adopting electronic health records and voice-over-internet protocol phone systems quickly realized that these were grave weaknesses when physicians and employees began working from home.
- Some practices lacked the leadership to multitask and respond to the changes brought on by the pandemic.

Strategic thinkers assess these weaknesses—ideally before a crisis—and work to convert them into opportunities.

**Opportunities**

There are constant opportunities for improvement in both patient care and practice management:

- The ability to get paid for telehealth services allowed (or compelled) practices to focus their attention on developing that capability, which will yield results well after COVID-19. Retina specialists have been remotely evaluating fundus photos for diabetic patients for years. With expanding telehealth capabilities and regulatory changes in billing, retina specialists may be able to expand their revenue streams by developing remote testing centers and telehealth services.
- Practices should use any downtime to train or retrain technicians, scribes, and billing staff.
- Practices have a unique opportunity to refine the pre-visit eligibility and prior authorization processes to minimize patient face-to-face time in the office.
- Now is a good time to ensure that staff members enroll eligible patients in relevant patient assistance programs.

- Practices should evaluate the effectiveness of their remote workers and determine whether remote work will remain a cost-effective solution for the long term. Many of these opportunities are easy to implement and can have a significant impact on your practice’s success.

**Threats**

Rising expenses are a threat when external forces drive practice revenue down. Managers must control costs by working smarter, not harder. Managers need to equip staff members with the tools necessary to succeed. These can include top-performing medical and computer equipment, coding resources, effective onboarding, and ongoing training.

Managers also need to create a culture of teamwork, particularly when employees are stretched thin with off-kilter work-life balances. Unfortunately, many practices do not think through the patient experience touch points, or the revenue cycle process. Keeping staff siloed in front desk, clinical, and back-office roles can pose a significant threat to practices that now need more flexible workflows.

Strategic thinking does not happen in silos. A practice’s patient experience and revenue cycle starts when the call center says hello, schedules the patient with the correct physician, and gathers accurate demographic and insurance information. It continues through to the staff that greets the patient and collects the copay or deductible, the technician who performs and documents testing services, and the physician who performs and documents the visit or procedure.

Billing processes many also pose a threat, as they can affect the patient experience; but many billing errors happen before the claim even reaches the billing office. Thus, practices must perform root-cause analysis of billing errors. Often this means adding billing expertise at the beginning of the revenue cycle. The key is to get the billing codes right the first time because the cost to collect can get extremely high.

**Final Thoughts**

Strategic thinking requires looking at all of the external factors that affect retina practices to determine how to respond to challenges. Practice managers should use AAO resources, sign up for listservs, and attend practice management meetings. They can use the knowledge they acquire to look inward at processes that are inefficient and find ways to reengineer them to preserve patient, physician, and staff time. If practice leaders think of each day as an opportunity for continuous process improvement, clinicians and patients will feel the difference every day.

*Sara Burns Rapuano, MBA, CPC, OCS, COE*

- Ophthalmology Practice Management Consultant, Philadelphia
- sbrapuano@gmail.com
- Financial disclosure: None

Sara Burns Rapuano, MBA, CPC, OCS, COE

= Ophthalmology Practice Management Consultant, Philadelphia

sbrapuano@gmail.com

Financial disclosure: None
As advisors to physicians and medical practices for more than 25 years, we have found that the leading short-term financial planning goal for most physicians in private practice is to reduce their income taxes. This is not surprising because everyone wants to reduce their taxes, especially with taxes likely to rise. In addition, exerting control over tax planning options is one of the reasons retina specialists want to remain in private practice and resist W-2 employment with larger employers.

The cash balance plan (CBP) is a qualified retirement plan (QRP) that can provide physicians with a way to increase tax deductions and boost retirement savings. A CBP is a powerful tax planning tool, and one that many private practices may want to consider. Let’s explore how they work.

**BENEFITS FOR PHYSICIAN PRACTICE OWNERS**

There are four compelling reasons why physicians in private practice are interested in CBPs:

**Increased deductions.** While 401(k) plans are subject to a 2021 maximum contribution limit of $19,500, and profit-sharing plans have a contribution limit of $58,000, properly structured CBPs allow tax-deductible contributions of $200,000 or more.

**Benefits outweigh costs.** CBPs have higher administrative costs and, typically, higher employer contributions compared with 401(k)s or profit-sharing plans. The tax savings for physicians, however, typically dwarf these expenses, making CBPs extremely attractive for many medical practices.

**More than one deduction.** For physicians whose income puts them above the tax code’s qualified business income (QBI) threshold limits, a CBP can be a tool to reduce taxable income enough to qualify for the QBI deduction, creating one deduction that leads to a second deduction.

**Top asset protection.** As an exempt asset under federal law and most state laws, ERISA-qualified QRPs are protected at the highest (+5) level. Unless a CBP is put in place for one owner with no employees, the ERISA protection will usually also apply to the CBP.

**PLAN BASICS**

In a CBP, a participating employee will have access to a specified sum upon retirement. To get to $100,000 at retirement, for example, the plan assumes a combination of employer contributions and compound interest over time. When the employee retires, he or she can take the $100,000 either as a lump sum or as an annuity that pays a portion of the $100,000 in periodic payments. Each participant’s account grows annually in two ways:

**Benefit credit.** This is a percentage of pay or a flat dollar amount that is specified in the plan document. The credit is often class-based so that higher dollar or percentage amounts accrue to owners or partners and lower dollar or percentage amounts to staff members. This, as one would expect, makes the CBP ideally suited for medical practices—the physicians or partners can be a separate class.

**Interest credit.** This guaranteed rate of return specified in the plan document is typically tied to federal long-term interest rates or set at a fixed rate around 5%. The interest credit is not dependent on the plan’s actual investment performance, but the investment portfolio should be structured to perform in line with the anticipated crediting rate.

**401(k) SIMILARITIES AND DIFFERENCES**

A CBP is similar to a 401(k) or other QRP in many respects, including rules on employee eligibility, nondiscrimination regulations, timing of deductible contributions, roll over eligibility, and early withdrawal penalties.

However, a CBP is also different from a 401(k) in several ways. With a 401(k), an employee makes contributions to the retirement plan. The employer sponsoring the 401(k)
may or may not make matching or profit-sharing contributions. The amount that the employee will have in retirement is not defined. Instead, the employee’s retirement benefits depend on the performance of their funds in the plan.

With a CBP, by contrast, the amount of money an employee can expect in retirement is defined. (That’s what makes it a defined benefit plan.) The employer, not the employee, bears the risk of market fluctuations. Also, participation in a CBP does not depend on employees contributing part of their compensation to the plan—contributions by employees are not permitted.

The costs of a CBP are certainly greater than for a 401(k) or profit-sharing plan. This is because the CBP’s funding must be certified by an actuary each year. However, the tax benefits of the CBP often significantly exceed the additional cost. The costs and tax benefits can be modeled on a case-by-case basis before any new plan is implemented.

MANAGING BOTH TYPES OF PLANS

CBPs and 401(k)s are not mutually exclusive. A medical practice can typically use both types of plans simultaneously. In fact, because so many medical practices already have 401(k) plans in place, physician owners often consider layering in a CBP on top of their existing 401(k).

IDEAL PRACTICES

In general, any medical practice with the necessary cash flow whose physician owners are looking for a retirement tool that provides greater deductible contributions is a good candidate for a CBP. Because it is not difficult to model CBP economics for a medical practice, it makes sense for most practices to explore what the financial model shows.

There are a few situations in which a CBP goes from a home run to a grand slam: practices with older physicians and younger staff; those with reasonable ratios of physicians to employees; and physicians with outside business income from moonlighting, speaking, or working with industry.

TWO DEDUCTIONS FOR THE PRICE OF ONE

In December 2017, the Tax Cuts and Jobs Act created a possible 20% deduction on QBI. Income limitations may preclude many retina specialists from meeting the criteria. A CBP can help to reduce taxable income enough to qualify for the QBI deduction. That is, a CBP can create one deduction that leads to a second deduction.

As an example, consider a solo ophthalmologist with a taxable income above the QBI threshold. This year, he creates a CBP, allowing a contribution of $210,000, which is deductible from the practice’s taxable income. The reduced taxable income for the practice could reduce the physician’s personal taxable income below the threshold amount, so that the ophthalmologist could take the 20% QBI deduction on his individual tax return.

CONCLUSION

CBPs are powerful planning tools that allow larger contributions than most plans. CBPs may be attractive to practice owners who are looking for larger tax deductions, asset protection, and superior retirement income.

SPECIAL OFFERS: The authors have recently completed Wealth Planning for the Modern Physician. To receive free print copies or ebook downloads of this book or Wealth Management Made Simple, text RETINA to 844-418-1212, or visit www.ojmbookstore.com and enter promotional code RETINA at checkout.

OJM Group, LLC. (“OJM”) is an SEC registered investment adviser with its principal place of business in the State of Ohio. SEC registration does not constitute an endorsement of OJM by the SEC nor does it indicate that OJM has attained a particular level of skill or ability. OJM and its representatives are in compliance with the current notice filing and registration requirements imposed upon registered investment advisers by those states in which OJM maintains clients. OJM may only transact business in those states in which it is registered or qualifies for an exemption or exclusion from registration requirements. For information pertaining to the registration status of OJM, please contact OJM or refer to the Investment Adviser Public Disclosure web site www.adviserinfo.sec.gov.

For additional information about OJM, including fees and services, send for our disclosure brochure as set forth on Form ADV using the contact information below. Please read the disclosure statement carefully before you invest or send money.

This article contains general information that is not suitable for everyone. Information obtained from third party sources are believed to be reliable but not guaranteed. OJM makes no representation regarding the accuracy or completeness of information provided herein. All opinions and views constitute our judgments as of the date of writing and are subject to change at any time without notice. The information contained herein should not be construed as personalized legal or tax advice. There is no guarantee that the views and opinions expressed in this article will be appropriate for your particular circumstances. Tax law changes frequently, accordingly information presented herein is subject to change without notice. You should seek professional tax and legal advice before implementing any strategy discussed herein.

DAVID MANDELL, JD, MBA
- Partner, OJM Group, Cincinnati
- david@ojmgroup.com
- Financial disclosure: Employee (OJM Group)

JASON O’DELL, MS, CWM
- Managing Partner, OJM Group, Cincinnati
- odel@ojmgroup.com
- Financial disclosure: Employee (OJM Group)
New Retina Radio is partnering with the Vit-Buckle Society to provide quick-hit reviews of journal articles delivered by VBS members—all from the comfort of your podcast feed.

CATCH UP ON THE LATEST DISCUSSIONS AT
https://eyetube.net/podcasts/new-retina-radio

RECENT TOPICS INCLUDE:
- PRO Study Group Papers
- OCT Biomarkers in New Onset GA
- Anti-VEGF vs Surgery + PRP for VH with PDR
- Phase 2 LADDER Study Data
- Imaging Modalities in DR

HEAR FROM LEADING VITREORETINAL SURGEONS AND EXPERTS:

- Sabin Dang, MD
- Brian Do, MD
- Avni Finn, MD, MBA
- Mrinali Gupta, MD
- John W. Kitchens, MD
- Marion R. Munk, MD, PhD, FEBO
- Eric Nudleman, MD, PhD
- Aleksandra Rachitskaya, MD
- Jayanth Sridhar, MD
- Aris Thanos, MD
- Lejla Vajzovic, MD
- David Xu, MD
- Yoshihiro Yonekawa, MD

Learn more about the Vit-Buckle Society at www.vitbucklesociety.org

New Retina Radio is available on Eyetube.net and through these platforms: