MEDICAL VOLUNTEERISM ABROAD

Volunteer-based missions offer ophthalmologists the chance to offer their skills to those in need .... 19

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Welcome to the new possible.
Our busy multicenter retina practices are running smoothly, and we are finally handling the anti-VEGF injection volume in an efficient manner. So, why throw a wrench in the gears by switching from paper records to an electronic medical record (EMR) system?

One of our practices has just recently fully implemented EMR into our practice, and the other is in the midst of transitioning, and in the past year, we have learned a good deal.

First, words of caution: the adoption process will be painful. Working with EMR will initially be slower, requiring more time from physicians and staff, training, and it is likely that you will need additional staff members even after the system has been well adopted. Expect frustration from physicians and ancillary staff, longer patient wait, and a significant liability in being able to fully capture the nuances from the patient’s previous exam in the mass of data that is captured. Technical glitches, hardware costs, and rebooting will be part of the process. One suggestion is to implement the system slowly. Frequently, vendors will recommend a “switch date” to pull the trigger on the new system. We have heard tales of practices needing to slash patient volumes for weeks up to months during this transition. For each of our offices, we are implementing a very slow phase-in, starting by using EMR for new patients only, then gradually adding a few patients each day. Although growing pains still exist, they have been minimized with this approach.

Certainly, the financial incentives of the meaningful use program are going to be far outweighed by the implementation costs and general pains to the neck. Then what is the reason to switch? Efficiency. Once you have suffered through the adoption process, EMR becomes efficient. Six months into using our system, we still are a bit slower than on paper. After learning the intricacies of the system, however, we are able to quickly determine exactly what is going on with a particular patient, with high precision. The process of writing letters to referring doctors becomes much more simple and reliable. Most importantly, chart notes are more comprehensive and filled with data.

At the end of the day, make sure you are comparing apples to apples. The patient record is far more robust when produced from an EMR than from paper. EMR records take a bit longer to produce, but the level of documentation and discussion is simply far superior. The merits of that level of documentation may be debated, but we are confident that the current and coming changes to our health care system will require and reward more complicated documentation.

The real promise of EMR will be from the data produced, which have the potential to allow for a refinement of practice patterns, development of evidence-based medicine, reduction in both medical errors, and expensive and unnecessary care. Using these data, however, will require execution at a high level, and currently, this remains an elusive goal.

Richard S. Kaiser, MD
Jonathan L. Prenner, MD
Chief Medical Editors
Persistent vitreomacular adhesion (VMA) may play a role in future vitreoretinal diseases.  

- Unresolved VMA can lead to vitreomacular traction (VMT), causing visual consequences such as decreased visual acuity.  
- Macular hole resulting from VMT can lead to vision loss.  
- Spontaneous resolution of VMT or macular hole occurs infrequently and is not predictable.

Resolution of persistent VMA can improve anatomical outcomes and visual acuity.

REFERENCES
Opportunities and Risks in Health Care Reform

ACOs, CINs, insurance exchanges, and other future possibilities.
By Paul Sternberg, MD

Currently, there are political, social, and economic forces—many of them beyond our control—that are influencing the environment in which we practice and the environment in which we are going to practice. Over the past few decades, the growth in the annual cost of health care has increased dramatically. In 1960, it was $150 per capita; by 1975, it was $600 per capita; and now it is greater than $8000 per capita and continuing to rise. Clearly, we cannot sustain these costs, and the government and commercial payers are trying to determine ways to address this unsustainable growth. There are several problems that must be fixed, including variability and inequality of costs, poor care coordination, failure to reliably apply what is known, and failure to engage patients and their families in the care process.

Several solutions have been proposed in response to these problems. An accountable care organization (ACO), originally described by Elliott Fisher, MD, at Dartmouth Medical School, is a model in which providers are jointly held accountable for the cost and quality of care of a defined patient population. There is another model being discussed, called a clinically integrated network (CIN). ACOs and CINs are very similar, but there are some slight yet important differences. With ACOs, the incentives are typically part of a capitated risk-based model, whereas in CINs, the shared savings do not require bundling or capitated payments. Instead of applying strict quality and outcome measures across a broad range as occurs with ACOs, in CINs, the focus is on integration of both acute and post-acute specialty and quality care. CINs can also set their own quality metrics, and you have the opportunity to reduce costs. Both ACOs and CINs require engagement of the physician, as well as some degree of infrastructure and technology, to be successful. CINs may be an effective way for a practice to learn how to function in a capitated model before participation becomes required. An organization can be in a CIN without participating in an ACO.

Advantages

There are several upsides to participating in a CIN. First, the physician can prepare for risk models while still enjoying some degree of fee-for-service reimbursement. You can also increase your focus on quality, defining your own metrics (rather than having the government define them for you), and you may gain access to patient volumes through referral networks within the CIN. You can define shared incentives and participate in regional health exchanges.

In a CIN, you promote increased capture of an employer’s employee base within the network. The employer contracts with your network, and then hopefully refers employees and their dependents to providers who participate in the network. The shared savings relate to your being incentivized to bend the cost curve by more efficient utilization of health care dollars; that reduction in claims will be shared partially by the employers and partially by the providers. You have a certain defined area of claims cost, but if you are able to reduce that, it will come back to you.

Disadvantages

There are several downsides to CINs as well. There will be increased attention on your ability to achieve those costs savings as well as quality and outcomes. There is a possibility that if you do not meet the metrics, you will be excluded from that network, which might decrease your ability to participate in mandated programs down the road. There may be some loss of autonomy, either real or perceived, and there is some downside risk to revenue. There may be withheld payment depending on CIN overall performance, placing you somewhat at risk.

To prepare, you first must focus on your being able to demonstrate good outcomes. You also need to focus on reducing variability in your care. You need to engage your patients, ensuring that you are getting good patient satisfaction and that your utilization of resources is appropriate. It is important to understand what behaviors within your
practice could have unexpected consequences in driving up costs—such as your use of ancillaries or high-cost drugs—and you must pay attention to your referral patterns: How much are you able to do within your practice, and how much do you send out?

**Effect on Retina**

How will retina fit into either of these models? It is likely that ophthalmology, and retina in particular, will be a peripheral component of ACOs. We certainly have the potential of being carved out, which will be to our benefit for a short period of time, but then we may be mandated to be included. If a CIN is being developed in your area, you should look to see if this is something in which you want to participate; if not, maybe even think about initiating one on your own.

An employer or payer will want to contract for eye care or retinal care mainly if you can demonstrate value. There is an intersection of cost to the consumer and outcome and benefit received. I think all of us know intrinsically that what we do truly provides great outcomes and benefits per cost, but that doesn’t mean that there aren’t opportunities for us to improve, and it also doesn’t free us from the obligation to demonstrate this.

**Insurance Exchanges**

Another component of the Affordable Care Act is insurance exchanges, which are designed to provide ways for the population of uninsured or underinsured patients to get at least some degree of insurance coverage. These insurance exchanges will create a population of additional paying patients, as there are a large number of previously uninsured or underinsured individuals who will now have access to lower-cost insurance products. This is good for the overall patient population and may provide an opportunity for you and your practice. It does, however, provide challenges around utilization, as uninsured patients are sometimes the greatest utilizers of services. It will require patient education, and bringing those patients into your practice may adversely affect your outcomes, as they may be some of the sickest patients you take care of.

**The Value Proposition**

At the end of the day, value and quality will be critical, whether we are talking about ACOs, CINs, or insurance exchanges. Administrators are going to look at clinical outcomes and at the health of the population being served. How are we providing our services? How easy is it for patients to schedule an appointment with us? Then finally, they will look at innovation. What are we doing that is special and unique? Are we reliably translating and applying evidence and discovery in our clinical practices? In retina, we should be looking at clinical outcomes and at the health of our populations. We should be working side by side with internists and endocrinologists to help improve the quality of care and the health of our patients.

You have an opportunity to improve your quality and to keep your costs low. This is value. There will be a premium on your quality and your costs. High cost relates both to the rates you charge and to your utilization. Low-quality, high-cost providers will not work in these networks. The payers have much more data than you think they do about what resources you use, how often you use them, what you charge for them, etc. There will be competition for lower-cost options to take to market. Quality and cost will be critical to be competitive in any model, whether ACO, CIN, or exchange. In particular, insurers will be pushing for lower market rates because they are not getting paid very much for these exchanges. So, the providers they are going to want for the exchanges are those that remain competitive in their pricing structure.

There are a number of examples in innovation that we can apply. The American Academy of Ophthalmology wants us to take an active role. Perhaps you could offer flat fees for retinal detachment management, meaning you would be paid a certain amount regardless of how many operations are required. Another possibility is that there will be a flat fee for care of neovascular age-related macular degeneration, and you will be paid a certain amount for a year of care per patient, regardless of how many optical coherence tomography images, angiograms, and injections you perform or which drug you use. You will assume the risk, thereby saying, “I can take care of this patient for this many dollars.” Then, you have to manage that patient. Remember, your outcomes will be watched. You cannot just provide care that is inexpensive; it must still be quality care with good outcomes.

At Vanderbilt, we are piloting a concept called diagnostic management teams, which are designed to help doctors diagnose conditions more quickly and accurately, thereby avoiding unnecessary tests and increasing the potential success of treatments. We have been exploring this concept with regard to conditions such as bleeding disorders, but it may also have potential in the treatment of patients with uveitis. Diagnostic management teams help ensure that a patient’s workup is focused and that the right tests are performed for the right symptoms, as opposed to sending the patient for an extensive battery of test and imaging studies, regardless of the specificity of the symptom complex.

(Continued on page 12)
Pediatric Ophthalmology
Maintenance of
Certification for the
Retinal Specialist

By Scott A. Larson, MD

As part of the “Road to Recertification” article series in New Retina MD, Scott A. Larson, MD, provides an overview of some of the pediatric ophthalmology topics that retina specialists may want to review in more detail for Maintenance of Certification. As with every article in this series, Dr. Larson’s overview is not meant to take the place of a comprehensive review course; rather, its purpose is to highlight some key areas within the oculoplastics subspecialty and to encourage a more thorough review prior to taking the Demonstration of Ophthalmic Cognitive Knowledge exam.

- Diana V. Do, MD

Diagnostic Tests

Vision testing in the pediatric ophthalmology and strabismus clinic may differ somewhat when compared to the retina clinic. A large part of the examination is devoted to testing ocular motility, alignment, and visual sensory status. It may be helpful to review some of the tests that may not be used on a daily basis by a retinal specialist.

Cover testing. This test is used to assess the binocular alignment with suspected strabismus and when combined with a prism can be used to quantitate the amount of ocular misalignment when strabismus is present, both manifest and latent. Cover testing is also useful to determine if the patient has monocular or binocular diplopia and assess for any dissociative phenomena such as dissociated vertical deviation or latent nystagmus.

The cover test is performed after visual acuity and sensory testing, such as testing for stereopsis, so that those who are prone to break down can be accurately assessed before interrupting fusion. The occluder is placed in front of the fixating eye and removed quickly, this is known as the cover-uncover test. The patient should be tested at distance and near. Observing refixation movement in the fellow eye will show manifest strabismus is present or a tropia. If there is no movement of the fellow eye then observe the covered eye as it is uncovered. If there is refixation movement, then a phoria is present. The cover procedure should be repeated on both eyes. If there is a misalignment present, a prism is placed over the eye that is not being covered the instant the occluder is placed over the fixating eye. This is called the simultaneous prism-cover test and measures the amount of tropia present. A prism can be held over one eye and the occluder can be placed over the fellow eye and moved back and forth between the eyes while the patient is fixating on an object. This is called the prism and alternate cover test. This measures the total amount of strabismus present, both phoria and tropia. This measure is most often used for strabismus surgery calculations. Patients with small angles of esotropia on the simultaneous prism-cover test often have larger angles of esotropia on the prism and alternate cover test. This is seen in patients with monofixation syndrome.

Patients with paretic or restrictive forms of strabismus such as in cranial nerve palsies or Graves orbitopathy may have a larger deviation if the prism is held over the eye without paresis or the eye with less muscle restriction. When performing cover testing on these patients, first place
the prism in front of the affected eye. The measurement obtained is called the primary deviation. If the prism is held over the less affected eye, the deviation will increase; this is called the secondary deviation and should not be used for surgical planning. Herring's law states that equal innervation is sent to either eye to move the eye in the desired direction. When the eye has a paretic or restricted muscle, the involved muscle will receive greater innervation to create the desired movement. This larger innervation will also be sent to the fellow eye and cause the secondary deviation.

Errors can be introduced in cover testing if the patient is not fixating well because of inattention or poor vision. Testing should always be preformed with the patient's best-corrected vision. It is important to repeat this test at a different time to ensure the alignment is stable. Variable alignment measurements over time may indicate a myopathic condition such as myasthenia gravis.

**Worth 4-dot test.** This is a useful test to quickly determine information about the sensory status of your patient. This test requires spectacles with a red filter on 1 side and a green on the other. In order to remember which eye is seeing which color, I place the red filter over the right eye. A light source with lights color-matched to your spectacle-mounted filters is also required. The light should have 1 red light, 2 green lights, and 1 white light. One should be careful with LCD-screen Worth 4-dot tests, as the LCD screen may bleed through other colors in the spectrum and invalidate the test. This test is performed with the patient's best correction on first. The light is held at one-third of a meter for peripheral visual field testing and at 6 meters for central visual field testing. After showing the patient the lights, ask him or her how many he or she sees. Four lights is a normal response. A response of 5 lights means diplopia. A response of 2 red lights means suppression (of the left eye if you placed the red filter over the right eye). Three green lights also means suppression (of the right eye with the red filter over the right eye) and more than 5 lights is functional disease. A patient with small-angle strabismus may see 4 lights at near (peripheral fusion), but only 2 or 3 lights at distance (central suppression) are seen in the presence of monofixation syndrome. Additionally, if strabismus is present on cover testing, but the patient only sees 4 lights at near, this is anomalous retinal correspondence.

**Three-step test for cyclovertical muscle palsies.** This is a test to determine the presence of monocular cyclovertical muscle palsy, particularly a superior oblique palsy, and identify which is the affected muscle. There is often confusion about this test and how it should be applied. The 3-step test should be used in cases where there is suspected isolated cyclovertical muscle palsy in the presence of hypertropia. This test is invalidated if there has been previous extraocular muscle surgery especially surgery on the obliques, restrictive strabismus, vestibular disease, supranuclear disease, or more than one cyclovertical muscle involved.

For this test, 3 measurements are required. First, it should be determined which eye is hypertropic in primary gaze. This eliminates the elevators in the palsied eye and the depressors in the fellow eye from being considered. Second, the presence of hypertropia should be determined in side gazes. This eliminates the cyclovertical muscles for which action is opposite the side with the greatest vertical deviation. Last, hypertropia should be evaluated in head tilts, also known as the Bielschowsky head-tilt test. Head tilt to the right stimulates incyclotorsion of the right eye (contraction of the right superior rectus and right superior oblique muscles) and excyclotorsion of the left (contraction of the left inferior rectus and left inferior oblique). The opposite is true with the opposite head tilt. The head tilt with the largest hypertropia will have an underacting intorter or extorter, and the ipsilateral normal muscle will be unopposed and become manifest causing a larger deviation. After eliminating from consideration which muscles are not involved, the one muscle that is left should be the affected muscle. In reality, if this test does not reveal a superior oblique palsy most of the time, it is probably being performed incorrectly.

**Conditions**

**Amblyopia.** Amblyopia is one of the most common causes of vision loss in children. Amblyopia is the result of changes in the occipital lobe neural circuitry from an unequal or bilaterally poor visual experience early in life. It can be caused by constant strabismus (particularly esotropia), anisometropia, or any condition that can occlude the visual axis. Bilateral amblyopia can be caused by high refractive error. This typically occurs in the setting of hyperopia greater than 4.00-5.00 D, astigmatism greater than 2.50-3.00 D, or myopia greater than 7.00-10.00 D. Amblyopia associated with strabismus has some abnormal findings that may be helpful for diagnostic testing. Grating visual acuity, such as in teller card testing, is typically better than Snellen visual acuity. Also, a neutral density filter as in the normally sighted eye does not as readily degrade the vision in the amblyopic eye. This is known as the neutral density filter effect. Lastly, there is often a small amount of eccentric fixation in patients with amblyopia, particularly when the vision is worse than 20/200.

Treatment of amblyopia involves correcting anisometropia with spectacles. Occlusion treatment to the better eye or the use of atropine to cause cycloplegia and blur the image in the better eye can be effective. Once treatment for amblyopia is complete, surgical realignment of the eyes is more effective. Any treatment for amblyopia can cause vision loss in the treated (better) eye. This is known as reverse amblyopia and can be treated reverse patching or stopping the patch altogether. A significant minority of children will have regression of vision in the successfully treated eye; therefore, monitoring of vision after discontinuation of the amblyopia treatment is warranted. If the child is compliant with patching, and the vision has not improved as expected, repeating the dilated eye examination is recommended to reassess the refractive
error or re-examine the optic nerve and macula to ensure there are no other explanations for vision loss. Optic atrophy, mild optic nerve hypoplasia, or macular abnormalities can masquerade as amblyopia and may be missed on a cursory fundus examination.

Bilateral amblyopia is treatable with proper spectacle correction. Vision improvement is typically slow and steady, with most children showing substantial improvement in 12-24 months.

Deprivation amblyopia is caused by something occluding the visual axis. Causes may be cataract, corneal opacity, ptosis, pupillary membrane, or vitreous hemorrhage. In these cases, the visual axis must first be cleared during the critical period of visual development in order to obtain good vision. Infants who have significant visual axis opacity that is not corrected in the first 3 months of life are much less likely to gain good vision after treatment. Once the visual axis is clear, patching treatment can be instituted.

**Esotropia.** Infantile esotropia occurs in the first 6 months of life and has some unique characteristics. The child often has a family history of strabismus. Infantile esotropia is associated with amblyopia in about 50% of children. They often have angles of deviation larger than 30.00 prism D. Dissociated vertical deviation and inferior oblique overaction is also common (50%) but often occurs later in childhood. Typically, children with this condition have a small amount of hyperopia (<+2.50 D), and latent nystagmus is common. When examining the child, cross-fixation may be present. This is the phenomenon where the child uses the adducted eye to view objects in the opposite visual field. It is prudent to ensure the eyes can abduct by noticing the child abduct under monocular occlusion or eliciting abduction by the vestibulo-ocular reflex. The most common treatment for this condition is symmetric recessions of the medial rectus muscles. A resection of one or both lateral rectus muscles can be added for deviations greater than 60.00 prism D.

Esotropia acquired after 6 months of life is most often the result of excess accommodation in the setting of high hyperopia (average + 4.50 D). This condition is best treated with prescribing the child’s hyperopic correction. Accommodative esotropia can present as sudden onset of esotropia in a child 2-3 years old. Acute-onset esotropia without significant hyperopia can rarely be associated with neurologic disease such as hydrocephalus, Arnold-Chiari malformation, and rarely brain tumors. If the suspicion of neurologic disease exists, a brain MRI is the most appropriate test in this age group.

**Duane syndrome.** Duane syndrome is the result of a congenital defect in the fourth cranial nerve or its nucleus with aberrant innervation from branches of the third cranial nerve. Simultaneous contraction of the medial and lateral rectus on attempted adduction causes globe retraction and palpebral fissure narrowing. This condition is usually sporadic but can be an autosomal dominant condition in 10% of cases. There is a predilection for the left eye and females. Depending upon the degree of aberrant innervation, the alignment may be orthotropic, esotropic, or exotropic in primary gaze position. Typically, there is a smaller angle of misalignment than in sixth cranial nerve palsy (<20.00 prism D). Anisometric amblyopia is not uncommon in the Duane syndrome eye because of astigmatism. The indications for surgery are misalignment in primary gaze with a head turn, upshoots, or downshoots. Esotropic Duane syndrome can be improved with recession of the ipsilateral medial rectus muscle or transposition of the vertical rectus muscles towards the lateral rectus insertion. Exotropic Duane syndrome can be improved with ipsilateral lateral rectus recession and upshoots and downshoots can be improved with a Y-split of the lateral rectus.

**Sixth nerve palsy.** The most common cause of acquired incomitant esotropia is sixth nerve palsy. The etiologies often involve head trauma or increased intracranial pressure. Other causes include meningitis, intracranial mass, inflammation, or microvascular insult involving the abducens nerve. Workup of sixth nerve palsy should be coordinated with the patient’s primary care provider or neurologist. When considering treatment for the palsy, surgical treatment should be delayed for 6 months or longer if spontaneous improvement is anticipated, such as in traumatic, infectious, inflammatory, or microvascular causes. Prisms can be used to alleviate diplopia, and children should be monitored for amblyopia. Botox injection into the medial rectus can help prevent progressive medial rectus tightening while the lateral rectus recovers. If the esotropia persists beyond 6 months without improvement, horizontal rectus recession and resection can be performed if abduction is present but deficient. Transposition of the vertical rectus muscles in the direction of the lateral rectus is preferred if abduction is very poor.

**Superior oblique palsy.** The most common cause of incomitant vertical deviation is superior oblique palsy. It can be unilateral or bilateral and congenital or acquired. Acquired cases are most often the result of trauma, but microvascular disease and tumors can lead to superior oblique palsy in rare cases. The 3-step test is helpful in determining the palsied muscle. In unilateral cases, the hypertropia will be worse in contralateral gaze and ipsilateral head tilt. The patient will typically be tilting his or her head away from the side of the superior oblique palsy.
In unrepaired congenital cases, a facial asymmetry may be present. Ipsilateral inferior oblique over-action and exyclotorsion are common. Torsion can be evaluated with the double Maddox-rod test, Bagolini lenses, or objectively by observing exyclotorsion on an ocular fundus examination. As in sixth nerve palsy, acquired forth nerve palsy may also improve spontaneously especially in the setting of trauma. Treatments are varied but include recession of overacting inferior obliques, tucking underacting superior obliques, recession contralateral inferior rectus muscles for deviations out of the field of action of the obliques, and recession ipsilateral superior rectus muscles if they are contracted and tight. The Harada-Ito procedure is helpful to eliminate exyclotorsion if there is no significant vertical deviation in primary gaze.

**Infantile nystagmus syndrome.** Nystagmus in infancy can be caused by a number of factors or may be idiopathic. Nystagmus results from an abnormal development of the calibration of the oculomotor system during the system’s development. Typical idiopathic infantile nystagmus is conjugate and primarily horizontal. It is more apparent with attempted fixation or fixation at distance. It decreases with convergence. Null zones are common with associated abnormal head positions. There is a reversal of the nystagmus with presentation of a spinning optokinetic drum. The nystagmus is absent during sleep. Eye movement recordings show accelerating slow phases. Nystagmus that falls outside this typical description may require additional testing. A complete eye examination will help to elicit vision loss as a cause of nystagmus. Any vision loss present in the prechiasmal visual system can result in nystagmus. Etiologies include bilateral optic nerve hypoplasia, albinism, achromatopsia, aniridia, bilateral cataract, or other retinal diseases if bilateral. If retinal disease is suspected because the child has poor vision and nystagmus but the retinal appearance is normal, an electoretinogram may be particularly helpful.

**Congenital glaucoma.** Glaucoma in infancy is typically the result of an abnormality of the trabecular meshwork or anterior chamber angle. Typically, the first interventions are surgical as opposed to typical treatment in open-angle glaucoma common in adults. Most cases are bilateral and do not have a family history, but if there is a family history, the inheritance is typically autosomal recessive. The clinical triad consists of epiphora, photophobia, and blepharospasm. Common findings include corneal edema, Haab striae, buphthalmos and corneal enlargement, poor vision, optic nerve cupping, indistinct landmarks on gonioscopy, and elevated intraocular pressure. Often, the compliance and stretching of the eye is such that the pressure is not as elevated as high as one would guess, and one must consider the entire clinical picture to make the correct diagnosis. Congenital corneal opacities in infants are most commonly the result of congenital glaucoma. If the cornea is too cloudy to see instruments in the anterior chamber, trabeculotomy is typically the procedure of choice. Goniotomy can be used if the cornea is clear. Valve implant surgery is typically reserved for cases that fail angle surgery. Corneal scarring and amblyopia are common causes of irreversible vision loss in this condition.

**Congenital cataracts.** Cataracts in infants and children represent a diagnostic and treatment challenge for ophthalmologists. Most cataracts are idiopathic if they are unilateral; however, pediatric cataracts may be caused by a myriad of causes especially if they are bilateral. Hereditary cataracts are typically passed on in an autosomal dominant manner but there are a few families with autosomal recessive or X-linked pedigrees. Trauma and other ocular abnormalities are frequent causes of cataract in children. Aniridia, persistent fetal vasculature, anterior segment dysgenesis, and posterior lenticous can be to blame. Systemic and infectious etiologies must be considered in bilateral cases. Down syndrome, galactosemia, corticosteroid exposure, rubella and less likely toxoplasmosis, cytomegalovirus, herpes, and syphilis must be considered. If a child has dysmorphic facial features or other organ system or limb abnormalities and bilateral cataracts, a consultation is indicated with a pediatrician trained in genetic diseases.

Surgical treatment for cataract in infants includes management of the high rate of posterior capsule opacity and secondary pupillary membrane formation. The iris should be manipulated as little as possible. A primary posterior capsulotomy and anterior vitrectomy can reduce but not eliminate secondary membranes that occlude the visual axis. An intact posterior capsule in an infant or young child is guaranteed to become opaque. Implantation of intraocular lenses causes intense postoperative inflammation and secondary membrane formation more frequently than when the eye is aphakic. This fact combined with the difficulty in predicting the appropriate intraocular lens power with the rapid growth of the eye has caused many surgeons to avoid implanting intraocular lenses in the first year of life.

Visual rehabilitation of these children requires a long-term commitment on the part of the child’s caregivers. Contact lenses, glasses, and patching are a mainstay of treatment. Good outcomes are possible with vigilant care.

**Shaken baby syndrome/nonaccidental trauma.** Recognizing the ocular signs of shaken baby syndrome can...
help guide pediatricians who are caring for children who are suspected to be victims of abuse. Shaken baby syndrome is the combination of intracranial and retinal hemorrhaging. It is caused by sudden acceleration and deceleration in a child with poor head and neck strength and leads to injury by bridging intracranial vessels. The adherent vitreous in these young eyes creates traction forces that translate into hemorrhages in the retina. Typically, this injury occurs before the age of 3 years. The child may lack external signs of trauma but may have subdural or subarachnoid hemorrhages with bone fractures of different ages. The ocular findings include hemorrhages in multiple layers of the retina. The hemorrhages can be flame shaped, dot, blot, white centered, preretinal, subretinal, or even intravitreal. The type and extent of the hemorrhages should be documented. The hemorrhages can be unilateral or bilateral and are not always found on the side with greater intracranial hemorrhage. Full thickness perimacular retinal folds are very specific for shaking injury. Traumatic retinoschisis as well as optic nerve edema can also be seen.

In cases of suspected abuse there is often a history that is inconsistent with the clinical picture. However, care should be taken to rule out hematologic disorders that could lead to retinal and intracranial hemorrhages such as coagulopathies and leukemia.

Full thickness perimacular retinal folds are very specific for shaking injury. Traumatic retinoschisis as well as optic nerve edema can also be seen.

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Retinal hemorrhages can occur in cases of accidental trauma, but the location and extent of the hemorrhages is typically much less dramatic. Serious accidents such as high-speed motor vehicle accidents and falls from windows do not cause retinal hemorrhages anywhere near the number and extent found in a shaken baby. Cardiopulmonary resuscitation does not cause retinal hemorrhages.

**Conclusion**

This was a brief review of some of the common topics that may be touched upon in the maintenance of certification examinations in pediatric ophthalmology. You can find a complete list of topics at the American Academy of Ophthalmology website: http://one.aoa.org/CE/MOC/POCTopics.aspx.

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**Washington Medical Matters**

*(Continued from page 7)*

Advanced medical home care is a model that is often brought up in the discussion of conditions such as diabetes, congestive heart failure, and hypertension. This concept has been proposed to better manage and control disease indicators with fewer office visits, using care coordinators. There is currently a study being conducted in patients with glaucoma in which investigators are looking very carefully at compliance with glaucoma medications in an attempt to reduce the number of visits the patient needs to make.

**Potential Risks**

What are the risks for retina moving forward? First, we will have less control over our clinical decision making. Theoretically, our drug costs can be very high. I think you will see more of these programs that will either be controlling what drugs we use or at least steering us in certain directions. Our imaging utilization has been growing exponentially; this already is coming under great scrutiny. As subspecialists become increasingly tethered to large primary care groups, this creates the potential for reduced control of reimbursement.

Other than those of us who participated in capitated plans in the 1990s, we do not have a lot of experience to carry with us. That door was open for a short time, but then it closed both because patients demanded access to a wider range of providers and, because the economy improved dramatically, reducing the impetus for stricter control of costs.

**Conclusion**

The growth in the cost of health care is not sustainable, and the government recognizes this. We all recognize this. The Affordable Care Act is only part of what is going to happen. If it were to be repealed, many of the market forces that it set in motion would continue even without the government mandates. However, there are several initiatives that accompany health care reform that are aimed at improving value and reducing costs. A lot of this reads like what we experienced in the 1990s with capitated care and sharing risk.

There is uncertainty about whether all of these formal initiatives will be implemented, but the environment is changing. Retina practices will be protected to a certain extent because much of what we do is peripheral to the larger drivers of cost. However, there are opportunities for us to demonstrate value. The take-home message is that I encourage you to take advantage of these opportunities; we have to do it before they do it to us. We must stay ahead of government-mandated changes.

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Pearls for Reducing the Risk of Adverse Surgical Outcomes

By John W. Kitchens, MD

Long before a patient is under the surgical drape and you are about to insert the first cannula into the eye, it is important to consider criteria for who is a good surgical candidate. The foundations of a good surgical outcome are laid in the clinic. To follow are critical pearls toward successful surgery.

Patient Criteria

Remember that you will never regret the surgery you didn’t perform. I am not advocating putting off a macula-on retinal detachment or fixing a macular hole, both of which are obvious conditions that require surgical repair. This statement, rather, is referring to those cases in which you feel conflicted whether the patient would notice any improvement in his or her vision with the surgical procedure. In other words, you want to perform surgery that will make a difference to the patient, preferably improving vision, or at the very least, reducing the risk for visual loss.

Know the situations in which to think twice (or 3 times) before signing a patient up for surgery. The first is the patient with an epiretinal membrane (ERM) and good visual acuity. In these patients, it is critical to elicit symptoms consistent with macular disease (particularly distortion). The second patient for whom you should pause before recommending surgery is the diabetic with a tractional retinal detachment and good vision. This type of scenario is a setup for failure. In the past (prior to the practice of using preoperative bevacizumab [Avastin, Genentech]), it was critical to use as much panretinal photocoagulation laser as possible to ensure that the neovascularization was quiescent before attempting surgery. Bevacizumab, however, has helped with that issue. Despite the benefits of bevacizumab, patients can still develop posterior breaks during surgery that can result in a progressively downhill slide into hand motions vision in an oil-filled eye. It is critical to be sure that tractional changes are progressing into the foveal area before considering surgery. Some of the most ominous-looking tractional retinal detachments can be stopped just short of the losing central vision and remain stable for years with the help of modern anti-VEGF therapies.

Understand the patient’s chief concern. This is particularly important prior to taking a patient to surgery for macular surface problems (ERM and vitreomacular traction [VMT]). If the patient has good vision, be sure that his or her symptoms are consistent with the optical coherence tomography (OCT) findings. I have often found that patients with good vision and an ERM present with symptoms of dry eye or presbyopia and no metamorphopsia, or other symptoms consistent with macular disease. ERM’s are not emergency cases, and often a follow-up visit can help build a relationship between the patient and the surgeon. If the ERM is worsening on OCT, it will be evident to the doctor, the patient, and the patient’s family on a follow-up visit. This tincture of time also gives the patient an opportunity to critically assess his or her symptoms for those specific to a macular problem and also offers better insight to patient expectations.

Prior to consenting anyone for a vitreoretinal procedure, look at the optic nerve. One of my most regrettable cases involved a patient with an ERM and 20/60 visual acuity. Her OCT and exam findings along with her visual acuity prompted me to perform a vitrectomy and membrane peeling. When her visual acuity did not improve beyond 20/200 postoperatively, I began to scrutinize her optic nerve only to discover that it was glaucomatous (in a very gradually sloping manner). Fortunately, the patient was very understanding as I explained to her what occurred, which leads to a pearl that should not need to be stated:
always be forthright and honest about complications or errors. Every retina specialist has access to an OCT. Almost all OCTs can perform optic nerve and/or nerve fiber layer analysis. Look at the optic nerve, and if there is a question, obtain a nerve fiber layer OCT scan.

Preoperative Counseling

Establish a routine for discussing risks and benefits.
I believe this is important, as having a routine can help prevent important points from being left out of the discussion that may influence the patient’s expectations or understanding of the risks of surgery. A good routine involves ensuring the patient understands what is happening in their eye, followed by a discussion of the procedure that is needed to address the problem (without going into too much technical detail). The most important part of the discussion should be the extent to which the patient will see a noticeable improvement in his or her vision as well as any chance that he or she will lose a noticeable amount of vision. Next, the discussion of possible severe complications (typically infection or severe intraoperative hemorrhage) that could result in substantial or complete vision loss should be mentioned to the patient and his or her family. In certain cases (such as a macular hole, ERM, or retinal detachment), the odds of a recurrence of the problem should be mentioned. The fact that visual recovery following retinal surgery is often slower and less noticeable than in cataract or refractive surgery should also be noted.

Document your discussion. Adverse outcomes often result from miscommunication. It is good to have a set routine that will prevent omitting critical facts from the doctor-patient discussion. As important as the discussion itself is the documentation of the discussion. The old adage of “if you didn’t document it, you didn’t do it” applies to the preoperative discussion with patients as much as any other point in a patient encounter. Often days or weeks will go by between the preoperative visit and the actual surgery, and it is important that the surgeon understands the expectations set forth for the patient prior to surgery. For example, a patient with a history of a chronic macular hole and 20/400 preoperative vision should have a different level of expectations than a patient with a new, small hole and 20/60 vision. The expectation level set by the surgeon must remain consistent.

Surgical Considerations

Pay attention to the details. This is particularly important to new surgeons. Every detail matters when it comes to surgery. You need to know the details about the patient such as the preoperative diagnosis, visual acuity, lens status, prior history of surgery, and status of the fellow eye (monocular patients should be of utmost concern). It is also important to know the patient’s medical history including allergies, prior experience with anesthesia, medical problems such as diabetes or hypertension, and use of anticoagulant medications. The details of the bed position, position of the wrist rest, and the height of the surgeon’s and assistant’s seats are also important. Proper prepping of the patient’s eye and periorbital area is key to reducing the risk of infection, and a properly prepped and dried periorbital region will allow the drapes to be applied properly. One detail worth special attention is that of draping the patient. An improperly draped patient can result in fogging of the lens that can be frustrating and distracting even to the most keen surgeon. Placement of the cannulas is important to give the surgeon the best access to the entire vitreous cavity while reducing the risk of iatrogenic trauma to the crystalline lens. One practice that has been helpful for me is to visualize the surgery while scrubbing for the case I am about to perform. Surgical skill may seem like a gift that some are born with, but it is not. What is often not seen or quantified is the amount of time, thought, and training that the surgeon has put into preparing to perform the surgery.

Be a good decision maker. One of the areas in which many young surgeons struggle is decision making. Vitreoretinal surgery is so diverse, and there is often more than one “right way” to approach a problem in the OR. Experience and excellent training can help ease this transition. A general rule is that not making a decision on how to deal with an intraoperative problem is paramount to making the wrong decision. In other words, you must deal with the problem encountered rather than spending too much time contemplating the problem. Another way of phrasing this is the following mantra: the first stage of any surgical complication is denial. It is normal to not want something bad to happen to your patient (particularly if you were directly responsible for it occurring). The key is to acknowledge the misstep and work to correct it as efficiently as possible.

Postoperative Considerations

Dictate details from start to finish. Mitigating adverse outcomes does not end once a procedure has been performed properly. Dictation is an area fraught with the potential for misunderstanding. In general, most medical records are difficult for anyone other than the physician reviewing the records to decipher. This leaves a large amount of variability for interpretation by patients, other health care providers, lawyers, judges, and juries. Any part of the record that is dictated is exempt from handwriting or scribe interpretation. Often, the letter to the referring physician and the operative report are the only dictated items found in the medical record. The dictated letter should include the rationale for intervention and the options discussed. This letter should also avoid statements such as “this membrane peel should only take me 15 minutes” which can only come back to haunt the overly
situation.

experience, this has never been abused by a postoperative problem or issue. Many young specialists worry about ensures that they have access to me should they have a
ences of the entire process. Calling to check on my patients

surgery.

example is a recent patient of mine who

understanding your patient's financial situation.

“ambitious” surgeon. The operative report is a key part of the medical record and certainly will be scrutinized in the case of an adverse outcome. Set dictation templates should not be used in any situation because in retina, each case is unique. A talented plaintiff's attorney will scrutinize whether a template was used with any surgical complication. If something did occur and it was not noted in the operative report because a "standard" template was used, the physician has 1 strike against him. Also, be sure to dictate the rationale for surgery before dictating the actual procedure itself. The rationale for surgery should include the patient’s presenting concern, visual acuity, and preoperative exam findings. It should then include a brief summary of the discussion with the patient in regard to the potential for improvement/loss of vision, as well as the chances of a recurrence of the problem and the major risks of the procedure. This ties back to the preoperative discussion with the patient about expectations. If you have not had this discussion or have not documented your discussion with the patient, then this portion of the operative note cannot be completed.

Call and check on your patients the night after surgery. This not only helps a young retina surgeon build a practice, but it can be one of the most rewarding experiences of the entire process. Calling to check on my patients ensures that they have access to me should they have a problem or issue. Many young specialists worry about patients having access to their cell phone number; in my experience, this has never been abused by a postoperative patient, and the good will that this builds is nothing short of remarkable.

The final key is to understand your patient’s financial situation. A properly educated patient will understand that no surgery is 100% guaranteed. Showing an understanding for their financial situation is a level beyond just caring for a patient’s eye. An example is a recent patient of mine who developed a retinal detachment that was initially repaired with a primary scleral buckle, cryotherapy, needle drainage of subretinal fluid, and C3F8 gas injection. His inferior retina never reattached due to a focal area of proliferative vitreo-retinopathy that I did not support adequately (I should have added a 287WG segmental element and positioned the buckle more posterior). When talking with the patient and his wife about the persistent retinal detachment, the patient informed me that he was considering not undergoing additional surgery to “fix” the detachment again. It would have been understandable for a discouraged patient after a somewhat uncomfortable postoperative period to consider not having surgery. It is also understandable that he may want to weigh all of his options after I had disclosed that he probably should have gotten a larger element to support the scar tissue in his eye (I had hedged my bets that a 41 band would be sufficient). Despite his macula-off status, I felt he had potential for a good outcome with another surgery. When I inquired about his rationale behind not wanting surgery, he informed me that his insurance would only cover 2 surgeries per year (he had undergone a successful retinal detachment repair in his fellow eye several months prior). This additional surgery was going to cost him out-of-pocket money, which he simply did not have. It was easy to remedy this situation and write off a significant portion of the surgery. A 5-minute phone call to the hospital billing administrator also alleviated a portion of his hospital bill for the second surgery.

Summary

Every vitreoretinal surgeon will encounter adverse outcomes in his or her career. The key is dealing with them with integrity and grace, which are learned traits that can be practiced and perfected. You and your patients will benefit from developing these skills. I would love to hear of any other practice pearls that you may have in regards to avoiding adverse outcomes. Please feel free to email me your tips at dr.kitchens@gmail.com.

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**INDICATION**
LUCENTIS® (ranibizumab injection) is indicated for the treatment of patients with diabetic macular edema (DME).

**IMPORTANT SAFETY INFORMATION**
LUCENTIS is contraindicated in patients with ocular or periocular infections or hypersensitivity to ranibizumab or any of the excipients in LUCENTIS.

**WARNINGS AND PRECAUTIONS**
Intravitreal injections, including those with LUCENTIS, have been associated with endophthalmitis and retinal detachment. Proper aseptic injection technique should always be utilized when administering LUCENTIS. Patients should be monitored during the week following the injection to permit early treatment, should an infection occur.

Increases in intraocular pressure (IOP) have been noted within 60 minutes of intravitreal injection. IOP and perfusion of the optic nerve head should be monitored and managed appropriately.

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

In a pooled analysis of Studies DME-1 and DME-2, the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg LUCENTIS, 5.6% (14 of 250) with 0.3 mg LUCENTIS, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg LUCENTIS, 1.2% (3 of 250) with 0.3 mg LUCENTIS, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.5 mg LUCENTIS, 10.8% (27 of 250) with 0.3 mg LUCENTIS; the stroke rate was 4.8% (12 of 249) with 0.5 mg LUCENTIS and 2.0% (5 of 250) with 0.3 mg LUCENTIS.
WHERE IT MATTERS

LUCENTIS is the first and only FDA-approved drug for DME shown to improve vision

- Nearly 40% of patients improved ≥3 lines vs 15% with sham
- Rapid and significant vision improvement as early as day 7 that continued through year 3

A pooled analysis of Studies DME-1 and DME-2 showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg LUCENTIS, in 2.8% (7 of 250) of patients treated with 0.3 mg LUCENTIS, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg LUCENTIS and in 4.4% (11 of 250) of patients treated with 0.3 mg LUCENTIS. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded.

ADVERSE EVENTS

Serious adverse events related to the injection procedure that occurred in <0.1% of intravitreal injections included endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract.

In clinical trials in diabetic macular edema, the most common ocular side effects included conjunctival hemorrhage, cataract, increased IOP, and vitreous detachment. The most common nonocular side effects included nasopharyngitis, anemia, and nausea.

As with all therapeutic proteins, there is the potential for an immune response in patients treated with LUCENTIS. The clinical significance of immunoreactivity to LUCENTIS is unclear at this time.

1.2 Macular edema and vitreous opacification

In a pooled analysis of Studies DME-1 and DME-2 (see Clinical Studies (14.3), the ARI rate at 2 years was 28% (9 of 32) with 0.5 mg LUCENTIS and 16% (5 of 31) with 0.3 mg LUCENTIS in patients with age-related Macular degeneration. The ARI rate was 14% (4 of 29) with 0.5 mg LUCENTIS and 8% (2 of 25) with 0.3 mg LUCENTIS in patients with diabetic retinopathy. The stroke rate was 2.6% (1 of 39) in patients treated with 0.3 mg LUCENTIS compared with 0.2% (1 of 52) in the combined group of LUCENTIS-treated patients compared to 0.8% in the control arm. See Table 4 for details.

3.5 Pulmonary disorders

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, including those with LUCENTIS, there have been some reports of new onset atrial fibrillation, which should be monitored following the injection to permit early treatment should an adverse reaction occur.

4.2 Hypersensitivity

LUCENTIS is contraindicated in patients with known hypersensitivity to ranibizumab or any of the excipients in LUCENTIS. Hypersensitivity reactions may manifest as anaphylaxis.

5.2 Increases in intraocular pressure

Increases in intraocular pressure (IOP) were observed in LUCENTIS-treated patients compared with the control group. The IOP increases were transient and generally resolved within 2 weeks after treatment.

8.1 Pregnancy

LUCENTIS is contraindicated in pregnant women.

8.4 Pediatric use

The safety and effectiveness of LUCENTIS in pediatric patients have not been established.

17 PATIENT COUNSELING INFORMATION

In the days following LUCENTIS administration, patients are at risk of developing endophthalmitis. If the eye becomes red, sensitive to light, painful, or develops a change in vision, the patient should immediately seek care from an ophthalmologist (see Warnings and Precautions (5.1)).
Nevis (St. Kitts-Nevis), WI

The first time that George Bresnick, MD, MPA, and his wife, Geraldine Hendriksen, visited the Caribbean island-nation of Nevis (St. Kitts-Nevis, West Indies) in 1994, they were on vacation. Nevis has been an exclusive tourist destination for many years that has remained largely untouched by overcommercialization. Although an independent nation, the vibe on Nevis is Caribbean with a heavy dose of British influence due to its long history as a British colony. Both of these features add to its appeal to those seeking a holiday off the beaten path.

The residents of Nevis are fortunate in that they do have access to care, but at the time that Dr. Bresnick visited, there was no eye care on the island.

“People either had to go off-island to see an eye doctor or as was the case with the elderly, many of them did without,” Dr. Bresnick explained. Having recently finished a course in public health administration, Dr. Bresnick had a particular interest in this area. After a series of discussions with government officials, he put together a proposal for a program that would provide comprehensive eye care to residents of Nevis. Dr. Bresnick said that the project moved forward in a swift manner, most likely because he was in the right place at the right time.

“I went back to Nevis in August 1996, sent a proposal to the government in September that was approved 1 month later, and we came back in November,” he said.

Initially, patients were brought into the 5 local community health centers spread around the island for eye examinations, at which time those who required surgical intervention were identified. After funds were raised to purchase more sophisticated equipment, Dr. Bresnick and his team were able to begin performing cataract procedures.

“I also knew that we needed a laser, because of the large numbers of patients with diabetes, and we were able to procure one from a private foundation in Wisconsin. So about a year after the program was initiated, we had a decent eye clinic and an OR set up,” he said.

In order to raise public awareness about the program, Dr. Bresnick said that the local nurses and nurses’ aids were key. “They are the ones who know which patients are diabetic, and who is having trouble with vision. We asked the nurses and the nurses’ aids to encourage as many older people to visit the clinic as possible so that we could screen for diabetic eye disease, glaucoma, and cataracts.”
Transition in Leadership

Dr. Bresnick and Ms. Hendriksen continued to run the Nevis Eye Care Program (NECP) for 12 years until they decided to step down because of other obligations including a diabetic eye care program in Mexico. The hope was that Nevis would be successful in recruiting a full-time ophthalmologist to run the clinic. Around that same time, however, a category-4 hurricane hit the island causing substantial damage. The largest hotel on the island was forced to shut down for several years, which had a significantly negative impact on the tourism economy.

Raymond Hubbe, MD, an ophthalmologist from Massachusetts who had been part of the NECP program for several years, recognized that it was unlikely that Nevis would be able to devote the time and resources to recruit an ophthalmologist to come down permanently. To help save the Program, he decided to take over as Chair.

“There is usually 1 ophthalmologist at any given time in St. Kitts from Cuba. Cuban ophthalmologists in St. Kitts typically practice on that island for 2 years at a time, and although they will see Nevisians, patients have to make the trip there,” said Dr. Hubbe. He was concerned that many of the older residents, who tended to have more severe vision problems would not travel to St. Kitts.

Dr. Hubbe has been running the program for the past 4 years, arranging at least 2 trips per year for volunteers.

“I have a lot of volunteer doctors, several of whom are retina doctors, and there’s a cataract surgeon from Milwaukee who has been very involved since the program’s early days, Peter Foote, MD,” said Dr. Hubbe. “He brings a whole team with him: 2 OR techs, an anesthesiologist, and an optometrist. They come down and do about 50 cataract surgeries in 1 week. They’ve done an amazing job in the 10 years that they have been visiting.”

All surgeries are performed at the Alexandra Hospital in Charlestown. The facilities are basic but they have the necessary equipment, said Dr. Hubbe. “There is an operating microscope and we even have a backup microscope. Dr. Foote’s team brings down phacoemulsification units, and Alcon Laboratories, Inc., donates most of the intraocular lenses.”

There are 2 lasers in the clinic: a green argon laser for glaucoma and retina procedures and a diode laser (both Iridex lasers). Dr. Hubbe said that on a recent trip a retina specialist from Brooklyn, NY, Robert Fieg, MD, brought an indirect ophthalmoscope attachment for the lasers, which widened the range of procedures that they were able to perform.

Dr. Hubbe estimates that approximately 500 patients are seen in the clinic, although the number of patient visits are greater in the November session than in April because more cataract procedures are performed that require follow-up visits.

All of the physicians who participate in the NECP are volunteers, said Dr. Hubbe. “The government provides the space to us and many of the businesses in Nevis help out with donations to fund equipment, and I have had private donations from people in the United States, as did Dr. Bresnick when he chaired the
program.” Several of the hotels on the island have helped by providing lodging for the project (see Getting Involved, page 23).

“We have been fortunate to have donations from some of the ophthalmic companies, most notably Alcon and Allergan,” said Dr. Hubbe. “They both provide huge numbers of glaucoma drops, antibiotics, and steroid drops, and this has made a big difference for the program.”

Challenges and Rewards

Although Dr. Hubbe said that there have been some challenges in getting patients to come in for the scheduled appointments, overall the compliance is good.

“It’s better than I expected. This is due in part to the fact that Nevis has a good public health system for an island of that size,” he said. “They’ve put a lot of energy into their local health clinics, so there’s a lot of oversight into how people are doing.”

He said that strong family ties also play a role. “Family members really look after the older folks and have a good handle on what’s going on with their health.”

When asked what is the most rewarding aspect of volunteering in Nevis, Dr. Hubbe said, “It’s the people. They’re a joy to work with and they’re appreciative. It’s a place where I feel I can really make a difference. At home, we have plenty of ophthalmologists who can take care of patients, but if we weren’t there in Nevis, there would be no one. It does make a big difference.”

Dr. Bresnick agreed. “The number one reward for volunteering medical services to an underserved community is the satisfaction of being able to help people that need help,” he said. “Another benefit is the cultural experience of going to a place and getting to know people. When you participate in an ongoing mission, you get to really develop relationships with your patients and the local clinic staff.”

Haiti

Richard K. Lee, MD, PhD, an Associate Professor of Ophthalmology and a Glaucoma Specialist from the Bascom Palmer Eye Institute (BPEI), University of Miami Miller School of Medicine, has been involved with several humanitarian projects since his residency, also at BPEI. The Mitchell Wolfson Sr. Department of Community Service (DOCS) at the Miller School of Medicine holds many health fairs throughout South Florida, such as in Hialeah, South Dade, Little Haiti, and the Florida Keys, providing health care to underserved and/or economically disadvantaged patients.

Stemming from Dr. Lee’s involvement with the DOCS program, he was tapped to become the Director of Community Ophthalmology for BPEI.

Following the Jan. 12, 2010 7.0-magnitude earthquake that struck near Port-au-Prince, Haiti, BPEI teamed up with the Haitian Ophthalmology Society and the American Academy of Ophthalmology (AAO) to create an ongoing mission to provide ophthalmic care.

“The University of Miami Miller School of Medicine has a long-standing presence in Haiti,” said Dr. Lee. “Two of our faculty members at the University of Miami—one in neurosurgery (Barth Green, MD) and another in family medicine (Arthur Fournier, MD) started a nongovernmental organization in 1994 that is based both in Port-au-Prince and in Miami named Project Medishare. Project Medishare provides care, mainly in the Central Plains of Haiti and now in Port-Au-Prince, since the earthquake.”

BPEI joined the effort with volunteer BPEI

Dr. Lee examines a patient with altered mental status after a car accident for papilledema secondary to raised intracranial pressure shortly after the earthquake at the Project Medishare tent hospital.

Beatrice Valerius, MD, a Haitian ophthalmologist and Richard K. Lee, MD, PhD, at the Haiti Eye Symposium held in Port-au-Prince, Haiti, in April 2012. Dr. Valerius participated in Project Medishare’s first mini-fellowship for pediatric ophthalmology.

The banner in front of the eye clinic at Hospital Bernard Mevs/Project Medishare.
ophthalmologists and ophthalmology residents to perform refractions, provide eyeglasses to patients, and perform cataract and glaucoma surgeries in the Central Plains and Cap Haitien in northern Haiti prior to the catastrophic event.

“When the earthquake happened, we were the first US ophthalmologists to arrive,” he said. “By now, in 2012, most of the other foreign missions have left Haiti, but because of our ongoing efforts, we are one of the few groups that are remaining and working on creating a sustainable footprint for eye care in Haiti.”

Immediately following the earthquake, Project Medishare set up a 300-bed trauma and critical care field center at the airport, but has since moved its operations to Hospital Bernard Mevs. Dr. Lee is currently the Medical Director for Ophthalmology along with Michael Kelley, MBA (Vice Chair for Administration at the University of Miami Miller School of Medicine).

Service and Training

Dr. Lee said that the project has several goals, the main 2 being service and training. “Only approximately 40 ophthalmologists practice in the entire country, and there are only about 6-9 residents at any given time, so we have set up a mini-fellowship program for subspecialty training. Many of the surgical procedures are performed by doctors in humanitarian organizations who fly down during the winter, do surgeries, and then leave. Although it’s great that they are providing a service like this, it has been a problem for many countries because the local physicians and health care workers become disenfranchised.”

In order to address the situation of not having enough trained surgeons in Haiti, BPEI, the AAO, and the Pan American Association of Ophthalmology (PAAO) are creating a training program for several specialties within ophthalmology. The first is in pediatric ophthalmology. A recent ophthalmology resident graduate from Haiti (Breatrice Valerius, MD) was flown to BPEI via a travel scholarship from the PAAO for 3 months to observe surgery (as a foreign doctor, she is not allowed to perform surgery in the United States). The plan is to arrange, through the AAO (with Michael Brennan, MD) and BPEI, to have a pediatric ophthalmologist travel to Haiti to directly train the resident with hands-on surgery, which would create a situation similar to a surgical fellowship.

“We have similar plans for oculoplastics and retina in the near future,” said Dr. Lee. “There are a huge number of eye tumors and lid injuries that need to be repaired. The retina component is important because there is no full-time vitreoretinal surgeon in the entire country,” he said. “There is one ophthalmologist who performs core vitrectomies a few times a year at best with old equipment.”

Dr. Lee noted that Alcon Laboratories, Inc., has donated a new, still-in-the-box Accurus system to the project, in addition to phacoemulsification units, intraocular lenses, and medical supplies. Alcon has partnered with BPEI, the AAO, and the HSO to have all ophthalmic donations funneled and approved through the HSO for all medical missions in Haiti so that there is coordinated care provided in association with local ophthalmologists. As stated prior, although they are hoping to have retina surgeons join the mission in the near future, the goal is to install the oculoplastics program next since the technical and equipment requirements are less and the Mevs Hospital/Project Medishare operates one of the few working CT scanners in Haiti.

The logistics of organizing a project of this size in an impoverished country that has the added burden of such devastation from the earthquake, Dr. Lee said, has been challenging.

“It’s been 2 years since the earthquake, and things happen slowly, as the process of building a sustainable program is complex and costly. We still have equipment that we’re trying to have sent down or acquire. This is becoming less of an issue due to our excellent relationship with the Haitian Government and working with organizations such as Alcon and Direct Relief,” he said. Additionally, because Project Medishare’s goal in Haiti is to achieve a skills transfer from volunteer surgeons to local physicians, the process takes more steps and time.

Despite the challenges, Dr. Lee has found these experiences to be personally fulfilling. “Ophthalmologists are fortunate to have transformative skills, with which we can prevent and treat eye disease and positively affect many lives in incalculable ways. For example, improving the vision of a wage earner can improve the quality of life for an entire family. When we apply our skills in the developing world, it is amazing that with something as simple as a pair of glasses, we are able to transform lives.”

Dr. Lee gave an example of running a clinic in the central plains of Haiti. “In some cases we worked by penlight because patients had ridden all day on burros to arrive at 6 or 7 am just to get a pair of glasses, and we couldn’t turn them away even as the clinic ran from day to night without electricity,” he said. “It’s remarkably satisfying to realize the big difference one can make when we put our skill to work in an environment where people really need and appreciate our help.”

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Richard K. Lee, MD, PhD, is Associate Professor of Ophthalmology at the Bascom Palmer Eye Institute, Miami University Miller School of Medicine, and the Medical Director for ophthalmology with Project Medishare. Dr. Lee may be reached at RLee@med.miami.edu.
Getting Involved

Nevis

To obtain more information about volunteering for the Nevis Eyecare Program, contact Raymond E. Hubbe, MD at Eye Physicians of Northampton in Florence, MA; email: rayhubbe@gmail.com. Interested parties can also visit the Nevis Eye Care Program’s website: http://qrf.in/l8c9zg.

American Airlines and USAirways fly to St. Kitts, and from there volunteers can take a ferry or water taxi to Nevis. There are limited direct flights to Nevis. Although there are no formal housing arrangements for volunteers, several island resorts and plantation inns have donated to the NECP and have opened their doors to program volunteers including Oualie Beach Resort (www.ouliebeach.com); Hermitage Plantation Inn (www.hermitagenevis.com); Montpelier Plantation Inn (www.montpeliernevis.com); Nisbet Plantation Beach Club (www.nisbetplantation.com); and The Four Seasons Resort (www.fourseasons.com/nevis).

Oualie Beach Resort. Guest cottages are scattered along the beach and have been constructed with an eye to traditional Caribbean architecture.

Guest cottage at Hermitage Plantation Inn, which is situated in the hills along the side of Mount Nevis. All of the private cottages are excellent examples of traditional Nevis architecture.

Haiti

For the Medishare program in Haiti, volunteer applicants are referred from the AAO but undergo a credentialing process. Once an applicant has been accepted, he or she is responsible for travel to Miami. Having arrived in Miami, Project Medishare will arrange airfare, ground transportation in Haiti, lodging, and meals for the length of the volunteer’s stay.

Interested volunteers can go to the project’s website to obtain more detailed information and the complete the initial application form: http://qrf.in/l8c9sw.
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6:30 – 8:00 PM
EDUCATIONAL PROGRAM
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By Tim Flatley

In 2006, Vince Young was drafted by the Tennessee Titans and negotiated a contract that included $26 million of guaranteed funds. Six years later, Vince is out of football and out of money. When you analyze his mistakes, it illustrates how quickly retirement planning can be sidetracked.

These mistakes include not adequately planning for the future, trusting inexperienced financial advisors, believing that the good times will last forever, and not managing lifestyle expenses. Let’s examine each one of these areas in further detail.

Planning for the Future

The US Bureau of Labor Statistics of retirees reports that there are a record number of people working past age 65, which can be attributed in part to poor planning. How do so many people arrive at retirement tremendously ill-prepared? Much of it is a result of procrastination and being overwhelmed with the prospect of having to accumulate a large sum of money on which to retire. Visualizing the accumulation of $4-$5 million during your working career can be quite daunting. Faced with such an astounding task, it can be tempting to delay the planning process. However, as the philosopher Lao-tzu said, “A journey of a thousand miles begins with a single step.”

The first step is to establish your retirement goal, that is, how much money you need to live comfortably. There are several software programs, such as Quicken (Intuit, Inc.), that can perform the calculations necessary to create your retirement scenarios. There are a great many unknowns, most notably, your future income and the performance of your investments.

Quality planning software can run a Monte Carlo analysis that displays a variety of outcomes based on a wide range of assumptions. This exercise will determine how much you should save each year to stay on track. This routine should be repeated on an annual basis to review how actual events have changed your retirement outlook. Your financial advisor can help interpret the reports and keep you focused on what needs to be done to realize your goals.

Experienced Financial Advisor

Vince Young turned to family friends for his financial advice and is now suing them for misappropriating funds. People often make rash decisions in reaction to big market swings that can substantially disrupt a well-conceived retirement plan.

This is not to say that you cannot use family friends for advisors, but they should be evaluated just as thoroughly as any other advisor. Among many qualifying factors, education, years in the industry and a clean regulatory record are the most important. Your advisor should provide a plan against which he or she is responsible for reviewing your progress on a periodic basis.

An experienced advisor has endured the volatility of the investment/job markets and witnessed the effects on people in different stages of their lives. People often make rash decisions in reaction to big market swings that can substantially disrupt a well-conceived retirement plan. Not only can your advisor institute an investment plan that fits your risk tolerance, they can act as a stabilizing force when you are tempted to abandon it.

All Good Things Must Come to an End

We live in a constantly evolving world. Just as a once sought-after quarterback can suddenly find himself in the unemployment line, all of us face the risk that our current earning power cannot be sustained. The financial planning process involves prioritizing family objectives, developing a budget on which you can comfortably live, and then aggressively saving the balance. We like to run scenarios as to how much is necessary for a client to retire at age 50 or 55, in addition to his or her normal retirement age. If we can fund to target a younger age, it protects against a future loss of earnings.

Changing professional landscapes, illness, or even unforeseen death can cause irreparable harm to a family’s financial well-being. A sound investment strategy, suitable insurance (life, long-term care, disability), and a prudent estate plan will go a long way toward cushioning against unforeseen events.
Managing Lifestyle Expenses

Budgets generally will increase to match increasing income. Sometimes, they may even exceed income growth, which is why the planning process is so essential. For example, people often presume that they are adding an asset when they purchase a vacation home, when in reality, they are purchasing a liability. Mortgage payments, taxes, and upkeep all contribute to an additional drain on your income and ability to save for retirement. Vacation homes bring a lot of joy, but their cost impact should be included in your financial plan to examine how they may affect your long-term wealth accumulation.

Another expense that is affecting more and more retirees is the ongoing financial support that their adult children require. The slack economy of the last several years has led to more challenges to the career development of younger people.

These types of expenses are what can quickly erode savings, when you have not prepared yourself for the unexpected.

The Next Step: How to Succeed

If you have already created a plan, pull it out to measure your progress. Rerun the numbers to see where you are and compare the differences to the original. If you do not have a plan, take the first step and build one yourself or hire an advisor.

The sooner you implement the plan, the easier it is to identify the future steps required to make a comfortable retirement a reality.

Tim Flatley is the President and CEO of Sterling Investment Advisors, Ltd. He has 30 years of experience in the financial service industry and is a frequent lecturer. He is a contributing writer for Worth Magazine and has been recognized by SmartCEO, Barron’s Winner Circle Organization and the National Association of Board-certified Advisor Practices for his work in financial services. www.sterling-advisors.com

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Visit the New Retina MD website for the current issue and complete archives

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Turning Ideas Into Products

Experts share insights on taking the napkin sketch through the patent process to reality.
Part 1 of 2 parts.

With Emmett T. Cunningham Jr., MD, PhD, MPH; Paul E. Tornambe, MD; and Eugene de Juan Jr., MD

WHAT IDEAS ARE WORTH PATENTING?

Emmett T. Cunningham Jr., MD, PhD, MPH: Any idea that you believe is good is worth filing as an invention disclosure with a patent counsel. Many fewer are worth advancing all the way through the patent process. The best I can do is to paraphrase United States Supreme Court Justice Potter Stewart and say that it’s sort of like pornography: You know it when you see it. Your attorney can help with novelty but will be less helpful judging clinical utility or unmet need.

Paul E. Tornambe, MD: One never knows what idea may become valuable in the future and how much someone else will be willing to offer for the rights to or use of that idea. The patent process can be quite expensive, depending on whether you do it yourself or hire a legal firm to do it for you. A provisional patent may cost $5000 to $10,000, fees that cover patent literature review, patent infringement review, and document creation. A final patent costs an additional $5000 to $10,000.

For example, 25 years ago I was interested in artificial blood for the possible treatment of central retinal artery occlusion (CRAO) or retinopathy of prematurity. I saw a picture of a submerged rabbit with a pink fundus reflex and thought this artificial blood, being developed by a company in San Diego, might be applicable to replace the vitreous with artificial blood and oxygenate it for several days until a CRAO reopened. However, I could not get the company interested in this application. Had I tried the substance in the eye I would have realized it was heavier than water. Incidentally, this artificial blood is perfluorocarbon liquid, and my idea of oxygenating the vitreous would have rapidly changed to using this substance as a tool in retinal detachment surgery. One never knows where an idea will take you.

Eugene de Juan Jr., MD: This is a complex and important question. Different people have different ideas about patenting, so it is important to understand that the purpose of a patent is to protect commercial interests.

It should be noted that the patent laws will be changing soon; in March 2013, the United States will begin following the first-inventor-to-file system, as opposed to the current first-to-invent. The rest of the world already follows the first-to-file system. What this means is that, even if you had the idea first and you worked on it, if someone else files for a patent on that idea before you, they have the right to that patent. It does not seem fair, but that is the way the law is going to go. So as soon as you have that idea, you need to get it filed because that’s the priority date.

Patents are expensive. The decision to go down the patent road depends on your confidence in the commercial potential of your idea. Perhaps a business can handle filing multiple patents from ideas more easily than a university can, and a university can do it more readily than an individual. You don’t necessarily know whether your idea is commercially valuable. Of the patents issued each year in the United States, very few have commercial value. If you are an individual filing for a patent, the first phase costs about $5000, so it’s not an insignificant decision. There are lots of costs related to it, and it takes 5 years or so for a patent to be examined and then granted. The US Patent and Trademark Office (PTO) has said that it wants to get that time down to 1 or 2 years, but currently it takes multiple years.
If you think you have a good idea, there is a problem with discussing it. You need to write it down, and when you disclose it to somebody, if you don’t want them to become a co-inventor with you, say, “Do you mind if I tell you my idea, and I don’t necessarily want you to invent around my idea.” You can tell them your idea, and they might say, “Well, I think it should be blue.” In a normal conversation you might say, “That’s a good idea, I like that, and I’ll include it.” And then they become an inventor with you if you include that in your patent. You can do it more officially by having someone sign a confidentiality or disclosure agreement, stating that the other party can receive the information in return for keeping it confidential.

**DOES THIS CAUTION INCLUDE MENTORS?**

**Dr. de Juan:** For people whose confidentiality you can really trust, you can explain the situation to them, saying, “I’d like your advice and guidance, but I’m not asking you to participate with me at this point.” People should understand. Now if that person actually contributes to the invention and makes it better, it’s OK. You can split the patent costs (chuckle).

There are people you can ask, like a relative or friend, who are not going to claim that they invented something even though they may have helped to stimulate your idea. If someone you are talking to casually makes an important contribution, you probably should include them because in inventorschip it is really important to be honest, and different people have different expectations around that.

**WHAT DO YOU DO ONCE YOU COME UP WITH AN IDEA?**

**Dr. Cunningham:** Protect it. Draft a dated and signed invention disclosure and file it with an attorney or technology transfer office. Be sure to file before you publish or present your idea; “prior art” is no longer patentable.

Unless you have a deep domain expertise that includes what has been patented, what is likely to be patented, and what the market needs are for any given invention, you need to get trusted counsel. This usually comes from a lawyer. If you think the idea is novel, you think the market is big enough, and you are willing to pay the costs to take a US and maybe EU patent all the way through, which can be $20,000 to $30,000 or more, you have to talk with a patent attorney.

I usually suggest that inventors go to a local law firm and ask who in the patent group has expertise in a certain area, surgical tools for example, and make an appointment to meet with that person with drawings and invention disclosure. Many firms will have an invention disclosure form (IDF) for you to fill out. That is very inexpensive to file; you file that with your patent attorney, and that sets the date of invention. The actual date of invention is the date you write on your notes when you came up with the idea. The IDF files it with an attorney, memorializing the date. So if someone comes up with an invention that looks like it was invented or filed after yours, you have proof of your originality. After this, you have to work with your lawyer to covert this into a patent, which includes a review of existing relevant patents and literature, etc.

The patent attorney will tell you broadly if your idea is novel or not. They almost always say they don’t know specifically, but for $1,000-$3,000 they can do a patent search to see if it looks like it’s worth pursuing. If it does, then you have to bite the bullet and decide if you’re going to pursue it in the US, Europe, or beyond. To file patents globally is very expensive, hundreds of thousands of dollars from initial filing to final execution. Most people consider the most valuable markets to be the US and Europe. If you are going to pursue just those 2, it’s probably a minimum of $20,000 and may easily be double that.

You should also understand what it takes to bring tools, devices, and drugs to market. Three broad categories are tools and instruments, 510(k) (also known as premarket notification) devices, and premarket approval (PMA) devices and drugs. Respectively, these categories progress from products that take less time and money and a smaller team to those that take more resources to develop. Tools and instruments often take under $500,000 and a year to develop; 510(k) devices, on the other hand, can cost $5 to $50 million to develop and take 3 to 5 years, and PMA devices and drugs may take $50 to $200 million and 5 to 10 years to develop. Tools and instruments can be developed by an individual, whereas sophisticated devices and drugs typically involve larger teams.

**WHAT DO YOU DO WITH THE PATENT ONCE IT IS FILED OR GRANTED?**

**Dr. Cunningham:** It depends on the scope, the type of patent, and what it’s for. The first question is whether you have a product or a company. Products can be such things as tools, instruments, small market devices, and small market drugs, whereas companies involve multiple products and large markets. Is your product big enough to build a company around it? Most often it’s not, in which case you can either license it or try to build it yourself and sell it. I believe one or more of the glaucoma drainage devices are essentially sold by the inventors, not big companies. There are other examples like that.

Once the patent is filed, then you can start telling people about it. I typically do that under a confidential dis-
closure agreement or nondisclosure agreement. Be sure to choose your advisors carefully. The ideal advisor is discrete, knowledgeable, and experienced.

Once it is granted, the patent has a lot more value, so it’s typically the granted patents that get traction, particularly with companies or incubators.

At this point you should start thinking about funding sources. Major funding sources today include industry players such as Alcon, venture capital firms, and the National Eye Institute, but there are many other sources. In the very early, pre-seed stage, you will likely invest your own savings as well as ask close friends and family to invest. These investments often total less than $500,000, but this may be enough to get your idea off the ground.

The next step might be to look into research grants and foundations, such as the National Eye Institute, Research to Prevent Blindness, or the Small Business Innovation Research Program, among others. Next, “angel” investors, such as Life Science Angels and Tech Coast Angels, and incubators, such as ForSight Labs and Biogen Idec Innovation Incubator, can provide funding of up to $2 million. Later on, you might look to venture capitalists for larger investments. Industry partnerships can be made at any point but typically are best after some creation. Give yourself enough time to raise funding, 12 months or more, and ask for enough money to reach an important milestone.

In order to sell your idea, you need to start thinking like a businessman. Come to pitch meetings practiced and prepared. Investors must be confident that you are organized, reliable, and trustworthy. Along the same lines, make sure your PowerPoint presentations are polished. Use a lot of graphics and as few words as possible; word slides are sleeping pills. Keep them simple and spartan. Our brains are compartmentalized, and it is difficult to listen and read at the same time. A master of this was Steve Jobs, and you should watch some of his presentations on YouTube.

Dr. Tornambe: If you go through the process and expense of filing a patent, in most cases you should have a business plan to follow through. If you determine that your widget is an instrument that will be widely accepted and used, you will need a company that can manufacture the prototype, engineer the final product, and have people familiar with government regulatory agencies and a marketing unit to promote and distribute the product. Early in the game it might be worth signing a confidentiality agreement with a company already in the business that has done all this before. You can negotiate a royalty, which may be about 6% of the sale price. I have worked with Insight Instruments and Dutch Ophthalmic, both of which have treated me fairly and are excellent companies to partner with. Of course you will not reap the financial reward you would have if you did it yourself, but it may be a good way to get your feet wet.

Dr. de Juan: Once the patent is filed, it’s easier to talk to people about the invention. In my experience, I have seen similar ideas appear at similar times, but I have never seen an idea stolen. But they say it does happen, so you need to be careful. You should keep confidentiality if you think you need it. Generally there’s an advantage to keeping things confidential. If you tell somebody your idea, they may not use that confidential information, but they may think about the idea and come up with another, potentially better way of doing it.

Once the patent is granted, there is the presumption that it is valid and novel. I have never seen a technology that doesn’t have some intellectual property issues around it; there’s almost nothing new under the sun. Everything is derivative and combinations to a degree, particularly on the device side.

Commercialization is probably the hardest leap to make—getting a company to make a product, distribute it, and sell it. Everybody has ideas, but few physicians end up benefiting financially from their ideas through patents and business development. You really have to be willing to get into it and stay in it for 10, 15, 20 years.

Nikolas J.S. London, MD; Andre Witkin, MD; and Alok Bansal, MD, are former second-year vitreoretinal fellows at Wills Eye Institute, Thomas Jefferson University in Philadelphia. Dr. London may be reached at nik.london@gmail.com; Dr. Bansal can be reached at alok.s.bansal@gmail.com; and Dr. Witkin can be reached at ajwitkin@gmail.com.

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This article first appeared in the January 2012 issue of Retina Today. Drs. London, Witkin, and Bansal have since completed their fellowship. Dr. London is an associate with Retina Consultants in San Diego; Dr. Witkin is an Assistant Professor at Tufts Medical Center in Boston; and Dr. Bansal is an associate with Northern California Retina Vitreous Consultants in San José.

They say there’s power in numbers. We can’t help but agree.

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2.3 Intravitreal injection procedure

Intravitreal injection procedure should be carried out under controlled aseptic conditions. Using aseptic technique, all of the LUCENTIS vial contents are withdrawn through a 5-micron, 19-gauge filter needle attached to a 1-cc tuberculin syringe. The filter needle should be expelled until the plunger tip is aligned with the line that marks 0.05 mL of LUCENTIS solution. The filter needle should be replaced with a sterile 30-gauge × ½-inch needle for the intravitreal injection. The contents should be expelled until the platinum tip is lined up with the line that marks 0.05 mL on the syringe.

2.6 Administration

The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include the use of sterile gloves, a sterile drape, and a sterile field (to avoid contamination). A well-lit, well-ventilated, and a broad-spectrum antiseptic solution should be given prior to the injection.

Prior to and 30 minutes following the intravitreal injection, patients should be monitored for intraocular pressure using tonometry. Monitoring may also consist of a check for a perforation of the optic nerve head immediately after the injection (see Warnings and Precautions (6.5)). Patients should also be monitored for 1 minute in case a new symptom appears suggestive of endophthalmitis without delay following the injection (see Warnings and Precautions (6.3)).

Each vial should only be used for the treatment of a single eye. If the contralateral eye needs to be treated within 6 months after the first four injections if multiple injections are not feasible. Compared to continued monthly dosing, dosing every 3 months will lead to an approximate 5-6% loss of vision. Retrospective studies in patients with macular edema have demonstrated a loss of vision at Month 7, whereas patients who were not treated at Month 6 did not show the same reduction in visual acuity.

6.3 Immunogenicity

As with all therapeutic proteins, there is a potential for an immune response in patients treated with LUCENTIS. The immunogenicity data reflect the percentage of patients whose tests result were positive.

8.1 Pregnancy

Pregnancy Category C. There are no studies of LUCENTIS in pregnant women. In a study of placental and embryo-fetal development in pregnant cynomolgus monkeys, skeletal abnormalities were seen in fetuses in the highest dose tested of 1 mg/kg which resulted in trough exposures up to 13 times higher than predicted Cmax levels with single eye treatment in humans (see Nonclinical Toxicology (13.12)). Skeletal abnormalities were not seen in monkeys at 0.125 mg/kg, a dose which resulted in trough exposures equivalent to single eye treatment in humans. Animal reproduction studies are not always predictive of human response. It is also not known whether ranibizumab can cause fetal harm when administered to a pregnant woman or can affect the reproductive capacity. Based on the anti-VEGF mechanism of action for ranibizumab (see Clinical Pharmacology (12.1)), skeletal abnormalities were not observed in DME or RVO patients with the highest levels of immunogenicity.

8.2 Nursing mothers

It is not known whether ranibizumab is excreted in human milk. Since many drugs are excreted in human milk, and because the potential for absorption and adverse effects in the nursing infant is unknown, the decision to give LUCENTIS to a nursing woman should be made with caution.

8.4 Pediatric use

The safety and effectiveness of LUCENTIS in pediatric patients have not been established.

8.5 Geriatric use

In Studies DME-1 and DME-2, approximately 72% (1366 of 1908) of patients randomized to treatment with LUCENTIS were ≥ 65 years of age and approximately 43% (822 of 1908) were ≥ 75 years of age. No differences in safety or efficacy were seen among the different age groups. Age did not have a significant effect on systemic exposure. Aged patients treated with LUCENTIS at higher doses are at increased risk of arterial thromboembolic events and decreased risk of neovascular AMD.

17 PATIENT COUNSELING INFORMATION

In the days following LUCENTIS administration, patients are at risk of developing endophthalmitis. If the eye becomes red, sensitive to light, painful, or develops a change in vision, the patient should immediately seek care from an ophthalmologist (see Warnings and Precautions (5.1)).
NOW FDA APPROVED FOR DME

DESIGNED FOR INTRAOCULAR ACTIVITY AND RAPID SYSTEMIC CLEARANCE

PRECISION AND PERFORMANCE WHERE IT MATTERS

LUCENTIS is the first and only FDA-approved drug for DME shown to improve vision

• Nearly 40% of patients improved ≥3 lines vs 15% with sham
• Rapid and significant vision improvement as early as day 7 that continued through year 3

INDICATION
LUCENTIS® (ranibizumab injection) is indicated for the treatment of patients with diabetic macular edema (DME).

IMPORTANT SAFETY INFORMATION
LUCENTIS is contraindicated in patients with ocular or periocular infections or hypersensitivity to ranibizumab or any of the excipients in LUCENTIS.

WARNINGS AND PRECAUTIONS
Intravitreal injections, including those with LUCENTIS, have been associated with endophthalmitis and retinal detachment. Proper aseptic injection technique should always be utilized when administering LUCENTIS. Patients should be monitored during the week following the injection to permit early treatment, should an infection occur.

Increases in intraocular pressure (IOP) have been noted within 60 minutes of intravitreal injection. IOP and perfusion of the optic nerve head should be monitored and managed appropriately.

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LUCENTIS clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

In a pooled analysis of Studies DME-1 and DME-2, the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg LUCENTIS, 5.6% (14 of 250) with 0.3 mg LUCENTIS, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg LUCENTIS, 1.2% (3 of 250) with 0.3 mg LUCENTIS, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.3 mg LUCENTIS and 10.8% (27 of 250) with 0.3 mg LUCENTIS; the stroke rate was 4.8% (12 of 249) with 0.5 mg LUCENTIS and 2.0% (5 of 250) with 0.3 mg LUCENTIS.

A pooled analysis of Studies DME-1 and DME-2 showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg LUCENTIS, in 2.8% (7 of 230) of patients treated with 0.3 mg LUCENTIS, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg LUCENTIS and in 4.4% (11 of 250) of patients treated with 0.3 mg LUCENTIS. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded.

ADVERSE EVENTS
Serious adverse events related to the injection procedure that occurred in <0.1% of intravitreal injections included endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract.

In clinical trials in diabetic macular edema, the most common ocular side effects included conjunctival hemorrhage, cataract, increased IOP, and vitreous detachment. The most common nonocular side effects included nasopharyngitis, anemia, and nausea.

As with all therapeutic proteins, there is the potential for an immune response in patients treated with LUCENTIS. The clinical significance of immunoreactivity to LUCENTIS is unclear at this time.

For additional safety information, please see LUCENTIS Brief Summary on adjacent page.