How can we evaluate new advances to see more clearly after cataract surgery?

Cataract, the clouding of the eye's lens, is a condition that affects a majority of the population 65 years and older, and is one of the most common surgeries performed in the Medicare population. To replace the natural, clouded lens, an artificial lens, known as an intraocular lens (IOL), is surgically implanted in its place. This lens replacement allows patients to see clearly again. This is a highly successful procedure, and the large majority of patients regain sufficient vision for driving purposes (20/40 or better). However, they may still need reading glasses or bifocals for near and intermediate distance to perform activities such as reading, computer usage, use of smartphones, etc. Many patients would like not to wear glasses for reading or other tasks.

To meet these patient expectations, a category of IOLs, known as premium IOLs, have been developed, to provide patients with good visual acuity across a range of distances. However, these need to undergo a rigorous approval process governed by the U.S. Food and Drug Administration (FDA) to assure their safety and effectiveness. Relatively few products have succeeded in gaining approval, approximately 10 by 2014. There are several reasons for this, including limited standards with respect to complication or adverse event (AE) rates, appropriate test methods for different premium IOLs to determine whether the IOL is safe and effective for viewing across a range of distances, and the need to evaluate on a case by case basis without more relevant standards.

Cognizant of this problem, the FDA and the American Academy of Ophthalmology collaborated on a workshop to bring together clinical experts, industry, patient representatives and regulators to discuss the problem and brainstorm specific solutions, which was held on March 24, 2014.

There was broad discussion about the science of premium IOLs, and how to improve the science of evaluating these new products so that relevant tests and processes would be available to assess product safety and effectiveness and streamline the premarket review by FDA. The workshop recommended future steps to address four major areas:

- Tool to measure patient-reported outcomes relevant to patients receiving premium IOLs
- Definitions of adverse events relevant to premium IOLs
- Tests to measure how well these IOLs allow the change of focus from distant to near objects and vice versa, known as accommodation
- Tests to evaluate a new category of IOLs that are intended for a range of viewing distances, especially for intermediate distances, known as extended depth of focus IOLs.

An important focus of the workshop was on patient-reported outcomes. What are the outcomes most relevant to patients? What are patient expectations prior to surgery, and what affects their satisfaction after surgery? The use of patient-reported outcomes will allow the voice of the patient to influence the determination of what IOLs meet the patients' needs and thus, meet an important

criterion for success. The group outlined several patient-centered concerns, including the desire not to wear glasses, the ability to see well at any distance, and visual symptoms affecting the quality of their vision, i.e.., glare or halos, poor vision at night, blurriness, etc.

The result of the workshop was the creation of an Academy Task Force to address these issues and develop documents that could be of use to FDA. This, in turn, will help to enhance the regulatory process' timeliness and standards for bringing safe and effective premium IOLs, i.e., products that meet the patient's defined needs, into the hands of clinicians for use in the appropriate patients.

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