



FDA / AGS Workshop

Validity, Reliability, and Usability of Glaucoma Imaging Devices

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Impact of Glaucoma on Public Health

- Open-angle glaucoma affects an estimated 2.2 million people in the United States, and that number is likely to increase to 3.4 million in 2020 as the population ages.*
- 130,000 in US are blind from glaucoma**

*Friedman DS, Wolfs RC, O'Colmain BJ; Eye Diseases Prevalence Research Group. Prevalence of open-angle glaucoma in the United States. Arch Ophthalmol 2004; 122:532-8.

**Congdon N, O'Colmain B, Klaver CC; Eye Diseases Prevalence Research Group. Causes and prevalence of visual impairment among adults in the United States. Arch Ophthalmol 2004;122:477-85.

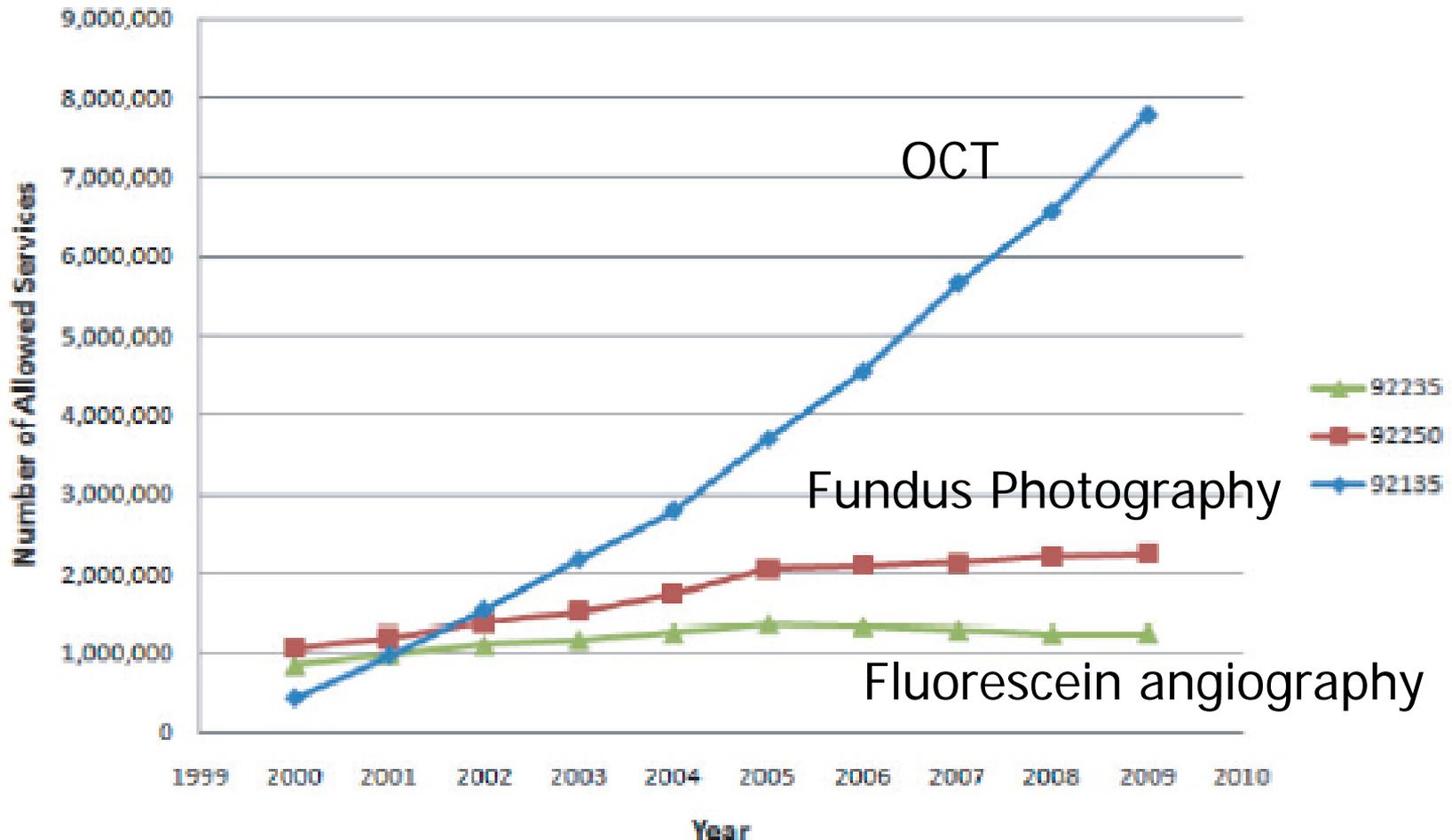
Use of Imaging Devices in Glaucoma Patients

- “From 2001 to 2009, [other ocular imaging] increased dramatically whereas VF testing declined considerably.” *

*Stein et al “Trends in Use of Ancillary Glaucoma Tests for Patients with Open-Angle Glaucoma from 2001 to 2009” Ophthalmology 2011

OCT Utilization

Allowed CPT 92135 Medicare Services vs Year



FDA's Motivation for the Workshop

- Glaucoma imaging devices are the focus of significant premarket activity
- These devices are increasingly used in clinical practice for clinical decision making and management
- Imaging device parameters are increasingly being used as part of the enrollment criteria in glaucoma therapeutic studies

Dependence on Technology



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Current Use of Imaging Devices in Glaucoma Diagnosis and Treatment

- “When clinicians observe red lettering in data printouts or see red numbers out of the normal range, the presumption is that those results are abnormal..” *
- “...we have become enamored with sophisticated analysis algorithms and colorful printouts before we have studies that show what the results of the tests mean.”**
- “Although there is objective image ... subjective quality assessment is still necessary to ensure that the image acquired is adequate for evaluation and that the analysis algorithm has functioned properly.”***

*Chong, Gabriel T.; Lee, Richard K. “Glaucoma versus red disease: imaging and glaucoma diagnosis” Current Opinion in Ophthalmology: March 2012 - Volume 23 - Issue 2 - p 79–88

**Marc F. Lieberman, Nathan G. Congdon, Mingguang He, “The Value of Tests in the Diagnosis and Management of Glaucoma” Am J Ophthalmol 2011;152:889–899

*** JS Schuman. “Detection and Diagnosis of Glaucoma: Ocular Imaging”. IOVS 2012; 53: 2488-90.

Workshop Objectives

- To highlight issues that the user should be aware of when interpreting the information from glaucoma diagnostic devices
- To provide industry insight into current FDA thinking
- To receive input from academia (clinicians and statisticians), industry, and other stakeholders on how to improve “regulatory science” in this product area:
 - » Fine tune endpoints and strategies for assessing the relative safety and effectiveness of this new diagnostic information in the management of glaucoma

The Challenge to Users of Glaucoma Imaging Devices

“...if future studies confirm our specific findings regarding the recent shift in eye care providers’ methods for following OAG and suspected glaucoma, **greater attention will need to be paid to more fully understand and overcome some of the known limitations associated with current [other ocular imaging] devices.**”

Stein et al “Trends in Use of Ancillary Glaucoma Tests for Patients with Open-Angle Glaucoma from 2001 to 2009” Ophthalmology 2011