Methods for Updating AE Rates and the FDA-AAO IOL Registry

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Objectives

- Define registries
- Describe use of registries
- Describe FDA-AAO-Quintiles/Outcome registry project
  - How it can help update adverse event rates
  - How it can help in medical device surveillance

Definition of Registry

- An organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s).
  - Source: AHRQ Registries for Evaluating Patient Outcomes: A User's Guide

Role of Registry in Medical Device Surveillance

Registries play a unique and prominent role in medical device surveillance because they can provide additional detailed information about patients, procedures, and devices not routinely collected by electronic health records, administrative or claims data.

- Promote the development of national and international device registries for selected products

Prior Medical Device Surveillance for IOLs

- Retrospective collection of data
  - After TASS has occurred and been identified
  - Missing data
    - Gaps in information about medical product use
  - Lack of information about specific patients and their outcomes
  - Difficult to assess causality

FDA-AAO-Quintiles/Outcome IOL Registry

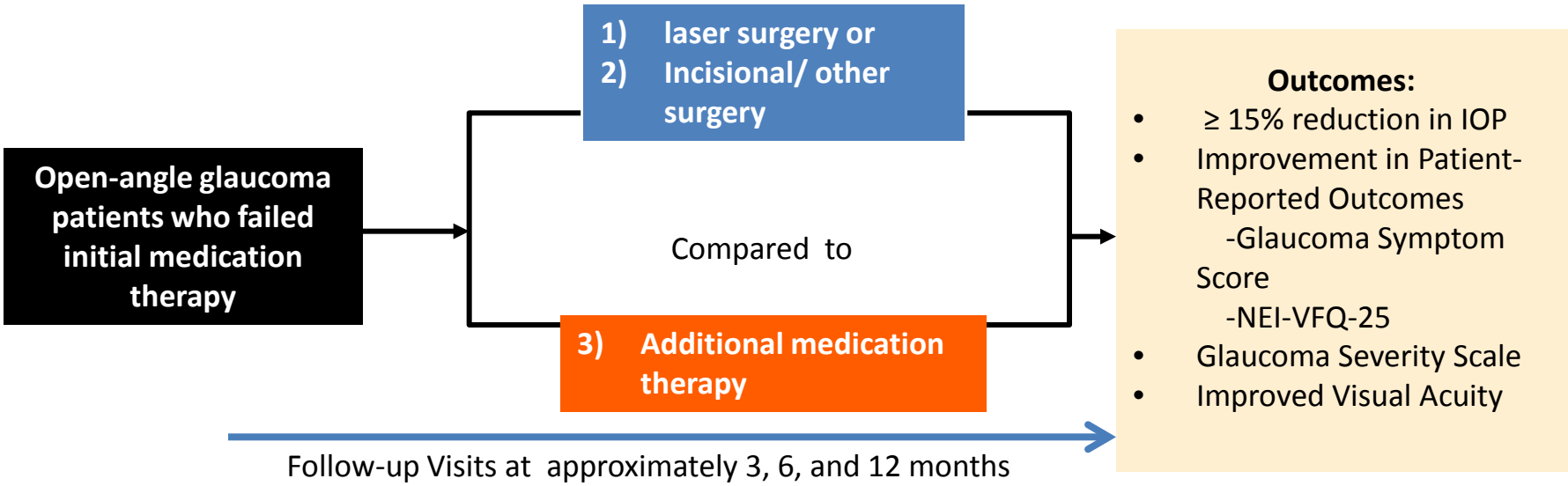
A prospective patient registry intended to provide:

- Advance warning of sentinel events associated with specific IOL types
- Extended post-market surveillance and safety monitoring of IOLs
- Active surveillance of this widely used group of medical devices

Data to be Collected

- Patient and provider characteristics
  - Systemic and ocular co-morbidities
  - Concomitant medications
  - Demographics (age, sex, race, region)
  - Surgeon training and practice type
- Details on operative procedure
  - Surgical technique
  - Medical products used in surgery
    - Brand, lot numbers, Unique Device Identification (UDI)
  - Surgical case ordering and date
- Details on complications

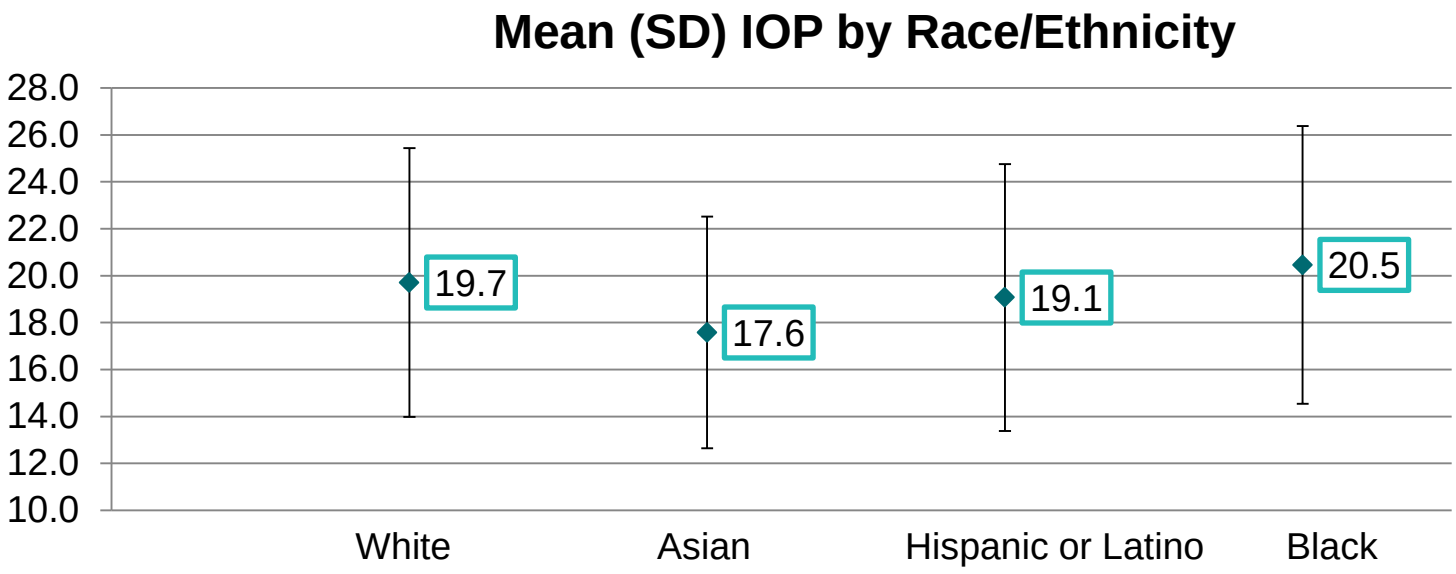
Study Design of RiGOR



- Prospective, observational cohort study in US
  - 45 community and academic ophthalmologic practices
- AHRQ priority populations (racial/ethnic minorities, Medicare/Medicaid insurance)
- Study Duration: ~2 years, 1 year of patient follow-up
  - Enrollment between March 2011 and April 2012
  - Follow-up ended in March 2013.

Baseline IOP

	Laser Surgery	Other Surgical Procedures	Additional Medication Therapy
Mean (SD)	19.2 (5.2)	21.0 (6.7)	19.7 (5.7)



Using Registries for Incidence Rates

Crude rate = C = R/N x 100,000

$a_1 = r_1/n_1$ X 100,000

Additional Methods for Updating Adverse Events

- Pooling of premarket approval data
- Multicenter cohort study

Summary

- Surveillance using a registry of cataract surgery could identify an early signal in a medical-device-related adverse events
- FDA in collaboration with Quintiles/Outcome and the Academy is rolling out the registry
- Data collected in the registry can be used to update historical grid adverse event rates, along with other methods
- Early identification of outbreaks will help to resolve device-related adverse events