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The African American Eye Disease Study: Design and Methods

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Abstract

Purpose: To describe the study design, operational and recruitment strategies, procedures and baseline characteristics of the African American Eye Disease Study (AFEDS), a population-based assessment of the prevalence of visual impairment, ocular disease, visual function and health-related quality of life in African Americans.

Methods: This population-based, cross-sectional study included over 6,000 African Americans 40 years and older residing in and around Inglewood, California. A detailed interview and eye examination was performed on each eligible participant. The interview included an assessment of demographic, behavioral, and ocular risk factors and health-related and vision-related quality of life. The eye examination included measurements of visual acuity, intraocular pressure, visual fields; fundus and optic disc photography; a detailed anterior and posterior segment examination; and measurements of blood pressure, glycosylated hemoglobin levels, and blood glucose levels.

Results: The AFEDS cohort includes more than 6000 participants that have completed a home questionnaire and a comprehensive eye examination. The majority of participants were female (63%), the average ($\pm$ standard deviation) overall age was 60.9 ($\pm$ 11.3). Participants are mostly working (40%) or retired (41%), non-smoking (57%), partial drinking (54%), and with at least some college education (38%). A trust-development recruitment strategy was refined in order to overcome challenges in study participation.

Conclusion: The AFEDS is the largest epidemiologic eye study among African Americans to date. The AFEDS cohort will provide information about the prevalence and risk factors of ocular disease in the largest ophthalmologic study population of African Americans in the United States.

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INTRODUCTION

African Americans (AAs) are one of the largest minority populations in the United States, representing approximately 13% of the population.¹ AAs remain under-represented in studies of vision health, even though they experience a disproportionate burden and different pattern of eye disease than other racial/ethnic groups. AAs experience higher rates of visual impairment (VI), blindness, open angle glaucoma (OAG), and diabetic retinopathy (DR) than Non-Hispanic Whites in the United States.^{2–6} Much of our knowledge about eye disease in AAs is based on population-based data collected more than 2 decades ago.^{2,7} Updated data, using modern clinical diagnostic procedures and definitions, are needed. Since these studies were published, numerous clinical trials have reported the benefits of tighter glycemic control⁸ and blood pressure⁹ on the prevention of DR, and the importance of lowering intraocular pressure to prevent the development and progression of glaucoma.¹⁰ The potential impact of changes in preventive and clinical care on the prevalence and severity of eye disease in AAs is unknown.

The United States is expected to experience rapid growth in the proportion of adults aged 65 years and older, with projections of 88.5 million people by 2050,¹¹ of which approximately 10.5 million will be AAs. With more adults in age brackets impacted by higher rates of eye disease,¹² the burden of age-related eye disease is likely to increase among AAs, who are disproportionately impacted by obesity^{13,14} and diabetes. Researchers need to characterize the prevalence, etiologic mechanisms, and impact on the activities of daily life of these eye diseases, in order to inform prevention, and targeted screening and treatment programs. Further, it is crucial to determine whether AAs are receiving needed vision care and to examine factors that influence obtaining care.

The African American Eye Disease Study (AFEDS) is designed to fill the gaps in our understanding of vision health in AA adults. The study will provide data to estimate the prevalence of VI, blindness, lens opacities, OAG, Age-related Macular Degeneration (AMD) and DR in AAs and to evaluate how these eye diseases impact quality of life. The study will evaluate the risk of eye disease associated with demographic, behavioral, and clinical factors, using standardized protocols in a population-based cohort of AAs aged 40 years and older; and illuminate factors that influence eye care utilization in AA adults.

MATERIALS AND METHODS

Study Design

This five-year, population-based study was designed to assess the prevalence and risk factors associated with VI, blindness, lens opacities, glaucoma, AMD and DR in 6500 non-institutionalized AAs, aged 40 years and older, in and around Inglewood, California, within Los Angeles County. A door-to-door census identified eligible individuals, who were invited into the study. Institution review board/ethics committee approval was obtained from the University of Southern California Health Sciences Review Board. This study complies with the Health Insurance Portability and Accountability Act of 1996, and adheres to all Declaration of Helsinki guidelines. All study participants provided written, informed consent.

Specific Aims

AFEDS has 3 specific aims:

- 1) To estimate the age-specific prevalence of VI, blindness, lens opacities, DR, AMD and OAG among AAs aged 40 years and older, and to compare these prevalence rates to those in Latinos in the Los Angeles Latino Eye Study (LALES) and Chinese Americans in the Chinese American Eye Study (CHES). Further, to examine the potential association of VI, blindness, and ocular diseases with health-related quality of life.
- 2) To evaluate demographic, behavioral, and clinical risk factors that may be associated with VI, blindness, lens opacities, DR, AMD and OAG in AAs, and to compare to those present in LALES and CHES. Measures include:
 - a) socio-demographic, anthropometric,
 - b) biological (e.g., glycosylated hemoglobin/HbA1c, blood pressure markers of microvascular disease, biometrics including axial length and optical coherence tomography of the anterior chamber), structural ocular, lifestyle or behavioral, and wellbeing and vision-specific quality of life, as described in the LALES and CHES design and methods publications.^{15,16}
- 3) To describe the proportion of AA participants who receive an annual preventive or follow-up eye examination for VI, DR, AMD, OAG, or lens opacities. Further, to identify determinants of obtaining eye care in the 12–18 months following the AFEDS baseline ophthalmic examination, among participants who are given a recommendation for follow-up care.

Organizational Structure

Resource centers for AFEDS include the Survey Research Center (SRC), Local Eye Examination Center (LEEC), Data Management and Analysis Center (DMAC), and SERI Ocular Reading Center (SORC), which make up the Study Coordinating Center (Figure 1). Advisory groups include: the Internal Advisory Group, which meets weekly to review study progress and address scientific and methodological issues; Community Advisory Group, which meets periodically to ensure community involvement and obtain advice from community stakeholders; and Data Monitoring and Oversight Committee, which meets once a year to provide external oversight.

Study Area

The study area includes 30 census tracts in and around Inglewood, which we chose because: (1) it is primarily residential; (2) it has a high proportion of AA residents; (3) its population provides an optimal number of individuals to ascertain precise prevalence estimates; (4) there is support and encouragement from its community and church leaders, as well as optometrists and ophthalmologists; (5) it is near the University of Southern California Medical Center, and (6) its demographic characteristics are similar to those of AA individuals in Los Angeles County, California, and the United States (Table 1).

Sample Size Considerations and Sampling Method

We set the AFEDS sample size recruitment goal based on the need to obtain robust prevalence estimates of ocular diseases, blindness, and VI. The sample size also needed to be adequate to detect relationships between demographic, clinical, biologic, and lifestyle factors and ocular disease. We estimate that a sample size of 6500 is adequate to obtain a minimum of 80% power and robust age-specific prevalence estimates for specific eye diseases and conditions. To obtain a precise prevalence estimate, the National Center for Health Statistics (NCHS) recommends that the standard error should be no more than 30% of the point estimate.¹⁷ The relative standard error (RSE) is the standard error divided by the mean and expressed as a percentage. A lower RSE is preferable, as it will result in a more precise measurement due to lower variance about the mean. Table 2 shows the RSEs for age- and disease- or condition-specific prevalence estimates for our study's projected sample size. To make these determinations of precision, we used estimates from population-based studies, including the Baltimore Eye Survey and The Barbados Eye Study.^{7,18} The sample was selected from all residential households within Inglewood and enumerated by the SRC.

Operational Strategies

Ascertainment of Eligibility

Household residence is determined using the US Census definition,¹⁹ which counts a household resident as anyone who considers this home as his or her permanent residence, and lives and sleeps at the household for at least 6 months of the year. Based on this definition, the eligibility criteria for AFEDS are: (1) a resident in 1 of the 30 tracts in and around Inglewood (including roomers, housemates, and household members with more than 1 residence who use this residence as a permanent mailing address, who live here most of the time while working, or who are temporarily away and will return before the end of the census period); (2) 40 years or older on the date of the household screening; and (3) self-identifying as AA.

Field Work and In-Home Survey Procedures

The SRC engages well-trained field staff, familiar with Inglewood, to knock on each household door within the selected census tracts to identify eligible participants. When encountering potential participants, the interviewers begin meaningful conversations to introduce the study and respond to concerns. They then obtain basic demographic information and informed consent, conduct a computer-assisted in-home interview, and schedule eye examinations at the LEEC.

In-Clinic Ocular Examination and Interview Procedures

The in-clinic examination consists of the following procedures in 7 designated areas; Appendix 1 demonstrates the data collection process in detail. Briefly,

Area 1: The participant checks in and completes the informed consent.

Area 2: The interviewer administers the clinical questionnaire (Appendix 2) and measures height, weight, and waist-to-hip ratio. The ophthalmic technicians measure pulse rate and blood pressure.

Area 3: Presenting distance, best-corrected visual acuity (VA), presenting near vision, refraction, lensometry, and contrast sensitivity

Area 4: Pupil assessment and visual fields (SITA Standard 24–2)

Area 5: IOP, angles assessment (HD-OCT), slit lamp examination, random blood glucose, HbA1c, DNA collection, and pupil dilation

Area 6: Cirrus, Spectral Domain OCT, fundus and optos photography, stereo disc photography, and A-Scan/Pachymetry

Area 7: Final exam, IOP, LOCS II grading for cataract grading, and fundus exam. The ophthalmologist discusses results and diagnoses with the participant after the examination. If follow-up care is needed, the ophthalmologist determines if the follow-up care should be emergent, urgent, or routine, and makes referrals to current or local providers to ensure continuity of care. Participants receive an easy-to-read participant's report that discusses the examination findings, as well as a detailed physician's report that includes all examination results and reasons for referral, if recommended.

The in-clinic examination takes approximately two-and-a-half to 3 hours to complete, with participants receiving a gift card to compensate for their time.

Follow-up Questionnaires

Twelve to 18 months after the initial examination, participants needing follow-up care will be called to evaluate if this care was obtained and to complete an updated psychosocial survey on motivation and barriers to care. Participants receive a phone call from trained field interviewers during evenings or weekends to increase the likelihood of contact, as well as a flat parcel in the mail that includes a cover letter explaining the purpose of the follow-up questionnaire, a printed copy of the questionnaire, and a pre-stamped return envelope.

Outcome Measures

AFEDS will focus on each of the following conditions:

Visual Impairment is defined in 2 ways: 1) the World Health Organization (WHO) definition of best corrected VA of worse than 20/60 in the better eye and; 2) the US definition of best corrected VA of worse than 20/40 in the better eye.

Blindness is defined in 2 ways for comparisons in populations-based studies of eye disease done in the United States and internationally: 1) the WHO definition of best corrected VA of worse than 20/400 in the better seeing eye (not including 20/400); ^{2,6,7,20,21} and 2) the US definition best-corrected VA of 20/200 or worse in the better seeing eye (including 20/200). US federal agencies use this definition, which is person-specific and not eye-specific (i.e., binocular blindness), ^{6,7,22} to define disability caused by blindness.

Lens Opacities are defined using the Lens Opacities Classification System II (LOCS II) Grading system.²³ As a wide spectrum of different types of lens changes may be present in 1

or both eyes, 3 definitions are used to describe lens opacity cases, ranging from broad to restrictive criteria.

1. *All lens changes* is defined as the presence, in at least 1 eye, of any gradable PSC, nuclear, or cortical lens opacity (LOCS II grade 2); lens opacities that are too advanced to grade; or previous cataract surgery. Each participant with unilateral or bilateral cataract extraction is assigned to the cataract extraction category.
2. *Any type of lens opacity* definition includes the presence of any gradable PSC, nuclear, or cortical lens opacity in at least 1 eye (i.e., LOCS II 2). The prevalence of any type of lens opacity will be based on participants with a gradable LOCS II finding in the relevant area. Participants with more than 1 type of opacity may be included in more than 1 category.
3. *Single and mixed types of lens opacities* are defined as the presence of 1 or more types of opacities in the same individual. Participants are considered to have a single opacity, categorized as PSC only, nuclear only, or cortical only, if that is the only type present in both eyes. This definition results in 4 mutually exclusive categories (PSC only, nuclear only, cortical only, and mixed). The prevalence of single and mixed types of lens opacities will be based on participants with gradable LOCS II findings in all regions (i.e., PSC, nuclear, and cortical).

Diabetic retinopathy is defined as retinopathy in persons with diabetes. Grading protocols for DR are modifications of the Early Treatment Diabetic Retinopathy Study (ETDRS) adaptation of the modified Arlie House classification of DR. For each eye, the maximum grade in any of the 7 standard photographic fields will be determined for each of the lesions. Eyes are graded per the following criteria: 1) no DR (levels 10–13); or 2) any DR (levels 14–85). DR is then classified as: 1) nonproliferative DR (mild [levels 14–20], moderate [levels 31–43], or severe [levels 47–53]); or 2) proliferative DR (levels 60–85).

Age-related Macular Degeneration drusen characteristics and other signs of AMD are assessed according to the Wisconsin AMD Classification system.²⁴

Open-angle glaucoma is the presence of an open angle, and both or either of the following criteria: 1) congruent, characteristic, or compatible glaucomatous visual field (VF) abnormality; and 2) evidence of characteristic or compatible glaucomatous optic disc damage in at least 1 eye.

Health care utilization and quality of life: Self-reported health-related quality of life is measured using the Short Form 12-item Health Survey (SF-12) and the 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25). The SF-12 measures general health-related quality of life, while the NEI-VFQ-25 yields 12 subscales that measure dimensions of vision-targeted health status important for persons with chronic eye disease. The subscales include general health and vision, near and distance vision activities, ocular pain, vision-related social function, vision-related role function, vision-related mental health, vision-related dependency, driving difficulties, color vision, and peripheral vision.^{25,26}

Quality Control Procedures

Quality control (QC) procedures are implemented throughout the study and in all resource centers to ensure that the final data set is as accurate and complete as possible. All field staff undergoes intensive training to ensure accuracy and uniformity in data collection procedures, with 5% validation of each interviewer's work to ensure that data is collected in an accurate and professional manner.

A 10% validation of the in-clinic interviewers' work is conducted by phone by the Project Coordinator. The validation includes a few key questions from the interview that are unlikely to be missed, a question about the interviewer's politeness, a question about the approximate interview length, and a question about willingness to participate in future studies.

Several variables measured in the clinical examination are re-measured, including blood pressure, presenting binocular and monocular VA of 20/40 or worse, visual field, IOP, random blood glucose, HbA1c, and lens grading.

After the first round of testing, additional validation schedules are developed at different intervals depending on need. If variation is minimal, quality control checks are performed every 5 months. For measurements producing moderate and high test/retest variability, the replication procedures are performed every month until minimal variability is achieved.

The LEEC's database incorporates data checks into the program at different parts of the examination, and error-trapping procedures are built into the system to clean the data electronically (e.g., signaling of potential unusual outliers to be verified in case of mis-entry). QC procedures at the SORC focus on reducing systematic and random errors in the grading procedures. After all databases from the SRC, LEEC, and SORC are merged, further QC is performed using different SAS programs, such as checking of commonly shared variables across databases, checking dates, and sorting and checking the data for duplicate records.

Statistical Analysis

Age-specific prevalence of VI, blindness, lens opacities, DR, and glaucoma are calculated as the ratio of the number of cases of each eye disease to the number of participants evaluated within a given age group (e.g., 40–49, 50–59, 60–79, 70–79, 80+ years). Prevalence estimates are calculated overall and by gender. Age-adjusted estimates of prevalence for each ocular disease and 95% confidence intervals (CIs) are calculated using the direct standardization method. Analysis of Covariance (ANCOVA) is used to evaluate differences in mean and median NEI-VFQ-25,²⁶ subscale, and composite scores between participants with and without eye disease or VI. Analyses based on item response theory are employed as a second approach for scoring and analyzing data to improve the interpretability of the scores.

Regression analyses are performed to measure the degree of association between factors of interest and prevalent lens opacities, OAG, AMD or DR. Factors of interest are considered based on conceptual models developed for each eye condition or disease including 5 categories: demographic, ocular, biologic, environmental, or lifestyle. The proportion of

participants with the factor will be assessed using questionnaire and clinical examination data from the baseline visit. Multivariate analysis will be used to evaluate the association between potential risk factors and measures of vision loss and eye diseases. Logistic models²⁷ will be run to calculate odds ratios and 95% CIs for dichotomous outcomes and linear regression for quantitative traits. All data analysis methods will be conducted using SAS/STATA.²⁸

Predictors of receiving follow-up eye care approximately 12–18 months after the AFEDS baseline clinical eye examination are evaluated among participants referred for eye care. Two theoretical frameworks are used to evaluate determinants of eye care utilization: the Health Behavioral Model (HBM)^{29–31} and the Integrated Behavioral Model (IBM) (Figure 2).³²

The analyses following the HBM are structured using 3 categories of independent variables: predisposing, enabling, and need variables based on information available from the AFEDS clinical and home questionnaire. This model was successfully used to evaluate determinants of health care access and utilization in our study of Latino adults.³³ Psychosocial predictors of obtaining follow-up eye care are evaluated using the IBM,³² which conceptualizes intentions as essential precursors of behavior. The 3 main categories of variables assumed to influence intentions are attitudes, perceived norms, and personal agency.

Utilization of follow-up eye-care is evaluated by a follow-up phone call and interview with each participant 12–18 months after the AFEDS baseline eye examination. We calculate the frequency of eye care utilization as the number of individuals who received follow-up eye care as a proportion of the total number of participants referred for follow-up eye care. Overall and age- and gender-specific incidence (with 95% CIs) is calculated. Multivariate analysis is used to evaluate the potential association between the predisposing, enabling, and need variables and obtaining follow-up eye care. The fit of the IBM and the individual paths in the model will be evaluated with structural equation models (SEM). The purpose of SEM is to investigate interrelationships among a set of observable variables through investigation of causal relationships among a set of theoretically developed constructs.

RESULTS

Cohort Description

The AFEDS cohort includes more than 6000 participants that have completed a home questionnaire and a comprehensive eye examination, making this the largest epidemiologic eye study within the AA population to date. More than half of the participants are between the ages of 50–69 years old, with women comprising 63% of the entire cohort. Almost 40% of the population report a household income above \$50,000, 91% self-reporting as having health insurance, and more than two-thirds stating they also have vision insurance. A majority of the population are working (40%) or retired (41%), non-smoking (57%), partial drinking (54%), and with at least some college education (38%).

Recruitment Strategies

Recruitment was informed by 2 decades of team experience in multiethnic cohort recruitment and tailored to be sensitive to the specific cultural and community characteristics of the AFEDS population. While use of existing social and political community structure was effective for successful recruitment of past cohorts (i.e., church organization in LALES and local political organization in CHES), we found trust to be a positive and necessary recruitment factor in AFEDS. Participation rates grew over the course of the study as participants told their neighbors and families that the eye examination was a useful, valuable, positive experience. Discussions with participants and field staff indicated that trust was built by an initial conversation focusing on the participant and their needs, rather than an immediate invitation for recruitment. Participants indicated that they needed the introductory conversation to evaluate if they felt comfortable enough with the interviewer to proceed. As trust is a common theme to the recruitment of AAs into research,^{34–38} our field staff training emphasized the need to build personal trust and a friendly rapport before introducing the study. Male participants and interviewers reported that men were more likely to participate in the study after encouragement from their wives. We also found that, unlike our previous cohorts in recent immigrant communities (e.g., Chinese or first-generation Latino) who sometimes prefer speaking to an interviewer of similar cultural background or primary language, our AA participants were receptive to interviewing with friendly and knowledgeable field staff of any race/ethnicity.

The trust-development recruitment approach was supported by radio and newspaper announcements, after which calls from eligible community members increased. Flyers, which included ophthalmologist photos and backgrounds, were disseminated at local businesses, such as beauty salons and barbershops. Our Community Liaison and Projector Director gave monthly presentations at health fairs, community centers, senior centers, block parties, city hall meetings, and women's groups. Simultaneously, study staff visited and provided written materials to all local ophthalmologists and optometry offices. These written materials included a description of the AFEDS clinical report to doctors about their patients requiring follow-up care.

For participants, other motivations included: the gain of knowledge about their personal eye health; the potential benefit to eye care for the AA community; and the overall significance to health research. Information on how the data would be used and the importance of adding AA-specific findings to ophthalmologic health research were intrinsic motivating factors³⁴ for this cohort.

DISCUSSION

AFEDS is the first comprehensive, population-based study of eye diseases and conditions in AAs in more than 2 decades. It was designed to fill the gaps in our understanding of the prevalence and risk factors for eye disease in AAs, using the latest technology and clinical definitions to assure the validity and precision of the estimates. Strengths of the study include the use of standard methods and protocols, utilized in LALES and CHES, to allow for comparison of prevalence and risk factor data across study populations. Limitations of the study include the reliance on self-reported medical history for select variables, such as

previous diagnosis and total duration of diabetes. With respect to generalizability, AFEDS is a population-based sample of AAs in Los Angeles with characteristics similar to those described in the US Census. However, no single population-based sample can be representative of all AAs in the United States.

The specific innovations include:

1. First population-based study of DR and diabetic macular edema in AAs in the United States using the 7 standard fields after papillary dilation.
2. Incorporation of detailed clinical measures to evaluate risk factors for eye disease in a population-based sample.
3. Evaluation of barriers in eye care utilization and follow-up eye care among AAs following the AFEDS comprehensive eye exam.

The data obtained from this study can be used to: identify the most urgent eye care needs in AAs; investigate associations of clinical, biologic, and lifestyle risk factors with ocular disease; and measure the association of VI/ocular disease with visual function. The data will be invaluable to public health professionals and policy experts for health care planning, counseling, and the provision of rehabilitation services. The data will also: inform the allocation of limited health care resources; provide baseline data for measuring temporal trends in disease rates; and estimate precise incidence rates of blindness, VI, and ocular disease.

In summary, AAs have unique ocular characteristics and demographic features that influence the incidence and progression of eye disease, and result in patterns of eye disease and eye care utilization distinct from other racial/ethnic groups. AFEDS will be the largest study of AA eye health and disease in the US and 1 of the first studies to provide precise prevalence estimates of VI, blindness, lens opacity, DR, and OAG using modern diagnostic techniques and clinical definitions. AFEDS will provide current data on eye health and utilization of care, and these data are essential to understanding the magnitude of the ocular disease burden upon quality of life and health care resources.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Structural organizational chart for the African American Eye Disease Study.

Figure 2.
 Integrated Behavior Model: Theoretical model for predictors of behavior.

Table 1.

Demographic and Socioeconomic Comparison of AFEDS Population to County, State and National African-American Population based on the 2010 U.S. Census Report

	Study Area	LA County	California	U.S.
All Ethnic Groups	112,482	9,818,605	33,871,648	281,421,906
Black or African American	53,060	930,957	2,299,072	34,658,190
% Black or African American	47	10	6	12
Age Distribution of Black or African American				
40 yrs.(%)	40	38	36	35
40–49 yrs.	15	15	15	14
50–59 yrs.	12	10	9	9
60–69 yrs.	8	7	6	6
70–79 yrs.	4	4	4	4
80+ yrs.	2	2	2	2
Gender of Black or African American (%)				
Female	56	53	51	52
Male	44	47	49	48
Education of Black or African American (18 years and over)				
Less than high school	15	21	21	28
High school graduate	23	24	25	30
Some college or more	44	38	39	29
College graduate or more	18	16	15	13
Black or African American Unemployed (%) (16 years and over)	10	8	7	7
Black or African American Household Annual Income (%)				
<\$50,000	66	68	65	73
>\$50,000	34	32	35	27

Table 2.

Age-Specific Percent Relative Standard Error (RSE) for Selected Ocular Diseases, Visual Impairment and Blindness for n=6500

Age Group (yr.)	Nuclear Cataract (%)	Cortical Cataract (%)	PSC (%)	OAG (%)	DR (%)	VI (%)	BL (%)
40–49	51.5	10.5	12.9	21.6	7.2	25.8	26.5
50–59	10.8	5.3	18.5	11.8	8.3	19.2	26.3
60–69	5.4	4.0	13.5	12.0	10.6	14.8	21.8
70–79	3.6	3.6	13.4	13.3	10.6	13.1	22.4
80+	2.9	2.3	9.4	15.4	---	11.5	18.3
Total	2.5	1.7	6.1	5.8	1.9	6.6	11.1

PSC: Posterior subcapsular Cataract; OAG: Open-Angle Glaucoma, VI: Visual Impairment, BL: Blindness