Published Examination-based Prevalence of Major Eye Disorders

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DISCLAIMER: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of NORC at the University of Chicago or the Centers for Disease Control and Prevention.

This report is currently undergoing Section 508 compliance review.

List of Abbreviations

ACG	Acute Angle-Closure Glaucoma
AHRQ	Agency for Healthcare Research and Quality
AIAN	American Indians/Alaska Natives
AMD	Age-Related Macular Degeneration
ARM	Age-Related Maculopathy
AREDS	Age-Related Eye Disease Study
ARIC	Atherosclerosis Risk in Communities
BCVA	Best-Corrected Visual Acuity
BDES	Beaver Dam Eye Study
BDOS	Beaver Dam Offspring Study
BES	Baltimore Eye Survey
BW	Birth Weight
CHES	Chinese American Eye Study
CNV	Choroidal Neovascularization
CPT-4	Current Procedural Terminology, 4th Edition
CRYO-ROP	Cryotherapy for ROP Study
CSME	Clinically Significant Macular Edema
DME	Diabetic Macular Edema
DR	Diabetic Retinopathy
DRIPS	Diabetic Retinopathy Inpatient Study
DRS	Diabetic Retinopathy Study
EDPRG	Eye Disease Prevalence Research Group
e-ROP	Telemedicine Approaches to Evaluating Acute-Phase Retinopathy of Prematurity
ETDRS	Early Treatment of Diabetic Retinopathy Study
ETROP	Early Treatment for Retinopathy of Prematurity
GA	Gestational Age
ICD-9CM	International Classification of Diseases, 9th Revision Clinical Modification
LALES	Los Angeles Latino Eye Study
MEPEDS	Multi-Ethnic Pediatric Eye Disease Study
MESA	Multi-Ethnic Study of Atherosclerosis
NHANES	National Health and Nutrition Examination Survey
NPDR	Nonproliferative Diabetic Retinopathy
OAG	Open-Angle glaucoma
PDR	Proliferative Diabetic Retinopathy
Proyecto VER	Proyecto Vision and Eye Research
PVA	Presenting Visual Acuity
RE	Refractive Error
ROP	Retinopathy of Prematurity
RPE	Retinal Pigment Epithelium
RW-ROP	Referral-Warranted Retinopathy of Prematurity

List of Abbreviations (cont'd)

SEE	Salisbury Eye Evaluation
SFGH	San Francisco General Hospital
SLVDS	San Luis Valley Diabetes Study
UCLA MEC	University of California, Los Angeles Mobile Eye Clinic
URE	Uncorrected Refractive Error
VA	Veteran Affairs
VA	Visual Acuity
VI	Vision Impairment
VEHSS	Vision & Eye Health Surveillance System
VKS	Vision Keepers Study
VTDR	Vision-Threatening Diabetic Retinopathy
WESDR	Wisconsin Epidemiologic Study of Diabetic Retinopathy

Introduction

This report details the findings of a literature review on the published prevalence of vision loss and major eye disorders. We conducted a systematic review of the published literature to identify existing measures of prevalence of vision loss and major eye disorders. This report reviews vision loss, uncorrected refractive error (URE), age-related macular degeneration (AMD), diabetic retinopathy (DR), glaucoma, cataract, and retinopathy of prematurity (ROP).

Studies reviewed here varied in their use of demographic variables, study populations, condition definitions, and inclusion of condition types and stages. This literature review summarizes existing published prevalence estimates organized by data source. Many studies are not directly comparable because of differences in study design or population this review makes no attempt to harmonize or directly compare estimates among studies.

Methods

To identify the prevalence estimates of six common eye disorders, we performed PubMed searches surveying literature published from 1991 to 2016. Searches were conducted between December 17, 2015 and October 6, 2017.

The search terms utilized were 'prevalence' and one of the following terms:

- "Age-related macular degeneration," and "age-related maculopathy."
- "Diabetic retinopathy."
- "Glaucoma."
- "Cataract."
- "Vision impairment," "visual impairment," and "acuity."
- "Blindness."
- "Uncorrected refractive error."
- "Retinopathy," and "prematurity."

We included studies conducted in the United States with prevalence estimates derived from primary data. We excluded articles with prevalence estimates based on survey data, statistical modeling, and articles with older prevalence estimates when newer estimates from the same study were available. Each article was further assessed for inclusion based on specified inclusion criteria:

Inclusion Criteria

- Publication:
  - Study is published in a peer-reviewed manuscript.

- Study was published after 1991.

- Data and population:
  - Population-based study that is representative of the target population from which the participants were sampled.
  - Data represents primary analysis or meta-analysis of primary data.
  - Age-specific and/or race/ethnicity-specific and/or location-specific prevalence estimates are reported.

- Vision and eye disease measurement:
  - Vision and eye disease are assessed using objective measures or grading, or the presence of a diagnosis code in administrative data.
  - Visual impairment is defined using measures of best-corrected visual acuity (to differentiate visual acuity impairment due to refractive error and eye disease).
  - Age-related macular degeneration/diabetic retinopathy - dilated eye exams were used to examine the retina, retinal images were taken, and graded using a systematic (and ideally validated) protocol (e.g. the Age-related Eye Disease Study [AREDS] grading scale).
  - Glaucoma–diagnosis is based on clinical assessment of intraocular pressure, visual fields, and cup to disk ratio.
  - Cataract–graded from lens photographs using a systematic and validated protocol (e.g., the Wisconsin Cataract Grading Scale).
  - Studies using chart review or other methods may be included in the literature review with discretion.

The final search yielded 77 articles, which are included in this report. For studies reporting prevalence estimates stratified by demographic variables, we provide graphs illustrating this data alongside a description of the summary.

1. Age-related Macular Degeneration

Age-related macular degeneration (AMD) is a disorder of the macula that may cause severe loss of central vision. There are three stages of AMD: Early, intermediate, and advanced/late. While some variation in stage classification exists, in general early stage AMD (also referred to as Age-related Maculopathy [ARM]) is described as having numerous small drusen (<63 μm) (lipid deposits) and fewer medium drusen (63-125 μm) under the retina, or mild hypo- or hyperpigmentation of the retinal pigment epithelium (RPE) in at least one eye.[1] Intermediate AMD is distinguished by large drusen (> 125 μm), retinal pigment changes, or geographic atrophy of the RPE not in the center of the fovea.[2] AMD with the presence of drusen is also known as dry AMD.[2] The Age-related Eye Disease Study (AREDS) simple classification system defined four stages of early/intermediate AMD, based on the cumulative number of risk factors evident (consisting of large drusen and/or RPE abnormalities) across both eyes.

There are two types of advanced or late stage AMD, which are the vision-threatening stages of AMD: neovascular/exudative AMD (also known as wet AMD) and pure geographic atrophy.[3] Neovascular/exudative AMD is indicated by the development of choroidal neovascularization (CNV). CNV is the growth of new blood veins under the macula that could potentially leak.[2, 3] Pure geographic atrophy is the degeneration of the RPE in the foveal center, causing scars in the foveal area and a loss of central vision. AMD is generally diagnosed through fundus photography.[4] The photographs image the retina and optic nerves and can be examined for signs of AMD and other eye conditions.[4]

1.0 Age-related Macular Degeneration Literature Review Results

Figure 1.0 shows 21 studies published between 1993 and 2016 that examined the prevalence of age-related macular degeneration (AMD):

1. The Chinese American Eye Study (CHES)
2. Telemedicine Screening Program
3. The Study of Osteoporotic Fractures (SOF)
4. National Health and Nutrition Examination Survey (NHANES) 2005-2008
5. Atlanta VA Medical Center Chart Review
6. Vision Keepers Study (VKS)
7. A Longitudinal Analysis of a Managed Care Network
8. The Beaver Dam Offspring Study (BDOS)
9. The Salisbury Eye Evaluation (SEE) Project
10. Multi-ethnic Study of Atherosclerosis (MESA)
11. Study on Visual Impairment Among Northwest American Indians/Alaska Natives (AIAN)
12. Proyecto VER
13. Los Angeles Latino Eye Study (LALES)
14. The Eye Disease Research Prevalence Group (EDPRG)
15. The National Long-Term Care Survey

16. Third National Health and Nutrition Examination Survey (NHANES III)
17. The Baltimore Eye Survey (BES)
18. The Atherosclerosis Risk in Communities (ARIC) Study
19. The San Luis Valley Diabetes Study (SLVDS)
20. The Beaver Dam Eye Study (BDES)
21. University of California, Los Angeles Mobile Eye Clinic (UCLA MEC)

These studies collected data between 1993 and 2013 and examined a variety of demographic variables including race/ethnicity, age, sex, income, and education level. The stages of AMD investigated varied among these studies.

Figure 1.0 Age-Related Macular Degeneration Prevalence Sources

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Stage of AMD
Varma R, Choudhury F, et al.	2016	Prevalence of Age-Related Macular Degeneration in Chinese American Adults: The Chinese American Eye Study	2010–2013	CHES	4,582	Age, Sex, Race	Early, Late, Wet, Dry, Any
Park D, Mansberger SL, et al.	2016	Eye Disease in Patients with Diabetes Screened with Telemedicine	2006–2009	Telemedicine Screening Program	424	Not stratified by demographic variables	Any
Pedula KL, Coleman A, et al.	2015	Age-Related Macular Degeneration and Mortality in Older Women: The Study of Osteoporotic Fractures	1996–1998	SOF	1,202	Age, Race	Early, Late, Any
Wu EW, Schaumberg DA, et al.	2014	Environmental Cadmium and Lead Exposures and Age-Related Macular Degeneration in US Adults: the National Health and Nutrition Examination Survey 2005 to 2008	2005–2008	NHANES 2005-2008	5,390	Age, Sex, Race/Ethnicity	Any
Maa AY, Evans C, et al.	2013	Veteran Eye Disease After Eligibility Reform: Prevalence and Characteristics	January 2008–February 2008	Atlanta VA Medical Center Chart Review	658	Not stratified by demographic variables	Early, Late, Wet, Dry, Any
Zhang X, Cotch MF, et al.	2012	Vision Health Disparities in the United States by Race/Ethnicity, Education, and Economic Status: Findings from Two Nationally Representative Surveys	2005–2008; 1988–1994	NHANES 2005-2008, NHANES III	5,704; 8,208	Race/Ethnicity	Any
Klein R, Chou CF, Klein BE, et al.	2011	Prevalence of Age-Related Macular Degeneration in the US Population	2005–2008	NHANES 2005-2008	5,553	Age, Race/Ethnicity, Sex	Early, Late, Wet, Dry, Any
Butt AL, Lee ET, Klein R, et al.	2011	Prevalence and Risks Factors of Age-Related Macular Degeneration in Oklahoma Indians: The Vision Keepers Study	1995–1998	Vision Keepers Study: Oklahoma Indians	986	Age, Sex	Early, Late, Wet, Dry

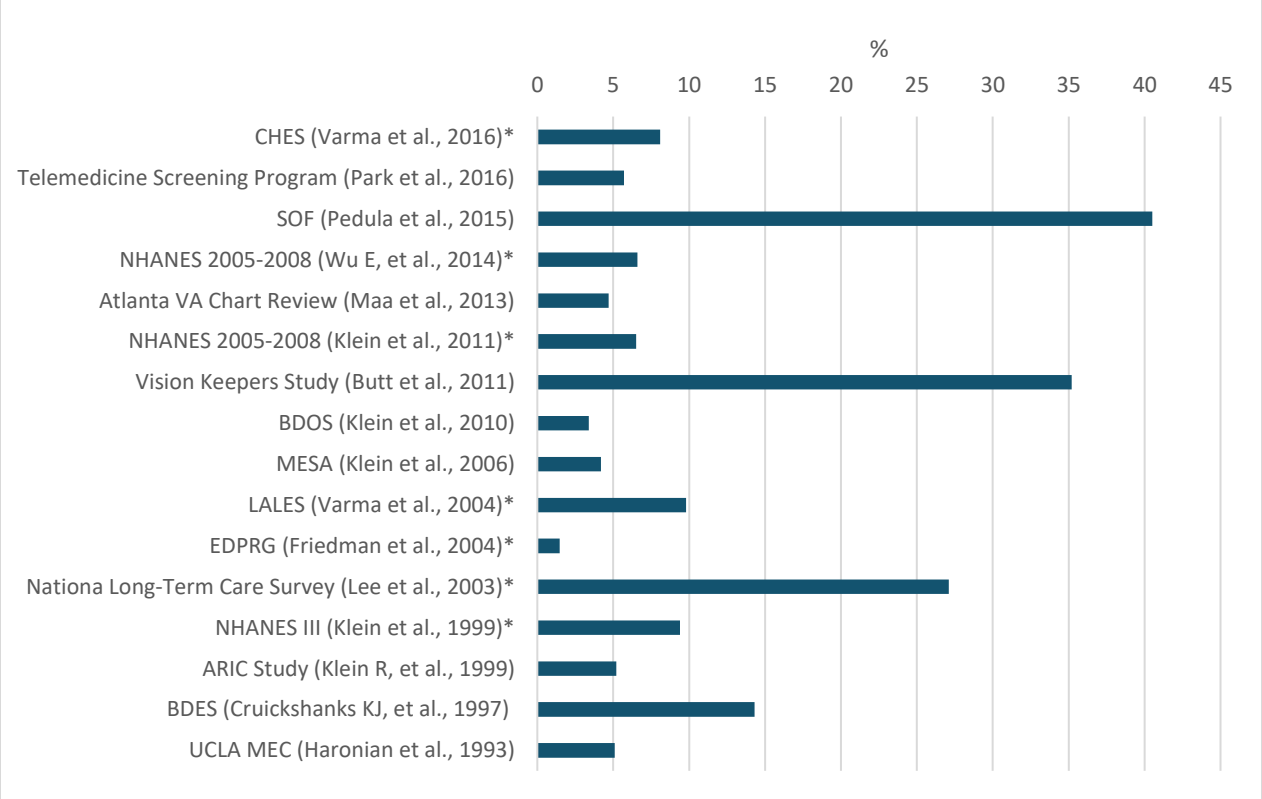
Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Stage of AMD
VanderBeek BL, Zacks DN, et al.	2011	Racial Difference in Age-Related Macular Degeneration Rates in the United States: A Longitudinal Analysis of a Managed Care Network	2001–2007	A Longitudinal Analysis of a Managed Care Network	1,772,962	Age, Sex, Race/Ethnicity	Wet, Dry
Klein R, Cruickshanks KJ, Nash SD, et al.	2010	The Prevalence of Age-Related Macular Degeneration and Associated Risk Factors	2005–2010	Beaver Dam Offspring Study.	2,810	Age	Early
Bressler SB, Muñoz B, et al.	2008	Racial Differences in the Prevalence of Age-Related Macular Degeneration	1993	The Salisbury Eye Evaluation (SEE) Project	2,520	Race	Early, Late, Wet, Dry
Klein R, Klein BE, Knudtson MD, et al.	2006	Prevalence of Age-Related Macular Degeneration in 4 Racial/Ethnic Groups in the Multi-Ethnic Study of Atherosclerosis	2000–2002	Multi-ethnic Study of Atherosclerosis (MESA)	6,176	Age, Sex, Race	Early, Late
Mansberger SL, Romero FC, et al.	2005	Causes of Visual Impairment and Common Eye Problems in Northwest American Indians and Alaska Natives	Unknown	Northwest AIAN	288	Race	Early, Late
Munoz B, Klein R, Rodriguez J et al.	2005	Prevalence of Age-Related Macular Degeneration in a Population-Based Sample of Hispanic People in Arizona: Proyecto VER	1997–1999	Proyecto VER	2,780	Age, Sex, Race/Ethnicity	Early, Late
Varma R, Fraser-Bell S, Tan S, et al.	2004	Prevalence of Age-Related Macular Degeneration in Latinos: The Los Angeles Latino Eye Study	2000–2008	Los Angeles Eye Study (LALES)	5,875	Age, Race/Ethnicity	Early, Late, Any
Friedman DS, O'Colmain BJ, Munoz B, et al;	2004	Prevalence of Age-Related Macular Degeneration in the United States.	1985–1998	EDPRG	N/A	Age, Race/Ethnicity, Sex	Early, Late, Any
Lee PP, Feldman ZW, Ostermann J, et al.	2003	Longitudinal Prevalence of Major Eye Diseases.	1999	National Long-Term Care Survey	Various	Sex, Age, Race	Any, Wet, Dry
Klein R, Klein BE, Jensen SC, et al.	1999	Age-Related Maculopathy in a Multiracial United States Population: The National Health and Nutrition Examination Survey III.	1988–1994	NHANES III	8,270	Age, Sex, Race	Early, Late, Wet, Dry

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Stage of AMD
Friedman DS, Katz J, et al.	1999	Racial Differences in the Prevalence of Age-related Macular Degeneration	1985–1988	The Baltimore Eye Survey	5,308	Age, Race	Early, Late, Wet, Dry
Klein R, Clegg L, et al.	1999	Prevalence of Age-Related Maculopathy in the Atherosclerosis Risk Communities Study	1993–1995	Atherosclerosis Risk in Communities Study	11,532	Age, Race, Sex	Early, Late, Wet, Dry
Cruickshanks KJ, Hamman, RF, Klein, R, et al.	1997	The Prevalence of Age-Related Maculopathy by Geographic Region and Ethnicity: The Colorado-Wisconsin Study of Age-Related Maculopathy	1983; 1988–1990	The San Luis Valley Diabetes Study; Beaver Dam Eye Study	1,541; 3,999	Age, Sex, Ethnicity	Early, Late, Wet, Dry
Klein R, et al.	1995	The Relationship of Age-Related Maculopathy, Cataract, and Glaucoma to Visual Acuity	1988–1990	Beaver Dam Eye Study	4,886	Age	Early, Late
Haronian E, Wheeler NC, et al.	1993	Prevalence of Eye Disorders Among the Elderly in Los Angeles	1982–1990	UCLA MEC	431	Age, Sex	Any

1.1 Overall Age-related Macular Degeneration Prevalence Rates

Figure 1.1 shows estimated prevalence rates for age-related macular degeneration (AMD) derived from 16 of the studies in this section that reported an overall rate. The figure is intended to illustrate the range of published prevalence values; direct comparison of the studies is impossible without considering the underlying differences in the studies. Most studies provided crude AMD prevalence estimates, while some only provided rates that were adjusted to an intended study population or a national standard. AMD prevalence rates varied widely and ranged from 1.1% in EDPRG to 40.5% in the Study of Osteoporotic Fractures (Figure 1.1). Although much of this variation is likely due to differences between study populations, some may also reflect differences in AMD definition, measurement methodology, and reporting. Many studies provided results stratified by age, race/ethnicity, and sex. However, age and race/ethnicity classifications differed across studies: some study populations included one race/ethnicity category, while others included two or three racial and ethnic subgroups. Similarly, age categories varied across studies as did the included age groups: some studies included adults 18 years and older, while others included individuals aged 40 or 65 years or older. The data presented for each study in this section focuses on differences by age, sex, and race/ethnicity.

Figure 1.1 Overall Prevalence Rates of AMD in Selected Studies

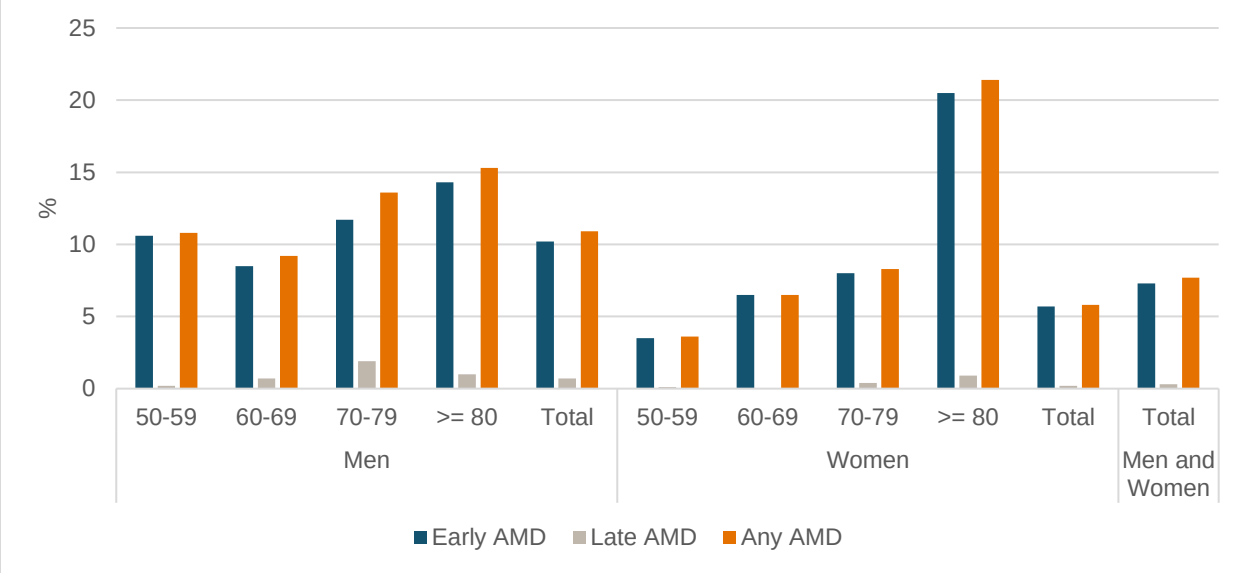


* Age- or Population-adjusted prevalence rate

1.2 The Chinese American Eye Study

The Chinese American Eye Study (CHES) aimed to determine the population-based prevalence of eye disease and visual impairment among 4,582 Chinese Americans. The participants were aged 50 and older and lived in 10 urban census tracts in Monterey Park, CA. The study was conducted from 2010 to 2013.[5] Study participants were identified by a door-to-door census, interviewed in their homes, and examined in clinical settings. Varma, at al. (2016) used a modified Wisconsin Age-Related Maculopathy Grading System [6] to perform grading; they defined early age-related macular degeneration (AMD) as the "presence of soft indistinct drusen or any drusen with retinal pigment epithelium (RPE) abnormalities in the absence of advanced lesions." Advanced AMD was defined as the presence of "geographical atrophy, neovascular AMD, macular thickening, hemorrhage, and disciform scar not associated with other conditions." After age-adjusting their results to the 2010 U.S. Census, they found an overall AMD prevalence rate of 8.1%. Data from this study showed that Chinese Americans had a higher rate of early and late AMD compared to the Chinese population in China. The findings also demonstrated that the rate of early and late AMD was lower among Chinese Americans compared to Non-Hispanic Whites (Figure 1.2).

Figure 1.2 The Age- and Sex-Specific Prevalence of AMD Among CHES Study Participants[5]



1.3 Telemedicine Screening Program

Park, et al. (2016) sought to determine the utility of telemedicine with nonmydriatic cameras as a mechanism to detect eye disease.[7] Researchers recruited and examined 424 diabetic patients aged 18 and older scheduled with primary care providers from Yellowhawk Tribal Health Center (Pendleton, OR) and Hunter Health Clinic (Wichita, KS). The study population was, consequently, primarily American Indians/Alaska Natives. Park, et al. (2016) defined age-related macular degeneration (AMD) as the presence of "soft drusen greater than 125 μm or drusen with pigmentary changes, not caused by any other disorder." After assessing fundus photographs, researchers found an overall AMD prevalence of 5.7%.

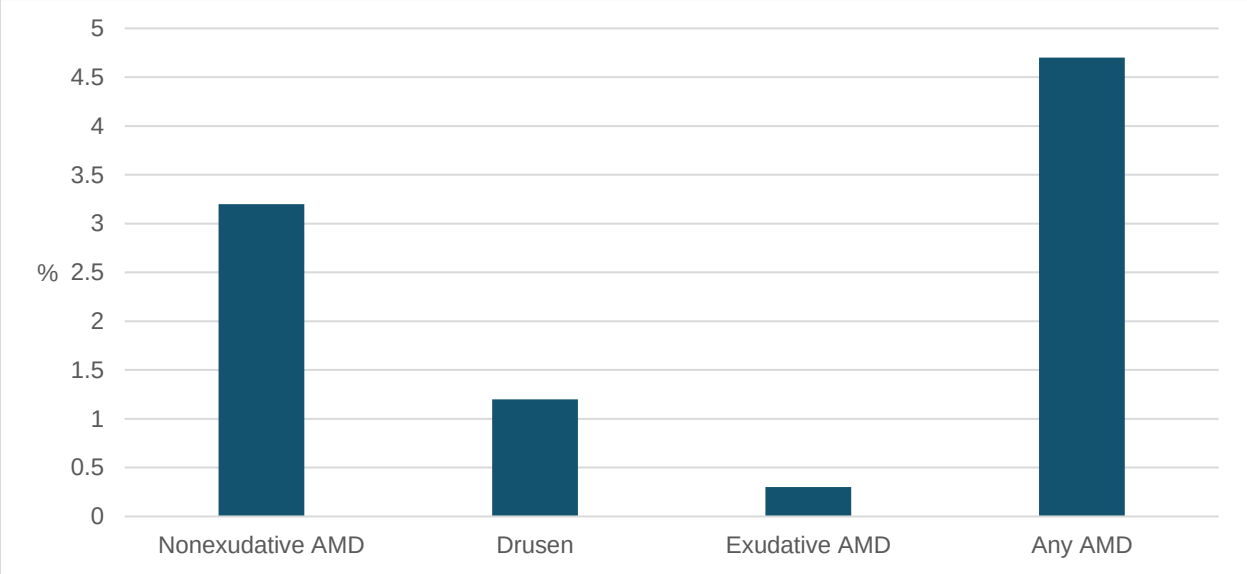
1.4 The Study of Osteoporotic Fractures

Pedula, et al. (2015) examined a subset of 1,202 women from the Study of Osteoporotic Fractures (SOF).[8] The SOF was a prospective multi-center study of 9,704 community-dwelling ambulatory women age 65 and older from four US metropolitan locations. The subset was selected at a 10-year follow-up in 1997-1998 and examined using fundus photography. A modified Wisconsin Age-Related Maculopathy Grading System [6] was used, and early age-related macular degeneration (AMD) Early AMD was defined as "the presence of soft drusen (≥95 μm diameter) and (i) drusen area of a circle with a diameter of less than 960 μm and retinal pigment epithelial depigmentation present or (ii) drusen area of a circle with diameter of 960 μm or more with or without pigmentary abnormalities in at least one eye." The authors defined late AMD as the "presence of subfoveal geographic atrophy or choroidal neovascularization in one eye." Among those examined, 40.5% had some form of AMD.

1.5. Atlanta Veteran Affairs (VA) Medical Center Medical Chart Review

As a first step to assessing whether the VA system is adequately prepared to serve patients under new eligibility reform, Maa et al. (2013) conducted this pilot study of the prevalence of various eye diseases among new "routine" eye patients at the Atlanta Veterans Administration (VA) Medical Center Comprehensive Eye Clinic.[9] Researchers reviewed the charts of 658 new patients. With the exception of refractive error, the patients had no known previous eye diagnosis and were seen between January 1, 2008 and February 1, 2008. The authors used the International Classification of Diseases, 9th Revision Clinical Modification codes (ICD-9CM) to identify ocular conditions and found an overall prevalence rate of age-related macular degeneration (AMD) of 4.7%. Prevalence rates for various stages of AMD among the study population are shown below in Figure 1.3.

Figure 1.3 The Prevalence of Various Stages of AMD Among VA Patients [9]



1.6 The 2005-2008 National Health and Nutrition Examination Survey (NHANES)

The 2005-2008 National Health and Nutrition Examination Survey (NHANES) is a nationally representative, population-based, cross-sectional study.[4] Using these data, Klein et al. (2011) calculated the prevalence of early, late, neovascular (exudative) age-related macular degeneration (AMD) and geographic atrophy for 5,553 adults 40 years and older. Early AMD was defined by "the presence of either soft indistinct drusen or the presence of RPE depigmentation or increased retinal pigment, together with any type of drusen, or by the presence of soft drusen with an area of 500 μm or larger in absence of signs of late AMD." The authors defined late AMD by the presence of "geographic atrophy or RPE detachment, subretinal hemorrhage or visible subretinal new vessels, subretinal fibrous scar or laser treatment scar, or self-reported history of photodynamic or anti–vascular endothelial growth factor treatment for exudative AMD." Early AMD was the most prevalent stage of AMD, and respondents 60 years and older had the highest rate. Figure 1.4 shows the AMD prevalence rates among survey respondents stratified by age, race, and ethnicity as reported by Klein et al. (2011). Wu et al. (2014) also used the same data to calculate AMD prevalence. They found a prevalence of 6.6% among 5,390 adults aged 40 and older. They also measured blood lead and cadmium to investigate the link between these environmental factors and AMD.[10] Zhang et al. (2012) compared NHANES 2005-2008 AMD prevalence rates of adults aged 40 years and older across various socioeconomic strata with data from the third National Health and Nutrition Examination Survey (NHANES III), described in Section 1.17.[11] Figure 1.5 shows the prevalence rates calculated by Zhang et al. (2012).

Figure 1.4 Crude Prevalence Rates of AMD in 2005-2008 NHANES [4]

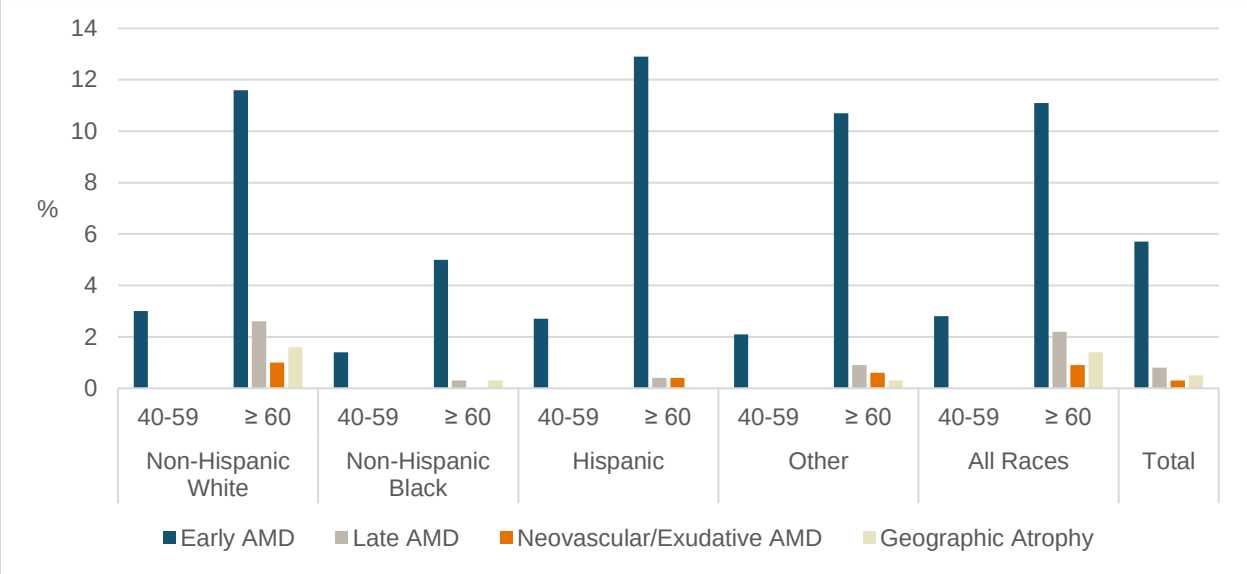
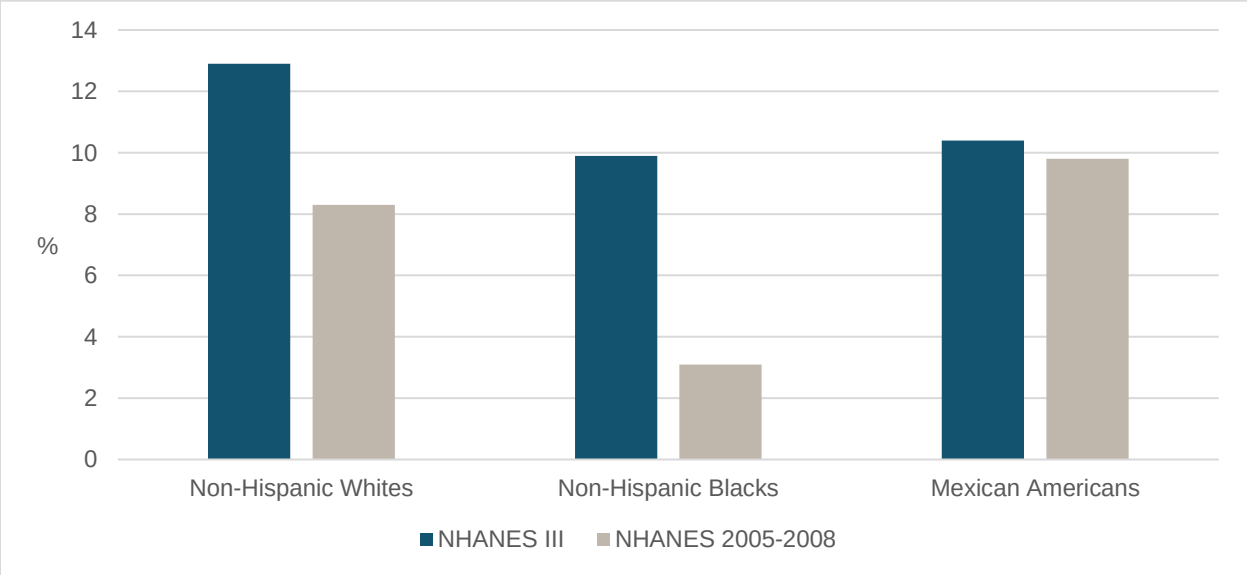


Figure 1.5 Age- and Sex- Standardized Prevalence of AMD Among Adults Aged 40 and Older from 2005-2008 NHANES and NHANES III [11]

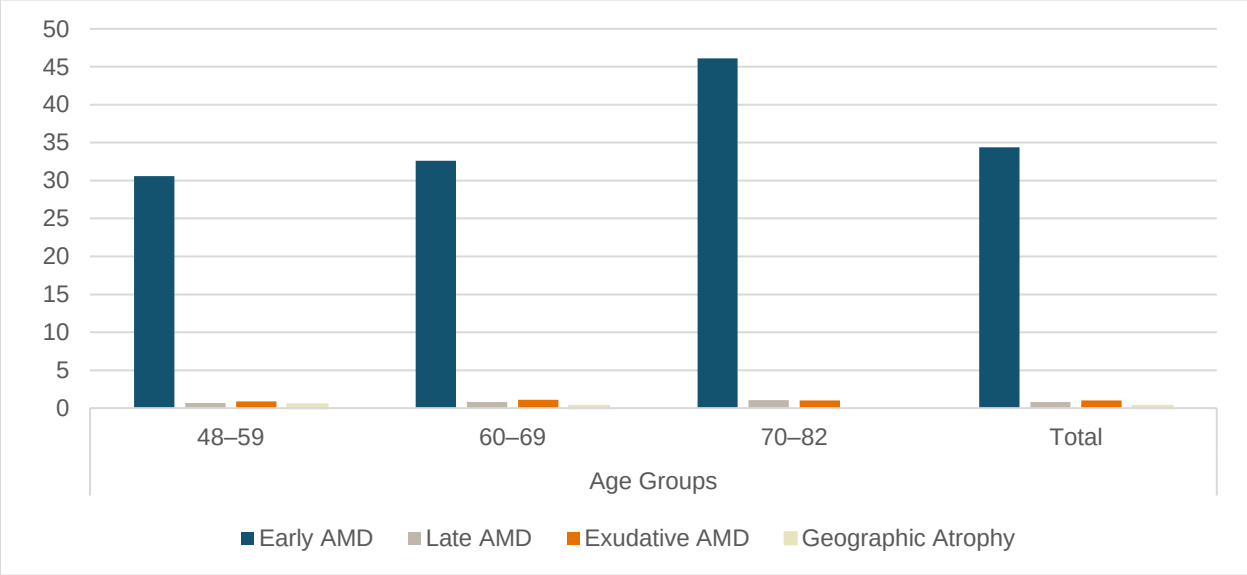


1.7 The Vision Keepers Study

The Vision Keepers Study included a subset of the participants of the Strong Heart Study, an epidemiologic study of cardiovascular disease among American Indians in Oklahoma.[12] Participants were between the ages of 45 and 74 years old. Retinal photographs of each eye were examined and graded for age-related macular degeneration (AMD) according to the Wisconsin Age-Related

Maculopathy Grading System.[6] Investigators studied the prevalence of early, late, exudative (neovascular) AMD, and geographic atrophy among age groups. Early AMD was defined by the presence of retinal pigment epithelium (RPE), increased pigmentation, and/or presence of drusen. Late AMD was defined by the presence of pure geographic atrophy or exudative AMD. Figure 1.6 shows the prevalence rates of AMD by stage and age group within this study.

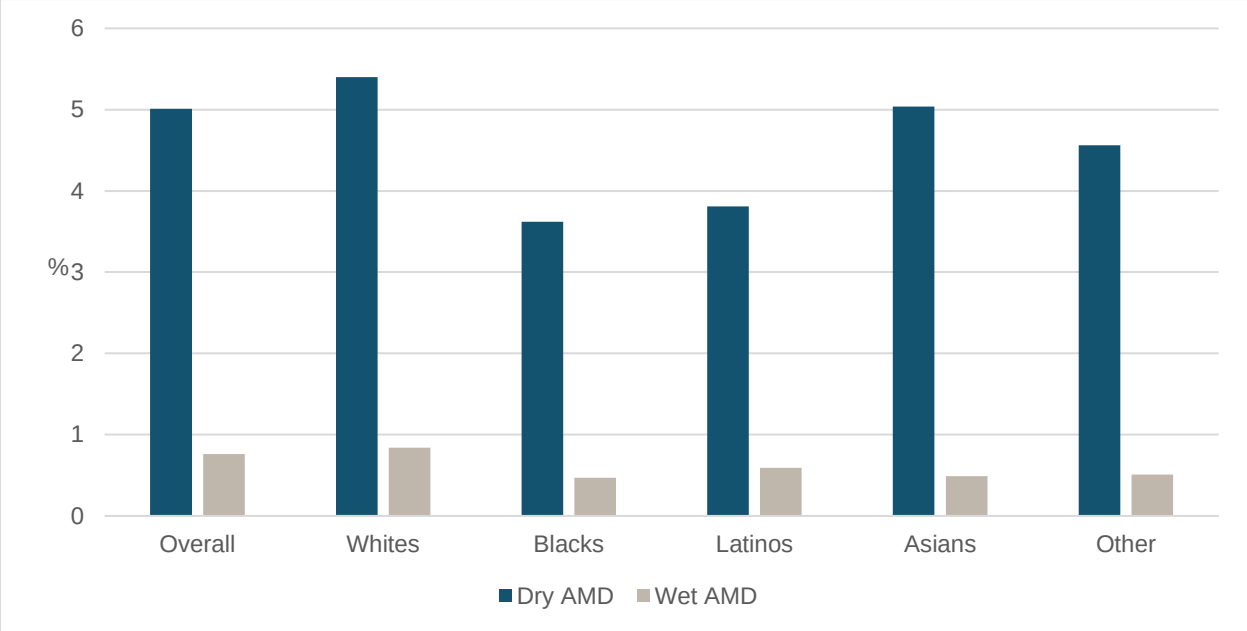
Figure 1.6 Prevalence of AMD in Oklahoma Indians in the Vision Keepers Study [12]



1.8 A Longitudinal Analysis of a Managed Care Network

To examine the prevalence of non-exudative and exudative age-related macular degeneration (AMD) among different racial groups, VanderBeek et al. (2011) utilized the i3 InVision Data Mart database. The database contained records of all beneficiaries in a large US managed care network.[13] Using International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes and Current Procedural Terminology, 4th Edition (CPT-4) codes, they identified 2,259,061 adults over the age of 40 who were in the database for a year or more and who had one or more visits to an eye care provider between January 1, 2001 and December 31, 2007. VanderBeek et al. (2011) found an overall prevalence rate of 5.01% for dry AMD and 0.76% for wet AMD. Both dry and wet AMD were more prevalent among Whites compared to other racial groups. Figure 1.7 shows the diagnosed prevalence rates for wet and dry AMD by racial groups among those patients who had an eye exam.

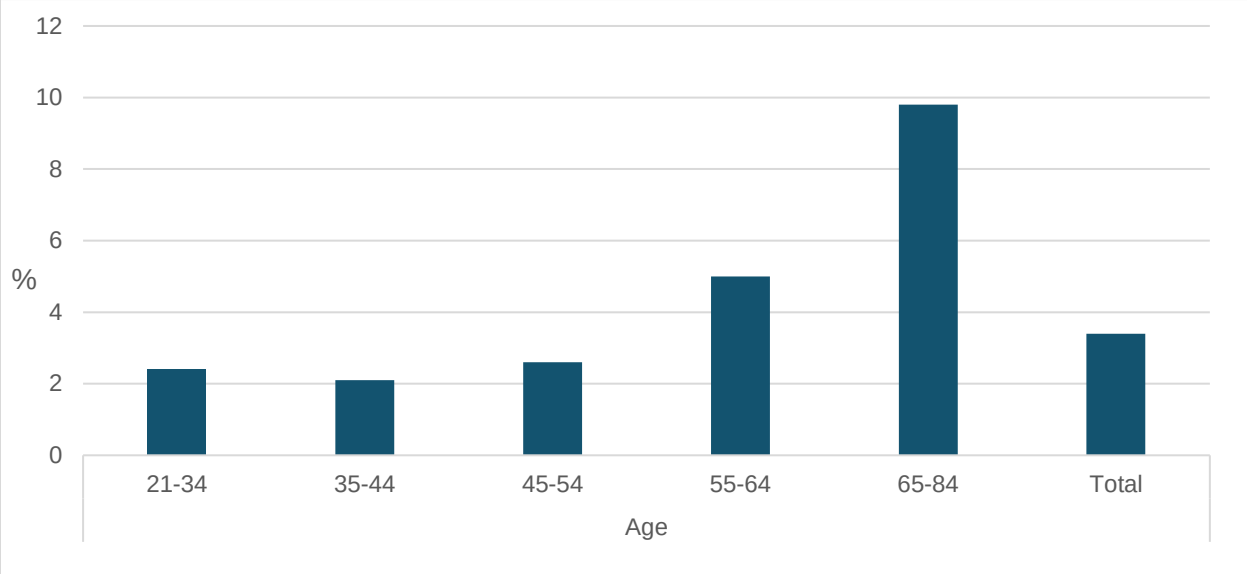
Figure 1.7 Prevalence Rates for Dry and Wet AMD Stratified by Race [13]



1.9 The Beaver Dam Off-spring Study

The Beaver Dam Off-spring Study (BDOS) participants were adults aged 42-84 whose parents participated in the Beaver Dam Eye Study (BDES).[14] The BDES participants were mostly Non-Hispanic Whites. The BDOS included 1,315 participants who were surveyed and had fundus photographs taken of each eye. Photographs were graded for age-related macular degeneration (AMD) using a modified Wisconsin Age-Related Maculopathy Grading System.[6] Early AMD was defined by the presence of drusen and/or retinal pigmentation abnormalities in the absence of late AMD. Late AMD was defined by the presence of exudative AMD or pure geographic atrophy. None of the participants exhibited signs of late AMD. (Figure 1.8).

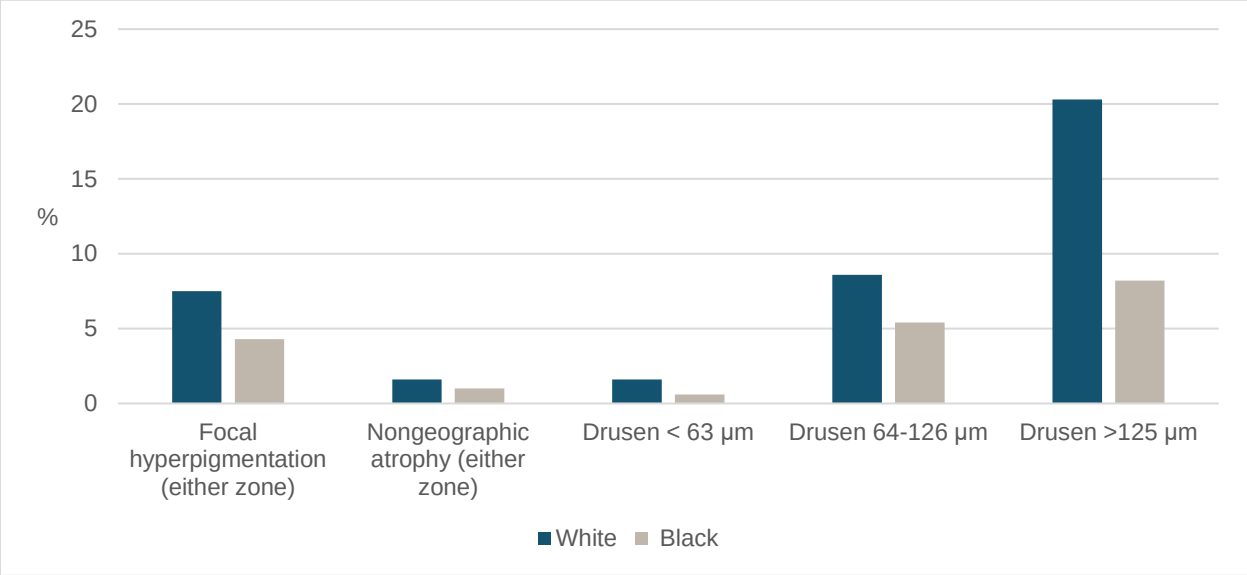
Figure 1.8 Prevalence of Early AMD in the Beaver Dam Offspring Study [14]



1.10. The Salisbury Eye Evaluation Project

The Salisbury Eye Evaluation (SEE) project included 2,520 participants who were aged 65-84 as of July 1, 1993.[15] Participants lived in Salisbury, MD. They were identified using Medicare claims and underwent ocular examinations in clinical settings. Bressler et al. (2008) found that 93% of the study population had drusen of any size, 1.6% had choroidal neovascularization, and 1.4% had geographic atrophy. The authors concluded that medium or large drusen, pigment abnormalities, and advanced age-related macular degeneration (AMD) were more prevalent among Whites than Blacks. Of White participants, 1.7% had choroidal neovascularization compared to 1.1% of Blacks, and 1.8% of Whites had geographic atrophy compared to 0.3% of Blacks. Figure 1.9 summarizes the SEE Project findings.

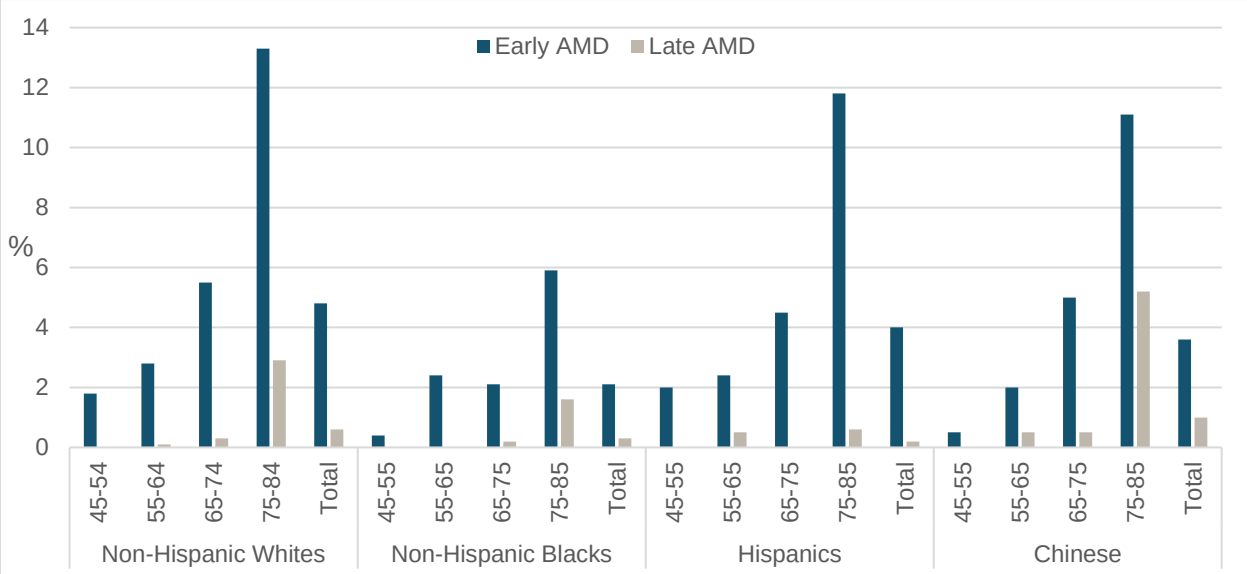
Figure 1.9 The Distribution of RPE Hyperpigmentation, Nongeographic Atrophy and RPE Abnormalities by Race [15]



1.11 The Multi-ethnic Study of Atherosclerosis

The Multi-ethnic Study of Atherosclerosis (MESA) was a 10 year longitudinal study of over 6,000 men and women aged 45-84 years in Baltimore, Maryland; Chicago, Illinois; Forsyth County, North Carolina; Los Angeles, California; New York, New York; and St. Paul, Minnesota.[16] The racial/ethnic distribution of the participants was 39% White, 27% Black, 21% Hispanic, and 13% Chinese. Fundus photographs were taken of each of the participant's eyes and graded for age-related macular degeneration (AMD). Researchers investigated the prevalence of early and late AMD. Early AMD was defined by the presence of any soft drusen, retinal pigmentation abnormalities, or drusen >125 µm in the absence of late AMD. Late AMD was defined by the presence of pure geographic atrophy or exudative AMD. Researchers concluded that the prevalence of AMD was higher among Non-Hispanic Whites compared to Non-Hispanic Blacks (Figure 1.10).

Figure 1.10 Prevalence of AMD by Worse Eye in MESA, Visit 2, 2002-2004 [16]



1.12 Study on Visual Impairment Among Northwest American Indians/Alaska Natives

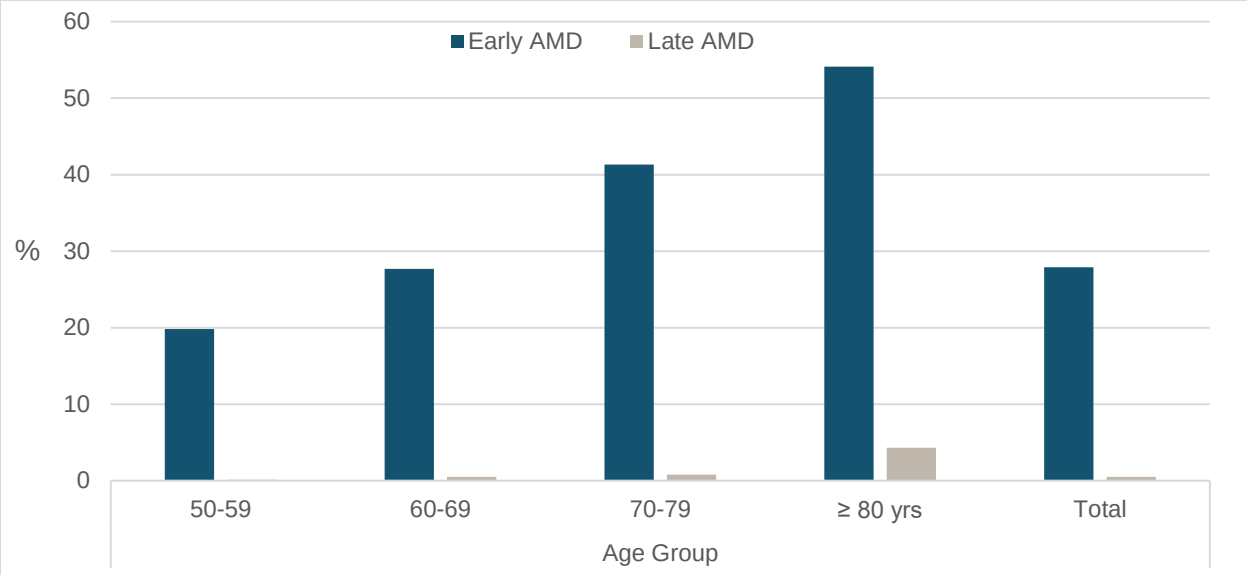
Mansberger et al. (2005) examined the prevalence of eye health disorders in a random sample of 288 American Indians/Alaska Natives (AIAN).[17] Researchers randomly selected participants from three tribes from three US Northwest states (Oregon, Washington, and Idaho) and collected participants' ocular examination data. They defined early age-related maculopathy (ARM) as the presence of soft drusen greater than "125 μm, or drusen with pigmentary changes without late ARM not caused by any other disorder"; they defined late ARM as "macular fluid, geographic atrophy, or neovascular maculopathy within the macula, not caused by another disorder." Mansberger, et al. (2005) found an early age-related macular degeneration (AMD) prevalence rate of 16.9% and a late ARM prevalence rate of 1.4%. They concluded that in this population ARM was among the most common causes of vision impairment. This study is limited because the reported prevalence of ARM and AMD is not stratified by demographic variables.

1.13 Proyecto VER

Proyecto Vision and Eye Research (VER) was a population-based vision impairment study conducted from 1997 to 1999.[18] It included Hispanics living in Tucson and Nogales, Arizona. To analyze the prevalence of AMD, investigators selected 3,178 participants who were 50 years and older, 2,780 of whom had gradable fundus photographs. Each participant had fundus photographs taken of at least one eye, which were graded for age-related macular degeneration (AMD) based on the Wisconsin Age-Related Maculopathy Grading system.[6] Early AMD was distinguished by the absence of late AMD and "signs of soft indistinct or reticular drusen or any drusen (except hard indistinct) combined with retinal pigment epithelium (RPE) in the macular area." Late AMD was defined by the presence of exudative

AMD or pure geographic atrophy. Both stages of AMD increased with age, and early AMD was the more prevalent of the two (Figure 1.11).

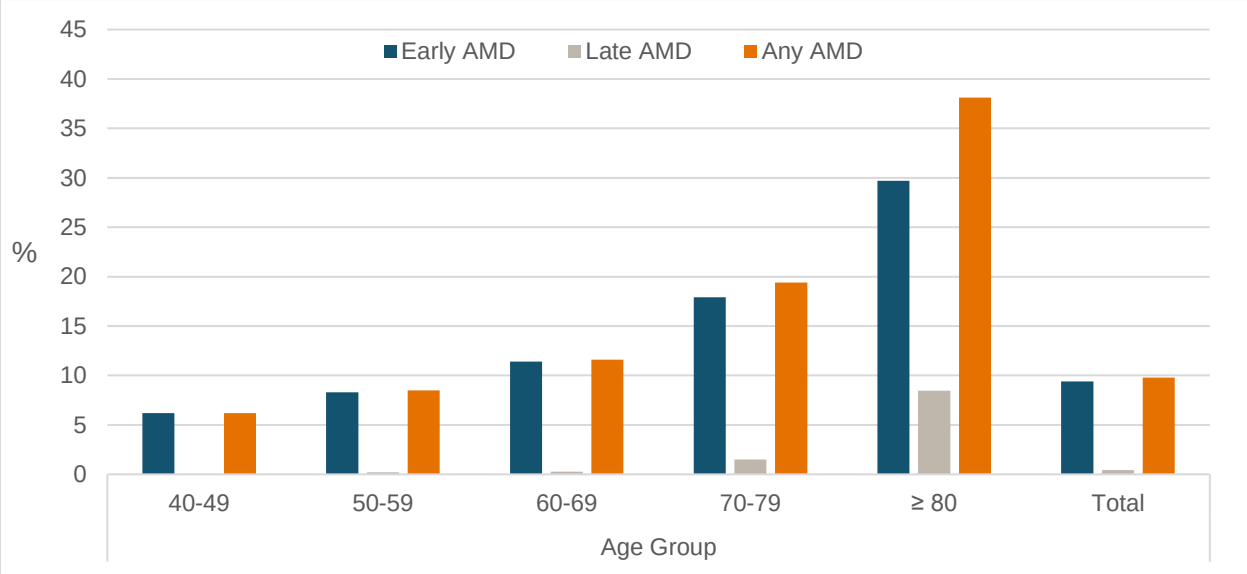
Figure 1.11 Prevalence of AMD in Proyecto VER [18]



1.14 The Los Angeles Latino Eye Study

The Los Angeles Latino Eye Study (LALES) was a population-based, cross-sectional study of over 6,000 Latinos of mostly Mexican heritage.[19] Participants were aged 40 years and older and from the Los Angeles area. Subjects were interviewed and had each eye examined and graded for age-related macular degeneration (AMD) through fundus photographs. Baseline examinations were conducted between March 2000 and June 2003, and follow-up examinations between July 2004 and June 2008. Varma et al. (2004) analyzed the LALES study for the prevalence of various stages of AMD. [20] Early AMD was defined by the presence of drusen >125 μm. Late AMD was defined as the presence of exudative AMD or geographic atrophy. They found that early AMD was more prevalent than late AMD, and that both stages were positively correlated with age (Figure 1.12).

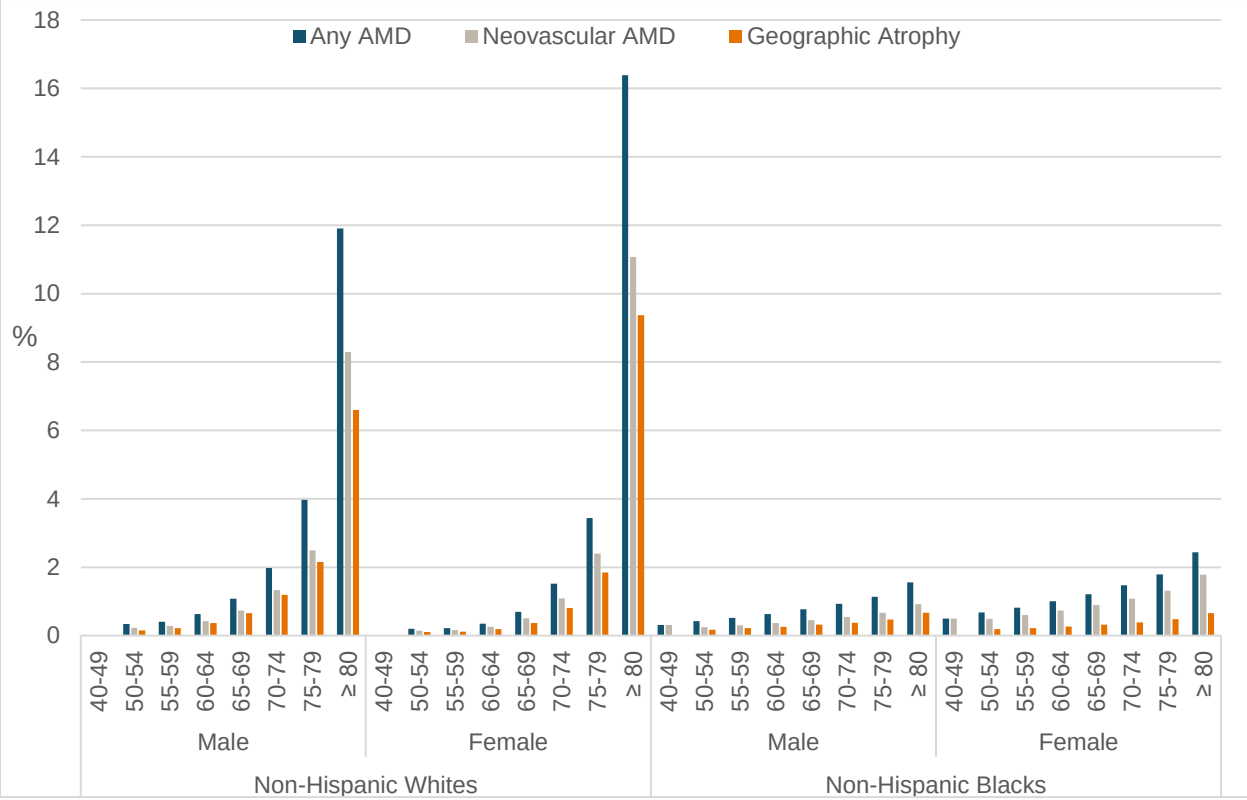
Figure 1.12 Prevalence of AMD in LALES [20]



1.15 The Eye Disease Prevalence Research Group

The Eye Disease Prevalence Research Group (EDPRG) obtained data from several large population-based surveys. The surveys included the Baltimore Eye Survey, Beaver Dam Eye Study, Barbados Eye Study, the Blue Mountains Eye Study, Rotterdam Eye Study, the Melbourne Vision Impairment Study, and the Salisbury Eye Evaluation Project. They defined age-related macular degeneration (AMD) using the International ARM Study Group's definition and differentiated between two groups of AMD: "(1) those with geographic atrophy, which is a discrete area of retinal depigmentation at least 175 μm in diameter with a sharp border and visible choroidal vessels in the absence of Neovascular AMD in the same eye; and (2) those with neovascular AMD, which is serous or hemorrhagic detachment of either the retinal pigment epithelium or sensory retina, the presence of subretinal fibrous tissue, or minimal subretinal fibrosis and widespread retinal pigment epithelial atrophy."[21] Researchers derived national age-, sex-, and race-specific US prevalence rates by "applying the modeled prevalence rate for each year of age to the 2000 US Census population and summing across the age range for each 5-year age category."[21] Figure 1.13 shows the age-specific prevalence rate estimates. All types of AMD increased with age, and early/intermediate AMD was the most prevalent.

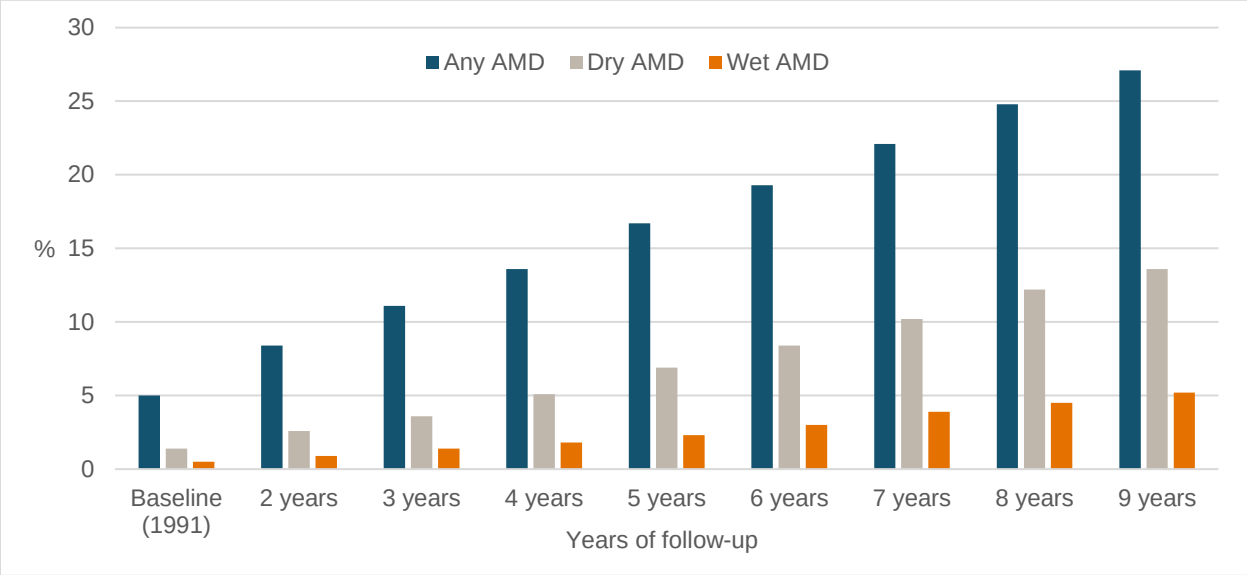
Figure 1.13 Pooled Prevalence of AMD in EDPRG Studies [21]



1.16 The National Long-Term Care Survey

Lee et al. (2003) analyzed Medicare claims of people aged 65 years and older who were enrolled in the National Long-Term Care Survey, a nationally representative sample of adults in the United States aged 65 and older collected by the US Census Bureau.[22] Lee et al. (2003) analyzed claims from a cohort of 20,325 individuals, and followed these beneficiaries from 1991 to 1999 (the cohort decreased to 10,476 by 1999 due to attrition). The study used the International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes to indicate diagnoses of diabetes mellitus, primary open-angle glaucoma, narrow-angle glaucoma, glaucoma suspects, other glaucoma, and age-related macular degeneration (AMD). As shown in Figure 1.14, they found that the prevalence of AMD among this nationally representative sample in 1991 was 5.0%. The prevalence rate within this cohort increased to 27.1% after 9 years.

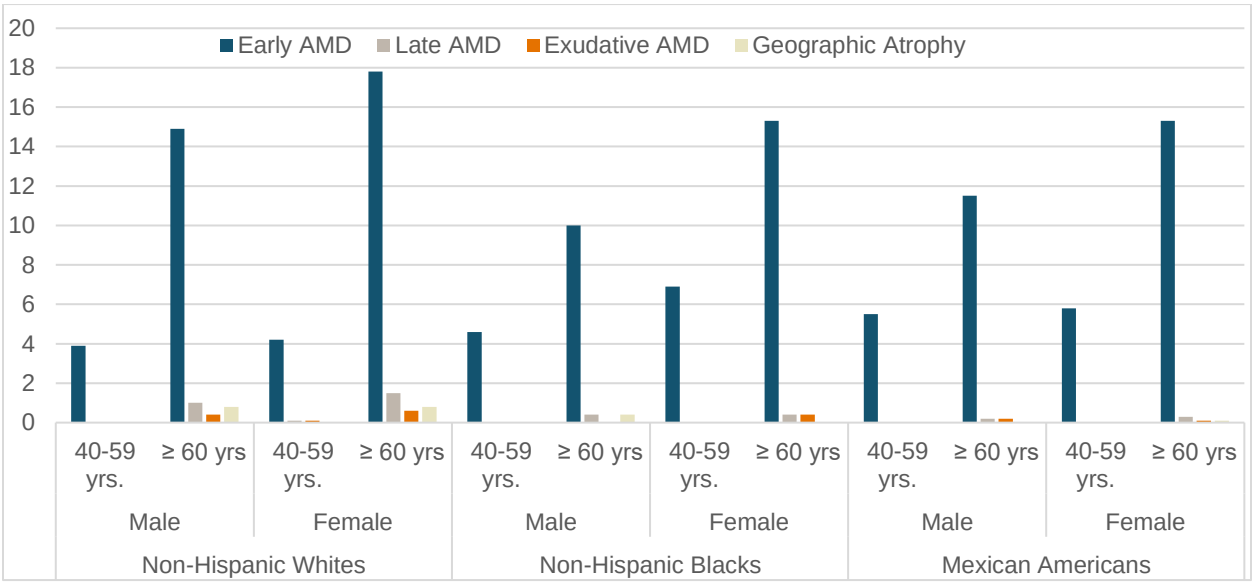
Figure 1.14 Prevalence of AMD in National Long-Term Care Survey Cohort, from Baseline (1991) to 9 years of follow-up [22]



1.17 The Third National Health and Nutrition Examination Survey

The Third National Health and Nutrition Examination Survey (NHANES III) was a national cross-sectional survey conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention from 1988-1994.[23] Based on fundus photographs from one eye, over 8,000 participants were graded for age-related macular degeneration (AMD).[23] Early AMD was defined as the presence of drusen > 63μm, retinal pigment epithelium (RPE) depigmentation, or increased pigmentation in the macula in the absence of late AMD. Late AMD was defined by the presence of exudative AMD or pure geographic atrophy. Klein, et al. (1999) analyzed NHANES III data to compare the prevalence of early, late, exudative (neovascular) AMD, and geographic atrophy by age, sex, and race/ethnicity. As demonstrated in Figure 1.15, early AMD had the highest prevalence among the four types of AMD. Females and non-Hispanic Whites had the highest prevalence rates.

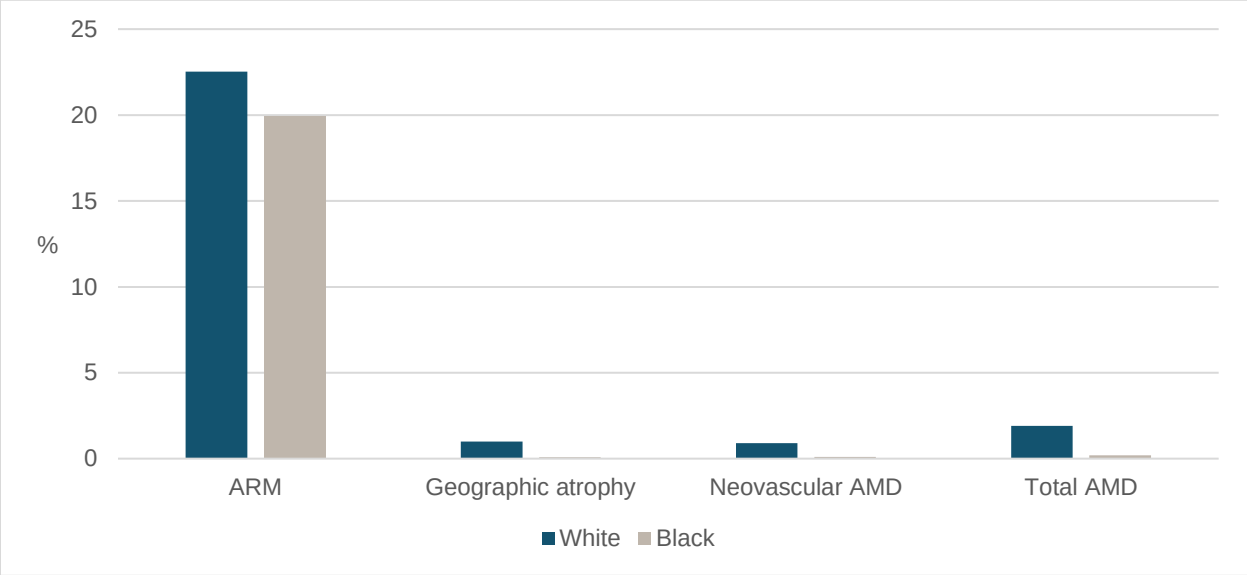
Figure 1.15 Weighted Prevalence of AMD in NHANES [23]



1.18 The Baltimore Eye Survey

The Baltimore Eye Survey was a cross-sectional population-based study that included 5,308 Black and White individuals aged 40 and older from East Baltimore. Examinations included physicals, visual acuity assessments, personal interviews, and stereoscopic fundus photography. Friedman et al. (1999) defined early stage age-related macular degeneration (AMD) as age-related maculopathy (ARM) and defined AMD as only including late-stage AMD, using the classification set forth by the International ARM Epidemiological Study Group.[24] Researchers estimated the prevalence of ARM (early stage AMD by the definitions in this section's introduction) to be greater among Blacks than Whites, and the prevalence of AMD (late stage AMD as defined by this section's introduction) to be 2.1% among Whites older than 70 and 0% among Blacks. Figure 1.16 shows the adjusted prevalence of ARM (early stage AMD) and total AMD (wet and dry late stage AMD) among Blacks and Whites in the Baltimore Eye Survey; estimates were adjusted to the age and race distribution of all individuals originally invited to participate in the study.

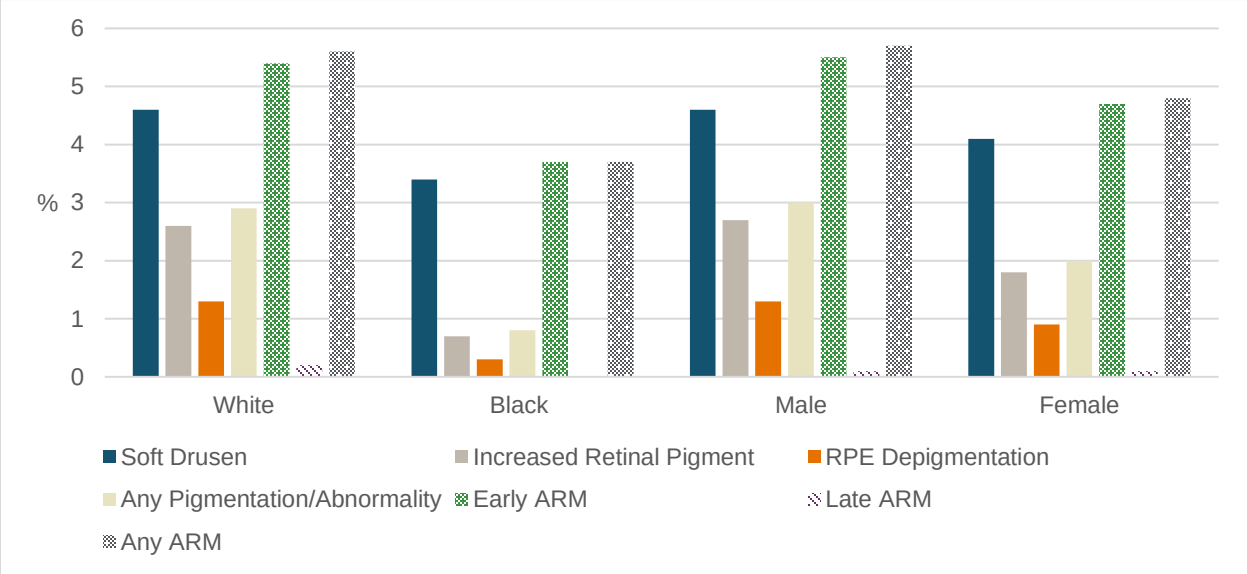
Figure 1.16 Adjusted Prevalence of ARM (Early Stage AMD) Geographic Atrophy, Neovascular AMD, and Total AMD Among Blacks and Whites in the Baltimore Eye Survey [24]



1.19 The Atherosclerosis Risk in Communities Study

The Atherosclerosis Risk in Communities (ARIC) Study examined the prevalence of age-related maculopathy (ARM) and its relation to cardiovascular disease risks and outcomes.[25] The study included 11,532 Black and White adults aged 48-72 in four U.S. communities: Forsyth County, NC; Jackson MS; selected suburbs of Minneapolis, MS; and Washington County, MD. Investigators used a modified Wisconsin Age-Related Maculopathy grading system to assess photographs.[6] Early ARM was defined as the presence of soft drusen (those with a diameter greater than 63 μm), retinal pigment epithelium (RPE) depigmentation alone, or a combination of soft drusen with increased retinal pigment and/or depigmentation. Late ARM was defined as either exudative age-related macular degeneration (AMD) or pure geographic atrophy. Klein, et al. (1999) reported the distribution of various ARM disease stages among races, age groups, and sex. They found an overall prevalence rate of all ARM of 5.2%. The overall ARM prevalence rate was greater among Whites (5.6%) than Blacks (3.7%). Figure 1.17 shows prevalence rates for various ARM disease states by age, race, and sex.

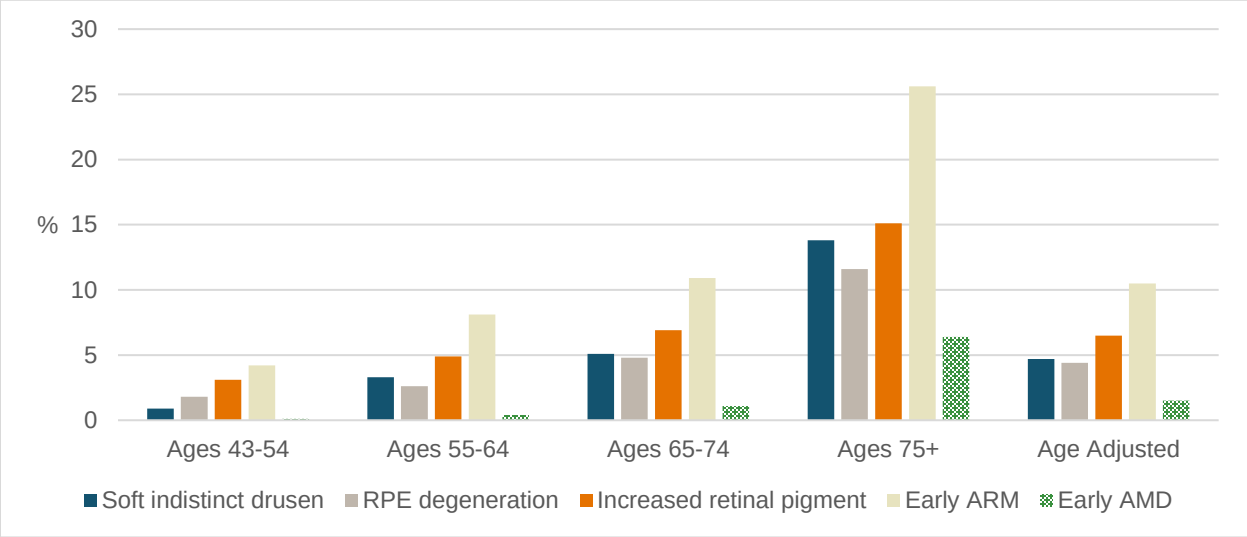
Figure 1.17 Prevalence Rates of ARM in the ARIC Study by Race and Sex [25]



1.20 The Beaver Dam Eye Study

The Beaver Dam Eye study identified all individuals aged 43 to 84 living in Beaver Dam, Wisconsin. Between 1988 and 1990, 4,926 of 5,925 eligible individuals were examined.[26] These examinations included a medical history and lifestyle questionnaire. They also included an ocular examination with nonstereoscopic color fundus photographs of the disc and macula, temporal to but including the fovea, of each eye. Investigators graded the photographs using the Wisconsin Age-related Maculopathy Grading system.[6] The Wisconsin system categorized early age-related maculopathy (ARM) as the presence "in any subfield of the grid of either soft, indistinct drusen or hard or soft drusen plus pigment abnormalities (increased retinal pigment or retinal pigment epithelial degeneration) in the absence of late age-related maculopathy." Late ARM was defined as the "presence of signs of wet age-related macular degeneration (AMD) or pure geographic atrophy." Klein et al. (1995) reported results for 4,886 individuals aged 43 to 84 who were measured for visual acuity (Figure 1.18).[26]

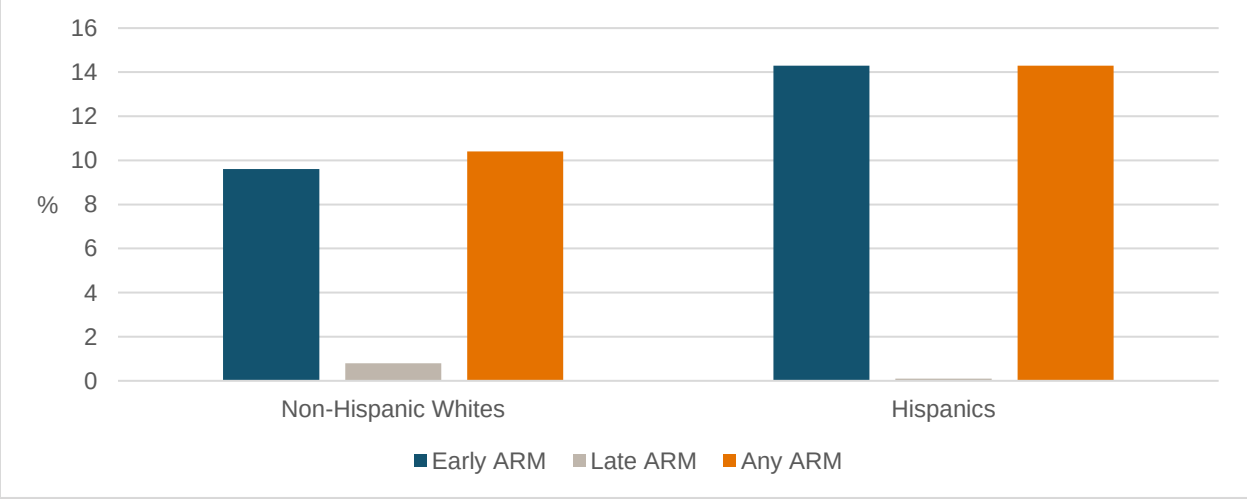
Figure 1.18 Frequency of Specific Lesions Associated with Age-Related Maculopathy in the Macular Area of the Right Eye (Any Subfield Involvement) in the BDES [26]



1.21 San Luis Valley Diabetes Study

The San Luis Valley Diabetes Study was a case-control study that began in 1983. It included 1,791 eligible persons with and without diabetes. Participant ages ranged from 20 to 74. They resided in two counties in south-central Colorado. By self-report, 53% described themselves as non-Hispanic Whites and 47% as Hispanic. The exam included glucose testing, a physical examination, medical history, and fundus photography of DRS fields 1, 2, and 4.[27] The prevalence rate of all types of AMD was 14.3% among Hispanics and 10.4% among non-Hispanic Whites. Cruickshanks et al. (1997) provided age- and sex-adjusted prevalence estimates for San Luis Valley Study participants to account for the probability of being selected (Figure 1.19).

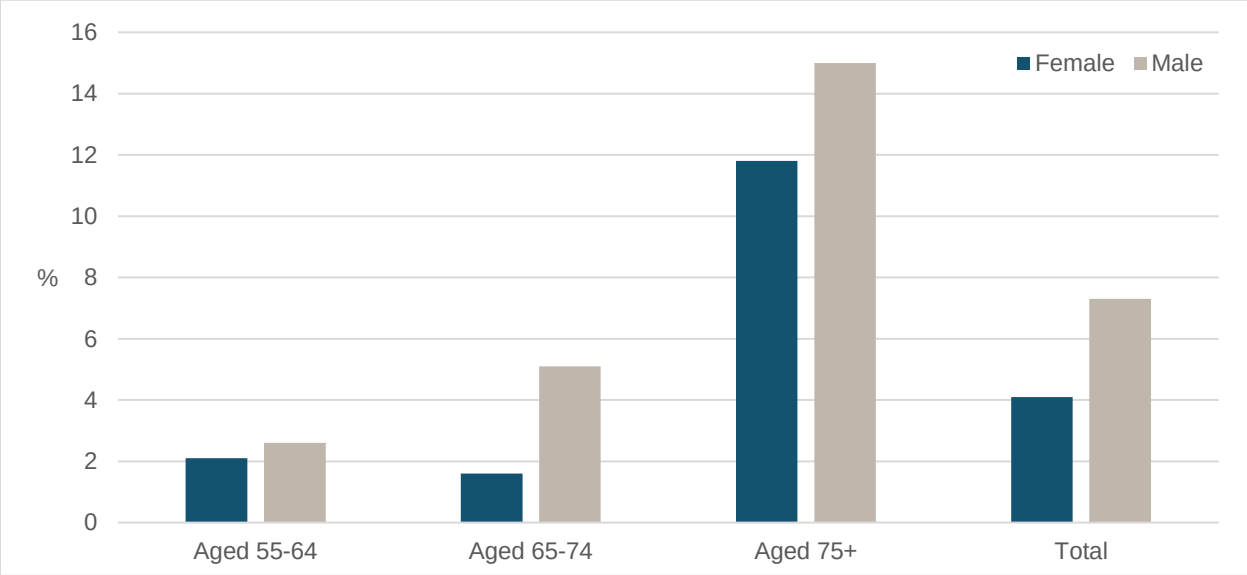
Figure 1.19 Age- and Sex Adjusted Prevalence Estimates for Stage of ARM [27]



1.22 The University of California, Los Angeles Mobile Eye Clinic

The UCLA Mobile Eye Clinic (MEC) was a bus that provided free vision screening to underserved Los Angeles, CA residents. Haronian et al. (1993) examined results for 431 patients aged 55-94. Patients received services from the MEC from 1982 to 1990 in two Los Angeles, CA senior centers.[28] Patients were examined for age-related macular degeneration (AMD), and Haronian et al. (1993) used the International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes to calculate prevalence estimates for various eye diseases. They found an overall AMD prevalence of 5.1%. Figure 1.20 shows AMD prevalence estimates stratified by age and sex.

Figure 1.20 Prevalence of Age-related Macular Degeneration of those Examine in the MEC, by Sex and Age [28]



2. Diabetic Retinopathy

Diabetic retinopathy (DR) occurs when high blood sugar damages the blood vessels of the retina. There are two primary types of DR: non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR).[29] With NPDR, the blood vessels of the retina leak, causing the macula to swell.[29] There are three stages of NPDR: mild, moderate, and severe. Mild NPDR refers to the early stages where blood vessels begin to swell and leak.[30] In moderate cases of NPDR, blood vessels continue to swell and become unable to transport blood. NPDR is considered severe when the retina becomes oxygen deprived and signals growth factors to form new blood vessels.[30] In PDR, new blood vessels form, but are weak and prone to leakage. Scar tissue forms which may lead to retinal detachment and blindness.[29] Nerve damage can also occur with diabetic retinopathy.[29] Diabetic macular edema (DME) is the swelling of the macula and can occur at any stage. The term vision-threatening DR (VTDR) is defined as the presence of severe NPDR, proliferative DR, or clinically significant macular edema (CSME).[31]

In 1968, a group of experts developed a grading system for DR called the Arlie House Classification of DR.[32] The system grades stereo photographs and classifies DR in 13 levels: level 10 indicates no retinopathy and level 85 signifies retinal detachment or severe vitreous hemorrhage.[32] This system was modified in the Early Treatment of Diabetic Retinopathy Study (ETDRS) [32]. The term CSME was introduced by the ETDRS and refers to a specific form of DME. It was defined as the "(1) thickening of the retina at or within 500 μm of the center of the macula; or (2) hard exudate at or within 500 μm of the center of the macula associated with thickening of adjacent retina; or (3) a zone of retinal thickening 1 disc area or larger, any part of which is within 1 disc diameter of the center of the macula."[32]

2.0 Diabetic Retinopathy Literature Review Results

Figure 2.0 shows 17 studies conducted between 1992 and 2016 that examined the prevalence of diabetic retinopathy (DR). These studies examined a variety of demographics including race/ethnicity, age, sex, income, and education level. Various stages of DR were examined including mild, moderate, and severe NPDR, diabetic macular edema (DME), and vision threatening DR (VTDR). The sources of data were:

1. The Chinese American Eye Study (CHES)
2. The Diabetic Retinopathy Inpatient Study (DRIPS)
3. Retrospective Chart Review
4. Telemedicine Screening Program
5. National Health and Nutrition Examination Survey (NHANES)
6. Atlanta VA Medical Center Chart Review
7. San Francisco General Hospital (SFGH) Eye Van
8. Multi-ethnic Study of Atherosclerosis (MESA)
9. Study on Visual Impairment Among Northwest American Indians/Alaska Natives (AIAN)
10. The Los Angeles Latino Eye Study (LALES)
11. Eye Disease Prevalence Research Group (EDPRG)

12. National Long-Term Care Survey
13. Proyecto VER
14. The Third National Health and Nutrition Examination Survey (NAHNES)
15. University of California Mobile Eye Clinic (UCLA MEC)
16. Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR)
17. New Jersey 725

Figure 2.0 Diabetic Retinopathy Prevalence Sources

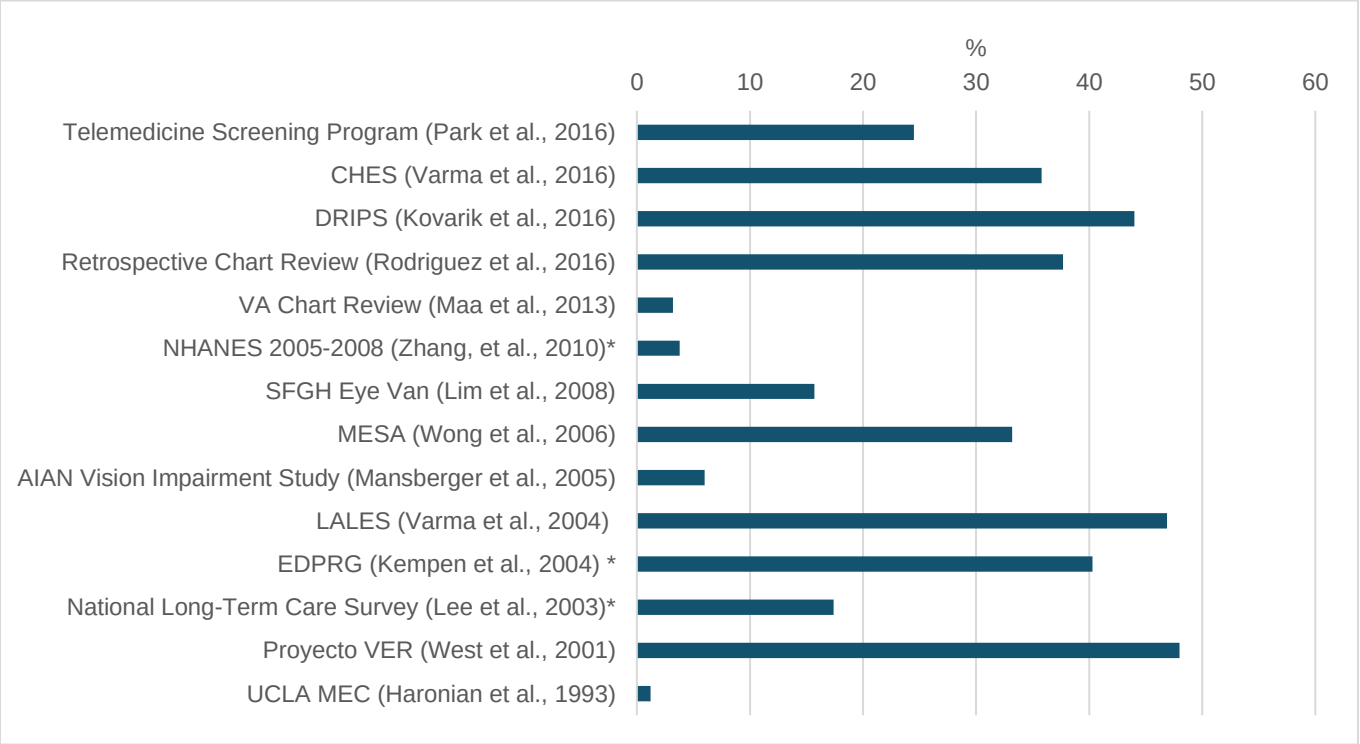
Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Type/stage of DR
Varma R, Wen G, et al.	2016	Prevalence of Diabetic Retinopathy in Adult Chinese American Individuals: The Chinese American Eye Study	2010–2013	The Chinese American Eye Study	665	Age, Sex, Race	Any, Mild NPDR, Moderate NPDR, Severe NPDR, PDR
Kovarik JJ, Eller AW, et al.	2016	Prevalence of Undiagnosed Diabetic Retinopathy Among Inpatients with Diabetes: The Diabetic Retinopathy Inpatient Study	2011–2012	DRIPS	113	Not stratified by demographic variables	Any, Mild NPDR, Moderate NPDR, Severe NPDR, PDR
Rodriguez N, Aguilar, S	2016	Prevalence of Diabetic Retinopathy in a Clinic Population from Puerto Rico	2001–2009	Retrospective Chart Review	411	Age, Sex	Mild NPDR, Moderate NPDR, Severe NPDR, PDR
Park D, Mansberger SL, et al.	2016	Eye Disease in Patients with Diabetes Screened with Telemedicine	2006–2009	Telemedicine Screening Program	424	Not stratified by demographic variables	Any, Mild NPDR, Moderate NPDR, Severe NPDR, PDR
Zhang X, Cotch MF, et al.	2012	Vision Health Disparities in the United States by Race/Ethnicity, Education, and Economic Status: Findings from Two Nationally Representative Surveys	2005–2008; 1988–1994	NHANES 2005-2008, NAHNES III	5,704; 8,208	Race/Ethnicity	Any
Maa AY, Evans C, et al.	2013	Veteran Eye Disease after Eligibility Reform: Prevalence and Characteristics	January 2008–February 2008	Atlanta VA Medical Center Chart Review	658	Not stratified by demographic variables	NPDR, PDR
Zhang X, Saadine J, et al.	2010	Prevalence of Diabetic Retinopathy in the United States, 2005-2008	2005–2008	2005-2008 NHANES	1,006	Age, Sex, Race/Ethnicity	Any, VTDR
Lim A, Stewart J, Chui TY, et al.	2008	Prevalence and Risk Factors of Diabetic Retinopathy in a Multi-Racial Underserved Population	2004–2006	SFGH Eye Van	1,073	Race/Ethnicity	Any, Mild, Moderate, Severe
Wong TY, Klein R, Islam FM, et al.	2006	Diabetic Retinopathy in a Multi-Ethnic Cohort in the United States	2000–2002	MESA	778	Race/Ethnicity	Any, Minimal, Early-moderate,

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Type/stage of DR
							Severe-proliferate, VTDR
Mansberger SL, Romero FC, et al.	2005	Causes of Visual Impairment and Common Eye Problems in Northwest American Indians And Alaska Natives	Unknown	Northwest AIAN	288	Race	NPDR, PDR
Varma R, Torres M, Pena F, et al.	2004	Prevalence of Diabetic Retinopathy in Adult Latinos: The Los Angeles Latino Eye Study	2000–2008	LALES	1,217	Age, Sex, Race/Ethnicity	Any, Mild NPDR, Moderate NPDR, Severe NPDR, PDR
Kempen JH, O'Colmain BJ, Leske MC, et al.	2004	The Prevalence of Diabetic Retinopathy Among Adults in the United States	1985–1998	EDPRG	N/A	Age, Race/Ethnicity, Sex	Any, VTDR
Roy MS, Klein R, O'Colmain BJ, et al.	2004	The Prevalence of Diabetic Retinopathy Among Adult Type 1 Diabetic Persons in the United States	1980–1982, 1993–1998	WESDR, New Jersey 725	594, 790	Sex, Age, Race	Any, VTDR
Lee PP, Feldman ZW, Ostermann J, et al.	2003	Longitudinal Prevalence of Major Eye Diseases	1999	National Long-Term Care Survey	Various	Not stratified by demographic variables	Any DR, PDR
West SK, Klein R, et al.	2001	Diabetes and Diabetic Retinopathy in a Mexican-American Population	1997–1999	Proyecto VER	1,044	Not stratified by demographic variables	Any, Moderate NPDR Severe NPDR, PDR
Harris MI, Klein R, Cowie CC, et al.	1998	Is the risk of Diabetic Retinopathy Greater in Non-Hispanic Blacks and Mexican Americans than in Non-Hispanic Whites with Type 2 Diabetes? A U.S. Population Study.	1988–1994	NHANES III	Various	Race/Ethnicty	Any, Mild NPDR, Moderate NPDR, PDR
Haronian E, Wheeler NC, et al.	1993	Prevalence of Eye Disorders Among the Elderly in Los Angeles	1982–1990	UCLA MEC	431	Age, Sex	Any
Klein R, Klein B	1992	Epidemiology of Proliferative Diabetic Retinopathy	1980–1982	WESDR	2,366	Age, Sex	PDR

2.1 Overall Diabetic Retinopathy Prevalence Rates

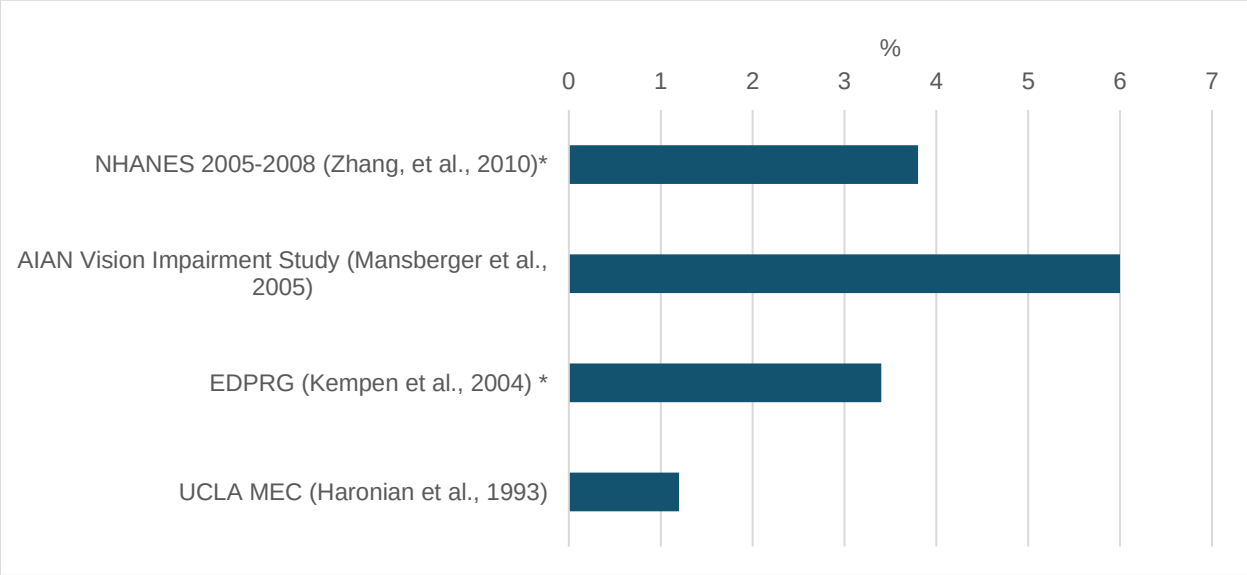
Figure 2.1 below shows diabetic retinopathy (DR) prevalence rates from 11 of the selected studies that reported an overall rate. The high degree of variation among the results in this figure is likely due to in part to methodological, disease definition and population differences among the studies. This figure excludes studies that did not report an overall rate for the study. The figure is intended to illustrate the range of published prevalence values; direct comparison of the studies is impossible without considering the underlying differences in the studies. Most studies determined the prevalence of DR from a study sample of diabetic individuals (Figure 2.1), while some reported the prevalence rates among a general population including individuals with and without diabetes (Figure 2.2). The studies described throughout this section compared DR prevalence rates across race/ethnicity, age, education level, and income. Variation among these studies could be a result of the different distributions of socio-demographic characteristics among the study samples as well as differences in the prevalence of diabetes. Further, three of the studies reported estimates that were adjusted to a national standard.

Figure 2.1 Overall Prevalence Rates of Diabetic Retinopathy Among Populations with Diabetes



*Age- or Population-adjusted prevalence rate

Figure 2.2 Overall Prevalence Rates of Diabetic Retinopathy Among Populations With and Without Diabetes (Not Restricted to Persons with Diabetes)

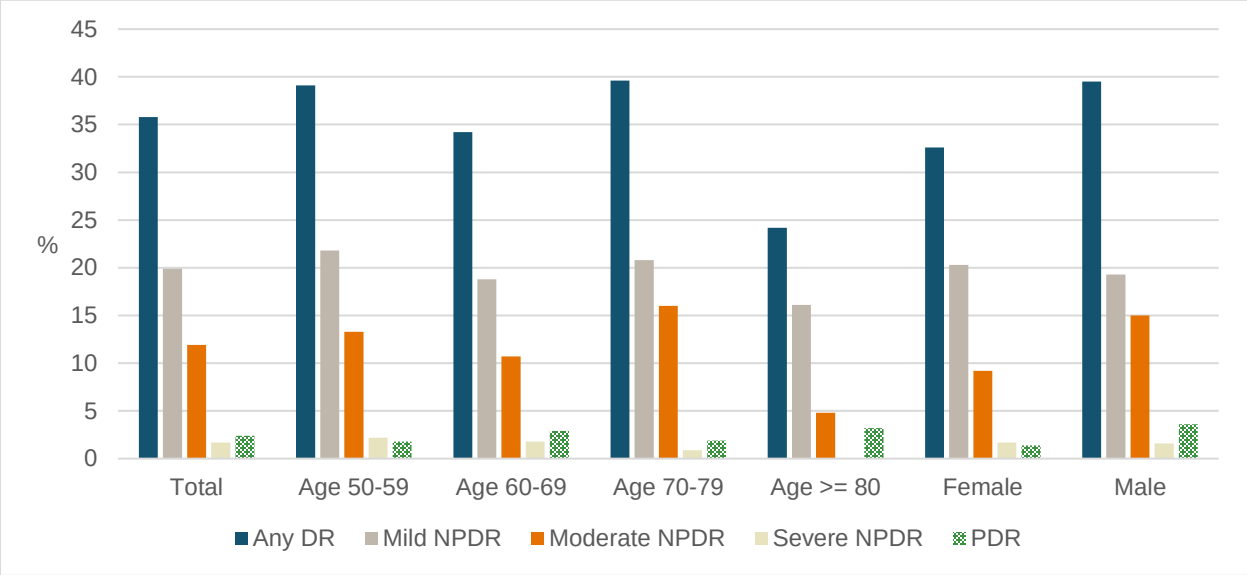


*Age- or population- adjusted prevalence rate.

2.2 The Chinese American Eye Study

The Chinese American Eye Study (CHES) consisted of 4,582 individuals aged 50 and older who were primarily first-generation immigrants from China living in Monterey Park, California. The study was conducted between February 2010 and October 2013. Varma et al. (2016) analyzed data from 665 individuals who had type 2 diabetes and gradable fundus photographs .[33] Participants were identified as having diabetes if they reported a history of diabetes and were undergoing treatment, or if participants' A1C level was measured at 6.5% or higher. Fundus photographs were graded using a modified Arlie house classification system. As shown in Figure 2.3, Varma et al. (2016) reported age- and sex-specific prevalence rates for various stages of diabetic retinopathy (DR). The authors found an overall DR prevalence rate of 35.8% among this population of diabetic patients. The authors concluded that DR prevalence rates among Chinese immigrants living in California were lower than rates reported among Asians living in China and Latino individuals living in Los Angeles County, California.

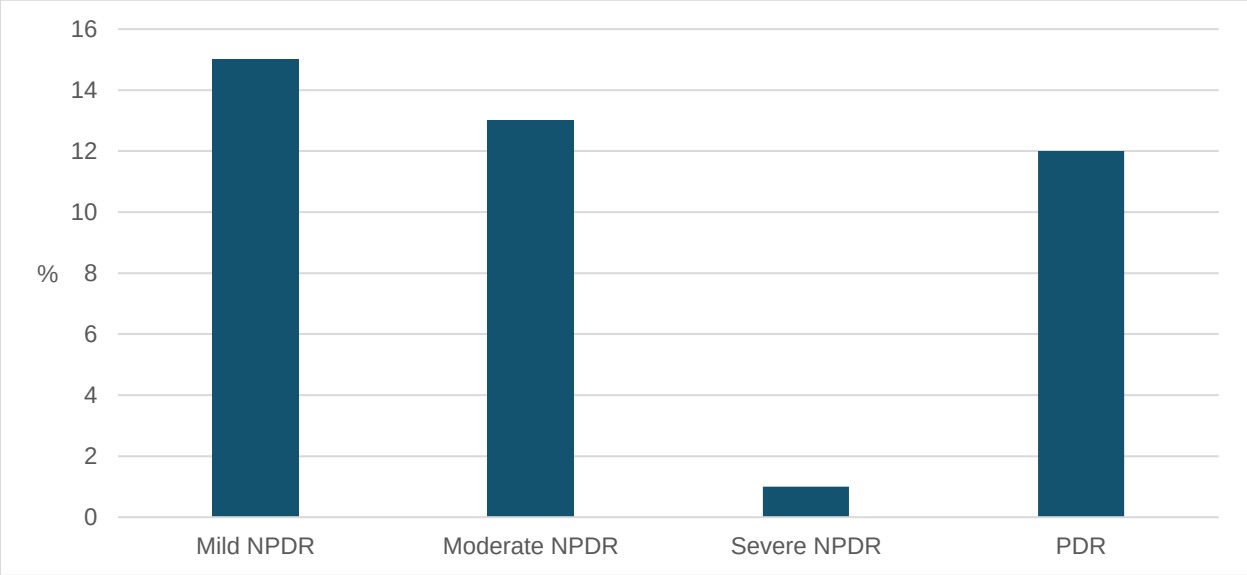
Figure 2.3 Age- and Sex- Specific Prevalence of DR in Chinese American Individuals with Type 2 Diabetes [33]



2.3. The Diabetic Retinopathy Inpatient Study

The Diabetic Retinopathy Inpatient Study (DRIPS) included 113 inpatients seen at UPMC Mercy Hospital in Pittsburg between September 2011 and August 2012.[34] Patients were randomly selected to participate if they were 18 years or older and diagnosed with diabetes. Participants were interviewed and examined using fundus photography. Kovarik et al. (2016) classified patients as having various stages of diabetic retinopathy (DR) and found an overall DR prevalence rate of 44% among this sample of diabetic patients. The researchers concluded that the prevalence of DR and vision-threatening diabetic retinopathy (VTDR) was significantly higher among the inpatient population compared to the general US adult population, indicating higher rates of advanced diabetes in the study sample than the general population. Figure 2.4 shows prevalence rates by DR classification reported by Kovarik et al. (2016).

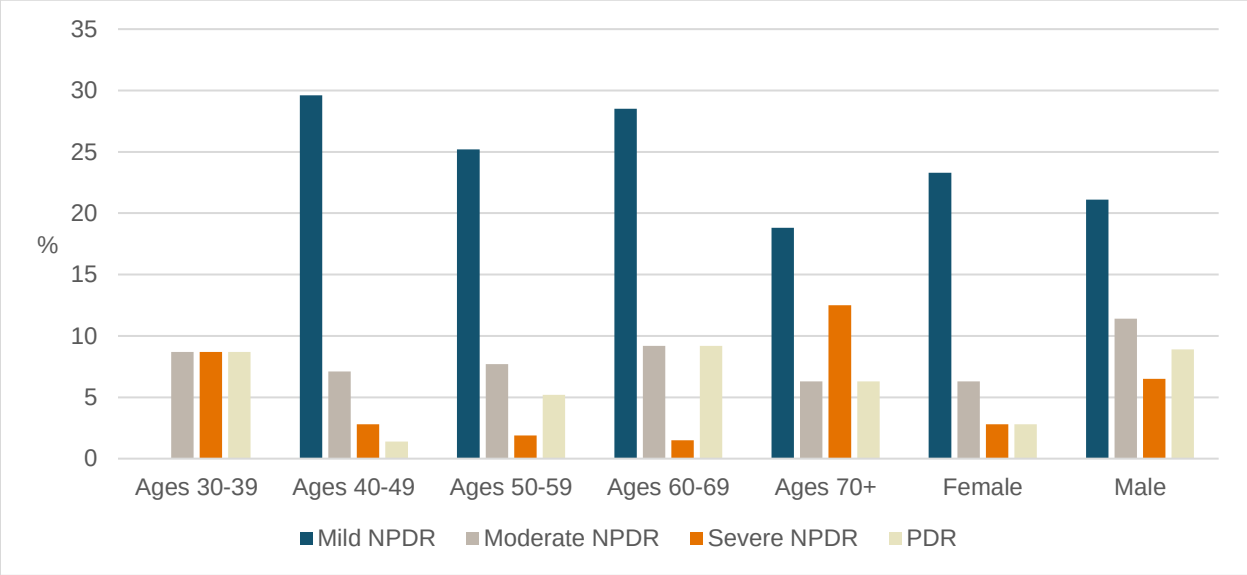
Figure 2.4 Prevalence of Various Stages of Diabetic Retinopathy Among DRIPS Participants [34]



2.4 Retrospective Chart Review of a Clinic Population in Puerto Rico

Rodriguez et al. (2016) selected 411 subjects with diabetes aged 30 and older who visited the Inter American University of Puerto Rico School of Optometry Eye Clinic between 2001 and 2009. The research team systematically selected patients to ensure a representative sample.[35] The team examined fundus photographs and categorized each as having no diabetic retinopathy (DR), mild nonproliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, or proliferative diabetic retinopathy (PDR). Researchers found an overall DR prevalence rate of 37.7% among this sample of diabetic patients. Stratified results show that in this study sample, mild DR was the most common type of DR and that DR was more common among males and patients aged 60-69 (Figure 2.5).

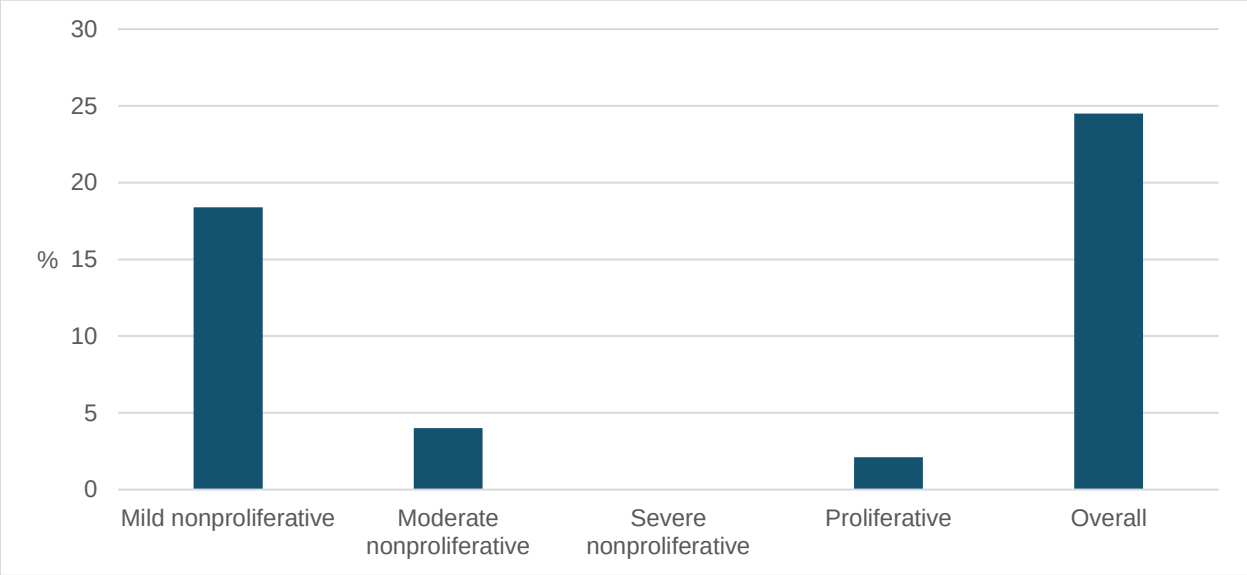
Figure 2.5 Prevalence Rates of Diabetic Retinopathy Among a Clinic Population with Diabetes in Puerto Rico Stratified by Age and Sex [35]



2.5. Telemedicine Screening Program

Park et al. (2016) sought to determine the utility of telemedicine with nonmydriatic cameras as a mechanism for detecting eye disease.[7] They recruited and examined 424 diabetic patients aged 18 and older scheduled with primary care providers from Yellowhawk Tribal Health Center (Pendleton, OR) and Hunter Health Clinic (Wichita, KS). The study population was, consequently, primarily made up of American Indians/Alaska Natives. Park, et al. (2016) reported an overall diabetic retinopathy (DR) prevalence of 24.5% among this population of diabetic patients. Figure 2.6 shows prevalence rates for various stages of DR.

Figure 2.6 Prevalence of Diabetic Retinopathy by Stage Among Diabetic Patients Screened via Telemedicine [7]



2.6 Atlanta Veteran Affairs (VA) Medical Center Medical Chart Review

As a first step to assessing whether the VA system is adequately prepared to serve patients given new eligibility reform, Maa et al. (2013) conducted this pilot study on the prevalence of various eye diseases among new "routine" eye patients at the Atlanta VA Medical Center Comprehensive Eye Clinic.[9] Researchers reviewed the charts of 658 new patients with no known previous eye diagnosis with the exception of refractive error who were seen between January 1, 2008 and February 1, 2008. The authors used International Classification of Diseases, 9th Revision Clinical Modification codes (ICD-9CM) to identify ocular conditions and found a prevalence rate of 2.4% for nonproliferative diabetic retinopathy (NPDR) and 0.8% for proliferative diabetic retinopathy (PDR). Maa et al. (2013) did not provide estimates stratified by demographic factors.

2.7 2005-2008 National Health and Nutrition Examination Survey

Zhang, et al. (2010) used the 2005-2008 National Health and Nutrition Examination Survey (NHANES) to examine prevalence rates of diabetic retinopathy (DR) and vision-threatening diabetic retinopathy (VTDR) among diabetics aged 40 and older.[36] They found an overall weighted DR prevalence rate of 28.5% and an overall weighted VTDR prevalence rate of 4.4% among respondents identified with diabetes. The authors extrapolated their results to the entire diabetic and non-diabetic US population and estimated that the prevalence of DR during the study period would have been 3.8%. Figure 2.7 shows crude DR and VTDR prevalence rates for individuals with diabetes aged 40 and older stratified by age, sex, and ethnicity. Figure 2.8 shows the crude DR and VTDR prevalence rates stratified by age, sex, and ethnicity for the entire US population during the study period. Zhang et al. (2012) concluded that the prevalence of DR and VTDR was particularly high among non-Hispanic Black individuals.[11] Zhang et

al (2012) also used NHANES 2005-2008 to compare DR prevalence rates of adults aged 40 and older across various socioeconomic strata with data from the third National Health and Nutrition Examination Survey (NHANES III), described in Section 2.15. Figure 2.9 shows the prevalence rates calculated by Zhang et al. (2012).

Figure 2.7 Estimated Crude Prevalence of Diabetic Retinopathy and Vision Threating Diabetic Retinopathy in Individuals with Diabetes Aged 40 Years and Older, by Age, Sex, and Race: NHANES 2005-2008 [36]

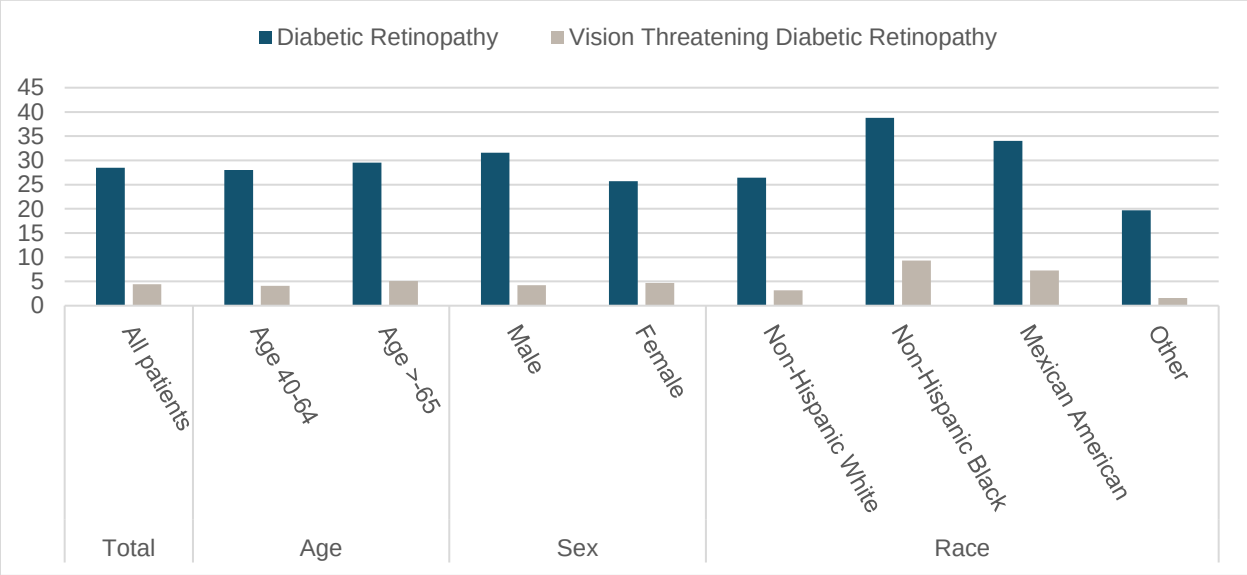


Figure 2.8 Estimated Prevalence of Vision Threating Diabetic Retinopathy Extrapolated to the Adult US Population, by Age, Sex, and Race: NHANES 2005-2008 [11]

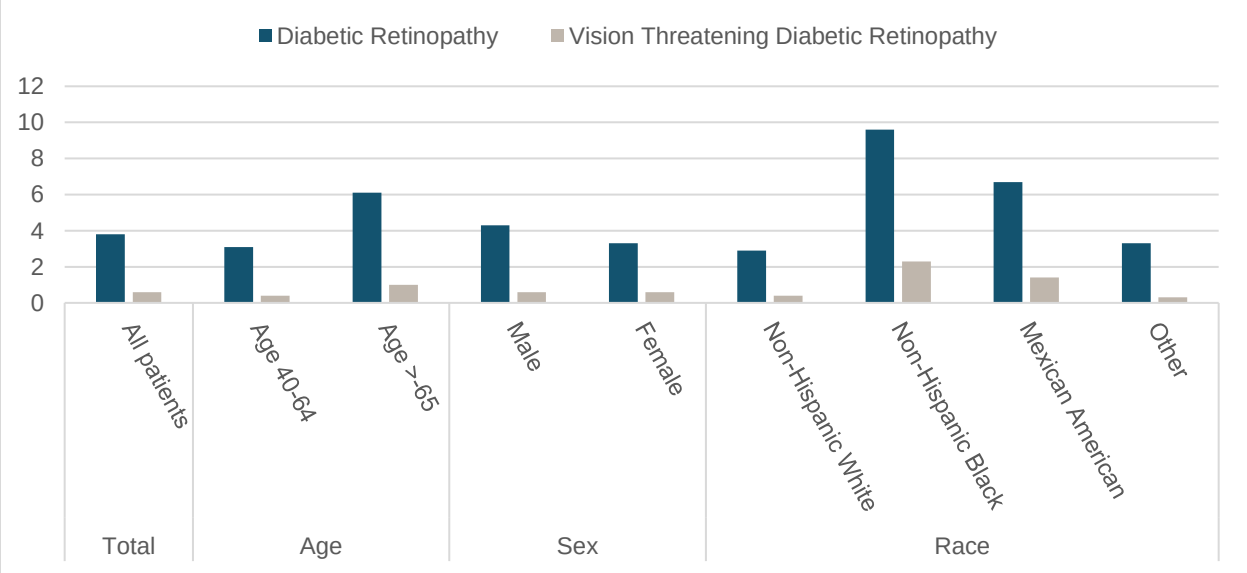
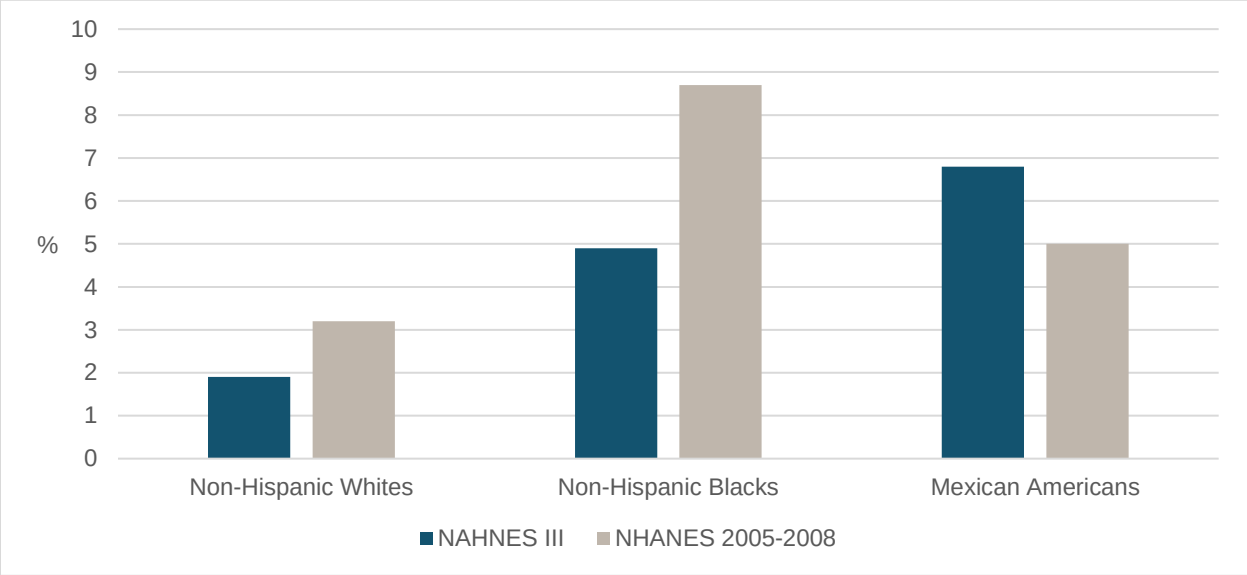


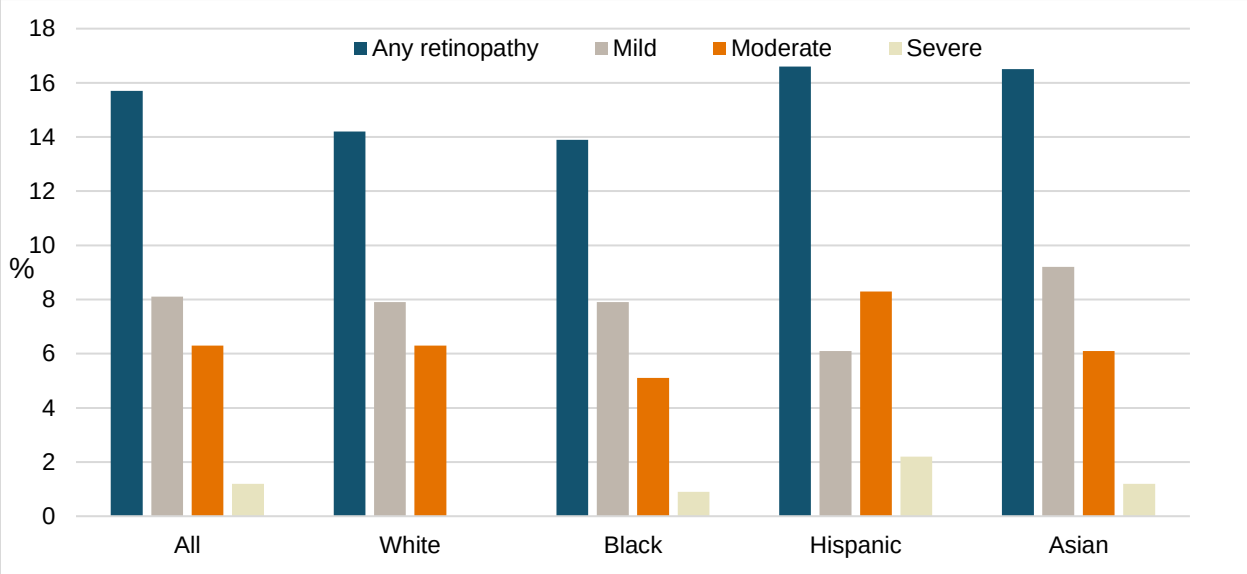
Figure 2.9 Age- and Sex- Standardized Diabetic Retinopathy among Adults Aged 40 and Older Participating in NHANES III and NHANES 2005-2008[11]



2.8 The San Francisco General Hospital Eye Van

The San Francisco General Hospital (SFGH) Eye Van was a mobile eye service run by the University of California San Francisco that provided eye screening services to San Francisco Community Health Network's medically underserved populations, particularly low income, elderly, and homeless populations.[37] From September 2004 and June 2006, 1,132 diabetic patients 30 years and older without a previous diagnosis for diabetic retinopathy (DR) were referred by health network primary care providers to the SFGH Eye Van. Fundus photographs were taken and graded for DR; the final analytical sample consisted of 1073 subjects. Hispanics and Asians had slightly higher rates of any DR than Whites and Blacks (Figure 2.10).

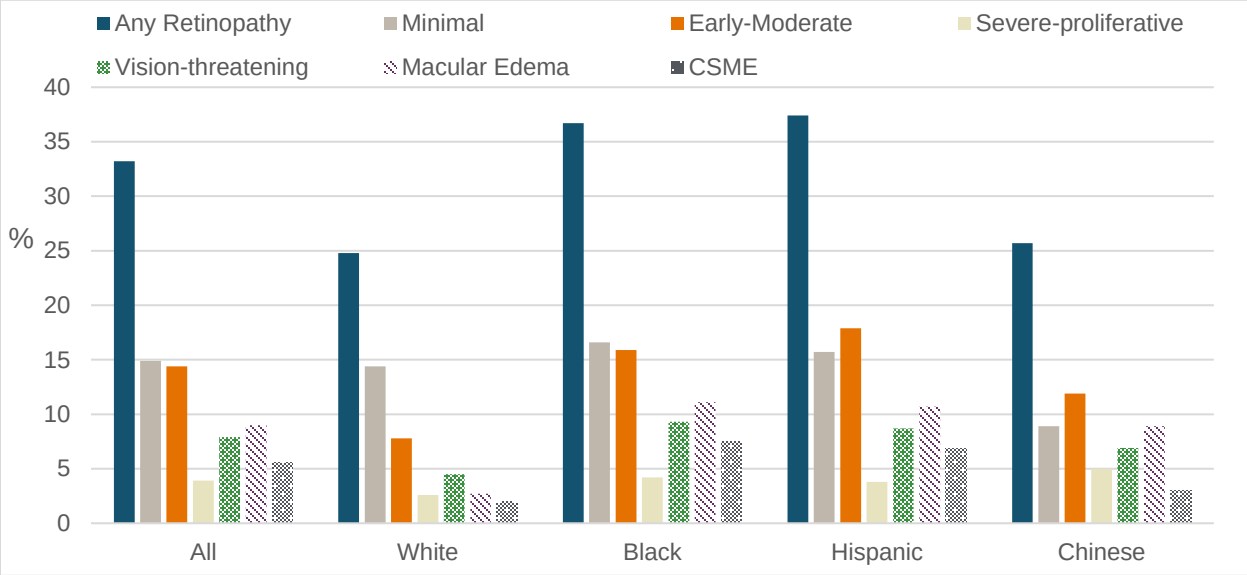
Figure 2.10 Prevalence by Stage of DR Among Diabetic Patients from the SFGH Eye Van [37]



2.9 The Multi-ethnic Study of Atherosclerosis

The Multi-ethnic Study of Atherosclerosis (MESA) was a 10-year longitudinal study of over 6,000 men and women 45-84 years of age in Baltimore, Maryland; Chicago, Illinois; Forsyth County, North Carolina; Los Angeles, California; New York, New York; and St. Paul, Minnesota.[16] The racial/ethnic distribution of participants was 39% White, 27% Black, 21% Hispanic, and 13% Chinese. Of this population, 778 individuals had diabetes. Fundus photographs were taken of each of the diabetic participants eyes and graded for diabetic retinopathy (DR) as defined by the Early Treatment Diabetic Retinopathy Study.[31] Macular edema was defined as either present or absent. Vision-threatening DR (VTDR) was defined as: “the presence of severe non-proliferative diabetic retinopathy (NPDR), proliferative DR, or clinically significant macular edema (CSME).” Wong et al. (2006) described the prevalence and severity of DR among different racial groups.[31] Minimal and early-moderate DR had the highest prevalence rates among the seven DR types, and Blacks and Hispanics had higher rates of DR than White and Chinese participants (Figure 2.11).

Figure 2.11 Prevalence of Diabetic Retinopathy among Diabetic Patients from the Multi-ethnic Study of Atherosclerosis [31]



2.10 Study on Visual Impairment Among Northwest American Indians/Alaska Natives

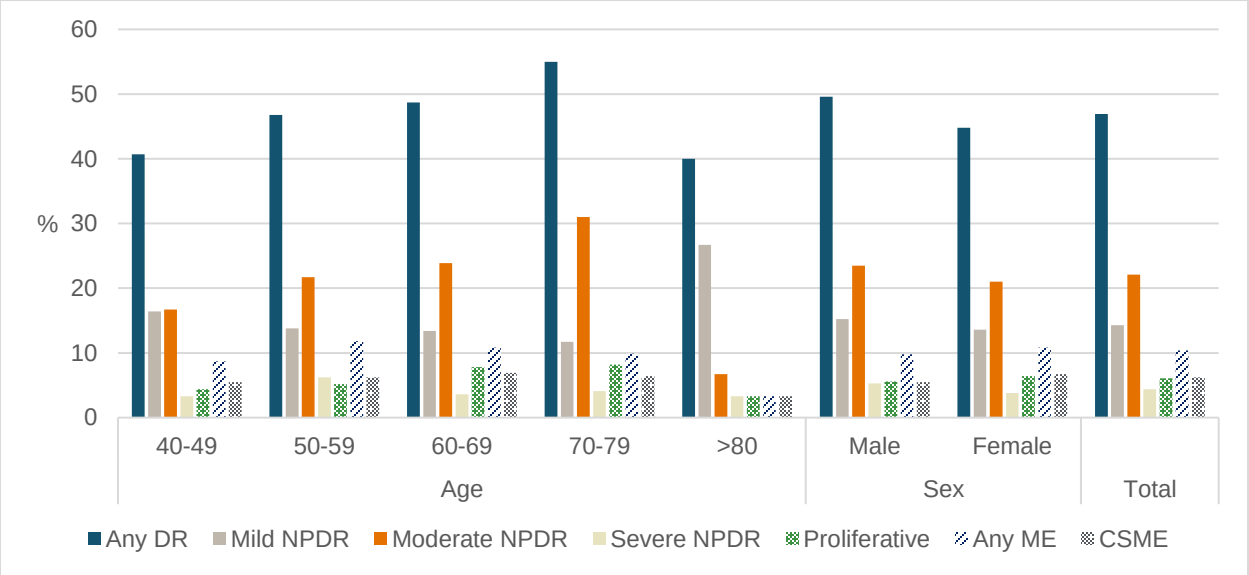
Mansberger et al. (2005) examined the prevalence of eye health disorders in a random sample of 288 American Indian/Alaska Native (AIAN) individuals.[17] Researchers randomly selected participants from three tribes from the Northwest region of the United States (Oregon, Washington, and Idaho) and conducted ocular examinations. Mansberger, et al. (2005) reported the demographics of their study sample and the prevalence of various eye diseases. They found a 4.2% prevalence rate of nonproliferative diabetic retinopathy (NPDR) and a 1.8% prevalence rate of proliferative diabetic retinopathy (PDR). Comparing this prevalence rate with that of other eye health diseases analyzed as part of this study, they concluded that diabetic retinopathy (DR) was not a common cause of vision impairment among the study sample.

2.11 The Los Angeles Latino Eye Study

The Los Angeles Latino Eye Study (LALES) was a 5-year population-based, cross-sectional study of over 6,000 Latinos of mostly Mexican heritage 40 years and older from the Los Angeles area.[19] Participants were interviewed and had fundus photographs taken of each eye. A total of 1,217 participants had definite diabetes and gradable fundus photographs. Researchers used diabetic retinopathy (DR) grading protocols modified from the Early Treatment Diabetic Retinopathy Study adaptation of the modified Arlie House classification system. Baseline examinations were conducted between March 2000 and June 2003, and follow-up examinations from July 2004 and June 2008. Varma et al. (2004) estimated the prevalence and severity of DR based on age and sex.[38] As shown in Figure 2.12, moderate nonproliferative diabetic

retinopathy (NPDR) and mild NPDR had the highest prevelance, and females had higher prevalence rates than males. DR was positively correlated to age, but rates decreased after age 80.

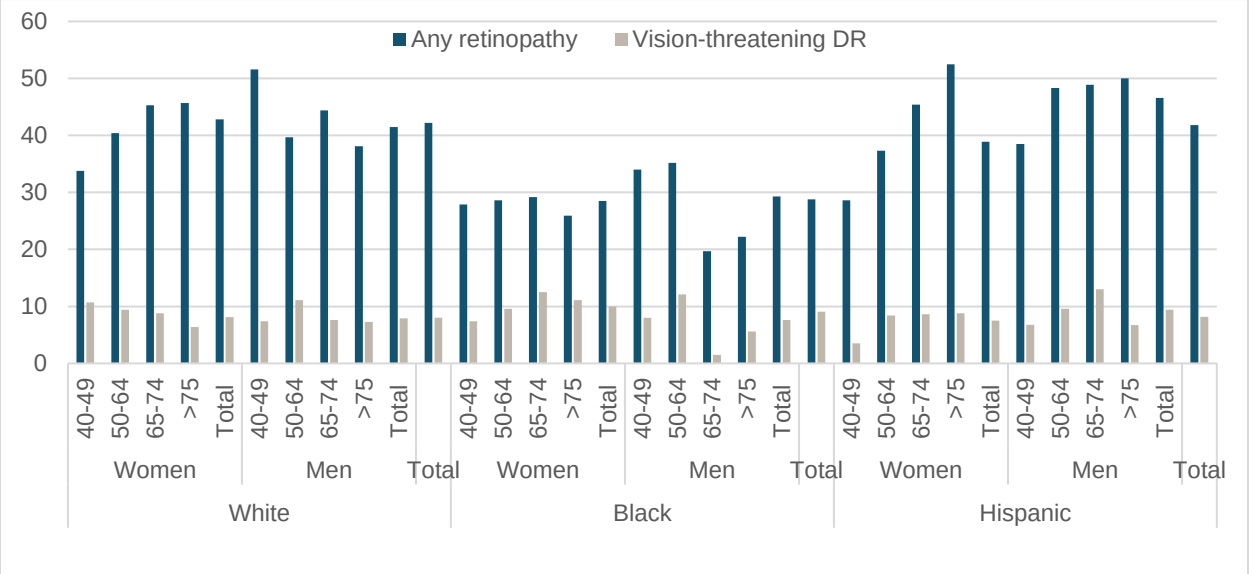
Figure 2.12 Prevalence of DR among Diabetic Patients in LALES [38]



2.12 The Eye Disease Prevalence Research Group

The Eye Disease Prevalence Research Group (EDPRG) obtained data from several large population-based surveys from inside and outside the US, including the Beaver Dam Eye Study, Proyecto Vision Evaluation Research, Barbados Eye Study, the Blue Mountains Eye Study, the Melbourne Vision Impairment Study, Wisconsin Epidemiologic Study of Diabetic Retinopathy, and the San Luis Valley Diabetes Study.[39] EDPRG collapsed severity scales based on fundus photography and came to a consensus on common definitions of diabetic retinopathy (DR) and vision-threatening diabetic retinopathy (VTDR) that could be applied across surveys.[39] Researchers used 1999 National Health Interview Survey to determine the number of individuals with diabetes mellitus within age-, sex- and race/ethnicity-specific strata and applied this to the 2000 US Census. Researchers used these estimates in conjunction with the stratum-specific pooled DR and VTDR rates among those with diabetes mellitus that they calculated to determine national DR and VTDR rates. The adjusted national prevalence rate estimate among persons with diabetes is shown above in Figure 2.2. Figure 2.13 shows the crude age-specific prevalence rates among diabetic patients. EDPRG found that the prevalence of DR increased with age and was higher among Whites and Hispanics than Blacks.

Figure 2.13 Pooled Prevalence of DR in EDPRG by Age, Sex, and Race [39]



2.13 The National Long-Term Care Survey

Lee et al. (2003) analyzed Medicare claims of 20,325 people aged 65 years and older in 1991 who were enrolled in the National Long-Term Care Survey, a random sample of adults in the US collected by the US Census Bureau.[22] Lee et al. (2003) analyzed claims from 1991-1999 for ICD-9CM codes indicating the diagnoses of diabetes mellitus, primary open-angle glaucoma, narrow-angle glaucoma, glaucoma suspects, other glaucoma, and age-related macular degeneration. The prevalence rate of diabetic retinopathy (DR) or macular edema among individuals with diabetes mellitus was 6.9% in the baseline year. This rate increased to 17.4% after 9 years of follow-up (Figure 2.14). Figure 2.15 shows the prevalence rates among the total population including patients with and without diabetes.

Figure 2.14 Prevalence of Diabetic Retinopathy Among National Long-Term Care Survey Participants with Diabetes Mellitus [22]

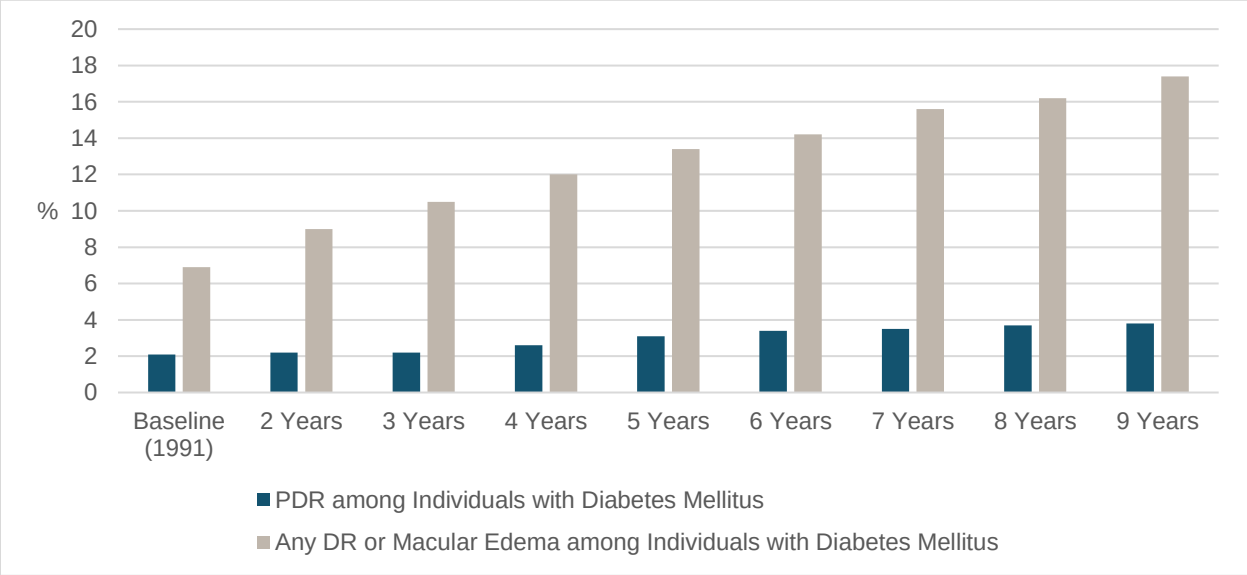
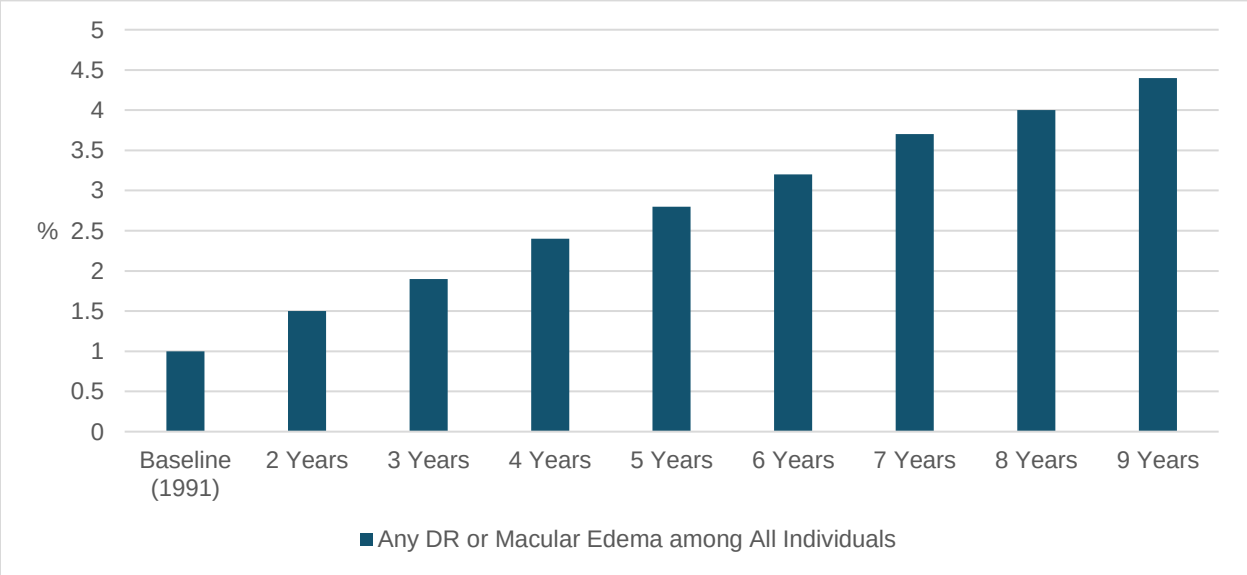


Figure 2.15 Prevalence of Diabetic Retinopathy Among National Long-Term Care Survey Participants With or Without Diabetes Mellitus [22]

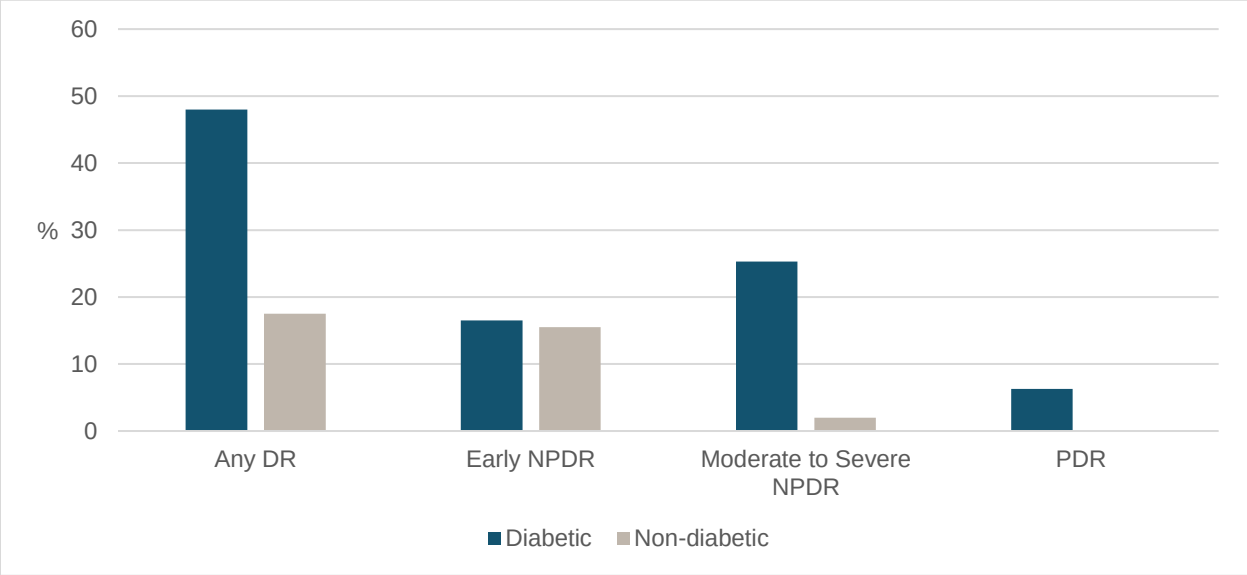


2.14 Proyecto VER

Proyecto VER was a population-based vision impairment study conducted from 1997 to 1999.[18] It included Hispanics living in Tucson and Nogales, Arizona. A total of 4,774 Hispanics aged 40 years and older were randomly selected using 1990 Census data. Of these study participants, 22% had diabetes; study participants were diagnosed with diabetes if they reported a diagnosis of diabetes or if they had an HbA1c value of 7.0% or greater.[40] Fundus photography was used to diagnose diabetic retinopathy

(DR); the authors considered grades 14-20 as early non-proliferative diabetic retinopathy (NPDR), 31-51 moderate to severe NPDR, and grades 60 and higher were classified as proliferative diabetic retinopathy (PDR). Among those with diabetes, West et al. (2001) found an overall DR prevalence rate of 48%.[40] As shown in Figure 2.16, West et al. (2001) reported prevalence rates for various stages of DR among those with diabetes and among a subsample of individuals without diabetes. In comparing these results to others studies, the authors concluded that, although the prevalence of diabetes was greater among Hispanics compared to Caucasians, the rates of DR among diabetic individuals was similar between these two ethnic groups.

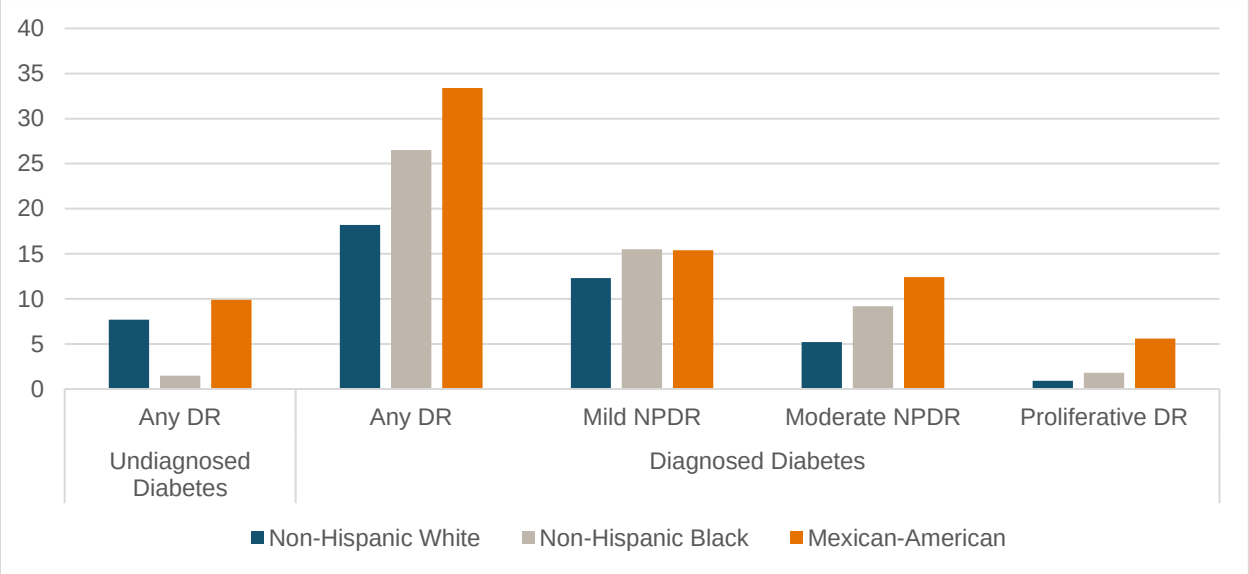
Figure 2.16 Prevalence Rates of Retinopathy for Proyecto VER Study Participants with and without Diabetes [40]



2.15 The Third National Health and Nutrition Examination Survey (NHANES III)

The Third National Health and Nutrition Examination Survey (NHANES III) was a national cross-sectional survey conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention from 1988-1994.[23] As part of the examination portion of the survey, nonmydriatic fundus photographs were taken of one eye for participants aged 40 years or older.[41] Diabetic status of respondents was determined by a medical history interview or a measurement of fasting plasma glucose. Harris et al. (1998) examined the fundus photographs of people who had previously been diagnosed with diabetes type 2 for diabetic retinopathy (DR).[41] The purpose of the study was to assess if there were ethnic/racial differences in the risk for DR. They found that Mexican Americans had higher rates of DR compared to non-Hispanic Whites. As shown in Figure 2.17, DR was highest among individuals with undiagnosed diabetes within each racial subgroup.

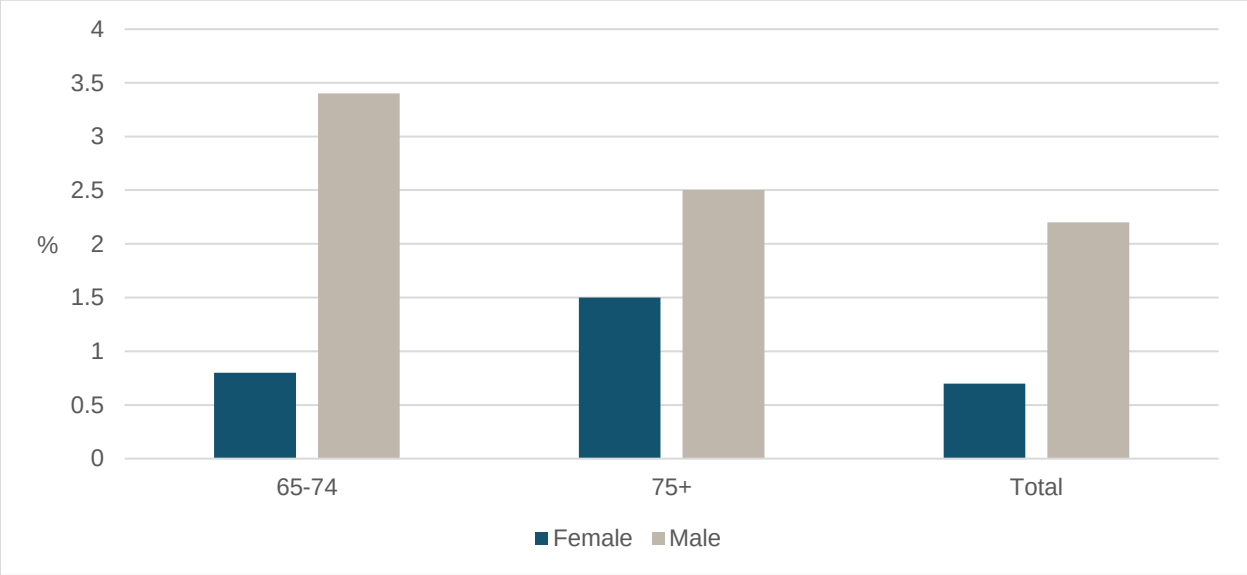
Figure 2.17 Prevalence of DR in NHANES III Among Respondents with Diabetes [41]



2.16 UCLA Mobile Eye Clinic

The UCLA Mobile Eye Clinic (MEC) was a bus that provided free vision screening to underserved individuals in Los Angeles, CA. Haronian, et al. (1993) examined results for 431 patients aged 55-94 who received services from the MEC from 1982 to 1990 in two senior centers in Los Angeles, CA.[28] Participants were diagnosed with diabetic retinopathy (DR) in the MEC, and Haronian et al. (1993) used the International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes to calculate prevalence estimates for various eye diseases. The researchers found an overall diabetic retinopathy (DR) prevalence of 1.2%. Figure 2.18 shows their DR prevalence estimates stratified by age and sex.

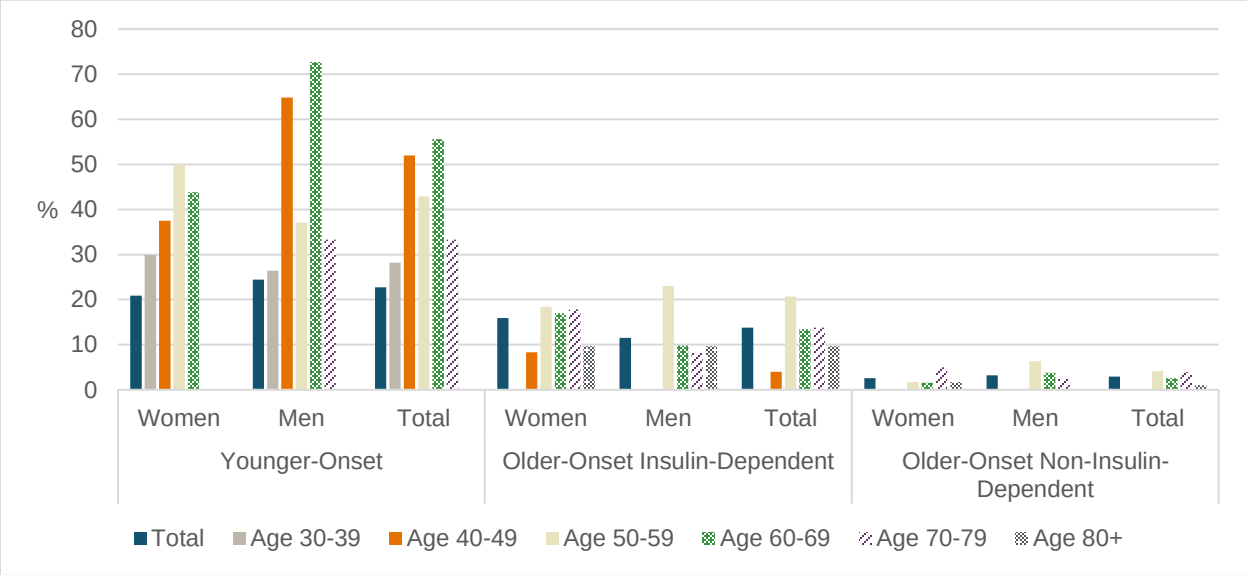
Figure 2.18 Prevalence of Diabetic Retinopathy Among All Patients Examined in the MEC, by Sex and Age [28]



2.17 The Wisconsin Epidemiologic Study of Diabetic Retinopathy

The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) collected baseline information from diabetic individuals living in an eleven county area in Wisconsin from 1980-1982. Klein, et al. (1992) analyzed data from 996 younger-onset insulin-dependent people who were diagnosed with diabetes when they were younger than age 30.[42] Researchers also analyzed the data of 1,370 older-onset individuals who were diagnosed with diabetes when they were 30 years of age or older. Klein, et al. (1992) assessed the prevalence of proliferative diabetic retinopathy (PDR) via fundus photographs taken during clinical examinations and found a 23% PDR prevalence rate among the young-onset insulin-dependent group. The prevalence of PDR was 10% in the older-onset insulin dependent group, and 3% in the older-onset non-insulin dependent group. Figure 2.19 shows age- and sex-specific PDR prevalence rates for individuals age 30 and older in these groups assessed at baseline in 1980-1982.

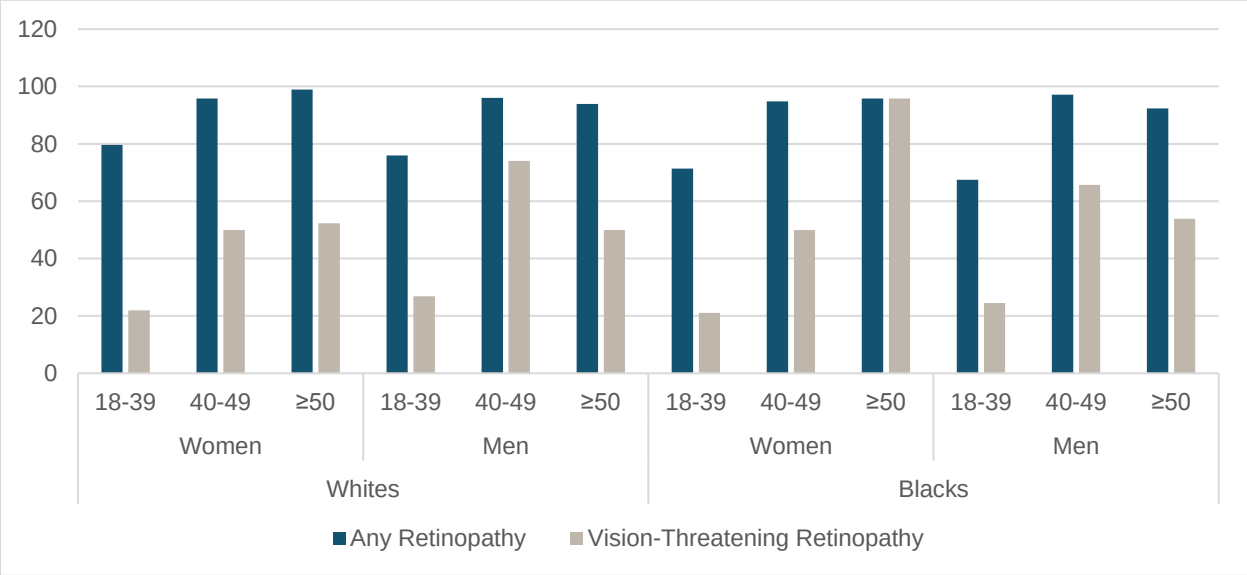
Figure 2.19 Prevalence of Proliferative Diabetic Retinopathy by Sex and Age (≥ 30) in the WESDR (1980-1982) [42]



2.18 New Jersey 725

Roy et al. (2004) combined data from Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) and New Jersey 725 study to determine the prevalence of diabetic retinopathy (DR).[43] The New Jersey 725 was conducted between 1993 and 1998. It examined 725 African-American patients from Newark, NJ and the surrounding area who had been diagnosed with Type 1 diabetes before age 30. Patients from both studies were examined using fundus photography and based on their worse eye, were graded for DR according to the Early Treatment Diabetic Retinopathy Study severity scale. Figure 2.20 shows prevalence rates for vision-threatening retinopathy and any retinopathy stratified by age, race, and sex.

Figure 2.20 Estimated Prevalence of Diabetic Retinopathy (DR) in Persons with Type I Diabetes Mellitus [43]



3. Glaucoma

Glaucoma is a general term for a number of eye conditions that progressively damage the optic nerve, consequently causing vision loss.[44] Diagnosis of glaucoma is complex, but is often associated with elevated intraocular pressure, optic nerve damage, and reduction in visual acuity and visual field.[44] The most common form of glaucoma is primary open-angle glaucoma (OAG). If the eye is functioning normally, fluid flows out of the anterior chamber through the open angle between the cornea and iris and out the eye. With OAG, the fluid flows out slowly and builds up, increasing the pressure on the eye that may cause gradual loss of vision. Acute angle-closure glaucoma (ACG), also known as angle-closure or narrow-angle glaucoma, is less common and occurs when the angle is blocked by the iris and may rapidly cause vision loss if left untreated.[44] Other forms of glaucoma include: secondary glaucoma (caused by medical complications such as diabetes or an injury to the eye); congenital glaucoma; and normal tension glaucoma (damage occurs although the eye pressure is normal). Patients with risk factors for glaucoma, such as elevated intraocular pressure, may be diagnosed with glaucoma suspect. Vision loss from glaucoma is permanent, but progression may be slowed or halted through early diagnosis and treatment.

3.0 Glaucoma Literature Review Results

Figure 3.0 shows articles from 13 studies published between 1991 and 2016 that examined the prevalence of glaucoma. These studies examined a variety of demographic variables including race/ethnicity, age, sex, income, and education level. Results are limited to open-angle glaucoma, acute angle-closure glaucoma, and glaucoma suspect (presence of glaucoma risk factors but no damage to the eye). The sources were:

1. Telemedicine Screening Program
2. National Health and Nutrition Examination Survey (NHANES)
3. Atlanta VA Medical Center Chart Review
4. Medicare Claims
5. Los Angele Latino Eye Study (LALES)
6. The Salisbury Eye Evaluation (SEE) Glaucoma Study
7. Eye Disease Prevalence Research Group (EDPRG)
8. Study on Visual Impairment Among Northwest American Indians/Alaska Natives
9. National Long-Term Care Survey
10. Proyecto VER
11. University of California, Los Angeles Mobile Eye Clinic (UCLA MEC)
12. Beaver Dam Eye Study (BDES)
13. The Baltimore Eye Survey (BES)

Figure 3.0 Glaucoma Prevalence Sources

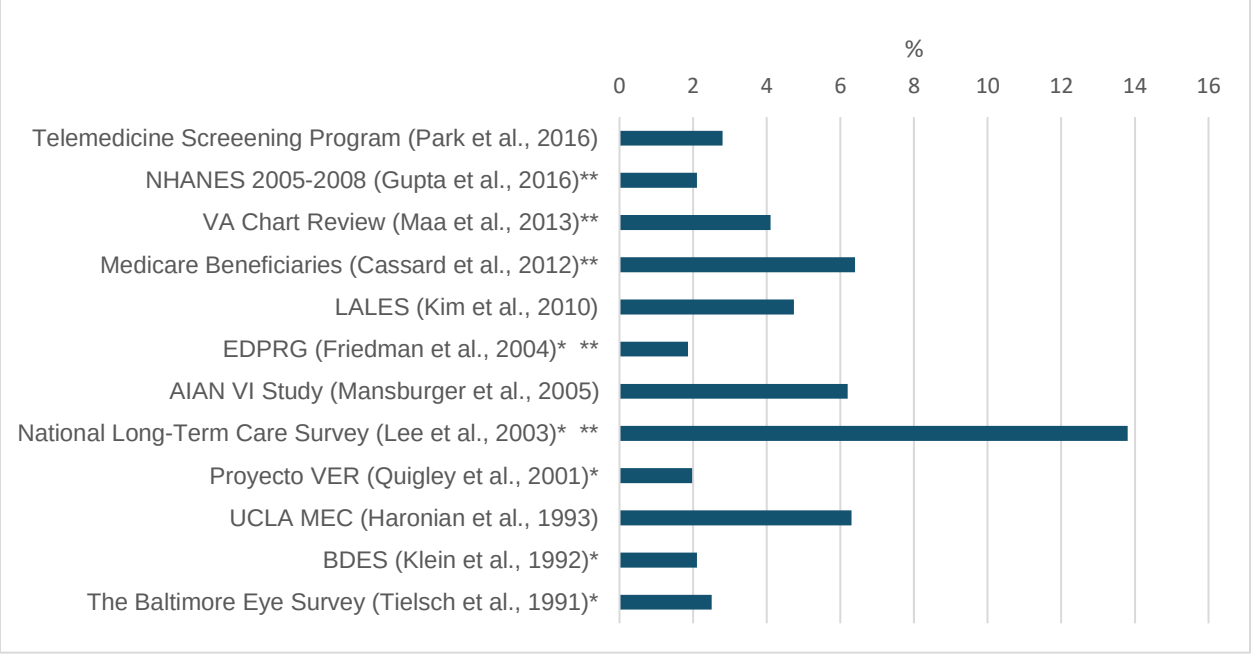
Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Type of glaucoma
Park D, Mansberger SL, et al.	2016	Eye Disease in Patients with Diabetes Screened with Telemedicine	2006–2009	Telemedicine Screening Program	424	Race	Any
Gupta P, Zhao D, et al.	2016	Prevalence of Glaucoma in the United States: The 2005-2008 National Health and Nutrition Examination Survey	2005–2008	NHANES 2005-2008	5,746	Age, Race/ Ethnicity, Sex	Any
Shaikh Y, Yu F, et al.	2014	Burden of Undetected and Untreated Glaucoma in the United States	2005–2008	NHANES 2005-2008	3,850	Not stratified by demographic variables	Possible, Probable, Definite, and Undiagnosed
Maa AY, Evans C, et al.	2013	Veteran Eye Disease After Eligibility Reform: Prevalence and Characteristics	January 2008–February 2008	Atlanta VA Medical Center Chart Review	658	Not stratified by demographic variables	OAG, ACG, suspect
Cassard SD, Quigley HA, Gower EW, et al.	2012	Regional Variations and Trends in the Prevalence of Diagnosed Glaucoma in the Medicare Population	2002–2008	Medicare Claims	N/A	Age, Sex, Race/ Ethnicity	OAG, OAG suspect, ACG, ACG suspect
Kim E, Varma R.	2010	Glaucoma in Latinos/Hispanics.	2000–2008	LALES	6,142	Age, Sex, Race/ Ethnicity	OAG
Friedman DS, Jampel HD, et al.	2006	The Prevalence of Open-Angle Glaucoma Among Blacks and Whites 73 Years and Older: The Salisbury Eye Evaluation Glaucoma Study	2001–2003	The SEE Glaucoma Study	1,233	Age, Race	OAG, ACG
EDPRG	2004	Prevalence of Open-Angle Glaucoma Among Adults in the United States	1985–2008	EDPRG	N/A	Sex, Age, Race/ Ethnicity	OAG
Mansberger SL, Romero FC, et al.	2005	Causes of Visual Impairment and Common Eye Problems in	Unknown	Northwest AIAN	288	Race	Any

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:	Type of glaucoma
		Northwest American Indians and Alaska Natives					
Lee PP, Feldman ZW, Ostermann J, et al.	2003	Longitudinal Prevalence of Major Eye Diseases	1999	National Long-Term Care Survey	Various	Not stratified by demographic variables	OAG, ACG, suspect
Quigley HA, West SK, Rodriguez J, et al.	2001	The Prevalence of Glaucoma in a Population-Based Study of Hispanic Subjects: Proyecto VER	1997–1999	Proyecto VER	4,774	Age, Race/ Ethnicity	OAG, ACG
Haronian E, Wheeler NC	1993	Prevalence of Eye Disorders Among the Elderly in Los Angeles	1982–1990	UCLA MEC	431	Age, Sex	Any
Klein B, Klein R, et al.	1992	Prevalence of Glaucoma: The Beaver Dam Study	1988–1990	BDES	4,926	Age, Sex	OAG
Tielsch JM, Sommer A, et al.	1991	Racial Variations in the Prevalence of Primary Open-Angle Glaucoma: The Baltimore Eye Survey	1985–1988	BES	5,308	Age, Race	OAG

3.1 Overall Any Glaucoma and Open-Angle Glaucoma Prevalence Rates

Figure 3.1 below shows the estimated prevalence rate for any glaucoma and open-angle glaucoma derived from the studies described in this section. General glaucoma rates ranged from 2.1% in NHANES to 25.5% among study participants in the Atlanta VA Chart Review, and open-angle glaucoma rates ranged from 1.86% in the EDPRG to 13.8% among a sub-population of the National Long-Term Care Survey. These studies identified and compared glaucoma prevalence rates across race/ethnicity, age, education level, and income. The high degree of variation among the results in this figure is likely due to in part to methodological, disease definition, and population differences among the studies. This figure excludes studies that did not report an overall rate for the study. The figure is intended to illustrate the range of published prevalence values; direct comparison of the studies is impossible without considering the underlying differences in the studies. Some studies only looked at the overall glaucoma rate while others examined different glaucoma types including glaucoma suspect, open-angle, and angle closure.

Figure 3.1 Overall Prevalence Rates of Any and Open-Angle Glaucoma in Selected Studies



*Estimate only includes open-angle glaucoma

** Age- or population-adjusted prevalence estimate

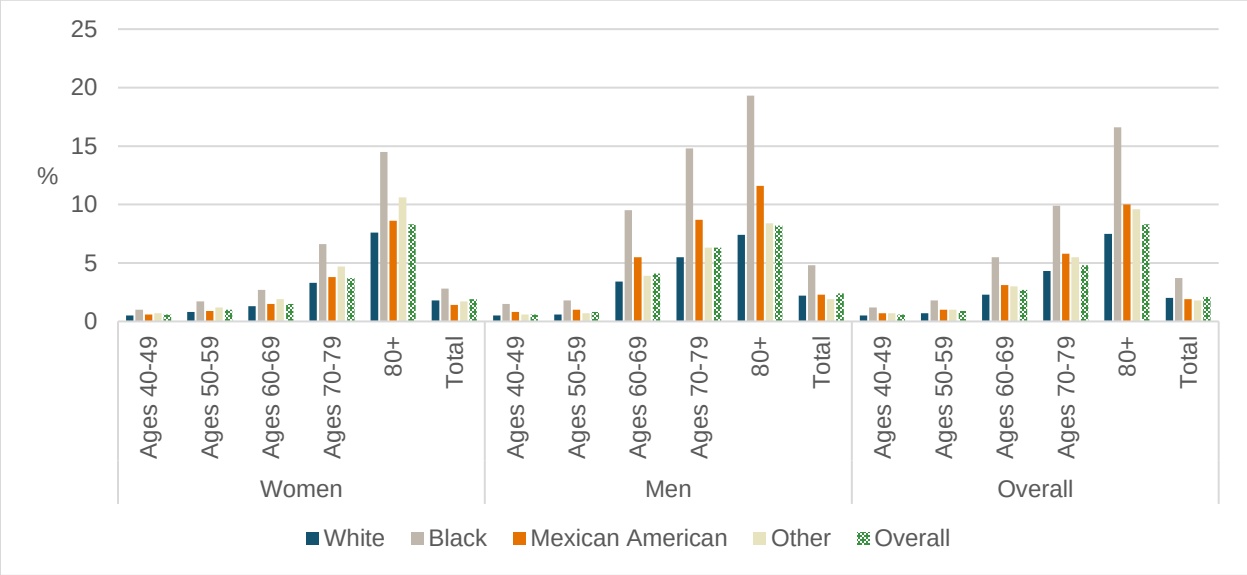
3.2 Telemedicine Screening Program

Park, et al. (2016) sought to determine the utility of telemedicine with nonmydriatic cameras as a mechanism for detecting eye disease.[7] Investigators recruited and examined 424 patients with diabetes aged 18 and older scheduled with primary care providers from Yellowhawk Tribal Health Center (Pendleton, OR) and Hunter Health Clinic (Wichita, KS). The study population was, consequently, primarily made up of American Indians/Alaska Natives. Researchers defined glaucoma as a cup-to-disc ratio of 0.7 or greater and found an overall glaucoma prevalence of 2.8%. Glaucomatous features were defined as "rim thinning, nerve fiber defect, or excavation." Researchers found a 10.4% prevalence rate of such glaucomatous features. Researchers concluded that after diabetic retinopathy, glaucomatous features was the most common eye disease in the study sample. The authors did not provide stratified estimates of glaucoma prevalence.

3.3 National Health and Nutrition Examination Survey 2005-2008

The National Health and Nutrition Examination Survey (NHANES) is a nationally representative population-based cross-sectional study of the civilian, non-institutionalized population of the US. Gupta, et al. (2016) examined data from 5,756 study participants age 40 and older who were surveyed as part of the 2005/2006 and 2007/2008 NHANES survey cycles and who had gradable fundus photographs.[45] To diagnose glaucoma among study participants, three specialists judged the appearance of the optic nerve on fundus photographs and came to a consensus on the presence of glaucoma. Using NHANES weights, researchers determined that the national prevalence of glaucoma among civilian, non-institutionalized adults aged 40 and older in the US was 2.1%. As shown in Figure 3.2, they found that the prevalence of glaucoma was highest among non-Hispanic Blacks. Shaikh et al. (2014) also used 2005-2008 NHANES data to determine the prevalence of glaucoma.[46] Because Shaikh et al. (2014) aimed to determine the prevalence of undiagnosed glaucoma among adults aged 40 and older, they utilized different exclusion criteria, excluding study participants with incomplete data on glaucoma-related questions.[46] They concluded that the overall prevalence of definite glaucoma was 3.7% and that the prevalence of undiagnosed glaucoma was 2.9%.

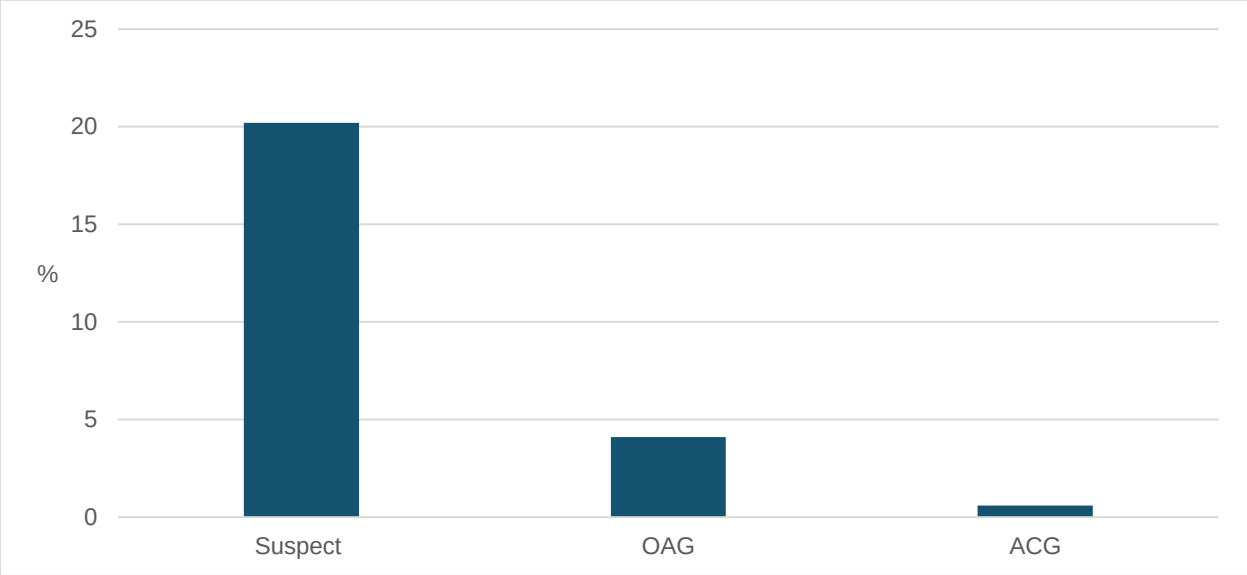
Figure 3.2 The Prevalence of Glaucoma in the US from NHANES 2005-2008 Data by Age and Race [45]



3.4 Atlanta Veteran Affairs (VA) Medical Center Medical Chart Review

As a first step to assessing whether the VA system was adequately prepared to serve patients given new eligibility reform, Maa et al. (2013) conducted this pilot study of the prevalence of various eye diseases among new "routine" eye patients at the Atlanta VA Medical Center Comprehensive Eye Clinic.[9] Researchers reviewed the charts of 658 new patients with no known previous eye diagnosis with the exception of refractive error who were seen between January 1, 2008 and February 1, 2008.[9] The authors used the International Classification of Diseases, 9th Revision Clinical Modification codes (ICD-9CM) to identify ocular conditions and found that glaucoma or glaucoma suspect were diagnosed in 25.5% of patients.. Figure 3.3 shows prevalence rates for different types of glaucoma. Maa et al. (2013) did not provide tabulations of prevalence rates stratified by demographic variables.

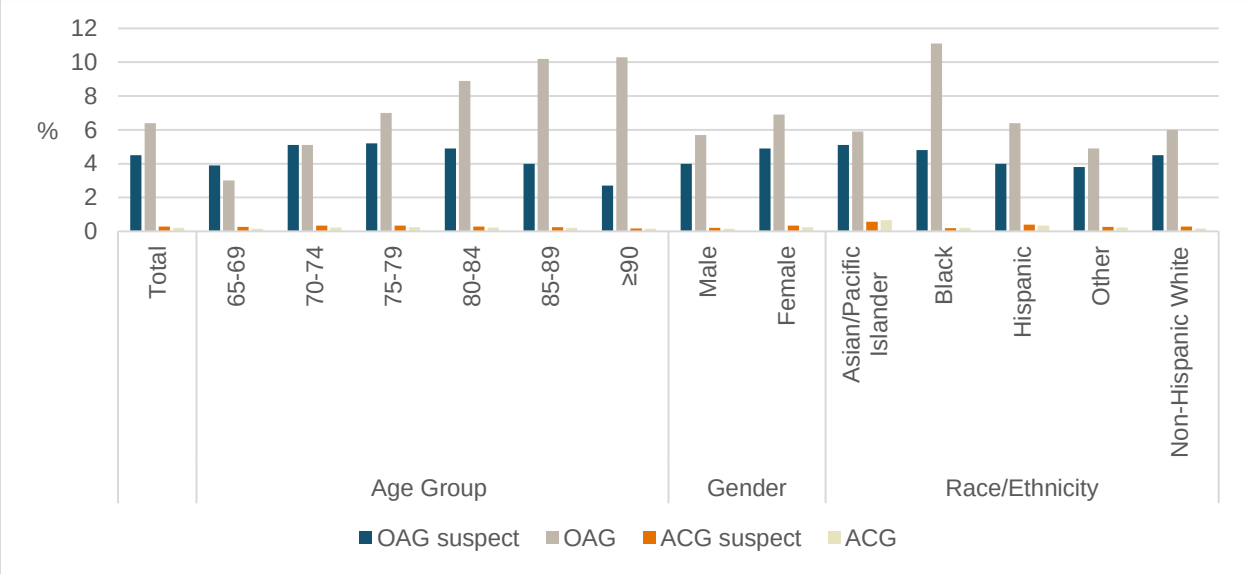
Figure 3.3 Prevalence of Different Type of Glaucoma Among "Routine" Eye Patients at the Atlanta Affairs Medical Center [9]



3.5 Medicare Claims

Cassard et al. (2012) took a random sample of Medicare beneficiary claims of people aged 65 years and older that were submitted between 2002 and 2008 to estimate the prevalence of glaucoma, particularly open-angle glaucoma (OAG) and acute angle-closure glaucoma (ACG).[47] The researchers found that the prevalence rates of OAG and ACG increased between the ages of 65 and 79, and then decreased after age 80. Females had higher rates of both OAG and ACG than males. Further, Non-Hispanic Whites had higher rates of OAG than Hispanics and the 'other' race category. Of all race/ethnicity groups, Asian Pacific Islanders and Hispanics had the highest rates of ACG. These trends are shown below in Figure 3.4.

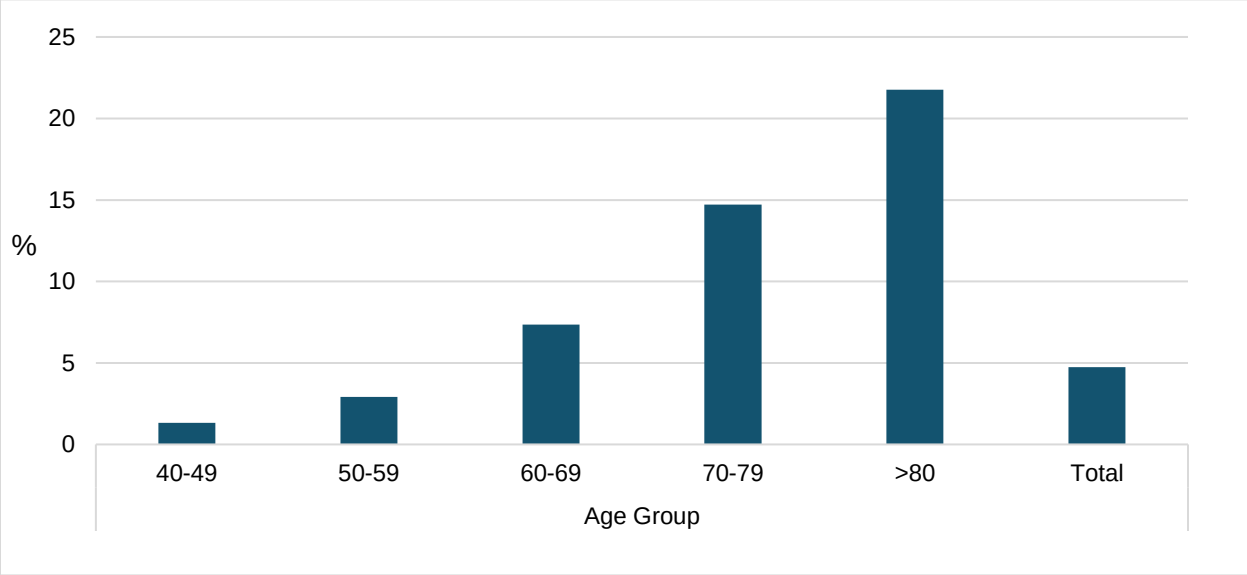
Figure 3.4 Prevalence of Glaucoma in Medicare Claims [47]



3.6 Los Angeles Latino Eye Study

The Los Angeles Latino Eye Study (LALES) is a population-based, cross-sectional study of over 6,000 Latinos of mostly Mexican heritage 40 years and older from the Los Angeles area.[19] The subjects were interviewed and had their eyes examined for any glaucoma.[48] Baseline examinations were conducted between March 2000 and June 2003, and follow-up examinations were conducted between July 2004 and June 2008. As shown in Figure 3.5, prevalence rates increased with age.

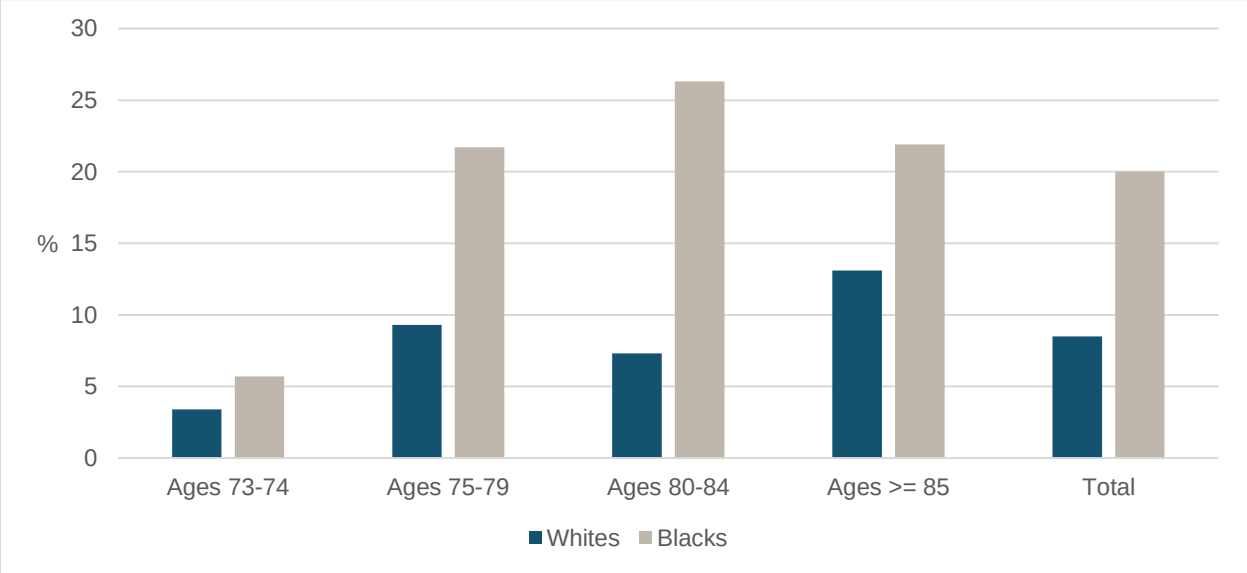
Figure 3.5 Prevalence of Glaucoma in LALES [48]



3.7 The Salisbury Eye Evaluation Glaucoma Study

To determine the prevalence of glaucoma among Black and White persons aged 73 and older, Friedman et al. (2006) studied a sample of 1,233 individuals participating in the fourth follow-up examination of the Salisbury Eye Evaluation (SEE) Glaucoma study.[49] Participants in this study were originally recruited between September 16, 1993 and September 25, 1995 from a random sample of individuals aged 65-84 years living in Salisbury, MD. Participants were identified through the Health Care Financing Administration Medicare Database. Follow-up examinations took place between July 21, 2001 and July 27, 2003. Participants with abnormal initial evaluation underwent preliminary eye evaluation, chart review, and a definitive examination. The ophthalmologists who examined study subjects diagnosed individuals with open-angle glaucoma (OAG) if the pigmented trabecular meshwork was visible for greater than 90 degrees without compression and if there were no peripheral anterior synechiae or if peripheral anterior synechiae were present but prior surgery had been performed. They diagnosed individuals with angle closure glaucoma if the pigmented trabecular meshwork was visible for 90 degrees or less or peripheral anterior synechiae were present without evidence of prior surgery or inflammatory disease. Participants with probable and definite glaucoma in either eye were classified as having glaucoma. As shown in Figure 3.6, researchers found that Black persons aged 75 years and older had a higher prevalence of OAG than White individuals.

Figure 3.6 The Prevalence of OAG Among SEE Glaucoma Study Participants, by Age and Race [49]

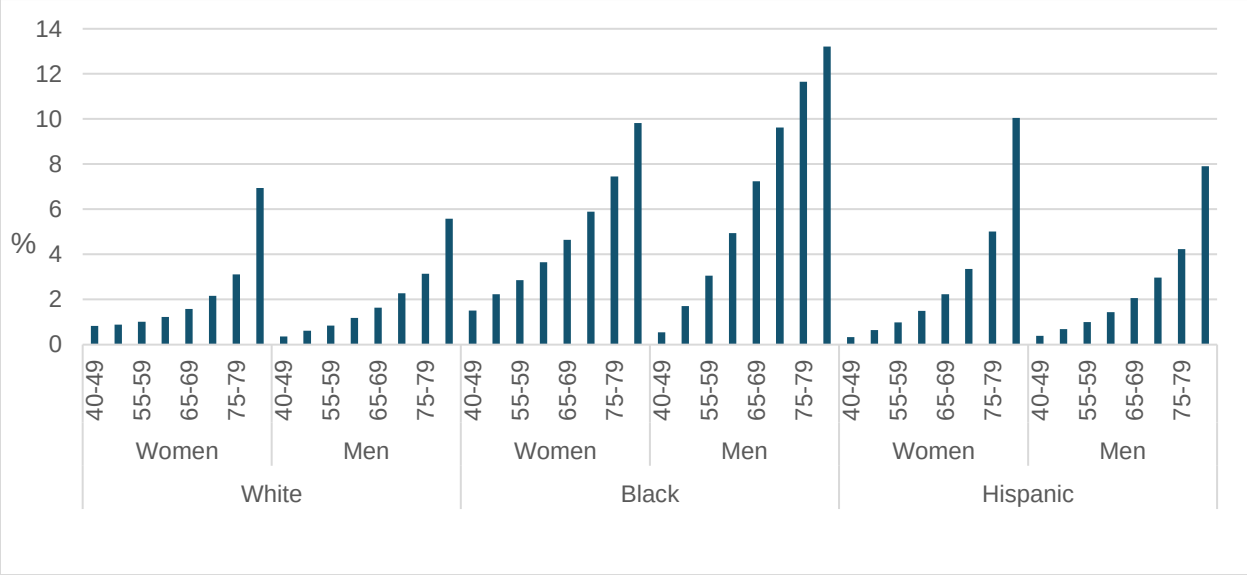


3.8 Eye Disease Research Prevalence Group

The Eye Disease Prevalence Research Group (EDPRG) obtained data from several large population-based surveys from inside and outside the U.S., including the Baltimore Eye Survey, Beaver Dam Eye Study, Proyecto Vision Evaluation Research, Barbados Eye Study, the Blue Mountains Eye Study, Rotterdam

Eye Study, the Melbourne Vision Impairment Study, and the Salisbury Eye Evaluation Project.[50] Researchers derived age-, sex- and race-specific pooled prevalence rates. To calculate the national prevalence rates, researchers applied "the modeled prevalence for each year of age to the 2000 U.S. Census population and summing across the range for each 5-year age category." The estimated national prevalence calculated using this adjustment is shown in Figure 3.1.[50] Figure 3.7 shows the age-specific prevalence rates pooled from the studies prior to adjusting these rates to the US Census. The EDPRG analysis found that glaucoma rates increased with age, were highest among Blacks, and lowest among Whites.

Figure 3.7 Prevalence of Glaucoma in EDPRG Studies [50]



3.9 Study on Visual Impairment Among Northwest American Indians/Alaska Natives

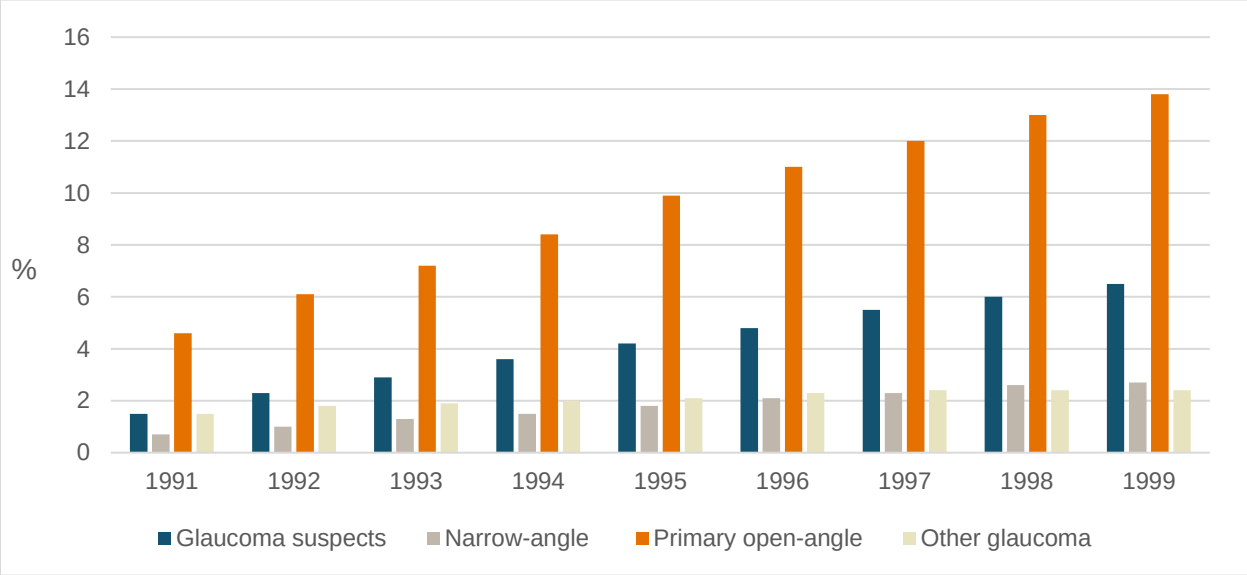
Mansberger, et al. (2005) examined the prevalence of eye health disorders in a random sample of 288 American Indian/Alaska Natives (AIAN).[17] Researchers conducted an ocular exam on randomly selected participants from three tribes from the Northwest region of the US (Oregon, Washington, and Idaho). Mansberger, et al. (2005) reported that 6.2% of the study population had glaucoma. The researchers did not provide stratified prevalence estimates for individuals with glaucoma.

3.10 The National Long-Term Care Survey

Lee et al. (2003) analyzed Medicare claims of people aged 65 years and older who were enrolled in the National Long-Term Care Survey, a random sample of adults in the US collected by the US Census Bureau.[22] Lee et al. (2003) analyzed claims from a cohort of 20,325 individuals, and followed these beneficiaries from 1991 to 1999 (the cohort decreased to 10,476 by 1999 due to attrition). In their analysis, researchers used the International Classification of Diseases, 9th Revision Clinical Modification

(ICD-9CM) codes indicating the diagnoses of diabetes mellitus, primary open-angle glaucoma, narrow-angle glaucoma, glaucoma suspects, other glaucoma, and age-related macular degeneration. They found that the prevalence rates were 6.5% for glaucoma suspect, 2.7% for narrow-angle glaucoma, 13.8% for primary open-angle glaucoma, and 2.4% for other glaucoma in 1999. Figure 3.8 below shows how rates of glaucoma among the study cohort increased from 1991 to 1999.

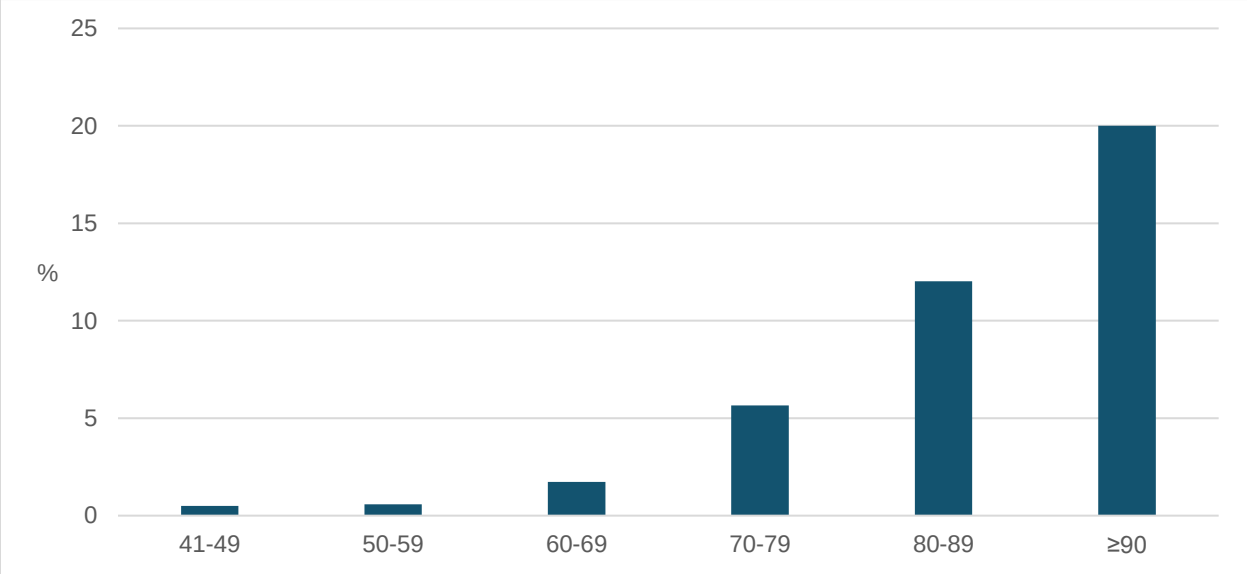
Figure 3.8 Prevalence of Glaucoma Types in Medicare Claims [22]



3.11 Proyecto VER

Proyecto Vision and Eye Research (VER) was a vision impairment study among Latinos in Tucson and Nogales, Arizona. The study was conducted between 1997 and 1999.[18]. Quigley et al. (2001) conducted detailed ocular examinations on 4,774 participants aged 40 years and older who were randomly selected using 1990 Census data.[51]. As shown in Figure 3.9, open-angle glaucoma increased with age.

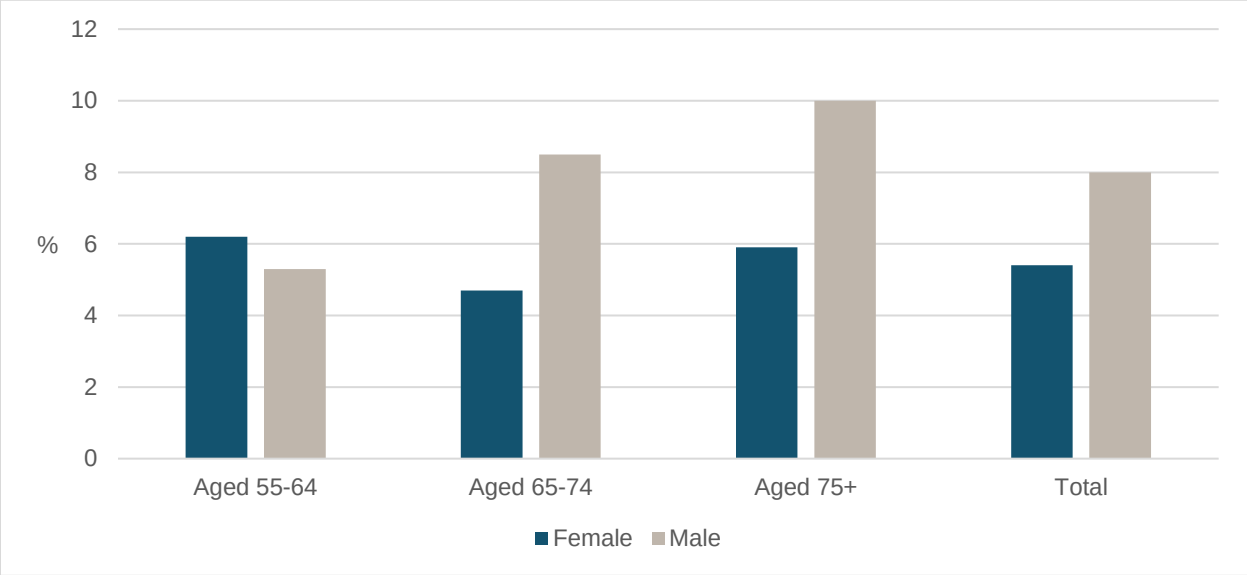
Figure 3.9 Prevalence of Open-Angle Glaucoma in Proyecto VER [51]



3.12 UCLA Mobile Eye Clinic

The UCLA Mobile Eye Clinic (MEC) was a bus that provided free vision screening to underserved individuals in Los Angeles, CA. Haronian et al. (1993) examined results for 431 patients aged 55-94 who received services from the MEC from 1982 to 1990 in two senior centers in Los Angeles, CA. Haronian et al. (1993) used the International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes to calculate prevalence estimates for various eye diseases and found an overall glaucoma prevalence of 6.3%.[28] Figure 3.10 shows glaucoma prevalence estimates stratified by age and sex.

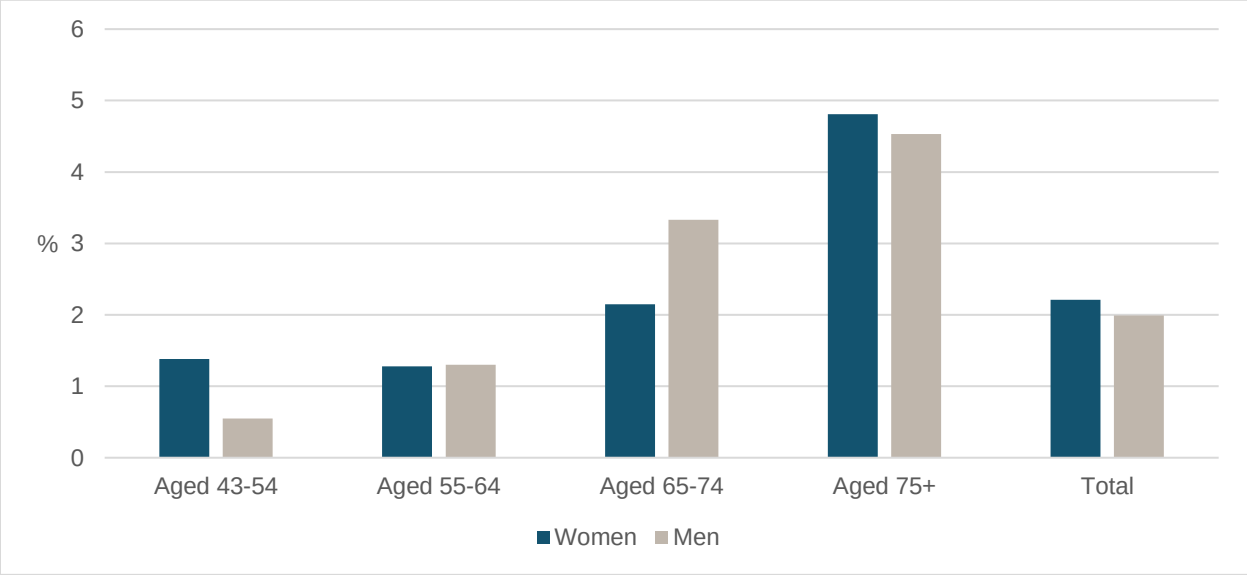
Figure 3.10 Prevalence of Glaucoma of Individuals Screened by the University of California, Los Angeles Mobile Eye Clinic [28]



3.13 The Beaver Dam Eye Study

The Beaver Dam Eye (BDES) study identified all individuals aged 43 to 84 years living in Beaver Dam, Wisconsin between 1988 and 1990. Of the 5,925 eligible individuals, 4,926 were examined.[52] These examinations included a medical history, lifestyle questionnaire, and an ocular examination that entailed visual field testing, intraocular pressure testing, and fundus photography. Data from all of these assessments were considered together to determine whether study participants had probable or definite glaucoma. Klein, et al. (1992) found an overall prevalence rate of open angle glaucoma of 2.1% among study participants.[52] Figure 3.11 shows prevalence rates stratified by age and sex. From these results, the authors concluded that the prevalence of open-angle glaucoma (OAG) among BDES participants was similar to studies including primarily White participants.

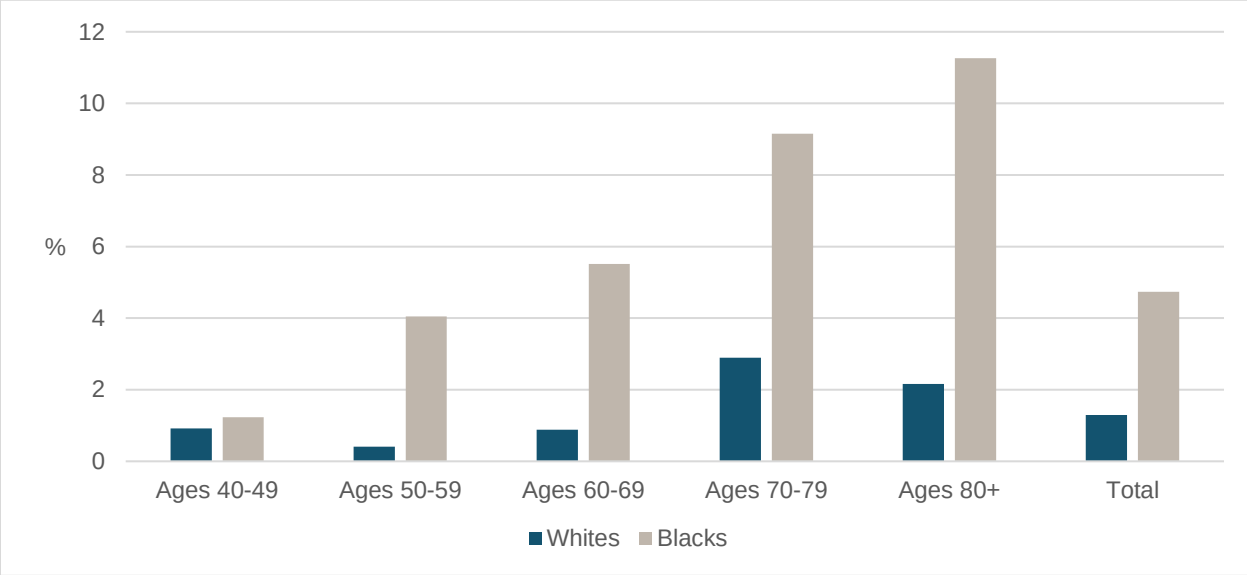
Figure 3.11 The Prevalence of Definite Open Angle Glaucoma Among Men and Women of Different Ages Participating in BDES [52]



3.14 The Baltimore Eye Survey

The Baltimore Eye Survey was a cross-sectional population-based study that included 5,308 Black and White individuals aged 40 and older from East Baltimore.[53] Examinations included physicals, visual acuity assessments, personal interviews, and stereoscopic fundus photography. Open-angle glaucoma (OAG) was defined based on evidence of glaucomatous optic nerve damage independent of intraocular pressure. As shown in Figure 3.12, Tielsch et al. (1991) provided prevalence estimates for definite OAG adjusted for nonresponse to the definitive examination nonresponse. These authors concluded that rates of OAG were higher for Blacks than for Whites.

Figure 3.12 Adjusted Prevalence of Definite Primary OAG Among Baltimore Eye Survey Participants, by Age and Race [53]



4. Uncorrected Refractive Error

There are four different types of refractive error (RE): myopia, hyperopia, astigmatism, and presbyopia. Myopia, also known as nearsightedness, refers to light focusing in front of the retina, causing distant objects to look blurry.[54] Hyperopia, also known as farsightedness, is caused if the cornea in the front of the eye is too curved and light does not focus correctly.[55] Closer objects are out of focus for people with hyperopia. Astigmatism refers to an irregularly curved lens.[56] Astigmatism often occurs with hyperopia and myopia.[56] Presbyopia is age-related and occurs when the lens loses the flexibility to change, making it hard to focus on close objects.

Refractive error is diagnosed through visual acuity testing, refraction, or a comprehensive eye examination.[57] Refractive error can be treated with corrective eye glasses, contact lenses, and refractive surgery. Refractive error that is not diagnosed or treated is called uncorrected refractive error (URE). Uncorrected refractive error is often defined as presenting visual acuity (VA) of 20/50 or worse, and best corrected VA of 20/40 or better, indicating that normal acuity may be achieved through refraction correction.[58] Refractive error can remain uncorrected due to the limited availability of practitioners, affordability of examinations and treatments, lack of awareness by the patient or family, and cultural stigmas against glasses.[59]

4.0 Uncorrected Refractive Error Literature Review Results

Figure 4.0 shows articles from 8 studies published between 2005 and 2016 that examined the prevalence of uncorrected refractive error. The eight sources were:

1. The Chinese American Eye Study (CHES)
2. Multi-Ethnic Study of Atherosclerosis (MESA)
3. National Health and Nutrition Examination Survey (NHANES)
4. Proyecto VER
5. The University of California, Los Angeles Mobile Eye Clinic (UCLA MEC)
6. The Multi-Ethnic Pediatric Eye Disease Study (MEPEDS)
7. Los Angeles Latino Eye Study (LALES)
8. Study on Visual Impairment Among Northwest American Indians/Alaska Natives (AIAN)

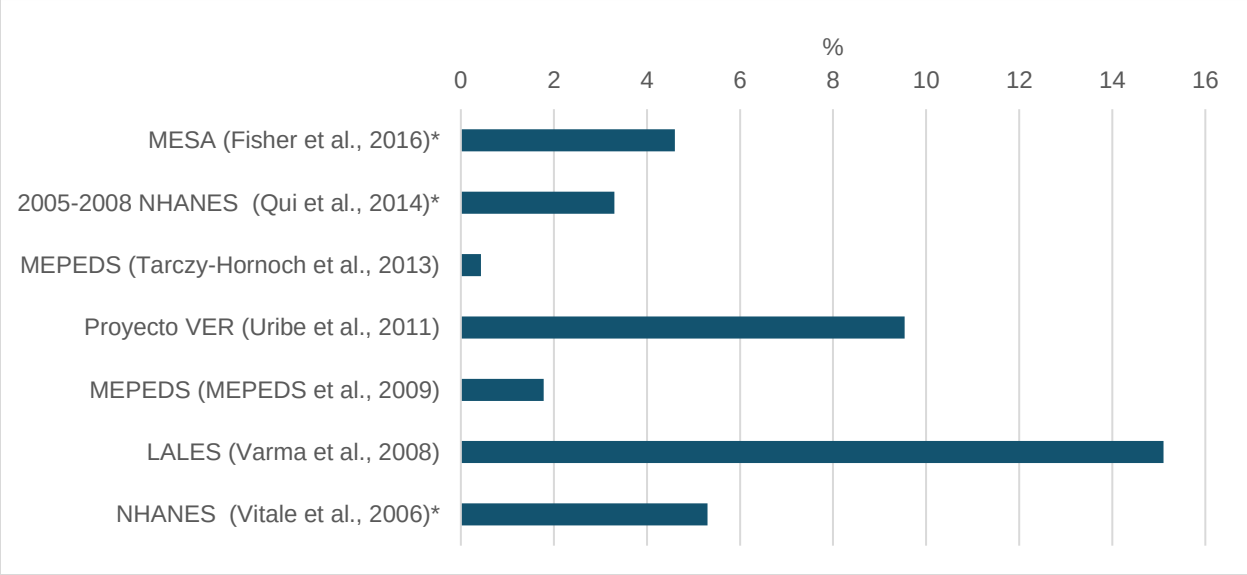
Figure 4.0 Uncorrected Refractive Error Prevalence Sources

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:
Varma R, Choudhury F, et al.	2016	Prevalence and Causes of Visual Impairment and Blindness in Chinese American Adults: The Chinese American Eye Study	2010–2013	CHES	4,582	Race
Fisher DE, Shraqer S, et al.	2015	Visual Impairment in White, Chinese, Black, and Hispanic Participants from the Multi-Ethnic Study of Atherosclerosis Cohort	2002–2004	MESA	6,134	Not stratified by demographic variables
Qiu M, Wang SY, Singh K, Lin SC.	2014	Racial Disparities in Uncorrected and Undercorrected Refractive Error in the United States	2005–2008	NHANES	12,758	Age, Race/Ethnicity
Uribe JA, Swenor BK, et al	2011	Uncorrected Refractive Error in a Latino Population: Proyecto VER	1997–1999	Proyecto VER	4,509	Age, Sex, Race/Ethnicity
Kodjebacheva G, Brown R, et al.	2011	Uncorrected Refractive Error Among First-Grade Students of Different Racial/Ethnic Groups in Southern California: Results a Year After School-Mandated Vision Screening	1999–2006	UCLA MEC	11,332	Age
Tarczy-Hornoch, K., et al	2013	Prevalence and Causes of Visual Impairment in Asian and Non-Hispanic White Preschool Children: The Multi-Ethnic Pediatric Eye Disease Study	Unknown	MEPEDS	1,840	Age, Race/Ethnicity
MEPEDS Group	2009	Prevalence and Causes of Visual Impairment in African-American and Hispanic Preschool Children: the Multi-Ethnic Pediatric Eye Disease Study	Unknown	MEPEDS	3, 207	Age, Race/Ethnicity
Varma R, Wang MY, Ying-Lai M, et al.	2008	The Prevalence and Risk Indicators of Uncorrected Refractive Error and Unmet Refractive Need in Latinos: The Los Angeles Latino Eye Study	2000–2008	LALES	6,129	Age, Sex, Race/Ethnicity
Vitale S, Cotch MF, Sperduto RD.	2006	Prevalence of Visual Impairment in the United States	1999–2002	NHANES	13,265	Age, Sex, Race/Ethnicity
Mansberger SL, Romero FC, et al.	2005	Causes of Visual Impairment and Common Eye Problems in Northwest American Indians and Alaska Natives	Unknown	Northwest AIAN	288	Not stratified by demographic variables

4.1 Overall Refractive Error Prevalence Rates

Figure 4.1 shows estimated prevalence rates for uncorrected refractive error (URE) derived from the studies described in this section. URE rates ranged from 1.8% in the 2013 MEPEDS study to 15.1% in LALES. The large degree of variation among prevalence estimates is likely primarily due to sociodemographic differences in the populations sampled. The high degree of variation among the results in this figure is likely due to in part to methodological, disease definition, and population differences among the studies. The figure is intended to illustrate the range of published prevalence values; direct comparison of the studies is impossible without considering the underlying differences in the studies.

Figure 4.1 Overall URE Prevalence Rates in Selected Studies



*Age- or population- adjusted prevalence rate.

4.2 The Chinese American Eye Study

The Chinese American Eye Study (CHES) aimed to determine the population-based prevalence of eye disease and visual impairment among 5,782 Chinese Americans aged 50 and older living in 10 urban census tracts in Monterey Park, CA from 2010 to 2013.[60] Of those who were eligible, 4,582 completed in-home interviews and underwent clinical examinations, including an assessment of presenting and best-corrected visual acuity (PVA and BCVA, respectively). Varma et al. (2016) found that, based on presenting visual acuity and US criteria for visual impairment, uncorrected refractive error (URE) accounted for 70.3% of visual impairment and 9.1% of blindness.[60] Varma et al, (2016) did not provide estimates of uncorrected refractive error stratified by demographic variables.

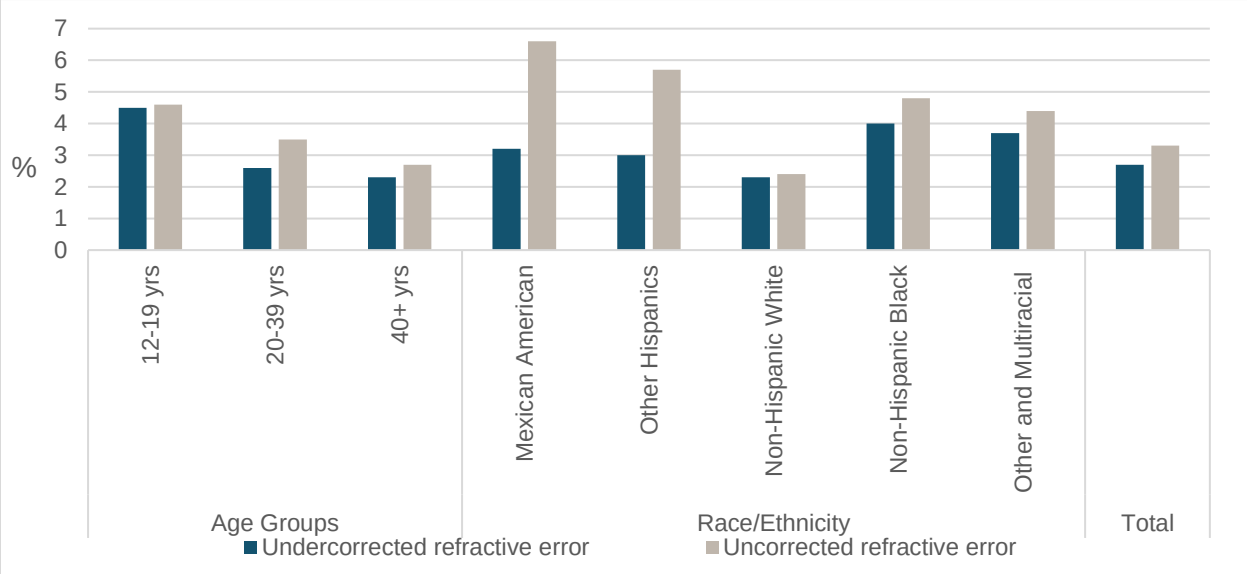
4.3 Multi-Ethnic Study of Atherosclerosis

The Multi-Ethnic Study of Atherosclerosis (MESA) consisted of a prospective cohort of adults aged 46-87 from six US communities (Baltimore, Maryland; Chicago, Illinois; Forsyth County, North Carolina; Los Angeles, California; New York, New York; and St. Paul, Minnesota).[61] Among those examined at baseline, 6,134 completed a visual acuity assessment between August 2002 and January 2004. The visual acuity assessment utilized the same equipment and protocol as was used in NHANES. Researchers defined visual impairment due to uncorrected refractive error (URE) as presenting visual acuity worse that 20/50 in the better eye that could be corrected to 20/40 or better following refractive correction. Among the 6,134 examined, 4.6% were visually impaired due to URE. The authors concluded that a majority of visual impairment, particularly among younger study participants, was due to URE. They did not provide prevalence estimates of uncorrected refractive error stratified by different demographic factors.

4.4 2005-2008 National Health and Nutrition Examination Survey

The National Health and Nutrition Examination Survey (NHANES) is a nationally representative, population-based, cross-sectional study of the civilian, non-institutionalized population of the US. A total of 12,758 participants 12 years and older with no history of refractive surgery were examined for vision impairment. Qui et al. (2014) looked at racial disparities in uncorrected and undercorrected refractive errors in 2005-2008 NHANES.[58] Undercorrected refractive error was defined as presenting visual acuity (VA) of 20/50 or worse, and best corrected visual acuity of 20/40 or better, and if the participant reported wearing glasses or contact lenses. Uncorrected refractive error (URE) was more prevalent than undercorrected RE; with 2.75% of individuals having undercorrected RE and 3.3% with URE. As shown in Figure 4.2, both uncorrected and undercorrected RE were more prevalent in 12-19 year olds, compared to other age groups. URE was more common among Mexican Americans and other Hispanics compared to other races/ethnicities.

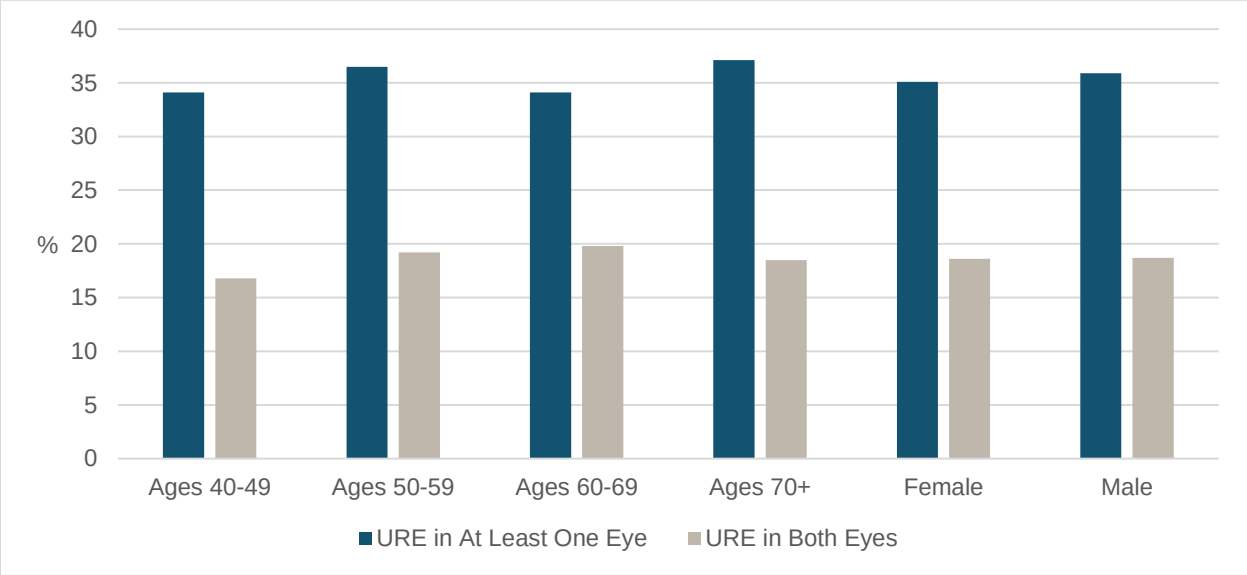
Figure 4.2 URE and Undercorrected RE in 2005-2008 NHANES [58]



4.5 Proyecto VER

Proyecto Vision and Eye Research (VER) was a population-based vision impairment study conducted from 1997 to 1999.[62] It included Hispanics living in Tucson and Nogales, Arizona. Of the eligible study participants identified, researchers obtained complete data for 4,509 Latinos who completed an in-home interview and ophthalmic examination, including visual acuity testing. Uribe et al. (2011) determined the prevalence of uncorrected refractive error (URE) among those with refractive error in at least one eye to be 35.4%. The overall prevalence rate for URE shown in Figure 4.1 was calculated using the number of participants who had URE in at least one eye as reported by the authors. As shown in Figure 4.3, the authors reported the proportion of URE among individuals with refractive error, stratified by age and sex.

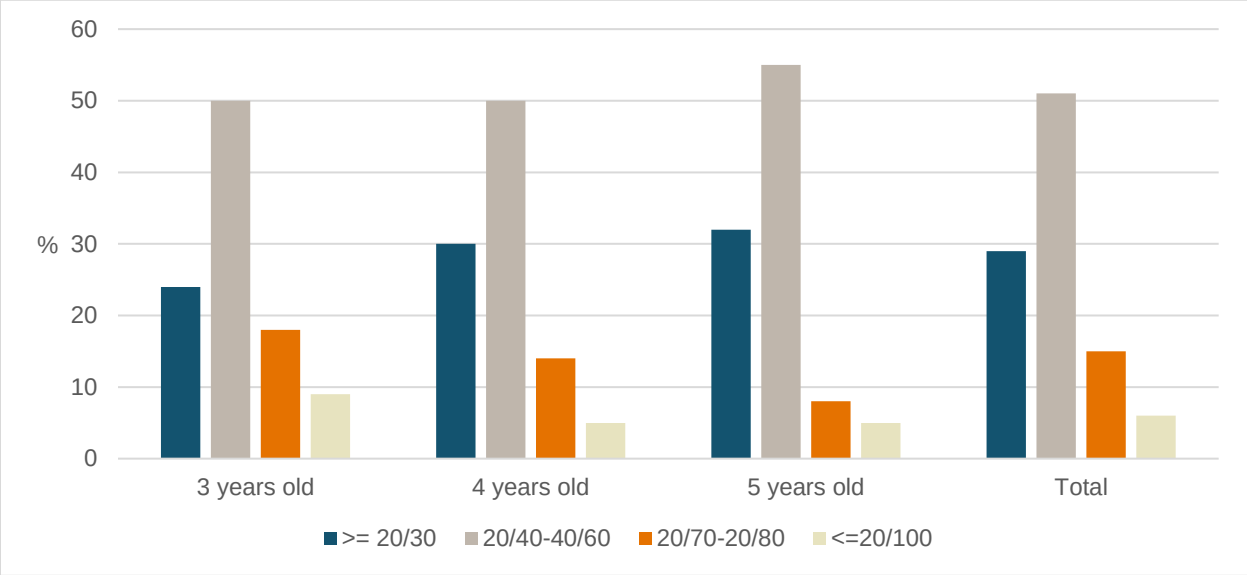
Figure 4.3 Proportion of Proyecto VER Participants With URE Among Those with RE, by Age and Sex [62]



4.6 University of California, Los Angeles Mobile Eye Clinic

The University of California, Los Angeles Mobile Eye Clinic (MEC) examined 11,332 first graders between 1999-2000 and 2005-2006.[63] The state of California requires kindergarteners to receive vision screening. Kodjebacheva et al. (2011) utilized data collected by the MEC to determine the prevalence of decreased visual acuity in children in the first grade to assess the extent to which decreased visual acuity is corrected.[63] Researchers defined decreased visual acuity due to uncorrected refractive error (URE) as any poor visual acuity that could be improved from 20/40 or worse to visual acuity 20/40 or better in at least one eye with the use of glasses. Kodjebacheva et al. (2011) found that 8.0% of the children examined had decreased visual acuity and that 94.7% of these children had decreased visual acuity as a result of uncorrected refractive error. Among all the children examined, this lead to an overall 7.6% prevalence rate of uncorrected refractive error (URE). As shown in Figure 4.4, Kodjebacheva et al. (2011) reported rates of URE in at least one eye among various ages, sexs, and race/ethnicities. They concluded that URE was more prevalent in boys compared to girls and in Latino and African American children compared to Non-Hispanic White children.

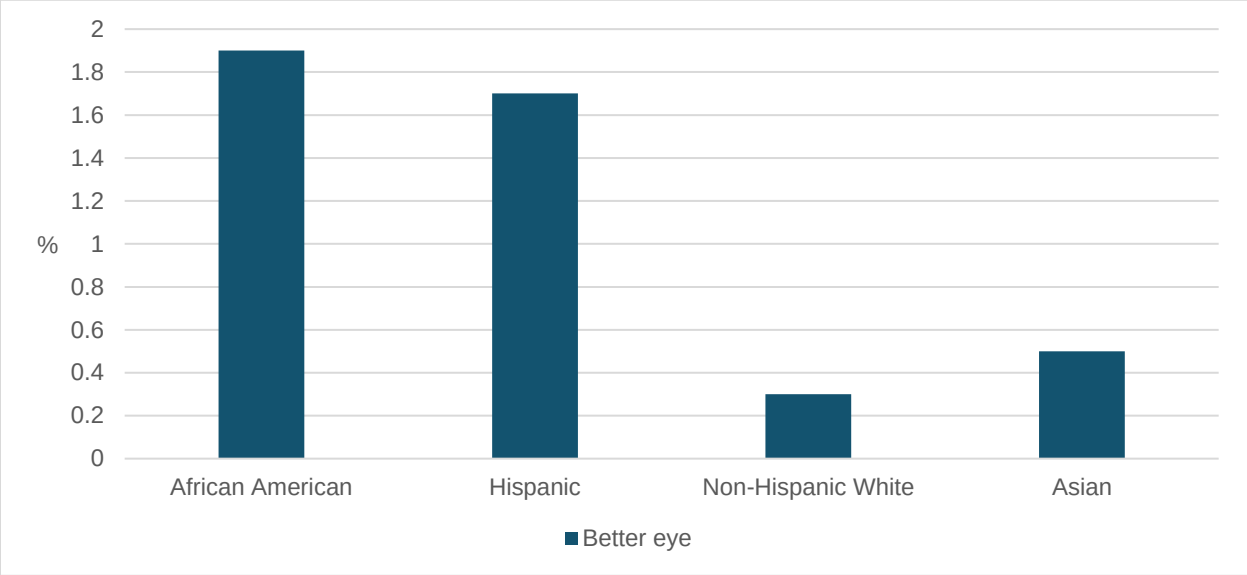
Figure 4.4 Prevalence of Uncorrected Refractive Error in at Least One Eye Among 11,332 First-Grade Students Examined by the UCLA MEC [63]



4.7 The Multi-Ethnic Pediatric Eye Disease Study

The Multi-Ethnic Pediatric Eye Disease Study (MEPEDS) included children aged 30-72 months living within 44 census tracts in Los Angeles, California.[64] Results were analyzed and reported separately for different racial and ethnic populations. In one paper, 3,207 African-American and Hispanic children were assessed for presenting visual acuity.[64] Authors of this study defined visually significant uncorrected refractive error (URE) using spherical equivalents. They categorized those presenting with glasses as having URE only if they had residual URE meeting certain criteria. Presenting visual acuity (VA) was tested with corrective eyewear if worn. As shown in Figure 4.5, African American children had a 1.9% rate of URE in the better eye and Hispanic children had a 1.7% rate of URE. Tarczy-Hornoch et al. (2013) analyzed presenting visual acuity (VA) in 1,840 Asian and Non-Hispanic White children who completed visual acuity assessments.[65] Also shown in Figure 4.5, the prevalence rate of URE among Asian children was 0.5% in the better eye, while for Non-Hispanic White children the prevalence of URE was 0.3% in the better eye. Overall prevalence rates for these two papers shown in Figure 4.1 were calculated using the numbers provided by the authors in the papers cited. Authors from both papers concluded that a high percentage of VI in children of all races was due to uncorrected refractive error or amblyopia due to refractive error.[65] [64]

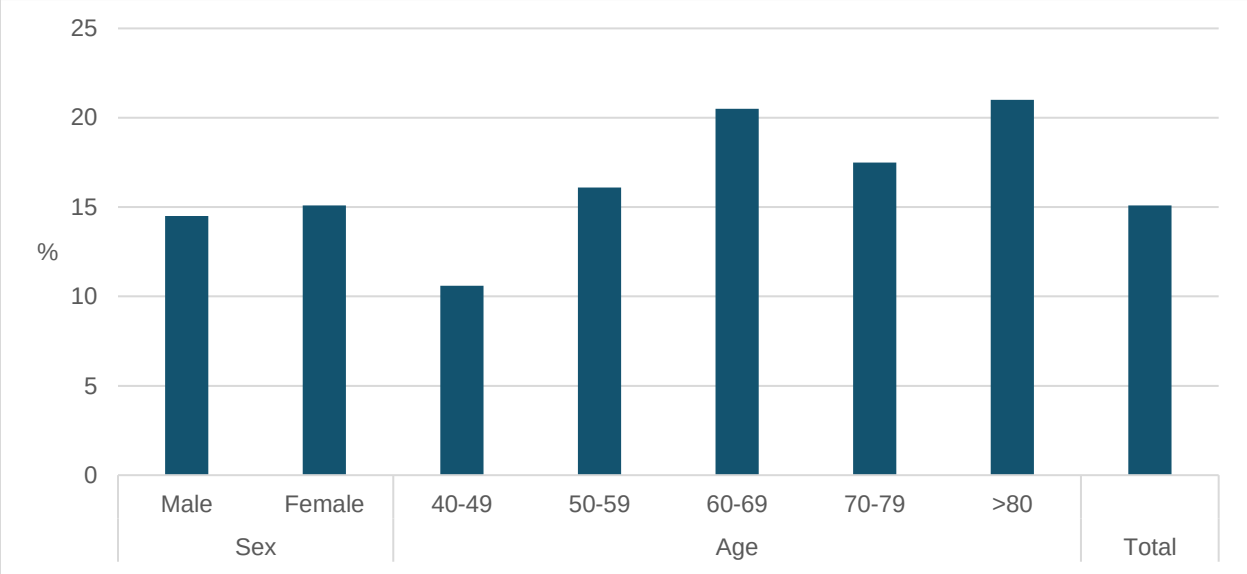
Figure 4.5 Prevalence of Uncorrected Refractive Error Based on Presenting Visual Impairment for Children in MEPEDS of Various Racial Groups [64] [65]



4.8 Los Angeles Latino Eye Study

The Los Angeles Latino Eye Study (LALES) is a population-based, cross-sectional study of over 6,000 Latinos of mostly Mexican heritage 40 years and older from the Los Angeles area.[19] Baseline examinations were conducted between March 2000 and June 2003 and follow-up examinations occurred from July 2004 to June 2008. The subjects were interviewed and their eyes were clinically examined. Varma et al. (2008) distinguished between uncorrected refractive error (URE) and unmet refractive need.[66] They defined URE as "improvement of two or more lines in visual acuity in the better seeing eye after refraction of the same eye." Two definitions were used for unmet refractive need: 1) participants that had presenting visual acuity (PVA) of worse than 20/40 in the better seeing eye, but could achieve 20/40 or better in the same eye, and 2) participants with PVA of 20/40 or worse and who could achieve an improvement of two or more lines with correction in that same eye. Using definition 1, researchers found that the overall prevalence of URE was 15.1% and unmet refractive need was 8.9% among all those examined; URE rates were highest among individuals aged 80 and older (Figure 4.6).

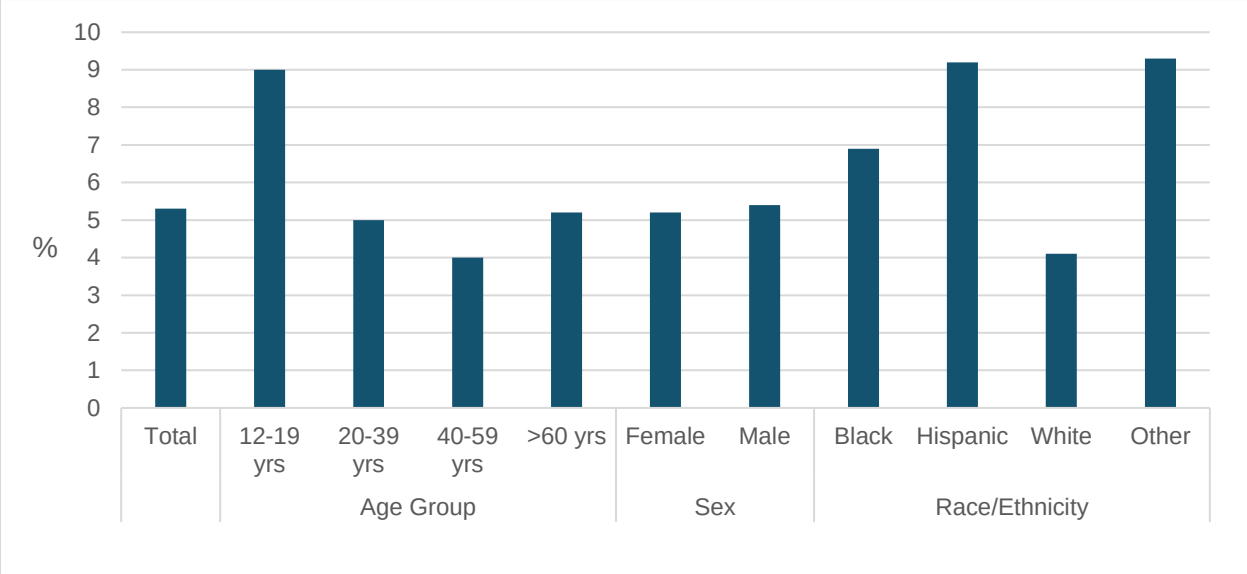
Figure 4.6 Prevalence of URE in the Los Angeles Eye Study [66]



4.9 1999-2002 National Health and Nutrition Examination Survey

The National Health and Nutrition Examination Survey (NHANES) is a nationally representative population-based cross-sectional study conducted by the National Center for Health Statistics. As part of the 1999-2002 cycles of the survey, a total of 13,265 participants aged 12 years and older had their eyes examined for visual acuity (VA) at the survey's mobile examination center.[67] Vitale et al. (2006) examined VA data to determine the prevalence of visual impairment, including visual impairment due to refractive error.[67] They defined uncorrected refractive error (URE) as "visual impairment that improved, aided by the automated refraction results, to 20/40 or better in the better seeing eye." As shown in Figure 4.7, the prevalence of visual impairment (VI) due to URE was 5.3%, and URE rates were highest among the 12-19 year age group. Further, URE rates were highest among Hispanics and the 'other' race/ethnicity compared to other race/ethnicity groups.

Figure 4.7 Prevalence of Visual Impairment Due to URE in 1999-2002 NHANES [67]



4.10 Study on Visual Impairment Among Northwest American Indians/Alaska Natives

Mansberger et al. (2005) examined the prevalence of eye health disorders in a random sample of 288 American Indian/Alaska Natives (AIAN).[17] Researchers conducted an ocular exam on randomly selected participants from three tribes from the Northwest region of the US (Oregon, Washington, and Idaho). Mansberger et al. (2005) did not provide prevalence estimates for individuals with uncorrected refractive error (URE) stratified by demographic factors, but provided summary estimates, which may or may not have been based on the better-seeing eye: 18.1% had URE affecting distance vision and 30.6% had URE affecting near vision. Researchers concluded that URE was the most common cause of decreased visual acuity.

5. Cataract

Cataract is the most frequent cause of age-related loss of vision in the world.[68] As defined by the National Eye Institute, a cataract is a clouding of the lens in the eye that affects vision.[69] The cloudiness, typically a result of changes in the proteins and fibers that make up the lens, causes images to be blurred when light is scattered on the opaque lens.[70] Symptoms of cataract include blurred or hazy vision, reduced intensity of colors, increased sensitivity to glare, increased difficulty seeing at night, and changes in the eye's refractive error.[70] Common causes include aging, diabetes mellitus, use of certain drugs, smoking, alcohol consumption, unprotected exposure to ultraviolet radiation and nutritional deficiency.[70]

Common treatment for cataract is the prescription of eye glasses or surgery to remove and replace the lens with an artificial one. In the United States, more than one million cataract surgeries are performed each year and more than half of Americans over the age of 80 are living with cataracts.[71] With the aging U.S. population, cataract is expected to become an increasing health burden,[68] especially for populations of lower socioeconomic status.[71]

5.0 Cataract Literature Review Results

Figure 5.0 shows articles from 7 studies published between 1992 and 2013 that examined the prevalence of cataract. The seven sources of data were:

1. Atlanta VA Medical Center Chart Review
2. Los Angeles Latino Eye Study (LALES)
3. Proyecto VER
4. Study on Visual Impairment Among Northwest American Indians/Alaska Natives
5. Eye Disease Research Prevalence Group (EDPRG)
6. University of California Mobile Eye Clinic (UCLA MEC)
7. Beaver Dam Eye Study (BDES)

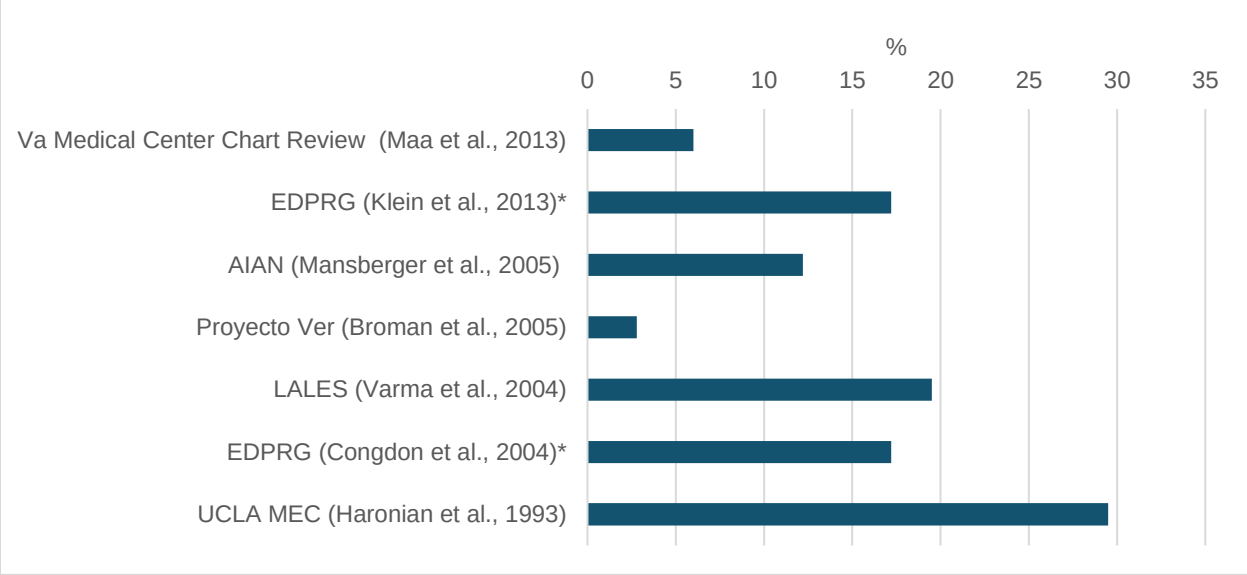
Figure 5.0 Cataract Prevalence Sources

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:
Maa AY, Evans C, et al.	2013	Veteran Eye Disease After Eligibility Reform: Prevalence and Characteristics	January 2008–February 2008	Atlanta VA Medical Center Chart Review	658	Not stratified by demographic variables
Richter GM, Chung J, et al.	2009	Prevalence of Visually Significant Cataract and Factors Associated with Unmet Need for Cataract Surgery: Los Angeles Latino Eye Study	2009	LALES	6,142	Age, Sex, Race/Ethnicity
Broman AT, Hafiz G, Munoz B, et al.	2005	Cataract and Barriers to Cataract Surgery in a US Hispanic Population	1997–1999	Proyecto VER	4,774	Age, Sex, Race/Ethnicity
Mansberger SL, Romero FC, et al.	2005	Causes of Visual Impairment and Common Eye Problems in Northwest American Indians and Alaska Natives	Unknown	Northwest AIAN	288	Race
Congdon, N, Vingerling, J.R., Eye Diseases Prevalence Research Group	2004	Prevalence of Cataract and Pseudophakia/Aphakia Among Adults in the United States	1988–2000	EDPRG	Various	Age, Sex, Race
Varma R, Torres M, Los Angeles Eye Study Group	2004	Prevalence of Lens Opacities in Latinos	2000	LALES	6,142	Age, Sex
Haronian E, Wheeler NC	1993	Prevalence of Eye Disorders Among the Elderly in Los Angeles	1982–1990	UCLA MEC	431	Age, Sex
Klein B, Klein R, Linton KLP	1992	Prevalence of Age-Related Lens Opacities in a Population. The Beaver Dam Eye Study	1988–1990	BDES	4,926	Age, Sex

5.1 Overall Cataract Prevalence Rates

Figure 5.1 shows the estimated prevalence rate for cataract from the seven studies reviewed in this section. Prevalence rates ranged from 2.8% in Proyecto VER to 29.5% in UCLA MEC. The high degree of variation among the results in this figure is likely due to in part to methodological, disease definition and population differences among the studies. The figure is intended to illustrate the range of published prevalence values; direct comparison of the studies is impossible without considering the underlying differences in the studies.

Figure 5.1 Overall Prevalence Rates of Cataract in Selected Studies



* Age- or population- adjusted prevalence rate.

5.2 Atlanta Veteran Affairs (VA) Medical Center Medical Chart Review

As a first step to assessing whether the VA system is adequately prepared to serve patients given new eligibility reform, Maa et al. (2013) conducted this pilot study of the prevalence of various eye diseases among new "routine" eye patients at the Atlanta VA Medical Center Comprehensive Eye Clinic.[9] Researchers reviewed the charts of 658 new patients with no known previous eye diagnosis with the exception of refractive error who were seen between January 1, 2008 and February 1, 2008. The authors used the International Classification of Diseases, 9th Revision Clinical Modification codes (ICD-9CM) to identify ocular conditions and found an overall prevalence rate of cataract of 5.9%. Maa et al. (2013) did not provide prevalence rates stratified by demographic variables.

5.3 Proyecto VER

Proyecto Vision and Eye Research (VER) was a population-based vision impairment study conducted from 1997 to 1999.[18] It included Hispanics living in Tucson and Nogales, Arizona. A total of 4,774

Hispanics aged 40 years and older were randomly selected using 1990 Census data. Broman et al. (2005) analyzed the results of the study and found that the prevalence of visually significant cataract was 2.8% and the prevalence of individuals having undergone bilateral cataract surgery was 5.1%.[72] Visually significant cataract was defined as acuity worse than 20/40 accompanying severe levels of opacity.[72] Figure 5.2 shows the prevalence rates for cataract by age and sex, while Figure 5.3 shows prevalence rates by age and race/ethnicity. The authors concluded that cataract was particularly common among Hispanic individuals and individuals of Mexican descent.

Figure 5.2 Prevalence of Cataract by Age and Sex from Proyecto VER [72]

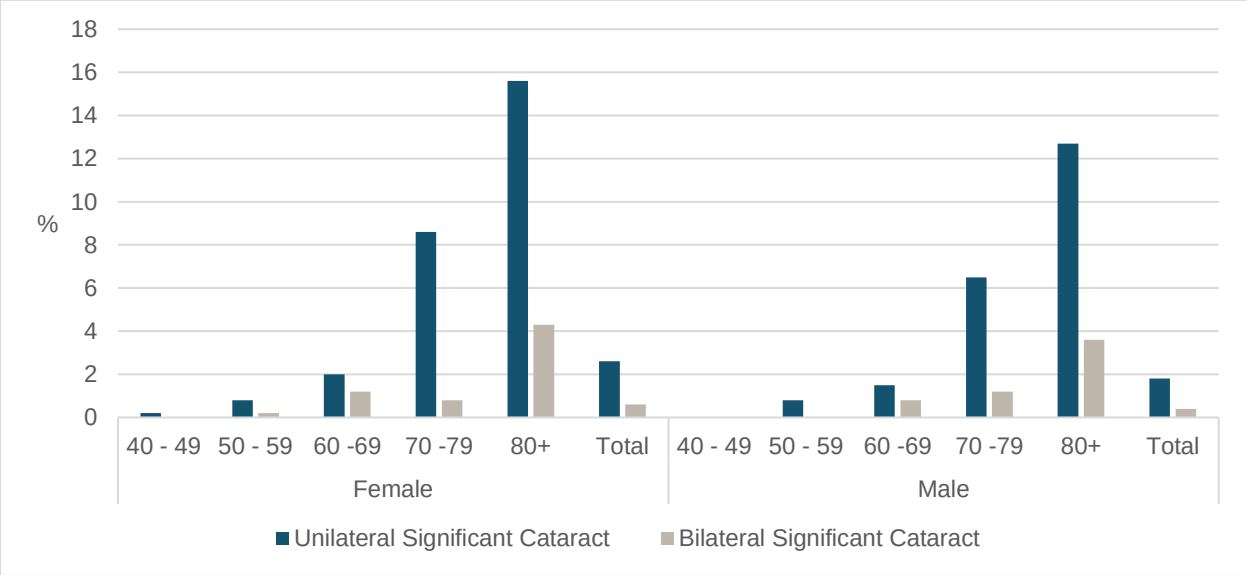
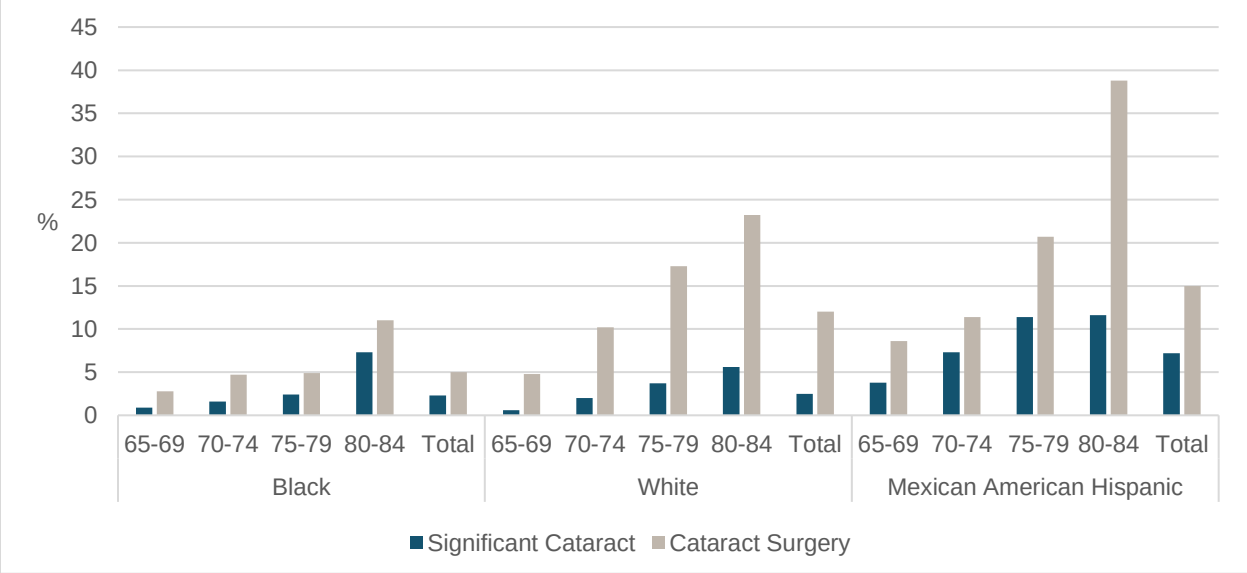


Figure 5.3 Prevalence of Cataract by Age and Race/Ethnicity from Proyecto VER [72]



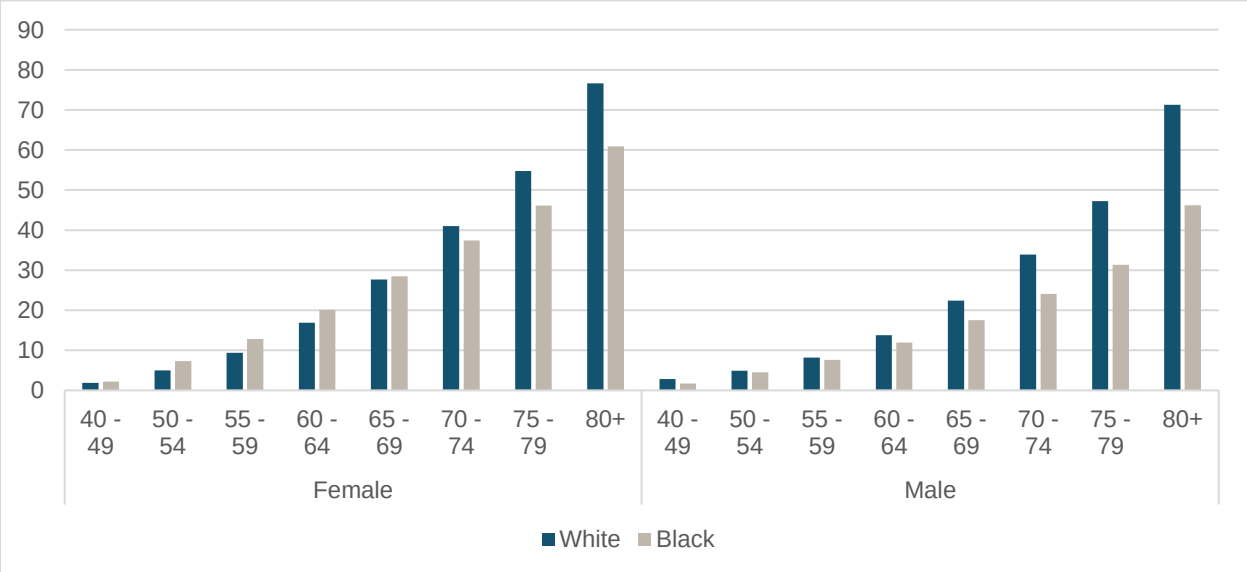
5.4 Study on Visual Impairment Among Northwest American Indians/Alaska Natives

Mansberger et al. (2005) examined the prevalence of eye health disorders in a random sample of 288 American Indian/Alaska Natives (AIAN).[17] Researchers randomly selected participants from three tribes from the Northwest region of the United States (Oregon, Washington, and Idaho). Participants underwent ocular examinations. Cataract was defined as Pseudophakia, aphakia, or vision less than or equal to 20/40 associated with lens opacities without any other cause of vision loss. Mansberger et al. (2005) reported the demographics of their study sample and the prevalence of various eye diseases. Investigators did not provide prevalence estimates for individuals with cataract stratified by demographic factors. Overall, 12.2% of the study population had cataract.

5.5 Eye Disease Research Prevalence Group

The Eye Disease Prevalence Research Group (EDPRG) obtained data from several large population-based surveys from inside and outside the U.S., including the Beaver Dam Eye Study, Proyecto Vision Evaluation Research, Barbados Eye Study, the Blue Mountains Eye Study, Rotterdam Eye Study, the Melbourne Vision Impairment Study, and the Salisbury Eye Evaluation Project. Cataract was defined as the eye having level 4 or 5 nuclear sclerosis and opacity of 25% or greater. Researchers derived age-, sex- and race-specific U.S. prevalence rates, by "applying the modeled prevalence rate for each year of age to the 2000 US Census population and summing across the age range for each 5-year age category." The estimated national prevalence calculated using this adjustment is shown at the beginning of this section (Figure 5.1). Figure 5.4 shows the age-specific prevalence rates pooled from the studies prior to adjusting these rates to the US Census.

Figure 5.4 Prevalence of Cataract from Eye Disease Prevalence Research Group [73]



5.6 The Los Angeles Latino Eye Study

The Los Angeles Latino Eye Study (LALES) was a population-based, cross-sectional study of over 6,000 Latinos of mostly Mexican heritage 40 years and older from Los Angeles, California.[74] Varma et al. (2004) investigated the prevalence of lens opacities among this population.[74] For this investigation, 6,357 individuals were evaluated for any nuclear, posterior polar cataract and/or cortical opacities using the Lens Opacities Classification System II and split lamp imaging. Figure 5.5 shows the prevalence of cataract from LALES found by Varma et al. (2004) stratified by age and sex. They found that the prevalence of all types of lens opacities increased with age. Richter et al. (2009) also used the LALES study sample to determine the prevalence of visually significant cataract, which they defined as any OSC II grading 2 or greater, best corrected visual acuity of less than 20/40 in the cataractous eye, cataract as a primary cause of vision impairment, and self-reported vision of fair or worse.[75] Among 6,142 Latinos who completed an in-home questionnaire and an ophthalmic examination, they found that 1.92% had visually significant cataract in at least one eye, demonstrating a need for cataract surgery among this population [75]. Figure 5.6 shows their results, stratified by age and sex.

Figure 5.5 Prevalence of Cataract from Los Angeles Latino Eye Study [74]

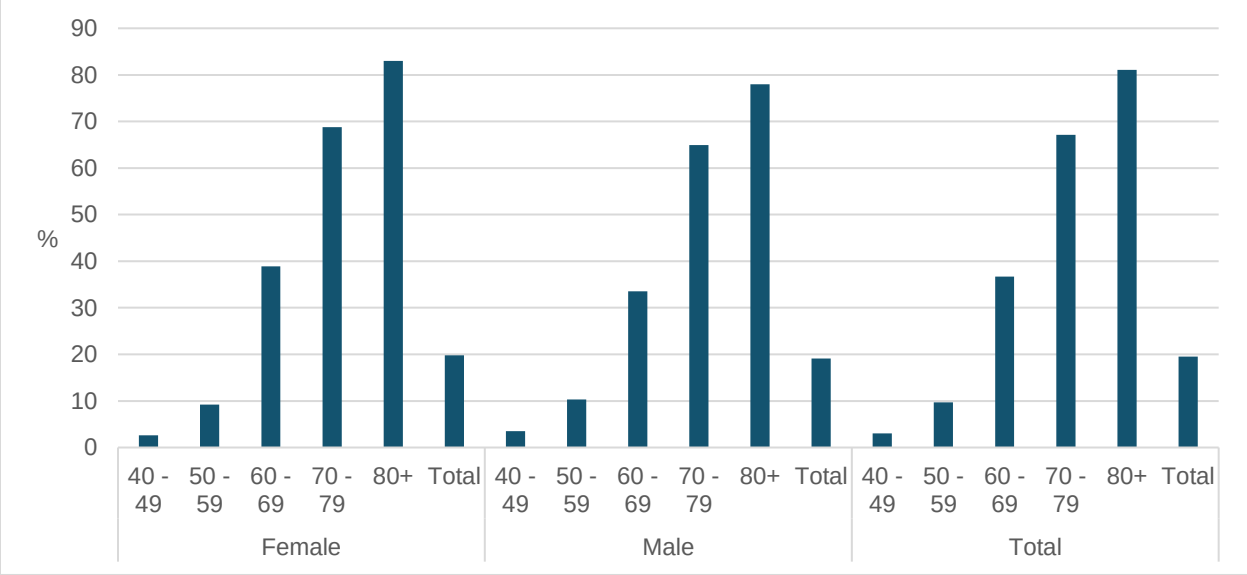
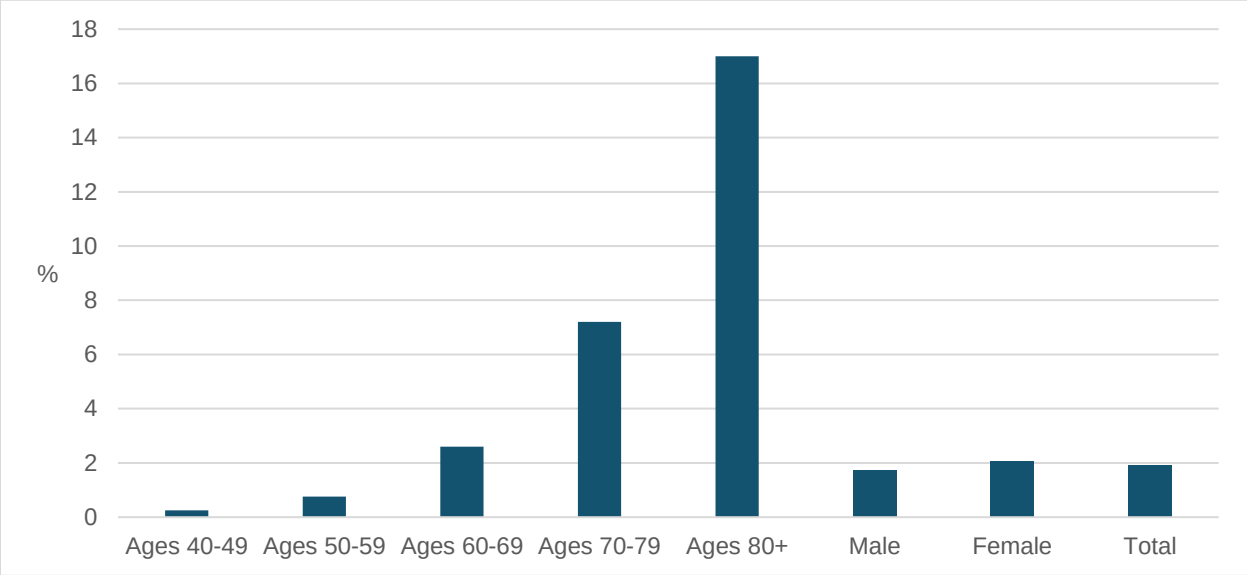


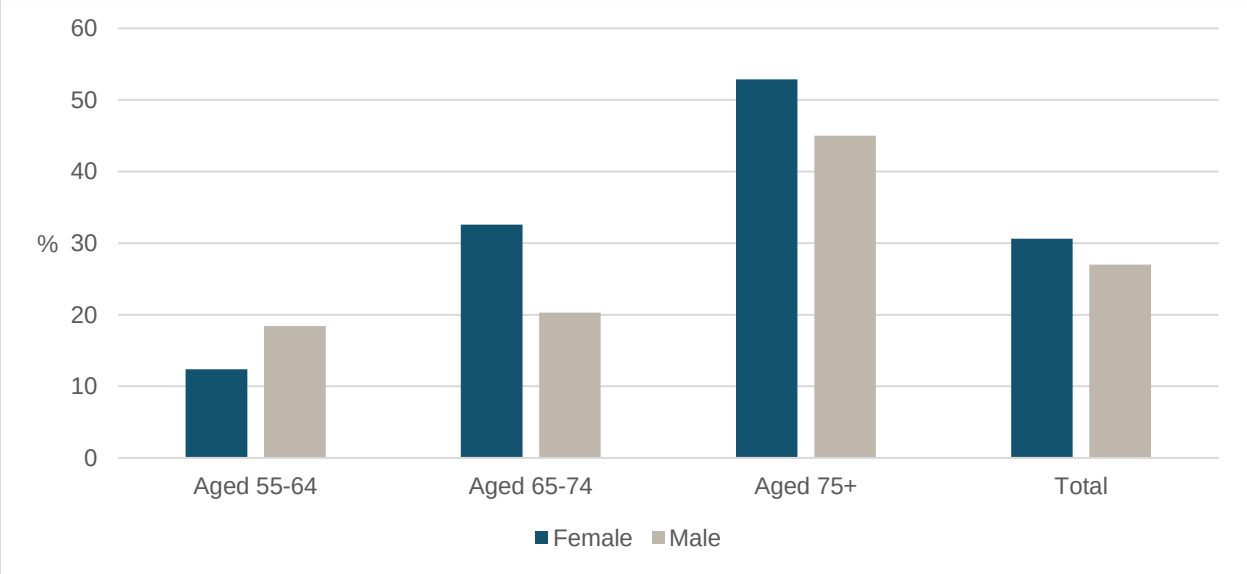
Figure 5.6 Prevalence of Any Visually Significant Cataract Among LALES Participants by Age and Sex [75]



5.7 University of California, Los Angeles Mobile Eye Clinic

The UCLA Mobile Eye Clinic (MEC) was a bus that provided free vision screening to underserved individuals in Los Angeles, CA. Haronian et al. (1993) examined results for 431 patients aged 55-94 who received services in the MEC from 1982 to 1990 in two senior centers in Los Angeles, CA. Researchers used International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes to calculate prevalence estimates for various eye diseases and found an overall cataract prevalence of 29.5%.[28] As shown in Figure 5.7, the prevalence of cataract increases with age. While the prevalence of cataract was greater among males in the 55-64 age group, it was higher among females aged 65 and older.

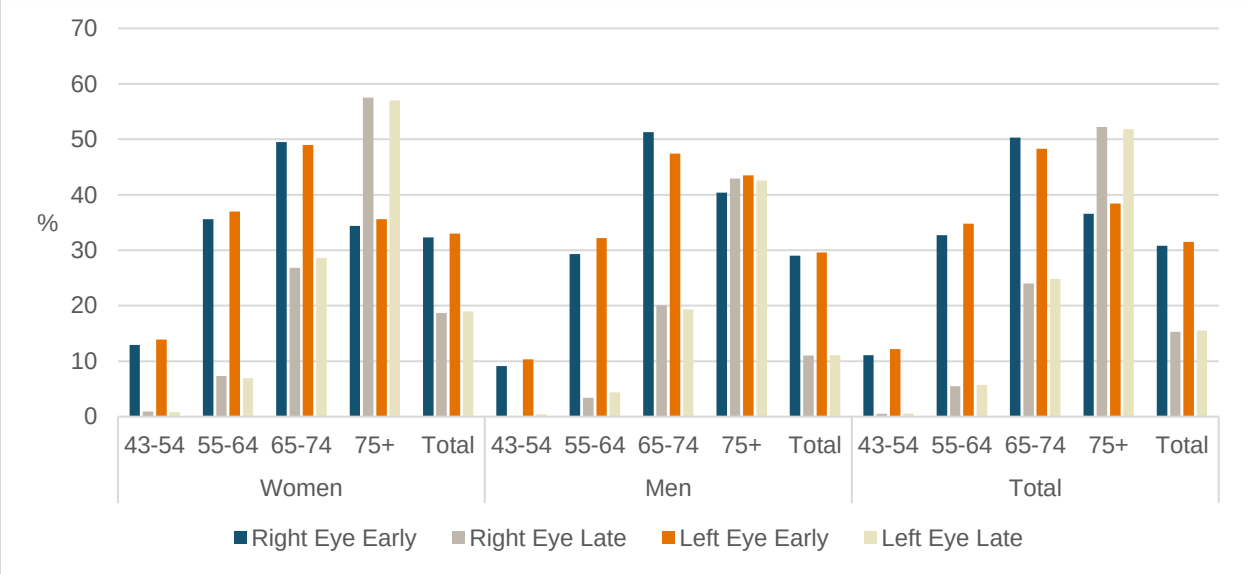
Figure 5.7 Prevalence of Cataract Adults Examined by the UCLA MEC, by Age and Sex



5.8 Beaver Dam Eye Study

The Beaver Dam Eye Study began in 1987 with the purpose of collecting information on the prevalence of age-related cataract, macular degeneration and diabetic retinopathy.[68] Approximately 5,000 residents of Beaver Dam, Wisconsin aged 43 – 84 participated in baseline examinations involving photographic imaging of the eye.[68] Images were graded based on a developed scale and prevalence rates for cataracts by age and sex were developed. For the purposes of this study, early cataract was defined as the presence of Level 3 nuclear sclerosis and/or 5 – 24% cortical and/or posterior subscapular opacity while late cataract was defined as the eye having level 4 or 5 nuclear sclerosis and opacity of 25% or greater. Figure 5.8 shows the results of the study, which evaluated the left and right eye separately and distinguished between early and late cataract. Rates were positively correlated with age and were higher for women than for men.

Figure 5.8 Prevalence of Early and Late Cataract from Beaver Dam Eye Study [68]



6. Vision Impairment and Blindness

Vision impairment (VI) is generally determined by measuring the best-corrected visual acuity (BCVA) of the better-seeing eye. Most studies in the United States measure visual acuity at a distance of 20 feet using the standardized Snellen Eye Chart.[76] Autorefractors may also be used to assess visual acuity and to estimate lens prescription. BCVA is a person's best distance vision while using optimal refraction correction (eye glasses, contact lenses, laser surgery etc.).[76] There is no universal definition of visual impairment and there are varying definitions of BCVA, including 20/40 to 20/63 (mild VI), 20/80 to 20/160 (moderate VI), 20/200 or worse (severe VI).[19] Legal blindness is defined by the US government (to determine eligibility for vocational training, rehabilitation, schooling, disability benefits, low vision devices, and tax exemption programs) as 20/200 or worse, and by the World Health Organization as 20/400 or worse.[19]

6.0 Vision Impairment and Blindness Literature Review Results

Figure 6.0 shows articles from the 12 studies published between 1995 and 2016 that examined the prevalence of vision impairment and blindness. The sources of data were:

1. The Chinese American Eye Study (CHES)
2. Multi-Ethnic Study of Atherosclerosis (MESA)
3. Atlanta VA Medical Center Chart Review
4. National Health and Nutrition Examination Survey (NHANES)
5. Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR)
6. Study on Visual Impairment Among Northwest American Indians/Alaska Natives (AIAN)
7. Los Angeles Eye Study (LALES)
8. The Eye Disease Research Prevalence Group (EDPRG)
9. Proyecto VER
10. The Salisbury Eye Evaluation (SEE)
11. The Baltimore Eye Survey (BES)
12. The Beaver Dam Eye (BDES)

Figure 6.0 Vision Impairment and Blindness Prevalence Sources

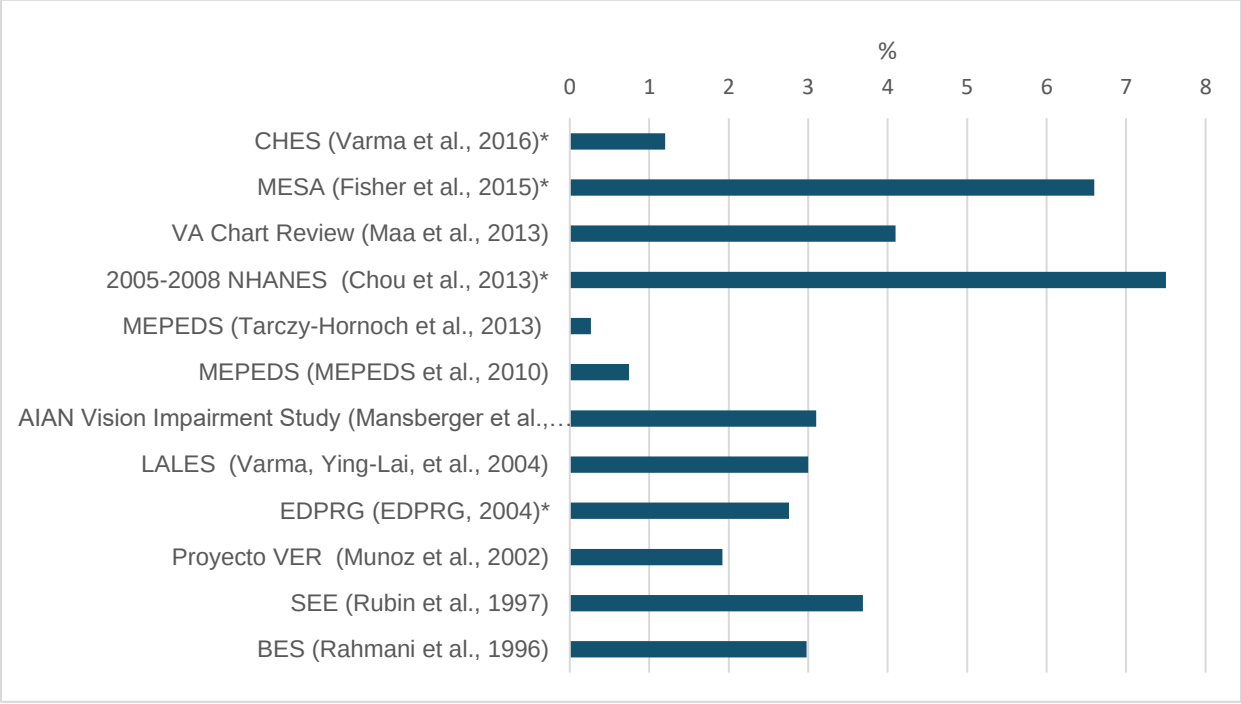
Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:
Varma R, Choudhury F, et al.	2016	Prevalence and Causes of Visual Impairment and Blindness in Chinese American Adults: The Chinese American Eye Study	2010–2013	CHES	4,582	Race, Age, Sex
Fisher DE, Shraqer S, et al.	2015	Visual Impairment in White, Chinese, Black, and Hispanic Participants from the Multi-Ethnic Study of Atherosclerosis Cohort	2002–2004	MESA	6,134	Age, Sex, Race/ Ethnicity
Maa AY, Evans C, et al.	2013	Veteran Eye Disease After Eligibility Reform: Prevalence and Characteristics	January 2008– February 2008	Atlanta VA Medical Center Chart Review	658	Not stratified by demographic variables
Chou, C.F., Cotch, M.F., Vitale, S., et al.	2013	Age-Related Eye Diseases and Visual Impairment Among US Adults	2005–2008	NHANES	5,222	Age
Klein R, Lee KE, et al.	2009	Changes in Visual Impairment Prevalence by Period of Diagnosis of Diabetes: The Wisconsin Epidemiologic Study of Diabetic Retinopathy	1980–2007	WESDR	Various	Not stratified by demographic variables
Mansberger SL, Romero FC, et al.	2005	Causes of Visual Impairment and Common Eye Problems in Northwest American Indians and Alaska Natives	Unknown	Northwest AIAN	288	Not stratified by demographic variables
Varma R, Ying-Lai M, Klein R, Azen SP, et al.	2004	Prevalence and Risk Indicators of Visual Impairment and Blindness in Latinos: the Los Angeles Latino Eye Study.	2000–2008	LALES	6,122	Race/Ethnicity, Sex, Age
The Eye Diseases Prevalence Research Group	2004	Causes and Prevalence of Visual Impairment Among Adults in the United States	1985–1998	EDPRG	Various	Age, Race/Ethnicity, Sex
Muñoz B, West SK, Rodriguez J, et al.	2002	Blindness, Visual Impairment and the Problem of Uncorrected Refractive Error in a Mexican-American Population: Proyecto VER.	1997–1999	Proyecto VER	4,774	Age, Sex, Race/Ethnicity

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size	Prevalence Data Stratified by:
Rubin GS, West S, et al.	1997	A Comprehensive Assessment of Visual Impairment in a Population of Older Americans. The SEE Study. Salisbury Eye Evaluation Project	1993–1995	The SEE Project	2,520	Age, Sex, Race
Rahmani B, Tielsch JM, et al.	1996	The Cause-Specific Prevalence of Visual Impairment in an Urban Population. The Baltimore Eye Survey	1985–1988	BES	5,300	Age, Sex, Race
Klein R, et al.	1995	The Relationship of Age-Related Maculopathy, Cataract, and Glaucoma to Visual Acuity	1988–1990	BDES	4,886	Age

6.1 Overall Vision Impairment and Blindness Prevalence Rates

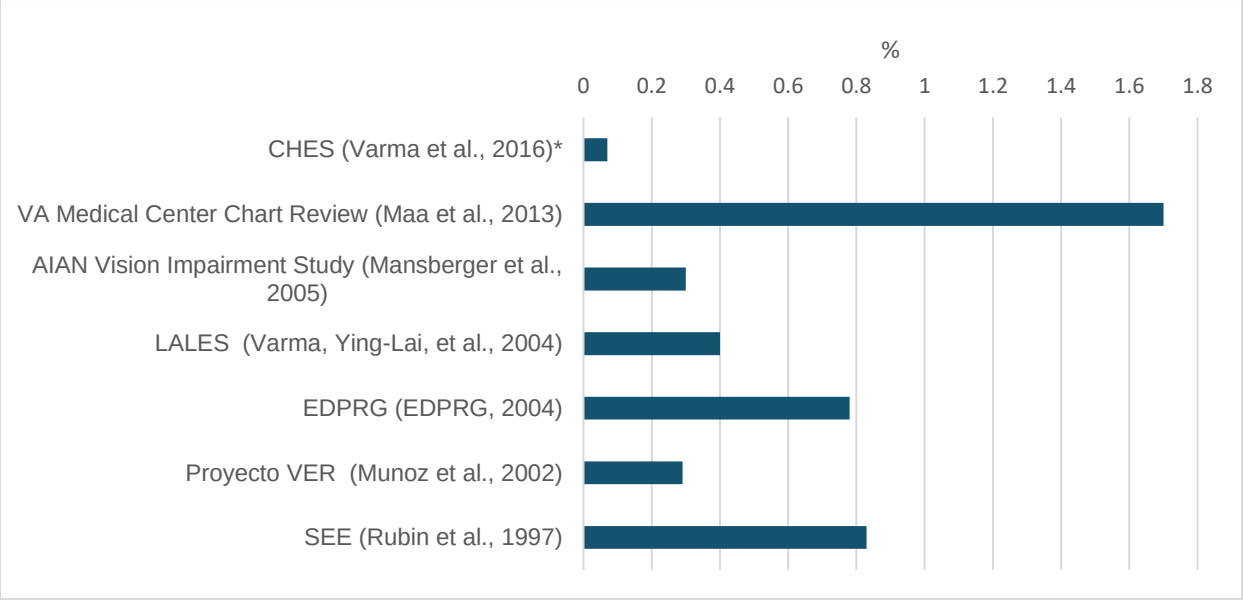
Figure 6.1 shows the estimated total population prevalence rate for vision impairment derived from selected studies. Overall visual impairment prevalence rates ranged from 0.27% in MEPEDs to 7.5% in the 2005-2008 NHANES, which included older, homeless adults. Figure 6.2 reports blindness prevalence from selected studies. Overall, blindness prevalence rates ranged from 0.07% in CHES to 1.7% in the Atlanta VA Medical Center Chart Review. The high degree of variation among the results in each figure is likely due to in part to methodological, disease definition, and population differences among the studies. These figures are intended to illustrate the range of published prevalence values; direct comparison of the studies is impossible without considering the underlying differences in the studies.

Figure 6.1 Overall Vision Impairment Prevalence Rates in Selected Studies



* Age-or population-adjusted prevalence rate.

Figure 6.2 Overall Blindness Prevalence Rates in Selected Studies**



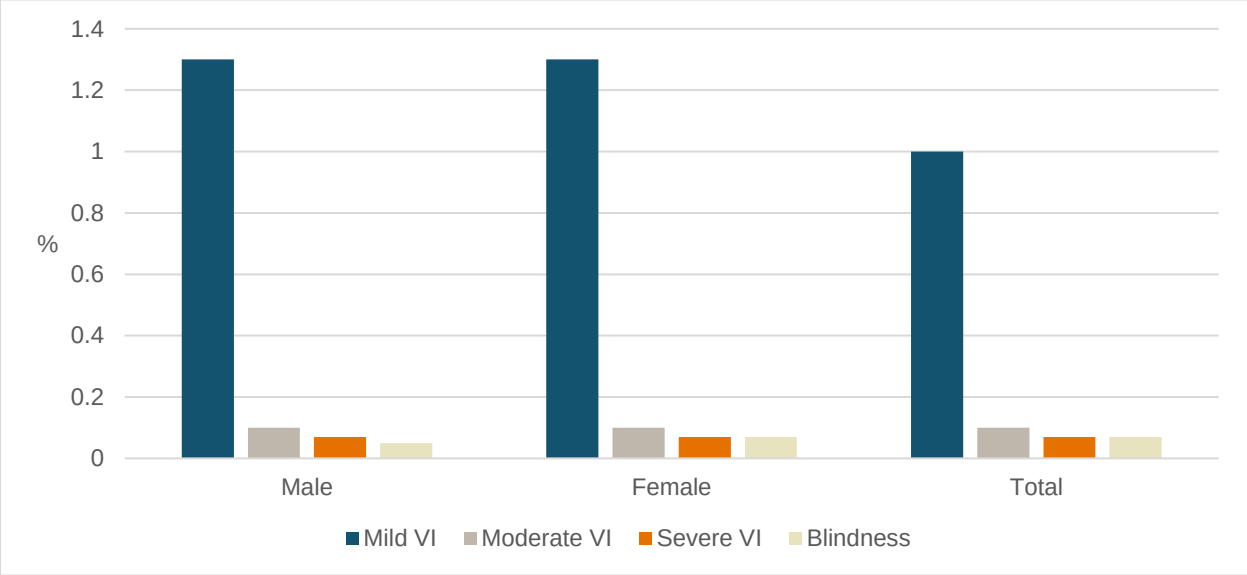
*Adjusted prevalence rate

**Blindness is defined by the U.S. government definition of best-corrected visual acuity of 20/200 or worse

6.2 The Chinese American Eye Study

The Chinese American Eye Study (CHES) determined the population-based prevalence of eye disease and visual impairment (VI) among Chinese Americans aged 50 and older.[60] Participants lived in 10 urban census tracts in Monterey Park, CA from 2010 to 2013. Of those who were eligible, 4,582 completed home interviews and underwent clinical examinations, including an assessment of presenting and best-corrected visual acuity (PVA and BCVA, respectively). Researchers classified vision impairment using US criteria as: mild (BCVA 20/40-20/63), moderate (BCVA 20/80-20/160), and severe (BCVA less than or equal to 20/200). They also used WHO criteria to classify vision impairment (BCVA of less than 20/63 but greater than or equal to 20/400). Blindness was classified using the US criterion of BCVA of 20/200 or less and the WHO criterion of 20/400 or less. Researchers age-adjusted their results to the 2010 US population standard for Asians. They determined that the overall prevalence of vision impairment was 3.0% based on presenting VI and 1.2% based on BCVA in the better-seeing eye, when using the US criteria.[60] The age-adjusted prevalence of blindness based on the US criteria was 0.08% based on presenting VI and 0.07% based on BCVA in the better-seeing eye.[60] Figure 6.3 below shows these age-adjusted prevalence rates.

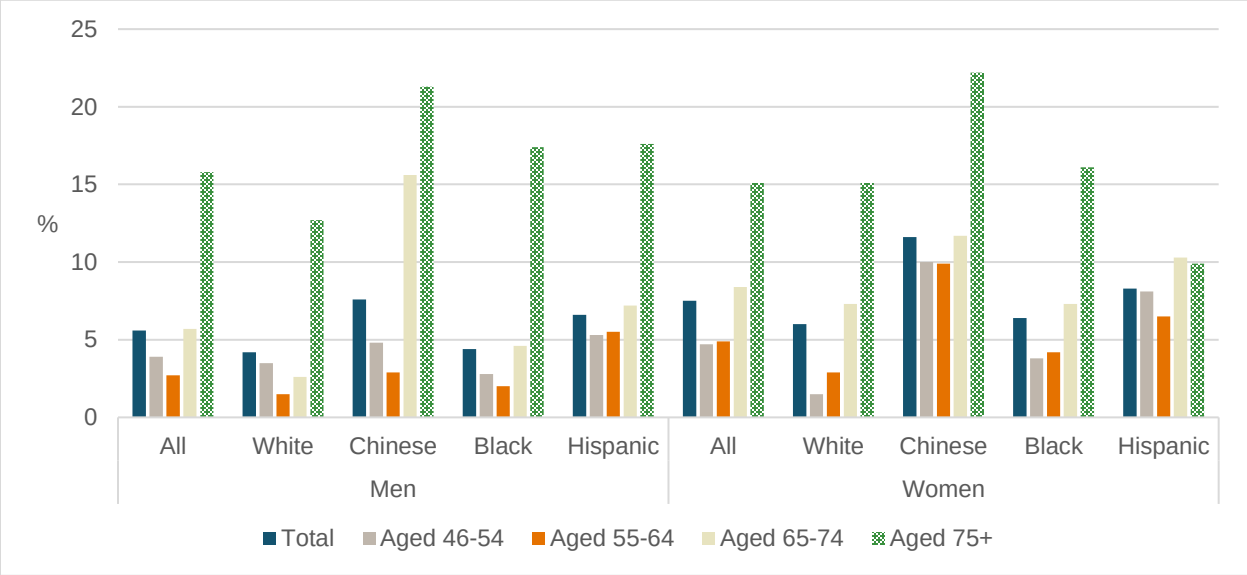
Figure 6.3 Prevalence of Vision Impairment and Blindness for Best-Corrected Visual Acuity in the Better-Seeing Eye based on US Criteria in the Chinese American Eye Study, Age-Adjusted [60]



6.3 Multi-Ethnic Study of Atherosclerosis

The Multi-Ethnic Study of Atherosclerosis (MESA) included a prospective cohort of adults aged 45-84 from six U.S. communities (Baltimore, Maryland; Chicago, Illinois; Forsyth County, North Carolina; Los Angeles, California; New York, New York; and St. Paul, Minnesota) that reported prevalence of presenting visual impairment.[61] Among those examined at baseline, 6,134 completed a visual acuity assessment between August, 2002 and January, 2004. The visual acuity assessment utilized the same equipment and protocol as was used in NHANES. Researchers defined visual impairment as presenting visual acuity worse than 20/50 in the better eye. They age-adjusted prevalence estimates to the 2000 US Census using the direct method. The study used autorefractors to identify the proportion of visual impairment that is due to URE and due to non-refractive causes, but do not separately report corrected acuity prevalence. Among the 6,134 examined, 6.6% were visually impaired due to both uncorrected refractive error and non-refractive causes. Figure 6.4 shows the overall prevalence of vision impairment by age, sex and race.

Figure 6.4 Prevalence of Presenting Visual Impairment Among MESA Study Participants, by Age, Sex, and Race [61]



6.4 Atlanta Veteran Affairs (VA) Medical Center Medical Chart Review

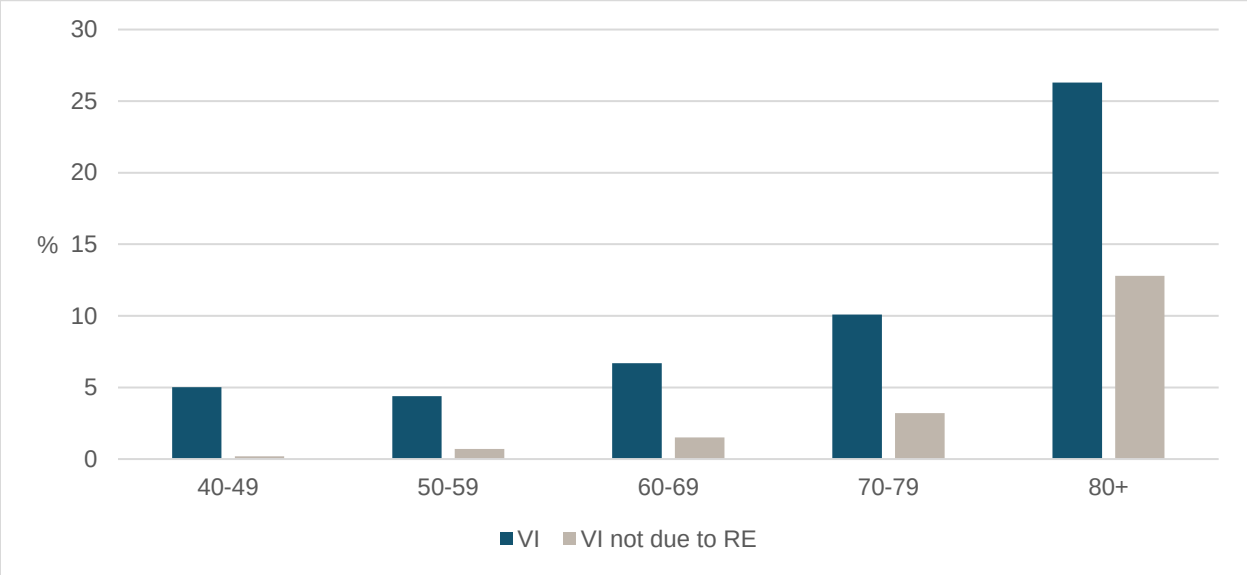
As a first step to assessing whether the Veteran Affairs system was adequately prepared to serve patients given new eligibility reform, Maa et al. (2013) conducted this pilot study of the prevalence of various eye diseases among new "routine" eye patients at the Atlanta Veteran Affairs Medical Center Comprehensive Eye Clinic.[9] Researchers reviewed the charts of 658 new patients with no known previous eye diagnosis with the exception of refractive error. They defined blindness as visual acuity worse than 20/200 in both eyes and visual impairment (VI) as best-corrected visual acuity (BCVA) of 20/70 or worse. Researchers found an overall prevalence rate of 4.1% and 1.7% for VI and blindness, respectively.[9] The authors did not provide prevalence estimates for VI or blindness stratified by other demographic variables.

6.5 2005-2008 National Health and Nutrition Examination Survey

The 2005-2008 National Health and Nutrition Examination Survey (NHANES) was a nationally representative population-based cross-sectional study conducted by the National Center for Health Statistics.[77] A total of 5,222 adults aged 40 years and older participated in NHANES, completed examinations, and had gradable photographs for one of their eyes available. Researchers measured presenting visual acuity in a dimmed room using an ARK-710 automated refractometer. Researchers then measured objective refraction after asking participants to remove refractive eyewear. Visual impairment was defined as presenting distance visual acuity of worse than 20/40 in the better-seeing eye. Visual impairment not due to refractive error (RE) was defined as visual acuity worse than 20/40 while aided with autorefraction. Patients who self-reported as blind in both eyes were excluded from acuity testing in NHANES, and these individuals were not included in the acuity-derived estimates of vision loss or blindness in this study, which would bias prevalence results downward. In addition, NHANES excludes

institutionalized or group quartered individuals, including those living in assisted living facilities. As illustrated by Figure 6.5, the study showed that the prevalence of presenting visual impairment slightly decreased after 40-49 years of age, and then increased with age.

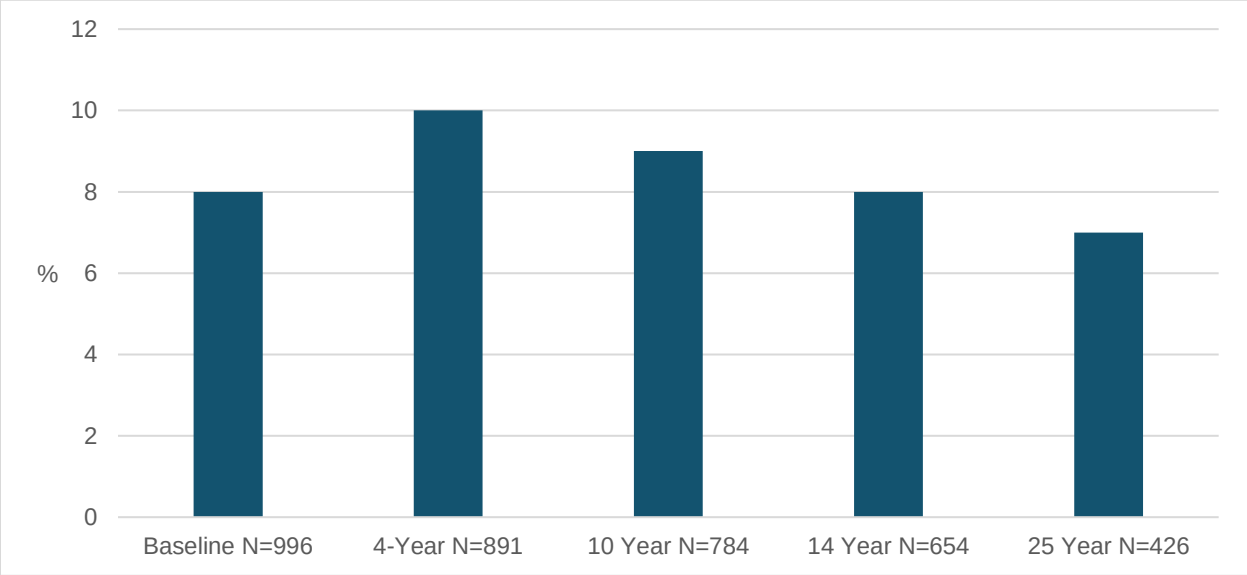
Figure 6.5 Prevalence of Presenting Vision Impairment and Blindness [77]



6.6 Wisconsin Epidemiologic Study of Diabetic Retinopathy

The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) collected baseline information from diabetic individuals living in eleven counties in Wisconsin from 1980-1982. Klein et al. (2009) examined the prevalence of vision impairment (VI) among a two-part sample of 2,990 study participants who had diabetes.[78] Five follow-up examinations occurred from 1984 to 2007, which included an assessment of best-corrected visual acuity for distance using a protocol in which charts were reduced in size for a two meter distance. Investigators used best-corrected visual acuity to assess VI, defining any VI as visual acuity (VA) of 20/40 or less in the better eye. As shown in Figure 6.6, Klein et al. (2009) reported the prevalence of VI among individuals who participated in each examination, ranging from 10% of those examined between 1984 and 1986 to 7% of those examined between 2005 and 2007.[78]

Figure 6.6 Prevalence of Visual Impairment among WESDR Participants Examined from 1980-1982 to 2005-2007 [78]



6.7 Study on Visual Impairment among Northwest American Indians/Alaska Natives

Mansberger et al. (2005) examined the prevalence of eye health disorders in a random sample of 288 American Indian/Alaska Natives (AIAN).[17] Researchers randomly selected participants from three tribes in the Northwest region of the United States (Oregon, Washington, and Idaho). These participants underwent ocular examinations. The researchers defined vision impairment as best corrected visual acuity of 20/40 or worse in the better eye and they defined blindness as best-corrected distance visual acuity of 20/200 or worse in the better eye. Although they did not provide prevalence estimates for vision impairment and blindness stratified by demographic variables, they provided summary estimates: 3.1% had vision impairment and 0.3% had blindness [17].

6.8 Los Angeles Latino Eye Study

The Los Angeles Latino Eye Study (LALES) was a population-based, cross-sectional study of over six thousand Latinos of mostly Mexican heritage 40 years and older from the Los Angeles area.[19] Baseline examinations were conducted between March 2000 and June 2003, and follow-up examinations occurred from July 2004 and June 2008. The subjects were interviewed and had their eyes examined and measured for best-corrected distance visual acuity (VA) using the standard electronic Early Treatment Diabetic Retinopathy Study Protocol (ETDRS) visual acuity algorithm.[79] Varma et al. (2004) looked at the age and sex specific prevalence of visual impairment and blindness among the study participants.[79] They included three definitions of visual impairment:

1. Definition 1: Best-corrected visual acuity (VA) of 20/40 in the better-seeing eye. Visual impairment (VI) was classified as mild (20/40 to 20/63), moderate (20/80 to 20/160) and severe (20/200 or worse).

2. Definition 2: Best-corrected VA worse than 20/40 but better than 20/200.

3. Definition 3: Best-corrected VA worse than 20/63 but better than or equal to 20/400.

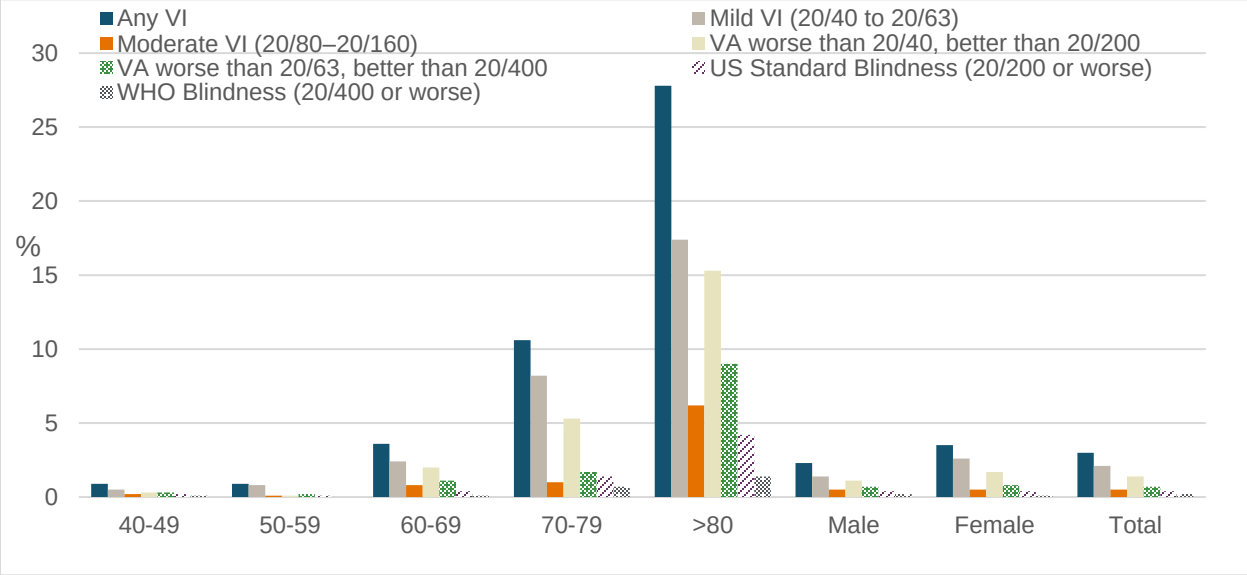
They also included two definitions of blindness:

1. Definition 1: Best-corrected VA of 20/200 or worse in the better-seeing eye (U.S. Standard).

2. Definition 2: Best-corrected VA of 20/400 or worse in the better-seeing eye (WHO Standard).

As shown in Figure 6.7, they found that mild VI and VA between 20/40 and 20/200 were the most prevalent and that individuals aged 80 years and older had the highest rates of vision impairment.

Figure 6.7 Prevalence of Vision Impairment and Blindness in LALES [79]

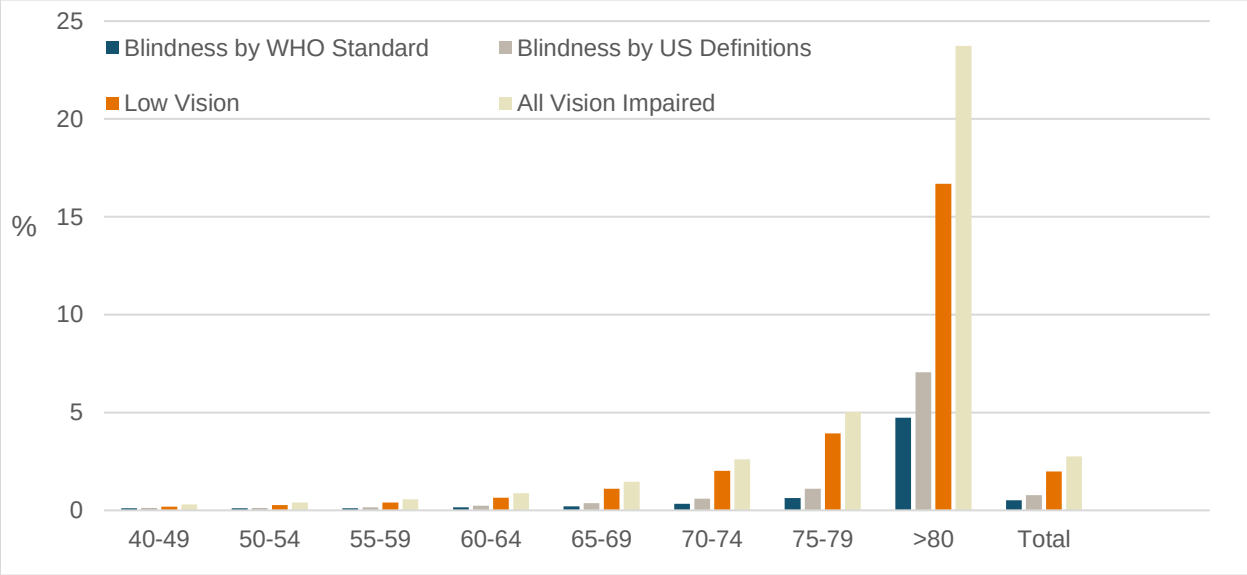


6.9 The Eye Disease Research Prevalence Group

The Eye Disease Prevalence Research Group (EDPRG) obtained data from several large population-based surveys from inside and outside the U.S., including the Baltimore Eye Survey, Beaver Dam Eye Study, Proyecto Vision Evaluation Research, Barbados Eye Study, the Blue Mountains Eye Study, Rotterdam Eye Study, the Melbourne Vision Impairment Study, and the Salisbury Eye Evaluation Project.[80] Investigators defined blindness using the World Health Organization's (WHO) standard of best-corrected visual acuity (VA) and by the US standard, and defined low vision as 20/40 or worse but better than 20/200 in the better-seeing eye. Researchers derived age-, sex- and race-specific summary prevalence

rates for the US populations by "applying the modeled prevalence rate for each year of age to the 2000 US Census population and summing across the age range for each 5-year age category." The estimated national prevalence calculated using this adjustment is shown at the beginning of this section (Figure 6.1). Figure 6.8 shows the age-specific prevalence rates pooled from the studies prior to adjusting these rates to the US Census.

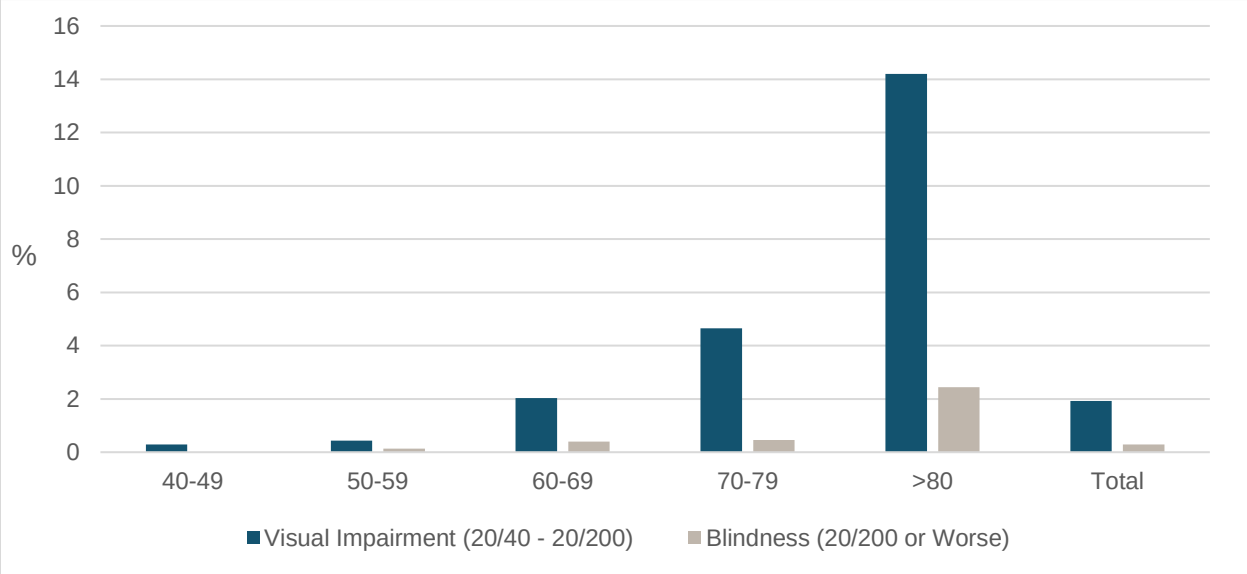
Figure 6.8 Prevalence of Vision Impairment and Blindness in EDPRG [80]



6.10 Proyecto VER

Proyecto Vision and Eye Research (VER) was a vision impairment study among Latinos in Tucson and Nogales, Arizona between 1997 and 1999.[81] A total of 4,774 participants aged 40 years and older were randomly selected using 1990 Census data. Detailed ocular examinations were conducted on the participants. Best corrected vision was ascertained among those with visual acuity (VA) worse than 20/30. VA was assessed using a modified Early-Treatment Diabetic Retinopathy Study Protocol cd/m2, and an autorefractor. The study defined visual impairment as best corrected visual acuity 20/40 or worse and better than 20/200 in the better seeing eye, and blindness as best corrected visual acuity of 20/200 or worse in the better seeing eye. As shown in Figure 6.9, Munoz et al. (2002) found that the prevalence of visual impairment was higher than blindness, and participants 80 years and older had the highest rates of visual impairment and blindness.

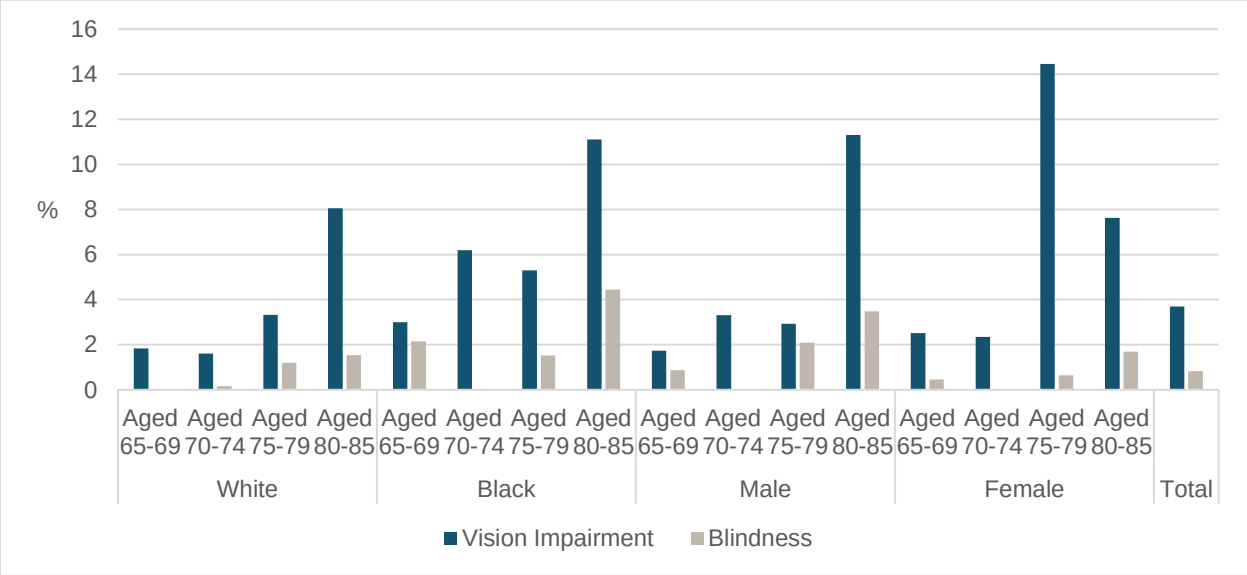
Figure 6.9 Prevalence of Vision Impairment and Blindness in Proyecto VER [81]



6.11 The Salisbury Eye Evaluation Project

The Salisbury Eye Evaluation (SEE) project included 2,520 Black and White participants aged 65-84 living in Salisbury, MD.[82] Participants were identified using the Health Care Financing Administration Medicare database and underwent visual acuity testing from September 16, 1993 and September 26, 1995. Visual acuity testing utilized the charts developed by the Early Treatment of Diabetic Retinopathy Study. Participants were also assessed using the following: Pell-Robinson contrast sensitivity testing with and without glare, Randot stereoacuity, and 60 degree Humphrey visual fields. Investigators reported out on the prevalence of vision impairment and blindness based on best-corrected visual acuity according to U.S. criteria (normal vision: 20/40 or better; visual impairment: 20/40-20/200; blindness: worse than 20/200) and the WHO criteria (normal vision: 20/60 or better; low vision: 20/60-20/400; blindness: worse than 20/400). As shown in Figure 6.10, the prevalence of vision impairment was higher among Blacks than Whites based on U.S. criteria.

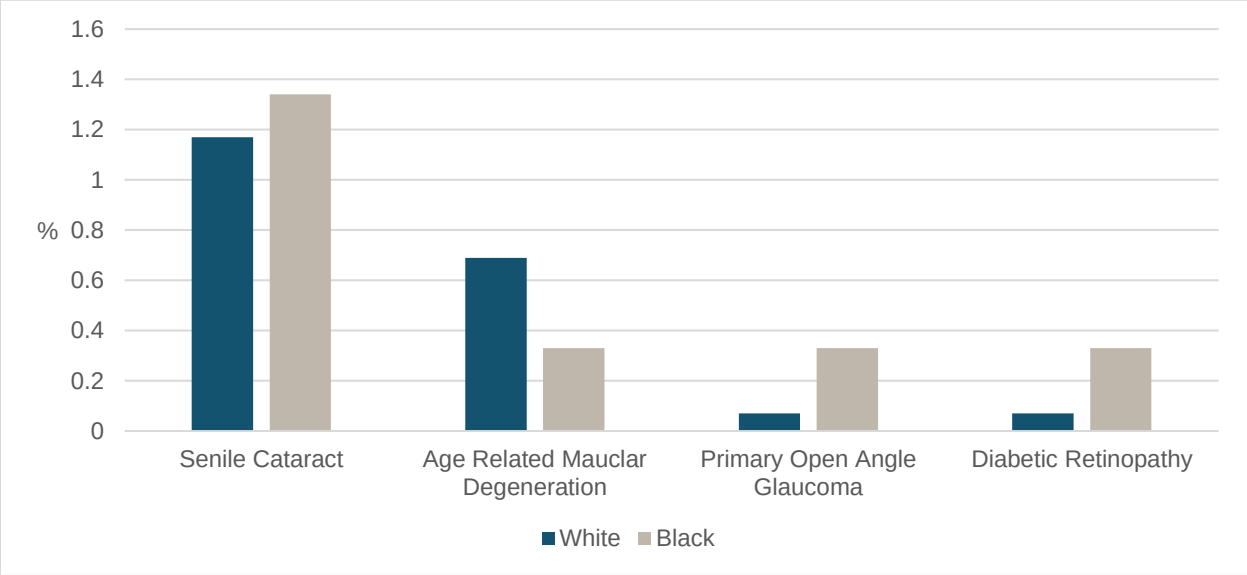
Figure 6.10 The Prevalence of Vision Impairment and Blindness Based on Best-Corrected Visual Acuity in the Better Eye Among SEE Study participants, by Age, Race and Sex [82]



6.12 The Baltimore Eye Survey

The Baltimore Eye Survey (BES) was a cross-sectional population-based study conducted 1985-1988 that included 5,308 Black and White individuals aged 40 and older from East Baltimore.[83] Examinations included physicals, visual acuity assessments, personal interviews, and stereoscopic fundus photography. Rahmani et al. (1996) reported the prevalence of vision impairment among study participants, defining vision impairment as best corrected visual acuity worse than 20/40 but better than 20/200 in the better eye. Among the 5,300 individuals with complete visual acuity results, 2.98% had visual impairment. As shown in Figure 6.11, investigators reported the prevalence of vision impairment for Blacks and Whites, stratified by the cause of vision impairment.

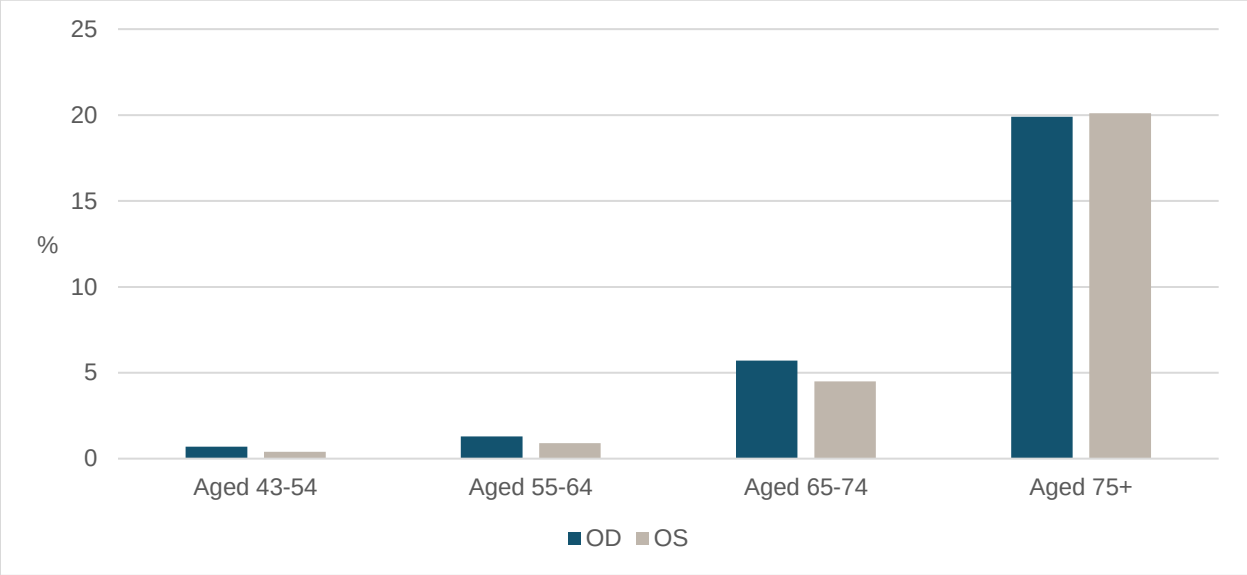
Figure 6.11 Prevalence of Vision Impairment Among BES participants by Cause and Race [83]



6.13 The Beaver Dam Eye Study

The Beaver Dam Eye Study (BDES) identified all individuals aged 43 to 84 years of age living in Beaver Dam, Wisconsin. Between 1988 and 1990, 4,926 of the 5,925 eligible individuals were examined. These examinations included a medical history, lifestyle questionnaire, and an ocular examination of each eye that entailed nonstereoscopic color fundus photographs of the disc and macula, and visual acuity testing. Klein et al. (1995) reported results for 4,886 individuals aged 43 to 86 who participated in the study and were measured for visual acuity.[26] Researchers defined impaired vision as best-corrected visual acuity of 40/40 or worse and included eyes that were blind. Blindness was defined as best-corrected visual acuity of 20/200 or worse. Using this criteria, researchers determined that 0.43% of study participants were blind. The age-adjusted prevalence of vision impairment was 4.8% (OD) and 4.3% (OS). Age-specific prevalence rates for vision impairment are illustrated below in Figure 6.12.

Figure 6.12 Age Specific Prevalence Rates of Vision Impairment among BDES Participants of Different Age Groups [26]



7. Retinopathy of Prematurity

Retinopathy of prematurity (ROP) is a proliferative condition of the retinal vasculature that primarily affects premature infants and is a leading cause of visual impairment and blindness among infants.[84, 85] Infants with a birth weight (BW) of less than 1250 grams and/or those with a gestational age (GA) of 31 weeks or less are particularly at risk. The development of ROP is due to abnormal retinal development likely tied to varying levels of oxygenation experienced by infants after birth.[85] There are five categorizations of ROP, ranging from mild to severe. Stage I and II involve mild and moderate abnormal vascular growth in the retina that can resolve without treatment and without subsequent vision impairment in most cases. Stage III is distinguished by severely abnormal vascular growth in the retina, in which vessels grow toward the center of the eye rather than along the surface of the retina. Some infants in stage II are considered to have "plus disease," characterized by enlarged or contorted vessels. In Stages IV, abnormal vessels cause the retina to become partially detached, and in Stage V, abnormal vessels cause complete retinal detachment. An assessment of which zone of the eye is affected in conjunction with time spent at each stage is used to gauge the severity of the disease.[86]

7.0 Retinopathy of Prematurity Literature Review Results

Figure 7.0 shows articles from four studies that published prevalence estimates for ROP from 1991 to 2016. The four sources of data were:

1. Telemedicine Approaches to Evaluating Acute-phase Retinopathy of Prematurity (e-ROP)
2. The National Inpatient Survey
3. Early Treatment for Retinopathy of Prematurity (ETROP) Study
4. Cryotherapy for ROP Study (CRYO-ROP)

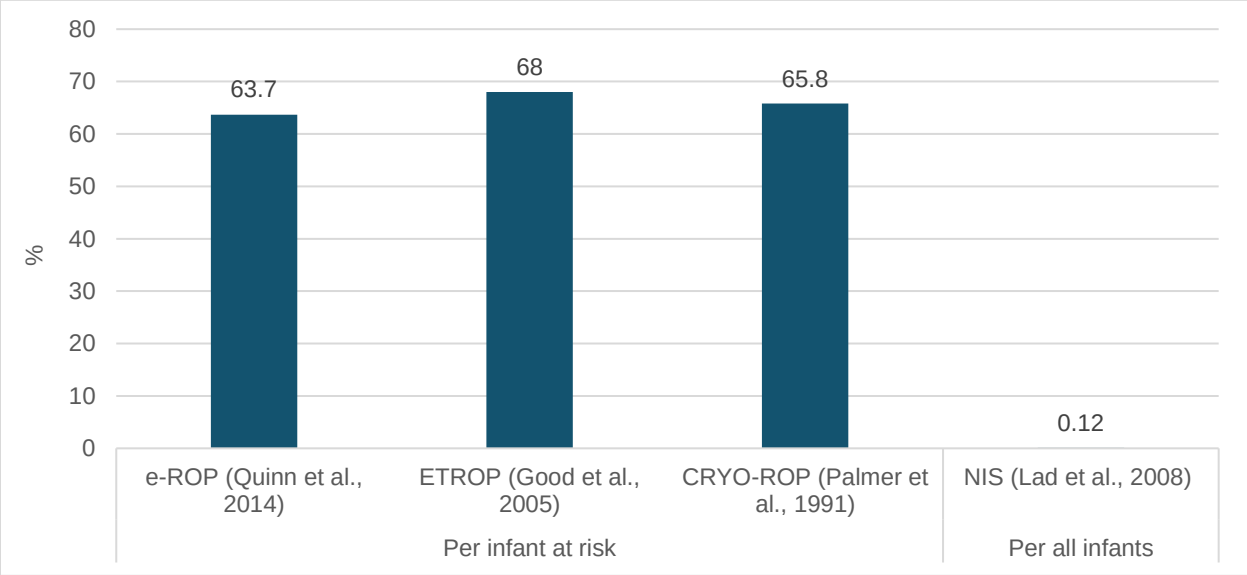
Figure 7.0 Retinopathy of Prematurity Prevalence Sources

Author	Date of Publication	Title	Date of Data Collection	Data Source	Sample Size
Quinn GE, Barr C, et al.	2016	Changes in Course of Retinopathy of Prematurity from 1986 to 2013: Comparison of Three Studies in the United States	1986-2013	CRYO-ROP, ETROP, e-ROP	4,099; 6,998; 1,284
Quinn, GE, et al.	2014	Telemedicine Approaches to Evaluating Acute-Phase Retinopathy of Prematurity: Study Design	2011-2013	e-ROP	1,284
Lad EM, Nguyen TC, et al.	2008	Retinopathy of Prematurity in the United States	1997-2002	NIS	22,939,000
Good WV, Hardy RJ, et al.	2005	The Incidence and Course of Retinopathy of Prematurity: Findings from the Early Treatment for Retinopathy of Prematurity Study	2000-2002	ETROP	6,998
Palmer EA, Flynn JT, et al.	1991	Incidence and Early Course of Retinopathy of Prematurity. The Cryotherapy for Retinopathy of Prematurity Cooperative Group	1986-1987	CRYO-ROP	4,099

7.1 Overall Retinopathy of Prematurity (ROP) Prevalence Rates

Figure 7.1 below shows prevalence estimates from the four studies included in this section. Estimates varied from 0.12% reported by Lad et al. (2008) to 68% reported by Good et al. (2005). The estimate reported by Lad et al. (2008) is based on the entire sample of newborns, whereas the estimates reported by Quinn et al. (2004), Good et al. (2005), and Palmer et al. (1991) are based on a high-risk population. The CRYO-ROP, ETROP and e-ROP studies determined the incidence of ROP by using ophthalmologists to diagnose infants enrolled in each respective study. These literature review results demonstrate the lack of data available on the burden of ROP among the general population and among different socioeconomic and demographic groups.

Figure 7.1 Overall ROP Prevalence Rates in Selected Studies



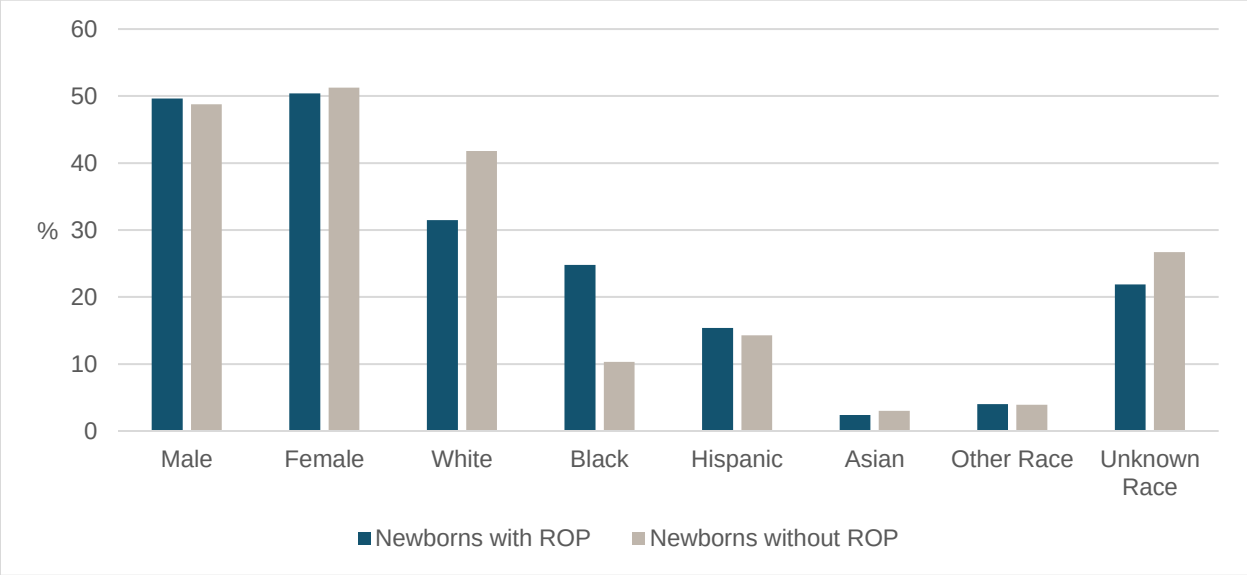
7.2 Telemedicine Approaches to Evaluating Acute-phase Retinopathy of Prematurity

The Telemedicine Approaches to Evaluating Acute-phase Retinopathy of Prematurity (e-ROP) consisted of 12 sites across the U.S. and Canada that were determining how to identify infants at-risk for ROP, particularly in remote areas.[87] In the U.S., 1284 infants weighing less than 1251 g were enrolled in the study from May 2011 to October 2013. These infants were examined by an ophthalmologist using the International Classification for ROP. Infants were deemed to have "referral-warranted ROP (RW-ROP)" if they had "ROP in zone I, stage 3 ROP or worse, or plus disease." Overall, 63.7% of infants were determined to have ROP. Quinn et al. (2016) performed secondary data analysis to compare the e-ROP study with CRYO-ROP and ETROP. Details are provided in Section 7.5. Figures 7.3, 7.4, and 7.5, below compare overall rates of ROP, moderately severe rates, and rates of plus with disease across these three studies.[86]

7.3 National Inpatient Sample

The National Inpatient Sample is a 20% sample based on a stratified probability sample of all U.S. hospital discharges; it is maintained by the Agency for Healthcare Research and Quality (AHRQ).[84] Lad et al. (2008) used International Classification of Diseases, 9th Revision Clinical Modification (ICD-9CM) codes to identify cases of retinopathy of prematurity (ROP) from a sample of 22,939,000 newborns who were born from 1997-2002, of which 0.01% (n=28,011) developed ROP. Figure 7.2 below shows the demographic characteristics of newborns who developed ROP. Further analysis by Lad et al. (2008) revealed that Hispanics were more likely to develop ROP.

Figure 7.2 The Distribution of Characteristics Among Newborns with ROP vs. Newborns without ROP [84]



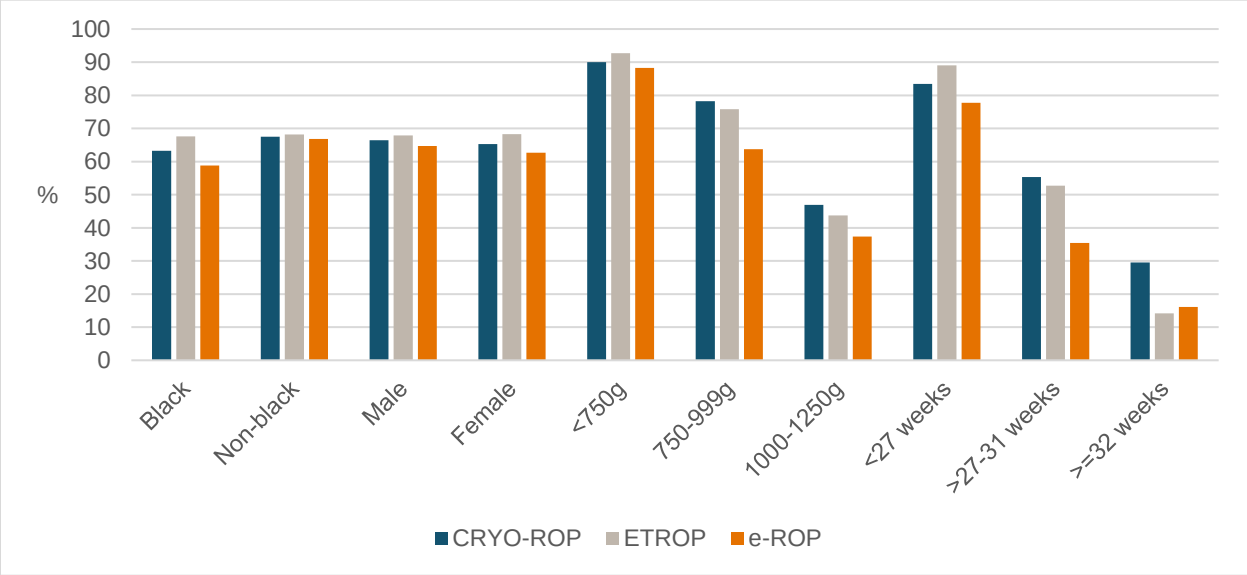
7.4 The Early Treatment for Retinopathy Study

The Early Treatment for Retinopathy Study (ETROP) examined 6,998 infants weighing less than 1,251 g from October 2000 to September 2002 in 26 centers across the United States.[88] Ophthalmologists utilized the International Classification of ROP to diagnose ROP during examinations. Similar to the CRYO-ROP study, described below, threshold ROP was defined as: “zone I and II, 5 contiguous or 8 composite hours of stage 3 ROP, plus disease.” Investigators defined prethreshold ROP as “zone I, any ROP; zone II, stage 2 ROP with plus disease; or zone II, stage 3 ROP with plus disease but less than required threshold hours.” Researchers found that 68% of infants developed ROP, which was similar to that of the CRYO-ROP study described below. Quinn et al. (2016) performed secondary data analysis to compare the ETROP study with CRYO-ROP and e-ROP.[86] Figures 7.3, 7.4, and 7.5, below compare overall rates of ROP, moderately severe rates, and rates of plus with disease across these three studies. In comparing their results to the earlier CRYO-ROP study, ETROP investigators concluded that severe ROP was more common among infants with ROP in the ETROP study compared to the CRYO-ROP study.

7.5 Cryotherapy for ROP Study

The Cryotherapy for Retinopathy of Prematurity study (CRYO-ROP) was a multicenter study that enrolled 4,099 infants weighing less than 1,252 g at birth from January 1986 to November 1987.[89] Infants underwent ophthalmic examinations beginning at 4-6 weeks to determine the incidence of ROP. Ophthalmologists utilized the International Classification of ROP to diagnose ROP during examinations. Overall 65.8% of infants developed some form of ROP. The CRYO-ROP study defined threshold ROP as: "zone I and II, 5 contiguous or 8 composite hours of stage 3 ROP, plus disease." Investigators defined prethreshold ROP as "zone I, any ROP; zone II, stage 2 ROP with plus disease; or zone II, stage 3 ROP with plus disease but less than required threshold hours." Palmer et al (1991) found that ROP was more common among infants that were of lower birth weight (BW) and younger gestational age (GA). Quinn et al (2016) performed secondary data analysis to ascertain the national burden of ROP using the CRYO-ROP study in conjunction with the ETROP and e-ROP study.[86] Figures 7.3, 7.4, and 7.5, below compare overall rates of ROP, moderately severe rates, and rates of plus with disease across these three studies.

Figure 7.3 Percentage of Infants with Any Form of ROP in CRYO-ROP, ETROP and e-ROP [86]



Quinn et al. 2016 notes that the ETROP trial used similar definitions for prethreshold and threshold, while e-ROP study used the term "referral warranted ROP" described above.[86] To compare rates of severe ROP, Quinn et al. 2016 equated "prethreshold or worse" to "referral warranted" ROP. These severe rates of ROP from CRO-ROP, ETROP, and e-ROP are shown below in Figure 7.4 Quinn et al. 2016 also compared rates of ROP plus disease among the three studies, shown in Figure 7.5. In looking at rates over time among these studies, Quinn et al. 2016 concluded that the birth weight (BW) and gestational age (GA) of infants enrolled in ROP studies has decreased, while the prevalence and onset of ROP has remained stable over time.

Figure 7.4 Percentage of Infants with Moderately Severe ROP: Prethreshold ROP or Worse from CRRO-ROP and ETROP Studies and Referral-Warranted ROP in e-ROP [86]

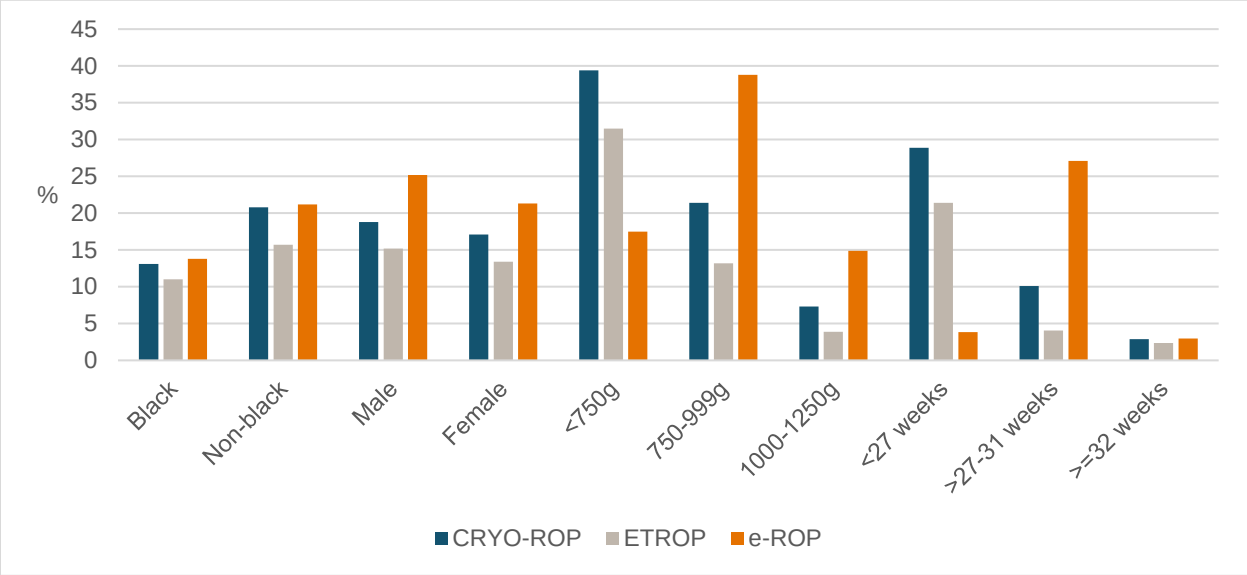
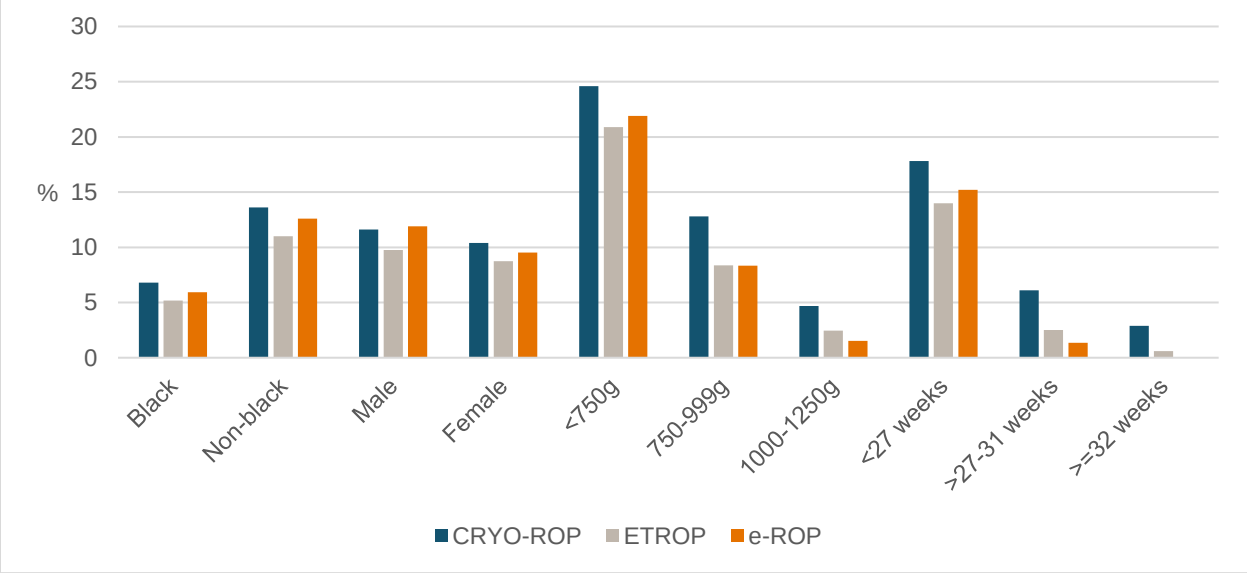


Figure 7.5 Percentage of Infants with Plus Disease from CRYO-ROP, ETROP, and e-ROP [86]



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