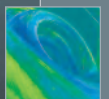
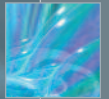


Chronic Disease and Medical Innovation in an Aging Nation

The Silver Book[®]: Vision Loss

VOLUME II



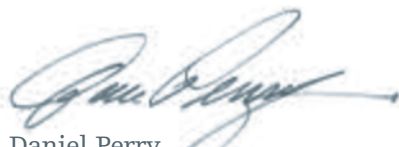
Preface

Chronic diseases and conditions impact 85% of Americans age 65 and older, and cost our nation \$1.7 trillion a year. With the leading edge of the Baby Boomers now entering the Medicare rolls and a Silver Tsunami of disease and disability threatening to cripple our economy, policymakers are urgently searching for ways to curb the growth of health spending.

In order to promote national policies that turn to investments in research and innovation rather than short-term cost-cutting and health care rationing, the Alliance for Aging Research publishes *The Silver Book®: Chronic Disease and Medical Innovation in an Aging Nation*. *The Silver Book* is an almanac of compelling statistics that spotlight this mounting burden of chronic diseases and the power of innovation to reduce that burden. *The Silver Book* extracts the key findings from dense reports and technical studies, and provides essential information in a single, easy-to-use, and well-referenced resource.

First launched in 2006, the original *Silver Book* and subsequent volumes have become trusted resources for policymakers and thought leaders. We are particularly pleased to partner with the Alliance for Eye and Vision Research (AEVR) during their *Decade of Vision* to produce Volume II of *The Silver Book: Vision Loss*. Volume II brings updated data on age-related macular degeneration (AMD), diabetic retinopathy, and glaucoma—which along with cataract are the eye diseases that disproportionately impact older Americans. This new volume also highlights the exciting changes and discoveries in vision research and treatment from the past 5 years. **All information pertaining specifically to the older population is in silver type.** Note that information may overlap or conflict in part—interested readers should examine the original source to determine which evidence is a better match for the population they are interested in, and to explore the science and methodology of the source. All original sources are available on-line at www.silverbook.org/visionloss; a site that is easily searchable and regularly updated.

More than 38 million Americans age 40 and older are blind, visually impaired, or have an age-related eye disease, and adult vision loss costs our economy more than \$51 billion a year. While for the most part we have not seen the number of Americans impacted by these eye diseases decrease since the release of Volume I, we have seen exciting new treatments decrease their burden. The use of anti-VEGFs to treat AMD, supplements for prevention, and combined statin treatment to slow progression of diabetic retinopathy, are just a few of the innovations that are bringing hope to millions of Americans. The Alliance for Aging Research and AEVR believe that this resource will showcase that value and enrich the national debate on health care and research funding.



Daniel Perry
President & CEO
Alliance for Aging Research



Advancing Science. Enhancing Lives.

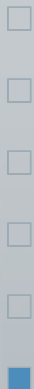
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Cost of Vision Loss

Innovative Medical Research

Conclusion

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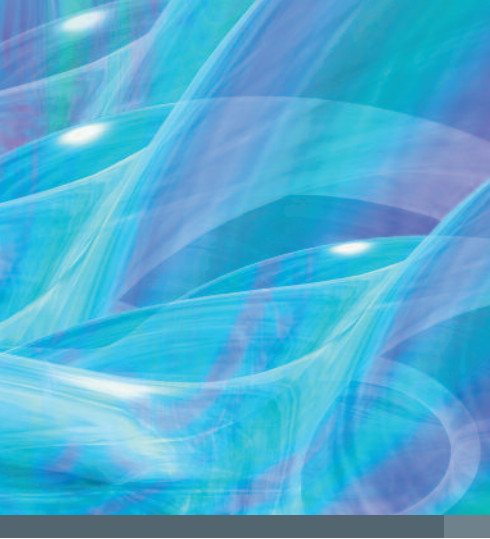


Chronic Disease and Medical Innovation in an Aging Nation

The Silver Book[®]: Vision Loss

VOLUME II

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Introduction

AEVRR is pleased to have partnered with the Alliance for Aging Research to produce *The Silver Book: Vision Loss Volume II*. It is being released as a resource of AEVRR's *Decade of Vision 2010-2020 Initiative (DOV)*, a sustained educational program on the benefits of federally funded vision research that saves and restores vision, thereby reducing healthcare costs, maintaining independence, and improving quality of life. The *DOV* grew out of the 40th anniversary celebration of the National Eye Institute (NEI), which leads our nation's vision research efforts from within the National Institutes of Health (NIH). In 2009, Congress passed H. Res. 366 and S. Res. 209 recognizing NEI's anniversary and designating 2010-2020 as the decade of vision.



This decade is especially important since the first wave of 78 million Baby Boomers began to turn 65 in 2010. Every day for the next 10 years, around 10,000 Americans will turn 65 and be at greater risk for eye disease. NEI predicts that by 2020, more than 50 million Americans will be blind, have low vision, or have an age-related eye disease such as age-related macular degeneration (AMD), glaucoma, diabetic retinopathy, or cataract.

Fortunately, NEI has an opportunity to build upon many of its research discoveries, including the discovery of eye-disease associated genes—about one-quarter of all genes discovered to-date—to develop new diagnostics and treatments. We are on the threshold of great discoveries and are already witnessing significant breakthroughs. As NIH Director Francis Collins, MD, PhD, stated before a June 2010 hearing of the House Energy and Commerce Committee, "Twenty years ago, we could do little to prevent or treat AMD. Today, because of new treatments and procedures based in part on NIH research, 1.3 million Americans at risk for severe vision loss over the next five years can receive potentially sight-saving therapies."

This updated volume of *The Silver Book: Vision Loss* brings together important information on the burden of vision loss and the promise of research. As with Volume I, this update focuses on the incidence and costs of AMD, glaucoma, and diabetic retinopathy. Cataract, the fourth of the major aging eye diseases, is now routinely treated through outpatient surgery that is proven to restore lost vision, be cost-effective, and have one of the most beneficial impacts on quality of life of all treatments reimbursed by public or private insurance.

Despite more than 5 years since the release of Volume I, the cost/benefit data are still scarce regarding approved ophthalmic drugs to treat AMD—also being studied to treat diabetic macular edema and retinopathy—although data on the clinical benefit is substantial. However, almost daily, vision researchers are announcing dramatic advances to benefit patients. These data will be added to the on-line version of Volume II, which can be found at www.silverbook.org/visionloss, so that readers can access the latest data resulting from innovation.

Stephen J. Ryan, M.D.
 President, Board of Directors
 Alliance for Eye and Vision Research



DECADE OF VISION
 an initiative of the
2010-2020
 Alliance For Eye And Vision Research



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The Human and Economic Burden

Cost of Vision Loss

■ **L**ately it seems you can't miss the headlines announcing the exciting breakthroughs scientists are making in preventing and even reversing vision loss. These significant advances—and the promise they hold for more—are coming none too soon for the millions of Americans living with low vision and blindness. The toll of vision loss in the U.S. is enormous and paid by the individual, their family, and our healthcare system and economy.

■ Every 7 minutes another American becomes blind or visually impaired, often finding that they face functional limitations, dependency, depression, and a greater risk of death. Patients are so concerned about impact on quality of life that they are willing to trade remaining years of their life for restored vision. Legally blind patients reported that they would be willing to trade 36% of their remaining years to regain perfect vision. Those with no light perception at all would be willing to trade 74% of their remaining years—3 out of every 4!

The expenses of vision loss also add up. People with vision loss tend to visit their doctors more, take additional medications and supplements, and need help with the activities of daily living that many of us take for granted. This is expensive for both the individual and our economy—chronic eye diseases and vision impairment cost the U.S. an estimated \$51 billion annually.

Age is a major risk factor for the most prevalent eye diseases with nearly 1 in 4 people age 80 and older either blind or vision impaired. The number of Americans with blindness, low vision, or an age-related eye disease is projected to grow to an estimated 50 million people by 2020. These individuals will also be living longer and seeing their vision loss and the cost of treating it progress.

While projections of future economic costs are scarce, they will surely be proportional to the rise in prevalence unless research and innovation provide some relief. Vision loss and blindness account for \$8 billion in lost productivity annually, posing a tremendous challenge to those who would otherwise remain in the workforce beyond age 65. In a nation urgently needing to encourage and support older workers, vision loss is going to become an enormous challenge for America.



Prevalence and Incidence of Vision Loss

Vision Loss

- More than 38 million Americans age 40 and older are estimated to experience blindness, low vision, or an age-related eye disease.

Eye Disease Prevalence Research Group 2004, *Blindness*

- Age-related eye diseases affect more than 35 million Americans age 40 and older. The most common eye diseases in that age group are macular degeneration, glaucoma, diabetic retinopathy, and cataract.

Eye Disease Prevalence Research Group 2004, *Blindness*

- An estimated 2.6 million Americans over the age of 40 are visually impaired.

Prevent Blindness America 2008, *Vision Problems in the U.S.*

- An estimated 1 million Americans over the age of 40 are legally blind.

Prevent Blindness America 2008, *Vision Problems in the U.S.*

- Every 7 minutes, someone in the United States becomes blind or visually impaired.

American Foundation for the Blind, *Statistical Snapshots*

Age-Related Macular Degeneration

- An estimated 2.07 million Americans age 50 and older have age-related macular degeneration.

Prevent Blindness America 2008, *Vision Problems in the U.S.*

- An estimated 6.5% of Americans age 40 and older have age-related macular degeneration (AMD).

Klein et al. 2011, *Prevalence of Age-Related Macular Degeneration in the U.S. Population*

- An estimated 1.75 million Americans age 40 and older have *advanced* age-related macular degeneration (AMD). Another 7.3 million are at substantial risk for vision loss from AMD.

Friedman et al. 2004, *Prevalence of Age-Related Macular Degeneration in the U.S.*

- Every year, 200,000 Americans develop *advanced* age-related macular degeneration (AMD).

National Alliance for Eye and Vision Research, *Vision Impairment and Eye Disease is a Major Public Health Problem*

- The number of Medicare beneficiaries newly diagnosed with wet age-related macular degeneration (AMD) more than doubled between 1994 and 2006.

Day et al. 2011, *Medicare Costs for Neovascular Age-Related Macular Degeneration*

Diabetic Retinopathy

- From 2005 – 2008, around 4.2 million diabetics age 40 and older had diabetic retinopathy. Of these, 655,000 had *advanced* diabetic retinopathy that could lead to severe vision loss.

Centers for Disease Control and Prevention 2011, *National Diabetes Fact Sheet*

- Between 40% and 45% of all diabetics have some stage of diabetic retinopathy.

National Eye Institute, *Facts About Diabetic Retinopathy*

- Up to 80% of diabetics who have had the disease for 10 years or more are affected by diabetic retinopathy.

Kertes et al. 2008, *Evidence-Based Eye Care*

- 1 in 12 diabetics age 40 and older has advanced diabetic retinopathy that threatens their vision.

Kempen et al. 2004, *The Prevalence of Diabetic Retinopathy Among Adults in the U.S.*

- Around 1 in 5 individuals with diabetes in the NEI-sponsored Los Angeles Latino Eye Study (LALES) was newly diagnosed during the study. Of those who were newly diagnosed, 23% were found to have diabetic retinopathy.

Varma et al. 2004, *Prevalence of Diabetic Retinopathy in Adult Latinos*

Glaucoma

- Close to 2.3 million Americans age 40 and older have glaucoma—1.9% of the 40 and older population.

Prevent Blindness America 2008, *Vision Problems in the U.S.*

- Around 50% of those with glaucoma are not aware that they have the disease.

Friedman et al. 2004, *Prevalence of Open-Angle Glaucoma Among Adults in the U.S.*

- Glaucoma is almost 3 times more common in African Americans than in whites.

Friedman et al. 2004, *Prevalence of Open-Angle Glaucoma Among Adults in the U.S.*

Age—A Major Risk Factor

Vision Loss

■ More than 2.1 million Americans age 80 and older have low vision or are blind—23.7% of the 80 and older population.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

■ More than 1.5 million Americans age 80 and older have low vision—16.7% of the 80 and older population.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

■ Around 648,000 Americans age 80 and older are blind—7% of the 80 and older population.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

■ 6.5 million Americans over the age of 65 have severe visual impairment that threatens to limit their mobility, independence, and quality of life.

American Foundation for the Blind, *Aging and Vision Loss Fact Sheet*

■ Americans age 80 and older have the highest rates of blindness. They are also the fastest growing segment of our population.

Prevent Blindness America 2008, *Vision Problems in the U.S.*

■ In one study, individuals age 80 and older made up less than 8% of the population, yet accounted for 69% of cases of blindness.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

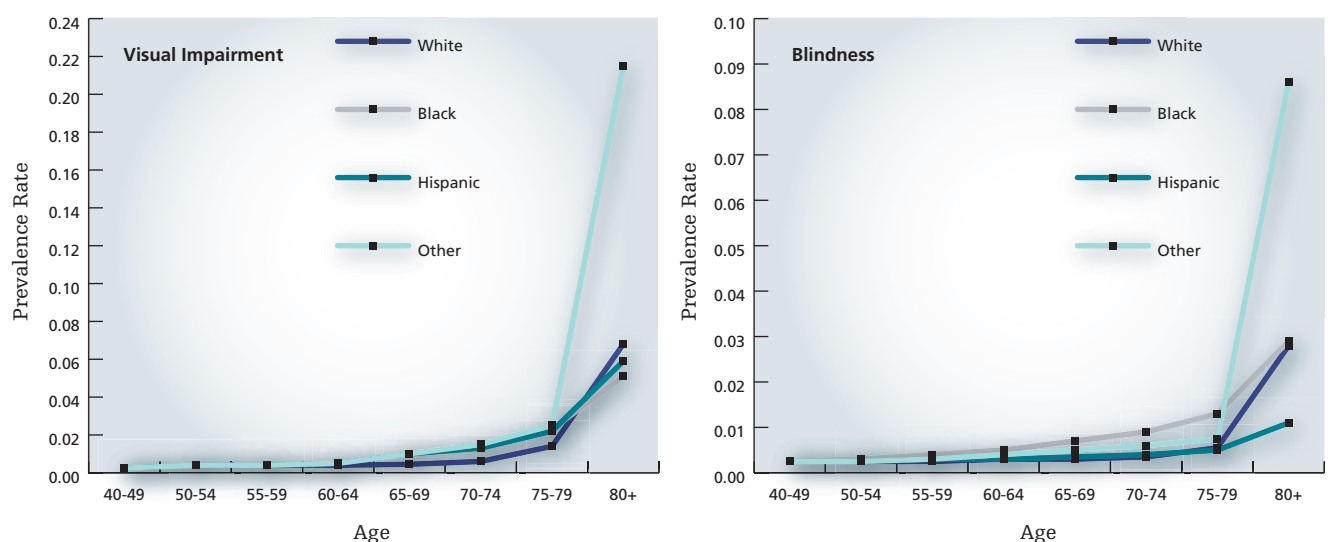
■ 10.3% of the non-institutionalized adults 65 years and older have some trouble seeing, even with glasses or contacts. That number increases to 16.5% in adults 75 years and older.

Centers for Disease Control and Prevention 2010, *Health*

■ A longitudinal study that followed Medicare patients found that after 9 years, almost 50% of survivors had developed a major chronic age-associated eye disease.

Lee et al. 2003, *Longitudinal Prevalence of Major Eye Diseases*

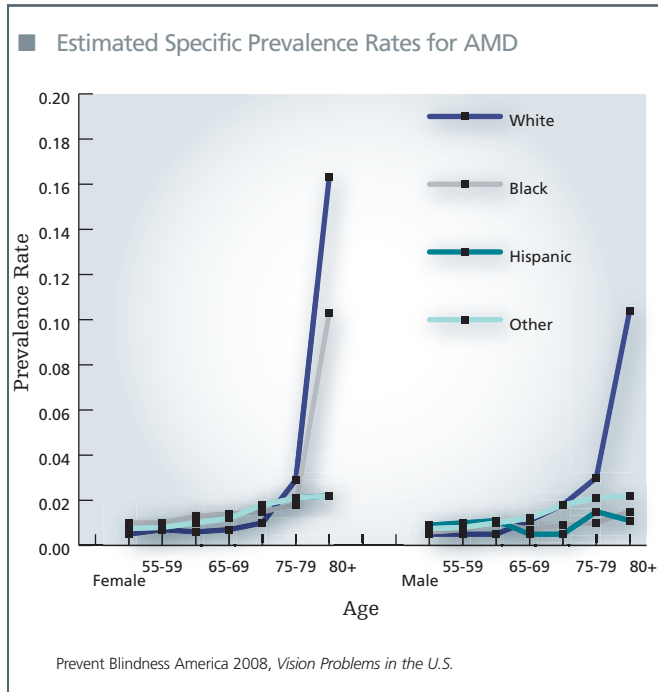
■ Estimated Specific Prevalence Rates for Visual Impairment and Blindness



Prevent Blindness America 2008, *Vision Problems in the U.S.*



Age-Related Macular Degeneration



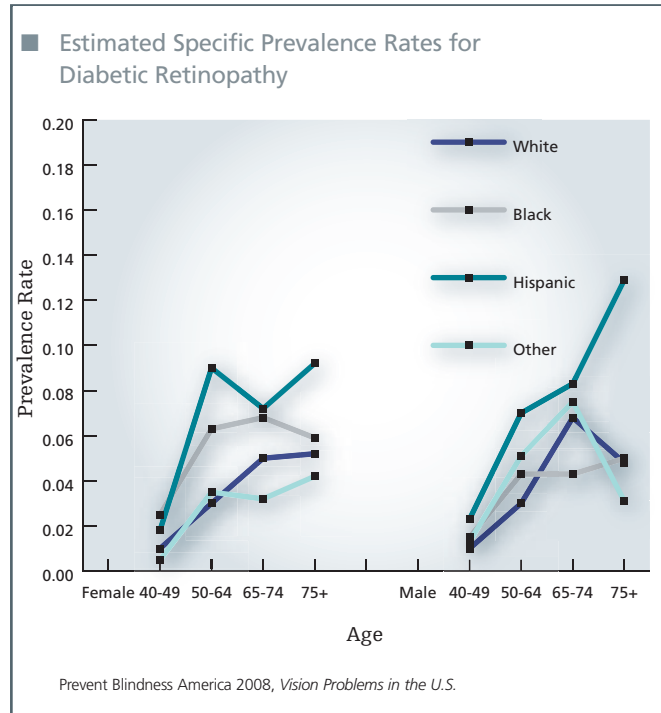
- The risk of getting age-related macular degeneration (AMD) increases from 2% for those ages 50-59, to nearly 30% for those over the age of 75.

National Eye Institute, *Facts About Age-Related Macular Degeneration*

- More than 1 in 10 Americans over the age of 80 has advanced age-related macular degeneration (AMD).

Friedman et al. 2004, *Prevalence of Age-Related Macular Degeneration in the U.S.*

Diabetic Retinopathy

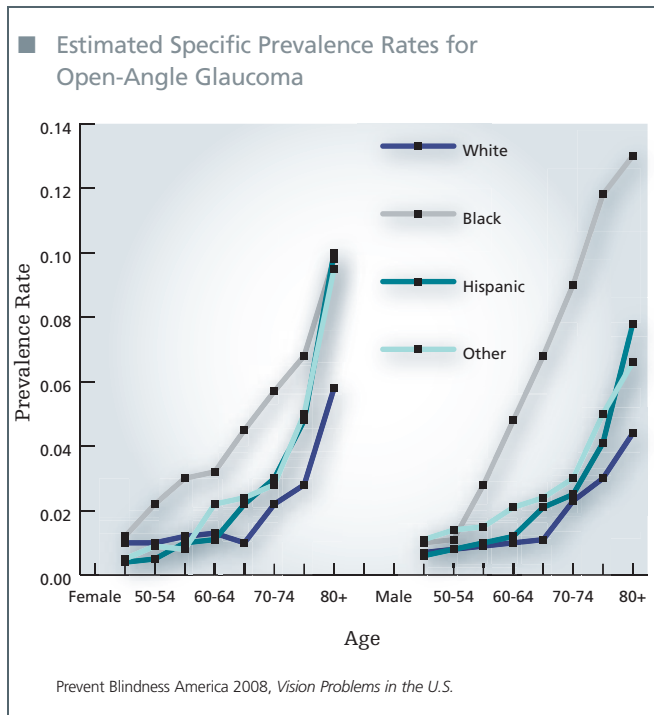


- Around 824,000 Americans age 75 and older have diabetic retinopathy—5% of the 75 and older population.

Kempen et al. 2004, *The Prevalence of Diabetic Retinopathy among Adults in the U.S.*

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Glaucoma



- Around 711,000 Americans age 80 and older have glaucoma—7.7% of the 80 and older population.
Friedman et al. 2004, Prevalence of Open-Angle Glaucoma Among Adults in the U.S.
- Glaucoma affects less than 1 in 100 people ages 40 to 49. That rate increases to close to 1 in 10 for individuals over the age of 80.
Friedman et al. 2004, Prevalence of Open-Angle Glaucoma Among Adults in the U.S.

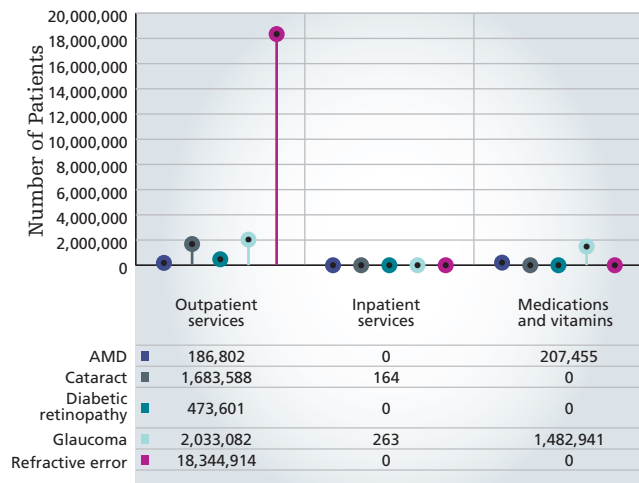


The Burden of Vision Loss

The Human Burden

Vision Loss

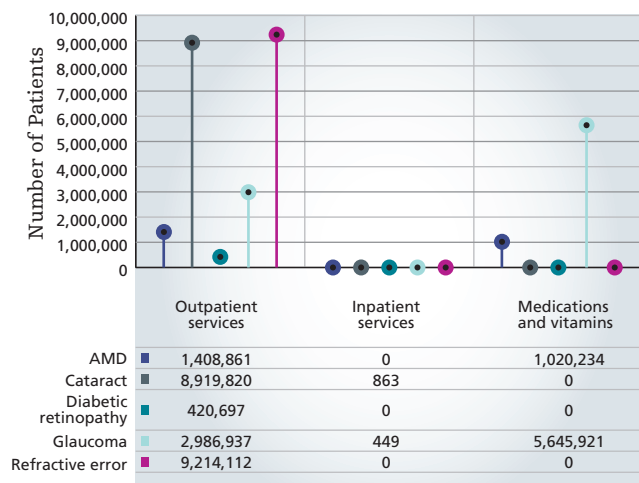
■ Number of Patients Aged 40 to 64 Using Medical Services, Medications and Vitamins



Prevent Blindness America 2007, *The Economic Impact of Vision Problems*

* Note that data on refractive error from the original graph has been removed.

■ Number of Patients Aged 65 and Older Using Medical Services, Medications and Vitamins



Prevent Blindness America 2007, *The Economic Impact of Vision Problems*

* Note that data on refractive error from the original graph has been removed.

- For assistance getting around, more than 100,000 visually impaired Americans use long canes, and more than 7,000 use guide dogs.

American Foundation for the Blind, *Facts and Figures on Adults with Vision Loss*

- Vision conditions cause activity limitations in 8.9% of Americans age 85 and older.

Centers for Disease Control and Prevention 2009, *Health*

- Vision loss is a leading cause of falls in the elderly. One study found that visual field loss was associated with a 6-fold risk of frequent falls.

Ramratten et al. 2001, *Prevalence and Causes of Visual Field Loss in the Elderly*

- The ability to recognize faces declines with age and requires, on average, being 5 feet closer to the face with every decade after the age of 60.

Lott et al. 2005, *Face Recognition in the Elderly*

- While only 4.3% of the 65 and older population lives in nursing homes, that number rises to 16% of those who are visually impaired and 40% of those who are blind.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- An estimated 424,801 more visually impaired and blind individuals live in nursing homes than would be expected if they had normal vision.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The data from the NEI-sponsored Age-Related Eye Disease Study (AREDS) found that persons with vision worse than 20/40 OU (oculus unitas, meaning "in both eyes") were more likely to be cognitively impaired than those with a visual acuity of 20/40 OU or better.

Clemons et al. 2006, *Cognitive Impairment in the Age-Related Eye Disease Study*

- In a study of new applicants for recent vision loss rehabilitative services, 7% had current major depression and 26.9% met the criteria for subthreshold depression.

Horowitz et al. 2005, *Major and Subthreshold Depression Among Older Adults Seeking Vision Rehabilitation Services*

- Progression of vision loss from normal to blind is associated with more than 1.5-fold increased odds of depression and injury, and 2.5- to 3-fold increased odds of utilization of skilled nursing facilities and long term care.

Javitt et al. 2007, *Association between Vision Loss and Higher Medical Care Costs in Medicare Beneficiaries*

- Individuals who are visually impaired are less likely to be employed—44% are employed compared to 85% of adults with normal vision.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- A study evaluating quality of life found that patients with no light perception in one eye who were asked to imagine the same scenario in their second eye, were willing to trade almost 3 out of every 4 years of their remaining life in return for perfect vision in both eyes. Those with light perception to counting fingers would trade around 1 of every 2 remaining years, and those with 20/200-20/400 would trade around 1 of every 3 remaining years.

Brown et al. 2001, *Utility Values Associated with Blindness in an Adult Population*

- The total annual loss for individuals in the U.S. who are visually impaired or blind is estimated at more than 209,000 quality-adjusted life-years.

Frick et al. 2007, *Economic Impact of Visual Impairment and Blindness in the U.S.*

- Even mild visual impairment more than doubles the risk of mortality over a 5-year period.

McCarty et al. 2001, *Vision Impairment Predicts 5 Year Mortality*

Age-Related Macular Degeneration

- Age-related macular degeneration (AMD) is the leading cause of irreversible vision loss in people over the age of 65.

National Eye Institute 2006, *Progress in Eye and Vision Research*

- Age-related macular degeneration (AMD) is the leading cause of blindness among white Americans—accounting for 54% of cases of blindness.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

- Patients with wet age-related macular degeneration (AMD) reported 45% worse vision-related functioning, 13% worse overall well-being, 30% more anxiety, and 42% more depression than those without the disease. They also reported a doubled fall rate and a quadrupled need for assistance with activities of daily living.

Soubrane et al. 2007, *Burden and Health Care Resource Utilization in Neovascular Age-Related Macular Degeneration*

- One study reported emotional distress scores in age-related macular degeneration (AMD) patients comparable to scores of individuals with life-threatening illnesses such as melanoma and HIV.

Mitchell and Bradley 2006, *Quality of Life in Age-Related Macular Degeneration*

- Compared to elderly persons without visual impairment, those with macular degeneration are 8 times more likely to report difficulty shopping, 13 times more likely to have difficulty managing finances, 4 times more likely to have difficulty preparing meals, 12 times more likely to have problems making phone calls, and 9 times more likely to have problems with light housework.

Williams et al. 1998, *The Psychosocial Impact of Macular Degeneration*

- Visual loss from subfoveal choroidal neovascularization, a characteristic of wet age-related macular degeneration (AMD), was found to have a profound impact on how patients felt about their health-related quality of life—rating it as low or lower than patients with renal failure and AIDS.

Bass et al. 2004, *Patients' Perceptions of the Value of Current Vision*

- Individuals with early-stage age-related macular degeneration (AMD) are almost 2 times more likely to have a stroke than those who do not have the eye disease.

Wong et al. 2006, *Age-Related Macular Degeneration and Risk for Stroke*

- Various studies found between 13% and 24% of age-related macular degeneration (AMD) patients had experienced visual hallucinations.

Mitchell and Bradley 2006, *Quality of Life in Age-Related Macular Degeneration*

- In 2001, an estimated 1.4 million age-related macular degeneration (AMD) patients visited physicians or hospitals for treatment of their disease.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- Over a 1-year period, 54% of individuals with age-related macular degeneration (AMD) reported a fall and 30% reported more than one. Of all reported falls, 63% resulted in an injury.

Wood et al. 2011, *Risk of Falls, Injurious Falls, and Other Injuries Resulting from Visual Impairment Among Older Adults with AMD*



Diabetic Retinopathy

- Every year, between 12,000 and 24,000 Americans lose their sight to diabetes.

American Diabetes Association, *State Legislative Priorities*

- Diabetes is the leading cause of new blindness among adults aged 20-74.

Centers for Disease Control and Prevention 2011, *National Diabetes Fact Sheet*

- Individuals with diabetes are more than twice as likely to be visually impaired as those without the disease.

Ryskulova et al. 2008, *Self-Reported Age-Related Eye Diseases and Visual Impairment in the U.S.*

- In 2001, approximately 420,000 diabetic retinopathy patients visited physicians or hospitals for treatment of their disease.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- Diabetic retinopathy often causes vision loss and blindness during working age years, resulting in more disability and person-years of vision lost than other eye disease.

Kempen et al. 2004, *The Prevalence of Diabetic Retinopathy Among Adults in the U.S.*

- A study evaluating quality of life using utility values, found that diabetic retinopathy patients with best-corrected visual acuity of 20/20 and 20/25, were willing to trade 15% of their remaining years of life for near perfect vision. Those who were legally blind (best-corrected visual acuity of counting fingers to hand motions) from diabetes were willing to trade 41% of their remaining years in return for perfect vision.

Brown et al. 1999, *Utility Values and Diabetic Retinopathy*

Glaucoma

- Approximately 120,000 people have gone blind because of glaucoma—9-12% of all cases of blindness in the U.S.

Glaucoma Research Foundation, *Glaucoma Facts and Stats*

- Glaucoma is responsible for 3 of every 4 cases of visual impairment in the U.S.

Friedman et al. 2004, *Prevalence of Open-Angle Glaucoma Among Adults in the U.S.*

- A study of glaucoma patients found that compared with control subjects, they were over 3 times more likely to have fallen in the previous year, over 6 times more likely to have been involved in 1 or more motor vehicle collisions in the previous five years, and more likely to have been at fault in the collision.

Haymes et al. 2007, *Risk of Falls and Motor Vehicle Collisions in Glaucoma*

- Of Medicare beneficiaries who were blind from glaucoma, 25.3% were placed in nursing homes, 17% had incident depression, 15.5% experienced a fall and/or an accident, 16.9% suffered an injury, and 7% fractured a femur.

Bramley et al. 2008, *Impact of Vision Loss on Costs and Outcomes in Medicare Beneficiaries with Glaucoma*

- Medicare beneficiaries with vision loss from glaucoma are significantly more likely to be placed in a nursing home and to develop depression, 67% more likely to fracture a femur, and 58.6% more likely to have a fall or an accident—compared to those with no vision loss.

Bramley et al. 2008, *Impact of Vision Loss on Costs and Outcomes in Medicare Beneficiaries with Glaucoma*

- In 2001, approximately 5.6 million prescriptions were filled for glaucoma patients.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- In 2001, approximately 2.9 million glaucoma patients visited physicians or hospitals for treatment of their disease.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- A common surgical procedure to relieve pressure in the eyes of glaucoma patients where other treatments have not been effective, has been found to increase the risk of cataract formation by 78%.

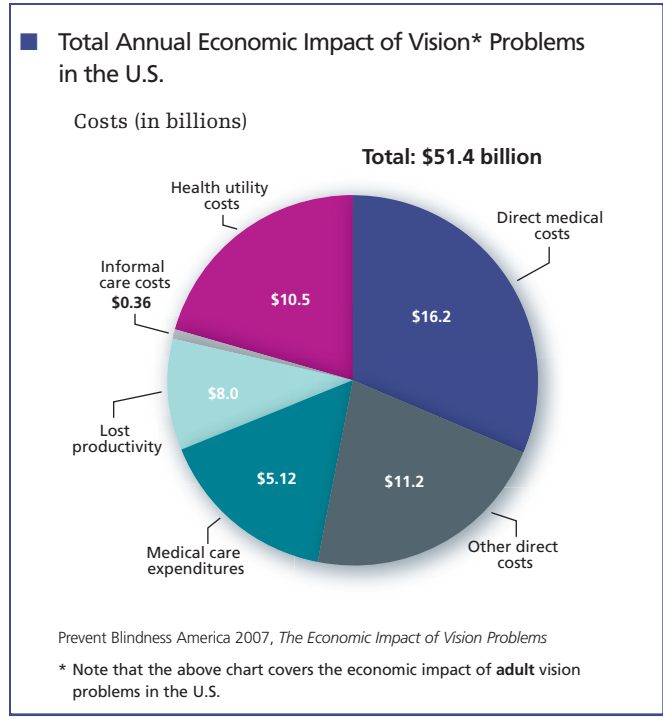
The AGIS Investigators 2001, *The Advanced Glaucoma Intervention Study*

The Economic Burden

Vision Loss

- The annual cost of adult vision problems in the U.S. is around \$51.4 billion.

Prevent Blindness America 2007, *The Economic Impact of Vision Problems*



- The annual burden to the U.S. economy of age-related macular degeneration (AMD), cataract, diabetic retinopathy, glaucoma, refractive errors, visual impairment, and blindness in adults age 40 and older is estimated at \$35.4 billion—\$16.2 billion in direct medical costs, \$11.1 billion in other direct costs, and \$8 billion in lost productivity.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

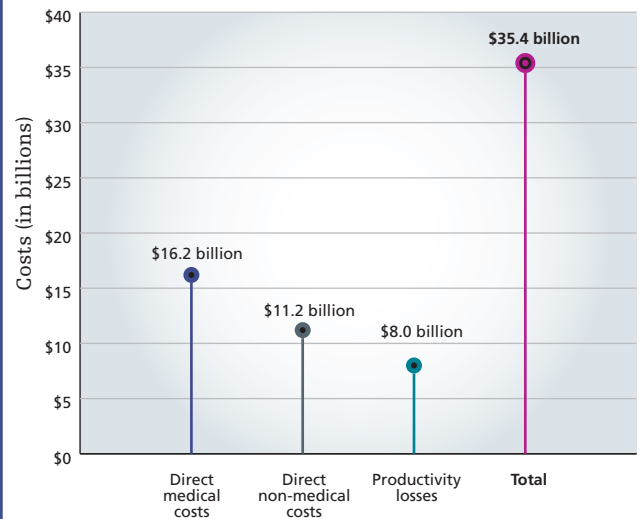
- Close to \$11 billion of the \$11.1 billion in direct nonmedical costs for adults with visual disorders, goes to nursing home care.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- Visual impairment and blindness account for \$8 billion in lost productivity annually.

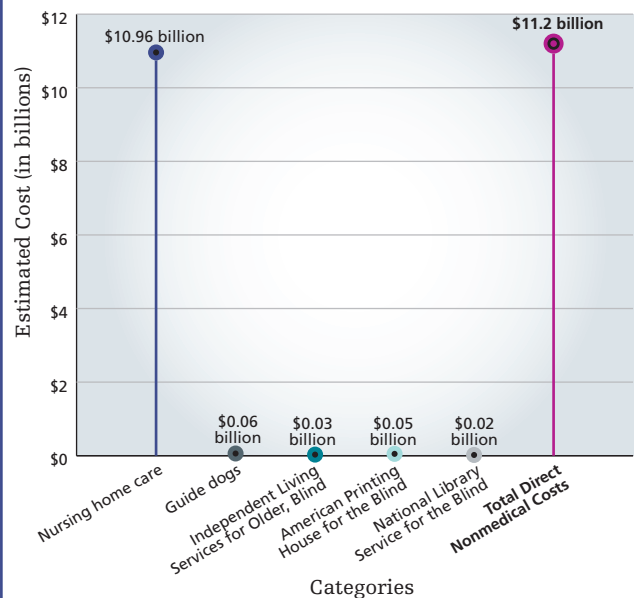
Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- Annual Total Burden to the U.S. Economy of AMD, Cataract, Diabetic Retinopathy, Glaucoma, Refractive Errors, Visual Impairment and Blindness



Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

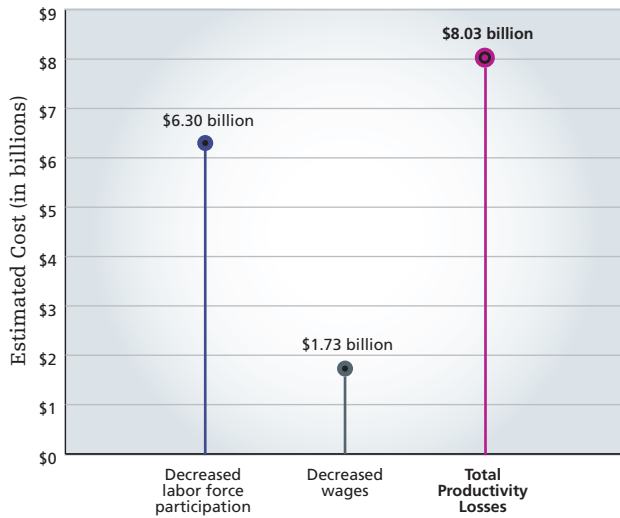
- Estimated Direct Nonmedical Costs for People Who Are Visually Impaired or Blind



Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*



Estimated Cost of Reduced Labor Force Participation by People Who are Visually Impaired or Blind



Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The excess economic burden of visual impairment and blindness of individuals age 40 and older on the individual, caregivers, and other health care payers is an estimated \$5.48 billion annually—\$5.12 billion in additional medical care expenditures and \$360 million in informal care costs.
Frick et al. 2007, Economic Impact of Visual Impairment and Blindness in the U.S.
- Visual disorders cause an annual health utility loss of approximately \$10.5 billion. This figure measures lost quality of life when a disease has little or no short-term impact on mortality.
Frick et al. 2007, Economic Impact of Visual Impairment and Blindness in the U.S.
- An individual who is visually impaired or blind accumulates nearly \$1,479 in vision-related expenses each year—not including health utility or QALY losses. At this rate, after 8 years an individual would accumulate \$10,000 in excess expenditures.
Frick et al. 2007, Economic Impact of Visual Impairment and Blindness in the U.S.
- The average annual salary for adults who are visually impaired is close to \$10,000 less than for those with normal vision.
Rein et al. 2006, The Economic Burden of Major Adult Visual Disorders in the U.S.

- The annual governmental budgetary impact of major adult visual disorders is estimated to be at least \$13.7 billion.

Rein et al. 2006, The Economic Burden of Major Adult Visual Disorders in the U.S.

- Visual impairment (compared to no visual impairment) is associated with more than \$1,000 in excess annual medical expenses per person.

Frick et al. 2007, Economic Impact of Visual Impairment and Blindness in the U.S.

- Blindness (compared to no visual impairment) is associated with more than \$2,000 in excess annual medical expenses per person.

Frick et al. 2007, Economic Impact of Visual Impairment and Blindness in the U.S.

- Medicare beneficiaries with vision loss incur significantly higher costs than individuals with normal vision. Approximately 90% of the higher annual costs are non-eye related medical costs—\$2,193 for those with moderate loss, \$3,301 for those with severe loss, and \$4,443 for those who are blind. Extrapolating to the entire Medicare population, blindness and vision loss are associated with \$2.14 billion in non-eye related costs (in 2003 dollars).

Javitt et al. 2007, Association between Vision Loss and Higher Medical Care Costs in Medicare Beneficiaries

- The excess yearly nursing home cost for those with vision loss, beyond the expected cost for those with normal vision, is \$450 for those with moderate vision loss, \$1,225 for those with severe vision loss, and \$3,275 for those with blindness.

Javitt et al. 2007, Association between Vision Loss and Higher Medical Care Costs in Medicare Beneficiaries

- Around \$62 million a year is spent on guide dogs for individuals 40 years and older with visual impairment (in 2004 dollars).

Rein et al. 2006, The Economic Burden of Major Adult Visual Disorders in the U.S.

Age-Related Macular Degeneration

Note that available data does not include the cost of using the latest generation of ophthalmic drugs or the value of the concomitant benefits.

- The annual direct medical costs (including outpatient, inpatient, and prescription drug services) for Americans age 40 and older with age-related macular degeneration (AMD) is \$575 million.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The average cost in 2004 per age-related macular degeneration (AMD) patient age 40 to 64 using outpatient services was \$305. The average cost per patient 65 years and older was \$272.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The average cost in 2004 per age-related macular degeneration (AMD) patient age 40 and older using medications and vitamins was \$110.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- For beneficiaries with wet age-related macular degeneration (AMD), annual Medicare Part B payments for vision care increased from \$1,504 per beneficiary in 1994 to \$3,263 in 2006—due in large part to anti-VEGF treatments.

Day et al. 2011, *Medicare Costs for Neovascular Age-Related Macular Degeneration*

Diabetic Retinopathy

Note that available data does not include the cost of using the latest generation of ophthalmic drugs or the value of the concomitant benefits.

- The annual direct medical costs (including outpatient, inpatient, and prescription drug services) for Americans age 40 and older with diabetic retinopathy is \$493 million.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The average cost in 2004 per diabetic retinopathy patient age 40 to 64 using outpatient services was \$629. The average cost per patient 65 years and older was \$463.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

Glaucoma

- The annual direct medical costs (including outpatient, inpatient, and prescription drug services) for Americans age 40 and older with glaucoma is \$2.86 billion.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- A study of Medicare beneficiaries with glaucoma showed that health care costs increased with degree of vision loss—ranging from \$8,157 per year for no vision loss to \$18,670 for blindness.

Bramley et al. 2008, *Impact of Vision Loss on Costs and Outcomes in Medicare Beneficiaries with Glaucoma*

- The average cost in 2004 per glaucoma patient age 40 to 64 using outpatient services was \$276. The average cost per patient 54 years and older was \$254.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The average cost in 2004 per glaucoma patient age 40 to 64 using inpatient services was \$2,270. The average cost per patient 65 years and older was \$4,929.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The average cost in 2004 per glaucoma patient age 40 to 64 using medications and vitamins was \$806.

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

- The average direct cost of glaucoma treatment ranges from \$623 per year for patients with early-stage glaucoma, to \$2,511 per year for end-stage patients. Medication costs make up the largest proportion of the total direct costs for all stages of the disease.

Lee et al. 2006, *A Multicenter, Retrospective Pilot Study of Resource Use and Costs Associated with Severity of Disease in Glaucoma*

- Expenditures for glaucoma medications are on the rise—mean annual glaucoma medication expenditures per individual increased from \$445 in 2001 to \$557 in 2006.

Lam et al. 2011, *Trends in Glaucoma Medication Expenditure*



The Future Cost of Vision Loss

Vision Loss

- Currently an estimated 38 million Americans suffer from blindness, low vision, or an age-related eye disease. That number is expected to grow to around 50 million by 2020.

Eye Disease Prevalence Research Group 2004, *Blindness*

- By 2020, the number of Americans age 40 and older who are blind or have low vision is projected to reach 5.5 million—growing from 3.3 million in 2004.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

- By 2020, the number of Americans age 40 and older with low vision is projected to reach 3.9 million—growing from 2.4 million in 2004.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

- By 2020, the number of Americans age 40 and older who are blind is projected to reach 1.6 million—growing 70% from 1 million in 2004.

Congdon et al. 2004, *Causes and Prevalence of Visual Impairment Among Adults in the U.S.*

Age-Related Macular Degeneration

- The number of cases of early AMD is projected to increase from 9.1 million in 2010 to 17.8 million in 2050.

Rein et al. 2009, *Forecasting Age-Related Macular Degeneration Through the Year 2050*

- The number of cases of visual impairment and blindness from age-related macular degeneration (AMD) is projected to increase from 620,000 in 2010 to 1.6 million in 2050—assuming no treatments.

Rein et al. 2009, *Forecasting Age-Related Macular Degeneration Through the Year 2050*

- The cost of age-related macular degeneration (AMD) is projected to increase to \$845 million over the next 10 years due to the growth of the older population.*

Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in the U.S.*

* See note in AMD section on pg. 14 for qualifications to these data.

Diabetic Retinopathy

- The number of Americans age 40 and older with diabetic retinopathy is projected to triple between 2005 and 2050—increasing from 5.5 million to 16 million. The number of people age 40 and older with vision-threatening diabetic retinopathy is also projected to grow from 1.2 million in 2005 to 3.4 million in 2050.

Saaddine et al. 2008, *Projection of Diabetic Retinopathy and Other Major Eye Diseases Among People with Diabetes Mellitus*

- The number of Americans age 65 and older with diabetic retinopathy is projected to close to quadruple between 2005 and 2050—increasing from 2.5 million to 9.9 million. The number of people age 65 and older with vision-threatening diabetic retinopathy is projected to grow from 0.5 million in 2005 to 1.9 million in 2050.

Saaddine et al. 2008, *Projection of Diabetic Retinopathy and Other Major Eye Diseases Among People with Diabetes Mellitus*

Glaucoma

- An estimated 2.3 million Americans 40 and older currently have glaucoma. That number is expected to grow by 50% to 3.36 million by 2020.

Friedman et al. 2004, *Prevalence of Open-Angle Glaucoma Among Adults in the U.S.*





Investing in Science

Innovative Medical Research

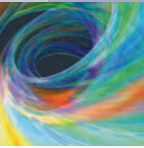
■ **T**he sheer numbers of our aging population guarantee that without significant breakthroughs, the impact of vision loss on our nation will only worsen. In less than 10 years, as many as 50 million Americans will be blind, have low vision, or be impacted by an age-related chronic disease. Our hope as a nation, and as individuals, lies in the advances in medical research that are already transforming vision care.

■ Scientists are making huge strides in understanding and treating age-related macular degeneration (AMD). Shortly before the release of Volume I of *The Silver Book®: Vision Loss* the FDA approved a wet AMD treatment that was found to maintain vision loss in 95% of patients and restore it in up to 34%. Recent studies are confirming and building upon the success of this drug.

■ The CATT Trial put two wet AMD treatments head-to-head to compare their safety and effectiveness. It sparked considerable debate on comparative effectiveness research, cost-based treatment decisions, potential impact on innovation, and more. It also made apparent how rapidly the field is developing. More than 300 clinical trials are underway to explore ways to treat AMD with fewer injections, even better outcomes, and in innovative ways. No doubt we will continue to see the landscape of AMD treatment and prevention rapidly change.

Hundreds of clinical trials are also looking at better treatment and prevention of other age-related eye diseases. The ACCORD Eye Study found that glycemic control and combined lipid/statin therapy could significantly reduce diabetic retinopathy progression. Scientists are also finding that the same drugs that are successfully treating wet AMD patients are causing substantial visual improvement in nearly 50% of diabetic retinopathy patients.

Medical innovation has already proven its value in reducing the impact of vision loss on individuals and reducing costs. As we enter a critical time in health care for older Americans, we must be sure to consider both the financial and human impact that medical innovation can have on vision loss. Short-sighted efforts to reduce spending too often target the initial expenses of investing in medical innovation while ignoring remarkable returns on investment.



The Human and Economic Value

Vision Loss

- Between 2008 and 2009, the number of Americans age 65-74 who reported trouble seeing (even with glasses or contacts) decreased from 14.3% to 10.3%. The number of Americans age 75 and older who reported trouble seeing also decreased during that time period—from 21.1% to 16.5%.

Centers for Disease Control and Prevention 2010, *Health*

Age-Related Macular Degeneration

“Retiree Luther W. takes nutritional supplements with the hope of keeping his AMD from progressing. When he’s fishing, he wears sunglasses to block the harmful ultraviolet and blue rays of the sun. ‘When you’re younger and working hard, life goes by in a blur,’ he says. ‘Now, I want to savor every detail.’ Research has led to new treatments to help preserve vision in patients with AMD.”

Research to Prevent Blindness, *Macular Degeneration*

- Omega-3 polyunsaturated fatty acids have been found to protect against the development and progression of deterioration of the retina (retinopathy).

Connor et al. 2007, *Increased Dietary Intake of -3 Polyunsaturated Fatty Acids Reduces Pathological Retinal Angiogenesis*

- The prevalence of age-related macular degeneration (AMD) in the 40 and older population has decreased from an estimated 9.4% from 1988 to 1994, to 6.5% for 2005 to 2008.

Klein et al. 2011, *Prevalence of Age-Related Macular Degeneration in the U.S. Population*

- Women taking vitamins B6 & B12 and folic acid—as compared to women not taking these supplements—were found to have a 34% lower risk of age-related macular degeneration (AMD) and a 41% lower risk of the advanced form.

Christen et al. 2009, *Folic Acid, Pyridoxine, and Cyanocobalamin Combination Treatment and AMD in Women*

- Treatment of patients with advanced dry age-related macular degeneration (AMD) with ciliary neurotrophic factor (CNTF) implants resulted in stabilization of visual acuity. A sub-group analysis found that 100% of patients receiving a high-dose lost <15 letters of acuity—compared with 55.6% in the combined low-dose/sham group. The high-dose group had a 0.8 mean letter gain while the low-dose/sham group had a mean 9.7 letter loss.

Zhang et al. 2011, *Ciliary Neurotrophic Factor Delivered by Encapsulated Cell Intracocular Implants for Treatment of Geographic Atrophy in AMD*

- Supplementation with lutein increases macular pigment optical density by 27%; which is correlated with benefits in visual function.

Günther et al. 2011, *Effects of Lutein Supplementation on Macular Pigment Optical Density and Visual Acuity in Patients with Age-Related Macular Degeneration*

- After 54 weeks of receiving bevacizumab, wet age-related macular degeneration (AMD) patients were more likely to gain at least 6 letters of contrast sensitivity than patients receiving standard care—35.4% versus 15.2%.

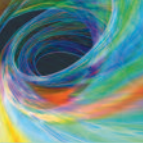
Patel et al. 2011, *Contrast Sensitivity Outcomes in the ABC Trial*

- A FDA-approved ophthalmic drug that treats wet age-related macular degeneration (AMD)—ranibizumab (Lucentis)—maintained vision in 95% of clinical trial participants and improved vision by 15 or more letters in approximately 25% to 34% of trial participants.

Rosenfeld et al. 2006, *Ranibizumab for Neovascular Age-Related Macular Degeneration*

- The NEI-sponsored Age-Related Eye Disease Study (AREDS) found that individuals at high risk of developing advanced stages of age-related macular degeneration (AMD) lowered their risk of disease progression by about 25% when treated with the AREDS nutritional formula (a daily, high-dose combination of vitamins C, E, beta-carotene, and zinc).

Age-Related Eye Disease Study Research Group 2001, *AREDS Report no. 8*



- A study exploring the impact of a healthy lifestyles on age-related macular degeneration (AMD) found that women whose diets were the healthiest (scored on the 2005 Healthy Eating Index) had 46% lower odds of developing early AMD than those whose diets were the least healthy. It also found that women with the most physical activity had 54% lower odds for early AMD compared to those with the least amount of physical activity.

Mares et al. 2011, *Healthy Lifestyles Related to Subsequent Prevalence of Age-Related Macular Degeneration*

- A study on the impact of diet on age-related macular degeneration (AMD) found that those who took the highest amounts of carotenoids, such as lutein and zeaxanthin, had a 43% lower risk of age-related macular degeneration than those who took the least amounts.

Seddon et al. 1994, *Dietary Carotenoids, Vitamins A, C, and E, and Advanced Age-Related Macular Degeneration*

Diabetic Retinopathy

“Judith L. didn’t know she had diabetes until signs of diabetic retinopathy were discovered at her annual eye exam. The ophthalmologist referred her back to her regular doctor for treatment of her diabetes and to a retina specialist for laser treatments for her macular edema, to help seal the leaking blood vessels. She’s also begun intraocular steroid injections to improve the results. Judith no longer drives at night and has trouble reading, but says she’s better off than her father who also had diabetic eye problems. ‘I want the next generation to be even luckier,’ she says.”

Research to Prevent Blindness, *Diabetic Retinopathy*

- It is estimated that proper treatment and monitoring of the eyes of diabetics could reduce new cases of diabetic retinopathy by 90%.

Tapp et al. 2003, *The Prevalence of and Factors Associated with Diabetic Retinopathy in the Australian Population*

- Current treatments for proliferative diabetic retinopathy have reduced the rate of blindness within 5 years from 50% to less than 5%.

National Eye Institute, *Early Treatment Diabetic Retinopathy Study*

- The ACCORD Eye Study found that intensive glycemia control—compared with standard blood sugar control—in high risk type 2 diabetics, decreased progression of diabetic retinopathy by around 1/3 over 4 years—from 10.4% to 7.3%.

ACCORD Study Group 2010, *Effects of Medical Therapies on Retinopathy Progression in Type 2 Diabetes*

- The ACCORD Eye Study found that combination lipid therapy with a fibrate and statin (compared with statin treatment alone) reduced progression of diabetic retinopathy in type 2 diabetics by around 1/3 over 4 years—from 10.2% to 6.5%.

ACCORD Study Group 2010, *Effects of Medical Therapies on Retinopathy Progression in Type 2 Diabetes*

- Nearly 50% of diabetic retinopathy patients who received ranibizumab—an anti-VEGF drug—experienced substantial visual improvement after a year of injections

Bressler et al. 2010, *Vision-Related Function after Ranibizumab Treatment by Better- or Worse-Seeing Eye*

- Laser treatment and vitrectomy reduce the risk of blindness in patients with severe diabetic retinopathy by 90%.

National Eye Institute, *Facts About Diabetic Retinopathy*

- Detection and treatment of proliferative diabetic eye disease and clinically significant macular edema with laser therapy can reduce severe vision loss progression by 50% to 60%.

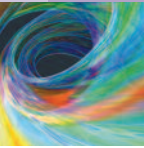
Centers for Disease Control and Prevention 2011, *National Diabetes Fact Sheet*

- Timely treatment and follow-up care can reduce the risk of blindness in individuals with proliferative retinopathy by 95%.

National Eye Institute, *Facts About Diabetic Retinopathy*

- Intensive glucose control (3 or more daily insulin injections or continuous subcutaneous insulin infusion) reduced the mean risk of retinopathy by 76% in type 1 diabetes patients who had not developed retinopathy.

Fong et al. 2004, *Diabetic Retinopathy*



- Intensive glucose control (3 or more daily insulin injections or continuous subcutaneous insulin infusion) reduced the mean risk of retinopathy progression by 54% in type 1 diabetes patients with minimal-to-moderate retinopathy.

Fong et al. 2004, *Diabetic Retinopathy*

- After 9 years of tight blood pressure control, patients with type 2 diabetes had a 34% reduction in retinopathy progression and a 47% reduction in risk of visual acuity deterioration by three lines, when they had a 10/5 mmHg reduction in blood pressure.

Turner et al. 1998, *Tight Blood Pressure Control and Risk of Macrovascular and Microvascular Complications in Type 2 Diabetes*

- In general, every 10 mmHg reduction in systolic blood pressure reduces the risk of diabetes complications by 12%.

Centers for Disease Control and Prevention 2011, *National Diabetes Fact Sheet*

- Screening and treatment for diabetic retinopathy in type 2 diabetes patients produces annual savings of 53,986 person-years of sight.

Javitt et al. 1994, *Preventive Eye Care in People With Diabetes is Cost-Saving to the Federal Government*

Glaucoma

“‘Five of my nine brothers and sisters had glaucoma,’ says 81-year-old Jean R. who for 20 years has depended on eye drops to decrease pressure inside her eyes. Jean is supporting research for genetic tests for glaucoma. ‘I want my children and grandchildren to know their risk for glaucoma,’ she says, ‘and then be able to prevent it.’ With science advancing in this direction, she could have her wish.”

Research to Prevent Blindness, *Glaucoma*

- The NEI-sponsored Ocular Hypertension Treatment Study (OHTS) found that lowering intraocular pressure (IOP) by at least 20% produced a 50% protective benefit for individuals who had an elevated IOP but no optic disc or visual field deterioration.

Kass et al. 2002, *The Ocular Hypertension Treatment Study*

- Prescription eye drops could delay or prevent half of glaucoma cases in African Americans.

Higginbotham, et al. 2004, *The Ocular Hypertension Treatment Study*

- High-intensity ultrasonic cyclocoagulation reduces intraocular pressure in refractory glaucoma patients.

Aptel et al. 2011, *Miniaturized High-Intensity Focused Ultrasound Device in Patients with Glaucoma: A Clinical Pilot Study*

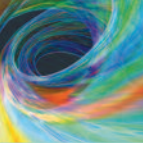
- Treatments that have been found to delay or prevent diabetic retinopathy save the U.S. \$1.6 billion annually.

Lighthouse International, *Diabetic Retinopathy Treatment and Care*

- The cost-effectiveness of detection and treatment of eye disease in diabetics is \$3,190 per quality adjusted life year (QALY).

Javitt and Aiello 1996, *Cost-Effectiveness of Detecting and Treating Diabetic Retinopathy*





The Future Value

- It has been estimated that monthly use of ranibizumab in individuals with age-related macular degeneration (AMD) would reduce the incidence of legal blindness by 72% and visual impairment by 37%, in 2 years. This means that 11,784 people would be spared blindness in that time period.

Bressler et al. 2011, *Estimated Cases of Legal Blindness and Visual Impairment Avoided Using Ranibizumab for Choroidal Neovascularization*

- The use of antioxidant vitamins and other new therapies for age-related macular degeneration (AMD) could reduce visual impairment and blindness from the disease by 35%.

Rein et al. 2009, *Forecasting Age-Related Macular Degeneration Through the Year 2050*

- Multifocal electroretinogram (mFERG) and flicker perimetry show abnormal function in the central macula in early age-related macular degeneration (AMD) and could enhance monitoring of the disease progression in individuals.

Gin et al. 2011, *Central Retinal Function as Measured by the Multifocal Electroretinogram and Flicker Perimetry in AMD*

- Cytokines in urine are associated with age-related macular degeneration (AMD) and could be developed as a biomarker and provide a practical tool for early detection.

Guymer et al. 2011, *Identification of Urine Biomarkers for AMD*

- Of the 8 million older Americans at high risk of developing advanced age-related macular degeneration (AMD), 1.3 million will develop advanced AMD within 5 years. However, the NEI-sponsored Age-Related Eye Disease Study (AREDS) nutritional formula could help 300,000 of those 1.3 million avoid the severe vision loss of advanced AMD over a 5-year period.

Bressler et al. 2003, *Potential Public Health Impact of Age-Related Eye Disease Study Results*

- A gene transfer process that produces a VEGF receptor prevents retinal vascular permeability (RVP) associated with diabetes that could have value in treating diabetic retinopathy.

Ramirez et al. 2011, *Vasoinhibin Gene Transfer by Adenoassociated Virus Type 2*

- Screening and treatment for eye disease in all type 2 diabetes patients would result in an estimated net savings of over \$472.1 million—in 1994 dollars.

Javitt et al. 1994, *Preventive Eye Care in People With Diabetes is Cost-Saving to the Federal Government*

- Screening and treatment for eye disease in all type 2 diabetes patients would result in an estimated net savings of 94,304 person-years of sight.

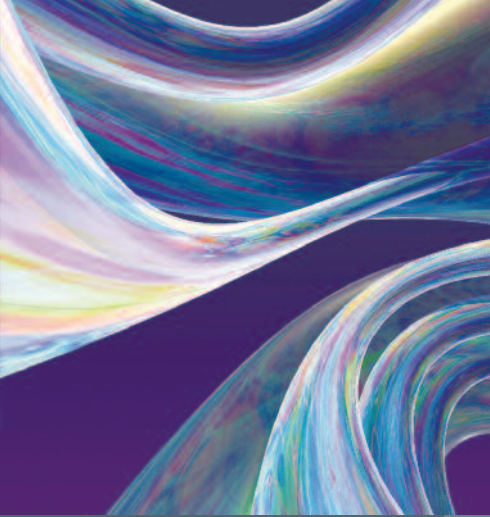
Javitt et al. 1994, *Preventive Eye Care in People With Diabetes is Cost-Saving to the Federal Government*

- Multifocal electroretinogram (mFERG) measures show abnormal function of the retina early in—and even prior to—diabetic retinopathy onset and could enhance monitoring of the early stages of disease progression in individuals.

Bearse et al. 2006, *A Multifocal Electroretinogram Model Predicting the Development of Diabetic Retinopathy*

- Because the resource use and direct cost of glaucoma treatment and management increases as the disease severity worsens—from an average \$623 per early-stage patient to \$2,511 per late-stage patient—a glaucoma treatment that delays the disease progression could significantly reduce its economic burden.

Lee et al. 2006, *A Multicenter, Retrospective Pilot Study of Resource Use and Costs Associated with Severity of Disease in Glaucoma*



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Conclusion

■ *The Silver Book®: Vision Loss Volume II* shares even more data on the growing burden of vision loss in America and continues to make the case that innovation is the key to lessening that burden. However, while new data is continuing to emerge on the value of advances in the field, there is still a lack of economic projections that address future value and consider the cost of innovations. We once again challenge health researchers and economists to fill these gaps in our statistical profile of vision loss and help make the case for continued investments in medical research. Any new data will of course be included in *The Silver Book* on-line at www.silverbook.org/visionloss.

■ We fully expect that Volume II will join *The Silver Book* collection as an invaluable tool that encourages advocacy and policies that support investments in medical research and innovation. The Alliance for Aging Research believes that sound public policy should strive for cost-containment strategies that also provide for high quality health care that is patient-centered, values driven, knowledge intense, innovation rich, and prevention oriented.

We also cannot ignore how long-range plans for research will reduce both the human burdens AND the economic burdens imposed by vision loss. Historically, investments that produce new medical innovations have paid for themselves many times over through decreased medical expenses and increased productivity. Vision loss research will not be the exception and is essential to producing older generations that live longer with good health and independence.

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