



▶ Evidence Based Primary Eye Care and Prevention of Diabetes-Related Vision Impairment

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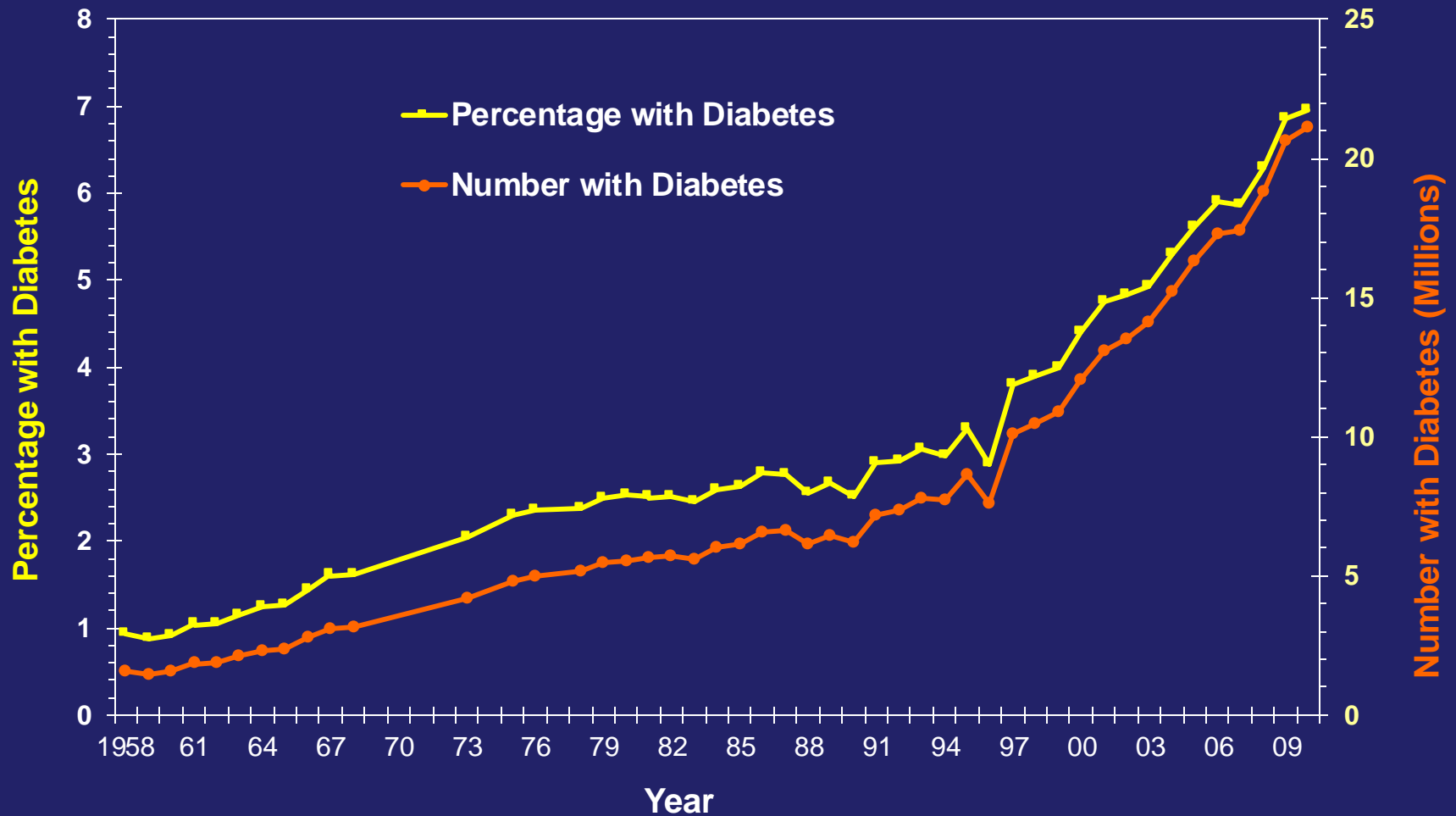
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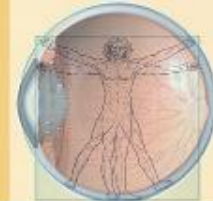
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Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958–2010



CDC's Division of Diabetes Translation. National Diabetes Surveillance System available at <http://www.cdc.gov/diabetes/statistics>





AOA **FIRST LOOK**

Today's news from newspapers, TV, radio and journals prepared exclusively for the members of the American Optometric Association





June 11, 2014



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Leading The News

CDC: Diabetes Epidemic Growing At An Alarming Rate.

Yesterday, the Centers for Disease Control and Prevention released its 2014 National Diabetes Statistics Report indicating growth in the rate of Americans with diabetes and prediabetes. The report garnered over two minutes of coverage on one major network news program as well as coverage by major wire sources, newspapers, and consumer medical websites.

In a segment on [NBC Nightly News](#) (6/10, story 5, 2:10, Williams), NBC News correspondent Tom Costello reported that new [statistics](#)   released June 10 from the Centers for Disease Control and Prevention in its 2014 National Diabetes Statistics Report indicate the diabetes "epidemic continues to grow at an alarming rate." Currently, some "29 million people in the US have diabetes...yet a quarter of those people don't know they're diabetic."

The [AP](#)   (6/11, Stobbe) reports that CDC "scientists calculated that more than nine percent of Americans have diabetes — or one in 11 people."

The [Los Angeles Times](#)   (6/11, Healy) reports that the CDC "said an additional 86 million American adults — nearly one in three — has prediabetes." Approximately 15 percent to 30 percent of people "with prediabetes will go on to develop the full-fledged metabolic disorder within five years, a transition that can sometimes be averted with substantial weight loss and increased physical activity." The CDC's latest "statistics are based on national health data gathered in 2012 and represent a nearly 12% increase in the number of those with diabetes since the last statistical report was issued in 2010."



Study: using Avastin to treat AMD, DME could save Medicare billions

Publish date: JUN 09, 2014



By: Colleen E. McCarthy

Ann Arbor, MI—A study from the University of Michigan, which was recently published in *Health Affairs*, found that if all eyecare practitioners (ECPs) prescribed Avastin (bevacizumab, Genentech) patient instead of the more-expensive Lucentis (ranibizumab, Genentech) for the treatment of wet age-related macular degeneration (AMD) and diabetic macular edema (DME), Medicare plans could save \$18 billion over a 10-year period.

Avastin costs \$55 per treatment, while Lucentis costs \$2,023—almost 40 times more—but the drugs have similar efficacy, side effects, and safety profiles when used to treat AMD or DME, according to the study. Choosing Avastin would also save patients \$4.6 billion in co-pays and would save \$29 billion in private insurance payments and other costs.

“As the Medicare-eligible population continues to grow, identifying savings while maintaining quality patient care is increasingly important. People don’t like to think there are tradeoffs between health and costs, but we certainly do need to think about cost when health care is 18 percent of the GDP and growing,” says David Hutton, PhD, lead author on the study.

Avastin was originally created as a cancer-fighting drug and was given in higher doses to inhibit the growth of tumors by slowing the development of blood vessels. For several years, it was used to treat AMD and DME off label, and because it was used in much lower doses than when treating cancer, the cost was also much lower. Genentech also makes Lucentis, which was FDA-approved to target these eye diseases, and priced the drug much higher.



THE INDEPENDENT WEDNESDAY 11 JUNE 2014

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Life > Health & Families > Health News

One in three adults 'on cusp of diabetes' in England





American Optometric Association
Evidence-Based
Clinical Practice Guideline

***Eye Care of the Patient with
Diabetes Mellitus***

AOA Guideline Development
Group - 2014

Evidence-Based Clinical Practice Guideline

Eye Care of the Patient With

**DIABETES
MELLITUS**



American Optometric Association

- ▶ Available at:
<http://www.aoa.org/documents/EBO/EyeCareOfThePatientWithDiabetesMellitus%20CPG3.pdf>



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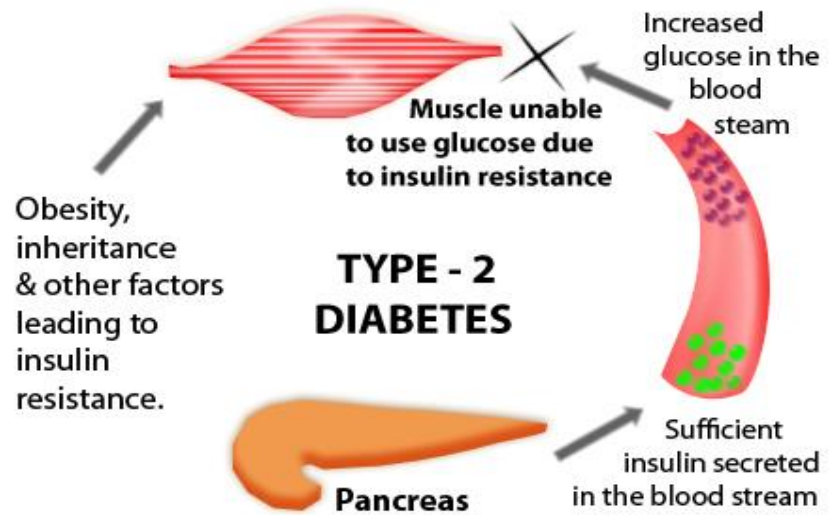
Objectives

- ▶ Identification of individuals at risk for, or with undiagnosed diabetes
- ▶ Identification of individuals at risk of vision loss from diabetes
- ▶ Preservation of vision by reducing risk of vision loss in persons with diabetes through timely diagnosis, determination of need for future evaluation, and appropriate referral
- ▶ Improvement in quality of care rendered to persons with diabetes
- ▶ Education of individuals and health care providers regarding ocular complications of diabetes
- ▶ Dissemination of information and education of individuals on benefits of vision rehabilitation
- ▶ Provision of vision rehabilitation care, or referral for care of persons with vision loss from diabetes



Why This Matters

Type 2 diabetes mellitus is most prevalent form and often goes undiagnosed



- ▶ Individuals are at risk of developing complications including chronic visual impairment, hypertension, renal failure, heart disease, and stroke
- ▶ Diabetic retinopathy is the leading new cause of new cases of visual impairment and legal blindness for 20-74 years of age group and accounts for 12% of all new legal blindness a year



Why This Matters

- ▶ Intensive blood glucose monitoring and treatment can decrease risk of retinopathy by as much as 76%
- ▶ Up to 40% of people with diabetes don't know they have the disease
- ▶ Signs of diabetes found during an eye examination may be the initial indication of the presence of the disease
- ▶ Optometrists and Ophthalmologists are often the first health care providers to examine people with undiagnosed diabetes



Institute of Medicine (IOM) Recommendations

- ▶ The IOM, through the Agency for Healthcare Research and Quality (AHRQ), issued two reports in March 2011
 - ▶ *Clinical Practice Guidelines We Can Trust*
 - ▶ *Finding What Works in Health Care: Standards for Systematic Reviews*
- ▶ In *Clinical Practice Guidelines We Can Trust*, IOM redefined the definition of Clinical Practice Guidelines (CPGs) as:

“CPGs are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options.”





evidence is a critical component of shared decision making and key to translating patient preferences into practice

Trustworthy Guidelines Descriptors (IOM)

- ▶ Be based on systematic review of existing evidence
- ▶ Be developed by knowledgeable, multidisciplinary panel of experts add key stakeholders
- ▶ Consider important patient subgroups and preferences
- ▶ Be based on transparent process that minimizes conflicts of interests and biases
- ▶ Provide clear explanation of logical relationships between alternative care options and health outcomes
- ▶ Provide grading of both strength of quality of evidence and strength of clinical recommendations
- ▶ Be revised as appropriate when new evidence warrants modifications of recommendations



Diabetes Mellitus

- ▶ Studies provide evidence-based care interventions that rely on early referral for eye care to lessen risk for, and severity of, vision loss related to diabetes
 - ▶ Diabetic Retinopathy Study (DRS)
 - ▶ Early Treatment Diabetic Retinopathy Study (ETDRS)
 - ▶ Diabetic Retinopathy Vitrectomy Study (DRVS)
 - ▶ United Kingdom Prospective Diabetes Study (UKPDS)
 - ▶ Diabetes Control & Complications Trial/Epidemiology of DM Interventions and Complications (DCCT/EDIC)
 - ▶ Diabetic Retinopathy Clinical Research Network (DRCR.net)
- ▶ **TAKE HOME:** timely diagnosis, intensive treatment, and consistent, long-term follow-up evaluations are essential for effective care, which can preserve vision and significantly lower the risk of vision loss



Diabetic Retinal Disease

- ▶ **Epidemiology and Association with Vision Loss**
 - ▶ 86% with type 1 and 40% with type 2 have clinically evident diabetic retinopathy (DR)
 - ▶ 2005-2008 4.3 million (29% of those with diabetes) had DR and 655,000 of group (4%) had advanced DR leading to severe visual loss
 - ▶ Americans 40 + with DR projected to triple by 2050 from 5.5 to 16 million for DR, and 1.2 to 3.4 million for vision threatening DR
 - ▶ Prevalence of DR and vision impairment associated with duration of disease, not age



Diabetic Retinal Disease

- ▶ Primarily manifests as diabetic retinopathy (DR) and/or diabetic macular edema (DME)
- ▶ Diabetic retinopathy is highly specific retinal vascular complication
 - ▶ Asymptomatic early on
 - ▶ Vision impairment primarily due to development of DME, vitreous hemorrhage or traction retinal detachment
 - ▶ Primary risk factors include diabetes duration and sustained hyperglycemia



Early Detection & Prevention

- ▶ Diabetes Prevention Program showed weight loss can delay and prevent type 2; people who lose 5-7% body weight and conduct moderate physical activity can reduce risk by 58% over four years and 34% after 10 years
- ▶ Every % point reduction in A1C can reduce risk of microvascular complications by nearly 40%
- ▶ Every 10 mmHg reduction in systolic BP reduces risk of diabetes complications by 12%
- ▶ Early diagnosis and appropriate treatment of retinopathy reduces risk of severe vision loss (5/200 or worse) in majority of people with diabetes



Diabetic Retinal Disease

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Summary Table of Estimated Proportions

TABLE 2		
Duration of Diabetes Mellitus and Presence of Diabetic Retinopathy and Diabetic Macular Edema		
Diabetes	Duration of Disease	Ocular Complication
Type 1	> 5 years	17 to 29% have some retinopathy
	> 10 years	60% have some retinopathy
	> 15 years	78 to 97% have some degree of retinopathy; 25% progress to proliferative diabetic retinopathy
	> 20 years	50 to 60% progress to proliferative retinopathy
	> 25 years	29% have diabetic macular edema; 17% have clinically significant macular edema
Type 2	At diagnosis	20 to 39% have some retinopathy
	> 4 years	4% progress to proliferative retinopathy
	> 10 years	25% of individuals on insulin have diabetic macular edema; 14% on oral medications have diabetic macular edema
	> 15 years	60 to 80% have some retinopathy; up to 20% progress to proliferative retinopathy



One- and Five-year Progression of DR

TABLE 3		
Severity of Condition	Natural Course Rate of Progression to	
	PDR (1 year)	HR PDR (5 years)
Mild NPDR	5%	15%
Moderate NPDR	12 to 27%	33%
Severe NPDR	52%	60 to 75%
Non-high-risk PDR		75%

Twenty-five to forty percent of individuals with high-risk proliferative diabetic retinopathy (HR PDR) develop severe vision loss within 2 years.



Non-Retinal Ocular Complications

▶ Visual Function

- ▶ Loss of Visual Acuity
- ▶ Refractive Error Changes
 - ▶ Transient changes; myopic or hyperopic shifts
 - ▶ Often a sign/symptom of undiagnosed DM
 - ▶ Can be several diopters or more
- ▶ Changes in Color Vision
 - ▶ Both blue-yellow and red-green discrimination
- ▶ Accommodative Dysfunction*
 - ▶ Transient; improves with glucose control
- ▶ Visual Field Changes*

* also from panretinal laser photocoagulation



Non-Retinal Ocular Complications

- ▶ **Eye Movement (Ocular Motility) Anomalies**
 - ▶ Third, Fourth or Sixth cranial nerves
- ▶ **Pupillary Reflexes**
 - ▶ Sympathetic innervation of iris may be affected
 - ▶ Miotic; sluggish; weak reaction to mydriatics
- ▶ **Conjunctiva**
 - ▶ Microaneurysms in bulbar conjunctiva; risk of bacterial infection
- ▶ **Tear Film**
 - ▶ Dry eye; tear film instability; ocular surface defects; impaired lacrimation



Non-Retinal Ocular Complications

▶ Cornea

▶ Corneal Wound Healing

- ▶ Susceptible to injury and slower to heal; high risk of superficial punctate keratitis, recurrent corneal erosions, persistent epithelial defects and endothelial damage
- ▶ Linked to tear secretion abnormalities, decreased sensitivity and poor adhesion between epithelial cells and basement membrane

▶ Reduced Corneal Sensitivity

▶ Corneal Abrasions

- ▶ Likely recurrent; involve detachment of basement membrane; delayed re-epithelization

▶ Contact Lens Wear

- ▶ Increased risk of CL-related microbial keratitis; slower recovery from corneal edema; especially for extended CL wear
- ▶ Studies show daily wear CLs safe option
- ▶ Require ongoing evaluation



Non-Retinal Ocular Complications

▶ Iris

- ▶ Depigmentation – pigment on corneal endothelium
- ▶ Neovascularization of the iris (Rubeosis iridis)
 - ▶ Pupillary margin or filtration angle; NVI can involve entire iris surface/angle
- ▶ Neovascular Glaucoma
 - ▶ Sequella of PDR due to VEGF-induced neovascularization of iris & angle



Non-Retinal Ocular Complications

▶ Lens

- ▶ Cataract – develop earlier, progress more rapidly
 - ▶ Increased posterior subcapsular (PSC) & cortical cataracts
 - ▶ Type 2 associated with nuclear sclerosis & cortical cataracts
 - High use of statins associated with age-related cataracts and occur earlier
 - Metabolic syndrome (MetS) increases cortical and PSC over 5 years

▶ Vitreous

- ▶ degeneration and posterior vitreous detachment (PVD)
- ▶ PDR associated with PVD => VH, retinal neovasc & tractional RD

▶ Optic Disc

- ▶ Papillopathy
- ▶ Ischemic Optic Neuropathy
- ▶ Open Angle Glaucoma



Non-Retinal Ocular Complications

▶ Optic Disc

▶ Papillopathy

- Distinct clinical entity from papilledema; unilateral or bilateral hyperemic disc swelling with or without afferent pupillary defect or VF defect
- Risk factor for progression of DR
- VA moderately reduced, prognosis for improvement is good (without treatment within a year and VA up to 20/30)

▶ Ischemic Optic Neuropathy

- DM independent risk factor for nonarteritic anterior ischemic optic neuropathy (NAION)
- Optic disc pallor, swelling/hemes, sudden decreased VA, APD, altitudinal VF defect



Individuals with Undiagnosed DM

- ▶ Eye exam may be basis for initial diagnosis
- ▶ Eye and vision care components provided to patients diagnosed with or suspected of having DM depend upon professional judgment and individual patient symptoms
- ▶ Findings may have a substantial impact on the nature, extent, and course of the services provided and recommended



Frequency and Composition of Evaluation and Management Visits for Retinal Complications of Diabetes Mellitus

Severity of Condition	Natural Course Rate of Progression to		Frequency of Follow-up	Components of Follow-up Evaluations	
	PDR (1 year)	HRC * (5 years)		Fundus Photography	OCT/ Fluorescein Angiography
Mild NPDR	5%	15%			
No macular edema			12 months	No	No
Macular edema			4 to 6 months	Yes	Based on clinical judgment
CSME			2 to 4 months**	Yes	Yes
Moderate NPDR	12-27%	33%			
No macular edema			6 to 8 months	Yes	No
Macular edema (not CSME)			4 to 6 months	Yes	Based on clinical judgment
CSME			2 to 4 months**	Yes	Yes
Severe NPDR	52%	60-75%			
No macular edema			3 to 4 months	Yes	No
Macular edema (not CSME)			2 to 3 months	Yes	Based on clinical judgment
CSME			2 to 3 months**	Yes	Yes
Very Severe NPDR	75%	75%			
No macular edema			2 to 3 months	Yes	No
Macular edema (not CSME)			2 to 3 months	Yes	Based on clinical judgment
CSME			2 to 3 months**	Yes	Yes
Non-high-risk PDR		75%			
No macular edema			2 to 3 months	Yes	No
Macular edema			2 to 3 months	Yes	Based on clinical judgment

Common Visual Impairments Associated with DR

- ▶ Reduced Central VA
- ▶ Central/Para-central Scotoma
- ▶ Loss of Peripheral, Mid-central Visual Field
- ▶ Reduced Dark Adaptation
- ▶ Difficulty with Glare
- ▶ Vision Loss From Vitreous/Preretinal Hemorrhage/Tractional Detachment
- ▶ Decreased Contrast Sensitivity



Functional Sequelae of Diabetes-related Vision Loss

- ▶ Inability to self-manage diabetes care including monitoring of blood glucose
- ▶ Difficulty addressing dietary, medical health-related issues
- ▶ Difficulty with health care tasks (i.e. checking feet)
- ▶ Loss of/restriction of driver's licensure
- ▶ Inability to maintain wellness and comply with preventive health measures



Chronic Visual Impairment

Refer to **AOA Clinical Practice Guideline on Care of the Patient with Visual Impairment*

ACTION: Individuals who experience vision loss from diabetes should be provided, or referred for, a comprehensive examination of their visual impairment by a practitioner trained or experienced in vision rehabilitation.

ACTION: Persons with diabetes who experience visual difficulties should be counseled on the availability and scope of vision rehabilitation care and encouraged to utilize these services.



Summary

- ▶ Preventive care is best; but emphasis must be on proper diagnosis, careful follow-up, timely treatment and vision rehabilitation
- ▶ All persons with diabetes should be informed of possibility of developing retinopathy or other non-retinal ocular complications
- ▶ Inform on natural course and treatment of DR and stress importance of lifelong eye examinations
- ▶ Advise on availability of vision rehabilitation and either provide or refer for treatment of chronic vision impairment



Thank You!

