

Deloitte Access Economics

Eyes on the future

A clear outlook on
Age-related Macular
Degeneration

Macular Degeneration
Foundation

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Deloitte Access Economics

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Professor Paul Mitchell is a world renowned medical retina specialist and Professor of Ophthalmology at the University of Sydney, and Director of Ophthalmology for the Sydney West Area Health Service.

Professor Mitchell served as Director on the Board of the Macular Degeneration Foundation since its inception in 2001 until 2004. He was appointed National Research Advisor to the Foundation in 2006 and has served for ten years as a member of the Foundation's Medical Committee.

Professor Mitchell has made outstanding contributions in the fields of public health and ophthalmic epidemiology especially through his work on the landmark Blue Mountains Eye Study. This was the first large Australian population-based study of age-related eye disease and is recognised throughout the world.

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Executive Summary

Age-related macular degeneration (AMD) is the most common cause of visual impairment in people over the age of 50 years in developed countries (Coleman et al, 2008). In Australia, it is the most common cause of blindness contributing to 50% of all blindness. AMD progressively destroys the macula (the central portion of the retina), impairing central vision and affecting quality of life and independence.

Generally, AMD can be classified into the early (typically not visually impairing) and late (visually impairing) stages. Late AMD can be further divided into 'wet' (neovascular) and 'dry' (atrophic) forms. Population studies indicate that two-thirds of late cases are neovascular and one-third are atrophic. However, over time, cases that are initially neovascular also develop atrophic signs.

- 'Early' AMD, defined by the development of large drusen or pigment changes at the macula may be associated with either no vision loss or early changes in reading/ central vision.
- 'Late' AMD includes both neovascular AMD and geographic atrophy, in a ratio of about 2:1.
 - Neovascular ('wet' or exudative) AMD is characterised by the appearance of blurring of the central vision and distortion with straight lines appearing crooked or wavy, with or without a dark or blank patch. Perception of colours is also often affected.
 - Geographic Atrophy ('dry' AMD) reduces capacity for near visual tasks as central vision becomes severely impaired. Note that some people include 'early AMD' within the category of 'dry AMD'. In this report, 'dry AMD' refers only to the late, atrophic stage.

Prevalence

The prevalence of AMD increases sharply with age, particularly from the age of 65 years (Wong et al, 2008). Demographic ageing will cause the prevalence of AMD to increase.

It is estimated that in 2010, there were 1.023 million Australians with AMD, equivalent to one in seven people over the age of 50. This comprises 856,000 with early AMD (Table 3.5), plus nearly 167,000 with late AMD in at least one eye (Table 3.7).

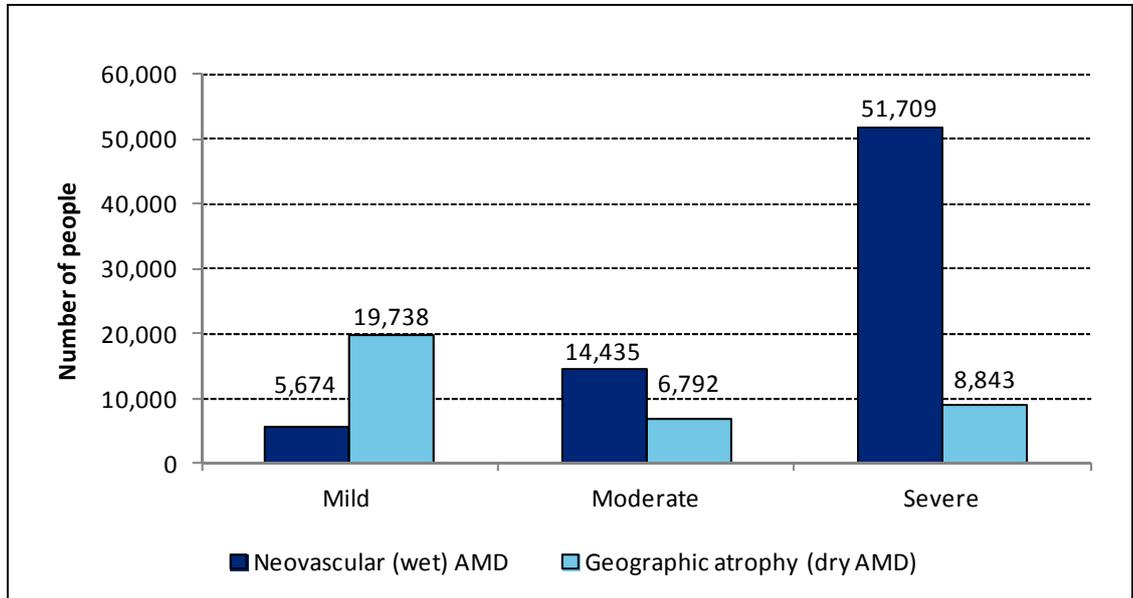
It is further estimated that by 2030, as a result of demographic ageing, the numbers with AMD would increase by over 70% to 1.77 million, in the absence of effective prevention and treatment efforts. This comprises 1.44 million with early AMD and 329,000 with late stage AMD in at least one eye.

- In the absence of prevention and treatment efforts, the number of Australians visually impaired in both eyes due to AMD would double from 107,000 in 2010 to over 215,000 by 2030 (Table 3.9).
- Estimates for the number of people who were legally blind due to AMD in 2010 range between 39,000 and 73,000¹ of whom about two-thirds have neovascular AMD.

¹ Estimates vary due to different models and assumptions. See section 3.1.5.3.

Chart i, shows the numbers of people with visual impairment from wet and dry AMD, by severity, in 2010. Chart ii, compares the prevalence of AMD to multiple sclerosis, dementia and diabetes.

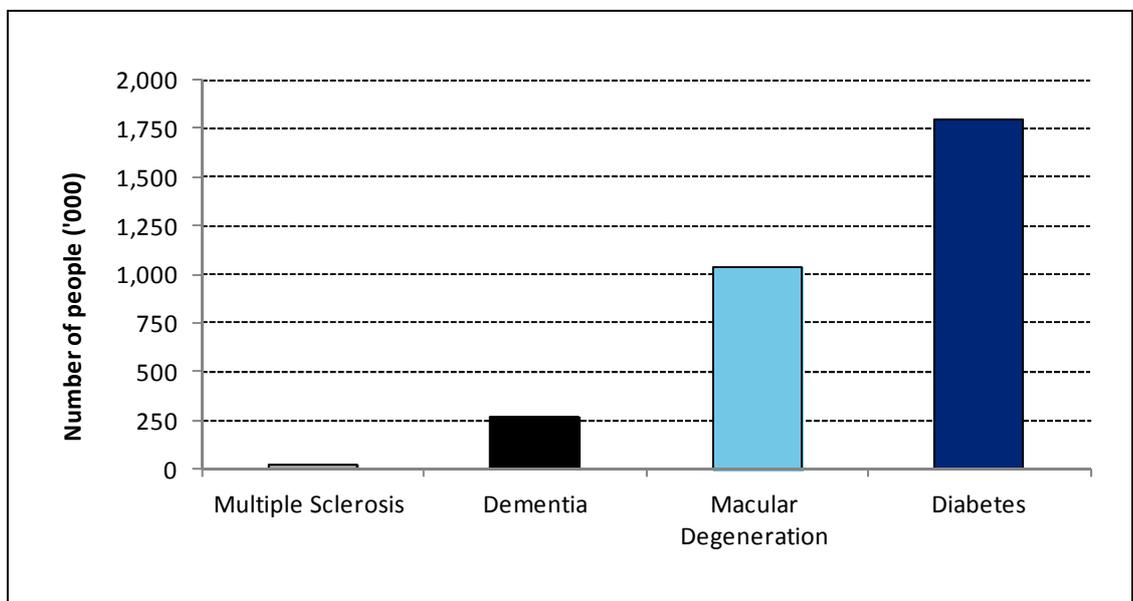
Chart i: Prevalence of visual impairment from AMD by severity of vision loss



Source: Deloitte Access Economics calculations.

Mild - worse than 6/12 and better or equal to 6/18; Moderate - worse than 6/24 but better or equal to 6/60; Severe - worse than 6/60 (blindness).

Chart ii: Prevalence of some key chronic diseases - Australia, 2010



Source:

Multiple Sclerosis: www.msaustralia.org.au/aboutms-faq.asp, Accessed 16/9/11

Dementia: www.alzheimers.org.au/understanding-dementia/statistics.aspx, Accessed 16/9/11

Diabetes: www.diabetesaustralia.com.au/en/Understanding-Diabetes/Diabetes-in-Australia/, Accessed 16/9/11. This figure is comprised of 1 million diagnosed, and an estimated 800,000 undiagnosed.

The Macular Degeneration figure includes 167,000 with late stage disease (vision impairment) and 856,000 with early disease.

Progression and prevention

Progression from early to late AMD can occur rapidly in some people, and more slowly in others (Wang et al, 2007). On average, about 4% of people with early AMD progress to late AMD each year. The progression rate from mild to moderate visual impairment is around 32% and from moderate to severe visual impairment around 46% over 2-3 years, without treatment (Wang et al, 2007).

Epidemiological studies have identified several risk factors that can increase the risk of developing AMD and increase the speed at which the disease progresses. Age, genetic factors and ethnicity are important non-modifiable risk factors. Cigarette smoking is a major lifestyle risk factor predicting the presence and development of AMD. Dietary antioxidants also play an important role in the occurrence, prevention and treatment of AMD. Some foods such as leafy greens (e.g., spinach), fish and nuts can decrease risk by at least 65% (Tan et al, 2008; Tan et al, 2009). Olive oil may also reduce risk (Chong et al, 2009). There is also recent evidence to suggest that diets with lower than average dietary glycaemic index (dGI) may reduce the risk of developing early and late AMD. Since there is currently no effective treatment for dry AMD, prevention is the first approach to reducing vision loss and the associated burden on society (Coleman et al, 2008).

Treatment of neovascular AMD

For neovascular AMD, substantial progress has been made in the development of new and effective treatments. Ranibizumab (Lucentis® - Novartis), an anti-VEGF agent, is a recent therapy that can halt the progression of neovascular AMD and may also provide some improvement. The MARINA and ANCHOR studies showed that around 95% of the eyes treated with ranibizumab (0.5 mg) at monthly intervals maintained stable vision within 15 letters (compared to 62%-64% of sham or PDT group) at one year. Between 34%-40% of the treated eyes improved by more than 15 letters of vision (compared to 4%-6% in the PDT or sham group).

Lucentis gained reimbursement for neovascular AMD on the Pharmaceutical Benefits Scheme (PBS) in August 2007 based on results from the ANCHOR, MARINA, and PIER trials. The listing was recommended at the price proposed in the submission on the basis of an average incremental cost per extra quality adjusted life-year (QALY) gained across all lesion types of between \$15,000 and \$45,000 (Table 6.2).

In patients who do not qualify for PBS reimbursed Lucentis, the closely related bevacizumab (Avastin® - Roche) is sometimes used "off-label". Avastin has been shown to provide similar visual acuity outcomes to Lucentis at 12 months, although small differences in retinal thickness, favouring Lucentis, have been shown. There is also some suggestion that relatively uncommon, but serious adverse events may be more common with Avastin. Further research is still needed to clarify the longer-term efficacy and safety of Avastin.

The anti-VEGF agents have essentially superseded older treatments such as photodynamic therapy (PDT) using verteporfin, laser photocoagulation and the injection of steroids such as triamcinolone.

Cost of AMD

This report updates results of an earlier study for the Centre for Eye Research (CERA) – *Centrally Focused: The Impact of Age-Related Macular Degeneration: a dynamic economic model and report* (Access Economics, 2006a). The cost of AMD is estimated based on health system data from the Australian Institute of Health and Welfare, and adding more recent cost estimates of Lucentis expenditure on the PBS. Other financial costs comprise primarily low vision aids, the cost of care, and the deadweight efficiency losses from welfare and taxation transfers, as well as a small component of productivity losses for people with AMD. The largest proportion (85%) of the economic cost of AMD results from the loss of quality of life associated with visual impairment, known as the ‘burden of disease’. This is measured in disability adjusted life years (DALYs) and converted to dollars using the value of a statistical life year of \$166,603 from the Department of Finance and Deregulation. Table i shows the total cost of vision loss associated with AMD in 2010.

In 2010, the total cost of vision loss associated with AMD was estimated to be \$5.15 billion (\$48,028 per person), of which the financial cost was \$748.4 million (\$6,982 per person).

Table i: Total cost of vision loss associated with AMD in 2010 by cost type

Cost type	Total cost (\$m)	Per person with AMD (\$)
Health system costs (a)	359.1	3,350
Productivity losses	18.7	175
Carer opportunity costs	47.5	443
Other indirect (aids/modifications/other carer and bring forward of funeral)	158.6	1,480
Dead Weight Losses	164.4	1,533
Total other financial costs (b)	389.2	3,631
Total financial costs (a) + (b)	748.4	6,982
Loss of wellbeing (c)	4,399.8	41,047
Total economic cost (a) + (b) + (c)	5,148.2	48,028

Source: Deloitte Access Economics calculations.

Benefits from AMD prevention and treatment

Comparing the overall savings to the cost of Lucentis, the social benefit cost ratio was estimated to be over 2:1, and the \$/DALY averted is estimated as \$41,792.

Even though there is currently no effective treatment for dry AMD, controlling for modifiable risk factors could prevent or delay the onset to the more advanced stages of AMD, suggesting substantial benefits through the possibility of alleviating some of these costs. For example, if cigarette smoking was halved, reducing the number of cases of AMD by one sixth over time, the total savings would be in the order of \$247 million per annum, in 2010 dollars.

From MARINA trial evidence, Lucentis improves average visual acuity by 17.6 letters over the treatment period of one year. The savings potentially associated with Lucentis are estimated to be \$887.5 million in 2010, if all neovascular AMD were treated. The largest savings is related to the reduction in the burden of AMD, but financial savings in 2010 would be worth some \$142.9 million, including fewer productivity losses from informal care, reduced need for low vision aids, and less downstream or alternative treatment for visual impairment (e.g., PDT).

Remaining barriers to treatment

Although the cost savings from using Lucentis are relatively large, there can be further improvements made through the removal of remaining treatment barriers. In unpublished research carried out by the Macular Degeneration Foundation in March 2010, it was found that the key reason people with neovascular AMD did not commence treatment was that they were diagnosed too late. The lack of early detection was most likely caused by a lack of awareness. It has also been shown that treatment of smaller lesions has a better visual prognosis, further emphasising the importance of early diagnosis (and the value of improved awareness). Adherence to therapy is also a significant barrier. Treatment for neovascular AMD should generally be continued in order to have ongoing therapeutic benefit. However, many people receiving treatment discontinue or have their treatment interrupted, for various reasons.

There are several recognised barriers to treatment, including out of pocket expenses (notably patient co-payments and travel costs), workforce supply and professional development constraints, demographic and socioeconomic disadvantage, and compliance and adherence issues. In this regard, it is recommended that:

- measures are adopted to maintain the work undertaken in awareness raising, to continue increasing population awareness of AMD in the 50+ age group beyond 83% awareness in 2010, and any gaps in awareness are addressed;
- awareness programs are increased to convey the importance of daily use of an Amsler grid in people with established AMD. This is the best way for the patient to pick up any sudden changes in vision which may indicate a progression to neovascular disease, and hence the need for immediate treatment;
- greater assistance is provided to meet patient co-payments, and travel costs for regional and disadvantaged Australians, since 15% of people receiving treatment for neovascular AMD consider discontinuing treatment due to out of pocket costs, and 3% do discontinue, despite the high priority they accord to their sight;
- workforce constraints are addressed, including increasing opportunities for Fellowship places for ophthalmologists;
- professional development to further the education of eye health professionals and specifically optometrists and general practitioners, to improve their understanding of the clinical sequelae of AMD, treatment options and referral guidelines and rates;
- measures are taken to improve the availability of free/bulk billed public treatment, either in public hospitals or via an alternate model; consideration be given to the addition of a Medicare item number for OCT scans, when performed as part of the management of AMD;
- measures are introduced to support the patient to help maintain and improve adherence with therapy. The issue of “injection fatigue” can be a major problem which

can lead to a desire by both patients and doctors to increase the time intervals between injections, potentially leading to under treatment, which can negatively impact outcomes;

- implementation of programs to improve communication between patients and their eye and health care professionals. The introduction of intra-vitreous injections has dramatically increased the demand for the ophthalmologist's services and access to these services can be limited. The time available with the specialist for discussion, explanation and questions can also be severely restricted; and
- careful review of effective best practice models which overcome some of these challenges would assist, along with a closer analysis of the supply and location of ophthalmologists, to aid future planning to meet the needs of the Australian community in the next 20 years.

Rehabilitation

Except for the effectiveness of managing risk and protective factors, there is no 'cure' for late stage AMD. While most people with neovascular AMD can now obtain highly effective treatment with anti-VEGF agents, some still experience a significant loss of vision. Many others have lost vision before effective treatments became available. For people with dry AMD, there is currently no treatment that can restore lost sight. Loss of vision affects quality of life and levels of independence. The emotional, social and economic impact on quality of life from visual impairment can be severe. Low vision rehabilitation is considered the best option for mitigating the impacts if medical treatment is unsuccessful in restoring an appropriate level of vision. Rehabilitation services can improve the capacity to read, provide opportunities for using low vision aids and technologies, increase confidence, address issues related to depression, increase daily living activities, improve mobility and functional ability and maintain and support workforce participation.

It has been estimated that 90% of people with vision impairment have useful residual vision, and could benefit from rehabilitation services, however, it is further estimated that only 20% of Australians that could benefit from rehabilitation services actually use the services. Several barriers to accessing rehabilitation services have been identified, such as a lack of awareness about services offered or their capacity to help, confusion with the referral process and problems with using transport. Personal factors can also act as barriers, such as culture and co-morbidities. There are also systemic barriers, such as poor communication with healthcare professionals and a reluctance to refer patients to low vision providers, especially in the earlier stages of vision loss. Patients may have to access more than one low vision service provider as many providers do not provide a comprehensive service. In some regional and rural communities, certain services may not even be available or accessible.

To improve uptake of rehabilitation services, it is recommended that:

- rehabilitation services are better tailored to client needs and preferences and there is regular assessment of services to ensure they are flexible to adapt to changing needs;
- adequate information and practical training is provided to people requiring low vision devices immediately or slightly in advance of requirement;
- access to rehabilitation services is enhanced by encouraging the development of additional services within the public hospital system and with private optometrists;

- referral pathways are strengthened by improving knowledge of AMD and low-vision rehabilitation services among health professionals, and encouraging health professionals to promote rehabilitation as an effective tool for reducing the impact of vision loss;
- rehabilitation should also be offered in the earlier stages of vision loss when patients are better able to learn new strategies; and
- national standards for low vision services are established to ensure the quality of services and facilitate comparison and choice.

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