

NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (NAMD):
A SOCIAL COST ANALYSIS

¹Roche spa, Monza, Italy ² AdRes - Health Economics and Outcome Research, Turin, Italy

Objective

- nAMD is a chronic condition, requiring life-long treatment, with substantial impacts on quality of life and extensive independence loss.
- It affects 14 million people worldwide today, and it’s expected to be around 19 million by 2030 [1].
- Anti-VEGF therapies represent current standard of care for nAMD but irreversible vision loss is too often observed in clinical practice.
- Aim of this analysis is to quantify people with vision loss that benefit of National Social Security (NSS) Income in the present and future decades. Social expenditure trend in Italy is also analyzed in different scenarios, in order to understand to which extent treatment inappropriateness is followed by appropriate social assistance.

Methods

Epidemiology and etiology

- The International Agency for the Prevention of Blindness database was interrogated to analyze location and time trend for vision loss prevalence [1].
- Data were available till 2020; a trendline was used to prolong the estimate for Italy up to 2040.
- A literature search was performed to investigate main disorders that lead to vision loss and blindness

Are we able to slow the growth?

- While the efficacy of anti-VEGF for the treatment of AMD (and also DME) is well established in controlled clinical trials (7-12 injections/year), strikingly sub-optimal outcomes are observed in clinical practice due to very low adherence to burdensome treatment regimens: an Italian RWE analysis on nAMD anti-VEGF treated patients highlights just 3.6 and 1.1 injections averagely received, in first and second years [2].
- Based on this awareness, we constructed a statistical model in order to simulate the hypothetical delay of vision worsening if adherence would be maximal
- The simulation was tuned and run separately for AMD and DME, using correlation between number of injections and vision loss from observational trials conducted by Ciulla and colleagues [3,4]
- Outcome was the incidence of blind patients defined as VA (visual acuity) ≤ 25 for both eyes

Social security expenditure and scenarios

- The Italian social security expenditure has been analyzed through the open-access National Social Security (NSS) Cost database. Attendance allowance (AA) and Social Security Income (SSI) tariffs trends were collected for both totally blind (TB) and partially blind (PB) patients.
- We compare different scenarios for the next decade (2033 vs today):
 - Same national social security budget, despite increased prevalence of recipients
 - Same per patient SSI, despite the need to contain public spending
 - Containing of the social security budget by improving treatment appropriateness

Results

Epidemiology and etiology

- In 2020 in Italy, there were an estimated 6.2 million people with vision loss. Of these, about 510,000 people were blind.
- As shown in Figure 1, this figure has been increasing during the last decades [1]
- Impaired vision is expected to affect 7.1 million patients within 2040, with blindness for 592 thousand people (Figure 2)
- AMD and DME appear among the first 5 causes for vision loss in western Europe [1], leading to 35% of the cases of blindness. Local data suggest that AMD is the most frequent cause of blindness (19% total + partial); 15% caused by diabetic retinopathy [5].

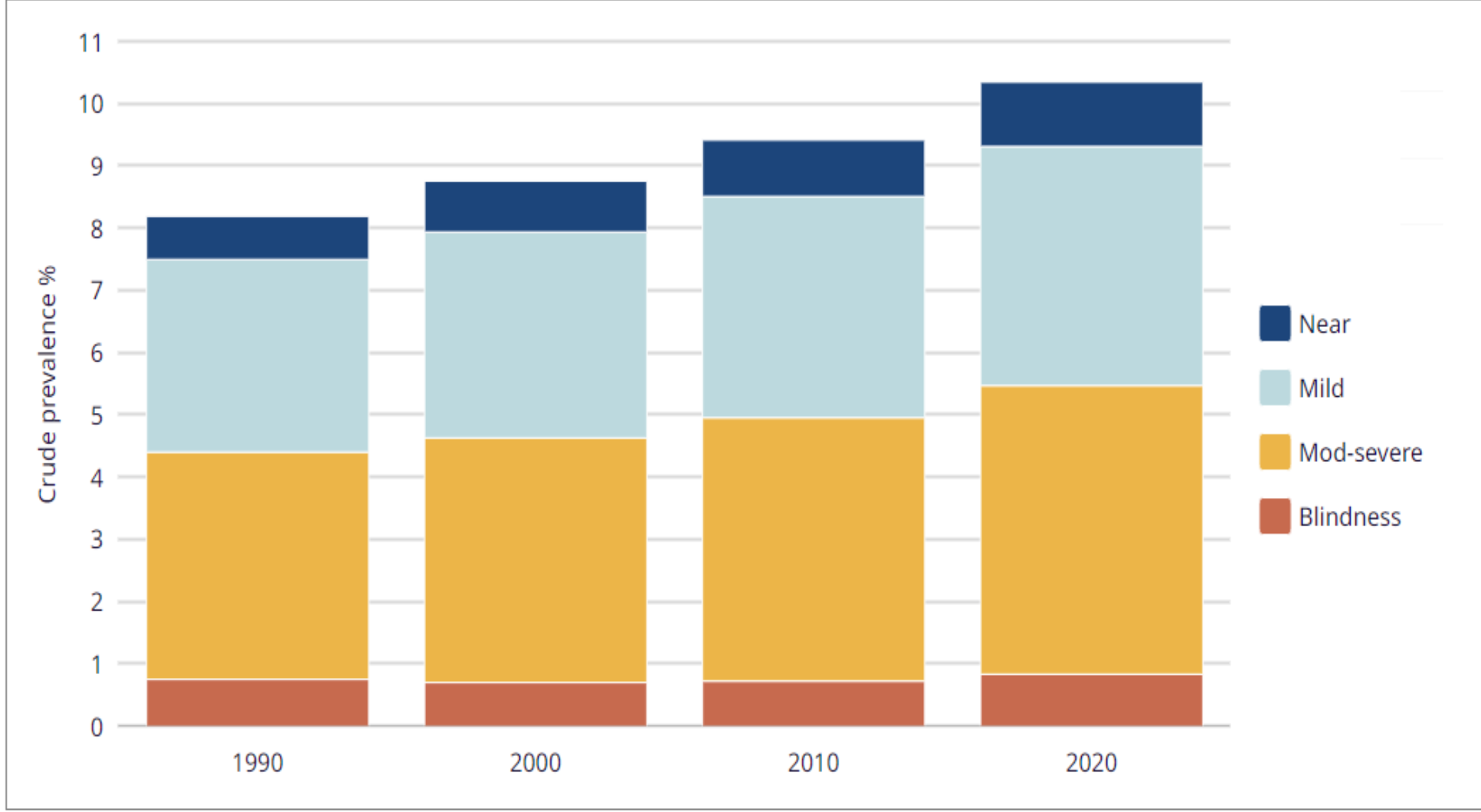


Figure 1 – Crude prevalence of vision loss, Italy, 1990 - 2020

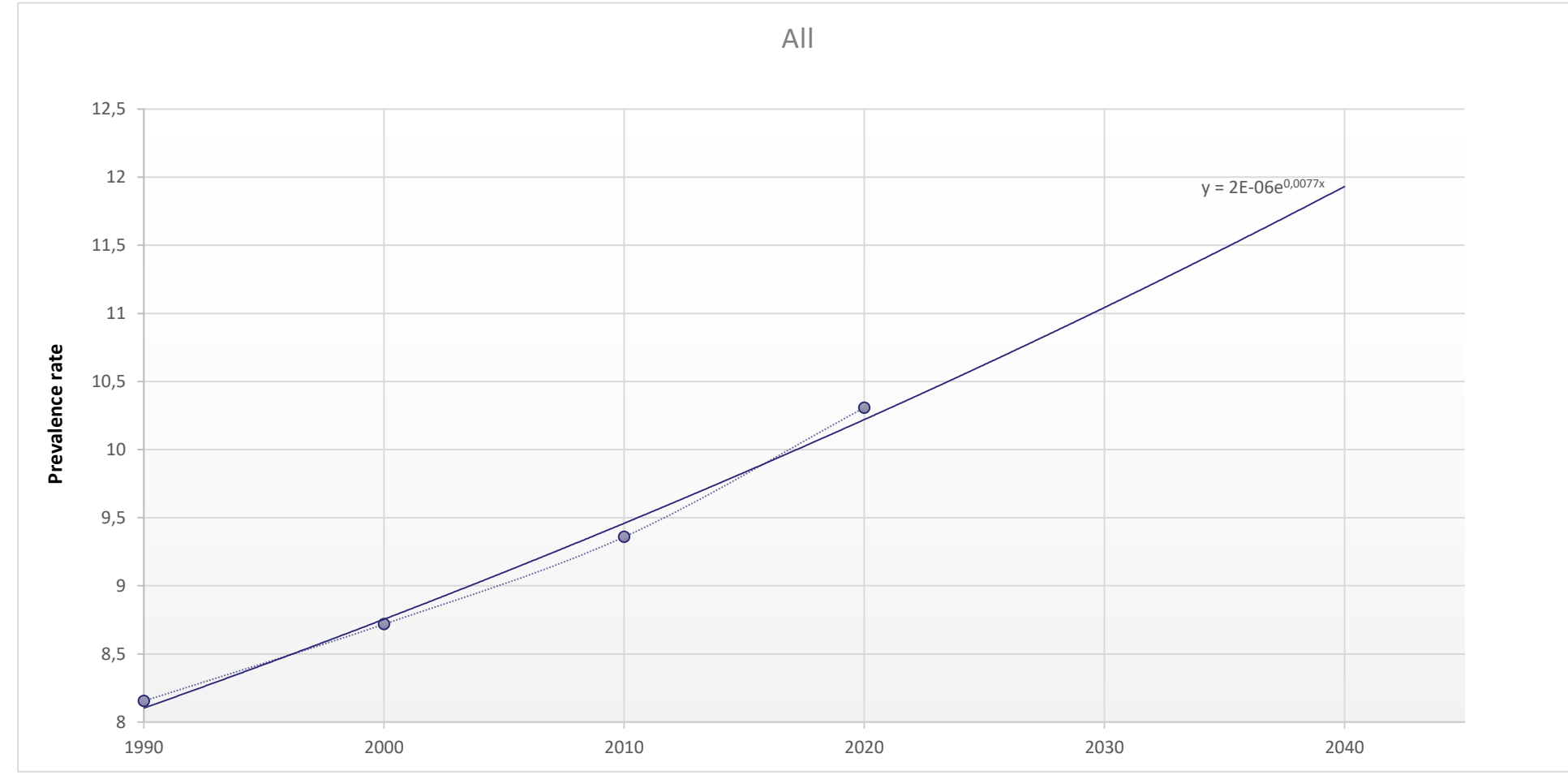


Figure 2 – Hypothetical trend of crude prevalence of vision loss in Italy (best fitting for exponential curve)

Are we able to slow the growth?

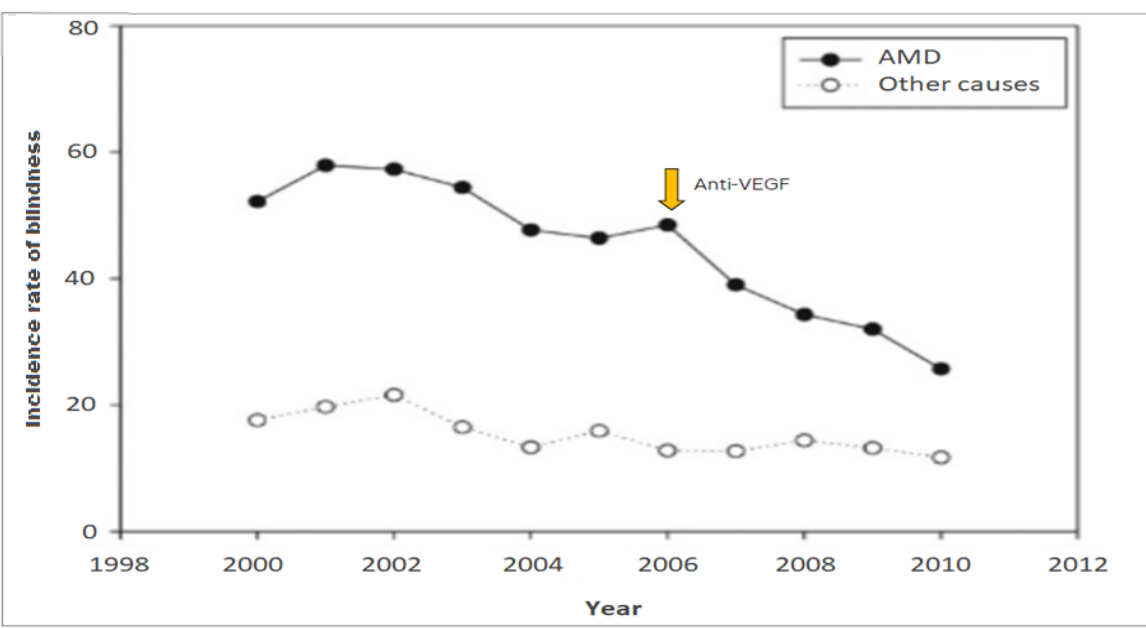


Figure 3 – Evolution of blindness incidence rate before/after anti-VEGF release on the market

- In Denmark the use of anti-VEGFs have halved the incidence of blindness due to AMD [6] (Figure 3)
- Italy is very far from this result due to very poor adherence
- Our *ad hoc* statistical model suggests that within ten years the complete adherence to anti-VEGF may reduce the incidence peak of blindness due to AMD by 40%; 36% for DME.
- The forecast effect of these data on the increasing number of blind people (about 41 thousand patients during the next decade) corresponds to a rough estimate of 5,600 avoided cases

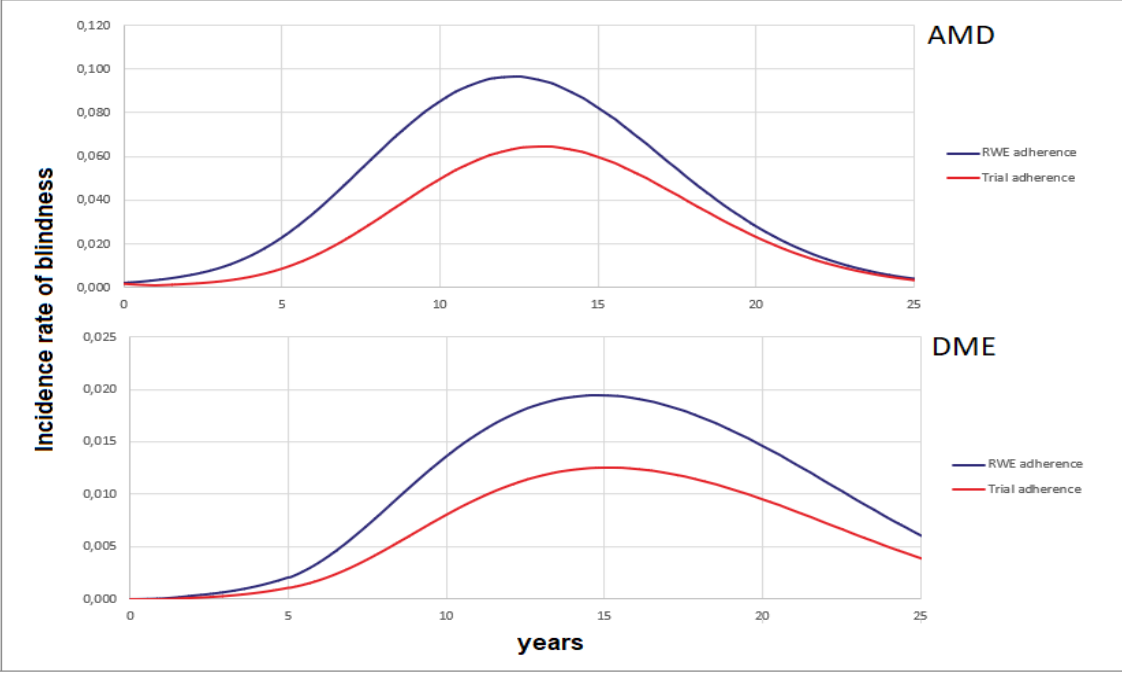


Figure 4 – Blindness incidence curves estimated by statistical model with adherence RW or complete

NSS expenditure for blindness and scenarios

- The total annual social expenditure for beneficiaries remains approximately stable at 1 billion euro since 2017 [7] as shown in Table I.
- Only a minor portion of blind patients receives an invalidity pension: main reasons may be related to administrative difficulties of accessing, income criteria, or socio-economic stigma.
- Since beneficiaries are steadily increasing, this trend inevitably corresponds to a decrease of unitary Attendance allowance (AA) and Social Security Income (SSI).
- Even if the single benefit is maintained stable, a lower purchasing power is obviously linked to them

Year	SSI		AA		Total per year in Italy
	N beneficiaries	€/month	N beneficiaries	€/month	
2017	118.842	524 €	78.823	317 €	1.072.108.079 €
2018	122.480	511 €	81.590	297 €	1.066.066.350 €
2019	122.712	514 €	81.971	300 €	1.076.574.516 €
2020	123.044	519 €	82.128	301 €	1.087.684.896 €

Table I – Expenditure for Social Security Incomes and Attendance Allowances

Scenarios in 2033

- Same Social Security budget: SSI would decrease down to 470 € per month, and AA down to 273€
- Same purchasing power of single SSI/AA for increased number of beneficiaries: the NSS annual expenditure would need to increase by about 360 million Euros
- Same purchasing power of single SSI/AA with adherence optimization: saving of 36 million Euros vs the expenditure of scenario 2

Conclusions

- Incidence rate of blindness is increasing, with progressive population ageing being the main factor
- Appropriate therapies are unable to drastically stop this trend, at least as long current very poor adherence values will be maintained
- Official NSS Cost database highlights that this worrying trend is not backed up by appropriate social expenditure, with a fragmented and not forward-thinking approach of stakeholders to the management of main vision loss causes.
- Payers, Institutions and Patients should reflect on this evidence and promptly act on both sides: improving therapy compliance and making social welfare adequate.

- IAPB Vision Atlas at <https://www.iapb.org/learn/vision-atlas/magnitude-and-projections/countries/italy>
- Perrone V et al. Int.J.Environ.Res. Public Health 2022,19 2548
- Ciulla TA et al. Br J Ophthalmol 2021;105:216–221.
- Ciulla TA et al. Ophthalmology Retina 2020; 4,1;19:30
- Cruciani F et al. La clinica terapeutica 2010; v 161 n1
- Brandi Bloch S et al. American Journal of Ophthalmology 2012; 153,2; 209-213
- NSS Cost database available at www.inps.it