



# POLICY RECOMMENDATIONS ON GEOGRAPHIC ATROPHY

How to tackle a chronic eye disease  
affecting five million people worldwide





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# I EXECUTIVE SUMMARY

Macular degeneration is the term used to describe various eye disorders affecting the macula, the central region of the retina which plays a vital role in our vision. Since this eye disease mainly affects people over 65, it is also called age-related macular degeneration, in short, AMD.

Advanced AMD is considered the largest cause of legal blindness in industrialised nations and includes two forms: **dry AMD**, also known as **geographic atrophy (GA)**, and wet AMD.

Different therapeutic options are available for wet AMD, while geographic atrophy, affecting approximately 5 million patients globally, currently has no available treatments. In contrast to wet AMD, which is characterised by acute vision loss, GA is a progressive disease leading to **irreversible blindness over time**. Early in the disease, GA interferes with daily activities such as driving, reading, writing and recognising faces, and negatively affects quality of life, impairing mobility, autonomy and independence. As eyecare is not featured in EU policies and scarcely at the national level, new policies are needed, to help integrate prevention, early diagnosis, monitoring and treatment of eye conditions across the European Union. In particular, the devastating impact of GA on patients' lives and the current lack of therapeutic options make GA the highest unmet medical need in ophthalmology and an important health care priority, which deserves attention from policy and decision-makers.

The set of policy recommendations presented here stems from inputs and suggestions provided directly by an independent group of advisors consisting of Patient Advocacy Groups and leading clinical experts in the field of retinal disorders in the EU. Such recommendations range from promoting new initiatives in favour of GA patients to advocating for the introduction of new proposals to integrate GA and eye conditions into the existing EU policy agenda.

**Chapter one** provides an overview of the disease and the overall burden this poses for patients suffering from GA.

**Chapter two** explores in depth the impact GA has on a patient's Quality of Life, including the emotional and psychological distress experienced by patients with visual impairment and vision loss. In this chapter patient advocates and clinical experts discuss the importance of devoting adequate attention and funding to the emotional and psychological support of patients with GA. They also highlight the need to include GA in existing EU policy initiatives, e.g., mandatory screenings for retinal diseases in the ongoing Revision of the Directive on Driving Licenses, as well as the importance of recognizing visual impairment caused by GA as a priority area for healthy ageing and long-term care by European Commission.

**Chapter three** focuses on the importance of facilitating early diagnosis of GA. In this chapter patient advocates and clinical experts discuss the importance of awareness raising campaigns and of national screening programs, the need for coordinated and effective communication with patients from diagnosis to management of retinal diseases, as well as strengthening patient registry infrastructures.

**Chapter four** looks at the socio-economic impact of GA. It stresses the importance of early detection of GA since not all patients may have reached retirement when diagnosed. This chapter, therefore, discusses the need for strategic workplace modifications in order to maintain the health and safety of all employees. In addition, there is lack of knowledge around the economic burden of GA, since there is limited information on the overall costs healthcare systems need to bear and the additional costs patients must pay out-of-pocket.

In **Chapter five** patient advocates and clinical experts highlight the steps that must be taken for healthcare systems to adapt, including investment in equipment needed to facilitate accurate detection of GA and addressing unequal access to diagnosis and treatment centres both cross-border and nationally.

# I FOREWORD FROM MEMBERS OF THE EUROPEAN PARLIAMENT

**Dear readers,**

As generally known, ageing of the European population is one of the most significant European demographic phenomena and social trends. The challenges that we must undergo, as a result, have been debated for a number of years now and are reflected in current global, European and national policies. All actions undertaken to date suggest that our society will increasingly depend on the health and independence of ageing persons.

When we consider health and independence of older citizens, a holistic approach to the vision of an ageing Europe is crucial. Ageing citizens with severe vision loss experience a great decline in activity and mobility which in turn contributes to overall wellbeing. Although the risk of eye problems is often associated with age, severe eye problems of ageing citizens are not simply a symptom of getting older and should not be perceived as such.

Healthy and active ageing must become a priority for policymakers if we want to promote independent living for ageing citizens. Beyond this angle of independence, good vision is crucial for work performance. We can observe substantial growth in the employment rates of older workers, which demands the 60+ generation to stay active, independent and healthy – and for that, health and safety at work must be improved. It remains of utmost importance to make sure that employees, in particular ageing people have the necessary vision checks.

Regular screening can lead to our societies being professionally active for longer – which is of key importance considering our demographic changes. It is vital that we find solutions which allow citizens to be a part of our societies, including the workforce, rather than feeding an environment in which these valued citizens are ostracized.

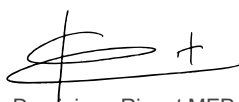
The interaction between vision and ageing Europe cannot be ignored and visual health should be an integral part of the European approach toward healthy and active ageing. As policymakers, we are committed to ensuring that vision impairment is placed at the forefront of the political agenda and is regarded as a grave public health concern.

When we consider geographic atrophy in age-related macular degeneration (AMD), which affects 5 million people globally and to which there is no treatment approved to slow disease progression, it is unquestionable that the burden of the disease contributes to the list of public health concerns.

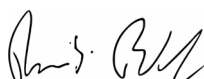
These recommendations encompass the key aspects of living with geographic atrophy and outline how to improve the current state of play related to the disease itself, alongside healthy ageing overall, greater autonomy and independence, and improved screening practices and work conditions. They represent a very first step at the EU level towards tackling a devastating disease affecting members of our societies.



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# I POLICY RECOMMENDATIONS

## BURDEN OF THE ILLNESS

- 1.** The European Commission as well as the Member States should guarantee adequate attention to the psychological and emotional aspects of people suffering from GA, to enable acceptance and guide patients after diagnosis. Support can be provided either through cooperation with national civil society organisations or through the European and national budgets available for emotional and psychological wellbeing. Where possible, specialised centres or organisations may consider having the support of a mental health specialist to support and guide patients.
- 2.** Member States and their regions should approve a national protocol for social and healthcare coordination of visual impairment, as a guide for patients and caregivers on access to services, benefits, and visual aids. The protocols should aim at defining actions to prevent the negative impact on physical and mental health and well-being that GA may have, both on patients and their caregivers.



3. As the European Commission is revamping the European approach to social care requirements through the European Care Strategy initiative, the needs of people with low vision, such as those with GA, should be taken into account.
4. The ongoing revision of the Directive on Driving Licences should harmonise the visual acuity tests across the European Union, and include the mandatory screening for retinal diseases, including GA, with the goal to improve road safety.
5. Under the European Pillar of Social Rights and in particular the proposal for a Council Recommendation on long-term care, the European Commission is exhorted to consider visual impairment, caused by chronic progressive diseases such as GA, as a priority area to address for healthy ageing and Long-term care. At the EU, national and regional level, policymakers must guarantee financial support to visually impaired people. Active ageing must be supported and motivated, psychologically and financially. A key objective must be access to the digital society for visually impaired people.



## EARLY DIAGNOSIS: KEY TO COLLECTING KNOWLEDGE AND COMBATTING THE DISEASE

6. Member States should implement and promote awareness-raising activities on GA screening, on the effects of low vision and the avoidance of blindness for those potentially affected, both at national and regional level. At the European level, the European Commission should dedicate funds to support civil society organisations, including patient organisations, in raising awareness about GA, including through the EU4Health funding mechanism.
7. Member States should implement plans for information, training and coordinated monitoring between care levels, as well as actions to promote and increase treatment adherence.
8. Following the example of the successful 2003 Cancer Screening Recommendation, the European Commission is urged to start working towards the Council Recommendation on Eye Health Screening, recommended for all European citizens above 50 years old. Member States should develop and appropriately implement regular eye examination programmes.



9. Member States should develop their own eye health registry, including AMD and GA, connected to ophthalmology practices' electronic medical records systems. The national registries should be further fostered through the upcoming health ecosystem, **European Health Data Space** and contribute to, amongst others, a better understanding of the disease.



## SOCIO-ECONOMIC IMPACT OF GEOGRAPHIC ATROPHY

- 10.** The European Commission should expand its vision on its ageing policy agenda through follow up actions to those outlined in the Green Paper on Ageing. Moreover, concrete policy options should be presented, including a comprehensive strategy for eye health. In addition, since the role of the Commission is to ensure a harmonised approach towards the implementation of European policies and soft laws, it should do its utmost to support Member States in tackling vision impairment in their healthy ageing national strategies. This can be done by producing a White Paper on Ageing, outlining concrete steps for national governments.
- 11.** Considering the role of the European Agency for Safety and Health at Work, it is called upon to prepare, collect and adequately disseminate information on occupational safety and health issues from the perspective of workers with low vision, including those suffering from GA.
- 12.** The European Commission should address the need for additional research on the economic burden of the disease through available funding mechanisms, including but not limited to the Horizon Europe programme as well as EU4health.



**13.** Member States should monitor relevant funding opportunities and invite national stakeholders to apply through available EU programmes – in particular the Cohesion Policy funds, including the European Regional Development Fund. Through these funding opportunities, stakeholders may be able to increase capacity for intravitreal injections, upgrade the existing equipment used for screening programmes or supply their institutions with additional equipment. This may also allow for an increase in the number of available treatment centres where necessary.

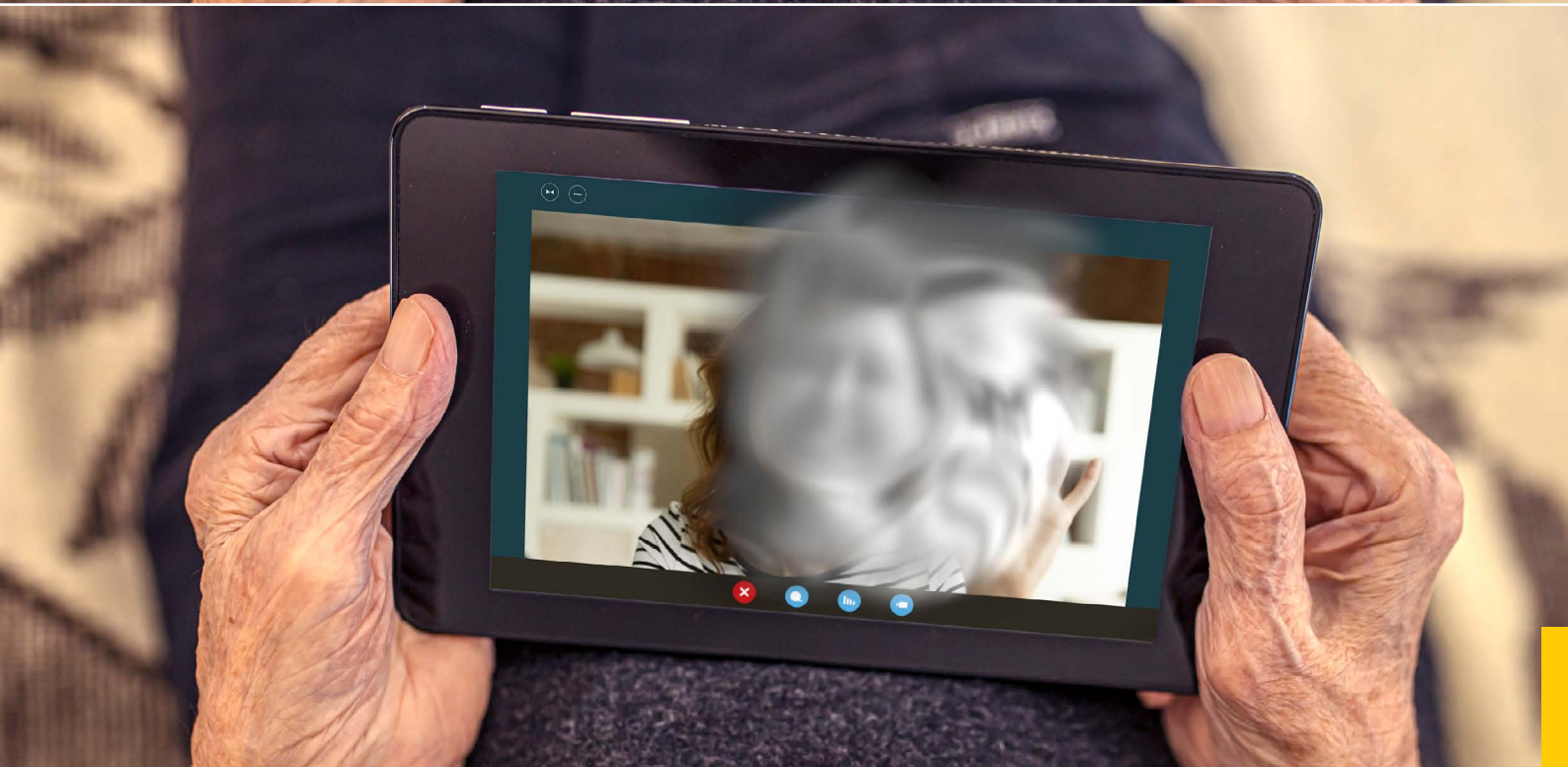
**14.** At the primary eye care level, healthcare professionals (e.g., GPs, opticians/optometrists) must be made aware of GA throughout education pathways and provided with the correct tools and resources to accurately detect signs of GA in order to refer patients to ophthalmologists/retina specialists. Member States should work towards enhancing education and training on GA in primary care. Further education needs to be delivered on what GA is and how to diagnose it correctly.



- 15.** Member States should address access barriers to health and social care for people living in rural and deprived areas, for example by increasing the number of available treatment centres and/or investing in the existing ones. Bearing in mind the availability of a potential GA treatment, further investment should be made to address potential capacity barriers to patients' access to treatments. This can be done through the use of existing EU funding mechanisms, notably through Cohesion Policy funds, including the European Regional Development Fund.







# 1. INTRODUCTION TO GEOGRAPHIC ATROPHY

Macular degeneration is the term used to describe various eye disorders affecting the macula, the central region of the retina which plays a vital role in our vision. Since this eye disease mainly affects people over 65, it is also called age-related macular degeneration, in short, AMD.

Advanced AMD is considered the largest cause of legal blindness in industrialised nations<sup>1</sup> and includes two forms: wet AMD and **dry AMD**, also known as **geographic atrophy** (GA).

Different therapeutic options are available for wet AMD, whilst geographic atrophy, affecting approximately 5 million patients globally – primarily the elderly – represents the currently **largest unmet medical need existing in ophthalmology with no available treatments**.

GA is characterised by the growth of lesions in the central region of the macula, which lead to a slow and irreversible vision loss. This devastating disease impairs patients' functional vision, impacts patients' QoL and limits autonomy and independence in the early stages, and ultimately leads to blindness. Approximately **eight out of ten** people diagnosed with AMD suffer from its dry form.<sup>2</sup>

Disease progression, which affects one or both eyes, is slow, and **symptoms of the disease do not appear suddenly**. Patients who have only one eye affected may be diagnosed at later stages, as significant changes in vision are not noticed, with the healthy eye compensating for the damaged vision.

Many patients are asymptomatic in the early stages of the disease. As lesions advance the central vision is significantly impaired, which leads to gradual loss of visual function. Patient advocates interviewed for these recommendations described the initial symptoms in a variety of ways: reduced ability to see at night, distortion of straight lines and increased visual blurriness. While the loss of visual function is more gradual than in wet AMD, the resulting visual impairment can be just as devastating due to the irreversible nature of GA.

The irreversible visual impairment and decreased central vision, which often affects both eyes (bilateral GA) with almost symmetrical deterioration, has a significant emotional and physical burden on patients. More precisely, it can cause a **loss of ability to perform basic activities such as reading, driving, recognising faces, and more generally mobility, autonomy and independence**. Greater visual impairment is also associated with an increased risk of falls, fractures and vision-related injuries.

To date, there are no approved treatments to reverse, prevent, or reduce the progression of GA – contrary to the wet form of AMD for which effective treatments are available. However, there are potential therapies in clinical trials that provide hope for GA patients.<sup>3</sup>

Due to the lack of approved treatment options for dry AMD, the current management approaches have focused on risk factor reduction. Patients are given only nutritional recommendations (e.g., supplements, vitamins) and advice on lifestyle modifications, such as quitting smoking. None of these treatments has established effectiveness and no therapy is currently approved. In addition, previous developments of therapies failed to demonstrate efficacy in GA. The literary research and interviews conducted to inform this paper report that there is an urgent and significant unmet need for GA due to the lack of treatment, given the profound impact of dry AMD on the lives of patients.

The aim of this paper is to provide an overview of the burden that GA presents for patients and their caregivers, as well as for the societies and economies of the EU. The paper provides a set of policy recommendations on how to effectively address any existing key challenges to improve current healthcare systems, and ultimately the lives of patients suffering from GA.



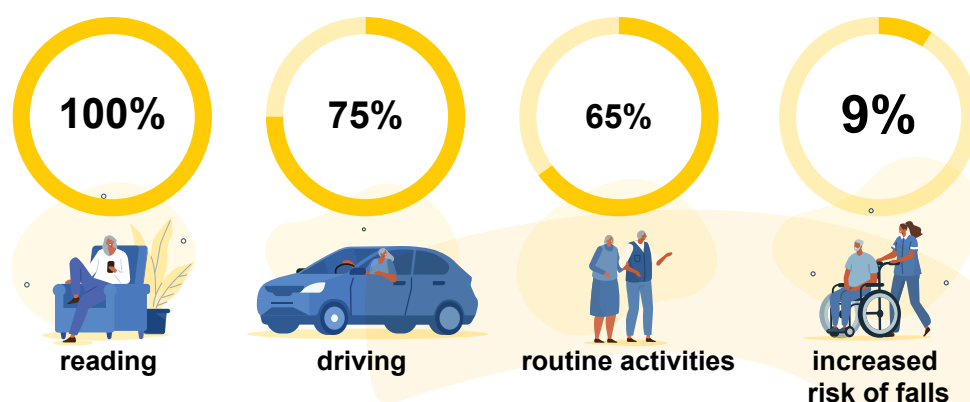
## 2. BURDEN OF THE ILLNESS: GA PATIENTS AND THEIR CAREGIVERS



### 2.1 The burden of GA: impact on Quality of Life

An ageing population demographic means that chronic and degenerative diseases are increasing every year. GA is a chronic eye disease that mainly affects the population over 60 years old.<sup>4</sup> The inexorable loss of sight cannot be seen only as a physical impairment for patients, as the condition inevitably entails a dramatic decline in Quality of Life (QoL). The more the disease progresses, the increasingly challenging it becomes to conduct essential daily living tasks such as grocery shopping or paying bills.

A cross-sectional ethnographic study found that consequences of GA vision loss significantly impacted GA patients' abilities in: reading (100%), driving (75%) and routine activities, such as personal hygiene (65%). Greater visual impairment is also associated with increased risk of falls, fractures and vision-related injuries, with 9% of GA patients experiencing a fall or fracture due to their impaired vision.<sup>6</sup>



Patients report a sense of frustration regarding the lack of autonomy and independence as well as the constant need to rely on others for help. For these reasons, GA patients face a greater risk for developing and experiencing depression<sup>7</sup>, anxiety<sup>8</sup>, and are more susceptible to falls as a result of poor visual acuity<sup>9</sup>, increased caregiver burden and absence of approved treatments.<sup>10</sup>

Considering the radical influence GA has on the lives of patients, all psychological and social aspects must be taken into account when this pathology occurs (higher depression<sup>11</sup> and mortality rates<sup>12</sup>, low self-esteem, falls, isolation, etc).



### 2.2 Mental health spotlight: emotional and psychological well-being

Generally speaking, patients with AMD are perceived to be at increased risk of worse emotional and psychological well-being compared with those who suffer from other visual impairments. The gradual loss of sight has a serious psycho-social impact on the life of the patient as well as on that of family members and caregivers. Patients may have to change their life plans and those of their families, learn to do things differently, often requiring appropriate support and training. Caregivers may report frustration too at watching patients struggle, and often they have to provide transportation, assist with household tasks and significantly adapt their lives to the patient's disease.<sup>13</sup>

A GA diagnosis is difficult for patients to accept, especially considering the lack of treatment. Psychological support should be part of the patient's journey from the moment of diagnosis. However, patients must often seek the required support through private means or through national and regional associations, since it is not offered by institutional facilities.

The support of patient organisations is crucial in helping newly-diagnosed patients cope with the disease. In fact, it may be easier to understand what one is facing and how to approach certain facets of the disease when those already living with the condition are available to explain and provide support. These individuals, who provide support on a voluntary basis, are difficult to find and does not lessen the fact that living with GA will continue to be a daily difficulty patients must face.

#### **RECOMMENDATION**

The European Commission as well as the Member States should guarantee adequate attention to the psychological and emotional aspects of people suffering from GA, to enable acceptance and guide the patients after the diagnosis. Support can be provided either through cooperation with national civil society organisations or through the European and national budgets available for psychological and mental well-being. Where possible, specialised centres or organisations may consider having the support of a mental health specialist to support and guide patients.

#### **RECOMMENDATION**

Member States and their regions should approve a national protocol for social and healthcare co-ordination of visual impairment, as a guide for patients and carers on access to services, benefits, and aids. The protocols should aim at defining actions to prevent the negative impact on physical and mental health and well-being that GA may have, both on patients and their carers.

In this regard, some examples of current best practices that emerged during the interviews come from Germany, France and Italy. German patients for example can benefit from the support provided by trained members of the nation-wide patient organisation PRO RETINA. The members, after having received specialised training, are available to support other affected people and their caregivers by providing mental health support, information about available visual aids, assistance in social law issues as well as and other relevant information the may patient need.<sup>14</sup>

In France, the DMLA Association offers a free hotline service<sup>15</sup> (numéro vert) to give information on screening, prevention and treatment of the disease, as well as offer psychological support, information on patients' rights and advice on daily life. Similarly, in Italy, the Associazione Comitato Macula has set up the "SOS Macula" service<sup>16</sup>, the first hotline dedicated to patients affected by macular degeneration, with the aim of listening to the needs of patients and their families and help them find the most suitable solution to their problems.

These examples clearly showcase that social care is put on family or other unpaid support.

#### **RECOMMENDATION**

As the European Commission is revamping the European approach to social care requirements through the European Care Strategy initiative, the needs of people with low vision, such as GA, should be taken into account.



### **2.3 Losing independence: driving autonomously**

Being diagnosed with GA does not mean that patients have to immediately stop driving and lose their independence. While driving is not automatically forbidden for GA patients, this right requires a regular re-evaluation of the patient's vision and an assessment of the risk they pose to themselves and others.

The European Union introduced the 2006/126/EC Driving Directive<sup>17</sup>, which included provisions on the medical examinations of eyesight. Yet, to date, there is a lack of uniformity in how visual standards are applied in the EU. For example, some countries introduce the obligation for drivers to assess their sight at 45 years (Finland, Hungary), 50 years (Italy, Latvia), while some Member States have not implemented this measure at all.<sup>18</sup>



The medical annex to the Directive states that for drivers of cars and motorcycles, the visual acuity standard is the binocular vision of at least 0.5 decimal (6/12 minimum vision). These minimum standards must be met by everyone applying for a licence or a renewal. The current recommendation for the visual acuity standard is to read a number plate – an approach which was widely criticised by the European Council for Optometry and Optics (ECOO) due to the test being an inappropriate method of determining whether a person has adequate vision for driving.<sup>19</sup>

Given the responsibility of policymakers in providing a framework to enable safe driving conditions for European citizens, the upcoming revision of the Directive on Driving Licences (new proposal foreseen for Q4 2022) should further improve the harmonisation of Member States' approaches to vision screening and ensure that AMDs are included in such lists.

#### **RECOMMENDATION**

The ongoing Revision of the Directive on Driving Licences should harmonise the visual acuity tests across the European Union, and include the mandatory screening for retinal diseases, including GA, with the goal to improve road safety.



#### **2.4 Lack of support: facilitating daily living for GA Patients**

GA patients require assistance in daily activities, most of which is unpaid care, and across the EU there is a clear lack of equity at regional and national level. In Spain for example, the interviewees reported a significant difference between people with legal blindness, and people with low vision and their access to services. The former can access services of the Spanish National Organisation of the Blind (ONCE) while the rest of the visually impaired do not have any public support.

Many GA patients need adjustments to their lives, including the acquisition of vision-related equipment, such as magnifiers, electronic video magnifiers, glasses or portable lighting – equipment that the interviewed patients judged as relatively expensive. An increasing number of companies producing smartphones or computers adjust their software to help those visually impaired, providing more accessibility features. With technological advancements, GA patients' daily lives can be facilitated.

New technologies, such as telemedicine, must also be used to also allow direct contact with doctors and specialists for consultations without having to travel, as this becomes increasingly complex for GA patients. During the interviews, it emerged that with the COVID-19 pandemic, teleophthalmology (telemedicine) has slightly increased and has indeed proved useful, in particular when it comes to the management of the disease (follow-up visits). However, some respondents emphasised that in the long term, patients may start to feel the lack of human contact, essential for a trusting relationship with patients. An appropriate balance must therefore be found.

Technological solutions, however, can be expensive. Interviewees from Germany pointed out that these technologies are often reimbursed, with the system being overall well-organised and structured. It should therefore be considered a good reference model. Across all Member States it is essential that governments show interest in the living conditions of the ageing population and bear in mind the substantial differences in personal circumstances and accessibility: a patient's financial situation, geographical location, as well as one's ability to familiarise themselves with new technology are in fact important accessibility factors. So far, support networks have played an important role in informing GA patients and caregivers about the existing aids.<sup>20</sup> Regardless, the interviewed patient organisations outlined not only the importance of providing reliable information about products that can support patients in assisting in their daily lives, but most importantly the need for GA patients (alongside other patients with low vision) to receive financial support from the national government to cover the indirect costs of illness.

**RECOMMENDATION**

Under the European Pillar of Social Rights and in particular the proposal for a Council Recommendation on Long-term care, the European Commission is exhorted to consider visual impairment, caused by chronic progressive diseases such as GA, as a priority area to address for healthy ageing and long-term care.

At the EU, national and regional level, policymakers must guarantee financial support to visually impaired people. Active ageing must be supported and motivated, psychologically and financially. A key objective must be access to the digital society for visually impaired people.

# 3. EARLY DIAGNOSIS: KEY TO COLLECTING KNOWLEDGE AND COMBATTING THE DISEASE

In the current climate with a lack of treatment, the major benefit of screening for GA is that a correct and early diagnosis can provide a window of opportunity for patients to find and enrol in ongoing clinical trials, adapt healthy lifestyles, get accustomed to the use of low vision aids as well as continue regular monitoring.

Knowing about the disease earlier gives patients more time to process and prepare for the permanent changes they will have to make to their lifestyle. Doctors and patients are able to work together to provide the individual with a high sense of autonomy by learning how to achieve daily tasks independently. This is also true for the patient's support network, who can similarly prepare and learn how to best provide support to the patient. Moreover, several clinical trials are currently ongoing for GA and a timely diagnosis can allow patients to enrol in these trials and potentially benefit from a new treatment. The following section analyses the advantages of an early diagnosis.



## 3.1 Raising awareness: the first step to a successful early diagnosis through screening

As explained above, GA is a disease that strikes and intensifies from the age of 60 years old. Regrettably, there is a generalised belief among the elderly population that getting older means losing vision, that this is “normal” and they do not need to do check-ups. Awareness campaigns are an effective method of familiarising the general population with health standards and the lack thereof.

In general, the culture of eye care and prevention **must be promoted and instilled in society**. Relevant associations and groups are undertaking awareness-raising activities for GA, but **institutional support** is essential for further and more widespread support. A number of interviewees mentioned some of the initiatives they would like to launch or that have been launched in the past that could support this cause, for example:

- Collaboration with pharmacies for advice/assistance (refer the patient to the correct specialist).
- Information leaflets or self-test charts in the waiting rooms of doctors and general practitioners.
- Institutional-supported initiatives in main town squares (e.g., tour with a camper van).
- TV and radio spots (to better connect with the target audience).
- Targeted press campaigns.

In order to raise awareness, the target demographic group must be taken into account, assessing which tools are most valuable to use (TV, face-to-face etc) or who they are mainly in contact with (GPs, pharmacists). Raising awareness can also be done on regional and local levels, such as providing leaflets in pharmacies, or educating pharmacists who in turn can inform customers of available screening programmes. In the Italian region Lombardy, the Free Outpatient Ophthalmologists Group (Goal), the Patients Association Comitato Macula and the Order of Physicians of the Province of Milan (OmceoMi) recently launched the awareness campaign 'TestalaVista' ('test your sight'), with the central aim of raising awareness on the importance of early diagnosis and prevention of maculopathies. This awareness campaign thus also speaks towards the importance of collecting epidemiological data.

The "Objetivo DMAE" study launched in Spain in 2020 is a great example of suggestions and several recommendations have been made on the need for awareness raising and social support to give visibility to this condition. As of yet, these recommendations have not led to the development of specific plans or proposals from regions and governments. As of yet, these recommendations have not led to the development of specific plans or proposals from regions and governments.

TV campaigns promoting early screening for AMD, driven by pharmaceutical companies in collaboration with Ophthalmology societies in both France and Spain, proved to be effective, with the general population becoming more familiar with the condition and individuals visiting a specialist at an earlier stage in their life to receive screening for AMD.

Another excellent example of best practice is the National AMD Information and Screening Days launched in 2007 by the Association DMLA in France. The first edition of this event took place in an in multiple geographical locations: a truck drove across France to meet the population in 13 major cities and more than 3000 people were screened. As a result, 609 cases of AMD, 84 cases of dry AMD and 54 cases of wet AMD were diagnosed in at least one eye. The event then evolved further in the coming years.

#### **RECOMMENDATION**

Member states should implement and promote awareness-raising activities on GA screening, on the effects of low vision and the avoidance of blindness for those potentially affected, both at national and regional level.

At the European level, the European Commission should dedicate funds to support civil society organisations, including patient organisations, in raising awareness about GA, including through the EU4Health funding mechanism.



### **3.2 Providing reliable information to patients and caregivers**

Some of the patients' representatives interviewed remarked that effective communication and plain language are crucial to get the attention of the older population and not "scare" them with the idea of a damning diagnosis. Family networks play an essential part in raising awareness because they can stimulate their older relatives to receive check-ups. Patients should always receive appropriate information from their doctors because there is a constant risk of misinformation. They may try to find resources themselves, for example on social networks. Caregivers need to receive the same information as the patient after diagnosis, as they will be a pillar in the patient's life.

This means that the disease must be communicated with the right words so patients are not faced with fear and worries, or conversely apathy, as they receive the diagnosis. Following a diagnosis, patients need to leave the room with the clear idea that GA is a chronic disease, which will affect their life and the life of their caregivers. This is crucial as interviewed experts outlined that a recurrent problem with patients suffering from wet AMD or similar maculopathies is that they give up treatment midway through, they are inconsistent, and/or do not show up for all check-ups.



## RECOMMENDATION

Member States should implement plans for information, training and coordinated monitoring between care levels, as well as actions to promote adherence and increase treatment adherence.



### 3.3 National screening programmes key in addressing blindness

Currently, there are no screening programmes in many EU Member States for GA, although the disease is detectable up to four years before disease onset.<sup>21</sup> When speaking about recommended eye health check-ups, the interviewed experts noted that European countries mainly offer eye examinations for people with diabetes.

National and regional screening programmes have the potential to identify early changes in the retina<sup>22</sup> and regular screening for AMD can have positive outcomes in preventing blindness.<sup>23</sup>



National screening programmes are closely linked to campaigns aiming to raise awareness, which was discussed in the previous section. The effectiveness of awareness-raising campaigns is easily identified. A 2012/2013 UK study on the impact of breast cancer screening awareness campaigns on mammography attendance showed that these awareness campaigns increased the uptake of self-examination behaviours and consequently the likelihood of attending a screening for breast cancer.<sup>24</sup> In the decade since this study was undertaken, breast cancer is now the most commonly diagnosed cancer worldwide, surpassing lung cancer, providing evidence for the effectiveness of awareness campaigns.<sup>25</sup> Studies on the uptake of cancer screenings have also been done at EU level. The Council 2003 Cancer Screening Recommendation, which urged Member States to introduce, or scale-up their cancer screening efforts for breast, cervical and colorectal cancer,<sup>26</sup> saw significant improvements in the implementation of screening uptake in all three cancers, but most significantly in cervical cancer screening (from 51.3% in 2007 to 72.3% in 2017) and colorectal cancer, where ongoing or completed roll-out of cancer screening in the Member States rose from five in 2007 to 17 Member States in 2016.<sup>27</sup>

Although there is no treatment available, screening in terms of GA is important in many aspects. First and foremost, given that the early signs start before the symptoms arrive, it is important for patients to understand the condition, to know what they could do with lifestyle modifications, how to adapt to upcoming changes and potentially enrol in clinical trials. The participation of patients in clinical research at the early stages of the disease would further support researchers in gaining a better understanding of the pathogenesis of disease progression.<sup>28</sup>

## RECOMMENDATION

Following the example of the successful 2003 Cancer Screening Recommendation, the European Commission is urged to start working towards the Council Recommendation on Eye Health Screening, recommended for all European citizens above 50 years old. Member States should develop and appropriately implement regular eye examination programmes.



### 3.4 Implementation of national registries

Patient registries are organised systems that collect standardised data about a group of patients faced with the same illness or disease. They are a key resource and must be present throughout Member States to collect important data on the natural history of the disease as well as its economic and societal burden. There are a number of countries that have introduced national patient registers, such as Denmark or the UK.<sup>29</sup> Such repositories are highly regarded internationally, due to the insights these large data sets can provide. These registries also exist for a number of eye-related diseases, such as the IRIS Registry in the US (Intelligent Research in Sight Registry), a comprehensive eye disease clinical registry, providing ophthalmologists with a way to compare patient outcomes, professional performances and different care processes. In the EU the MACUSTAR project is an ongoing observational study, which is following more than 700 AMD patients all over Europe and aims to develop and validate appropriate clinical endpoints for future clinical developments in AMD.<sup>30</sup>

Having a European and/or national registry for GA patients is a crucial infrastructural element.

By having specific data sets on each patient, a widescale joint analysis of the disease characteristics can be facilitated, thus **strengthening the knowledge about the disease and informing clinical trials**. Registries also allow doctors to access a wide range of data provided by studies undertaken by peers and further facilitate knowledge exchange and opportunities for collaboration.

The added benefit of having a central repository is that this provides further epidemiological data, and thus increasingly builds momentum into research and treatment options. **Once treatment is made available, patient registries already provide healthcare systems with insight as to who needs treatment, creating an efficient opportunity for distribution and uptake of treatment.** Additionally, through these data insights, healthcare systems can further **learn where regional inequities** may exist and act on these accordingly. Although the need for national registries prevailed during the interviews, it was pointed out that adequate resources are needed in order to first set them up, and subsequently maintain them.

The European Health Data Space proposal provides a valuable opportunity to help shape and securely implement national GA registries. Between May and June 2021, the European Commission conducted a public consultation, gathering the public's views on an EU initiative for a European Health Data Space (EHDS).<sup>31</sup> The consultation gathered priorities from all stakeholder types, including:

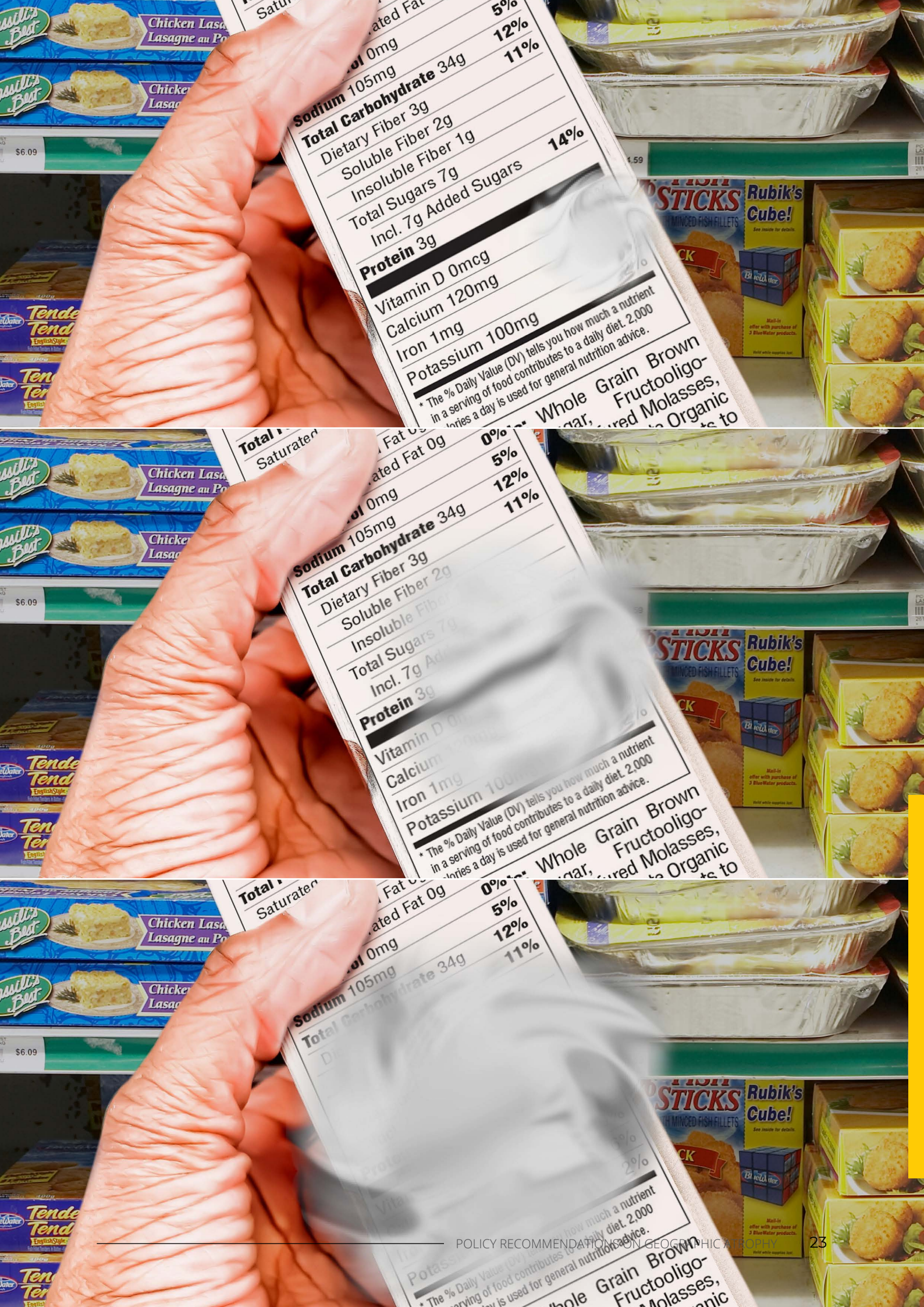
- supporting and accelerating research in health (89%)
- access to health data and transmission of their health data in electronic format (88%).<sup>32</sup>

Around €77 mil was earmarked to establish the European Health Data Space, which proposal was published by the Commission in May 2022.<sup>33</sup>

## RECOMMENDATION

Member States should develop their own eye health registry, including AMD and GA, connected to ophthalmology practices' electronic medical records systems. The national registries can be further fostered through the upcoming health ecosystem, European Health Data Space and contribute to, amongst others, a better understanding of the disease.





Sodium 105mg 5%  
Total Carbohydrate 34g 12%  
Dietary Fiber 3g 11%  
Soluble Fiber 2g  
Insoluble Fiber 1g  
Total Sugars 7g 14%  
Incl. 7g Added Sugars  
Protein 3g  
Vitamin D 0mcg  
Calcium 120mg  
Iron 1mg  
Potassium 100mg

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Whole Grain Brown Fructooligo-  
sugar, Pure Molasses,  
Organic

Total Saturated Fat 0g 0%  
Sodium 105mg 5%  
Total Carbohydrate 34g 12%  
Dietary Fiber 3g 11%  
Soluble Fiber 2g  
Insoluble Fiber 1g  
Total Sugars 7g  
Incl. 7g Added Sugars  
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## 4. SOCIO-ECONOMIC IMPACT OF GEOGRAPHIC ATROPHY



### 4.1 Eyesight as an important element of healthy and active ageing

The majority of the elderly population exhibits high levels of pro-social values and, at a time when our populations tend to have a high and increasing life expectancy, the social participation of the elderly has a positive impact on health and overall well-being.

GA, and AMD in general, while related to ageing, should not be merely accepted as a normal part of ageing. Strengthening access to high quality and affordable eye care, starting with ensuring affordable access to vision screening, is a key element to ensuring that ageing Europeans continue having a positive impact on societal engagement, can continue being professionally active, and remain independent.

The European Commission, to enable a thriving ageing society, published the Green Paper on Ageing that reflects the impact of ageing on personal and wider societal implications of the ageing trends. The paper lists a number of non-communicable diseases being on the rise that are the main causes of avoidable deaths – however, fails to make a link between healthy ageing with the loss of vision. This aspect was outlined by stakeholders through a public letter,<sup>34</sup> calling on the European Commission to include vision and eye health into any upcoming work strands and accompanying policies.

#### RECOMMENDATION

The European Commission should expand its vision on its ageing policy agenda through follow up actions to those outlined in the Green Paper on Ageing. Moreover, concrete policy options should be presented, including a comprehensive strategy for eye health.

In addition, since the role of the Commission is to ensure a harmonised approach towards the implementation of European policies and soft laws, it should do its utmost to support Member States in tackling vision impairment in their healthy ageing national strategies. This can be done by producing a White Paper on Ageing, outlining concrete steps for national governments.



### 4.2 Early detection and occupational health and safety

Although GA is closely linked with age, not all patients have reached retirement age. When patients are diagnosed, GA diagnosis does not and should not equal the end of the patient's professional working ability; however, it may influence the patient's decision to apply for early retirement or disability benefits.

Should a patient decide to keep working, strategic workplace modifications must be adjusted, touching upon the importance of adapting appropriate occupational health and safety policies for those with low vision.

The older a population demographic gets, the more prevalent GA will become. As the EU is faced with an ageing demographic, an unnoticed decline in eyesight across an entire workforce poses great dangers to workers themselves as well as their co-workers. If this decline goes unnoticed, workplaces will be faced with increased danger due to workplace accidents. In this respect, companies must be adequately trained and working conditions must be adapted to the patient's needs.

Good health and safety practices are key to keeping GA patients professionally active. This is of crucial relevance keeping in mind the fact that older workers are a growing part of the European workforce. According to the EU statistics, approximately 7% of the European population between 55 and 74 is employed.<sup>35</sup> To date, many EU countries extended, or are planning to increase the retirement age to keep adults in the workforce for longer. Alongside implementing new retirement policies, Member States must take a proactive approach and recognise GA as a priority now rather than addressing it when it has become a widespread problem.



### RECOMMENDATION

Considering the role of the European Agency for Safety and Health at Work, it is called upon to prepare, collect and adequately disseminate information on occupational safety and health issues, from the perspective of workers with low vision, including those suffering from GA.



### 4.3 Cost of GA: gaps in evidence on the economic burden of GA

There have been few studies conducted to evaluate the direct and indirect costs of GA. Costs related to GA include direct medical resources (for example visits, procedures, tests, follow-up, etc), out-of-pocket costs, the use of support services (visual aids, recommended vitamins supplements, counselling, rehabilitation, transportation and support groups), as well as caregiver costs.

In Europe, the associated mean annual costs for direct ophthalmological resources per patient amount to €1.772 (mainly driven by diagnostic costs and procedures) and €234 for indirect costs.<sup>36</sup> The interviewed experts, however, noted that GA-related costs are higher than the ones studied, as they do not factor in out-of-pocket costs, such as magnifying systems, flashlights and talking watches. These extra costs as well as transportation costs and assistance with household chores, should be factored into the overall costs that GA patients are faced with. Indirect costs of living with GA should also consider the risk of injury, especially resulting from falls or accidents. Many activities of daily living require functional central vision acuity. As the elderly population with poor vision are twice as likely to fall compared to people with healthy eyesight, GA patients are at risk of falls and fractures, which can generate substantial costs to the healthcare system. Approximately 9% of GA patients experience a fall or fracture due to their impaired vision.<sup>37</sup>

Given the low likelihood of GA being associated with significant indirect costs, there is a clear need for studies on the overall economic impact of GA to policymakers. Research should encompass studying indirect costs of GA, to take into account societal costs of the disease (including the costs of family caregiving), productivity impact as well as further evidence related to falls and fractures. There is limited research on the topic and robust data is needed for the shaping of effective healthcare policies.<sup>38</sup>

### RECOMMENDATION

The European Commission should address the need for additional research on the economic burden of the disease through available funding mechanisms, including but not limited to the Horizon Europe programme as well as EU4health.

## 5. ADAPTATION OF HEALTHCARE SYSTEMS

The prevalence of GA increases with age. Based on published studies, approximately 5 million people suffer from GA globally, whilst the prevalence in the EU is estimated to be 0.7-1.5% in the population over 60 years old.<sup>39</sup> It is estimated that, due to population ageing, the current number of AMD patients is expected to increase by 15% until 2050.<sup>40</sup> This steadily increasing number will require considerable additional healthcare service and resource allocation, which should be considered already today across all European healthcare systems.



### 5.1 Readiness of healthcare systems

#### Disease diagnosis: equipment

After initial identification of the disease at the primary care level (e.g., from an optometrist or a general practitioner), GA patients need to be referred to an ophthalmologist (retina specialist) for a definitive diagnosis. However, a significant issue with GA is that it is likely to be underdiagnosed, and therefore underreported. Whilst there are no studies evaluating the number of underdiagnosed patients, around 25% of patients suffering from AMD remain undiagnosed under a dilated exam performed by a primary eye care physician, as previously mentioned.<sup>41</sup> There is a need to educate healthcare professionals in primary care (e.g., optometrists/opticians/GPs) about the disease and its characteristics, to make sure patients are referred to ophthalmologists in a timely manner.

Currently, diagnosis for GA is done manually and different options are available, which include a dilated exam or retinal imaging. When it comes to structural imaging, GA can be imaged through a variety of methods, including the use of either colour fundus photography or spectral domain optical coherence tomography (OCT) and fundus autofluorescence (FAF).<sup>42</sup> New innovations to support healthcare professionals in disease detection and monitoring progression are underway, including the use of Artificial Intelligence algorithms. These developments are promising as they have higher chances of recognising GA before the symptoms appear: AI algorithms can discriminate image features and colours at a much higher resolution and greater bandwidth than humans.<sup>43</sup>

Although the AI technology does not have a reliability rating, the AI approach should be further prioritised during research efforts, as it has the potential to transform patient management in GA. Not only can it contribute to supporting awareness-raising, and screening processes,<sup>44</sup> but it can also strengthen the monitoring progression procedures – which in turn would contribute to collecting and analysing evidence<sup>45</sup> about the disease.

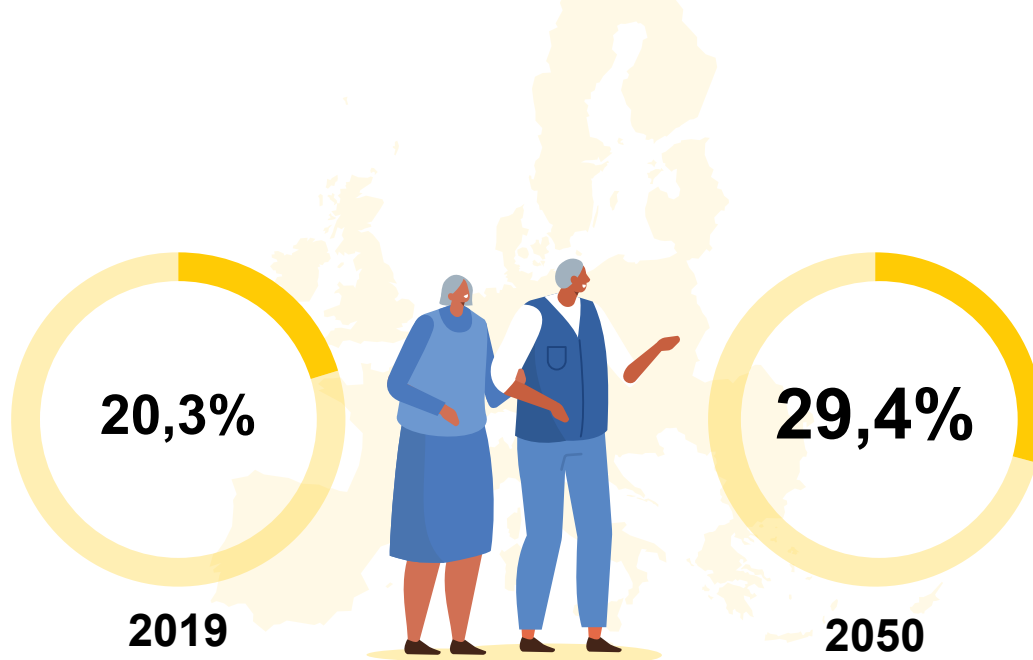


### 5.2 Unequal access to diagnosis and treatment centres: distribution and capacity constraints

According to the 2021 Ageing report of the European Commission, ageing drivers of healthcare expenditure are likely to exert a continuous pressure on European healthcare systems finances, extending even beyond the ongoing trends in population ageing.<sup>46</sup> The share of older people, as defined by the European Commission as those aged 65 and older, within European society is projected to gradually increase from 20.3% in 2019 to 29.4% in 2050. Monitoring of GA as well as potential entry of a treatment into the market will require additional healthcare resources to ensure adequate capacity e.g., enough personnel as well as operating rooms (if national regulations dictate so).

If GA treatments currently at the stage of clinical trials prove successful, the number of AMD patients receiving intravitreal injections would double. As reported by the interviewed experts, this can have major implications for EU healthcare systems, healthcare preparedness and treatment implementation.

The capacity issue will inevitably occur with the increase of GA patients to manage and in the onset of



promising investigational treatments. As people are getting older, the need for these injections will only increase and will place further burden on hospitals. Therefore, it remains clear that ophthalmology resources will be at maximum capacity to deliver the treatment, on a regular basis, faced with an ever-increasing number of new patients. It is of paramount importance to act now and have more people specialised in the retina and able to give injections, and simultaneously provide increased investment in hospitals.

Moreover, despite access to healthcare, people living in remote communities, face barriers to eye care due to costs and difficulties of travel. As well as for the general awareness of the disease, there is also a need for patient education and an increase in the population's trust in healthcare systems. Patients often hold onto the belief that some doctors are better than others, which provides them with the motivation to travel great distances to receive treatment (including diagnosis) from a specific doctor. There is a need to communicate the reliability of facilities and the qualifications of doctors to do screening and treatment.

#### RECOMMENDATION

Member States should monitor relevant funding opportunities and invite national stakeholders to apply through available EU programmes – in particular, the Cohesion Policy funds, including the European Regional Development Fund. Through these funding opportunities, stakeholders may be able to upgrade the existing equipment used for screening programmes or supply their institutions with additional equipment. This may also allow to increase the number of available treatment centres where necessary.

#### RECOMMENDATION

At the primary eye care level, healthcare professionals (e.g., GPs, opticians/optometrists) must be made aware of GA throughout education pathways and provided with the correct tools and resources to accurately detect signs of GA in order to refer patients to ophthalmologists/retina specialists. Member States should work towards enhancing education and training on GA in primary care. Further education needs to be delivered on what GA is and how to diagnose correctly.

#### RECOMMENDATION

Member States should address access barriers to health and social care for people living in rural and deprived areas, for example by increasing the number of available treatment centres and/or investing in the existing ones. Bearing in mind the availability of a potential GA treatment, further investment should be made to address potential capacity barriers to patient access to treatments.

This can be done through the use of existing EU funding mechanisms, notably through Cohesion Policy funds, including the European Regional Development Fund.

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