

# **The importance of geographic atrophy:** *acting now for a better future*

A health policy roundtable discussion

*Brussels, Belgium; 21-22 June 2016*



# **Executive summary**

## Executive summary

This roundtable discussion on 'The importance of geographic atrophy: acting now for a better future' was hosted by Roche in Brussels on 21–22 June, 2016, in line with their long-term commitment to ophthalmology.

The meeting was attended by representatives from a range of patient organisations and other groups with a focus on eye disease/prevention of vision loss as well as experts in ageing and personalised medicine.

## Participants



Prof Ian Banks  
The European Forum  
Against Blindness  
(EFAB)



Ms Julie Heraghty  
Macular Disease Foundation  
Australia



Ms Daniela Brolburg  
PRO RETINA



Mr Denis Horgan  
The European Alliance  
for Personalised Medicine  
(EAPM)



Ms Fabienne Eckert  
The European Council  
of Optometry and Optics  
(ECOO)



Dr Giuseppe Lo Giudice  
Italian Association of  
Doctors Oculisti (AIMO)



Ms Christina Fasser  
Retina International



Prof Dr Sehnaz Karadeniz  
The International Diabetes  
Foundation European Region  
(IDF-EU)



Mr Markus Georg  
PRO RETINA



Dr Keith Gordon  
Canadian National  
Institute for the Blind (CNIB)



Ms Ina Voelcker  
The International Longevity  
Centre Brazil (ILC-Brazil)

## Guest speaker

Dr Sobha Sivaprasad, Moorfields Eye Hospital and King's College Hospital, London, UK

## Roche representatives

Dr Christopher Brittain

Dr Atul Dandekar

Mr André Trottier

## Agency

Mr Ralph Sutton, meeting facilitator, Madano

Dr Cindy Macpherson, medical writer, Madano

## The meeting objectives were:

- to share knowledge of geographic atrophy (GA)
- to share perspectives on the policy implications of GA
- to gain a consensus on what could be done to raise the priority for GA with policy makers.

## Agenda

21 June 2016		
Time (CET)	Agenda item	Facilitator / Spokesperson
1830 – 1900	<b>Welcome reception</b>	All
1900 – 1920	<b>Welcome and meeting objectives</b>	André Trottier, Roche Ralph Sutton, Madano, Meeting Facilitator
1920 – 2130	<b>Working dinner: formal introductions and overview of organisations</b>	All
22 June 2016		
0900 – 0925	<b>A medical overview of geographic atrophy</b> Presentation by Dr Sobha Sivaprasad	Dr Sobha Sivaprasad, Moorfields Eye Hospital and King's College Hospital, London, UK
0925 – 1000	<b>A medical overview of geographic atrophy</b> Discussion and Q&A session	All
1000 – 1100	<b>The impact of geographic atrophy</b> Workshop and discussion on the impact of geographic atrophy on patients, society and health policy	All
1100 – 1115	Break	
1115 – 1230	<b>Sharing perspectives and organisational priorities on geographic atrophy</b> A roundtable discussion	All
1230 – 1330	Lunch	
1330 – 1500	<b>What are the policy gaps to better serve GA patients and how do we address them?</b> A roundtable discussion	All
1500 – 1530	<b>Next steps, summary and meeting close</b>	Ralph Sutton, Madano, Meeting Facilitator André Trottier, Roche

## Medical overview of GA

Guest speaker, Dr Sobha Sivaprasad, gave a clear, evidence-based presentation that provided a comprehensive overview of GA and other forms of age-related macular degeneration (AMD). Lively discussion ensued, focusing on the following themes:

- the most appropriate terminology/definitions to use when describing GA, including the need for consistency going forward
- the complexity of the condition and its corresponding impact on diagnosis and classification, underscoring the need for clear understanding around the pathophysiology of the disease and effective markers of functional vision that are appropriate for GA
- the importance of education in order to manage patient expectations, both before and after a treatment becomes available
- the possibility for visual impairment groups to collaborate with other groups focusing on ageing and comorbid conditions such as Alzheimer's and Parkinson's Disease.

## Impact of GA

The impact of GA on different stakeholders was also discussed, including patients, caregivers, ophthalmologists/optometrists and policy makers.



**Patients:** while all stakeholders need to understand the huge impact of the condition on patients, participants discussed the importance of positive messages that give a sense of optimism, focusing on rehabilitation for people with visual impairment and encouraging them to live as full a life as possible.



**Caregivers:** as for neovascular AMD, the caregiver burden is significant in GA, although its impact needs to be assessed more fully. It is critical that caregivers are given sufficient support as they are pivotal to the welfare and outcomes of patients.



**Ophthalmologists/optometrists:** Concerns were raised around that, if a treatment for GA was approved, ophthalmologists would not have the capacity to manage the condition. Possible solutions to overcome this challenge were discussed in detail.



**Policy makers:** despite the prevalence and economic burden of visual impairment/loss, many governments do not treat it as a matter of urgency and there is a need to raise awareness around GA, and the importance of investment in diagnosis, treatment and rehabilitation for affected patients rather than just focusing on patients who have already lost their vision.

## Policy priorities for GA

Finally, the participants divided into two workshop groups to discuss the policy priorities for GA, including:

- what the policy objectives should be for GA over the next two years
- what the major barriers would be
- who the most important stakeholders were, and
- what were the key tactics that should be employed.

**After a lively discussion, agreed priorities for next steps were as follows:**

**1** Establish a coalition of interested organisations to raise the profile of GA

**2** Produce a short 'call to action' paper, covering the burden of disease plus the need for research with the purpose of briefing policy makers

**3** Follow up with a longer paper including emerging burden of illness data

There was a general consensus to establish a group to continue the dialogue around GA and promote a long-term exchange of expertise. There was also great enthusiasm regarding the potential of future treatments for the condition.

# Meeting report

## Meeting report

### A medical overview of geographic atrophy

In line with the objective of sharing knowledge, Dr Sobha Sivaprasad provided a comprehensive overview of GA and other forms of AMD. The participants complimented her on her presentation, commenting on the benefits of clear, evidence-based communication around the condition. It was suggested that a distilled version of her presentation would be a useful tool to use with policy makers.

Dr Sivaprasad also played a short video that simulated the impact of GA on vision and its effect on everyday activities, developed with reference to microperimetry measures of visual function from GA patients. It was considered to be a very useful tool that could be circulated more widely to raise awareness of the impact of the condition on patients' daily lives, e.g. for use with patient organisations/ caregivers.

### Key points from Dr Sivaprasad's presentation

#### AMD

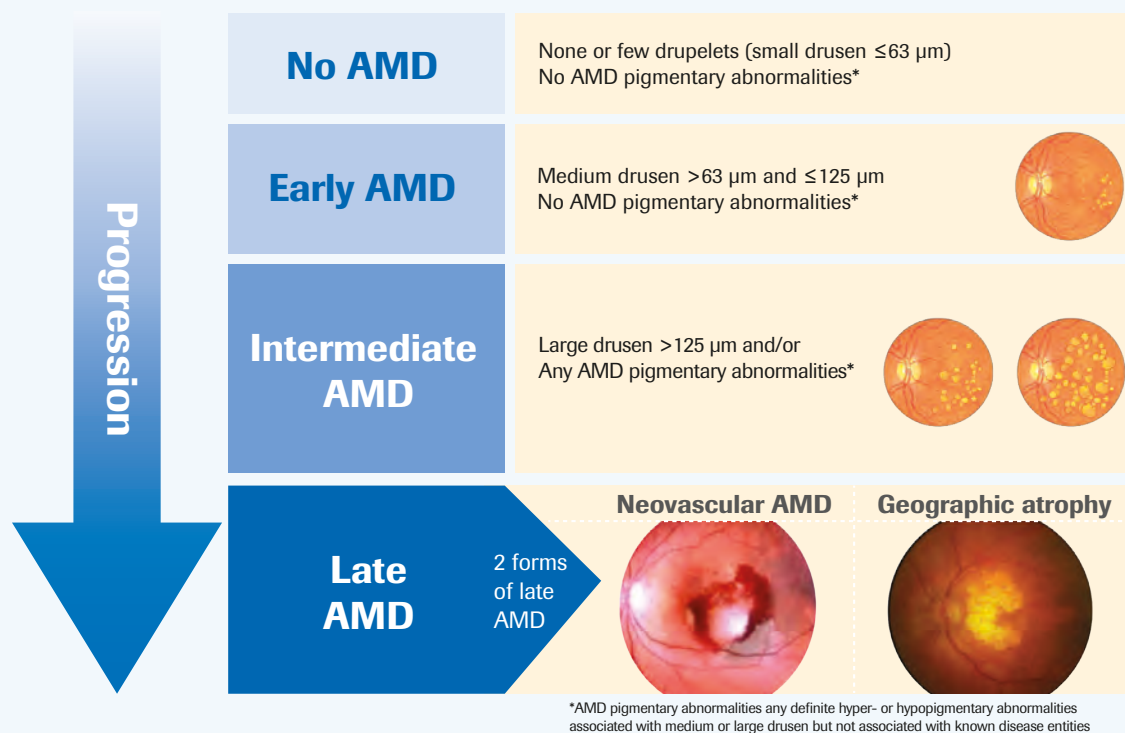
- AMD is an ophthalmic condition which can ultimately lead to loss of visual function; the term applies to ageing changes of the macula without any other precipitating causes in people aged  $\geq 55$  years<sup>1</sup>
- The symptoms may not be noticeable in the early stages of the disease but, over time, blurring, distortion and loss in sharpness of vision may occur<sup>2</sup>
- AMD is a leading cause of severe and irreversible vision loss in the developed world in people aged  $>50$  years, accounting for  $>50\%$  of blindness<sup>3,4</sup>
- Global estimate of people with AMD: 30-50 million<sup>5</sup>
- Global estimate of people who are blind due to AMD: 2 million<sup>6</sup>
- Despite the size of the burden of AMD, many people are unaware of the extent of the impact on people with the condition (Figure 1)

Figure 1. Burden of AMD<sup>7</sup>

Severity of AMD	Comparable to
Mild	All cancer, HIV symptomatic, moderate angina, osteoporosis
Moderate	Fractured hip, TB hospitalised, moderate stroke
Severe	Home dialysis
Very severe	Severe stroke (bed ridden), advanced prostate cancer

- AMD can be classified into four stages (Figure 2)

Figure 2. Beckman Initiative for Macular Research Committee Classification of AMD<sup>8</sup>



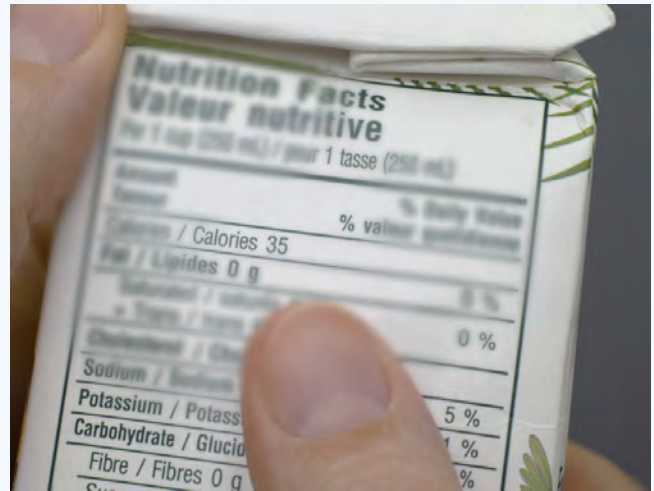
## GA

- GA, one of the two types of late AMD, is a complex, multifactorial disease which has a devastating effect on patients' visual function and quality of life
- There is significant unmet need for a treatment for GA, which is estimated to affect >5 million people worldwide<sup>9,10</sup>
- The pathology of GA involves severe disruption of Bruch's membrane, leading to degeneration of retinal pigment epithelium (RPE) and photoreceptors, as well as other cells of the retina<sup>11</sup>
- GA is characterised by defined areas of RPE atrophy, leading to sharply demarcated round/oval areas of hypopigmentation with corresponding areas of reduced vision<sup>12,13</sup>
- The rate of progression of GA varies, both between individuals and within individuals over the course of the disease. Drivers of disease progression are not fully understood but appear to be influenced by a number of factors, including lesion size, morphology and atrophic pattern<sup>14,15</sup>
- GA progression causes severe deterioration of visual function, but standard single-letter visual acuity tests often do not detect the extent of the problem and other methods of assessing visual function are required
- Visual function impairment from GA significantly impacts everyday life (Figure 3), affecting reading, mobility, driving, shopping, leisure activities, feelings of frustration and annoyance, concerns with coping with everyday life, and dependence on help from others<sup>16</sup>. Furthermore, one-third of patients with advanced AMD have clinical depression<sup>17</sup>

Figure 3. Effect of GA on vision in everyday life scenarios



'Normal' vision



Patient with Geographic Atrophy



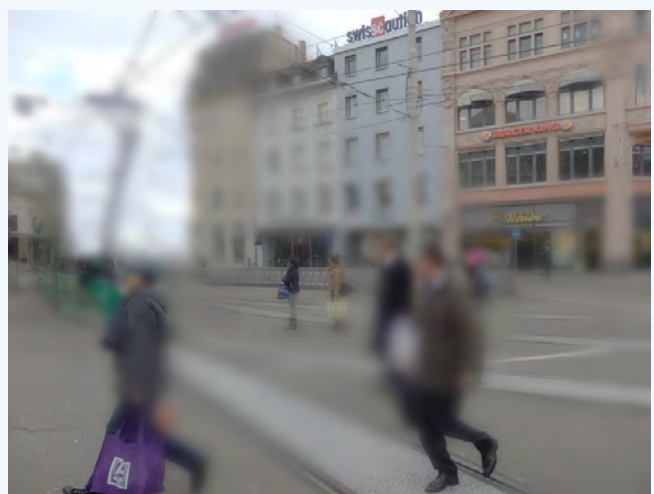
'Normal' vision



Patient with Geographic Atrophy



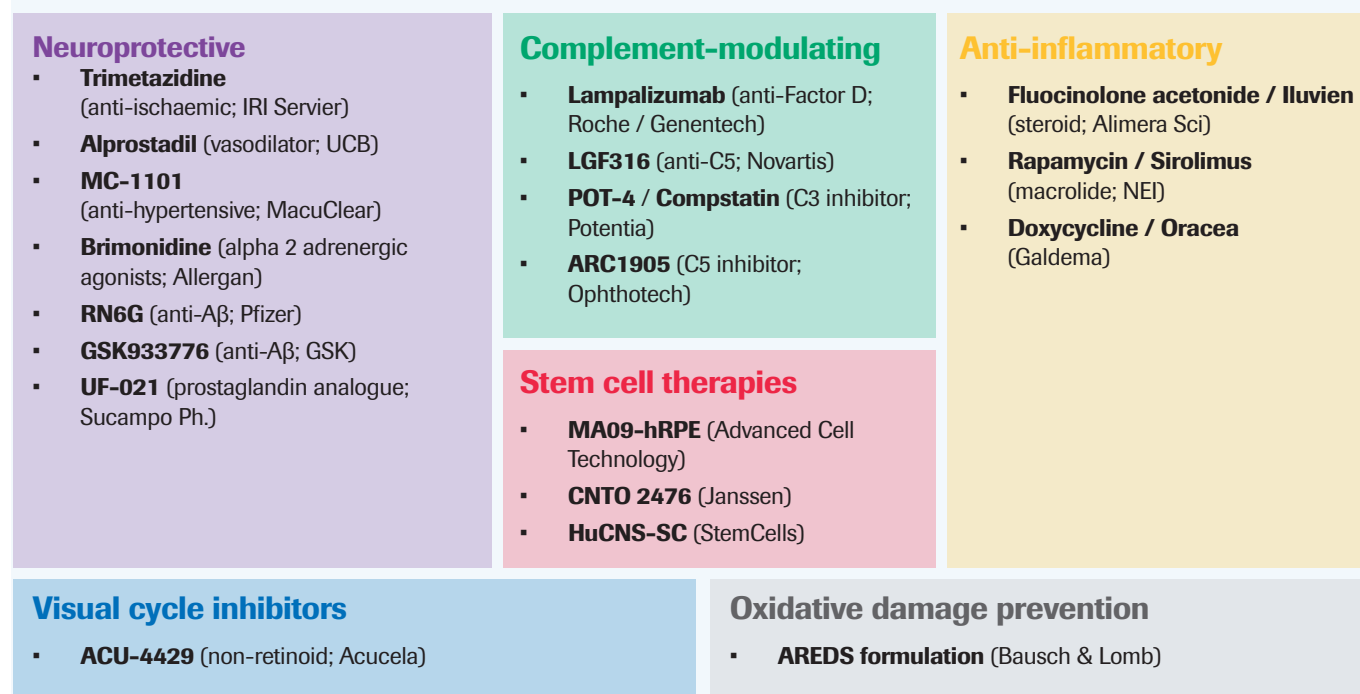
'Normal' vision



Patient with Geographic Atrophy

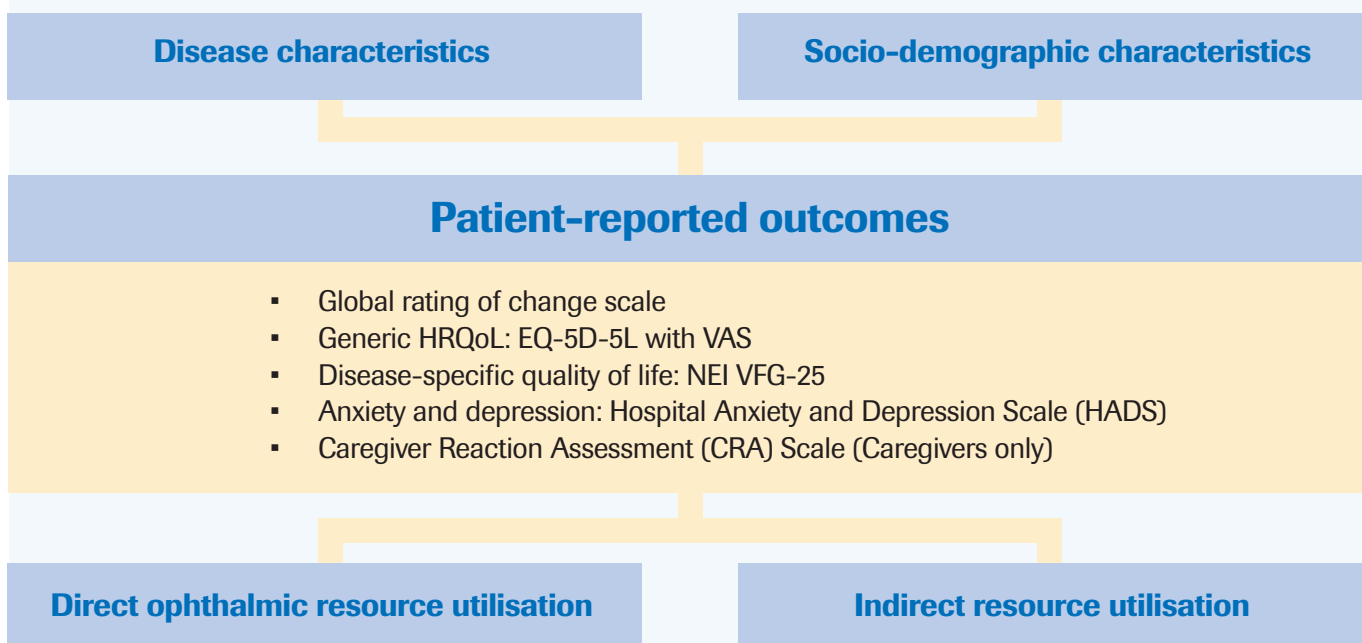
- Search is underway for a treatment for GA (Figure 4), with therapeutic targets including:
  - prevention of oxidative damage
  - neuroprotective agents
  - stem-cell therapies
  - complement modulating therapies
  - anti-inflammatory agents
  - visual cycle inhibitors.

Figure 4. Drugs in clinical development for GA



- In the meantime, there are burden of illness studies underway in GA to demonstrate its economic, clinical and societal impact
- Key research questions will include:
  - How does GA impact a patient’s health-related quality of life (HRQoL) and how does HRQoL differ with control patients (i.e. non-GA patients)?
  - What is the economic impact of GA on the patient?
  - What is the burden to a caregiver of someone with GA?
- A large body of data will be captured from a retrospective chart review of 12–24 months (Figure 5)

Figure 5. Data being captured in burden of illness studies



- Global rating of change scale
- Generic HRQoL: EQ-5D-5L with VAS
- Disease-specific quality of life: NEI VFG-25
- Anxiety and depression: Hospital Anxiety and Depression Scale (HADS)
- Caregiver Reaction Assessment (CRA) Scale (Caregivers only)

**Direct ophthalmic resource utilisation**

**Indirect resource utilisation**

Most of the discussion around the presentation focused on four areas:

- the most appropriate terminology/definitions to use when describing GA,
- the complexity of the condition and its corresponding impact on diagnosis and classification,
- the importance of education in order to manage patient expectations, and
- the possibility for collaboration with other groups focusing on comorbid conditions

**Need for consistent and appropriate terminology around GA**

The participants warned of the need for sensitivity around use of the terms ‘blind’ or ‘blindness’. This language can be frightening for patients and it is preferable to construct a dialogue around visual impairment/vision loss, although facts around ‘blindness’ may make more of an impact when communicating with policy makers.

There is also a need for a consistent, preferably World Health Organization (WHO)-led international definition of severe visual impairment/vision loss given that there are a number of conflicting definitions at present. While the European Coalition for Vision Loss is currently looking at developing a pan European definition, a global version is also required. This is important given that blindness allowances are commonly linked to these definitions.

Terminology should be tailored for different audiences. Communications can be targeted for several different stakeholder groups, including policy makers, patients and general awareness campaigns. In particular, medical jargon needs to be turned into terminology that is meaningful for patients. For example, many clinicians do not use the terms neovascular AMD and GA with their patients, preferring to refer to wet and dry AMD instead. In addition, early AMD is often incorrectly called dry AMD, and clarification is required around this terminology.

Use of the term ‘late stage’ AMD may also have negative connotations, and it would be better to seek an alternative. The group also discussed whether ‘progression’ of the disease was acceptable terminology to use, or whether progress may be misinterpreted as an improvement in the condition.

## Complexity of the condition obscures diagnosis and classification

The pathophysiology of GA is complex and many people (and even some clinicians) do not fully understand the differences between wet and dry AMD.

Further difficulties of classification stem from the fact that GA and neovascular AMD can coexist in the same patient or even in the same eye. Diagnosis of GA is further complicated because gold standard tests of visual acuity are often ineffective in detecting the condition, as patients may compensate for their visual impairment by scanning across the letters in the test or moving the head from side to side in order to see more clearly. Hence other markers of functional

vision are required for diagnosis of GA, and the participants discussed different options, including optical coherence tomography (OCT), autorefractometry, colour fundus photography and the Amsler grid.

The group also debated the potential role of the genetic test that is available in North America to identify an individual's risk of AMD. The general consensus was that it is too expensive, especially given that there is currently no treatment available for GA (except for use of vitamins, which may slow progression of GA).

## Education is needed to encourage early diagnosis and to manage patient expectations

The first step in increasing diagnosis of eye diseases such as GA is not just raising awareness of the condition, but also educating around the need for regular eye checks in order to ensure early diagnosis and to maximise the chance of preserving good vision. This can be very effective, as illustrated by a successful disease awareness campaign from Macular Disease Foundation Australia, which focused on the key messages "Have your eyes tested" and "Make sure the macula is checked"<sup>18</sup> (see case study on page 11).

*"When treatments become available, the more patients who come in early (with GA), the less the societal burden as the patients will be identified and treated early"*

Dr Sobha Sivaprasad



**Don't let Macular Degeneration take away the centre of your world**

**MUST DO**  
Have an eye test and make sure my macula is checked

Call the MD Foundation on 1800 111 709  
[www.md.foundation.com.au](http://www.md.foundation.com.au)

Macular Degeneration takes away central vision and is the leading cause of blindness\* in Australia. You can have the early signs without knowing. Early detection is vital. How's your macula?

**Macular Degeneration Foundation**  
Our focus is your vision

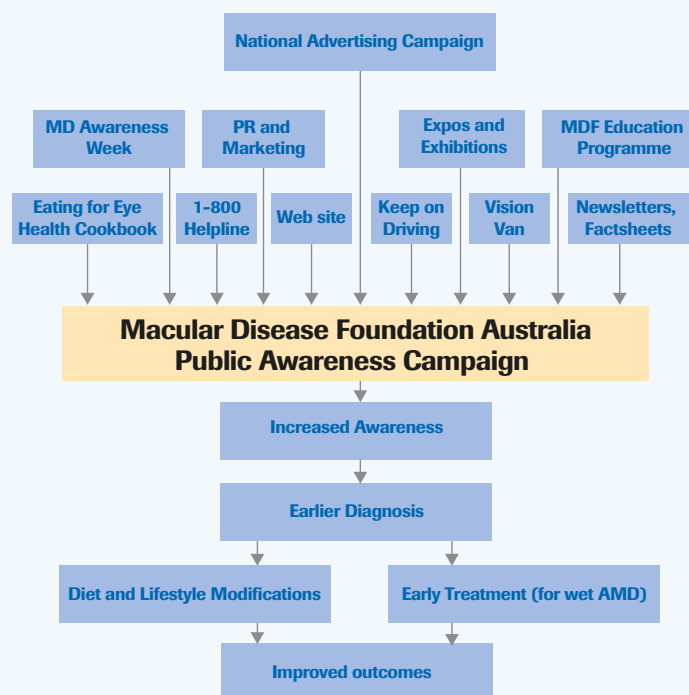
**OPTOMETRISTS**  
SPECIALIST SERVICES

Today's the day  
**BLACKMORES**

**NOVARTIS**  
\*Legal blindness

### Case study: disease awareness campaign from Macular Disease Foundation Australia<sup>18</sup>

- Macular Disease Foundation Australia conducted a multifaceted campaign to increase public awareness of macular degeneration between 2007 and 2011 (key components of campaign are shown below)



- Regular national polls conducted by an independent research company showed an increase in awareness of macular degeneration, from 47% to 80% in Australians aged  $\geq 16$  years and from 58% to 92% in those aged  $\geq 50$  years
- The percentage of people aged  $\geq 50$  years who reported having had their macula checked in the 2 years prior to the survey increased, from 33% to 70% between 2007 and 2011
- There was an increase in understanding that macular degeneration is a disease affecting the eyes, from 32% to 73%
- In the most recent poll, 59% of people reported that they became aware of macular degeneration from television or radio advertising
- Key outcomes of the campaign were as follows:
  - More patients are receiving information to reduce the risk of the disease and facilitate early detection
  - Many others who have already lost sight are obtaining practical support to help maintain independence and quality of life
  - The investment in raising awareness of macular degeneration has led to an increase in early diagnosis of other eye diseases and promoted allied key health messages targeted by the Australian Commonwealth Government, including smoking cessation, reducing obesity, and improving diet

Discussion followed as to whether drivers should be screened for visual impairment in order to improve road safety. In some countries, it is mandatory for clinicians to disclose details regarding their patients' eyesight to licensing authorities if they may be a danger to other road users. However, several barriers to this approach exist. In countries where this is not yet mandatory, clinicians may be resistant due to the extra administrative load that this may place on their practice. In addition, the threat of having their driving licence taken away may discourage patients from presenting with visual impairment, particularly if their job depends on their licence.

GA may also be underdiagnosed because there is no treatment currently available for the condition. Some clinicians may consider that it is better not to tell patients that they have GA until a treatment becomes available. However, patients have a right to know and participants emphasised the important role of clinicians and nurses in managing patient expectations. The desire to not frighten patients often has the opposite effect.

*“Where there is a lack of information, fear fills the vacuum”*

Prof Ian Banks

## **Perception of visual impairment in the context of other conditions**

There was a discussion around how visual impairment is perceived relative to other conditions. It was noted that visual impairment is often not given much consideration in the context of patient groups that focus on ageing, and that it should be given higher priority. Similarly, hearing loss and its impact on social inclusion is often disregarded and put down to being an inevitable consequence of old age.

However, an example of a successful collaboration between visual impairment and ageing groups was the Global Ageing & Vision Advocacy Summit, co-hosted in Barcelona in 2013 by Macular Disease Foundation Australia and the International Federation on Ageing<sup>19</sup>. This summit raised awareness of the impact of vision loss including serious personal, health, social and economically related consequences, and concluded that growing older with vision loss should not be accepted as inevitable or 'the norm'.

Developing treatments is challenging given the complexity of the disease and the fact that there are no preclinical models for GA. Educating the community regarding the steps involved in the research process is therefore important. In general, the participants thought that diagnosis will increase once successful treatments are available for GA. Currently, cases are often diagnosed at accident and emergency departments following road traffic accidents or falls/hip fractures.

Once a treatment becomes available, there is likely to be a dramatic increase in concordance if patients become part of the decision making process.

Communication with patients is key, including use of good quality patient education materials, and physicians/nurses need to listen longer to patients and speak less. However, physicians often have insufficient time available. Patient organisations can help to fill this gap and it is important to have advice from people who have experienced the condition themselves.

Treatment guidelines for AMD constitute a very important component of the management framework for healthcare professionals, and are likely to be a key policy driver. Although guidelines exist in different countries, there are no up-to-date global/harmonised guidelines for AMD.

In terms of comorbid conditions, many patients with Alzheimer's Disease or Parkinson's Disease may also have visual impairment, and symptoms in these individuals may be misdiagnosed as cognitive rather than vision-related. There is therefore a need for cooperation between patient organisations for Alzheimer's/Parkinson's and visual impairment groups.

In people with diabetes, regular eye checks (every 1–2 years) are recommended in order to screen for diabetic retinopathy<sup>20</sup> and the same priority should be given to screening for AMD.

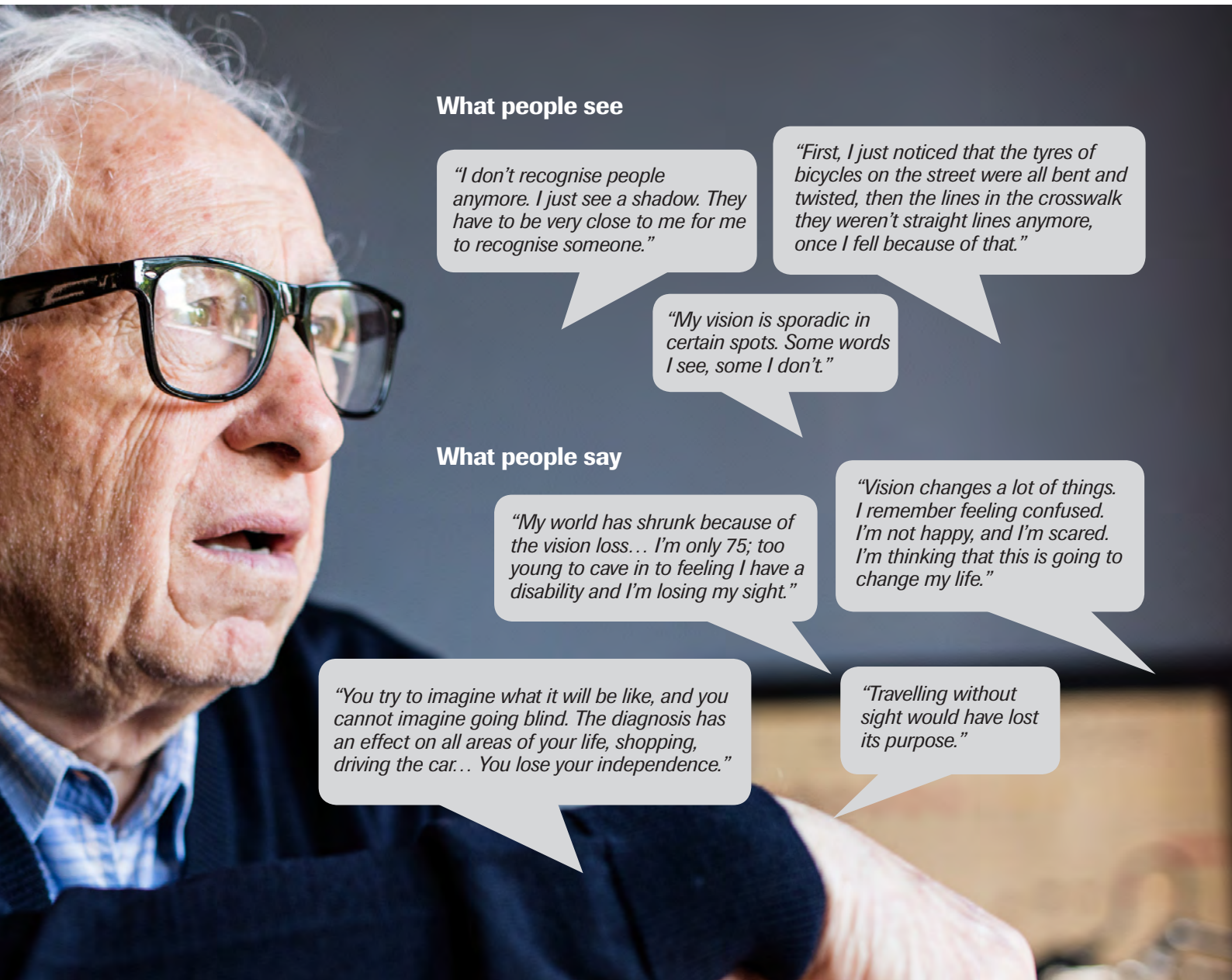
## The impact of geographic atrophy

The participants went on to discuss the impact of GA on different stakeholders, including patients, caregivers, ophthalmologists/optometrists and policy makers.



### Impact on the patient

Roche has been conducting research to find patient insights regarding the impact of their condition on their daily life. Some of the patient quotes from this research were shared with the participants.



#### What people see

*"I don't recognise people anymore. I just see a shadow. They have to be very close to me for me to recognise someone."*

*"First, I just noticed that the tyres of bicycles on the street were all bent and twisted, then the lines in the crosswalk they weren't straight lines anymore, once I fell because of that."*

*"My vision is sporadic in certain spots. Some words I see, some I don't."*

#### What people say

*"My world has shrunk because of the vision loss... I'm only 75; too young to cave in to feeling I have a disability and I'm losing my sight."*

*"Vision changes a lot of things. I remember feeling confused. I'm not happy, and I'm scared. I'm thinking that this is going to change my life."*

*"You try to imagine what it will be like, and you cannot imagine going blind. The diagnosis has an effect on all areas of your life, shopping, driving the car... You lose your independence."*

*"Travelling without sight would have lost its purpose."*

While acknowledging the impact of these patient insights, the participants warned of the negativity of the messages that they may communicate. They emphasised the importance of communicating a feeling of hope and underlined the need for positive messages, focusing on rehabilitation for people with visual impairment and encouraging them to live as full a life as possible. Some spoke of their own experiences of visual impairment, explaining how travel becomes more challenging with vision loss but can still be fulfilling. They also described the extensive support aids available, in particular those that utilise new technologies.

One participant spoke of the parallel situation in the ageing arena, where messaging has perhaps gone too far and become naively positive at times, e.g. describing old age as ‘the best age’. The group agreed that it was important to get the right balance between being positive but also realistic. They felt that rehabilitation is key in order to ensure that people are fully able to contribute to society rather than becoming increasingly alienated by their condition.

The impact of cultural and gender differences was also discussed. For example, loss of vision is associated with the stigma of being a burden to your family in some cultures instead of embracing diversity. It is important to tailor support according to these different groups and the success of setting

up Canadian National Institute for the Blind peer groups of visually impaired patients speaking their own native language (Punjabi, Chinese) was discussed.

The participants also debated on the important impact of visual impairment in the workplace and the need for occupational health involvement, potentially even involving discrimination legislation where necessary. Institutional incentives may supplement the important role of patient education, e.g. to ensure that individuals have regular vision checks for driving.

Rather than promoting the fear of losing a driving licence, it is important to turn the message into a positive, for example, communicating that early diagnosis and treatment of visual impairment can allow solutions to be found to ensure that the individual can maintain their independence and won't lose their job. It may also be effective to incentivise the patient by contextualising the potential impact on society as a whole, for example, the rights of the pedestrian to feel safe in the knowledge that drivers are regularly screened for visual impairment. The outcomes need to be beneficial to both the individual and to society as a whole, without the patient feeling that they are being penalised for having their eyes tested. Approaches utilised by Macular Disease Foundation Australia to increase diagnosis include inserting free ophthalmology information packs into new driving licences as well as increasing diagnosis via a mobile screening unit.

## Impact on caregivers



Few studies have evaluated the associated caregiver burden.<sup>21-25</sup> One participant noted that a Canadian study will also be published soon. It is crucial that studies are carried out early for GA as the role of the caregiver may be even more important for this condition, given the lack of clarity around the best endpoint to use to assess GA.

There is a significant impact on caregivers, many of whom do not perceive themselves as such and are therefore missing out on many of the associated benefits such as caregiver payments. The extent of the burden is great, with caregivers for neovascular AMD having three times the rate of depression compared with the general population. The burden is comparable to that experienced by caregivers for rheumatoid arthritis/multiple sclerosis or caregivers of patients with atrial fibrillation

who require regular hospital appointments for monitoring their thromboprophylaxis<sup>22</sup>. The support that healthcare professionals provide to caregivers is often lacking, with very few carers reporting any form of support despite the vital role that they carry out.<sup>22</sup>

The participants discussed the need to collaborate and align their efforts with carer organisations such as Carers Australia and to encourage them to put vision on their agenda, although not all countries will have access to these organisations. Since caregivers are often looking after people with multiple comorbidities, other stakeholders may also be important. Caregivers are often essential to patients attending their medical appointments and are also more likely to embrace new technologies to assist people with visual impairment. One participant noted that IDF run national programmes for caregivers, which have led to improvements in treatment outcomes and compliance. The Blind Foundation in New Zealand also emphasises the important role of caregivers, using them as a conduit to communicate with patients. In the UK, NICE does not currently consider caregiver burden in the context of visual impairment, although they are starting to recognise its importance in some other therapy areas, for example, Alzheimer's Disease.

## Impact on ophthalmologists/optometrists



The group also considered the impact on ophthalmologists and optometrists. There were some concerns that, if a treatment for GA was approved, ophthalmologists would not have the capacity to manage the condition. However, others felt that healthcare systems would be forced to adapt, as they had done following the introduction of anti-VEGF treatments for neovascular AMD.

In the UK, use of nurses and optometrists to carry out injections has been very successful in easing the burden on ophthalmologists. However, this may not be viable in all countries. This may be due to resistance to change or fear that optometrists may encroach on retina specialists and ophthalmologists. In addition, there are national differences in the framework of treating eye disease, e.g. there are no optometrists in France.

## Impact on policy makers



Despite the prevalence and economic burden of visual impairment/loss, many governments do not treat it as a matter of urgency.

Accurate prevalence data can form a powerful advocacy tool, as demonstrated by Macular Disease Foundation Australia's drive to map the projected prevalence of macular degeneration across Australia by federal, state and territory electorates. This was done to empower the community and policymakers with clear evidence of the substantial number of people affected by macular degeneration, and to highlight where appropriate resources would be needed to support people with macular degeneration, providing hard facts to support its Federal Election 2016 Policy Platform.<sup>26</sup>

The group went on to discuss the relative priorities of policy makers regarding visual impairment versus vision loss. Funding has historically focused on people who have already lost their vision rather than on prevention of vision loss, and there is a

*“It is a problem  
(for funding) that vision  
loss is life changing,  
but not life threatening.”*

Dr Keith Gordon

need for a mind shift to treat preservation of vision as a funding priority. Blindness has a huge economic impact, for example, the cost of blindness is estimated to be \$5 billion in Australia, but there is currently far less investment in diagnosis, treatment and rehabilitation of visual impairment. However, some progress has been made, for example, AMD has recently been shortlisted as a priority by the Innovative Medicines Initiative (IMI). Other research support was discussed, including the HORIZON 2020 grant/EYE-RISK study.

*“If you don’t have evidence, you can’t drive policy... or reimbursement... or support.”*

Julie Heraghty

It is vital that policy makers increase diagnosis of macular disease and other types of visual impairment by promoting regular eye tests and encourage preventative measures such as diet and lifestyle changes. However, the desire to focus on prevention of further visual impairment should not be at the expense of those who already have vision loss. There is a need for careful use of terminology around prevention, as it may be better to focus on

preservation of vision given that the disease cannot be prevented.

A ‘multi-pronged attack’ may be required involving multiple layers of messages and multiple stakeholders, which targets different stages of prevention (e.g. early > late stage visual impairment, late stage visual impairment > vision loss). It is important to consider the ‘ripple effect’ of the impact of visual impairment/loss, not only on the patient and their family/caregiver, but also on tax payers and society as a whole. Once a treatment is available, it will be important to communicate to the public that vision loss can be prevented in people with GA. For policy makers, it is also important to communicate the population effect, i.e. the impact not only on the patient but also on families and carers.

There is also a need for strong pharmacoeconomic support for reimbursement. It is vital that policy makers/payers have the holistic picture, encompassing both direct and indirect costs for patients and carers, incorporating early admission to nursing homes, falls, depression, caregiver burden, etc.

*“To allow people to go blind where there is a treatment is unacceptable in modern civilised society.”*

Prof Ian Banks

## How can we raise the policy priority of geographic atrophy?

The participants broke into two workshop groups to discuss:

- what the policy objectives should be for GA over the next two years
- what the major barriers would be
- who the most important stakeholders were, and
- what were the key tactics that should be employed.

The groups then reconvened for further debate. A summary of the key points arising from the discussions is shown below.

Breakout Group 1	Breakout Group 2
<b>1. Objectives</b>	
<ul style="list-style-type: none"> <li>▪ Inform policy makers of hard data on burden of disease to support best practice activities</li> <li>▪ Raise awareness of the extent and impact of GA among                             <ul style="list-style-type: none"> <li>- Patients</li> <li>- Carers</li> <li>- Healthcare professionals</li> <li>- Wider community</li> </ul> </li> <li>▪ Importance of acting on an international level first, then regionally</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increase awareness of what GA is and the importance of GA within the visual impairment and ageing sectors</li> <li>▪ Improve access to diagnosis, treatments, rehabilitation, new technologies and auxiliary aids, and promote a better environment, e.g. train travel (better adapted public transport)</li> <li>▪ Prepare the ground for new medications</li> </ul>
<b>2. Barriers</b>	
<ul style="list-style-type: none"> <li>▪ No means of prevention</li> <li>▪ No treatment available (but there are emerging therapies)</li> <li>▪ Low awareness/knowledge/action</li> <li>▪ Not a policy priority</li> <li>▪ Lack of uniformity – fragmented community</li> </ul>	<ul style="list-style-type: none"> <li>▪ Lack of information on GA</li> <li>▪ Cannot just talk about GA, need to put in context of AMD</li> <li>▪ Accurate diagnosis: need clear explanation around AMD                             <ul style="list-style-type: none"> <li>- Distinguish between neovascular AMD and GA</li> <li>- Ensure consistent and appropriate use of terminology</li> </ul> </li> <li>▪ Challenges of ensuring social inclusion and rehabilitation</li> <li>▪ Lack of funding/cost of medicines</li> <li>▪ In EU, need to talk about equal access</li> <li>▪ Disparity within EU and beyond</li> </ul>

Breakout Group 1	Breakout Group 2
<b>3. Stakeholders</b>	
<ul style="list-style-type: none"> <li>▪ Government</li> <li>▪ Carers</li> <li>▪ Healthcare professionals</li> <li>▪ Patients</li> <li>▪ Researchers</li> <li>▪ Industry</li> <li>▪ Scientists</li> <li>▪ Medicine agencies</li> <li>▪ Health economists</li> <li>▪ Ageing organisations</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patient organisations</li> <li>▪ Vision loss groups</li> <li>▪ World Blind Union/EU Blind Union</li> <li>▪ Ophthalmic groups</li> <li>▪ Scientific organisations</li> <li>▪ Organisations for ageing and elderly</li> <li>▪ International Agency for Prevention of Blindness</li> <li>▪ WHO – Vision 2020, strategy on healthy ageing</li> <li>▪ Groups focused on human rights for people with disability – equal access</li> <li>▪ Carer organisations</li> <li>▪ Rare eye disease organisations</li> <li>▪ Broader medical associations</li> <li>▪ Medico-legal organisations</li> <li>▪ National payer organisations</li> <li>▪ Health technology assessment bodies</li> <li>▪ Long-term care community</li> <li>▪ Political                             <ul style="list-style-type: none"> <li>– Those willing to help</li> <li>– Those who ultimately make a decision</li> </ul> </li> <li>▪ Pharma industry</li> <li>▪ Insurers</li> <li>▪ Broad news media</li> <li>▪ Companies supporting regulatory applications</li> </ul>

Breakout Group 1	Breakout Group 2
<b>4. Tactics</b>	
<ul style="list-style-type: none"> <li>▪ Create a strategic plan on what needs to be done (SGA = strategic general action)</li> <li>▪ Develop a call to action for policy makers, with the aim of:                             <ul style="list-style-type: none"> <li>– Increasing research (global/EU/national)</li> <li>– Integrating AMD into existing healthcare policies</li> </ul> </li> <li>▪ Build narrative about AMD: prevention &gt; treatment &gt; rehabilitation</li> <li>▪ Leverage from neovascular AMD &gt; GA: “Silent majority with GA”</li> <li>▪ Increase diagnosis by providing support/ reimbursement for prompt, regular, standardised eye testing, particularly in at risk groups (e.g. ≥50 years, smokers, family history)</li> <li>▪ For those individuals diagnosed with GA, register on database ready for when treatment becomes available</li> <li>▪ Clear messaging/advocacy</li> </ul>	<ul style="list-style-type: none"> <li>▪ Research on overall burden                             <ul style="list-style-type: none"> <li>– Establish baseline e.g. waiting time, access, guidelines</li> </ul> </li> <li>▪ Background paper                             <ul style="list-style-type: none"> <li>– Statistics</li> <li>– Explanation of condition</li> <li>– Use common terminology, translate into multiple languages</li> </ul> </li> <li>▪ Background paper leads to short material for websites/infographics/ video, etc.                             <ul style="list-style-type: none"> <li>– Multilingual glossary</li> <li>– Media background</li> <li>– Image gallery/simulation</li> </ul> </li> <li>▪ Clear messaging</li> <li>▪ Develop a group of advisory global KOLs                             <ul style="list-style-type: none"> <li>– Note: make sure that the campaign is not biased by one pharma company</li> </ul> </li> <li>▪ Create a coalition of different companies and organisations</li> </ul>

## Next steps

Following the workshop, priorities were discussed in terms of next steps. There was a general consensus that the following three actions should be prioritised:

<p><b>1</b> Create a coalition of interested organisations to raise the profile of GA</p>	<p><b>2</b> Produce a short ‘call to action’ paper, covering the burden of disease plus the need for research</p> <ul style="list-style-type: none"> <li>▪ What is the problem, what is the evidence (literature review and case studies, patient quotes), what needs to be done?</li> <li>▪ Keep it simple and ensure consistent use of appropriate terminology</li> </ul>	<p><b>3</b> Follow up with a longer paper including burden of illness data</p> <ul style="list-style-type: none"> <li>▪ Start with a review of the existing evidence (GA vs neovascular AMD)</li> <li>▪ Build in new burden of illness data for GA (due in 2017)</li> </ul>
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The participants debated which should come first, the shorter call to action or the longer burden of illness paper, with merits found on both sides. They also discussed the need to frame any new activities within the broader picture, ensuring that they tie in with existing initiatives rather than duplicating previous efforts.

Finally, the general consensus of the group was that they had enjoyed the lively discussion and interaction during the course of the meeting and would be willing to form a coalition to drive forward the proposed initiatives.

## References

1. The Royal College of Ophthalmologists (UK), Age-Related Macular Degeneration: Guidelines for Management. September 2013. Available at <https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2013-SCI-318-RCOphth-AMD-Guidelines-Sept-2013-FINAL-2.pdf>.
2. National Eye Institute, Facts about age-related macular degeneration. 2012. Available at: [https://www.nei.nih.gov/health/maculardegen/armd\\_facts](https://www.nei.nih.gov/health/maculardegen/armd_facts).
3. Congdon, N., et al., Causes and prevalence of visual impairment among adults in the United States. *Arch Ophthalmol*, 2004. 122(4): p. 477-85.
4. Owen, C.G., et al., The estimated prevalence and incidence of late stage age related macular degeneration in the UK. *Br J Ophthalmol*, 2012. 96(5): p. 752-6.
5. Singer, M., Advances in the management of macular degeneration. *F1000Prime Rep*, 2014. 6: p. 29.
6. World Health Organization, Global Data on Visual Impairments, 2010. Available at <http://www.who.int/blindness/GLOBALDATAFINALforweb.pdf>.
7. Brown, G.C., et al., The burden of age-related macular degeneration: a value-based medicine analysis. *Trans Am Ophthalmol Soc*, 2005. 103: p. 173-84; discussion 184-6.
8. Ferris, F.L., 3rd, et al., Clinical classification of age-related macular degeneration. *Ophthalmology*, 2013. 120(4): p. 844-51.
9. Wong, W.L., et al., Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. *Lancet Glob Health*, 2014. 2(2): p. e106-16.
10. Rudnicka, A.R., et al., Age and gender variations in age-related macular degeneration prevalence in populations of European ancestry: a meta-analysis. *Ophthalmology*, 2012. 119(3): p. 571-80.
11. van Lookeren Campagne, M., et al., Mechanisms of age-related macular degeneration and therapeutic opportunities. *J Pathol*, 2014. 232(2): p. 151-64.
12. Biarnes, M., et al., Update on geographic atrophy in age-related macular degeneration. *Optom Vis Sci*, 2011. 88(7): p. 881-9.
13. Panorgias, A., et al., Multimodal assessment of microscopic morphology and retinal function in patients with geographic atrophy. *Invest Ophthalmol Vis Sci*, 2013. 54(6): p. 4372-84.
14. Lindblad, A.S., et al., Change in area of geographic atrophy in the Age-Related Eye Disease Study: AREDS report number 26. *Arch Ophthalmol*, 2009. 127(9): p. 1168-74.
15. Holz, F.G., et al., Progression of geographic atrophy and impact of fundus autofluorescence patterns in age-related macular degeneration. *Am J Ophthalmol*, 2007. 143(3): p. 463-72.
16. Hassell, J.B., E.L. Lamoureux, and J.E. Keeffe, Impact of age related macular degeneration on quality of life. *Br J Ophthalmol*, 2006. 90(5): p. 593-6.
17. Brody, B.L., et al., Depression, visual acuity, comorbidity, and disability associated with age-related macular degeneration. *Ophthalmology*, 2001. 108(10): p. 1893-900; discussion 1900-1.

18. Heraghty, J. and R. Cummins, A layered approach to raising public awareness of macular degeneration in Australia. *Am J Public Health*, 2012. 102(9): p. 1655-9.
19. Macular Disease Foundation Australia and International Federation on Ageing, Global Ageing and Vision Advocacy Summit, Barcelona 2013. Meeting report available at [http://www.mdfoundation.com.au/resources/BarcelonaSummit\\_Final%20Report\\_Web\\_2013-09.pdf](http://www.mdfoundation.com.au/resources/BarcelonaSummit_Final%20Report_Web_2013-09.pdf).
20. International Diabetes Federation and The Fred Hollows Foundation, Diabetes eye health: A guide for health care professionals. Brussels, Belgium: International Diabetes Federation, 2015. Available at [http://www.idf.org/sites/default/files/Diabetes\\_Eye\\_Health.pdf](http://www.idf.org/sites/default/files/Diabetes_Eye_Health.pdf).
21. Gopinath, B., et al., Predictors of psychological distress in caregivers of older persons with wet age-related macular degeneration. *Aging Mental Health*, 2015. 19(3): p. 239-246
22. Gohil, R., et al., Caregiver burden in patients receiving ranibizumab therapy for neovascular age related macular degeneration. *PLoS One*, 2015. 10(6): p. e0129361.
23. Varano, M., et al., The emotional and physical impact of wet age-related macular degeneration: findings from the wAMD Patient and Caregiver Survey. *Clin Ophthalmol*, 2016. 10: p. 257-67.
24. Varano, M., et al., Current barriers to treatment for wet age-related macular degeneration (wAMD): findings from the wAMD patient and caregiver survey. *Clin Ophthalmol*, 2015. 9: p. 2243-50.
25. Vukicevic, M., et al., Caregiver perceptions about the impact of caring for patients with wet age-related macular degeneration. *Eye (Lond)*, 2016. 30(3): p. 413-21.
26. Macular Disease Foundation Australia, Federal Election 2016 Policy Platform. Available at <http://www.mdfoundation.com.au/election2016.aspx>.

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