Retinal Diseases in Europe

Prevalence, incidence and healthcare needs

EURETINA
European Society of Retina Specialists

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Executive summary

The majority of blindness and severe vision loss in Europe is due to age-related retinal diseases. Considering current demographic trends, both an increase in prevalence and incidence of, as well as an increase in the lifetime lived with age-related retinal disease is expected. This will put enormous pressure on European health care systems.

In order to allow for both tailored health service planning as well as focussed research to address these future challenges, we provide a comprehensive situation analysis and future prediction for retinal diseases in Europe.

We performed a systematic review and meta-analysis of the European literature on prevalence and incidence as well as health care services for age-related macular degeneration (AMD), diabetic eye disease (DED) and retinal vein occlusions (RVO).

We estimated that AMD currently affects around 34 million people in the European Union (EU) and 22 million people in the five most populous European countries alone: Germany, France, the United Kingdom (UK), Italy and Spain. The number of patients affected by AMD in the EU is expected to rise by almost 25% based on population growth and ageing until 2050. For diabetic eye disease, the current and future situation is similar. More than 25% of diabetic patients are affected by any DED, amounting to nearly 4 million individuals in the EU. Nearly one million individuals are estimated to require treatment due to proliferative DED or clinically significant macular oedema. As the prevalence of diabetes is increasing considerably due to both demographic trends and lifestyle changes, DED in turn will increase too. European countries have introduced very heterogeneous approaches to screen for DED with some countries using national registers and/or programmes. Reported uptake of screening for DED was highest in the UK (83%) which has a national screening programme, and lowest for Italy (11%) with no systematic screening programme. National screening programmes incur high health care expenditures, but there is evidence for a significant reduction in blindness due to diabetic retinopathy in England after the implementation of the National Diabetic Eye Screening Programme.

With the introduction of intravitreal (IVT) therapy, both AMD and DED have much improved visual outcomes but available health care service data demonstrate that IVT treatment provision puts a con-siderable strain on healthcare systems and alternative approaches to service provision including delegation to auxiliary cadres have been implemented in for example the UK.

Data on RVO were fewer, but sufficient to perform a meta-analysis. More than one million Europeans aged 55 years and older are affected by RVO and also require IVT as well as laser and other treatment which puts additional strain on ophthalmic healthcare systems.

Retinal diseases are the main causes of blindness and severe visual loss in Europe already today and will continue to increase. Both health service provision and future research should focus on this in order to address these challenges and preserve sight for the ageing European populations.

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Abbreviations

AMD	Age-related macular degeneration
CRVO	Central retinal vein occlusion
CSMO	Clinically significant macular oedema
DED	Diabetic eye disease
DM	Diabetes mellitus
DR	Diabetic retinopathy
DMO	Diabetic macular oedema
EU	European Union
FAG	Fluorescein angiography
GA	Geographic atrophy
GP	General practitioner
HES	Hospital eye services
IVT	Intravitreal
nAMD	Neovascular age-related macular degeneration
NDESP	NHS Diabetic Eye Screening Programmes
NHS	National Health Service
NPDR	Non-proliferative diabetic retinopathy
OCT	Optical coherence tomography
PAT	Preferences and Trends
PDR	Proliferative diabetic retinopathy
RVO	Retinal vein occlusion
UK	United Kingdom
VEGF	Vascular endothelial growth factor

Facing an ageing population - major challenges for European ophthalmology

With age-related macular degeneration (AMD) and diabetic eye disease (DED), two of the main causes for blindness and severe visual loss in Europe are retinal diseases [1, 2]. These as well as most other common retinal diseases are age-related diseases, which leads to increasing prevalence with age or diabetes duration in the case of DED.

Europe is facing intense demographic changes due to population ageing and in turn an increase in age-related retinal diseases. These may give rise to an increase in visual impairment and blindness in older Europeans in the years to come. Visual impairment increases the risk for unemployment, depression and anxiety disorders as well as number of falls and accidents [3–15]. It leads to reduced independence and quality of life of affected individuals [7, 9]. With an increasing emphasis on participating more actively for longer in life in regards to both work and private life in all European societies, avoiding visual loss becomes more and more important. Therefore, special focus should be placed on the prevention and treatment of retinal diseases.

To date, there is a lack of comprehensive data on the current situation as well as future projections of retinal diseases in Europe. A bigger picture is needed for the development of prevention and intervention strategies. This report aims to provide a situation analysis for retinal diseases and health care provision in Europe as well as an outlook on future challenges.

Thus, in a systematic fashion, all available data on the main retinal diseases were collated including prevalence, incidence and health service provision in the European Union (EU) as well as its five largest countries Germany, the United Kingdom (UK), France, Italy and Spain for AMD, DED, including both diabetic retinopathy and diabetic macular oedema, and retinal vein occlusions (RVO).

On the following pages we present a summary of our analysis for a quick but detailed overview of our findings at the European level. Detailed descriptions of methods and more granular results are presented in the extended report.

Age-related macular degeneration in Europe

AMD is, by definition, a retinal disease affecting older individuals. Early stages of the disease, which include early and intermediate AMD and are mostly asymptomatic, slowly progress to late stages of the disease, which can cause severe visual loss. Studies vary slightly when staging AMD, so some of the stages had to be grouped together to reflect this.

- One in four Europeans over the age of 60 is affected by AMD

Keeping this in mind, we estimate that 26.3% of Europeans over the age of 60 are affected by AMD, be it early, intermediate or late AMD. Of these 24.1% have early and intermediate AMD and 2.2% have any late AMD. Late AMD can be subdivided into two types, the wet (neovascular AMD, nAMD) and the dry (geographic atrophy, GA) form. Only nAMD can be treated at present.

- AMD in general and any late AMD seem most prevalent in Italy and France

We found the highest pooled prevalence of any AMD in Italy (52.2%) followed by the UK (43.6%) and Spain (26.4%), whereas prevalence seems lower in France (37.3%) and Germany (32.8%), according to published data (Figure 1 and Figure 2).

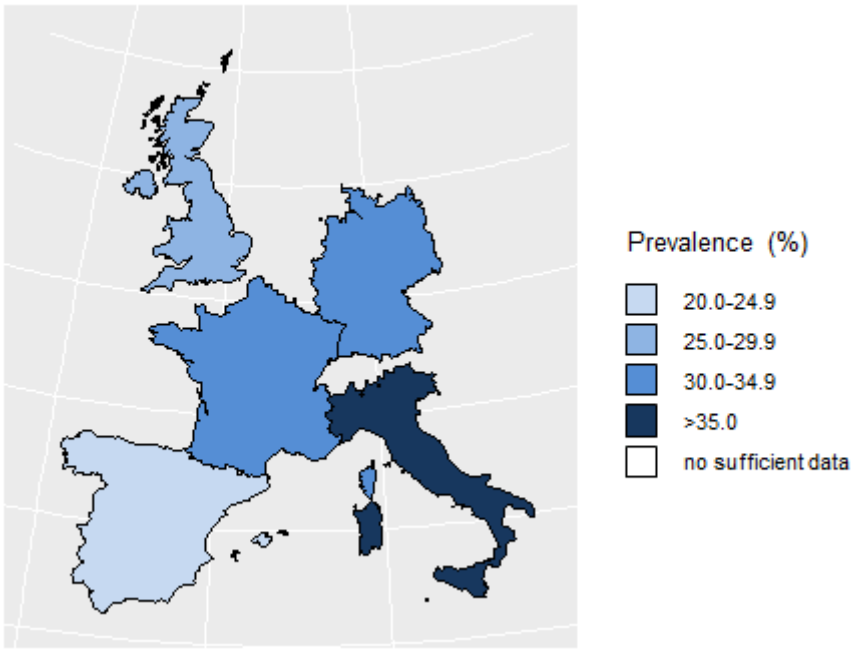

Figure 1: Colour-coded map of the prevalence of early and intermediate AMD by country

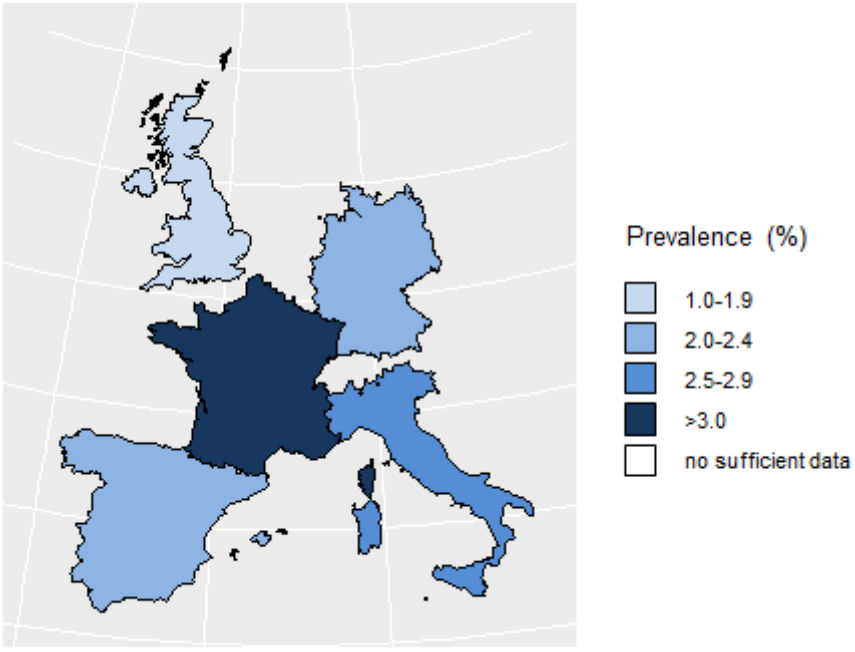

Figure 2: Colour-coded map of the prevalence of any late AMD by country

France, on the other hand, accounted for the highest pooled prevalence estimate of late AMD (3.3%), closely followed by Italy (3.2%), Germany (2.4%) and Spain (2.3%). Lowest prevalence of any late AMD was found in the UK (1.8%).
Of the two types of late AMD, nAMD was 1.7 times more common than GA, with a prevalence of 1.3% and 0.8%, respectively.

One in four EU citizens is currently older than 60 years. Germany and Italy have the largest proportion of older individuals (27.4% and 28.0%, respectively), whereas the population in Spain and the UK are comparatively younger (24.3% and 23.3%, respectively).

- More than 34 million EU inhabitants are affected by AMD

Applying our calculated pooled prevalence to EU population statistics, we estimate that at least 33.6 million individuals over the age of 60 years in the EU are currently affected by AMD. Any late AMD may be present in 2.8 million people, with nAMD accounting for 1.7 million people. Germany, being the largest country, has most persons affected by any AMD with currently more than 5.8 million people (Figure 3).

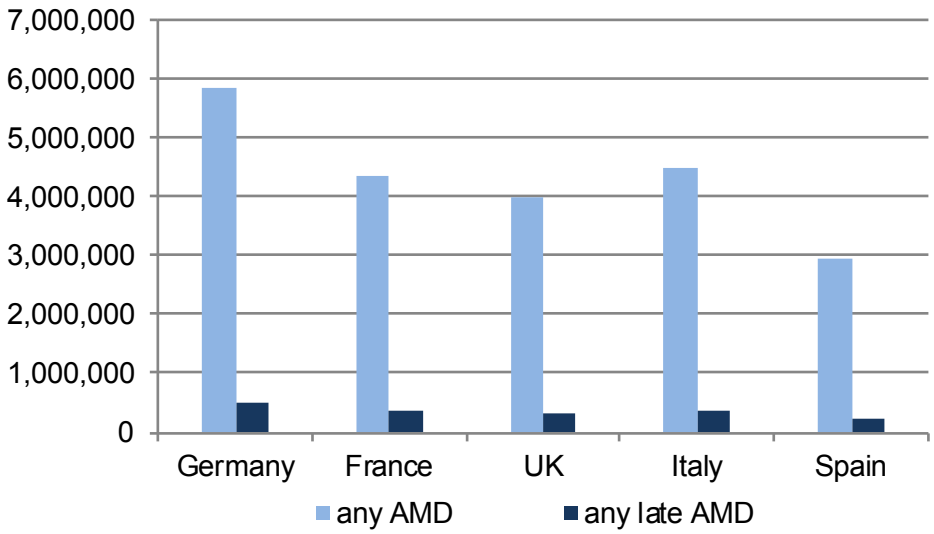

Figure 3: Estimated total number of individuals with any AMD and any late AMD by country

- Late AMD occurs newly in 1.4 per 1,000 individuals each year

Assessing how many persons will develop late AMD per year, incidence data from three longitudinal studies, one each from France, Iceland and the Netherlands [16–18], were pooled. Based on this, we estimated a pooled annual incidence of 1.4 per 1,000 individuals in a population over the age of 60. This corresponds to more than 170,000 Europeans newly affected by late AMD each year, total numbers for each country are presented in Figure 4.

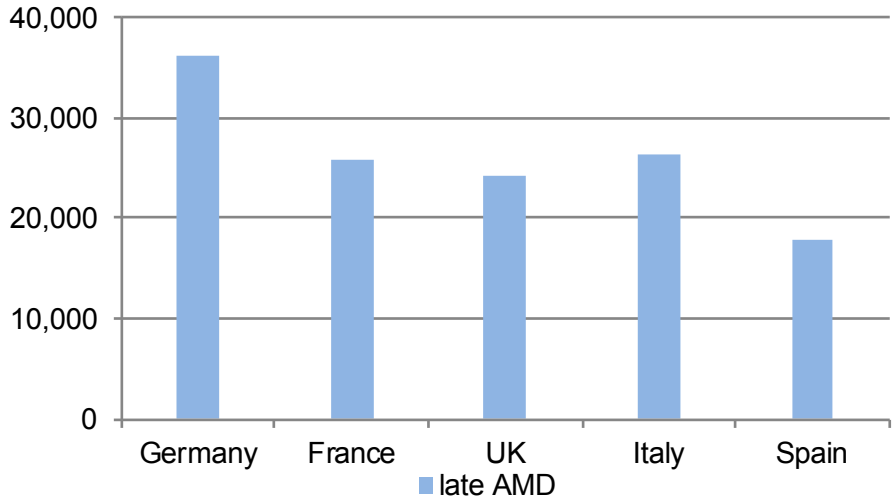

Figure 4: Estimated total annual number of individuals newly affected by late AMD by country

Projecting AMD to 2050

- The prevalence of AMD is about to rise by 20% until 2050

We applied our prevalence estimates to EU population projections data. Due to mathematical reasons, a population aged 55 to 84 years was considered for the extrapolation. Accordingly to the ageing of the population, an increase in AMD prevalence is to be expected. In the year 2050, more than 25 million people in the EU will be affected by any AMD (Figure 5), corresponding to an increase of approximately 20% over the next 35 years. Predictably, the most apparent increase will be in those 75 years and older: from 4.3 million up to 7.2 million, corresponding to an increase of 67%.

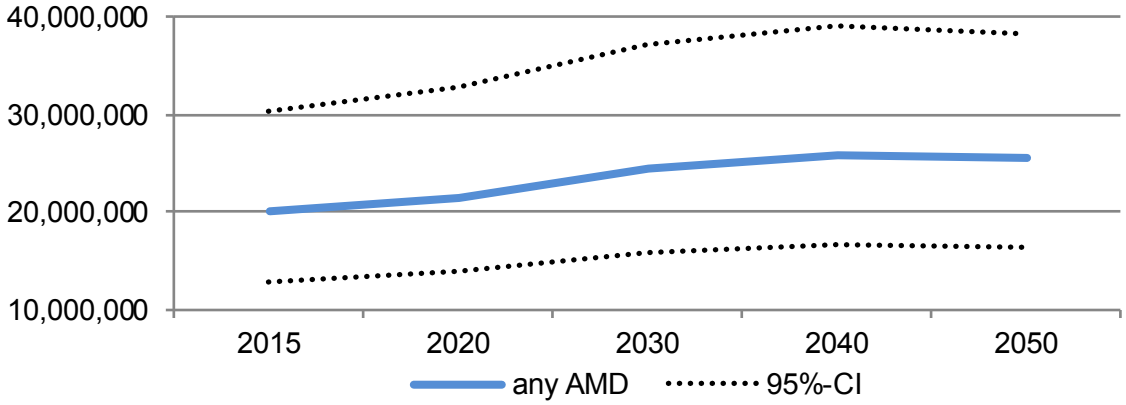

Figure 5: Extrapolation of the total number of individuals with any AMD in the EU

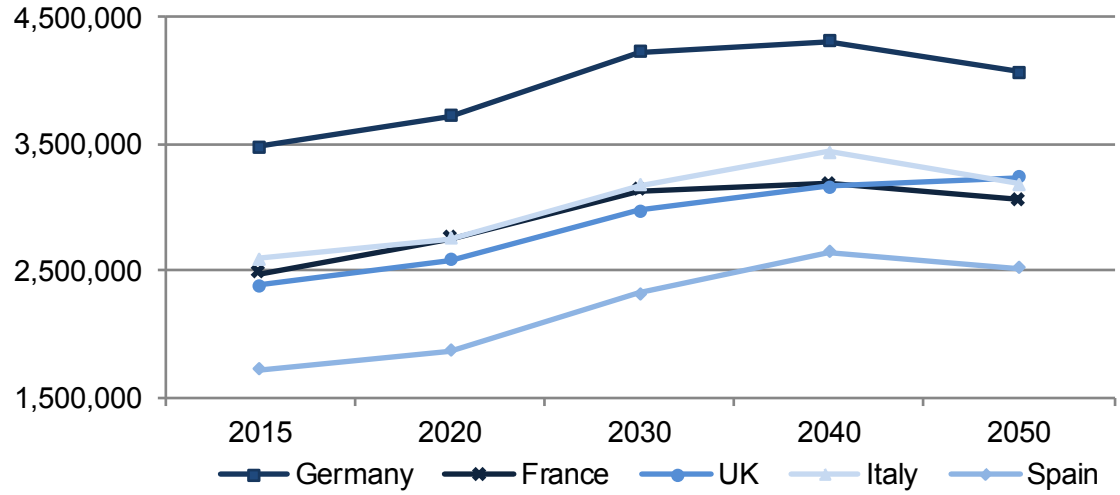

Figure 6: Extrapolation of the total number of individuals with any AMD by country

The extrapolation by country shows a nearly parallel increase in the number of affected individuals until 2040 (Figure 6). After 2040, a further increase is only expected in the UK. In France, Germany, Italy and Spain, a decrease of population is expected, mainly due to low birth rates [19–21].

Healthcare services for AMD

- Publications and data on healthcare services for AMD in Europe are limited

AMD raises a major challenge to European healthcare systems. Screening for AMD is generally not performed. Given the expected large increase in persons affected by AMD who would be at risk of visual loss, screening for early stages of the disease might be worthwhile in high risk groups, in particular implementing telemedicine approaches as an ageing population might be less mobile.

The development and widespread application of intravitreal (IVT) application of anti-vascular endothelial growth factor (VEGF) drugs has revolutionized the ophthalmological landscape in the last decade. Existing data implies a discrepancy between guidelines and the real-life uptake of diagnostics and treatment for neovascular AMD, resulting in insufficient treatment of millions of patients. For nAMD, early initiation of treatment for nAMD is key, but an increase in public awareness of AMD is required to reduce the reported delay between symptoms and first consultation of an ophthalmologist as well as any subsequent delays. Therefore, we urgently need AMD awareness campaigns in Europe.

- Logistical challenges in the sufficient coverage of IVT administration

With a rising number of IVT injections in the coming years, we are also facing logistical issues. One-stop clinics are installed throughout European eye clinics, other concepts for the improvement of processes need to be evaluated. In Europe, IVT injections are more commonly performed in a semi-sterile or operation room environment, as compared to the United States, where 81.5% of retina specialists perform IVT injections in the office [22].

- Observational studies indicate existing barriers to treatment of nAMD

In Germany, ophthalmologists are visited more frequently by AMD patients (1.69 per quarter) compared to other eye diseases (1.37 per quarter) with low rates of optical coherence tomography (OCT) imaging (5.9%) and IVT injections (15.9%). These problems are present to some extent all across Europe. Patients with nAMD experience delays in accessing treatment, a low treatment frequency and suboptimal monitoring including only few OCT examinations. This leads to treatment outcomes which are worse than what was achieved in clinical phase III studies and what should be possible under routine conditions.

- We are facing major challenges in the provision of treatment and follow-up of nAMD patients

Regionally, treatment delay varies considerably. In Germany, comparing metropolitan to rural areas, the delay was significantly longer in rural areas (14.1 compared to 25.4 days) [23]. Similarly, the variability in treatment frequency was 40-fold between different health service trusts in the UK, demonstrating geographical variation in access [24].

However, treatment provision and outcomes did improve since the introduction of IVT treatment in 2006. In France, studies demonstrate that the delay between diagnosis and treatment could be significantly reduced from 12.6 to 7.7 days since 2006 [25].

- In the UK, different innovative approaches to nAMD treatment provision have been implemented

In 2012, Action on AMD, a group of UK healthcare professionals and patient representatives, described clinical capacity reaching its limits already [26]. By that time, delay in adherence to recommended follow-up intervals was already seen in National Health Service (NHS) clinics, mostly caused by shortage of retinal consultants and medical staff, as well as suboptimal supply with OCT imaging equipment.

Efforts have been made to increase retina clinics capacities by optimizing internal infrastructures. A one-stop clinic service involving more and more optometrists and nurse practitioners was introduced in an increasing number of clinics which were found to be safe and effective. [27]. In certain clinics, telemedicine pilot projects, virtual clinics as well as mobile screening units using OCT scan vans in remote areas have been implemented in addition to cover in particular remote rural areas [26].

Due to the suboptimal recruitment of ophthalmic medical manpower, nurse-delivered IVT administra-tion has been evaluated and implemented in the UK [28]. This leads to a significant increase in IVT injections without increasing the number of serious complications [29, 30].

Health service provision might differ between countries but the high and increasing numbers of older persons affected by all stages of AMD pose the same challenges for all European countries. Against this background, more research into the causes for AMD and its progression is needed to develop preventative interventions. At the same time, health services need to be made available for the already high but still increasing need as well as tailored to the unique requirements of older persons across all of Europe.

Diabetic eye disease in Europe

People with diabetes are at risk of developing diabetic eye conditions, including diabetic retinopathy (DR) and diabetic macular oedema (DMO). Microvascular changes resulting from poorly controlled blood sugar may damage blood vessels in the retina and lead to severe vision loss or blindness. DR is commonly classified as mild, moderate and severe non-proliferative DR (NPDR) and proliferative DR (PDR), according to the "International Clinical Classification Diabetic Retinopathy Severity Scale" [31]. Studies vary when defining DMO. Agreement is higher for definitions of clinically significant macular oedema (CSMO).

- One in four Europeans with diabetes is affected by any DED

According to our estimate, any DED is prevalent in 25.0% of European diabetic patients managed in primary healthcare. Reported prevalence of any DED was highest in Italy (34.1%), the UK (29.8%) and Spain (26.5%), as presented in Figure 7. 17.7% of diabetics are estimated to show signs of mild or moderate non-proliferative DR (NPDR). Approximately 2.0% are affected by severe NPDR.

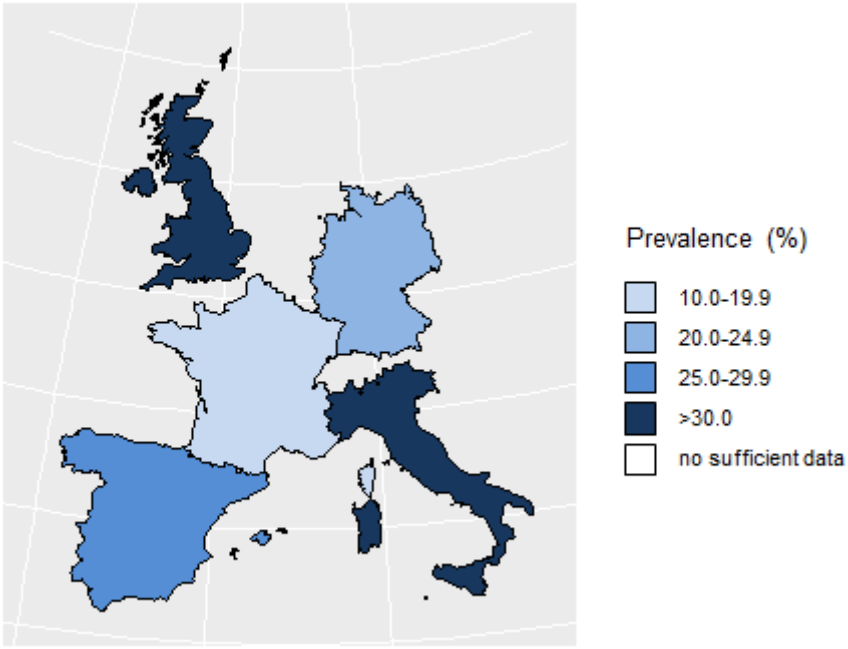

Figure 7: Colour-coded map of the prevalence of any DED by country

Ophthalmologic treatment, such as panretinal or focal laser coagulation or IVT injections, is required in 2.1% and 3.5% of European diabetics due to PDR and CSMO, respectively. The highest prevalence of PDR was found in Italy (4.6%), Spain (2.8%) and Germany (2.3%). The UK and Spain had the highest prevalence rates of CSMO: 5.2% and 2.7%, respectively.

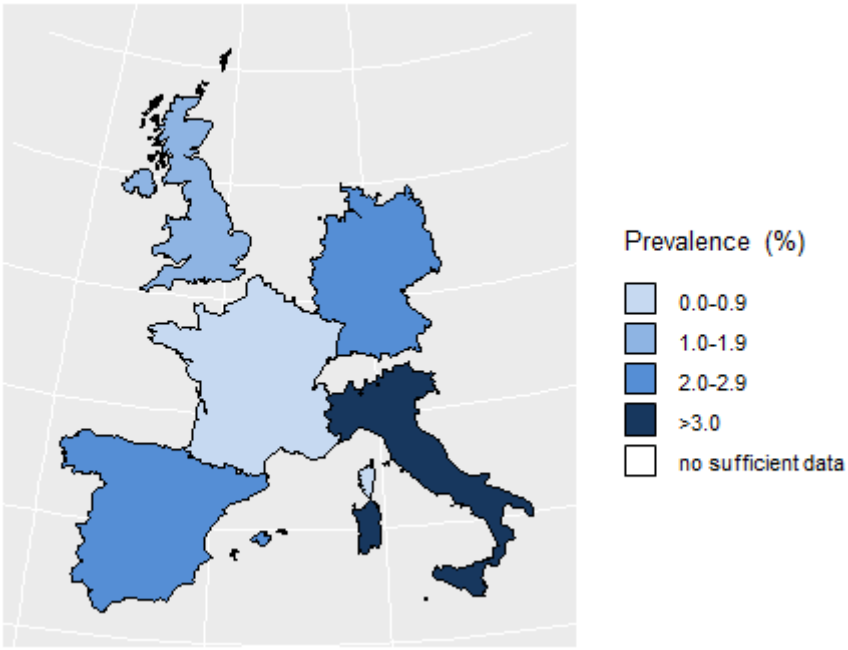

Figure 8: Colour-coded map of the prevalence of PDR by country

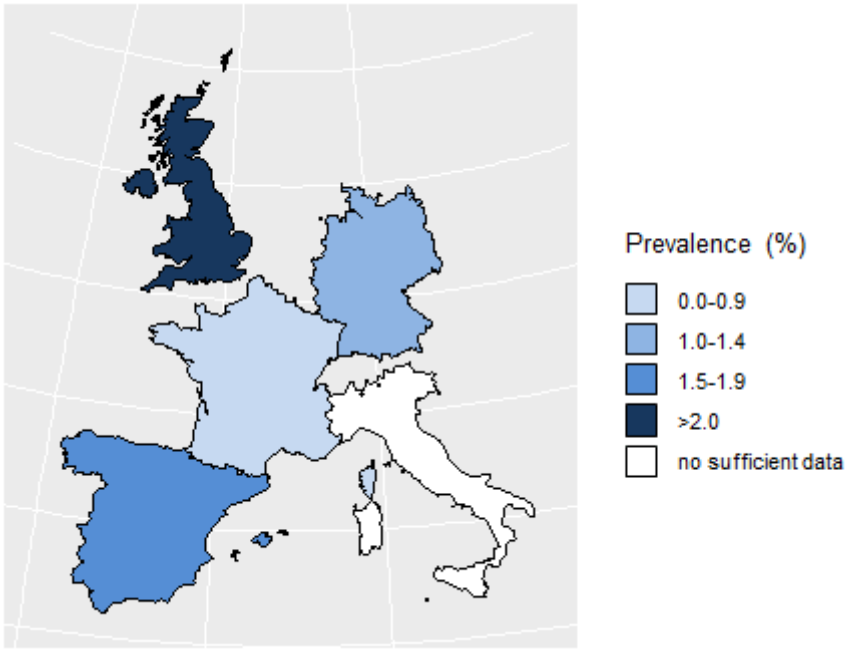

Figure 9: Colour-coded map of the prevalence of CSMO by country

- The total number of individuals with DED is highest in Germany and Italy

In the EU, nearly 4 million individuals over the age of 40 are currently affected by any DED. The highest numbers are found in Germany and Italy with nearly one million individuals each (Figure 10). Of these, at least 100,000 have PDR or CSMO requiring further ophthalmological treatment and management. We found the lowest number of affected individuals in France with around 300,000 affected by any DED.

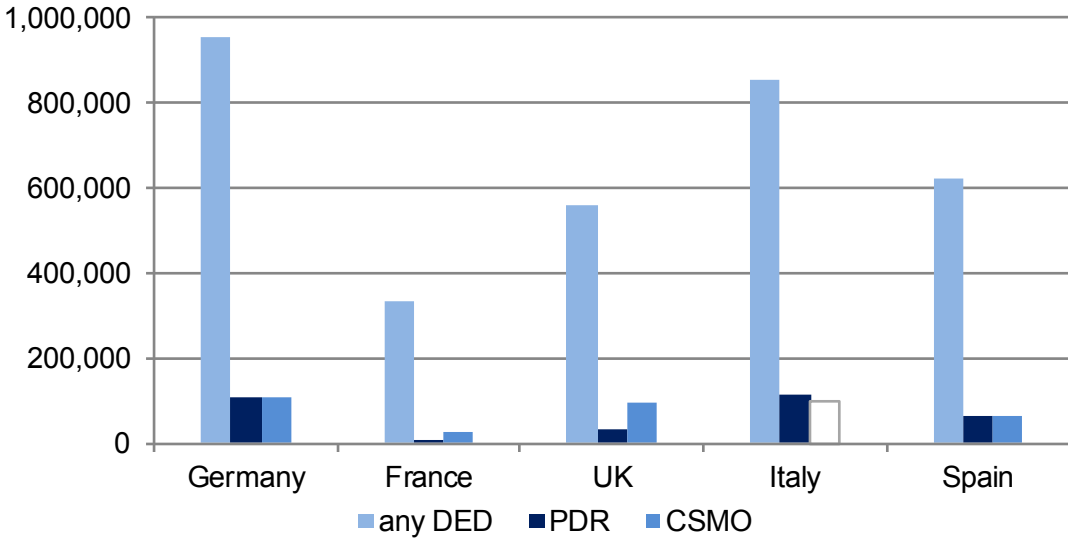

Figure 10: Estimated total number of individuals with any DED, PDR and CSMO by country. No country specific data for CSMO in Italy

Each year, 4.6% of Europeans with diabetes are newly affected by any DED, corresponding to more 770,000 individuals in the EU per year (Figure 11).

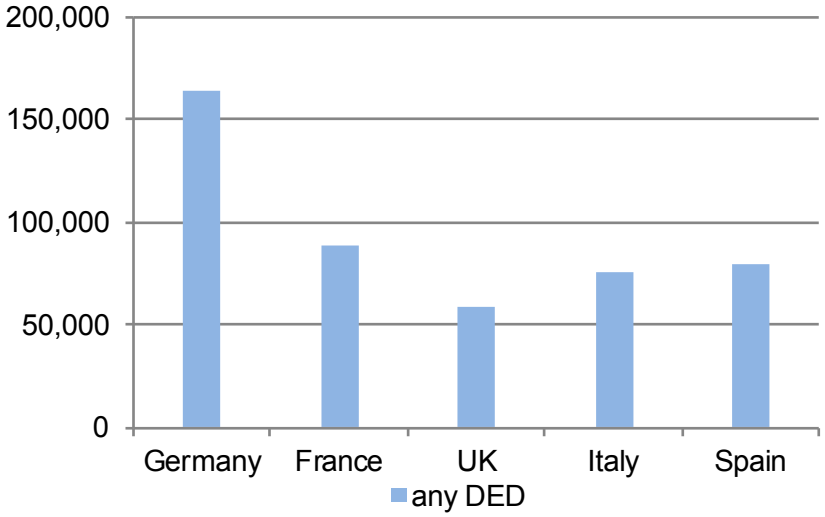

Figure 11: Estimated total annual number of individuals newly affected by any DED by country

Projecting DED to 2050

- The number of people affected by any DED in the EU is expected to increase by 6% until 2040

Our projection shows an increase of the number of EU inhabitants affected by any DED from 3.6 million to 3.8 million in 2040 (Figure 12). After 2040, a further increase is only seen in the United Kingdom and Italy (Figure 13).

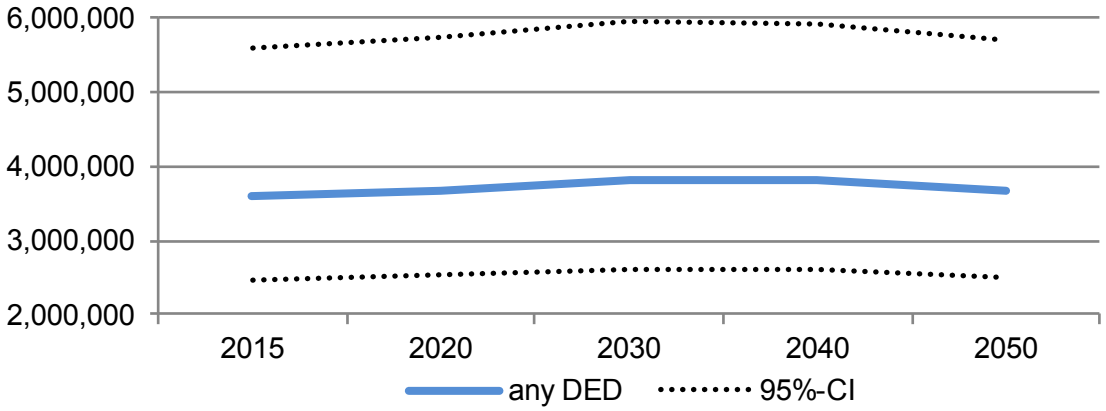

Figure 12: Extrapolation of the total number of individuals with any DED in the EU

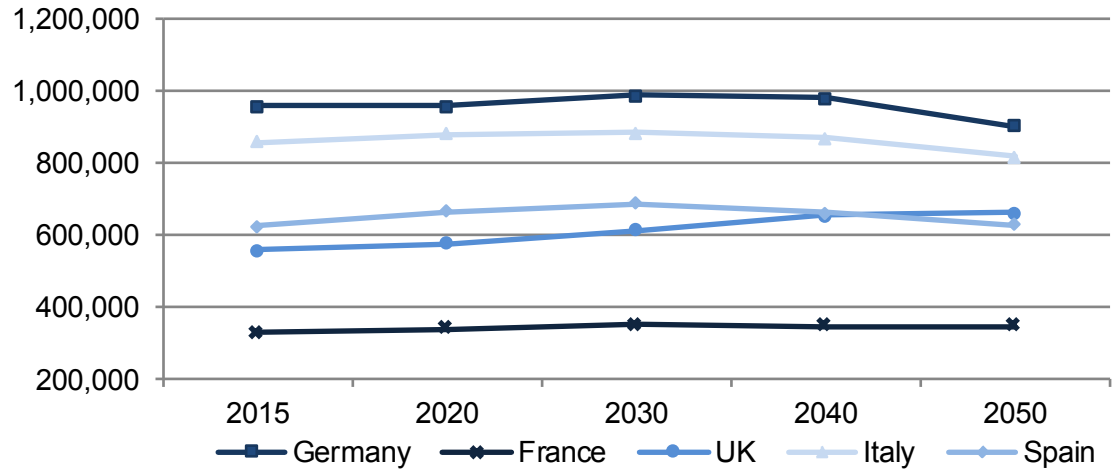

Figure 13: Extrapolation of the total number of individuals with any DED by country

We applied our pooled prevalence estimate to a population aged 40 to 80 years, according to age limitations of the underlying studies. As the EU's working-age population is expected to decrease in size – from 334 million people in 2014 to 292 million people in 2080 [32] –, the modelled scenario is rather conservative and not as much affected by the overall population ageing as the AMD scenario. Still, as the risk of DED increases with duration of the DM, chances are high that the burden will increase considerably as persons with DM live longer and thus have a higher lifetime chance to develop DED.

Healthcare services for DED

- Healthcare services for DED stand and fall by the provision and utilization of screening

Preventing the occurrence of DED is an important goal, as an extensive economic burden arises from the loss of workforce due to visual impairment and blindness caused by DED [33]. Contrary to AMD, DED is a disease affecting not only an elderly population, but also to a large part the working population. In a working population, delivery of screening and other health services is challenging as it is competing for time during working hours [34].

- Systematic national screening programs only exist in the United Kingdom

Screening is the essential and dominating topic regarding healthcare services for DED. A systematic national screening program is existent in the UK. The national diabetic eye screening programme (NDESP) was introduced by the NHS [35]. Since 2008, all persons with diabetes older than 12 years are invited to nationwide retinal screening programmes [36]. Free screening is delivered not only by ophthalmologists, but various screening models, such as fundus photography in general practitioner (GP) surgeries, hospitals, diabetic centres or in mobile screening units, or funduscopic evaluation by accredited optometrists, have been implemented. OCT imaging is not yet provided extensively, but coverage is spreading. Consequently, DED as a cause of certifiable blindness decreased from 17.7% in the year 2000 to 14.4% in the year 2010, and was replaced by hereditary retinal disorders as the main cause of blindness certification (20.2%) in a working age population [37]. In other countries, screening and pilot telemedicine programs have only been initiated in solitary projects at a regional level.

There is a broad consensus on the necessity of regular screening of diabetic patients, although, the extension of screening intervals for patients with low risk for developing DED has been discussed, which is expected to decrease the expenditures for screening significantly [38, 39]. The NDESP has reportedly led to a remarkable increase in referrals to hospital eye services (HES) [40]. Data on the provision of ophthalmological treatment indicate a rather acceptable situation. After referral to tertiary care, 82% and 85% of appointments and lasers, respectively, took place within the recommended time frame [41].

- Screening uptake is alarmingly low in Italy according to published data

Reported uptake of screening was highest in the UK (82.8%), while the reported numbers were alarmingly low for Italy (11.1%). DR screening coverage in Germany and France is estimated 68% and between 36.5% and 50%, respectively, and is primarily performed by funduscopy in private ophthalmology practices [42–44]. In Spain, non-mydriatic photography eventually combined with teleophthalmology has been broadly implemented [42, 45–49]. Figures of screening uptake range between 33% and 82% [42].

- A comprehensive primary healthcare structure is crucial for prevention and treatment of DED

Preventive healthcare plays an important role in the incidence of DED. Meeting targets for glycemic control and regular check-ups with a GP or diabetologist need to be integrated within a comprehensive provision of primary healthcare including DED screening. For this, communication between different healthcare providers involved in DM care needs to be good. In some countries like Germany and the UK, standardized report forms have been implemented to facilitate good communication [50, 51].

Globally, diabetes is increasing. Thus, healthcare systems need to be equipped to deal with this.

Retinal vein occlusions in Europe

- More than one million Europeans are affected by RVO

More than 1.1 million people over the age of 55 are currently affected by a RVO in the EU with 15 to 25% due to central RVO (CRVO) and 75-80% due to branch RVO (BRVO). This corresponds to a prevalence of RVO in either eye of 0.7%. Data were not sufficient for a prevalence estimate for each country. Therefore we applied our European pooled prevalence estimate to EU population statistics of a population aged 55 years and older (Figure 14).

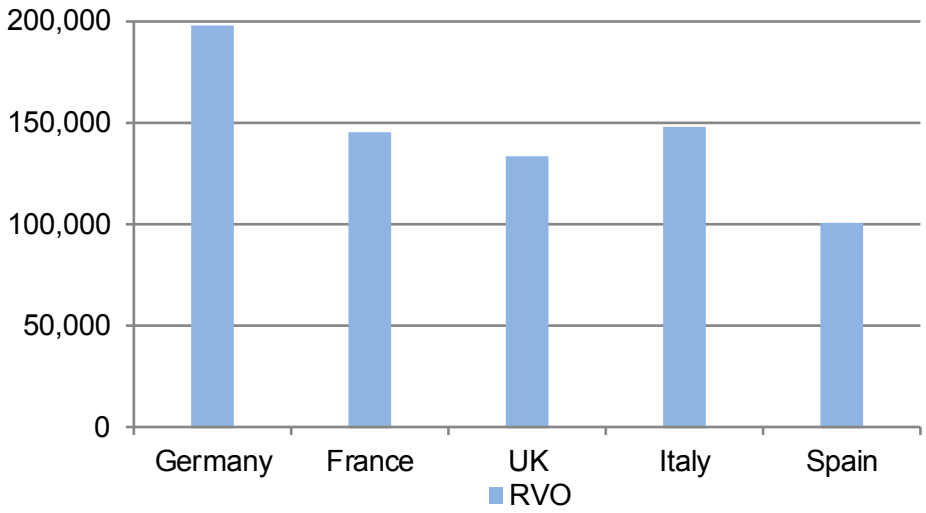

Figure 14: Estimated total number of individuals with RVO by country

Projecting RVO to 2050

- The total number of Europeans with RVO will increase by more than 20% until 2040

We applied our pooled prevalence estimate to EU population projections data of a population aged 55 to 80 years. The total number of individuals affected by retinal vein occlusion in this age group is expected to rise from 900,000 to 1.1 million (Figure 15).

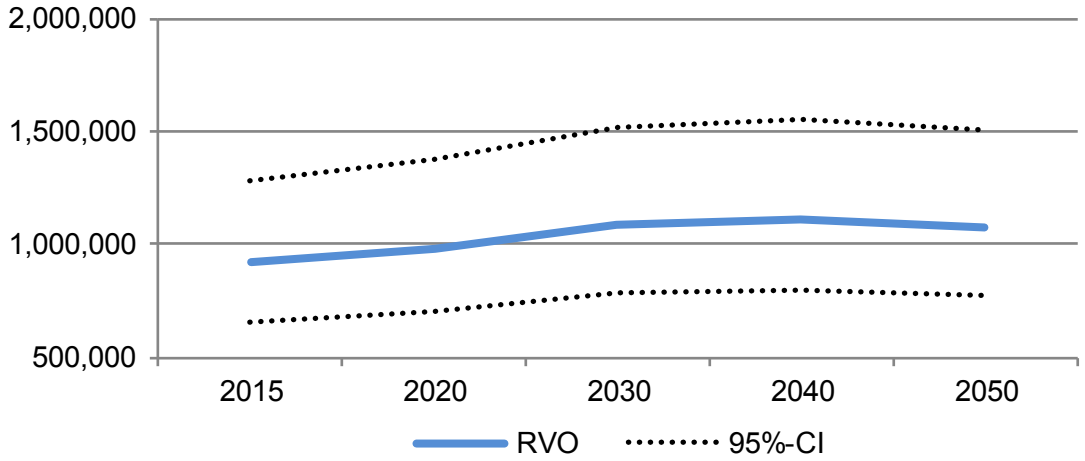

Figure 15: Extrapolation of the total number of individuals with RVO in the EU

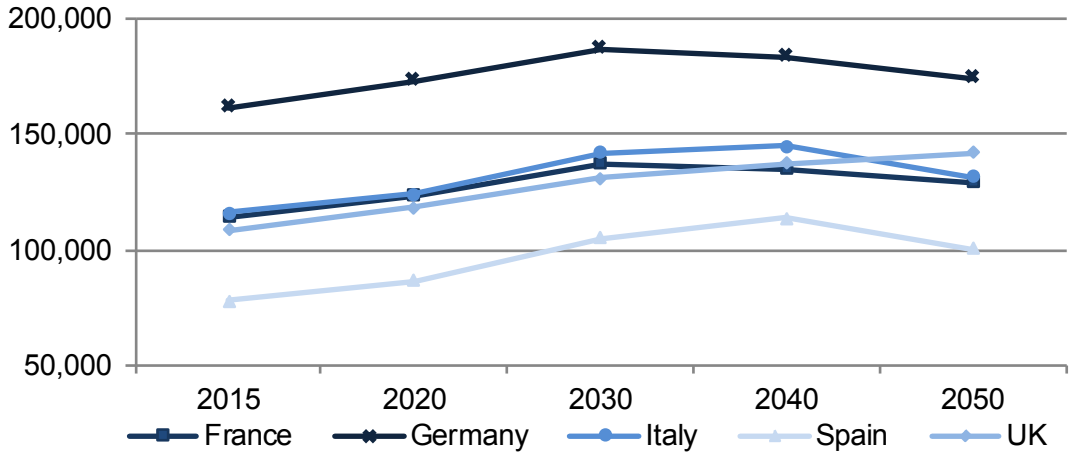

Figure 16: Extrapolation of the total number of individuals with RVO by country

Similarly to our projection estimation for diabetic eye disease, we also included a working-age population. This may contribute to the fall of the absolute number of patients with RVO from 2040 to 2050, which is also seen in the analysis by country (Figure 16). Only in the United Kingdom, figures are expected to increase continuously.

Healthcare services for RVO

Publications on healthcare services for RVO in Europe were few.

- Treatment modalities vary between European countries

Treatment patterns and costs of macular oedema due to RVO treated in France, Italy and Germany from 2005 to 2007 were compared in a multicentre study [52]. Fluorescein angiography (FAG) was performed most frequently in Italy (78%), and rarely in Germany (33%) and France (21%), whereas retinal photography was commonly performed in France (95%), Italy (100%) and less often in Germany (10%). Additionally, OCT was performed in 53% of Italian RVO patients and only in 18% of French and 4% of German patients. Germany had the highest rate of inpatient treatment (34 to 42%), compared to France (14.8 to 23%) and Italy, where no patient was hospitalized for treatment.

In a more recent German study, baseline FAG and OCT were performed in 75% of patients [53]. Patients underwent a mean 4.1 OCT examinations during the observation period of 12 months with a mean 4.35 ranibizumab injections. Mean time between diagnosis and first IVT injection was 3.8 months.

- Healthcare expenditures for RVO are substantial in European countries

Health care expenditures are substantial in all examined countries. Total direct and indirect costs per patient and year were £14,692 in the UK and 11,434€ in France. In the UK, 42% of costs derived from monitoring of the disease including OCT procedures, 16% from drug treatment, 15% from treatment of adverse events and 20% from cost of blindness. Guidelines vary between examined countries, especially regarding inpatient treatment for haemodilution, which is only performed regularly in Germany [54]. Available data were too limited for a more comprehensive discussion. There is a need for further research.

Limitations

The presented scenarios are based on a systematic review of the literature and subsequent meta-analyses where enough data were available. Thus it is based on the best available source of evidence. Age-stratified data were only available for age groups up to age 84. Thus, the extrapolations to 2050 are an underestimate as they exclude those aged 84 years and above. Future extrapolations are difficult at the best of times and the presented future scenarios are based on the projected population growth only. This takes ageing into consideration, but not future, yet unforeseeable changes in lifestyle, available treatments or preventative measures. Thus, the presented forecasts should be interpreted as a worst case scenario based on the assumption that our preventive and therapeutic armamentarium remains as it is now and that Europeans will not live much healthier lifestyles in the future.

Assessing available healthcare services based on the published scientific literature – even when including grey literature and reports by professional bodies and governmental institutions – generates a somewhat patchy overview of what is really available, as health services evolve much faster based on demand and available resources than what is reflected in the literature and other freely available sources. Thus, this report includes all major health services available in all respective countries, but very recent developments may have not been included.

Current & future challenges in Europe

Already today, the majority of cases of blindness and severe visual impairment in Europe is caused by retinal diseases such as AMD, DED and RVO. All of these diseases need to be managed by specialized medical professionals and required regular check-ups as well as treatment. This requires considerable healthcare resources but maintains vision in most cases, in particular when assessing anti-VEGF IVOM outcomes.

Given the adverse impacts of vision loss and blindness such as a loss of independence, quality of life, ability to participate in the labour market or society at large, as well as increased levels of depression, falls, traffic accidents and need for care or institutionalization, this is money well spent.

Against the background of ageing European populations, AMD, DED and RVO will affect more people for a longer period of their respective lives. This necessitates adjustments in both current and future service provision as well as research.

All countries have increasing demand for the delivery of IVOM services which have revolutionized AMD, DED and RVO treatment in the last ten years. Similarly, demand for DED screening is increasing and only the UK has implemented a national, systematic screening programme. This could be shown to be highly effective in reducing blindness due to DED, in particular in the working age population. Thus, currently available eye healthcare services need to be expanded in all countries, including the extension of currently available DED screening networks as well as available IVOM treatment capacity. For this, not only the training of additional specialized medical staff but also delegation of tasks by ophthalmologists or other physicians to non-physicians and tele-ophthalmology may be viable models.

Current and future research should be steered towards both health service research and preventative research on the major retinal diseases AMD, DED and RVO. Health service research ascertains an efficient translation of available evidence into clinical practice by for example addressing barriers to implementing evidence or suggesting potential appropriate models for service delivery of required services. More preventative research, including research on risk factors for the onset and progression of retinal diseases, may ultimately decrease the number of persons affected by AMD, DED or RVO at risk of loss of vision and in need of treatment. Preventative research has a less immediate impact compared to health services research but should nevertheless be funded appropriately given the increasing challenges posed by AMD, DED and RVO in the decades to come.

Allowing for a fast translation of evidence into practice when novel diagnostic, preventative or therapeutic interventions become available by accelerating regulatory review processes as well as access to funding has the potential to reduce some of the challenges outlined above. However, more importantly, decision makers at all levels need to be aware of these current and future challenges so that they can be addressed appropriately. European populations are faced with increasing rates of retinal diseases which put them at risk of vision loss. In order to avoid increasing number of blind and severely visually impaired Europeans in the decades to come, health services and research efforts need to be planned accordingly now.

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