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ORIGINAL RESEARCH

Burden of Disease Study of Patients with Neovascular Age-Related Macular Degeneration in Spain

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ABSTRACT

***Introduction*:** Neovascular age-related macular degeneration (nAMD) is a progressive retinal disease that causes severe and irreversible vision loss. The disease can therefore have a significant impact on the life of patients' and their families. The aim of this study was to evaluate the socioeconomic burden of nAMD in Spain.

***Methods*:** The annual cost per patient with nAMD was estimated for the first, second, and third year (or beyond) of treatment since diagnosis. Several cost categories were considered including direct healthcare costs (DHC), direct non-healthcare costs (DNHC), labor productivity losses (LPL), and intangible costs (IC) related to loss of quality of life. The average annual cost per patient was estimated by assigning a unit price or financial proxy to the resources consumed per patient. Reference year of costs was 2021.

***Results*:** The mean annual cost of nAMD was estimated at €17,265, €15,403, and €14,465 per patient in the first, second, and third year of treatment after diagnosis. There was an additional one-off cost of €744 associated with the diagnosis of nAMD. DHC accounted for most of the total annual cost per patient independent of the year of treatment since diagnosis (48% in year 1; 42% in year 2; 39% in year 3). Similarly, DNHC had an important contribution to the total costs (32% in year 1; 35% in year 2; 37% in year 3), followed by IC (20% in year 1; 23% in

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year 2; 24% in year 3), while the contribution of patients' LPL was minimal.
Conclusion: This study estimated a high economic burden associated with nAMD for patients and their families, the healthcare system, and society at large. There is a need to improve the management of these patients to reduce the impact of nAMD disease progression.

Keywords: Burden of disease; Resource consumption; Healthcare costs; Non-healthcare costs; nAMD; Productivity losses; Quality of life

Key Summary Points
Neovascular age-related macular degeneration (nAMD) is a progressive retinal disease that causes severe and irreversible vision loss.
In Europe, 1.4% of the population aged 60 years or older have nAMD.
The aim of this study was to evaluate the socio-economic burden of nAMD in Spain.
The total cost (TC) of nAMD was estimated at €17,265 per patient in year 1, reducing to €15,403 in year 2 and €14,465 in year 3+.
Direct healthcare costs (DHC) accounted for the largest proportion of the TC irrespective of the year since diagnosis, followed by direct non-healthcare costs, and intangible costs. The contribution of labor productivity losses to the TC was minimal.
This study showed that DHC decreased from year 1 to year 3+, given reductions in the number of visits, tests, and intravitreal injections in year 2 and year 3+.

INTRODUCTION

Age-related macular degeneration (AMD) is a chronic, neurodegenerative, progressive disease that can lead to blindness if left untreated [1]. More specifically, this disease affects the neural tissue of the retina, and is characterized by the presence of retinal lesions called drusen that lead to a loss of visual acuity and a distorted, wavy perception [1]. There are two types of AMD depending on the development of new blood vessels: non-neovascular and neovascular (nAMD) [1]. The latter is characterized by macular neovascularization associated with a choriocapillaris spatial distribution impairment [2]. Moreover, nAMD is the most common cause of irreversible vision loss in people over 60 in developed countries [3]. Accordingly, nAMD has been associated with a greater risk of injurious falls [4], impaired activities of daily living [5], and worse psychological well-being than non-neovascular AMD [5].

First-line treatment of nAMD consists of anti-angiogenic therapies that target abnormally formed vascular vessels in the eye, while second-line treatment consists of photodynamic therapy [6]. There are a series of adverse events (AEs) and complications associated with intravitreal injections in patients with nAMD, including retinal detachment, corneal damage, and endophthalmitis [7]. Accordingly, the management of nAMD places a considerable burden on the healthcare system. In 2021, the average annual cost per patient with nAMD in Spain was estimated to be €4627.6 [8], with most of the costs being associated with diagnostic tests and treatment.

Moreover, loss of central vision may impair the patient's activities of daily living (e.g., self-care, shopping, driving, etc.), leisure activities (e.g., watching television, reading, etc.), as well as work productivity for both patients and caregivers [9, 10], causing an important burden for families and society at large. In addition, fall-related fractures may further impair patients' mobility and independence. In fact, elderly patients with nAMD may suffer from falls and associated fractures, presenting a significantly higher risk of falling than those without nAMD [4]. Furthermore, these patients present depression and anxiety disorders [11] with an incidence of depression twice as high as that for people without nAMD [12].

In Europe, 1.4% of the population aged 60 years or over have nAMD [13]. The number of people affected by nAMD will continue to increase in the coming years as a consequence

of the exponential aging of the population [3], just as the number of people affected by blindness due to nAMD will increase [14].

The progression of nAMD leads to vision loss, which in turn carries a significant economic and social burden for the patients, their families, and society as a whole [15]. Understanding its burden can help optimize resource use and support making informed health-related decisions to prevent vision loss. Prompt diagnosis and treatment of nAMD has the potential to maintain vision as there are pharmacological therapies that significantly improve the prognosis of these patients [16]. Therefore, the aim of this study was to estimate the burden per patient with nAMD in Spain from a societal perspective, according to the time since diagnosis.

METHODS

Study Design

The burden of nAMD was estimated using a prevalence approach, from a societal perspective, per patient and year of treatment since diagnosis. Four cost categories were considered, namely direct healthcare costs (DHC), direct non-healthcare costs (DNHC), labor productivity losses (LPL), and intangible costs (IC) associated with loss of quality of life. The cost of diagnosis was included separately as a one-off cost.

Cost items associated with nAMD were obtained through a narrative literature review carried out in PubMed®. Subsequently, an online meeting was held with a group of four well-known experts in nAMD in Spain to discuss and validate the information extracted from the literature review. These experts were three ophthalmologists specialized in retina-vitreous diseases and one hospital pharmacist.

As considerable differences in resource consumption were expected over time since diagnosis, three groups of patients were considered: (a) patients in their first year of treatment after diagnosis (year 1), (b) patients in their second year of treatment after diagnosis (year 2), and (c) patients in their third year of treatment after diagnosis or later (year 3+). Likewise, the number of eyes affected by nAMD was considered. Hence, the proportion of patients with unilateral and bilateral nAMD at the time of diagnosis and over the first 3 years of treatment was estimated (see the Supplementary Material Table S1).

Cost items

Items Associated with Diagnosis One-Off Costs

The costs of diagnosis included medical visits and specific tests which are presented in Table 1.

Items Associated with Direct Healthcare Costs

DHC include treatment and follow-up costs associated with medical visits, tests, intravitreal injections, and AEs. The number of intravitreal anti-VEGF injections by year since diagnosis was based on a treat-and-extend regimen, which was discussed and validated by the advisory committee of this study. Detailed descriptions of cost items used to estimate DHC are

Table 1 Items associated with diagnostic one-off costs

	Number per patient	References
Medical visits		
Medical visits	1.0	Assumption
Medical tests		
Visual acuity test	1.0	[17]
Fundus photographic examination	1.0	[17]
OCT	1.0	[17]
OCT-A	1.0	[17]
Fluorescein angiography	1.0	[17]
Tonometry	1.0	[17]

OCT optical coherence tomography, *OCT-A* optical coherence tomography–angiography

presented in Tables 2 and 3. Cost items associated with AEs or comorbidities are applicable annually regardless of the year since diagnosis and the treatment.

Items Associated with Direct Non-Healthcare Costs

DNHC included informal care, formal care, non-visual technical aids, out-of-pocket expenditure, and commuting for medical visits. Informal care was defined as unpaid personal care provided by the patient's relatives or close friends. A total of 492.5 annual hours of informal care per patient with nAMD were estimated. This estimate was obtained by multiplying the percentage of patients with nAMD and an informal caregiver (59.2%) [5] by the annual hours of informal care provided per patient with AMD (832.0 h) [5]. This calculation can be found in the Supplementary Material Table S4. Regarding formal care (e.g., paid care provided by professionals), the probability of a patient with AMD needing formal care (0.139) was assumed for nAMD [5], regardless of the year since diagnosis. On the subject of non-visual technical aids (e.g., magnifying glass, special lamp, computer application, or smoke sensors, among others) for patients with nAMD, the probability of a patient with

Table 2 Items associated with treatment and follow-up by year since diagnosis

	Number per patient			References
	Year 1	Year 2	Year 3+	
Medical visits				
Visits to the specialist	6.0	4.0	3.0	[17]
Medical tests				
OCT	6.0	4.0	3.0	[17]
Fundus photographic examination	6.0	4.0	3.0	[17]
Treatment				
Intravitreal anti-VEGF injections[a,b]	7.5	6.0	5.3	[17]
Intravitreal anti-VEGF injections (per eye)	7.0	5.0	4.0	[17]

anti-VEGF anti-vascular endothelial growth factor, *OCT* optical coherence tomography

[a]See calculation in the Supplementary Material Table S2

[b]Weighted average according to the level of uni-/bilateral involvement

Table 3 Items associated with adverse events and comorbidities

Adverse events or comorbidities	Probability per patient	References
Anxiety or depression	0.264	[11]
Fall requiring medical attention (patient ≥ 50 years)[a]	0.072	[18]
Fall-related fracture per year (patient ≥ 50 years)[a]	0.058	[18]
Endophthalmitis	0.006	[7]
Corneal damage	0.004	[7]
Retinal detachment	0.004	[7]

[a]See calculation in the Supplementary Material Table S3

Table 4 Items associated with commuting for medical visits by year of treatment since diagnosis

	Number per patient			Reference
	Year 1	Year 2	Year 3+	
Commutes for medical visits [a]	12.0	8.0	6.0	[17]

[a]See calculation in the Supplementary Material Table S5

AMD needing non-visual technical aids was assumed (0.370) [5], regardless of the year since diagnosis. Annual out-of-pocket expenditure related to a patient with AMD [5] was assumed for a patient with nAMD. Finally, cost items associated with commuting for medical visits are presented in Table 4.

Items Associated with the Cost of Labor Productivity Losses

LPL consider the impact of the disease on the patient's work. In this case, LPL associated with attending medical visits were contemplated (Table 5).

Items Associated with Intangible Costs

IC included the impact of nAMD on patients' activities of daily living and quality of life. Regarding the impact on activities of daily living, the probability that a patient with nAMD would have difficulty going to the movies or sporting events was assumed (0.211), regardless of the year since diagnosis [5]. Moreover, to estimate the impact on quality of life, quality-adjusted life years (QALYs) were used, where one QALY is equivalent to 1 year in perfect health [20]. Table 6 presents an estimate of the mean annual QALYs of patients with nAMD in comparison to the general population, regardless of the year since diagnosis.

Costs Estimation

The burden per patient with nAMD by year since diagnosis was calculated by multiplying cost items by their unit prices or financial proxies. The latter can be found in the Supplementary Material Tables S8 to S10. Unless otherwise specified, they were applied irrespective of the year since diagnosis.

DHC were estimated indirectly by multiplying cost items by their unit prices, with the exception of the cost of medication that

Table 5 Items associated with the cost of labor productivity losses due to medical visits by year since diagnosis

	Hours per patient			References
	Year 1	Year 2	Year 3+	
Time of work productivity lost due to medical visits (hours)[a]	1.1	0.7	0.6	[17, 19]

[a]See calculation in the Supplementary Material Table S6

Table 6 Items associates with intangible costs due to the impact of nAMD on patients' quality of life

	Lost profit per patient	References
Loss of utility in patients ≥ 50 years with bilateral nAMD in comparison to the general population [a]	0.160	[18, 21]

nAMD neovascular age-related macular degeneration

[a]See calculation in the Supplementary Material Table S7

was estimated from the laboratory price of an intravitreal injection with ranibizumab (Lucentis®, Novartis Farmacéutica S.A., 10 mg/mL^{-1} prefilled syringe of 0.165 mL or one vial of 0.23 mL) or aflibercept (Eylea®, Bayer Hispania S.L., 40 mg/mL^{-1} prefilled syringe of 90 µL or one vial of 100 µL) which was €742.0 for both medications. Regarding DNHC, the cost of informal care was estimated using the proxy good method, whereby the time spent by the informal caregiver in caring for the patient due to the disease is valued at the cost of replacing that person with a non-qualified worker. Therefore, the minimum hourly wage for domestic workers (€7.6) [22] was used as a proxy for the cost of informal care per hour and multiplied by the number of hours of informal care that a patient with nAMD receives per year (492.5 h) [5]. Moreover, to estimate the cost of formal care, the annual cost of formal care for patients with AMD was assumed (€1421.6) [5]. Moreover, the cost of non-visual technical aids was estimated assuming the annual expenditure per patient with AMD on non-visual technical aids (€28.5) [5]. The annual out-of-pocket expenditure was estimated assuming the annual expenditure per patient with AMD (€192.3) [5]. Regarding the cost associated with commuting for medical appointments, the number of commutes was multiplied by the cost per commute (€8.0). This cost was calculated as the average cost per commute by car (€5.3), bus (€6.0), and taxi (€12.0) [5]. The cost per commute by car and bus was calculated by multiplying the number of kilometers per commute (27.9 km and 31.8 km, respectively) by the financed cost per kilometer travelled (€0.2) [5].

The human capital method was used to estimate LPL, whereby hours not worked are considered lost hours and are valued at market prices (average earnings per hour of work). Therefore the LPL per patient was obtained by multiplying the number of working hours lost in medical visits per patient with AMD by the average wage per working hour (€16.3) [23].

Regarding IC, the impact of nAMD on activities of daily living was estimated by applying the average annual expenditure per person on leisure and culture (€466.0), as a proxy for the difficulty in going to the cinema or to sporting events [24]. Moreover, the average annual utility loss per patient with nAMD was monetized by multiplying this loss by the incremental cost-effectiveness threshold per QALY gained (€21,000.0) [25].

Total costs (TC) per patient with nAMD were calculated as the sum of the four cost categories (DHC, DNHC, LPL, and IC) according to the year since diagnosis. Given the prevalence approach used in the present study, the cost of diagnosis was not included in the TC [26]. Moreover, it is a varying one-off cost that cannot be ascribed to a specific time range [5]. Finally, the focus of the present study was on patients with neovascular type AMD which may have been previously diagnosed with AMD.

The reference year for all the costs is 2021, with the exception of the cost of medication, obtained from the drug database of the General Council of Official Colleges of Pharmacists (Consejo General de Colegios Oficiales de Farmacéuticos) [27–31] and the cost of health services, for which the median of the health tariffs from the official bulletins of all the autonomous communities of Spain (previously updated as indicated in each bulletin) was estimated. The other costs were updated to the year 2021 using the Consumer Price Index [32].

This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors. The four members of the advisory committee are authors of this manuscript and were informed that their advice would be used in the development of this article.

Sensitivity Analysis

When two different data points associated with same resource were identified in the literature, the lowest value was used in both the baseline and lower scenarios, while the highest value was used in the upper scenario. This criterion follows a conservative approach to prevent overestimating the burden of disease, as both the baseline and lower scenarios represent the minimum burden, while the upper scenario suggests how far the cost can potentially increase. Resource use and costs presented in

this article refer to the baseline scenario, and those of the lower and upper scenarios can be found in Supplementary Material.

RESULTS

TC for year 1 was estimated at €17,264.6 per patient, allocated to DHC (48.2%), followed by DNHC (31.6%), IC (20.1%), and LPL (0.104%). In year 2, TC per patient would be reduced by 10.8% amounting to €15,402.8 per patient, allocated to DHC (42.2%), followed by DNHC (35.2%), IC (22.5%), and LPL (0.078%). In year 3+, TC per patient would be further reduced by 6.1% amounting to €14,465.5 per patient, allocated to DHC (38.6%), followed by DNHC (37.4%), IC (24.0%), and LPL (0.062%). Furthermore, the proportion of DHC would be lower the longer the time since diagnosis, while the weight of DNHC and IC would be slightly higher. A detailed description of the costs associated with nAMD per year since diagnosis is presented in Table 7. Moreover, Fig. 1 includes the results of the sensitivity analysis for TC represented as error bars.

Regarding DHC, the burden for year 1 was estimated at €8323.1 per patient. In year 2, they would be reduced by 21.9% from year 1, and in year 3+, they would be reduced by 14.1% from year 2. In addition, diagnosis would generate an estimated additional one-off cost of €743.7 per patient, not included in the TC. On the other hand, DNHC for year 1 was estimated at €5457.0 per patient. In the second and subsequent years

Table 7 Costs per patient and distribution of the total cost stratified by year since diagnosis, total and by category of cost (€2021)

	Year 1	Year 2	Year 3+
Direct healthcare costs	€8323.1 (48.2%)	€6499.2 (42.2%)	€5580.8 (38.6%)
Medical visits	€534.9	€356.6	€267.4
Medical tests	€1199.9	€799.9	€600.0
Intravitreal injections	€6249.2	€5003.6	€4,374.3
Adverse events	€339.2	€339.2	€339.2
Direct non-healthcare costs	€5457.0 (31.6%)	€5425.1 (35.2%)	€5409.1 (37.4%)
Informal care	€3718.7	€3718.7	€3718.7
Formal care	€1421.6	€1421.6	€1421.6
Non-visual technical aids	€28.5	€28.5	€28.5
Out-of-pocket expenditure	€192.3	€192.3	€192.3
Travel to medical visits	€95.9	€63.9	€47.9
Patients' labor productivity losses	€17.9 (0.104%)	€12.0 (0.078%)	€9.0 (0.062%)
Intangible costs	€3466.6 (20.1%)	€3466.6 (22.5%)	€3466.6 (24.0%)
Impact on daily activities	€98.3	€98.3	€98.3
Impact on quality of life	€3368.3	€3368.3	€3368.3
Total cost	€17,264.6 (100%)	€15,402.8 (100%)	€14,465.5 (100%)

Costs are presented for the baseline scenario

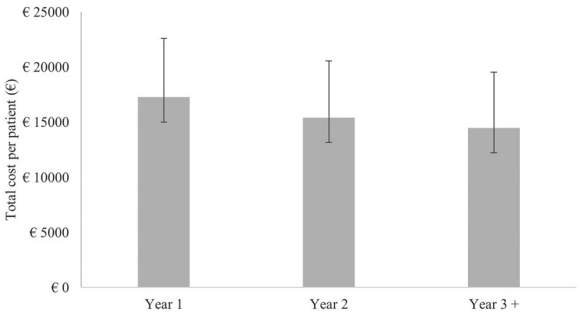

Fig. 1 Total costs per patient stratified by year since diagnosis (€2021). Error bars represent the results of the sensitivity analysis

of treatment, the DNHC per patient would decrease slightly compared to year 1.

Regarding LPL, the burden for year 1 was estimated at €17.9 per patient. In year 2, LPL would be reduced by 33.3% compared to year 1, and in year 3+ by 25.0% compared to year 2. Finally, IC were estimated at an annual €3466.6 per patient, regardless of the year since diagnosis.

DISCUSSION

This study estimated the burden of nAMD per patient and year since diagnosis, from a societal perspective. The total cost of nAMD was estimated at €17,264.6 per patient in year 1, reducing to €15,402.8 in year 2 and €14,465.5 in year 3+. In addition, a one-off cost of €743.7 associated with the diagnosis of nAMD was considered. DHC accounted for the largest proportion of the TC irrespective of the year since diagnosis, followed by DNHC and IC. The contribution of LPL to the TC was minimal.

Previous studies have shown that nAMD generates large DHC [33]. A recent observational retrospective study evaluated healthcare resource consumption associated with nAMD in a sample of 126 patients from tertiary hospitals of Spain. The authors concluded that the high frequency of monitoring and injection visits generated a large burden for both the healthcare system and the patients [33]. Accordingly, in the present study, the costs associated with intravitreal injections represent the largest proportion of the DHC. The administration of more effective treatments would allow more time between injections and, in turn, reduce healthcare resource consumption as well as the burden for the patients and their families [33]. In fact, this study showed that DHC decreased from year 1 to year 3+, due to the reduction in the number of visits, tests, and intravitreal injections in year 2 and year 3+.

Scientific literature on the socio-economic burden of nAMD in Spain is limited. In a recent study, Ruiz-Moreno et al. (2021) explored the DHC in a sample of 1164 patients with AMD and estimated a mean annual cost of €4627.6 ± 2383.9 per patient, mostly attributed to diagnostic examinations (mainly OCT) and anti-VEGF treatment [8]. Our estimates of DHC are higher than those reported in Ruíz-Moreno et al. (2021), especially in the first year of treatment, which can be expected considering that more intense treatment and closer monitoring is necessary at such point in time and the advanced disease stage of nAMD. In an older study, Ruiz-Moreno et al. (2008) estimated an annual cost of €5733 per patient with bilateral nAMD in Spain and, as in our study, DHC accounted for the largest proportion of the total cost [18]. The higher cost found in the present study could be explained in part by the contribution of informal care and IC to the burden of nAMD, as these items were not accounted for by Ruiz-Moreno et al. (2008) [18].

Some limitations should be considered when interpreting the results of the present study. The cost of diagnosis may have been underestimated as diagnostic tests were included in a single visit to specialized care; thus, some patients may have incurred more costs in the event of a delay in diagnosis. The cost of medical visits prior to diagnosis has been estimated at €261.6 per patient with AMD (+65.1% with respect to the single diagnostic visit contemplated in the present study) [5]. Nevertheless, this study focused on patients with neovascular-type AMD, which may have been previously diagnosed with AMD. Another limitation is that most DNHC were based on resource use and costs associated with AMD, possibly underestimating the burden of nAMD. In terms of LPL, the

hours of work productivity lost in medical visits were the only item considered. Had the overall impact of nAMD on the patient's working life been considered LPL would have been higher, especially from the second year of treatment onwards, due to the greater probability of bilateral involvement. Finally, regarding IC and due to the lack of information published in the scientific literature in this regard, the same loss of utility was considered regardless of the year since diagnosis. However, a greater loss of utility may have been expected from the second year onwards, considering disease progression. On the other hand, a decrease in the loss of utility over time may be expected, given the less demanding and more effective treatment.

The present study contemplated possible differences in resource consumption, depending on the year since diagnosis and the level of involvement (unilateral or bilateral), throughout the first 3 years of treatment since diagnosis. This contributed to a more accurate estimation of the costs associated to nAMD. Moreover, in addition to most commonly reported DHC, DNHC, LPL, and IC were further considered, allowing for a more comprehensive estimation of the burden of disease.

CONCLUSION

To our knowledge, this is the first study that estimates the cost of nAMD considering year of treatment since diagnosis and disease progression. Regarding disease progression, calculations incorporated the patient's level of eye involvement at diagnosis (unilateral or bilateral) and its expected evolution over the first 3 years of treatment. Findings from this study highlight the large socio-economic burden of nAMD for the healthcare system, patients, and society at large. This burden is expected to increase given exponential ageing of the population. Reducing the need for high frequency monitoring and injections through more effective, long-lasting treatments may help prevent vision loss and optimize resource use.

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Authors' Contributions. María Merino, Teresa Martín Lorenzo, Paulina Maravilla-Herrera, and Beatriz Gil Jiménez contributed to the study conception and design. María Merino, Teresa Martín Lorenzo, and Paulina Maravilla-Herrera acquired the data. Maximino J. Abraldes, Pilar Calvo, María Gámez Lechuga, María Merino, Teresa Martín Lorenzo, Paulina Maravilla-Herrera, Beatriz Gil Jiménez, and José M. Ruiz-Moreno analysed and interpreted the data. María Merino and Paulina Maravilla-Herrera drafted the manuscript. Maximino J. Abraldes, Pilar Calvo, María Gámez Lechuga, María Merino, Teresa Martín Lorenzo, Paulina Maravilla-Herrera, Beatriz Gil Jiménez, and José M. Ruiz-Moreno critically revised and approved the final manuscript.

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Data Availability. The datasets may be available from the corresponding author upon reasonable request.

Declarations

Conflict of Interest. Maximino J. Abraldes, Pilar Calvo, María Gámez Lechuga, and José M. Ruiz-Moreno declare having received payments from Roche for participating as members of the advisory committee for this study. María Merino, Teresa Martín Lorenzo, and Paulina Maravilla-Herrera declare that they are employees of Weber, a company that has received payments from Roche to conduct this study. Beatriz Gil Jiménez declares to be an employee of Roche Farma, a company that has funded this study.

Ethical Approval. Due to the type of study, no clinical research ethics committee approval was required. Nevertheless, the present study conforms with the ethical principles of the Declaration of Helsinki. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors. The four members of the advisory committee are authors of this manuscript and were informed that their advice would be used in the development of this article.

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