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Consensus on evidence gaps and unmet needs in childhood myopia: findings from a European Delphi study with eye care professionals and payers

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ABSTRACT

Background/aims Childhood myopia is a growing global concern, associated with significant burdens. This study aimed to identify evidence gaps and unmet needs in childhood myopia management through a European Delphi panel involving eye care professionals (ECPs) with expertise in childhood myopia management and payers (ie, individuals with experience in health technology assessment, healthcare funding, drug pricing and/or reimbursement decisions).

Methods A modified Delphi method was employed, involving two rounds of online questionnaires followed by a final virtual workshop. The panel included 12 ECPs and 13 payers from seven European countries. Consensus was defined as ≥70% agreement among panellists.

Results Consensus was achieved on all 37 statements across six categories: disease background, clinical burden, psychosocial/humanistic burden, economic burden, treatment options and unmet needs. Key findings included recognition of ethnicity and age as crucial factors in evaluating childhood myopia, as well as the minimal clinically important difference for progression reduction. The panel emphasised the need for long-term studies on the efficacy and safety of myopia treatments, especially their impact on reducing future complications. The impact of high myopia on quality of life and economic burden was also highlighted. Regarding unmet needs, despite some known factors, the exact mechanisms behind myopia development remain unclear. There is a need for comprehensive epidemiological data on European childhood myopia and regulatory-approved pharmacological treatments in Europe.

Conclusions Consensus was reached among European ECPs and payers on the evidence gaps and unmet needs in childhood myopia management. These findings can guide future research to establish the best strategies for childhood myopia management and mitigate the burden.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Childhood myopia is a widely studied area of ophthalmology. However, treatment strategies, available options, reimbursement coverage, economic impact and clinical opinions vary across countries.

WHAT THIS STUDY ADDS

⇒ To our knowledge, this is the first Delphi study on myopia to capture perspectives from both eye care professionals (ECPs) and payers (ie, individuals with expertise in health technology assessment, healthcare funding, pricing, and/or reimbursement decisions). This modified Delphi panel study, involving ECPs and payers across seven European countries, reached consensus on 37 statements regarding disease background, clinical burden, humanistic burden, economic burden, treatment options for progressive myopia and unmet needs.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ As the first Delphi study on myopia to capture perspectives from both ECPs and payers, it highlights that, despite differences across stakeholder groups, there is strong alignment on the consensus regarding evidence gaps and unmet needs. This study lays a foundation for bringing together policymakers, academia, ECPs and the pharmaceutical industry to align on evidence generation, develop innovative treatments and implement impactful measures to reduce the burden of childhood myopia.

INTRODUCTION

Myopia is a refractive error (RE) that impairs vision and typically develops between ages 6 and 13 years.[1–3] While the causes of myopia remain unclear, risk factors include limited

time outdoors, female sex, ethnicity, family history and higher education levels.[4–6]

The global prevalence of childhood myopia is rising, especially in Asia, imposing substantial clinical and economic burdens on patients and healthcare systems.[2 7] Axial elongation in myopic eyes increases the risk of ocular complications like myopic macular degeneration, retinal detachment, cataract and glaucoma-associated optic neuropathy, which may lead to visual impairment.[8 9] Progressive myopia also affects health-related quality of life (HRQoL), contributing to anxiety, depression and reduced learning abilities.[10–12] The economic burden is increasing, including costs for eye examinations and refractive correction,[13–15] and, in high myopia, treatment for ocular complications.[2 13]

The current management of childhood myopia varies considerably across the globe, largely influenced by the experience of eye care professionals (ECPs) and the local availability of specific therapeutic options. Widely accepted optical interventions include orthokeratology, multifocal contact lenses and peripheral defocus spectacles, while atropine is the most commonly used pharmacological agent.[16–18]

Given the increasing prevalence of childhood myopia and its associated burden, a modified Delphi panel was conducted to develop consensus among European ECPs and payers (experts of drug pricing and reimbursement) on key unmet needs and evidence gaps in childhood myopia, where clinical opinions and treatment strategies differ. The findings will help raise awareness, guide future research and decision-making, and support the establishment of best practices for childhood myopia management.

MATERIALS AND METHODS

Study design

The modified Delphi method uses questionnaires over multiple rounds to collect expert feedback and build consensus when evidence is lacking or contradictory.[19–21] This Delphi study involved experienced childhood myopia ECPs with at least 10 years of experience, along with experienced payers knowledgeable in health technology assessment (HTA), healthcare funding, pricing and/or reimbursement decisions, from various European countries, as further specified below.

This anonymous Delphi study included two rounds of statement reviews followed by a final virtual workshop. The study design is detailed in figure 1. Customised online questionnaires programmed via DECIPHER were used in the first two rounds to collect voting. A copy of the questionnaires is provided in the online supplemental material. In round 1, panellists were blinded and evaluated statements using a questionnaire with four response options: 'agree', 'partially agree, but additional information is required', 'disagree' and 'this is not within my area of expertise'. Panellists were asked to provide rationale if they voted 'disagree' and to suggest improvements if they voted 'partially agree, but additional information is required'. A free-text response also allowed panellists to propose additional statements.

In round 2, statements that had reached consensus (agreement or disagreement) in round 1 were removed. Panellists were asked to vote on: (1) statements that did not achieve consensus in round 1 and were refined based on panel feedback and (2) new statements derived from suggestions provided by panellists in round 1. The same four response options were used.

Round 3 was a 3-hour online workshop where panellists voted statements individually and anonymously, using the same four options. Again, statements that had reached consensus in previous rounds were removed from voting, and only statements that did not achieve consensus in previous rounds were included after further refinement. Panellists unable to attend submitted votes via email.

Delphi experts

Scientific steering committee (SSC): The objectives and key hypotheses to explore in this Delphi panel study were validated by an SSC, including three experts (ECPs) in ophthalmology and one payer expert based in Europe. The SSC was involved in advising on the methodology, reviewing and providing feedback on the protocol and statement generation and revision, but did not participate in voting.

Panellists: A panel of experts, including key opinion leader-level ECPs (ophthalmologists, optometrists or orthoptists) and European payers (former or current payers with expertise in HTA, healthcare funding, pricing and/or reimbursement decisions), was formed to evaluate statements across all voting rounds. Box 1 specifies the selection criteria for the panellists.

Statements generation

Initial statements were based on a targeted literature review conducted in January 2024 (online supplemental table 1) and refined with feedback from the SSC. Final statements were grouped into six categories: including disease background, clinical burden, psychosocial/humanistic burden, economic burden, treatment options for progressive myopia and unmet needs.

Data analysis

In this Delphi study, consensus was reached if at least 70% of panellists selected either 'agree' or 'disagree'. This threshold is commonly used for a panel of 24±4 panellists.[22 23] Votes of 'This is not within my area of expertise' were excluded from consensus calculation to reflect the consensus among only those who felt they were able to provide opinions for a specific statement. Open-text comments in the first two Delphi rounds were analysed qualitatively to help refine statements for subsequent rounds. Comments related to statements that did not reach consensus were thematically grouped to inform the revision.

RESULTS

Delphi panellists

The Delphi panel comprised 12 experienced ECPs specialising in childhood myopia, and 13 former or

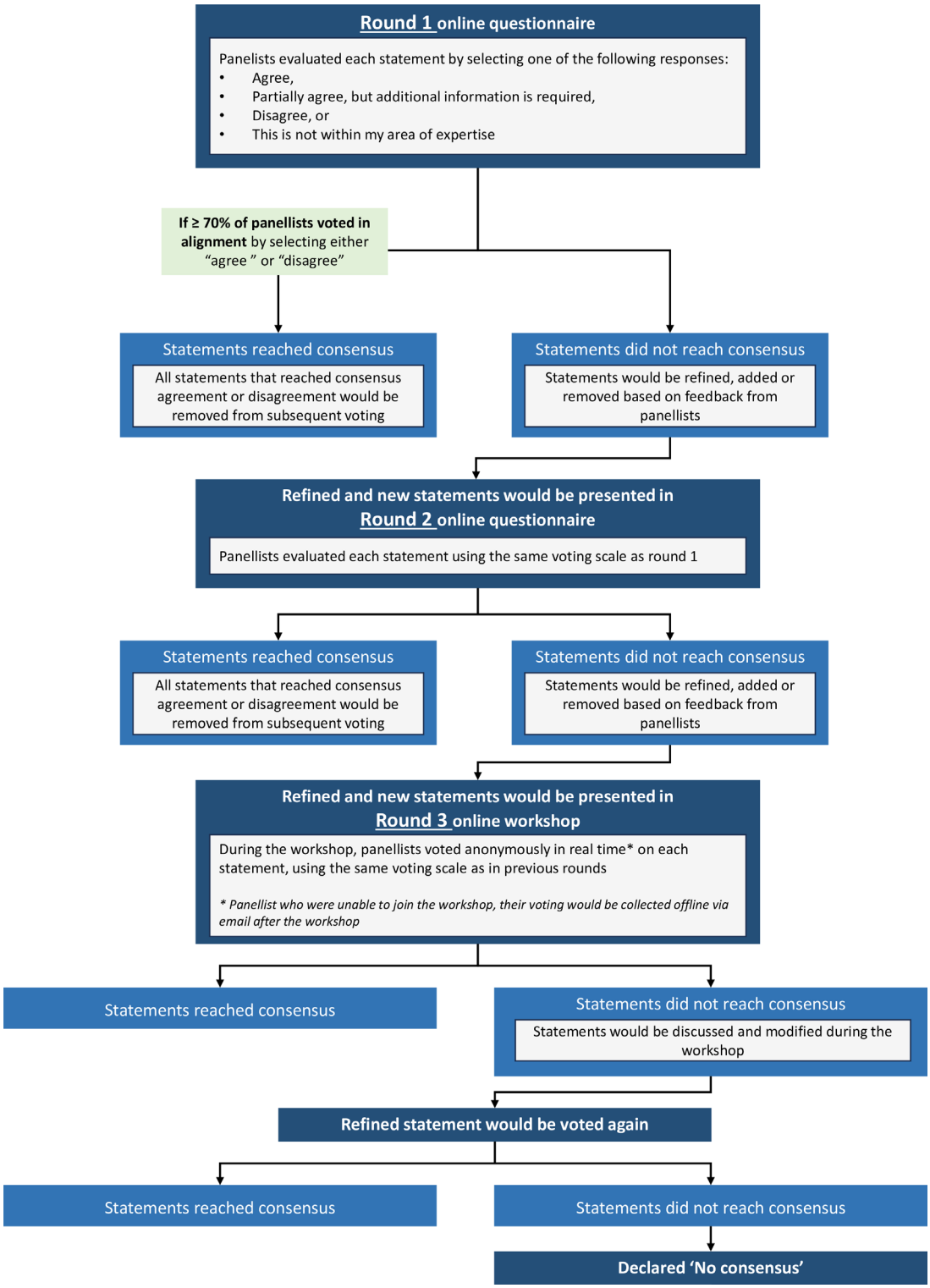

Figure 1 Flow chart of the Delphi rounds.

current payers with expertise in pricing and reimbursement from seven European countries (see table 1). All panellists met the inclusion criteria. In total, 100% of panellists completed the online questionnaires in rounds 1 and 2. For round 3, 72% (18/25) participated in the virtual workshop, while 24% (6/25) provided votes offline and 4% (1/25) neither participated in the workshop nor voted offline.

Delphi panel voting results

Figure 2 illustrates the number of statements reaching consensus in each Delphi round. In round 1, 33 statements were presented, of which 12 (36%) achieved consensus on agreement and were removed from round 2 voting. In round 2, 21 statements that had failed to reach consensus in round 1 were revised and four new statements were added based on panellists' suggestions.

Box 1 Full inclusion criteria of the Delphi panellists

Criteria for KOL-level ECPs:

ECPs should meet all of the following criteria to be eligible for inclusion in the study:

⇒ Currently practising ophthalmology, optometry or orthoptics in one of the following countries: Germany, Spain, France, Italy, the Netherlands, Denmark or the UK.

⇒ Having at least 10 years of experience in ocular care since completion of their formal training.

⇒ Actively making management decisions for at least 5 paediatric patients (up to 18 years old) with myopia in a typical month.

⇒ Who have prescribed low-dose compounded atropine to paediatric patients for myopia in the last 5 years.

⇒ KOL criteria: Must have undertaken at least 1 of the following three activities in the past 5 years in the field of ophthalmology: (1) Contributed as a coauthor to the development of clinical guidelines, (2) Published three or more times in international or national scientific journals papers and (3) Been a Member of the Board or Scientific Committee of a scientific society.

⇒ Must be familiar or have previous experience with the collection of clinical effectiveness and safety, cost-effectiveness and budget impact, organisational and social aspects, and/or ethical and legal issues.

⇒ Proficiency in English, as all panel rounds will be conducted in English.

Criteria for payers:

Payers should meet all of the following criteria to be eligible for inclusion in the study:

⇒ Country health technology assessment experience in Denmark, France, Germany, Italy, the Netherlands, Spain or the UK,

⇒ Formerly employed as (or advisor to) pricing, funding and/or market access decision-maker within a hospital/country formulary/diagnosis-related group authority or currently employed as local/regional payer or payer advisor.

⇒ Involvement in guideline development, funding/budget management, formulary inclusion decisions, reimbursement, purchasing, procurement, pricing negotiations (eg, cost effectiveness, benefit, health technology assessment).

⇒ For those currently employed as local/regional payer or payer advisor, must have no restrictions imposed by third parties (either current employer or country legislation) forbidding the participation in this study.

⇒ Experience in a payer/payer advisor role of at least 2 years.

⇒ Be familiar/have experience with the national/regional pricing schemes and reimbursement process.

⇒ Proficiency in English, as all panel rounds will be conducted in English.

ECP, eye care professional; KOL, key opinion leader.

Of these, 11 (44%) reached consensus on agreement and were removed from round 3 voting. The remaining 14 statements that did not reach consensus in round 2 were reviewed, revised and voted on during the round 3 online meeting. Ultimately, consensus was achieved for all 14 statements.

Online supplemental table 2 summarises all statements that reached consensus. A detailed breakdown is provided in online supplemental tables 3–5, including the statements reviewed in each round, the percentage of agree/disagree response, and the number of panellists who answered 'This is not within my area of expertise' for each statement.

The following sections summarise the overall consensus rates for each statement by category and the differences between payers and ECPs.

Disease background

All 11 statements in the Disease Background category reached consensus, with over 70% of panellists (excluding those who indicated that the topic was outside their area of expertise) agreeing. Agreement was generally higher among payers than ECPs, except for statement 6a, where over 90% of ECPs agreed that early-onset myopia is linked to rapid progression, compared with 63% of payers (online supplemental table 2).

Regarding childhood myopia measurement, ECPs achieved no agreement on the approaches of classifying severity (statement 1a: 67% and statement 1b: 58%) and measuring fast progression (statement 5: 64% and statements 6b: 58%). In contrast, payers widely agreed (statement 1a: 83% and statement 1b: 100%) that both spherical equivalent (SE) of refraction and axial length (AL) are appropriate for classifying severity. Similarly, all payers (100% for both statements 5, 6b) supported using changes of AL or cycloplegic SE for measuring progression. The deviations showed that different importance was attached to the reference to increase in AL. At least 70% of both groups agreed that axial elongation varies by ethnicity and decreases with age (statement 4).

Panellists reached strong consensus on myopia-related ocular complications (statements 2, 3, 8), with agreement exceeding 85%. Most panellists concurred that myopia is associated with ocular complications such as early cataracts, retinal detachment, open-angle glaucoma and myopic macular degeneration, particularly in high myopia. Furthermore, it was acknowledged that while myopia can lead to ocular complications, the impact on utility decrements (refers to a decrease in satisfaction or benefit that an individual derives from experiencing a particular situation) varies significantly depending on severity and stage (statement 9).

Table 1 Delphi panellists distribution by country

Delphi panel composition	Denmark	France	Germany	Italy	Netherlands	Spain	UK	Total
ECPs*	1	2	2	2	1	2	2	12
Payers	1	2	2	2	1	3	2	13

*Including KOL-level ophthalmologists, optometrists or orthoptist.
ECP, eye care professionals; KOL, key opinion leader.

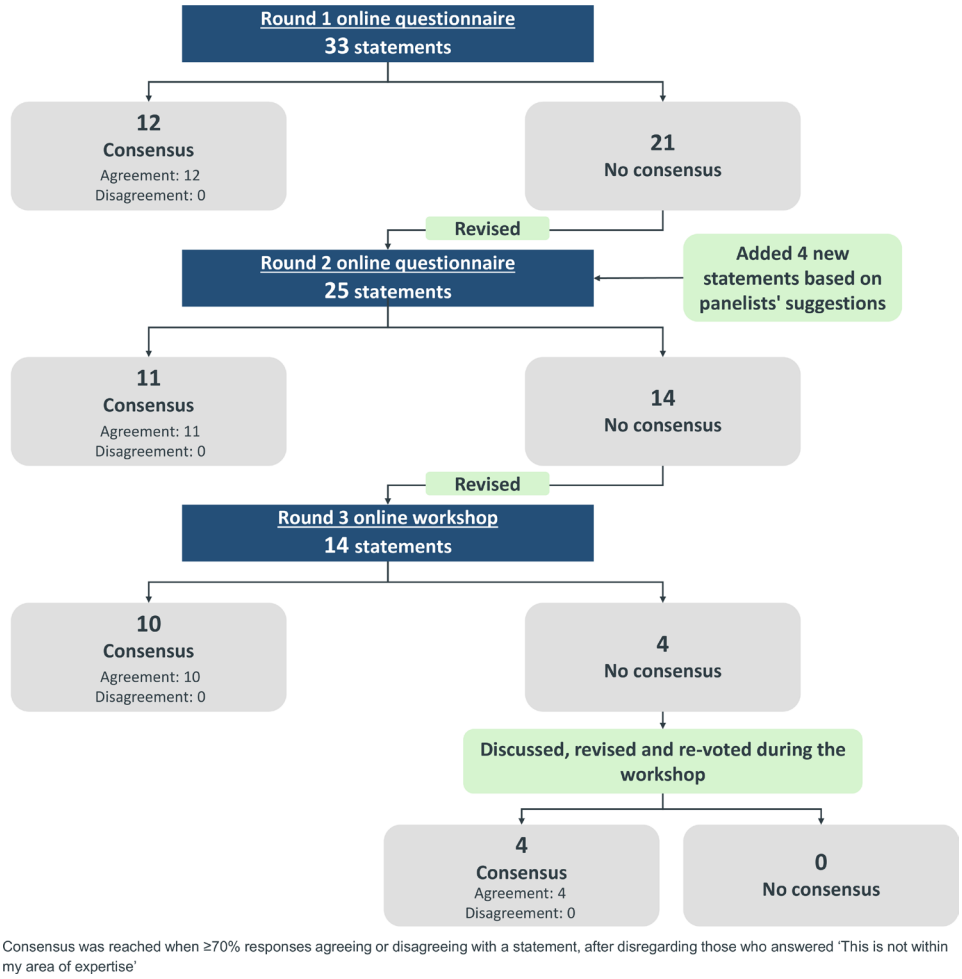

Figure 2 Overview of the number of statements reaching consensus or not in each Delphi panel round.

Lastly, myopia was widely agreed to typically begin around age six or older in European children (statement 7). Payers unanimously (100%) supported this, while 36% of ECPs dissented.

Clinical burden

Both statements in the Clinical Burden category reached consensus, highlighting the association between myopia progression and risks of developing eye complications. Statement 10 emphasised that myopic maculopathy and retinal detachment are sight-threatening complications, with risk increasing significantly beyond −6.0 dioptre (D), though complications can still occur at lower myopia levels. This statement received 84% of agreement among panellists, with 75% of ECPs and 100% of payers in agreement (online supplemental table 2). Statement 11 further discussed rapid myopia progression linked to an increased risk of long-term visual impairment. Consensus was achieved at 86%, with 92% agreement within ECPs and 80% of agreement within payers, respectively.

Psychosocial/humanistic burden/impact on activities of daily living

While fewer than 70% of ECPs agreed with the statements highlighting the potential impact of high myopia on anxiety and low self-esteem in children (statement 12a), or on mobility limitations in visually impaired adults (statement 14), a higher proportion (82%) agreed that it can affect career choices and activities (statement 12b) (online supplemental table 2). Notably, both ECPs (82%) and payers (85%) widely recognised that untreated or underdiagnosed childhood myopia can significantly affect daily life, particularly in school and social participation (statement 13).

Economic burden

ECPs (82%–92%) widely agreed that the economic burden of fast-progressing and high myopia is significant, such as high costs for spectacles and reduced productivity (statements 15, 32) (online supplemental table 2). In contrast, payers (85%) placed greater emphasis on costs related to eye examinations, refractive corrections and complication management (statement 31). More than 90% of payers supported conducting cost-effectiveness analyses for myopia interventions to evaluate their impact on long-term healthcare costs, compared with 64% of ECPs (statement 33). Lastly, most ECPs (83%) agreed that uncorrected myopia can lead to productivity losses in adulthood (statement 16).

Treatment options for progressive myopia

All seven statements in this category reached consensus. Over 70% of both payers and ECPs agreed that non-pharmacological treatments, including spectacles, contact lenses, orthokeratology, lifestyle changes and repeated low-level red-light therapy show promise, though their use varies globally and has some limitations (statements 17, 18) (online supplemental table 2). The most widely agreed treatment strategy was a multimodal approach (88%, statement 23). There was a gap in agreement on two statements about low-dose atropine. Over 80% of payers acknowledged its effectiveness in slowing myopia progression but noted its limited global approval. In contrast, about 70% of ECPs shared this view (statements 20, 21). In terms of rebound effect, both groups strongly agreed (>90%) that low-dose atropine has a lower rebound effect than high-dose (statement 22). Another gap was seen in benefits of early treatment for slowing myopia progression, with 90% of payers agreeing vs only 67% of ECPs (statement 19).

Unmet needs in childhood myopia

Consensus was reached on all eight statements addressing unmet needs in childhood myopia. Over 70% of both groups agreed that lack of awareness delays diagnosis (statement 25) and that regulatory-approved atropine is currently limited in Europe and preferable over compounded versions (statements 28a, 28b) (online supplemental table 2). Statements on myopia mechanisms (statement 24), and epidemiology and early intervention (statement 27) had lower agreement among ECPs (67%) compared with payers (78%–82%). In contrast, recognising myopia as a public health issue requiring greater awareness reached higher agreement among ECPs (75%) compared with payers (67%) (statement 26). Two statements showed a notable gap: 83% of payers supported early detection and treatment to reduce the risk of long-term complications (statement 29), but only 58% of ECPs agreed that there was already sufficient evidence. Meanwhile, 83% of ECPs agreed that axial elongation is a more suitable measurement over RE for tracking myopia progression, compared with just 60% of payers (statement 30).

DISCUSSION AND ONCLUSION

Key findings

Due to the rising prevalence of myopia, particularly in Asia and to a lesser extent in Europe, there is growing interest in strategies to slow progression.[7 24] This Delphi study, involving European ECPs and payers, provides expert consensus on evidence gaps and unmet needs in childhood myopia.

The panel emphasised the importance of patient characteristics, such as ethnicity, age and gender, in evaluating childhood myopia and defining fast progression. AL is considered the gold standard for assessing myopia.[25–27] Some panellists suggested referring to guidelines developed by prominent ophthalmic societies.[4 28] Notably, payers widely agreed that cycloplegic SE could serve as an alternative when AL is unavailable, while ECPs were more cautious against introducing a surrogate outcome. SE measurements are the result of cornea and lens power as well as AL; whereas, only AL is the optical component determinant directly related to myopic complications. SE is more variable and less reliable than AL.[8 29–31] Some ECPs noted that AL measurement equipment is now widely accessible outside hospital settings.

Currently, no uniform definition of fast myopia progression exists. A French study defined childhood myopia progressors as those with an average rate greater than −0.50 D/year.[32] Another study of Caucasian children defined rapid progression as at least −0.75 D/year.[33] In this Delphi study, the panel agreed that no fixed numeric threshold has been established for fast progressors, as progression rates depend on age and individual factors.[34] In addition, since AL is becoming the standard measurement for myopia assessment, it has been suggested that the rate of progression should be reported in mm/year rather than D/year whenever AL measurement is possible.

This Delphi study also explored what level of treatment effect is considered meaningful for slowing myopia progression. No minimal clinically important difference (MCID) has been published. Some clinicians consider a 40% relative reduction over 3 years as meaningful, but this lacks critical evidence and remains an individual assessment, not a standardised benchmark.[35] In addition, relying solely on relative reductions can be misleading because these values depend heavily on baseline progression rates and demographic differences, and small absolute differences may appear large when expressed as percentages, even though their clinical impact is minimal.[29 36] Relative reductions also do not indicate whether the residual progression remains clinically meaningful. The panel did not reach consensus on a universal numeric threshold. Some suggested using age-associated AL growth curves to assess whether a child's progression aligns with expected changes.[37] Payers highlighted the implications of MCID on reimbursement. They suggested using absolute measures, such as the proportion of children who experience slower myopia progression. From a HTA perspective, an absolute risk reduction (ARR) of 10% (10% of children did not progress 'fast' with treatment) was viewed as a clinically relevant, yet ARR can be contentious, as it depends on both treatment and reference groups' characteristics. For HTA endorsement, ARR should be linked to a specific time horizon, given myopia's chronic course.

Defining fast progression in childhood myopia is complex. Long-term studies could clarify the progression rates and identify rates leading to high myopia and the most effective age window for intervention. A standardised fast progression definition could serve as a practical endpoint in HTA for assessing success of myopia interventions. Panellists also valued patient-relevant

outcomes, such as reading, performing daily activities or fewer lens changes.

ECPs and payers agreed that myopia increases ocular complications risk, particularly in high myopia. Notably, while high myopia (SE ≤−6.0 D) poses the greatest risk, a larger number of low to moderate myopia (SE ≤−0.5 D) may also be affected and should not be overlooked, given its higher prevalence.[8] A few ECPs disagreed linking high myopia to an increased risk of complications, citing insufficient evidence on the timing of onset and frequency of complications by severity of myopia. Future research should clarify incidence rates of complications across severity levels. On the other hand, while the panel agreed that rapid myopia progression is associated with risks of long-term complications,[38] uncertainty remains about whether early intervention slows long-term progression and prevents later complications, the optimal timing of early treatment and applicability across subgroups.

The economic burden and impact of myopia on HRQoL were discussed in this Delphi study. Consensus was reached that myopia imposes a significant economic burden on both healthcare systems and patients, including costs for eye examinations, refractive corrections or laser treatments, particularly for fast-progressing and high myopia.[13 14] Additionally, the panel agreed that uncorrected myopia is associated with potential productivity losses in adulthood.[39] ECPs agreed that visual impairment and complications from high myopia lead to an economic burden, like increased unemployment, caregivers' dependency and greater demand for healthcare resources. In contrast, payers were less certain, as the statement lacked supporting evidence. Regarding HRQoL, both payers and ECPs agreed that underdiagnosed childhood myopia can hinder reading blackboards and limit participation in sports, leading to a frustrating school experience and negative self-confidence.[12] Future research should understand the prevalence of underdiagnosed or delayed diagnosis childhood myopia and assess its impact on daily tasks before diagnosis and treatment.

Myopia management varies across countries. Although the panel reached consensus on all unmet needs statements, the nature of these needs differed between countries. For instance, low myopia awareness can delay diagnosis, but this is less concerning in France because of a nationwide school screening. That said, several unmet needs persist across Europe. First, the exact mechanisms linking genetic, environmental and lifestyle factors to childhood myopia are still unclear, despite several hypotheses being tested.[40–42] Second, robust epidemiological data on the incidence, prevalence and progression of childhood myopia are lacking to understand the true burden of childhood myopia and plan effective treatment strategies. Last, while a regulatory-approved atropine could provide consistent quality assurance than compounded atropine,[43] its long-term efficacy and safety and real-world data are still needed for broader adoption and regulatory approvals.

Although national contexts differ, clinical practice and payer expectations should balance individual assessments with emerging consensus to support earlier and more consistent myopia care.

Strengths and limitations

This Delphi study provides valuable insights into the unmet needs and evidence gaps in childhood myopia management. To the best of our knowledge, this is the first myopia Delphi study that has involved various ECPs as well as payers and captures a widely shared perspective rather than a single viewpoint. While some differences emerged between ECPs and payers, particularly in defining disease severity and economic burden, thereby highlighting an understanding gap, consensus was ultimately reached on all. Expert alignment is crucial for identifying gaps and establishing effective strategies to delay myopia onset and slow its progression. This study serves as a foundation to encourage policymakers, academia, ECPs and the pharmaceutical industry to generate robust evidence, develop innovative treatments and implement impactful measures to lessen the burden of myopia.

However, the study has limitations. First, while participants were from multiple countries, consensus did not require 100% agreement, meaning not all statements reflected the views of everyone due to individual and cross-country differences. Additionally, the findings may have limited generalisability to the broader European context, as experts from some European countries (eg, Eastern European countries) were not represented. However, the inclusion of five Western European countries, along with countries from the Benelux and Nordic regions, helped mitigate this limitation by representing a diverse cross-section of European healthcare systems. Second, the small sample size prevented robust comparisons across countries or subgroups. Third, the Delphi panel included only experts and did not involve key stakeholders such as children, carers, individuals with myopia-related complications or community-based healthcare professionals involved in myopia management. Fourth, to maximise recruitment, the eligibility criteria for payers did not require prior knowledge of ophthalmology. All included payers, however, had expertise in HTA, pricing and/or reimbursement that typically involve evaluating humanistic and economic burden, which are the two primary domains addressed in this Delphi study. For statements involving clinical aspects such as disease definition, measurement and treatment effect, some payers indicated, ‘This is not within my area of expertise,’ reflecting the absence of prior ophthalmology-specific expert-level knowledge. These responses were excluded from consensus calculations to ensure validity. While this approach broadened participation, it may have reduced the depth of payer input on clinically focused statements

and limited the generalisability of findings where payer expertise was less established.

Fifth, this Delphi study only focused on myopia control treatments rather than lifestyle interventions. Lastly, there were inherent biases in the Delphi study, including that the results may be affected by the choice of the statements presented or that participants' opinions might be influenced by previous rounds or dominant voices in the group.

Despite these limitations, the study encourages a Europe-wide collaboration and supports future research to address childhood myopia evidence gaps.

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Ethics approval The study was conducted in accordance with market research codes and guidelines such as the British Healthcare Business Intelligence Association (BHBIA), Market Research Society (MRS), European Pharmaceutical Marketing Research Association (EphMRA) and European Society for Opinion and Marketing Research (ESOMAR). The study adhered to all local and regional laws on data protection and privacy. Institutional Review Board (IRB)/Independent Ethics Committee (IEC) exemption determination was obtained prior to the initiation of the study as necessary per local regulation (Pearl IRB; IRB ID: 2024-0398) exempted this study. Participants gave informed consent to participate in the study before taking part.

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terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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