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CLINICAL SUMMARY

IMI Industry Guidelines and Ethical Considerations for Myopia Control

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INTRODUCTION

Myopia affects approximately 30% of the global population and is predicted to affect 50% by 2050. Increasing levels of myopia are associated with a higher risk of potentially blinding ocular pathologies such as myopic macular degeneration, glaucoma, cataract and retinal detachment, prompting interest in therapies to prevent myopia onset and progression. This raises a number of ethical concerns and challenges for researchers and clinicians in treating vulnerable populations.

This paper discusses the ethical considerations associated with the development and prescription of treatment intended for myopia control, based on the critical review of the literature and guidance documents. Recommendations to regulatory bodies, manufacturers, academics and clinicians in the use of products for myopia control are summarized.

RECOMMENDATIONS

1. Regulatory bodies, manufacturers, academics and eye care practitioners have an ethical responsibility to promote the patient's welfare and to interact in an honest, open and fair manner in questions related to the quality of, and access to, vision health care.

    a. The practitioner, in particular, should be fully cognizant of the risks for the patient of developing different levels of myopia, the implications that progression to higher levels of myopia may have, the likely benefits of treatment, the side-effects of treatment, and other associated factors, so as to provide appropriate advice and care.

2. All entities involved in myopia control practice or product development must disclose any potential conflict of interest, including, for example, any research funding sources, gifts, and financial interest in the products under discussion.

3. Patients should be well informed about whether the treatment product is approved for myopia control or whether it is considered off-label. Adequate informed consent prior to their use should be obtained to minimize potential misinterpretations and/or legal claims.

4. Cost of treatments should not be considered in isolation but rather as the cost-to-benefit ratio for each individual patient. Benefits will be measured in terms of slowing the progression of myopia compared to what would be expected for that specific patient (considering the age of the patient, age of onset, number of parents with myopia, recent progression, amount of myopia, and visual environmental risks).

5. Eye care practitioners have a responsibility to care for their patients by recommending treatments using evidence-based practice and their informed clinical judgement.

6. Regulatory bodies have the essential role to ensure that medical products meet the highest standards of safety, efficacy, and quality before they become commercially available

    a. The lack of approved treatment options represents an unmet medical need and a challenge for all stakeholders concerned.

7. Academics have an important role in disseminating scientific information related to the safety and efficacy of approved and non-approved uses of myopia control treatments.

8. There is a need to create standardized educational materials on myopia risk and myopia control treatments.

CONCLUSION

All parties share an ethical responsibility to ensure that the products used for myopia control are safe and efficacious and that patients understand the benefits and potential risks of such products. This IMI report highlights these ethical challenges and provides stakeholders with a framework to consider such issues in the development, financial support, prescribing, and advertising of products for myopia control.

Reference: Jones L, Drobe B, Gonzalez-Meijome JM, et al. IMI - Industry Guidelines and Ethical Considerations for Myopia Control Report. Invest Ophthalmol Vis Sci 2019; 60(3): M161-M83. https://iovs.arvojournals.org/article.aspx?articleid=2727312

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