Contact Lens Update
CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Industry Guidelines and Ethical Considerations for Myopia Control

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Jones L, Drobe B, et al.: IMI – Industry Guidelines and Ethical Considerations for Myopia Control Report. Invest Ophthalmol Vis Sci 2019; 60;3: M161-M183.

The purpose of this review was to undertake a critical analysis of published papers and guidance documents, with a view to carefully considering the ethical standards associated with the investigation, development, registration, marketing, prescription and use of myopia control (MC) treatments. The review describes in detail the roles and responsibilities of a wide variety of stakeholders, including regulatory bodies, manufacturers, academics, eye care practitioners (ECPs) and patients. Particular attention is given to the ethical considerations for deciding whether to implement a myopia control strategy and how to implement this within a clinical trial or practice setting. Finally, the responsibilities in marketing, support and education required to transfer required knowledge and skills to eye care practitioners and academics are discussed.

There are a variety of important ethical considerations to reflect upon when undertaking MC treatments on vulnerable populations. Some of these considerations for ECPs, industry and researchers and educators are summarised in the tables below.

For ECPs, it is essential to provide appropriate information to patients who are at risk of developing myopia or for whom myopia-related pathology could occur due to rapidly progressing myopia. An ability to convey these potential risks, in an unbiased and unemotional way, is the first step in ensuring that children and parents understand why consideration of undertaking MC management is of importance. These considerations place a burden of responsibility on the practitioner to 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.

What ethical considerations should ECPs contemplate?

Efficacy	Prescribers need to be aware of the likely impact of the various MC management options and provide these data to the patient in an unbiased manner, to avoid inflated levels of likely success and to enable the patient to compare between treatments and the effect of doing nothing at all.
Safety	Consultation should include an unbiased discussion about the potential side-effects or complications with each MC strategy - particularly relevant for contact lens and pharmaceutical options.

On-label vs off-label prescribing	Clearly convey whether the MC options under discussion are approved for that use or not. Off-label prescribing is common in many forms of medicine, but it is important the patient understands their particular situation prior to starting any therapy.
Referral	To apply general medical ethics guidelines to MC treatments. These dictate that clinical decisions must be targeted toward ensuring the individual patient's welfare. This includes referral to another healthcare practitioner if they have more expertise in the area and access to the best treatment for the patient in question.

What ethical issues need to be considered by industry?

Clinical studies	These need to be undertaken using the highest level of ethical consideration, given that the results will be used to guide clinical management in a vulnerable population.
Advertising to ECPs and patients	Must be fair and balanced in terms of likely outcomes (efficacy) and risks of use.
Accreditation and training	To ensure ECPs are appropriately informed and trained on the use of MC management options. This requires industry to develop appropriate training materials, educational seminars and where required, accreditation, prior to the prescribing of the device or pharmaceutical agent.

What ethical considerations are relevant for educators and researchers?

Publications	Need to be honest and balanced in terms of their analysis and conclusion of data from trials. This includes the publication of "negative data" that shows no or limited efficacy, to prevent further use of such interventions which may have little or no impact.
Conflict of interest	These could arise (or be perceived) if an educator writing an article, giving a lecture, or prescribing MC treatments for patients is a paid consultant for the company who makes the product. Receiving research funds from a company or holding a patent in a related area can also cause conflicts of interest. All such situations should be openly and clearly declared.

In conclusion, undertaking myopia control treatment in minors creates an ethical challenge for a wide variety of stakeholders. Regulatory bodies, manufacturers, academics and clinicians all 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 issues to consider in the development, financial support, prescribing and advertising of such treatments.