

# IMI white papers: key findings

"Advancing myopia research, education and management, to prevent future blindness."

Chair: Professor Serge Resnikoff
Executive Director: Dr Monica Jong
Secretariat at BHVI Sydney, Contact: m.jong@bhvi.org





#### **Disclosures**

- IMI is a **non-profit** project founded by BHVI Ltd.
- All advisory board, taskforce chairs and committee members **donate** their time and expertise.

- Original full length papers published in IOVS Feb 2019 Volume 60 Issue 3
- Read the IMI white papers & official clinical summaries https://www.myopiainstitute.org/





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#### The need

- Currently there is a large body of information on myopia in the public domain.
  - BUT no guidance for practitioners, policy makers and the general community on how to approach
    the issue of the increasing prevalence of myopia worldwide, and the major risks to vision that
    accompany that.
- There are many scientific meetings worldwide that have myopia sessions, and a dedicated International Myopia Conference,
  - These meetings disseminate the latest research,
  - BUT a significant limitation is that the findings do not reach beyond the scientific community.
- There is a need to bring together all the researchers in a forum where they can discuss and contribute to key policy documents (white papers) on myopia, based on the current body of research.
  - The aim is to provide guidance to practitioners and policy makers based on the latest scientific knowledge, and guidance for future research directions.



#### **Overall Aims**

- To investigate, understand and collect evidence regarding the worldwide epidemic of myopia and related refractive errors.
- To build consensus on the current understanding of myopia.
- To hold seminars, discussions and editorial meetings to review and communicate information on myopia and its impact.
- To investigate, develop and make available evidence on possible solutions to the direct and indirect effects of myopia on world vision impairment and blindness.
- To make aware, educate and advocate
- To provide guidance and resources accessible to policy makers, governments, councils, and societal and educational bodies, as to the evidence on the influence of myopia on health, education, and the social and economic welfare of individuals and society that ultimately help in the implementation of appropriate programs to manage myopia.



## Who we are

#### **Advisory board of experts:**



**Prof Serge Resnikoff** Chair



Professor Kyoko Ohno-Matsui



Professor Jason J. Nichols



Professor Christine F. Wildsoet



Professor Tien Y. Wong



**Prof Earl Smith**Chief Scientist



Professor Hugh R. Taylor



Professor David S. Friedman



Professor Jost B. Jonas



Professor Serge Resnikoff



**Dr Monica Jong**Executive Director



Professor Earl L. Smith III



Professor Mingguang He



Professor James S. Wolffsohn



Professor Padmaja Sankaridurg



## **The Committees**

	Committees	Committee Chair
1	Defining and classifying myopia	Prof Ian Flitcroft (DIT, Children's Uni Hospital)
2	Interventions for myopia control	Prof Christine Wildsoet (UC Berkeley)
3	Clinical trials and instrumentation	Prof James Wolffsohn (Aston Uni)
4	Industry guidelines and ethical considerations	Prof Lyndon Jones (Uni Waterloo)
5	Clinical management guidelines	Dr Kate Gifford (QUT)
6	Experimental models of emmetropization and myopia	Profs Earl Smith (Uni Houston) & David Troilo (SUNY)
7	Genetics of Myopia	Prof Caroline Klaver (Erasmus Med Ctr & Radboud Uni Med Ctr)
8	Harmonization	Prof James Wolffsohn (Aston Uni)









Prof lan Fliteroft

Prof Christine F. Wildsest

Prof James S. Welffsehn









Dr Kate L. Gifford

Prof Earl L. Smith III



Prof David Trollo

**Prof Lyndon Jones** 





Prof Caroline C. W. Klaver



#### **Committee members**

**Defining and Classifying Myopia** 

Prof. Ian Flitcroft (Leader)

Committee members:

- · Prof. Kyoko Ohno-Matsui
- · Prof. Lawrence Yannuzzi
- Prof. Jost Jonas
- · Prof. Jugnoo Rahi
- · Prof. Serge Resnikoff
- Dr. Monica Jong
- · Prof. Mingguang He
- Prof. Kovin Naidoo
- Dr. Susan Vitale

Interventions for Myopia Onset and Progression

Prof. Christine Wildsoet (Leader)

Committee members:

- Dr. Klaus Trier
- · Prof. Seang Mei Saw
- · Prof. Padmaja Sankaridurg
- Dr. Jeff Walline
- · Prof. Jez Guggenheim
- Prof. Audrey Chia Wei Lin
- · Prof. Pei-Chang Wu
- · Dr. Scott Read
- · Dr. Pauline Cho
- Dr. Jan Polling

Clinical Myopia Control Trials and Instrumentation Report

Prof. James Wolffsohn (Leader)

Committee members:

- Dr. David Berntsen
- · Dr. Alexandra Benavente
- Dr. Takohiro Hiraoka
- · Dr. Scott Read
- · Dr. David Atchison
- · Dr. Takashi Fujikado
- · Dr. Hetal Buckhurst
- Dr. Pete Kolbaum
- Dr. Arthur Bradley
- Dr. Debbie Jones
- Dr. Hidemasa Torii
- Dr. Michael Collins
- Dr. Nicola Logan
- Dr. Linda Lundstrom
- Masakazu Hirota

Industry Guidelines and Ethical Considerations for Myopia Control

Prof. Lyndon Jones (Leader)

Committee members:

- · Dr. Fuen Vera-Diaz
- · Dr. Jacinto Santodomingo-Rubido
- Dr. Timo Kratzer
- · Dr. Katrina Schmid
- · Prof. Jose Gonzales-Meijome
- · Dr. Stephanie Ramdass
- · Dr. Steve Newman
- · Prof. Jason Nichols
- · Dr. Bjorn Drobe
- · Dr. Lyle Gray
- · Prof. Donald Tan
- Dr. Kah Ooi Tan
- · Dr. Arne Ohlendorf
- Dr. Yee Ling Wong

Refer to www.myopiainstitute.org

86 committee members and 750 general members



#### **Committee members**

Clinical Myopia Management Guidelines

Dr Kate Gifford (Leader)

Committee Members:

- Dr. Langis Michaud
- · Dr. Tom Aller
- Dr. Pauline Kang
- Dr. Kathryn Richdale
- Prof. Carly Lam
- Mr. Jeroen Mulder
- Dr. Dirk Seidel
- Dr. Kathryn Saunders
- Dr. Maria Liu
- Dr. Willem Tideman
- Dr. Janis Orr
- · Prof. Kathy Rose

Experimental Models of Emmetropizationand Myopia

Prof. Earl Smith and David Troilo (Leaders)

Committee Members:

- Prof. David Troilo
- · Prof. Siegfried Wahl
- Dr. Lisa Ostrin
- . Dr. Kee Chea-su
- · Dr. Tim Gawne
- Dr. Andrei Tkatchenko
- · Prof. Machelle Pardue
- Dr. Regan Ashby
- Dr. Debora Nickla
- · Dr. Jody Summers
- Dr. Falk Schroedl

**Myopia Genetics** 

Prof. Caroline Klaver (Leader)

Committee Members:

- · Dr. Virginie Verhoeven
- · Prof. Chris Hammond
- · Dr. Magda A. Meester-Smoor
- Dr. Milly S. Tedja
- Dr. Jaakko Kaprio
- Dr. Annechien E.G. Haarman
- · Prof. David A. Mackey
- · Prof. Jeremy A. Guggenheim
- CREAM Consortium

**Harmonisation Committee** 

Professor James Wolffsohn (Leader)

Committee Members:

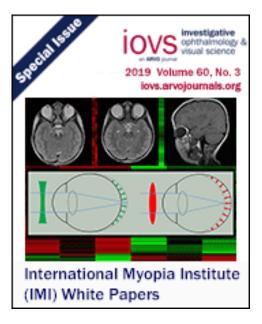
- · Prof. Padmaja Sankaridurg
- · Prof. Serge Resnikoff
- Prof. Earl L. Smith
- · Prof. Lyndon Jones
- · Prof. Kovin Naidoo
- Dr. Kate Gifford
- Dr. Monica Jong

86 committee members and 750 general members



# IMI white paper special issue IOVS- Feb 2019

- Editorial
- Introduction
- Seven white papers
- All freely downloadable from IOVS and the IMI website
  - https://iovs.arvojournals.org/issues.aspx?issueid=937872#issueid=937872
  - www.myopiainstitute.org



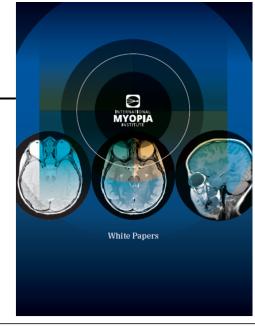


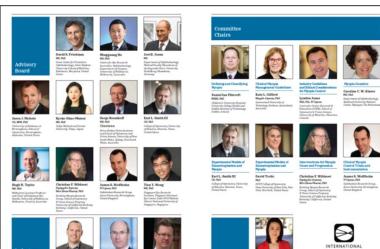
#### **IMI** booklet

#### · Aims:

- To create awareness about myopia as a major public health issue.
- To build awareness of the IMI as the expert body providing evidence based guidance in myopia.
- Audience: Researchers, practitioners, industry, health workers, health bodies.
- Contents: Editorial, introduction and overview of white papers
- Distribution: Freely downloadable and available at select meetings

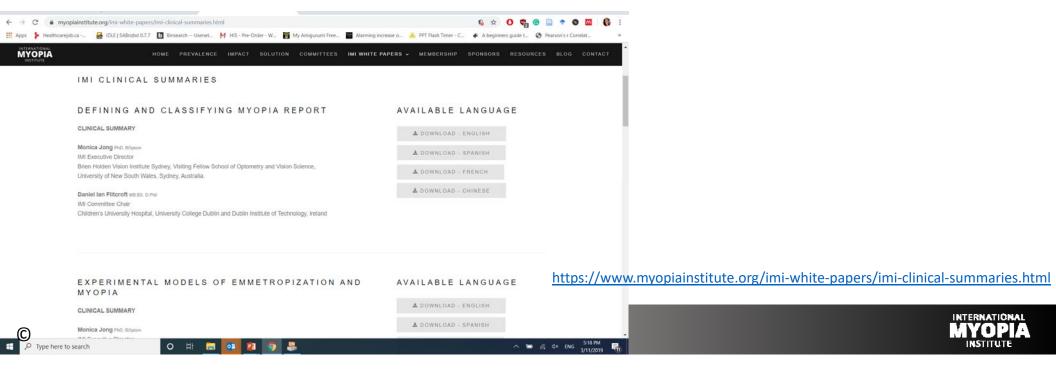
https://www.myopiainstitute.org/imi-white-papers.html





## Clinical summaries of white papers

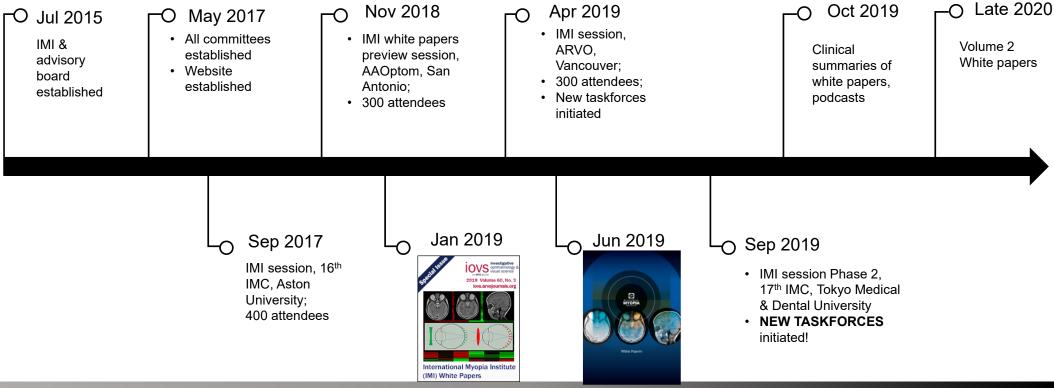
- AVAILABLE NOW FREE: English, French, Chinese, Spanish
- In near future: German, Dutch, Italian, Greek, Portuguese, Nepalese, Japanese, Vietnamese!
- Spreading the evidence and knowledge in managing MYOPIA everywhere!



#### **IMI** Activities

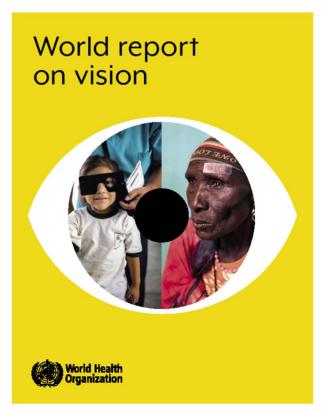
#### **Continual dissemination & advocacy**

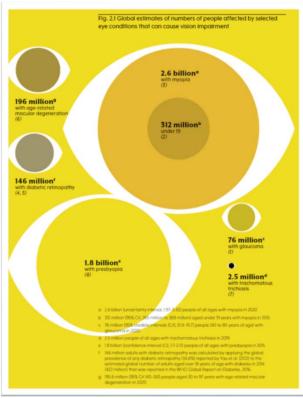
- E-blasts
- Website
- · Translated summaries
- · Speakers at meetings
- Peak body advocacy



INTERNATIONAL MYOPIA INSTITUTE

## Myopia is mentioned 56 times!





- 1st WHO world report on vision released on World Sight Day 2019
- IMI white papers served as a key reference.
- Myopia is mentioned 56 times!

https://www.who.int/news-room/detail/08-10-2019-who-launches-first-world-report-on-vision



# The white paper findings





# Defining and Classifying Myopia

Chair Professor Ian Flitcroft



# **Held Back By Centuries of Terminology**

Basis of Classification	Associated Descriptive Terms For Different Types Of Myopia		
Presumed Etiology	axial, benign, component, correlational, curvature, index, lenticular, physiologic, physiological, refractive, school, simple, syndromic		
Age of Onset	childhood, congenital, acquired, juvenile onset, youth-onset, school, adult, early adult onset, late adult onset		
Progression Pattern	permanently progressive, progressive, progressive high, progressive high degenerative, stationary, temporarily progressive		
Amount of Myopia	low, medium, intermediate, moderate, high, pathologic, pathological, physiologic, physiologic, physiological, severe, simple		
Structural Complications	degenerative, degenerative high, malignant, pathologic, pathological, pernicious, progressive, progressive high, progressive high degenerative		



## **Key findings**

- Recommended set of terminology for different forms of myopia
- Consensus and evidence based thresholds for low myopia and high myopia
  - Myopia: S.E. refraction ≤ -0.50 D when ocular accommodation is relaxed.
  - High Myopia: S.E. refraction ≤ -6.00 D when ocular accommodation is relaxed.
- A set of clinical and structural definitions for pathologic myopia



#### **New IMI Definition**

#### Pre-Myopia

"A refractive state of an eye of ≤ +0.75 D and > -0.50 D in children where a combination of baseline refraction, age, and other quantifiable risk factors provide a sufficient likelihood of the future development of myopia to merit preventative interventions."



Term	Definition	
Qualitative definitions		
Myopia	A refractive error in which rays of light entering the eye parallel to the optic axis are brought to a focus in front of the retina when ocular accommodation is relaxed. This usually results from the eyeball being too long from front to back, but can be caused by an overly curved cornea and/or a lens with increased optical power. It also is called nearsightedness.	
Axial myopia	A myopic refractive state primarily resulting from a greater than normal axial length.	
Refractive myopia	A myopic refractive state that can be attributed to changes in the structure or location of the image forming structures of the eye, i.e. the cornea and lens.	
Secondary myopia	A myopic refractive state for which a single, specific cause (e.g., drug, corneal disease or systemic clinical syndrome) can be identified that is not a recognized population risk factor for myopia development.	

Term	Definition		
Quantitative definition	ons		
Myopia	A condition in which the spherical equivalent refractive error of an eye is ≤ −0.50 D when ocular accommodation is relaxed.		
Low myopia	A condition in which the spherical equivalent refractive error of an eye is ≤ −0.50 and > −6.00 D when ocular accommodation is relaxed.		
High myopia	A condition in which the spherical equivalent refractive error of an eye is ≤ −6.00 D when ocular accommodation is relaxed.		
Pre-myopia	A refractive state of an eye of $\leq +0.75$ D and $> -0.50$ D in children where a combination of baseline refraction, age, and other quantifiable risk factors provide a sufficient likelihood of the future development of myopia to merit preventative interventions.		



Term	Definition		
Descriptive definitions			
Pathologic myopia	Excessive axial elongation associated with myopia that leads to structural changes in the posterior segment of the eye (including posterior staphyloma, myopic maculopathy, and high myopia-associated optic neuropathy) and that can lead to loss of best-corrected visual acuity.		
Myopic macular degeneration (MMD)	A vision-threatening condition occurring in people with myopia, usually high myopia that comprises diffuse or patchy macular atrophy with or without lacquer cracks, macular Bruch's membrane defects, CNV and Fuchs spot.		
Diagnostic subdivisions of MMD			
Myopic maculopathy	Category 0: no myopic retinal degenerative lesion.		
	Category 1: tessellated fundus.		
	Category 2: diffuse chorioretinal atrophy.		
	Category 3: patchy chorioretinal atrophy.		
	Category 4: macular atrophy.		
	"Plus" features (can be applied to any category): lacquer cracks, myopic choroidal neovascularization, and Fuchs spot.		
Presumed myopic macular degeneration	A person who has vision impairment and vision acuity that is not improved by pinhole, which cannot be attributed to other causes, and:		
	• The direct ophthalmoscopy records a supplementary lens < −5.00 D and shows changes such as "patchy atrophy" in the retina or,		
	• The direct ophthalmoscopy records a supplementary lens $< -10.00$ D.		
Specific clinical conditions characteristic of pathologic	ic myopia		
Myopic traction maculopathy (MTM)	A combination of macular retinoschisis, lamellar macula hole and/or foveal retinal detachment (FRD) in eyes with high myopic attributable to traction forces arising from adherent vitreous cortex, epiretinal membrane, internal limiting membrane, retinal vessels, and posterior staphyloma.		
Myopia-associated glaucoma-like optic neuropathy	Optic neuropathy characterized by a loss of neuroretinal rim and enlargement of the optic cup, occurring in eyes with high myopia eyes with a secondary macrodisc or peripapillary delta zone at a normal IOP.		





# Experimental models of emmetropization and myopia

Chairs Professor Earl L.Smith III and David Troilo



## **Summary**

- 1. Understanding of emmetropization and myopia development has been transformed by experimental studies using animal models
- 2. Visual signals (retinal defocus) guide emmetropization and the refractive development of the eye
- 3. The visual signals controlling eye growth are processed locally within the eye
- 4. The choroid is an active component in the visual control of eye growth and refraction
- 5. The eye growth response to visual signals involves changes to sclera extracellular matrix synthesis and biomechanical properties
- 6. Light intensity and spectral composition of light affects eye growth
- 7. Atropine affects eye growth and prevents experimentally imposed myopia that may act through muscarinic and non-muscarinic actions
- 8. Studies have identified biochemical compounds that are involved in the modulation of eye growth
- 9. Gene expression changes suggest that the retina may signal hyperopic and myopia defocus for eye growth through different pathways



#### **Conclusion**

Research with experimental models continues to inform our understanding of the mechanisms of eye growth control, enabling the development of new, and even more effective, treatments for myopia possible.





# Interventions for Controlling Myopia Onset and Progression

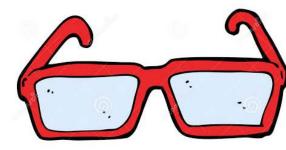
Chair Professor Christine Wildsoet



#### Special Issue

# IMI – Interventions for Controlling Myopia Onset and Progression Report

Christine F. Wildsoet, <sup>1</sup> Audrey Chia, <sup>2</sup> Pauline Cho, <sup>3</sup> Jeremy A. Guggenheim, <sup>4</sup> Jan Roelof Polling, <sup>5,6</sup> Scott Read, <sup>7</sup> Padmaja Sankaridurg, <sup>8</sup> Seang-Mei Saw, <sup>9</sup> Klaus Trier, <sup>10</sup> Jeffrey J. Walline, <sup>11</sup> Pei-Chang Wu, <sup>12</sup> and James S. Wolffsohn <sup>13</sup>





- 2. Pharmacological
- 3. Environmental (behavioral)
- 4. Surgical

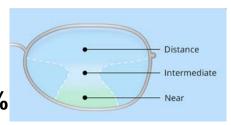




# 1. Optical – Spectacles



- Undercorrection spectacles
  - Conflicting results
- Peripheral defocus spectacles
  - Current designs without clinically significant treatment effects (14-30%)



PALS

- Multifocal spectacles
  - PALs statistically significant but not clinically meaningful\* (11-32%)
    - · Work better in subgroups with accommodative lag or near esophorias.
  - Executive bifocals (39-51%)
    - High set adds with BI prism clinically significant & best control of spectacle options





# 2. Optical – Contact Lenses

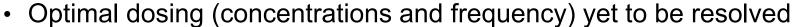
- Standard RGPs
  - No myopia control effects
- Soft multifocal (mf) contact lenses
  - Slowed myopia progression and axial elongation by weighted average 38% (interstudy variability)
    - Simultaneous defocus, concentric bifocals, distance centred, EDOF options
    - MF design related differences in efficacy
- Orthokeratology contact lenses
  - Slowed axial elongation 30 60% (interstudy variability)
  - 30% average slowing in longest 5-year study





# 3. Current Pharmacological Options

## Topical atropine



- 1% very effective but rebound & greater side-effect issues
- Combination low concentration with orthokeratology appears to improve efficacy compared to alone

## Oral 7-methylxanthine

- Clinical data & use limited to Denmark
- Apparently less effective than topical atropine



Atropine o.o.





- Increased outdoor time
  - Additional 80 mins per day reduces new cases of myopia by up to 50%
  - Does not consistently slow progression of myopia (0.13 to 0.23 D)

Minutes per day	Duration (year)	Δ Spherical equivalent	Δ Axial length
80	1	0.13 D	Not measured
40	3	0.17 D	0.03 mm
120 (up to 11 hours/week)	1	0.23 D	0.15 mm



# Time outdoors - Underlying mechanism(s)?

- Bright light
  - Increase retinal dopamine?
  - Increased serum vitamin D?
    - Low serum vitamin D and myopia progression association not consistently observed
    - · Possible surrogate for time outdoors
- Altered wavelength distribution
- Altered visual environment (spatial profile)
  - Less hyperopic defocus
  - Less near visual demand





# 4. Surgical Interventions

- Mostly directed at pathologic myopia & adults
- Posterior scleral reinforcement (PSR)
  - Current options limited
- Options under development
  - Injection-based scleral strengthening (SSI)
  - Collagen cross-linking scleral strengthening (CCL)



# **Key Take-Home Messages**

- Evidence-based options for reducing incident myopia & slowing myopia progression exist.
- Combining treatments from different categories may improve control
  - assuming different underlying mechanisms are involved
- Consistent, objective baseline measurements & monitoring after intervention (including cycloplegic refraction & axial length)
  - critical to establishing efficacy & understanding inter-subject differences in efficacy
- Improved understanding of mechanisms for current options is critical to further advancements in myopia management
- There is room for exploration of additional novel treatment options





## Clinical Trial and Instrumentation Guidelines

Chair Professor James Wolffsohn



### Clinical trials and instrumentation

This white paper reports on the current and future state of:

1. Myopia control study design:

Study length

participant selection

appropriate control group

randomisation and masking

use of cycloplegia

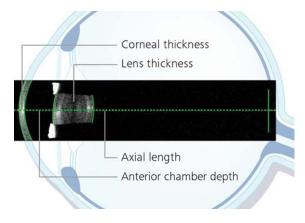
assessing rebound

safety and clinically meaningful effect

primary outcome (axial length and refractive error);



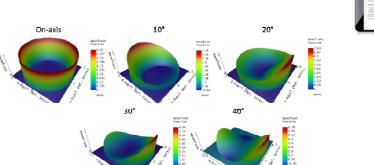






## Clinical trials and instrument

2. Secondary end-points:
patient reported outcomes
treatment compliance
exploratory measures:
peripheral refraction
accommodative changes
ocular alignment, pupil size
outdoor activity/lighting levels
anterior and posterior segment imaging
tissue biomechanics







# **Key recommendations**

- Declaration of Helsinki / IRB / informed consent / AE reporting / clinical trial registration
- Min 3 years + 1 follow-up
- Inclusion / exclusion criteria clearly defined: age, SE Rx, astigmatism, anisometropia and ocular pathology. Exclude previous myopia control treatment
- Randomisation (stratified) + control group. Ideally double masked
- AL (non-contact optical biometry) primary outcome measure + Rx (cyclo autoref as SE & power vectors) when applicable.
- Consider PRO, compliance and exploratory measures (mechanism)
- Same instrumentation used throughout study, calibrated and validated, using eye-model.
- Procedure carefully described to allow comparison, replication and benchmarking.



# Clinical trials and instrumentation

 These key findings will inform regulators, researchers and clinicians as to the standards which should be followed in the development of future treatments for retarding myopia development.



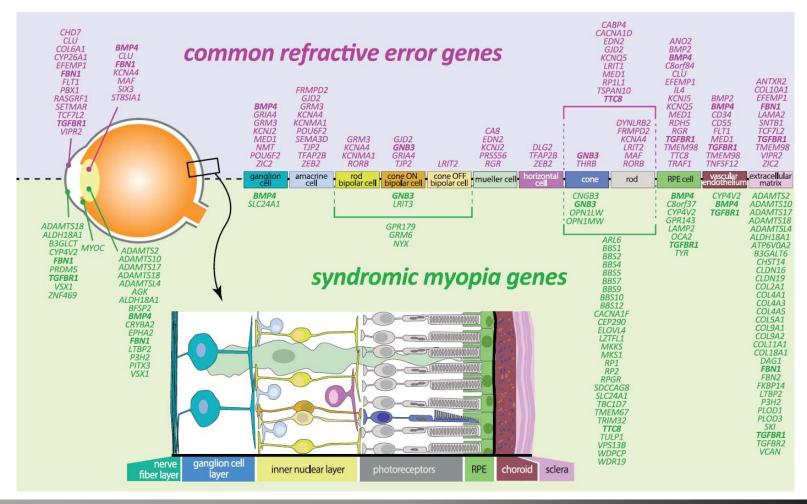


# Myopia Genetics Report

Chair Professor Caroline Klaver



### From GWAS to cell types – expression & in silico studies





#### **Conclusions**

- Genetic studies have found >200 genetic loci. They explain ~10% of refractive error;
   ~20% of high myopia
- Genetic functions are extremely diverse. All retinal cell types appear to be involved.
- Gene-environment interaction is a major player in myopia
- Genetic testing for myopia is unlikely to become a clinical application.
- Most important contribution of genetic findings is elucidation of molecular mechanisms underlying myopia





# CLINICAL MANAGEMENT GUIDELINES

Chair Dr Kate Gifford



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- 3. Myopia control treatments: risks, benefits and expectations
- 4. Key elements of the baseline examination for myopia control
- 5. Selecting a treatment strategy
- 6. Guidelines for advice and clinical care
- 7. Future research directions on intervention and treatment
- 8. Clinical references, education and communication



- 1. Identifying the myopia management patient
- Risk factors –
   age, family history, ethnicity, visual environment, binocular vision
- Identifying and managing the pre-myope



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- Lay discussion of causes
- Lay discussion of eye health risk



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- 3. Myopia control treatments: risks, benefits and expectations
- Lay discussion of options
- Lay discussion of efficacy and additional corrections
- Lay discussion of safety, other risks and challenges
- Informed consent and prescribing off-label treatments



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- 3. Myopia control treatments: risks, benefits and expectations
- 4. Key elements of the baseline examination for myopia control
- Standard procedure
- Binocular vision evaluation
- Dry eye evaluation
- Exploratory tests



#### 4. Key elements of the baseline examination for myopia control

#### **Clinical Tests**

#### All visits

- Appropriate history taking relative to treatment
- · Distance and near VA
- · Subjective and/or objective refraction
- Accommodative and binocular vision assessment
- · Ocular health examination

#### Annually (or on indication)

- Cycloplegic refraction
- Dilated fundus examination

#### If Available

Axial length measurement (every 6 months)

#### **Treatment Specific**

#### **Atropine**

- · Pupil size and function
- IOP

#### Orthokeratology

· Comeal topography

#### **Exploratory tests**

- Relative peripheral refraction
- Higher order aberrations
- Pupil size
- Sub-foveal choroidal thickness
- Wearable devices



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- 3. Myopia control treatments: risks, benefits and expectations
- 4. Key elements of the baseline examination for myopia control
- 5. Selecting a treatment strategy
- Predicting progression rate
- Selecting a treatment
- Add powers in multifocal SCLs
- Clinical spectacle myopia control



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- 3. Myopia control treatments: risks, benefits and expectations
- 4. Key elements of the baseline examination for myopia control
- 5. Selecting a treatment strategy
- 6. Guidelines for advice and clinical care
- Wearing time; back up corrections; environmental advice
- Minimising risk with CL wear; review schedules
- When to change and stop treatments; rebound effects



- 1. Identifying the myopia management patient
- 2. Discussing myopia and associated risks with parent and patient
- 3. Myopia control treatments: risks, benefits and expectations
- 4. Key elements of the baseline examination for myopia control
- 5. Selecting a treatment strategy
- 6. Guidelines for advice and clinical care
- 7. Future research directions on intervention and treatment
- OK and MFSCL optimization
- 7-MX, scleral reinforcement, circadian rhythms and other research

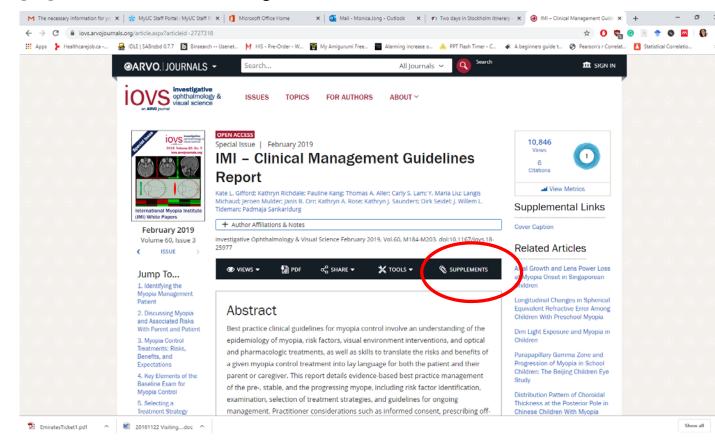


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- 7. Future research directions on intervention and treatment
- 8. Clinical references, education and communication



# Additional supplementary material

- Online practitioner education resources
- Resources for practitioner-patient communication https://www.myopiaprofile.com/
- Software tools available
- Sample informed consent form
- BHVI myopia calculator <u>https://globalmyopiacentre.org/</u>
- BHVI online myopia education program - continuing education accredited <a href="https://education.bhvi.org/">https://education.bhvi.org/</a>







# Industry Guidelines and Ethical Considerations

Chair Professor Lyndon Jones



#### Special Issue

#### IMI – Industry Guidelines and Ethical Considerations for Myopia Control Report

Lyndon Jones, <sup>1</sup> Björn Drobe, <sup>2</sup> José Manuel González-Méijome, <sup>3</sup> Lyle Gray, <sup>4</sup> Timo Kratzer, <sup>5</sup> Steve Newman, <sup>6</sup> Jason J. Nichols, <sup>7</sup> Arne Ohlendorf, <sup>5,8</sup> Stephanie Ramdass, <sup>9</sup> Jacinto Santodomingo-Rubido, <sup>6</sup>

Increasing prevalence of myopia is driving Tx options for MC

Prescribing a product, regardless of marketing authorization, decided between Px & HCP

#### **Companies**

- Not typically permitted to promote MC Tx not approved for that indication
- Scientific information that is truthful and not misleading is permitted

#### **ECPs**

- MUST educate themselves about MC Tx
- To make **balanced clinical decisions** to provide **best possible care** for Pxs (till approved guidelines available)
- Ideally consider on-label FIRST and off-label ONLY if on-label fails (not all options approved in all countries)
- Off-label/unlicensed therapies for MC Tx? Based on the most credible available evidence
- Increased level of caution & monitoring is required
- Information must be provided to Px in neutral, balanced, and non-biased way
- Informed consent and assent forms for Px are strongly recommended



Special Issue

#### IMI – Industry Guidelines and Ethical Considerations for Myopia Control Report

Lyndon Jones, <sup>1</sup> Björn Drobe, <sup>2</sup> José Manuel González-Méijome, <sup>3</sup> Lyle Gray, <sup>4</sup> Timo Kratzer, <sup>5</sup> Steve Newman, <sup>6</sup> Jason J. Nichols, <sup>7</sup> Arne Ohlendorf, <sup>5,8</sup> Stephanie Ramdass, <sup>9</sup> Jacinto Santodomingo-Rubido, <sup>6</sup>

#### **Patients**

- Should be well-informed
- Product marketing authorization
- Off-label/unlicensed Txs Risks might be unknown & difficulties with costs reimbursement



# IMI next steps



# New taskforces initiated Sep 2019









Taskforce	Chair
1. Impact of myopia	Prof Padmaja Sankaridurg (Australia)
2. Paediatric high myopia	Prof lan Flitcroft (Ireland)
3. High myopia in adults and their associated complications	Prof Kyoko Ohno-Matsui (Japan)
4. Preferred practice patterns (PPPs)	Prof Jost Jonas (Germany)
5. Environmental risk factors in myopia	Prof Ian Morgan (Australia)
6. Accommodation and binocular vision in myopia	Dr Nicola Logan (UK)
7. Yearly Digest 2020	Prof Earl Smith (USA) and Dr Monica Jong (Australia)









# **Continued advocacy**

• ICD 11

• 2.4 Topics of future WHO consultations

. . .

 "Another potential area of work that was mentioned included the potential harmonization of current definitions of myopia."



Description of Vision Impairment in ICD 11 – Technical Consultation

Minutes

25-26<sup>th</sup> of March 2019 Geneva, Switzerland



