Team USA vs Team GB

With a little Aussie Rules thrown in

The Education

- 4 years undergraduate degree
  - Typically in biology, chemistry, or other sciences
- 4 years optometry school
  - Now 22 accredited schools in U.S., 2 in Canada and climbing
  - New "add-on" model to pharmacy/osteopathy
- Optional one-year post graduate residency with about 300 accredited slots

The Scope

- Varies state to state
- Most restrictive: no glaucoma
- Least restrictive: lasers and minor surgery

How did we get from there to here…

- Back in Paul and Murrays "day"
- Diagnostic drugs illegal in most states
- State by state, diagnostic bills passed with required 100 hour courses to become "certified"
- 1976-1990 were when most of these bills were passed

Therapeutic Legislation in Stages

- Example: Georgia
- 1980: diagnostic drugs
- 1987: topical antibiotics, steroids
- 1993: glaucoma and oral narcotics
- 2007: oral antibiotics and antivirals

How to Pass a Bill in the U.S.

- Grassroots
- Lobbying/Campaigning/Money buys you a seat at the table
- Bill is introduced with a sponsor in either the House or Senate
- Committee hearings, votes, then to the full House and to the other side
- Governor's signature and enactment

How Optometry Succeeded

- Malpractice rates lowest of any healthcare profession
- No bills ever reversed
- Access is always an issue and there are 34K OD's and only 12K ophthalmologists
- Training + Personality + Grassroots = Success!

Modes of Practice in the U.S.

- Private practice
- Commercial practice
- MD practices
- Veterans Affairs Hospitals
- Teaching at optometry schools
- Military
- Miscellaneous
  - E.g. Federal employment in non-TPA State

How Many Practice Full Scope?

- By setting:
- VA-full Private-Partial Commercial-Minimal
  MD -varies

- By disease:
- Infection-full Uveitis-partial
- Glaucoma - small percentage do most of it

Optometry and Therapeutics

- United States – no national licensure
  - Each individual state regulates the profession of optometry within their borders
  - Each state determines the scope of practice either by legislation or in a few places, the board of optometry can decide what ODs may do
  - States utilize national licensure exams (ie. National Boards)
    - All do to some extent
- 1977 – West Virginia therapy bill
- 1978 – North Carolina therapy bill

Optometry and Therapeutics

- What is the scope of practice for OD's
- Varies significantly
- From use of topical medications to treat local eye conditions > treatment of glaucoma topically> use of systemic medications (oral antibiotics > systemic medications including steroids> topical eye procedures (punctal plug, foreign body removal)>excision of local lesions around eye>laser procedures such as SLT, PI
- General trend has been that states that are rural have a greater ratio of ODs to population
- Greater need for ODs to perform procedures

Trends

- Board certification
  - What does that mean ?
- Educational delivery
  - Internships ?
- The role of the insurer ?
- Canadian experience
  - From the sublime (Ontario) to the ridiculous (BC)

Optometry and Therapeutics

- What is the education that allows ODs to treat
  - Ocular conditions
  - Glaucoma
  - Laser and surgical procedures
- Are the colleges of optometry prepared to educate in regards to the treatment and management of eye disease?
- What is the relationship with ophthalmology in the United States?

Australia/NZ

- Investigated scope of practice 1983
- Teeth of extreme opposition
- No Hospital Optometrists
- No Ophthalmology teaching optometry
- Adopted USA outreach programme
- Victoria first state

Required

- Strong Academic-Professional-Practice link
- Vision
  - A characteristic of Australian optometry
- Government support
  - Most political parties were anti organised medicine because seen as a powerful and entrenched lobby
  - Optometry access seen as freedom of choice
  - Embraced Medicare
  - Commitment to stop denial of access to training

Jim Kokkinakis

- Sydney based Optom
  - First course 1991 (not recognised)
  - Next 1996 (VCO, Melbourne) recognised in Vic.
- 1996-2007 Worked with Ophthalmologists who wrote scripts under supervision
  - Legislation Victoria 1999
  - Legislation NSW 2007
  - New courses needed, of course !

Scope of practice

- No controlled or parenteral
- All glaucoma is co-management
  - Often alongside non-glaucoma ophthalmologists !
- CL complications remains bulk of work
- Jim reckons an 80:20 rule
  - 20% optoms do 80% TPA activity
  - Minimum 10 per week viability of exposure
- Independent sector only

Future

- A split
  - Refracting optometrist
  - Optometric Physician (GP of the eye)
  - Contrast Melbourne (5yr OD), Geelong (3.5yrs)
- Independent sector embrace TPA because its differentiation and opportunity
  - Corporates little vision outside retail
  - Pressure from corporates, internet as here

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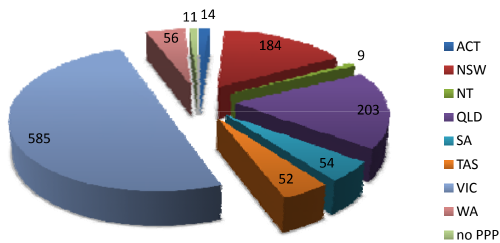
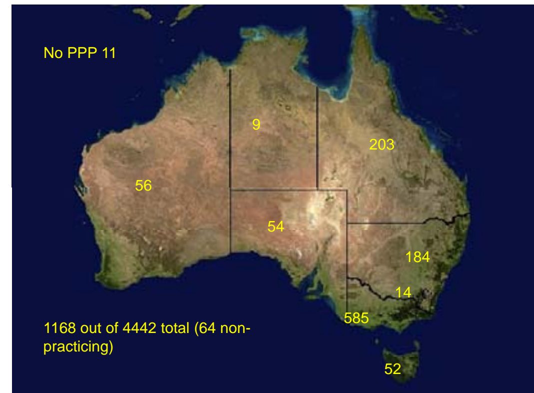
Aussie numbers





Access to medicines

- Prescribing endorsement under Commonwealth law
  - Section 94
  - Accreditation by OCANZ (Optometry Council Australia New Zealand)
- Medicines Access
  - Schedules 2, 3, 4, section 52D Therapeutic Goods Act 1989

www.optometryboard.gov.au
www.ocanz.org

Management

Scheduled Medicines Advisory Committee Terms of Reference

- Chair; Board Optometrist
- 2 TPA optometrists
- Pharmacist
- 1 Ophthalmologist
- 1 MD
- 1 Academic Pharmacist
- 1 Academic Optometrist

Medicines

- Schedule 2
  - Pharmacy (may require pharmacist advice)
- Schedule 3
  - Pharmacy only (supplied by pharmacist)
- Schedule 4
  - Prescription only
  - May vary within state
- Schedule 8
  - Controlled drug

Schedule 4 PoM's for optoms

- Most States have all
  - Tasmania and ACT missing a few
- Anti-infectives
- Anti-inflammatories
- Anti-allergic
- Anti-glaucoma
- Miotics, mydriatics
- Local Anaesthetics

New Zealand

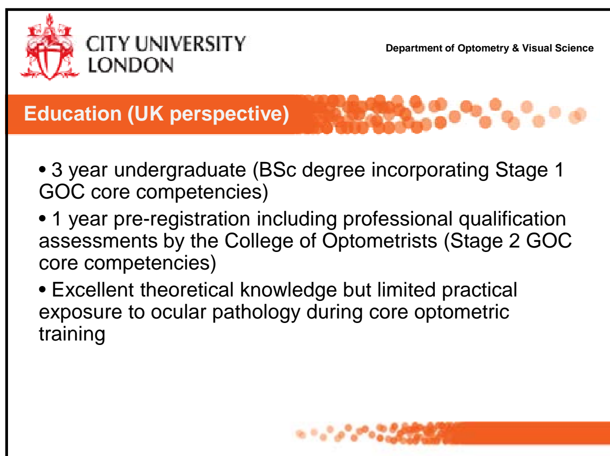
- TOA legislation passed 2005
  - Auckland TPA courses
- B.Optom Auckland
  - TPA at registration from 2006
- 250/500 qualified
- Optometrists differentiate themselves
  - http://www.mgoptometrist.co.nz/eyehealth_a2.aspx
  - http://www.patersonburn.co.nz/prescription_treatment.cfm

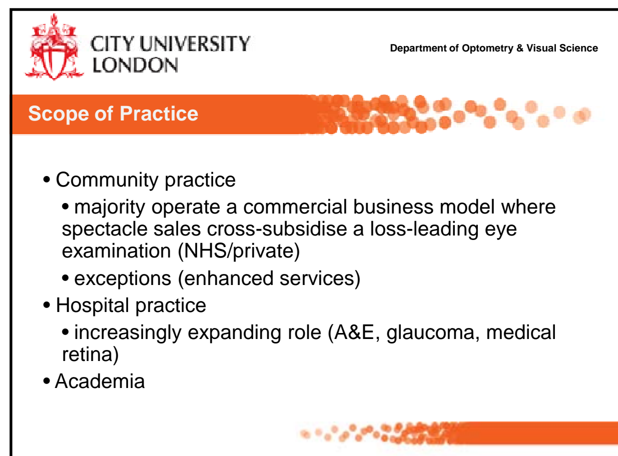
Medicines Schedule NZ (optoms)

- 1 Acyclovir
- 2 Atropine
- 3 Betamethasone
- 4 Chloramphenicol
- 5 Ciprofloxacin
- 6 Cyclopentolate
- 7 Dexamethasone
- 8 Diclofenac
- 9 Fluorometholone
- 10 Flurbiprofen
- 11 Framycetin
- 12 Fusidic acid
- 13 Gentamicin
- 14 Gramicidin
- 15 Homatropine
- 16 Hyoscine
- 17 Ketorolac
- 18 Neomycin
- 19 Olopatadine
- 20 Polymyxin B
- 21 Prednisolone
- 22 Tobramycin
- 23 Trimethoprim
- 24 Tropicamide

Issues

- TPA uplift courses have a live of 5-7 years
  - Because new graduates are already qualifying and demand dries up
- OCANZ policy on overseas entry
  - Controversial, counter to optometry schools
  - Wish to cease non TPA licensed migrants
- UoA
  - Wishes to up skill ALL optometrists





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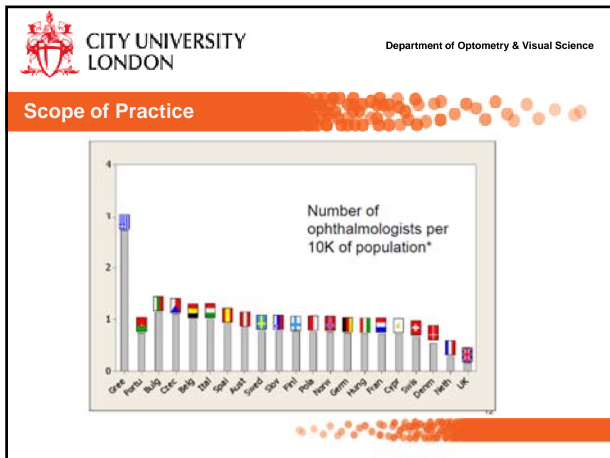
Scope of Practice



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Diagnostic drugs

- Use of ocular diagnostics by optometrists pre-dates the Opticians Act (1958, 1989)
- Mydriatics, cycloplegics, topical anaesthetics and prophylactic topical antibacterials
- Teaching in pharmacology and assessment of the use of drugs part of the training and accreditation of optometrists for over 50 years
- Never been a malpractice case in relation to the inappropriate use of ophthalmic drugs

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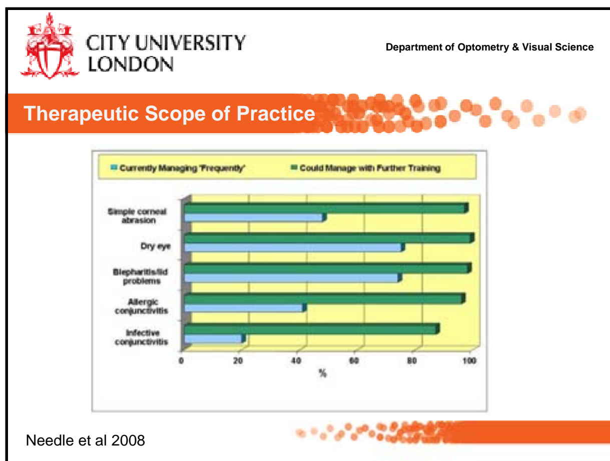
Therapeutic Scope of Practice



Needle et al 2008

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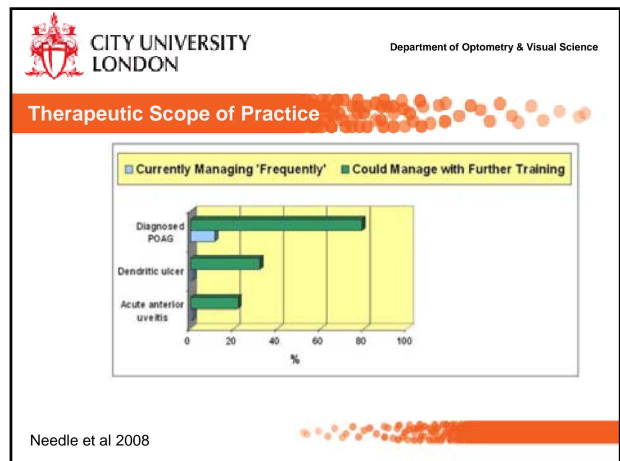
Therapeutic Scope of Practice



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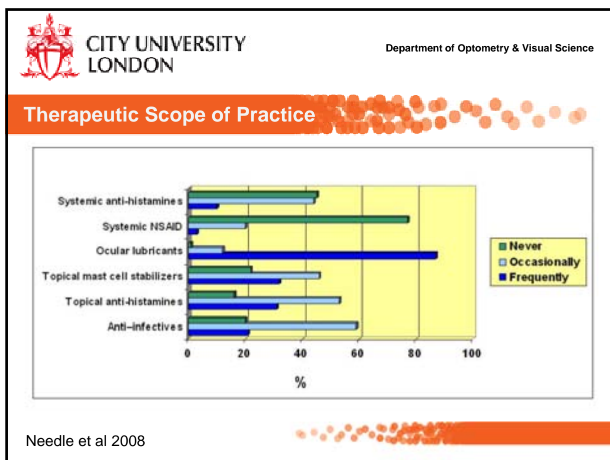
Therapeutic Scope of Practice



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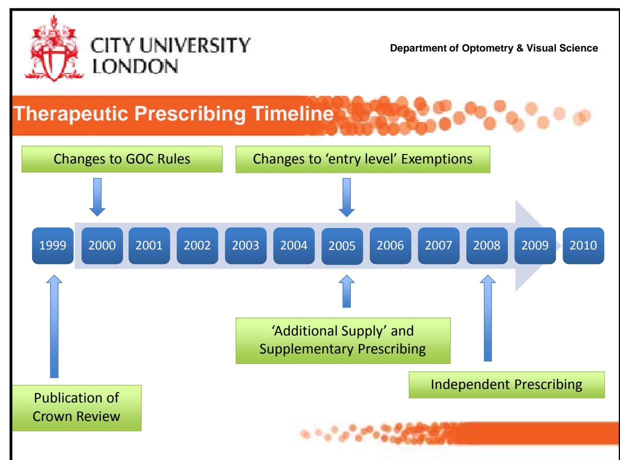
Therapeutic Prescribing Timeline



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Therapeutic Prescribing Timeline

Changes to GOC Rules

1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010

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GOC Rules for Referral

- **GOC Rules relating to Injury or Disease of the Eye**
  - 1960: mandatory to refer all abnormalities of the eye
  - 1999: introduced discretion not to refer
  - 2000: new rules came into effect
  - 2005: further rewording of rules

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GOC Rules for Referral

Rule 6: 'If in the professional judgement of a registered optician there is no justification to refer a person to a registered medical practitioner, or that it would impractical or inexpedient to do so, the registered optician may at his discretion decide not to refer that person on that occasion but in that event he:

(a) Shall record in respect of the person consulting him

- a sufficient description of the injury or disease from which the person appears to be suffering

- his reason for deciding not to refer on that occasion

- details of the advice or medical or clinical treatment tendered to the patient

(b) If appropriate, and with the consent of the person consulting him, shall inform the persons general practitioner of those matters recorded in accordance with rule 6(a)'

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Therapeutic Prescribing Timeline

Changes to 'entry level' Exemptions

1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010

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Changes to 'Entry Level' exemptions

- *The Medicines for Human use (Prescribing) (Miscellaneous Amendements) Order 2005 SI No.1507*

Sale or supply direct by optometrist in the course of professional practice and in an emergency & pharmacy on the presentation of an order signed by a registered optometrist	POM medicines for administration (as opposed to sale or supply) containing the following substances:
Chloramphenicol Cyclopentolate hydrochloride Fusidic Acid Tropicamide	Amethocaine hydrochloride Lignocaine hydrochloride Oxybuprocaine hydrochloride Proxymetacaine hydrochloride

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Changes to 'Entry Level' exemptions

Medicines (Pharmacy and General Sale-Exemptions) Order 2005 SI No.1476

- Removal of 'emergency' caveat for the supply of pharmacy only (P) medicines

Opticrom | Alomide | Otrivine Antistin | piriton allergy tablets

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The CE Mark

Medical Devices Directive (93/42/EEC)

- Increasing numbers of ophthalmic products are licensed as medical devices. The CE mark means that a product conforms to the requirements of the European Devices Directive and that it is fit for its intended purpose.

CE

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Therapeutic Prescribing Timeline

1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010

'Additional Supply' and Supplementary Prescribing

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Additional Supply

The Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations SI 2005 No. 1520

- Further training required
- Specialist CET for continued accreditation
- Includes drugs previously designated 'entry level'
- Formulary for the management of common non-sight threatening disorders of the eye

Sale or supply direct by optometrist in the course of professional practice and in an emergency & pharmacy on the presentation of an order signed by a registered optometrist

Acetyl cysteine
Atropine sulphate
Azelastine hydrochloride
Diclofenac sodium
Emedastine
Homotropine hydrobromide
Ketotifen
Levocabastine
Lodoxamide
Nedocromil sodium
Olopatadine
Pilocarpine hydrochloride
Pilocarpine nitrate
Polymyxin B/ bacitracin
Polymyxin B/ trimethoprim
Sodium cromoglicate
Thymoxamine hydrochloride

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Supplementary Prescribing

The Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations SI 2005 No. 1507

Supplementary prescribing - a partnership between 3 people: **a medical practitioner** (*independent prescriber*) who establishes the diagnosis and initiates treatment, an **optometrist** (*supplementary prescriber*) who monitors the patient and prescribes further supplies of medication and the **patient** who agrees to the supplementary prescribing arrangement.

For each patient, the framework for supplementary prescribing is set out in an individual **clinical management plan** which contains details of the patient, their condition, treatment with medicines and when the patient should be referred back to the independent prescriber.

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Therapeutic Prescribing Timeline

1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010

Independent Prescribing

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Independent Prescribing

The Medicines for Human use (Prescribing) (Miscellaneous Amendments) Order 2008 SI No.1161

- Statutory legislation to introduce independent prescribing (IP) in 2008
- First IP optometrists entered the specialist register late 2009
- Upon registration IP optometrists specify their intended area of practice e.g. glaucoma, primary care etc.
- IP specialist registration is renewed annually and optometrists may be asked to provide a record of their prescribing activity for each renewal
- In addition must obtain specialist CET points (18 in 3 year cycle)

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Clinical Management Guidelines

CHM's recommendation was that suitably qualified optometrists should be able to prescribe any licensed medicines (except for controlled drugs or medicines for parenteral (injected) administration) for ocular conditions affecting the eye, and the tissues surrounding the eye, within their recognised area of expertise and competence. In making the recommendation, the Commission made clear that the extent of independent prescribing for optometrists would be controlled in detail through guidelines. Therefore, while these amendments to medicines legislation enable an optometrist independent prescriber to prescribe any licensed medicine, except for controlled drugs or medicines for parenteral administration, the College of Optometrists will provide clinical guidelines, and the General Optical Council (GOC) will amend its rules, to ensure that optometrist independent prescribers only prescribe licensed medicines for ocular conditions affecting the eye, and the tissues surrounding the eye, within their recognised areas of expertise and competence

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Clinical Management Guidelines

THE COLLEGE OF OPTOMETRISTS

Clinical Management Guidelines

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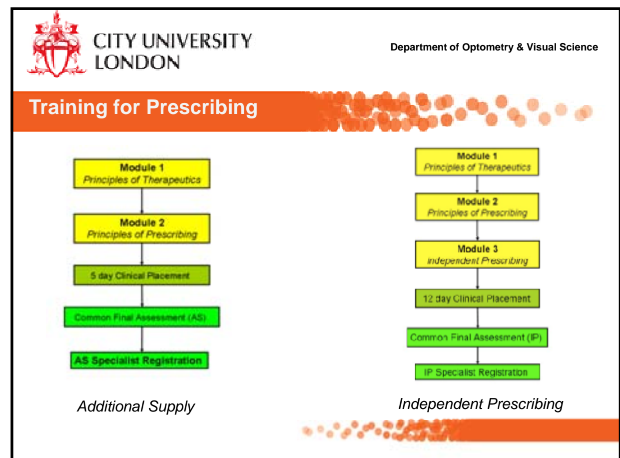
Specialist Registrants

	AS N (%)	AS +SP N (%)	SP only N (%)	CPNP N (%)	IP N (%)	TOTAL N (%)
Optometrists	41 (0.3)	34 (0.2)	N/A	N/A	131 (0.5)	135 (1.1)
Pharmacists	N/A	N/A	1483 (3.0)	N/A	875 (1.8)	2358 (4.8)
Nurses	N/A	N/A	N/A	34,000 (4.9)	12,398 (1.7)	46,398 (6.6)



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Course Requirements for IP

1. Applicants should define their intended area of practice, this is likely to be Primary Eye Care and / or Glaucoma.
2. Applicants should provide evidence that they have up to date knowledge and experience in their intended area of practice.
This evidence may include:
   - Details of relevant courses attended and qualifications obtained;
   - Details of the type and extent of clinical experience in the intended area of practice;
3. Additional documentation may also include the following:
   - Supporting letter from a Registered Medical Practitioner;
   - Supporting letter from a Professional Services Director or equivalent;
   - Supporting letter from a commissioning organisation;
4. It is recommended that applicants should have identified a mentor prior to commencing the course

Perspective from a recent DipTP(IP)

- Issues
  - Maturity of profession
  - Role of Guidance, specifically of CMG's
  - Use in practice
  - Development of training
  - Strategy
    - Undergraduate
    - Cost to public health of NOT having TPA trained optometrists in primary care
    - Integration into health commissioning

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Clinical Placement

- Within the context of the relevant specialism the period of practice-based learning should ensure that the optometrist:
- Is competent in the assessment, diagnosis and management of the ophthalmic conditions for which the optometrist intends to prescribe;
- Is able to recognise sight-threatening conditions that should be referred;
- Is able to consult effectively with patients;
- Is able to monitor the response to treatment, to review both the working diagnosis and to modify treatment or refer/ consult/ seek guidance as appropriate;
- Makes clinical decisions based on and with reference to the needs of the patient;
- Is aware of their own limitations and makes clinical decisions based on the needs of the patient;
- Critically analyses and evaluates his or her ongoing performance in relation to prescribing practice.
- Clinical training should be structured to ensure that each trainee is exposed to sufficient numbers of patients presenting with the conditions that he or she will manage therapeutically. In addition, the optometrist should be exposed to a range of ophthalmic conditions so as to develop differential diagnostic skills.

http://www.college-optometrists.org/en/professional-development/Therapeutics/qualifying.cfm

Clinical Management Guidelines

- Evidence base treatment, CMGs grew from need to establish overall safety of optometric diagnosis and treatment by virtue that patients needed to have access to the "same standard of care" irrespective of who delivered; A&E, GP, Ophthalmologist, Optometrist.
- Other non-medical prescribing (nurses, pharmacists) developed around limited formularies, usually treating defined conditions without the sense of autonomy optometrists envisaged would be needed to manage their patients and ensure the improved access, quality and cost benefits of optometric prescribing

Clinical Management Guidelines

- As the consultation on scope of practice developed CMG's were offered as means to demonstrate that optometrists would be able to deliver appropriate treatment based on the publically available evidence
- Intention being that patients should be accessing the correct and scientifically evidenced appropriate treatment wheresoever it was delivered and whosoever delivered it

Quote

- In its original press release (28/08/2007) (Appendix 5) announcing Independent Prescribing the then Minister; Dawn Primarolo envisaged that
- *"Optometrists' prescribing practice will be informed by guidelines from the College of Optometrists".*

CFA Guidance to Candidates (08/03/2012)

- Evidence base – not what you would do with a patient
- One of the issues that we have identified is that candidates need to understand that the examination is not asking what they would do with a patient in their practice, but what the evidence available says they should do. In particular you will be expected to have a thorough knowledge of the College's Clinical Management Guidelines (CMGs) and any other evidence-based guidance (including NICE guidelines on glaucoma). The answers to the questions strictly adhere to the pathways of care for each condition laid down in the CMGs and the prescribing data in the British National Formulary. When the profession was permitted to prescribe independently for any eye condition, using non parenteral drugs, this was because the profession itself (through the College as the professional body) provided a safeguard in the form of the CMGs.

College opinion of Guidelines

- Chapter 00: Preface and Principles
- The guidance represents the College‟s view of good practice, this being defined by the College Council as being *"what a competent optometrist is able to do in practical and achievable terms and within existing training and skills"*. It is not a set of instructions and does not constitute a "check list" of clinical or professional procedures that must be carried out. It is for each practitioner to exercise his or her professional judgement.
- http://www.college-optometrists.org/en/utilities/document-summary.cfm/docid/70E16B99-0B5E-4153-85C53270BEB039DB

Guidelines ?

- NICE CG85 Full Guidance Page 4
- Despite meticulous methodology and attention to detail there will always remain areas of uncertainty. Trial evidence may be absent, and where this exists it cannot refer to those patients whose clinical features lie outside the inclusion criteria and extrapolations are required when stepping beyond the fringes. Even within the boundaries of the evidence there are uncertainties, hence the clinically familiar use of confidence intervals around effect sizes. Dealing with uncertainty in the economic evaluation requires a different approach, a sensitivity analysis varies the model's input parameters and examines the impact this has on the model outputs. Science and medicine aside, the circumstances and views of individual patients must be taken into account and 'one size' will never 'fit all'. Thus there will always be clinical exceptions and the intention of the guideline is to provide recommendations which will apply to 80% of clinical situations on 80% of occasions.
http://www.nice.org.uk/nicemedia/live/12145/43887/43887.pdf

Who owns the CMG's

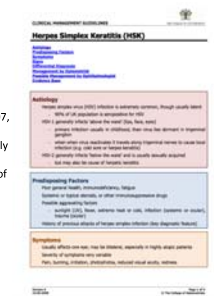
- **Taken from RCOphth Annual Report**
- **VISION 2020 Primary Eye Care Group**
- The group has completed 61 clinical management guidance documents for the College of Optometrists and these are being updated as the evidence base changes. The documents were written by Professors Lawrenson and Buckley with input from other members of the group. The Professional Standards Committee of The Royal College of Ophthalmologists has approved the contents of the guidance and they are available for use on the web.
- Currently all the guidance documents are for anterior segment eye conditions. Guidance for treatment of retinal conditions will be produced if the College of Optometrists agrees and is prepared to fund the work involved. If so, expertise will be needed from Fellows of the RCOphth.
- http://www.rcophth.ac.uk/page.asp?section=388§ionTitle=Annual+Reports

CMG's

- http://www.college-optometrists.org/en/professional-standards/clinical_management_guidelines/explanatory_notes.cfm/#evidence
- The most frequently used definition of evidence-based practice is the *'conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'* (Sackett et al, 1986 BMJ 312:71-2). A standardised search protocol was used to establish the evidence base for each ophthalmic condition

Evidence or Opinion

- Herpes simplex keratitis
- Evidence base
- Wilhelmus K. Therapeutic interventions for herpes simplex virus epithelial keratitis. Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD002898. DOI: 10.1002/14651858.CD002898.pub3. Author's conclusion: currently available anti-virals are effective and nearly equivalent. Topical application of aciclovir or ganciclovir results in a high proportion of resolutions within one week of treatment. Insufficient placebo-controlled studies are available to assess debridement.
- Centre for Evidence-based Medicine Level of Evidence = 1a



Evidence or Opinion

Management by Optometrist
Non-pharmacological
None
Pharmacological
Acute Herpes Simplex: no treatment, as starting therapy could make confirmation of the diagnosis by the Ophthalmologist more difficult Recurrent Herpes Simplex: where there is:
Version 9 Page 2 of 3 23.09.2009 © The College of Optometrists
CLINICAL MANAGEMENT GUIDELINES
(a) a clear history of previous attacks
(b) no doubt about the diagnosis and
(c) only epithelial involvement
- commence aciclovir therapy
- oc aciclovir 3%, e.g. Zovirax, ophthalmic preparation, 5x daily
If stroma involved, or if epithelium not healed after seven days, refer urgently to Ophthalmologist
Management category
A3 (if acute, or if recurrent but severe or with stromal involvement): urgent referral to Ophthalmologist
B2 (if recurrent and no stromal involvement): alleviation or palliation; but refer urgently to Ophthalmologist if epithelium not healed after seven days

Evidence or Opinion

- The CMG's are a very carefully drawn up evidence base with regard to investigation, diagnosis, differential diagnosis, management and treatment
  - By whoever is competent to deliver it, but
- There is no published evidence with regard to pathways
- Drawn up in a political context

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Assumptions

- Ophthalmology care is accessible enough to be available
- Ophthalmology care is uniform and better than that provided by a therapeutically trained and competent prescribing optometrist
- Anecdotal evidence suggests that once qualified IP optometrists follow the “evidence” in treatment but not necessarily the opinions on pathways
- Anecdotally and for pragmatic reasons an IP qualification is being treated as an “at entry” competence with further expertise and experience developing and modelling to suit local needs

Fitness to Practice

- No cases as yet
- Where will the test lie ?
  - CMG’s on treatment ?
  - CMG’s on pathway ?

Training

- IP mentor
  - Consultant ophthalmologist
- IP placement delivery ?
  - More junior grades in practice
- Placements short in supply
- Prescribing legislation does not say what “sort” of IP is needed to mentor
- What happens when we have 500 IP optometrists some with years experience

Education

- UK optometry
  - Unique in being classed as non clinical discipline
  - Courses are pressurised to deliver basic practical competence
  - New PQP has risen to challenge (hats off to the College)
  - But…..
  - When will we get at registration prescribing optometrists ?

The US opinion

- Our professional development
  - The therapeutic imperative
- Our educational development
- What would you do differently ?

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