RANZCO The Royal Australian and New Zealand College of Ophthalmologists
THE MEDICAL EYE SPECIALISTS

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Mr Colin Waldron
Chair, Optometry Board of Australia
Australian Health Practitioner Regulation Agency
Level 7, 111 Bourke Street
Melbourne VIC 3000

By email: optomconsultation@ahpra.gov.au.

Dear Mr Waldron

Re: Public Consultation – Amendments to Guidelines for the use of scheduled medicines

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to comment on the consultation paper from the Optometry Board of Australia through Australian Health and Practitioner Regulation Agency (AHPRA) on proposed amendments to its Guidelines for the use of scheduled medicines by optometrists.

RANZCO's mission is to drive improvements in eye health care in Australia, New Zealand and Asia Pacific Region through continuing exceptional training, education, research and advocacy. Underpinning all of the College's work is a commitment to best patient outcomes providing contemporary education, training and continuing professional development, evidence based decision making, collaboration and collegiality. RANZCO also seeks to educate the general public in all matters relating to vision and the health of the human eye and advocates for accessible ophthalmology services for patients.

In assessing the amendments documented within the consultation paper, RANZCO harnessed the expertise of its members through the Australian and New Zealand Glaucoma Interest Group (ANZGIG), the Australian and New Zealand Corneal Society and considered the matter at Board level. Our members' principal concerns were related to the proposal that optometrists initiate treatment for glaucoma and their use of fluoro-quinolones.

Glaucoma

Glaucoma is the leading cause of irreversible blindness worldwide; any proposed changes to current practice that impact on the management of this lifelong disease should be scrutinized carefully to optimize patient care, maintaining safety and a reasonable cost to both patients and health care providers/subsidizers. We wish to engage collaboratively with all eye health care workers, including optometrists, in our efforts to achieve these goals. As evidence of this we recently participated in the development of the *Guidelines for the Screening, Prognosis, Diagnosis, Management and Prevention of Glaucoma*, published by the National Health and Medical Research Council (NHRMC)[1]. This major effort defined the roles of optometrists and ophthalmologists, and the panel

included several senior members of the optometry academic community. The current consultation paper appears to completely ignore the recommendations of this study.

In assessing the proposed amendments, our concerns were firstly the proposal that optometrists initiate treatment for glaucoma or suspicion of glaucoma (Attachment A - Section 7) and secondly how this relates to the guideline to store and sell S4 drugs (Attachment A - Section 3) - the stated rationale being the perceived limited access to ophthalmology services in emergency situations.

Glaucoma emergencies are true medical emergencies and must be referred immediately for surgical or laser intervention, which is outside the purview of optometry. In such emergencies it is the responsibility of the nearest ophthalmologist or hospital to care for that patient.

Provided the involved optometrist recognizes the nature of the emergency and communicates clinical findings appropriately, this can be provided in all but the most remote of settings. Most other perceived glaucoma emergencies are not true surgical emergencies but rather an identification of a problem that needs to be dealt with without delay in consultation with an ophthalmologist, they do not require 'on the spot' treatment.

1. **Patient Safety**

Patient safety may be compromised by optometrists not having a full understanding of the complete range and complex nature of systemic and topical drugs, their interactions and side effects of the medications they wish to prescribe. Some of these side effects are potentially fatal. An example is a report of severe anaphylaxis and pulmonary oedema after one dose of oral acetazolamide (as proposed in an angle closure management protocol in the submission (Appendix D)[2], indeed acetazolamide is rarely used because of its toxicity.

A further example is that optometrists could not possibly be expected to know without medical training the symptoms, signs and terminology surrounding various types of heart-block – administering a beta blocker such as timolol (which is in all fixed-combination glaucoma drops) could hospitalize or kill the patient via a cardiac arrest. Optometrists see very few patients in their undergraduate training, and even fewer serious pathological cases. They have no training in medicine and cannot be expected to detect the subtle differences and clinical manifestations of atypical glaucoma cases which can turn out to be brain tumors, giant cell arteritis or other optic neuropathies associated with autoimmune diseases, which all require urgent and very different treatment. Therefore all glaucoma patients must be reviewed by an ophthalmologist at some stage, who will have experienced clinical training involving thousands of patient consults.

To further define the differences in training between an ophthalmologist and an optometrist, one only needs to investigate the disparity in supervised clinical training an optometrist may receive by undertaking a Graduate Certificate in Therapeutics compared to the number of hours of clinical training an ophthalmologist will need to undertake to be accredited to practice. 50 hours of clinical supervised training are required by both the University of New South Wales and the University of Melbourne to complete the Graduate Certificate of Therapeutics[3]. An ophthalmologist currently acquires 12,000 hours of clinical training based around pathology and the treatment of eye disease before being authorized to responsibly initiate treatments for patients[4]. In addition, accumulated

clinical hours for prevocational training (as an undergraduate or postgraduate medical student[4], internship and as a Resident Medical Officer) exceed 10,000 hours.

The significant difference in clinical training experience between an ophthalmologist and an optometrist suggests that the complexity arising from potential glaucoma cases may be beyond the realm of an optometrist who has recently been awarded a Graduate certificate in Therapeutics.

2. The Potential for Unnecessary Treatment

All the current modalities used by optometrists to diagnose glaucoma have high false positive rates. Visual fields are notorious for false diagnosis. The specificity of Humphrey SITA has been reported at only 38% at first test and 73.7% after two tests[5]. HRT of the optic nerve head in an over 50s Australian population resulted in a false positive glaucoma detection rate of 30%[6]. Even expert graders could not agree on results from imaging modalities used to diagnose glaucoma such as OCT (specificity 68% to 81%) and HRT (specificity 68-80%)[7]. The recent experiment by the Guide Dogs to fund free imaging screening at UNSW Optometry has led to a large number of false positive patient referrals to ophthalmologists as the referring optometrists have not known how to interpret the results and cannot ignore a positive test result. These patients experience real and unnecessary anxiety until they are reassured the tests were falsely positive.

Non-contact tonometry (NCT) which is widely used by optometrists yields large numbers of ocular hypertension patient (OHT) referrals that turn out to have normal IOPs when measured by the ophthalmologist with Goldmann applanation tonometers (GAT). A study of non-contact tonometers evaluated against a calibrated GAT exhibited mean errors of 0.5 to 2.9 mm Hg[8]. The NCT significantly underestimates GAT measurements at lower IOP and overestimates these at higher IOP[9, 10]. While in thicker corneas, non-contact tonometry systematically yields significantly higher readings than GAT[10] Therefore the error rates and the higher variability between tests makes NCT unsuitable for glaucoma diagnosis and monitoring, particularly in those with thicker corneas; the values are not inter-changeable with IOP measured by ophthalmologists.

It is absolutely contrary to our gold standards of practice to suggest that optometrists could “manage” glaucoma without the use of GAT; corneal thickness must be considered as well before a diagnosis is made. No mention is made of this in the current submission.

Based on the recent experience of referral-refinement schemes for screening glaucoma in the United Kingdom, the majority of referrals for glaucoma suspicion from the non-expert trained optometrist was raised IOP (>21mmHg) measured by NCT with no consideration of corneal thickness, a known confounding factor (see above). Referral from expert trained optometrists utilising GAT, usually under the supervision of an ophthalmologist, resulted in identification of a false positive rate of approximately 50%[11, 12, 13].

Identification of acute angle closure events is included in the submission but no mention is made of angle closure suspects. The absence of any further explanation implies a lack of an understanding of what constitutes an angle closure suspect and the ramifications of such a gap in knowledge could be dangerous. Even optometrists expertly trained and supervised to identify patients at risk of angle closure on the basis of Van Herrick grading strike trouble as they did not acquire the necessary

gonioscopy skills. In an optometry based community screening scheme, for an occludable anterior chamber angle (Van Herick grading versus gonioscopy), sensitivity, specificity, and negative predictive values were 69, 88, and 94%, respectively[12].

These studies indicate that an optometrist is highly likely to falsely identify a high number of glaucoma suspects with a false positive rate of at least 50%. If optometrists were also allowed to initiate treatment, the costs to the Australian health system from glaucoma medications would likely double: from the current $100 million per annum (2005 figures)[14]. If optometrists were able to dispense these medications from their practices there would be a clear financial conflict of interest with an incentive to treat all positive results, independent of ophthalmological opinion. Patients would be unnecessarily exposed to medications they may not need; the side effect profile of glaucoma medications is not trivial and in the case of some, potentially life threatening[14].

The rate of progression of glaucoma is highly variable and difficult to predict. The decision to initiate treatment is not something which should be done lightly, both because of the potential morbidity and because many patients will not suffer significant visual loss in their lifetime. While there is a subset of patients who require aggressive intervention, there are many who do not. It requires considerable skill to differentiate between these groups[15]. Even glaucoma specialist ophthalmologists cannot always be certain on the basis of an initial assessment whose disease is going to progress and at what speed over time[16].

In the current proposal:

i. There would be financial incentive for optometrists to investigate for glaucoma and then to initiate treatment (including provision of drugs) without consultation with or over-sight from ophthalmologists;

ii. There would be incentive for optometrists to do this indefinitely;

iii. There are no clear criteria when to refer a patient to an ophthalmologist. This is contrary to all principles associated with the model for collaborative care developed over the years between ophthalmologists and optometrists.

iv. As it is outside the purview of optometrists to offer the full range of medical, laser and surgical treatments for glaucoma, this limits treatment options available for the patient, at the risk of irreversible vision loss.

v. Coupled with the difficulty to identify patients at risk of disease progression, particularly fast progression, general optometrists mostly would be over-treating ‘suspect’ patients and even more worryingly under-treating others.

vi. Patients would be denied access to ophthalmologists who are capable of offering more definitive management.

Bacterial conjunctivitis and keratitis - use of fluoro-quinolone eye drops

In an effort to slow the development of bacterial resistance, restrictions on the use of fluoro-quinolones in humans and animals were introduced in Australia in the 1990s. We now benefit from a remarkably low rate of resistance to these agents for a range of pathogens. Ophthalmologists have played an important role in this success by agreeing to restrict the use of ofloxacin and ciprofloxacin eye drops to the treatment of bacterial infections of the cornea. We believe that the broadening of unsupervised prescribing rights to a non-medical group will encourage both the empiric use of quinolones before appropriate specimens are taken and their increased use for less threatening conditions such as blepharitis, conjunctivitis and dacryocystitis. Other antibiotics can and should be used for infections of the ocular adnexae; quinolones are best reserved for a medical emergency such as bacterial keratitis.

We believe that medical supervision of the use of quinolone eye drops is important. As well as the benefits to individual patients, the current policy has proved successful in minimising inappropriate prescribing and thus lowering the risk of the development of resistance to these valuable drugs[16].

In our experience, microbial keratitis (corneal infection) and conjunctivitis are currently managed well and patients both rural and city based are typically able to be seen urgently by ophthalmologists. Review by an ophthalmologist allows a corneal scrape to be performed which has the benefits of

i. Providing important epidemiological data on the microbes responsible for microbial keratitis and their sensitivity/resistance patterns. This assists the selection of the most appropriate therapy.

ii. Allowing use of anti-microbial therapy, as once the sensitivities of the micro-organism (or micro-organisms as 10% of cases are polymicrobial) is/are known allows therapy to be targeted and rationalised. This has savings in terms of medication and socioeconomic costs, as intensive drug regimes for these conditions often prevent patients from returning to work or their role as carers

iii. Earlier diagnosis of non-bacterial keratitis, as non-bacterial conditions will be identified on a scrape by culture and/or PCR. This is important as clinical studies have shown that it is not possible to differentiate between the causes of microbial keratitis (bacterial vs. viral vs. fungal vs. acanthamoeba) based on clinical examination alone, and late diagnosis of fungal, viral and acanthamoeba keratitis are associated with a poorer prognosis[17].

iv. The current world-wide standard of care for patients with microbial keratitis can also involve ancillary testing (PCR, confocal, microscopy), due to the difficulties in distinguishing the causes clinically. The results of such tests require medical training for accurate and meaningful interpretation. These tests are not available to optometrists and cannot be adequately interpreted without appropriate training.

v. Further once topical antibiotic therapy has been commenced the ability to obtain positive corneal scrape results is significantly reduced. In such cases, a surgical procedure (corneal biopsy) is needed with associated costs and permanent corneal scarring.

Review of data from other countries on resistance patterns of organisms responsible for microbial keratitis, for example psuedomonas, shows that countries where fluoro-quinolones are more freely available such as the United States and India have high rates of resistance to early generations of these drugs. Unrestricted use of topical fluoro-quinolones as prophylaxis after intra vitreal injections has led to substantially increased rates of resistance among the conjunctival flora[18]. Repeated use of topical fluoro-quinolones may have a detrimental effect on eye health.

Treatment of microbial keratitis, in these countries therefore requires later generation fluoro-quinolones, which are more expensive and not currently commercially available in Australia. Similarly for endophthalmitis (devastating ocular infection that may follow intra-ocular, surgery or trauma), chloramphenicol is currently used as a prophylactic antibiotic in most cases in Australia and the United Kingdom. Resistance patterns in countries such as the United States, where fluoro-quinolones are freely available dictate that later (more expensive) generations of fluoro-quinolones are routinely given after cataract surgery. This has implications for health costs, as cataract surgery is the most frequently performed surgical procedure. Recent laboratory work has clearly demonstrated that recent topical fluoro-quinolone use is significantly associated with resistance in staph aureus isolates from ocular cultures[19, 20].

Patients who suffer from microbial keratitis are typically either patients who have suffered ocular trauma, contact lens wearers or patients with ocular surface disease[21]. It is uncommon for infection to occur in otherwise a normal eye. Management of microbial keratitis also involves the concomitant management of trauma and ocular surface disease. Optometrists are not adequately trained in the management of ocular trauma and complex ocular surface disease. Further, topical fluoro-quinolones contain the preservative benzalkonium chloride. This preservative has been shown, in clinical and laboratory studies to be an important cause of ocular surface toxicity[22]. In patients with ocular surface disease, such toxicity leads to non-healing ulcers, corneal scarring with loss of vision and even corneal melting with the risk of perforation.

The availability of fluoro-quinolones to optometrists has risks for patient safety:

i. Delay in appropriate treatment

Gram-negative infections account for only 20% of cases of infection in contact lens wearers and 6% of trauma. Further, 1 in 10 cases of microbial keratitis are polymicrobial, such that fluoro-quinolone monotherapy in these patients is inadequate[23]. For example, MRSA is being increasingly recognised as a cause of microbial keratitis. Fluoro-quinolones have poorer coverage of such gram-positive organisms such that management requires fortified vancomycin for MRSA or fortified cephalothin for other gram-positive organisms. Inappropriate management of microbial keratitis can result in cavernous sinus thrombosis due to retrograde spread of organisms from the eye to the brain, this has a significant mortality rate

ii. Side-effects of therapy

Side-effects of fluoro-quinolone include corneal melting and deposits. Such side-effects can lead to irreversible loss of vision for the patient and corneal melting has the risk of perforation with subsequent loss of the eye.

Fluoro-quinolones have been known to potentiate the anti-coagulant warfarin and therefore result in haemorrhage especially gastro-intestinal which can be catastrophic.

Topical fluoro-quinolone use may also produce allergy or even anaphylaxis.

iii. Over-treatment

There are many non-microbial causes of keratitis and conjunctivitis. Inadequately trained optometrists (limited/no time in clinics managing patients) would mean that many cases would be over-treated. This has implications in terms of costs to the patient, healthcare budget and exposure of patients to potential risks of therapy.

Concluding Remarks

In conclusion, true ocular emergencies are rare and often require surgical or laser intervention which are outside the purview of optometry. In such emergencies it is the responsibility of the nearest ophthalmologist or hospital to care for that patient in a timely fashion. Provided the involved optometrist recognises the nature of the emergency and communicates clinical findings appropriately, this can be provided in all but the most remote of settings. Most other perceived corneal and glaucoma emergencies are not true surgical emergencies, but rather identification of a problem that requires urgent consultation with an ophthalmologist. They do not require 'on the spot' treatment.

Optometrists do not have comprehensive medical training. The additional "therapeutic training" received by accredited optometrists which amounts to only a few hours spent in the office of a colleague, cannot be compared to the significant education received by ophthalmologists, who are medically qualified specialists. Despite the fact that optometrists are authorised to prescribe topical glaucoma medications, initiating and diagnosing such conditions should remain strictly within the realm of the medical field. The diagnosis and management of glaucoma requires training that has trainee ophthalmologists seeing a significant number of patients under clinical supervision. Whilst the consultation paper denotes that the newly trained optometrists "are at a level of competence to engage in independent decision making in diagnosis and management," one cannot acquire such adequate skill level until one undertakes thorough experience under clinical supervision. The academic study prescribed within the optometry curriculum cannot be equated with the minimum of 14 years of medical training required to become an ophthalmologist. The vast difference in knowledge levels adversely affects the manner in which glaucoma patients may be treated in the future under these proposed amendments.

The consultation paper is fraught with the danger of patient harm and inappropriate utilization of limited financial and human resources. We strongly oppose unsupervised use of fluoro-quinolones by optometry. Regrettably, the consultation paper also represents a deviation of practice from the ***Guidelines for the Screening, Prognosis, Diagnosis, Management and Prevention of Glaucoma*** published by the National Health and Medical Research Council (NHRMC). The document was only recently published in 2010 and was composed by leaders from all interest groups, defining the roles of optometrist and ophthalmologist, and clearly assigning approval of

ongoing medical management decisions to the realm of the ophthalmologist. The changes endorsed by the Optometry Board of Australia are clearly in contravention to this carefully performed national study.

Acknowledging that both professions seek to minimize visual disability from the glaucomas more dialogue will be required on how best optometry and ophthalmology could continue to collaborate within our health system to improve quality glaucoma detection and management throughout Australia. Any amendments to the current status could be made after consensus had been reached, based on evidence, thus minimizing potential harm for patients as well as inappropriate use of limited health care resources.

Kind regards

Stephen Best
RANZCO President

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< http://handbook.unimelb.edu.au/view/2012/OPTO90012 >
< http://www.handbook.unsw.edu.au/postgraduate/courses/2013/OPTM7117.html >

4: An ophthalmology trainee undertakes 30 hours of clinical training a week for 48 weeks a year for a total of 5 years before becoming an ophthalmologist.
Clinical training hours = (30 hours) x (48 weeks) x (5 years) = 12,000 hours of clinical training

Undergraduate Student = [(12 days of clinical training in the first two years) x 8 hours] + [(50 hours of clinical training) x (18 weeks) x (2 semesters) x (4 years)
Undergraduate Student = 7392 hours of clinical training

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