



Europe Economics

Health Risk Assessment of Illegal Optical Practice

Final report for the
General Optical Council

27 August 2013

Europe Economics
Chancery House
53-64 Chancery Lane
London WC2A 1QU

Tel: (+44) (0) 20 7831 4717
Fax: (+44) (0) 20 7831 4515

www.europe-economics.com



Europe Economics is registered in England No. 3477100. Registered offices at Chancery House, 53-64 Chancery Lane, London WC2A 1QU. Whilst every effort has been made to ensure the accuracy of the information/material contained in this report, Europe Economics assumes no responsibility for and gives no guarantees, undertakings or warranties concerning the accuracy, completeness or up to date nature of the information/analysis provided in the report and does not accept any liability whatsoever arising from any errors or omissions © Europe Economics. All rights reserved. Except for the quotation of short passages for the purpose of criticism or review, no part may be used or reproduced without permission.

Contents

1	Introduction.....	1
	Summary of Offences.....	1
	Structure of Report.....	2
2	Research Methodology.....	3
	Information Gathering Tools.....	3
	Analytical Tools.....	3
	Terminology.....	4
3	Risks in Legal Optical Practice.....	5
	Introduction.....	5
	Sight Tests.....	5
	Spectacle Dispensing.....	13
	Contact Lens Wear.....	16
	Contact Lens Fitting.....	19
	Contact Lens Supply.....	21
	Summary.....	23
4	Typology of Illegal Practice.....	27
	Introduction.....	27
	The Aim of this Typology.....	27
	Typology of Illegal Practice.....	30
5	Risks in Illegal Practice.....	35
	Introduction.....	35
	Unlawfully Conducting Sight Tests.....	35
	Unlawfully Supplying Spectacles.....	37
	Unlawfully Fitting Contact Lenses.....	38
	Unlawfully Supplying Prescription Contact Lenses.....	39
	Unlawfully Supplying Zero-powered Contact Lenses.....	41
	Misuse of Protected Title.....	45
6	Comparative Analysis.....	48
	Comparative Analysis of Legal and Illegal Practice.....	48
	Summary of Contextual Factors.....	55
	Areas of Insufficient Information.....	55
	Recommendations on the Most Risky Practice Areas.....	56
7	Appendix 1: Data Analysis.....	59
	Fitness to Practise Hearings.....	59
	Complaints Data.....	60
8	Appendix 2: Clinical Risks from 2010 Risk Assessment.....	64

References 67

1 Introduction

- I.1 The General Optical Council (GOC) wishes to understand the harm suffered by patients using optical services. This presents Europe Economics' final health risk assessment for illegal optical practice, based upon our review of existing research and other data.
- I.2 This work covers illegal optical practice that breaches the requirements of the Sale of Optical Appliances Order of Council 1984 and the Opticians Act 1989 (as amended), as well as legal practice that complies with these and other statutory requirements.
- I.3 Our work has gathered information from a wide range of sources in order to identify:
- The areas of legal practice with the greatest likelihood of an adverse event.
 - The areas of legal practice where an adverse event will cause the most serious harm.
 - The areas of illegal practice with the greatest likelihood of an adverse event.
 - The areas of illegal practice where an adverse event will cause the most serious harm.
 - The contextual factors that could mitigate or aggravate the risks.
- I.4 Our information is drawn from published evidence wherever possible, compiled through a comprehensive review of peer-reviewed articles from medical journals. Additional information has been obtained from interviews with and questionnaires addressed to a wide range of professional optical bodies, and analysis of data held by the GOC. The robustness of non-academic information can vary, and this is discussed throughout the report as and where relevant. The purpose of the work is to provide a *technical* analysis of the potential health and safety *risks* posed by different types of illegal practice. We have not therefore included feedback from patient or consumer groups. As it is, the risks associated with illegal practice are difficult to identify even by medical experts. We understand that the GOC will obtain input from public interest and patient groups in further developing its strategy for dealing with illegal practice.
- I.5 For this study we have also drawn on the knowledge of our external advisor Dr Bruce Evans¹ and his long experience in the optometry profession (from a practitioner, academic and legal witness perspective).
- I.6 Based on the information gathered, we make recommendations on the practice areas (whether legal or illegal) that carry the greatest risk to public health and safety. We also identify the areas where there is insufficient information to assess the risk.

Summary of Offences

- I.7 The Sale of Optical Appliances Order of Council 1984 and the Opticians Act 1989 (as amended) set out a number of legal requirements, the breach of which could amount to a criminal offence. The offences relate to restricted functions and protected titles. The main offences which are the subject of this study are listed below:

¹ Professor Bruce JW Evans BSc, PhD, FCOptom, DipCLP, DipOrth, FAAO, FBCLA is Director of Research at the Institute of Optometry and a Visiting Professor to City University and the London South Bank University. He was awarded Fellowship of the British Contact Lens Association in 2006. He has authored over 200 scientific and professional papers, five books on binocular vision and two on dyslexia and vision, and has given more than 250 invited lectures.

- Unlawfully conducting sight tests.
 - Unlawfully supplying spectacles.
 - Unlawfully fitting contact lenses.
 - Unlawfully supplying prescription contact lenses.
 - Unlawfully supplying zero-powered contact lenses.
 - Misuse of protected title.
- I.8 Our research into illegal practice covers all of these areas, whilst our work on legal practice includes these and other areas of optical practice.

Structure of Report

- I.9 Our report is set out in the following way:
- Chapter 2 describes our research methodology and defines the key terms used in our work.
 - Chapter 3 presents the evidence relating to the severity and likelihood of adverse events in legal optical practice.
 - Chapter 4 presents our typology of illegal practice and describes the framework we have used to assess the risks in illegal practice.
 - Chapter 5 presents the evidence relating to the severity and likelihood of adverse events in illegal optical practice, and the results of our analysis where direct evidence is lacking.
 - Chapter 6 presents our comparative analysis of the severity and likelihood of adverse events in legal and illegal practice; our recommendations on the areas that pose the greatest risk to public health; and our suggestions for areas of further research where information is insufficient to assess the risks.
 - The Appendices contain the results of our data analysis and a summary of the clinical risks extracted from our 2010 study.

2 Research Methodology

Information Gathering Tools

- 2.1 We gathered evidence on both the severity and likelihood of adverse events in legal and illegal optical practice from a range of sources:
- Literature review of peer-reviewed articles gathered from medical journals and databases. Relevant articles were identified by our advisor through a comprehensive key word search, as well as through our interaction with stakeholders and research into optical practice in other jurisdictions. Our literature review included an update of our 2010 report on risks in optical practice to ensure that any changes in circumstances since that date were accounted for.²
 - Discussions with and questionnaires to professional bodies, educational bodies and industry associations (BCLA, ACLM, FMO, AOP, FODO, and OCCS).³
 - Discussions with the GOC's illegal practice team.
 - Data analysis of the GOC's Fitness to Practise (FtP) data and illegal practice complaints data. We note that complaints data do not necessarily reflect the accurate likelihood of illegal practice or the risks associated with it, as complaints can be driven by a number of other factors, such as the ease of identifying the illegal practice and the perceived importance of the illegal practice among the public and the profession. FtP data are more robust in this regard, as they are based on cases that are deemed serious enough to warrant a full investigation. However, these data may still not fully represent the whole optical profession. Further, FtP data relate largely to *legal* practitioners who fall within the GOC's existing remit. For this reason, as explained later, our final analysis does not place material weight on complaints data.
- 2.2 As far as possible, we have based our analysis on published evidence. Where this is insufficient we use information gathered from our expert advisor and also from professional and industry bodies. We describe where stakeholders agree — or indeed disagree — on particular issues.

Analytical Tools

- 2.3 The evidence gathered forms the basis of our analysis of the severity and likelihood of adverse events in legal optical practice: the majority of available evidence relates only to areas of legal practice.
- 2.4 A smaller part of the evidence base relates directly to illegal practice. Therefore in order to analyse the severity and likelihood of adverse events across all areas of illegal practice we developed a typology of illegal practice — drawing upon discussions with our advisor, and the professional and industry bodies, — about the risks associated with each area of illegal practice, the underlying drivers of these risks, and the factors affecting the likelihood of adverse events occurring as a result of illegal practice. We then used this framework, together with the evidence on risks in legal practice, to assess the potential severity and likelihood of risks associated with illegal practice. This means that in some areas our analysis focuses on *potential* rather than *actual* risks. Given the

² Europe Economics (2010) 'Risks in the optical profession', prepared for the GOC http://www.optical.org/goc/filemanager/root/site_assets/revalidation/revalidation_-_risk_report.pdf.

³ Contact lens manufacturers were also approached to contribute to the work but no response was received.

limited evidence, we believe that this approach can provide a valuable steer to the GOC in terms of the areas of illegal practice likely to pose the greatest risk to public health.

Terminology

2.5 To aid the reader we define certain key terms used in this report below:

- Registered/unregistered practitioner. The terms ‘optometrist’ and ‘dispensing optician’ are protected titles and cannot be used to refer to unregistered practitioners. We therefore use the generic terms “registered practitioner” to refer to optometrists and dispensing opticians, and “unregistered practitioner” to refer to practitioners operating illegally throughout the report. In some cases we refer specifically to ‘optometrist’ or ‘dispensing optician’ — this always implies that the practitioner is registered. Where the reference applies to *any* practitioner (e.g. either registered or unregistered) we simply use the term “practitioner”.
- Adverse events. We define an ‘adverse event’ to be the harm from a clinical complication (e.g. development of a disease; infection) that is influenced by the practitioner. For example, an adverse event could be:
 - The development of an eye disease resulting from a practitioner missing the signs and failing to treat it.
 - An infection from contact lens use resulting from the insufficient provision of advice on recommended wear and hygiene.
 - An infection resulting from a contact lens that has been poorly fitted by a practitioner.

2.6 The exception here is an ‘adverse event’ directly resulting from the misuse of protected title, which does not imply a clinical complication.

3 Risks in Legal Optical Practice

Introduction

- 3.1 In this chapter we present the findings from our research into the risks in legal optical practice. As per the Research Specifications, this is to identify:
- the areas of legal practice where an adverse event will cause the most serious harm, and
 - the areas of legal practice with the greatest likelihood of an adverse event.
- 3.2 This provides the evidence base against which we will later compare the risks in illegal practice. Our research covers both the areas of optical practice relevant to illegal practice identified in the ITT as well as practice areas not directly related to illegal practice, e.g. practice areas that do not include restricted functions.
- 3.3 The areas of legal practice included are:
- Sight tests, including testing sight, and diagnosing and managing eye conditions.
 - Spectacle dispensing, including dispensing to adults and children, and dispensing spectacles with certain lens types.
 - Contact lens fitting.
 - Contact lens supply, including the supply of prescription and zero-powered lenses, and online supply.
- 3.4 We discuss the evidence on each of these areas of legal practice according to:
- The severity of the potential harm caused by an adverse event (specifically here the underlying clinical harm).
 - The likelihood of an adverse event occurring as a result of registered practitioner action.
 - The contextual factors that could mitigate or aggravate the risks, where relevant.
- 3.5 Our discussion focusses on the risks of optical *practice*, i.e. those areas influenced in some way by registered practitioner behaviour. There is a distinction between clinical risk (e.g. the risk of a patient developing glaucoma; or the risk of infection through contact lens wear), and those risks associated with optical practice (e.g. the diagnosis and management of diseases; or the steps taken to control infection from contact lenses). Of course, clinical and practical risks are linked, and poor practice will exacerbate clinical risks in the same way as good practice may mitigate them. Understanding clinical risks is also important in understanding the harm caused by an adverse practice event.
- 3.6 As discussed in Chapter 2, an adverse event refers to the clinical harm arising from registered practitioner action. For example, the clinical harm involved if a registered practitioner misdiagnoses a disease.

Sight Tests

- 3.7 Testing sight is a function restricted to registered optometrists and registered medical practitioners, with special provision for students. There are three main areas of practitioner risk associated with sight tests, namely:

- misdiagnosis and mismanagement of optical diseases and conditions;
- incorrect prescriptions; and
- trauma from incorrectly used equipment.

Misdiagnosis and mismanagement of optical diseases and conditions

3.8 Optometrists and medical practitioners who conduct sight tests have an obligation to detect injury, disease or abnormalities within the eye.⁴

Severity of harm

3.9 The clinical risks associated with such diseases and conditions are summarised below. Our research indicates that these have not changed since our 2010 report and more detail can be found there.^{5,6} We do incorporate additional information from our recent research where relevant.

- Glaucoma. This refers to a group of eye diseases that damage the optic nerve, and are often associated with raised pressure within the eye. Damage to the optic nerve is irreversible, and can even result in blindness, but can be halted and the disease treated through medication or surgery. Diagnosis and the referral of glaucoma have been shown to be more accurate when inter-ocular pressure (IOP) measurement, visual field testing and optic disc assessment are all performed.⁷ To further increase the predictive value of referrals, it has also been recommended that IOP measurements and visual fields should be repeated. Early detection of the disease is essential.⁸
- Retinal detachment. Retinal detachment is a rare but sight-threatening event which occurs when the retina becomes separated from the underlying tissue.⁹ This can result in loss of sight or blindness. Flashing lights, showers of dark spots called floaters, a visual field defect and loss of vision (often in the form of a shadow or curtain spreading across the vision of one eye) are the four most common presenting symptoms relating to a retinal break or retinal detachment.¹⁰ Key factors of retinal detachment can be elucidated by the optometrist taking careful patient history and symptoms (for example to identify any subjective field defects), and by looking for signs during the examination.
- Diabetic eye conditions. The most damaging diabetic eye condition is diabetic retinopathy, where the fine network of blood vessels in the retina leak fluid. Currently at least two per cent of the UK population is known to have diabetes, of whom 10-13 per cent have sight-threatening diabetic retinopathy.¹¹ Cataracts also develop earlier and progress more rapidly in

⁴ See the Opticians Act 26(1)(a).

⁵ Europe Economics (2010) 'Risks in the Optical Profession' A report for the General Optical Council.

⁶ We attach as an appendix the table from the 2010 work that summarises the clinical risks.

⁷ Bell RWD and O'Brien C (1997) 'Accuracy of referral to a glaucoma clinic' *Ophthalmic and Physiological Optics* Vol 17(1) p7-11 and Theodossiadis J and Murdoch I (1999) 'Positive predictive value of optometrist-initiated referrals for glaucoma' *Ophthalmic and Physiological Optics* Vol 19(1) p62-67.

⁸ Weinreb RN, Khaw PT (2004) 'Primary open-angle glaucoma', *Lancet*; 363(9422):1711-1720.

⁹ College of Optometrists (2009) 'Information for the Public: Detached Retina' http://www.college-optometrists.org/index.aspx/pcms/site.Public_Related_Links.Common_Eye_Diseases_and_Problems.Detached_Retina/

¹⁰ Tanner V, Harle D, Tan J, Foote B, Williamson T.H, and Chignell A.H (2000) 'Acute posterior vitreous detachments: the predictive value of vitreous pigment and symptomology' *British Journal of Ophthalmology* Vol 84, p1264-1268.

¹¹ Royal College of Ophthalmologists guidelines

<http://www.mrcophth.com/focus/Screening%20for%20Diabetic%20Retinopathy.htm>, accessed October 2009.

diabetics than in other people, and retinal vascular occlusions¹² and extraocular muscle palsy¹³ are also common in diabetics.¹⁴ Serious eye problems are less likely if the diabetes is well controlled or in its early stages, and most sight loss from diabetic eye disease can be prevented if detected early and treated. This requires vigilant monitoring and treatment of the eyes.

- Age-related macular degeneration (AMD). AMD is the leading cause of vision loss for people over the age of 50 in the Western world. Macular degeneration erodes central vision and can make it difficult or impossible to read or recognize faces, although enough peripheral vision remains to allow other activities of daily life. There are two types of AMD: the 'dry' form (more common, but less severe) and the 'wet' form (less common but significantly more severe, with rapid onset and a high risk of sight loss).¹⁵ There is currently no treatment for dry AMD but the wet form can be treated in several ways. Any treatment requires early detection and rapid treatment, and the consequences of missing the signs of the disease are serious. Research has linked AMD and associated visual impairment with falls and other injuries.¹⁶
- Brain tumours can be identified in a sight test, for example through ophthalmoscopy (which examines whether the optic disc at the back of the eye is swollen) or visual field testing. Other rare conditions that can be identified through eye examinations are eye cancer and cardiovascular diseases.

3.10 For the main eye diseases and complications described above, early detection and treatment are crucial to prevent severe and permanent damage to sight. Optometrists undergo a significant amount of training in disease detection and management. The skills required for this include recognising high-risk patients (where good patient communication skills are necessary to elicit detailed history), knowing what tests to conduct, conducting (or supervising) the tests correctly (including recommended repeats) and interpreting the results.

3.11 The key potential adverse event here relates to the failure by an optometrist to identify a particular disease or condition, or the misdiagnosis of one condition as something else. This could result in severe complications and the loss or damage of a patient's sight. In rarer cases, failure to identify a condition such as a brain tumour could lead to a loss of life.

Likelihood of an adverse event

3.12 Our 2010 report concluded that registered practitioner risks in these areas are relatively low, and again our recent research has not identified any articles that suggest otherwise. There are no studies that provide evidence of diseases being missed completely or mismanaged due to registered practitioner behaviour, or that provide any indication of this risk. The only real evidence of risk relates to failure to conduct all necessary tests recommended for the detection of conditions, or failure to identify patients from high-risk groups. For example:

- A study into the content of eye examinations of a patient at higher risk of glaucoma (in this case, of African descent) found that of the 100 optometrists visited by a standardised patient, only six per cent advised the patient of increased risk of open-angle glaucoma risk in those of

¹² Blockage in the blood vessels of the retina.

¹³ Paralysis of the extraocular muscles that control the movements of the eye.

¹⁴ Batterbury, M and Bowling, B (2002) 'Ophthalmology: An illustrated colour text' Churchill and Livingstone, London

¹⁵ See Chodpar A, Chakravarthy U and Verma D 'Clinical review: age-related macular degeneration' *BMJ* Vol 326, p485-8; and National Institute for Health and Clinical Excellence (2003) 'Macular degeneration (age-related) – photodynamic therapy', London.

¹⁶ Wood et al. (2011) 'Risk of falls, injurious falls, and other injuries resulting from visual impairment among older adults with age-related macular degeneration.' *Invest Ophthalmol Vis Sci* 2011; 52(8):5088-5092.

African descent; five per cent discussed the increased risk of glaucoma with age, and 40 per cent made no reference to family history influencing the risk of glaucoma.¹⁷ No single test can reliably detect glaucoma and the College of Optometrists (Guidelines Section D3.03) advises that the assessment of patients at risk of primary open angle glaucoma should include two tests (assessment of optic nerve head and tonometry) and may also include visual field assessment. This study found that 95 per cent of the examinations included the first two tests and 35 per cent included all three tests.¹⁸

- A clinical study into the content of eye examinations for a presbyopic patient with symptoms of flashing lights (a symptom of potential retinal tears) found mildly concerning results regarding the tests and history taking conducted by the optometrists. Only 35 per cent of optometrists asked four or more of the questions listed by experts as appropriate to identify the nature of the patient's presenting symptoms of flashing lights. Thirty-six per cent of optometrists in the study did not comply with College of Optometrists' guidance regarding the use of dilated fundoscopy as a test for patients with flashing lights. The authors also found it concerning that three of the 102 optometrists did not check the IOP using any method on a patient of this age group.¹⁹ Evidence gathered from stakeholders for our 2010 report suggests that retinal detachment, although a serious condition, is not a large area of registered practitioner risk. Once a detachment has occurred it is highly unlikely that it will be missed, and thus any risk is confined to the optometrist missing signs of a tear or break and a potential detachment. Given the difficulty in diagnosing small tears or breaks, stakeholders were of the opinion that not much more could be done to improve diagnosis.²⁰
- With regard to diabetic eye conditions, there is little evidence of even indirect registered practitioner risk. The fact that diabetics receive free eye tests and that optometrists are in most cases aware of their patient having the disease further reduces the likelihood of misdiagnosis. Screening diabetics for retinopathy is recommended, as the disease is frequently detected this way, although the provision of such services varies greatly across the UK.^{21,22} Expert opinion considers the actual diagnosis of diabetes not to be such an important task for optometrists nowadays, as GPs and nurses are fully equipped to diagnose the disease and a patient is generally more likely to see a GP/nurse than an optometrist. In consequence the effects of a missed diagnosis of diabetes by an optometrist are not likely to be serious.
- The diagnosis of wet AMD can be complicated by the difficulty in separating out more than one age-related condition, such as the relative shares of cataract and AMD in a patient's vision loss. In addition, 'dry' AMD can occur at the same time as 'wet', or even change into wet, further complicating diagnosis. However, our research did not identify any evidence of a lack of competence among optometrists in diagnosing and referring wet AMD. Research on AMD predominantly covers the effects of the disease and the link with falls and injuries.

¹⁷ Shah et al (2008) 'Glaucoma detection: the content of optometric eye examinations for a presbyopic patient of African racial descent' *British Journal of Ophthalmology*, published online 5 December 2008.

¹⁸ The risk of community optometrists under-diagnosing glaucoma is difficult to specify and until referral refinement schemes (Parkins and Edgar, 2011) are implemented nationwide it seems that most community optometrists react to diagnostic uncertainty by over-referral of glaucoma suspects (Shah and Murdoch, 2011).

¹⁹ Shah et al. (2009a) 'The content of optometric eye examinations for a presbyopic patient presenting with symptoms of flashing lights.' *Ophthalmic Physiol Opt* 2009; 29(2):105-126.

²⁰ Europe Economics 'Risks in the optical profession' page 22

²¹ Royal College of Ophthalmologists guidelines

<http://www.mrcophth.com/focus1/Screening%20for%20Diabetic%20Retinopathy.htm>, accessed October 2009.

²² Batterbury, M and Bowling, B (2002) 'Ophthalmology: An illustrated colour text' Churchill and Livingstone, London.

- 3.13 However, there is *some* evidence of registered practitioners missing diseases from the GOC's Fitness to Practise records and expert opinion. An analysis of GOC FtP hearings from between 2007 and 2012 found that of the hearings classified as deficient professional performance, 20 received a sanction (representing 13 per cent of all hearings). Of these, the underlying complaints included failure to conduct certain tests for glaucoma and retinal detachments, failure to conduct mandatory ophthalmoscopy, and lack of appropriate equipment for glaucoma testing. In one case the registered practitioner failed to identify a possible case of glaucoma. This represents a small proportion of all hearings, and an even smaller proportion of optometrists.²³ Our advisor for this study is aware of litigation cases (settled out of court) regarding the misdiagnosis of conditions such as glaucoma, retinal detachment and wet AMD, although there is no publically available evidence on the frequency of such cases. Typically in these cases the presentation of the disease is not straightforward and it is unclear whether the registered practitioner was incompetent or at fault. It is thought that the adverse events would have been less likely with a registered practitioner of higher levels of competence.
- 3.14 It is maintained by experts that registered practitioners take a cautious approach to the detection of diseases and are aware of their individual abilities. Uncertain cases are referred to senior colleagues or to hospitals. Indeed, expert opinion suggests that optometrists are more likely to over-refer cases to hospitals than under-refer. For example, studies have found that between 20 and 65 per cent of optometrist referrals for glaucoma are false positives (i.e. subsequently found not to have the disease).^{24,25} In our 2010 report we investigated whether over-referrals reflected a lack of knowledge among optometrists in terms of diagnosing glaucoma; this was found not to be the case.^{26,27}

Contextual factors

- 3.15 There is a significant amount of on-going training available through Continuing Education and Training (CET) to help optometrists keep up to date with the skills and techniques necessary to identify and treat diseases correctly. There is also guidance issued by professional and educational bodies, such as the College of Optometrists and the National Institute for Health and Clinical Excellence (NICE), and through peer-reviewed articles.²⁸ Local PCT guidance on referral guidelines is also a valuable source of information to improve the diagnosis and treatment of diseases and conditions, although the continuation of this under the new system of commissioning is unclear. Research into the effects of increased training of optometrists in diagnosing and managing glaucoma as part of the GOS contract in Scotland has found that additional training in glaucoma testing and

²³ Although, as discussed in Chapter 2, data held by the GOC is not fully representative, FtP hearings data provide a more accurate reflection of risk than complaints data. The former are based on cases deemed serious enough to warrant a full investigation, and are thus not influenced by public perceptions.

²⁴ Cited in Azuara-Blanco A, Burr J, Thomas R, MacLennan G and McPherson S (2007) 'The accuracy of accredited glaucoma optometrists in the diagnosis and treatment recommendation for glaucoma' *British Journal of Ophthalmology*, Vol 91, p1639-1643.

²⁵ Bowling B, Chen S and Salmon J (2005) 'Outcomes of referrals by community optometrists to a hospital glaucoma service' *British Journal of Ophthalmology*, Vol 89 p1102-1104.

²⁶ See Europe Economics 'Risks in the Optical Profession', Appendix I

²⁷ Pierscionek et al. (2009) 'Referrals to ophthalmology: optometric and general practice comparison', *Ophthal. Physiol. Opt.*, 2009 29: 32–40.

²⁸ For example, Weinreb RN, Khaw PT (2004) 'Primary open-angle glaucoma', *Lancet*; 363(9422):1711-1720; and Steele, C. (2010) 'Medical Management of Chronic Open-angle Glaucoma', *Optometry in Practice 2010*, Volume 11 Issue 3 111 – 122; and Hannan and Lotery (2008) 'Medical Management of Maculopathy', *Optometry in Practice*, Vol 9, 35–42.

diagnosis has positive results.²⁹ This implies that there is room within the current levels of training and qualification to improve glaucoma diagnosis.

- 3.16 In summary, the adverse event of an optometrist missing or misdiagnosing an optical disease or condition could have very serious consequences, including the permanent loss or damage of sight, and even death in extreme cases. Based on available evidence and expert opinion, the likelihood of such adverse events occurring in legal practice is, however, low. The most likely possible risk is failure by optometrists to conduct all necessary tests for the detection of conditions, which does not necessarily lead to conditions being missed or misdiagnosed. Further, the risks are mitigated by the availability of information and guidance on the diagnosis and management of diseases, including the requirement for registered optometrists to remain up to date through CET.
- 3.17 A contextual factor that may exacerbate the potential risks of adverse events is patient profiles. For example, given the aging population it is likely that optometrists will be faced with increasing numbers of glaucoma- or AMD-suspect patients, which could add to the risk of misdiagnosis.³⁰ Patients from certain groups are also at a higher risk of developing eye conditions and diseases.

Incorrect prescriptions

- 3.18 Another adverse event related to the testing of sight is failure on the part of the optometrist to test sight properly, leading to incorrect prescriptions for spectacles or contact lenses.

Severity of harm

- 3.19 This can result in spectacle non-tolerances which can have a range of consequences, depending on the extent of the non-tolerance and the patient type. The most common distinction is between adults and children. We note that spectacle intolerances can also arise from 'correct' prescriptions which are nevertheless not tolerated by the patient. Spectacles and contact lenses fulfil a prescription accurate within a small positive and negative range (i.e. within a set tolerance) but some patients may be particularly sensitive. Equally some mismatch between fitting and an aspect of actual patient usage may result in non-tolerance.
- Adults: Spectacle non-tolerances do not constitute a serious risk to adults but are not uncommon and can have unwanted consequences (headaches, blurred vision, etc. and — more trivially — the time and inconvenience of returning to the optometrist for adjustments). Expert opinion suggests that incorrect prescriptions that are not immediately noticeable by a patient could also slow down the process of changing focus, which could be problem when driving (no evidence in the literature was found to support this potential risk). There is some debate about the effects of non-tolerances. Some studies show that even small focal errors can have an impact for sensitive patients.³¹ Others suggest that patients can tolerate magnitudes of errors greater than those typically found in adverse reactions to optical prescriptions,³² and others that patients are not sensitive to small prescription changes.³³ One study found an increased rate of falls in older people who had their refractive error changed

²⁹ Azuara-Blanco A, Burr J, Thomas R, MacLennan G and McPherson S (2007) 'The accuracy of accredited glaucoma optometrists in the diagnosis and treatment recommendation for glaucoma' *British Journal of Ophthalmology*, Vol 91, p1639-1643; and Ang GS, Ng WS and Azuara-Blanco A (2009) 'The influence of the new general ophthalmic services (GOS) contract in optometrist referrals for glaucoma in Scotland.' *Eye* Vol 23, P351-355.

³⁰ Ang *et al* (2009).

³¹ Miller A.D, Kris M.J and Griffiths A.C (1997) 'Effect of small focal errors on vision' *Optometry and Vision Science* Vol 74, p521-526.

³² See Duke-Elder and Abrams 1970; Comas *et al.* 2007; Lovasik and Szymkiw 1985; Atchison *et al.* 2001 cited in Freeman and Evans (2009) *Ophthalmic and Physiological Optics* Vol 29, p1-11.

³³ Appleton C.B (1971) 'Ophthalmic prescription in half-diopter intervals' *Archives of Ophthalmology* Vol 86, p263-267.

versus a control group. Many of the refractive error changes were over 0.75D which led the authors to suggest that large prescription changes may increase the risk of falling. Another study therefore suggested prescribing large refractive error changes in stages (over two sets of glasses) to ensure adaptation is as easy as possible.³⁴ Expert opinion in our 2010 study suggested that the impact of the majority of non-tolerances is not significant or serious, and this remains the case. A key mitigating factor is that adults will generally notice and report if spectacles or contact lenses do not enable accurate vision. However, vulnerable adults (e.g. the elderly or those with learning difficulties) may be additionally at risk as they may be less able to identify, report or cope with spectacle non-tolerances.

- Children: Errors in prescriptions of spectacles and lenses can have long-lasting effects on children's vision and also affect other areas such as the absorption of information and learning development.³⁵ Errors are also likely to go unnoticed for longer than in adults. Various studies have highlighted the importance of correct spectacle prescriptions for the correction of sight defects such as amblyopia (lazy eye) and strabismus (squint) in children.^{36 37 38} There is conflicting opinion, however, regarding the scope for damage from prescription errors, with some experienced optometrists stating that, although the risk is greater in children than adults, it is still small.³⁹ There is no clear evidence in the literature (or provided by stakeholders) of incorrect prescriptions resulting in vision complications for children; most of the research relates more indirectly to the importance of corrective prescriptions.

Likelihood of an adverse event

- 3.20 There have been relatively few studies on the causes and effects of spectacle non-tolerances, and there is little information concerning the average rate of return of spectacles. The available evidence in the literature on the proportion of patients that returns to the optometrist or dispensing optician with a spectacle non-tolerance ranges from 1.6 per cent to 2.8 per cent.⁴⁰
- 3.21 A study into the causes of spectacle non-tolerances, in which 62 out of 3,091 eye examinations conducted at a large community optometric practice were non-tolerance examinations (2 per cent), classified the main reasons for the non-tolerances in five main categories.⁴¹ Prescription related errors accounted for 61 per cent of the non-tolerances (of which 17 per cent were adaptation problems, where the prescription was felt to be correct but the patient could not adapt to it).⁴² The study found that most of the non-tolerances could be resolved by small changes to the

³⁴ See Cummings *et al* 2007; and Harley *et al* 2007 cited in Freeman and Evans (2009) *Ophthalmic and Physiological Optics* Vol 29, p1-11.

³⁵ Powell C, Wedner S, Hatt SR (2009) 'Vision screening for correctable visual acuity deficits in school-age children and adolescents' The Cochrane Collaboration.

³⁶ For example, a common cause of squints and lazy eye in children is uncorrected long-sightedness. See Birch EE, Fawcett SL, Morale SE, Weakley DR, Jr., Wheaton DH (2005) 'Risk factors for accommodative esotropia among hypermetropic children, *Inest Ophthalmol Vis Sci*, 46(2) pages 526-529.

³⁷ Simons and Presland (1999) 'Natural history of amblyopia untreated owing to lack of compliance', *Br. J. Ophthalmol.* 83;582-587.

³⁸ Atkinson J, Braddick O, Robier B, Anker S, Ehrlich D, King J *et al* (1996) 'Two infant vision screening programmes: prediction and prevention of strabismus and amblyopia from photo- and videorefractive screening' *Eye (London)* 10 (Pt 2) pages 189 – 198.

³⁹ Based on stakeholder feedback from our 2010 risk assessment report.

⁴⁰ Freeman C, Evans BJW. 'Investigation of the causes of non-tolerance to optometric prescriptions for spectacles.' *Ophthal Physl Opt* 2010; 30(1):1-11.

⁴¹ Freeman C, Evans BJW. 'Investigation of the causes of non-tolerance to optometric prescriptions for spectacles.' *Ophthal Physl Opt* 2010; 30(1):1-11.

⁴² It must be noted that these 62 examinations concerned non-tolerances that could not first be addressed by the dispensing optician. It may be that in addition to trivial fitting problems more serious errors (such as an

prescription. This finding, and the low prevalence of non-tolerance examinations, implies this is a low risk area. Further, according to an academic expert (and one of the co-authors of a recent study of the subject) non-tolerance is largely due to the patient's adjustment to the glasses and, as such, is rather more an 'unavoidable event' than anything that could be addressed by changing optometrists' behaviour. That said, experience does tend to lead to a better 'fit' being prescribed, and a less experienced optometrist who goes solely on the facts (rather than judgement) may have more non-tolerances.⁴³ This is particularly relevant for patients who cannot adapt to a 'correct' prescription, whereby optometrists must use information other than the sight test results (for example, the reading distance required) to prescribe an appropriate fit.

- 3.22 With regard to incorrect prescriptions in children, our review of the literature, and stakeholder engagement (both for this study and for our 2010 report) found little evidence of clinical incompetence on the part of registered optometrists or dispensing opticians in the handling of children. None of the GOC's FtP hearings that resulted in a sanction (or any, for that matter) have concerned children, and available information on insurance claims from professional bodies does not highlight child management as an area of risk. Failure to detect or appropriately treat squints or binocular vision has also not been highlighted as common. However, it is agreed by professionals that child management can be difficult as detecting problems in children can be difficult if their age prevents them from adequately participating in tests.

Contextual factors

- 3.23 Relevant contextual factors that have been identified include that adults will generally detect incorrect prescriptions and have these corrected. (An exception may be vulnerable adults.) With regard to child management, it has been suggested by experts that optometrists will generally not take on a child management case unless this is an area with which they are comfortable. Optometrists and opticians managing children are therefore likely to have a higher degree of experience and additional competencies than other registered practitioners.⁴⁴ There is also continuing guidance and training on the management of child vision through peer reviewed articles⁴⁵ and CET.
- 3.24 In summary, the severity of harm caused by the adverse event of an incorrect prescription is unlikely to be serious in adults. The likelihood of spectacle non-tolerances is relatively low, and it is not clear the proportion of these that are directly attributable to the actions of the optometrist.
- 3.25 Expert opinion indicates that the potential harm caused by incorrect prescriptions in children is relatively more serious, as this can have lasting negative consequences for the development of vision. However, the likelihood of this adverse event occurring is unclear, and, based on the available evidence, likely to be relatively low, although higher than in adults.

Trauma from incorrectly used equipment

- 3.26 A final possible risk area in conducting sight tests is trauma from incorrectly used equipment.

inappropriate lens type) were dealt with by the optician, and therefore the results of the study are likely to underestimate the true prevalence of dispensing errors and data entry errors.

⁴³ View expressed by academic expert, practicing optometrists and professional organisations.

⁴⁴ See Europe Economics (2010) 'Risks in the optical profession', page 34 for more details.

⁴⁵ Leat, S. (2011) 'To prescribe or not to prescribe? Guidelines for spectacle prescribing in infants and children', *Clin Exp Optom* 2011; 94: 6: 514–527.

Severity of harm

- 3.27 This could include mechanical damage during an eye examination, most likely through tonometry (which applies the 'puff of air' to the patient's eye). Trauma during gonioscopy is also possible (where the device's lens is placed directly on the cornea) although very unlikely as very few optometrists carry out this procedure.
- 3.28 Trauma could also involve photo-damage from optical instruments, such as over-exposure to intense light during ophthalmoscopy or surgery.⁴⁶

Likelihood of an adverse event

- 3.29 Evidence on the possible risks of trauma is limited, and our literature review has not revealed any direct evidence of adverse events resulting from registered practitioners' actions in these areas. In terms of likelihood, again there is no clear evidence relating to this. With regard to potential risks resulting from over-exposure to intense light, this is more likely to occur during surgery and thus not directly related to optical practice (overhead surgical lamps produce a radiance that could be dangerous if endured for a long time). However, the cited article dates to 1980 and implies that major design changes would have subsequently occurred to extend the 'safe' time for use of overhead surgical lamps.

Contextual factors

- 3.30 There are no clear contextual factors that may mitigate or exacerbate the risks of trauma from incorrectly used equipment.

Spectacle Dispensing

- 3.31 The supply of spectacles must be conducted by or under the personal supervision of a registered medical practitioner, registered optometrist or registered dispensing optician if the user is under 16, or registered blind or partially sighted. For other users, there is an exemption from this requirement and there is no restriction on the supply of spectacles, although there are additional requirements for spectacles with certain prescriptions.
- 3.32 The main risks associated with spectacle dispensing are the use of incorrect lenses or prescriptions, or poorly fitted spectacles (spectacles must conform to the tolerances set out in the relevant British Standards).

Severity of harm

- 3.33 The harm arising from this adverse event will vary according to the patient and lens type.
- Adults. The risks related to incorrect spectacle dispensing for adults are similar to spectacle non-tolerances resulting from incorrect sight tests, as incorrect dispensing can include prescription errors (e.g. as a result of incorrect data entry). Expert opinion indicates that spectacles that do not fit properly can also result in non-tolerances and the associated effects (blurred vision, headaches, etc.).⁴⁷

Dispensing errors may be problematic to adults requiring bi- or multi-focal lenses. Our expert advisor is of the view that the positioning (fit) of multi-focal glasses is very important,

⁴⁶ See, for example, J. L. Calkins and B. F. Hochheimer. Retinal light exposure from ophthalmoscopes, slit lamps, and overhead surgical lamps. An analysis of potential hazards. *Invest Ophthalmol.Vis.Sci.* 19 (9):1009-1015, 1980.

⁴⁷ The literature also points to the effects of non-tolerances: see for example Freeman C, Evans BJW. 'Investigation of the causes of non-tolerance to optometric prescriptions for spectacles.' *Ophthal Physl Opt* 2010; 30(1):1-11.

as is the type of multi-focal lens used, and that in the training of optometrists and dispensing opticians great importance is placed on the fit. If the reading section of a multi-focal is positioned too high then this could lead to falls or to accidents whilst driving, if the reading segment of the lens encroaches on the distance vision part.⁴⁸ A correlation has been demonstrated between multi-focal lenses and falls in older people, although the studies focus on multi-focal lenses in general, rather than simply incorrectly fitted ones.^{49,50} (On the other hand, we have not identified any papers to support a link between poorly fitting multi-focal spectacles and driving accidents.) Research into the accuracy of dispensing progressive adjustment lenses (PALs), a type of multi-focal, suggests that small errors are unlikely to cause non-tolerances or have negative side effects.⁵¹

- Children. In addition to the importance of accurate prescriptions in correcting vision problems in children cited above, the fit of spectacles is also important to ensure that the greatest benefit is obtained from their wear. Although there does not appear to be direct evidence relating to risks associated with dispensing problems, our expert advisor and some professional bodies believe that if spectacles are poorly fitted then the child could look over them instead of through them, negating the beneficial effects of the corrective prescription and leaving the child at risk of developing conditions such as a squint or lazy eye (or, in certain circumstances, failing to correct these conditions). Accurate measurements are essential in ensuring the correct fit.

Likelihood of an adverse event

- 3.34 As noted already, the available evidence on the proportion of patients that returns to the optometrist or dispensing optician with a spectacle non-tolerance ranges from 1.6 per cent to 2.8 per cent.⁵² These data do not distinguish the cause of the non-tolerance (i.e. prescription errors resulting from incorrect sight tests, or dispensing errors). More relevant is the study into the causes of spectacles non-tolerances, which found that dispensing-related errors were the cause in 22 per cent of the 62 non-tolerance eye examinations conducted. Data entry errors were present in just under seven per cent of the non-tolerance examinations.⁵³ For both adult and child dispensing our research did not uncover much evidence on the likelihood of harm occurring as a result of dispensing errors.
- 3.35 Feedback from one professional body suggests that the likelihood of adverse events in child dispensing may be higher than otherwise indicated in our analysis, due to inadequate supervision practices of optical assistants who dispense to children. Similar evidence was not forthcoming from other stakeholders or the literature. This is, anyway, possibly more relevant to the discussion on illegal practice.

⁴⁸ This could also occur with bi-focals that consist of a reading lens within a plano segment, although in this case the reading segment is unlikely to be a very strong prescription and the risk of blurred vision resulting from an incorrect fit is lower.

⁴⁹ Haran et al. (2010) 'Effect on falls of providing single lens distance vision glasses to multifocal glasses wearers: VISIBLE randomised controlled trial.' *BMJ* 2010; 340:c2265.

⁵⁰ Lord SR, Smith ST, Menant JC (2010) 'Vision and falls in older people: risk factors and intervention strategies. *Clin Geriatric Med*; 26(4): 569-581.

⁵¹ Sullivan and Fowler (1989), 'Investigation of Progressive Addition lens patient tolerance to dispensing anomalies', *Ophthal. Physiol. Opt.*, Vol. 10, January 1990.

⁵² Freeman C, Evans BJW. 'Investigation of the causes of non-tolerance to optometric prescriptions for spectacles.' *Ophthal Physiol Opt* 2010; 30(1):1-11.

⁵³ Freeman C, Evans BJW. 'Investigation of the causes of non-tolerance to optometric prescriptions for spectacles.' *Ophthal Physiol Opt* 2010; 30(1):1-11.

- 3.36 It has also been indicated to us by optical professionals that problems may be more common — or at least harder to resolve — with the distance selling of spectacles. A distance supplier may not find all of the information needed to interpret a prescription properly, and it is possible that a prescription could be “technically correct but practically wrong” for the patient, resulting in non-tolerance. For example, working distance can be a key variable in getting the dispensed prescription right (e.g. reading a book versus reading a PC screen). This risk would be mitigated by the presence of suitably knowledgeable individuals who could effectively interact with customers remotely to obtain all necessary information. However, it is not a legal requirement to have a qualified optical professional present at the supply of spectacles, and such individuals may thus not always be present.

Contextual factors

- 3.37 The contextual factors are similar to those relevant to non-tolerances arising from incorrect prescriptions, namely that adults are likely to identify and report significant dispensing errors (although a possible exception may apply to vulnerable groups such as the elderly or those with learning difficulties), and that registered practitioners tend to undertake child management if this is a particular area of expertise. In particular with multi-focal lenses, patients should be able to identify an incorrect fit as soon as he or she looks up.
- 3.38 A new contextual factor is the online supply of spectacles. A US study reports that nearly half of prescription spectacles (both single and multi-focal) delivered directly by online vendors did not meet either the optical requirements of the patient's visual needs or the physical requirements for the patient's safety.⁵⁴ The study involved the twelve most visited websites as identified by the researchers. The authors conclude that as medical devices, spectacles carry a small risk to patients if the prescribed requirements are not met or glasses are manufactured incorrectly. The errors found in the orders were thought to be potentially problematic for patients, especially in cases of patients requiring multi-focal glasses (e.g. some errors involved single-vision lenses being provided rather than multi-focal ones). The problems cited by the authors are similar to previous descriptions of the effects of spectacle intolerances (headaches, blurred vision, etc.). No more serious risks were identified by the authors. Similar studies relating to the UK have not been found.
- 3.39 Expert opinion on the online supply of spectacles to children is that this can be problematic if full measurements are not available for the child, given the importance of the fit of spectacles described above. Online suppliers may well not have access to the inter-pupillary distance measurement (as this is not required to be on a prescription), and therefore remote supply is generally not considered in the best interests of the child, even if supervised by a registered optometrist or dispensing optician. Whilst remote supply may in some cases be in the best interests of the child (for example, if the spectacles break whilst on holiday then the optometrist can mail a replacement pair), this is unlikely to be the case if the supplier has never seen or measured the child.⁵⁵ These concerns reflect the opinion of optometrists experienced in the optical care of children and familiar with professional guidance on the subject. However explicit reference to these potential problems has not been found in literature.

⁵⁴ Citek et al. (2011) 'Safety and compliance of prescription spectacles ordered by the public via the Internet', *Optometry*, Vol. 82, 549-555.

⁵⁵ Information from the College of Optometrists.

Contact Lens Wear

- 3.40 This section adopts a different structure than for the other areas of optical practice in order to provide the necessary background information on the clinical risks associated with contact lens wear. Contact lens wear in itself is not an area of optical practice: subsequent to these opening explanations, the sections revert to the usual structure as these discuss the areas of optical practice of fitting and supplying contact lenses.
- 3.41 According to the Association of Contact Lens Manufacturers (ACLM) there are approximately 3.7 million contact lens wearers in the UK which represents 7.5 per cent of the adult population. There are a number of clinical risks associated with contact lens wear. Whilst these can be related to optical practice, they are not necessarily directly caused by it; indeed, good optical practice mitigates these risks. We therefore first present evidence on the clinical risks of contact lens wear, and then discuss how optical practice in terms of fitting and supply can exacerbate these risks (or fail to mitigate them sufficiently).

Clinical evidence

- 3.42 The main clinical risks associated with contact lens wear are infection (such as keratitis) and corneal ulcers.⁵⁶ There are around 1,200 new cases of contact lens-related microbial keratitis each year in the UK.⁵⁷ A health risk assessment on cosmetic contact lenses for Health Canada compiled evidence of adverse events associated with contact lens wear. It found that the approximate incidence of severe injuries amongst users of soft daily wear contact lenses ranged from 0.5 per cent to 1 per cent, and that the incidence of overall complications among the same population was approximately 10 per cent.⁵⁸
- 3.43 Additionally, there is a clinical risk associated with general contact lens wear derived from the reduced amount of oxygen that reaches the cornea. Among common infections caused by poorly-fitted contact lenses are conjunctivitis (pink eye), corneal abrasions and eye irritation.⁵⁹ The consequences of these conditions can be severe, and include permanent damage to or loss of sight. Acanthamoeba keratitis, possibly the most serious condition, is a rare but very painful and potentially blinding infection of the cornea. The infection rate is approximately one in 30,000 contact lens wearers, and in around 85 per cent of cases the condition is associated with contact lens use.
- 3.44 There are 1,200 new cases of keratitis each year among 3.7 million contact lens wearers in the UK, an incidence of 0.032 per cent.⁶⁰
- 3.45 Another study analysing emergency department visits by children (0 to 21 years of age) found that contact lens complications were the most common cause of cases (23 per cent). The most common diagnoses were corneal abrasions, haemorrhage and conjunctivitis. According to the

⁵⁶ Steinemann TL, Pinninti U, Szczotka LB, Eiferman RA, & Price FW, Jr. (2003). Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors. *Eye Contact Lens* 29, 196-200.

⁵⁷ NHS Trust News (2010) 'Expert warns 'lazy' contact lens wearers not to snub advice: Audit at Southampton General Hospital'

<http://www.uhs.nhs.uk/AboutTheTrust/Newsandpublications/Latestnews/2010/Expertwarnslazycontactlenswearersnottosnubadvice.aspx>

⁵⁸ Health Canada (2003) 'Human Health Risk Assessment of Cosmetic Contact Lenses', by Dillon Consulting Limited, Final Report, 30 September 2003.

⁵⁹ <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048900.pdf>.

⁶⁰ NHS Trust News (2010) 'Expert warns 'lazy' contact lens wearers not to snub advice' <http://www.uhs.nhs.uk/AboutTheTrust/Newsandpublications/Latestnews/2010/Expertwarnslazycontactlenswearersnottosnubadvice.aspx>.

- authors the majority of the complications were a consequence of altering recommended wearing and replacement schedules and non-compliance.⁶¹
- 3.46 The risk of infection and complications will vary according to patient profiles. Younger users are thought to be at higher risk. A recent patient audit at the eye unit in Southampton General Hospital showed that the number of infections was higher among the common lens-wearing ages of 20 to 40 year-olds. Experts at the hospital speculated that members of this age-group are possibly being “lazy” and not following professional advice.⁶²
- 3.47 The organisms that cause infection have been found in most environments including domestic tap water, chlorinated swimming pools, hot tubs and bottled water. Hygiene is therefore of utmost importance in preventing infection, and most cases of keratitis are preventable if contact lens wearers follow the instructions given to them by their registered contact lens practitioner.
- 3.48 There are a number of studies that directly link eye infections among contact lens wearers with poor patient hygiene and compliance with wear instructions, usually as a result of poor compliance with the registered practitioner’s instructions.^{63,64,65} Risk factors for infection in contact lens wearers are:
- The use of tap water during lens care (to rinse lenses or the storage cases)
 - Wearing lenses while swimming (without goggles), showering or in hot tubs
 - Use of ineffective lens care solutions
 - Failure to follow lens care instructions
- 3.49 It is also well established that overnight wear significantly increases the risk of corneal infection among soft contact lens wearers.^{66 67} Stapleton (2007) finds that overnight wear leads to 4.6 times more risk of infection.⁶⁸
- 3.50 Indeed, full compliance with hygiene and wear standards has been found to be rare among most lens users. Morgan et al (2011) evaluated compliance with contact lens use in 14 countries). This study recommended the importance of the role of practitioners in examining patients’ case cleaning, handwashing and contact lens rinsing at aftercare examinations, especially among young male wearers.⁶⁹ Other studies have also shown lack of compliance among contact lens wearers. For example, Michaud et al (2001) estimates that two-thirds of contact lens users do not conform

⁶¹ Wang et al. (2010) "Emergency Department Visits for Medical Device-Associated Adverse Events Among Children", *Pediatrics*, Vol. 126 No. 2, 1 August 2010, pp. 247 -259.

⁶² NHS Trust News (2010) 'Expert warns 'lazy' contact lens wearers not to snub advice' <http://www.uhs.nhs.uk/AboutTheTrust/Newsandpublications/Latestnews/2010/Expertwarnslazycontactlenswearersnottosnubadvice.aspx>.

⁶³ See Dart JKG, Stapleton F, Minassian D (1991) 'Contact lenses and other risk factors in microbial keratitis' *Lancet* Vol 338.

⁶⁴ Schein OD, Glynn RJ, Poggio EC, et al. (1989) 'The relative risk of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses' *New England Journal of Medicine* Vol 321.

⁶⁵ Dart JK, Radford CF, Minassian D, Verma S, & Stapleton F (2008). Risk factors for microbial keratitis with contemporary contact lenses: a case-control study. *Ophthalmology* 115, 1647-54, 1654.

⁶⁶ See Dart JKG, Stapleton F, Minassian D (1991) 'Contact lenses and other risk factors in microbial keratitis' *Lancet* Vol 338.

⁶⁷ Schein OD, Glynn RJ, Poggio EC, et al. (1989) 'The relative risk of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses' *New England Journal of Medicine* Vol 321.

⁶⁸ Stapleton et al. (2007) "The Epidemiology of Contact Lens Related Infiltrates", *Optometry and Vision Science*, Vol. 84, No. 4, April 2007.

⁶⁹ Morgan et al. (2011) 'An international analysis of contact lens compliance', *Contact Lens & Anterior Eye* 34, 223– 228.

to recommendations;⁷⁰ and Collins and Carney (1998) report that of the 100 consecutively presenting patients at two clinics in Australia, only 26 per cent were fully compliant with recommended care and maintenance procedures.⁷¹ Other studies show patients have imperfect compliance with instructions concerning wear time and replacement schedules,⁷² and cleaning and care guidelines.⁷³ Patients seen by ECPs can also be non-compliant in that they miss or delay follow-up consultations, with recorded delays of over one year.⁷⁴

- 3.51 The importance of contact lens hygiene is emphasised to both patients and registered practitioners by a number of optical bodies and associations, including the College of Optometrists, and in all related peer reviewed articles.
- 3.52 Studies also show that the use of daily disposable lenses is associated with a lower risk of infection.⁷⁵

PLs versus ZPLs

- 3.53 Much of the evidence on clinical risks associated with contact lens wear relates to powered, or corrective lenses (PLs), rather than cosmetic or zero-powered lenses (ZPLs). There is limited information about the size of the ZPL market compared to the PL market. A 2011 survey by YouGov indicates that one per cent of the UK population (aged 16+) wears contact lenses for cosmetic/fashion purposes, compared to 13 per cent of the population that wears them for sight correction.⁷⁶ This implies that ZPL wear is much less common than PL wear.⁷⁷ Given that the main underlying causes of risk are patient behaviour and compliance with wear and hygiene regimes, the type of clinical harm caused will be the same across PLs and ZPLs. (Our section on illegal optical practice discusses other factors that may make ZPL wear more risky). However, opinion of clinical experts and professional bodies suggests that ZPLs may pose a higher clinical risk as they are less likely to be made from the latest materials that maximise oxygen flow to the cornea, and may also contain dyes that could leak into the eye. Experts also maintain that ZPLs are typically produced and distributed on a 'one size fits all' basis, and not tailored in any way to the specific needs of wearers.⁷⁸ Experts have cautioned that these lenses will therefore not fit properly in some instances, thus increasing the risk of ocular complications.⁷⁹

⁷⁰ Michaud L, Quesnel N-M, Giasson C.J (2001) 'Avis D'Expertise – Les lentilles corneennes de puissance plano et leurs effets sur la santé oculaire', cited in Health Canada (2003) 'Human Health Risk Assessment of Cosmetic Contact Lenses', by Dillon Consulting Limited, Final Report, 30 September 2003.

⁷¹ Collins M.J and Carney L.G (1998) 'Patient compliance and its influence on contact lens wearing problems', *American Journal of Optometry and Physiological Optics*, Vol 63, 952 – 956.

⁷² Dumbleton KA, Woods CA, Jones LW, and Fonn D (2011) 'The relationship between compliance with lens replacement and contact lens-related problems in silicone hydrogel wearers', *Contact Lens Anterior Eye* 34, 216-222.

⁷³ Ky W, Scherick K, & Stenson S (1998). 'Clinical survey of lens care in contact lens patients', *CLAO J* 24, 216-219.

⁷⁴ Sauer et al. (2011).

⁷⁵ Morgan et al. (2011) 'An international analysis of contact lens compliance', *Contact Lens & Anterior Eye* 34, 223– 228; Stapleton et al. (2007) "The Epidemiology of Contact Lens Related Infiltrates", *Optometry and Vision Science*, Vol. 84, No. 4, April 2007.

⁷⁶ See YouGov and SixthSense 'Opticians' (2011).

⁷⁷ As users of ZPLs would tend to wear these far less frequently than users of PLs, it is likely that the market for PLs in revenue terms is significantly larger than the market for ZPLs.

⁷⁸ Fonn, D (2001) 'Re: Cosmetic contact lenses' Centre for Contact Lens Research expert opinion for the Canadian Association of Optometrists.

⁷⁹ Michaud L, Quesnel N-M, Giasson C.J (2001) 'Avis D'Expertise – Les lentilles corneennes de puissance plano et leurs effets sur la santé oculaire', cited in Health Canada (2003) 'Human Health Risk Assessment of Cosmetic Contact Lenses', by Dillon Consulting Limited, Final Report, 30 September 2003, and Fonn, D (2001) 'Re: Cosmetic contact lenses' Centre for Contact Lens Research expert opinion for the Canadian Association of Optometrists.

- 3.54 On the other hand, ZPLs are likely to be thinner (which facilitates oxygen flow to the eyes). A report conducted for a cosmetic lens manufacturer shows that there are no additional health concerns associated with the cosmetic lenses compared with powered lenses.⁸⁰ Feedback from some professional bodies also suggests that in general the clinical risks are similar across PLs and ZPLs.
- 3.55 ZPLs are linked to a higher rate of infection and complications. However, all the evidence we have reviewed shows that this is due to lower levels of compliance among ZPL wearers. For example, a French study analysed 256 patients with microbial keratitis in French Hospital eye clinics. Of these, 32 (12.5 per cent) were ZPL wearers. The ZPL wearers were younger and more recent wearers than the PL wearers.⁸¹ They had a greater risk of acanthamoeba infections than the other group. The ZPL-wearing group had a significantly greater risk of having no information about lens care or handling. (The reason why they had less information ties in directly with the illegal supply of ZPLs, and we discuss this in more detail in the section on illegal optical practice). Given that the market for ZPLs is significantly smaller than the market for PLs, despite the link to a higher rate of infection, it may be that the absolute number of complications is lower from ZPL wear than from PL wear.
- 3.56 In addition, Steinemann et al. (2003) describes contact lens wearing habits that are far below the usual recommendations for safe wear. Examples include sharing such cosmetic contact lenses with friends, purchasing ZPLs from unlicensed vendors, and even one case of a user getting the cosmetic lenses from the garbage. Also, a study reported a subject who wore disposable lenses continuously for up to five months at a time. Continuous overnight wear is also identified as a risk factor for bacterial keratitis. Cleaning habits described in the literature include wearing lenses repeatedly without cleaning them and using tap water instead of cleaning solution. Relatedly, Sauer et al. (2011) found that 64 per cent of patients seen with microbial keratitis caused by decorative lens use were unaware of the name of the cleaning solution they used, while this was only the case in 19 per cent of patients wearing corrective contact lenses.
- 3.57 The characteristics of ZPL wearers may be a significant influencing factor on the increased risk of infection, due to their generally lower levels of compliance. Opinion from all professional bodies interviewed suggests this is due to their youth and the context in which cosmetic lenses are worn (at parties, with the possibility of swapping lenses, or drinking alcohol which could reduce compliance even further, such as encouraging overnight wear). Wearers of ZPLs may never have attended a proper eye care appointment and may place less importance on aftercare appointments; thus reducing the possibility of negative side-effects from being discovered and treated. This behaviour may be regardless of whether the wearer has received adequate information and advice on care regimes from the supplier (although non-compliance is likely to be higher if no information is given).

Contact Lens Fitting

- 3.58 We now turn to the areas of optical practice that are related to contact lens wear. The main risks in optical practice associated with contact lenses are incorrect/inappropriate fitting and supply.

⁸⁰ EF Chemical Consulting Ltd (2011) 'Cosmetic Product Safety Report', In Compliance with EC Regulation 1223/2009, 6 December 2011. Available at: http://www.painfulpleasures.com/body_jewelry/gallery/Cosmetic_Tattoos/COS-088-Cosmetic_Safety_Assessment.pdf.

⁸¹ Sauer A & Bourcier T (2011). 'Microbial keratitis as a foreseeable complication of cosmetic contact lenses: a prospective study.' *Acta Ophthalmol* 89, e439-e442.

3.59 The fitting process should involve a number of appointments with the registered practitioner (specifically, an optometrist or an appropriately qualified dispensing optician), during which preliminary information is recorded and different lenses inserted and tested, both for comfort by the patient, and by the registered practitioner's examination through a biomicroscope, using dyes to reveal any abrasions or dead cells that could indicate a poor fit. These tests for fit can be conducted over a number of aftercare appointments. During fitting appointments, instructions are given to patients on all aspect of contact lens wear such as hygiene, wear and maintenance, and risk factors (such as swimming or overnight wear). Advice is also given regarding danger signs of infection or complications and what the patient must do in such an event.⁸²

Severity of harm

3.60 The risks associated with contact lens fitting are:

- Lenses that are too loose or too tight
- Failure of the practitioner to provide sufficient information on care and hygiene

3.61 Lenses that fit too tightly can increase the risk of infection as debris is more easily trapped beneath the lens. Tight lenses can also cause abrasions on the cornea which increases the risk of corneal ulcers. Tight lenses generally feel comfortable to patients, who are unlikely to detect a problem.⁸³ Failure of the registered practitioner to provide adequate aftercare appointments for the patient will exacerbate any risk as the effects of the incorrectly fitted lenses (e.g. dead cells; corneal abrasions) will not be discovered nor appropriate remedial action taken.

3.62 Lenses that are too loose may not cover the whole cornea and will affect the patient's vision. However, loose lenses tend to move around when the patient blinks and feel uncomfortable, and so are likely to be reported quickly.

3.63 Failure of any practitioner (whether registered or unregistered) to provide sufficient information to patients could increase the likelihood of non-compliant behaviour. Given the vital importance of patient compliance in preventing infections and complications associated with contact lens wear, this risk could have potentially serious consequences. Studies on contact lens complications, discussed above, show that in many cases patients were ignorant about precautions, hygiene measures and complications associated with contact lens use.

Likelihood of an adverse event

3.64 Our 2010 risk report investigated in detail the likelihood of registered practitioner risk (among registered optometrists and registered opticians) in relation to contact lens fitting, and concluded that this likelihood is very small. In terms of complaints and insurance claims (which are very low in number) the main issues appear to be with patient adherence to hygiene standards, as opposed to any issue with the nature or fitting of the contact lenses. In our updated literature review we have similarly not discovered any clear evidence of registered practitioners failing to provide adequate advice and information to patients. This reiterates the importance of good communication skills and thorough record keeping, as often risks arise when advice about contact lens care is not followed properly, and the registered practitioner needs to be able to prove that such advice was in fact given.

⁸² Gasson A, Morris J (2010) 'The contact lens manual. A practical guide to fitting', 4th Edition, Edinburgh: Butterworth-Heinemann.

⁸³ Information obtained from our expert advisor, professional bodies and Steinemann TL, Pinninti U, Szczotka LB, Eiferman RA, & Price FW, Jr. (2003). Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors. *Eye Contact Lens* 29, 196-200.

Contextual factors

- 3.65 As discussed above, the key contextual factor in relation to contact lens fitting appears to be patient behaviour and access to/compliance with appropriate contact lens wear, which is likely to be influenced by patient profiles.
- 3.66 A possible mitigating factor relating to the wear of ZPLs is that these, by their nature, are generally worn less often and for shorter durations than corrective lenses. This is likely to reduce the risk of infection.⁸⁴

Contact Lens Supply

Severity of harm

- 3.67 The potential risks related to contact lens supply are similar to those for contact lens fitting, namely failure to provide adequate information about wear and risk factors to patients. Given the importance of patient compliance in mitigating the risks of infection caused by contact lens wear, failure to provide adequate advice during supply could increase the risk of infections and complications.

Likelihood of an adverse event

- 3.68 As with contact lens fitting, there are relatively few cases of incompetence or misconduct in this area as recorded by the GOC's fitness to practise or complaints data.⁸⁵ Registered practitioners are kept up to date through CET; in particular, dispensing opticians with a contact lens speciality are required to undertake a set number of CET points related to contact lenses.

Contextual factors: online substitution

- 3.69 An area of contact lens supply that may potentially have a greater likelihood of adverse events is the online supply of contact lenses. The legal sale of contact lenses online requires that the supply takes place under the general direction of a registered medical practitioner, optometrist or dispensing optician, or that the specification is verified with the original prescriber. Stakeholder feedback suggests that online supply practiced under these requirements is no more risky than direct supply by a registered practitioner, as the patient would still be required to visit a registered practitioner to update his or her prescription and attend aftercare appointments as advised. However, research does suggest that online users are more likely to miss aftercare appointments.⁸⁶
- 3.70 However, an aspect of legal online supply that is a cause for concern, at least amongst the profession, is the substitution of contact lenses.
- 3.71 According to our expert advisor, there is a 'spectrum' of types of substitution:
- Substitution by a registered ECP when the patient is seen at an aftercare appointment. This would be without the several follow-up appointments needed for a full new fitting.
 - Substitution by a registered ECP when the patient is not seen (this might be an internet supplier adhering to best practice for remote supply). An ECP would personally look at the

⁸⁴ Health Canada (2003) 'Human Health Risk Assessment of Cosmetic Contact Lenses', by Dillon Consulting Limited, Final Report, 30 September 2003.

⁸⁵ See Europe Economics (2010) 'Risks in the Optical Profession'.

⁸⁶ Wu et. al (2010) 'Contact lens user profile, attitudes and level of compliance to lens care', Contact Lens and Anterior Eye, Vol. 33, Iss. 4, August 2010, pp 183–188.

lens specification and choose an alternative from a range of options to be as close as possible to the original specification.

- Substitution by a non-ECP under supervision or general direction of a registered practitioner, usually on the basis of an 'equivalence' document for different lens types.
 - Substitution by a non-ECP without supervision or under the general direction of a registered practitioner. This would be classified as illegal substitution.
- 3.72 In the first case, substitution will need to take place occasionally when a lens type is discontinued. If this is done at an aftercare appointment, the ECP would choose a lens similar to the discontinued one and a proper fitting will take place, where the new lens will be examined on the eye and the fit checked. It is possible that a lens substituted online, even if done by a registered practitioner who chooses an alternative from a range of lens options as close as possible to the original specification, will not fit as well because the patient is not present to be checked. This could increase the risks of infection before the patient visited his or her practitioner for a check-up.
- 3.73 The risks associated with substitution could be greater if it is performed by a non-registered practitioner under supervision or general direction of a registered practitioner, but without a careful assessment of the original specification and the available alternatives. This could be done, for example, just by comparison of the original specification with a list of 'equivalent' lenses. Patients can also be encouraged to self-substitute by shopping around for 'similar' lenses.
- 3.74 There are a number of elements of a contact lens specification that can have important implications for a patient's safety. These include the material of the lens (particularly how this affects the flow of oxygen to the eye), including any particular features such as UV inhibitors; the shape and size of the lens; the brand of the lens (some brands can have a better fit with patients than others for no 'measurable' reason); and the associated wear requirements. If any one of these elements is substituted with an alternative this could increase the risk of poor fit and infection. For example, a registered practitioner may have prescribed a lens suitable for extended wear, and if the patient receives a substituted lens not designed for this purpose the risk of infection could be high.
- 3.75 There are a number of studies that highlight the differences between lens types and thus the implications of substituting different lenses. For example, Ozkan et al (2013) show that different soft contact lens materials change their fitting characteristics in different ways. Absent a direct fitting of a substitute lens (where registered practitioners usually check the patient after he or she has been wearing the lens for a few hours to detect fitting changes), online substitution could lead to a patient changing from a well-fitting lens to one that fits unsatisfactorily.⁸⁷ Other studies highlight the differences between daily disposable lenses of different materials and designs, and that these elicit different ocular and patient responses. Some lenses were found to perform less clinically well than others.^{88 89} Further studies provide insight into the differences between lenses with different modalities (e.g. daily, monthly).⁹⁰ Dart et al (2008) show that although the risk of

⁸⁷ Ozkan et al. (2013) 'Lens parameter changes under in vitro and ex vivo conditions and their effect on the conjunctiva', *Contact Lens & Anterior Eye*, Article in Press.

⁸⁸ Diec J, Lazon DJ, Willcox M, Holden BA. The clinical performance of lenses disposed of daily can vary considerably. *Eye Contact Lens* 2012; 38(5):313-318.

⁸⁹ Santodomingo-Rubido et al. (2008) 'Compatibility of two new silicone hydrogel contact lenses with three soft contact lens multipurpose solutions', *Ophthal. Physiol. Opt.* 2008, 28: 373-381.

⁹⁰ See, for example, Chalmers et al. (2012) 'Multicenter Case-Control Study of the Role of Lens Materials and Care Products on the Development of Corneal Infiltrates', *Optometry and Vision Science*, Vol. 89, No. 3, March 2012 and Fahmy M, Long B, Giles T, Wang CH. 'Comfort-enhanced daily disposable contact lens reduces symptoms among weekly/monthly wear patients', *Eye Contact Lens* 2010; 36(4):215-219.

- microbial keratitis is not reduced in daily disposable wearers compared with reusable soft contact lenses, the effects of the infection are less severe and long-term.⁹¹
- 3.76 Whilst these studies do not enable us to quantify the risk associated with the use of different lenses, they clearly show that not all lens types are the same (even within the narrower daily disposable lens family), and that there are benefits to patients of wearing the exact lens fitted to them and prescribed by their registered practitioner. Given the variety of differences between lenses and materials, substitution could lead to a poorer fit for the patient and sub-optimal outcomes.
- 3.77 Ascertaining the likelihood of the risks of substitution is further complicated by the fact that the consequences are only often identifiable in the long term and are therefore difficult to prove as directly related to substitution itself. More severe problems reported in hospitals may not be properly recorded as being caused by substitution (even if this was demonstrable). Consequently, there is no direct evidence of direct harm caused by substitution.

Summary

- 3.78 The table below summarises the evidence relating to areas of legal practice in terms of the severity of harm resulting from an adverse event, and the likelihood of an adverse event occurring as a result of optical practice. The Discussion column includes a brief summary of the issues and relevant contextual factors.

⁹¹ Dart JK, Radford CF, Minassian D, Verma S, & Stapleton F (2008). 'Risk factors for microbial keratitis with contemporary contact lenses: a case-control study'. *Ophthalmology* 115, 1647-54, 1654.

Table 3.1: Summary of severity and likelihood of an adverse event in legal optical practice

Area of legal practice	Risk area of legal practice	Harm from an adverse event	Likelihood of an adverse event	Description
Sight tests				
	Misdiagnosis/Missed diagnosis/ Mismanagement of diseases and conditions	High	Low	The consequences of particular diseases going untreated can be severe, but the likelihood of this risk in legal practice is perceived to be low. Certain patient types are at greater risk of some conditions and this contextual factor may exacerbate risk. Keeping up to date with clinical developments is important.
	Incorrect prescription	Low/Medium-low	Medium-low	The harm caused by incorrect prescriptions is unlikely to be severe in adults, but is generally more significant in children, where the result can be visual problems not being corrected, leading to long-term visual and developmental complications. Partly due to being more likely to be noticed and corrected in adults than in children and vulnerable adults.
	Trauma through incorrect use of equipment	Unknown. Possibly low	Very low	There is little evidence on the harm caused by incorrect use of equipment, or on the likelihood with which this occurs. Expert advisor suggests low.
Spectacle dispensing				
Dispensing spectacles to adults	Poor fit/ Incorrect prescription	Low	Medium-low	Spectacle non-tolerances can be relatively common, although not always due to practitioner error (i.e. it is partly unavoidable). No significant harm caused to adults where problems detected and reported. Vulnerable adults may be less able to identify, report and cope with non-tolerances.

Area of legal practice	Risk area of legal practice	Harm from an adverse event	Likelihood of an adverse event	Description
Dispensing spectacles to children	Poor fit/ Incorrect prescription	Medium	Low (Medium-low with online dispensing).	Incorrectly fitted spectacles or incorrect prescriptions can negate the benefits of spectacles in correcting visual problems in children, leading to long-term vision and developmental complications. More likely to go unnoticed by patients than with adults. Online dispensing could lead to poorer fit if all necessary measurements are not available.
Dispensing multi-focal spectacles	Poor fit/ Incorrect prescription/ Incorrect type of lens	Medium-low	Unknown - thought to be low	If the height of the reading part of the lens is incorrect the patient may look through the wrong section of the lens. This can result in falls (and it is claimed accidents while driving). Likely to be noticed by patients and corrected; less so among vulnerable patients.
Contact lens fitting				
	Incorrect fitting/lack of follow up: too tight fit	Medium	Low	Lenses that fit too tightly can increase risk of infection, or risk of cornea being starved of oxygen. Unlikely to be noticed by patient as will feel comfortable. Incorrect fit must be determined on examination.
	Incorrect fitting/lack of follow up: too loose fit	Low	Very low	Lenses that are too loose pose less of a risk of harm, and are less likely to go unnoticed by the patient.
	Not providing sufficient advice on aftercare and hygiene at the time of fitting.	Medium-high	Low	Complications are directly influenced by patient behaviour, and the harm caused by patient non-compliance resulting from insufficient information can be high. The likelihood of this as a direct result of registered practitioner negligence in legal practice is low. Patient non-compliance regardless of practitioner input is not uncommon.
Contact lens supply				

Area of legal practice	Risk area of legal practice	Harm from an adverse event	Likelihood of an adverse event	Description
	Not providing sufficient advice on aftercare and hygiene	Medium-high	Low	Complications are directly influenced by patient behaviour, and the harm caused by patient non-compliance resulting from insufficient information can be high. The likelihood of this as a direct result of registered practitioner negligence in legal practice is low. Patient non-compliance regardless of practitioner input is not uncommon.
	ZPLs	Medium-high	Low-medium	The complications associated with ZPLs are similar to PLs, and are influenced by patient compliance. ZPLs may be more or less risky depending on the materials used, although this is mitigated by appropriate wear. ZPL users however can be more likely to non-comply, therefore likelihood of adverse event is higher (although the likelihood of <u>practitioner</u> -related risk will be the same as the supply of PLs, i.e. low.)
	Online supply	Medium-high	Low-medium	Proper, legal online supply will have similar risks to direct supply. Risks may be slightly higher if online customers less likely to attend follow-up checks.
	Online substitution	Low/medium	Low/medium	Risks from substitution depend on the nature of the practice. Substitution using a general 'equivalence' list may provide a lens that differs on important elements and could be unsuitable for the patient. Substitution performed directly by trained registrant after careful examination of specification would be less risky. In all cases where the patient is not present to be fitted with the new lens this could pose risk of incorrect fit.

4 Typology of Illegal Practice

Introduction

- 4.1 In this section we describe the areas of illegal practice subject to our investigation. Illegal activity is defined with reference to the Sale of Optical Appliances Order of Council (1984) and the Opticians Act 1989, as amended ('the Act'). We focus on the areas that are considered an offence under the Act.
- 4.2 The evidence presented in the previous section relates to the risks in general legal optical practice. We discussed the severity of possible adverse events and the likelihood of these events occurring as a result of optical practice. It is likely that the majority of *clinical* risks will be similar across legal and illegal practice, but the likelihood of these occurring and the severity with which they occur may differ.
- 4.3 The subsequent chapter will present the evidence on risks in illegal optical practice, also covering the severity of possible adverse events and the likelihood of these events occurring as a result of illegal practice. However, as will be discussed, there is limited evidence *directly* related to illegal optical practice.⁹² Few studies specifically address the adverse events caused (for example) by illegal practitioners, or by the illegal supply of optical appliances.⁹³ For those areas of illegal practice where direct evidence is lacking, we need to extend our analysis to make the best use of the available evidence. We do this by identifying the key underlying reasons for why an area of optical practice is illegal, and how this may influence the clinical harm associated with that area of optical practice (we term these the 'drivers' of risk).
- 4.4 Information on these drivers and the likelihood of adverse events in illegal practice have been drawn from the available literature, and supplemented by material received from the GOC, feedback from professional and educational bodies and our expert advisor, and our own analysis.

The Aim of this Typology

- 4.5 The aim of this typology is to provide a framework to better understand the types of illegal practice and the underlying risks involved. Where direct evidence on illegal risks is lacking, we use this framework to analyse the severity and likelihood of adverse events in illegal practice.
- 4.6 Our framework therefore provides:
 - A definition of the offence
 - Possible ways in which this could manifest
 - Associated risks
 - Possible drivers of risks

⁹² A key exception is the unlawful sale of cosmetic, or zero-powered lenses; and to a lesser extent, the illegal online sale of contact lenses.

⁹³ The reasons for this could be difficulties in identifying illegal practitioners; difficulties in identifying patients who have seen illegal practitioners; or the limited scale of illegal activity.

Areas of illegal practice

4.7 The main offences covered in the legislation are as follows:

- Unlawfully conducting sight tests: Sight testing can be conducted only by a registered medical practitioner or registered optometrist, with special provision for students. (Section 24 of the Opticians Act 1989).
- Unlawfully supplying spectacles: If the user is under 16, registered blind or registered partially sighted, spectacles can be supplied only by or under the personal supervision of a registered medical practitioner, registered optometrist or registered dispensing optician (who must be present at the time of the supply). For other users, anyone can supply spectacles, but there are additional requirements for spectacles with certain prescriptions. (Article 3 of the Sale of Optical appliances Order 1984 and Section 27 of the Opticians Act 1989).
- Unlawfully fitting contact lenses: Contact lenses can be fitted only by a registered medical practitioner, registered optometrist or registered dispensing optician, who is in possession of an in-date spectacles prescription (Section 25 of the Opticians Act 1989).
- Unlawfully supplying prescription contact lenses: Prescription contact lenses can be supplied by or under the personal supervision of a registered medical practitioner, registered optometrist or registered dispensing optician. They can also be supplied under the general direction of a registered medical practitioner, registered optometrist or registered dispensing optician (who need not be present at the supply), provided that the supplier first verifies the wearer's in-date specification with the prescriber. If the user is under 16, registered blind or registered partially sighted, prescription lenses can be supplied only by or under the supervision of a registered medical practitioner, registered optometrist or registered dispensing optician. (Section 27 of the Opticians Act 1989).
- Unlawfully supplying zero-powered contact lenses: Zero powered contact lenses can be supplied only by or under the supervision of a registered medical practitioner, registered optometrist or registered dispensing optician.
- Misuse of protected title: It is an offence to use a protected title or to misrepresent registration status with the GOC. An unregistered individual cannot use the titles "optometrist", "dispensing optician", "registered optometrist"; an unregistered body corporate cannot use the titles "ophthalmic optician", "optometrist", "dispensing optician", "registered optician"; an unregistered individual or body corporate cannot use the title "optician" unless it would be unreasonable for anyone to think it is registered with the GOC (Section 28 of the Opticians Act 1989).

Ways in which illegal practice could manifest

4.8 Before developing our framework for each area of illegal practice, we summarise here the ways in which illegal practice could manifest, or the underlying reasons for why a practice would be illegal. Given that the majority of offences relate to restricted functions and protected titles being performed and used by those not registered with the GOC, by definition the main (although not only) cause of illegal activity is an absence of appropriate registration, or lack of supervision/general direction by a registrant. This could include:

- Practitioners whose registration with the GOC has lapsed
- Practitioners who have been removed or suspended from the relevant register
- Practitioners who are not sufficiently qualified to be registered with the GOC

- Practitioners who are registered with the GOC, but perform restricted functions for which they are not registered (i.e. not registered on the correct register)
- 4.9 Other ways in which illegal activity could manifest include:
- Misuse of a protected title by a body corporate
 - Insufficient supervision of a restricted function
 - Failure to follow the requirements of the Act
- 4.10 These manifestations may vary across the types of offence, as shown in our subsequent discussion of each offence.

Associated risks

- 4.11 The risks of adverse events associated with illegal practice will differ according to the area of illegal practice. In many cases these risks will be similar in nature to those in legal practice, although the severity and likelihood of the adverse event is likely to be different.
- 4.12 The risks associated with areas of illegal practice have been informed by our expert advisor and professional bodies such as the College of Optometrists, the Royal College of Ophthalmologists, the AOP, FODO, ABDO, ACLM and BCLA. We discuss the associated risks for each area of illegal practice in our framework.

Possible drivers of risk

- 4.13 The possible drivers of risk are associated with the ways in which illegal practice could manifest. These drivers will influence the severity and likelihood of adverse events. Possible drivers can be summarised as:
- Inadequate qualifications or competence to carry out the restricted functions. This is considered by all stakeholders contributing to this study to be the key driver of risk, as nearly all clinical risks in optical practice are in some way mitigated by the actions of registered practitioners, which rely on knowledge and skill.
 - Unregistered practitioners have no obligation to keep up to date or undertake continuing education and training (CET). In certain areas of optical practice, keeping up to date with developments in diagnosing and treating diseases, or the use of new equipment, is very important.
 - No redress by the GOC. This would remove any deterrence effect on poor performance.
 - No professional indemnity insurance to compensate patients suffering adverse events caused by the illegal practice. Adverse events may therefore result in longer-term harm than if compensation was available to the patient to remedy the damage.
- 4.14 We now discuss each offence in turn.

Typology of Illegal Practice

Unlawfully conducting sight tests

4.15 Sight testing can only be conducted by a registered medical practitioner or a registered optometrist, with special provision for students.⁹⁴

Ways in which illegal practice could manifest

- 4.16 This offence can manifest in a number of ways, for example if sight testing is undertaken by:
- Practitioners whose registration with the GOC has lapsed or those who have chosen not to be registered.
 - Practitioners who have been removed or suspended from the register.
 - Practitioners who are not sufficiently qualified to be registered with the GOC as optometrists (this would include dispensing opticians who are registered with the GOC, but unable to test sight legally).

The associated risks

4.17 The main risks associated with this type of illegal practice are:

- Missed or misdiagnosis of diseases and eye conditions
- Incorrect prescriptions
- Trauma through the incorrect use of equipment

The likely drivers of risk

- Inadequate qualifications or competence to carry out the sight test properly, adequately interpret the results, or follow correct referral pathways.
- No obligation to undertake CET or keep up to date with clinical developments. This is likely to be particularly important in the diagnosis and management of diseases and conditions.
- No redress through the GOC for poor performance.⁹⁵
- No professional indemnity insurance to compensate patients suffering adverse events caused by the illegal practice.

Unlawfully fitting contact lenses

4.18 Contact lenses can be fitted only by a registered medical practitioner, registered optometrist or registered dispensing optician, who is in the possession of an in-date prescription.⁹⁶

⁹⁴ Recognised student optometrists may be able to test sight if this is carried out as part of an approved course of instruction or an approved examination, or under the continuous supervision of a registered optometrist or a registered medical practitioner (Section 24 of the Optician's Act 1989 and GOC 'The testing of sight by persons training as optometrists rules' 1993).

⁹⁵ Although if the practitioner engaging in the offence is registered with the GOC on a different register reason (e.g. is a dispensing optician) then the GOC's FtP procedure might deal with them.

⁹⁶ Section 25 of the Optician's Act 1989.

Ways in which illegal practice could manifest

- 4.19 Illegal practice therefore entails the fitting of contact lenses by an individual without the appropriate professional registration. This could manifest as:
- Practitioners whose registration with the GOC has lapsed.
 - Practitioners who have been removed or suspended from the register.
 - Practitioners who are not sufficiently qualified to be registered with the GOC.
- 4.20 It would also be illegal to fit contact lenses without an in-date prescription, regardless of registration status.

The associated risks

- 4.21 The main risks associated with this type of illegal practice are:
- Incorrect fitting of lenses (too loose or too tight).
 - Failure of the practitioner to provide sufficient information to the patient on care and hygiene.

The likely drivers of risk

- Inadequate qualifications or competence to fit contact lenses properly. This could include failure to provide adequate care instructions or patient follow-up; or failure to detect ill-fitting lenses.
- No obligation to undertake CET or keep up to date with clinical developments.
- No redress through the GOC for poor performance.
- No professional indemnity insurance to compensate patients suffering adverse events caused by the illegal practice.

Misuse of protected title

- 4.22 It is an offence to use a protected title or to misrepresent registration status with the GOC. This could entail an individual practicing as a registered optometrist or dispensing optician without being appropriately registered with the GOC.

Ways in which illegal practice could manifest

- 4.23 This can manifest itself in a number of ways:
- Practitioners whose registration with the GOC has lapsed.
 - Practitioners who have been removed or suspended from the register due to, for example, misconduct or negligence.
 - Practitioners who are not sufficiently qualified to be registered with the GOC as either optometrists or dispensing opticians.
- 4.24 Misuse of protected title also can also apply to bodies corporate using a protected title without being registered with the GOC.⁹⁷

⁹⁷ Protected titles include (for individuals) “optometrist”, “dispensing optician” and “registered optometrist”; (for bodies corporate) “ophthalmic optician”, “optometrist”, “dispensing optician”, “registered optician”. An unregistered individual or body corporate also cannot use the title “optician” unless it would be unreasonable for anyone to think it is registered with the GOC. Section 28 of the Opticians Act 1989).

The associated risks

- 4.25 The main underlying risk associated with this type of illegal practice is that of misleading the public with regard to the individual's or body corporate's registered status. This in turn means:
- Undermining public confidence in the optical profession.
 - Specific risks associated with other areas of illegal practice that are related to an unregistered practitioner performing restricted functions.

Likely drivers of risk

- No obligation to undertake CET or keep up to date with clinical developments.
- No redress by the GOC for poor performance by the practitioner of body corporate.
- Inadequate qualifications to undertake restricted functions.

Unlawfully supplying spectacles

- 4.26 The supply of spectacles to certain patient groups (e.g. children under 16 years, and those registered blind or partially sighted) can only be carried out by, or under the direct supervision of, a registered medical practitioner, registered optometrist or registered dispensing optician, who must be present at the time of supply. For other users, anyone can supply spectacles, but there are additional requirements for the supply of spectacles with certain prescriptions.

Ways in which illegal practice could manifest

- 4.27 Illegal practice can therefore manifest itself if the supply of spectacles to these patient groups is by an unregistered individual, for example:
- Practitioners whose registration with the GOC has lapsed.
 - Practitioners who have been removed or suspended from the register due to, for example, misconduct or negligence.
 - Practitioners who are not sufficiently qualified to be registered with the GOC as either optometrists or dispensing opticians. or
 - Where the registered individual is not present at the time of supply.

The associated risks

- 4.28 The risks associated with the unlawful supply of spectacles include:
- Poorly fitted children's spectacles, reducing the benefits of corrective spectacles, leading to risk of visual and developmental problems.
 - Poorly fitted bi-or multi-focal lenses, or incorrect multi-focal lens types, leading to non-tolerances and risk of accidents/falls.

Likely drivers of risk

- Inadequate qualifications or competence to fit spectacles properly.
- No obligation to undertake CET or keep up to date with clinical developments.
- No redress through the GOC for poor performance.
- No professional indemnity insurance to compensate patients suffering adverse events caused by the illegal practice.

Unlawfully supplying prescription contact lenses

4.29 Prescription contact lenses (PLs) can be supplied by or under the personal supervision of a registered medical practitioner, registered optometrist or registered dispensing optician. They can also be supplied under the general direction of a registered medical practitioner, registered optometrist or registered dispensing optician (who need not be present at the supply, i.e. remote supply), provided that the supplier first verifies the wearer's in-date specification with the prescriber. If the user is under 16, registered blind or registered partially sighted, prescription lenses can be supplied only by or under the supervision of a registered medical practitioner, registered optometrist or registered dispensing optician (who must be present at the time of supply).⁹⁸

Ways in which illegal practice could manifest

4.30 Illegal practice in this area can manifest in a number of ways, with the issue being complicated by the sale of PLs online:

- Failure of registered practitioners to provide appropriate supervision or general direction, resulting in unregistered individuals supplying the lenses.
- Remote supply (e.g. online) without the general direction of a registered practitioner and the verification of the specifications with the prescriber. This would include illegal substitution. Illegal substitution is defined as the substitution of one lens specification for another that does not take place under the general direction of a registered medical practitioner, registered optometrist or registered dispensing optician.⁹⁹
- Remote supply (e.g. online) to users under 16, registered blind or registered partially sighted without personal supervision of a registered practitioner.

The associated risks

4.31 The risks associated with the unlawful supply of PLs include:

- Failure to provide adequate information to patients on appropriate wear behaviour and risk factors, including advice regarding the importance of eye examinations. This could increase the risk of patient non-compliance and thus infection.
- Incorrect contact lens specifications resulting in a poor fit for the patient, increasing the risk of infection or complications.
- Incorrect contact lens specifications relating to prescription errors, resulting in intolerances. As with spectacle non-tolerances, this is more harmful to children than adults.
- Reduced incentive for patients to attend regular check-ups with registered practitioners if not required to show an in-date specification, which could lead to eye damage going unnoticed.

Likely drivers of risk

- Inadequate qualifications or competence to supply contact lenses.
- No requirement to undertake CET or keep up to date on clinical developments.
- No redress by the GOC for poor performance.

⁹⁸ Section 27 of the Opticians Act 1989.

⁹⁹ There are forms of legal substitution, which are described in Section 3.69 onwards.

- No professional indemnity insurance to compensate patients suffering adverse events caused by the illegal practice.

Unlawfully supplying zero-powered contact lenses

4.32 Zero-powered contact lenses (ZPLs) must be supplied by or under the supervision of a registered medical practitioner, registered optometrist or dispensing optician, who must be present at the time of the supply.

Ways in which illegal practice could manifest

- 4.33 This kind of illegal supply would, for example, involve stores supplying ZPLs with no supervision by a registered practitioner (e.g. pharmacies, fancy dress stores, certain online sites). Illegal practice in this area can manifest as:
- Failure of registered practitioners to sufficiently supervise the supply of the ZPLs, resulting in unregistered individuals supplying the lenses.
 - Absence of registered practitioners at the supply of ZPLs, resulting in unregistered individuals supplying the lenses.

The associated risks

- 4.34 The risks associated with the unsupervised supply of ZPLs include:
- Failure to provide adequate information to patients about inserting and removing the lenses (as a prior appointment and specification with a registered practitioner is not required) which could increase the risk of patients damaging their eyes.
 - Failure to provide adequate information to patients on appropriate wear and hygiene behaviour and risk factors, including advice regarding the importance of eye examinations. This could increase the risk of patient non-compliance and thus infection.

Likely drivers of risk

- Inadequate qualifications or competence to supply contact lenses.
- No obligation to undertake CET or keep up to date with clinical developments.
- No redress by the GOC for poor performance.
- No professional indemnity insurance to compensate patients suffering adverse events caused by the illegal practice.

5 Risks in Illegal Practice

Introduction

5.1 In this section we present the results of our research into areas of illegal practice, namely:

- Unlawfully conducting sight tests.
- Unlawfully supplying spectacles.
- Unlawfully fitting contact lenses.
- Unlawfully supplying prescription contact lenses.
- Unlawfully supplying zero-powered contact lenses.
- Misuse of protected title.

5.2 We discuss the evidence on risks in legal practice according to:

- The potential harm caused by an adverse event.
- The likelihood of an adverse event occurring.
- The contextual factors that could mitigate or aggravate the risks, where relevant.

Nature of evidence

5.3 As discussed in the previous section, there is very limited *direct* evidence relating to illegal practice. Therefore in this section we present the available evidence, and where necessary draw on our typology of illegal practice (and information supplied by our expert advisor and professional bodies) to assess:

- areas of illegal practice where an adverse event will cause the most serious harm, and
- areas of illegal practice with the greatest likelihood of an adverse event.

Likelihood of an adverse event

5.4 When discussing the likelihood of an adverse event associated with illegal practice, two aspects must be considered:

- The likelihood of an adverse event on a case-by-case basis. This will be driven by the extent of poor practice associated with illegal practitioners. For example, the likelihood that a particular illegal practitioner's action would result in an adverse event.
- The likelihood of an adverse event occurring in the whole population of illegal practice. This will be driven by the scale of illegal practice (for example, the number of illegal practitioners operating in an area).

Unlawfully Conducting Sight Tests

5.5 Our evidence base does not include direct evidence in the literature or from stakeholders on the risks associated with unlawfully conducting sight tests. All professional bodies contributing to this study agreed that the main driver of risk in this area is insufficient training and qualifications of an

individual who is not legally entitled to test sight. All but one professional body was of the opinion that there is a spectrum of risk associated with unregistered practitioners, ranging from a relatively high risk of someone with no training or qualifications, to the relatively low risk of someone just about to qualify and to be registered as an optometrist. The risks associated with someone removed or temporarily suspended from the register were thought to be lower than an individual with no training, although this would depend on the reasons for the removal.

- 5.6 Conducting sight tests with insufficient training raises the following risks:
- Missed/misdiagnosis and mismanagement of diseases and eye conditions
 - Incorrect prescriptions
 - Trauma from improper use of equipment.
- 5.7 As set out in our chapter on legal risks, misdiagnosing or mismanaging eye diseases and conditions could have very severe consequences such as permanent damage to or loss of sight, or even death in extreme cases. The extent of harm of an adverse event in illegal practice is likely to be greater than in legal practice, as with most conditions timing is crucial to effective treatment. Conditions are likely to go unnoticed and untreated for longer with an unregistered practitioner with insufficient training, thus exacerbating the overall harm caused.
- 5.8 Incorrect prescriptions are unlikely to cause significant harm in adults, but are more serious in children as these may lead to long-term visual and development problems. Vulnerable adults (e.g. the elderly or those with learning difficulties) may be at additional risk as they may be less able to identify, report or cope with spectacle non-tolerances. Again, the extent of this harm may be greater under illegal practice if the prescription errors are greater, or if illegal practitioners are less able to adequately address problems that arise. In some cases, prescriptions can be technically correct (based on the test results) but practically not tolerated by the patient, and additional expertise is required by the practitioner to adjust for this.
- 5.9 The risks of trauma through the incorrect use of equipment are far less well documented, although potential risks include over exposure to intense light and subsequent damage to the eye. Our expert advisor's view is that non-qualified practitioners may well use easier to use equipment such as automated non-contact tonometry, and would be likely to use the simpler direct ophthalmoscopy (which has safer light levels than the binocular indirect ophthalmoscopy), and thus perhaps the overall risk associated with illegal practice would not necessarily be higher.

Likelihood of an adverse event

- 5.10 Although there is little evidence in the literature on the likelihood of adverse events from the unlawful testing of sight, is it logical to infer that the risks associated with the legal testing of sight are likely to be exacerbated if testing is undertaken by an individual with insufficient training or qualifications. This is likely to be particularly the case with risks associated with misdiagnosing and mismanaging diseases. Optometrists are trained to look for symptoms of diseases, many of which can be subtle and difficult to detect. An individual with lower levels of training would almost certainly be less likely to make a correct identification.
- 5.11 A key driver of increased risk is the lack of an obligation on non-registered practitioners to remain up to date through CET. The evidence base in relation to legal practice highlighted that on-going developments in the diagnosis and management of diseases are published in peer reviewed articles and guidelines. For example, in 2009 NICE issued guidelines on the management of glaucoma that

- made a significant change to clinical practice concerning this condition.¹⁰⁰ A practitioner not keeping up to date with such developments (regardless of his or her baseline qualification) could pose an increased risk to patients.
- 5.12 The risks associated with incorrect prescriptions in children are also likely to be higher in unregistered practitioners. Child management is more difficult (children often do not want to wear glasses, and their age can prevent them from participating in certain tests) and training on good communication skills on the part of the optometrist, both with the child and parents, is vital.
- 5.13 Less than five per cent of complaints relating to illegal practice received by the GOC involve the unlawful testing of sight. We note that complaints data do not necessarily reflect the accurate likelihood of this illegal practice, as complaints can be driven by a number of other factors, such as the ease of identifying the illegal practice and the perceived importance of the illegal practice among the public and the profession,

Unlawfully Supplying Spectacles

- 5.14 The research has not identified any direct evidence in the literature or from stakeholders relating to the unlawful supply of spectacles. The professional bodies contributing to our study agreed that the main risk associated with the unlawful supply of spectacles involves unqualified individuals supplying spectacles to children without appropriate supervision. The evidence gathered in the chapter on legal supply highlights the importance of correctly fitting spectacles in correcting visual problems in children and preventing long-term problems such as squints and lazy eye. An unregistered practitioner who is untrained or insufficiently qualified who supplies incorrectly fitting spectacles to children (or who is unable to adequately address problems that arise) will increase the risk of long-term problems in susceptible children.
- 5.15 Little feedback was received about the illegal supply of bi- and multi-focal lenses. Our evidence base does not include any studies relating to directly to poorly fitted bi-or multi-focal spectacles. Given the importance of wearers being able to see through the correct section of the lens, unlawful supply poses the potential heightened risk of adverse events in this area (e.g. accidents whilst driving, falls).
- 5.16 A further possible manifestation of illegal practice in this area is the extent to which practitioners comply with British Standards. Every optical lens and spectacles frame sold by a registered practice will conform to the tolerances set out in the relevant British Standards (which have recently been updated). It is part of standard practice to check compliance with these standards before fitting. Unqualified practitioners may not have the necessary training or experience to undertake such checks, which could exacerbate the incidence of spectacle non-tolerances. However, as it is not illegal for unqualified practitioners to supply spectacles (unless to certain patient groups) this issue is not directly relevant to this work.

Likelihood of an adverse event

- 5.17 Between five and ten per cent of complaints relating to illegal practice received by the GOC concern to the unlawful supply of spectacles. Whilst complaints data do not necessarily reflect the accurate likelihood of this illegal practice (as complaints can be driven by a number of other factors, such as the ease of identifying the illegal practice and the perceived importance of the illegal practice), this relatively low proportion does not contradict the view of some of the professional bodies that the risks associated with the unlawful supply of spectacles are not widespread. Others,

¹⁰⁰ NICE (2009) 'Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension.' (Available at <http://publications.nice.org.uk/glaucoma-cg85>).

- however, do feel that standards with respect to child dispensing are low across the profession, and that optometrists do not always supervise dispensing to children by unregistered individuals, nor is there a registered DO present.
- 5.18 An untrained and unqualified practitioner is likely to perform less well than a registered optometrist or dispensing optician, and thus the likelihood of an adverse event is likely to be greater under unlawful supply. However, it is not possible to quantify the extent to which this may be so. This is particularly the case as (based on the agreement of all but one association body contributing to this study, who felt that there is no sliding scale – either unregistered practitioners are competent or not) there is a spectrum of risk associated with unregistered practitioners, ranging from relatively high risks of someone with no training or qualification, to relatively low risk of someone just about to qualify and be registered as an optometrist or dispensing optician. Therefore the level of risk will be influenced by the type of illegal, unregistered practitioner.
- 5.19 The likelihood of adverse events associated with the unlawful supply of bi-and multi-focal lenses is not considered to be high. A key contextual factor that may mitigate any risk is the ability of the wearer in most cases to detect if they are looking through the wrong part of the lens, although this mitigating factor could be reduced in the case of vulnerable adults (i.e. the elderly).

Unlawfully Fitting Contact Lenses

- 5.20 The main risks associated with the unlawful fitting of contact lenses are the incorrect fitting of lenses, and failure of the practitioner to provide sufficient information to the patient on care and hygiene. Risks also include failure to provide adequate aftercare for the patient to ensure a correct fit.
- 5.21 Our research has not identified any direct evidence in the literature or from stakeholders relating to the unlawful fitting of contact lenses. Stakeholders agree that, given the way in which illegal practice manifests, a likely driver of risk in this area is a lack of sufficient qualification or training on the part of the individual acting illegally (presuming this is what prevents the individual from being registered with the GOC). One professional body stated that it was unlikely that someone with no training at all would attempt to fit contact lenses, and that unlawful fitting would most likely involve a practitioner acting beyond the scope of his or her registration. Our evidence on legal contact lens fitting highlights the potential harm involved if lenses are not fitted correctly (including possible trauma through incorrect insertion) or sufficient advice given to patients, and the level of harm is considered to be similar in the case of illegal fitting. It is thought that harm may be more severe, if patients are not provided with information on danger signs associated with contact lens complications or about what to do if these occur, as this may lead to conditions going longer without being treated.
- 5.22 In addition, an unregistered practitioner who is not properly trained is likely to fit certain patients routinely that a qualified registrant would fit with extreme caution. Diabetics and patients with chronic lid disorders or medical conditions that affect the metabolism of the cornea need a greater level of care and advice as to the risks they are undertaking.
- 5.23 Some stakeholders (including our expert advisor) argue that lens substitution could constitute illegal (re)fitting, as patients can be provided with a new lens type without a valid prescription for this new type, and with no direct contact with a registered practitioner.¹⁰¹

¹⁰¹ Legal contact lens fitting must be carried out by a registered medical practitioner, optometrist or dispensing optician, who is in the possession of an in-date prescription.

Likelihood of an adverse event

- 5.24 Of the complaints received by the GOC on illegal practice, less than five per cent are related to the illegal fitting of contact lenses. Complaints data do not necessarily reflect the accurate likelihood of this illegal practice because, for example, a complaint is simply an indication of concern about a particular practice and the level of complaints can be influenced by public awareness of the GOC's role in dealing with an issue. However, this low proportion of complaints is consistent with perceptions of stakeholders, who suggest that illegal fitting of contact lenses is unlikely to be common (with the most likely scenario to be a registrant acting beyond the bound of his or her registration, such as a student optometrist).
- 5.25 Our evidence on legal contact lens fitting, gathered from the literature and expert opinion, and described in Section 3, shows that contact lens fitting introduces risk to the patient, and this is mitigated by the steps taken by properly qualified and trained practitioners to check the fit of the lens and provide detailed advice about wear and aftercare. Any de-coupling of the fitting process from this qualified input removes this risk mitigant, and thus the likelihood of an adverse event must be at least as high as with legal fitting.
- 5.26 Our expert advisor's opinion is that, as modern soft disposable lenses fit the majority of patients acceptably, the overall risk of illegal fitting is not likely to be very high (although certainly higher than the risk of an adverse event from legal fitting).

Unlawfully Supplying Prescription Contact Lenses

- 5.27 Discussions with our expert advisor and feedback from the professional bodies suggest that the most common manifestation of the illegal supply of contact lenses is remote supply without the general direction of a registered practitioner or the verification of the specifications with the prescriber. This usually entails online supply. A related manifestation is the remote supply of contact lenses to users under 16 without the personal supervision of a registered practitioner.
- 5.28 There is research that shows that consumers purchasing contact lenses online are less likely to follow recommended contact lens behaviour.¹⁰² In addition, subjects of the Fogel et al (2008) US study who bought their contact lenses on the internet were more likely to do so without a prescription than those buying from a store or at their doctor's office. However, such studies do not provide evidence on the prevalence of actual complications associated with online purchases.
- 5.29 We identified one study on the risks associated with the illegal supply of contact lenses. The Contact Lens European Evidence Report (CLEER) Project examined feedback on adverse incidents received from eye care practitioners across 13 countries. The data included whether contact lens sales had been made with ("regulated sale") or without ("unregulated sale") a prescription. The data showed that the unregulated sale of all contact lenses is associated with a statistically significant higher rate of incidents than the regulated sale.¹⁰³
- 5.30 Feedback from professional bodies contributing to our study highlighted a number of risks associated with the illegal supply of contact lenses, relating mostly to illegal online sales. These risks are related to the manifestation of illegal supply whereby an in-date specification is not verified

¹⁰² Fogel et al, 'Contact lenses purchased over the internet place individuals potentially at risk for harmful eye care practices.' *Optometry*, Jan 2008; 79 (1): 23-35).

¹⁰³ Schweizer et al. (2011) 'The European contact lens forum (ECLF) - the results of the CLEER-project.', *Cont Lens Anterior Eye* 2011; 34(6): 293-296.

with the original prescriber and the supply does not take place under the general direction of a registered practitioner.¹⁰⁴

- First, without a valid specification the lenses supplied to the patient could be the wrong fit, or of poor quality. This can result in lenses being too tight or restricting the flow of oxygen to the cornea. This can lead to a build-up of red blood vessels over the cornea, affecting the long-term viability of contact-wear for the patient. Debris can also become more easily trapped under a wrongly fitted lens leading to an increased risk of infection. As discussed in the section on substitution, there are important characteristics of lenses specific to a patient that are detailed in a specification and, if ignored, could increase the risk of complications for the patient.
- Second, with no requirement for an in-date specification, patients do not have an added incentive to visit their registered practitioner for a regular check-up. This is very important to ensure that the lenses continue to fit correctly and to detect and treat any signs of damage or infection. Any problems caused by the wrong lenses being supplied will be compounded if the patient does not attend regular check-ups. A study by Wu et al (2010) found that failure to attend regular check-ups is 3.8 per cent more likely in those who have purchased lenses online.¹⁰⁵
- Third, and most important, is that the illegal supply of lenses without the input of registered practitioners exposes patients to the risks of contact lens wear without the mitigating factors of professional fitting and advice on wear and aftercare. This is particularly the case if the supplier is an unregistered practitioner with insufficient qualifications and training on the importance of giving patients advice, or the type of advice that must be given. As we have seen, non-compliance with recommended behaviour is a significant driver of complications and infections among contact lens wearers, and the absence of this advice is therefore a high potential risk.
- There is also the risk that the supply of contact lenses without the input of registered practitioners may result in prescription errors such that the users experience non-tolerances. This is particularly important with users under 16 who, as with spectacles, are more vulnerable than adults to prescription errors. Incorrect prescriptions could have implications for vision (i.e. exacerbate squints) and long-term development.

5.31 There are also potential risks of direct supply of contact lenses by unregistered practitioners, without the supervision or general direction of a registered practitioner. Stakeholders however did not highlight this as an area of much concern. This could occur within optical practices, whereby unregistered practitioners are left to supply contact lenses unsupervised, or within other retail stores by unregistered individuals with no supervision or general direction of a registered practitioner. The associated risks would be similar to those of illegal online supply as described above, and the most significant risk would be inadequate provision of information and advice on good aftercare. The scale of the risks to patients would depend on patients' prior knowledge of recommended contact lens use. For example, a patient being supplied on a one-off basis by an individual acting illegally is likely to be at a much lower risk of non-compliance than a patient regularly seen by an individual acting illegally. Stakeholder feedback suggests that the risk of continuous illegal supply is greater with online supply than direct supply.

5.32 Further, if an individual is not registered with the GOC then this limits the form of redress available to patients if the practitioner is found to be negligent. Whilst some such practitioners may fall

¹⁰⁴ We note that all professional bodies shared these views on the illegal supply of contact lenses.

¹⁰⁵ Wu et. al (2010) 'Contact lens user profile, attitudes and level of compliance to lens care', *Contact Lens and Anterior Eye*, Vol. 33, Iss. 4, August 2010, pp 183–188.

under the GOC's fitness to practise regime (e.g. if they should return to the register), those who have never been registered would fall outside of the GOC's remit. In addition, stakeholders contributing to this study agree that unregistered practitioners are unlikely to have professional indemnity insurance. Patients suffering harm or sub-optimal outcomes may therefore be unable to claim compensation to rectify the harm, thus exacerbating the long-term negative effects of the harm caused. Whilst there is no direct evidence of this occurring in relation to illegal practice, our expert advisor (who also acts as an expert witness in court cases) is aware of a number of civil litigation cases in which patients have been unable to work due to the loss of sight from alleged malpractice, and that where the case has been proven have benefitted significantly from the compensation paid.

Likelihood of an adverse event

- 5.33 Complaints to the GOC about the illegal supply of prescription contact lenses make up between 10 and 15 per cent of all complaints.¹⁰⁶ Complaints data do not necessarily reflect the accurate likelihood of this illegal practice as complaints can be driven by a number of other factors (such as the ease of identifying the illegal practice and the perceived importance of the illegal practice) and may not turn out to be justified.
- 5.34 There is little other evidence of the likelihood of illegal supply of prescription contact lenses, or of the likelihood that such supply would result in an adverse event. All stakeholders contributing to the study believe that illegal supply (in particular online supply) is relatively common, and cite many websites selling contact lenses that make no mention of good contact lens use and do not advise on the importance of check-ups with registered practitioners. It is also held that users are easily able to source lenses online without a proper specification (13 out of the 15 UK companies investigated by Which? allowed this form of self-substitution).¹⁰⁷ There is also anecdotal evidence of websites referring users to another site offshore if they do not have a specification.
- 5.35 Given the main manifestation of illegal practice in this area (i.e. unregistered individuals supplying contact lenses without the supervision or under the general direction of a registered practitioner), a key driver of risk is likely to be insufficient qualifications and training on the part of the individual that would enable them to be registered with the GOC. This implies that at the very least, the likelihood of an adverse event in the illegal supply of contact lenses will be greater than that in the area of the legal supply of contact lenses.

Unlawfully Supplying Zero-powered Contact Lenses

- 5.36 The main risks associated with the unlawful supply of zero-powered lenses (ZPLs) are:
- Failure to provide adequate information to patients about inserting and removing the lenses (as a prior appointment with and specification from a registered practitioner is not required) which could increase the risk of patients damaging their eyes.
 - Failure to provide adequate information to patients on appropriate wear and hygiene behaviour and risk factors, including advice regarding the importance of eye examinations. This could increase the risk of patient non-compliance and thus infection.
- 5.37 As a prescription is not required for ZPLs and patients do not need to attend a fitting with a registered practitioner, there is a risk that ZPLs will not fit a patient properly (i.e. could be too tight or too loose). In particular, too tight lenses can increase the risk of infection by trapping

¹⁰⁶ As provided in the Research Specifications for this work.

¹⁰⁷ Which? (2012) '10 things to watch when buying glasses online. Which? finds potential dangerous practice online' <http://www.which.co.uk/news/2012/05/10-things-to-watch-when-buying-glasses-online-286294/>

- debris under them or by causing corneal abrasions. The advice given by the supplier on correct wear and lens care and, in particular, on how to identify danger signs, is therefore likely to be even more valuable than with PLs, as PL wearers generally attend a fitting with a registered practitioner. If this advice is not provided at the time of supply, patients are likely to be exposed to higher levels of risk from poorly fitting lenses.¹⁰⁸ This may be in part mitigated by the fact that cosmetic lenses are in general worn less frequently and for shorter duration than PLs.¹⁰⁹
- 5.38 As discussed in the section on risks in legal practice, patient compliance with correct contact lens wear and maintenance advice is essential in mitigating the risks of infection and complications that may arise with contact lens wear. If such advice is not provided at the time of supply, patients may well be unaware of the appropriate way to wear and care for contact lenses. This will increase the risk of complications such as corneal abrasions and infection.
- 5.39 The nature of clinical harm potentially resulting from the illegal supply of ZPLs is the same as the clinical harm associated with improper wear of all contact lenses, namely microbial keratitis, conjunctivitis, corneal edema and peripheral infiltrates.¹¹⁰ However, the severity of the complications may be worse if the patient has not received information on how to recognise danger signs and what to do if they occur. This may result in complications going untreated for longer and having more severe and long-term consequences.¹¹¹
- 5.40 Research from outside the UK provides some evidence that ZPLs are more likely to be obtained by patients from illegal sources than PLs:
- Sauer et al (2011) analysed 256 patients with microbial keratitis in French Hospital eye clinics. The ZPL wearers were 26.5 times more likely to have had their lenses supplied by a friend, local market or internet only than PL wearers.
 - A report for Health Canada (2003) reviewed cases listed in the US's database on adverse events relating to medical devices since 1995. Of all 206 cases studied, 24 (11.5 per cent) were linked with cosmetic contact lenses. The frequency of illegal dispensing was much higher with cosmetic lenses (79.2 per cent of cosmetic lenses were illegally dispensed) compared with prescription lenses (only 10.5 per cent).¹¹²
- 5.41 Research also shows that the illegal supply of ZPLs is linked with a lack of information provision about appropriate contact lens wear. Together with the above evidence, this implies that ZPL wearers in general are therefore less likely to receive information about appropriate contact lens wear and thus be more at risk of complications.
- Snyder et al (1991) reviewed five cases of cosmetic contact lens wearers who developed microbial keratitis. Of these, three were a consequence of improper care and two related to overnight use. The authors highlighted the lack of care information available to the wearers. The authors also state that users of cosmetic lenses may be at higher risk of developing complications since lenses are generally acquired 'from friends or through mail order'.¹¹³

¹⁰⁸ View of our expert advisor.

¹⁰⁹ Reference from stakeholders and others health Canada (see legal)

¹¹⁰ Steinemann TL, Pinninti U, Szczotka LB, Eiferman RA, & Price FW, Jr. (2003). 'Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors.' *Eye Contact Lens* 29, 196-200.

¹¹¹ We have not found any research relating to the relative severity of complications in wearers of ZPLs obtained from illegal versus legal sources. This point has been raised by our expert advisor and a number of professional bodies contributing to this study.

¹¹² Health Canada (2003) 'Human Health Risk Assessment of Cosmetic Contact Lenses', by Dillon Consulting Limited, Final Report, 30 September 2003

¹¹³ Snyder et al. (1991) 'Microbial Keratitis Associated with Plano Tinted Contact Lenses', *CLAO Journal*, Vol 17 No 4: 252-255, October 1991

- Steinman et al (2003) conducted retrospective case studies of six patients in the US with acute eye pain and redness after wearing ZPLs. The patients seen had no previous experience wearing corrective eyewear and had not had their lenses dispensed by an ECP. The paper describes contact lens wearing habits so far below the usual recommendations for safe wear that it seems extremely unlikely that this would occur if an ECP had initiated the fitting or prescription. However, the study involves a very small sample and provides no information on the prevalence of the risks associated with ZPL wear.¹¹⁴
 - Steinman et al (2005) conducted retrospective case studies of 12 patients in the US seen urgently for acute eye pain and redness after wearing ZPLs. None of the lenses were prescribed by ECPs. Four of the 12 cases had such serious eye infections that they required hospital admission. The study also includes a survey of 159 adolescent patients attending a routine clinic to explore the use of ZPLs. Thirty-seven (23 per cent) reported using ZPLs. These lenses were obtained from an unlicensed provider 51 per cent of the time. The study provides a limited insight into the use of ZPLs, but no evidence on the prevalence of the associated risks.¹¹⁵
 - The Sauer et al (2011) study found that, of the 256 patients with microbial keratitis examined, the ZPL wearers were younger and more recent wearers than PL wearers. They were 26.5 times more likely to have had their lenses supplied by a friend, local market or internet only than PL wearers. The ZPL-wearing group had a significantly greater risk of having no information about lens care or handling. They also had a greater risk of acanthamoeba infections than the other group. The study shows that ZPL-wearers are more likely to lack important knowledge about lens care and to have more serious complications than PL wearers. It does not provide any insight into the prevalence of the risks associated with ZPL wear.¹¹⁶
 - Singh et al (2012) conducted a retrospective study of 13 patients in India who developed severe eye infections after the use of ZPLs. All the patients were ignorant about the precautions, hygiene measures and complications related to contact lens use; none had followed the recommended handling and storage techniques.¹¹⁷ However, the paper did not explore whether the lenses were obtained through regulated or unregulated channels.
- 5.42 There is also research that directly implies that the unregulated sale of contact lenses leads to a greater risk of complications than their regulated sale. This is applicable to the unlawful supply of ZPLs and PLs:
- The Contact Lens European Evidence Report (CLEER) Project was carried out in 2008 and 2009 by the European Contact Lens Forum (ECLF). The CLEER Project was an online data gathering exercise with the objective of supporting policy discussions at the European and national levels. All eye care professionals eligible to fit contact lenses were invited to submit reports of significant incidents and data was collected on sales, specifying whether they were done with or without a valid prescription. A total of 1276 reports were collected in 13 countries. Just over 83 per cent of ZPL cases were related to unregulated suppliers. The

¹¹⁴ Steinemann TL, Pinninti U, Szczotka LB, Eiferman RA, & Price FW, Jr. (2003). 'Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors.' *Eye Contact Lens* 29, 196-200.

¹¹⁵ Steinemann TL, Fletcher M, Bonny AE, Harvey RA, Hamlin D, Zloty P, Besson M, Walter K, & Gagnon M (2005). 'Over-the-counter decorative contact lenses: Cosmetic or Medical Devices?' *A Case Series. Eye Contact Lens* 31, 194-200.

¹¹⁶ Sauer A & Bourcier T (2011). 'Microbial keratitis as a foreseeable complication of cosmetic contact lenses: a prospective study.' *Acta Ophthalmol* 89, e439-e442.

¹¹⁷ Singh S, Satani D, Patel A, & Vhankade R (2012). 'Colored cosmetic contact lenses: an unsafe trend in the younger generation.' *Cornea* 31, 777-779.

study found that that coloured contact lenses resulted in statistically significant more incidents than non-coloured powered contact lenses. The data also showed that the unregulated sale of all contact lenses is associated with a statistically significant higher rate of incidents than the regulated sale.¹¹⁸

Likelihood of an adverse event

- 5.43 Whilst the available evidence enables us to draw some conclusions regarding the comparative likelihood of adverse events (i.e. clinical risks of infection etc.) between the illegal and legal supply of contact lenses, in particular ZPLs, it does not enable us to quantify the absolute likelihood of adverse events arising from the illegal sale of ZPLs, either in terms of how likely it is that a user will be supplied illegally, and in terms of how likely it is that this illegal supply will result in an adverse event. Whilst there is some information about the size of the ZPL market (according to a consumer survey by YouGov, one per cent of the UK population aged 16+ wears contact lenses for cosmetic/fashion purposes, compared to 13 per cent of the population that wears them for sight correction)¹¹⁹ this does not shed any light on the proportion of ZPL users who obtain their lenses illegally, nor provide insight into the relative frequency of adverse events among ZPL wearers and PL wearers. The smaller ZPL market may mean, however, that the absolute number of adverse events is lower among ZPL wearers than PL wearers.
- 5.44 The majority of the studies cited above are based on small samples sizes and are retrospective (i.e. they investigate ZPL wearers who already have problems), and do not provide sufficient evidence on the likelihood of obtaining complications through ZPLs. Even those studies that do indicate that the likelihood of complications is greater for ZPL wearers than for PL wearers do not provide an indication of how widespread the problem is, particularly in the UK.
- 5.45 Complaints about illegal practice received by the GOC indicate that the illegal supply of ZPLs is a common area of complaint — over 70 per cent of complaints are in this category.¹²⁰ Although the number of complaints cannot be directly linked with the scale of the problem (other factors, such as the perceived importance of this issue among complainants, could drive the number of complaints) it does indicate that the illegal sale of ZPLs is at least perceived to be relatively common. Feedback from all the professional bodies participating in this study suggests that a large proportion of ZPLs are sold through retail outlets such as fancy dress stores, pharmacies, markets and online, and that these retail outlets are very likely to be acting illegally due to not having supervision by a registered medical or registered optical practitioner.
- 5.46 However, the available evidence does allow us to infer the following:
- The incidence of complications is higher where the level of compliance with recommended contact lens wear is lower.
 - Compliance is positively influenced by the provision of information and advice (whilst there is no available evidence on the extent to which this is true, all stakeholder contributing to this study share this opinion. At the very least, the provision of *no* advice, particularly to a wearer with no prior experience of contact lens wear, cannot be expected to positively influenced compliance.
 - The provision of information is likely to be lower among illegal channels, and ZPLs are more likely to be obtained through illegal channels. There is also direct evidence that wearers of illegal ZPLs are at greater risk than wearers of lenses obtained through legal routes.

¹¹⁸ Schweizer et al. (2011) 'The European contact lens forum (ECLF) - the results of the CLEER-project', *Cont Lens Anterior Eye* 2011; 34(6): 293-296.

¹¹⁹ YouGov and SixthSense 'Opticians' (2011).

¹²⁰ As reported in the Research Specifications for this study.

- The behaviour of cosmetic lens wearers implies lower levels of compliance (no obligation to attend eye examinations as prescription not needed; not necessarily any prior experience with contact lens wear; more likely to engage in risky behaviour such as sharing lenses).
- 5.47 This all implies that the wear of ZPLs obtained through illegal supply is likely to result in a greater incidence of harm than either the legal sale of ZPLs, or the legal sale of corrective contact lenses. We can benchmark this against the risks associated with the use of corrective contact lenses: incidence of severe injuries among contact lens wearers of approximately 0.5 – 1.0 per cent, with the incidence of all complications approximately 10 per cent.
- 5.48 The crucial importance of patient adherence to recommended contact lens use in mitigating the risks associated with contact lens wear is a key contextual factor to the risks associated with the illegal supply of ZPLs.
- 5.49 If users of ZPLs were provided with clear written information on correct insertion, removal and wear of lenses, this is likely to mitigate some of the risks associated with the illegal supply of ZPLs. It is not clear the extent to which the physical presence of a registered practitioner increases the 'weight' of information provided, and risks could be reduced if manufacturers were responsible for the information provision.
- 5.50 Another important contextual factor is the characteristics of ZPL wearers. Previous evidence has shown that perfect compliance with recommended contact lens wear is rare, even among wearers of corrective lenses who attend check-ups with registered practitioners. Wearers of ZPLs may be less likely to comply with care instructions if they are younger, more risk-loving, and have never attended a proper eye examination. These factors would not change whether the user was supplied through a legal or illegal channel.^{121, 122} This raises the question as to the extent to which an increase in the legal supply of ZPLs would significantly reduce the associated risks.

Misuse of Protected Title

- 5.51 Feedback from all the stakeholders contributing to this study (professional bodies, industry bodies and our expert advisor) agree that the misuse of protected title by an individual is a far more significant risk than the misuse of protected title by a body corporate.
- 5.52 There is the *possible* risk that the public would perceive the body corporate using the protected title to be registered and accountable, and would thus be misled in this perception in the case of a misuse of protected title. However, it is thought that the public does not generally distinguish between registered bodies corporate using a protected title and unregistered bodies corporate that do not use a protected title; or indeed other business types such as partnerships that can use the protected titles without having to be registered. There is also no immediate reason why a body corporate using a protected title without being registered would be any more risky than a body corporate not using a protected title and not registered. We therefore focus on the risks associated with the individual misuse of protected title.
- 5.53 The main *direct* risk of the misuse of protected title is that the public would be misled with regard to the individual's registration status and, therefore, qualifications levels and accountability to the regulator. If patients were to discover that a practitioner using a protected title was not registered with the GOC, this might undermine their trust in the optical profession as a whole, casting doubt on the value of registration status, qualifications and oversight of possibly all registered

¹²¹ This view of the characteristics of ZPL wearers is supported by the literature, as well as by the majority of professional bodies contributing to this study.

¹²² The legal supply of ZPLs must be carried out by, or under the supervision of a registered practitioner. This fact would not affect the inherent characteristics of ZPL wearers.

- practitioners. In terms of health risks, this could lead to patients placing less value on the services of registered optometrists and dispensing opticians, potentially foregoing eye examinations and risking eye conditions going unnoticed and untreated.
- 5.54 There are also *indirect* risks associated with the misuse of protected titles that relate to the nature of the individual misusing the title. The main indirect risks relate to levels of qualification and training — the less able any practitioner is to perform restricted functions, the more risk there is to patient health.
- 5.55 With the exception of one industry body, all stakeholders contributing to this research consider there to be a ‘spectrum’ of risk associated with individuals who misuse protected titles:
- Individuals with no or little qualifications or training. These pose a significant risk if they pose as registered practitioners as they lack the skills to carry out restricted functions, or to mitigate the risks associated with some areas of optical practice. The risks involved would be a *combination* of all the above unlawful areas of optical practice, e.g. unlawfully testing sight, fitting and supplying contact lenses and supplying spectacles. Feedback from one professional body suggests that the misuse of title among genuinely untrained individuals would usually entail an optical assistant posing as a registered dispensing optician, or an dispensing optician posing as an optometrist.
 - Individuals with some level of appropriate training, but not (yet) registered. This would include students who are near qualification but not registered practising as if they were. It is argued that these pose much less risk than an unqualified individual. It has also been suggested by a professional body that this could include dispensing opticians acting as optometrists. Dispensing opticians are familiar with a number of eye conditions and can appropriately refer patients who present with serious conditions. It is argued that patients who think they are seeing a dispensing optician but actually see an optical assistant (perhaps with very little training) could be exposed to the most risk; at least a dispensing optician posing as an optometrist should have some requisite understanding of sight threatening conditions.
 - Individuals who have been previously registered with the GOC. These would include those whose registration has temporarily lapsed (very little perceived risk) and those who have been removed or suspended from the register (higher risk, but unlikely to be as high as someone with no training).
- 5.56 Despite this risk spectrum, there are some characteristics of those who misuse a protected title that imply increased risk, regardless of their level of training (these have been suggested by stakeholders):
- Those who purposefully pose as being registered presumably do not have a problem with unlawful behaviour. This could imply a risk-seeking attitude and one that is more concerned with being employed than with patient health and safety.
 - People who pose as being more qualified than they really are may realise they are doing wrong and compensate through over cautious behaviour (thus reducing risk). On the other hand, such unregistered practitioners may undertake more serious risks such as not properly referring a patient for fear of being caught out.
- 5.57 Overall the potential harm arising from the indirect risks of the misuse of protected title can be high; indeed as high as the risks associated with specific areas of unlawful practice. These are likely to be significantly more harmful than the direct risk of undermining public trust in the profession.

Likelihood of an adverse event

- 5.58 The likelihood of the direct risks associated with the misuse of protected title (e.g. patients losing trust in the optical profession) is unknown. The complaints relating to misuse of protected title received by the GOC form approximately five to ten per cent of all complaints regarding illegal practice.
- 5.59 The likelihood of the indirect risks is also unknown, although where there is overlap with other areas of unlawful practice then there would be a similar likelihood of an adverse event occurring.
- 5.60 Feedback from stakeholders suggests a 'spectrum' of risk depending on the nature of the individual posing as a registrant. However, as information is not available on the range of individuals misusing protected titles (or indeed on their actual number) it is not possible to assess the likelihood of associated risks. Some stakeholders are of the opinion that the most common reasons for an unregistered person working as if he or she were registered is either a registrant who has allowed his registration to lapse, or a student who has passed his exams and assumes he is qualified and registered before this is the case.

6 Comparative Analysis

Comparative Analysis of Legal and Illegal Practice

- 6.1 The table below summarises our analysis on the severity and likelihood of an adverse event in illegal practice. It also provides a comparison with the severity and likelihood of an adverse event in legal practice.
- 6.2 The final column summarises our analysis on the *overall* likelihood of adverse events across illegal practice. This is based on the likely scale of illegal practice.
- 6.3 As discussed above, direct evidence on the severity and likelihood of an adverse event in illegal practice is not available for a number of practice areas. Therefore our analysis partly reflects *potential* risks.
- 6.4 Given the issues related to complaints data (in that they do not necessarily reflect the scale or likelihood of risks arising from illegal practice and can be influenced by other factors such as public perception or even the way in which the GOC deals with an issue) our analysis below places very little weight on the level of the complaints about illegal practice received by the GOC.

Table 6.1: Summary of severity and likelihood of an adverse event in legal and illegal practice

Practice Area	Risk area of legal practice	Harm from an adverse event (legal)	Likelihood of an adverse event (legal)	Harm from an adverse event (illegal)	Likelihood of an adverse event (illegal)	Overall likelihood of adverse events across illegal practice	Discussion
Sight tests							
	Misdiagnosis/Missed diagnosis/ Mismanagement of diseases and conditions	High	Low	Unknown: Implied higher than legal (timing is a crucial factor in diagnosis and treatment)	Unknown - likely to be higher than legal. Implied Medium-high.	Unknown. Likely to be less common than illegal dispensing or supply of contact lenses. Implied low.	The likelihood of an unregistered practitioner misdiagnosing or mismanaging an optical condition is likely to be high, given the importance of training and on-going education in identifying and treating diseases. The overall scale of this illegal practice is likely to be relatively low compared to other forms of illegal practice.
	Incorrect prescription	Low/Medium-low	Medium-low	Low/ Medium (assuming extent of errors is greater)	Unknown - likely to be higher than legal. Implied medium.	Unknown. Likely to be less common than illegal dispensing or supply of contact lenses. Implied low.	The harm from incorrect prescriptions (for children and vulnerable adults) is likely to be greater in illegal practice if the extent of prescription errors is greater.
	Trauma through incorrect use of equipment	Unknown. Possibly low	Very low	Unknown. Possibly low	Unknown - implied low	Unknown. Likely to be less common than illegal dispensing or supply of contact lenses. Implied low.	The harm arising from incorrect use of equipment would be the same in legal and illegal practice. The likelihood of harm occurring in illegal practice may be the same (or lower) than in legal practice if simpler, less damaging, equipment is used.

Practice Area	Risk area of legal practice	Harm from an adverse event (legal)	Likelihood of an adverse event (legal)	Harm from an adverse event (illegal)	Likelihood of an adverse event (illegal)	Overall likelihood of adverse events across illegal practice	Discussion
Spectacle dispensing							
Dispensing spectacles to adults	Poor fit/ Incorrect prescription	Low	Medium-low	Not illegal to dispense to adults	Not illegal to dispense to adults	Not illegal to dispense to adults	NA
Dispensing to children	Poor fit/ Incorrect prescription	Medium	Low (Medium-low with online dispensing).	Medium/ Medium-high (assuming extent of errors is greater)	Unknown - likely to be higher than legal. Implied medium.	Unknown. Likely to be more common than some other types of illegal practice: Implied Medium-low	The harm caused by illegal dispensing to children is likely to be greater than that caused by legal dispensing to the extent that the error made is greater (i.e. at least some of the time). Lack of training and CET makes it possible that an illegal practitioner would be more likely to cause an adverse event. The overall likelihood of this occurring may be relatively high, such as optical assistants dispensing whilst the supervisor is not present.
Dispensing of multifocal spectacles	Poor fit/ Incorrect prescription/ Incorrect type of lens	Medium-low	Unknown - thought to be low	Same as legal: Medium-low	Unknown - likely to be higher than legal. Implied Medium.	Unknown - could be similar to likelihood of illegal dispensing to children: Implied Medium-low	The harm caused by adverse events will be the same in legal and illegal practice (i.e. if someone falls, how bad the fitting was does not impact upon the harm). The likelihood of an illegal practitioner causing an adverse event is likely to be higher than in legal practice given lack of training and CET. The overall likelihood of this occurring is unknown, but may be driven by similar factors as illegal dispensing to children if conducted under the same circumstances.

Practice Area	Risk area of legal practice	Harm from an adverse event (legal)	Likelihood of an adverse event (legal)	Harm from an adverse event (illegal)	Likelihood of an adverse event (illegal)	Overall likelihood of adverse events across illegal practice	Discussion
Contact lens fitting							
	Incorrect fitting/lack of follow up: too tight fit	Medium	Low	Same as legal: Medium	Unknown - higher than legal. Implied Medium	Unknown. Likely to be less common than illegal supply of contact lenses. Likelihood of 're-fitting' greater. Implied Medium-low.	Given that skill and training are important in fitting lenses, an illegal practitioner would be more likely to cause an adverse event assuming he has lower levels of training. Risks may be mitigated in part due to general acceptability of fit of most modern disposable lenses. The overall likelihood of this occurring is unlikely to be very high, as practitioners with no training less likely to undertake an invasive function like fitting. However, likelihood of illegal 're-fitting' through substitution likely to be higher.
	Incorrect fitting/lack of follow up: too loose fit	Low	Very low	Same as legal: Low	Unknown - higher than legal. Implied Medium-low	Unknown. Likely to be less common than illegal supply of contact lenses. Likelihood of 're-fitting' greater. Implied Medium-low.	Given that skill and training are important in fitting lenses, an illegal practitioner would be more likely to cause an adverse event assuming he has lower levels of training. Risks may be mitigated due to discomfort felt by patient that should alert them to incorrect fit.

Practice Area	Risk area of legal practice	Harm from an adverse event (legal)	Likelihood of an adverse event (legal)	Harm from an adverse event (illegal)	Likelihood of an adverse event (illegal)	Overall likelihood of adverse events across illegal practice	Discussion
	Not providing sufficient advice on aftercare and hygiene at the time of fitting.	Medium-high	Low	Higher than legal: Medium-high/High	Unknown - higher than legal. Implied Medium	Unknown. Likely to be less common than illegal supply of contact lenses. Likelihood of 're-fitting' greater. Implied Medium.	Harm from an adverse event likely to be higher in illegal practice as practitioner may fail to provide advice on danger signs, leading to complications going unnoticed and hence untreated for longer. Likelihood of an adverse event unknown but likely to be greater in illegal practice (lower levels of training on importance of patient information).
Contact lens supply							
	Not providing sufficient advice on aftercare and hygiene	Medium-high	Low	Higher than legal: Medium-high/High	Unknown - higher than legal. Implied Medium-high	Unknown, but likely to be Medium-high/High as implied by available information	Harm from an adverse event likely to be higher in illegal practice as practitioner may fail to provide advice on danger signs, leading to complications going untreated for longer. Likelihood of an adverse event unknown but likely to be greater in illegal practice if lower levels of training on importance of patient information. Key contextual factor is provision of patient information with the lenses.

Practice Area	Risk area of legal practice	Harm from an adverse event (legal)	Likelihood of an adverse event (legal)	Harm from an adverse event (illegal)	Likelihood of an adverse event (illegal)	Overall likelihood of adverse events across illegal practice	Discussion
	ZPLs	Medium-high	Low-medium	Higher than legal: Medium-high/High	Unknown - higher than legal. Implied Medium-high	Unknown, but likely to be High as implied by available information	Likelihood of an adverse event associated with the illegal sale of ZPLs is likely to be relatively high given the characteristics of ZPL wearers and the probability of no patient information provided at time of supply. Individuals involved more likely to be retail staff with no optical training at all. Overall likelihood of an adverse event unknown as scale of ZPL wear unknown. Possibly similar to overall likelihood of an adverse event from illegal PL supply (i.e. the supply of lenses without the supervision or general direction of a registered practitioner). Key contextual factor is provision of patient information with the lenses.
	Online supply	Medium-high	Low-medium	Same as other CLs illegally supplied, although could be higher if illegal substitution introduces different lens types.	Unknown - higher than legal. Implied Medium-high	Unknown, but likely to be Medium-high/High as implied by available information	The likelihood of harm caused by illegal online supply is likely to be the same as illegal direct supply if no information is provided. However, online substitution could introduce more risk if inferior lenses are substituted. Some risk mitigation if user has prior knowledge of CL recommended wear (as compared with ZPL use). Key contextual factor is provision of patient information with the lenses.

Practice Area	Risk area of legal practice	Harm from an adverse event (legal)	Likelihood of an adverse event (legal)	Harm from an adverse event (illegal)	Likelihood of an adverse event (illegal)	Overall likelihood of adverse events across illegal practice	Discussion
Misuse of protected title (individuals)							
	Misleading public/undermining trust	N/A	N/A	Unknown: Implied low	Unknown: Implied low	Unknown: Implied low	The direct harm caused by misuse of protected title likely to be low.
	Indirect risks: not qualified to perform restricted functions of a registrant	N/A	N/A	High (but depends on the function being undertaken illegally)	Unknown. Implied Medium/ Medium-High, given combined nature of illegal tasks	Unknown. Implied Medium	Indirect harm from adverse events relating to unlawfully conducting restricted functions could be high, depending on the restricted function. Combined likelihood likely to be high. Overall likelihood unknown but not likely to be very high based on complaints.
Misuse of protected title (BCs)	Misleading public/trust	N/A	N/A	Negligible	Negligible	Negligible	Public appear unlikely to place much importance on protected titles for bodies corporate.

Summary of Contextual Factors

- 6.5 There are a number of contextual factors that are likely to mitigate or exacerbate the risks in the different practice areas:
- Patient profiles. The characteristics of certain patients may place them at greater risk of an adverse event regardless of practitioner influence. This includes contact lens wearers who do not comply with advice regardless of how it is provided. This may be particularly relevant to wearers of ZPLs who tend to be younger and more likely to engage in risky behaviour.
 - Similarly, older patients and those from certain demographic background are at greater risk of developing certain diseases (such as glaucoma).
 - Adults' ability to detect spectacle non-tolerances and ill-fitting contact lenses (in some cases) partly mitigates the associated risks of adverse events.
 - Vulnerable adult groups (e.g. elderly patients or adults with learning difficulties), and children may be more vulnerable to errors in spectacles and contact lenses and less likely to notice or report these.
 - The provision of written information to patients on correct insertion, removal and wear/hygiene procedures of contact lenses on supply. This may mitigate some of the risks associated with the illegal supply of contact lenses where the main underlying risk is a lack of information and advice provided by the supplier. This would apply to the supply of both PLs and ZPLs.
 - The continuing education and training (CET) of registered practitioners helps to mitigate the risks associated with legal practice.
 - The FtP regime of the GOC provides some deterrent effect on poor practice by registered practitioners.

Areas of Insufficient Information

- 6.6 The majority of illegal practice areas (with the possible exception of the supply of ZPLs, where direct research has been undertaken to assess the harm caused by wearing ZPLs sourced through unregulated channels) lack sufficient information to assess definitively the severity of harm. However, we believe that the evidence base on the severity of harm in legal practice areas provides a constructive benchmark, as it can be safely assumed (we believe) that adverse events arising from illegal practice will be at least as harmful as those arising from legal practice.
- 6.7 Where the absence of information is more limiting is with respect to the *likelihood* of an adverse event occurring in illegal practice. Although it is again implied that an illegal practitioner is more likely to cause an adverse event than a legally practising one, there is no direct evidence that enables us to quantify this effect. This is compounded by the lack of information about the overall scale of illegal practice.
- 6.8 Possible ways to increase the evidence base would be to:
- Set up an anonymous online reporting system for illegal practice, requiring complainants to submit sufficient detail to enable the auditing of such complaints. This would still not inform the relative likelihood of illegal practice relative to the total population.
 - Information on the scale of risks in legal practice could be further informed by analysis of legal cases (preferably including those settled out of court).
 - The best way to establish clear likelihood of risk is to set up randomised controlled trials (this may be beyond the resources of the GOC).

- 6.9 Further research into other areas would also help to move forward analysis of the risks of illegal optical practice. This might be undertaken by the professional bodies, suppliers/manufacturers or academics. Relevant areas include:
- Online substitution. More evidence is needed on the extent to which online substitution of contact lenses results in the provision of sub-optimal lenses. Indeed, it would also be valuable to have more data on the prevalence of online substitution.
 - Relatedly, more evidence is needed on the adverse effects arising from patients wearing sub-optimal substituted lenses.

Recommendations on the Most Risky Practice Areas

- 6.10 In assessing which practice areas carry the greatest risk to public health (whether legal or illegal), we consider both the severity of harm caused by an adverse event and the likelihood of an adverse event occurring.

Legal practice

- 6.11 Information on risks in legal practice is drawn primarily from published evidence, and complemented by qualitative evidence gathered from professional bodies and our expert advisor, as well as by data gathered by the GOC.
- 6.12 Some areas of legal practice do not pose a significant risk in terms of the likelihood of an adverse event occurring, or in terms of the harm that an adverse event might cause. For example, as shown in our summary Table 3.1 the harm from an adverse event is relatively low for incorrect spectacle prescriptions and poorly fitted spectacles for adults; contact lenses that are too loose; and (legal) online substitution of contact lenses. The likelihood of an adverse event occurring is low for the misdiagnosis of diseases; trauma through incorrect use of equipment; poorly fitting spectacles for adults and children; and contact lens fitting.

Most risky area of legal practice

- 6.13 The area of legal practice where an adverse event would cause the most serious harm is the misdiagnosis of optical conditions and diseases (termed high in our summary Table 3.1). The potential consequences of certain conditions going untreated — such as glaucoma, AMD and retinal detachments — can be severe, leading to partial or complete loss of sight. However, the likelihood of an adverse event occurring in relation to misdiagnosing diseases is low, given the lack of evidence of optometrists missing diseases outright, and the propensity of optometrists to be cautious when diagnosing and referring suspect cases.
- 6.14 The harm caused by adverse events relating to contact lens fitting and supply is also relatively high (termed medium-high in our summary table). Adverse effects include infection caused by ill-fitted lenses or patients' inadequate adherence to care and maintenance regimes. The areas of contact lens supply that are related to the relatively highest likelihood of an adverse event, together with the medium-high severity of an adverse event, are the online supply of contact lenses and the supply of ZPLs.
- 6.15 The likelihood of an adverse event with the supply of ZPLs is in part exacerbated by the behaviour of ZPL wearers, and therefore we consider it possible that the online supply of contact lenses is the area of legal optical practice that relatively carries the greatest health risk to the public.

Illegal practice

- 6.16 Our analysis of illegal practice has greater ambiguities due to the limited direct evidence available. Where available, we have drawn from published evidence of the risks, but have also needed to use the evidence gathered on legal risks along with our own analysis to reach conclusions on the risks of and harm associated with illegal optical practice.
- 6.17 The potential clinical harm from adverse events arising from illegal practice is in some cases the same as the potential harm related to legal practice. Exceptions include the misdiagnosis of diseases (whereby the timing of diagnosis and referral is key and may be more delayed under illegal practice); incorrect prescriptions (provided the extent of errors is greater under illegal practice); the lack of provision of care and maintenance advice (if illegal practitioners fail to give advice on detecting signs of infection this could remain untreated for longer); the sale of ZPLs; and illegal substitution of lenses (during which inferior lenses may be provided).

Most risky area of illegal practice

- 6.18 Our analysis indicates that the misdiagnosis of diseases has both a high severity of an adverse event, and a medium-high likelihood of an adverse event occurring under illegal practice. This implies that this is the practice area that carries the greatest risk to the public. This also suggests that the misuse of protected title, with its indirect link to the unlawful conducting of sight tests, is an area of high overall risk.
- 6.19 The practice areas of the illegal fitting and supply of contact lenses also pose a relatively high overall risk to the public (with a medium-high/high severity of harm and a medium-high likelihood of an adverse event), although the misdiagnosis of diseases through unlawfully conducted sight tests is above this.



Appendices



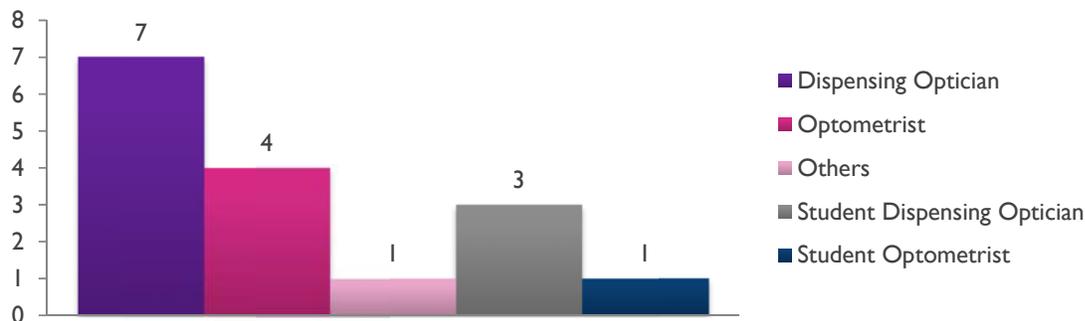
Europe Economics

7 Appendix 1: Data Analysis

Fitness to Practise Hearings

- 7.1 We explored the GOC Fitness to Practise (FtP) hearings for evidence of risks related to illegal practice. These represent complaints that were deemed serious enough by the GOC's Investigating Committee to pursue through a formal hearing. They provide some insight on the potential scale of such risks within the optical profession, although eliciting the complete set of underlying factors in each case is not possible.
- 7.2 The aim of our analysis is to inform our findings on the likelihood of adverse events in illegal practice, so as to supplement the evidence we have gathered.
- 7.3 Building on our 2010 report, we have reviewed all hearings from 2007 until 2012, compiling a database consisting of 153 FtP cases. Among these, we found 16 cases relevant to illegal practice in the optical sector (i.e. just over 10 per cent). Here, we provide a high level description of the hearings associated to illegal optical practice.
- 7.4 The chart below presents the distribution of the 16 cases according to the individual's registration status.

Figure 7.1: Total FtP cases relating to illegal practice by registration status



Nature of the Cases

- 7.5 Our rationale for determining whether a case is relevant to the issue of illegal practice is based on the areas of risk identified in the chapter Typology of Illegal Practice. In general terms, all the relevant hearings fall under one of the following cases:
- Operating as a registrant while not being registered at all with the GOC.
 - Operating as a registrant on a particular register without being registered on that register.
 - Conducting contact lens fitting without a valid prescription.
 - Not providing patients with a prescription after fitting.
- 7.6 Of the relevant cases, 13 related to the individual not being registered with the GOC, of which two individuals had previously been removed from the register and one had let his registration lapse. Seven individuals (including three who were registered with the GOC) were not registered on the appropriate register either because they had not obtained the qualification relevant to the

restricted function they were carrying out, or because they were students who had not yet completed the necessary qualifications to be registered.

Classification

7.7 The outcomes of FtP hearings can range from no sanction to erasure from the GOC register. Of the 16 hearings, the most common sanctions were suspension (nine cases) and erasure from the register (three). In two cases, no sanction was given and fines were imposed in three.

Complaints Data

7.8 We also examined the complaints to the GOC regarding illegal practice. These are cases which do not fall under the GOC's FtP remit. This information was provided by the GOC. We note that the percentages of all complaints represented by each area of illegal practice differ slightly to those reported in the main body of the text. The latter were provided by the GOC in the Research Specification. As this data analysis appendix is for our internal analysis, we report the figures provided in the publically available Research Specification in the main body of the report.

7.9 We note that complaints do not necessarily provide a good indication of the distribution of risks, and can be heavily influenced by either the ease with which an illegal practice can be identified or the perception of the complainants regarding the severity of the practice.

7.10 Given the issues related to complaints data our analysis of the most risky areas of illegal practice does not explicitly take into account the complaints about illegal practice received by the GOC.

Classification

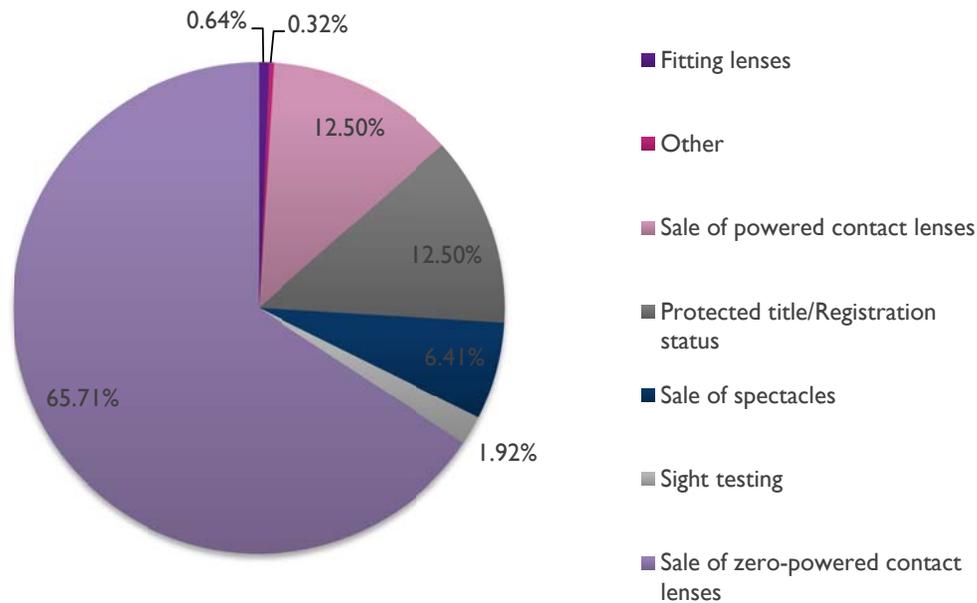
7.11 The GOC recorded a total of 312 complaints between 2010 and 2012. Of these, the GOC has closed 102 cases, 33 per cent of the total.

7.12 All complaints are categorised according to the nature of the alleged offence:

- Sale of zero-powered contact lenses
- Sale of powered contact lenses
- Fitting of contact lenses
- Sale of spectacles
- (Abuse of) Protected title/ Misrepresentation of registration status
- Sight testing
- Unclear

7.13 We present below the distribution of complaints according to this classification. As can be seen, the sale of ZPLs is the source of the largest number of complaints.

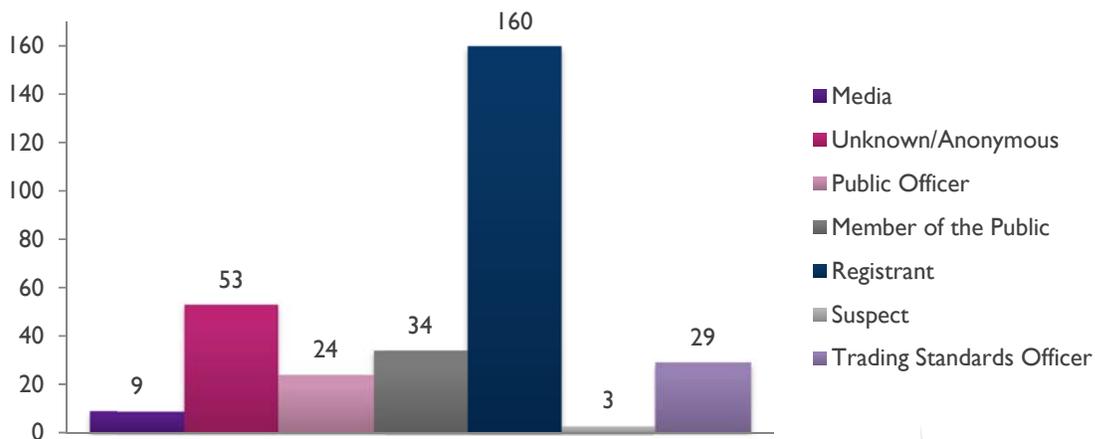
Figure 7.2: Classification of criminal cases



Source and Nature of the Complaint

7.14 The complaints recorded show that most of them are submitted by registrants, registered either with the GOC or with the GMC.

Figure 7.3: Informants by type



7.15 We identify the following general points regarding the nature of the complaints: 123

- All complaints relating to sight testing involved the practitioner not being qualified and/or registered.

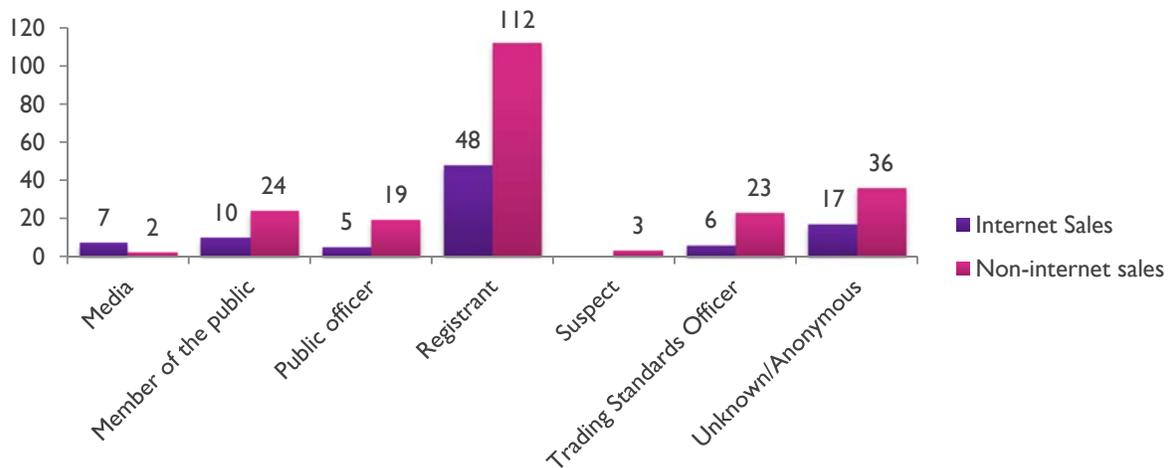
¹²³ As a caveat we note that the level of detail recorded did not always enable us to identify the illegal nature of each complaint.

- Complaints linked to the sale of spectacles were mostly related to unqualified individuals selling spectacles to minors without supervision and to non-registrants using a protected title.
- In the cases relating to the sale of powered lenses, the most common causes of complaint were the remote supply (online and by post) to minors, the misuse of a protected title and the sale of contact lenses without requesting a prescription.
- For cases falling under the protected title classification, the complaints naturally relate to the misuse of a protected title by businesses and non-registrants, the misuse of such titles in commercial advertisements and the display of the GOC logo without a valid registration.
- Complaints for the sale of zero-powered contact lenses related to:
 - Eye infections and complications resulting from wearing zero-powered contact lenses.
 - Shops selling such lenses without the presence of a qualified professional.
 - Online sale of zero-powered contact lenses by merchant websites such as eBay and Amazon.

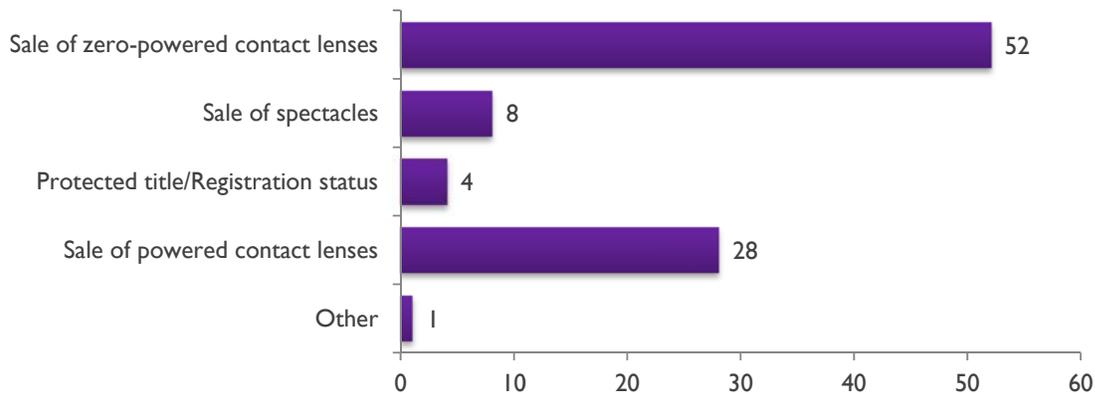
Internet sales

7.16 Out of all 312 complaints recorded, 93 related to internet sales, i.e. just under 30 per cent. These complaints come mostly from registrants, members of the public and anonymous informants. The chart below illustrates this distribution:

Figure 7.4: Complaints about internet sales by type of informant



7.17 The majority of complaints are in relation to the online sale of zero-powered lenses (52 complaints), followed by the online sale of powered contact lenses amounting to (28 cases).

Figure 7.5: Complaints related to internet sales

Harm

7.18 In total there were five complaints in which actual harm was reported. All related to the sale of zero-powered contact lenses. That accounts for 2.4 per cent of the complaints relating to zero-powered contact lenses, or 1.6 per cent of all complaints. The types of harm reported are:

- Temporary vision loss
- Scratch on the eye
- Eye infections
- Eye swelling
- Staining of the eye

Conclusions

7.19 The sale of ZPLs is the largest source of complaint. It is also the only area where actual harm has been recorded. However, it is not possible to draw conclusions regarding the prevalence of harm related to the sale of ZPLs. The data analysis suggests a very low prevalence, but it is possible that much information about harm caused is not reported.

7.20 It is also not clear how the harm caused by ZPLs relates to harm caused by other areas of illegal practice. Complaints do not necessarily provide a good indication of the distribution of risks, and can be heavily influenced by either the ease with which an illegal practice can be identified or the perception of the complainants regarding the severity of the practice. For example, it is likely that the illegal sale of ZPLs by a fancy dress store is far easier to identify than a practitioner misusing a protected title.

8 Appendix 2: Clinical Risks from 2010 Risk Assessment

- 8.1 The table below summarises the clinical risks analysed in our 2010 Risk Assessment of legal optical practice.

Table 8.1: Summary of Practitioner and Contextual Risks Relating to Adverse Events

Adverse Event	Clinical Risk	Practitioner Risk	Related Contextual Factors	Scope for Revalidation
Glaucoma	High	Medium	Patient profile (age and ethnicity) Domiciliary care (related to patient profile; accuracy of equipment) Length of time in practice (being up to date with equipment and testing techniques)	Medium. Largely concerns appropriate tests and referral refinement.
Detached retina	High	Medium	Length of time in practice (being up to date with equipment and testing techniques)	Medium/low. Largely concerns eliciting and recognising symptoms.
Spectacle non-tolerance	Low	Low	Length of time in practice (less experience may result in greater incidence of non-tolerances) Isolated/sole practitioners (those that do no work with dispensing opticians and may not be up to date with appliances) Locums (not around to learn from re-visits)	None. However, outside of revalidation auditing could be promoted as good practice.
Diabetic conditions	High	Medium/low	Patient profile (age and diabetic) Domiciliary care (patients may not have access to screening programmes)	Medium/low. Perhaps include targeted CET in this area.
Macular degeneration	Medium (more so for the wet kind as dry cannot be treated)	Medium/low	Patient profile Domiciliary care	Low. Mainly concerns distinguishing between AMD and other age-related conditions.
Contact lenses	Medium	Low	Isolated/rural practice (less likely to refer to more experienced colleague) Locums (may not be around for after care)	Low. Largely concerning communication of hygiene regimes.
Children	Medium	Low	Patient profile Isolated/rural practice (less likely to refer to more experienced colleague)	Low. Target CET in this area.
Independent prescribing	Medium/high	Low/not known	Most likely to be carried out in hospital setting.	Low. Area of practice should be monitored.
Decision-making	N/A	Medium	Particularly important for more rare conditions where opportunity for refinement is	Medium. Increase exposure to cases, either in practice or

Adverse Event	Clinical Risk	Practitioner Risk	Related Contextual Factors	Scope for Revalidation
			less frequent.	through simulation.
Communication	N/A	Low	Particularly important for child care, contact lenses, suspected retinal detachments, spectacle non-tolerances, locums and domiciliary care.	Low. Focus CET on the importance of communication, with emphasis on areas highlighted.
Record-keeping	Not classified as a risk		Particularly important for Domiciliary care; Locums; contact lenses	None.

References

Ang GS, Ng WS and Azuara-Blanco A (2009) 'The influence of the new general ophthalmic services (GOS) contract in optometrist referrals for glaucoma in Scotland.', *Eye*, Vol 23, P351-355

Appleton C.B (1971) 'Ophthalmic prescription in half-diopter intervals', *Archives of Ophthalmology*, Vol 86, p263-267

Atkinson (2008) "Buying Contact Lenses Online: A Critique of the Fogel and Zidile Optometry Journal Study", *The Information Technology & Innovation Foundation*, June 2008 [Available here]

Atkinson J, Braddick O, Robier B, Anker S, Ehrlich D, King J et al (1996) 'Two infant vision screening programmes: prediction and prevention of strabismus and amblyopia from photo- and videorefractive screening', *Eye (London)*, Vol. 10 (Pt 2) pp 189-198

Australian Competition and Consumer Commission (2007) "Novelty Contact Lenses, safety alert" [Available here]

Azuara-Blanco A, Burr J, Thomas R, MacLennan G and McPherson S (2007) 'The accuracy of accredited glaucoma optometrists in the diagnosis and treatment recommendation for glaucoma', *British Journal of Ophthalmology*, Vol 91, p1639-1643

Batterbury, M and Bowling, B (2002) 'Ophthalmology: An illustrated colour text', Churchill and Livingstone, London

Bell RWD and O'Brien C (1997) 'Accuracy of referral to a glaucoma clinic', *Ophthalmic and Physiological Optics*, Vol 17(1) p7-11

Birch EE, Fawcett SL, Morale SE, Weakley DR, Jr., Wheaton DH (2005) 'Risk factors for accommodative esotropia among hypermetropic children', *Invest Ophthalmol Vis Sci*, 46(2) pages 526-529.

Bowling B, Chen S and Salmon J (2005) 'Outcomes of referrals by community optometrists to a hospital glaucoma service', *British Journal of Ophthalmology*, Vol 89 p1102-1104

California State Board of Optometry (2012) "Cosmetic Contact Lenses - Change the Look of Your Eyes Safely and Legally" [Available here]

Calkins, J. L. and B. F. Hochheimer (1980) 'Retinal light exposure from ophthalmoscopes, slit lamps, and overhead surgical lamps. An analysis of potential hazards', *Invest Ophthalmol. Vis. Sci.*, Vol. 19, Iss. 9:v1009-1015

CAO (2011) "Cosmetic contact lens legislation sees the light of day!", *Press Release* (5 October 2011) [Available here]

CAO (2012) "Bill C-313: An act to amend the Food and Drug Act (non-corrective contact lenses)" [Available here]

CAO (2012) "Thinking about buying eyewear online...", *Statement in Response CBC Marketplace* (24 February 2012) (Accessed on 15 January 2013) [Available here]

cgvExpert (2012) 'Aspects juridiques de la vente de lunettes et lentilles sur Internet', 2 August 2012. [Available [here](#)]

Chalmers et al. (2012) 'Multicenter Case-Control Study of the Role of Lens Materials and Care Products on the Development of Corneal Infiltrates', *Optometry and Vision Science*, Vol. 89, No. 3, March 2012

Chodpar A, Chakravarthy U and Verma D (2003) 'Clinical review: age-related macular degeneration', *BMJ*, Vol 326, p485-8

choissirsleslunettes.com (website) 'Nouvelle réglementation pour la vente de lentilles et de lunettes sur internet'. Accessed on 6 March 2012. [Available [here](#)]

Citek et al. (2011) 'Safety and compliance of prescription spectacles ordered by the public via the Internet', *Optometry*, Vol. 82, 549-555

Collins M.J and Carney L.G (1998) 'Patient compliance and its influence on contact lens wearing problems', *American Journal of Optometry and Physiological Optics*, Vol. 63, 952 - 956

COS (2012) "Non-corrective contact lenses become medical devices – Bill C-313 has received royal assent", 17 December 2012 [Available [here](#)]

Cummings et al 2007; and Harley et al 2007 cited in Freeman and Evans (2009) *Ophthalmic and Physiological Optics* Vol 29, p1-11

Duke-Elder and Abrams 1970; Comas et al. 2007; Lovasik and Szymkiw 1985; Atchison et al. 2001 cited in Freeman and Evans (2009) *Ophthalmic and Physiological Optics* Vol 29, p1-11

Dart JK, Radford CF, Minassian D, Verma S, & Stapleton F (2008) 'Risk factors for microbial keratitis with contemporary contact lenses: a case-control study', *Ophthalmology*, Vol. 115, 1647-54

Dart JKG, Stapleton F, Minassian D (1991) 'Contact lenses and other risk factors in microbial keratitis', *Lancet*, Vol. 338

Destinationsante.com (2009) 'Lentilles « cosmétiques » : attention les yeux !', 28 October 2009. Accessed on 6 March 2012. [Available [here](#)]

Diec J, Lazon dlj, Willcox M, Holden BA. The clinical performance of lenses disposed of daily can vary considerably. *Eye Contact Lens* 2012; 38(5):313-318

Dumbleton KA, Woods CA, Jones LW, and Fonn D (2011) 'The relationship between compliance with lens replacement and contact lens-related problems in silicone hydrogel wearers', *Cont Lens Anterior Eye* 34, 216-222

ECJ (2010) "Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete " *Case C-108/09* [Available [here](#)]

ECOO (2008) "ECOO Blue Book", [Available [here](#)]

EF Chemical Consulting Ltd (2011) 'Cosmetic Product Safety Report', In Compliance with EC Regulation 1223/2009, 6 December 2011. [Available [here](#)]

EUbusiness (2011) "Contact lens law is clarified by EU Court", 26 January 2011 (Accessed on 14 January 2013) [Available [here](#)]

Europe Economics (2010) 'Risks in the Optical Profession', A report for the General Optical Council

French-Mowat and Burnett (2012) "How are medical devices regulated in the European Union?" *Journal of the Royal Society of Medicine*, 105: S22–S28. [Available [here](#)]

Ginn (undated) "Losing more control" *Eurotimes*, Vol. 16, Issue 3 [Available [here](#)]

Fahmy M, Long B, Giles T, Wang CH. 'Comfort-enhanced daily disposable contact lens reduces symptoms among weekly/monthly wear patients', *Eye Contact Lens* 2010; 36(4):215-219

FDA (2006) "Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers, Decorative, Non-corrective Contact Lenses Document Issued", *Center for Devices and Radiological Health*, 24 November 2006 [Available [here](#)]

FDA (2008) "Focusing on Contact Lens Safety", *Consumer Health Information*, 18 November 2008. [Available [here](#)]

FDA (2012) "Medical Devices, Decorative Contact Lenses", *Updated on 10 October 2012* (Accessed on 14 January 2013) [Available [here](#)]

FDA (2012) "Medical Devices, List of Contact Lenses", *Updated on 2 February 2012* (Accessed on 14 January 2013) [Available [here](#)]

FDA (2012) "Medical Devices, Decorative Contact Lenses: Is Your Vision Worth It?", *Updated on 31 October 2012* (Accessed on 14 January 2013) [Available [here](#)]

FDA (2008) 'Focusing on Contact Lens Safety', *Consumer Health Information* [Available [here](#)]

Fogel and Zidile (2008) "Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices", *American Optometric Association*, 79, pp.23-35 [Available [here](#)]

Fonn, D (2001) 'Re: Cosmetic contact lenses', *Centre for Contact Lens Research expert opinion for the Canadian Association of Optometrists*

Freeman C, Evans BJW (2010) 'Investigation of the causes of non-tolerance to optometric prescriptions for spectacles', *Ophthal Physiol Opt*, Vol. 30, Iss. 1:1-11

Gasson A, Morris J (2010) 'The contact lens manual. A practical guide to fitting', 4th Edition, Edinburgh: Butterworth-Heinemann

GOC (1984) 'Sale of Optical Appliances Order'

GOC (1993) 'The testing of sight by persons training as optometrists rules'

Hannan and Lotery (2008) 'Medical Management of Maculopathy', *Optometry in Practice*, Vol 9, 35–42

Haran et al. (2010) 'Effect on falls of providing single lens distance vision glasses to multifocal glasses wearers: VISIBLE randomised controlled trial', *BMJ*, 340:c2265

Health Canada (2003) 'Human Health Risk Assessment of Cosmetic Contact Lenses', by Dillon Consulting Limited, Final Report, 30 September 2003

Kontaktlinseninfo.com (website). Accessed on 6 March 2012. [Available [here](#)]

Ky W, Scherick K, & Stenson S (1998). 'Clinical survey of lens care in contact lens patients', *CLAO J*, Vol. 24, 216-219.

Leat, S. (2011) 'To prescribe or not to prescribe? Guidelines for spectacle prescribing in infants and children', *Clin Exp Optom*; Vol. 94. Iss. 6: 514–527

LeGuide.com (website) 'La vente de lentilles de contact sur Internet'. Accessed on 6 March 2012. [Available here]

Lord SR, Smith ST, Menant JC (2010) 'Vision and falls in older people: risk factors and intervention strategies', *Clin Geriatr Med*, Vol. 26, Iss. 4: 569-581

Michaud L, Quesnel N-M, Giasson C.J (2001) 'Avis D'Expertise – Les lentilles corneennes de puissance plano et leurs effets sur la santé oculaire', cited in Health Canada (2003)

Miller A.D, Kris M.J and Griffiths A.C (1997) 'Effect of small focal errors on vision', *Optometry and Vision Science*, Vol 74, p521-526

Morgan et al. (2011) 'An international analysis of contact lens compliance', *Contact Lens & Anterior Eye* 34, 223– 228

National Institute for Health and Clinical Excellence (2003) 'Macular degeneration (age-related) – photodynamic therapy', London

NICE (2009) 'Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension.' [Available at <http://publications.nice.org.uk/glaucoma-cg85>]

NHS Trust News (2010), 'Expert warns 'lazy' contact lens wearers not to snub advice: Audit at Southampton General Hospital' [Available here]

Opticians Act (1989, as amended)

Opticians Association of Canada (2012) "FAQ (Accessed on 15 January 2013) [Available here]

Optometrists Association Australia (2011) "Contact Lenses" [Available here]

Optometry Board of Australia (2011) "Policy on supply of novelty contact lenses" [Available here]

Ozkan et al. (2013) 'Lens parameter changes under in vitro and ex vivo conditions and their effect on the conjunctiva', *Contact Lens & Anterior Eye*, Article in Press

Parliament of Tasmania (2010) "Optometry Offences Act 2010" [Available here]

Pierscionek et al. (2009) 'Referrals to ophthalmology: optometric and general practice comparison', *Ophthal. Physiol. Opt.*, 2009 29: 32–40

Queensland Parliamentary Council (2009) 'Health Practitioner Regulation National Law (2009)', Act No. 45 of 2009 [Available here]

Royal College of Ophthalmologists guidelines. [Available here, accessed October 2009]

Royal College of Optometrists (2009) 'Information for the Public: Detached Retina' [Available here]

Santodomingo-Rubido et al. (2008) 'Compatibility of two new silicone hydrogel contact lenses with three soft contact lens multipurpose solutions', *Ophthal. Physiol. Opt.* 2008, 28: 373–381

Sauer A & Bourcier T (2011) 'Microbial keratitis as a foreseeable complication of cosmetic contact lenses: a prospective study', *Acta Ophthalmol*, Vol. 89, e439-e442

- Schein OD, Glynn RJ, Poggio EC, et al. (1989) 'The relative risk of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses', *New England Journal of Medicine*, Vol. 321
- Schweizer et al. (2011) 'The European contact lens forum (ECLF) - the results of the CLEER-project.', *Cont Lens Anterior Eye* 2011; 34(6): 293-296
- Shah et al (2008) 'Glaucoma detection: the content of optometric eye examinations for a presbyopic patient of African racial descent' *British Journal of Ophthalmology*, published online 5 December 2008
- Shah et al. (2009a) 'The content of optometric eye examinations for a presbyopic patient presenting with symptoms of flashing lights.' *Ophthalmic Physiol Opt*; 29(2):105-126.
- Simons and Presland (1999) 'Natural history of amblyopia untreated owing to lack of compliance', *Br. J. Ophthalmol.*, Vol. 83: 582-587
- Singh S, Satani D, Patel A, & Vhankade R (2012). 'Colored cosmetic contact lenses: an unsafe trend in the younger generation', *Cornea*, Vol. 31, 777-779
- Slater, J. (2011) "Your Webinar Questions Answered", Optometrists Association Australia [Available here]
- Snyder et al. (1991) 'Microbial Keratitis Associated with Plano Tinted Contact Lenses', *CLAO Journal*, Vol 17 No 4: 252-255, October 1991
- Steele, C. (2010) 'Medical Management of Chronic Open-angle Glaucoma', *Optometry in Practice* 2010, Volume 11 Issue 3 111 – 122
- Stapleton et al. (2007) "The Epidemiology of Contact Lens Related Infiltrates", *Optometry and Vision Science*, Vol. 84, No. 4, April 2007
- Steinemann TL, Fletcher M, Bonny AE, Harvey RA, Hamlin D, Zloty P, Besson M, Walter K, & Gagnon M (2005) 'Over-the-counter decorative contact lenses: Cosmetic or Medical Devices?', *A Case Series, Eye Contact Lens*, Vol. 31, 194-200
- Steinemann TL, Pinninti U, Szczotka LB, Eiferman RA, & Price FW, Jr. (2003) 'Ocular complications associated with the use of cosmetic contact lenses from unlicensed vendors', *Eye Contact Lens*, Vol. 29, 196-200
- Sullivan and Fowler (1989) 'Investigation of Progressive Addition lens patient tolerance to dispensing anomalies', *Ophthal. Physiol. Opt.*, Vol. 10, January 1990
- Tanner V, Harle D, Tan J, Foote B, Williamson T.H, and Chignell A.H (2000) 'Acute posterior vitreous detachments: the predictive value of vitreous pigment and symptomology', *British Journal of Ophthalmology*, Vol 84, p1264-1268
- Theodossiades J and Murdoch I (1999) 'Positive predictive value of optometrist-initiated referrals for glaucoma', *Ophthalmic and Physiological Optics*, Vol 19(1) p62-67
- US Congress (2005) "Public Law 109-96" Amending the Federal Food, Drug, and Cosmetic Act, 9 November 2005 [Available here]
- U.S. Immigration and Customs Enforcement (2012) "Federal agencies warn against counterfeit decorative contact lenses", *News Releases*, 29 October 2012 [Available here]

Wang et al. (2010) 'Emergency Department Visits for Medical Device-Associated Adverse Events Among Children', *Pediatrics*, Vol. 126 No. 2, 1 August 2010, pp. 247 -259

Weinreb RN, Khaw PT (2004) 'Primary open-angle glaucoma', *Lancet*; 363(9422):1711-1720

Wood et al. (2011) 'Risk of falls, injurious falls, and other injuries resulting from visual impairment among older adults with age-related macular degeneration.', *Invest Ophthalmol Vis Sci*; 52(8):5088-5092

Wu et. al (2010) 'Contact lens user profile, attitudes and level of compliance to lens care', *Contact Lens and Anterior Eye*, Vol. 33, Iss. 4, August 2010, pp 183–188