General Optical Council

GOC response to call for evidence on the Opticians Act and consultation on associated GOC policies

April 2023

Contents page

Executive summary

1. The General Optical Council (GOC) is using the opportunity offered by the Department of Health and Social Care's (DHSC) programme of legislative reform for the healthcare regulators to review whether further changes are required to the aspects of the Opticians Act 1989 ('the Act') that are unique to the GOC or the practice of optometry and dispensing optics.

2. We released a call for evidence on the Act and associated GOC policies between March and July 2022 and received 353 responses which included over 8,000 individual comments. This document summarises our analysis of the consultation responses and our initial response to the analysis.

3. Our vision for legislative reform is to ensure that we can continue to protect the public and that the Act is fit for the future given the ever-changing political, commissioning, technological, delivery of care and business landscape.

4. Our analysis is that legislative reform is necessary, but we have also identified opportunities to advance public protection without legislative change, for example, through our forthcoming standards review and position statements.

5. The table below outlines the commitments we have made in the GOC response sections of this report and our decision in respect of our consultation on refraction by dispensing opticians for the purposes of the sight test.

Areas we intend to address through a request to change legislation

- *Regulatory objectives:* Patient and public safety should remain the GOC's overriding statutory objective in common with the other healthcare regulators. We propose an additional secondary consumer protection objective on the face of the legislation, reflecting the nature of risks to the public in the optical sector and our plans for expanding business regulation.
- *Restricted functions:* We are not proposing changes to the list of restricted functions now, but the optical sector is changing rapidly. To future-proof the legislation we propose a mechanism for the GOC to make recommendations to the Secretary of State to alter the list of restricted functions without the need for primary legislation.
- *Business regulation:* We welcome the broad stakeholder support for extending regulation to all businesses carrying out restricted functions. We think regulation should apply to all such businesses regardless of their name, corporate structure or who owns and manages them. We will next develop proposals and consult on an updated framework for business regulation.

- *Verification of contact lens specifications:* We agree that verification of a copy of a contact lens specification is no longer necessary, provided that the specification is clear, does not contain any obvious errors and has not obviously been tampered with. We therefore intend to seek legislative change to allow us to set out more detailed requirements in rules/guidance.

- *Definition of low vision:* We have reviewed the definition of low vision appliances in the legislation[1] and agree that it could be clearer. We produced a position statement on low vision aids in 2012. We will review the legislation in the context of our statement and consult on any changes as part of a future consultation on any new draft legislation for the GOC as part of the DHSC's legislative reform programme.

- *Protected titles in section 28(1)(a) of the Opticians Act 1989:* We will review the ordering of the wording in this section of the Act listing protected titles, as the ordering is not logical and we think it could be made clearer in any new legislation as part of the DHSC's legislative reform programme.

Areas we intend to address through the review of our standards

- *Dispensing to vulnerable patients:* Where services are provided to patients who could be considered 'vulnerable', we will consider whether any issues can be addressed by amending our standards.

- *Use of technology:* We have heard from stakeholders that the use of technology and artificial intelligence (AI) can cause uncertainty for registrants, for example, as the boundaries of decision-making and accountability become blurred. We will address these issues in the review of our standards and guidance to reflect developments in this field.

Areas we intend to discuss further with DHSC

- *Regulations related to criteria for visual impairment:* Under the Care and Support (Sight-impaired and Severely Sight-impaired Adults) Regulations 2014, a person is to be treated as being sight impaired / severely sight impaired if so certified by a consultant ophthalmologist. We will discuss with DHSC whether it would be possible to have regulations that provide a different definition but are concerned that the resulting inconsistency could be complicated.

[1] Regulation 1(2)(d)(b) of the Sale of Optical Appliances Order 1984: "any appliance sold or to be sold in pursuance of a prescription which identifies the appliance to be sold as being a low vision aid (whether by means of the words "low vision aid" or some other similar words), and includes frames or mounts which are intended for use as part of eyeglasses so designed and are sold or supplied without lenses and lenses so intended which are sold or supplied without frames or mounts"

- *Online spectacle sales:* We note that the Sale of Optical Appliances Order 1984 does not reflect the reality of online supplies since it predates internet sales. We will discuss this further with DHSC.

Areas we will consider addressing through a GOC position statement

- *Refraction by dispensing opticians:* At this point in time we are not satisfied that dispensing opticians should be permitted to refract for the purposes of the sight test. Our main concern is undetected pathologies, including subtle clues about eye health that may be missed if different professionals conduct the refraction and other components of the sight test.

- We will consider updating our 2013 statement on testing of sight to clarify the position in relation to pre-screening tests and triage checks related to the sight test that may be carried out by persons other than the optometrist or registered medical practitioner. Over time, advances in technology have meant various steps in the patient journey have become automated and safely delegated as part of pre-screening and triage. If we decide to update our 2013 statement, we will carry out further consultation on this aspect of the testing of sight.

- Our interpretation is that the Act does not specifically prohibit separation of the elements of the sight test by time, place or person. Business models are evolving alongside developments in technology. There were a range of views about this, and we plan to consider developments in more detail. We may clarify our position in a statement or seek a change in the law.

- We will further discuss the issues connected with orthoptists refracting for the purposes of sight testing with the Health and Care Professions Council (HCPC – the regulator for orthoptists) and the British and Irish Orthoptic Society.

- *Verification of contact lens specifications:* We will consider issuing a position statement to say we will not enforce the requirement to verify a copy of a specification (until such time that legislation can be amended). We will also consider extending this statement to prescriptions for spectacles.

- *Definition of aftercare:* We will consider whether it would be helpful to provide a definition of aftercare in a GOC position statement so that it is clear what sellers of contact lenses are obliged to do in order to meet their legal obligations.

Areas we will consider returning to and/or keep under review

- *Domiciliary care:* We recognise that domiciliary care is a particular area of risk and will continue to monitor fitness to practise and Optical Consumer Complaints Service (OCCS) complaints in this area, working with the optical

sector, governments and national health services to review the position as research and evidence emerges.

- *Zero powered contact lens legislation:* There may be a risk that the current legislation drives zero powered contact lens wearers to unregulated sources, thereby increasing the potential risk of harm to the public. At the current time we do not propose to make any changes to legislation in this area but we may return to the issue in the future.

- *Public protection threats of growing online sales and optical services delivered online:* We recognise that overseas online sales, whether illegal or otherwise, are a genuine challenge facing the sector. We have recently updated our illegal practice protocol; the Professional Standards Authority for Health and Social Care (PSA) endorsed this approach recognising that our scope is constrained by geography. Even so, the PSA has challenged DHSC to provide regulators with the agility to respond to these issues. We will keep our position under review and work with relevant healthcare regulators, the PSA and governments to explore possible solutions in these areas.

- *Spectacles prescription contents:* We have considered the suggestion that The Sight Testing (Examination and Prescription) (No. 2) Regulations 1989 should be changed so that a prescription should include the tested visual acuities for any prescribed working distances. We will discuss this further with the professional bodies to understand the case for change.

- *Substitution of contact lenses:* We do not propose introducing a specific legal requirement to supply contact lenses only in accordance with the contact lens specification since the evidence suggests that professionals exercising their clinical judgement can substitute safely. We will continue to keep this situation under review as research progresses.

- *Latest developments in technology:* The optical sector would benefit from a shared understanding of the latest developments in technology and a mechanism to keep this knowledge up to date. We will discuss with stakeholders how best to achieve this.

- *Deposits for sight tests:* It seems reasonable to be able to take a deposit for a sight test given that other healthcare professionals may charge cancellation fees. If we consider that we do wish to pursue a change in this area, we will carry out further consultation to further understand the impacts and ensure that there are no unintended consequences of a change in policy and/or legislation.

Areas outside the scope of the call for evidence

- *Further guidance on supervision of students and trainees, including how employers can support supervisors:* We will keep this under review with

education providers and professional bodies. It may be that it is more appropriate for providers of approved qualifications to issue this guidance to those employers or placement providers offering periods of professional and clinical experience or other forms of experiential learning.

- *Review of declarations guidance:* The Association of Optometrists (AOP) raised the need to review our declarations guidance, as they often receive queries from members on this process related to health declarations. We are planning a review of this guidance and will take the AOP's comments into consideration as part of the review.
- *Paediatric dispensing:* ABDO asked us to provide good practice guidance on paediatric dispensing. This falls outside the scope of the call for evidence but we will discuss the issues further with ABDO.

Next steps

6. We will review the commitments set out in the above table and prepare a timetable. Where we consider changes to legislation or GOC policy are necessary and can be evidenced, we will carry out further public and targeted stakeholder consultation activities on our proposals. We look forward to engaging further with stakeholders.

Introduction

7. The GOC is one of a number of organisations in the UK known as health and social care regulators. These organisations oversee the health and social care professions by regulating individual professionals and some businesses/premises. We are the regulator for the optical professions in the UK. We currently register around 33,500 optometrists, dispensing opticians, student opticians and optical businesses.

8. We have four primary functions:

    - setting standards for optical education and training, performance and conduct;
    - approving qualifications leading to registration;
    - maintaining a register of those who are qualified and fit to practise, train or carry on business as optometrists and dispensing opticians; and
    - investigating and acting where registrants' fitness to practise, train or carry on business is impaired.

Background to the consultation

9. The GOC's governing legislation is the Opticians Act. The original Opticians Act was published in 1958. This was replaced by the Opticians Act 1989 ('the Act'), but still retained large sections of the 1958 Act. There have been various amendments since 1989 such as introducing Continuing Professional Development (CPD) in 2005. During this time, the sector has evolved significantly with the roles of optometrists and dispensing opticians developing to realise their full professional capability as well as occupying different roles, including enhanced clinical roles, across each nation of the UK. Technological developments including remote care have also impacted on the way optical services are delivered to patients. We were keen to gather evidence and insight to better understand how our legislation needs to develop to match advances in technology, service delivery and professional capability, and associated risks to patient care and public benefit.

10. In addition, the Act contains other areas that may require reform, such as protecting function (i.e. activities such as sight testing) and professional title. We need to ensure the Act is fit for purpose and does not create unnecessary restrictions that limit the ability of registrants to fully utilise their professional capability to the benefit of patients. We were also keen to understand where the limit of such changes should be and their impact, so as to not unnecessarily restrict competition in the market. These factors must be balanced against the need to maintain patient care, safety and public benefit.

11. The DHSC is currently carrying out a review of all healthcare regulators' legislation to ensure consistency between the powers that all healthcare regulators have to deliver their regulatory functions of registration, education, fitness to practise, standards and the overall governance and operating framework of the regulator. We used the opportunity offered by the DHSC to review whether further changes are required to the aspects of the Act that are unique to the GOC or the practice of optometry and dispensing optics.

Consultation process

12. We published a call for evidence on the Act and a consultation on associated GOC policies to seek views, information and factual evidence on the need for change to the Act and any associated GOC policies. The call for evidence was open for 16 weeks from 28 March to 18 July 2022.

13. We received 353 written consultation responses from a range of stakeholders. These were made up of:

- five members of the public;
- one optical patient;
- 182 optometrists;
- 76 dispensing opticians;
- 20 contact lens opticians;
- seven student optometrists;
- four student dispensing opticians;
- ten business registrants/employers;
- four education providers;
- one CPD provider;
- 24 professional/representative bodies (including two charities and six local optical committees); and
- 19 'other' (four individuals and 15 organisations including two charities, three business registrant/employers, two local optical committees and two government/NHS bodies).

14. The organisations that were willing to be named were:

- Association of British Dispensing Opticians (ABDO)
- Association of Optometrists (AOP)
- Association for Independent Optometrists and Dispensing Opticians (AIO)
- Aston University
- Avon Local Optical Committee
- Bexley, Bromley & Greenwich Local Optical Committee
- BBR Optometry Ltd
- British Contact Lens Association (BCLA)
- The College of Optometrists

- Dudley Local Optical Committee
- FODO (The Association for Eye Care Providers)
- Glaucoma UK
- Gloucestershire Local Optical Committee
- Kensington Chelsea Westminster Hammersmith and Fulham Local Optical Committee
- Local Optical Committee Support Unit (LOCSU)
- Macular Society
- The Northumberland, Tyne and Wear Local Optical Committee
- Optical Consumer Complaints Service (OCCS)
- Optical Suppliers' Association
- Optometry Northern Ireland
- Optometry Schools Council
- The Professional Standards Authority for Health and Social Care (PSA)
- RNIB
- Royal College of Ophthalmologists
- SeeAbility
- Specsavers Optical Group
- Staffordshire Local Optical Committee
- Welsh Government
- Wolverhampton Local Optical Committee
- The Worshipful Company of Spectacle Makers

15. We are grateful for all the feedback we received and have taken this into account in deciding our next steps.

Approach to producing this response

16. Respondents were encouraged to provide comments throughout the call for evidence. We reviewed every comment received, of which there were just over 8,000. We are unable to include individual responses to all of these comments within this report due to the volume that we received.

17. Any comments that have been included are produced verbatim, although we have made minor corrections to spelling and/or grammatical errors where we considered that these were obvious.

18. We have only included comments where the respondent has consented to their response being published (either alongside their name or anonymously). It is our practice not to include the names of individual respondents, even where they have given their consent for us to publish their response.

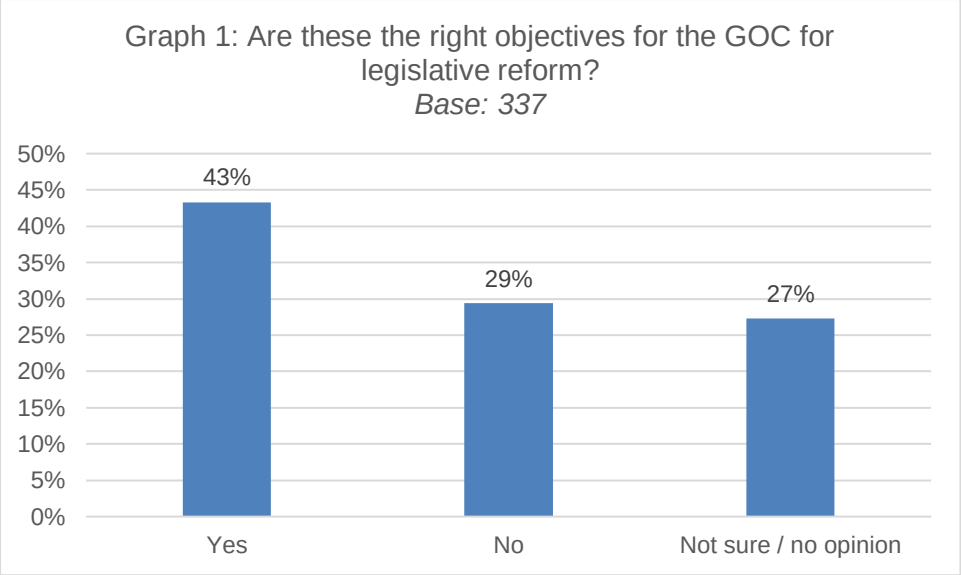
Findings

Section 1: Objectives for legislative reform

19. We set out eight non-hierarchical objectives for legislation reform:

    - objective 1: maintaining patient and public safety – our primary objective in everything we do as a regulator;
    - objective 2: ensuring that legislation reflects current and future context of healthcare delivery and is more flexible to accommodate changes going forward;
    - objective 3: ensuring that our legislation is flexible enough to accommodate future workforce needs and does not unnecessarily restrict the development of different roles needed to deliver the eye care needs of the UK;
    - objective 4: the GOC has sufficient powers to regulate a changing landscape in terms of developments within technology and the potential increase of care delivered into the UK;
    - objective 5: ensuring that there is consistency in the regulation of optometry/optician practices/businesses, i.e. the regulation of the system in which our optometrists and dispensing opticians work;
    - objective 6: regulatory interventions should take account of the national objective to reduce healthcare inequalities where possible and not put up any unnecessary regulatory barriers to this aim;
    - objective 7: reform should take the path of least resistance where this is appropriate, i.e. considering other regulatory levers, such as standards and guidance if these would be more effective than changing legislation; and
    - objective 8: ensuring that any changes do not impose disproportionate administrative or financial impacts on patients, the sector and our stakeholders.

20. We asked stakeholders whether they thought these were the right objectives. Of the 337 respondents that answered the question, 43% considered that these were the right objectives, 29% did not and 27% were not sure or had no opinion.



21. The following themes were identified from the comments:

- general support for the objectives but the first objective around patient and public safety should be the over-arching priority – it should not be part of the non-hierarchical objectives;
- there should be an objective about better regulation of online sales (particularly those suppliers who are currently operating illegally);
- the importance of education and training for the current and future optical workforce could be better highlighted, so that integration of health and social services can be realised through a workforce trained to work in multi-professional and multi-disciplinary teams, with the skills to work in different models of care;
- some of the objectives regarding regulation should refer to appropriateness and/or proportionality (e.g. objectives 4, 7 and 8);
- suggestion for the word 'maintaining' (patient and public safety) in objective 1 to be replaced with 'enhancing';
- objective 2 is too vague; and
- the 'path of least resistance' in objective 7 should be reworded to be clearer.

22. A sample of comments is available in the box below.

"These are acceptable objectives provided the over-riding statutory objective to protect the public is never forgotten and given primary importance."
Gloucestershire Local Optical Committee

"…The objectives should also explain that the burden of proof for any prospective case for the removal of existing legal restrictions should be a robust demonstration that changes to the Act will maintain public protection, and not introduce new risks of harm…" AOP

"We feel that objective 1 should be amended to 'Enhancing patient and public safety'. The aim of reviewing the legislation should be to improve the protections currently offered, not to maintain the status quo." Local optical committee

"Objective 2: This is too vague. Changes to models and delivery of care need to be scrutinised heavily by GOC before delivery. The current system promotes an 'acceptable unless told otherwise' model of change with the GOC taking a reactive stance. We would prefer to see the GOC take a proactive role in the progression of healthcare and be more active in discussions relating to change…" AIO

"On Objective 7, we agree that some important and urgent reforms may not need a change in legislation, which could be a long and uncertain process to achieve. However, any decision to use alternative ways such as standards and guidance should be made in full consultation with stakeholders. We suggest rewording this objective as follows: "reform should take the simplest approach where this is appropriate and agreed in consultation with registrants and our stakeholders, i.e. considering other regulatory levers, such as standards and guidance if these would be more effective than changing legislation." The College of Optometrists

"Objective 8 should be extended to ensure that there is no undue or disproportionate restriction on how patients choose to access services and goods." Optical Suppliers' Association

GOC response – objectives for legislative reform

23. It is important to distinguish the objectives of the GOC's legislative reform project from the GOC's future statutory objectives. The DHSC's intention is to set common statutory objectives for all the healthcare regulators through legislative change. The draft orders will be subject to public consultation.

24. We agree that patient and public safety should be the over-riding objective separate to the others in line with our purpose as a healthcare regulator.

25. We consider that the GOC should have an additional secondary objective to protect consumers reflecting the nature of risks to the public in the optical sector and our plans for expanding business regulation. However, these two objectives would sit in a clear hierarchy: should there be any conflict, the safety objective would always have primacy.

26. The DHSC is currently consulting on a draft section 60 order, which would allow the General Medical Council (GMC) to regulate anaesthesia associates and physician associates. This is intended to serve as a template for the future

regulation of other healthcare professionals, including dispensing opticians and optometrists. Our reading of the draft legislation is that it would allow the GOC to support workforce planning efforts where this is consistent with our statutory objectives and functions, which we would support.

27. The DHSC intends to incorporate the better regulation principles (e.g. proportionality) into legislation and the GOC supports this move.

28. The statutory objectives will only be viable if we have the right statutory functions to deliver them. Some suggestions, such as educating the public, are not currently within our core functions and would therefore require legislative change and we would need to be resourced to deliver them. It is likely that resourcing such an additional function would need to come from registrant fees rather than public funds or other sources. At present we are not convinced that the GOC should acquire new statutory functions. We provide commentary on public education in paragraph 248 of this document.

29. We note that some stakeholders are seeking reassurance from us that we will commit to further consultation prior to any changes to legislation to ensure that we consider any unintended consequences of changing legislation. It is our intention to consult further where we consider that any changes to legislation might be necessary so that we can fully understand the impact of these.

30. We note that even where there are areas where we might wish to seek legislative change, the timetable for this is uncertain and we will therefore make best use of the current framework until then. Further, in some areas, such as developments in technology, we consider that it would be both possible and preferable (for example, due to the need to be agile) to make progress by revising our standards and guidance instead of updating legislation.

Section 2: Protection of title, restricted activities and registers (sections 7, 8A, 9 and 24-30A of the Act)

31. Protection of title means that certain titles in section 28 of the Act are reserved for individual or business registrants of the GOC and it is illegal for anyone else to use them. All health and social care regulators protect titles as this is a key aspect of public protection and provides assurance to the public that someone using that title is competent and safe to practise.

32. Our Act goes further than protection of title and also restricts the activities of non-registrants[2]. For example, part IV of the Act restricts the testing of sight (section 24), fitting of contact lenses (section 25), and the sale and supply of optical appliances (with specific exemptions) and zero powered contact lenses[3] (section 27).

33. In effect, the Act specifies those activities which only our registrants can do, or which require their supervision or general direction. The Act protects the public from unregistered persons who are not bound by the GOC's standards, as well as from dishonest individuals who mislead people as to their registration status.

Restrictions for registrants and non-registrants

34. We asked stakeholders what activities non-registrants should be restricted/prevented from doing.

35. There was a clear view that the current restrictions under the Act should remain. In addition, there was a long list of other activities which respondents suggested should also be restricted to registrants:

- any dispensing activities;
- dispensing/supplying without supervision of a registrant;
- dispensing high/complex prescriptions;
- dispensing/supplying to vulnerable patients (examples included those with learning disabilities, dementia, facial/head abnormalities, special educational needs, reduced capacity to consent and living in care homes);
- dispensing to drivers/pilots;
- dispensing safety spectacles e.g. for sport;

[2] Non-registrants are those persons who are not registered with the GOC as dispensing opticians or optometrists

[3] Zero powered contact lenses are cosmetic, non-corrective lenses (i.e. without a prescription) to change the colour or appearance of the eye

- refraction for the purposes of prescribing optical appliances;
- testing of binocular vision[4];
- prescribing prism lenses (including plano[5] prisms);
- carrying out 'pre-screening' tests prior to the sight test, including using an autorefractor;
- interpreting results of tests;
- supplying contact lenses;
- teaching patients how to insert, remove and care for contact lenses;
- supplying a different contact lens to that specified on the contact lens specification;
- contact lens review/aftercare appointments;
- supplying prescription spectacles;
- supplying 'ready-readers'[6];
- supplying bifocals/varifocals (with additional measurements);
- enhanced/community services;
- referring patients to secondary care;
- myopia management[7] advice and treatment;
- treatment for visual stress and behavioural optometry;
- triaging patients; and
- giving advice to patients.

36. In the responses to this section, ABDO provided detailed commentary regarding the need for paediatric dispensing to be restricted to registrants, i.e. that non-registrants should not be allowed to do this, even under the supervision of a registrant. They asked us to consider producing good practice guidance in this area, consider revising our standards to specifically mention

[4] The ability to maintain visual focus on an object with both eyes, creating a single visual image https://www.moorfields.nhs.uk/faq/eye-conditions
[5] Lenses that provide no corrective focusing power
[6] Ready-made reading spectacles are available without a prescription, each lens of which has spherical surfaces and is of a positive power not exceeding five dioptres
[7] Myopia management is an intervention to slow down the progression of myopia (short-sightedness), normally through use of spectacles, contact lenses or eye drops

paediatric dispensing and called for further research into the quality of paediatric dispensing.

37. They made arguments for preventing non-registrants from providing advice on or carrying out treatment for myopia management. They also made a case for restricting non-registrants from dispensing to vulnerable groups (as did the AOP), which is explored further in section 6. Recognising that legislative change could take some time, they suggested we revise our standards "to make clear the need for specialist expertise in relation to dispensing spectacles to patient groups that may be described as vulnerable and giving advice and treatment in relation to myopia management and the importance of registrants operating within their individual scopes of practice".

38. A sample of comments is available in the box below.

"ABDO's view is that the overarching need to protect the public makes it necessary to continue to prevent non-registrants from:

- *testing sight*
- *fitting contact lenses*
- *selling optical appliances to children under 16, including sports eyewear*
- *selling optical appliances to people registered as visually impaired*
- *selling zero-powered contact lenses…"* ABDO

"The current balance of protections and restrictions works well, and these should remain as they are… we see no evidence-based reason to require any change to the existing framework…

During our engagement events, some stakeholders expressed frustration with NHS commissioning standards in England and felt that the Opticians Act could be amended to compel NHS England to improve standards of commissioning. We find no evidence to support this approach and feel that any changes to the Opticians Act to try and force NHS England to commission differently would be unsuccessful, increase the risk of unintended consequences, and be inconsistent with the GOC objectives in section one." FODO

"The Act currently protects the public from unregistered persons who are not bound by the GOC standards, by protecting both title and function. We believe that the current restrictions on the activity of non-registrants should remain for the benefit of the public. This protection ensures all people receive safe and appropriate care, maintain good eye health and avoid preventable sight loss…" The College of Optometrists

"We see no case for change from the present restrictions. The current system protects patient and public safety without setting unnecessary barriers to effective primary eye care provision. All registrants should work within their scope of

practice and although this may evolve over time, the Act does not and has not prevented that from happening..." LOCSU

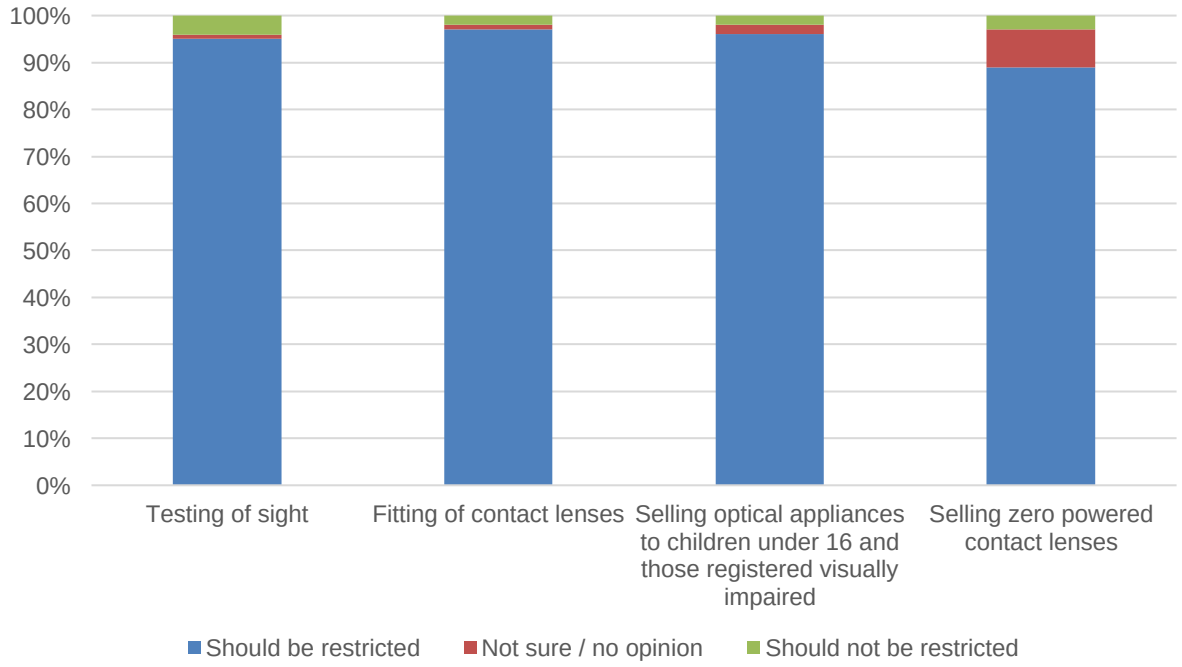
Continuation of existing restricted activities

39. We asked stakeholders what their views were about continuing to restrict/prevent non-registrants from carrying out the following activities:

    - testing of sight;
    - fitting of contact lenses;
    - selling optical appliances to children under 16 and those registered visually impaired; and
    - selling zero powered contact lenses.

40. Graph 2 shows that for the first three categories mentioned above, more than 95% of respondents who answered the questions felt that these categories should be restricted. There was slightly more variation in relation to selling zero powered contact lenses, with 89% of respondents answering that this should be restricted and a slightly higher percentage of respondents being unsure or having no opinion (8%). There was little variation between categories of respondent.

Graph 2: What are your views about continuing to restrict/prevent non-registrants from carrying out the following activities?
Base: 343-345



Additional restricted activities

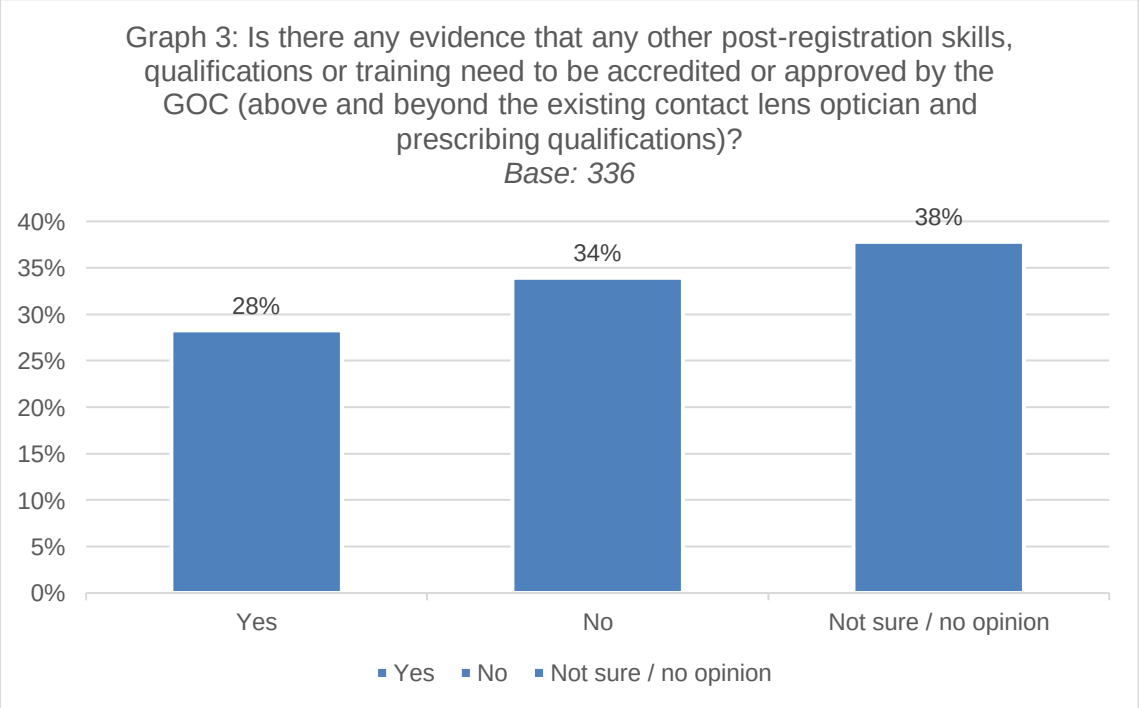
41. We asked stakeholders whether there were any additional activities they thought should be restricted to registrants. No additional activities were identified that had not already been mentioned in response to the question around what activities non-registrants should be restricted/prevented from doing (at the beginning of section 2).

42. The College of Optometrists considered that we might need to provide additional clarity in the Act to ensure a) it is clear that the testing of sight remotely and the testing of sight by automated means (in person or virtual) must be restricted to UK-based registrants or registered medical practitioners, and b) that the supply of optical appliances from non-UK jurisdictions must be prevented or provided under the supervision of a UK-based registrant or registered medical practitioner. (We have responded to these points at the end of this section.)

Post-registration skills, qualifications or training

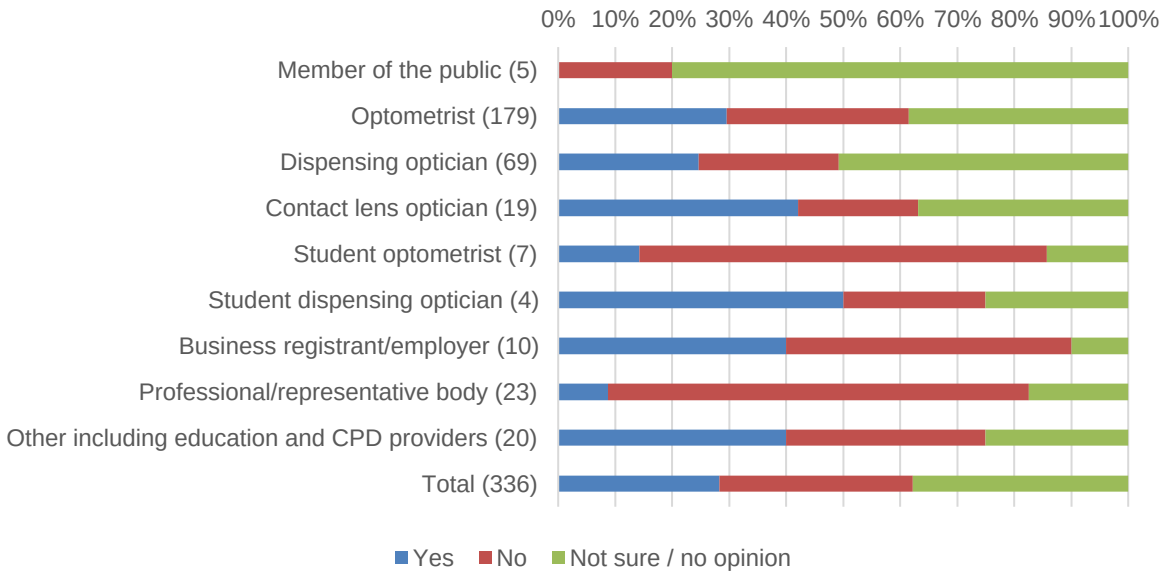
43. We asked stakeholders whether there was any evidence that any other post-registration skills, qualifications or training need to be accredited or approved by the GOC (above and beyond the existing contact lens optician and prescribing qualifications).

44. Of the 336 respondents that answered the question, graph 3 shows that 34% did not think that there was any evidence, 28% felt that there was evidence and 38% were not sure or had no opinion.



45. Graph 4 shows that professional/representative bodies and student optometrists were more likely to answer no to this question than other categories of respondent.

Graph 4: Is there any evidence that any other post-registration skills, qualifications or training need to be accredited or approved by the GOC (above and beyond the existing contact lens optician and prescribing qualifications)?
By category of respondent



46. Those who thought that we should approve or accredit further qualifications commented on changing professional roles and the specialist expertise needed in advanced areas of practice (Masters level or equivalent) and that regulation would improve public safety and reassure the public. Inconsistencies were highlighted where the GOC approves some specialist qualifications but not others. Another argument was that it would support a strategic and coordinated sector approach to training as part of a stronger focus on upstream regulation which prevents harm from occurring in the first place.

47. Separately, it was also argued that the GOC should have the ability to add new qualifications as time progresses in areas like technology.

48. Suggestions for further qualifications/services that should be approved or accredited by the GOC included:

- refraction qualification for dispensing opticians;
- glaucoma management/refinement;
- medical retina monitoring;
- macular degeneration referral filtering and monitoring;

- myopia control;
- emergency eye care;
- minor eye conditions (such as the Minor Eye Conditions Service (MECS) or Community Urgent Eyecare Services or COVID-19 Urgent Eyecare Service (CUES)) such as dry or red eyes, discomfort or pain;
- children's services;
- low vision services;
- clinical imaging, including interpretation of results;
- behavioural optometry / visual stress testing;
- therapeutic laser therapy;
- consultations and aftercare for refractive laser surgery; and
- all postgraduate qualifications.

49. Those not in favour of the GOC approving or accrediting further qualifications made the following points:

- there is no evidence to support this change and existing controls are sufficient to mitigate the risks. These controls include the existing CPD system and GOC's standards for registrants (e.g. recognise and work within the limits of your scope of practice);
- concern this would lead to the need for further CPD requirements for registrants (in the same way that the current specialty registers do);
- other healthcare regulators do not accredit postgraduate qualifications, so this would make the GOC an outlier;
- concern about possible unintended consequences including negative impact on service commissioning, delivery and patient access (as people would assume existing accreditation is not sufficient), which could lead to slowing down or reducing commissioning altogether; and
- some evidence was presented about the success of existing schemes in the community requiring postgraduate qualifications[8], presented in the context of the GOC not needing to accredit those qualifications.

[8] Gunn, P.J.G. *et al.* (2019), Clinical effectiveness of the Manchester Glaucoma Enhanced Referral Scheme, *Br J Ophthalmol*. 2019 Aug; 103(8):1,066-1,071

50. Although not within the remit of the question, many commented in the context of the GOC's new education and training requirements that the four-year optometry degree course should provide all the skills required for a modern optometrist including glaucoma, medical retina management and prescribing.

51. Some commented that the GOC register could better support patient choice by giving information about additional qualifications and that it could assist with decisions on commissioning services in specific geographical areas.

52. A sample of comments is available in the box below.

"There could be value in having specialist post-registration qualifications or training for treating dry eyes. There are an increasing number of specialist dry eye clinics without any specialist expertise in how to treat dry eyes appropriately. It's important that any specialist public health service has professionals with the right qualifications and training to ensure the best quality of care for patients.

Additionally, introducing standard qualifications for low vision or extended roles specialising in glaucoma, AMD [age-related macular degeneration] *or similar could further improve consistency and quality of care. We would also be supportive of other additional qualifications being introduced if it could further improve the quality of care provision."* RNIB

"Currently the addition qualification skills are enough, but this should be expanded as technology and knowledge advances (eg skills in detecting pathology using new technology)" Local optical committee

"…We have concerns about the possible thinking behind this proposal. While we recognise that the Act does not legislate the scope and delivery of NHS General Ophthalmic Services (GOS) or NHS extended primary eyecare services, this proposal if enacted would likely impact on service commissioning, delivery and patient access to relevant services… The consequence of this proposal would be that commissioners and potentially patients would likely infer that the current mix of registrant core competencies and legislated post-qualification skills are insufficient for service delivery… We urge the GOC to very carefully consider the wider ramifications of this proposal and unintended consequences to national objectives." LOCSU

"…We do not think there is evidence that GOC accreditation or approval of additional post-registration qualifications or training is necessary. It is unclear from the call for evidence what kind of process the GOC would use to accredit additional qualifications. We are not aware of other healthcare professional regulators, such as the General Medical Council (GMC), undertaking accreditation of additional post-registration qualifications. Were any such accreditation process to be introduced, it would need to be properly resourced, structured and

implemented by the GOC, and we think there would be risks of the process not working properly or creating unintended problems…" AOP

"…the GOC should only seek to add to the burden of regulation where this is necessary to protect the public and where this is the case, should choose the most proportionate form of regulatory intervention. Regulating additional further qualifications would increase costs for stakeholders, including qualification providers, employers, practitioners and ultimately patients.

We welcome the GOC's new focus on continuing professional development and having recently introduced a more flexible regulatory framework in this area, the GOC should avoid creating barriers to professional development and stifling the development and delivery of further qualifications." ABDO

"The professional bodies for optometry and dispensing optics – The College of Optometrists and The Association of British Dispensing Opticians (ABDO) – are best placed to define and accredit qualifications that enable registrants to acquire new knowledge, skills and recognised qualifications. Registrants should be supported to develop and evolve their scope of practice and training autonomously, but within the high-level oversight and governance of the GOC's Standards of Practice…" The College of Optometrists

"NHS Wales is utilising optometrists with additional post graduate qualifications in medical retina, glaucoma and Independent Prescribing…The GOC only accredit/approve Independent Prescribing; however, it is not clear why the other post-graduate qualifications led by the College of Optometrists are not approved/accredited. It is also not clear what the GOC criteria is to accredit/approve. Optometrists must be able to develop their clinical skills without unnecessary barriers/bureaucracy, therefore consideration should be given to ensure that the GOC and College of Optometrists are aligned in their post-graduate programme to ensure quality standards. This is important due to the additional clinical pathways delivered in Wales but increasingly important to enable the rest of the UK to evolve." Welsh Government

GOC response – restricted activities

53. Our view is that the current activities restricted to optometrists and dispensing opticians (and registered medical practitioners) should remain so.

54. We note the comments regarding dispensing to vulnerable groups and respond in section 6 of this document. In summary, for reasons of insufficient evidence of harm and difficulty of practical implementation, we do not consider these activities should be restricted. As suggested by ABDO, where such services are provided by registrants, issues may be addressed by amending our standards, and we will consider this as part of our current review of the standards. ABDO also asked us to produce good practice guidance on paediatric dispensing.

Producing good practice guidance falls outside the scope of the call for evidence and we will discuss the issues further with ABDO.

55. As set out in the introduction, the roles of optometrists and dispensing opticians are developing to realise their full professional capability. This includes enhanced clinical roles involving treatment and management decisions that until recently were carried out in hospitals but are now increasingly available in primary care settings. Given the inherent risks to patient safety and the expertise needed to perform some of these roles, we see a case in principle to add these services to the list of restricted activities. Balanced against this, NHS commissioners perform an important quality assurance role – although there is scope for a private market to develop in England. Further, the GOC's standards apply to all services performed by registrants, not just the restricted activities, offering a measure of existing protection. There may also be challenges in defining the scope of these additional activities in legislation.

56. On balance, we do not consider the evidence is strong enough to justify restricting these activities now but see the conditions could change over time. Given the rapidly changing landscape and that opportunities to amend legislation are rare, it is important for our legislation to have in-built flexibility to adapt to future developments. Therefore, we will discuss with DHSC the possibility of a statutory mechanism for the GOC to make recommendations to the Secretary of State to add or remove from the list of restricted activities without the need for primary legislation. Should this proposal gain traction, we would consult on how such a mechanism would work in practice.

57. We note The College of Optometrists' comment that we might need to provide additional clarity in the Act to ensure that the testing of sight remotely and the testing of sight by automated means (in person or virtual) must be restricted to UK-based registrants or registered medical practitioners. We do not consider there to be a need to clarify the Act because:

    - the testing of sight is already restricted to optometrists and registered medical practitioners regardless of the methods used; and

    - since our regulatory jurisdiction extends beyond the UK (i.e. all our registrants irrespective of the country in which they are based are bound by our standards) it would not be appropriate to restrict testing to UK-based registrants.

58. We also note The College of Optometrists' comment that we might need to provide additional clarity in the Act to ensure that the supply of optical appliances from non-UK jurisdictions must be prevented or provided under the supervision of a UK-based registrant or registered medical practitioner. We do not consider that this is a point of clarity – rather, it would be a change in the Act that we would need to discuss with DHSC and provide evidence to justify

the need for. We provide further commentary on the sale and supply of optical appliances from overseas jurisdictions in paragraphs 312 to 315 of this document.

GOC response – post-registration qualifications and annotations on the register

59. The issues of restricted activities, approval or accreditation of post-registration qualifications and annotations on the register are closely linked. Like other healthcare regulators, our scope to approve post-registration qualifications in future will be determined by the outcome of the DHSC-led legislative reforms. We understand DHSC's policy intent is for regulators to continue to have the power to approve post-registration qualifications and to include such information on their registers as they see fit.

60. While responses indicate a shared aim for a system that supports registrants to reach their full professional capabilities and meet the public's eye care needs, views were mixed about whether the GOC should approve or accredit any further post-registration qualifications. Currently, we do not intend to approve or accredit further post-registration qualifications, although we see scope in the changing landscape for a more strategic, coordinated sector-wide approach. Should the GOC revisit this issue we will take account of stakeholder views and any proposals to accredit or approve additional post-registration qualifications would be subject to public consultation.

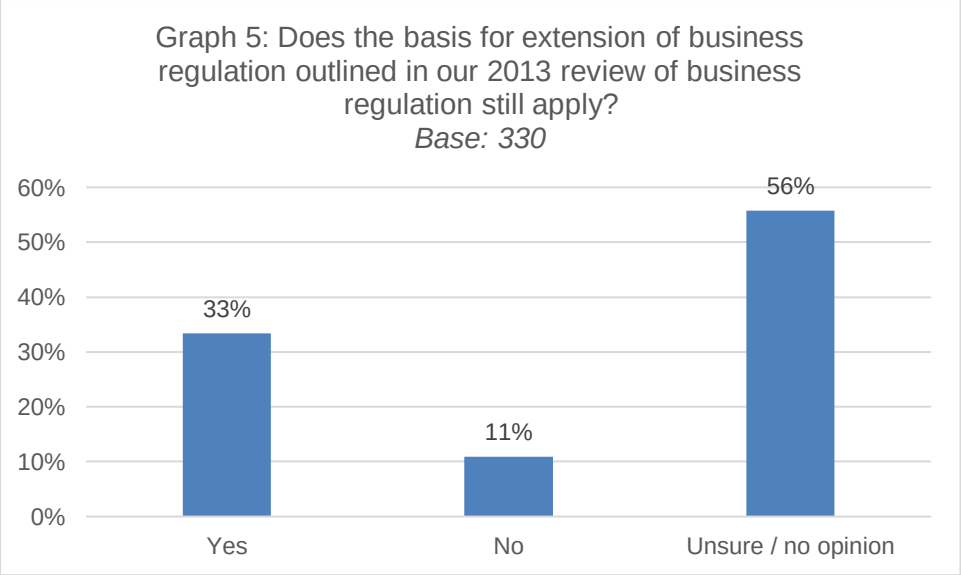
Section 3: Regulation of businesses (sections 9 and 28 of the Act)

61. The legislation around GOC business regulation is complex and does not currently provide for a clear and consistent system of regulation for optical businesses. In summary, the Act only allows us to register bodies corporate and only then if they meet certain eligibility requirements. Some bodies corporate must register and others can only do so if they change their structure. Further information can be found in section 3 of our call for evidence.

Extension of business regulation

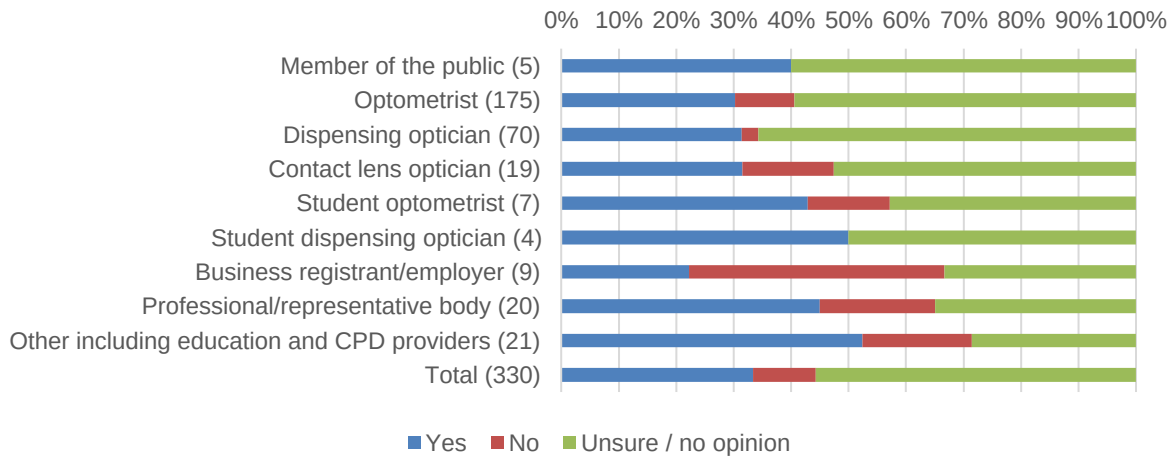
62. We asked stakeholders whether they thought the basis for extension of business regulation outlined in our 2013 review of business regulation still applied.

63. Of the 330 respondents who answered the question, 33% thought that the basis for extension of business regulation still applied, 11% thought that it didn't and 56% were unsure or had no opinion.



64. Graph 6 shows that business registrants/employers were significantly more likely than other categories of respondent to think that the basis of extending business regulation did not apply (although it should be noted that the base number is small).

Graph 6: Does the basis for extension of business regulation outlined in our 2013 review of business regulation still apply?
By category of respondent
Base: 330



65. The main themes that arose from the comments were:

- at the moment the system is complex, unequal and confusing to patients and the public as it's unclear why some businesses have to register with the GOC and others do not;
- there is support for a level playing field i.e. with all businesses carrying out restricted functions being required to register with the GOC. This would help ensure that all businesses adhere to the same regulatory standards set by the GOC which will help improve patient experience and patient care;
- business regulation should be extended to all businesses carrying out restricted functions because the patient experience is not just dependent on the individual providing the care but also the clinical environment in which care is delivered. This includes the premises, the equipment, internal business policies such as referral policies, record keeping, internal audit, pay incentives, and training and oversight of staff including unregulated staff and staff working under the supervision of a GOC registrant (including pre-registration placements undertaken by GOC registered optical students);
- since 2013 the growth of the internet is likely to mean the unregulated sector has also grown. The range of providers and the scope of services they offer is expanding, including remote optical care. Regulation needs to keep pace with these changes and should cover online businesses selling contact lenses and spectacles as this is where the greatest risks lie;

- the 2013 GOC statement on business regulation does not consider the transformation of eye care in terms of more remote care for patients and the introduction of new technologies. These factors are likely to increase the risk profile of optical care and it is important for all businesses providing these services to be registered with the GOC;
- business regulation and regulatory standards may help deter businesses from putting profits ahead of patient care;
- it is not always appropriate to hold an individual registrant to account but the business itself, so it is important that all businesses are held accountable and are required to register with the GOC;
- the market is already effective at disciplining itself with patient choice providing a powerful incentive for providers to improve quality and choice. Based on turnover, the large amount of primary eye care is delivered by GOC registered businesses and this sets market norms. Businesses also have a strong incentive to maintain high standards to keep insurance premiums low; and
- current levels of fines are small related to industry turnover and for business regulation to be effective the GOC needs proper powers of sanction.

66. A sample of comments is available in the box below.

"The basis for the extension of business regulation as outlined in the GOC's (July 2013) Review of business regulation: consultation still applies; and we welcome the latest proposals to extend the regulation to register all businesses who provide legally restricted optical services in the UK. With the introduction of new technologies, remote consultations and optometrists increasing clinical work since 2013, there may now be additional reasons to regulate all businesses in a more consistent way." The College of Optometrists

"In summary, the evidence shows that current optical regulation is working effectively and is not in need of a major change. There are sufficiently good incentives in primary eye care under the Act to drive competition based on safety and quality. There is no policy problem which needs solving by adding new GOC powers or cost to business regulation. There might however be some additional benefits by requiring all businesses which provide restricted activities to register with the GOC to safeguard and strengthen the existing model which works well in patients' interests." FODO

"The AIO are of the opinion that regulation of businesses should be compulsory. It is necessary in order to regulate the actions of a practice when it may not be appropriate to hold a registrant practitioner to account." AIO

"There remains a strong case for reforming business regulation. The increasing role of high street providers of health and care services and the growing importance of large corporate bodies and multi-nationals has raised a range of issues which current legislation may not be fully equipped to respond to. The current system for regulating optical business is complex, piecemeal, and may not be fit for purpose." PSA

"My personal opinion is that GOC registration should be compulsory to all businesses conducting restricted procedures on their premises. In the same way as an Optometrist or Dispensing Optician must be registered to practice so the business should be registered and agree to the key principles of code of conduct for business. Protecting the autonomy of the practitioner is paramount to protecting patients." Optometrist

"The BCLA would welcome any mandatory extension of business regulation. Unregulated supply of contact lenses remains an issue - and therefore risks patient eye health. Online suppliers are a challenge to audit, therefore extending business registration to these businesses could be a way to improve this." BCLA

"The current situation is unfair and it seems likely that businesses who are most in need of regulation avoid meeting the requirements for business registration so that can be essentially unregulated. I support the view that all UK businesses providing eye care services and/or supplying spectacles or contact lenses should have to be registered." Optometrist

"In my view it is important that any businesses providing optical services and/or appliances to the general public are registered with the GOC and meet the appropriate requirements that allow them to do so. Route to registration and regulation for business should be uniformed but robust and with strict criteria around compliance with current GOC regulation." Dispensing optician

Advantages, disadvantages and impacts of extending business regulation

67. We asked stakeholders whether there were any advantages, disadvantages and impacts (both positive and negative) of extending business regulation in addition to those identified in our 2013 review of business regulation. No new points were made that had not already been raised above or in the previous consultation, other than in relation to ownership restrictions.

Ownership restrictions

68. The current GOC requirements for business registration were considered to be potentially onerous, particularly in relation to the requirement that a majority of directors of a GOC registered business must be GOC registrants.

69. Arguments in favour of removing this requirement included:

- it allows businesses to avoid regulation;
- it is not reflective of many current business models;
- it is a barrier to small providers becoming regulated since they cannot fund sufficient individuals to meet the requirement; and
- alternative models could ensure standards without the requirement (e.g. a nominated person with overall responsibility for compliance).

70. Arguments in favour of retaining the current requirement included:

- a concern that non-clinical staff owning businesses has compromised standards of care due to a focus on commercial imperatives; and
- standards are already ensured since smaller providers comply with the GOC standards by virtue of their owners being individual registrants and/or employing individual registrants.

71. A sample of comments is available in the box below.

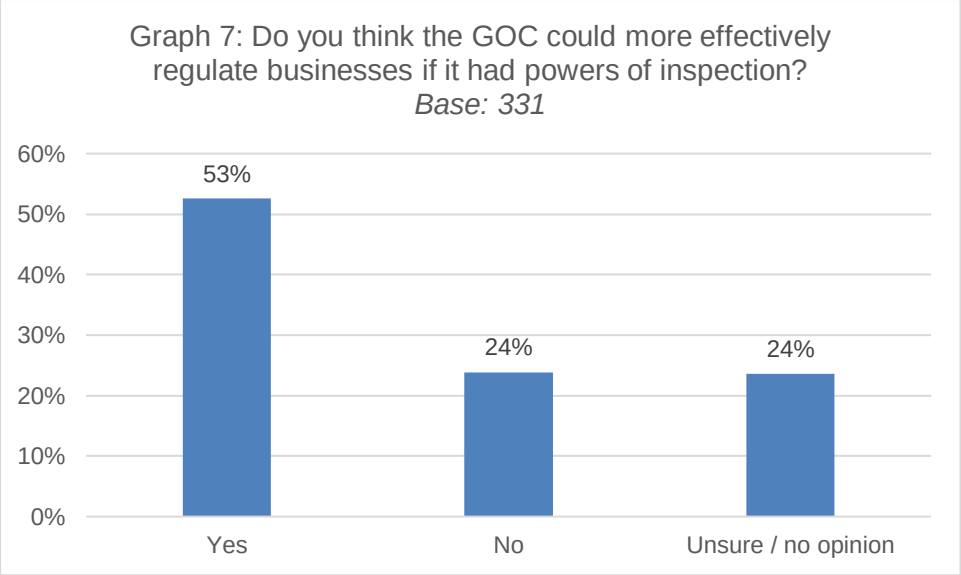
"We recognise the important role which registrant directors play in promoting high standards, but we think there would be value in reviewing whether it is proportionate to require a majority of registrant directors. This can lead to difficulties, including creating a barrier to business registration, encouraging businesses to have a single director and adding to administrative costs." ABDO

"The restriction to have a majority of directors as GOC registrants to register as a body corporate doesn't reflect many current business models, and therefore allows them to slip through the net of GOC business standards, to a certain extent. To ensure the Act reflects changes in business ownership structure this, needs to change to encompass any business that sells prescription optical appliances, and to ensure public safety." Dispensing optician

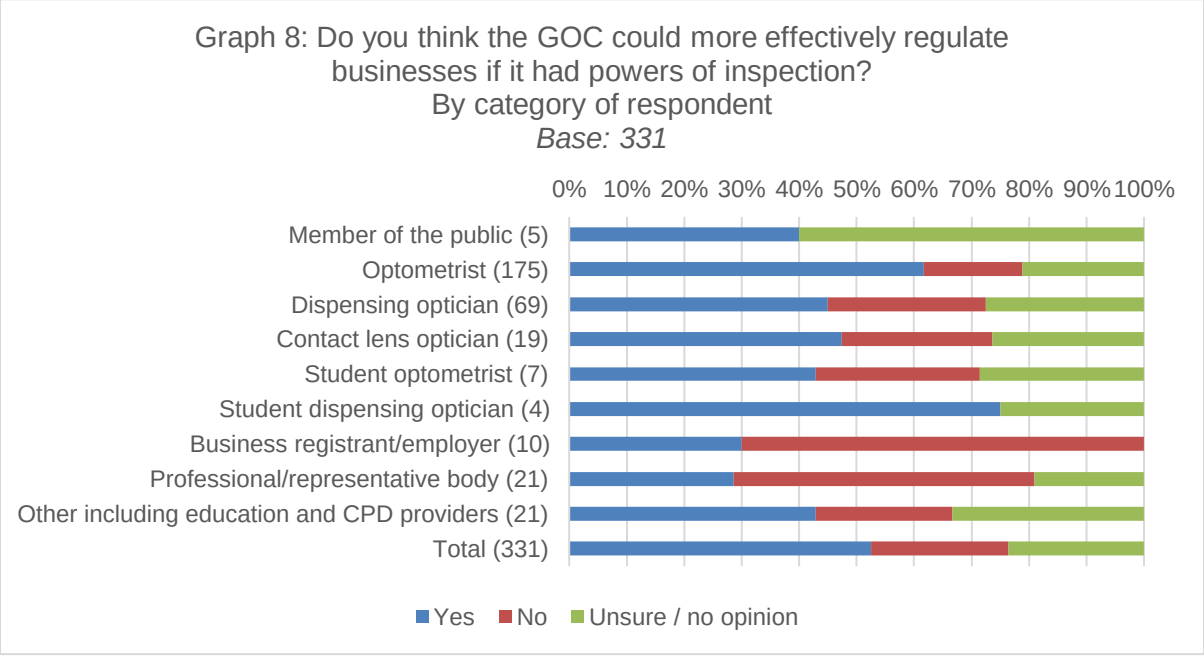
Inspection powers

72. We asked stakeholders if they thought that the GOC could more effectively regulate businesses if it had powers of inspection.

73. Of the 331 respondents who answered the question, 53% thought that the GOC could more effectively regulate businesses if it had powers of inspection, 24% thought that it couldn't and 24% were unsure or had no opinion.



74. Graph 8 shows that business registrants/employers and professional/representative bodies were significantly less likely than other categories of respondent to consider that the GOC could more effectively regulate businesses if it had powers of inspection.



75. The main themes that arose in support of inspection powers were:

- it could help ensure that GOC regulatory standards are complied with and effectively implemented which would help improve the quality of patient care and boost public confidence in optical services, for example, it could help prevent businesses from poor internal practices such as lack of / ineffective internal audit and record keeping;

- it could help ensure company sales and profit margins are not at the expense of patient care, for example, by helping to mitigate against poor clinical practice such as inadequate time limits for sight tests and unrealistic targets for the amount of sight tests conducted in a day;
- it could facilitate the transfer of care from the secondary to the primary care sector since secondary clinicians would have more confidence about standards of care optometrists and dispensing opticians could provide; and
- it would fill the gaps and inconsistencies in the current inspection regime.

76. The main themes that arose against the GOC having inspection powers were:

- the GOC must provide evidence that an inspection regime is a proportionate response to the level of risk it is seeking to manage;
- it is unclear where the evidence is to support any increase in regulatory powers and it was noted that there is a difference in risk between the regulation of pharmacy premises and optical premises;
- the Europe Economics research report (that the GOC commissioned in 2013) did not recommend introducing inspections and it is unclear why the GOC is now suggesting this approach without providing any evidence of risk or increased risk since 2013;
- the powers the GOC currently has are proportionate for the sector it regulates;
- since 2013 the GOC has effectively increased business regulation via its enhanced Standards for Optical Businesses, so further powers are not necessary;
- an inspection regime would result in increased costs for registrants which would be passed onto the public and patients;
- the cost and administrative burden on small businesses would be disproportionate and unfair;
- concern about how GOC inspections would fit with other inspection and contractual arrangements without duplicating or overlapping with regimes already in place or planned within the UK, particularly where General Ophthalmic Services (GOS) are commissioned; and
- the GOC could have more proactive powers to investigate potential breaches of regulatory standards that are raised, for example, via whistleblowing.

77. A sample of comments is available in the box below.

"GOC needs to inspect to ensure business profits are not put before patient safety." Dispensing optician

"Businesses should have more responsibility to have appropriately trained non-registered staff and I feel that the expectation of being inspected would instil a need to ensure that appropriate training is carried out." Dispensing optician

"While we would support certain powers of inspection in principle, we would welcome more details about the GOC's intention before being able to comment. We need to understand what the purpose of these inspections would be and how they would fit with the current inspections of GOS contract holders carried out by national health services, and to assess the benefits of these inspections to patients and practice." The College of Optometrists

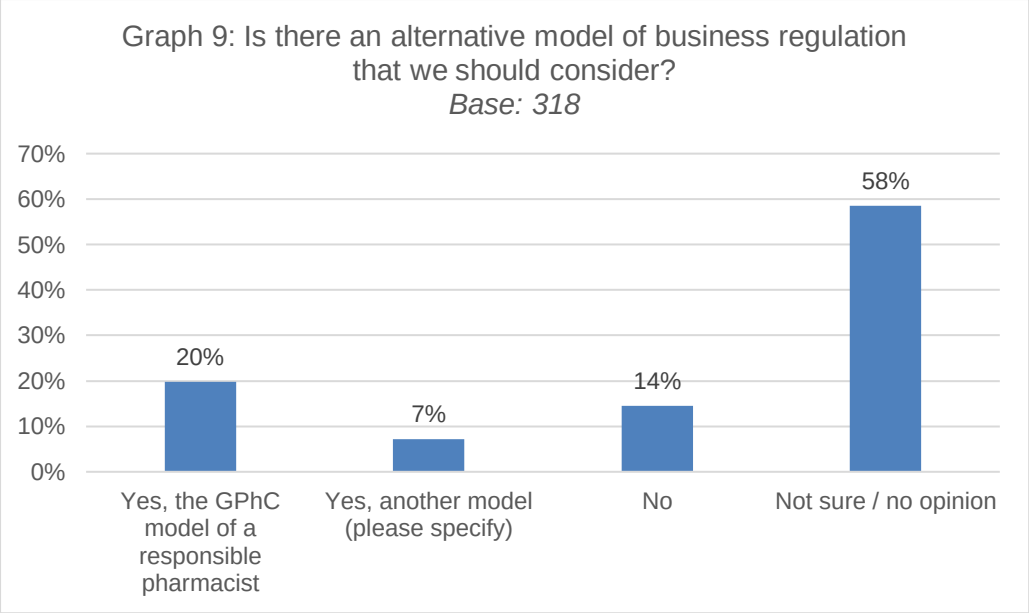
"We recognise how giving the GOC inspection powers could allow the GOC to assure itself that businesses are meeting its standards. However, we believe the use of inspection powers would place burdens on the sector that are likely to be disproportionate to the risks posed to the public and patients. In fact, a burdensome inspection regime could impair the ability of practices to deliver care services. The effectiveness of inspection regimes has been called into question several times in recent years when organisations which passed inspections were nonetheless found to be operating unsafely. Mid Staffordshire NHS hospital trust is the most notable example of this..." AOP

"In Scotland, a designated optometrist inspects every practice every 3 years to ensure NHS standards are met. Any GOC inspection would be unlikely to have different findings and as such they should utilise their resources doing other things rather than duplicating the work of others." Optometrist

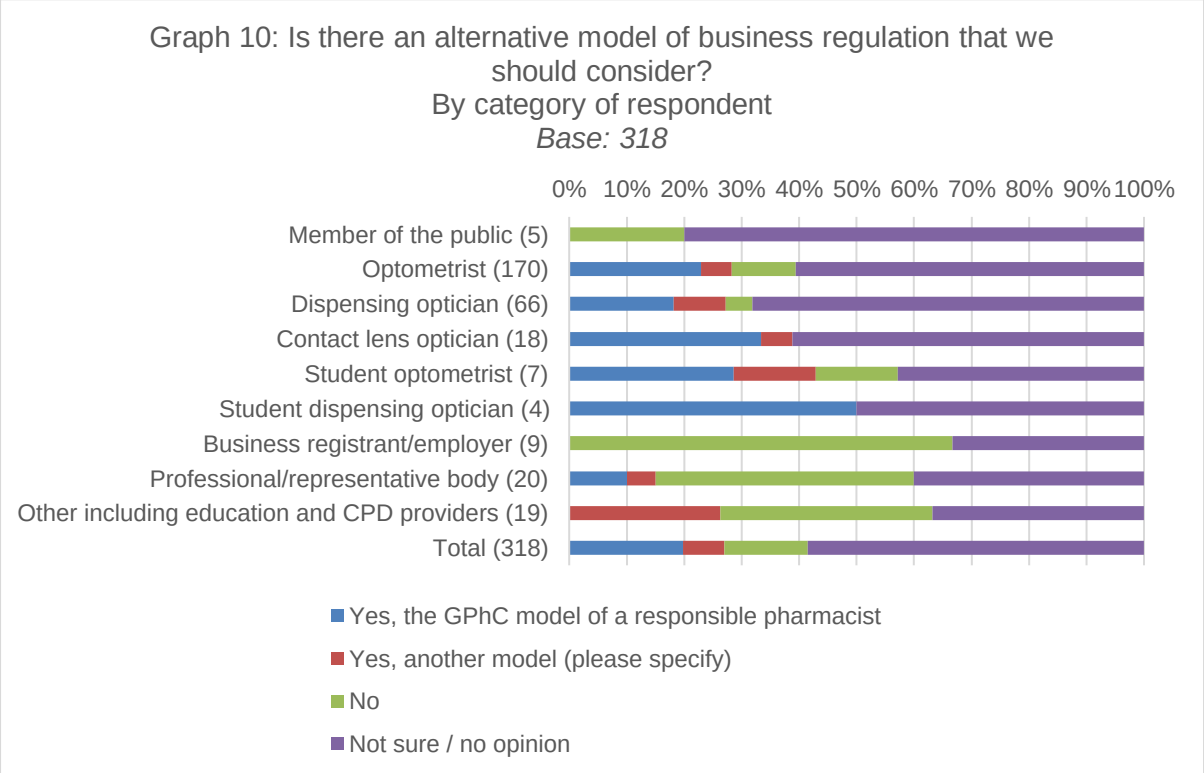
Alternative models of business regulation

78. We asked stakeholders if there was an alternative model of business regulation that they thought we should consider.

79. Of the 318 respondents who answered the question, 20% thought that the GPhC model of a responsible pharmacist should be considered, 7% thought another model should be considered, 14% thought that no other model should be considered and 58% were not sure or had no opinion.



80. Graph 10 shows that business registrants/employers, professional/representative bodies and other including education and CPD providers were more likely than other categories of respondent to conclude that an alternative model of business regulation should not be considered.



81. The main themes that arose in respect of different models of regulation were:

- not enough is known about the GPhC model of business regulation to give a view on whether it would be appropriate;

- an advantage of the GPhC model is that it would help increase accountability as one person would take overall responsibility for the business;
- there were concerns about whether the 'responsible pharmacist' model would work in our sector (i.e. a "responsible pharmacist" is a registered pharmacist who is appointed by the business to secure the safe and effective running of the pharmacy):
    - there were doubts about one person taking overall responsibility for the business, for example, an optometrist spends the vast majority of the day in a closed room so how could they effectively oversee the staff and business;
    - if responsibility rested with a GOC registrant (as the responsible officer), this could remove any liability from the non-registered business owner;
    - optical businesses differ to pharmacies as they are often a lot bigger in terms of the amount of staff they employ, and they employ staff who are not regulated, such as optical assistants. This could deter GOC registrants from taking on a role as the responsible officer as there may be an increased risk in overseeing a high number of staff who are not regulated and are not required to have any formal qualifications but who are involved in delivering patient care;
    - there would be a financial impact particularly for small businesses if there needed to be a responsible officer on the premises at all times;
    - the GOC should not assume that the GPhC model of business regulation is without flaws and can be easily replicated in optometry;
- the Care Quality Commission (CQC) model was another recognised model of regulation applying to dentists and pharmacists. There was little detail given on how this might work or be adapted to the optical sector;
- other models of care that were less well known but nonetheless mentioned as an alternative were the Ofsted model and models in countries such as The Netherlands, the United States of America, New Zealand and in Europe; and
- the GOC should provide other models of business regulation that are evidenced based and appropriate for the sector.

82. A sample of comments is available in the box below.

"Whilst there are examples of optometrists in large practices taking on a supervisory role with confidence, we believe that the "responsible optometrist" concept could deflect responsibility for quality from the business owners – who set the organisational policies, procedures and culture. This could mean that individual registrants become scapegoats for problems caused by matters beyond their control. At this point in time, we are not clear what alternative model of business regulation would be appropriate for the profession." AOP

"We do not believe that the responsible registrant model would be appropriate or applicable to optometry in the same way that it works in pharmacy settings, as the operational nature and business model of pharmacy is different to that of optometry. For example, although pharmacy colleagues are supervised by the responsible registrant, there isn't formal delegation of clinical roles as there is in optometry. It is also far more common for community pharmacists to operate alone, or with just one other pharmacist in the pharmacy." The College of Optometrists

"As explained above, the evidence shows that the current regulatory regime works well. We think it is unhelpful to frame the GPhC model of responsible pharmacist in this way. We understand the GOC might have an interest in this model (paragraph 29), but it is not clear how The Medicines Act 1968: The Personal Control Requirement, the Health Act 2006, and the subsequent Department of Health consultations, read across to eye care regulation.

We have been unable to find evidence to support replicating the pharmacy model in primary eye care settings, as the risk profiles of the professions are not comparable in context. This non-comparison in risk profile is strongly supported by our members who also provide pharmacy services." FODO

"There is a lower level of risk in relation to optical practices and introducing the 'responsible pharmacist' model would stand in the way of efficient practice management in line with the GOC's standards, without being justified by the risks involved.

Reinventing the system of regulation for optical businesses would also carry substantial transitional costs, making it even more important for there to be a clear, evidence-based case for change." ABDO

GOC response – regulation of businesses

83. We welcome the broad stakeholder support for extending regulation to all businesses carrying out restricted functions. We think regulation should apply to all such businesses regardless of their name, corporate structure or who owns and manages them. Referencing our proposed statutory objectives, we consider this is necessary to both deliver patient safety and protect consumers.

84. A lot more work is needed to determine an appropriate model of regulation. This will need to be developed in depth ahead of any further consultation, including the issues relating to business and ownership structures, regulatory supervision (including assessing the effectiveness and cost of any potential assurance or compliance activity), enforcement approach and sanctions, access to consumer redress and registration fees charged to optical businesses.

85. Changes to business regulation may need to take account of the changing commissioning and provider landscape in England. For example, where prime provider companies act as the contracting vehicle between NHS commissioners and optical/optometry practices to provide a range of locally enhanced or extended eye health services beyond the sight test. These can include pre- and post-operative cataract services, glaucoma filtering, and urgent and minor eye conditions services. While care is delivered by registrants, sub-contractual and clinical governance requirements are agreed between the prime provider company and individual practices. We note that some prime provider companies may be registered with the Care Quality Commission (CQC) where the care being delivered extends into post-referral management, monitoring and treatment.

86. We continue to see merit in a system where named individuals have specific responsibilities within a wider system of regulation that demands accountability on individual professionals and businesses. This would promote effective leadership and culture in the context where business-level systems impact on patient safety. We need to identify the best model to achieve this aim reflecting the specific needs and characteristics of our sector. We note points about the benefits and drawbacks of different elements of the GPhC model and will consider this and similar models operating outside of the healthcare sector.

87. The GOC needs the right combination of tools to ensure that businesses are complying with our standards. As we develop a draft framework for business regulation, we will consider models of assurance in broad terms by exploring tools commonly used by regulators in other sectors, such as thematic reviews. We will not duplicate existing inspection regimes, although note that NHS-led inspections are not designed to cover all GOC standards. At present, we do not consider a comprehensive programme of regular inspections is necessary, but we do consider there is a need for us to have assurance, compliance and information gathering powers to support investigation of specific concerns.

88. Following the closing date of the call for evidence, we commissioned research to update the evidence base and help us understand more about the business landscape that is beyond our current remit. The research is published on our website alongside this response document. The research:

- estimated that there were around 5,500 optical businesses in the UK, with around 2,600 of these not regulated by the GOC;
- found that while the risks associated with optical businesses were low, there were “potential areas where risks could undermine patient care and outcomes”, with the key to addressing these risks being “the consistent application of GOC regulation and oversight”; the potential risks identified were:
    - the absence of formal clinical governance within businesses at the same time as an increasing scope of practice for practitioners;
    - growing/future risk areas such as remote care or the use of new technology;
    - gaps in regulatory oversight for online businesses such as the online supply of contact lenses;
    - the management and oversight of locum practitioners; and
- examined a range of possible regulatory models (all of which centred on extending business regulation to all businesses providing restricted functions) and estimated one-off and ongoing costs for implementing these models, both for businesses and the GOC.

89. This research will help us to consider next steps in extending business regulation and estimating the scale of the number of businesses that will fall within our remit should there be a change in legislation. As outlined above, there will be further consultation before any changes are made.

90. We recognise that legislative change will take some time and we are considering whether there are ways of bringing more businesses within our remit without a change in legislation but using other regulatory levers. For example, we could consider whether it would be appropriate to amend our Standards of Practice for Optometrists and Dispensing Opticians to require any individual responsible for owning or managing a business to ensure that they also comply with the Standards for Optical Businesses.

Section 4: Testing of sight (sections 24 and 26 of the Act)

91. Restrictions in relation to testing of sight are set out in section 24 of the Act, and only optometrists or registered medical practitioners can test sight (with special provision for students). Our 2013 statement on testing of sight sets out that no part of the sight test can be delegated to a dispensing optician or contact lens optician, even under supervision. However, aspects of sight testing can be undertaken by others for purposes other than the sight test, for example, dispensing opticians undertaking refraction[9] to check accuracy of lenses, or optical assistants completing triage checks prior to the sight test. We have heard from some stakeholders that the Act and/or GOC policy is too prescriptive, for example, in terms of who can carry out a sight test and how this must be done, particularly as the roles of optometrists and dispensing opticians have evolved and expanded over the last few years, along with increasing pressures in ophthalmology departments. Further information can be found in section 4 of our call for evidence.

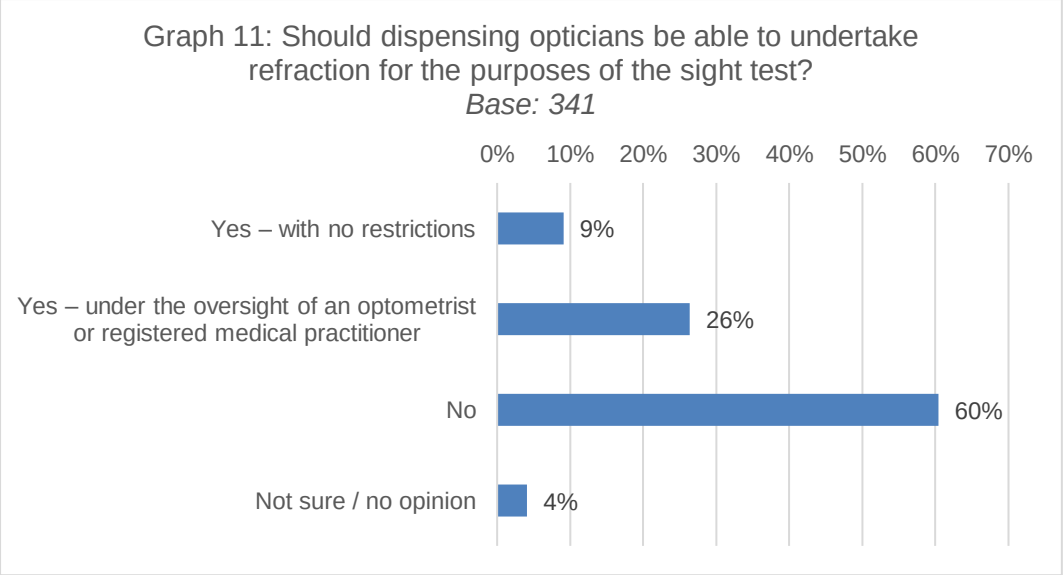
4.1 Consultation: refraction by dispensing opticians

Refraction by dispensing opticians for the purposes of the sight test

92. We asked stakeholders whether dispensing opticians should be able to undertake refraction for the purposes of the sight test, giving two options if they thought that dispensing opticians should be able to refract – one being with no restrictions and the other under the oversight of an optometrist or registered medical practitioner.

93. Of the 341 respondents that answered the question, 60% answered no, 26% answered that dispensing opticians should be able to refract for the purposes of the sight test under the oversight of an optometrist or registered medical practitioner, 9% answered that dispensing opticians should be able to refract without any restrictions and 4% were not sure or had no opinion.

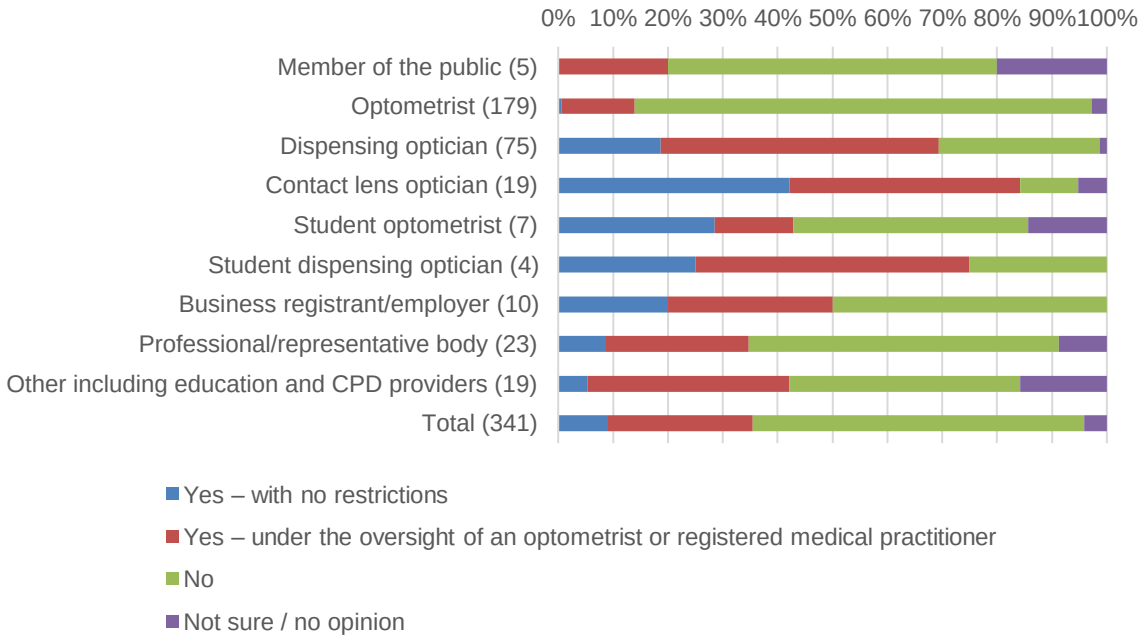
[9] Refraction as part of the sight test refers to a check of the patient's visual acuity i.e. how well they can see, and whether any corrective measures such as spectacles or contact lenses are required



94. Although FODO answered 'no' to the question of whether dispensing opticians should be able to undertake refraction for the purposes of the sight test, they went on to clarify that they would be supportive of us amending the 2013 statement on testing of sight to allow an optometrist or registered medical practitioner to work within a multidisciplinary team to test sight and meet patient needs in a safe and effective way that is consistent with the Act.

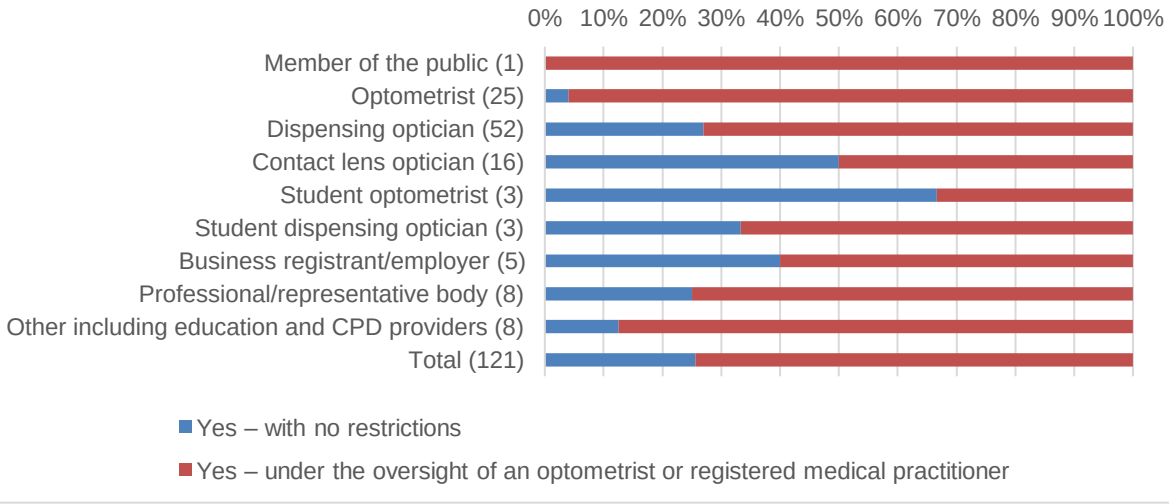
95. Graph 12 shows the responses broken down by category of respondent. The vast majority of optometrists were not supportive of refraction by dispensing opticians (even under oversight). It was interesting to note that of the 69% of dispensing opticians who felt that dispensing opticians should be able to refract for the purposes of the sight test, almost three-quarters of these felt it should be under the oversight of an optometrist or registered medical practitioner.

Graph 12: Should dispensing opticians be able to undertake refraction for the purposes of the sight test?
By category
Base: 341



96. Graph 13 shows those respondents who answered yes to whether dispensing opticians should be able to refract, with over 70% of respondents in most categories arguing that this should be under the oversight of an optometrist or registered medical practitioner, with the exceptions being contact lens opticians, student optometrists, student dispensing opticians and business registrants/employers.

Graph 13: Should dispensing opticians be able to undertake refraction for the purposes of the sight test?
'Yes' responses by category
Base: 121



Arguments in favour of refraction by dispensing opticians for the purposes of the sight test

97. The following themes were identified from the comments received in support of refraction by dispensing opticians and those who noted the advantages and positive impacts of amending or removing our 2013 statement on refraction so that dispensing opticians could refract for the purposes of the sight test:

- it would free up optometrists to deliver more medical ophthalmic care, provide additional services and/or see more patients, thereby easing the pressure on hospital eye services;
- support for a multidisciplinary team approach to patient care where healthcare professionals work together under the oversight of an optometrist or registered medical practitioner in a safe and effective manner. This was positioned in the context of the evolution of professional roles, new delivery models including developments in technology and challenges around ensuring access to a wide range of services in all geographical areas;
- dispensing opticians are already trained in refraction and would know how to detect signs of disease;
- standalone refractions could be done in between full sight tests, supported by technology, which could aid earlier diagnosis of disease – this would give a better service to patients who only need a re-check of their vision following a recent sight test, have dispensing issues or who are seen regularly by hospital eye services;
- some of the functions of the sight test, sometimes knows as 'pre-screening' tests/checks, are already delegated (e.g. visual field tests, fundus photography, intraocular pressures, optical coherence tomography (OCT), auto-refraction);
- dispensing opticians could expand their scope of practice, advance their careers and/or achieve better salaries;
- support for refraction by dispensing opticians, conditional on a series of factors:
    - they were trained and under the supervision of an optometrist;
    - if the training includes how to detect possible signs of pathology;
    - if the refraction and eye health checks are linked and not carried out separately;

- access to eye care could be improved (particularly in remote areas) by more refraction / sight test appointments becoming available to the public;
- reduced labour costs for businesses and reduced costs for patients, as dispensing opticians are cheaper to employ than optometrists; and
- enable patient care to be provided in a more flexible way rather than the current model.

98. A sample of comments is available in the box below.

"It is crucial that optometrists are freed up and empowered to deliver more of the medical ophthalmic care as part of the transformation of eye care services and the integration of primary eye care into the whole end to end eye care pathway. To do so they need to be able to devolve as many aspects of their lower risk activities or "non medical" activities to other colleagues. This is exactly what has happened in hospital as technicians, health care assistants, orthoptic assistants etc do more, to allow in-hospital nurses, orthoptists and optometrists deliver enhanced and extended roles which were traditionally only done by doctors. I would argue that you should consider whether there are activities which can also be done by other colleagues beyond dispensing opticians eg by other technicians." Consultant Ophthalmologist

"I have always worked in areas where a proportion of my patients would have their eye health examination privately from an ophthalmologist…and then visit a dispensing optician for dispensing. Many ophthalmologists would rather not refract and in this environment it would make sense for dispensing opticians to be able to refract and issue the prescription for the spectacles they supply..." Dispensing optician

"The DO is in an excellent position to accurately refract due to the nature of their training and expertise... By creating this opportunity under the supervision of an Optometrist a two tier sight test would be avoided which would be in the patient's best interest. We must avoid circumstances where patients forgot [forego] *vital regular eye health checks."* Business registrant/employer

"With refraction being able to be carried out by Dispensing opticians, practices in remote areas could run a clinic, with the DO in store and the optometrist in another location, remotely supervising the overall examination and with the ability to intervene and recommend further tests or referral as necessary. More frequent refraction only appointments (perhaps yearly?) would give our profession more opportunities to intervene early, if a patient's visual acuity or prescription changed markedly…" Business registrant/employer

"RCOphth supports a competency based approach to assessing which clinician or health professional should perform a specific task. Given dispensing opticians will already undertake refraction for purposes other than the sight test, we can

therefore see a case for amending the GOC's legislative approach to potentially allow dispensing opticians (under the oversight of an optometrist or registered medical practitioner) to undertake refraction for the sight test.

This could help increase workforce capacity (coupled with a broader workforce strategy across the entire eye care workforce to ensure we have the staff needed to meet patient demand), enabling optometrists greater ability to support more clinical activities…" Royal College of Ophthalmologists

"…A refraction carried out by a dispensing optician for the purposes of the sight test would be under the oversight of an optometrist or medical practitioner. Therefore, an optometrist or medical practitioner would still have overall responsibility for the sight test and patients would continue to benefit from an eye health examination at the same time as a refraction. This is a major strength of the UK's system of eye care and enables eye and wider health issues to be identified and addressed at an early stage in line with the wider health policy focus on prevention…

…Enabling dispensing opticians to refract as part of the sight test would form part of the wider and positive trend towards a multi-disciplinary approach to delivering primary eye care. By optimising the use of the primary care workforce rather than seeking to maintain outmoded professional boundaries, we can help to relieve the strain on hospital eye departments and improve the quality of eye care which we provide for the UK public…

Enabling dispensing opticians to refract as part of the sight test under the oversight of an optometrist or medical practitioner would be a limited change to the GOC's 2013 statement on sight-testing. The statement already allows dispensing opticians to refract outside of the sight test, e.g. to check a prescription, meaning that some dispensing opticians already have experience of carrying out refraction.

Dispensing opticians already learn about refraction as part of their initial education and ABDO would provide additional training so members' skills and knowledge are up-to-date. The GOC's new outcomes for registration will ensure that future DOs are fully versed in refraction from the outset.

Enabling dispensing opticians to support optometrists and medical practitioners in carrying out sight tests would enable patient care to be provided in a more flexible way while upholding the principle that a sight test should involve both a refraction and an eye health examination at the same time." ABDO

"…Clinical services are evolving at pace in Wales as described through the NHS Wales Future Approach for Optometry Services. These clinical pathways require optometrists to work at the top of their clinical licence, reducing demand upon specialist secondary eye care services. To enable this clinical shift in services, and reduce the demand for secondary care services, the roles of all members of the primary care MDT [multi-disciplinary team] *will need to evolve to ensure that demand for primary care services can continue to be met. This includes*

dispensing opticians refracting patients as part of the MDT. There should be no separation of the eye health aspect from the testing of sight to ensure patient safety. The oversight of the responsible optometrist provides the required clinical governance to the clinical pathways and this process enables better use of the full multidisciplinary team..." Welsh Government

"We…are of the view that the GOC's 2013 statement is factually accurate. We therefore see no merit in simple removal of the statement as this would create further confusion and result in the same questions which led to the 2013 statement being published in the first instance…we also see no case for changing the legislation.

Considering the GOC objectives and our engagement with members, we feel that the principles here which need to be acknowledged are that with population needs changing:

- *Optometrists and medical practitioners will increasingly need to work on a multidisciplinary team (MDT) basis if the country is to meet growing patient needs in a sustainable way*
- *Each member of an MDT will need to be appropriately trained, overseen and competent in any support they provide to an optometrist or medical practitioner who is performing a sight test*

In considering this, and having undertaken an extensive consultation both with members and other optical bodies, we feel the most proportionate approach, and one that is aligned with all GOC objectives for this call for evidence and consultation, would be to update the 2013 statement…" FODO

"It is correct that no element of the sight test (a restricted activity) can be delegated, however, there is no contradiction in simultaneously recognising that as in all areas of modern clinical practice, a multidisciplinary team will naturally support and assist the registrant in their work – and it is here that trained colleagues, including registered dispensing opticians, can assist. ...the practitioner (optometrist) should continue to retain responsibility as well as accountability for performing the sight test, but can be assisted in so doing. It would be in line with the stated objectives for regulatory reform, to encourage the use of the multidisciplinary team to assist in this way, and could be achieved by updating the 2013 statement and by encouraging the professional bodies to issue guidance in support." Optometry Northern Ireland

Arguments against refraction by dispensing opticians for the purposes of the sight test

99. The following themes were identified from the comments received against refraction by dispensing opticians and those who noted the disadvantages and negative impacts of amending or removing our 2013 statement on testing of

sight so that dispensing opticians could refract for the purposes of the sight test:

- concerns that the sight test would completely separate the refraction and eye health checks resulting in eye disease and/or other health conditions going undetected, which could ultimately lead to increased pressure on hospital eye services, delayed treatment, preventable sight loss and a further increase in health inequalities due to:
    - businesses deliberately abusing the process by separating the different parts;
    - people being discouraged from having a full eye examination, perhaps due to costs (particularly for those on low incomes) or because they do not understand the importance of an eye health examination;
    - patients being confused, believing they have had a full sight test and not attending a further eye health examination;
- optometrists gather information during the history taking and refraction which leads to further investigation in eye health checks or a different approach to the refraction – this could result in a lower quality sight test where things could be missed that might result in eye disease and/or other health conditions going undetected;
- concerns about the risks of 'delegating' parts of the sight test, with an example of the Honey Rose case where pre-screening tests/checks were delegated;
- it is not clear there is any evidence of a need/demand for dispensing opticians to refract for the purposes of sight testing (particularly as many optometrists already use technology to assist) or how this would benefit patient safety;
- different aspects of the sight test are interdependent on each other and could not be carried out effectively by different people, even if one of those was under the oversight of an optometrist or registered medical practitioner;
- dispensing opticians don't have the qualifications, training or experience to undertake refraction and/or to identify pathology as part of the refraction;
- dispensing opticians can already take advantage of conversion courses to become an optometrist;
- refraction by dispensing opticians will only benefit practice/business owners keeping labour costs down and won't benefit patients –

commercial interests could force fast refractions and eye health checks where things could be missed;

- money may be saved in one area but might ultimately lead to higher costs in another area (e.g. the time it takes for an optometrist to check the work of a dispensing optician could increase the workload of an optometrist);
- oversight of dispensing opticians by optometrists could increase the pressure on optometrists, which could lead to shorter and inadequate sight testing times for checking work of others, ultimately leading to reduced patient care;
- concerns about who would be ultimately responsible/liable for the refraction and whether an optometrist would be able to rely on the results of a refraction that they had not carried out themselves, again resulting in more pressure on optometrists;
- it could de-value and de-skill optometrists and result in lower salaries and less of a need for them;
- it could bring the professions into disrepute and/or risking public confidence through lowering of standards;
- patients with additional needs such as dementia, learning disabilities or social anxiety will struggle with two people carrying out different aspects of the sight test – it might discourage them from going at all; and
- patient care/experience would suffer as it would be more complex/disjointed and they would be confused about the different roles.

100. A sample of comments is available in the box below.

"This would discourage people from choosing to have a full eye examination, and hence allow disease to go undetected. We already see this in patients who present with advanced glaucoma in our glaucoma clinic - they have saved money by buying ready-readers, but it has cost them their sight." Optometrist

"There are many occasions where a refraction needs to be tailored due to ocular health or patient history and this can only be done effectively if this is all done by one individual." Optometrist

"A separation between refraction and eye examination can lead to lots of patients not getting what can be life saving eye examination in some cases. Vision and eye health are interlinked." Local optical committee

"…we do not believe it would be of benefit to the public and may risk causing confusion and lowering standards. Refraction is a fundamental part of the sight

test, but a sight test is clearly more than a refraction and should not on public protection grounds be split into its component parts…" Specsavers Optical Group

"We are concerned about vulnerable individuals who have additional needs for example people with dementia, glaucoma, keratoconus for whom refraction might be more complicated." Glaucoma UK

"…from a patient perspective, we envisage little to no benefit to patients by allowing dispensing opticians to refract for the purposes of the sight loss [test]*. In our view, this change will not increase the number of patients seen and will only lead to a more fragmented sight test with an increased risk of patients missing out on vital eye health checks."* RNIB

"…the proposal on delegation of refraction comes with little evidence or data to support the public benefit case for it. Without seeing the evidence for a clear patient benefit (which is how the proposal should be judged), we do not support delegation. There does not seem to be any evidence of a shortage of eye examination appointments nationally and long waiting times. The proposal may suit commercial considerations, but in respect of eye health it could lead to further fragmentation and confusion as to the different elements of the sight test being performed by different people. As an example, breaking down of different elements of the eye examination in hospital eye care services can prove an ordeal as a person with a learning disability sees various different people at different times. This could happen in community practice if refraction is delegated." SeeAbility

"…Allowing dispensing opticians to refract, in particular without supervision, would create a significant risk of missed pathology which could endanger the nation's eye health… If we consider a scenario where dispensing opticians were able to perform refraction under the oversight of an optometrist or registered medical practitioner, that would serve to partially mitigate the risk of missed pathology. However, this could produce an unintended consequence in the form of increased pressure on optometrists who are in the role of providing this oversight. Our members, who are GOC registrants, have expressed concern that they may be provided with shorter appointment times that are insufficient to robustly check the refraction. This could increase workplace pressures and lead to clinical errors. These registrants have told us that the clinical governance, audit, and risk measures would need to be sufficiently robust to always ensure patient safety. Clarity of roles and responsibilities was also identified as a key requirement and was felt to be particularly important for locum practitioners." AOP

"…The College supports the general principle of collaborative working and delegation wherever possible, and we recognise that registrants should be able to utilise technology and innovative methods in order to perform the sight test, where they are satisfied it is in the patient's best interest…

…However refraction, due to its interdependence on binocular vision and ocular health assessment, cannot be performed effectively by another person, either independently or with oversight...

…We conducted a literature review and found no high quality or compelling scientific or economic evidence for the need to delegate refraction, or that it was advantageous to the public to enable dispensing opticians to perform refraction under supervision. In addition, we found no evidence it resulted in a more sustainable or accessible means of delivering population-led eye care in socioeconomically deprived populations…

There is no evidence that delegation of refraction would enable optometrists to provide more enhanced or advanced clinical services and alleviate pressures on hospital eye services.

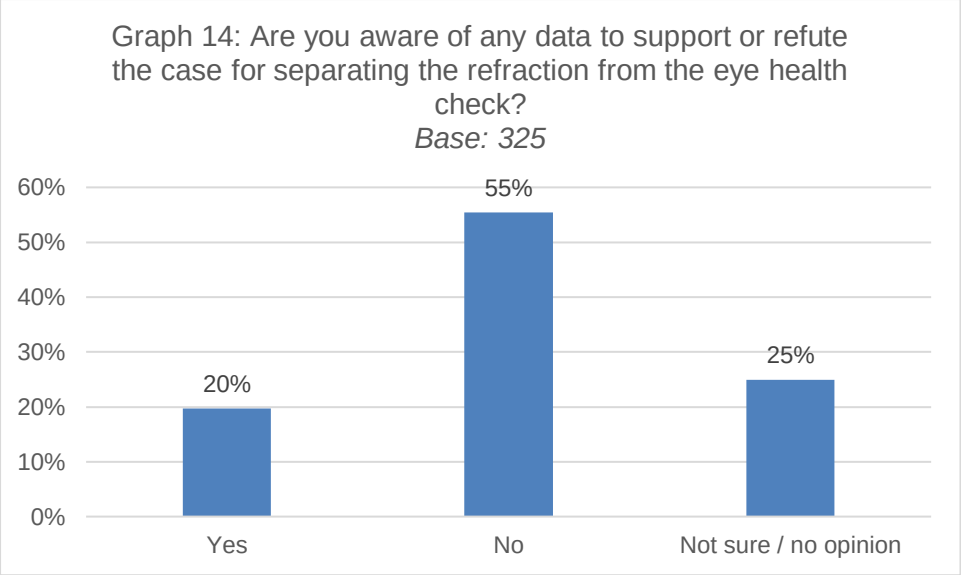
The College supports these new models of care and believes that optometrists can play a central role in delivering more services and improving patient outcomes. We are also leading work to model the eye care workforce, so we can understand current gaps or limitations and better support workforce planning in future.

However, we see the main lever to achieving new models of care relates to the appropriate funding and commissioning of services, and will not be solved by the delegation of refraction as part of the sight test.

The Act and supporting 2013 statement is for the benefit of the public and must continue to ensure all people receive safe and appropriate care, maintain good eye health and avoid preventable sight loss." The College of Optometrists

Data to support/refuse separating refraction from the eye health check

101. We asked stakeholders if they were aware of any data to support or refute the case for separating the refraction from the eye health check. Only 20% of respondents answering the question were aware of any data.



102. Respondents signposted us to case studies or articles that they felt were relevant to refute the case for separating the refraction from the eye health check, but these did not specifically address the case for keeping the refraction and eye health check together. Some of these studies pointed us to evidence such as the global figure for avoidable sight loss, concerns about how much avoidable sight loss and glaucoma in the UK is already unidentified, and the value of routine eye health examinations (including for the detection of glaucoma by optometrists). There was significant concern from the vast majority of respondents that the refraction and eye health check should not be separated, pointing out the vital public health role that the sight test plays in preventing and identifying disease, and the pressure that it would put on GPs and the hospital eye services.

103. The following are some studies that we were made aware of:

- the AOP told us about a study from Thomas *et al.* (2011)[10] which involved a robust and detailed comparative analysis of the primary eye care systems in the UK, France and Germany. They said it concluded that each system had its own advantages, and all delivered effective services which were capable of high-quality delivery, and that whilst this paper does not show that the UK system is unambiguously better than other European countries, it shows that the system already delivers capably and effectively. The AOP also said that the study concluded that France and Germany should consider increasing the participation of dispensing opticians and optometrists to deal with upcoming challenges, in their view suggesting that the UK has the most sustainable eye care model;

[10] Thomas, D., Weegan, L., Walendzik, A., Wasem, J., Jahn, R. (2011), *Comparative Analysis of Delivery of Primary Eye Care in Three European Countries*, IBES Diskussionsbeitrag

- The College of Optometrists advised us that the Italian optometric system is predominantly based around optometrists refracting with no obligation to detect ocular pathology. They advised that a study by Cheloni *et al.* (2021)[11] reported that there were several conditions that would likely remain undetected in this type of eye care model, and that the authors indicated that around 20% of patients may have ocular pathology that required treatment or monitoring and that would be undetected without the requirement for concurrent refraction and eye health examination; and

- several respondents pointed us to a study by Bowling *et al.* (2005)[12] which found that 95% of suspected glaucoma cases, a leading cause of sight loss in the UK, are referred into the hospital eye service by optometrists.

104. We were advised to look at preventable sight loss rates in countries where the eye health system is different to the UK. There was a suggestion to commission our own literature review including late presentation of glaucoma cases due to the introduction and availability of 'ready readers' in retail settings.

105. We were also warned that the absence of evidence should not in itself be a reason not to change something, as it could simply be a weakness in the collection of evidence or not possible to collect.

106. FODO warned about drawing international comparison as many 'optometrists' in European countries operate at the level of a dispensing optician in the UK, and those countries have approximately double the number of ophthalmologists than we do.

GOC response – refraction by dispensing opticians for the purposes of the sight test

107. We recognise there are strongly held views on the issue of dispensing opticians refracting for the purposes of the sight test. As well as carefully considering submissions to the call for evidence, we commissioned independent research to provide an expert clinical perspective, commissioned independent qualitative and quantitative research with the public and patients, and carried out in-house desk research to explore international comparisons. All this research is published on our website alongside this response document.

108. In reaching conclusions on this matter, we are mindful of variations in sight test models used by optical businesses, differences in commissioning and funding arrangements across the nations of the UK, as well as developments in technology, including the growing use of autorefractors. The expanding clinical

[11] Cheloni, R., Swystun, A.G., Frisani, M., & Davey, C.J. (2021), Referral in a routine Italian optometric examination: towards an evidence-based model*, Scandinavian Journal of Optometry and Visual Science*, 14(1), 1–11. https://doi.org/10.5384/sjovs.v14i1.129

[12] Bowling, B., Chen, S.D., Salmon, J.F. (2005), Outcomes of referrals by community optometrists to a hospital glaucoma service, *The British Journal of Ophthalmology*, 89(9), pp. 1102-4

roles of eye health professionals, which the GOC's education and training reforms support, is another contextual factor. It is likely that the sight test will continue to evolve over the next five to ten years in response to these and other drivers of change.

109. The patient and public research[13] found that most of the public would be supportive of dispensing opticians performing refraction as part of the sight test, provided that appropriate training and safeguards (such as supervision) were in place. The majority of the public spend little time thinking about eye care and have limited embedded knowledge about procedures during sight tests. The public recognise there may be potential negative consequences of dispensing opticians refracting for the purposes of the sight test, but these were all considered to be surmountable with suitable safeguards put in place, with enhanced training being the most important of these.

110. The clinical research on refraction in the sight test[14] found that:

- there were differences in business models, with larger corporates making significant use of optical assistants during the sight test;
- there was a lack of consensus among healthcare professionals in relation to dispensing opticians refracting for the purposes of the sight test, with the greatest concern being the risks related to a 'refraction only' sight test;
- the eye health checks should be carried out by the same person who carries out the refraction, as retinoscopy (a kind of objective refraction) gives subtle clues about eye health;
- retinoscopy is a difficult clinical skill but this technique is increasingly being replaced by automated refraction technologies;
- there was concern that risks would increase if sight test components were carried out at different times or in different places, with their advice being that further research should be carried out to address the risks before making any changes in community practices; and
- orthoptists were capable of refracting young children during their work in the hospital eye service and argued for them to be able to issue prescriptions and optical vouchers.

111. Our in-house desk research into international comparisons on refraction with the UK sight test[15] noted the lack of research available to consider dispensing

[13] WA Research (2023), *Public views on refraction: Research report for the General Optical Council*
[14] Evans, B., Shah, R., Conway, M. and Chapman, L. (2023), *Clinical research on refraction in the sight test*
[15] General Optical Council (2023), *International comparisons on refraction services with the sight test model in the UK*

opticians refracting or the risks of different people carrying out different elements of the sight test; differences in professional roles across countries (including the role of ophthalmologists in Europe in carrying out the sight test); an interesting risk-based model where the equivalent of dispensing opticians can refract in parts of Canada but where experience has been mixed; and international comparison statistics on sight loss being inconclusive.

112. Our overriding consideration is patient safety. Based on the information collected during the call for evidence and findings from the subsequent research, at this point in time we are not satisfied that dispensing opticians should be permitted to refract for the purposes of the sight test. Our main concern is undetected pathologies, including subtle clues about eye health that may be missed if different professionals conduct the refraction and other components of the sight test[16]. The evidence underlined the importance of the end-to-end nature of the sight test that enables the optometrist to take a holistic view of eye health. The risk of undetected pathologies would remain even if dispensing opticians were to receive further training/accreditation and be under the supervision/oversight of an optometrist or registered medical practitioner. We are satisfied that with appropriate training, dispensing opticians could competently perform refraction. However, our concern is that permitting dispensing opticians to refract for the purposes of the sight test would undermine the safety and other benefits of the end-to-end care model.

113. We nevertheless are very supportive of dispensing opticians continuing to develop their skills and meet their full professional capabilities. The development of contact lens opticians is a good example of where this has been achieved. We would welcome discussion about other opportunities to advance the profession that would be a natural extension of dispensing opticians' current scope of practice.

114. We will further discuss the issues connected with orthoptists refracting for the purposes of sight testing with the Health and Care Professions Council (HCPC – the regulator for orthoptists) and the British and Irish Orthoptic Society.

115. We will consider updating our 2013 statement on testing of sight to clarify the position in relation to pre-screening tests and triage checks related to the sight test that may be carried out by persons other than the optometrist or registered medical practitioner. Over time, advances in technology have meant various steps in the patient journey have become automated and safely delegated as part of pre-screening and triage. Use of autorefractors is one example of this

[16] Section 26 of the Act defines the duty of those testing sight "to perform such examinations of the eye for the purpose of detecting injury, disease or abnormality in the eye or elsewhere" as regulations may require; regulation 3 of The Sight Testing (Examination and Prescription) (No. 2) Regulations 1989 requires "an examination of the external surface of the eye and its immediate vicinity", "an intra-ocular examination, either by means of an ophthalmoscope or by such other means" and "such additional examinations" as appear to be clinically necessary

and we understand further developments, including in relation to refraction, are on the horizon. If we decide to update our 2013 statement, we will carry out further consultation on this aspect of the testing of sight.

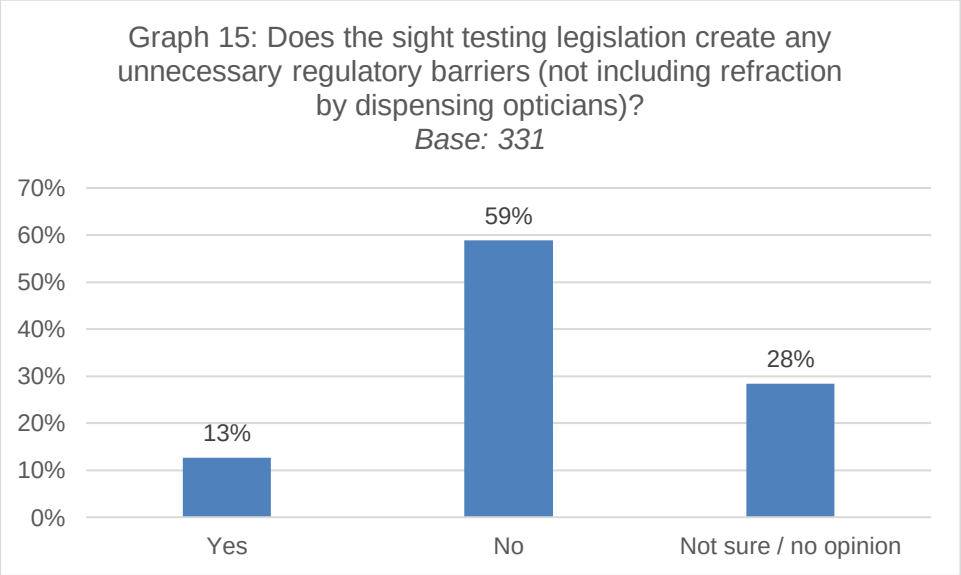
116. Our interpretation is that the Act does not specifically prohibit separation of the elements of the sight test by time, place or person. Business models are evolving alongside developments in technology. While relevant to refraction, this issue relates more generally to how the sight test is conducted, rather than which type of optical professional should perform different elements of the sight test. The call for evidence identified a range of views about this and we plan to consider developments in more detail. Depending on the outcome of this work, we may clarify our position in a statement or seek a change in the law.

4.2 Duties to be performed on sight testing

117. Section 26 of the Act sets out the duties to be performed on sight testing, which are commonly known as the refraction and the eye health check. The difference between these two areas is not always clearly understood by patients and the public. Current practice is that the refraction and the eye health check must be undertaken at the same time or within a reasonable time period of each other. Our interpretation is that the Act does not specifically prohibit separation of the elements of the sight test by time, place or person. Further information can be found on page 14 of the call for evidence.

118. We asked stakeholders if they thought that the sight testing legislation created any unnecessary regulatory barriers (*not* including refraction by dispensing opticians).

119. Of the 331 respondents who answered the question, 59% said no, 13% said yes (only one of which was a professional/representative body) and 28% were not sure or had no opinion.



Arguments in favour of duties to be performed on sight testing legislation remaining as it is

120. When reviewing the comments in response to this question, we noted that there appeared to be some confusion about the question – some respondents were commenting on refraction by dispensing opticians, whereas the question asked about any unnecessary regulatory barriers in the sight testing legislation that were *not* related to refraction by dispensing opticians.

121. The overwhelming theme from the majority of those who commented was that the sight testing legislation does not contain any unnecessary regulatory

barriers – it creates an appropriate framework whereby a full eye examination is carried out.

122. We asked stakeholders what the advantages, disadvantages and impacts (both positive and negative) would be of sight testing legislation remaining as it is currently. The following themes were identified from the comments received that identified advantages and positive impacts of the sight testing legislation remaining as it is currently:

- it will keep the public safe by ensuring that they receive an eye health check (carried out by appropriately qualified and trained professionals) and help early detection of pathology;
- patients understand the current system and what the sight test includes;
- it allows the refraction and eye health checks to be conducted at the same time which keeps the public safe by giving the opportunity to detect pathology – it also provides continuity of care for the patient;
- a high standard of care will be delivered by one individual (an optometrist);
- it allows good access to and affordability of sight tests for the population; and
- it protects the profession.

123. A sample of comments is available in the box below.

"… the sight testing legislation has provided a firm foundation on which the UK's eye health system is run, and without it we would have no effective way of meeting vision and eye health needs in a primary care (out of hospital) setting..." Business registrant/employer

"From the perspective of operating in many different markets, we regard the sight test as defined and regulated, offered and commissioned in the UK as a world leading model which provides significant patient and public health benefits. We cannot identify any disadvantages of sight testing legislation remaining as it is." Specsavers Optical Group

"The current legislation does not provide unnecessary regulatory barriers. Instead, it establishes a framework to ensure that when sight is tested, the eye health of the patient is also evaluated. This provides an opportunity for the detection of asymptomatic eye disease that otherwise may not be identified until significant, irreparable damage has already occurred. Given the importance of this role and the potential risk to the public, the profile/type of clinician who is able to conduct sight tests is quite reasonably restricted, to ensure that those testing sight are suitably qualified and trained…

…We do not recognise any disadvantages to the sight testing legislation remaining as it is, as in our members' view the current legislation is successful in serving to protect patients. However, we do feel that there could be a small risk that the legislation and/or associated guidance as it stands could restrict innovation and the ability to be flexible and reactive to change at the pace required to keep the profession agile within a complex and fast-paced primary eye care system. In our view this risk is not relevant as technological advancements that are used by the optometrist are already permitted, therefore the Act does not prevent their use." AOP

"The GOC's public perceptions research shows a high level of public satisfaction with and confidence in the services provided by registrants. This is an important indication that the current system of primary eye care is serving patients and the public well by providing accessible, high-quality, affordable and innovative care. This is in contrast with other parts of the primary care system, where there is an ongoing struggle to meet patient demand. In particular, patients benefit from a sight test that includes an eye health examination, which is consistent with the wider health policy focus on prevention." ABDO

"The UK has well-functioning, accessible and efficient primary eye care services and at the heart of these is the comprehensive sight test (or eye examination in Scotland), which all patients can access with no or low waiting times. This model of optometrist-led primary eye care has been recognised as one which benefits patients[17], and the current legislation is a key factor in maintaining the safety and integrity of the sight test. This protection for the benefit of the public must continue to ensure all people can see as well as possible, maintain good eye health and avoid preventable sight loss..." The College of Optometrists

"There is no evidence base to suggest that the sight testing legislation needs to change. The sight test, firmly anchored within the safety framework provided by the Opticians Act, has been one of the few healthcare services which has been able to innovate and change over time whilst keeping real terms costs down for patients." FODO

Arguments in favour of changing the duties to be performed on sight testing legislation

124. Some respondents believed the sight testing legislation needed amending in the following areas (although no evidence was presented as to why this should be the case):

[17] Thomas, D., Weegan, L., Walendzik, A., Wasem, J., Jahn, R. (2011), *Comparative Analysis of Delivery of Primary Eye Care in Three European Countries*, IBES Diskussionsbeitrag

- change in terminology from sight test to eye examination – we do not think this is necessary as it has not stopped commissioning bodies from using any terminology that they see fit;

- clarity is required around sight testing for diagnostic purposes in a hospital setting – we think that The Sight Testing (Examination and Prescription) (No. 2) Regulations 1989 are clear with regard to specific exemptions for sight testing "where the testing of sight is carried out by a doctor at a hospital or clinic in the course of diagnosing or treating injury or disease of the eye";

- definition of the sight test needs amending to reflect modern working practices and technology (including autorefraction) and/or to allow for the scope of the sight test to change – it is not clear why this needs to change and respondents did not give evidence as to what the Act restricted from happening;

- allowing for refraction/sight testing and eye health checks to be identified as separate for the purposes of proper funding by the NHS – we believe this is not required as Scotland already has a system in place whereby funding for eye health checks can be provided without the need for the full sight test (called an eye examination in Scotland);

- optometrists being able to deviate from the full sight test if a patient presents with an emergency – it is our interpretation that the Act does not place any requirements on optometrists to carry out a full sight if a patient presents with emergency symptoms, although in some cases they may wish to do so. This is likely to be another matter that relates to funding for those practices that are not registered to provide additional services;

- recognition and use of other healthcare professionals (e.g. orthoptists) – it is not immediately clear how these should be recognised within the Act and it may not be appropriate to do so given the remit of the GOC;

- dispensing opticians being allowed to modify a prescription if they suspect it is wrong and carry out a visual acuity check – no evidence was presented to justify this suggestion; and

- rules for orthoptics, including dispensing opticians being allowed to carry out school vision screening and binocular vision assessment – there was no evidence to support this and it is unlikely to be within the remit of the Act or the GOC.

125. There was some confusion that the sight testing legislation put up regulatory barriers including paying for a sight test up-front, autorefraction, electronic prescriptions and prescriptions being emailed to patients. We do not consider

that the Act either requires or prevents any of these things from happening. We also do not consider that it prevents the scope of the sight test changing if national health services wish to fund this.

126. Many respondents mentioned the sight testing fee for General Ophthalmic Services (GOS). This is a matter for national health services and we know that many of the optical sector professional/representative bodies work with these services to represent the views of the professions on this point.

127. The following themes were identified from the comments received that identified disadvantages and negative impacts of the sight testing legislation remaining as it is currently:

- it restricts the roles of optometrists and dispensing opticians (and other healthcare professionals such as orthoptists) and does not allow for agility and changes in technology;
- optometrists will not be able to fully utilise their skills and/or focus on eye health (although it was recognised there was a lack of funding in this area);
- patients will continue to receive a poor quality service and delayed treatment due to capacity delays within the NHS;
- increasing pressure in hospital eye services, particularly with an ageing population;
- it would cause confusion to the public; and
- workforce shortages of optometrists in some areas of the UK, potentially affecting number of appointments available.

128. A sample of comments is available in the box below.

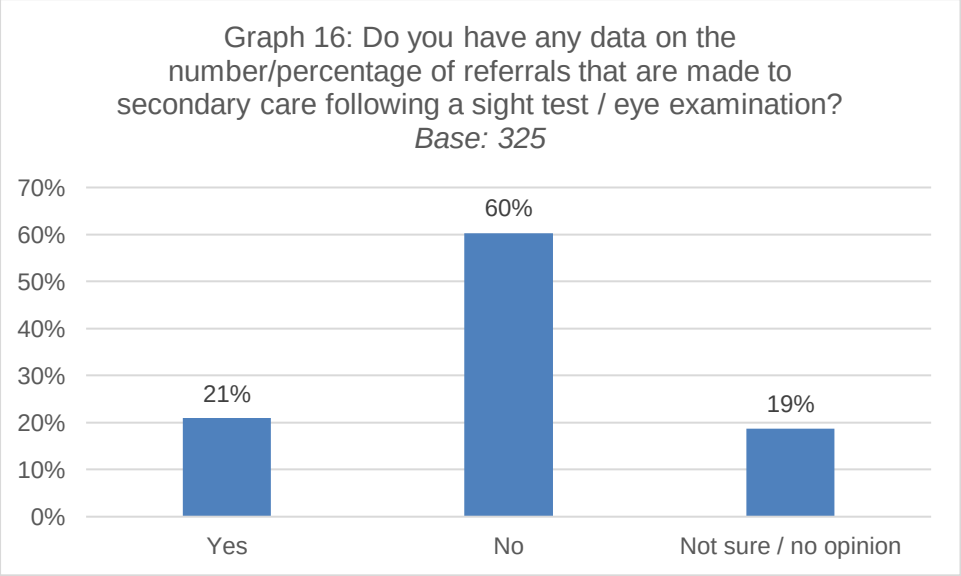
"Optometrists will not be able to utilise their full skills to benefit patients and eye care services, patients will continue to be delayed, harmed, with poor quality service and poor experience due to capacity delays in the NHS services. Optometrists will feel frustrated that they cannot use all their skills with consequent moral, retention and other issues." Consultant Ophthalmologist

"…More thought therefore needs to be given to what regulation may be necessary for technology led sight testing and how this could be managed. It is important that the revision to the Opticians Act does not automatically (and likely inadvertently) prevent such a development. In our view, an ECP [eye care professional] *should be able to use technology where either a) the final decision of treatment or prescription falls to the ECP, or b) where the technology has been clinically validated and regulatory approved.*

Without properly considering and supporting the use of technology, the GOC will both prevent and deter companies from entering the market. As a result, UK eye care patients will not be able to take advantage of new and emerging technologies which potentially could provide them with better or more convenient care." Optical Suppliers' Association

Data on referrals to secondary care

129. We asked stakeholders if they had any data on the number/percentage of referrals that are made to secondary care following a sight test / eye examination. Only 21% of respondents answering the question said that they had data.



130. Estimates from individual comments ranged from 2.5-15% (with an example of around 20% in the over 60s and an extreme example of 90% on some days in a deprived town). Several people commented that the rates varied depending on geographical area (including whether national health services have commissioned any further diagnostic tests in that area, such as a glaucoma referral/refinement pathway) and experience of the optometrist. There were some comments from those who worked in secondary care that a large proportion of referrals were unnecessary. There was also a complaint about having to refer to a GP rather than to secondary care directly.

131. In terms of actual data/studies:

- one optical business said that their patient management system showed 9% onward referrals; another optometrist said 15% from their system; another business said 6% for one large group of practices;

- a study undertaken in England and Scotland[18] showed a 5.1% referral rate to secondary care;

- we were advised that 2019/20 data from Public Health Scotland[19] showed that of just under 2.2 million eye examinations carried out in Scotland (including just under 1.6 million primary eye examinations and just over 586,000 supplementary eye examinations): 4.1% are referred to an eye clinic; 1.4% are referred to a GP; 0.8% are referred to care pathway; and 0.3% are referred to another optometrist; and

- the Welsh Government informed us that 2019/20 data from Wales showed a total of 813,922 GOS sight tests and 201,208 eye health examinations (Eye Health Examination Wales) were performed. Referral to hospital eye care services during the same period totalled 103,627 (10%) of which 23,345 were from GPs and 81,282 referrals were received from non-medical practitioners (optometrists).

132. Some respondents drew our attention to the difficulties in feedback from secondary care back to primary. For example, one study[20] found that in 72.8% of cases the community optometrist remained unaware of the outcome of their referral.

133. Several of the professional/representative bodies were concerned about what the GOC was intending to do with this data. FODO in particular wanted to ensure that any data that we received about false positive glaucoma referrals was not misunderstood – they argued that the referrals are appropriate and that where the NHS commissions referral refinement pathways, for example, enhanced diagnostic procedures in primary care, referral accuracy can be further improved. They also argued that if the NHS wishes to bring down the rate of false positive glaucoma referrals, it would need to fund additional diagnostic procedures, including glaucoma referral refinement pathways. The College of Optometrists also suggested caution about false positive referrals. We were also cautioned by several organisations that many optometrists are able to refer within primary care, particularly if there is a pathway or an independent prescribing optometrist.

134. A sample of associated comments is available in the box below.

[18] Shah, R. *et al*. (2021), Referrals from community optometrists to the hospital eye service in Scotland and England*, Eye* (https://www.nature.com/articles/s41433-021-01728-2#Sec8)
[19] https://www.publichealthscotland.scot/publications/ophthalmic-workload-statistics/ophthalmic-workload-statistics-statistics-as-at-year-ending-31-march-2020/
[20] Harvey, K., Edgar, D.F., Agarwal, R., Benwell, M.J., Evans, B.J.W. (2022), Referrals from community optometrists in England and their replies: a mixed methods study, *Ophthal Physiol Opt.* 42(3), 454-470 (https://onlinelibrary.wiley.com/doi/epdf/10.1111/opo.12948)

"I work in a triage clinic where we see any routine referral coming from primary care instead of them going to HES [hospital eye service]*. We generally discharge 75% of those referrals as they don't need secondary care they just need a competent optom with enough time to fully investigate the issue rather than referring because they don't want to get sued"* Optometrist

"I also work secondary care. 60% of referrals are unnecessary" Optometrist

"Why optometrists are not allowed to refer directly to ophthalmology in my area is a mystery to me. Optometrists should be the primary eye care providers and ophthalmology should be treating more complicated cases and in theatre." Optometrist

"Some have in the past claimed that the sight test results in excessive false positive referrals to secondary care, however the evidence does not support this assertation… some stakeholders make assumptions that a high false positive rate following a sight test is evidence itself that the sight test needs reform. This is erroneous logic and no public policy decisions should be based on such assertations…if the NHS wishes to reduce the false positive rate of referrals for glaucoma following a sight test, it simply needs to fund additional diagnostic procedures, including glaucoma referral refinement pathways. The evidence has long shown this would solve the issue of false positive referrals associated with glaucoma." FODO

"There have been many studies evaluating the quality of optometric referrals. Variation in the rate of referral is often confused by varying definitions of how a "false positive" is defined and do not always take account of factors that contribute to a referral decision, such as IT connectivity, local commissioning arrangements and the level of local hospital engagement (specifically whether feedback and discharge information is routinely provided to the referring optometrist). In locations where additional services are not commissioned and funded in primary care, referral following a sight test may be the only option for optometrists whose patient requires further tests or follow up...

We do not feel that the legislation is a barrier to clinical decision-making or referrals, and instead believe that communication, digital connectivity, commissioning and improved pathways are more likely to impact on referral numbers and outcomes." The College of Optometrists

GOC response – duties to be performed on sight testing

135. We have not been presented with any evidence that the sight testing legislation creates unnecessary regulatory barriers. We have responded to points in the main body of the text (see paragraph 124) where we believe that there are misinterpretations about restrictions in the legislation or where they relate to funding issues that we have no control over.

136. We have noted concerns from the professional/representative bodies about what we are going to do with the data that we have asked for in this section. We asked for this data to inform our thinking on refraction and to understand if there was any information on the levels of referrals to find out how often pathologies were detected in a sight test. We do not intend to take any action in relation to the data provided.

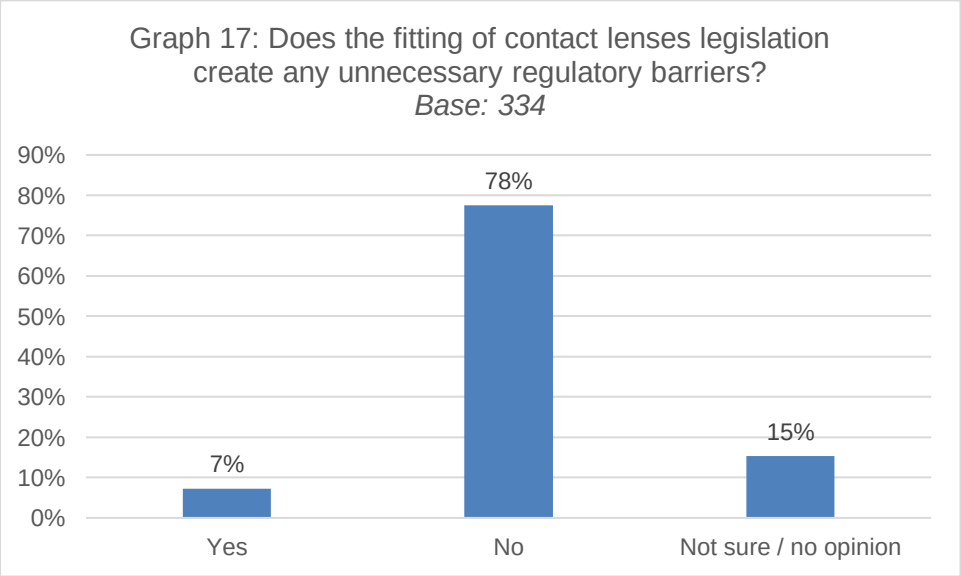
Section 5: Fitting of contact lenses (section 25 of the Act)

137. Section 25 of the Act provides that contact lenses can only be fitted by a dispensing optician[21], optometrist or registered medical practitioner, with special provision for students. Fitting must begin before the re-examination date specified in a valid prescription (dated less than two years ago). For further information please see section 5 of the call for evidence.

Unnecessary regulatory barriers

138. We asked stakeholders whether the fitting of contact lenses legislation creates any unnecessary regulatory barriers.

139. The vast majority of respondents (78%) considered that the fitting of contact lenses legislation did not create any unnecessary regulatory barriers, with only 7% responding that it did and 15% not being sure or having no opinion.



140. Respondents addressed themes considered elsewhere in the call for evidence, which we will not repeat here: the need for fitting of contact lenses to remain a restricted function (see section 2); stronger enforcement of online sales (see section 7); substitution of contact lenses (see section 6); and lack of regulation around the supply of plano/cosmetic/zero powered lenses (see section 6).

141. The overall sentiment was that the current system of contact lens regulation is effective in protecting patients and does not create any unnecessary regulatory barriers. There were very few comments about the ongoing need for specific restrictions required in the Act, for example that fitting must begin before the re-examination date specified in a valid prescription. The implication was that these restrictions should remain due to inherent risks around the fitting of

[21] Dispensing opticians need to have completed an additional contact lens speciality and be on the contact lens speciality register in order to be able to fit contact lenses

contact lenses, i.e. that since they are medical devices there must be proper fitting and aftercare advice to minimise risk of harm to patients.

142. A sample of comments is available in the box below.

> *"Our experience of having fitted millions of patients with contact lenses, in compliance with UK legislation, when compared to our experience in the other markets in which we operate, does not suggest to us that there are unnecessary regulatory barriers in the UK."* Specsavers Optical Group
>
> *"We would support the legislation to remain to ensure optimum patient care. The teaching of insertion and removal lenses using technology to support patients should be included."* BCLA
>
> *"The current system of regulation has meant that over time people have benefited from constant monitoring of eye health, lenses and care regimes being updated in line with advancing technologies, and contact lens complications being addressed in a timely manner, minimising rates of avoidable sight loss. Put simply, the current legislation has helped create a very accessible and safe contact lens market for the public. There is no evidence to support removing existing safeguards which protect the public."* FODO
>
> *"In our opinion the current legislation is there to protect patients and therefore it is beneficial for patient safety that this legislation remains in place."* RNIB
>
> *"Contact lenses fitting is regulated and even now, contact lenses can be bought online without a valid prescription. This is a risk to patients. If deregulated more, more loopholes will appear that will put patients at risk. Deregulation potentially causes more cl* [contact lens] *complications and referrals to secondary care. This is exactly what we are trying to avoid. Keep cl regulation at least as strict as now. Deregulation of this area should not happen."* Optometrist

Advantages, disadvantages and impacts of existing legislation

143. We asked stakeholders what the advantages, disadvantages and impacts (both positive and negative) would be of the fitting of contact lenses legislation remaining as it is currently.

144. The main themes raised in relation to the advantages and positive impacts were:

- the current regulatory framework for contact lenses is effective in protecting patients and should be maintained; and
- de-regulation or easing current restrictions around fitting of contact lenses and aftercare advice would likely increase the risk of harm to patients and

likely result in more referrals to secondary care which would exacerbate the existing burden on hospital eye services.

145. The main theme raised in relation to the disadvantages and negative impacts was that any relaxation of the current regulatory requirements would likely result in increased risk harm to patients, for example, if unqualified and unregulated people were able to fit contact lenses without any training or qualifications.

146. A sample of comments is available in the box below.

> *"…Deregulating the fitting of contact lenses, or allowing this to be done by non-registrants has the potential to increase the incidence of significant contact lens related problems due to inappropriate fitting, advice and aftercare."* Business registrant / employer
>
> *"To ensure patient safety, it is both clinically appropriate and necessary that contact lens fitting can only be legally carried out by registered optometrists or dispensing opticians with a contact lens specialty. Contact lenses are medical devices which carry numerous risks of harm*[22] *including infection, corneal damage and sight loss. Initial fitting, refits and rechecks with registered optical professionals are vital to ensure that patients are protected from these risks of harm... The UK has an accessible network of optical practices which are able to offer fittings and follow-on care to patients who want to wear contact lenses."* AOP
>
> *"We believe it is important to maintain this restriction in the best interests of patients, and to reduce the risks associated with contact lenses that have not been correctly fitted, or supplied without advice on safe handling and wearing schedules. It is important to avoid suggestions that current challenges around enforcement mean that this protection should be abandoned, as that would simply increase risk for millions of people on the basis that a small proportion of contact lens users and companies based abroad today do not comply with UK legalisation."* Optometry Northern Ireland

GOC response – fitting of contact lenses

147. We have heard from stakeholders that the current regulations around the fitting of contact lenses are effective in protecting the public and do not create any unnecessary regulatory barriers. We are therefore not proposing to make any changes to the GOC's regulations around the fitting of contact lenses.

148. We address related issues elsewhere in the document.

[22] Wolffsohn, J.S. *et al.* (2021), BCLA CLEAR – Evidence-based contact lens practice, *Contact Lens and Anterior Eye*, *44*(2), 368-397

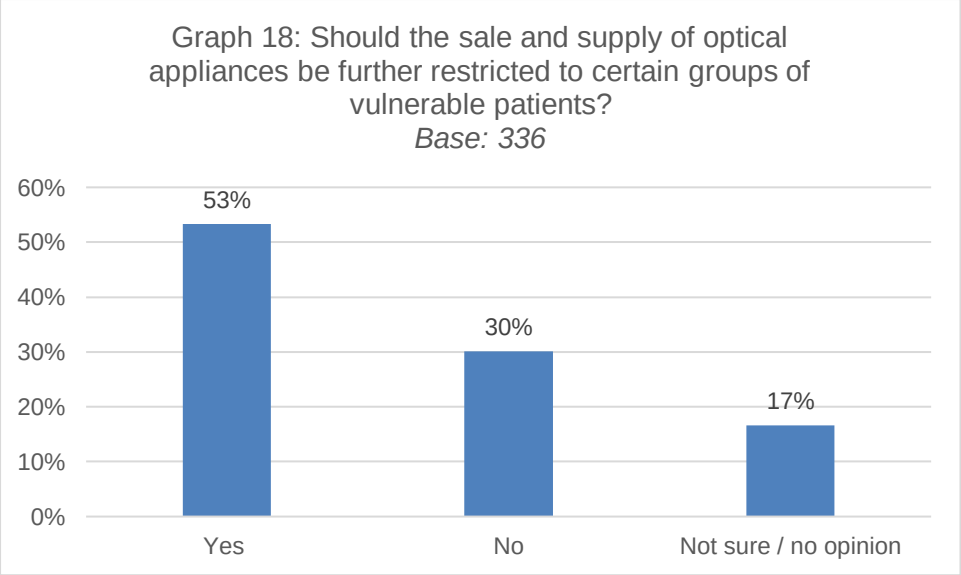
Section 6: Sale and supply of optical appliances (section 27 of the Act)

6.1 Supply to under 16s and those registered visually impaired

149. Under section 27 of the Act, only dispensing opticians, optometrists and registered medical practitioners (or those acting under their supervision) can supply certain optical appliances to children under 16 or those registered visually impaired. We explained on page 17 of the call for evidence that some stakeholders would like these restrictions to be extended to certain groups of vulnerable patients because other professionals do not have the necessary skills and knowledge to understand and address their specific needs.

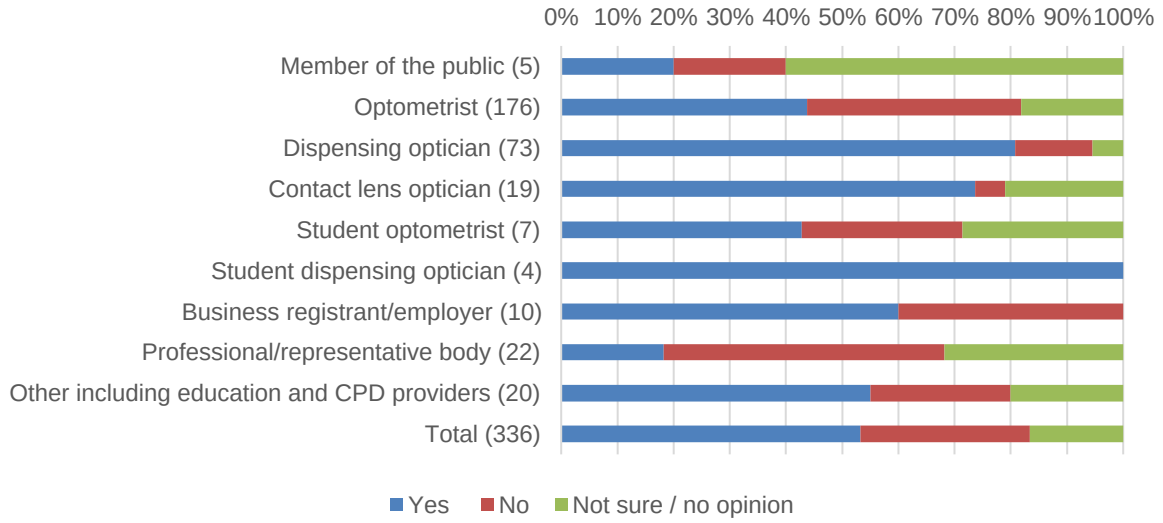
Further restrictions for vulnerable patients

150. We asked stakeholders whether the sale and supply of optical appliances should be further restricted to certain groups of vulnerable patients. Over half of respondents (53%) felt that they should be, 30% answered no and 17% were not sure or had no opinion.



151. Graph 19 shows that opinion was divided among the professional/representative bodies, with this group being much more likely to think that there shouldn't be further restrictions for groups of vulnerable patients than other categories of respondents. Dispensing opticians, contact lens opticians and student dispensing opticians were significantly more likely than other respondents to think that the sale and supply of optical appliances should be further restricted for certain groups of vulnerable patients.

Graph 19: Should the sale and supply of optical appliances be further restricted to certain groups of vulnerable patients?
Base: 336



152. When asked to explain which groups of vulnerable patients the sale and supply of optical appliances should be further restricted to (including reasoning and evidence), the following groups were identified:

- adults with reduced mental capacity or recognised capacity issues;
- children or adults with a mental or physical disability (particularly those patients who have facial disabilities or difficulties with head posture);
- patients with dementia;
- patients with a learning disability;
- patients with difficulties communicating (e.g. autism or dementia);
- older patients;
- patients requiring home visits, such as those in care homes or domiciliary settings;
- patients with complex prescriptions (e.g. a prism or a high prescription);
- patients with high prescriptions (what was considered high varied between +/-3.00, +/-4.00, +/-5.00 and +/-10.00 dioptres), as the prescription may need to be adjusted for back vertex distance;
- patients with low vision (particularly those whose vision isn't 'bad' enough to be registered sight impaired);

- patients requiring safety spectacles for work (to ensure the safety of themselves and others);
- patients who require optical appliances for driving (for the protection of themselves and other road users);
- patients undergoing myopia management interventions;
- patients with strabismus; and
- patients who require sports eyewear (currently only restricted for the under 16s).

153. Many of the responses did not contain reasoning for the suggestions (other than that enhanced skills or knowledge was required) or any evidence to support these.

154. As first referred to in section 2, ABDO was supportive of extending dispensing by a registrant to vulnerable groups, in particular, people with learning disabilities or people diagnosed with dementia. Dispensing to children with learning disabilities is already restricted to dispensing by or under the supervision of a registrant, but ABDO would like to see this restricted to registrants only i.e. not under supervision. They presented evidence that these children were 28 times more likely to have a serious sight problem but that only seven per cent will be able to access a community eye test, resulting in NHS England establishing a Special Schools Eyecare Programme to address this need.

155. ABDO also made a connection between those with dementia and those living in care homes, impaired vision in older people and increased risk of accidents such as falls. As outlined in section 2, they also asked us to carry out further research into the quality of paediatric dispensing and suggested that we may need to consider restricting paediatric dispensing so that it cannot be carried out under supervision.

156. While not related to the question about vulnerable patients, some respondents felt that the fitting of optical appliances to all patients should be restricted to registrants, but did not provide any evidence to support this. Some felt that children should be seen by an optometrist only. There were also suggestions that:

- people who meet the criteria for visual impairment shouldn’t have to be certified as visually impaired to fall within the Act (as not all may wish to register for the certification); and

- online dispensing of spectacles should not be permissible for anyone with a prescription of +/-5.00 dioptres because it is not possible to check the fitted vertex distance.

157. A sample of comments is available in the box below.

"According to the GOC Rules on Supply 1984 (and the associated British Standards - specifically British Standard 2738 Note 4 in the introduction) all patients whose Rx is over +/-5.00D require a vertex distance to be measured on the frame they have selected, which must then be compared to the vertex distance of the refraction (trial frame or phoropter) and where there is a difference the prescription recalculated and compensated so that the patient experiences the same effective power at the eye. Currently 99% of non-registered dispensers are incapable of making this calculation and unaware of this requirement. Online sellers are also unable to take this measurement because it would require the frame to be on the patient's face and the measurement needs to be taken from the side - it cannot be done by the patient looking in the mirror, or holding a credit card to their forehead, or even as yet by highly sophisticated 3D scanning apps used on the latest iPhones with 3 cameras built in. Therefore patients whose Rx is over +-5.00D in the highest principal power meridian (and including any reading addition where applicable) should be afforded the protection of being dispensed by or under the direct supervision of a registrant..." CPD provider

"…Sports eyewear, including swimming goggles, sports goggles and diving masks, the visual performance of these appliances is greatly compromised if the prescription is not modified to take into account that many of these appliances fit in a different position to spectacles or the prescriber's trial frame. Sports wear is often used for a variety of very dangerous sports and the consequences of poor vision could be life threatening…" Business registrant/employer

"We believe that there is a case to consider adding patients with learning disabilities, older people in residential care and those with complex conditions which increase the likelihood of eye problems to the list of vulnerable groups who need to have optical appliances supplied to them under the supervision of an optometrist, dispensing optician or medical practitioner. It is accepted that vulnerable patient groups may include:

· Those with a dementia disease such as Alzheimer's
· Adults with a learning disability
· Adults with a complex physical disability
· Older adults in a residential care setting
· Those patients with an existing sight condition such as glaucoma.

These groups have a high prevalence of eye disease[23] [24], which means that they would benefit from having their optical appliances provided under clinical supervision…" AOP

"SeeAbility would like to see greater restrictions on the sale and fitting of glasses to people with learning disabilities so these can only be provided by registrants, in the same way as for children under 16 and those registered visually impaired. This was an agreed position statement by the Vision UK learning disability committee in 2018 and was based on both data and evidence that the vast majority of people with learning disabilities will need glasses – 6 in 10 adults and in our work in special schools over 4 in 10 children.

The committee took on board anecdotal reports from people with learning disabilities and professional bodies of poorly fitting glasses or adherence to glasses wear. The expertise of an optometrist and in particular a dispensing optician is needed to help establish if there are adaptations or styles of glasses that can support individuals, and provide any follow up advice or support.

While we recognise that there may be some commentary that this restricts patient choice, this is not an issue that people with learning disabilities or parent/carers have raised with SeeAbility, conversely many report that they would appreciate more professional support and advice." SeeAbility

"…We also believe that prescription with a power ±5.00 in any meridian should require in-person dispensing. This is because an online retailer cannot verify the dispensed prescription without being able to check the fitted vertex distance and account for the effective power of the lens.

We would also like to see the Act change to recognise those that may not be registered as visually impaired but meet the criteria for visual impairment (Best vision of 6/18). It should not be mandatory to be certified. There are many reasons that a patient may not be registered and we believe those patients still require the same protections under the Act as those that are registered." AIO

"…The dispensing of spectacles to children with learning disabilities must already be carried out by or under the supervision of a registrant. At least this same level of protection should be extended to adults with learning disabilities. However, given the particular expertise involved in dispensing spectacles to this patient group, in our view this activity should be restricted to registrants only.

We note that children with learning disabilities are 28 times more likely to have a serious sight problem and only seven per cent will ever have had a community eye test or be able to access community services. To respond to this need, NHS England established the Special Schools Eyecare Programme and in developing

[23] Purbrick, R.M.J., Ah-Chan, J.J. and Downes, S.M., Eye disease in older people, *Reviews in Clinical Gerontology* 23.3 (2013): 234-250

[24] Emerson E. and Robertson J. (2011), *The estimated prevalence of Visual Impairment among people with learning disabilities in the UK,* RNIB

the relevant care pathway specified that spectacles should be dispensed by a registrant, recognising the enhanced skills and knowledge required to dispense spectacles to this patient group. More information about this programme is available on the NHS England website: https://www.england.nhs.uk/learning-disabilities/improving-health/eye-care-dental-care-and-hearing-checks/eye-care/" ABDO

158. Of those that did not support further restricting dispensing to certain groups of vulnerable adults, this was mainly because of the difficulties associated in identifying these patients, whether patient outcomes would be improved and/or the lack of evidence supporting the restriction. There were also suggestions that there were already some services in place to help vulnerable patients. Reponses also began to mention unintended consequences which were more relevant to the next question and so have not been dealt with here.

159. A sample of comments is available in the box below.

"We are aware of the debate regarding extending restriction to certain groups but believe the challenges this presents would outweigh any theoretical advantage and comparable benefits could be achieved through expanded professional guidance." Specsavers Optical Group

"Identification of vulnerable groups, especially in marginal cases (e.g. early dementia) would be difficult and onerous" Dudley Local Optical Committee

"We are unaware of any clinical evidence that would necessitate further restrictions. Any change in guidance should be evidence based and premised around the protection of patients and minimise the risk of unintended consequences." LOCSU

"• We are not aware of any clinical evidence that would require the sale and supply of optical appliances to be further restricted to groups of vulnerable patients in paragraph 42 or any other group

• It would be difficult, if not impossible, to enforce protecting supply based on learning disabilities and dementia, without either missing a large proportion of people in these broad groups or inadvertently breaching the Equality Act 2010 – e.g. restricting choice based on a default assumptions about mental capacity etc

• We also believe patients, friends and family might take offence to the suggestion that they are 'all the same', further increasing the risk of such a proposal being seen as discriminatory. This also poses a risk to the relationship between patient and clinician." BBR Optometry Ltd (Business registrant/employer)

"The current regulations for restricted groups are difficult to manage in primary care optometry, for example, many sight impaired and severely sight impaired patients either do not advise you of their registration, or do not wish to share this.

By further expanding the group of vulnerable patients it would lead to complications in primary care, as many disabilities are hidden or cannot be assessed, and therefore could lead to barriers for a group of patients where access to eye care is of utmost importance." Business registrant/employer

"…We also consulted the sector-wide Domiciliary Eyecare Committee (DEC), which includes providers that are more likely to care for people with dementia and learning disabilities relative to practice-based settings. DEC said that suitably trained optometrists and dispensing opticians can already make judgements about capacity and that, beyond this, it would be difficult to justify limiting the human rights to equal treatment and access to health care-based factors such as learning difficulties or mild impairments even if these could be identified in advance." FODO

"…56% of our members who responded to our survey think that the sale and supply of optical appliances should be further restricted to certain groups of vulnerable patients, but a further analysis of their responses showed that they wanted to ensure that these vulnerable groups were looked after, suggesting that service provision models and funding were likely to be more of an issue than the primary legislation.

Instead of legal restrictions, we would recommend that better training is available to all members of staff within an optical practice, so that they can recognise when patients may have additional needs, provide appropriate information and support with using new appliances. These should not require additional qualifications." The College of Optometrists

Advantages, disadvantages and impacts of further restrictions for vulnerable patients

160. We asked stakeholders what the advantages, disadvantages and impacts (both positive and negative) would be of further restricting the sale and supply of optical appliances to certain groups of vulnerable patients.

161. The following themes were identified from the comments received that identified advantages and positive impacts of further restricting the sale and supply of optical appliances to certain groups of vulnerable patients:

- they will benefit from a registrant's expert knowledge and skills and safeguard against poor patient care;
- it would be safer as patients would receive better eye care, more accurate and appropriate/comfortable dispensing and better protection regarding sight related concerns, reducing the risk of harm occurring (such as falls and road traffic accidents) and leading to better quality of life;
- it will protect/enhance the profession and save money for both businesses and patients through less mistakes and 'bad' pairs of spectacles being sold, ultimately leading to less complaints;

- vulnerable patients wouldn't be taken advantage of and would have a course of legal redress; and
- it would promote equality and inclusion.

162. A sample of comments is available in the box below.

"It is advantageous that a standard of care that is determined by professional standards established by a regulator is likely to be of a higher level than the unregulated. There is a counter-argument that restriction could reduce access to supply but it is our feeling that there are sufficient sources of supply available from registered outlets to negate this view." Gloucestershire Local Optical Committee

"The advantage would be less complaints as well as less remakes." Education provider

"Enabling more vulnerable patient groups to benefit from enhanced dispensing skills would promote more equal treatment and increase inclusion.

Maintaining the current approach to regulation would have a disproportionately negative impact on vulnerable patient groups, namely children, people with learning disabilities and people with dementia. In particular, where paediatric dispensing is not carried out or supervised by registrants with appropriate expertise, patient groups with facial characteristics that are different to white British children are likely to be even less well protected." ABDO

"There are as many advantages and disadvantages of further restricting the sale and supply to certain vulnerable groups…

• These vulnerable groups are already at greater risk of eye disease and would benefit from the requirement to see a registered professional to obtain optical appliances.

• This would help ensuring that patients' appliances are prescribed and fitted optimally, and their use described clearly, helping keep their vision is at its best to keep their quality of life high.

• Optometrists and dispensing opticians have the necessary clinical and communication skills to effectively manage, understand and treat these patients." The College of Optometrists

163. The following themes were identified from the comments received that identified disadvantages and negative impacts of further restricting the sale and supply of optical appliances to certain groups of vulnerable patients:

- more registered staff would be required and this could lead to cost implications for businesses and patients;

- it may restrict where vulnerable patients are able to purchase optical appliances e.g. they may not be able to purchase online and this may increase their costs;
- it could put registrants and businesses at risk of inadvertently breaking the law as it would be very difficult to identify certain categories of vulnerable patients;
- many people within vulnerable groups may not require additional support, and may not wish to be classified as vulnerable, and this could lead to perceptions of unfairness and barriers to accessing care; and
- not all vulnerable patients might be able to access an appropriate register due to inequality in care at a local level, leading to further inequalities.

164. A sample of comments is available in the box below.

"The disadvantage of not changing the Act to recognise those that are sight impaired but not registered is that there may be patients who encounter barriers to registration due to inequality in care and by removing their protections due to non-registration we would be widening the gap in inequality even further." AIO

"The main disadvantages of adding these groups to the list of vulnerable groups is that many people within these vulnerable groups may not require additional support. This could lead to issues and perceptions of unfairness and barriers to access for them. It may also create an increased cost burden on these groups. Provision of clinical support for people with learning disabilities is likely to work better in areas where targeted eye care and support services have been commissioned, but this varies across the UK.

There would also be practical challenges in how to identify the patients who belong to these vulnerable groups. Registers for people with learning disabilities, living with complex conditions and in residential care do exist, but there is no national register equivalent to that for people with a visual impairment." AOP

"…risks registrants and practices inadvertently breaking the law if they cannot identify an individual from one of the above vulnerable groups or if an individual does not want to disclose information that identifies their vulnerable status…

• This may further limit patients' access to care and add more barriers to a group who already face greater difficulties accessing healthcare equitably

• With a growing number of the population affected by (for example) learning disabilities or dementia, some patients from vulnerable groups may have further limitations on when their appliances can be dispensed and this could cause more barriers to care and increase distress for these patients." The College of Optometrists

GOC response – supply to under 16s and those registered visually impaired

165. We recognise that there are vulnerable patients who would benefit from being dispensed by a registrant. However, we do not consider that adding to the list of restricted activities is the right way forward for reasons including insufficient evidence of harm, difficulties of categorisation of patients and practical implementation, reluctance of patients to be categorised as vulnerable, and risks of unintended consequences relating to costs and access for patients.

166. We recognise that domiciliary care is a particular area of risk and will continue to monitor fitness to practise and OCCS complaints in this area, working with the optical sector, governments and national health services to review the position as research and evidence emerges. As noted in paragraph 54, we will also work with ABDO to understand concerns about paediatric care. The proposed mechanism set out in paragraph 56 for the GOC to recommend changes to the scope of restricted activities could be used to extend protection to specific patient groups should our analysis change in future.

167. Extending regulation to all optical businesses providing restricted activities could help reduce risks to these patient groups, as we could use standards and guidance to support individual registrants and businesses to ensure that these patients are appropriately advised. We will consider this as part of the forthcoming review of our standards.

168. There is a role for public education to encourage vulnerable patients and their carers to use regulated professionals and businesses. We will also discuss with the optical sector and relevant charities how they can show professional leadership in this area and provide registrants, businesses and patients with the information and advice that they need.

169. We note the concern that people who meet the criteria for visual impairment should not have to be certified as visually impaired to fall within the Act. The certificate of visual impairment (CVI) is an indirect requirement under the Act as it restricts dispensing of appliances for use by someone who is registered blind / partially sighted or sight impaired / severely sight impaired. This originally referred to local authority registers of disabled (including blind / partially sighted) people as required under section 29(4)(g) of the National Assistance Act 1948, but now refers to the registers of sight impaired / severely sight impaired people required by section 77 of the Care Act 2014. Under the Care and Support (Sight-impaired and Severely Sight-impaired Adults) Regulations 2014, a person is to be treated as being sight impaired / severely sight impaired if so certified by a consultant ophthalmologist. We will discuss with DHSC whether it would be possible to have regulations that provide a different definition but are concerned that the resulting inconsistency could be complicated.

170. We note that the Sale of Optical Appliances Order 1984 does not reflect the reality of online supplies since it predates internet sales. We will discuss this further with DHSC.

6.2 Prescription contact lenses and verification

171. Prescription contact lenses can be sold:

- by or under the supervision of a dispensing optician, optometrist or registered medical practitioner; or
- (as long as the user is not under 16 or registered visually impaired) under the general direction of a dispensing optician, optometrist or registered medical practitioner, who need not be on the premises at the time, if the supplier first receives the original specification or verifies the specification with the prescriber.

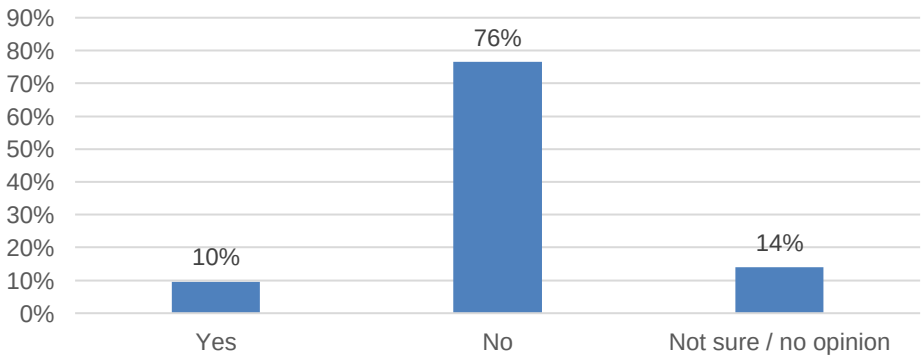
172. In order to be supplied with prescription contact lenses, a patient must have a contact lens specification which has been issued following a contact lens fitting/check and has not expired (i.e. is in-date). Where the sale is being made under the general direction (rather than supervision) of a registrant, and an original of the contact lens specification is not provided, section 27(3)(ii) of the Act requires the specification information (referred to as 'particulars of the specification') or a copy of the specification to be verified with the person who provided the original specification.

Unnecessary regulatory barriers - general direction / supervision

173. We asked stakeholders if the general direction / supervision legislative requirements relating to the sale of prescription contact lenses create any unnecessary regulatory barriers.

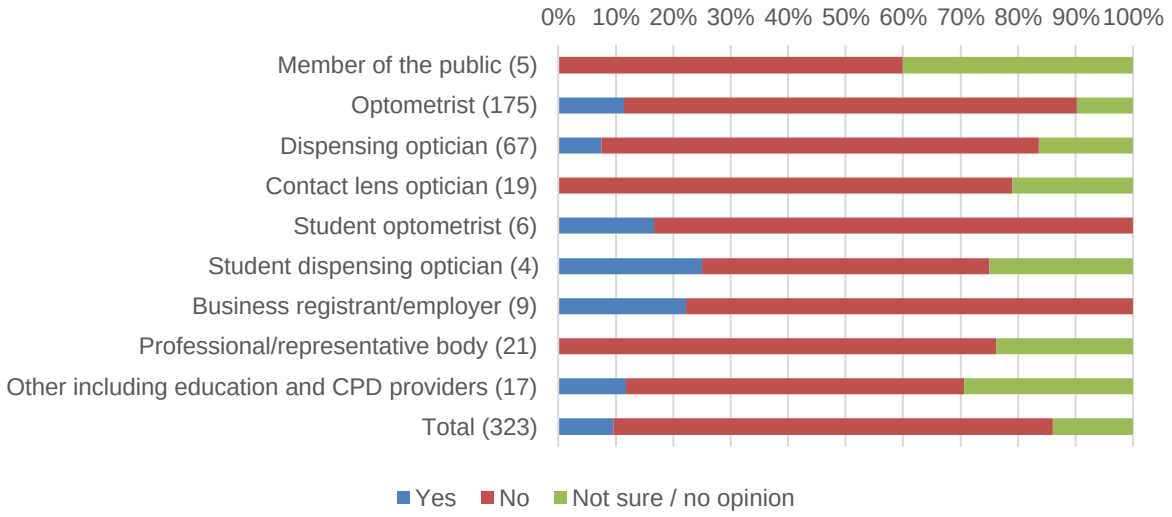
174. Only a small proportion of respondents (10%) thought that they did create unnecessary regulatory barriers, with over three quarters (76%) thinking that they did not and 14% not being sure or having no opinion.

Graph 20: Do the general direction / supervision legislative requirements relating to the sale of prescription contact lenses create any unnecessary regulatory barriers?
Base: 323



175. Graph 21 shows the breakdown by category of respondent. The professional/representative bodies were all in agreement that there were no unnecessary regulatory barriers (or were unsure / had no opinion).

Graph 21: Do the general direction / supervision legislative requirements relating to the sale of prescription contact lenses create any unnecessary regulatory barriers?
By category of respondent
Base: 323



176. The following themes were identified from the comments:

- prescription contact lenses are medical devices and so the regulatory barriers are necessary and there to protect patients from harmful side effects of inappropriate contact lens use;
- the requirement that a contact lens specification must be in date in order for contact lenses to be supplied is an unnecessary barrier and should be left to the professional judgement of the practitioner;
- online suppliers do not comply with the rules (e.g. selling without a specification) – this puts patients at risk, is not fair to individuals and businesses who are observing the law and there should be a level playing field;
- there are loopholes in the law that put patient safety at risk (e.g. being able to supply a different contact lens to that specified on the contact lens specification – we were provided with a link to peer review literature which found that contact lenses should “never be substituted for another lens

type in the absence of a new prescription further to a full finalised fitting, for the simple reason that all soft contact lenses are not created equal"[25]);

- there should be more regulation, for example:
    - for online supply of contact lenses;
    - contact lenses should only be sold by optometrists / qualified professionals;
- assertions that the GOC is not enforcing the rules; and
- recognition that overseas supply cannot be regulated and/or that enforcement of the rules is difficult – ABDO requested us to clarify our approach to enforcing legislation and how it applies to suppliers registered overseas but operating in the UK (please see the GOC response to our consultation on illegal practice strategy and protocol for more information on this point).

177. Many responses mentioned verification of the contact lens specification, but this is dealt with in one of the following questions in this section so not addressed here.

178. A sample of comments is available in the box below.

"No, they do not create any unnecessary barriers, contact lenses are an optical/medical appliance and should be regulated as such… the general public should not be able to acquire contact lenses without a comprehensive fitting as they can pose a risk not only to themselves but others e.g. if their visual acuity is subpar. It's not unusual to see patients in practice who have self prescribed and fall below driving standards despite operating heavy machinery or driving commercially. If it is made any easier for unregulated sellers to operate then these sorts of problems will only increase." Dispensing optician

"The current problem is that the law…is so unclear. Essentially providing the consumer has an in date specification for any old lens they can order a different lens to a completely different specification... I've supervised or been the "generally directing" practitioner for several direct to consumer contact lens businesses since the early 1990s and the only way to make a profit is to ignore the rules on verification - what's the point of verifying if all you are checking is the date and not the lens specification?" CPD provider

"…we think it would be helpful for the GOC to clarify its approach to enforcing the legislation relating to the supply of contact lenses. We appreciate that following the consultation on its revised illegal practice protocol, the GOC will be developing a

[25] Efron, N. *et al.* (2022), All soft contact lenses are not created equal, *Contact Lens and Anterior Eye* 45 (2022) 101515

wider illegal practice strategy. As part of this work, it would be helpful to clarify how the legislation applies to suppliers who are registered overseas, but operate from the UK." ABDO

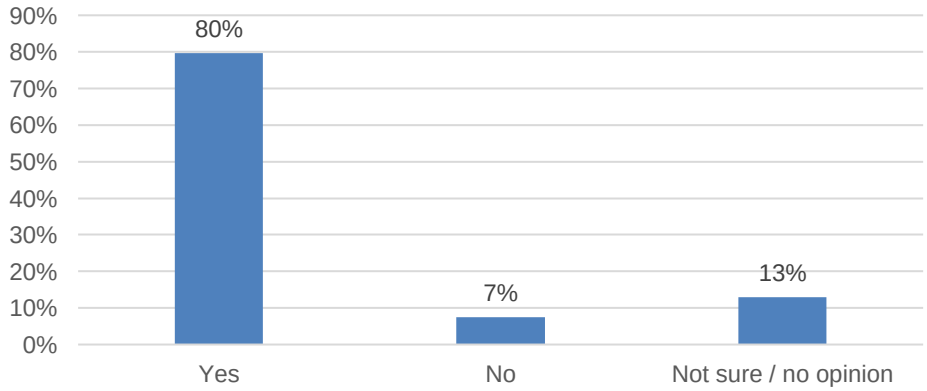
"…the requirement that a contact lens specification must be in date is a barrier to registrants acting in the patients' best interests in exceptional circumstances. During the pandemic, while practices were following the College's and GOC's amber phase guidance and policies, easements enabled registrants to act in their patients' best interests to support an ongoing supply in exceptional circumstances. This discretion helped members of the public safely maintain an ongoing contact lens supply, and for appropriate care to be scheduled as soon as reasonably possible. Continuing this policy of discretion would be of benefit as a permanent change and may reduce the number of people driven to unregulated contact lens supply in exceptional circumstances (for example when they run out of lenses and are waiting for their next appointment). The regulations must be supportive of clinicians using their professional judgment, to ensure members of the public can maintain a safe supply of contact lenses and good vision." The College of Optometrists

Risk of harm – changes to general direction / supervision

179. We asked stakeholders if there would be a risk of harm to patients if the general direction / supervision requirements relating to the sale of prescription contact lenses changed.

180. The vast majority of respondents (80%) felt that there would be a risk of harm to patients, with only 7% saying no to the question and 13% not sure or no opinion.

Graph 22: Would there be a risk of harm to patients if the general direction / supervision requirements relating to the sale of prescription contact lenses changed?
Base: 323



181. The following themes were identified from the comments (if themes were already identified in the previous question, we have not repeated them here):

- if the general direction / supervision requirements for sale of prescription contact lenses were relaxed there would be a risk of harm to patients because:
    - they would not get regular check-ups from professionals to detect any adverse changes and pathology could go undetected, resulting in more hospital attendances;
    - their contact lens compliance is poor and would worsen without education from professionals;
    - they change their contact lens specifications (type and size of contact lenses) with no guidance and reduced regulation could increase this possibility, potentially causing damage to the eyes;
- there would not be any risk of harm if the general direction / supervision requirements for sale of prescription contact lenses were relaxed provided that the patient was an existing wearer and ordered lenses that were in accordance with a valid contact lens specification;
- if the general direction / supervision requirements for sale of prescription contact lenses were tightened there would be less risk of harm to patients because public protection would be increased, ensuring more regular check-ups and compliance with the contact lens specification; and
- the rules around general direction should be removed or tightened because they are not sufficient to protect the public.

182. We were pointed to evidence[26] which found that contact lens wear carries various risks of infection and corneal damage and the importance of teaching an aftercare routine to ensure an appropriate care regimen and cleaning instructions.

183. A sample of comments is available in the box below.

"If the supervision requirements were relaxed suppliers would be free to supply lenses to patients who may need an eye exam or contact lens check, they could supply additional lenses to patients that have been told not to wear lenses by the practitioner for health reasons, change lens type, prescription etc" Optometrist

"Several respondents felt that the public perception of contact lenses is less driven by clinical requirements, and that patients may be less able to understand the clinical differences between products, leading to self-prescribing and a primarily cost-driven purchase decision. One mentioned the importance of counselling for

[26] Wolffsohn, J.S. *et al*. (2021), CLEAR - Evidence-based contact lens practice, *Contact Lens and Anterior Eye*, 44(2), 368-397

contact lens patients provided by the contact lens practitioner, particularly in relation to swimming and driving." The Northumberland, Tyne and Wear Local Optical Committee

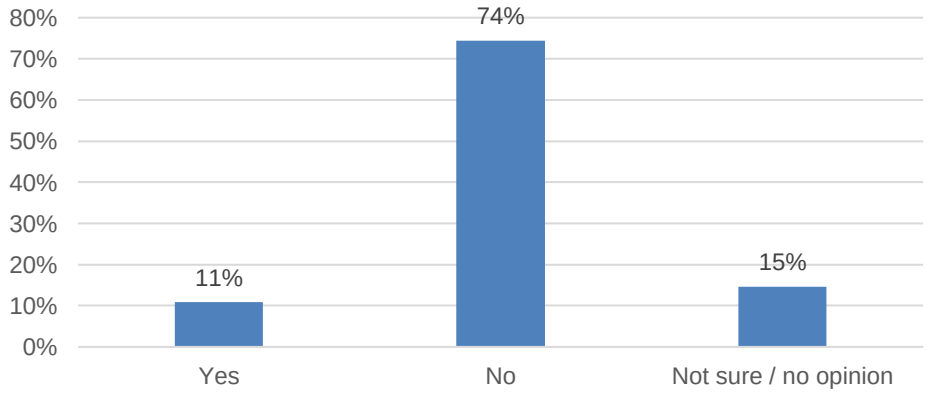
"Removal or relaxation of these supply restrictions could lead to a risk of patients using contact lenses without regular refits and rechecks with an optical professional, or in some cases having never being fitted for them. Contact lens wear carries various risks of infection and corneal damage[27]. …without appropriate advice about how to care for, clean, and store their lenses, there is a significant risk that patients develop unsafe contact lens habits. This may increase the risk of developing sight loss-causing infections[28]." AOP

Unnecessary regulatory barriers – verification of specifications

184. We asked stakeholders if the legislative requirements for verification of contact lens specifications create any unnecessary regulatory barriers.

185. Almost three-quarters of respondents (74%) thought there weren't any unnecessary regulatory barriers, with 11% thinking there were and 15% not being sure or having no opinion.

Graph 23: Do the legislative requirements for verification of contact lens specifications create any unnecessary regulatory barriers?
Base: 321



186. The following themes were identified from the comments from those who did not think that the legislation created any unnecessary regulatory barriers:

- the legislation is necessary as it protects patients; and
- it is largely ignored by online retailers and should be better enforced.

[27] Wolffsohn, J.S. *et al.* (2021), CLEAR – Evidence-based contact lens practice, *Contact Lens and Anterior Eye*, 44(2), 368-397
[28] Stapleton, F., Keay, L., Jalbert, I., and Cole, N. (2007), The epidemiology of contact lens related infiltrates, *Optometry and vision science*, 84(4), 257-272

187. A sample of comments is available in the box below.

> *"Unfortunately, it seems as though these legislation requirements are seldom conformed to. We have experienced incidences where incorrect lenses have been supplied and clients have not been able to reach driving standards in supplied lenses without follow up. These requirements not only need to be upheld but need to be enforced better"* Business registrant/employer
>
> *"We do not believe the current requirements for verification creates any unnecessary barriers, the guidance during the pandemic was relaxed which was right for the time however this guidance does not need to be carried forward any further."* Business registrant/employer

188. The following themes were identified from the comments from those who thought that the legislation created unnecessary regulatory barriers (themes already identified in previous questions in this section are not repeated here):

- it shouldn't be necessary to verify a copy of a signed and in-date contact lens specification (unless clarification is required) – virtual/scanned copies should be accepted;
- it can be difficult to verify a contact lens specification with the exact person who signed it; and
- verification creates inefficiencies that are then passed on as costs to patients.

189. There was concern from some that although it would be acceptable not to verify an electronic copy of a specification, verification of the particulars of a specification (where a copy had not been provided) should still be required because otherwise this could lead to patients requesting contact lenses without having had a recent fitting. The optical sector professional/representative bodies appeared to be in agreement on this point. FODO believed that this could be clarified in a guidance note rather than a change in legislation being required.

190. The AOP (and others) cautioned us against drawing lessons from the COVID-19 pandemic in this context, advising that contact lens wear decreased during this time[29] and that it is still too early to evaluate the impacts of the changes made during the pandemic as sight loss takes time to develop.

191. A sample of comments is available in the box below.

[29] Morgan, P.B. (2020), Contact lens wear during the COVID-19 pandemic, *Contact Lens and Anterior Eye*, 43(3), 213

"Verification creates confusion and inconvenience for patients who wish to purchase lenses from different suppliers, creating inefficiencies and increasing costs which are then passed onto the patient." Business registrant/employer

"…on balance the current system works. However, we anticipate that while most suppliers will operate within the spirit of the legislative requirements, one aspect, namely verification of a copy "with the person" providing the specification, will be particularly challenging. Clearly the workforce is fairly mobile with an increasing proportion of practitioners choosing to locum, and of course people work part-time, take annual leave and so forth - so while it may be easily possible to verify a specification with someone who has access to the record of fitting, the realistic possibility of confirming directly with 'the person' who provided the specification, may not have been properly considered when the legislation was originally drafted." Specsavers Optical Group

"The…LOC [local optical committee] *believes that the requirements for verification of contact lens specifications creates unnecessary regulatory barriers. Mistakes do happen but in the vast majority of cases there is no need for verification and as such it is not justifiable to follow this protocol."* Local optical committee

"…The need to verify the specification should remain in place where there is doubt about the particulars of the specification, although there is scope safely to update the verification requirement to allow acceptance of electronic specifications…" AOP

"We believe that prescriptions should not need to be verbally validated with practices, but a prescription should be verified to have been written to the correct standards..." AIO

"…it is arguable that a patient should be able to provide an electronic copy of their in-date contact lens specification without the need for this to be separately verified with the supplier of the specification, provided it can be read clearly… However, we do not agree with the GOC's view that the requirement to verify the particulars of a specification should be removed entirely as this would potentially enable contact lenses to be sold without a patient having an in-date specification and therefore without receiving appropriate aftercare." ABDO

"…we believe the current system could be improved by enabling the use of electronic copies of the contact lens specification and removing the need to verify it unless the specification (or duplicate of it) is unclear, contains an obvious error or the registrant believes it has been altered or tampered with…" The College of Optometrists

Advantages, disadvantages and impacts of removing verification requirements

192. We asked stakeholders what the advantages, disadvantages and impacts (both positive and negative) would be of removing the requirement to verify a copy of or the particulars of a contact lens specification.

193. The following themes were identified from the comments around the advantages and positive impacts of removing the requirement to verify a copy of or the particulars of a contact lens specification:

- easier and quicker access to contact lenses for patients (especially in an 'emergency' such as a patient from overseas);
- convenience for patients, the prescriber and supplier; and
- financial benefits for businesses, particularly online businesses.

194. A sample of comments is available in the box below.

> *"Make supply easier as sometimes difficult to verify"* Optometrist
>
> *"…Reduce the time the patient has to wait for the verification to take place…"* Local optical committee
>
> *"Advantages include reducing the burden of time on practice teams and removing barriers to purchase optical appliances for patients."* Optometrist

195. The following themes were identified from the comments around the disadvantages and negative impacts of removing the requirement to verify a copy of or the particulars of a contact lens specification:

- risk to patient safety and the public (leading to accidents, pathology and hospital eye services being even more stretched) due to, for example:
  - inappropriate lenses being supplied due to inaccuracy in type, size and/or strength of contact lenses;
  - improper use of contact lenses through lack of advice;
  - patients being able to order whatever lenses they want without an in-date contact lens specification (including those who have been told that they cannot wear contact lenses and/or those who have never had a contact lens fitting);
  - patients not getting regular check-ups;
- patients would be more likely to order online;

- the change would make no difference as so many patients order online anyway from website that do not request and/or verify specifications; and
- it would destroy/downgrade the profession.

196. A sample of comments is available in the box below.

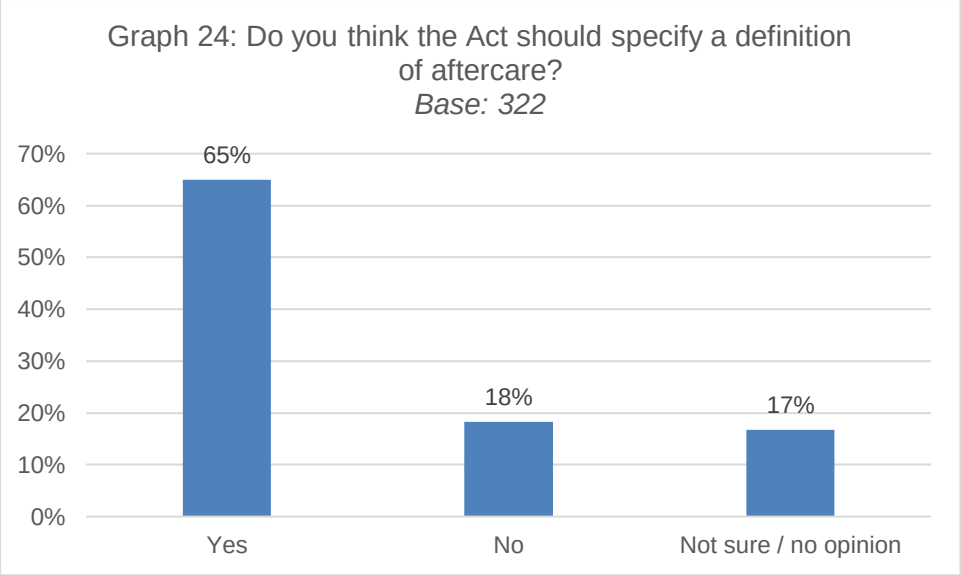
> *"Removing the verification procedure would give the patient freedom to order whatever they want online and this may have a potential harm to their ocular health and promote misuse of contact lenses."* Optometrist
>
> *"Anyone could write in any specifications and therefore contact lens associated pathology would increase, sight loss would increase and people may be wearing inappropriate prescriptions for driving etc leading to potential death"* Optometrist
>
> *"…Supply of contact lenses without verification/validation puts the consumer at risk and perpetuates this damaging notion that you can stick anything in your eye without ramification. As a CLO I too often see patients who have fallen victim to companies…who have been lured in by a cheap deal and a marketing ploy and end up with corneal events, poor VA* [visual acuity]*, poor comfort/lens tolerance all due to lack of proper fitting and aftercare. Not the mention that many who fall victim to this only attend for AC* [aftercare] *every 3-4 years as the casual nature of the purchase leads them to believe regular AC is unnecessary…"* Dispensing optician
>
> *"…a recent study of patients buying contact lenses on the internet found a growing number who initiated lens wear independently without professional care and advice[30]. Less frequent contact lens care and advice from optical professionals will increase the risk of patients developing poor contact lens hygiene habits and increasing the risk of developing harmful infections that could lead to sight loss…"* AOP

Aftercare

197. Section 27(3B) of the Act requires the seller of contact lenses to make arrangements for the user to receive reasonable 'aftercare' in so far as, and for as long as, may be reasonable in that individual's case. We asked stakeholders if they thought the Act should specify a definition of aftercare.

198. Almost two-thirds of respondents (65%) thought the Act should specify a definition of aftercare, 18% did not, and 17% weren't sure or had no opinion.

[30] Mingo-Botín, D., Zamora, J., Arnalich-Montiel, F., & Muñoz-Negrete, F. J. (2020), Characteristics, behaviors, and awareness of contact lens wearers purchasing lenses over the internet, *Eye & Contact Lens*, 46(4), 208-213



199. We asked stakeholders who had responded positively to whether the Act should specify a definition of aftercare to say what they thought that should be. The following themes were identified:

- history taking and symptoms;
- checking the fit of the lenses;
- health checks (examination of the anterior eye both with and without contact lenses);
- visual acuity and prescription checks;
- suggestion of a maximum time between appointments (12 and 24 months were most frequently suggested);
- requirement to provide a contact lens specification after the aftercare appointment with an expiry date;
- discussion and advice around the cleaning regime, handling and compliance with wearing time; and
- in line with recommendations from the professional bodies.

200. A sample of comments is available in the box below.

"Practices use the term aftercare to refer to what professional associations commonly call a check or fit/re-fit. It is important that the GOC defines the differences between both of these otherwise there is the potential that practitioners will be caught out. This was highlighted by the GOC Covid-19 statements which called out the perceived differences from a GOC perspective." Optometrist

"We suggest the Act should stipulate an aftercare must include an assessment of ocular health as it relates to contact lens wear. It should be the GOC's responsibility to define the aftercare and we suggest that the GOC should adopt the definition supplied by the College of Optometrists." AIO

"…as the online market for contact lenses grows, there has been and is likely to be an increasing separation of fitting from supply. This makes the sellers' duty of aftercare even more important to protect patients. Providing a definition of aftercare could help to ensure that patients who purchase from online suppliers are given suitable advice on how to safely use their lenses and what to do if they experience problems with them. Our suggested definition for aftercare would be:

'To ensure that those who sell or supply contact lenses to patients are mandated to ensure follow-on arrangements for care are in place, which provides the patient with a reasonable means to safely use the supplied contact lenses, identify signs of infection or other harm and to obtain suitable care or advice if problems occur.…' " AOP

201. Although the question did not ask for this information, numerous stakeholders commented on why it was not necessary to provide a definition of aftercare in the Act, including the following themes:

    - the issue is with supply, not aftercare;
    - it should be dealt with in professional guidance (or a GOC position statement) rather than legislation;
    - it should be for the professional judgement of the registrant; and
    - it would be difficult to future-proof a definition.

GOC response – prescription contact lenses and verification

202. We have heard that verification of a copy of a contact lens specification is no longer necessary, provided that the specification is clear, does not contain any obvious errors and has not obviously been tampered with. We therefore intend to seek legislative change to allow us to set out more detailed requirements in rules/guidance but in the meantime, we will consider issuing a position statement to say we will not enforce the requirement to verify a copy of a specification, with the provisos outlined in the previous sentence. We will also consider extending this statement to prescriptions for spectacles. If we decide to issue a statement, we will carry out further consultation on these areas to further understand the impacts and ensure that there are no unintended consequences of a change in policy and/or legislation.

203. We have been persuaded by arguments to continue to require verification of the particulars of a specification and therefore do not propose to make any changes in this area.

204. We note concerns regarding suppliers who supply contact lenses that are not the exact type of contact lenses specified on the contact lens specification. We have considered recent peer reviewed evidence which suggests that the decision to substitute a contact lens should usually only be made on the advice of a qualified eye care practitioner due to the potential risk of adverse clinical events. The paper states that there is currently no direct evidence to show clinical harm resulting from substitution (in part because harm is likely to take time to occur and underreporting[31]). Currently, we do not propose introducing a specific legal requirement to supply contact lenses only in accordance with the contact lens specification since the evidence suggests that professionals exercising their clinical judgement can substitute safely. We will continue to keep this situation under review as research progresses.

205. With regard to whether a definition of aftercare is required in the Act, we note the confusion between the use of the term aftercare provided by registrants under s25(5)(b) (which is essentially part of the appointment to assess the fit of contact lenses, sometimes referred to as a contact lens check-up) and aftercare within the meaning of section 27(3B) of the Act which relates to a seller (whether or not GOC registered) of contact lenses being obliged to make arrangements for the patient to receive aftercare in so far as and for as long as may be reasonable in the particular case – our consultation question was in relation to the latter point. We consider that the current drafting of the legislation allows for a broad interpretation which would allow for change over time. However, we will consider whether it would be helpful to provide a definition of aftercare in a GOC position statement so that it is clear what sellers of contact lenses are obliged to do in order to meet their legal obligations.

206. We do not propose to give detailed advice about what aftercare appointments undertaken by registrants should involve, as this is a matter for clinical judgement. Any GOC guidance in this area would likely consider the current guidance issued by The College of Optometrists and ABDO, and will require further consultation to understand the impacts and ensure that there are no unintended consequences of a change in policy and/or legislation.

[31] Efron, N. *et al.* (2022), All soft contact lenses are not created equal, *Contact Lens and Anterior Eye* 45 (2022) 101515

6.3 Zero powered contact lenses

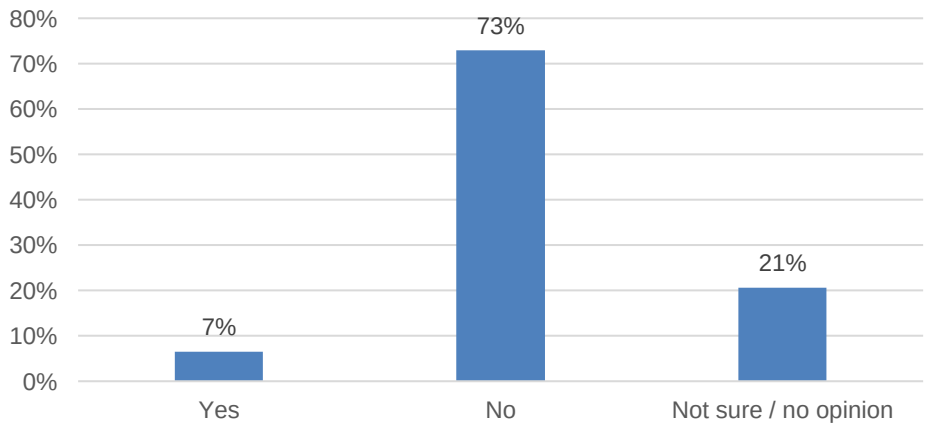
207. Section 27(1)(b) of the Act provides that zero powered contact lenses can be sold only by or under the supervision of a dispensing optician, optometrist or registered medical practitioner. Case law and our standards require that the supervisor must be on the premises at the time of the sale, exercising their professional judgement as a clinician and in a position to intervene in the patient's interests.

Unnecessary regulatory barriers – zero powered contact lenses

208. We asked stakeholders whether the zero powered contact lenses legislation creates any unnecessary regulatory barriers.

209. Of the 321 respondents who answered the question, 73% thought that the legislation didn't create any unnecessary regulatory barriers, 7% thought that it did and 21% were not sure or had no opinion.

Graph 25: Does the zero powered contact lenses legislation create any unnecessary regulatory barriers?
Base: 321



210. The comments indicated overwhelmingly that the zero powered contact lenses legislation did not create any unnecessary regulatory barriers. The BCLA and The College of Optometrists provided links to articles about the ocular complications associated with the use of cosmetic contact lenses, with one article concluding that "uninformed lens wearers are experiencing acute, vision-threatening infections and inflammation"[32].

[32] Steinemann, T.L., Pinninti, U., Szczotka, L.B., Eiferman, R.A., Price Jr, F.W. (2003), Ocular Complications Associated with the Use of Cosmetic Contact Lenses from Unlicensed Vendors, *Eye & Contact Lens* 29(4): 196–200

211. The following themes were identified from the comments:

- non-registrants are not aware of the legislation and there are many unregulated sales where the legislation is not enforced;
- sale of zero powered contact lenses online should be against the law;
- contact lenses are the same regardless of whether they are powered or zero powered;
- zero powered contact lenses have a higher risk factor as they are:
  - often not fitted, therefore wearers do not receive proper advice on insertion, removal and infection prevention;
  - not usually worn by people who are used to wearing contact lenses; and
- the Medicines and Healthcare products Regulatory Agency (MHRA) has agreed to re-classify zero powered contact lenses as medical devices[33].

212. A sample of comments is available in the box below.

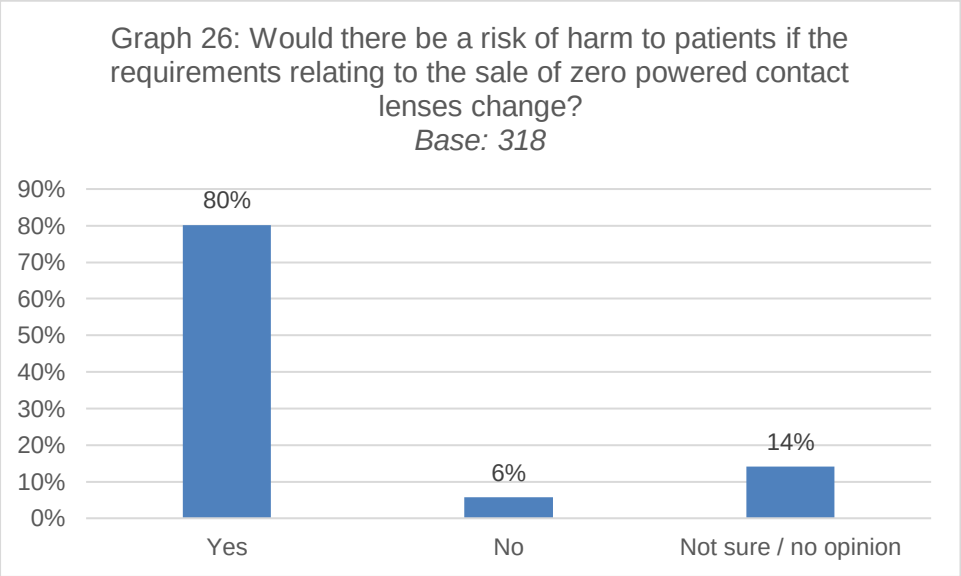
> *"The risk of harm from zero power contact lenses is if anything greater than powered contact lenses due to the attitude of a fashion item rather than a medical device. The GOC must protect the public"* Dudley Local Optical Committee
>
> *"Zero powered are lenses not for correction of vision (e.g. therapeutic, cosmetic, bandage etc). Older technology and materials and cosmetic use makes them more prone to abuse and the potential for higher risk of contact lens adverse effects."* BCLA
>
> *"The zero powered contact lenses legislation provides sensible protections for casual purchasers who would not otherwise be contact lens wearers, and who may be unaware of risks associated with contact lens use. These requirements were introduced due to issues with over-the-counter contact lenses being purchased with no instruction, guidance or aftercare…"* FODO

Changes to zero powered contact lens legislation

213. We asked stakeholders whether there would be a risk of harm to patients if the requirements relating to the sale of zero powered contact lenses changed.

[33] https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

214. Of the 318 respondents that answered the question, 80% thought there would be a risk of harm, 6% that there would not be and 14% were not sure or had no opinion.



215. Many of the themes from the comments to this question had already been identified in the previous question (particularly those related to the risk profile of prescription and zero powered contact lenses being the same, if not greater for zero powered contact lenses) and are therefore not repeated here. The remaining themes from the comments, most of which relate to the risk of harm of buying zero powered contact lenses online, are as follows:

- risk of delayed identification of pathology and risk of complications (e.g. corneal ulcers and infections, microbial keratitis) leading to sight loss;
- increased burden on optometrists, contact lens opticians and/or hospital eye services;
- concern that patients would not even be fitted for lenses;
- concern about the quality of some zero powered contact lenses;
- those who purchase online are less likely to attend eye examinations and more likely to forget aftercare advice (evidence was provided to support these points); and
- a suggestion for the GOC to tackle the problems with online suppliers through the contact lens manufacturers.

216. We were pointed to a large number of articles about the risks associated with the wearing of contact lenses, particularly those who buy online and those who are not advised about the proper handling of contact lenses around water.

217. A sample of comments is available in the box below.

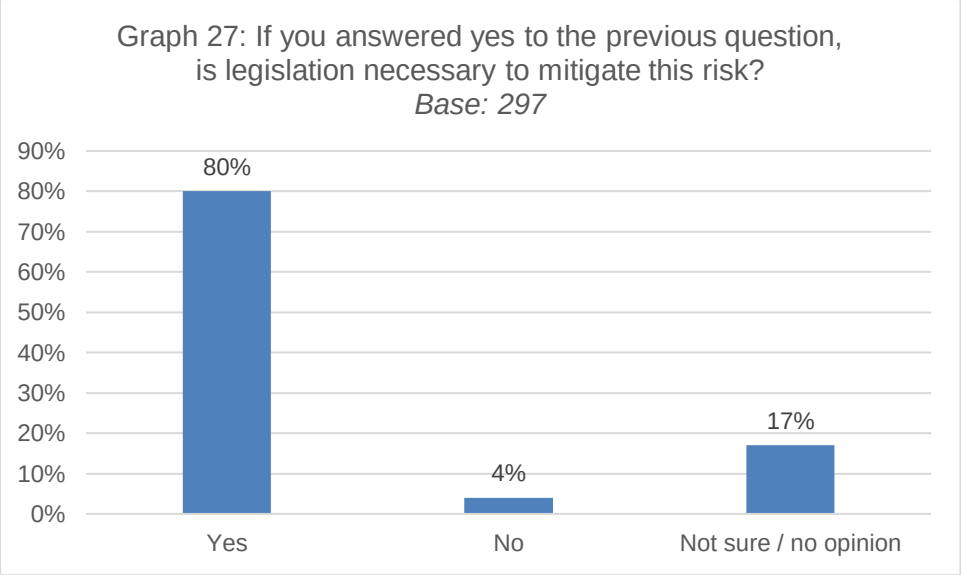
> *"Contact lens wear is distinct from wearing spectacles due to the interaction of the lens with the ocular surface, tear film and surrounding structures. This is irrespective of the prescription involved and as such involves health risks to the wearer."* Welsh Government
>
> *"There is evidence that contact lens users who buy their lenses through alternative supply routes may be more susceptible to poor hygiene procedures and to an increased risk of infection[34]."*
>
> *A US study found that consumers who bought contact lenses from sources other than their eye care practitioner were less likely to comply with good eye care health practices and have reported cases of serious corneal ulcers and infections associated with wear of zero powered contact lenses[35]. Corneal ulcers can progress rapidly, leading to internal ocular infection if left untreated. Uncontrolled infection can lead to corneal scarring and vision impairment. In extreme cases, this condition can result in blindness and eye loss."* The College of Optometrists
>
> *"…'Patients who acquire [Cosmetic contact lens] are less likely to be instructed on appropriate lenses use and basic hygiene rules. Consequently, [Cosmetic contact lens] wearers are experiencing acute vision-threatening infections.'[36]*
>
> *We believe that removing restrictions on the sale of zero-powered contact lens will make access to these lenses more widely available, whilst reducing contact with a qualified practitioner who can properly instruct them. In turn, this will increase the prevalence of cases of microbial keratitis and increase the burden on primary and secondary care."* AIO

Mitigation of risk

218. If they answered yes to the previous question (whether there is a risk of harm to patients if the requirements relating to the sale of zero powered contact lenses changed), we asked stakeholders whether legislation is necessary to mitigate this risk.

219. Of the 297 respondents who answered the question, 80% thought that legislation was necessary to mitigate this risk, 4% did not and 17% were not sure or had no opinion.

[34] Steinman, T.L. *et al.* (2005), Over-the-counter decorative contact lenses: cosmetic or medical devices? A case series, *Eye & Contact Lens* 31; 5: 194-200
[35] Snyder, R.W. *et al.* (1991), Microbial keratitis associated with plano tinted contact lenses, *CLAO J* 17; 4: 252-5
[36] Sauer, A. and Bourcier, T. (2011), Microbial keratitis as a foreseeable complication of cosmetic contact lenses: a prospective study, *Acta Ophthalmologica* 2011: 89: 439-442



220. Themes identified from the comments were already identified in previous questions in this section and so have not been repeated here. The overwhelming response from the comments was in support of legislation being required to mitigate the risk and that legislation in this area needed to be better enforced.

221. The AOP recommended non-legislative approaches, as well as arguing for the legislative restrictions to remain in place. These included public education (although they argued that the younger age group who may never have had a contact lens fitting are heard to reach) and prominent warnings on contact lens packaging. ABDO argued that legislation is necessary because GOC statements would not cover non-registered businesses.

222. A sample of comments is available in the box below.

"Only legislation could ensure that these lenses are sold by a registrant to ensure patient safety." Local optical committee

"We believe that the current legislation protects users of zero-powered lenses and is necessary. There would be a significant risk of increased harm to wearers of cosmetic lenses if current restrictions on the sale of zero-powered lenses are relaxed or removed… Legislative restrictions reduce the risks of harm, but sellers are likely to continue to operate outside the legal framework and zero powered lens users will need additional messages about how to reduce their risks of harm from lens wear." AOP

"Legislation on its own will not and has not solved the issue. It also needs effective policing of the legislation." Business registrant/employer

"Yes, legislation is necessary to mitigate the risk of patient harm as in the absence of such legislation, zero-powered contact lenses could be supplied by businesses,

such as hairdressers or market stalls, that would not be registered with the GOC and therefore, not required to follow GOC policy statements." ABDO

Advantages, disadvantages and impacts of current zero powered contact lenses legislation

223. We asked stakeholders what the advantages, disadvantages and impacts (both positive and negative) would be of zero powered contact lenses legislation remaining as it is currently.

224. The following themes were identified from the comments around the advantages and positive impacts of the zero powered contact lens legislation remaining as it is:

- it would protect eye health as patients will be fitted and educated by a healthcare professional, will have better fitting lenses, will be better monitored, and hospital eye services are less likely to be required as there are less likely to be problems; and
- it avoids zero powered contact lenses being bought online.

225. A sample of comments is available in the box below.

"…There are advantages that patients will be properly cared for in optical practices. The correct advice will be given. This means they are less likely to have an eye infection and end up in hospital costing the NHS money." Dispensing optician

"Reduce the risk of harm if customers never used lenses before. Avoid the use of coloured lenses bought in internet" Member of the public

"…the current legislation reduces the risk of harm, including sight threatening conditions that can result when contact lenses are poorly fitted or patients are not aware of the risks involved in handling and storing of lenses, and do not act on signs and symptoms as a result." FODO

"Zero-powered contact lenses would be fitted correctly and people buying such lenses would receive professional advice on how to wear and look after them. They would be less likely to experience complications as a result…" ABDO

226. Many stakeholders commented that there were no disadvantages of the legislation remaining as it is.

227. The following themes were identified from the comments around the disadvantages and negative impacts of the zero powered contact lens legislation remaining as it is:

- it is difficult to enforce against non-UK based companies;
- companies are already abusing / not complying with the legislation;
- the legislation is confusing for the public; and
- it is more costly and harder to access for the public.

228. A sample of comments is available in the box below.

> *"Will increase the cost to the general public."* Business registrant/employer
>
> *"…The potential disadvantages of retaining the current restrictions centre around challenges in enforcing the current regulations and dealing with the risks associated with online sales:*
>
> - *The GOC may lack appropriate resources of enforcements to tackle all UK websites and retail outlets selling cosmetic lenses without oversight from an optical professional*
> - *The GOC may find it particularly challenging to mitigate the risks to the public from non-UK sales of cosmetic lenses, as consumers increasingly switch to online purchasing habits – again there is likely to be a disproportionate risk of harm to young people who have not had a contact lens fitting…"* AOP
>
> *"…People may continue to buy contact lenses online from unregistered professionals or suppliers based on lower costs. This could lead to an increased risk of harm occurring to the consumer. Strengthening the GOC's power…would help mitigate this."* The College of Optometrists

GOC response – zero powered contact lenses

229. There was no evidence raised during the consultation to suggest that the zero powered contact lenses legislation creates any unnecessary regulatory barriers. However, it is our understanding that very few registrants sell zero powered contact lenses and therefore there may be a risk that the current legislation drives zero powered contact lens wearers to unregulated sources, thereby increasing the potential risk of harm to the public. At the current time we do not propose to make any changes to legislation in this area but we may return to the issue in the future.

230. We note comments in this section that the legislation could be better enforced. Our core statutory functions relate to the regulation of our registrants. We do not have statutory powers in relation to the activities of non-registrants, and it may not be practical or proportionate to take formal action in response to every complaint. We take a risk-focused approach when considering whether it is necessary to act to protect the public under our Illegal Practice Protocol, which

includes considering criteria such as whether zero powered contact lenses are being sold to children or vulnerable adults, or whether there is potential for serious harm or there has been actual harm. Where a case does not meet our criteria for action, we may refer to and support other agencies, including Trading Standards, in acting where a retailer may be trading illegally.

231. We noted one comment that sale of zero powered contact lenses online should be against the law. Zero powered contact lenses can only be sold by or under the supervision of a registrant and, based on case law, we consider that the supervision requirement (of a non-registrant) cannot be met in relation to online sales. However, there is no specific prohibition in the legislation against an online sale by a registrant. We do not consider that it would be appropriate to restrict registrants' professional discretion by preventing them from directly supplying zero powered contact lenses online. This should be a matter for professional judgement in the same way as it is for distance supply of spectacles for users under 16 or sight impaired.

6.4 Offences under the Act

232. The Act creates the following criminal offences:

- illegally conducting sight tests (section 24);
- illegally fitting contact lenses (section 25);
- illegally supplying spectacles (section 27);
- illegally supplying prescription contact lenses (section 27);
- illegally supplying zero powered contact lenses (section 27); and
- misuse of protected title or misrepresentation of registration status with the GOC (section 28).

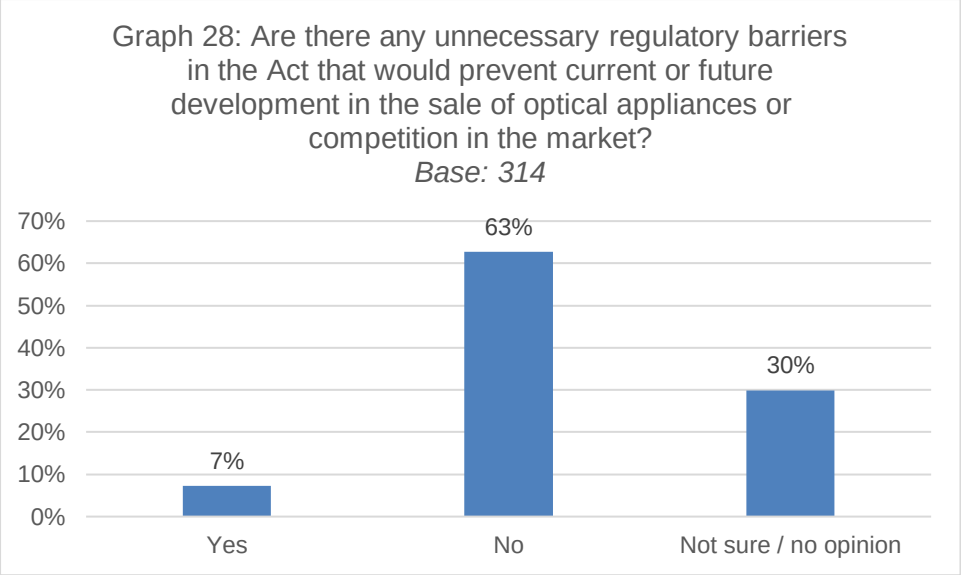
233. We noted in our call for evidence that professional bodies and registrants have said in responses to our recent illegal practice strategy review consultation that we should do more to protect the public from illegal online sales, both UK and non-UK, and that the Act requires reform to address the consumer shift to online purchases. Responses have also levelled criticism that in failing to tackle illegal online sellers we are allowing an unlevel playing field.

234. We also said that the reality is that the enforcement of our legislation relating to sales – bringing a private prosecution in the magistrates' court – is not practicable for an organisation the size of the GOC or in relation to sales in a global online market. Moreover, it is not realistic to expect the GOC to achieve legislative reform that enables us to routinely act against non-UK sellers. We suggested that de-regulation could be a way to achieve a level playing field if transferring the onus of compliance to the consumer, except for restricted categories, does not expose the consumer to a level of risk that is necessary to be mitigated by legislation.

Unnecessary regulatory barriers – prevention of development or competition

235. We asked stakeholders if there were any unnecessary regulatory barriers in the Act that would prevent current or future development in the sale of optical appliances or competition in the market.

236. Of the 314 respondents who answered the question, 63% didn't think there were any unnecessary regulatory barriers, 7% thought that there were and 30% were not sure or had no opinion.



237. Respondents were asked to comment if they said 'yes' to the question above. The main theme from these comments was that the legislation around sight testing and contact lens fitting would not allow for changes in technology which might mean that safe care is possible remotely (both in terms of refraction and eye health checks). Digital screening by non-registrants was also mentioned, with the argument that it would increase access to eye care.

238. A sample of comments is available in the box below.

"…re-issue of a specification to an asymptomatic established wearer must be done in a face to face setting. It is likely that technology will make it possible to check the health of the anterior eye remotely in the future but since this is considered a fit, if the legislation does not change, to use such technology would be considered unlawfully fitting. It would be useful to consider this to make the legislation fit for the future." Contact lens manufacturer

"The Act does not foresee or allow for advances in technology which will change the way in which sight tests are delivered and spectacles are supplied. As it currently stands it would prevent changes to provide digital and/or online eye care which would be safe and for many patients would be their preferred option." Optical Suppliers' Association

"…Digital remote screening of elderly (for instance by a home care nurse) has a proven effect on the identification of poor sightedness in a home care population. These patients can be referred for visual aids or optical appliances. A lower entry to the identification of these cases, will improve general wellbeing." Business registrant/employer

239. The majority of comments received in this section were from stakeholders who were arguing that there were *no* unnecessary regulatory barriers and that

regulation should be increased (e.g. particularly in relation to all online businesses having to register with the GOC to create a level playing field).

Risks on consumer if barriers removed

240. If they answered yes to the previous question, we asked stakeholders what the risk would be on the consumer if these barriers were removed. The following points were identified:

- there would be no risk on the consumer if barriers were removed;
- small risk of over sales / upselling of optical appliances;
- less risk of a monopoly by particular businesses and more choice for patients; and
- patients would be more likely to receive eye health care if they could attend appointments remotely.

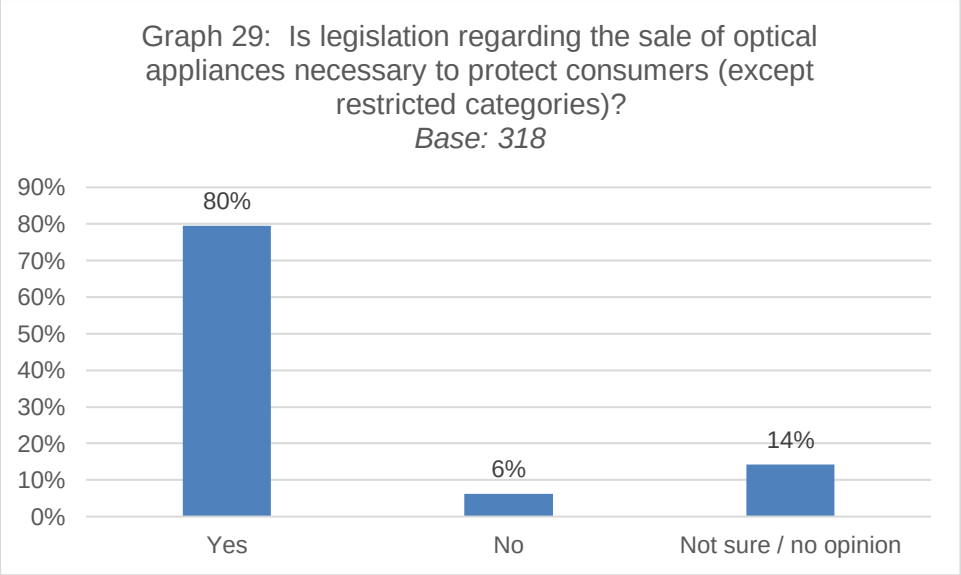
241. A sample of comments is available in the box below.

> *"small risk of over sales of optical appliances. No serious patient safety impact."* Consultant Ophthalmologist
>
> *"Insights suggest that one of the factors influencing online contact lens purchase (potentially from non-regulated sellers) is the avoidance of opticians appointments. By allowing easier access to clinical care remotely, practices would be able to free up chair time and provide care and advice to more patients..."* Contact lens manufacturer

Necessity of sale of optical appliances legislation

242. We asked stakeholders if legislation regarding the sale of optical appliances is necessary to protect consumers (except restricted categories).

243. Of the 318 respondents who answered the question, 80% said that legislation was necessary, 6% that it wasn't and 14% were not sure or had no opinion.



244. The following themes were identified from the comments:

- legislation regarding the sale of optical appliances is necessary to:
  - reduce pressure on hospital eye services;
  - protect patients from ordering the wrong optical appliances or delaying sight tests;
  - maintain high standards and give the public confidence in the professions;
- online retail presents a threat and risks the consumer not having properly fitted optical appliances;
- the GOC needs to enforce the sale of optical appliances legislation and should do more to prevent online illegal sales in the UK, particularly from overseas suppliers; and
- suggestions to work with sector bodies to explore how the GOC standards could be used to apply to other areas that are not directly covered by the legislation.

245. The College of Optometrists wanted the GOC to run regular public education campaigns about the risks of contact lenses and to have powers to address two main future areas of what it perceived to be harm, including the “growing online sales of optical products” and the “emergence of unregulated online refraction and optical services” which they argued were “threats to public protection”.

246. A sample of comments is available in the box below.

"The Sale of Optical Appliances Order of Council 1984 is sensible legislation that strikes a good balance between removing unnecessary restrictions on supply and protecting patients from poor quality spectacles made by unscrupulous businesses… The removal of these standards could lead to spectacles being made outwith specifications causing poor vision, eyestrain and potentially accidents." Business registrant/employer

"It is clear from the substantial evidence of risk of harm to patients that can result from sale and supply regulations not being followed that continued GOC enforcement of this legislation is necessary to protect the public. The current restrictions fundamentally help protect the public…" AOP

"Optical appliances are medical devices and current legislation works well and proportionately with higher levels of safeguards for spectacles and goggles for children, visually impaired and severely visually impaired adults and for contact lenses which sit on the surface of the eye. There is no evidence that this needs to change or that new legislation is necessary… there might be value in the GOC collaborating with sector bodies – e.g. College of Optometrists – to explore how existing GOC standards apply to areas such as myopia control and innovative appliances, but new legislation is unlikely to be a proportionate response or necessary." FODO

"The current legislation is vital to protect the public, both through safeguards to the supply of appliances and because of the impact of article 3 of The Sale of Optical Appliances Order 1984, which effectively ensures members of the public using optical appliances are encouraged to have regular sight tests. The definition of optical appliance as defined within the Act should not be changed. 89% of our members who responded to our survey think that legislation regarding the sale of optical appliances is necessary to protect consumers..." The College of Optometrists

GOC response – offences under the Act

247. We have not been presented with any arguments to suggest that there are any unnecessary regulatory barriers to this part of the legislation. In relation to technology, some of the comments suggest that the Act requires face to face care. However, we consider that the Act leaves this to the professional judgement of the registrant.

248. We also note the request for us to run public education programmes about the risks of contact lenses. We acknowledge that there is a role for public education programmes and where there is a regulatory dimension to this we might consider contributing to an initiative led by the sector. However, we consider that professional bodies and others are best placed to lead public education campaigns, and this should not be a core regulatory function for the GOC.

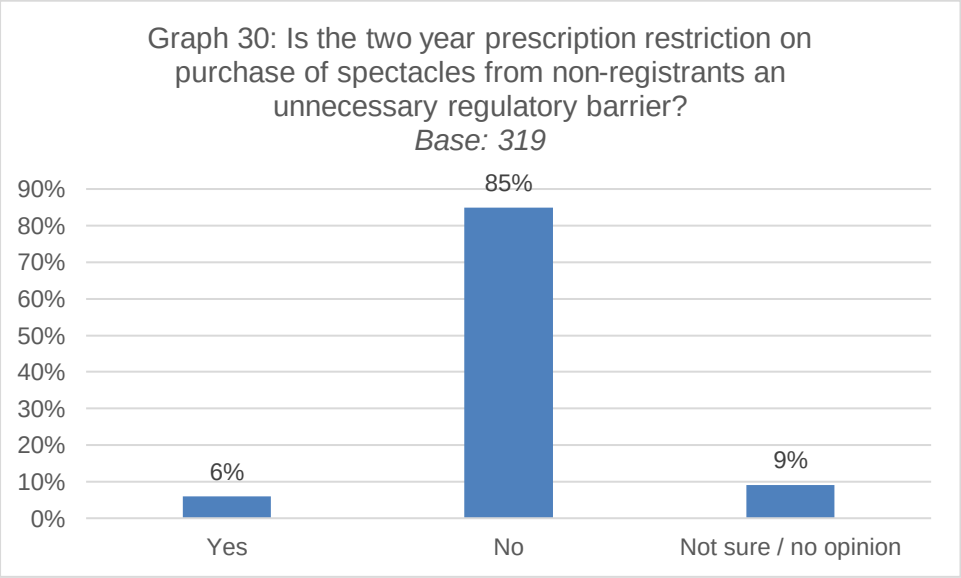
249. There were suggestions that we should have additional powers to address the public protection threats of growing online sales and optical services delivered online. We have addressed this matter in section 7.

6.5 Sale and supply of spectacles by non-registrants

250. Currently the Act does not restrict the supply of spectacles by (or under the supervision of) optometrists and dispensing opticians, including for users aged under 16 or registered visually impaired. However, article 3 of The Sale of Optical Appliances Order 1984 requires (among other matters) that non-registrants may supply spectacles only in accordance with a written prescription issued within the previous two years.

251. We asked stakeholders if the two-year prescription restriction on purchase of spectacles from non-registrants was an unnecessary regulatory barrier.

252. Of the 319 respondents who answered the question, 85% said that the restriction did not create an unnecessary regulatory barrier, 6% said that it did and 9% were not sure or had no opinion.



Arguments in favour of the two-year prescription restriction remaining as it is

253. The vast majority of respondents considered that the two-year prescription restriction on purchase of spectacles from non-registrants was *not* an unnecessary regulatory barrier. The following themes were identified:

- two years is a reasonable barrier to protect the public by ensuring patients are wearing the correct prescription, by increasing the likelihood that patients are receiving regular eye health checks, enabling early detection and treatment of eye diseases (particularly those that are asymptomatic) and preventing sight loss, falls and accidents;
- patients will have the right visual acuity, especially in relation to the legal limits for driving;

- patients will receive advice and guidance from a healthcare professional to enable them to make the right decisions about their spectacles and eye health;
- hospital eye services are not over-used under the current system of ensuring regular eye health checks through a sight test;
- registrants can use their professional judgement to provide spectacles without a prescription where it is appropriate to do so;
- current legislation has prevented an increase in health inequalities by ensuring everyone is encouraged to attend regular sight tests;
- some questioned whether the frequency should be lowered to a one year prescription; and
- changing the legislation might lead to:
    - a reduction in uptake of regular sight tests resulting in health conditions, eye disease and sight loss (and the ability to detect these early will be decreased) and a potential increase in inequalities in eye health among different groups of the population;
    - spectacles of an inappropriate strength resulting in poor vision for patients – this could increase the risk of falls and would be particularly problematic for drivers who might not pass the visual driving standard, which would pose a risk to the public by increasing the possibility of road traffic accidents;
    - financial loss to:
        - practices and registrants from lack of sight tests, with the potential for some practices to be put out of business;
        - national health services due to undetected pathology;
        - patients when they have to purchase additional spectacles because of an out of date prescription;
    - public harm as non-registrants do not have the same level of knowledge as registrants and cannot advise where a sight test might be necessary;
    - liability being unclear if spectacles are made up to inaccurate prescriptions;
    - public health messaging to have a sight test every two years being obscured; and

- more businesses being encouraged to enter the UK market that are unqualified, unregistered and inadequately trained.

254. A sample of comments is available in the box below.

"Without this many of the patients who have their eye health checked as part of our current comprehensive eye care model would not have this done, this would lead to more undetected pathology and an ever more increasing burden of poor eye health on the NHS which is already struggling." Optometrist

"In my clinics the highest level of preventable sight loss is amongst adult patients who buy glasses without a prescription (and therefore eye care as well) and only seek professional advice by the time they have a significant loss of vision..." Optometrist

"With approximately 25% of the patients we refer being asymptomatic, this would undoubtedly result in pathology being missed and sight being lost unnecessarily." Business registrant/employer

"If consumers wish to purchase spectacles made to a prescription that is older than two years, there is wide access to registrants who are able to advise and facilitate such a request as appropriate. This maintains the important safeguard that, where it would be inappropriate to do so without first seeking a further sight test, the registrant can guide accordingly. 70% of patients in the UK (and 100% in Scotland) have access to a sight test paid for by the NHS every two years, or more frequently if this is clinically indicated, so this in itself is not a barrier. The inclusion of the 2 year limit was introduced in 1984, since which time there will have been in the order of 400 million prescriptions issued, so in this context we would be surprised if the current restriction has an impact on a substantive group of patients, and removing a restriction intended to provide public protection, in order to meet the request of such a small minority would not be in line with the stated objectives for legislative reform." Specsavers Optical Group

"…While some patients might not appreciate that a sight test involves an eye health examination and therefore, appreciate the benefit of having a sight test every two years, this approach is a successful example of preventative health care. Early identification and treatment of eye disease reduces the risk of sight loss…" ABDO

"…Allowing non-registrants to dispense spectacles without a prescription dated in the previous two years will inevitably encourage unqualified, unregistered, inadequately trained and potentially non-UK based businesses to enter the UK market. These entrants will have little or no incentive to dispense safely and appropriately, lack accountability or transparency, and, in many cases, will be beyond the reach of GOC regulation…" LOCSU

"…The risks associated with removing the requirement for an in-date spectacle prescription are likely to exacerbate health inequalities as patients who are less

health literate will be most likely to delay sight tests, and severe disease such as glaucoma disproportionately impacts some ethnic groups more than others. It could also delay the detection of systemic conditions through case findings during the sight test, such as cardiovascular disease in groups who are otherwise unlikely to engage with healthcare professionals…" AOP

"The disadvantage and impact of removing the two-year requirement, would be to effectively separate supply of ocular appliances from ensuring a regular ocular health assessment… This would result in higher rates of preventable sight loss and conditions such as glaucoma not being detected in the early asymptomatic stages..." The College of Optometrists

"…The Opticians Act does not present barriers to care, and in fact (as stated in our responses above) has helped provide one of the most advanced and accessible primary eye care services in the world. As a result, the Opticians Act, as it currently stands, has improved equity in access overall." FODO

Arguments in favour of the two-year prescription restriction being removed

255. A very small minority of respondents that thought the two-year prescription restriction on purchase of spectacles from non-registrants was an unnecessary regulatory barrier. The following themes were identified:

- people have the right to take ownership of their health and make their own judgements (with one comment that they should be made aware of the risks) – the public perceives the current approach as unnecessary and against personal choice, resulting in a negative image of optometry;
- a challenge as to whether a sight test is required every two years and what the clinical evidence for this is, especially for the under 60s (except those with diabetes), and/or if a vision check (whether by a person or an auto-refractor) is carried out to double-check the prescription;
- inconvenience for the consumer who may have to wait longer for spectacles if they cannot be seen quickly by an optometrist;
- costs to the patient; and
- changing the legislation would promote consumer choice, be cheaper and more convenient for patients, save unnecessary sight tests and increase revenue for online businesses.

256. A sample of comments is available in the box below.

"All citizens should have the right to take full ownership of their health (including eye health), I believe that prescriptions and other similar restrictions should be discarded as they only help companies to profit and take away people's freedom of choice!" Patient

"Inconvenient to the consumer to impose it, leading to the delay in supply of glasses, and in any event, any qualified DO/OO has the ability to use a prescription of any date provided they can justify it's in the consumers best interests, so it's easy to circumvent this legislation, therefore it's unnecessary." Dispensing optician

"…If a patient/client rates the quality of vision with [h]is prescription as good/excellent, and a vision screener identifies that the visual acuity is on par/unchanged, why should one then be referred to an optometrist to redo the measurement. The chances that this investigation will create added value is small, while the costs are almost the same for a new prescription, or a complex prescription…" Business registrant/employer

"There is no clinical evidence to support a new Rx [prescription] *every two years -- nothing. People know if they see clearly -- another reason to be rid of the two year validity."* Business registrant/employer

"…if restricted groups were extended to include all voucher patients and all patients requiring a vertex distance according to the 1984 GOC Rules then I think this restriction could be removed for everyone else except possibly the over 60s since they are at greatly increased risk of sight threatening eye disease…" CPD provider

"It should be for the consumer to have the right to make that decision." Optical Suppliers' Association

GOC response – sale and supply of spectacles by non-registrants

257. We have considered the personal responsibility vs public health debate in the responses. We consider that the regulatory barriers that prevent non-registrants from supplying spectacles without an in-date prescription is in line with national health services' objectives for preventative healthcare (preventable sight loss which would have an impact on national health services) and necessary to protect the public. We have not been presented with any evidence to suggest that the legislation is significantly detrimental to patients and note that it is possible for patients to approach a registrant for spectacles who can advise them about whether it is necessary for them to have a further sight test and discuss the risks and benefits with them.

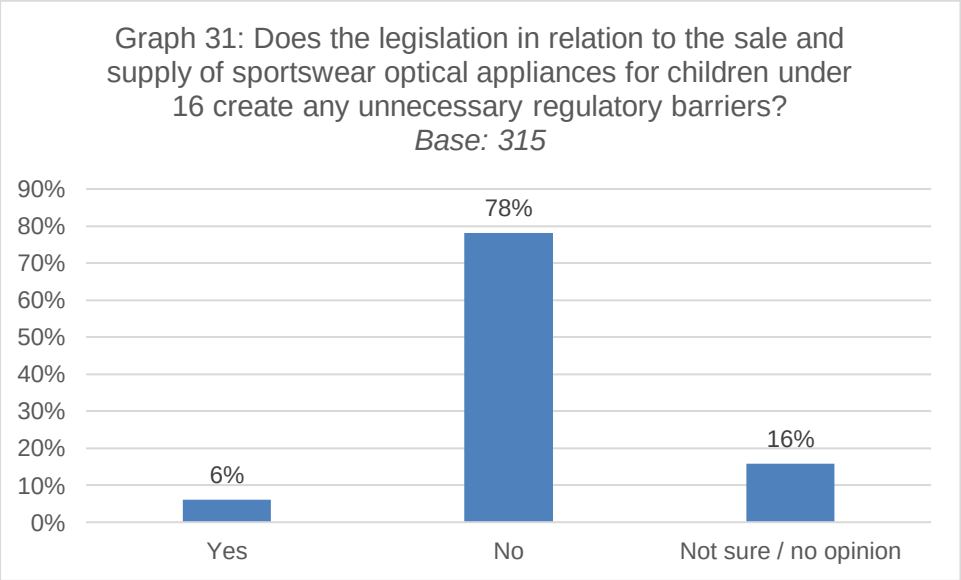
258. We have not been presented with persuasive arguments that the two-year limit should either be extended or reduced.

6.6 Supply of sportswear optical appliances to children under 16

259. The restrictions under the Act relating to supply of optical appliances to children under 16 apply to sportswear prescription optical appliances (such as prescription swimming goggles and dive masks), not just spectacles and contact lenses. This means that this type of sportswear cannot be provided over the internet by non-registrants.

260. We asked stakeholders if the legislation in relation to the sale and supply of sportswear optical appliances for children under 16 created any unnecessary regulatory barriers.

261. Of the 315 respondents who answered the question, 78% did not think the legislation created any unnecessary regulatory barriers, 6% thought that it did and 16% were not sure or had no opinion.



Arguments in favour of sportswear optical appliances legislation remaining as it is

262. The following themes were identified from the comments where respondents thought that the regulatory barriers were necessary and saw advantages and positive impacts of the legislation remaining as it is:

- there is no evidence that the legislation is a problem for children or their parents or that the legislation needs to change;
- the current restrictions protect children – under 16s should always be fitted properly regardless of the appliance, as poor optical appliances can harm their eye development and lead to reduced vision in the longer term;
- fitting requirements for sportswear optical appliances are more complex than ordinary optical appliances;

- continued protection of children under 16 through well-fitted, correct and safe use of optical appliances, with appropriate advice – it gives an opportunity to safeguard children's sight and supply will be subject to GOC regulation;

- changing the legislation might lead to:

    - it being unsafe for children if they were incorrectly fitted with sportswear optical appliances, as this could have a negative impact on the development of children's eyes and/or facial growth/features, and lead to eye strain, blurred vision, muscle imbalance, binocular vision problems, amblyopia (a lazy eye) and/or a change in prescription;

    - patients ending up with the wrong prescription which could lead to damage to the eyes longer term – this is a particular issue because children are less likely to be able to tell if they have problems with their vision;

    - the appliances being unsafe, with the potential to cause injury to the eyes or another person when playing impact sports;

    - patients being more likely to buy incorrect sportswear optical appliances online; and

    - risk of inappropriate advice by non-registrants.

263. While being supportive of the legislation remaining as it is, some respondents suggested that it depended on the type of sportswear optical appliance (e.g. impact sports create a higher risk than swimming and the regulations could be separated out) and/or the environment in which it is used – (e.g. the risks are greater with some sportswear optical appliances because of the higher risk environment in some cases – poorly fitting appliances have the potential to obstruct vision and the restrictions therefore protect others who the wearer might come into contact with).

264. A sample of comments is available in the box below.

"…Many children opting for sports eyewear only do so because they are of moderate-high ametropia [refractive error] as often those with low ametropia will attempt to cope without. With moderate-high ametropia it is of course more imperative that the frames and lenses are dispensed appropriately so as to provide adequate vision. In addition, poorly fitted sports eyewear could lead to injury and so it only makes sense that a qualified registrant with both the capacity and enthusiasm determine suitability should dispense such an appliance…" Dispensing optician

"…It would be worth separating out swimming googles (where vision is compromised anyway by being underwater, best correction is adequate, and the PD [pupillary distance] *can be altered by adjusting the bridge) and sports specs with high wrap and impact resistant requirements as these are complex appliances and require additional in person measurements. In fast paced sports like squash, badminton, football, cricket it is not good enough to allow approximate prescriptions as it puts the player, and other players at risk of serious injury."* CPD provider

"…The current restrictions on the supply of sports eye wear to children under 16 are necessary to protect the public. Sports eyewear is fitted not only to ensure optimum vision but to afford protection to the wearer and, for contact sports, to other participants. As a result, it is more rather than less complex to fit, requiring detailed questioning about usage and enhanced dispensing skills to ensure a safe, optimum fit…

…The call for evidence also suggests that the restrictions might be unnecessary because sportswear is 'usually only worn for short periods'. While diving masks, swimming goggles or sport goggles can be worn for short periods, they can also be worn over an extended length of time. In any case, if such optical appliances have not been fitted correctly and/or appropriate advice has not been given, there is clearly an increased risk of harm if a child is unable to see clearly under water or is wearing a poorly fitting pair of rugby goggles. This could also result in harm to team members or competitors." ABDO

"…Children under 16 need to be fitted by suitably trained and qualified professionals, in particular children with squints and binocular problems. Where children are undergoing treatment for squint or lazy eye, it is important to ensure they wear sportswear with their accurate prescription incorporated, to continue the beneficial effect of their treatment… Correct fitting of optical appliances, including sportwear, is therefore imperative for optimum vision. A failure to do so can lead to lifelong impacts on children's vision and risks harm in the short and long term…" The College of Optometrists

"Unsupervised sales of optical appliances to children are a significant area of risk. This is because children's eyes are still developing, and poorly fitting and inappropriate prescription eyewear, provided without appropriate clinical oversight, can lead to discomfort[37]. There is also a risk that the incorrect impact protection may be provided if the process is not overseen by registrants. The call for evidence says that risks associated with sports eyewear may be less because the appliances are being worn infrequently. However, the problem of children having inappropriate vision correction leading to harm are made more significant because

[37] Powell, C., Wedner, S., Hatt, S.R. (2009), Vision screening for correctable visual acuity deficits in school-age children and adolescents, *The Cochrane Collaboration*

they will be engaging in higher risk activities such as swimming, sports, and outdoor pursuits." AOP

"If unqualified professionals are able to sell sportwear optical appliances there is a risk that the products might not fit, have unnecessary coatings, inappropriate frames or that safety considerations are not taken into account. As children's eyes are not yet fully developed it's essential they have the correct prescription which can only come from a qualified and registered professional." RNIB

Arguments in favour of sportswear optical appliances legislation restrictions being removed

265. The following themes were identified from the small number of comments where respondents thought that the regulatory barriers were unnecessary and from comments about the disadvantages and negative impacts of the legislation remaining as it is:

- the risk for sportswear is lower because they are not worn permanently;
- fitting requirements for most sportswear is not as complex as other eyewear;
- greater cost for patients; and
- changing the legislation would result in greater access to the appliances and financial benefit to the purchaser.

266. A sample of comments is available in the box below.

"…the risk is negligible and the restrictions are simply not warranted." Consultant Ophthalmologist

"OTC [over the counter] *devices such as rx* [prescription] *swim goggles are not permanent corrections so should be able to be sold as an accessory."* Optical manager

"Cost can be impact on inclusion." Dispensing optician

"The cost of sportwear optical appliances would be more expensive." Local optical committee

"Financial benefit would be present because without having to fund a professional salary the retail price could be reduced." Business registrant/employer

GOC response – supply of sportswear optical appliances to children under 16

267. We have considered the arguments for and against a change in legislation and are not convinced that there is sufficient evidence to justify a change. We are

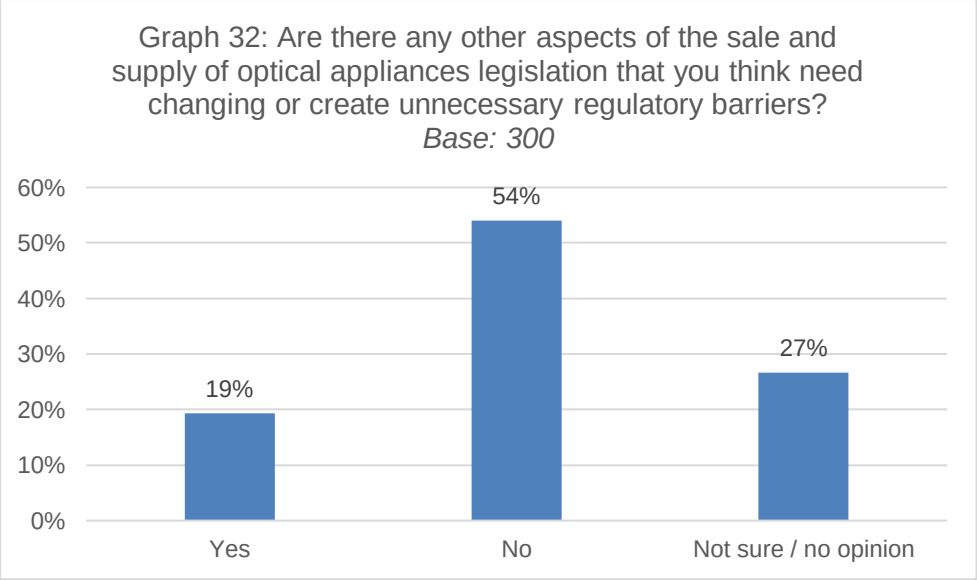
persuaded by public protection arguments that sportswear prescription optical appliances for children should only be supplied by or under the supervision of a registrant (or registered medical practitioner) due to the extended length of time that some sportswear optical appliances are worn and the risk of injury to others, not just self, particularly in impact sports.

6.7 Other

Sale and supply of optical legislation that requires changing or creates unnecessary regulatory barriers

268. We asked stakeholders if there were any other aspects of the sale and supply of optical appliances legislation that they thought needed changing or created unnecessary regulatory barriers.

269. Of the 300 respondents who answered the question, 54% thought that there weren't any other aspects of the legislation that needed changing or that created unnecessary regulatory barriers, 19% thought that there were and 27% were not sure or had opinion.



270. The following themes were identified from the comments (we have not included themes already identified in other parts of this consultation):

- the legislation around low vision aids should be clearer, including what are considered low vision aids, and opening up the restrictions for low vision specialists;
- it should be clear that the responsibility for the product lies with the seller, not the optometrist that performed the sight test;
- either abolishing the sale of ready readers or restricting them to +2.5, as there is concern that anything above this could be correcting latent (hidden) hypermetropia[38]; and
- a prescription should include the tested visual acuities for any prescribed working distances.

[38] https://www.nhs.uk/conditions/long-sightedness/

271. We asked stakeholders what the advantages, disadvantages and impacts (both positive and negative) would be of the sale and supply of optical appliances legislation remaining as it is currently. The main themes related to patient safety and public protection.

272. A sample of comments is available in the box below.

> *"Need to make it clearer regarding low vision aids"* Optometrist
>
> *"…We also believe that a valid prescription must also include the tested visual acuities for any prescribed working distances."* AIO
>
> *"Enhanced patient safety measures for the current vulnerable groups"* Local optical committee
>
> *"We feel the current legislation works well as it protects patients and the public from harm. As previously stated above, the legislation should remain in order to continue to maintain a risk-based approach. This will also help in enabling ICSs* [integrated care systems] *to better commission and deliver consistent and equitable care."* AOP

GOC response – other

273. We have reviewed the definition of low vision appliances in the legislation[39] and agree that it could be clearer. We produced a position statement on low vision aids in 2012. We will review the legislation in the context of our statement and consult on any changes as part of future consultation on any new draft legislation for the GOC as part of the DHSC's legislative reform programme. At the time of writing, it is not clear how much of part IV of the Act will be repealed to allow us to deal with issues such as these in position statements and standards/guidance which do not require legislative change. This is something that we will continue to discuss with DHSC as it consults on its legislative reform programme. Our preference would be to deal with these issues in standards/guidance as it allows for a more flexible approach.

274. It was suggested that the legislation should make it clear that responsibility for the product lies with the seller, not the optometrist that performed the sight test. We infer that this relates to situations where, for example, spectacles are made up to a prescription, but the patient is not content with the spectacles. It would not be appropriate to make any changes to the Act because this is a matter of

[39] Regulation 1(2)(d)(b) of the Sale of Optical Appliances Order 1984: "any appliance sold or to be sold in pursuance of a prescription which identifies the appliance to be sold as being a low vision aid (whether by means of the words "low vision aid" or some other similar words), and includes frames or mounts which are intended for use as part of eyeglasses so designed and are sold or supplied without lenses and lenses so intended which are sold or supplied without frames or mounts"

general consumer law. However, we fund the Optical Consumer Complaints Service (OCCS) which can assist consumers and businesses in these cases.

275. We have considered comments related to ready readers. There would need to be a high evidence bar to reverse this matter which was debated extensively in Parliament in the 1980s when the change was introduced. We have not been presented with evidence of public harm that would justify a change in legislation in this area.

276. We have considered the suggestion that The Sight Testing (Examination and Prescription) (No. 2) Regulations 1989 should be changed so that a prescription should include the tested visual acuities for any prescribed working distances. We will discuss this further with the professional bodies to understand the case for change.

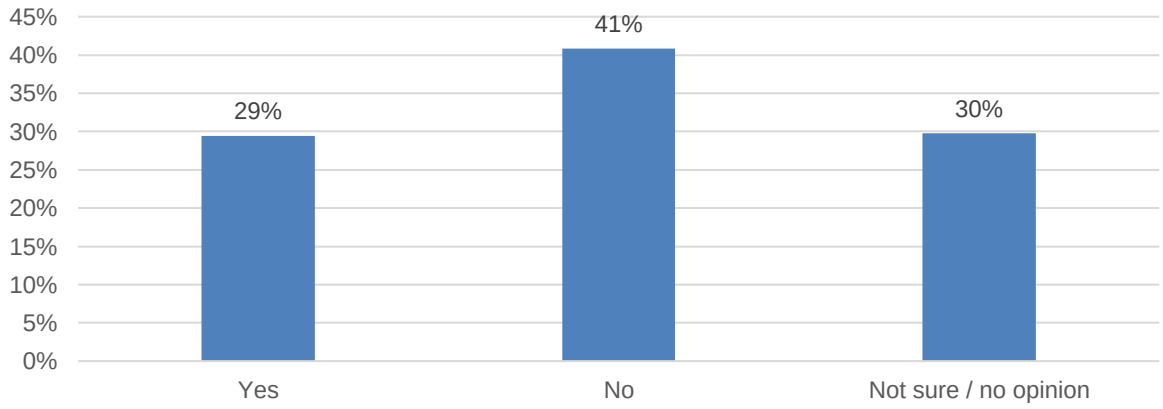
Section 7: Delivery of remote care and technology

Technological development

277. We asked stakeholders if they had any knowledge or experience of areas of technological development that the GOC should be aware of when considering changes to the Act.

278. Of the 316 respondents who answered the question, 41% said that they didn't have any knowledge or experience, 29% said that they had and 30% were not sure or had no opinion.

Graph 33: Do you have any knowledge or experience of areas of technological development that the GOC should be aware of when considering changes to the Act?
Base: 316



279. The following themes were identified from the comments:

- there were no areas of the Act that had restricted innovation in technology or prevented artificial intelligence (AI) developments, as these developments have happened despite the Act being in place;
- some examples given of developments and advancements in optics are:
    - remote delivery of services such as sight tests, refraction, triage and healthcare professionals sharing virtual diagnostic information;
    - remote testing and diagnostic tools such as home visual acuity monitoring apps, digital imaging, remotely operable slit lamp and iPhone ophthalmoscopes;
    - optical coherence tomography (OCT) and use of AI;
    - clear-lens extraction;
    - free-form lenses; and

    - online purchasing of spectacles and contact lenses;

- the GOC must clarify and distinguish between words and terms such as ‘technology’, ‘remote care’, ‘remote refraction’ and ‘AI’. These are all very different terms with different policy implications. Moreover, terms such as technology and AI are umbrella terms that encompass a wide range of developments, all with different levels of risks and benefits to patients;

- COVID-19 accelerated the provision of remote care and remote consultations which was beneficial to patients (some good examples are Minor Eye Conditions Service (MECS) or Community Urgent Eyecare Services or COVID-19 Urgent Eyecare Service (CUES)) and helped to reduce the burden in secondary care);

- the GOC should distinguish between, for example, remote care done under the supervision of a GOC registrant and care delivered remotely unsupervised;

- there are many benefits in relation to remote care such as: increasing access for some groups of patients as it is easier to dial in than attending in person; reducing patient waiting times; freeing up services for more complicated cases; and reducing the burden in secondary care. However, remote care is not beneficial for all types of patients, and could exacerbate health inequalities within some groups. Some patients may not be digitally literate or have access to smart phones and digital devices, so it is important that patients can access care in a method suitable for them;

- there may be financial barriers that could prevent some businesses (for example, smaller businesses) from being able to afford new technology and offer this to patients, or patients having to pay more, for example, for a sight test with OCT. Both these situations could exacerbate health inequalities as some patients either won’t have access to or will not be able to afford to pay extra to access new technologies;

- while technological developments and AI have the potential to benefit patients, there are also risks associated with these developments, for example, the availability of online sight tests is seen as a risk to patients as it is unclear how this method of testing could offer the same quality and data as an in person test, and could result in conditions going undetected. Online sight testing and online refractions provided by companies based outside the UK were also seen as a risk as they did not fall within the GOC’s regulatory remit;

- to mitigate against potential risks, competent and registered healthcare professionals must remain at the centre of clinical decision making; and

- the Act should not restrict innovation but equally it must protect the public.

280. A sample of comments is available in the box below.

"We do not see anything in the current Act precluding the utilisation of technological developments. It is important to note as well that Remote care, technology and AI are not the same things. They will also mean different things to different eyecare providers and patients. Definition of what is meant by these terms is necessary." LOCSU

"We have seen the huge benefits in the sector and for the patient in the optometrist-led remote care which was delivered during the COVID pandemic. Remote care was an advantageous tool especially for patients who couldn't attend a face-to-face appointment for health risks or who were unable to travel." AOP

"I work with low vision patients and people with learning disabilities and I have seen the use of telemedicine during the lock down be almost totally inaccessible to these groups with very little options offered." Optometrist

"Smart phone apps and other remote technology is developing constantly and is a risk to patient safety if not managed and regulated correctly. Technology advancement can be positive as seen during the pandemic but needs consideration and caution." Bexley, Bromley & Greenwich Local Optical Committee

"The central principle for optical regulation and practice should be that registered, competent optical professionals must remain in control of clinical decision-making as new technologies and innovations are deployed. The Opticians Act should not unduly restrict innovation, but should also maintain its current fundamental principles to ensure the public benefits from safe care and regular and complete sight tests." The College of Optometrists

"There are a huge range of technological developments that are changing how ophthalmic care is being delivered, across the whole patient pathway from primary to secondary care. These include AI, video consultations, home visual acuity monitoring apps, virtual diagnostics and shared electronic patient referral systems." Royal College of Ophthalmologists

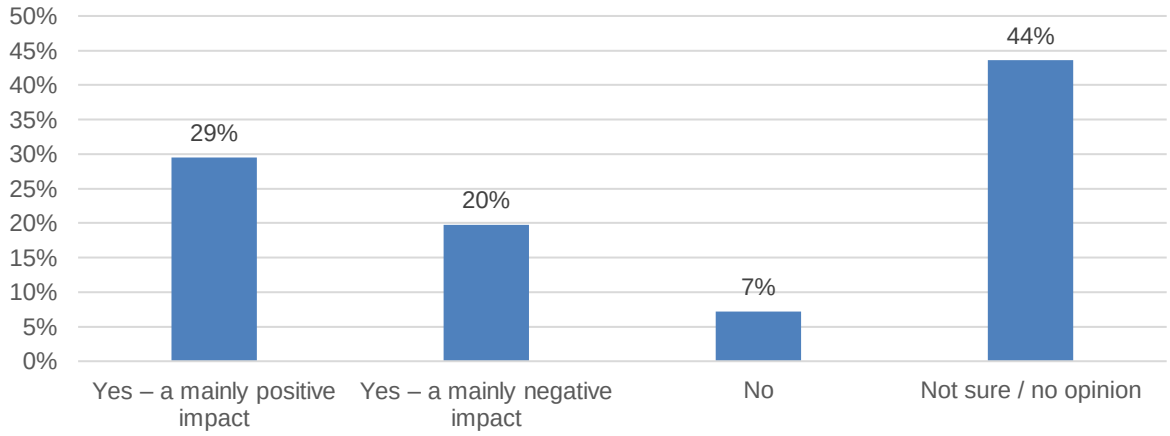
Impact on patient safety/care

281. We asked stakeholders whether there was any evidence that increased use of technology or remote care may have an impact on patient safety or care in the future.

282. Of the 319 respondents who answered the question, 29% said that the evidence suggested a mainly positive impact, 20% said that the evidence

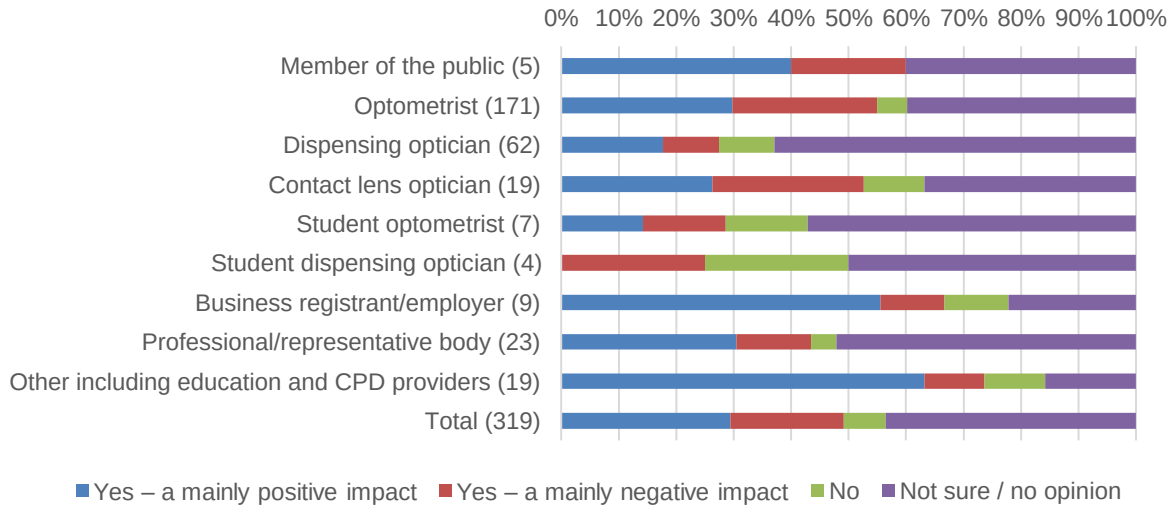
suggested a mainly negative impact, 7% thought there wasn't any evidence and 44% were not sure or had no opinion.

Graph 34: Is there any evidence that increased use of technology or remote care may have an impact on patient safety or care in the future?
Base: 319



283. Graph 35 shows that members of the public, business registrants/employers and other including education and CPD providers were more likely than other categories of respondent to think that the evidence showed a mainly positive impact on patient safety or care in the future.

Graph 35: Is there any evidence that increased use of technology or remote care may have an impact on patient safety or care in the future?
By category of respondent
Base: 319



284. The following themes were identified from the comments (where not covered in responses to the previous question):

- there was support for both use of technology and remote care but only under the right conditions i.e. if it is in the best interests of that particular patient and works as well as a face to face interaction;
- increased accessibility is one of the main advantages of remote care and this could help with patient compliance with treatments as they have more access to healthcare professionals. On the other hand, a risk is that details about a patient could be missed from a remote care appointment that might have been picked up by an in person appointment;
- technology has helped with record sharing between patients and healthcare professionals, and also between primary and secondary care;
- robust evidence and further research is needed when evaluating the impacts of remote care / technology / AI;
- compliance with GOC standards is key in protecting patients, and risks should be addressed via standards rather than changes to the Act;
- the risk is with companies based outside of the UK who are not bound by GOC standards and legislation; and
- telemedicine worked well during COVID, but the sight test must not be done remotely.

285. A sample of comments is available in the box below.

"Remote care can give greater access to services when an in person visit is not possible however I feel that in the majority of cases an in person examination is more appropriate." Dispensing optician

"I am incredibly concerned about the concept of remote refractions and their accuracy. The potential to miss pathologies, send customers (not pxs [patients]*) out to drive or operate machinery in spectacles prescribed in this way is frightening."* Optometrist

"It has the potential to impact on the patient safety of people who have barriers to accessing the internet… However, there is no clear-cut answer to this question, technology can bring a lot of positive elements but it relies heavily on how it is implemented and put to use. Technology for example has improved communication between primary and secondary care, but remote care can risk excluding some patients who are not digitally literate, especially if remote care is the only easily available option." RNIB

"Technology and remote care are two different topics that should be addressed separately. The GOC should not combine the two when considering the outcomes of this Call for Evidence … there have been many advances in eye care-related technology, which create both opportunities and risks. There needs to be robust analyses of these impacts on patient and public health. There is not yet a robust evidence base on the overall impact of the increased use of technology or remote care on future patient safety or care, although individual studies are being published and adding to our growing knowledge." The College of Optometrists

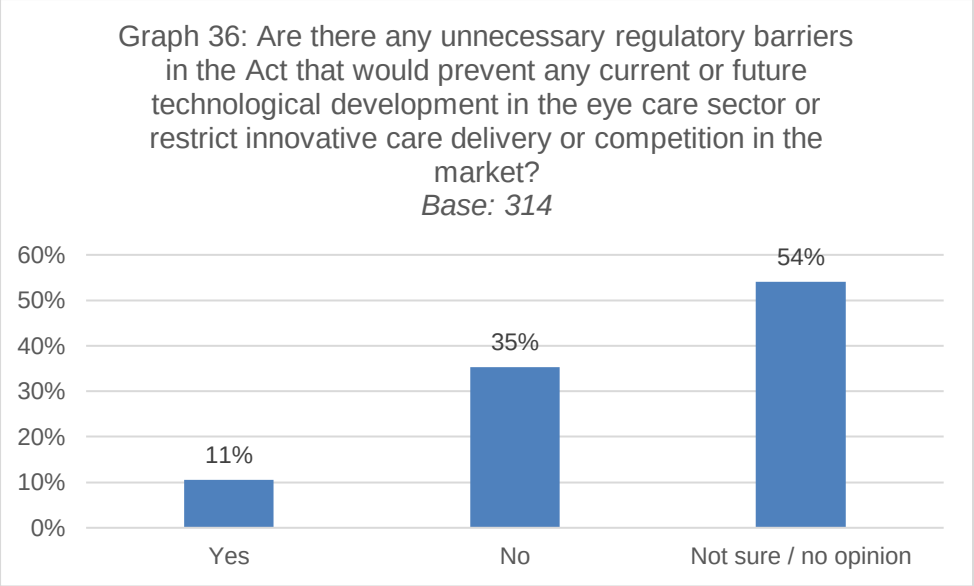
"The use of technology in optical practice raises different issues to the application of remote care so this is a difficult question to answer and there would be value in breaking it down further. The use of technology in practice in line with legislative requirements and GOC standards is likely to continue to enhance patient care by, for example, improving the diagnosis of eye disease and wider health issues. The use of remote care has the potential to increase the risk to patients if it is carried out by offshore business that are not bound by UK legislation and without the involvement of GOC registrants." ABDO

"The answer is more complicated than the options allow. Both technology and remote care will have an impact on patient care but, whether this is positive or negative, will depend in large part on the robustness and clarity of the GOC's standards. FODO and our members support all clinical and service innovations that advance safety, effectiveness, and patient and public benefit. We also support choice and innovations in optical technologies that improve outcomes for patients and advance eye care provision for populations." FODO

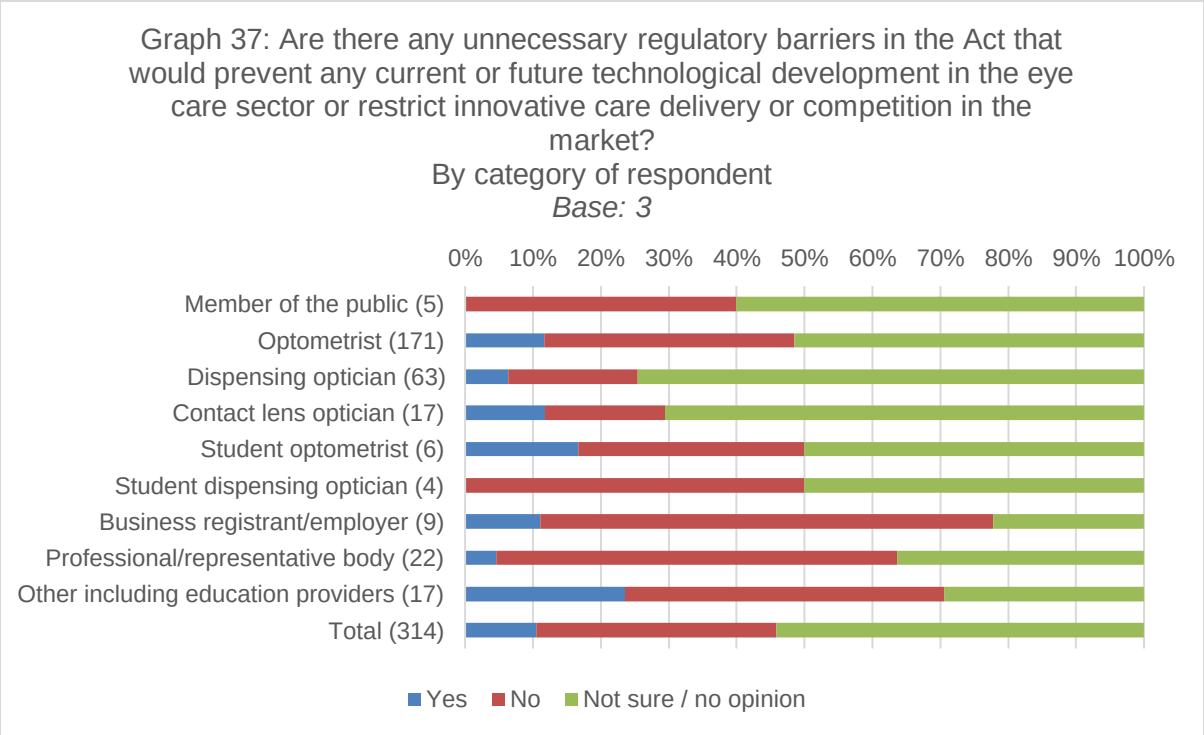
Unnecessary regulatory barriers – preventing technological development

286. We asked stakeholders whether there were any unnecessary regulatory barriers in the Act that would prevent any current or future technological development in the eye care sector or restrict innovative care delivery or competition in the market.

287. Of the 314 respondents who answered the question, 35% didn't think there were any unnecessary regulatory barriers, 11% thought that there were and 54% were not sure or had no opinion.



288. Graph 37 shows that student optometrists and other including education providers were more likely than other categories of stakeholder to think that there were unnecessary regulatory barriers.



289. The following themes were identified from the comments that had not already been raised previously:

- the Act doesn't take account of remote care or remote consultations as it pre-dates these developments; and

- there should be more guidance for registrants from the GOC on technological developments to help them better understand how to deliver this in a safe and efficient way to benefit patient care.

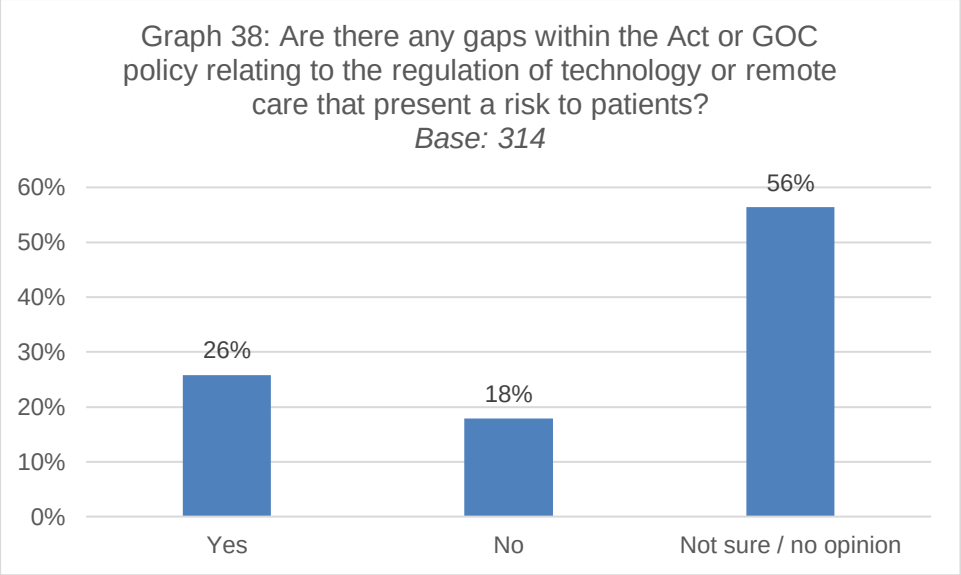
290. A sample of comments is available in the box below.

> *"Thus far it has proven possible to adopt the use of chosen technologies without finding that current legislation creates a barrier. Rather, by using technology to work within current legislation assures the patient protections the legislation intended, and provides guiding principles for how the technology is used and further developed."* Optometry Northern Ireland
>
> *"Although most technological developments that are currently and commonly used in practice did not exist or envisaged when the Opticians Act came into effect or was amended in 1989, the Act does not restrict the type of equipment, products or technology that can be used by registrants."* The College of Optometrists
>
> *"No, the longstanding adoption of latest diagnostic testing equipment and changing therapeutics by the optical sector is clear evidence of this. It may be the case that some stakeholders might perceive barriers when a technology is advertised but not actually available. This however is in fact because new advertised technologies are not supported by good evidence and registrants rightly do therefore not deploy them. Hence, rather than a barrier, such examples are evidence of the Act working well to protect patients and the public. This is achieved via GOC standards for protecting patients and securing high quality care."* FODO

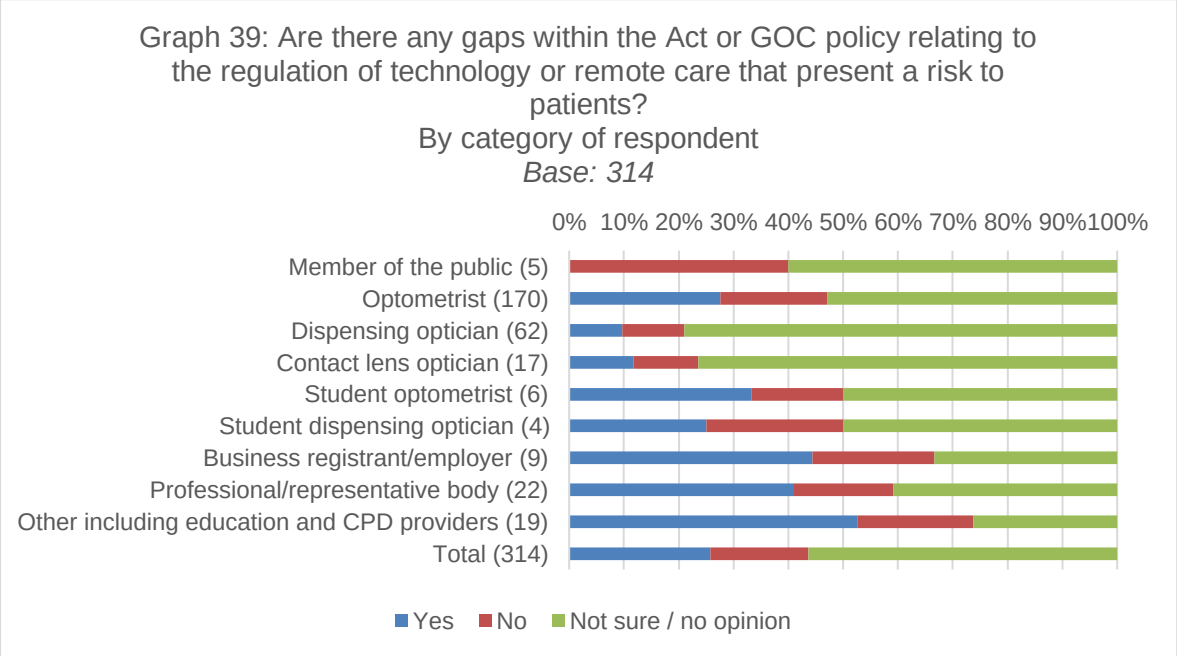
Gaps in regulation of technology or remote care

291. We asked stakeholders whether there were any gaps within the Act or GOC policy relating to the regulation of technology or remote care that present a risk to patients.

292. Of the 314 respondents who answered the question, 26% thought that there were gaps, 18% didn't think there were gaps and 56% were not sure or had no opinion.



293. Graph 39 shows that student optometrists, business registrants/employers, professional/representative bodies and other including education and CPD providers were more likely than other categories of respondents to think that there were gaps within the Act of GOC policy.



294. Respondents returned to the same themes as in their answers to previous questions in this section, for example, that the legislation has not held back innovation and use of technology, the role of GOC standards and guidance in supporting registrants, the merits of sight tests conducted remotely and regulation of online sales by overseas providers.

295. Respondents challenged us to evolve our regulatory approach to meet the challenges posed by technological developments and remote care.

296. A sample of comments is available in the box below.

> *"I'd like to see the GOC working with tech developers/suppliers to better understand the direction of travel. Any use of technology is, I think, down to the registrant to decide whether it's appropriate, which could prove problematic, so some regulation, or at least changes to policy/guidance, working with ABDO, College of Optometrists, is needed to protect registrants and the public."* Dispensing optician
>
> *"We are concerned that the GOC has not evolved its regulatory approach to meet these challenges and protect patients from companies offering components of online/remote optical care without appropriate registrant involvement and/or standards of care. Regulatory oversight needs to adapt to maintain public protection. We note with interest (and support) that the Medicines and Healthcare products Regulatory Agency (MHRA) has announced plans to strengthen regulation of medical devices including medical devices that involve AI. Appropriate regulatory mechanisms should be used to manage the risks that arise from new technologies, such as AI and remote care. This includes standards for individuals and businesses, including GOC regulatory action where care is being delivered in novel ways that pose risks to patients."* AOP

Suggestions for addressing gaps in regulation of technology or remote care

297. If they answered yes to the previous question, we asked stakeholders whether they had any suggestions about how these gaps in the regulation of technology or remote care could be addressed.

298. The following themes were identified from the comments:

- any gaps in regulation should be addressed via GOC standards and guidance rather than amendments to the Act, for example, there was support for the GOC providing guidance on remote care;
- there must be clear lines of accountability for registrants with the advancement of new technologies, AI and remote care. Technological and AI innovations will likely challenge the traditional roles of GOC registrants and blur the lines of accountability and responsibility for decision making;
- GOC registrants must continue to have oversight and responsibility for clinical decision making if remote care is delivered to patients;
- regulation must evolve and be agile and flexible so as not to hinder technological developments but at the same time patient protection must remain at the forefront of any developments in technology and AI;

- the GOC should look at what the MHRA is doing, for example, some AI developments are being treated as medical devices and therefore subject to greater regulation; and
- new risks will emerge as technology and AI develop, and it is not always easy to foresee what these might be in future.

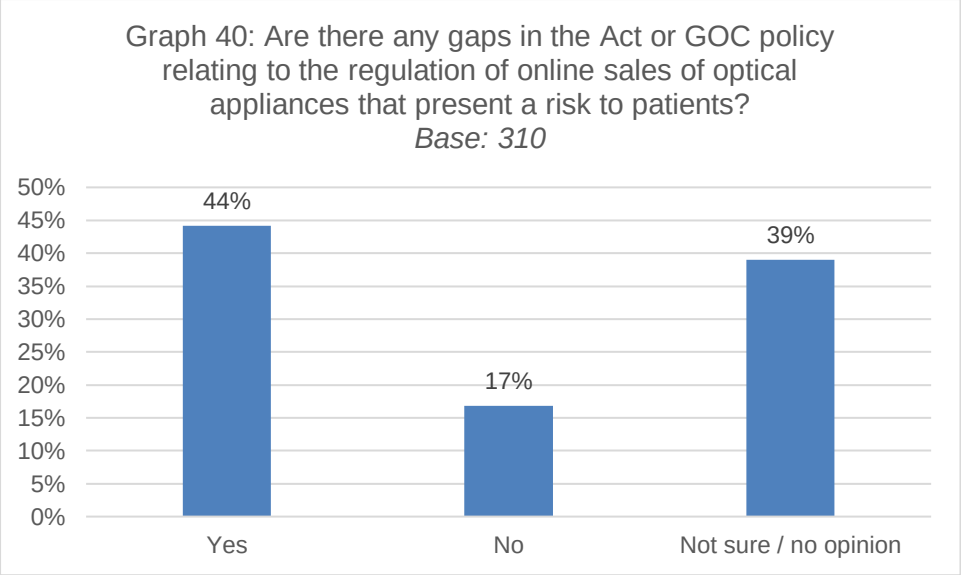
299. A sample of comments is available in the box below.

> *"The GOC should review its policy statement on supervision to reflect developments in the delivery of eye care, including hybrid models. It should also ensure this is enforced effectively. The GOC should consider further how it might promote technological literacy through, for example, its education requirements, standards of practice, business standards and CPD scheme."* ABDO
>
> *"Regulation should ensure that appropriately skilled optical professionals remain responsible for decision making around eye care, and that their role for patient care is not adversely affected by the use of new technology or remote care. Good regulation in this sphere would help in managing the implications of new technology. The growth of the use of artificial intelligence to support diagnostic decision-making and screening raises questions about the interaction between regulation of individual practitioners and the regulation of devices. The increasing delivery of services and sales of medical devices via the internet is challenging the traditional limits of regulation. Regulation must evolve to maintain public protection."* AOP
>
> *"We recommend that all regulators, including the GOC, review how they will determine lines of accountability for new technologies. It will be important for regulators to collaborate both with other regulators and other stakeholders with involvement in this area to ensure a consistent approach which will be necessary to ensure clarity for professionals, patients and service users."* PSA

Gaps in regulation of online sales

300. We asked stakeholders if there were any gaps in the Act or GOC policy relating to the regulation of online sales of optical appliances that present a risk to patients.

301. Of the 310 respondents who answered the question, 44% said that there were gaps that presented a risk to patients, 17% said that there weren't any gaps and 39% were not sure or had no opinion.



302. The following themes were identified from the comments:

- there is frustration that the GOC is not able to do more to deal with the online supply of spectacles and contact lenses from companies based outside of the UK;
- there are risks of remote care being delivered outside of the UK without supervision or oversight from a GOC registrant including:
    - risks that patients are unaware that the company providing the service is not subject to UK regulation and do not have to abide by regulatory standards;
    - risks that if something goes wrong there is no remedy for the patient as the company is based outside of UK jurisdiction;
- the lack of regulatory oversight presents risks to patients, for example, as many online companies based outside the UK:
    - do not require an up to date sight test and prescription before dispensing spectacles and contact lenses;
    - do not verify the dispensing measurements which can result in badly and incorrectly fitting spectacles and contact lenses;
    - can substitute the contact lenses prescribed by a GOC registrant with an alternative[40];
    - put profits before patient care;

[40] NB It should be noted that there is no specific legal requirement in the Act to supply contact lenses only in accordance with the contact lens specification

- patients may be unaware of these and other types of risks;
- there is a burden on registrants and the NHS as they have to deal with eye care issues that patients have had from buying online;
- online supply should be restricted to exclude those with more complex needs, for example, patients under 16 years old, patients with high prescriptions (for example, +5.00), bifocal, multifocal; and
- there is a risk that patients buying online will go less regularly for sight tests and potentially put their eye health at risk, for example, as asymptomatic conditions like glaucoma are not picked up early.

303. A sample of comments is available in the box below.

"Online businesses should not be claiming it's ok to buy glasses online and to simply "pop along to your local optician for an adjustment", they shouldn't be selling/supplying contact lenses without any evidence of a valid specification and they shouldn't be villainising the optician as a marketing ploy. We have all had the experience of a patient buying random contact lenses online, only to end up with terrible vision, ulcers, a lens "stuck" in their eye etc since they've had no appropriate instruction or care provided." Dispensing optician

"Online sales need to be regulated. It is not safe for people to be able to purchase online without a registrant who has examined the patient verifying the prescription and specifications." Optometrist

"The inability to regulate non-UK online sellers is the greatest risk to patients. Inevitably, a non-regulated seller is less likely to adhere to GOC standards which are in place to protect the public." Business registrant/employer

"In terms of remote care - there is very little evidence around this area in eyecare so clearly defined scope of practice underpinned with regulations is needed." Education provider

"There is nothing to restrict the testing of sight of a patient by an unregulated professional that is situated in another country via remote care technology. They would fall outside the jurisdiction of the GOC. The risk to patients is that they are unregulated and could cause harm. There is also risk in the GOC not being able to enforce the Act on the individual as it will continue to happen. We know this to be true from the sale of contact lenses by overseas sellers. Over the years the GOC has not been able to enforce rules on these sellers." AIO

Suggestions for addressing gaps in regulation of online sales

304. If they answered yes to the previous question, we asked stakeholders if they had any suggestions about how these gaps in the regulation of online sales of optical appliances could be addressed.

305. The following themes were identified from the comments:

- require all optical business to register with the GOC;
- all businesses providing optical appliances into the UK must be required to register with the GOC even if the company is based outside of the UK;
- the GOC should be given more regulatory powers to investigate and prosecute illegal sales. Also, the GOC should work more with overseas regulators and enforcement agencies to notify them when companies are supplying optical appliances into the UK;
- there should be more public awareness raising by the GOC about the risks of buying online and the harm that patients might face from poorly and incorrectly fitting spectacles and contact lenses;
- there must be oversight by a GOC registrant when selling online to patients;
- introducing a GOC kitemark could show the public that the business is registered with the GOC; and
- specific regulatory safeguards, including:
    - online sellers must be required to verify that the patient has an up to date sight test and prescription;
    - restrict the supply of certain lenses online, for example, prescriptions not exceeding +5.00, bifocal and multifocal; and
    - ensure that online companies are providing aftercare advice after selling contact lenses to patients.

306. A sample of comments is available in the box below.

"Ensure all websites with a .co.uk domain are registered with the GOC and following UK rules. Making sure spectacles and contact lenses are treated as medical devices and ensure that personal importation of them follows the same rules as other medical devices." Business registrant/employer

"Awareness to the public about who does and doesn't conform to GOC standards. A bit like ATOL protection for holidays where holiday goers can be reassured. A

GOC stamp of approval for optical sales where patients know they have some protection in terms of the supplier can be held to account." Business registrant/employer

"The verification of dispensing measurement by a registrant is missing. Currently patients can take their own measurements and submit them online and this can create errors in the spectacles that the patient receives meaning that patient cannot use them safely." Education provider

"The GOC should seek statutory powers of investigation to enable it to take more effective action to deal with the online sales of optical appliances. It should also give more priority to related activities, such as liaising with trading standards departments, the Advertising Standards Authority, the Competition and Markets Authority and with overseas organisations responsible for regulation and enforcement. It would not be appropriate for significant additional activity in this area to be funded by registrants so the GOC should seek public funding for this work." ABDO

"We would like to see full consideration given to these questions as part of the Government's regulatory reform programme. This should include a full review of all regulatory powers and whether they are sufficient to address current and future challenges and protect the public." PSA

GOC response – delivery of remote care and technology

307. Respondents argued persuasively that the Act has not impeded or restricted advancements in technology and remote care. In our view, the optical sector would benefit from a shared understanding of the latest developments and a mechanism to keep this knowledge up to date. We will discuss with stakeholders how best to achieve this.

308. If the existing legislation is not impeding innovation or harming patients, we recognise our own responsibility to ensure that the GOC's regulatory arrangements are proportionate and that we help to foster innovation that maintains public trust. Regulation needs to strike the right balance between protecting patients and fostering innovations in the sector which would benefit patient care.

309. We have heard from stakeholders that the use of technology and AI can cause uncertainty for registrants, for example, as the boundaries of decision-making and accountability become blurred. It was suggested that we should review our standards and guidance to reflect developments in this area and provide more advice for registrants. We will take on board these comments as part of the review of our Standards of Practice for Optometrists and Dispensing Opticians, Standards for Optical Businesses, Standards for Optical Students and guidance documents that is already in progress.

310. Issues concerning lines of accountability for decision-making are challenging all healthcare regulators, and indeed regulators across the economy and public services. It is possible that the law will evolve over time and the GOC will continue to engage with these developments. Indeed, we would welcome collaboration and cross-sector working between government departments and healthcare regulators to help develop shared approaches.

311. Other regulatory changes we are proposing, such as expanding the scope of business regulation, will also assist in managing risks that may develop. All businesses within the scope of the legislation will be subject to our standards whether they operate physically or online. Similarly, these standards require registrants to provide safe and effective care whatever tools they use.

312. The GOC's ability to act against online providers is limited by geography. This applies to providers based outside of the UK operating lawfully but providing poor quality goods and services, as well as to providers operating illegally. In its 'Safer care for all' report[41], the PSA used examples from the pharmacy, dentistry and care sectors, as well as optical services, to demonstrate this is a cross-cutting issue that has accelerated following the COVID-19 pandemic. In its report the PSA challenges governments to "ensure regulators have the agility to address the challenges brought about by new approaches to funding and delivering care, including the introduction of new technologies". We welcome the PSA's challenge and will work with relevant healthcare regulators, the PSA and governments to explore possible solutions in these areas.

313. In our GOC response to our consultation on illegal practice strategy and protocol we said:

    "The Opticians Act applies only in the UK. It is difficult to use UK law to prosecute an overseas company even where the purchaser is in the UK. There would be practical problems in presenting a hearing without the power to compel the defendant to attend a UK court. It would also be extremely hard to enforce any conviction or order.

    In addition, the criminal offences relating to supply do not arise at distribution stage - they arise at the point of sale. The Act does not provide the GOC with any legislative basis on which to act against distribution centres and we consider that to do so would be beyond our statutory remit.

    We note the comments seeking reform of the Act including additional powers for the GOC to act against illegal practice. An extension of our remit through legislative reform will require a clear evidence base linking illegal online supply and risk of harm, or risk of potential harm, to the public. The GOC encourages

[41] Professional Standards Authority for Health and Social Care (2022), *Safer care for all: Solutions from professional regulation and beyond*

the sector to provide evidence of harm caused by illegal online supply as part of our call for evidence on the Opticians Act and consultation on associated GOC policies and explain how the evidence base necessitates additional offences and enforcement powers in order for the GOC to protect the public."

314. The PSA has noted in its report for our performance review 2021/22 that we have published an updated illegal practice protocol which demonstrated a clear focus on public protection and clarified our approach to concerns about businesses or individuals outside the UK (that these should be closed, or referred elsewhere, as they fall outside the remit of UK). It welcomed the focus on our statutory remit.

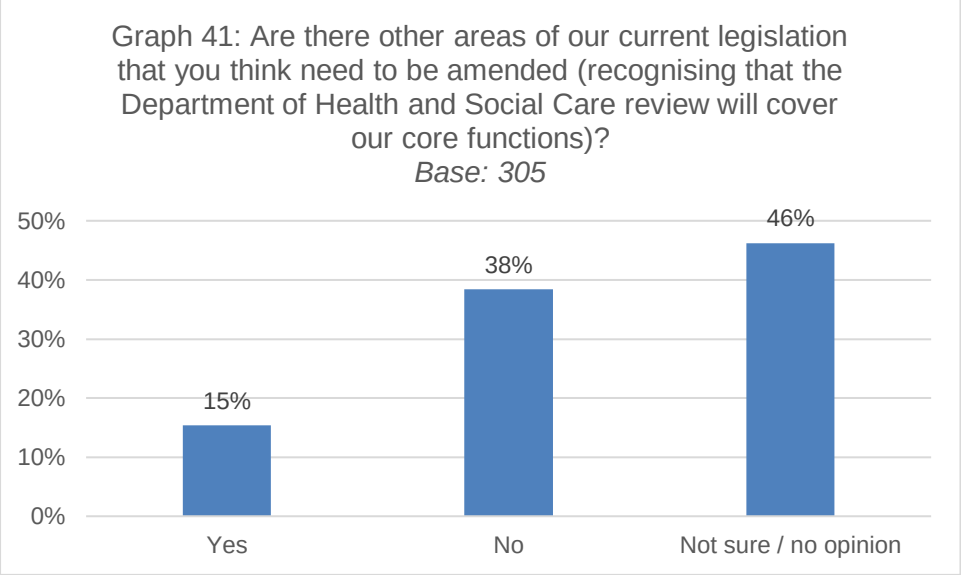
315. In summary, we recognise this is a rapidly changing area and that patient safety concerns are widely held, but that the current evidence base is weak. We will continue to keep these matters under review and discuss future approaches with DHSC, the PSA and regulators facing similar challenges.

Section 8: Any other areas

Any other areas of current legislation requiring amendment and gaps in regulation requiring legislative change

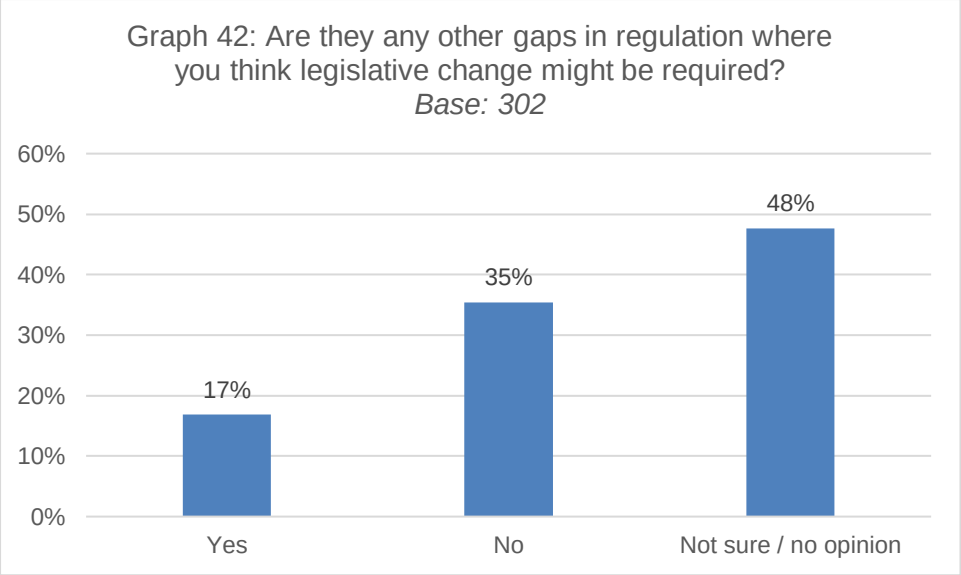
316. We asked stakeholders if there were any other areas of our current legislation that they thought needed to be amended (recognising that the DHSC review will cover our core functions).

317. Of the 305 respondents who answered the question, 38% did not think that there were any other areas of legislation that needed to be amended, 15% thought that there were and 46% were not sure or had no opinion.



318. We asked stakeholders if there were any other gaps in regulation where they thought legislative change might be required.

319. Of the 302 respondents who answered the question, 35% did not think that there were any other gaps in relation where legislative change might be required, 17% thought that there were and 48% were not sure or had no opinion.



320. Most of the comments in response to the previous two questions had already been mentioned in previous sections of the consultation and/or were not relevant to Act. The following themes were identified from the comments:

- the Act should specify a minimum length of time for the sight test – we have previously advised that it is not appropriate for the GOC to specify minimum appointment times and this extends to the Act. These can vary for a number of reasons (e.g. history of patient or size of premises) and is a matter of professional judgement. Safeguards are in place through our standards which ensure safe and effective care, and it is open to anyone to complain about a registrant putting patients at risk through inappropriate testing times;

- optometrists should be able to prescribe – optometrists can already prescribe a specific list of medicines specified in the Human Medicines Regulations 2012 and it is not clear what further amendments the respondents had in mind or the evidence for it;

- removal of student registration – this is expected to happen as part of the DHSC's legislative reform programme; and

- it should be possible to take a deposit prior to a sight test – see GOC response at the end of this section.

321. There were some specific suggestions including:

- that general practitioners (GPs) should have their right to prescribe removed – the reason and evidence basis for this was not clear and this would be a matter for other legislation, not the GOC's;

- the sections of the Act related to exemption of 'Ministers of the Crown of Government department' (sections 27(4) and 27(5)) should be removed –

we have reviewed these sections and our view is that the exemptions appear to be reasonable, for example, there should be stricter processes for supplies to individual users than supplies to a government department, NHS body and GOC registrants. We are not aware of any public protection risks associated with supplies to government bodies and it would seem inappropriate for Parliament to bind itself by preventing a "Minister of the Crown or Government department" from purchasing optical appliances;

- '…title of registered optometrist' should be replaced with 'title of optometrist' in section 28(1)(c) of the Act – we do not consider this amendment to be necessary as using the title of 'optometrist' alone is already covered in section 28(1)(a) of the Act, however, we will review the ordering of the wording in this section as we think it could be made clearer in any new legislation as part of the DHSC's legislative reform programme; and

- section 26(1)(b)(i) of the Act should be more than an optometrist confirming that he has carried out 'the examinations that the regulations require' – the reasons for this requested change were not clear and we do not consider that any changes are necessary.

322. A sample of comments is available in the box below.

"…I feel a minimum testing time of 30 minutes should be enforced in all stores…" Optometrist

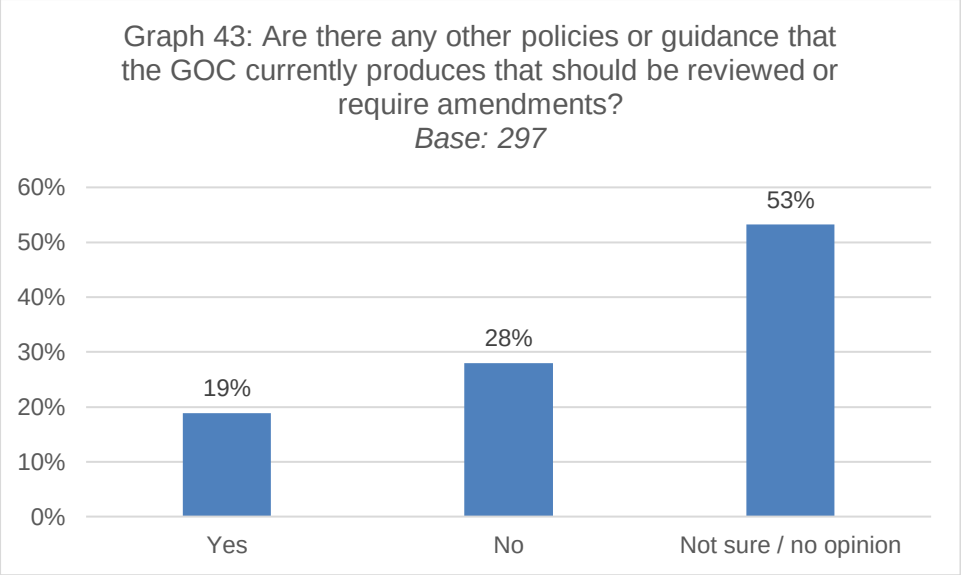
"all optometrists should be able to prescribe eye medication" Student optometrist

"The part where is says that the patient is not allowed to pay before the appointment. We should be able to take a deposit for bookings in order to protect our business as why should we have to lose out if patients do not turn up for their appointments. Other healthcare businesses are allowed to charge, why not opticians?..." Optometrist

Policies or guidance requiring review or amendment

323. We asked stakeholders if there were any other policies or guidance that the GOC currently produces that should be reviewed or required amendments.

324. Of the 297 respondents who answered the question, 28% didn't think there were any other policies or guidance that should be reviewed or required amendments, 19% thought that there were and 53% were not sure or had no opinion.



325. The following themes were identified from the comments:

- minimum sight testing times (this had already been mentioned in the context of legislation but some thought that GOC policy or guidance was a more appropriate place to address it) – as outlined in paragraph 320 we have previously advised that it is not appropriate for the GOC to specify minimum appointment times;

- further guidance on supervision of students and trainees, including how employers can support supervisors – we will keep this under review with education providers and professional bodies. It may be that it is more appropriate for providers of approved qualifications to issue this guidance to those employers or placement providers offering periods of professional and clinical experience or other forms of experiential learning; and

- if student registration is not removed, further guidance on the responsibility of students to register with the GOC – under current handbooks, providers have a responsibility to ensure that students are registered with us and we carry out student roadshows / welcome events to raise awareness of the need to register and retain. In the new education and training requirements we have two related standards: S1.1 emphasises that there must be policies and systems in place to ensure students understand and adhere to GOC standards; and S1.4 emphasises the providers' role in informing students that they must be registered with the GOC at all times whilst studying on a programme. We are not prescriptive about what the policies and systems need to be but draw attention to the requirement to have robust systems in place. This could include a system to ensure that the GOC is appropriately and regularly informed regarding any changes to class lists and having policies in place to deal with any individuals who are not registered with the GOC during their studies.

326. The AOP raised concerns about the "appropriateness and quality of the GOC's framing of allegations in FtP cases", arguing that improvement was needed in our policies, processes and training in this area. Further training on allegation drafting has taken place and we have introduced lawyers into our investigations process which we consider will improve the end-to-end approach to investigations, including the drafting of allegations.

327. The AOP also raised the need to review our declarations guidance, as they often receive queries from members on this process related to health declarations. We are planning a review of this guidance and will take the AOP's comments into consideration as part of the review.

328. There were some suggestions from individuals or organisations where the Standards of Practice for Optometrists and Dispensing Opticians and Standards for Optical Businesses could be made clearer and we will consider these as part of our review of the standards.

329. A sample of comments is available in the box below.

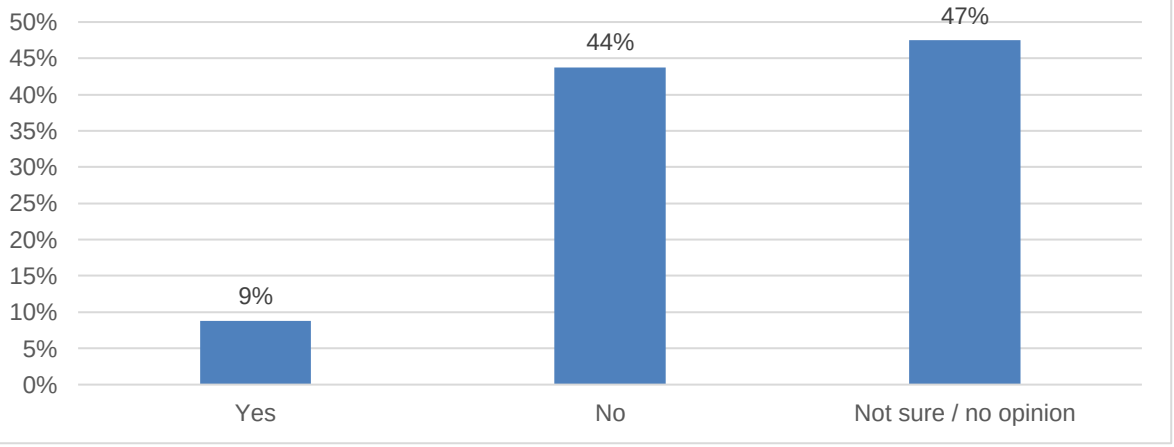
> *"Supervision of trainees and how employers can support supervisors so that they can train the future workforce safely without the commercial pressures of selling/productivity, etc."* Optometrist
>
> *"…If student registration is maintained, we suggest that the GOC make responsibility for registration 'sit' with the individual trainee, rather than making policing each student's registration part of the educator's responsibility. Monitoring of student registration by the GOC and HEIs* [higher education institutions] *at the present time is resource heavy and inefficient when individual students should be tasked with taking responsibility for their registration and the consequences of not being registered. The consequence of an individual trainee's lack of registration should not endanger a programme's accreditation status."* Optometry Schools Council
>
> *"…If student registration is maintained, we feel it is unreasonable to pass on the responsibility to check student registration on to the training provider, but this should sit with the individual registrant as it will do once they are qualified."* Aston University

Impacts of legislation

330. We asked stakeholders if there were any other impacts of our legislation that they would like to tell us about, including financial impact or impact on those with protected characteristics under the Equality Act 2010 (i.e. age, sex, race, religion or belief, disability, sexual orientation, gender reassignment, pregnancy or maternity, caring responsibilities).

331. Of the 297 respondents who answered the question, 44% did not have anything to tell us about in relation to impacts of our legislation, 9% did and 47% were not sure or had no opinion.

Graph 44: Are there any other impacts of our legislation that you would like to tell us about, including financial impact or impact on those with protected characteristics under the Equality Act 2010?
Base: 297



332. The following areas were identified from the comments:

- legislation should protect the most vulnerable, particularly those who are seen in domiciliary settings, with concern that the current legislation doesn't protect those with learning disabilities – this will be taken into consideration when we carry out impact assessments on any changes that we are proposing to make, which will then be consulted upon to allow for further views on impact;
- the language in the Act should be gender neutralised – we agree that gender neutral language should be used and that would be our expectation for any new Act; and
- any changes to legislation might impact on other healthcare professionals and disciplines (e.g. workforce needs and multidisciplinary teams) or cause unwanted financial burden for the optical sector – this will be taken into consideration when we carry out impact assessments on any changes that we are proposing to make, which will then be consulted upon to allow for further views on impact.

333. A sample of comments is available in the box below.

"…The vulnerable need greater protection through greater sanction of the use of registrants by businesses particularly when the patient is dispensed, or the optical appliance delivered to them for fitting, in their own home…" CPD provider

"…It is our opinion that regulation and associated guidance should be predicated on ensuring equality of access and that any patient is not disadvantaged because of a protected characteristic or at any point over their life course.

Some patients with a protected characteristic are more susceptible/at risk of eye disease or sight loss for reasons including:

- *Eye disease is more prevalent in some groups, for example Asian and Black ethnic groups are at greater risk of eye disease such as glaucoma and diabetic retinopathy*[42]
- *Contributing factors, for example pregnancy or fertility treatment can cause blurred vision or cause refractive change*[43]
- *Some people can be excluded or disadvantaged from accessing healthcare, for example black communities in the UK are less likely to attend primary eye care appointments despite the increased risk of sight loss*[44]*"* AOP

"Please see elements of our response elsewhere with relation to people with learning difficulties, in its current form the legislation puts them at greater risk of sight loss." RNIB

GOC response – any other areas

334. We have considered the suggestions in this section. The one area that we agree where a change in the Act may be required is in relation to enabling a deposit to be taken prior to a sight test – our initial view is that it seems reasonable to be able to take a deposit for a sight test given that other healthcare professionals may charge cancellation fees. If we consider that we do wish to pursue a change in this area, we will carry out further consultation to further understand the impacts and ensure that there are no unintended consequences of a change in policy and/or legislation.

[42] Scase, M.O. and Johnson, M.R. (2005), Visual impairment in ethnic minorities in the UK, *International Congress Series* 1282 (2005) 438-442

[43] https://www.aop.org.uk/advice-and-support/for-patients/eye-care-blogs/2020/09/17/how-your-eyesight-changes-during-pregnancy

[44] Elam, A.R. and Lee, P.P. (2013), High-risk populations for vision loss and eye care underutilization: a review of the literature and ideas on moving forward, *Surv Ophthalmol*, 2013 Jul-Aug; 58(4): 348-58