GOC – Call for evidence on the Opticians Act and consultation on associated GOC policies

About us

FODO is the leading association for eye care providers working in primary and community care settings across the UK. Each year, our members provide the vast majority of eye care in these settings, including over 18 million eye examinations and a wide range of other eye care services.

About our response

We have undertaken an extensive review of the legislation and literature, met with subject matter experts to discuss technical issues and consulted our membership to help inform our submission to this GOC call for evidence and consultation. This has included holding 15 workshops with more than 100 people from a representative sample of our members, including individual GOC registrants, independent practices, and regional and national eye care providers.

Our work has shown the Opticians Act to be a robust and successful piece of patient protection legislation which has stood the test of time – evidenced by high standards, relatively low levels of patient complaints and fitness to practise sanctions, enabling the safe adoption of new technologies, care models and changing the scope of practice.

The evidence we have reviewed and shared in our submission below also demonstrates that the sight test in the UK (by virtue of being a comprehensive assessment of vision and eye health) is a major population and public health benefit. Few countries have an eye care service that is as accessible, safe, and cost-effective as primary eye care in the UK.

The only changes that would help improve equality in access to eye care in the UK are linked to NHS commissioning, which is outside the scope of this consultation. The Opticians Act is predicated on safe patient choice for all and does not need to be updated in this regard.

Our response below provides an overview of our analysis of the evidence against the GOC's stated objectives. We would be happy to work with the GOC and sector partners following this call for evidence and consultation to ensure the UK population continues to benefit from world-class primary eye care services both now and in the future.

Our response

We answer the consultation questions below.

1. What is your name?

Daniel Hodgson

2. What is your email address?

healthpolicy@fodo.com

3. Which category best describes you?

☒ Professional/representative body

4. Are you responding on behalf of an organisation?

☒Yes

☐ No

Q5 : Are these the right objectives for the GOC for legislative reform?

☒Yes

☐No

☐Not sure / no opinion

We acknowledge that while the GOC notes the objectives are “non-hierarchical” it also clearly states that objective 1 – maintaining patient and public safety – is its primary objective (Paragraph 14). We fully support objective 1 being the primary objective.

As our evidence submission demonstrates, the UK population in all four home nations

- can access high quality eye care from GOC registrants
- report high levels of satisfaction with primary eye care and few complaints
- benefit from access to comprehensive and advanced diagnostic tests
- do not have waiting lists to access primary eye care services[i]
- continue to access affordable eye care and vision correction (spectacles, contact lenses and other visual aids) to meet all needs.

These benefits are driven by primary eye care responding and investing, as it always has, in workforce, premises and equipment to meet patient needs in a timely and safe way. This is through registered eye care professionals and support staff operating in a responsive care setting underpinned by the patient and population safeguards set out in the Opticians Act.

Whether the optical sector is reviewed in isolation or in comparison to other healthcare sectors, it is clear that the Opticians Act is a robust piece of patient protection legislation which has stood the test of time whilst enabling safe adoption of new technologies, care models, and changing scope of practice.

We therefore support the GOC’s view in section one:

[i] Most GOC registrants work in primary eye care settings. A small proportion work in secondary care where there are significant issues in accessing timely care, resulting in avoidable sight loss. The root cause of those issues is NHS commissioning decisions, not the Opticians Act. We would be happy to discuss NHS commissioning issues separately with the GOC if that would be helpful but, in our view, it is not in the public interest to muddle commissioning choices (public financing in particular) with healthcare regulation (this consultation).

- "A successful case for change will need robust and compelling evidence" (paragraph 14)

This is the right approach, and in our view, provided the GOC follows the objectives it sets out in section one, this will help

- avoid unnecessary legislative change
- minimise the risk of unintended and adverse impacts on 67 million people across the UK, who currently benefit from the provisions of the Opticians Act by way of easy and affordable access to safe primary eye care, and the sight test which is the bedrock of the whole UK eye care system and the gold standard for other nations.

Q6. What activities should non-registrants be restricted/prevented from doing?

The current balance of protections and restrictions works well, and these should remain as they are.

Having taken account of

- our review of the literature
- our consultation with our members and other sector bodies
- the GOC's requirement for evidence to support change and the objectives set out in section one

we see no evidence-based reason to require any change to the existing framework.[ii]

Please see our responses to later questions in this consultation for more detail.

Q7. What activities do you think must be restricted to our registrants?

Please see our response to question six.

Q8. What are your views about continuing to restrict/prevent non-registrants from carrying out the following activities?

On patient and population protection grounds, the evidence suggests that

- ☒Testing of sight: should be restricted
- ☒Fitting of contact lenses: should be restricted
- ☒Selling optical appliances to children under 16 and those registered visually impaired: should be restricted
- ☒Selling zero powered contact lenses: should be restricted

[ii] 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.

Q9. Are there any additional activities that you think should be restricted to registrants?

No. Please see our response to question six.

Q10. 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)?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

Our members

- provide most primary eye care in the UK – e.g. >80% of sight tests, and a large proportion of all contact lens fits, aftercare, and supply of optical appliances, and enhanced eye care services
- include individual registrants with a wide range of qualifications who have expanded their scope of practice – e.g. IP optometrists
- include practice owners (of all sizes) who train and employ more than 95% of all pre-registration optometrists and dispensing opticians.

In our workshops on the GOC call for evidence and consultation on the Act and associated policies, most of our members said

- the GOC's current system strikes the right balance regarding what post-registration skills, qualifications and training need to be accredited or approved by the GOC
- there is no evidence-based reason to expand this further.

To meet GOC objectives 1, 6, 7 and 8, members also felt strongly that the GOC should

- avoid creating unnecessary barriers to further education and training
- avoid creating any new monopolies in the education supply chain which could increase costs and stifle innovation in, and access to, training
- support registrants to expand their scope of practice in more modern and flexible ways.

Members who also work with or employ registered audiologists[iii] pointed to the HCPC's more flexible approach which has helped audiology evolve to meet changing patient needs by trusting registrants to develop and comply with regulations as they expand their scope of practice (see boxes below).

Based on this feedback

- we support GOC registrants having access to a wide range of post-registration, training skills and qualifications but do not think the GOC should have overly prescriptive or unduly restrictive processes in place to approve these programmes
- the current regulatory regime strikes the right balance and does not require the GOC to accredit other skills/qualifications etc

[iii] HCPC registered hearing aid dispensers and clinical scientist with a specialism in audiology

- we would welcome statements like that from the HCPC, which would support GOC registrants in developing their skills and providing a wider range of eye care services over time, whilst protecting the public – e.g. registrants seeking advice from professional bodies and their medical malpractice insurance provider that they are working within the scope of UK law and are covered by appropriate insurance to comply with GOC standards.

This approach would meet all eight of the GOCs objectives in section one, and especially objectives 3, 6, 7 and 8.

Identifying your current scope of practice

The HCPC does not define our registrants' scope of practice

This means there is a not a set list of tasks that our professions can and cannot perform and this will vary from registrant to registrant.

When you first join the Register, the Standards of proficiency will be your guide. These set clear expectations of our registrants' knowledge and abilities when they start practising.

As you progress in your career, you may enter into more specialist practice roles where you are no longer meeting all the Standards of proficiency. Your scope of practice will develop with you and may become narrower in scope.

Determining what is and is not part of your scope of practice will be for you to decide using your professional judgement.

When deciding whether a particular activity falls within your scope of practice, or when moving into a new scope of practice, you will need to consider whether the training and support you've received adequately equips you to perform the activity safely and effectively.

You will also need to consider whether the activity falls within the general scope of practice of your profession.

Your scope of practice may also depend on the limits of your job role, legal restrictions (such as prescribing or protected functions) and whether you would be covered to undertake the activity by your professional indemnity insurance.

You may find it helpful to speak to your professional body who may be able to offer further advice in this area.

Source: HCPC[1]

Your scope of practice

[….]

As long as you make sure that you are practising safely and effectively within your given scope of practice and do not practise in the areas where you are not proficient to do so, this will not be a problem. If you want to move outside of your scope of practice, you should be certain that you are capable of working lawfully, safely and effectively. This means that you need to exercise personal judgement by undertaking any necessary training or gaining experience, before moving into a new area of practice.

Source: HCPC[2]

Q11. Does the basis for extension of business regulation outlined in our 2013 review of business regulation still apply?

☐Yes

☒No

☐Not sure / no opinion

Summary

- Based on member feedback, research, and paragraphs 21-25 of the GOC document, we agree that there is merit in exploring the benefits and costs of requiring all providers which offer restricted activities (as defined in paragraph 24) to register with the GOC. The final decision however should be based on evidence and the GOC meeting objectives 1, 5, 7 and 8 in section one. This warrants further consultation with key sector bodies.

- We have significant concerns about how paragraphs 27-30 have been framed. In our view, this risks not meeting the objective in section one of being evidence-based. Analysis of evidence, including the original GOC commissioned research from European Economics, and meeting objectives 6, 7 and 8, will show there is no case for the GOC to have new powers to inspect premises. Drawing parallels with pharmacy regulation and CQC registration is misplaced given very different risk profiles.

- Overall, the evidence presented below demonstrates a well-functioning sector, with high levels of patient satisfaction, with good access to accountable eye care providers. There is no evidence of market failure that warrants adding costs and complexity to existing business regulation, especially not inspection visits, which would ultimately be funded by patients or the NHS to the detriment of forgone clinical care.

Full response

Section three risks muddling different issues and unintentionally confusing the content of past reports and the body of evidence for enhanced regulatory powers. We therefore think it is important to address this question in two parts, as below.

Paragraphs 21 to 25 – 'level playing field'

We agree with the GOC that the current business regulatory regime can be confusing and create, in some cases, an unlevel playing field (paragraphs 21-23).

We consulted members for their views on this issue. There is general support for the GOC to consider bringing all providers which offer restricted activities (as defined in paragraph 24) into the scope of business regulation for reasons the GOC sets out in paragraphs 21 to 24.

However, there are important caveats:

1. Paragraph 23 of the GOC consultation refers to data from 2013 which suggests there were then 4,000 optical businesses not registered with the GOC. Even if this data holds true today, and it is most unlikely that it does, then it still misses the point that GOC registered businesses provide more than 80% of primary eye care in the UK.

2. Many smaller providers who cannot register (for reasons set out in paragraph 23) already comply with the GOC business standards by virtue of their owners being individual registrants and/or employing individual registrants. Many smaller providers would also be willing, and in some cases wish to, change their name to include a protected title and register with the GOC, but are prohibited from doing so because they cannot fund sufficient individuals to meet the requirement for over 50% of directors to be GOC registrants.

3. The evidence shows that patients are very satisfied with primary eye care providers across the UK,[3,4] complaints are relatively rare,[5,6] and primary eye care continues to perform well relative to other healthcare services in recent surveys.[7]

4. Regulation is not the only driver to secure standards and patient centric care at a provider level. Eye care providers for example have shown over a sustained period, that patient choice and competition results in responsive services and investment in evidence-based technologies (e.g. OCT) and other improvements, while keeping costs down for patients and the NHS.[8,9,10,11.]

Hence the marginal benefits of extending regulation vs the real scale of risks and the costs of doing so, needs to be considered in more detail.

Taken together, it is clear that primary eye care is functioning well from a public policy perspective, and there is no evidence of market failure including safety issues. On the contrary, there is evidence that UK patients and healthcare systems continue to benefit from the existing regulatory framework as providers invest to meet patient needs by enhancing the care offering whilst controlling costs (See endnote 12 for more information).

There is a theoretical risk of future market failure (just as there was at the time of the original European Economics report), on grounds of an unfair playing field, where providers which operate outside the GOC business standards might start to adversely impact the existing eye care infrastructure in the UK and put downward pressure on the standards of incumbent providers. It is for this reason the GOC bringing all providers which offer restricted activities (as defined in paragraph 24) into the scope of business regulation looks attractive but there are still questions about whether it is worth amending legislation given the scale of risk.

In summary

- Although the principle of bringing all businesses, that offer restricted activities (as defined in paragraph 24), into the scope of GOC registration looks appealing, we feel there should be further exploration of the evidence (which paints a mixed picture on the pros and cons) before any legislative amendment is considered
- As part of this process, it would be important to explore and address current obstacles to business registration – e.g. requiring the majority of directors to be GOC registrants

We would be happy to help the GOC explore these issues and develop solutions in more detail.

Paragraphs 26 to 30 – non-evidence based

We were disappointed to see how information has been presented in paragraphs 26 to 30.

We are concerned that this might lead some readers to misunderstand the evidence, and wrongly assume the GOC's references to the CQC, GPhC and GOS compliance somehow

suggest GOC business regulation needs to be strengthened when there is no evidence to support doing so (see endnote 13 for more information).

In 2013 the GOC Council reviewed research it had commissioned from European Economics (EE) on Benefits and Costs of Business Regulation.[14]

The GOC has since referred to learnings from that EE research, and Council discussions on that research, without examining the wider body of evidence about whether potential risks identified in the EE paper have been realised. Certain assumptions by EE researchers have stood the test of time but others have not, and these factors must be considered when thinking about the future of business regulation. For example:

- The GOC, on reading EE research, had "concluded that there was little direct evidence of patient harm arising from poor business practices".[15]

This remains the case today as primary eye care is provided by GOC registrants in accordance with the Opticians Act and GOC standards, and in most cases also by GOC registered businesses (see above) and again in compliance with GOC standards.

Also, although EE research found little evidence of harm from business practices, researchers provided a conceptual framework to understand potential risks. EE for example hypothesised:

  - Competition could result in cutting costs as practices compete on price[16], and this could result in "under-investment in equipment" due to the NHS underfunding the sight test[17]

  - By nature of being private profit-making businesses, providers might support business practices that increase the risk of missed pathology etc.[18]

Hence EE proposed a framework for "areas of optical practice that are essential for good patient care and which are influenced by business practice"[19]. This was, in the main, at the time logical and based on a traditional model of economic incentives.

Today, knowledge about health and behavioural economics has significantly advanced. It is not that surprising therefore that many EE assumptions have been disproved. For example:

- The NHS has continued to underfund the GOS sight test, however practices have continued to invest in diagnostic equipment, driven by professionalism and patient choice and competition, which have accelerated take-up, a trend which has seen digital photography, OCTs and other tests normalised for millions of people over a very short period involving significant capital equipment and training investments for businesses.

- The average number of sight tests performed by an optometrist has reduced over time, as eye tests take longer. Today FODO members for example report that the average optometrist performs 11-13 sight tests per day. In contrast, non-profit providers, including NHS hospitals, and other primary care professionals, like GPs, are all suffering from overstretched capacity and despite the population ageing, number of patients needing to be forced through the system each day has increased significantly since 2013.

- Today patients spend less of their income on eye care than in the past but receive more complex care from GOC registrants.[20]

- The GOC's own research shows that 96% of people surveyed in 2021 were satisfied with their optician. It also found that 90% remained confident of receiving high standards of care from an optician, compared to 91% from a pharmacist, 90% from a GP and 89% from a dentist.[21] This is in contrast to the wider trend highlighted in the most recent British Social Attitudes (BSA) survey which shows that overall "satisfaction with the NHS is now at 36 per cent, down 17 percentage points from 2020, the lowest level recorded since 1997".[22]

The real value in a framework to understand risks, is how well it predicts (or validates) actual events. In the case of business regulation and the original EE framework, time has shown that increased business regulation was not necessary to secure good patient care. This is unsurprising because we know

- Providers that provide most eye care are already registered with the GOC. Hence most of the market complies with GOC standards and this sets norms
- Both NHS and paying patients can exercise the same choices; and given asymmetric information in primary eye care is less of a problem than in other areas of healthcare, patient choice provides a powerful incentive for providers to improve quality and choice
- This is boosted by the fact that any asymmetric information between the provider and patient is self-correcting in most cases[iv], enhancing provider incentives to improve care
- Primary eye care providers fund their own, non-subsidised, medical malpractice insurance premiums. As poor claims history can result in unsustainable insurance costs providers have an incentive to maintain high standards
- The sector is customer centric and has continued to innovate to meet expectations. Hence investment in technology and offering advanced evidenced-based diagnostics, rather than cutting cost to maximise hypothetical profits
- Put simply patient choice and competition have worked in primary eye care services, and benefited patients and the NHS

The incentives and safeguards provided by the Opticians Act, combined with GOC rules and standards consequent to the Act, operate incredibly well. This is efficient and works in the interests of patients and consumers and outperforms many other healthcare sectors in these regards.

In the latest GOC public perceptions research for example, Steve Brooker, Director of Regulatory Strategy at the GOC said the GOC was "delighted that public satisfaction remains high" adding praise for "delivering high-quality eye care to the public."[23]

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.

Q12. Are there any advantages, disadvantages and impacts (both positive and negative) of extending business regulation in addition to those identified in our 2013

[iv] For example, people know they cannot see well when they collect spectacles and can return for a recheck, complaint, select a different optician etc, but don't know whether a surgery to remove a cancer has been successful or not unless a doctor explains it.

review of business regulation? (Impacts can include financial and equality, diversity and inclusion.)

☒Yes

☐No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these

If the GOC is to extend business regulation it will need to review current obstacles to business registration. For example, our smaller members have told us that, sole traders or small family run companies might not have the staff numbers to appoint GOC registrants as directors; and especially not meet the requirement for >50% of directors to be GOC registrants.

The GOC should therefore consider how to modernise this requirement – e.g. instead require a board of directors to put proportionate arrangements in place to ensure a GOC registrant(s) are involved in designing practice systems and helping secure compliance with GOC standards.

In addition, please see our response to question 11.

Q13. Do you think the GOC could more effectively regulate businesses if it had powers of inspection?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

We address some concerns we have with this proposal in our response to question 11.

This proposal is not evidence-based and risks failing to achieve GOC objectives 6, 7 and 8.

In November 2012 the GOC commissioned European Economics (EE) to undertake research into the Benefits and Costs of Business Regulation. That research did not support the case for business inspections, see table copied below.

Option	**Cost: ongoing**	Cost: one-off	Benefit	**Wider Impact**	**Proportionate**	Targeted	Transparent
Option 5 – Extend business registration, enhance code of conduct **and establish inspections and audit**	**High**	Low	Greater oversight	**Not proportionate to risk**	**No**	Yes	Yes

Extract: Summary table, page 64 of evidence presented to GOC council in 2013.[24]

In 2013 the direct ongoing cost of this proposal, was estimated to average out at £1,000,000 per year (£1.13mn in 2021 prices) for the GOC.[25] It noted each inspection would take on average 1.2 days but this estimate did not estimate the cost of this regime for optical businesses.

EE noted the costs to businesses was uncertain but estimated it would take a compliant business a day of registrant's time per premises to prepare for inspection and be present at an inspection. It then assumed the total cost would be £400,000 per year (£452,000 in 2021 prices).[26] This was based on a cost of £150 as "daily forgone earnings of an optometrist". Those familiar with the sector and such regulatory regimes will know

- that even compliant businesses will have to invest more time than this for a practice visit
- the forgone income of an optometrist is more than £940 per day[v], not £150

Hence, conservative estimates would suggest the direct cost to business would be at least £2.5 million per year, plus the increase cost of GOC fees of £1 million. In total £3.5m per annum.

More importantly, this would represent a significant impact on clinical capacity, and use of clinician time for a non-evidence-based inspection regime, time which would be better spent seeing patients.

It is therefore not surprising that the GOC has also noted that EE "did not consider the risks relating to business practice to be significantly high but concluded that there was enough evidence to suggest that a proportionate yet comprehensive system of business registration would be desirable".[27] An inspection regime would not be a proportionate system of regulation based on evidence in the public domain.

Hence, on reviewing the body of evidence, the current framework of business regulation would be the most proportionate mechanism in terms of cost versus benefit. As noted above, there is merit in exploring bringing all businesses into the existing regulatory regime, but nothing further than this (see our response to question 11).

In summary, given the lack of evidence to support an inspection regime, we strongly oppose the diversion of registrant funds and sector resources to fund an inspection regime, as this cost will ultimately be borne by patients and the NHS, and is essentially a proposal which the GOC's own research showed was not proportionate to risk even when likely costs and use of registrants time was underestimated.

Q14. Is there an alternative model of business regulation that we should consider?

☐Yes, the GPhC model of a responsible pharmacist

☐Yes, another model (please specify)

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these

As explained above, the evidence shows that the current regulatory regime works well.

[v] Assuming conservatively, an average 12 tests per day, at £22 each (£224), 50% of patients having new spectacles with an average dispense of £120 (£720).

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.

UK governments have been clear that they support proportionate regulation, and that cost of regulation is always funded by patients – either directly through higher prices, via NHS funding, or forgone care because the NHS has fewer resources to allocate to frontline care. We think any new regulatory burdens on providers, especially given lack of new NHS funding for clinical care, need to be avoided.

Q15. Should dispensing opticians be able to undertake refraction for the purposes of the sight test? (NB This would be possible only if the GOC were to amend or remove its 2013 statement on refraction.)

☐Yes – with no restrictions

☐Yes – under the oversight of an optometrist or registered medical practitioner

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

Having undertaken a wide consultation with members, sector partners, and reviewed the evidence of what works, in our view there is strong agreement:

- the sight test should remain as it is and should not be split up into a refraction and separate eye health examination (see our response to questions 17-20)
- Section 24 and 26 of the Act should not be changed, to do so would be inconsistent with GOC objectives in Section one, especially objectives 1, 7 and 8.

On this basis, it is not possible, practical or proportionate (when considering patient benefits and overall costs and risks) to support ‘yes without restrictions’ as this would fall short of many GOC objectives in Section one. We also feel that answering yes to this question (given how it is framed) would risk failing to meet GOC objective 7 and 8. That is why we have answered “no”.

However, we take the thrust of this question to be to clarify whether and how optometrists and medical practitioners can be supported in performing a sight test in a way that is consistent with Section 24 and 26 of the Act. In this case, we do not feel this warrants any change to legislation although it would require some minor clarification of the GOC’s 2013 statement. We set out our proposal in response to question 16.

Q16. What would be the advantages, disadvantages and impacts (both positive and negative) of amending or removing our 2013 statement on refraction so that dispensing opticians can refract for the purposes of the sight test? (Impacts can include financial impacts and equality, diversity and inclusion impacts.)

Please give your reasons and provide any evidence to support these.

We have taken legal advice and 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.

As we have set out in our response to question 15, 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 as follows:

The General Optical Council statement on the testing of sight.

Statement on testing of sight

Refraction for the purpose of issuing a prescription is an essential part of the sight test [1]. As such, refraction for the purpose of sight testing is restricted [2] and can only be conducted by a registered optometrist, a registered medical practitioner or a student optometrist under supervision.

Sight testing therefore remains the responsibility of a registered optometrist or registered medical practitioner. However, this does not prevent a registered optometrist or medical practitioner working with a multidisciplinary team to test sight and meet patient needs in a safe and effective way that is consistent with the Opticians Act.

This might for example include trained staff collecting initial clinical information (e.g. fields, pressures and refractive data) which the optometrist or medical practitioner then uses and interprets as part of the sight test.

Footnotes

[1] under Section 26 of the Opticians Act 1989 (as amended by the Opticians Act 1989 Amendment Order 2005) and the Sight Testing (Examination and Prescription) (No. 2) Regulations 1989.

[2] by Section 24 of the Opticians Act and Rule 3 of the Testing of Sight by Persons Training as Optometrists Rules 1993.

Q17. Does the sight testing legislation create any unnecessary regulatory barriers (not including refraction by dispensing opticians)?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

If access to primary eye care services and quality of care across the UK are compared with other health services, it is clear that the current sight testing legislation has stood the test of time and secured widespread access to care. It is also a fundamental enabler to improving access to affordable, innovative and world leading primary eye care services in all four home nations.

As we set out in more detail in our response to question 20, the sight testing legislation has provided a firm foundation which underpins the UK's eye health system and, without it we would have no effective way of meeting vision and eye health needs either in primary or secondary care.

As the current legislation is working in the best interests of patients and meets the GOC's objectives in Section one, no change that we can see is required.

Q18. What would be the advantages, disadvantages and impacts (both positive and negative) of sight testing legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

As set out in our response to questions 15-17 and 20, the sight test in the UK (by virtue of being a comprehensive assessment of vision and eye health) is a major population and public health benefit. Few countries in the world have an eye care service that is as accessible, safe, cost-effective, as primary eye care in the UK.

When considering the value of a sight test, and the level of rapid population access to this service, it is a remarkable success. Public satisfaction is high, and primary eye care invests heavily in meeting changing population needs and wishes.

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.

Q19. Do you have any data on the number/percentage of referrals that are made to secondary care following a sight test / eye examination?

☒Yes

☐No

☐Not sure / no opinion

If yes, please provide details of the evidence and where it can be obtained.

Referrals to secondary care following a sight test/eye examination

We have some concerns about inferences the GOC hopes to draw from this question, as it risks missing an opportunity to fully capture the value of the care registrants provide and the full benefits of a sight test.

To start however, we answer the GOC's specific question:

- Historically FODO collected referral data from members following a sight test. Between 1982 and 2014 the referral rate ranged between 3% and 5%.[28] This is supported by published peer-reviewed research, for example:

    - El-Abiary et al. report on ISD statistics that show the referral rate from community optometry in Scotland to hospital was 4.1% in 2018/19.[29]

    - Shah et al. report on an analysis performed by other researchers of 650,000 GOS sight tests in England showing a referral rate of 5.1%, with patients aged 60 and older four times more likely to be referred than a child [30]

We would like to add the following evidence.

False positive referrals

We would like to take this opportunity to address a common misrepresentation of referral data and incorrect inferences that follow about the quality of the sight test.

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.

- In response to such claims, an audit of 1,000 referrals to an eye hospital found "data do not support any opinion that would suggest that referrals from optometrists following community-based sight tests result in disproportionally high levels of false-positives for our borough." The research found the false-positive rates of only 6.2% which was "very similar to those observed by Pierscionek et al"[31]

- Davey et al., found that the "proportion of false positive referrals generated by optometrists decreases with experience at a rate of 6.2% per year since registration ($p<0.0001$)"[32], which shows that as optometrists gain more experience they, on average, refer less. This is also to be welcomed as it shows newly qualified optometrists work within their scope of practice, err on the side of patient safety, and that their skills and confidence in clinical decision-making grow over time.

- Harvey et al., provides more information on the reason for referral, with cataract being the leading cause, followed by referrals for YAG laser, glaucoma, wet-AMD. The paper adds that referral quality was also generally good, with the optometrist's provisional diagnosis being accurate in most cases.[33]

- In Scotland GOS data show that sight tests detected 480,287 cataracts, noted 261,346 cases of external eye disease, 56,477 cases of glaucoma/hypertension, 130,038 macular problems, and more than 27,468 neurological disorders and other conditions.[34]

This is important, because 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.

The specific issue at hand in fact relates to a subset of referrals for suspect glaucoma, where there is often a 50% false positive referral rate in regions where the NHS does not fund enhanced diagnostics. Even here, those who conclude the false positive referral rate for glaucoma is through some defect in the sight test misunderstand what the sight test is (vision correction and preliminary case finding) and confuse NHS commissioning choices with clinical issues.

Firstly, it is perfectly reasonable that an optometrist or medical practitioner should conclude a sight test once they have met legislative requirements guided by The College of Optometrist standards for performing a sight test, and that is what happens today. It is unreasonable for an optometrist or any health care provider to be expected to provide additional unfunded repeat and enhanced diagnostics, as this is a standard which no GP or hospital would meet either.

For example, a GP would not be failing a patient by referring patients exhibiting signs of a disease to hospital if that were the only place the NHS funded additional tests to confirm a suspect diagnosis, nor would it be possible for the GP to invest in diagnostic tests which the NHS chooses not to fund in primary care for millions of patients.

The statistics are supported by Professor Nicolas Rumney who has explained that given the low prevalence of glaucoma and the nature of a sight test, and the fact it is not a glaucoma refinement service, a 50% false positive rate is what one would expect.[35] Thus, the high positive referral rate in this instance is the consequence of local NHS decisions not to commission enhanced diagnostics in primary care, not the sight test.

Thus, 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.[36,37,38,]

It is therefore important not to conflate and confuse the false positive rate for glaucoma referrals with other referrals rates following a sight test or the sight test itself. The evidence presented above shows referral quality following a sight test is, in general, very good.

We would therefore ask the GOC to examine any claims that a sight test is not fit for purpose because of false positive referral rates for glaucoma referrals, with caution as this at best misunderstands the disease, diagnostics and scope of a sight test, and at worse deliberately aims to mislead.

Referrals to extended services and other healthcare professionals

We appreciate the GOC question focusses on referrals to secondary care following a sight test, however this risks overlooking the fact that optometrists increasingly provide enhanced eye care services and therefore refer within primary care following a sight test. For example, referral refinement following a sight test which can help improve the accuracy of referrals that go to secondary care enabling more patients to be managed within primary care – e.g. by an IP optometrist or special interest optometrist etc.

Optometrists also refer to GPs following the detection of risk factors for poor health during a sight test – e.g. signs of potential high blood pressure, elevated cholesterol levels, and diabetes risks etc.

All of these are benefits which flow from the sight test. For example, GOS data in Scotland show:

- sight tests resulted in more than 19,000 cycloplegic refractions for children, additional diagnostic tests for >78,000, and a dilation in more than 9,000 adults[39]
- in 2019, 33,459 patients were referred to a GP, 96,315 to a hospital, 5,828 to another optometrist, 17,929 to a care pathway, and more than 2 million were managed by the optometrist without referral.[40]

We would be happy to share the source files for this and other data with the GOC, please email healthpolicy@fodo.com for copies.

Q20. Are you aware of any data to support or refute the case for separating the refraction from the eye health check?

☒Yes

☐No

☐Not sure / no opinion

If yes, please provide details of the evidence and where it can be obtained.

Summary

There is no evidence to support separating refraction from the eye health examination in a UK setting. On the contrary, there is a strong case to maintain the sight test as now - a comprehensive assessment of ocular and vision health – which picks up most pathology at an early stage.

As defined in Section 24 and 26 of the Act, the sight test prevents sight loss through early identification and referral (often before symptoms are noticed by the patient and irreversible sight loss sets in), detects other health conditions, reduces pressure on other health and social care services, including the human and financial costs associated with falls and permanent vision loss.

The sight test as defined in the Opticians Act also provides the bedrock of the UK's eye health system (universal primary care infrastructure, high levels of training and professionalism for all eye health professionals when compared say with Europe etc.), and any changes could have significant adverse effects on the whole system including the sustainability of primary eye care services, and increasing pressure on the wider health (GPs and hospital eye services) and care (greater visual impairment and disability) system.

We provide our detailed feedback in a series of themes that have emerged from our workshops with members and the sector, and our desk-based research of the evidence.

Leading primary eye care services

The UK has one of the world's most advanced primary eye care services, and the sight test provides the basis for this.

The sight test has driven investment in primary eye care infrastructure and education and training, and as a result, the average optician practice in the UK has diagnostic equipment and optometrists trained to a level one will not find in optician practices in Europe (Ireland being the exception which also has a national sight test model).

This is only possible because of the comprehensive nature of a sight test in the UK.

Population and public health benefits

Our advanced sight test service, supported by highly qualified optometrists, dispensing opticians, and world class primary eye care infrastructure means 67 million adults and children in the UK can access an eye health examination and refraction (with detailed binocular vision assessment) close to home.

There is no credible evidence to support separating the refraction from an eye health examination, and to do so would put the nation's eye health at risk – e.g. due to missed pathology and harming investment in primary eye care infrastructure with knock on effects on the rest of the NHS, including GPs and the hospital eye service.

To explain further, each year optometrists provide the vast majority of 22 million sight tests in the UK.[vi] This is a major population and public health intervention, which helps detect and manage eye conditions in a timely and accurate manner (see data shared in our response to question 19) and helps correct sight and prevent vision loss. Separating the refraction and sight test would be undoing what other countries hope to achieve.

Also, there would be significant consequences for the rest of the NHS, for example

- Today most eye conditions are detected during a sight test. Most optometrist referrals are accurate (see our response to question 19) and this is how the NHS in the UK prevents avoidable sight loss. Separating the refraction from an eye health examination would increase risk without any benefits. It would for example increase pressure on ophthalmology departments, with people presenting later and as more complex patients due to delays in identification and diagnosis.

- Even with one of the most advanced primary eye care services in the world, it is estimated that 1.5% of GP consultations in the UK are for eye problems (50 consultations per 1,000 population per year).[41] If the refraction and eye health was split, it is very likely more patients would visit their GP about eye health related issues which is the opposite of what UK governments and health systems are trying to achieve. This is at a time when GPs are struggling to meet needs of patients, and when we have finally seen a positive trend showing more patients are now likely to consult an optometrist first if they have an eye related issue compared to in the past.[42]

For a scale of eye health risks (in addition to the data shared in response to question 19 and above)

- Based on an epidemiological model, there are likely to be more than 5.7 million people in the UK living with a sight-threatening eye condition.[43] A large proportion of these people will have their eye condition detected or monitored during a sight test only if it includes an eye health and a refraction check, as the two in combination offer a more comprehensive picture and help clinicians form a more accurate diagnosis

- Fight for Sight notes that every day 250 people start to lose their sight in the UK. There are more than 600,000 people with AMD, and more than 500,000 people are referred for cataract surgery each year.[44] Almost every single one of these people benefits from a UK defined sight test

[vi] A small proportion are provided by pre-registration students and a smaller proportion by OMPs.

People understand and value the preventive aspect of a sight test

The GOC's own research shows that a large percentage of the population invest in regular sight tests.[45] A survey of 10,000 adults across the UK has also shown that

- 93% agreed that a routine sight test could save someone's sight
- 80% knew a sight test can detect problems such as cataracts, glaucoma etc.
- 61% were aware that general health issues can be spotted via a routine sight test[46]

However, GOC research has also shown that people delay having a sight test if they can see well.[47] Reduced vision is therefore a significant trigger to attend for a sight test, and because eye health is checked at the same time as a refraction in the UK, we are able to identify diseases and conditions which could otherwise result in irreversible vision loss (e.g. glaucoma) or poorer heath (e.g. high blood pressure). These opportunities would be lost in a refraction-only model. It would not for example be possible in most cases to guess somebody had glaucoma, an ocular tumour, high blood pressure or diabetes from a refraction alone.

Based on the GOC's own research (cited above), there would also be a risk, that people would have their vision corrected and see well and therefore put off visiting an optometrist for an eye health check, further increasing the risk of avoidable sight loss for individuals and populations.

The UK cannot afford to abandon the sight test

The cost of sight loss in the adult population to the UK economy is estimated to be £28.1 billion in 2013. [48] Separating the sight test would increase the risk of preventable sight loss, and the associated economic impacts.

Taking care with international comparisons

We would also like to address paragraph 37 of the GOC consultation about variation in models of eye care worldwide.

The GOC is correct that there are many different models of eye care across the world. Care must be taken however when making international comparisons.

This is particularly important because international comparisons of any healthcare service are incredibly complex, and often mask historical and local economic and professional variables. Incorrect assumptions could lead to erroneous policy decisions which could result in avoidable systems failure and harm to patients.

At the heart of this, it is important to understand how the sight test has driven our workforce, training and education, and the provision of eye care services in the UK in general. For example

- Optometrists in the UK (and Ireland) are generally more qualified than their European counterparts.
- They need to be because they, as a core competency, provide a sight test which includes a health assessment and refraction
- All UK optometrists are classified at least a category 3 under the World Council of Optometry – a global competency model of scope of practice. This means they can provide ocular diagnostic services: investigation, examination and evaluation of the eye and adnexa and associated systemic factors to detect.

- IP optometrists in the UK are in the highest category, 4, which means they can use pharmaceutical agents and other procedures to manage ocular conditions/disease.
- In contrast most EU based optometrists/opticians are category 1 and 2, and are more akin to the dispensing optician role in the UK. In countries with more category 1 and 2 opticians/optometrists, the health system has trained more ophthalmologists to meet eye health needs.
- Morjaria et al, have undertaken an exercise to map the global optometry workforce based on the World Council of Optometry category model. The key data table can be accessed here, which provides evidence that UK optometry is only second to the USA in the scope of practice and scale of workforce.

The foundation on which all this rests is the national sight test service as defined in the Opticians Act which also prevents NHS commissioners from splitting the refraction and eye examination and jeopardising long-term population health for short-term and artificial cost reductions. Without this, there would be less investment in education and training of optometrists, and primary care infrastructure. Hence, because of the sight test (as defined in UK law), in the UK optometrists perform functions ophthalmologists perform in the EU and elsewhere. This also means we have far more optometrists in category 3 and 4 than other European countries (see key data table shared above), and about half as many ophthalmologists (see box below).

The UK, France and Germany have similar population sizes and economies and rates of sight loss but very different models of eye care delivery.

- In 2020 in the UK, there were an estimated 4.3 million people with vision loss. Of these, 170,000 people were blind. The UK has 46 ophthalmologists per million.
- In 2020 in France, there were an estimated 4.3 million people with vision loss. Of these, 110,000 people were blind. France has 92 ophthalmologists per million.
- In 2020 in Germany, there were an estimated 5.8 million people with vision loss. Of these, 230,000 people were blind. Germany has 90.5 ophthalmologists per million.

Source: IAPB Vision Atlas

The only evidence we are aware of that looks at different eye care systems in a structured way is a 2011 project in the Netherlands, which examined the UK, French and German eye care systems.[49] Some of the key points were

- Primary eye care services (as we understand them in the UK) are almost exclusively provided by ophthalmologists in France
- Ophthalmology training is very similar in all three countries.
- Optometry education is not comparable, with significant differences (as noted above)
- The authors note
    - “the UK-systems is built on a strong position of optometrists who provide almost all sight tests and eye examinations in primary eye care”
    - “UK optometrists show an extended range of competencies in comparison to their German counterparts by being entitled to determine diagnoses or to use diagnostic therapeutic agents”
    - It also found that people paid less in the UK compared to France and Germany for eye care overall.

The GOC should therefore note the sight test (eye examination and refraction), our workforce, eye health delivery, and meeting the nation's eye health needs are entwined, and undoing the current model of sight testing would have significant and predictably adverse impacts on patient eye care and outcomes in the UK.

International comparisons are unlikely to provide any credible evidence for changing our existing comprehensive sight test. On the contrary, they provide evidence for other countries to adopt a similar service to the UK if they wish to develop sustainable models of primary eye care services for ageing populations.

Q21. Does the fitting of contact lenses legislation create any unnecessary regulatory barriers?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

More than 8% of the UK population between the ages of 15 and 64 wear contact lenses, which is more than 4 million people.[50]

The current regulatory regime strikes the right balance between

- protecting patients against the risks associated with poorly fitted contact lenses and poor compliance with wear and care regimes
- supporting patient choice and competition, which has meant patients can access competitively priced lenses and solutions.

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.

Q22. What would be the advantages, disadvantages and impacts (both positive and negative) of fitting of contact lenses legislation remaining as it is currently? (Impacts can include financial impacts and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these

We are sure that colleagues at the BCLA and ACLM will be providing substantive evidence for this and other questions about contact lenses. We provide high level feedback as follows

- Detailed research of existing literature shows that contact lens problems are common and can result in sight-threating complications[51]
- The same research shows contact lens related problems are in fact relatively common, and often present as discomfort and other signs and symptoms. Most of these can be

managed by GOC registrants in primary eye care settings. Left unaddressed these could increase the risk of more serious contact lens complications

- This is supported by research commissioned by the GOC which showed that "Just over three quarters of respondents have experienced at least one problem in relation to wearing their contact lenses at some point (77%). This is most commonly dry eyes (52%), followed by sore eyes (36%) and damaged a contact lens (29%). Some 16% said that they had experienced an eye infection in relation to them wearing contact lenses." [52]
- The same GOC research showed that patients shop around for contact lenses based on price with limited barriers to doing so, most have regular check-ups and value their aftercare and were aware of, and reported compliance with, the BCLA 'dos and don'ts' of contact lens use
- Contact lens complications have been shown to account for 9% of referrals to ophthalmic A&E, with microbial keratitis as the most common diagnosis[53]
- Issues such as keratitis are not necessarily reduced simply because modern contact lenses are better or because more people use daily disposables, with research finding "no statistically significant difference in the incidences of severe keratitis among wearers of daily wear daily disposable lenses versus daily wear hydrogel lenses that are replaced less frequently"[54]

In summary, contact lenses as medical devices are not risk free and can cause sight threating conditions. The current regulatory regime does not, and no regulation can, remove all risks associated with contact lens use. The current regime however provides sufficient safeguards for patients and helps minimise the risk of more severe complications, including sight loss. Removing existing regulations would not be in the public interest and would increase the risks of complications and pressure on eye care services which would need to treat more complex cornea problems.

Q23. Should the sale and supply of optical appliances be further restricted to certain groups of vulnerable patients?

☐Yes – please specify which groups of patients

☒No

☐Not sure / no opinion

Please explain which group(s), give your reasons and provide any evidence to support these.

Summary
Existing regulation strikes the right balance and should remain unchanged.

Full response

Having consulted with members on paragraph 42, there is a consensus that this should not be extended to the proposed groups. Our member feedback is as follows:

- 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 cognitive impairment, 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 at 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.

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.

Q24. If you answered yes to the previous question, what would be the advantages, disadvantages and impacts (both positive and negative) of further restricting the sale and supply of optical appliances to certain groups of vulnerable patients? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these

Not applicable

Q25. Do the general direction / supervision legislative requirements relating to the sale of prescription contact lenses create any unnecessary regulatory barriers?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

The general direction / supervision legislative requirements provide appropriate protections for patients which should be maintained. See our response to question 22 on why we feel the current regulatory regime continues to protect the public, and meets the objectives set out in section one of the GOC call for evidence and consultation document.

The general direction requirement rightly provides a public safeguard that a GOC registrant, complying with GOC standards, has been involved in the design of the supply chain.

Q26. Would there be a risk of harm to patients if the general direction / supervision requirements relating to the sale of prescription contact lenses changed?

☒Yes

☐No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

See our response to question 22 on why we feel the current regulatory regime continues to protect the public, and meets the objectives set out in section one of the GOC call for evidence and consultation document.

Q27. Do the legislative requirements for verification of contact lens specifications create any unnecessary regulatory barriers?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

More than 4 million people use contact lenses in the UK. Research shows patients can shop around for the best value, and yet protect their eye health by easy access to GOC registrants who can help reduce risks associated with contact lenses. See our response to question 22 on why we feel the current regulatory regime continues to protect the public, and meets the objectives set out in section one of the GOC call for evidence and consultation document.

Q28. What would be the advantages, disadvantages and impacts (both positive and negative) of removing the requirement to verify a copy of or the particulars of a contact lens specification? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

The proposal to remove the requirement to verify a copy of the particulars is difficult to justify based on the evidence presented in paragraph 45. For one, easements during the pandemic do not provide sufficient evidence (time frame too short) to justify changing the current system of regulation. In addition, 4 million people use contact lenses in the UK and the research to date shows they do not face barriers to obtaining lower cost lenses but do benefit from understanding the risks of contact lens use and how to reduce these (see our response to question 22).

On balance the disadvantages would exceed the advantages, and therefore there seems to be no credible case on which to change existing requirements.

However, we do think there is merit in clarifying the definition of a valid specification, for example many patients now hold their original clinical data on a mobile phone, including their original specification. This is also becoming more common as we move to a paperless society. This however should not require a change to legislation and can be clarified by a guidance note.

Q29. Do you think the Act should specify a definition of aftercare?

☐Yes

☒No

☐Not sure / no opinion

If yes, please specify what you think the definition of aftercare should be.

It would be odd for the Act to have a prescriptive definition of aftercare given the body of evidence related to contact lens use, satisfaction with eye care in the UK, access to aftercare and patient outcomes and risks (see our response to question 22).

We are not aware of any evidence or feedback that not defining aftercare in the Act causes risks to patients, nor are we aware of any complaints about the provision of aftercare.

If the GOC feels it would be beneficial to raise awareness about what aftercare is likely to include, we recommend working with the BCLA to raise public awareness, as the GOC's research has shown the public have a good understanding of BCLA do's and don'ts for contact lenses, and this could be replicated to raise awareness about the importance and content of aftercare, which could more readily be updated in the future compared to a legislative definition of aftercare. This approach would also be more consistent with objective 7.

Q30. Does the zero powered contact lenses legislation create any unnecessary regulatory barriers?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

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.

Zero-powered contact lenses are equivalent to prescription contact lenses (medical devices) in terms of risk. This is now recognised by the MHRA following a public consultation which asked whether non-prescription contact lenses should be classified as a medical device, based on the logical premise it is a contact lens and have similar risks to prescription contact lenses. This has received strong support and the MHRA intends to classify coloured contact lenses/zero-powered contact lenses as medical devices.[55]

Hence there are no unnecessary barriers created by zero powered contact lenses legislation but only essential safeguards

Q31. Would there be a risk of harm to patients if the requirements relating to the sale of zero powered contact lenses change?

☒Yes

☐No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

As explained in response to question 21,22 and 30 above, if these requirements were to be removed or loosened, there would likely be an increased risk of harm to patients – e.g. greater numbers and severity of contact lens related problems including infections, inflammation, corneal damage and in worst case permanent loss of sight.

Q32. If you answered yes to the previous question, is legislation necessary to mitigate this risk?

☒Yes

☐No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

Yes, legislation helps clarify that zero powered contact lenses are medical devices and should therefore be subject to the same checks and balances as other contact lenses for reasons set out above. Current legislation arrangements are appropriate to mitigate the risk to patients.

Q33. What would be the advantages, disadvantages and impacts (both positive and negative) of zero powered contact lenses legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

As noted in our response to question 21, the current legalisation 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.

Q34. Are there 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?

☐Yes

☒No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

Not applicable

Q35. If you answered yes to the previous question, what would be the risk on the consumer if these barriers were removed?

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

Not applicable

Q36. Is legislation regarding the sale of optical appliances necessary to protect consumers (except restricted categories)?

☒Yes

☐No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

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.

In accordance with GOC objective 7, 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.

Q37. Is the two year prescription restriction on purchase of spectacles from non-registrants an unnecessary regulatory barrier?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

This restriction protects patients and acts as a safeguard, in line with objective 1 of this call for evidence.

There are more than 21 million sight tests in the UK each year, of which 10 million might result in the dispensing an optical appliance, and more than 4 million contact lens patients accessing a supply of contact lenses. Most patients are satisfied with the care they receive (see our responses above for evidence to support this).

In this context we note the GOC feedback in paragraph 55 that “some patients [are] not happy with this requirement”, but it is not clear how many ‘some’ are and how their numbers compare with the millions of patients who understand and value the benefits of regular sight testing and aftercare or benefit from it even if they do not (see our responses above for evidence to support this).

Q38. What would be advantages, disadvantages and impacts (both positive and negative) of patients being able to purchase spectacles from non-registrants without a prescription dated in the previous two years? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

Optometrists set a clinical recall period based on best practice, taking account of a person's ocular and family history, individual patient presentation and needs etc. The sight test is an important health check (see our response to section four of the consultation above). In addition to the risks associated with undue delay to having a sight test, there is also a risk that somebody might not have their refractive error fully corrected, perhaps falling short of vision standards for driving, and increasing their own risk of falls etc.

Also given the public health benefits of a sight test, which patients now increasingly recognise[56], it would be unwise on public health grounds to add delays between sight tests.

Given that 70% of sight tests in the UK (100% in Scotland) are funded by the NHS, and private patients can access affordable sight tests, this would also seem an unwise public health risk to run as always, the inverse care law would apply, widening health inequalities. It is therefore difficult to see how many fully informed patients would decide (informed consent) to forgo the benefits of a sight test, and to bring their eye health checks and refraction up to date, before investing in a new pair of spectacles.

In summary, there is no evidence base to change existing requirements, as these are currently consistent with the GOC objectives set out in section 1.

Q39. What would be advantages, disadvantages and impacts (both positive and negative) of the legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

As noted above, the current model of primary eye care works well and safely. There are high levels of patient satisfaction, and quality eye care is readily accessible close to home. In addition to this, through the current patient choice led model of care, patients today spend less of their income on eye care than in the past.[12]

Changes that are required in eye health services are linked solely to NHS commissioning decisions or NHS regulations (e.g. NHS services for homeless people and children/young people in special schools), which are outside the scope of this consultation. 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.

There is no evidence to suggest any changes to the Opticians Act is required.

Q40. Does the legislation in relation to the sale and supply of sportswear optical appliances for children under 16 create any unnecessary regulatory barriers?

☐Yes

☒No

☐Not sure / no opinion

Please give your reasons and provide any evidence to support these.

We note the GOC has had some feedback from stakeholders who think this is an overly restrictive practice (paragraph 58).

However, having consulted members, who provide most primary eye care in the UK, they do not have evidence of this being a problem that is reported by children or their families. They can also organise timely access to such devices and ensure these are suitable for the sport in question (e.g. prescription PPE for squash) and that an average spherical power is suitable and will not increase the risk of accidents (e.g. swimming goggles for myopic and astigmatic patients).

It is unclear whether the stakeholders that have approached the GOC are online distributors or parents. Irrespective of the time children spend wearing sportswear, they are still children and benefit from the Act which protects their eyes and vision. We, with optical sector partners, would be happy to work with the GOC to ensure children and their families have information on how to safely access the prescription sportswear they need. We feel that simple guidance and support would also meet objective 7 in Section one.

Q41. What would be advantages, disadvantages and impacts (both positive and negative) of children under 16 being able to buy sportwear optical appliances outside the supervision of a registrant / registered medical practitioner? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

In many cases sportswear will act as a form of PPE (e.g. goggles for squash) and require suitable selection, fitting and checking to reduce the risk of accidents and trauma related vision loss.

Our members also reported that

- in most sports where sportwear warrants a prescription, vision is important for that sport and therefore there will be a risk of harm if the appliance is not supplied in line with the current legislative requirements
- appliances for sport are often more complex to fit than traditional spectacles, due to their different structure and issues with their manufacture (i.e. they often cannot be manufactured with the same accuracy as traditional lenses)
- having them supplied and fitted by a registered individual (who is appropriately trained) is an important patient protection

Q42. What would be advantages, disadvantages and impacts (both positive and negative) of the legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

Please see our responses above (especially to questions 36-39). Based on evidence and the experience of our members, the advantages (against all the parameters including financial and equality, diversity and inclusion) of the legislation remaining as it is, on patient safety and public protection grounds, far outweigh the risks for change for change's sake.

Q43. Are there any other aspects of the sale and supply of optical appliances legislation that you think need changing or create unnecessary regulatory barriers?

☐Yes

☒No

☐Not sure / no opinion

If yes, please give your reasons and provide any evidence to support these

Not applicable

Q44. What would be the advantages, disadvantages and impacts (both positive and negative) of the sale and supply of optical appliances legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

As noted above, the current legislation has stood the test of time, and is working well for patients who continue to benefit from risk-based regulation and are able to access affordable eye care and refractive correction throughout the UK.

The only changes that would help improve equality in access are linked to NHS commissioning which is outside the scope of this consultation. The Opticians Act is predicated on safe patient choice for all and does not need to be updated in this regard.

Q45. 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?

☒Yes

☐No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

FODO, along with sector partners, jointly commissioned Project Foresight Report (2016) which provides useful background information on likely technological developments.

In response to the consultation question, there is nothing in the Act that would need to change to accommodate these technological developments.

The Act is not a barrier to the diffusion of evidence-based technologies, as is self-evident when visiting primary eye care sites across the UK.

We would also like to take this opportunity to flag the use of terminology and the role of the MHRA in regulation of medical devices in a UK context.

Terminology

The sector (including the GOC) should, in our view, be more mindful of the definitions of and distinctions between emerging technologies to help avoid misunderstandings as this can distort analysis and policy. For example,

- Some stakeholders often use the term “AI” interchangeably when in fact they can be referring to anything from using a normative database to machine learning, or to AI in the broader sense. The policy implications of these technologies differ
- Telehealth and virtual care are also ill defined and used interchangeably in most cases

Introducing clarity in terminology and what exactly is meant when referring to a technology, would help prevent the sector and regulators talking at cross purposes and allow new innovations to be objectively appraised.

MHRA

The optical sector has a long history of adopting and mainstreaming cutting edge technologies, and this is set to continue. The GOC's role is to maintain patient and public safety as its primary objective (objective 1 section one). In terms of technology, this should focus on ensuring GOC registrants work within their scope of practice which includes understanding the technology they deploy.

The MHRA, on the other hand, has a broader role in advising on risk classification and use of technologies (for example the use of software including AI as a potential medical device), as set out in the government's response to medical device regulation in the UK.[57] The GOC in our view should avoid duplication between the two areas to ensure clarity, safety and cost minimisation. Hence in our view the GOC does not need to take any action with respect to the Act in response to new technologies.

Q46. Is there any evidence that increased use of technology or remote care may have an impact on patient safety or care in the future?

☒Yes – a mainly positive impact

☐Yes – a mainly negative impact

☐No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

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.

Where technology and remote models of care are evidence-based, comply with public protections in the Opticians Act, and are used with knowledge of the limitations of any given technology/intervention, then the overall impact is likely to be positive.

Negative effects are likely to arise if unproven technologies are used outside GOC standards. Registrants are already required to understand the tools they are using and work within their scope of practice etc and so provided standards are followed, avoidable negative effects should not arise.

Q47. Are there 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?

☐Yes

☒No

☐Not sure / no opinion

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.

The Act is fundamentally a piece of public protection regulation, which does not create unnecessary barriers to using new evidence-based technologies.

Q48. Are there any gaps within the Act or GOC policy relating to the regulation of technology or remote care that present a risk to patients?

☒Yes

☐No

☐Not sure / no opinion

If you answered yes, please give details of what these are, including your reasons and provide any evidence to support these.

Summary

There are no gaps within the Act. There are potential gaps in GOC policy – e.g. more information for the public on how to use online services safely. Based on objective 7 in section one, this can be addressed using standards or guidance, and does not require new legislation.

There is scope for the GOC to issue, or support, guidance on the use of technology and remote care in ways which are consistent with objectives 1,5, 6, 7 and 8. We set out proposals in more detail below.

Full response

There are no gaps in regulations.

However, considering GOC objective 7, we think there are opportunities to improve policies/standards, to support registrants to harness the use of technology and remote care in a way that best serves patients, and to manage potential illegal practice in the future.

We set out the problem, our research and some proposals below.

The problem

Our members welcome the use of technology to improve patient care, including the use of remote care and advanced diagnostics when this is in the best interests of patients. They have concerns however about non-regulated individuals and businesses operating remotely in the UK and using non-UK status to bypass safeguards for patients. Our members are concerned that

- providers offering remote care while based outside the UK will not be subject to the safeguards and standards in the Opticians Act which are designed to protect patient and public safety

- patients might wrongly assume the provider they access online is regulated and accountable by the same standards as their UK-based optician

- patients who suffer harm will have no way to make a medical malpractice claim to ensure they are compensated when things go wrong

These are legitimate concerns and would evidence a form of market failure if allowed to occur. Therefore, there is merit in the GOC taking a proactive but proportionate approach at this stage to help mitigate these risks and support the spread of best practice.

Research

In 2018, European Economics published GMC commissioned research into regulatory approaches to telemedicine around the world.[58] This included

- Reviewing approaches to regulating telemedicine
- Understanding how regulators define telemedicine, and requirements imposed
- How they dealt with healthcare professionals providing care form a different jurisdiction.

Some of the main findings were

- Regulators have all had challenges with people practising medicine across jurisdictions
- Requirements for telemedicine in most cases required "the same standard of care as that of face-to-face healthcare" (including confidentiality, consent, and securing outcomes)
- Despite some countries dealing with telemedicine for some time, this was still an evolving field and required ongoing monitoring of new risks and challenges
- That when considering the regulatory requirements, regulators needed to be clear on where a service is occurring
  a. Could deem to take place in the jurisdiction of the patient
  b. Could deem to take place in the jurisdiction of the health care professional
  c. Could deem to take place in the jurisdiction of the healthcare provider.

  That in the USA and Canada option (a) dominates, because

  "interpretation is that should anything go wrong, the patient should have recourse to a regional regulatory body, which could then investigate the complaint on the patient's behalf."

- It also considered the consequences of non-compliance. Under a similar framework to UK regulation, in that compliance could be assessed against
  - Requirements in law
  - Standards
  - Guidelines and code of conduct

Recognising the global reach of the internet, it also noted significant challenges with regulators challenging those outside their jurisdiction. However, one US regulator told researchers in these cases

- "it is often quicker and more effective to work with the offending doctor and the regulator who has direct jurisdiction over them (including non-USA regulators) to address the problem, rather than to formally notify appropriate agencies and attorney generals about the violation of USA law."

Recommendations

In our view it would be helpful for the GOC to consider consulting on guidance for remote care and online prescribing to ensure

- Patient and public awareness and safety
- GOC registrants and eye care providers understand duties when providing remote care
- The public know what to look for before accessing remote care, including confirming the legal jurisdiction of the provider and implications of using international providers
- That such guidance is formed on the evidence of what has already been show to work

Q49. If you answered yes to the previous question, do you have any suggestions about how these gaps in the regulation of technology or remote care could be addressed?

Please include your reasons and any evidence or impacts of your suggestions.

As noted in our response above, we believe existing gaps can be addressed with guidance.

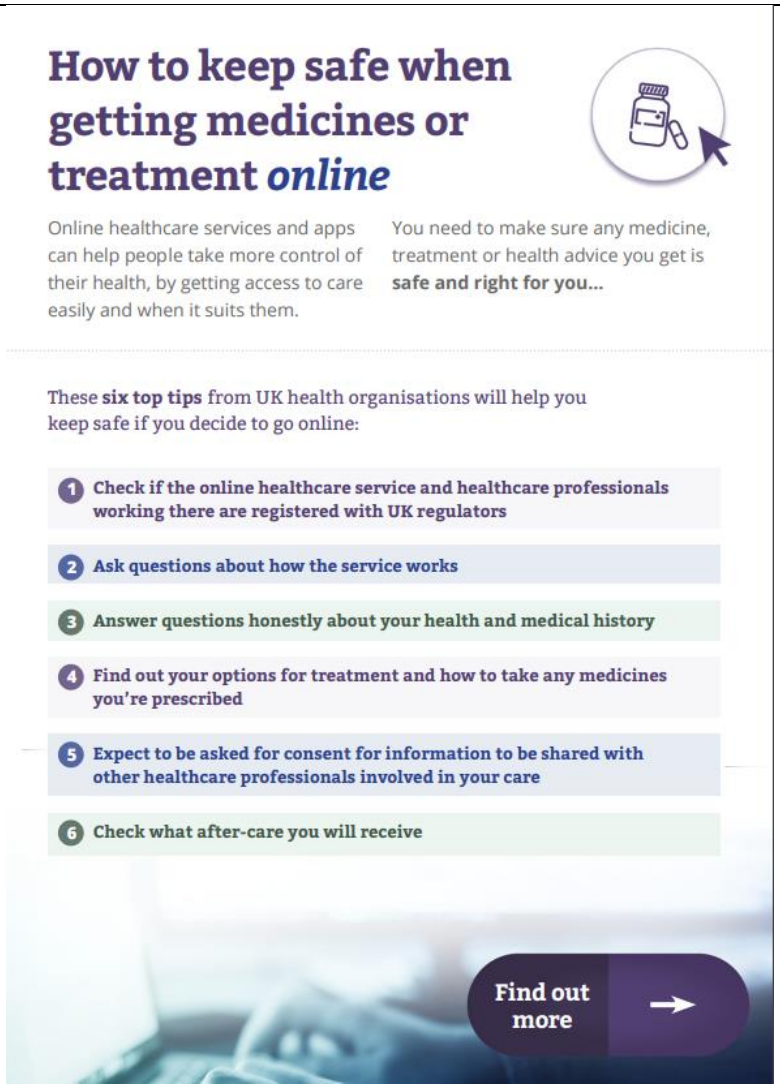
We think the GMC offers a useful template for the sector to learn from, as guidance is pitched at registrants and the public (see boxes below).

For registrants

1. Its standards of good practice apply to both face to face and remote consultations
2. If you can't meet our standards for safe prescribing in a remote consultation, you should change to face to face
3. You should agree with the patient the most suitable method of consultation within the resources available

Source: GMC, Remote consultations[59]

For the public



Source: GMC, How to keep safe when getting medicines or treatment online[60]

We believe GOC registrants and the public might benefit from similar resources designed for primary eye care settings.

Q50. Are there any gaps in the Act or GOC policy relating to the regulation of online sales of optical appliances that present a risk to patients?

☐Yes

☒No

☐Not sure / no opinion

If you answered yes, please give details of what these are, including your reasons and provide any evidence to support these.

Not applicable

Q51. If you answered yes to the previous question, do you have any suggestions about how these gaps in the regulation of online sales of optical appliances could be addressed?

Please include your reasons and any evidence or impacts of your suggestions.

Not applicable

Q52. Are there other areas of our current legislation that you think need to be amended (recognising that the Department of Health and Social Care review will cover our core functions)?

☐Yes

☒No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

Not applicable

Q53. Are they any other gaps in regulation where you think legislative change might be required?

☐Yes

☒No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

Not applicable

Q54. Are there any other policies or guidance that the GOC currently produces that should be reviewed or require amendments?

☐Yes

☒No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

Not applicable

Q55. 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 (i.e. age, sex, race, religion or belief, disability, sexual orientation, gender reassignment, pregnancy or maternity, caring responsibilities)?

☐Yes

☒No

☐Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

Not applicable

References and additional supporting information

[1] HCPC, Identifying your current scope of practice https://www.hcpc-uk.org/standards/meeting-our-standards/scope-of-practice/what-is-your-scope-of-practice/identifying-your-current-scope-of-practice/

[2] HCPC, The standards of proficiency for hearing aid dispensers, https://www.hcpc-uk.org/standards/standards-of-proficiency/hearing-aid-dispensers/

[3] GOC, 2015, Public perceptions research

[4] GOC, 2021, Public perceptions research

[5] Optical Consumer Complaints Service, 2020, Annual report 2019-20, Future vision, complaint mediation supporting optical practice, patient relationships and regulation

[6] Optical Consumer Complaints Service, 2021, Annual report 2020-21, Supporting the professions to be fit for the future

[7] Based on comparison of general feedback to the GOC, 2021, Public perceptions research and Kings Fund and Nuffield Trust, 2021, Public satisfaction with the NHS and social care in 2021, https://www.kingsfund.org.uk/sites/default/files/2022-03/BSA%20Survey%20Report%202nd%20pp_0.pdf

[8] European Economics, 2013, Evidence of Business Risks, as presented in GOC Council papers of 11 July 2013

[9] IBES Diskussionsbeitrag, 2011, Comparative Analysis of Delivery of Primary Eye Care in Three European Countries

[10] Primary Eye Care in England, A vision for the future, College, FODO, AOP and ABDO (2015)

[11] Optical Consumer Complaints Service, 2021, Annual report 2020-21, Supporting the professions to be fit for the future

[12]
Research in FODO archives shows that in 1982 the average weekly wage was £137.06, the average single vision pair of spectacles was £43, and therefore 1.6 working days were needed to buy a single vision pair of spectacles.

Uprated for inflation since then, today an average single vision pair of spectacles would cost £123, however the reality is today people can readily access these for less than £100.

Today's products and services are also without doubt of higher quality than in 1982.

However, even if we assumed the average single vision dispense was still £123, today the average weekly wage is £590 (Source: ONS, Figure 1, average weekly earnings, Nov 2021 (here)), which means people only have to work 1 day.

In context of primary eye care today – e.g. access to state of the art diagnostics like OCT etc – it is clear the market is functioning well and patients are benefiting from access to better care, and providers have driven efficiencies, so patients are better off today in real terms.

[13]
CQC regulation is not a useful example of provider regulation for primary eye care. Primary eye care providers do not fall within scope because the government, correctly in our view, decided it would be disproportionate regulation to require optical businesses to be CQC registered given risks, this is also the case for primary care audiology. Other UK nations (via Health Improvement Scotland, Health Inspectorate Wales, and Regulation and Quality Improvement Authority (Northern Ireland)) have taken the same approach as England.

References to GPhC inspection visits and "practice principal" without context is unhelpful and potentially misleading. This regulatory regime recognises the high risk involved in the supply of pharmaceutical products, with immediate risks to life should regulatory safeguards fail. As such the Department of Health undertook an extensive consultation on proposals for the content of the Responsible Pharmacist Regulations. It would not be proportionate to the risk, nor evidence-based, to propose a similar scheme for primary eye care.

It should be noted that all new premises offering General Ophthalmic Services (GOS) are visited and that visits as part of contracting monitoring are continually undertaken. However, references to GOS contract performance suggest limited further work has been done since the GOC commissioned European Economics in November 2012 to look at evidence of business risks. The point is that GOS (pan UK) compliance is well tested and proportionate to risk, and also takes account of commissioner resources – e.g. level of compliance required relative to other higher risk services they commission. Likewise, the NHS Standard Contract in England applies different levels of compliance to different services groups – e.g. acute vs community etc. This common-sense approach is found in all sectors, and forms one part of a wide range of checks and balances.

[14] GOC, 2013, Council papers, Business regulation project Public C32(13)

[15] GOC, 2013, Council papers, Business regulation project Public C32(13), paragraph 80

[16] European Economics, 2013, Evidence of Business Risks, Section 3.3.2, as presented in GOC Council papers of 11 July 2013

[17] European Economics, 2013, Evidence of Business Risks, Section 3.1.9, as presented in GOC Council papers of 11 July 2013

[18] European Economics, 2013, Evidence of Business Risks, Section 3.1.2.1 as presented in GOC Council papers of 11 July 2013

[19] European Economics, 2013, Evidence of Business Risks, Section 3.4 as presented in GOC Council papers of 11 July 2013

[20] See endnote 12. This is in the context of people now having access to more advanced diagnostics close to home and out of hospital

[21] GOC, 2021, Public perceptions research

[22] Kings Fund and Nuffield Trust, 2021, Public satisfaction with the NHS and social care in 2021, https://www.kingsfund.org.uk/sites/default/files/2022-03/BSA%20Survey%20Report%202nd%20pp_0.pdf

[23] GOC, 2022, GOC reveals insights from public perceptions research, https://optical.org/en/news/news-and-press-releases/goc-reveals-insights-from-public-perceptions-research/

[24] GOC, 2013, European Economics Business regulation project summary, p 52,

[25] European Economics, 2013, Evidence of Business Risks, Section 6.2.5.1 as presented in GOC Council papers of 11 July 2013

[26] European Economics, 2013, Evidence of Business Risks, Section 6.2.5.3 as presented in GOC Council papers of 11 July 2013

[27] GOC, 2013, Council papers, Business regulation project Public C32(13), paragraph 81

[28] FODO, Optics at a Glance, 1982 to 2014 accessible https://www.fodo.com/members/data-hub/optics-at-a-glance/ (if the GOC would like to access this resource please email healthpolicy@fodo.com)

[29] El-Abiary, M., Loffler, G., Young, D. *et al.* Assessing the effect of Independent Prescribing for community optometrists and referral rates to Hospital Eye Services in Scotland. *Eye* **35,** 1496–1503 (2021). https://doi.org/10.1038/s41433-020-1095-6

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[33] Harvey K, Edgar DF, Agarwal R, Benwell MJ, Evans BJ. Referrals from community optometrists in England and their replies: A mixed methods study. Ophthalmic Physiol Opt. 2022 May;42(3):454-470. doi: 10.1111/opo.12948. Epub 2022 Feb 2. PMID: 35106831.

[34] Ophthalmic Data Warehouse, 2019, Figure 4a. Number of clinical conditions relevant to eye care, Scotland; 2018/19

[35] Professor Nicholas Rumney, NHS future forum discussion https://future.nhs.uk/system/login?nextURL=%2Fconnect%2Eti%2FNationalEyeCareHub%2Fview%3FobjectId%3D16899531

[36] Devarajan, N., Williams, G., Hopes, M. *et al.* The Carmarthenshire Glaucoma Referral Refinement Scheme, a safe and efficient screening service. *Eye* **25,** 43–49 (2011). https://doi.org/10.1038/eye.2010.136

[37] Bourne, R., French, K., Chang, L. *et al.* Can a community optometrist-based referral refinement scheme reduce false-positive glaucoma hospital referrals without compromising quality of care? The

community and hospital allied network glaucoma evaluation scheme (CHANGES). *Eye* **24,** 881–887 (2010). https://doi.org/10.1038/eye.2009.190

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[39] Ophthalmic payment system: 2010/11 to 2016/17 (OPTIX), 2017/18 to 2018/19 Ophthalmic Data Warehouse, Percentage of supplementary exams by reason and year; Scotland, 2018/19.

[40] Ophthalmic payment system: 2006/07 to 2016/17 (OPTIX), 2017/18 to 2018/19 Ophthalmic Data Warehouse., Number of referrals by "Referred to" category, Scotland; 2006/07 to 2018/19.

[41] GP online, 15.5 Eye Problems https://www.gponline.com/rcgp-curriculum/eye-problems; also supported by more historical data, e.g. 2% estimated in - North Staffs, Medical Audit Advisory Group, Management of Acute Eye Conditions in Community Evaluation Report, cited in Primary Eye Care in England, A vision for the future, College, FODO, AOP and ABDO (2015)

[42] GOC, 2021, Public perceptions research

"When asked where they would go or who they would see if they woke up tomorrow with an eye problem, the most common response was a GP (38%). An optician was the second most commonly selected option, chosen by 30% of respondents. The fact that three in ten respondents would speak to an optician first is a new high in this research, representing an 11-percentage point increase since 2015. As shown in Figure 2, there has been an ongoing upwards trajectory in the proportion who would seek assistance from an optician since 2015. Between 2015 and 2019, the gap in the proportions choosing a GP and an optician as a source of advice has narrowed. Since the last wave of this research in 2019, there has been a concurrent rise in those who would contact a GP or an optician first. Therefore, the percentage point gap between those who would contact a GP over an optician has remained stable year on year (+7 2019, +8 2021)."

GOC's 2022 public perceptions survey shows this trend continues

[43] RNIB and Specsavers, 2 The State of the Nation: Eye Health 2016, https://www.rnib.org.uk/sites/default/files/RNIB-State-of-the-Nation-2016-APDF%20format.PDF

[44] Fight for Sight, Facts about sight loss, https://www.fightforsight.org.uk/about-the-eye/facts-about-sight-loss

[45] GOC, 2021, Public perceptions research

"Three quarters (75%) of the population reported visiting an optician in the last two years. This is an increase of 6-percentage points from the 69% that was recorded in 2019. So while 33% of respondents indicate they have delayed or put off making an appointment for a routine sight test during the pandemic, this has been insufficient to reduce the overall percentage who have visited an optician over this longer two-year timeframe

When asked when they are next likely to see an optician, 71% of respondents envisage that this will be within the next 12 months. Within this, 13% suggest that this visit will be in the next three months, and a further quarter (25%) suggest that their next visit will be within the next six months. This gives an indicator of likely service demand in the short term"

[46] RNIB and Specsavers, 2 The State of the Nation: Eye Health 2016, https://www.rnib.org.uk/sites/default/files/RNIB-State-of-the-Nation-2016-APDF%20format.PDF

[47] GOC, 2015, Public perceptions research

[48] RNIB and Specsavers, 2 The State of the Nation: Eye Health 2016, https://www.rnib.org.uk/sites/default/files/RNIB-State-of-the-Nation-2016-APDF%20format.PDF

[49] Thomas et al, 2011, Comparative Analysis of Delivery of Primary Eye Care in Three European Countries

[50] Euromcontact, Figure 3, https://euromcontact.org/wp-content/uploads/2019/03/Tables-Publication-Report-2018.pdf

[51] Alipour F, Khaheshi S, Soleimanzadeh M, Heidarzadeh S, Heydarzadeh S. Contact Lens-related Complications: A Review. *J Ophthalmic Vis Res*. 2017;12(2):193-204. doi:10.4103/jovr.jovr_159_16

[52] Dr Michael Turner, Research Director and Gemma Baker, Research Manager, 2016, BMG research GOC 2015 contact lens survey,

[53] Contact lens referrals to Hull Royal Infirmary Ophthalmic A&E Unit - Contact Lens and Anterior Eye https://www.contactlensjournal.com/article/S1367-0484(08)00055-6/ppt#secd1550599e110

[54] Morgan PB, Efron N, Hill EA, et al Incidence of keratitis of varying severity among contact lens wearers British Journal of Ophthalmology 2005;**89:**430-436.

[55] The government response to the MHRA consultation shows that 89% of respondents said non-prescription contact lenses should be regulated in the under UK medical device regulations and the MHRA's intention to extend regulation to all contact lenses if they have similar risk profiles to contact lenses which are already classified as a medical device https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085333/Government_response_to_consultation_on_the_future_regulation_of_medical_devices_in_the_United_Kingdom.pdf pages 7 and 14

[56] See survey results in RNIB and Specsavers, 2 The State of the Nation: Eye Health 2016, https://www.rnib.org.uk/sites/default/files/RNIB-State-of-the-Nation-2016-APDF%20format.PDF

[57] MHRA, 2022, Government response to consultation on the future regulation of medical devices in the United Kingdom, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085333/Government_response_to_consultation_on_the_future_regulation_of_medical_devices_in_the_United_Kingdom.pdf

[58] European Economics, 2018,Regulatory approaches to telemedicine https://www.gmc-uk.org/-/media/documents/regulatory-approaches-to-telemedicine_docx-73978543.docx

[59] GMC, Remote consultations https://www.gmc-uk.org/ethical-guidance/ethical-hub/remote-consultations

[60] GMC, 2021, GMC urges patients to stay safe when going online for treatment, https://www.gmc-uk.org/news/news-archive/gmc-urges-patients-to-stay-safe-when-going-online-for-treatment