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

15 July 2022

Call for evidence on the Opticians Act and consultation on associated GOC policies - General Optical Council - Citizen Space

LOCSU answers and comments.

Our engagement: basis for positions

LOCSU (Website: Support services for Local Optical Committees (LOCs) in England | LOCSU) supports over seventy Local Optical Committees (LOCs) in England. LOCs are bodies established by the 1940s NHS Acts and have primary care equivalents in local Medical, Pharmacy, and Dental Committees. Each LOC works with neighbouring LOCs to form regional forums based on NHS geographical footprints which LOCSU also supports.

In response to the GOC's proposals, LOCSU has embarked on a comprehensive engagement programme with all LOC regional forums; individual LOCs including officers and members; other UK optical sector bodies; and wider stakeholders including individuals working in front-line optical practice. LOCSU also attends the GOC's workforce meetings regularly.

LOCSU's responses to these proposals reflect both this engagement and our experience and expertise as a leading eyecare organisation in England. As LOCSU is an England-only support body, our engagement and therefore comments pertain to that country only, except where otherwise specified.

Q5[1]: Are these the right objectives for the GOC for legislative reform?

a) **Yes**
b) No
c) Not sure / no opinion

If no, please provide details.

Q.5 Yes, but with hierarchy/weighting.

While we agree with the objectives outlined, we question the lack of hierarchy/weighting offered. In our view, the GOC, as with all regulators, has public and patient safety as its overarching objective and this should be made clearer. As the GOC's proposals themselves state, maintaining patient and public safety (objective 1) is 'our primary objective,' which therefore contradicts the non-hierarchical statement (14, para 1).

Outside of the eyecare sector, the GOC's medical equivalent, the GMC, has its overarching objective being the protection of the public defined in legislation (Source: The General Medical Council (Fitness to Practise and Over-arching Objective) and the Professional Standards Authority for Health and Social Care (References to Court) Order 2015 (legislation.gov.uk).

We would therefore suggest that consideration is given to hierarchy and weighting, at least in respect of objective 1, in order for consistency with the GOC's declared 'primary objective' and to underline the GOC's core function.

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

No change.

We are unaware of any evidence base for amending this portion of the Opticians Act ('the Act'). Therefore, we do not see any case for change from the present restrictions on non-registrants. These restrictions exist for good reason as per the GOC's primary objective: to maintain and promote public and patient safety. Relaxing restrictions on non-registrants can have no obvious patient benefits, given the plethora of choice of optical practices already available to the public (see

[1] These question numbers deliberately start at '5' to account for the fact that our consultation hub will ask four preliminary questions about who is completing the consultation. Only the substantive questions are included in this document.

our answer below on the diversity of the primary eyecare sector), and, as the GOC's document itself makes clear (para 19), potentially introduces risks to public safety for no obvious gain.

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

No change.

We see no case for change from the present restrictions. The current system protects patient and public safety without setting unnecessary barriers to effective primary eye care provision. All registrants should work within their scope of practice and although this may evolve over time, the Act does not and has not prevented that from happening.

In our view, the only case for the relaxation of restrictions would be where the supply of professional skills was exceeded by patient demand, leading to a shortage of timely and quality eyecare appointments and any subsequent detrimental impact on public health. We do not believe this to be the case. In fact, the opposite is the case. In England alone, the number of NHS-funded sight tests carried out in the NHS year 2019-2020 was 13,355,060 with millions more private sight tests: an increase to NHS sight tests of 1.0% from 2018-19 and of 38.2% since 2002-03 (Source: General Ophthalmic Services Activity Statistics England, year ending 31 March 2020 - NHS Digital). In England alone as of 31st December 2019 there were over fourteen thousand primary eye care practitioners (Source: General Ophthalmic services workforce statistics - 31 December 2019 - NHS Digital) This is an increase of 594 (4.3 per cent) since 2018 and means there were 25.5 practitioners per 100,000 population. This compares to 2009 when there were 19.2 practitioners per 100,000 population (Source: General Ophthalmic services workforce statistics - 31 December 2019 - NHS Digital).

Moreover, the GOC's own recent data points to overwhelming patient satisfaction with the care they receive in optical practices. 96% of UK patients were both satisfied with care provided by their optician (GOC terminology) during their last sight test, and satisfied with their last opticians visit overall. Indeed, opticians recorded the highest confidence levels of all primary care professionals. Only 10% of respondents indicated that they had ever experienced a situation where something had gone wrong with the care/service they received from a registrant, down from 13% in 2019. (Source: 2021_public_perceptions_research_pdf.pdf (optical.org).

This points to a healthy and choice-based, non-list sector where patients are well served by the current restrictions, both in terms of accessibility and quality. For this reason, our view is that the

present registrant restrictions in the Act maintain the balance between safety and choice and therefore meet the GOC's objectives.

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

a) **Testing of sight: should be restricted** / not sure / should not be restricted
b) **Fitting of contact lenses: should be restricted** / not sure / should not be restricted
c) **Selling optical appliances to children under 16 and those registered visually impaired: should be restricted** / not sure / should not be restricted
d) **Selling zero powered contact lenses: should be restricted** / not sure / should not be restricted

No change.

All of these restrictions should remain as per our response to Q6. We see no scope for improving patient and public safety by changes to the Act. As our answers above also show, the breadth of choice and variety that the UK optical sector offers to both private and NHS patients, does not indicate any gaps in capacity in meeting growing patient need.

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

No.

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)?

a) Yes
b) No
c) Not sure / no opinion

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

Risk to perceptions of registrants' core competencies.

We have concerns about the possible thinking behind this proposal. While we recognise that the Act does not legislate the scope and delivery of NHS General Ophthalmic Services (GOS) or NHS extended primary eyecare services, this proposal if enacted would likely impact on service commissioning, delivery and patient access to relevant services. Therefore, our answer refences NHS commissioning and delivery even these are not governed by the Act itself.

The consequence of this proposal would be that commissioners and potentially patients would likely infer that the current mix of registrant core competencies and legislated post-qualification skills are insufficient for service delivery. We know this is not the case from the wide range of services registrants provide to NHS (and private patients) already, as we detail below. The consequence of this proposal would be to make further commissioning more difficult, contrary to the Government and NHS's objective for an enhanced role for out of hospital, integrated and preventative eye health care (Source: NHS Long Term Plan - LTP) and NHS planning guidance (NHS England » 2022/23 priorities and operational planning guidance).

GOC-registered optical professionals already deliver a wide range of primary eyecare services throughout the UK, within their core competencies and skillset. As well as the millions of GOS and private sight tests that registrants deliver, registrant core competencies are refreshed when extended eyecare services are commissioned. This is done through the established theoretical and practical assessment training programmes offered by Cardiff University's School of Optometry and Vision Science's Wales Optometry Postgraduate Education Centre (WOPEC), as supported by LOCSU: (Websites: WOPEC Extended Primary Eye Care Services Training (locsu.co.uk) and Wales Optometry Postgraduate Education Centre // WOPEC).

These training programmes have helped result in growing service coverage of non-GOS NHS services provided by optometrists, dispensing opticians (DOs) and contact lens opticians (CLOs) all over England. Almost all LOCs in England have at least one commissioned service in place: (Webpage: LOCSU helps LOCs develop Services Directory Clinical Pathways). As of May 2022:

- 84% of CCGs had a glaucoma repeat readings service with a further 8% of CCGs in commissioning discussions.
- 81% of CCGs had an urgent and emergency eyecare service in place with a further 8% in commissioning discussions.
- 58% of CCGs had a post-cataract service with a further 26% of CCGs in commissioning discussions.

- 54% of CCGs had a pre-cataract service with a further 20% of CCGs in commissioning discussions.
  22% of CCGs had a glaucoma monitoring service with a further 45% of CCGs in commissioning discussions.
  22% of CCGs had a paediatric service with a further 22% of CCGs in commissioning discussions.
- 12% of CCGs had an enhanced case findings service in place with a further 48% of CCGs in commissioning discussions.

These services are an important way of meeting the national objectives detailed above. The services make full use of registrants' core competencies: please see examples below:

- Glaucoma Referral Filtering and Monitoring/enhanced case findings (ECF). Registrants play a vital part in referral filtering and monitoring glaucoma.

  Evidence of impact (Source: development data by LOCSU for NHS England/Improvement - NHSEI):

  - Manchester – 2013-2016 Audit showed 53.5% of patients seen in enhanced case findings service did not need onward referral to secondary care.
  - Manchester – ECF cost effective in saving an average £2.76 per patient seen in primary care .
  - Repeat Measures – Over 70% of patients discharged without onward referral over a 4-year audit period.
  - Repeat Measures – Savings of up to 62% compared with hospital eye service (HES) tariffs
- Integrated Cataract (pre and post-operative). Primary eyecare registrants have a vital role in helping manage cataracts outside of surgery.
  This is a high-volume pathway: cataract surgery is the most commonly performed surgical procedure in the UK. In England alone, over 414,000 cataract operations were undertaken during 2017-18 (Source: National Ophthalmology Database Audit: Key Findings Summary 2019.pdf (nodaudit.org.uk). With the existing core competencies of optometrists, this means that there is the potential to release more than 400,000 hospital eye service outpatient appointments in England alone.
- People with Learning Difficulties. The primary eyecare workforce, as a trusted and skilled local resource working within core competencies, is well placed to help treat

people with leaning difficulties in a familiar and convenient setting.

Evidence of impact (source as in development by LOCSU for NHS EI):

- Special Schools – 80% of children with Learning Disabilities attend Special schools, and although approximately 50% have a problem with sight, only around 10% have any history of eye examinations. This is often not at regular intervals.
- Special Schools – 40-50% of children have previous HES involvement often due to Learning Disabilities but not eyecare needs.
- PwLD: 6 in 10 adults will require visual correction often with a higher prescription than previous. The service also supports with advice and guidance around adaptation and correct use of spectacles.

Other services in place across England where the primary eyecare workforce delivers care within their core competence include (Webpage: LOCSU helps LOCs develop Services Directory Clinical Pathways):

- Minor Eye Conditions Service (MECS)
- Healthy Living Optical Practice Framework
- Low Vision
- Maculopathy Referral Filtering and Monitoring
- Medical Retina Monitoring (Hydroxychloroquine).

In our experience of developing these pathways and supporting the services that are commissioned based on our established pathways, the fundamental problem for patient outcomes is not workforce skills gaps, and the consequence of this proposal is to give this misleading impression. The real issue for the public/patients is fragmented and inefficient commissioning, as the NHS LTP and recent Health and Care Act 2022 make clear. In order to encourage wider and deeper commissioning to improve patient outcomes, LOCSU has been centrally involved in end-to-end eye care pathway design as part of the National Eye Care Recovery and Transformation (NECRT) Programme (Webpage: National Eye Care Recovery and Transformation Programme - LOCSU and NHS England » Elective Care Transformation Programme). A vital part of the transformation programme is the testing and roll out of Optometry First (OF). OF utilises the skillsets of all participating optometrists, DOs and practice teams and is supported by optometrists and DOs with the higher qualifications already defined in the Act. OF enjoys the support of primary and secondary care eye specialists and

their representative bodies (including the College of Optometrists and the Royal College of Ophthalmologists), who recognise its utilisation of already in place core competencies, without the need for additional qualifications. This proposal runs the risk of inadvertently making the delivery of these workstreams more difficult.

We urge the GOC to very carefully consider the wider ramifications of this proposal and unintended consequences to national objectives.

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

a) Yes
b) No
c) Not sure / no opinion

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

Conflation of issues

We recognise the arguments summarised by this passage in the GOC's 2013 review of business regulation (para 24):

> *We consider that the most proportionate response to the risks associated with optical business practice is to extend regulation to all businesses providing restricted functions and to enhance the code of conduct by making it more targeted at the risks. This will lead to improved regulation of optical businesses, with a stronger emphasis on, for example, supervision of employees who are not registered with the GOC as individuals.*

Extending GOC regulation to all UK optical businesses makes sense in this context so we are in support of this element of the proposal. (Although we question whether it is still the case that there are over 4,000 optical businesses providing restricted functions and would welcome updated GOC reporting on this).

However, we cannot support the full proposals as, in in our view, the GOC already adequately fulfils the requirements of a sector regulator meaning there is no need for additional regulatory powers. We see no need for regulation through CQC or any other mechanism. Presently the primary ophthalmic sector is exempt from CQC regulation on grounds of proportionality and, as we have said above, consider the GOC with its current powers an appropriate regulator for the sector.

In addition, we do not understand the commentary on General Ophthalmic Services (GOS) contract assurance (para 30) in the context of regulation, whether by the GOC or other body. NHS GOS contract assurance is carried out by NHS teams for reasons of contractor contractual adherence, not regulatory purposes. NHS GOS contractual compliance works well. Evidence of this is the engagement by NHS England teams with the Quality in Optometry GOS contract compliance function developed by the sector latterly in conjunction with NHS Digital (website: Quality in Optometry - Welcome). Regulation and contractual scrutiny are separate, and we think it is important that the GOC clarifies what it means by its apparent conflation of the two in subsequent documents and guidance.

Q12. Are there any advantages, disadvantages and impacts (both positive and negative) of extending business regulation in addition to those identified in our 2013 review of business regulation? (Impacts can include financial and equality, diversity and inclusion.)

a) Yes

b) No

c) Not sure / no opinion

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

Broadly in support but mindful of potential cost burdens.

As above, we understand the rationale of extending business regulation to those identified in the GOC's 2013 review. However, it is important for the GOC to weigh the impacts and balance of risks particularly in respect of financial burdens on smaller businesses before progressing this further. The GOC must be mindful of the small numbers of staff many optical businesses have. and part of the judgement exercise should be to understand the reticence those businesses have had in the past with regard registering as optical businesses.

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

a) Yes

b) No

c) Not sure / no opinion

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

Unnecessary

Any response to this question depends on what is meant by 'effectively.' In our judgement, the GOC's powers are already sufficient. On the whole, we believe that the GOC adequately fulfils its remit as set out by the Act. We also recognise, and welcome, the GOC's continued efforts to engage with optical sector bodies including LOCSU.

We support the continued existence of the GOC as an optical-sector specialist regulator and have previously opposed any moves towards merged regulators or a 'mega-regulator.' Regulatory specialism is important. It saves time, reduces the likelihood of confusion and, while all regulators will come under scrutiny from those they regulate and wider stakeholders, specialism at least assures the profession that its regulatory body understands the issues at hand. Was the GOC to assume CQC-like powers, in our view, this would potentially lead to contractor-regulator alienation as there is no evidence this is necessary, and it would like regulatory creep for no benefit which the contractors themselves would have to pay twice for (once through fees and then again through reporting and visits). This in turn would make the GOC's role harder to fulfil to the detriment of its patient and public safety objectives.

It is also important to remember that the cost burden of any additional work falling on registrants would ultimately be met by patients or the NHS, which is something we could not support. There are higher risk areas of eye health for patients and the NHS to spend scarce resources on.

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

a) Yes, the GPhC model of a responsible pharmacist
b) Yes, another model (please specify)
c) No
d) Not sure / no opinion

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

As per our answer to Q13 above.

CONSULTATION

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.)

a) Yes – with no restrictions
b) Yes – under the oversight of an optometrist or registered medical practitioner
c) No
d) Not sure / no opinion

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

No

Our answer of 'no' to this question reflects our engagement with our LOC members.

For commentary on the issues around this proposal please see the responses to this question from our parent organisations:

- Association of British Dispensing Opticians (ABDO)
- Association of Optometrists (AOP)
- Federation of Ophthalmic and Dispensing Opticians: The Association for Eye Care Providers (FODO).

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.

Please see commentary from LOCSU's parent organisations in their responses (as per Q.15 above).

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

a) Yes
b) No
c) 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.

Not at all

We are concerned by the implications to patient and public safety of this proposal. We are unaware of any patient demand for changes to optical sector regulation. As the GOS statistics in our answer to Q7 demonstrate, the optical sector is healthy and robust and attuned to meeting patient needs. While there are many problems in the optical sector, we do not think barriers to business or practice are among them.

In respect of evidence, we are unaware of any evidence suggesting that the UK optical sector suffers from overly onerous or complex regulation. We are aware that in most other European countries, the eye care model is significantly different from that of the UK, with optometrists afforded fewer clinical responsibilities, and a greater role for ophthalmologists (for example, France and Germany have more than double the number of ophthalmologists per million of the population than does the UK (Source: Country Map & Estimates of Vision Loss Country – The International Agency for the Prevention of Blindness (iapb.org). These differences reflect the UK's unique health architecture and the existence of free at the point of need healthcare that the NHS delivers. We think it is very important that the GOC recognises the unique dimension that the NHS brings to healthcare in the UK, giving full regard to the LTP and Health and Care Act 2022 (Health and Care Act 2022 (legislation.gov.uk) which outline the need for greater, not lesser, primary care involvement across care pathways.

We request that the GOC is very careful when considering call to evidence responses that might seek to overlook or obscure the fundamental differences between the way eyecare and wider healthcare architecture is structured as regards UK and other European systems. As the GOC itself says (para 14), any case for change made in responses to these proposals must be wide-reaching, thoroughly

persuasive, and demonstrate how patient outcomes will be improved. In our view, we do not see such a case for change.

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.

No change

We believe that current sight testing legislation should remain as it is in the interests of public and patient safety. It provides a vital population health function and is something that should be preserved.

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

a) **Yes**
b) No
c) Not sure / no opinion

5.1% in England

A 2021 analysis of approximately 650,000 GOS sight test forms in England found a referral rate of 5.1% from primary care optometrists into secondary care (Source: Referrals from community optometrists to the hospital eye service in Scotland and England | Eye (nature.com)).

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

As above.

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

a) **Yes**
b) No

c) Not sure / no opinion

Yes, to the refute the case

It is our firm view that the best way to mitigate avoidable sight loss is to maintain the sight test as currently defined by the Act. Given that 78% of the public fear losing their sight more than the loss of any other sense (Source: Facts about sight loss | Fight for Sight) all of us in the sector have a duty to do everything in our powers to reduce the risk of avoidable sight loss. Separating refraction from the eye health check would be detrimental to patient safety and population health. As sections 24 and 26 of the Act make clear, the importance of the sight test is as the early identifier of ocular issues including the mechanism for referral that, if left untreated or undetected, may result in avoidable sight loss.

Even in an advanced and comprehensive health care environment such as that in the UK, avoidable sight loss is still a major problem. The RNIB found in 2012 that over 50% of sight loss is avoidable (Source: Preventing avoidable sight loss Preventing_avoidable_sight_loss_August_2012.pdf (rnib.org.uk)). Globally, the figure for avoidable sight loss is estimated by the IABP to be 90% (Source: Vision Atlas - The International Agency for the Prevention of Blindness (iapb.org)).

One key cause of sight loss is glaucoma. The International Glaucoma Association found in 2014 that over 50% of glaucoma cases remain undetected in the UK alone (Webpage: https://www.pharmatimes.com/news/over_50_of_glaucoma_cases_undetected_in_uk_1002033). One reason for this is patients not accessing primary eyecare regularly. Given that patients from black and minority ethnic groups are more prevalent to developing glaucoma, this is particularly worrying in respect of health inequalities. It is clear to us that health inequalities and wider population health depend on regular patient presentations at optical practices. Splitting refraction from the eye health check is the worst possible course of action for public health and wellbeing.

Cataracts are another major cause of sight loss. Cataract surgery is the most commonly performed surgery in the UK (Source: National Ophthalmology Database Audit: Key Findings Summary 2019.pdf (nodaudit.org.uk) and is usually identified at a sight test. Again, the public health role of the sight test is clear.

A further cause of sight loss is Age-related Macular Degeneration (AMD). There are around 600,000 people with AMD in the UK presently (Source: Facts about sight loss | Fight for Sight). These patients almost all of the time will have their AMD detected by optometrists during the sight test.

The Act allows for the provision of a comprehensive and whole population clinical service:

- In 2019-2020, 13.4m patients received NHS sight tests in England alone (and millions more via private presentation).
- This has increased year-on-year from 2002-2003 by almost 40%, a greater increase than population increase would suggest. General Ophthalmic Services Activity Statistics England, year ending 31 March 2020 - NHS Digital

Nor does the Act place any barrier to innovation within the sight tests or the commissioning of repeat measures and extended services across the four home nations – all safely under the auspices of the Act as a piece of UK legislation – is evidence of this.

In addition, the likely impact of splitting the sight test would be additional presentations of patients to general practice, or overstretched hospital eye services where ophthalmology outpatient appointments are the highest by specialism in England (Source: Hospital Outpatient Activity 2020-21 Hospital Outpatient Activity 2020-21 – NHS Digital.)

Therefore, it is our strong view that public and patient safety can only be harmed through the splitting of the sight test and we oppose this proposal.

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

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

a) Yes
b) No
c) 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.

Risk of change

As the professional qualifications currently delineated in the Act shows, becoming a contact lens optician requires additional training and skills. This is for good reason: to safely fit lenses to new

users; to provide safe guidance to users; to monitor patients at clinically indicated intervals and ensure lenses continue to be suitable and safe, to address patient clinical queries, and more.

In terms of patient and public safety, deregulating contacts lens legislation conveys no benefits at all, but would exacerbate risks to the public in our view.

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.

Danger of change

We think that it is important to maintain existing restrictions in the best interests of patients and the population, and to reduce the risks associated with contact lenses that have not been correctly fitted or supplied without advice on safe handling and wearing schedules. It is important to avoid suggestions that current challenges around enforcement mean that this protection should be abandoned, as that would simply increase risk for millions of people on the basis that a small proportion of contact lens users and companies based abroad today do not comply with UK legalisation.

The British Contact Lens Association and the GOC itself have found 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 a damaged contact lens (29%).' (Source: Love your lenses Week 25-31 March 2017 (bcla.org.uk)). This shows that even with existing safeguards, contact lens use carries significant risks. It would be remiss therefore to make changes to legislation that would erode the existing safeguards that registered professionals provide.

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

a) Yes – please specify which groups of patients
b) No
c) Not sure / no opinion

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

No.

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

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.

N/A

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

a) Yes
b) No
c) Not sure / no opinion

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

As per our answer to Q21 and Q22. The general direction legislation ensures registrant input to the supply chain for patients seeking resupply within specification from UK-based third-party suppliers.

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?

a) Yes

b) No

c) Not sure / no opinion

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

As per our answer to Q21, Q22 and Q25.

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

a) Yes

b) No

c) Not sure / no opinion

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

As per our answers to Q21, 22 and 25.

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.

As per our answer to Q21, 22 and 25.

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

a) Yes

b) No

c) Not sure / no opinion

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

Overly prescriptive and no evidence of harm or need for this change.

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

a) Yes

b) No

c) 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.

As per our answer to Q21.22 and 25. On the contrary it is an important wearer safeguard especially for non- lens wearers who may be unaware of risks.

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

a) Yes

b) No

c) Not sure / no opinion

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

As per our answer to Q21,22. 25 and 30.

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

a) Yes

b) No

c) Not sure / no opinion

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

Existing legislation is suitable and important for mitigating risks of plano contact lens use by inexperienced wearers .

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.

No change.

We cannot see any advantages for public and patients' safety regarding existing zero powered contact lens by changing existing legislation. Doing so would implicitly sanction, and therefore encourage, the sale and supply of such appliances to sections of the public, without the safety and expertise that contact lens opticians and optometrists provide. It is clear to us that the result of this would be an increase of infections and other eye injuries to the cornea and other ocular areas as the result of unsafe lens wear.

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?

a) Yes
b) No
c) Not sure / no opinion

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

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.

N/A

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

a) Yes
b) No
c) Not sure / no opinion

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

Yes.

We are unaware of any evidence suggesting that patient and public safety will be improved through this proposed deregulation.

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

a) Yes
b) No
c) Not sure / no opinion

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

No change.

We are unaware of any evidence suggesting that patient and public safety will be improved through this proposed deregulation. Two years is assessed as a reasonable period within which vision changes may happen and eye pathology may develop. It is therefore an important encourager for patients to have sight test even there has been no change and spectacles do not need changing. As per our answers above, millions of sight tests are carried out successfully in the UK each year with overwhelmingly high patient satisfaction. Therefore, we see no need for change.

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

Unnecessary and risky.

We see no advantages at all to public and patient safety.

The disadvantages are numerous. Allowing non-registrants to dispense spectacles without a prescription dated in the previous two years will inevitably encourage unqualified, unregistered, inadequately trained and potentially non-UK based businesses to enter the UK market. These

entrants will have little or no incentive to dispense safely and appropriately, lack accountability or transparency, and, in many cases, will be beyond the reach of GOC regulation.

The recommendation for sight tests every two years is in place for a reason. It allows optical professionals not only to prescribe spectacles suitable to a patient's unique ocular circumstances, but also detect pathologies that, if untreated, may lead to avoidable sight loss as a cost to the wider health system. This proposed deregulation carries significant risks both to individuals and wider society including:

- Patients, particularly the elderly, potentially more subject to falls if relying on inappropriate spectacles (Falls - Prevention - NHS (www.nhs.uk))
- Children potentially with uncorrected refractive error or other problems (Eye tests for children - NHS (www.nhs.uk))
- Drivers with untreated ocular issues potentially will pose a risk to themselves and others (Driving eyesight rules - GOV.UK (www.gov.uk)
- Urgent referrals may not be made: Routine eye test led to woman's brain tumour discovery - BBC News
- Exacerbating the impact of critical events on people accessing eyecare by obscuring the public health messaging of registrant-delivered sight tests every two years: Coronavirus: 'Eyesight of thousands at risk due to missed care' - BBC News
- Exacerbation of eye health inequalities. Addressing health inequalities is a top priority of the NHS (Webpage: NHS England » The Equality and Health Inequalities Hub). It is known that sight test inequalities exist (Source: Geographical inequalities in uptake of NHS funded eye examinations: Poisson modelling of small-area data for Essex, UK - PubMed (nih.gov)). It is also known that certain groups are more at risk of eye conditions, such as the greater predisposition of people of African, Caribbean or Asian origin to glaucoma. In our view, enabling provision of spectacles outside of a two-year prescription will reduce the likelihood of timely eyecare appointments among the general population but particularly to certain groups including those which are likely to need them most. This will exacerbate health inequalities and increase the likelihood of avoidable sight loss.

The GOC has a duty to maintain patient and population safety in the UK. As the examples above illustrate, we believe that it would be wrong for the GOC to confuse messaging regarding the vital public health importance of two-yearly sight tests. Therefore, we strongly oppose this proposal.

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 above.

We are unaware of any evidence suggesting that patient and public safety will be improved through this proposed deregulation and therefore believe that legislation should remain as is.

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

a) Yes
b) No
c) Not sure / no opinion

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

Unnecessary and risky.

Any changes to regulation must rest on a firm evidence base, premised on protection of patients and minimising the risk of unintended consequences. We are unaware of such an evidence base. Therefore, we believe that restrictions relating to the supply of sports eye wear to children should be maintained to protect the wearer and other participants, as well as optimising vision.

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.

Unnecessary and risky.

Any changes to regulation must rest on a firm evidence base, premised on protection of patients and minimising the risk of unintended consequences. We are unaware of such an evidence base.

Children's eye and vision are essential to their futures and should not be put at risk. Therefore, we believe that restrictions relating to the supply of sports eye wear to children should be maintained to protect the wearer and other participants, as well as optimising vision.

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 answer above.

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?

a) Yes
b) No
c) Not sure / no opinion

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

No.

We are unaware of any evidence suggesting that patient and public safety will be improved through this proposed deregulation.

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.

See our response to Q38.

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?

a) **Yes**
b) No
c) Not sure / no opinion

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

Important to be clear what is meant.

We do not see anything in the current Act precluding the utilisation of technological developments.

It is important to note as well that Remote care, technology and AI are not the same things. They will also mean different things to different eyecare providers and patients. Definition of what is meant by these terms is necessary.

In terms of **remote care**, in the first months of the COVID-19 pandemic, LOCSU with sector partners developed the Covid-19 Urgent Eyecare Service (CUES) to ensure that patients with urgent eyecare needs were treated by primary eyecare professionals, and kept out of secondary care as far as possible (Webpage: COVID-19 Urgent Eyecare Service (CUES) - LOCSU). CUES enabled patients to gain prompt access to a remote consultation, leading to a care plan for the patient to:

> Self-manage their ocular condition (with access to appropriate topical medications where appropriate); or
>
> Be managed by their optical practitioner with advice, guidance and remote prescribing as necessary by a hospital ophthalmology service; or
>
> Be appropriately referred to hospital ophthalmology services.

Evidence of impact:

- Manchester CUES – in an 8-week period, 2461 patients were assessed with 85.7% entirely managed in Primary care
- Manchester Royal Eye Hospital – triage by telephone redirected 32% of referrals to hospital urgent services out to primary care
- Central Mersey – improved care navigation with 25% of CUES activity signposted from general practice.

More generally, GOC research from February 2021 also showed that 62% of patients would consider an initial consultation via video or telephone after COVID restrictions ease (Source: GOC Public Perceptions Research 2021_public_perceptions_research_pdf.pdf (optical.org).

However, while this may point towards the evolution and further potential of new care models, this does not necessarily mean that 'technology' and 'AI' will meet the eyecare needs of the population now and into the future. We advise strong caution regarding new entrants to the market that claim patient needs can be met without registrant involvement. This is particularly the case where such companies are based outside of UK regulatory scope. As we have said above, we see no evidence pointing to existing regulation supressing patient choice or inhibiting service efficiency . Given that the GOC as a regulator is responsible for ensuring patient safety, we strongly caution against any changes to the Act that erode the role of the professional in serving and treating patients.

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?

a) Yes – a mainly positive impact
b) Yes – a mainly negative impact
c) No
d) Not sure / no opinion

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

Not possible to say

At the present time, as we have said above, we view remote care as positive and indeed vital during periods of disruption, such as COVID-19. This is why LOCSU worked with partners to create CUES to ensure that patients could continue to access quality and timely care. In this respect, we are fully supportive of remote care.

However, it is impossible to say whether 'technology' may have an impact on patient safety in the future. Even at the present time, 'technology' is such a broad term as to render any assessment of its impact too imprecise as a value judgement. This is even more the case regarding the future. What we would say is that any use of technology must be subject to rigorous testing and long-term evaluation. As above, it is also important to specify terminology and delineate between remote care, technology and AI.

Also as above, there is nothing in the Act to preclude the use of technology in practice, as evidenced by new equipment and infrastructure implemented by practices since 1989. Matters such as the safe adoption of new technologies are best addressed through GOC standards which can change to meet emerging requirements or challenges.

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?

a) Yes
b) No
c) Not sure / no opinion

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

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?

a) Yes
b) No
c) 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.

Legislation no, policy yes.

There is nothing within the Act that disbars innovation regarding technology or remote care. This is shown by the new methods of working and equipment used in practices relative to 1989.

However, we have serious concerns about the impact of non-regulated individuals or businesses potentially acting in ways not consistent with the GOC's objective of maintaining patient and public safety. We believe that the GOC should adapt its policies to ensure that its patient and public safety objective incorporates any potential risks of remote care or technology. The GOC should ensure that those under its regulatory auspices understand the duties according to the Act including as set out in GOC standards. It should also ensure that patients are provided with as full information as possible on the risks of relying upon non-regulated, extra-UK providers.

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.

See our answer above.

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?

a) Yes
b) No
c) 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.

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.

N/A

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)?

a) Yes
b) No
c) Not sure / no opinion

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

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

a) Yes
b) No
c) Not sure / no opinion

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

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

a) Yes
b) No
c) Not sure / no opinion

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

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)?

a) Yes
b) No
c) Not sure / no opinion

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

Risk of financial impact

As stated above, we are concerned by the apparent conflation of regulatory and contractual compliance mechanisms in the GOC's proposals. Our concerns are that this conflation is not only confusing and inappropriate in our view, but that financial burdens would likely fall to the sector. We ask for prompt GOC clarification on what is meant here.

EDI

In terms of EDI and the Equality Act 2010, we do not see any correlation between the existing or proposed regulatory framework as defined by the Opticians Act, providing that regulation is carried out equitably and transparently.