OPTICAL CONFEDERATION AND LOCAL OPTICAL COMMITTEE SUPPORT UNIT RESPONSE TO GOC CONSULTATION ON DRAFT CONSENT GUIDANCE

Section 1: Our guidance

1. **Do you support the GOC's approach in providing supplementary guidance on consent to support registrants in meeting their obligations in the Standards of Practice for Optometrists and Dispensing Opticians and Standards for Optical Students?**

Yes.

The Optical Confederation (OC) and the Local Optical Committee Support Unit (LOCSU) support the provision of supplementary guidance on consent for registrants in order to provide clarity and support on obtaining valid consent from patients for examinations and procedures. However, as we outline below, the OC and LOCSU have significant reservations about the content and tone of the draft guidance in its current format.

2. **Does the new supplementary guidance on consent make it clear what the GOC expects of its registrants?**

No.

Unfortunately, while lengthy, we are concerned that the guidance will not achieve the desired objective of helping to make clear to registrants what is expected of them.

In part this is a failing of style and format: the guidance as drafted looks and reads more like the GOC Standards than it does additional guidance. While stating in the opening paragraphs that it is not intended to cover every circumstance and that a registrant must use their professional judgement, it then goes on throughout to use language such as "you must", which calls into question therefore whether this is guidance to explain the Standard, or a document which adds to the legal requirements of the Standard.

Insofar as the document provides guidance, it is inconsistent in that it veers between being onerous and prescriptive on matters where it would be reasonable to allow a flexible, common sense approach (for example, on the process of seeking and recording consent), while being vague and ambiguous in areas where registrants would welcome clear guidance, for example on issues such as assessing competence, and consent to refer.

It is notable throughout that the guidance does not address the different circumstances in which a registrant will need to seek consent from a patient. This would appear to lead to the assumption that the same process should be followed in all circumstances. But this is clearly neither sensible nor necessary. We would expect guidance – as opposed to the Standard - to make clear to registrants that the process for obtaining consent for a person who attends for their first ever sight test might be different to a patient who has attended sight tests on a regular basis, and different again where a patient is undergoing treatment (where, for example, the issue of risks might need to be more explicitly addressed).

3. Is the guidance on consent presented in a way that is clear, accessible and easy to use?

No.

We have set out our detailed comments in response to question 4. However, in summary, we consider the guidance to be too long, with a significant amount of repetition, and in some cases contradiction. Clearer sub-headings and a more logical structure would help remove some of the duplication and sign post registrants more easily through the guidance.

We are also concerned that the guidance alternates between being unduly prescriptive on some matters and vague and imprecise on others.

If this is to serve as useful and practical guidance for registrants, it is essential that real life examples of how the issues may arise in practice are used to illustrate the points made. Without these, the guidance will be open to misinterpretation and misapplication.

4. Is there anything missing, incorrect or unclear in the guidance on consent?

Yes.

The numbering in our comments below relate to the paragraph numbers in the draft guidance.

4. This provision is very broad and needs to be narrowed down – we suggest that the following paragraph be added:

“For employees, these requirements (and any practice or employer specific requirements) should be communicated to you by your practice owner/manager/HR/professional services/training departments.”

“Similarly, for optical practice owners and managers, it is legitimate to rely on the GOC, your Optical Confederation representative body (including Optometry Scotland/Wales/NI) and the College of Optometry to keep you advised of any changes to the law, NHS and employment policies. This will be by means of newsletters, guidance, website updates, alerts and other media.”

6. Amend “your professional body” to “your professional or representative body” .

9. Add to the final sentence: "Poor handling of the consent process may also result in complaints from patients which could result in regulatory action by NHS England, Health Boards or the General Optical Council (General Medical Council for ophthalmic medical practitioners"

10. Add "including referral" after treatment.

There are no specific sections in the guidance that deal directly with the issue of obtaining consent from a patient to refer them to other services. While paragraph 39 outlines the necessity to obtain consent to share patient information with other healthcare professionals it does not directly address the requirement of practitioners to receive the consent of a patient before referring them for further treatment. We suggest that the GOC add a specific paragraph to this guidance dealing explicitly with consent to refer to remove any ambiguity about registrants' obligations in this area.

12. Add in "or the decision to refer". This provision should also make clear that consent is needed from the patient or their carer, guardian or other person with legal authority.

14. This should include a duty on the part of the registrant to satisfy themselves that the patient has understood the information provided to them.

15. We suggest the second sentence is amended to make clear the discussion should be focussed on the patient's concerns – "You should address any issues the patient is concerned about, such as why the treatment is prescribed, the risks of not receiving the treatment, the risks and benefits of undertaking the treatment and any alternative forms of treatment that may be available. The patient should be aware of the potential for any adverse outcomes when giving consent to treatment or investigation."

16. As drafted this would imply that all registrants in a practice responsible for ensuring consent. The first sentence should be amended to read:

"You are personally responsible for making sure that a patient you are treating has given valid consent."

The frequent use of the term 'treatment' within the guidance, needs clarification as it could give rise to misunderstanding. A better phrase to use throughout for care beyond the sight test or a contact lens fitting or aftercare, would be "investigations/interventions/treatment".

Paragraphs 20-24 – this section is headed "Example of explicit consent", however the subsequent paragraphs do not give examples of consent but instead set out very prescriptive and disproportionate requirements for explicit consent. Moreover, these paragraphs contradict those that have gone before and those that follow (on implicit consent).

Additionally these paragraphs as drafted refer only to eye examinations. They therefore fail to recognise the differing needs for providing information and seeking consent that are likely to arise in

differing circumstances. Indeed the guidance could be interpreted as imposing a higher standard of consent for eye examinations – where the process appears to be prescribed – than for other procedures, where the guidance leaves the decision of the type of consent needed to the registrant's professional judgement.

20. The requirement in this paragraph for explicit consent for all aspects of an eye examination contradicts paragraph 19, which states that the registrant must use their professional judgement to decide what type of consent to get.

It would be helpful here to provide a distinction between and advice on obtaining consent in different circumstances. The guidance needs to recognise the range of different procedures that consent may be needed for, some of which will be unfamiliar, some of which will have greater levels of risk to take into account, and then others which are routine. It should also recognise that many patients will attend for regular eye examinations and consent can reasonably be implied, whereas for a new patient it will be more important to talk the patient through the process.

21. While we agree that consent cannot always be implied on the basis of a patient attending an eye examination, it is not unreasonable to assume consent from a patient who has attended eye examinations previously. As per our previous comment, the guidance should make clear that how consent is requested and given should depend on each set of circumstances – that is, what treatment the patient is receiving, whether it is routine, and whether they are a regular patient (as will usually be the case for eye examinations).

Furthermore, the guidance goes further than that for other professions. The General Medical Council guidance on consent provides a good example on how this could be phrased: "Patients can give consent orally or in writing, or they may imply consent by complying with the proposed examination or treatment, for example, by rolling up their sleeve to have their blood pressure taken." (Para 45. GMC guidance on consent)

22. The suggestion that you need to seek explicit consent for every stage of a standard eye examination is excessive and does not reflect usual practice across primary care: a GP would not ask for consent at each stage of a routine medical check-up, nor would a dentist ask a patient for consent when using each individual implement involved in a filling. And as already noted, it contradicts paragraph 28 of the guidance. Much of this paragraph can simply be removed if the guidance is redrafted so that it is preceded by paragraph 23. This paragraph would then simply need to say:

"It is good practice to check at each stage of testing or treatment that the patient understands and consents to the next procedure, especially when a registrant plans to move equipment close to them or carry out a physical procedure such as instilling drops or inserting a contact lens. Seeking a positive re-affirmation of consent is particularly important if any aspect of the examination is delegated to a colleague or where the patient may not be familiar with the test or apparatus. If a

patient who initially consents finds any aspect of the eye examination objectionable during it, they can withdraw their consent at any point."

23. The guidance would be clearer to follow if this paragraph on how information can be provided to a patient preceded paragraph 22 on how patient can give consent. The paragraph also needs redrafting to be clearer. We suggest:

"For a patient undergoing an eye test, investigation, intervention or treatment, consent should be explicit and can be oral or written. This can be achieved either by providing written material in advance and asking the patient at the start of the examination whether they have understood it; or by using such phrases as:

"I am just going to use this equipment to look at the back of your eye, is that all right?

"I am now just going to pop this lens in your eye, is that all right?"

"I would like to put some drops in your eye so that I can……. . They will sting a little for [TIME]. They also mean that you will not be able to drive for [TIME], is that all right?

Paragraphs 25 and 26

These two paragraphs provide guidance on recording consent, and should be given a heading to that effect. It would also make more sense if they were to follow the section on implied consent, rather than fall between it and the section on explicit consent.

25. The requirement to note verbal consent in a patient record is disproportionate. Again, other health care professionals who receive verbal consent for administering a treatment or performing an examination are not required to note that consent in the record of a patient's visit to their practice e.g. even where a GP performs a digital examination on a patient, which is a minor but invasive procedure, verbal consent is normally sought but there is no requirement on them to record that consent. There is no good reason why it should be different for the optical sector. In practice for sight testing such a requirement would literally be nothing more than a tick box. We suggest that it would make more sense to clarify that a written note should be included on the patient's record to show what they have consented to for treatments that are not usually part of the sight test, where a material risk has been identified or where the patient has refused consent.

26. The reality is that there are no material risks in a sight test, and yet this section does not recognise that. We suggest that this paragraph should be reworded to read:

"It is good practice to record consent where the procedure, treatment or examination being proposed is not routine or has greater risks involved – for example where you have outlined any material risks involved to the patient [e.g. use of eye drops] – in these case the patient should be asked to confirm they have understood the risks and agree to the procedure. A note should be made on the patient record to reflect that the patient understood the risks involved when consenting to a procedure, treatment or examination (e.g. 'patient is aware that drops may affect ability to drive for a short while and has given consent')"

28. We agree with this paragraph – however as noted above, it is contradicted by paragraphs 20-23 above.

33. Could benefit from a practical example of how to apply this.

36. Could benefit from a practical example of when this might arise "e.g. if you would like to use their anonymised data for your own research purposes."

37. This could be made clearer if simplified. We suggest:

If a patient says that they do not want some or all of their personal information shared within your own healthcare team, or with others involved in their care [suggest giving an example here, e.g. their GP, another healthcare professional, or their spouse, parent or adult child]you must respect this, unless disclosure would be.....

It would also be helpful to include examples of where disclosure would be in the public interest [driving], required by law [safe-guarding], the best interests of a patient who lacks capacity.

39 & 40 – There may be circumstances when a person (due to disability, for example) may not be able to give either verbal or written consent but can consent with a gesture and this should be included in the guidance.

Capacity to Consent

We are concerned that this section lacks clarity and does not always provide sufficient information (e.g. on differing powers of attorney). We believe it would be wise to refer registrants to existing advice from the College of Optometrists and ABDO.

49. There is an issue about assessment of capacity which arises with patients who may have mild cognitive impairment (mci) or early stages of dementia. The Mental Capacity Act requires a patient to be able to retain the information provided to them in order for consent to be valid. A circumstance may arise where a patient with dementia or mci could be lucid enough to, on the face of things, consent to a treatment/examination but the registrant providing them with their treatment/examination feels that this patient may have problems recalling or accepting a diagnosis in the short term. The guidance needs to be clearer on what to do in circumstances such as the above and whether a professional can perform the examination in the patient's best interest, where there is doubt about their capacity to consent. Perhaps a similar approach as that outlined in the Scottish legislation in 59 would suffice.

52. This would be clearer if the highlighted words were added:

"A patient's capacity to consent may be temporarily affected by **a variety of** other factors....."

53. We suggest adding "or seek advice from a more experienced colleague" at the end of the last sentence.

55. Delete the word "just".

61. The word Bill in the last sentence should be changed to Act.

62. The highlighted words should be added:

"If you are unsure about a patient's capacity **to give consent** you should get advice from other colleagues, healthcare professionals or people involved in their care. If you are still unsure you may need to consult your **professional representative body or legal defense association** or obtain legal advice. Any advice you get or assessments carried out should be properly recorded, along with the outcome."

63. This sentence is incomplete and it is therefore unclear what point is being made.

66. This provision should be reworded to read:

"When examining or treating adults who lack capacity, it is important that you comply with the law of the relevant country."

67. There are various types and nuances to Power of Attorney provisions across all the nations. It would be preferable if a short guide to these was included in the annex to this guidance, perhaps with some examples.

68. We strongly suggest replacing the phrase "their loved ones" with more precise and useful language – family, next of kin, friends or carer would all be more acceptable language.

The guidance should also be more explicit to address the situation where there is no legally appointed attorney or deputy, just a concerned family member, and informed/inferred consent of the patient cannot be concluded. In such circumstances registrants would benefit from advice on how much information they can share with a family member. In England and Wales, Section 5 of the Mental Capacity Act confers a general authority to allow decision makers to take action in providing care for individuals who lack capacity, as long as those decisions are in the best interests of the incapacitated individual, and all reasonable steps have been made to ensure the person in question cannot make the decision for himself. Deciding what is in a person's 'best interests' will ultimately lie with the professionals responsible for care. A problem could therefore arise if there was a dispute with the family members and the health professionals as to what is within the person's 'best interests'. It would be helpful if the guidance could provide more clarity on this as the ambiguity of the current wording could lead to confusion.

72. Assessing maturity and understanding may not always be clear cut and relies mostly on the subjective opinion of the registrant. As per 78 – children must demonstrate their competence in order to be judged to have capacity. However this is, more than likely, something that will have to be probed by the registrant in order to make a proper determination. It might be better if the guidance included some sample questions that a registrant could ask to help them come to a determination of the young person/child's capacity to consent.

79. As the comment on 72 above.

80. The following highlighted words should be added:

"If you consider that the decision of a competent child to give consent is not in their best interests, you should consult colleagues, your **professional, legal defense or representative association** or obtain legal advice before proceeding."

83. The guidance could be clearer about the potential outcomes in these circumstances and the liabilities/responsibilities on a registrant who knows and has communicated that treatment is necessary to prevent a condition deteriorating (potentially to the point where vision may be lost or severely reduced) but cannot obtain the consent from the child.

86. Add the highlighted words:

"**The person** who will be considered to have parent responsibility may also vary. **You should seek advice from your professional, legal defense or representative association, obtain legal advice and** refer to relevant national legislation as appropriate."

87. We suggest that "you may wish to seek further advice" should be changed to "you should seek further advice."

5. **Are there any specific issues or barriers that could prevent stakeholders from implementing or complying with the guidance on consent?**

Yes.

The length and format of the document and the very formulaic and legalistic manner in which it is presented does not make it easy for registrants or their professional representative bodies to engage with the guidance.

It would be preferable to condense some of the guidance and also use to provide some practical examples to help illustrate and clarify the kinds of circumstances that are likely to arise and how to deal with them.

As discussed at length in previous questions, and specifically in question 4, the guidance is unduly onerous and prescriptive. It does not distinguish between the different types of treatment and levels of risk when providing advice on how the Standard should be applied. As a result in many circumstances the guidance is impractical and unrealistic.

Unfortunately on those issues where registrants would welcome clear guidance (such as the issue of capacity), this draft guidance is, as set out in response to question 4, unclear and likely to give rise to confusion.

6. **What action could the GOC (or other organisations) take to help registrants to implement the guidance on consent? Please give your comments below:**

The guidance should be shorter, easier to engage with and contain more practical examples for each of the provisions that it covers. Case studies/scenarios/condensing of information into graphic format should all be considered as beneficial additions that would make the guidance a much more user friendly, coherent and impactful document.

7. **Overall, do you expect that the guidance on consent will be beneficial to, or have a positive impact on, the protection of the public?**

No.

The public are at very minimal risk when treated by optical professionals and there is no evidence to suggest that there have been any significant concerns about obtaining consent. The guidance therefore cannot be beneficial since there is no problem to address. Furthermore the one area where greater clarity could be helpful for both registrants and patients – that of determining capacity to consent – is not well addressed.

8. **Are there any aspects of the guidance that could have an adverse or negative impact on certain groups of patients, optometrists, dispensing opticians, optical students, optical businesses, optical training institutions or any other groups?**

Yes.

The suggested approach in the guidance to obtaining consent, particularly for routine procedures, is unnecessarily bureaucratic. This will add an unnecessary administrative burden. More importantly rather than benefiting patients there is a serious risk that it will simply irritate people to be constantly asked if the practitioner can proceed with an eye examination. This could cause patients to fear the risks are higher than is the case, because they are so constantly flagged up, and could undermine the important relationship of trust between patient and practitioner.

9. **Are there any areas of the guidance that could discriminate against stakeholders with specific characteristics? Please consider sex, age, race, religion or belief, disability, sexual orientation, gender reassignment, pregnancy or maternity, caring responsibilities or any other characteristics.**

Yes.

The guidance inadvertently discriminates against those who may have a disability causing them to be unable to provide written or verbal consent but who may be able to communicate by alternative means.

10. Do you have any additional comments you wish to make on the guidance for consent?

No.