PUBLIC
C23(16)

COUNCIL

Standards strategic review: candour and consent guidance consultation

Meeting: 11 May 2016

Status: for decision

Lead responsibility: Alistair Bridge, Director of Strategy

Council Champions: Paul Carroll, Peter Douglas, Fiona Peel, Helen Tilley and Selina Ullah

Project director: Marcus Dye (Acting Head of Education and Standards)

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Project Board: SMT

Project team members: Simon Grier (Communications Manager), David Rowland (Head of Policy) and Marie Bunby (Policy Manager)

Purpose

1. To update Council on plans for producing supplementary guidance as part of implementation of the standards for optometrists, dispensing opticians and optical students and seek approval for consultation on draft guidance.

Recommendations

2. Council is asked to:
   - 2.1 **consider** the proposed guidance on consent (annex one) and **approve** it for public consultation;
   - 2.2 **consider** the proposed guidance on candour (annex two) and **approve** it for public consultation;
   - 2.3 **consider** and **agree** the proposal to not produce further guidance on care and compassion; and
   - 2.4 **consider** the working group's views on producing guidance on legal requirements of practice and **agree** that the legislation should be gathered together in one place on the GOC website.

Strategic objective

3. Reviewing our approach to standards is a project in the 2016/17 Business Plan. This project contributes to our mission of protecting and promoting public health and safety by helping to achieve our strategic objectives in the 2014-17 Strategic Plan to increase public trust and awareness and to promote higher standards across the optical professions.

Risks

4. In order to mitigate risks to patient safety in the optical sector, it is key that our standards and accompanying guidance remain clear and up to date. The production of guidance for our registrants on new elements of the standards will help ensure they understand how to incorporate the new standards into their day to day practice, and patients might not be adequately protected.

5. We have established a project specific risk register to capture and monitor risks associated with this project. The risk register is reviewed at regular intervals by the project team and the SMT Project Board. The main risks linked to implementation of the new standards are as follows:
   - 5.1 **Failure to take account of the patient voice, good regulatory practice, the outcomes of healthcare reviews, differences in the devolved nations and developments within the optical professions means that the content of the standards is either set too low or too high or does not apply to optical practice and is rejected by stakeholders**. This is addressed through extensive research through the development phase, an extensive consultation to understand whether the standards would work in practice and what their impact will be;
   - 5.2 **Lack of engagement with our stakeholders, particularly registrants, which may result in a lack of awareness of our new standards and these not being applied in practice.** This will require a wide-ranging programme of implementation to ensure that stakeholders are aware of the new standards and have the support they need to apply them. This is being addressed through our extensive consultation and implementation plans which aim to support stakeholders based on their specific needs, including communications, production of guidance and reviewing CET provision and requirements;
   - 5.3 **Confusion over the role of the GOC in standards setting and how this relates to other organisations.** This is being addressed through clear communications about the standards framework in both the consultation and the implementation phases; and
   - 5.4 **Delay between the production of the standards of practice and the standards for optical businesses leading to conflict between employers and employees.** This is being addressed through extensive consultation and changes to the Code of Conduct for business registrants so that it refers to the new standards of practice for individual registrants. Review of the Code of Conduct for business registrants will take place in 2017/8.

Background

6. At its meeting in July 2015 the Council approved the publication of a standards framework to define our role in setting standards for individual registrants and

new standards for optometrists, dispensing opticians and optical students following an extensive consultation with a range of stakeholders. The decision was taken after extensive consultation with our stakeholders – please refer to the Council papers from this meeting for further information: https://www.optical.org/download.cfm?docid=E13F85CE-9EB9-4452-90B55DFCDFA386AA

7. In our standards framework and our response to the consultation we stated that we would be producing supplementary material, such as guidance and case studies, to help registrants understand how some of the standards apply in an optical context.

8. We identified four priorities for guidance based on the consultation responses. These were:
   - 8.1 candour;
   - 8.2 consent;
   - 8.3 care and compassion; and
   - 8.4 legal requirements of practice.

9. The GOC Standards Framework states that the GOC will produce supplementary guidance in the following circumstances:
   - 9.1 address issues that are relevant to all healthcare professionals, such as consent and duty of candour (often in response to a direction from Government or recommendations from the Professional Standards Authority);
   - 9.2 explain legal requirements which are complex or confusing in nature, such as regulations on the sale and supply of optical appliances or the use of medicines;
   - 9.3 address issues arising persistently in fitness to practise cases; and/or
   - 9.4 provide clarity in circumstances where third party guidance is conflicting.

10. In October 2015 the Standards Committee considered a provisional set of guidance notes, which were developed following a review of guidance produced by other healthcare regulators, the outcomes of recent government reviews into poor patient care and the legal basis of practice. It was agreed to convene a working group of professional members to consider the guidance further and particularly the level to which we can contextualise it for the optical profession. The working group consisted of representatives from the Standards Committee, Education Committee and the optical business sector.

11. The working group met on 13 November 2015 and was asked to consider the guidance in terms of both its necessity and the content. Feedback from this meeting was used to refine the decisions and the content of the proposed guidance.

12. Following the working group, the guidance was presented to the Standards Committee at its meeting on 8 March 2016.

13. The new standards of practice (for both fully qualified registrants and students) came into effect on 1 April 2016. We have carried out the following activities to raise awareness about the standards across different groups of stakeholders:
    - 13.1 directly emailed registrants about the standards;
    - 13.2 posted paper copies of the standards to all registrants;
    - 13.3 required registrants to confirm they have read and will follow the standards both as part of retention and the first time they use MyCET for the new cycle;
    - 13.4 articles in eBulletin;
    - 13.5 attendance at 100% Optical, Optometry Tomorrow, Optrafair and the Northern Optometric Society, including conducting CET sessions;
    - 13.6 promotion in optical trade press, through proactive press releases, handling reactive enquiries and articles written by the GOC;
    - 13.7 general revamp of the website, including two videos, and Twitter;
    - 13.8 liaison with professional bodies to ask them to promote the standards to their members; and
    - 13.9 in respect of patients and the public, we are currently revamping our booklet *What to expect from your optician* and arranging to get patient feedback on this through focus groups with patients and members of the public. We hope to be able to publish a revised version of this booklet in July 2016.

Analysis

Consent

14. The Standards Committee noted the following points:
    - 14.1 two types of consent (explicit and implied) were proposed within the guidance and that it would be important to ensure that cultural differences were taken into account in understanding when implied consent had been given;
    - 14.2 proposed some specific amendments to the guidance, which were incorporated;
    - 14.3 that the guidance should be shared with a consent expert prior to public consultation; and
    - 14.4 the working group had considered whether more detailed examples should be provided in the guidance and concluded that this would potentially cause issues in an FTP context; and
    - 14.5 more generally, it was important to ensure that the guidance was not overly prescriptive in terms of how registrants should deliver their care. The principle set out in the draft guidance on registrants being able to use their professional judgement to decide what type of consent to get

was important in delivering the highest possible quality of care – this was particularly important in the context of everyday healthcare practice.

15. Expert advice on the consent guidance was obtained following the Standards Committee meeting. Minor amendments have been made to the guidance, which largely related to the differences in the legal position on candour and consent in the four nations.

16. It should be noted that the GOC is currently part of an inter-regulatory working group which is in the process of developing a joint statement with the other healthcare regulators on implied consent for sharing confidential information. The statement is still in the process of being drafted and we need to ensure that our guidance reflects the principles in the statement. We think it is important to consult on our guidance now rather than wait for this statement to be agreed, as we are not sure when this will be.

17. The guidance is now ready for consultation, which we propose to take place for a 12 week period starting in early-mid June 2016. During the consultation period we propose to carry out focus groups with registrants and patients, to ensure that their views are obtained. We will also contact all of our key stakeholders, such as our registrants, the optical professional bodies, optical businesses and patient organisations.

Candour

18. The Standards Committee noted that:
    18.1 the working group had clarified that the basis for this guidance is the professional duty of candour rather than any statutory or contractual duty of candour. This professional duty was agreed by healthcare regulators in October 2014;
    18.2 stakeholders had expressed concern that a medical professional issuing an apology in instances where patients had experienced unanticipated difficulties during or following their healthcare would be considered as putting the professional at the risk of liability. The GOC's position on candour is consistent with other healthcare regulators in that it does not consider an apology as an admission of liability - saying sorry does not mean admitting liability or wrongdoing but it is important to patients that you express regret for any harm, distress or adverse consequences to their health and wellbeing. Guidance from the NHS Litigation Authority (NHS LA)[1] states: *"saying sorry is not an admission of legal liability; it is the right thing to do. The NHS LA…will never withhold cover for a claim because an apology or explanation has been given"*; and

[1] NHS Litigation Authority (undated), *'Saying Sorry'*; http://www.nhsla.com/Claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf

18.3 the intention behind the duty of candour was to ensure that professionals were open and honest with their patients when something has gone wrong with patient care and to take appropriate action to ensure patient safety. This includes being candid with the patient, offering an apology, outlining what you will do to put the matter right and informing that patient of what you will do to ensure it does not happen again. It is not to put healthcare professionals at greater risk of liability; it was however hoped that a duty of candour could indirectly encourage registrants to reflect on their practice.

19. The Standards Committee were content with the guidance and recommended that it should be consulted upon. We propose that the consultation takes place for a 12 week period starting in early-mid June 2016. During the consultation period we propose to carry out focus groups with registrants and patients, to ensure that their views are obtained. We will also contact all of our key stakeholders, such as our registrants, the optical professional bodies, optical businesses and patient organisations. We will also hold a specific meeting with insurers.

Care and compassion

20. Standard 4 of the *Standards for Optometrists and Dispensing Opticians* states:

> *'4. Show care and compassion for your patients*
> *4.1 Treat others with dignity, and show empathy and respect.*
> *4.2 Respond with humanity and kindness to circumstances where patients, their family or carers may experience pain, distress or anxiety.'*

21. The working group discussed whether guidance was needed in light of the reasons outlined in paragraphs 8.3 and 8.4. The group felt that it was difficult to see how further guidance would support understanding of this area as the standard is self-explanatory in terms of expectations and does not contain any complex areas of practice. It was considered that the message the profession would need is that care and compassion are applicable to the optical professions as well as other healthcare professions.

22. The working group concluded that guidance was not necessary for this area and that it would be more useful for scenarios to be developed which illustrate care and compassion. It was also concluded that these were not necessary for the GOC to produce and other organisations such as the professional bodies or CET providers could fulfil this role.

23. The Standards Committee agreed that further guidance on care and compassion should not be produced.

Legal requirements of practice

24. The working group noted that it had previously been suggested that the legal requirements of practice are complex and not clearly understood by the profession. This was proposed to be addressed through the production of a guidance document collating the legal information in one place. A draft of this document was presented to the working group for discussion.

25. The discussion concluded:
    25.1 that a guidance document could not sufficiently outline the legal areas of practice;
    25.2 that attempts within the guidance to clearly outline the legal aspects of practice in plain English led to interpretation of the law by the GOC and the potential for misinterpretation or a loss of meaning. This posed a risk to the GOC; and
    25.3 it would be better to simply collate the laws relating to practice in one area of the website for reference by our stakeholders and produce individual regulatory statements where necessary on the basis of external legal advice.

26. The Standards Committee agreed that in view of the working group's views on producing guidance on legal requirements of practice, legislation be gathered together in one place on the GOC website.

Impacts

27. The following implications have been identified:
    27.1 Reserves – none.
    27.2 Budget – within project budget for 2016/17.
    27.3 Legislation – that guidance needs to reflect UK law and that external legal advice has been sought to ensure this.
    27.4 Resources – already included within current business plan for 2016/17.
    27.5 Equality, diversity and inclusion (EDI) – standards guidance must be accessible to all stakeholders – large text and Welsh versions are planned for both consultation and published guidance.
    27.6 Human Rights Act – none.
    27.7 Sustainability – none.

Devolved nations

28. The project has previously considered the emerging differences in scopes of practice and delivery of healthcare services in each of the nations of the UK.

29. We have taken advice to ensure that the differences in the legal positions in relation to candour and consent in the nations are taken into account in the draft guidance.

30. The following activities have allowed us to ensure our standards for individual registrants (optometrists, dispensing opticians and optical students) will be applicable to those practising in all parts of the UK:
    30.1 differences in legal frameworks, contractual obligations and scopes of practice were identified during the development of the new standards for individual registrants;
    30.2 we pro-actively engaged with key stakeholders in the four nations in the consultation on individual standards for individual registrants; and
    30.3 we have specifically addressed those issues relating to the nations identified through our analysis of the feedback from the consultation in finalising the standards for individual registrants.

31. The implementation plan for the standards for individuals identifies specific activities to support the adoption of the new standards in all four nations.

Communications

32. Communication is a key element to implementation and a plan is being established for both the consultation on and promotion of published materials in the same manner as that for the original Standards consultation.

Timeline for future work

33. Key dates for Council to note are listed below:

Date	Action
June – September 2016	Consultation on guidance documents
September/October 2016	Analysis of consultation feedback
October 2016	Standards Committee asked to review consultation outcomes
November 2016	Council asked to approve changes and to publish guidance
December 2016	Standards guidance published and sent out in registrant retention packs

Attachments

Annex 1 – Draft consent consultation and guidance
Annex 2 – Draft candour consultation and guidance

C23(16) – ANNEX ONE

Consultation: Supplementary guidance on consent

X June 2016

(front cover to be added)

Contents page

Section 1: About the General Optical Council

1. We are one of 12 organisations in the UK known as health and social care regulators. These organisations oversee the health and social care professions by regulating individual professionals.
2. We are the regulator for the optical professions in the UK. We currently register around 29,000 optometrists, dispensing opticians, student opticians and optical businesses.
3. Our primary legislation is the Opticians Act 1989 (as amended) ('the Act'), and we also have a series of related rules that describe how we carry out our statutory functions. Our legislation can be found on our website at http://www.optical.org/en/about_us/legislation/index.cfm
4. The GOC has four main functions:
    - setting standards for optical education and training, performance and conduct;
    - approving qualifications leading to registration;
    - maintaining a register of those who are qualified and fit to practise, train or carry on business as optometrists and dispensing opticians; and
    - investigating and acting where registrants' fitness to practise, train or carry on business is impaired.
5. More information about the GOC can be found on our website: https://www.optical.org/

Section 2: Consultation summary

7. This consultation seeks the views of stakeholders on the new supplementary guidance (annex 1) we have developed on obtaining valid consent.

8. The aim of the guidance is to give registrants further support and clarity on the principles set out in the GOC's *Standards of Practice for Optometrists and Dispensing Opticians* and *Standards for Optical Students.*

9. The guidance on consent gives further information on:

   - what consent is;
   - the process of obtaining valid consent;
   - consent to share patient information;
   - refusal or withdrawal of consent;
   - capacity to consent;
   - advance decisions on healthcare arrangements; and
   - what to do in emergencies.

10. The consultation will run from **X June 2016 to X August 2016** and applies to the whole of the UK.

Background

11. The GOC's new *Standards of Practice for Optometrists and Dispensing Opticians and Standards for Optical Students* came into effect on 1 April 2016 replacing the previous Code of Conduct for individual registrants.

12. The standards are designed to make clear what we expect of our registrants, while allowing room for them to use their professional judgement in deciding how to meet the standards in any given situation.

13. To view the standards please use the following link: https://www.optical.org/en/Standards/index.cfm

Obtaining valid consent

14. Patients have a basic right to be involved in decisions about their healthcare and agree or 'consent' to any examination or treatment that is proposed by their healthcare professional. The process of obtaining consent is a fundamental part of respect for patients' rights.

15. The new standards framework provides more detailed information for registrants on how to obtain valid consent from patients. The new standard also makes explicit reference to the legal obligations registrants have in relation to consent, for example, towards children, young people and vulnerable adults.

Supplementary guidance

16. When we first consulted stakeholders in 2015 in relation to our new standards framework, a number of stakeholders expressed a view that the GOC should

provide additional support and guidance to registrants on how to meet some of the standards, including the standard on consent.

17. We considered this feedback and decided that additional guidance was required.

18. The aim of the supplementary guidance is to give registrants more detailed information on how to meet a specific standard.

Consultation

19. The aim of the consultation is for stakeholders to review the draft guidance and provide their feedback in the consultation questions.

Next steps

20. After the consultation period, we will analyse the consultation responses and present a revised version of the supplementary guidance on consent, along with our response to the consultation, to Council at their meeting on 16 November 2016.

21. We will aim to publish the guidance shortly after approval by Council.

Section 3: How to respond

The simplest way to provide a response is through our online consultation response form, which can be accessed here: [LINK TO BE ADDED]

If you are unable to submit your feedback online, then please use the form below to submit your written feedback. If you are unable to provide your response in writing or you require the consultation form in a different format, please contact us on +44 (0)2007 580 3898 to discuss reasonable adjustments that would help you to respond.

This form should be emailed or posted to:
Angharad Jones
General Optical Council
10 Old Bailey
London
EC4M 7NG

Email: ajones@optical.org

The data presented in our analysis will be summarised and supported by direct quotes from some of the responses received. These quotes will either be attributed to a named respondent or anonymised, depending on your preference as indicated in the consultation response form.

Alongside the analysis, we intend to publish the individual responses that we have received, unless you have indicated that your response is to remain private.

All data submitted will be stored securely and in accordance with data protection principles.

Publication of consultation responses

Unless you state otherwise we will assume you are happy for us to publish your response, including your name, and to share it with other appropriate bodies and stakeholders. We would however encourage named responses where possible and particularly from representative organisations so that we can reflect that the response is on behalf of members / stakeholders rather than an individual response.

Please tick here if you are only happy for us to share your responses anonymously: ☐

Your name or the name of your organisation:

_____

Which category of respondent best describes you?

☐ Member of the public
☐ Optical patient

- ☐ Optometrist
- ☐ Dispensing optician
- ☐ Student – optometry
- ☐ Student – dispensing
- ☐ Optical business
- ☐ Education or training provider
- ☐ Optical professional body
- ☐ Other optical employer
- ☐ Healthcare regulator
- ☐ Other (please specify below)

Consultation questions

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 ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

6. What action could the GOC (or other organisations) take to help registrants to implement the guidance on consent?

   ☐ Yes ☐ No

   Please give your reasons below:

7. 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 ☐ No

   Please give your reasons below:

8. 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 ☐ No

   Please give your reasons below:

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

☐ Yes ☐ No

Please set out your additional comments below:

Annex 1 – Draft guidance on consent

About this guidance

1. This guidance should be read alongside the *Standards of Practice for Optometrists and Dispensing Opticians* (‘Standards of Practice’) which all optometrists and dispensing opticians must apply to their practice.

2. This document gives guidance on standard 3 of the Standards of Practice which states:

   ‘Standard 3. Obtain valid consent

   3.1 Obtain valid consent before examining a patient, providing treatment or involving patients in teaching and research activities.

   For consent to be valid it must be given:

   3.1.1. Voluntarily

   3.1.2. By the patient or someone authorised to act on the patient’s behalf

   3.1.3. By an appropriately informed person. “Informed” means explaining what you are going to do and ensuring that patients are aware of any risks and options in terms of examination, treatment, sale and supply of optical appliances or research they are participating in. This includes the right of the patient to refuse treatment or have a chaperone or interpreter present.

   3.2 Be aware of your legal obligations in relation to consent, including the differences in the provision of consent for children, young people and vulnerable adults. When working in a nation of the UK, other than where you normally practise, be aware of any differences in consent law and apply these to your practice.

   3.3 Ensure that the patient’s consent remains valid at each stage of the examination or treatment and during any research in which they are participating.’

The status of this guidance

3. This document gives guidance on how to meet the standard of consent. The guidance is not intended to cover every situation and it does not give detailed legal advice.

4. You must use your professional judgement to apply this guidance to your own practice and the variety of settings in which you might work. You must make sure that you keep up to date with the law, and with any NHS or employment policies for consent that apply to your practice.

5. You must also make sure that any staff members you are responsible for are aware of this guidance and are appropriately trained in all areas that are relevant to their duties.

6. If you are not sure about how the law applies in a specific situation, you should always ask for advice from appropriate professional colleagues, your employer, your professional indemnity insurance provider, your professional body, or obtain independent legal advice.

   This guidance describes:

   - the process of obtaining consent;
   - the importance of establishing whether the person has capacity to give consent;
   - what constitutes valid consent;
   - the form that consent might take; and
   - the duration of that consent.

7. It highlights the need to ensure that the consent is given voluntarily and that sufficient information has been imparted to allow valid consent to be given.

8. It is a general legal and ethical principle that valid consent must be obtained before starting treatment, conducting a physical investigation, or providing care. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice. Failure to respect this principle may result in legal action or fitness to practise proceedings.

9. If healthcare professionals (or other healthcare staff) fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the healthcare professional involved, or even be the basis of criminal proceedings. Poor handling of the consent process may also result in complaints from patients resulting in regulatory action.

What is consent?

10. Patients have a basic right to be involved in decisions about their healthcare and agree or ‘consent’ to any examination or treatment that is proposed by their healthcare professional. The process of obtaining consent is a fundamental part of respect for patients’ rights.

11. Obtaining consent is also essential in forming and maintaining effective communication between you and your patients (standard 2 of the Standards of Practice).

12. You have a professional and legal duty to obtain a patient's consent for the services, treatment or care you provide, or to use or share patient information.

13. You must know and comply with the law, Standards of Practice and the good practice requirements relating to consent, which apply to you in your day-to-day practice.

Obtaining consent

14. When obtaining consent you must ensure you provide your patient with clear and accurate information presented in a way that they can understand. For example, you must consider any disabilities, literacy or language barriers that may affect a patient's understanding and amend your communication approach to take account of this.

15. You should not make assumptions about the patient's level of knowledge and you should give them the opportunity to ask questions. You should discuss risks that occur commonly, those that are serious, and those that the patient is particularly concerned about, so the patient is aware of the potential for adverse outcomes when giving consent to treatment or investigation.

16. You are personally responsible for making sure that a patient has given valid consent. This includes ensuring that the patient understands what they are consenting to, is aware of relevant risks and is consenting voluntarily.

17. Getting consent is an on-going process between you and the patient. Consent cannot be presumed just because it was given on a previous occasion. You must get a patient's consent on each occasion that it is needed, for example, when there is a change in treatment or service options.

18. There are two types of consent:

    a. explicit (or 'express') consent: when a patient gives you specific permission to do something, either spoken or written; and

    b. implied consent: when a patient indicates their consent indirectly. This is not a lesser form of consent but might be appropriate only for more minor or routine procedures, where you are confident that the patient understands your intended treatment and the reasons for it.

19. You must use your professional judgement to decide what type of consent to get, taking into account legal requirements.

Example of explicit consent:

20. When conducting an eye examination consent must be obtained for all aspects of the examination. This should be explicit and can be verbal or written.

21. Consent cannot be implied simply on the basis of a patient having attended an eye examination. In order for consent to be valid you must satisfy yourself that

the patient understands what the eye examination will involve. This understanding cannot be automatically assumed just because the patient has attended the appointment.

22. The patient must also be given the opportunity to consent to all elements of the examination, for example, refraction, tonometry, visual fields etc. This may mean seeking a positive affirmation that the patient continues to consent at different stages of the examination. This 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.

23. Information explaining what an eye examination involves may be given to the patient either verbally during the course of the examination, for example, before conducting a refraction by stating “I am now going to ask you to read the letters on this chart. This will allow me to determine your prescription. Are you happy for me to continue?” or in written form such as a leaflet prior to the examination explaining what the examination will involve. In either case the patient must be given the opportunity to ask questions.

24. The patient must positively acknowledge that they have understood what they are consenting to and that they are happy to proceed.

25. When consent is given verbally it should be noted in the patient’s record what they have consented to. This does not have to be detailed, but should clearly outline the consent given.

26. It is good practice to obtain written consent in circumstances where you have outlined the material risks involved to the patient; the patient should be asked to sign to confirm they have understood the risks and agree to the procedure. You should also obtain written consent where the procedure, treatment or examination being proposed is not routine or has greater risks involved.

27. Regardless of whether consent has been given verbally or in written form, a patient can still subsequently change their mind and withdraw consent at any time. Please refer to paragraphs 43 to 46 of this guidance on withdrawal of consent.

Example of implied consent

28. There may be some aspects of the eye examination where consent can be implied as a result of the information already given to the patient or by the patient’s behaviour.

29. For example, when conducting tonometry, you may explain to the patient you are going to test their eye pressure; this will involve small puffs of air into their eye and they will need to place their chin on the rest and look into the device. If the patient proceeds to place their chin on the rest and look into the device,

consent can be assumed based on the patient's behaviour. This is implied consent.

30. If you are not sure whether you have obtained implied consent, you should obtain explicit consent, i.e. by asking the patient to confirm that they understand and consent to the procedure.

31. Implied consent should not be used in circumstances involving an invasive procedure or physical contact such as instilling drops or inserting a contact lens. Before any physical contact the patient should be asked to provide explicit verbal consent.

Consent to share patient information

32. Information in a patient's record is subject to professional, ethical and legal duties of confidentiality. But most patients understand and expect that some confidential information will be shared between health and social care professionals in order to provide their care.

33. The usual basis for sharing information in order to provide care is the patient's consent, whether it is explicit (when a patient actively agrees, either verbally or in writing, to a particular use or disclosure of information), or implied (circumstances in which it would be reasonable to assume that the patient agrees to the use of their information, even though this has not been directly expressed).

34. As a regulated optical professional you may rely on implied consent to share confidential information with those who are providing (or supporting the provision of) direct care to the patient if you are satisfied that all of the following apply:

    a. the person accessing or receiving the information is providing or supporting the patient's care;

    b. information is readily available to patients explaining how their information will be used, and they have the right to object;

    c. the patient has not objected; and

    d. that anyone to whom confidential information is disclosed understands that it is given to them in confidence, which they must respect.

35. Information for patients can be provided in leaflets, posters, on websites or face to face. It should be tailored to individual needs as far as possible.

36. Patients should not be surprised to learn about how their personal information is being used, accessed or disclosed. If information is being used in ways that patients would not reasonably expect you should seek explicit consent for this from the patient.

37. The patient has the right for their wishes to be respected if they object to particular personal information being shared within your own healthcare team or with others involved in their care – unless disclosure would be justified in the public interest, is required by law, or it is in the best interests of a patient who lacks capacity to make the decision.

38. If a patient cannot be informed about the disclosure of their information, for example, in an emergency, you should pass relevant information promptly to those providing care. If and when the patient is capable of understanding, you should tell them how their personal information was disclosed if it was in a way they would not reasonably expect.

Example of explicit consent to share patient information:

39. *Verbal* – You have explained to your patient that you need to refer them to the hospital for further tests, and that this may require you to share their information with other healthcare colleagues. You ask the patient to confirm they understand and agree for their information to be disclosed to other professionals involved in their care.

40. *Written* – The patient has signed the NHS sight test form which asks them to confirm their consent for all relevant information to be disclosed to Her Majesty's Revenue and Customs (HMRC) and local authorities.

Example of implied consent to share patient information:

41. The patient has chosen to have their prescription dispensed by your practice, and in placing an order for spectacles or lenses the patient's consent for their prescription to be shared with colleagues involved in the dispensing process can be implied.

Example of implied consent to access patient information:

42. You are asked to cover a colleague's appointments. The patients have been telephoned and advised of this fact and have confirmed they are happy for the appointment to go ahead. In these circumstances the patient's consent for you to have access to their record can be implied.

Refusal or withdrawal of consent

43. A person with capacity has the right to refuse treatment or care or to withdraw consent at any time. You must respect their decision even if you believe the treatment to be in their best interests.

44. In these circumstances you should clearly explain the consequences of their decision but you must make sure that you do not pressure the patient to accept your advice; if the patient agrees only as a result of pressure they perceive was put on them, then this may not be considered valid consent.

45. You should make a detailed record if a patient refuses to give consent. This should include the discussions that have taken place and the advice you gave. If the patient has stated why they are withdrawing consent you should include this in your notes. However, the patient is not required to give a reason for withdrawing consent.

46. If you believe that the patient is at risk of serious harm due to their decision to refuse a service or treatment, you must raise this issue with appropriate healthcare colleagues or people involved in their care, and your employer (if applicable). Consider getting legal advice if necessary.

Capacity to consent:

47. In order for consent to be valid it must be given by someone with the capacity to consent.

48. 'Capacity' refers to your patient's ability to:

    a. understand and retain information relevant to the decision required relating to their treatment or care;

    b. weigh up the information provided and the options available (including the consequences of not consenting); and

    c. communicate their decision (verbally, by signing or by any other means of communication).

49. You must make an assessment of your patient's capacity based on their ability to make a specific decision at the time it needs to be made. There may be some circumstances where a patient may be capable of making some decisions but not others.

50. In some situations, a patient may be able to understand the relevant information if they are given an appropriate explanation, such as by using simpler language or visual aids. In these situations, the patient must be considered as having capacity and you must take reasonable steps to communicate the relevant information in a way the patient understands and can choose to consent (or not to consent to).

51. You must not assume that because a patient lacks capacity on one occasion, or in relation to one type of service, that they lack capacity to make all decisions or the capacity to make decisions at all times.

52. A patient's capacity to consent may be temporarily affected by other factors, for example, illness, shock, panic, fatigue, confusion, pain or the effects of drugs or alcohol.

53. The existence of these factors should not lead to an automatic assumption that the patient does not have the capacity to consent. Instead you should use your

professional judgement to make a decision based on the individual circumstances.

54. In some circumstances it may be appropriate to defer the decision until the temporary effects subside and capacity is restored.

55. You must not assume that a patient lacks capacity based just upon their age, disability, beliefs, condition, or behaviour, or because they make a decision you disagree with.

56. Your assessment should be objective and you should bear in mind the principle that, where possible, patients should be assisted to make informed decisions about their treatment and care.

57. In England and Wales, patients over the age of 16 are presumed to have the capacity to consent unless it is established that they lack capacity, although the position for young people aged 16 and 17 is discussed in more detail below. In Scotland and Northern Ireland, persons over 16 are presumed to have full legal capacity.

58. In England and Wales, the Mental Capacity Act 2005 states that a person is deemed to lack capacity if:

    a. he or she has an impairment or disturbance (whether temporary or permanent) that affects the way their mind or brain works; and

    b. that impairment or disturbance means they are unable to make a decision at the time it needs to be made. In order to make a decision, they must be able to understand, retain and weigh up the information relevant to the decision as well as communicate their decision.

59. In Scotland the Adults with Incapacity (Scotland) Act 2000 sets out the criteria and procedures to be followed in making decisions when people aged 16 and over lack the capacity to take some or all decisions for themselves, because of a mental disorder or inability to communicate. It also allows other people to make decisions on their behalf. The Act provides various methods of intervening (that is, taking decisions or action) on behalf of an adult who lacks capacity, including in relation to healthcare. The Act sets out the principles that must be followed when deciding whether to intervene. Any intervention must be necessary and must benefit the person, and must be the minimum necessary to achieve the purpose. Those making decisions must (a) take account of the person's present and past wishes and feelings, and must try every possible means of communicating with the person to find out what these are, (b) take into account the views of the person's nearest relative and primary carer, and of any other person with powers to intervene in the person's affairs or personal welfare, or with an interest in the person, so far as it is reasonable and practical to do so, (c) encourage the person to use any skills they have to make

decisions and (d) consider whether it would be possible to intervene without using the Act. In this Act, incapacity means being incapable of acting on, making, communicating, understanding, or remembering decisions by reason of mental disorder or inability to communicate due to physical disorder. The Act is supported by codes of practice setting out guidance for those acting under the legislation, including doctors and other healthcare professionals who are treating adults with incapacity. The *Code of Practice for Practitioners Authorised to Carry out Medical Treatment or Research Under Part 5 of the Act*[1] covers decisions about medical treatment and research.

60. The Mental Health (Care and Treatment) (Scotland) Act 2003 makes provision as to when a person can be taken into hospital against their will, when they can be given treatment against their will, the rights of patients with an order of the Act applied to them and provides for safeguards to make sure their rights are protected.

61. In Northern Ireland, the Mental Capacity Act 2016 (not yet in force) will set out the criteria and procedures to be followed in making decisions when people aged 16 and over lack the capacity to take some or all decisions for themselves, because of a mental disorder or inability to communicate. The process of establishing capacity has two components requiring the person making the determination to consider (a) whether all practical help and support has been given to help the person make the decision and then (b) whether the person lacks the capacity to make a particular decision at a material time. The Act requires any substitute decision maker to consider what is in the individual's best interests in all the relevant circumstances before intervening and lists relevant people who might be consulted on this (where practicable and appropriate). The Department of Health, Social Services and Public Safety (DHSSPS) is required to produce one or more codes of practice in relation to the Bill which will contain guidance for those acting in connection with the care, treatment and personal welfare of those over 16 who lack capacity.

62. If you are unsure about a patient's capacity you must 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 association or obtain legal advice. Any advice you get or assessments carried out should be properly recorded, along with the outcome.

Adults who lack capacity

63. If your patient is not able to make decisions for themselves, you must work with people close to members and other healthcare colleagues.

[1] http://www.gov.scot/Publications/2010/10/20153801/0

64. The law sets out the criteria and processes to be followed in making decisions and providing care services when a patient lacks capacity to make some or all decisions for themselves. It also grants legal authority to certain people to make decisions on behalf of patients who lack capacity.

65. If you believe that a patient lacks capacity to make decisions for themselves, you should consult the codes of practice that accompany the Mental Capacity Act 2005 for England and Wales, or the Adults with Incapacity (Scotland) Act 2000 for Scotland. (The code of practice for Northern Ireland is not yet in force.) These set out who can make decisions on the patient's behalf, in which decisions, and how they should go about this.

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

67. A person may be authorised to provide consent for your patient to be treated if they have previously been named by the patient as someone to be consulted, if they are caring for or are interested in the patient's welfare, under a lasting power of attorney or when appointed by the Court (i.e. as a deputy appointed by the Court of Protection), if that person is authorised in respect of personal welfare matters.

68. These principles also apply to decisions about the use of information about patients who lack capacity. For example, the codes of practice must be consulted when deciding to share confidential information about a patient who lacks capacity with their loved ones, as well as making decisions about treatment.

Young people and children

69. The capacity to consent depends more on the patient's ability to understand and consider their decision than on their age.

70. In this guidance, a young person means anyone aged 16 or 17 and a child means anyone aged under 16.

71. People gain full legal capacity in relation to healthcare treatment at a different age in Scotland than in England, Northern Ireland and Wales. In Northern Ireland, a child is defined as a person under the age of 18, although the presumed age of capacity is 16.

72. As with any patient, a young person or child may have the capacity to consent to some services or treatments but not to others. Therefore it is important that you assess maturity and understanding individually, and bearing in mind the complexity and importance of the decision to be made.

73. If a young person or child does not have the capacity to consent, consent must be provided by a person with parental responsibility. If a person with parental

responsibility is required to provide consent, you may need to get legal advice if:

a. you are in any doubt about who has parental responsibility for the individual; or

b. the views of those that have parental responsibility differ.

74. Young people and children should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own.

Young people with capacity

75. Young people are presumed to have the capacity to make their own decisions and give consent for a service or treatment, unless there is enough evidence to suggest otherwise.

76. To decide whether a young person has the capacity to consent to a service or treatment, use the same criteria as for adults (see paragraphs 47 to 62, 'Capacity to consent').

77. While not a legal requirement, you should encourage young people to involve their parents in making important decisions. However, you should respect a competent young person's request for confidentiality.

Children with competence

78. Children are not presumed to have the capacity to consent; instead, the issue is whether children can demonstrate their competence.

79. A child is competent and can give consent if you are satisfied that they have the maturity, intelligence and ability to fully understand the information given and what they are consenting to, including any implications of the treatment they are consenting to. In this case you do not also need consent from a person with parental responsibility.

80. Where a competent child has been provided with appropriate information and voluntarily gives his or her consent to treatment, that consent cannot be overridden by a person with parental responsibility. If you consider that the decision of a competent child to give consent is not in their best interests, you should consult colleagues and get legal advice before proceeding.

When competent young people and children refuse to give consent

England, Northern Ireland and Wales

81. In some circumstances, the courts can override the refusal of consent of a competent young person or child if health and care professionals involved in their care believe that the refused treatment would be in their best interests. You should get legal advice if needed on this issue.

82. The law is complex when a competent young person or child refuses to give consent for a treatment or service and someone with parental responsibility wants to override their decision. You should get legal advice if you are faced with this situation.

Scotland

83. When a child has capacity to make a decision and the child declines the recommended treatment, it is likely that the law would expect you to respect and comply with an informed decision. If such a situation arises, you should obtain legal advice. Of course if circumstances change, for example, the child's condition is at risk of deterioration, a further dialogue will probably be necessary. Depending on the circumstances, it might be necessary to involve another member of the healthcare team or other family members or carers in that dialogue, depending on any issues of confidentiality. As with all these discussions and decisions, full and proper records should be kept.

Young people without capacity

England, Northern Ireland and Wales

84. A person with parental responsibility for a young person who is not considered to have capacity can give consent on behalf of that young person to investigations and treatment that are in the young person's best interests. If you are concerned that the investigations or treatment may not be in the young person's best interests you should get legal advice before proceeding further.

Scotland

85. The rights of a person with parental responsibility to make decisions on behalf of a child ends when the child reaches the age of 16. (Please see paragraph 59.)

Children without competence

86. When a child lacks competence to give consent, any person with parental responsibility for that child, or the court, can give consent on their behalf, but this will vary depending on the nation and the child's age. Who will be considered to have parent responsibility may also vary. You should refer to relevant national legislation as appropriate.

87. While the consent of only one person with parental responsibility is required, where there is disagreement between those with parental responsibility you may wish to seek further advice.

Advance decisions on healthcare arrangements

88. People with capacity can say in advance how they want to be treated if they later suffer loss of mental capacity. An advance decision can only refuse later treatment, as a patient cannot demand specific treatment.

89. An unambiguous advance refusal for a treatment, procedure or intervention which is voluntarily made by an adult with capacity and does not appear to have been withdrawn or not applicable in the circumstances is likely to have legal force.

90. An advance refusal of treatment cannot override the legal authority to give compulsory treatment under the mental health laws.

91. Any advance decision can be superseded by a later decision by the person concerned at any time when they have capacity. This later decision may be made at any point between the making of the advance decision and the beginning of treatment. An advance decision will only apply in relation to treatment if the person giving it does not have capacity at the point that consent would be sought or treatment is given.

England and Wales

92. Advance decisions are covered by the Mental Capacity Act 2005. For an advance refusal of treatment to be legally valid, it must meet certain criteria set out in sections 24 to 26 of the Mental Capacity Act 2005.

93. If an advance decision does not meet these criteria, it is not legally binding but can still be used in deciding the patient's best interests.

94. You must follow an advance decision if it is valid and applicable to current circumstances.

Scotland

95. The Adults with Incapacity (Scotland) Act 2000 does not specifically cover advance decisions. However, it says that health professionals must take account of the patient's past and present wishes, however they were communicated.

96. Advance decisions are also known as advance directives, living wills, advance directions and advance statements. Provided that the advance decision was made by an adult with capacity who was properly informed, and clearly sets out the person's intentions, it is likely that a Court would consider it binding. If however the factual situation falls outwith the scope of the advance decision, or if the assumptions upon which it was based are rebutted, then the advance decision is likely to cease to be effective. You should obtain legal advice on the effectiveness of any advance decision.

Northern Ireland

97. In the absence of specific statute provisions, the position in Northern Ireland is governed by common law principles. An advance decision is still binding, and must be followed by healthcare professionals, provided they know about it.

98. In all jurisdictions, an advance decision requires the same level of capacity as a contemporaneous decision.

Emergencies

99. In an emergency, if you cannot get consent, you can provide treatment that is in the patient's best interests and is needed to save their life or prevent deterioration in the patient's condition (this applies to children, young people and adults).

100. There is an exception to this if you know there is a valid and applicable advance decision to refuse a particular treatment. For more information see the relevant incapacity legislation and its code of practice (see paragraph 65), or ask your professional indemnity insurance provider or a legal adviser.

Additional information

England and Wales

Mental Capacity Act 2005

www.legislation.gov.uk/ukpga/2005/9/contents

Mental Capacity Act Code of Practice

www.publicguardian.gov.uk/mca/code-of-practice.htm

Department of Health Reference guide to consent for examination or treatment (Second edition)

https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

Northern Ireland

Mental Capacity Act 2016 (hyperlink to be added when this legislation comes into force)

Scotland

Adults with Incapacity (Scotland) Act 2000

The Age of Legal Capacity (Scotland) Act 1991

Adults with Incapacity (Requirements for Signing Medical Treatment Certificates) (Scotland) Amendment Regulations 2012 SSI 2012/170

www.legislation.gov.uk/asp/2000/4/contents

www.scotland.gov.uk/Topics/Justice/Civil/awi

Contact us

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10 Old Bailey
London
EC4M 7NG
Website: www.optical.org/standards
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C23(16) – ANNEX TWO

Consultation: Supplementary guidance on duty of candour

X June 2016

(front cover to be added)

Contents page

Section 1: About the General Optical Council

1. We are one of 12 organisations in the UK known as health and social care regulators. These organisations oversee the health and social care professions by regulating individual professionals.
2. We are the regulator for the optical professions in the UK. We currently register around 29,000 optometrists, dispensing opticians, student opticians and optical businesses.
3. Our primary legislation is the Opticians Act 1989 (as amended) ('the Act'), and we also have a series of related rules that describe how we carry out our statutory functions. Our legislation can be found on our website at: http://www.optical.org/en/about_us/legislation/index.cfm
4. The GOC has four main functions:
   - setting standards for optical education and training, performance and conduct;
   - approving qualifications leading to registration;
   - maintaining a register of those who are qualified and fit to practise, train or carry on business as optometrists and dispensing opticians; and
   - investigating and acting where registrants' fitness to practise, train or carry on business is impaired.
5. More information about the GOC can be found on our website: https://www.optical.org/

Section 2: Consultation summary

6. This consultation seeks the views of stakeholders on the new supplementary guidance (annex 1) we have developed on duty of candour.

7. The aim of the guidance is to give registrants further support and clarity on the principles set out in the GOC's *Standards of Practice for Optometrists and Dispensing Opticians* and *Standards for Optical Students.*

8. The guidance on candour includes further information on:

   - being open and honest with patients before commencing treatment;
   - what to do if something goes wrong;
   - being open and honest with patients about near misses;
   - encouraging a learning culture by reporting errors;
   - additional duties for optometrists and dispensing opticians with management responsibilities and for senior or high profile clinicians;
   - contractual and statutory duties of candour in the UK; and
   - the relationship between organisational and individual duties of candour.

9. The consultation will run from **X June 2016 to X August 2016** and applies to the whole of the UK.

Background

10. The GOC's new *Standards of Practice for Optometrists and Dispensing Opticians* and *Standards for Optical Students* came into effect on 1 April 2016 replacing the previous *Code of Conduct* for individual registrants.

11. The standards are designed to make clear what we expect of our registrants, while allowing room for them to use their professional judgement in deciding how to meet the standards in any given situation.

12. To view the standards please use the following link: https://www.optical.org/en/Standards/index.cfm

Duty of candour

13. As part of the standards framework, we introduced a new standard on duty of candour.

14. This standard places an explicit duty on GOC registrants to be open and honest with patients when things go wrong. Patients should know what happened, be offered an apology and be informed of what action is being taken to put things right.

15. This standard was introduced following recommendations from the Francis Inquiry into the failings at Mid Staffordshire NHS Foundation Trust in 2013 on the importance of embedding a culture of openness and honesty in the healthcare system.

16. This standard also reflects the principles outlined in the joint statement on duty of candour that was agreed by all the UK regulators in October 2014.[1]

Supplementary guidance

17. When we first consulted stakeholders in 2015 in relation to our new standards framework, a number of stakeholders expressed a view that the GOC should provide additional support and guidance to registrants on how to meet some of the standards, including the standard on duty of candour.

18. We considered this feedback and decided that additional guidance was required.

19. The aim of the supplementary guidance is to give registrants more detailed information on how to meet a specific standard.

Consultation

20. The aim of the consultation is for stakeholders to review the draft guidance and provide their feedback in the consultation questions.

Next steps

21. After the consultation period, we will analyse the consultation responses and present a revised version of the supplementary guidance on candour, along with our response to the consultation, to Council at their meeting on 16 November 2016.

22. We will aim to publish the guidance shortly after approval by Council.

[1] http://www.optical.org/filemanager/root/site_assets/publications/media_statements/joint_statement_on_the_professional_duty_of_candour_final.pdf

Section 3: How to respond

The simplest way to provide a response is through our online consultation response form, which can be accessed here: [link to be added]

If you are unable to submit your feedback online, then please use the form below to submit your written feedback. If you are unable to provide your response in writing or you require the consultation form in a different format, please contact us on +44 (0)2007 580 3898 to discuss reasonable adjustments that would help you to respond.

This form should be emailed or posted to:
Angharad Jones
General Optical Council
10 Old Bailey
London
EC4M 7NG

Email: ajones@optical.org

The data presented in our analysis will be summarised and supported by direct quotes from some of the responses received. These quotes will either be attributed to a named respondent or anonymised, depending on your preference as indicated in the consultation response form.

Alongside the analysis, we intend to publish the individual responses that we have received, unless you have indicated that your response is to remain private.

All data submitted will be stored securely and in accordance with data protection principles.

Publication of consultation responses

Unless you state otherwise we will assume you are happy for us to publish your response, including your name, and to share it with other appropriate bodies and stakeholders. We would however encourage named responses where possible and particularly from representative organisations so that we can reflect that the response is on behalf of members / stakeholders rather than an individual response.

Please tick here if you are only happy for us to share your responses anonymously: ☐

Your name or the name of your organisation:

_____

Which category of respondent best describes you?

☐ Member of the public

- ☐ Optical patient
- ☐ Optometrist
- ☐ Dispensing optician
- ☐ Student – optometry
- ☐ Student – dispensing
- ☐ Optical business
- ☐ Education or training provider
- ☐ Optical professional body
- ☐ Other optical employer
- ☐ Healthcare regulator
- ☐ Other (please specify below)

Consultation questions

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

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

   ☐ Yes ☐ No

   Please give your reasons below:

6. What action should the GOC (or other organisations) take to help registrants to implement the guidance on candour?

   ☐ Yes ☐ No

   Please give your reasons below:

7. 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 ☐ No

   Please give your reasons below:

8. 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 ☐ No

   Please give your reasons below:

9. Do you have any additional comments you wish to make on the guidance for candour?

   ☐ Yes ☐ No

   Please set out your additional comments below:

Annex 1 – Draft guidance on professional duty of candour

1. All healthcare professionals have a professional duty of candour – this is a professional responsibility to be open, honest and transparent with patients when things go wrong.

2. This professional duty of candour was agreed in October 2014 in a joint statement from eight regulators of healthcare professionals in the UK. This was in response to findings and recommendations of both the Francis Inquiry into poor patient care at Mid Staffordshire NHS Foundation Trust in 2013 and the UK Government's response to this Inquiry: *Hard Truths: The Journey to Putting Patients First* published in January 2014.

3. The General Optical Council's *Standards of Practice for Optometrists and Dispensing Opticians* and *Standards for Optical Students* reflect this professional duty of candour as follows:

> ***'Standards of Practice for Optometrists and Dispensing Opticians:***
>
> *19. Be candid when things have gone wrong*
>
> *19.1 Be open and honest with your patients when you have identified that things have gone wrong with their treatment or care which has resulted in them suffering harm or distress or where there may be implications for future patient care. You must:*
>
> *19.1.1. Tell the patient or, where appropriate, the patient's advocate, carer or family) that something has gone wrong.*
>
> *19.1.2. Offer an apology.*
>
> *19.1.3. Offer appropriate remedy or support to put matters right (if possible).*
>
> *19.1.4. Explain fully and promptly what has happened and the likely short-term and long-term effects.*
>
> *19.1.5. Outline what you will do, where possible, to prevent reoccurrence and improve future patient care.*
>
> *19.2 Be open and honest with your colleagues, employers and relevant organisations, and take part in reviews and investigations when requested and with the General Optical Council, raising concerns where appropriate. Support and encourage your colleagues to be open and honest, and not stop someone from raising concerns.*
>
> *19.3 Ensure that when things go wrong, you take account of your obligations to reflect and improve your practice as outlined in*

standard 5.'

'Standards for Optical Students:

18. Be candid when things have gone wrong

18.1 Be open and honest with your patients when you have identified that things have gone wrong with their treatment or care which has resulted in them suffering harm or distress or where there may be implications for future patient care, seeking advice from your tutor or supervisor on how to proceed. They will advise on whether further action is required such as:

18.1.1 Telling the patient (or, where appropriate, the patient's advocate, carer or family) that something has gone wrong.

18.1.2 Offering an apology.

18.1.3 Offering appropriate remedy or support to put matters right (if possible).

18.1.4 Explaining fully and promptly what has happened and the likely short-term and long-term effects.

18.1.5 Outlining what you will do, where possible, to prevent reoccurrence and improve future patient care.

18.2 Be open and honest with your supervisor or training provider and take part in reviews and investigations when requested and with the General Optical Council, raising concerns where appropriate. Support and encourage your peers to be open and honest, and not stop someone from raising concerns.

18.3 Ensure that when things go wrong, you reflect on what happened and use the experience to improve.'

When does candour apply?

4. Candour applies to all circumstances where something has gone wrong and should not be confused with handling complaints. Candour applies whether or not a complaint has been made or a concern raised. Being candid should also not be misunderstood as admitting liability or wrong doing.

About this guidance

5. As an optometrist, dispensing optician or optical student, you must be open and honest with patients, with colleagues, and with your employers. In addition, if something goes wrong when you are providing care, you must report it whether or not it leads to actual harm.

6. This guidance builds on the joint statement from the healthcare regulators and gives more information about how to comply with the principles set out in the *Standards of Practice for Optometrists and Dispensing Opticians* and the *Standards for Optical Students*. It applies to all individuals registered with the GOC.

7. The guidance is divided into two main parts:

   a. Your duty to be open and honest with patients, or those close to them, if something goes wrong, including advice on apologising (paragraphs 12-27).

   b. Your duty to be open and honest with your organisation, and to encourage a learning culture by reporting adverse incidents that lead to harm, as well as near misses (paragraphs 28-32).

8. Throughout the guidance we talk about your responsibilities towards patients or people in your care. We recognise that care is often provided by a number of different optical professionals or in conjunction with other types of healthcare professionals and that you may be one of several healthcare professionals involved in a patient's care.

9. While every professional will have a duty of candour, we would not expect every professional involved in the care pathway to talk to the patient about the same incident. But you must make sure that an appropriate person – usually the lead or accountable clinician – takes responsibility for speaking to the patient or (in certain situations) those close to them if something goes wrong.

Being open and honest with patients in your care, and those close to them, when things go wrong

Do what you can before beginning treatment

10. Patients in your care must be fully informed about all the elements of their treatment. When discussing treatment options with patients, you must discuss the risks as well as the benefits of any options.

11. You or an appropriate person must have a clear and comprehensive conversation with the patient about risks. You should discuss risks that occur commonly, those that are serious, and those that the patient is particularly concerned about, so the patient is aware of the potential for adverse outcomes when giving consent to treatment or investigation. (See standards 2, 3 and 4 of *Standards of Practice for Optometrists and Dispensing Opticians* and *Standards for Optical Students*.)

12. You must record on the patient's record that consent has been obtained, the risks discussed and any advice given.

What to do if something goes wrong

13. As soon as you recognise that something has gone wrong and a patient in your care has suffered physical or psychological harm or distress, or where there might be implications for their future care, you should do what you can to put matters right immediately. This might include minor incidents that cause temporary distress (for example, use of incorrect eye drops which might cause irritation) or more serious incidents resulting in partial or full loss of sight.

14. You must then speak to the patient, unless you are sure that another, appropriate member of the healthcare team is taking on this responsibility.

15. You should first tell the patient that something has gone wrong with their care and give them the opportunity to say they do not want to be given any more information. Most patients will want to know more about what has gone wrong. But, if the patient does not want more information, you should try to find out why. If, after discussion, the patient insists they do not want more information, you should respect their wishes as far as possible, having explained the potential consequences.

16. You must record the fact that the patient does not want this information and make it clear to the patient that they can change their mind and have more information at any time.

17. You should speak to a patient as soon as possible after you realise something has gone wrong with their care, and you are able to give them some information about what has happened and the likely short-term and long-term effects. You should share all the information you have, explain if anything is still uncertain or any further inquiries are being undertaken and respond honestly to any questions. You should also discuss what you intend to do to prevent the situation happening again to other patients.

Apology – say sorry

18. If someone in your care has suffered harm or distress because something has gone wrong, then you should apologise as soon as you become aware of this.

19. Offering an apology is an important part of being candid as it shows that you recognise the impact of the situation on the patient and that you empathise with them.

20. Saying sorry does not mean admitting liability or wrongdoing but it is important to patients that you express regret for any harm, distress or adverse consequences to their health and wellbeing.

21. When apologising to a patient – or in certain situations those close to the patient – you should consider the following points below.

a. You must share information in a way that the patient can understand and, whenever possible, in a place and at a time when they are best able to understand and retain it.

b. You should give information that the patient may find distressing in a considerate way, and respect your patient's right to privacy and dignity, making sure that conversations take place in appropriate settings where possible.

c. Patients and those close to them are likely to find it more meaningful if you personally apologise for something going wrong, rather than offer a general expression of regret about the incident.

d. Patients and those close to them expect to be told three things as part of an apology:

   i. what happened;

   ii. what can be done to deal with any harm caused; and

   iii. what will be done to prevent someone else being harmed.

e. You should make sure the patient knows who to contact to ask any further questions or raise concerns.

f. You should record the details of your apology in the patient's clinical record. A verbal apology may need to be followed up by a written apology, depending on the patient's wishes (or the wishes of those close to the patient), and your workplace policy.

22. If you do not feel able to apologise to the patient, or those close to them, with the required tact and sensitivity, you should:

    a. make sure that an appropriate person takes on the responsibility to talk to the patient. This could be within your own optical team or a different healthcare professional who is working with you in delivering care for the patient, i.e. an ophthalmologist; and

    b. undergo training as soon as possible to develop your skills and experience in this area.

23. You should not wait until the outcome of an investigation to apologise to a patient, or someone close to them, when something has gone wrong. But you should be clear that the facts have not yet been established, tell them only what you know and believe to be true, and answer any questions honestly and as fully as you can.

Speaking to those close to the patient

24. In rare circumstances, if the patient lacks consciousness or capacity, you must be open and honest with those close to the patient. Take time to convey the

information in a compassionate way, giving them the opportunity to ask questions at the time and afterwards. You should refer to our consent guidance for more information on when it is appropriate to discuss a patient's care with those close to them.

25. You should make sure, as far as possible, that those close to the patient have been offered appropriate support, and that they have a specific point of contact in case they have concerns or questions at a later date.

Being open and honest with patients about near misses

26. You must use your professional judgement when considering whether to inform patients about near misses – adverse events that did not result in injury, illness, harm or damage, but had the potential to do so. Often there will be information that the patient would want or need to know about and, in these cases, you should talk to the patient about the near miss, following the guidance in paragraphs 12–18.

27. Some patients will want to be informed about near misses, and failure to be open could damage their trust in you and the healthcare team. However, in some circumstances, patients do not need to know about something that has not caused (and will not cause) them harm, and telling them may distress or confuse them unnecessarily. If you are not sure about whether to talk to a patient about a near miss, seek advice from a senior colleague.

Encouraging a learning culture by reporting errors

28. When things go wrong with patient care, the cause is usually either a flaw in an organisational system or human error. It is crucial that errors are reported at an early stage to put matters right and to learn any lessons so that future patients may be protected from harm.

29. You should adhere to any local policy for reporting adverse incidents or near misses that may be in place, including any policy operated by your employer.

30. A number of schemes exist around the UK for reporting adverse incidents and near misses. These include:

    a. The UK-wide Yellow Card Scheme run by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines for reporting suspected adverse drug reactions. Please refer to the independent prescribing guidelines for optometrists for further details.

    b. The UK-wide MHRA reporting system for reporting adverse incidents involving medical devices. Medical devices include spectacles and contact lenses.

c. The National Reporting and Learning System for reporting adverse events and patient safety incidents in England and Wales (for registrants working within the NHS).

d. The Healthcare Improvement Scotland national framework, which outlines consistent definitions and a standardised approach to adverse event management across National Health Service (NHS) for Scotland.

e. The procedure for the reporting and follow-up of serious adverse incidents in Northern Ireland which is set out on the Department of Health, Social Services and Public Safety's website.

31. In addition to contributing to these systems, you should comply with any system for reporting adverse incidents that put patient safety at risk within your own place of employment (see paragraphs 34-46 on the organisational duty of candour).

32. As a healthcare professional, you should regularly review your own standards and performance as outlined in the standards for optometrists and dispensing opticians which states: '5.4 Reflect on your practice and seek to improve the quality of your work through activities such as reviews, audits, appraisals or risk assessments. Implement any actions arising from these.' You must take part in regular reviews and audits of the standards and performance that your team, practice or employer operates for this purpose and take steps to resolve any problems.

Additional duties for optometrists and dispensing opticians with management responsibilities and for senior or high profile clinicians

33. Senior optometrists and dispensing opticians have a responsibility to set an example and encourage openness and honesty in reporting adverse incidents and near misses. In particular, more junior colleagues should be able to come to more senior colleagues for advice and guidance on complying with the duty of candour.

Contractual and statutory duties of candour in the UK

34. Whilst this guidance refers to the professional duty of candour for individuals, registrants should be aware of other duties of candour which apply to organisations in the different nations of the UK.

England

35. **Contractual duty of candour** – A contractual duty of candour has applied to all providers of NHS care in England since 1 April 2013. The contract will be used by all organisations commissioning NHS healthcare services, with the

exception of services commissioned under primary care contracts. The contract requires all NHS and non-NHS providers of services to NHS patients to comply with the duty of candour. Please refer to https://www.england.nhs.uk/nhs-standard-contract/16-17/

Statutory duty of candour – A legal requirement for organisations to be candid came into effect on 1 April 2015. This applies to organisations regulated by the Care Quality Commission (CQC) in England and further details can be found on the CQC website: http://www.cqc.org.uk/content/regulation-20-duty-candour

36. The aim of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in relation to care and treatment.

37. Many of the requirements of the statutory duty of candour on organisations are similar to those required by the *Standards of Practice for Optometrists and Dispensing Opticians* and *Standards for Optical Students*. However you should not confuse your responsibilities under the standards and this guidance with your organisation's responsibilities under the statutory duty of candour. For more information see paragraphs 47 to 49.

Northern Ireland

38. In January 2015, former Northern Ireland Health Minister Jim Wells MLA announced plans to introduce a statutory duty of candour for Northern Ireland. This announcement followed the publication of the Donaldson Report, which examined the governance arrangements for making sure health and social care is of a high quality in Northern Ireland. The annual report of the Chief Medical Officer for Northern Ireland 2014, published in May 2015, restated the commitment to introduce a statutory duty of candour in Northern Ireland:

'In response to the Donaldson review the Minister announced plans to introduce a statutory duty of candour for Northern Ireland. That duty came to prominence in England as a result of conclusions from the Francis report – a public inquiry into the Mid Staffordshire NHS Foundation Trust. Openness and transparency are crucial elements of patient safety. When things go wrong, patients, service users and the public have a right to expect that they will be communicated with in an honest and respectful manner and that every effort will be made to correct errors or omissions and to learn from them to prevent a recurrence.

The Health and Social Care service in Northern Ireland already operates under statutory duties of both quality and involvement. Meaningful engagement with patients and clients, carers and the public will improve the quality and safety of services. It is not the intention of the duty of candour to promote a culture of

fear, blame and defensiveness in reporting concerns about safety and mistakes when they happen.'

Scotland

39. The Healthcare Quality Strategy for NHS Scotland is aiming to achieve an NHS culture in which care is consistently person-centred, clinically effective and safe for every person, all the time.

40. The Scottish Patient Safety Programme is a national initiative that aims to improve the safety and reliability of healthcare and reduce harm.

41. The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 introduced a duty of candour in health and social care settings. The purpose of the duty of candour provisions of the Act are to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm, that is not related to the course of the condition for which the person is receiving care. An apology or other step taken in accordance with the duty of candour procedure under the Act does not of itself amount to an admission of negligence or a breach of a statutory duty.

42. The duty of candour procedure (which will be set out in regulations to be made using powers in the Act) will emphasise learning, change and improvement – three important elements that will make a significant and positive contribution to quality and safety in health and social care settings.

43. The new duty of candour on organisations will create a legal requirement for health and social care organisations to inform people (or their families/carers acting on their behalf) when they have been harmed (physically or psychologically) as a result of the care or treatment they have received. There will be a requirement for organisational emphasis on staff support and training to ensure effective implementation of the organisational duty.

Wales

44. The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 place a number of duties on responsible bodies providing NHS care. This includes a duty to be open when harm may have occurred:

    'Where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern and involve the patient, or his or her representative, in the investigation of the

concern'. (Regulation 12(7)) http://www.wales.nhs.uk/governance-emanual/health-and-care-standards

45. The Welsh Government's *Health and Care Standards Framework*, includes a standard called 'listening and learning from feedback' (standard 6.3). In meeting this standard, the framework advises that 'health services are open and honest with people when something goes wrong with their care and treatment'. The standards provide a framework for how services are organised, managed and delivered on a day-to-day basis.

46. Following the findings from the recent independent reviews of complaints by NHS Wales and of Health Inspectorate Wales, the Welsh Government released a consultation on a Green Paper on health and governance in the NHS in Wales. This asked whether there should be a statutory duty of candour within the NHS in Wales, to which the response was largely positive. This proposal may be developed by the new Welsh Government elected in May 2016.

Relationship between the organisational and individual duties of candour

47. Organisations should have policies and procedures in place to support a culture of openness and transparency, and ensure that staff follow them. Action should be taken to tackle bullying, harassment and undermining, and investigate any instances where a member of staff may have obstructed another in exercising their duty of candour.

48. Organisations should also have systems in place to identify and deal with possible breaches of the professional duty of candour by staff who are professionally registered.

49. The GOC will consider the professional obligations on optical businesses in its review of the *Code of Conduct for business registrants*.