General Optical Council

Supplementary guidance on the duty of candour

For consultation

June 2016

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 **14 June 2016 to 6 September 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: https://www.optical.org/en/get-involved/consultations/index.cfm

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

Section 1: Our guidance

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?

   Please give your comments below:

Section 2: Impact

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

   ☐ Yes ☐ No

   Please give your reasons below:

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 ☐ No

   Please give your reasons below:

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 ☐ No

Please give your reasons below:

Section 3: Additional comments

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

☐ Yes ☐ No

Please set out your additional comments below:

More about you

The GOC strives to be as diverse as the public it protects and welcomes consultation responses from everyone, regardless of age, disability, gender reassignment, race, religion or belief, ethnicity, sex, sexual orientation, marriage and civil partnership, pregnancy and maternity. We monitor the diversity of all the individuals who respond to our consultations to ensure that we have heard from a diverse range of people and that we can identify where further engagement or consultation may be required. To help us to monitor this, please complete the following questions if you feel comfortable to do so. Providing this information is optional, but we would be grateful for your co-operation. Information provided will be treated in the strictest confidence under the Data Protection Act 1998 and will be only used for monitoring purposes. **No information in this section will be published or used in any way which allows any individuals to be identified.**

Gender

☐ Female ☐ Male ☐ Prefer not to say

Age

☐ 16-24 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 55-64 ☐ 65+

☐ Prefer not to say

Sexual orientation

☐ Bisexual ☐ Heterosexual/Straight ☐ Gay/Lesbian/Homosexual

☐ Other ☐ Prefer not to say

Disability
The Equality Act 2010 defines disability as a physical or mental impairment which has a substantial long-term effect on a person's ability to carry out normal day to day activities.
Do you consider yourself to have a disability?
☐ Yes ☐ No ☐ Prefer not to say

Gender Identity
My gender identity is different from the gender I was assigned at birth:
☐ Yes ☐ No ☐ Prefer not to say

Pregnancy/Maternity
Are you pregnant, on maternity leave, or returning from maternity leave?
☐ Yes ☐ No ☐ Prefer not to say

Ethnicity
White
☐ English / Welsh / Scottish / Northern Irish / British
☐ Irish
☐ Gypsy or Irish Traveller
☐ Any other white background – please specify:

Mixed / multiple ethnic groups
☐ White and Asian / British
☐ White and Black Caribbean / British
☐ White and Black African / British
☐ Any other mixed / multiple ethnic background – please specify:

Asian / Asian British
☐ Indian / Indian British
☐ Pakistani / Pakistani British
☐ Bangladeshi / Bangladeshi British
☐ Chinese / Chinese British
☐ Any other Asian background – please specify:

Black / Black British
☐ African / African British
☐ Caribbean / Caribbean British
☐ Any other Black background – please specify:

Other ethnic group
☐ Arab / Arab British
☐ Any other ethnic group – please specify:

☐ Prefer not to say

Marital status

☐ Civil partnership ☐ Divorced/legally dissolved
☐ Married ☐ Partner ☐ Separated
☐ Single ☐ Not stated ☐ Prefer not to say

Carer Responsibilities

Do you perform the role of a carer?
☐ Yes ☐ No ☐ Prefer not to say

Religion/Belief

☐ No religion ☐ Buddhist ☐ Christian
☐ Hindu ☐ Jewish ☐ Muslim
☐ Sikh
☐ Any other religion / faith – please specify _____
☐ Prefer not to say

Many thanks for completing this confidential monitoring form.

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 10-25).

   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 26-33).

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 13–17.

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*.