Implementing a 'Duty of Candour':
A new contractual requirement on providers

Proposals for consultation

Reply Form

Closing date for responses; 31 January 2012

Please fill in and/or tick the appropriate response.

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Before submitting your response to the Department, please make sure that it has been saved in a name (e.g. *yourname*Candour.doc) that will make it easier for us to track. Many thanks.

Freedom of Information

We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter.**

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. The relevant legislation in this context is the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic

confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.

I do not wish my response to be passed to other UK Health Departments ☐

I do not wish my response to be published in a summary of responses ☐

Please indicate the country the consultation and your comments relate:

UK-wide	■	*and/or:*	
England	☐	*Northern Ireland*	☐
Scotland	☐	*Wales*	☐

Are you responding:

- *as a member of the public*
- *as a health or social care professional* ☐
- *on behalf of an organisation* ■

About you

The answers to the questions in this section will only be used for analytical purposes.

You do not have to complete this section if you do not want to.

Area of work:

NHS	
Social Care	
Private Health	
Third Sector	
Regulatory Body	
Professional Body	
Education	
Trade Union	
Local Authority	
Trade Body	
Other (Please give details)	
Independent Contractor to NHS	
Manufacturer	
Supplier	
Other (where relevant)	

If you are responding on behalf of an organisation, please indicate which type of organisation you represent:

NHS	
Social Care	
Private Health/Independent Secto	
Third Sector	
Regulatory Body	
Professional Body	
Education	
Trade Union	
Local Authority	
Trade Body	✓
Other (Please give details)	

In which of the following areas do you live: (please tick <u>one</u> box only)	
North East	
North West	
West Midlands	
South East	
London	
Humberside/Yorkshire	
East Midlands	
East of England	
South West	
No answer	

1 What is your sex?
Tick one box only.

Male	
Female	
Prefer not to say	

2 What is your Age?

Age	
Prefer not to say	

3 Are your day to day activities limited because of any health problem or disability which has lasted, or is expected to last at least 12 months?

Tick one box only.

- Yes, limited ☐
- Yes, limited, a little ☐
- No ☐
- Prefer not to say ☐

4 Do you look after, or give any help or support to family members, friends, neighbours or others because of either long term physical or mental ill-health/disability or problems related to old age?
Tick one box only.

- Yes ☐
- No ☐
- Prefer not to say ☐

5 What is your ethnic group?
Tick one box only.

A White

- British ☐
- Irish ☐
- Any other White background, ☐

B Mixed

- White and Black ☐
- White and Black African ☐
- White and Asian ☐
- Any other Mixed background ☐

C Asian, or Asian British

- Indian ☐
- Pakistani ☐
- Bangladeshi ☐
- Any other Asian background ☐

D Black, or Black British

- Caribbean ☐
- African ☐
- Any other Black background ☐

E Chinese, or other ethnic group

- Chinese ☐
- Any other, write below ☐

F Prefer not to say ☐

6 What is your religion or belief? Tick one box only.

Christian includes Church of Wales, Catholic, Protestant and all other Christian denominations.

- None ☐
- Christian ☐
- Buddhist ☐
- Hindu ☐
- Jewish ☐
- Muslim ☐
- Sikh ☐
- Prefer not to say ☐
- Other, write below

☐

7 Which of the following best describes your sexual orientation? Tick one box only.

Only answer this question if you are aged **16** years or over.

- Heterosexual Straight ☐
- Lesbian / Gay Woman ☐
- Gay Man ☐
- Bisexual ☐
- Prefer not to say ☐
- Other, write below

☐

Implementing a `duty of candour'; a new contractual requirement on providers – proposals for consultation

The Optical Confederation represents the 12,000 optometrists, 6,000 dispensing opticians, 7,000 optical businesses and 45,000 ancillary staff in the UK, who provide high quality and accessible eye care services to the whole population. As a Confederation we work with others to improve eye health for the public good.

We welcome the opportunity to comment on this consultation.

Principles of Candour

As two regulated professions, optometry and dispensing, we fully support the principles of candour (Paragraph 2.4). Moreover, operating, as we do, in a fully open, highly competitive market, we are already incentivised by the structures within which we deliver care to comply with those principles. Uniquely within the NHS, optical patients, their relatives or carers, who have any concerns or issues about their care can

- immediately move to another contractor/practitioner, who will not only care for them, but also support them in any complaint they may have
- have recourse to several routes for complaint, apology, explanation and redress via the practitioner/practice themselves; the NHS Commissioner; or the General Optical Council (GOC).

As with the other primary care professions, the mandatory GOC Codes of Conduct, require that practitioners, practices and businesses 'make the care of the patient [their] first and continuing concern'.

As professions, we agree entirely with the principles of:

- acknowledging, apologising and explaining when things go wrong
- conducting a thorough investigation and reassuring patients, their families and carers that lessons were learned and will help prevent the incident happening again
- providing support for those involved to cope with what happened (paragraph 2.4).

Like all other NHS organisations, we too are required under the Health Act 2009 to 'have regard' to the NHS constitution, which in turn replicates these duties. (Paragraph 3.2)

As registered professions, we also support *Being Open,* published by the National Patients' Safety Agency.

As previously mentioned, as professions we operate in an open, highly competitive market place, which delivers the benefits of quality, access, choice and low costs so valued by patients and the NHS. Adding unnecessary additional burdens would jeopardise this. We therefore entirely support the Government's aim 'to balance any appropriate requirements against the need to avoid a new, costly bureaucratic mechanism'. (Paragraph 2.11)

Community Optometry: Consultation Question 5.

As community optometrists and optical practices, our main concern is with Question 5.

We agree with the Department of Health that 'the contracts entered into by primary care contractors are different, in that they are not NHS Standard Contracts'.

The Government is also correct that 'primary care contracts must comply with the provisions of profession-specific secondary legislation and that these contracts will contain sector-specific rules on such matters as dealing with information or with contractual breaches'.

We further agree that the procedures outlined in the consultation document for directly provided NHS services 'could not, as described, automatically be applied to GPs, dentists, providers of primary ophthalmic services and pharmacists' and that:

- any contractual amendment in relation to primary care contractors is a complex process, requiring amendments to secondary legislation
- consultation is required with the professional representative bodies – in our case, the Optical Confederation and the British Medical Association in relation to any changes
- 'the wording of the contractual requirements will be more complex to reflect differences in other obligations, for example around wider reporting, between primary care and other providers' (Paragraph 4.11).

We would add three further points.

First, although intended for general application, the tone and substance of most of the discussion seems to be about death, serious injury or harm and the type of cases that are currently reported to the National Patient Safety Agency and the Care Quality Commission. In our case, the community optometric service provides 21 million sight tests a year with very few complaints or adverse effects and, to the best

of our knowledge, no issue from our sector has ever needed to be referred to the NHS Patient Safety Agency or higher authorities.

Second, uniquely in our case, professional indemnity insurance is not underwritten by the NHS Litigation Agency, the Medical Defence Union or the Medical Protection Society and is provided – in the main – by five major insurers with whom arrangements for openness are already established. These parties would also all need to be consulted and the outcomes signed up to by these underwriters, in order to ensure that both patients and practitioners were appropriately protected.

Third, again unlike most areas of NHS care, the provision of primary ophthalmic services is identical for both NHS and private patients – this is a major strength of the current system. The duties to be performed in a sight test are defined in legislation. Irrespective of whether it is NHS or privately funded by the patient, the required elements of a sight test are identical and have to be delivered to the same high standards. As now, we would want any duties that applied to NHS primary ophthalmic services providers to apply equally to any care provided to private patients.

We therefore strongly support the view that implementation of the duty of candour in NHS standard contracts for wholly-owned NHS services, e.g. NHS trusts, community services, should not be delayed while discussions about primary care take place.

Moreover, whilst we can understand the Government's desire to have a single model for all NHS services, we do not believe that a contractual amendment is either necessary or the best way of achieving this for primary ophthalmic services.

Instead we would propose working with the Department of Health to review our current arrangements and if necessary develop a sector-specific requirement which, when incorporated within guidance from the professional bodies, would then automatically be included by definition in all NHS contracts but would also apply to all private services as well.

In the light of the above comments, our responses to the other consultation questions, where appropriate to us or where we feel we have something of value to contribute, are attached.

We are happy for this response to be made public.

Mark Nevin
Optical Confederation

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Consultation Questions

For questions 1-5 please refer to section 4 of the associated consultation document

1. Do you think the contractual mechanism described here including the requirement for a declaration or commitment on openness, provides an effective mechanism for requiring openness?

Yes	
No	✓

Comments

We cannot help thinking that a contractual requirement (paragraph 4.2) and the sanctions listed at paragraph 4.8 should be more than sufficient to achieve the policy objective without adding the additional requirement of an annual "declaration of a commitment to openness". Either this is in the contract and is therefore a contractual requirement, or not. At a time of financial stringency in the NHS, we would advise against adding further unnecessary reporting requirements which would inevitably involve additional costs and divert resources which would otherwise go to front-line patient care.

In our view, the contractual requirement in paragraph 4.5 that 'where a provider breaks their openness commitment by not being open with a patient or their representatives about an incident, and the patient or their representative complains, the Commissioner could take action through the contract management process' is already provided for by the fact that:

- the contractual requirement could be widely publicised in NHS Communications
- the contract management processes would bite
- the list of sanctions would be open to the Commissioner to use.

We cannot see what further benefit would be achieved therefore through the additional bureaucracy of annual statements.

2. Do you think there should be a range of consequences available for use depending on circumstances?

Yes	✓
No	

3. **Do you have any suggestions for what the consequences should be – either as a range or as a single consequence?**

Suggested consequences

Throughout the whole of this policy process, implementation and communications, the principles of "reasonableness" and "proportionality" should apply. Commissioners should therefore choose - against those principles - from the range of consequences available (paragraph 4.8). The right of appeal to the First Tier Tribunal against breaches of these principles and unreasonable behaviour by Commissioners should, in our view, provide sufficient counter-balance within the system to ensure that only appropriate action is taken.

4. **Should the level of escalation include suspension / termination of the contract?**

Yes	✓
No	

Comments

Suspension or termination of the contract should only apply in the most extreme circumstances where identified concerns had not been addressed and non-openness is likely to be, on the balance of probabilities, indicative of care so deficient that it represents a serious risk to patients. Again, proportionality is key.

5. **Do you think a requirement should be placed on primary care contractors and if so how might this be achieved?**

Yes	
No	✓

If yes, how might this be achieved?

Please see our main response above. Primary ophthalmic services are already covered by separate contractual arrangements, the duty to have regard to the NHS Constitution, and quite separate professional indemnity and legal defence funding systems from the NHS Litigation Authority. Both professionals and optical bodies corporate have a duty to "make the care of the patient [their] first and continuing concern" and there is no evidence that any further or duplicatory requirements are necessary.

For questions 6-7 please refer to section 5 of the associated consultation document

6. **Are these requirements reasonable and clear, including the 5 working day deadline?**

Yes	
No	✓

Comments

We would query whether 5 working days is feasible in all circumstances. If this were to apply, we would wish to work with the Department of Health on the practicalities of this in optics - including where it is not possible, the alternative methods of reaching the same goals.

7. Is there anything that should be included that isn't?

Yes	
No	✓

Comments

For questions 8-12 please refer to section 6 of the associated consultation document

8. Do clinicians, including GPs, feel able to assist their patients in identifying cases where there has been a failure to be open, and then either supporting their patient in raising these concerns, or simply referring the concern to the Commissioner to investigate?

Yes	
No	✓

Comments

Clearly where something significant has gone wrong, an apology and openness as set out in *Being Open* are essential and this should be part of all clinicians' basic training in patient and carer communications. For existing clinicians, this could also be part of relevant CPD and re-accreditation.

However a balance does need to be struck. There is an element of risk, in all clinical intervention and non-intervention. As much should be done as possible to enable a patient to give informed consent, but part of that informed consent must include the understanding that something can occasionally go wrong through human error or system failure. Patients are more than capable of assessing these risks (with their clinicians) for themselves. Constant openness about every minor failure, where no harm is caused, could serve to undermine the confidence of the public in the health care system and in a way which lay people could easily misunderstand. The consequences of this might be more serious than the benefits of full openness. For example, airlines and

railway operators frequently manage system failures and near misses without constantly reminding passengers of them. Passengers are reassured to know that the systems are in place to maximise their safety albeit that flying is never without risk.

Healthcare is not dissimilar in that regard and great care needs to be taken to:

- support clinicians and institutions in being open with patients and carers wherever appropriate – and the default position should always be openness;
- train clinicians and organisations in exercising this duty reasonably;
- support both clinicians and organisations when – as inevitably will occasionally occur - there is an error either in the direction of too much or too little openness.

9. What support and advice do clinicians feel would assist them in this?

Comments

Please see above.

10. What additional support and advice would assist patients in raising concerns that could be made available through Local HealthWatch services?

Comments

Patients and their carers should be made aware of the commitment to openness/candour in the same way that they are about the patient complaints mechanism e.g. in all communications with them from provider organisations and in local HealthWatch communications and on respective websites.

11. Does a 'road map' or 'flowchart' of 'What To Do When Things Go Wrong' sound like a useful tool for patients?

Yes	✓
No	

Comments

There is plenty of this guidance around already, but we wonder whether the flow chart should not rather be entitled 'what happens when things go wrong' and if it should:

- explain that no procedure is risk free;
- set out what, in the rare eventualities that things go wrong, should happen;
- and advise patients and their carers what they can do if they feel this has not happened in their particular circumstances.

12. Are there any equalities issues with this proposal? Will any groups be at a disadvantage and therefore less likely to receive openness[1]?

Yes	✓
No	

Comments

Inevitably, these sorts of systems will favour the more articulate groups in society. It is important, therefore, that local HealthWatch publicises its advocacy role including for those whose first language is not English.

For questions 8-12 please refer to section 6 of the associated consultation document

13. Are the expectations on Commissioners clear and reasonable?

Yes	✓
No	

Comments

14. Should Commissioners be expected to do anything else?

Yes	
No	✓

[1] By equalities group, we are referring to any group with a protected characteristic. These are groups with the following protected characteristics; age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.

Comments

15. Are the public reporting requirements clear and reasonable?

Yes	✓
No	

Comments

Openness is an important patient benefit and part of the “grown-up” clinical system which we entirely support. However, for the sake of everyone, this has to be approached “reasonably” and “with proportionality”.

It has to be remembered that no clinical intervention (including non-intervention) is without risk of human error (both patients and clinicians are human) and occasional system failure.

Openness needs to be seen in this context with patients being protected to the maximum, clinicians and organisations being as open as possible with patients when anything does go wrong, and appropriate compensation being applied where necessary.

For the reasons outlined above, we do not think this new duty needs to apply to primary ophthalmic services which already operate to these standards without needing to be brought within additional regulation.

However we would be happy to participate in discussions with the Department of Health/NHS Commissioning Board about:

- how our existing systems already align with the principles of *Being Open* and the duty of candour in standard NHS contracts and
- if necessary, issuing further binding guidance on our professions to ensure this is so.

This we believe, would be a more efficient way of achieving the same ends without adding further burdens and cost to the NHS commissioning, contracting and delivery processes.

General comments

Do you have any other comments you would like to make in relation to this consultation?

Before submitting your response to the Department, please make sure that it has been saved in a name (*e.g. yourname*Candour.doc) that will make it easier for us to track. Many thanks.