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DUTY OF CANDOUR & BEING OPEN – DRAFT POLICY PROPOSALS FOR CONSULTATION

Summary

In January 2018, Justice John O'Hara published his report on the Inquiry into Hyponatraemia-Related Deaths (IHRD). His first recommendation was that a statutory Duty of Candour should be enacted in Northern Ireland and that it should apply to Healthcare Organisations and everyone working for them. Justice O'Hara also recommended that criminal liability should attach to breach of this duty and to obstruction of another in the performance of this duty. He made further recommendations about the guidance, support and protection that should be provided for staff in order to create a more open culture.

In response, the Department of Health (DoH) established an Implementation Programme to take forward the recommendations arising from the Inquiry and the Duty of Candour Workstream, and its Being Open subgroup, have been responsible for developing the proposal options to address the recommendations on candour.

Through a co-production process, the Worksream and Subgroup have developed policy options for the statutory Duty of Candour and the policy framework for Being Open guidance, taking account of: research commissioned and evidence submitted; feedback from staff and service users; and input from other key stakeholders.

The DoH is now seeking your views on the following proposals developed by the Workstream and Subgroup:

a. Policy options for the statutory organisational Duty of Candour; and

b. Policy options for the statutory individual Duty of Candour; and

c. The policy framework for Being Open guidance.

A detailed summary of these proposals is available here on the DoH website.

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Ways to respond

The consultation opened on 12 April 2021 and will close on 2 August 2021. Stakeholders can respond by completing this questionnaire, or by submitting their own written response, to the policy proposals to:

E-mail: **IHRD.implementation@health-ni.gov.uk**

Written: IHRD Implementation

Department of Health

Room D1

Castle Buildings

Stormont Estate, BELFAST

BT4 3SQ

In addition, an online questionnaire is available on the Citizen Space website here, which allows stakeholders the opportunity to respond to the consultation questions online.

If, for any reason, you are unable to access the electronic versions of the documents you can request a paper copy by e-mailing IHRD.implementation@health-ni.gov.uk or by writing to the address below. The consultation documents, including the questionnaire, may also be requested in an alternative format by also contacting this address.

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Terminology (paragraphs 2.25 – 2.27)

1. Do you agree with the terminology and definitions adopted by the Workstream in respect of "openness" and "candour"? If yes, please provide any additional information and / or insights.

Yes

It is important to define them clearly, and to differentiate between the two concepts for clarity of discussion and policy making

2. If not, do you suggest a preferred terminology that should be used to describe this policy and the statutory duty? Please provide evidence to support any alternative proposal.

Candour is a less commonly used word, it might put off some people.

Another term might be ""honesty"".

Not disclosing, freely, all relevant information can be a form of dishonesty, and most people would say they use and understand the term honesty (albeit with differing definitions, so it would need to be defined clearly and carefully

Note, this survey talks of honesty on the next page, in relation to the Staffordshire report, so honesty is used here as well, instead of candour

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Statutory Organisational Duty of Candour (Section 3)

Scope (paragraph 3.8 – 3.9)

3. Do you agree with the proposed scope of the statutory organisational Duty of Candour? If yes, please provide any additional information.

Why should the duty of honesty only apply to medical/quasi medical institutions or professionals?

Harm, and over ups of that harm, occur in many different scenarios. Scouts, religious organisations, sports organisations are classic examples.

Perhaps the criterion should be: any organisation which receives public money or public accreditation of its work.

However, maybe that expands the scope and resistance too much for this round, maybe future rounds.

4. If not, do you have a preferred approach for the scope of the statutory organisational Duty of Candour? For example, should the scope be limited to regulated organisations that directly provide health and social care services? Please provide evidence to support any alternative proposal.

See above

Routine Requirements (paragraphs 3.10 – 3.11)

5. Do you agree with the routine requirements of the statutory organisational Duty of Candour? If yes, please provide any additional information.

Yes

provided that the costs (financial mainly) to individuals or organisations are not greatly increased by honesty.

There should be some recognition, in damages available, sanctions etc for organisations or individuals who meet their duty of honesty. For example, it should not affect an insurance policy that disclosure was made under a duty of honesty, and damages should be raised where an organisation or individual has not met their duty of honesty

6. If not, do you have a preferred approach for the routine requirements of the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Routine disclosure should balance the cost to organisations of providing information. Fulfilling the duty will not be cost free. That cost will be eventually borne by all patients/consumers/taxpayers, so the value for money needs to be kept in mind in drafting thresholds etc.

There should be a threshold of materiality when the duty of honesty requires disclosure.

Requirements – When Care Goes Wrong (paragraphs 3.12 – 3.18)

7. Do you agree with the proposed definition for the significant harm threshold for the Duty of Candour procedure? If yes, please provide any additional information.

The definitions appear reasonable

8. If not, do you have a preferred definition for the significant harm threshold for the Duty of Candour procedure? Please provide evidence to support any alternative proposal.

no

Statutory Duty of Candour Procedure (paragraphs 3.19 – 3.23)

9. Do you agree with the proposed requirements under the statutory organisational Duty of Candour when things go wrong? If yes, please provide any additional information or insights.

"Calling the actions after ""serious harm"" as ""Duty of Candour"" is confusing, as the requirement for candour/honesty is described in very similar terms in the first few pages of this survey. The duty after severe harm should have a clearly different name.

""Homicide"" appears an inappropriate term to use here. ""Death"" seems perfectly adequate without bringing in the criminal concept of homicide (which the police would investigate, rather than hospitals).

The organisation should record or keep contemporaneous records of all conversations or communications with he relevant persons.

Proposed future actions or investigations should be included, and the results of those future actions reported back to the relevant persons.

10. If not, do you have a preferred approach for the requirements under the statutory organisational Duty of Candour when things go wrong? Please provide evidence to support any alternative proposal.

Apologies (paragraphs 3.24 – 3.26)

11. Do you agree with the proposed legislative requirement to provide an apology as part of the Duty of Candour procedure? If yes, please provide any additional information or insights.

Formulaic responses should be avoided. The Ex Men of any legislation should discuss this issue clearly and expansively, so that organisations, and courts, will have good and clear guidance of what type of response will fulfill the obligation. Ex Mems are woefully under used to provide this sort of guidance and context of the intentions of legislation.

The main issue to avoid, which will be the most difficult, will be to prevent organisations having their apologies filtered, served, directed, rewritten, rewritten and directed again by their lawyers or their insurer's lawyers. In general, they are the most conservative. Legislating to take apologies etc. out of litigation (civil and criminal) will reduce the need for lawyers, and will reduce the potency of their redactions.

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12. If not, do you have a preferred policy approach in respect of apologies in circumstances where the threshold for the Duty of Candour procedure has been met? Please provide any evidence to support any alternative proposal.

It would have been easier if this issue had been flagged in the previous question.

When discussing liability and civil sanctions, a duty of candour, and a statutory apology should in turn reduce/prevent the imposition of any punitive damages on organisations. The duty of candour, and provision of all information will make civil litigation easier when relevant persons are pro-actively given all of the evidence needed for such civil litigation. The quid pro quo ought to be that punitive damages are not applied to an organisation that has fulfilled all of its Duty of Honesty obligations (in the spirit as well as letter). That will provide a carrot to organisations for fulfilling their DoH obligations

Civil damages ought also be more restricted to providing the services needed to ameliorate the harm caused to the affected person, rather than a cash windfall. That would reduce much litigiousness, and make meeting their DoH obligations easier for organisations and their insurers, but is probably beyond the scope of this review.

13. Do you agree with the proposals in respect of apologies under the statutory organisational Duty of Candour? If yes, please provide any additional information or insights.

14. If not, do you have a preferred approach for the proposals in respect of apologies under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Support and protection for staff (paragraphs 3.27 – 3.28)

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15. Do you agree with the proposals for support for staff under the statutory organisational Duty of Candour? If yes, please provide any additional information or insights.

Publication within the organisation of each case of compliance with DoH will ensure that staff see fulfilling their DoH duties as standard and routine. Hopefully, very few staff will need to be involved in one. However, if they have seen cases go past previously and reported within the organisation (and the affected staff members not have their careers ruined from DoH) it will be easier for them to comply fully with their DoH obligations. Organisations should have a non-lawyer staff member, more extensively trained in DoH, to assist each staff member involved in a DoH case through the process. Similar to staff who assist in FOI cases within organisations. The DoH staff member should have access to the board or other governing body with a reporting role to oversee the organisation's compliance with its DoH responsibilities.

16. If not, do you have a preferred approach for the support for staff under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Reporting and monitoring (paragraphs 3.29 – 3.32)

17. Do you agree with the proposed reporting and monitoring requirements under the statutory organisational Duty of Candour? If yes, please provide any additional information.

Any report or statement must be provided to the board or governing body, so they cannot deny knowledge or responsibility. DoH should be a standing item on the governing body's agenda

18. If not, do you have a preferred approach for the reporting and monitoring requirements under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Criminal sanctions for breach (paragraphs 3.33 – 3.40)

19. Do you agree with the proposed criminal sanctions for breach of the statutory organisational Duty of Candour? If yes, please provide any additional information.

"£5,000 will be seen as a very cheap risk to take. It is close to the hourly rate of senior counsel which an organisation might consult in a DoH matter. £50,000 would be barely material for most organisations which will have DoH obligations Non-monetary provisions will be more effective, such as compulsory compliance programmes with approval by the relevant regulator or professional body, regular additional statutory reporting, compulsory additional staff training (especially management staff) etc."

20. If not, do you have a preferred approach for the criminal sanctions for breach of the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Obstruction offence (paragraphs 3.41 – 3.42)

21. Do you agree with the proposed obstruction offence under the statutory organisational Duty of Candour? If yes, please provide any additional information.

For the individuals likely involved in wilfully obstructing a DoH obligation, £5,000 will be a small, non-deterrent fraction of their salary. It is materially too low for a maximum

Again, non-monetary sanctions or corrections should be expressly and statutorily part of the available deterrent/correction suite

22. If not, do you have a preferred approach for the obstruction offence under the statutory organisational Duty of Candour? Please provide evidence to support any alternative proposal.

Additional feedback

23. Is there any additional evidence, or observations that you wish to provide in respect of the policy proposals for the statutory organisational Duty of Candour?

The three elements must be:

1. removing inhibitory factors e.g. litigation costs/risks

2. increasing the palatability/normality of complying with DoH obligations

3. making sanctions both financially material and non-financially effective and appropriate

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Statutory Individual Duty of Candour (Section 4)

Policy Proposal – Statutory Individual Duty of Candour with criminal sanction for breach (paragraphs 4.13 – 4.22)

24. Please provide comments on the policy proposal for the statutory individual Duty of Candour.

Current medical circumstances are littered with whistleblowers being harassed by their organisations, by government bodies and others.

Current medical circumstances are littered with ""professional""organisations being quite selective in how they support or don't support their members.

The current process has clearly failed patients and junior professionals.

It is no longer acceptable to accept the ""professional bodies"" as the agency for DoH.

There should be a personal statutory obligation, with all the supports and protections discussed.

Leaving things as is cannot continue.

Alternative Policy Proposals (paragraphs 4.23 – 4.35)

25. Please provide comments on the alternative policy proposals for the statutory individual Duty of Candour.

Option 3 seems the most feasible.

There are already criminal sanctions for all sorts of things professionals are required to do or not do, and they work perfectly ably within those requirements. This would not be materially different.

Sanctions are necessary.

Separate criminal sanctions appear an acceptable compromise.

However, O'Hara's observations remain quite persuasive for introducing a simple criminal sanction. He spent a long time looking at the issues and his views should be given material weight.

Different levels of duty and sanction may be appropriate for different levels of responsibility e.g. a cleaner observing matters vs a doctor actually involved in conducting the procedure that led to the harm"

26. If you do not agree with any of the three high-level policy proposals, do you have a preferred alternative policy approach for implementation of the recommendations relating to the statutory individual Duty of Candour? Please provide evidence to support an alternative proposal.

Scope (paragraphs 4.36 – 4.38)

27. What is your preferred policy approach in respect of the scope of the statutory individual Duty of Candour? Please outline the reasons for your preference, and provide evidence to support your reasoning.

The individual statutory DoH should be tailored to reflect the differing levels of responsibility and organisational power of different individuals and levels of profession. For example, cleaners observing an incident should be required to report it, and disclose to relevant persons, but their DoH responsibilities and sanction should be materially lower than a professional involved in the actual procedure that led to the harm

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Routine Requirements & Requirements When Care Goes Wrong (paragraphs 4.39 – 4.43)

28. Do you agree with the proposals in relation to the requirements under the statutory individual Duty of Candour? If yes, please provide reasons for your agreement.

It is truly difficult to conjure up circumstances where ""clinical or professional judgement"" means candour may not be appropriate. This appears to be medical professionals closing ranks with no evidence to support their claims. Any person who makes the proposal about ""clinical or professional judgement"" should be required to provide verifiable evidence of cases (not hypotheticals conjured from their imaginations) where such ""clinical or professional judgement"" should override the clear benefits of a DoH before any weight should be given to this unreliable proposition.

The exceptions might be where full candour would disclose to third persons issues which affect the right to privacy of the affected person or persons. Provision should be made to ensure that the DoH does not compel a person to breach GDPR or other privacy provisions.

29. If not, do you have a preferred approach for the requirements under the statutory individual Duty of Candour? Please provide evidence to support any alternative proposal.

Exemptions (4.44)

30. Do you have any comments to make on the case for exemptions from the requirements under the statutory individual Duty of Candour? Please provide evidence to support your position.

Clearly, the DoH should not force a person to breach any other law or requirement imposed upon them. Either, the DoH should ahve a clear exception for the relevant provisions which are not to be breached, or, those provisions need an exception which allows the DoH to override their requirements.

Until the specific provisions are identified, and the alternative benefits and costs are assessed, it is difficult to determine which provision should be given legislative precedence.

Clearly it will take some time to work through all of the potential legislative or other provisions to assess where the balance lies in each case of conflicting provisions.

Additional Feedback

31. Is there any additional feedback that you wish to provide in respect of the policy proposals for the statutory individual Duty of Candour? If so, please provide evidence to support alternative proposals, if possible.

"Clearly, from the number of cases where whistle blowers have been litigated against by the government and medical institutions, the current system is not working.

Government and the medical establishment are currently spending hundreds of thousands of pounds trying to prevent whistle blower doctors from reporting cases. These cases are on the public record, as is the amount of money the UK government and medical/health institutions have spent trying to prevent the whistle blowers being heard (including costs threats of a fully financed health system against individual doctors).

Clearly, the government and health institutions are not to be trusted with matters that may affect their reputations or costs.

A statutory system of DoH is required, with criminal sanctions against those who try to prevent the matters being heard or reported.

A separate, independent body should also be set up to assist and protect doctors and other persons who seek to comply with their DoH obligations but feel that they are being oppressed by government or medical institutions. The independent body should be entitled to enquire into any litigation or action taken by government or health institutions in seeking to litigate or defend against a health professional seeking to comply with their DoH obligations."

Being Open Framework (Section 5)

Policy Proposals (paragraphs 5.1 – 5.8)

32. Do you agree with the policy proposals in respect of the Being Open Framework? If yes, please outline your reasoning.

The proposals sound positive,

However, implementing them will take time and resources. They will, of necessity, create extra work for HSC staff. Openness doesn't magically appear out of a policy statement. It needs to be implemented. Reporting and disclosing take time and resources. HSC staff will need to take some time out of doing the other things they currently do in order to document, communicate, learn, participate in all the openness requires. That time needs to be explicitly and expressly made available. That needs to be addressed in rosters and other staffing measures. Otherwise it is just piling more obligations and duties on staff, many of whom are already overloaded.

The other side of the coin is that there should be an expectation that a culture of openness and honesty will reduce accidents and untoward events in future, and when they do occur, the consequences in terms of litigation and enquiry will be materially reduced and be greater savings than the investment in time of openness and honesty.

33. If not, do you have a preferred policy approach in respect of openness and candour in health and social care? Please provide evidence to support alternative policy proposals.

Level 1 – Service Users and Carers (paragraphs 5.9 – 5.11)

34. Do you agree with the policy proposals at Level 1 of the Being Open Framework for Service Users and Carers? If yes, please outline your reasoning.

35. If not, do you have a preferred policy approach in respect of Level 1 of the Being Open Framework for Service Users and Carers? Please provide evidence to support alternative policy proposals.

Implementation will be the determinant of whether the Level 1 Policy is worth anything.

Information needs to be both comprehensive and comprehensible.

My personal experience is that HSC staff do not ahve the time to implement it, and senior staff pay lip service to it.

My experience of a colonoscopy was that the consultant spoke with me prior to the procedure, explained his level of experience, told me that he may possibly cause me harm if things went wrong, and asked me to sign a consent form.

In theatre, he advised that a trainee constant would be doing the procedure, but that he would be overseeing the procedure. During the procedure, I watched the consultant (I took no sedative), and he was on the other side of the room, in conversation with other staff, with his back to the procedure, and did not, in my observation, come to the site of the procedure once. All the boxes were ticked, and then the consultant went and did something entirely different.

There will be enormous challenges in changing the attitudes of senior medical staff.

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Level 1 – Staff (paragraphs 5.12 – 5.13)

36. Do you agree with the policy proposals at Level 1 of the Being Open Framework for Staff? If yes, please outline your reasoning.

As drafted, yes.

Implementation is another thing.

37. If not, do you have a preferred policy approach in respect of Level 1 of the Being Open Framework for Staff? Please provide evidence to support alternative policy proposals.

Level 1 – Organisations (paragraphs 5.14 – 5.15)

38. Do you agree with the policy proposals at Level 1 of the Being Open Framework for Organisations? If yes, please outline your reasoning.

"Th policy proposal ticks all the right boxes, but it is very high level and approaches motherhood in most of its statements.

Proper assessment will depend on the detailed policy documentation and the attitude of senior management in implementing it when actual cases occur which may affect the organisation's reputation or that of senior staff. That is usually where grand policies fall over."

39. If not, do you have a preferred policy approach in respect of Level 1 of the Being Open Framework for Organisations? Please provide evidence to support alternative policy proposals.

Level 2 – Service Users and Carers (paragraphs 5.18 – 5.19)

40. Do you agree with the policy proposals at Level 2 of the Being Open Framework for Service Users and Carers? If yes, please outline your reasoning.

This will impose material resource requirements in doing the analysis, preparing the information material, presenting the material, attending/reading the training material. Given the size of the HSC there could be a large volume of such ""near miss"" incidents and other learning occasions. The HSC needs to assess the resource requirements of this policy proposal and indicate clearly and formally how it will be resourced within the already constrained work environment of the HSC and its staff.

Otherwise, it will be more work for staff and it will be shelved as urgent day to day tasks pour through and management require the urgent matters to be attended to. In such cases Level @ Openness will swirl away as more management degreed detritus that front line staff don't ahve time for, and management don't have a palate for.

41. If not, do you have a preferred policy approach in respect of Level 2 of the Being Open Framework for Service Users and Carers? Please provide evidence to support alternative policy proposals.

Level 2 – Staff (paragraphs 5.20 – 5.21)

42. Do you agree with the policy proposals at Level 2 of the Being Open Framework for Staff? If yes, please outline your reasoning.

See previous responses about resourcing, implementation and senior management committment.

43. If not, do you have a preferred policy approach in respect of Level 2 of the Being Open Framework for Staff? Please provide evidence to support alternative policy proposals.

Level 2 – Organisations (paragraphs 5.22 – 5.23)

44. Do you agree with the policy proposals at Level 2 of the Being Open Framework for Organisations? If yes, please outline your reasoning.

Many of these "near misses" will be complex, complicated, highly fact specific, highly person specific and difficult to generalise. Many of them will not provide a great deal of learning which is transferable to other circumstances or generalisable. There needs to be some filtering of these cases being transferred to generalised learning that all HSC staff need to be informed of or to learn.

45. If not, do you have a preferred policy approach in respect of Level 2 of the Being Open Framework for Organisations? Please provide evidence to support alternative policy proposals.

There is nothing in the guidelines above which require organisations to have clear, audible systems in place for these Level 1 and Level 2 policies to be implemented, and nothing to sheet home responsibility to senior and middle management.

Without clear and published procedures to which management can be held accountable all the policies in the world become just more folders sitting, gathering dust on shelves.

Level 3 – Service Users and Carers (paragraphs 5.26 – 5.29)

46. Do you agree with the policy proposals at Level 3 of the Being Open Framework for Service Users and Carers? If yes, please outline your reasoning.

Yes, appears sensible

Persons affected should be asked to initiate discussions with the organisation or their contact person before commencing litigation or other avenues of redress or complaint. They should be advised that there is some degree of reciprocity desirable if the HSC is going to commit to a culture of openness and honesty, for affected persons to work with the organisation to resolve issues before considering litigation or other avenues of redress. This could, in theory, be imposed by a privative clause in the legislation, but that would appear unlikely in NI's litigious environment.

47. If not, do you have a preferred policy approach in respect of Level 3 of the Being Open Framework for Service Users and Carers? Please provide evidence to support alternative policy proposals.

Level 3 – Staff (paragraphs 5.30 – 5.31)

48. Do you agree with the policy proposals at Level 3 of the Being Open Framework for Staff? If yes, please outline your reasoning.

This will only be effective if staff have seen in the past that their organisation has delivered on these fine objectives.

Its effectiveness lies in the hands and behaviours of the organisation and its senior management before the fact.

49. If not, do you have a preferred policy approach in respect of Level 3 of the Being Open Framework for Staff? Please provide evidence to support alternative policy proposals.

Level 3 – Organisations (paragraphs 5.32 – 5.33)

50. Do you agree with the policy proposals at Level 3 of the Being Open Framework for Organisations? If yes, please outline your reasoning.

Yes, as written

51. If not, do you have a preferred policy approach in respect of Level 3 of the Being Open Framework for Organisations? Please provide evidence to support alternative policy proposals.

Additional Feedback

52. Is there any additional feedback that you wish to provide in respect of the policy proposals for the Being Open Framework? If so, please provide evidence to support alternative proposals, if possible.

The proposals are welcome and have the potential to be highly beneficial to patients, staff, and organisations.

Implementation, especially commitment of senior management when things do go wrong will be essential.

Current circumstances for many whistle blowers in the UK health system does not provide confidence.

Consultation & Impact Screening (Section 6)

53. Do you have any feedback about the possible ways we could measure whether or not this policy is useful?

Independent review of a statistically significant number of adverse incidents by an independent external body with no affiliation or beholdence to the government or Dept of Health or HSE . This should be done annually or biannually at the start, and the results shared around HSE Trusts and with in the Department and to the Minister.

54. Do you have any feedback or suggestions about how we can engage and involve stakeholders to develop this policy and put it in place?