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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.

If candour is to be the term used then adopting the same definitions as specified by Sir Robert Francis is appropriate.

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.

Openness is likely to be understood better by the population than 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.

It is correct to ensure public accountability for the delivery of open and honest health and social care and ensuring organisations are open and honest about mistakes. The scope of the statutory organisational Duty of Candour should be restricted to those organisations that are directly providing health and social care services to the population.

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.

The scope of the statutory organisational Duty of Candour should be restricted to those organisations that are directly providing health and social care services to the population. Other organisations would not be in a situation to identify a patient-identifiable error and to share that information with a patient.

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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.

It is appropriate that the broad overarching statutory duty should ensure that the service received by patients, service users, carers and families is routinely and proactively open. Staff should be required and supported to give full and honest answers to any question reasonably asked by a patient about their treatment. Support for this from within the organisation where the service was being delivered is essential.

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.

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.

Inclusion of moderate harm may increase the number of incidents to the level where they cannot be dealt with in a timely fashion and risk being unable to deal with the serious incidents appropriately. Moderate harm as defined by a “moderate increase in treatment” may be inconsistently applied and not always recognised. In relation to “may have resulted in” harm, this may not be apparent until long after an episode of care and may only come to light with a look back exercise or similar. This is important when considering findings of potential actions or omissions that were not recognised at the time and would not have presented as issues to report.

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.

Inclusion of moderate harm as defined by a "moderate increase in treatment" would appear to be too low a threshold. This would include a range of medical and surgical treatments and the outcome may be the same with no impact other than the treatment increase. Having to change treatment is being included in moderate harm will encourage the least risky treatment option which may produce less good patient outcomes.

Serious harm is a clearer level of impact to include. Harm which has been significant with a high level of impact on the patient for a prolonged period, but not permanent, may need to be considered for inclusion. Aligned to this would be a similar threshold for psychological harm in terms of severity and duration. At present the psychological harm definition does not have level of severity described, in contrast to the physical harm definitions.

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.

Notification is appropriate but interactions should not be by writing alone.

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.

The concern that legislating for an apology in these circumstances could lead to a standardised or formulaic approach, which does not guarantee a genuine and sincere apology for the patient, service user, carer or family involved is real. Organisations should describe what happened and explain why events occurred and what is being done to avoid similar events. As part of this an apology should be made when errors have been identified.

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.

The concern that legislating for an apology in these circumstances could lead to a standardised or formulaic approach, which does not guarantee a genuine and sincere apology for the patient, service user, carer or family involved is real. Organisations should describe what happened and explain why events occurred and what is being done to avoid similar events. As part of this an apology should be made when errors have been identified.

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.

This question is difficult to answer at this point as the relevant guidance is not yet available: “further information on compliance with the requirement to provide an apology will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour”

In relation to: “Any legislation drafted in respect of the Duty of Candour should also include a provision which clarifies that an apology or other step taken in accordance with the Duty of Candour procedure should not, of itself, amount to an admission of negligence or a breach of a statutory duty to provide health and/or social care services” without this organisations will be reluctant to provide an apology early in any process.

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.

This question is difficult to answer at this point as the relevant guidance is not yet available: “further information on compliance with the requirement to provide an apology will be included within the accompanying guidance issued by the DoH to support implementation of the statutory organisational Duty of Candour”

In relation to: “Any legislation drafted in respect of the Duty of Candour should also include a provision which clarifies that an apology or other step taken in accordance with the Duty of Candour procedure should not, of itself, amount to an admission of negligence or a breach of a statutory duty to provide health and/or social care services” without this organisations will be reluctant to provide an apology early in any process.

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Support and protection for staff (paragraphs 3.27 – 3.28)

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.

The open and adjust culture is essential. A blame culture in an organisation will not enable staff to meet the expectations of the population

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.

Sharing of learning without blame will be essential for organisational learning and development.

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.

The timing of reports may not need to be aligned to the financial year. No other comments

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.

The timing of reports may not need to be aligned to the financial year.

No other comments

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.

The definitions of the breaches should include knowing there had been a notifiable incident and intending to provide a false or misleading statement.

The impact of being in breach of the requirements on organisations will be considerable for reputational, governance and audit reasons. These impacts will be drivers of good practice rather than the financial penalties of the magnitude described.

Paragraph 3.40 relating to officers of the organisation should be considered under the individual Duty of Candour section of the consultation.

Adding a criminal element to the organisation duty of candour is out of step with patient safety initiatives across the world and may reinforce a culture of fear and blame, rather than one that promotes openness and learning.

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.

The definitions of the breaches should include knowing there had been a notifiable incident and intending to provide a false or misleading statement.

The impact of being in breach of the requirements on organisations will be considerable for reputational, governance and audit reasons. These impacts will be drivers of good practice rather than the financial penalties of the magnitude described.

Paragraph 3.40 relating to officers of the organisation should be considered under the individual Duty of Candour section of the consultation.

Adding a criminal element to the organisation duty of candour is out of step with patient safety initiatives across the world and may reinforce a culture of fear and blame, rather than one that promotes openness and learning.

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.

It would not be acceptable for an organisation to obstruct another in the performance of their duties. There may be a risk that it is only apparent at a later stage that an individual was not acting honestly or with full information when reporting an issue under Duty of Candour.

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?

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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.

The focus of any criminal liability if implemented should be about whether individuals have been open and honest about mistakes which have been made, or accidents which have happened.

Any criminal liability introduced in Northern Ireland would be expected to negatively impact on recruitment and retention of healthcare staff for the region (including doctors and dentists in training). This is particularly the case where similar sanctions do not apply in the other Nations of the UK or in RoI.

It isn't clear if the introduction of criminal liability in any form will help improve openness and honesty or drive up standards of care.

Within the region we should be ensuring that we have the right staffing levels, appropriate service models and excellent supporting infrastructure to ensure we are providing the highest standards of care and reduce the number of contributors to why things may go wrong.

Alternative Policy Proposals (paragraphs 4.23 – 4.35)

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

The existing professional Duty of Candour is a strong influence on the practice of healthcare staff. Where an individual member of staff breaches these requirements the range of actions that can be taken against a member of staff by regulators and employers are already considerable.

Intentionally suppressing, concealing or destroying information would already be treated seriously by employers and regulators. The introduction of criminal sanction for these activities alone would be more appropriate than for all level of actions it is not clear that this would help produce a culture of openness. The possibility of sanctions being applied in this situation is still expected to negatively impact on recruitment and retention of healthcare staff in the region.

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.

As an organisation our responsibilities are for doctors and dentists in training and it will be for others to comment on how the proposals relate to staff who are not in regulated professions.

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 may be necessary to define that the requirement is in relation to reporting identified instances which constitute a notifiable incident as this may not always be apparent at the time. Staff would be expected to report and participate openly and honestly under the requirements of their employer and the regulators.

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.

This should be kept under high level review and may need a central source of advice to clinicians.

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.

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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 for the framework are appropriate.

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.

Appropriate

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.

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.

Appropriate

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.

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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.

Appropriate

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.

Any contract changes as indicated in 5.16 should be standardised across the region.

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.

Appropriate

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.

The expectation that where a "system or procedural weakness" caused a mistake is remedied, is essential for improving patient outcomes. This may not have always happened in the past.

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.

Appropriate

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.

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.

Appropriate

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.

Appropriate. The foot note (41) relates to contract change and disciplinary offences. Any such change should be standardised and agreed by the relevant parties for contract negotiations.

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.

The foot note (41) relates to contract change and disciplinary offences. Any such change should be standardized and agreed by the relevant parties for contract negotiations.

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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.

Appropriate

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.

None.

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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?

The annual reporting mechanisms being developed. Staff focus groups on the implementation and impact on culture in their organisation.

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?

As a training organisation, NIMDTA would be well placed to contribute to raising awareness of the final policy through our generic education programmes for Doctors and Dentists in training.