Pharmaceutical Society ni

Protecting Registering Regulating

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 Workstream 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.

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.

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.

We agree with how candour is defined, in the same broad terms as specified by Sir Robert Francis, Chair of the Mid-Staffordshire Inquiry (2013). This broad definition is the basis of the Joint Statement from the Chief Executives of statutory regulators of healthcare professionals on the professional Duty of Candour[1]. This definition is also in line with the other jurisdictions in the UK, maintaining consistency across the broader Health Service. This broad definition is, however, different to the Statutory Obligations outlined, particularly in relation to the thresholds defined (Pgs. 25&26) where an unintended or unexpected incident has occurred. Healthcare professionals will potentially be working under two thresholds in relation to the Duty of Candour - professional and statutory. We also agree with how 'openness' is defined in the consultation document and consider it to be consistent with our Guidance on Raising Concerns (Whistleblowing) 2019[2], and in particular those sections of the guidance relating to employers and managers.

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.

N/A

[1] https://www.pharmacyregulation.org/sites/default/files/joint_statement_on_the_professional_duty_of_candour.pdf
[2] https://www.psni.org.uk/wp-content/uploads/2012/09/Guidance-on-Raising-Concerns-2019-Final.pdf

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.

We disagree with the proposed scope of the Statutory Organisational Duty of Candour.

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.

Whilst we are very supportive of a Statutory Duty of Candour and consider this, along with the Being Open Framework and Guidance, to be key to making the necessary culture change across the relevant institutions in Northern Ireland, we have a number of broad concerns about the breadth of scope as outlined. These concerns bring into question the workability of the proposals and raise questions about the independence of regulation and the potential for the Department of Health becoming a regulator in this space, whilst also being the sponsoring department of most of the organisations subject to the proposed Duty of Candour. We also have specific concerns relating to how the proposals will work in relation to community pharmacy in Northern Ireland. **Broad Concerns** In England, the Organisational Duty of Candour applies to all NHS Trusts, Foundation Trusts and Special Health Authorities as well as private sector providers – service providers that have to be registered with the Care Quality Commission (CQC). The CQC was given responsibility and a clear remit for the implementation of relevant Regulations. The CQC has the power to prosecute an organisation for a breach of the regulations. The Department of Health and Social Care (DHSC), as sponsoring department to most of the organisations registered with the CQC and the CQC itself, has a leadership, funding and supportive role in ensuring these organisations either meet the Organisational Duty of Candour or, in the case of the CQC, hold them to account if they do not. There are clear lines of responsibility and clarity of roles, and accountability. Very importantly, the independence of the CQC is acknowledged and respected through the arrangements implemented. The principle of independent regulation is well established and its importance widely acknowledged.

Whilst we recognise IHRD recommendation 1(i), which recommends that every healthcare organisation and everyone working for them must be open and honest in all their dealings with patients and the public, the proposal as it stands creates a significant amount of uncertainty as to who will have responsibility in relation to organisations that are not registered with the RQIA - both in terms of the Being Open Framework and Guidance and prosecutorial powers.

We note IHRD Recommendations 8 and 86(iii) which state that the RQIA should review overall compliance and that the Department should expand both the remit and resources of the RQIA in order that it might scrutinise adherence to the Duty of Candour. The proposals outlined in the consultation are far from clear on whether and how these recommendations will be delivered. Does this expansion extend to all the organisations listed? If not, it appears from the consultation that the Department of Health (DoH) may have some role in relation to organisations that are not registered with the RQIA, However, the consultation is far from definitive on this point. We have some concerns that the sponsoring Department for the organisations not registered with the RQIA may have a regulatory role this area, whilst simultaneously being subject to the Organisational Duty of Candour itself.

The picture is further confused by proposals that compliance reports (paragraph 3.31), in relation to the requirements of the framework/guidance for all organisations subject to the duty, will be sent to both DoH and the RQIA. This issue raises questions of clarity of purpose and the independence of the RQIA and regulation in general – if the RQIA is to scrutinise adherence, what role is DoH playing in this regard? We would also question under what circumstances organisations such as the Patient Client Council and the Public Health Agency would create outcomes which would trip the proposed significant harm threshold and, therefore, query the benefit of them being subject to the duty. Policy interventions and legislation should be proportionate and purposeful.

Community Pharmacy

We note the consultation states that 'community pharmacists (who are individuals)' will be subject to the Organisational Duty of Candour and we conclude from this that community pharmacies (which are businesses) will be the organisation subject to the duty.

In Great Britain, community pharmacies are not subject to the Statutory Duty of Candour as community pharmacies are not registered with the CQC. The systems regulator for community pharmacies in GB is the General Pharmaceutical Council (GPhC). The GPhC regulates pharmacy premises through The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 and the related Standards and

Guidance documents it produces. This includes Standards relating to creating an open, honest and learning culture. Individual pharmacists are subject to a professional Duty of Candour within this framework. The GPhC holds community pharmacies to account through an inspection regime, improvement programme and sanctioning powers.

In Northern Ireland, the Pharmaceutical Society NI is the systems regulator of community pharmacies. All community pharmacies must be registered with the Pharmaceutical Society of Northern Ireland and we currently produce and publish Premises Standards. However, whilst we consulted upon new Premises Standards in 2018, these have not been implemented as the relevant sections of The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 have not been commenced but are expected to come into operation in the near future. The inspection regime for community pharmacies, against our current Standards and relevant medicines legislation, is the legal responsibility of the Medicines Regulatory Group within the Department of Health.

We are uncertain how the current proposals intend to fit into this regulatory space and are concerned that, should the Department of Health and/or the RQIA take on an enhanced regulatory role in this space, it may become cluttered and unnecessarily confusing for community pharmacy owners, pharmacy professionals and staff. As we also regulate individuals, there is the potential for an incident to involve us looking at owners and professionals whilst RQIA or DoH are simultaneously investigating the same incident around candour.

We would like to explore with the Department the options in this area, in particular the potential to replicate the situation in England, whereby the Pharmaceutical Society NI is given the necessary powers to provide enhanced regulation of community pharmacy organisations, which could include the Duty of Candour, through legislatively based Premises Standards.

Or, if the Department introduces a Statutory Duty of Candour for community pharmacies, the Pharmaceutical Society NI, working with the Medicines Regulatory Group, could be given the responsible legal authority for ensuring compliance and accountability. This would ensure the independence of regulation, reduce the potential for overlap of regulatory activity and would allow the regulator/MRG to simultaneously pursue statutory and regulatory investigations, thereby reducing time and duplication.

We would very much welcome the opportunity to discuss these issues with the IHRD working group and the Department of Health and would be able to support the scope of the powers set out if delivery is as set out 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. To bring it into line with aspects of our Code of Conduct, Ethics and Performance[3], the routine requirements might be extended to ensure that organisations not only answer any question reasonably asked by a patient about their care but also information that the patient either requests or requires about their treatment and care is proactively provided by organisations in a way that the patient can understand so they are engaged and supported in their care.

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.

N/A

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.

Yes - We broadly agree with the definition for the significant harm threshold – it is appropriate and is also in line with current legislative requirements in GB. The term 'significant harm threshold' itself is, however, potentially confusing given that the definition goes on to define 'moderate harm', 'serious harm' and 'prolonged psychological harm'. A better term may be 'unintended' or 'unexpected incident threshold' or 'notifiable incident threshold'. We note that pharmacists and other healthcare professionals are subject to a professional Duty of Candour. The threshold for the professional Duty of Candour is lower than the significant harm threshold outlined. Under the Code of Conduct Ethics and Performance, the duty is outlined as such: *When something goes wrong with a pharmacy service, explain fully to the patient or service user what has happened, and where appropriate:*

[3] https://www.psni.org.uk/wp-content/uploads/2012/09/22504-PSNI-Code-of-Practice-Book-final.pdf

- *offer an apology*
- *offer an appropriate and effective remedy*
- *explain the short and long-term effects*
- *provide support and assist to put matters right.*

This is supplemented by the regulators' of healthcare professionals joint statement on the professional Duty of Candour[4].

The consequences for a pharmacist whose fitness to practise has been found to be impaired for failing to comply with the professional Duty of Candour is significant. The Indicative Sanctions Guidance[5], published by the Council of the Pharmaceutical Society NI, states that the Statutory Committee should take the issue very seriously and consider sanctions at the upper end of the scale, which means removal from the Register or suspension from the Register. If the Statutory Committee determines to give a less severe sanction, it must provide clear reasons for doing so including how the public's confidence in the profession has been maintained and how the public has been adequately protected.

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.

N/A

<u>Statutory Duty of Candour Procedure (paragraphs 3.19 – 3.23)</u>

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.

We agree with the proposed requirements under the Statutory Organisational Duty of Candour when things go wrong. We consider the proposals to be appropriate, proportionate and largely in line with the requirements placed on pharmacists in Northern Ireland in relation to their professional Duty of Candour when things go wrong.

[4] https://www.psni.org.uk/wp-content/uploads/2012/09/Joint-statement-on-the-professional-duty-of-candour-FINAL.pdf
[5] https://www.psni.org.uk/wp-content/uploads/2012/12/Indicative-Sanctions-Guidance-January-2019.pdf

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.

N/A

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.

Subject to the clarifications made later in the consultation that an apology does not amount to an admission of negligence or a breach of a statutory duty to provide health and/or social care services, or that an apology would not indemnify organisations or individuals against liability or restrict the civil rights of patients, we agree. We see no risk that legislating in this area will result in apologies becoming standardised or formulaic, which appears to be the counter argument outlined in consultation against legislating. Apologies are vitally important to patients and their families and are an appropriate human response to what are often extremely difficult circumstances for patients and/or families.

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.

N/A

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.

We agree with the proposals on the provision of a genuine apology, preferably in person by an appropriate member of the organisation. We would expect the guidance to be developed to support implementation of the statutory duty to be consulted upon and we would welcome the opportunity to review and comment on it at that stage.

We further agree with the proposal that any legislation 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 breach of statutory duty to provide health and/or social care services. It is important that the legal implications of apologising are appropriately addressed in the legislation to ensure the rights of patients and healthcare professionals are respected and maintained.

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.

N/A

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.

We agree with the proposals outlined. For both the Organisational Duty of Candour and the Individual Duty of Candour to work, there must be related activities and requirements that drive cultural change and ensure it is embedded across all areas of organisations. The proposals are also broadly in line with requirements in our yet to be implemented Premises Standards, the Code of Conduct and Ethics for Pharmacists and our related Guidance documents, in particular our Guidance on Raising Concerns (Whistleblowing).

We suggest that any guidance produced to support the implementation of the Organisational and Individual Statutory Duty of Candour, must recognise that the

scope of the duty, as proposed, will include multiple organisations of different sizes and widely varied functions. The guidance must be able to be adaptable to different organisations' size, capacity and functions whilst maintaining the same outcomes. Similarly, any compliance regime must be able to acknowledge and be responsive to differences in organisations. It should be focused on quality of outcome for patients and not necessarily comparing procedures.

Reflecting on our response to Question 4 and, whilst acknowledging IHRD recommendation 3, we have some concerns that DoH will be tasked to produce the guidance. In England, the main Guidance relating to the Statutory Organisational Duty of Candour is produced by the regulator in this space, the CQC. We consider that the Guidance for the Statutory Organisational Duty of Candour should be produced by the RQIA or any other systems regulators covering the organisations that will be subject to the Duty. This ensures regulatory independence, which we consider crucial for public protection, and clear lines of responsibility and accountability. Some of the issues in this regard emanate from the proposed scope of the Statutory Organisational Duty and the remit of the RQIA.

This situation is further complicated by the fact that DoH and RQIA will both be subject to the Duty and presumably their own guidance. More thought may need to be given to the principles at stake in this area and the practicalities of the current proposals.

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.

N/A

<u>Reporting and monitoring (paragraphs 3.29 – 3.32)</u>

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.

No

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.

We support the detail of what must be reported. However, as outlined in our response to Question 15, we are concerned that reports have to be made to both DoH and RQIA and that both are subject to same obligations.

We consider that, for regulation to be effective, regulatory decisions should be taken independently of Government which has multiple objectives and pressures which are, understandably, often in tension.

In England, the main Guidance relating to the Statutory Organisational Duty of Candour is produced by the regulator in this space, the CQC. We consider that the Guidance for the Statutory Organisational Duty of Candour should be produced by the RQIA, or any other systems regulators covering the organisations that will be subject to the Duty. Reporting and monitoring requirements under the Statutory Organisational Duty of Candour should also be made to the RQIA or any other systems regulatory which has a legislative duty to regulated organisations that will be subject to the Duty. This ensures regulatory independence, which we consider crucial for public protection, and maintaining clear lines of responsibility and accountability. Much of the issues in this regard emanate from the proposed scope of the Organisational Statutory Duty.

Lack of clarity over roles and responsibilities (in relation to regulation) is not consistent with good governance and runs the risk that accountability could be reduced which runs counter to the intentions of the proposals.

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.

We agree. This seems like a proportionate proposal which will meet its stated objectives.

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.

N/A

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.

Yes. This proposal is crucial to ensure an open and honest culture in organisations and to protect individuals to deliver on their proposed statutory obligations.

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.

N/A

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?

We note the Department of Health and Social Care's White Paper *Integration and innovation: working together to improve health and social care for all,* published in February 2021 which, in relation to Section 60 Orders of the Health Act 1999, set as a proposal to clarify the definition of professions covered by Section 60 to include senior managers and leaders and other groups of workers, enabling DHSC to potentially extend regulation to those groups in the future. We note that health and social care is an entirely devolved matter to the Northern Ireland Assembly including the regulation of healthcare professionals. We consider that exploring the potential for regulating senior managers and leaders could potentially bolster the proposals and allow for focused regulatory work to hold responsible people to account in relation to open and honest cultures within organisations. This is in relation to instances that meet the Statutory Duty of Candour thresholds and, importantly, those that would meet a potentially lower professional threshold. Reflecting on this and our response to Question 4, we consider that greater thought should be given to the context within which the Organisational Duty of Candour will be introduced and, in particular, the importance of independent regulation and regulatory decisions.

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.

We disagree with the proposal to have a Statutory Individual Duty of Candour with criminal sanction for breach.

The consultation proposals acknowledge that developing an open and honest culture within organisations is vital to empowering individuals within those organisations to be candid when things go wrong. We are concerned that introducing a Statutory Individual Duty of Candour with criminal sanction for breach will create a defensive approach towards the circumstances and investigations related to incidents which may meet the threshold to initiate the Statutory Individual Duty of Candour.

Whilst not being directly comparable, as a member of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board (the Board), we have experience to suggest that, when criminal offences are introduced into an area of medical practice, it can create a fear factor amongst practitioners that leads to less openness, not more.

The Medicines Act 1968 contains "strict liability" consumer protection offences concerning the sale and supply of medicines. Section 63 covers the adulteration of medicinal products, for example, an error by a pharmacy professional in preparing or "making-up" a medicine for a patient. Section 64 covers the sale of any medicinal product, or supply against a prescription, which is "not of the nature or quality demanded by the purchaser".

The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 ("the Registered Pharmacies Order"), which was approved in Parliament in December 2017 and came into force on 16 April 2018, introduced defences for the offences in Sections 63 and 64 of the Medicines Act 1968 for inadvertent preparation and dispensing errors made by registered pharmacy professionals working at or from registered pharmacies, subject to certain conditions. A consultation for extending this defence to hospital pharmacists was concluded in September 2018.

The Government consultation outlined the rationale for the change in legislation as follows:

"…prosecutions are relatively straightforward to bring, resulting in a "fear factor" amongst pharmacy professionals, who are reluctant to admit errors as it may mean

that they will face prosecution. In fact, prosecutions have to date been rare and have largely only been brought in the most serious cases, for example, where the error has resulted in death.

"Despite the relative rarity of prosecutions, the evidence demonstrates that the "fear factor" persists. The fundamental premise on which this draft Order and the related Registered Pharmacies Order is based is that reduction in the risk of prosecution will increase the number of reported errors.

Recent cases, relating to the threshold for Gross Negligence Manslaughter involving healthcare professionals, have again demonstrated that uncertainty relating to the threshold for criminal prosecutions has created a sense of fear for healthcare professionals and which, according to the Williams Review, can result in patient safety being jeopardised "*as they become cautious about being open and transparent, impeding the opportunity for lessons to be learnt*" [6].

An individual professional Duty of Candour already exists for pharmacists and other healthcare professionals through regulatory standards. It is a lower threshold with serious consequences if a registrant's Fitness to Practise is found to be impaired for non-compliance – the Council of the Pharmaceutical Society NI's Indicative Sanctions Guidance suggests removal from the register or suspension.

If the Statutory Individual Duty of Candour with criminal offence is introduced in relation to registered healthcare professionals, there is a real possibility that regulatory investigations and outcomes will be severely delayed, as criminal investigations regularly and appropriately take precedence over regulatory investigations.

Given our concerns outlined in Question 4, regarding the scope of the proposals and the lack of clarity regarding who will be the regulatory authority in certain areas including community pharmacy, we consider that a Statutory Organisational Duty of Candour with greater clarity of scope and regulatory responsibility, combined with a regulatory Individual Duty of Candour, is the most likely scenario to deliver the required results for patients and the public. This could be combined with the regulation of healthcare managers and leaders which is within the power of the Northern Ireland Assembly.

If, however, the Department of Health proceeds with the Individual Duty of Candour with criminal breach, we would welcome engagement around who will be the regulatory authority in relation to pharmacists concerning potential breaches. We suggest that there is potential for giving existing regulators the statutory powers in

[6] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717946/Williams_Report.pdf

relation to a Statutory Individual Duty of Candour, which would allow regulators to simultaneously pursue statutory and regulatory breaches of the Duty of Candour, thereby reducing duplication, potential delay and confusion for healthcare professionals and the public.

Alternative Policy Proposals (paragraphs 4.23 – 4.35)

25. Please provide comments on the alternative policy proposals for the Statutory Individual Duty of Candour.

Alternative A:

We are uncertain as to how a Statutory Duty of Candour without a criminal sanction will work in practice. The consultation states the Statutory Individual Duty will be largely 'symbolic', in this scenario. However, we are uncertain as to whether this is a realistic prospect, once legislated for. If something is a criminal offence, regardless of whether there is a related criminal sanction, is there a duty on the RQIA or another regulatory authority to carry out a criminal investigation? Will the Courts be obliged to make a finding of guilt?

If it is the case that an investigation will be carried out and the Courts are obliged to make a decision, this will equally delay any regulatory investigations and proceedings which are designed to protect the public, uphold professional standards and maintain public confidence in healthcare professionals with the stated intention of only a symbolic outcome.

Again, if the Department of Health proceeds with Alternative A, we would welcome engagement around who will be the regulatory authority in relation to pharmacists concerning potential breaches. We suggest that there is potential for giving existing regulators the statutory powers in relation to a Statutory Individual Duty of Candour, which would allow regulators to simultaneously pursue statutory and regulatory breaches of the Duty of Candour, thereby reducing duplication, potential delay and confusion for healthcare professionals and the public.

Alternative B:

We are supportive of a criminal sanction for obstruction to an investigation. This would help protect the public and promote honest and open culture. However, for reasons outlined in response to Alternative A, this should not be linked to a Statutory Individual Duty of Candour but should be a standalone offence.

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.

Notwithstanding our concerns outlined in Question 4, regarding the scope of the proposals and the lack of clarity regarding who will be the regulatory authority in certain areas including community pharmacy, we consider that a Statutory Organisational Duty of Candour with greater clarity of scope and regulatory responsibility, combined with a regulatory Individual Duty of Candour, is the most likely scenario to deliver the required results for patients and the public. This approach is simpler, builds on what already exists and has the potential to reduce delay which can have a significant impact upon public safety. This could be combined with the development of the regulation of healthcare managers and leaders, which is within the power of the Northern Ireland Assembly to develop. This would mean healthcare managers and leaders can be held individually accountable for failing to meet their requirements in relation to developing open and honest working environments and the Duty of Candour.

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.

Based on our response to Question 26, we believe that if a Statutory Individual Duty of Candour is to be legislated for, it should extend only to all unregulated healthcare professionals, healthcare managers and leaders.

Our preferred option is that a regulatory Individual Duty of Candour is maintained for regulated groups for the reasons outlined above.

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.

Bar our position on the Statutory Individual Duty of Candour, outlined above, the proposals appear proportionate.

The proposals appear to be largely in line with our Code of Conduct, Ethics and Performance for pharmacists in Northern Ireland and our related guidance documents. However, we have some concerns that guidance produced by the Department of Health, particularly around routine requirements, differed in emphasis or content from standards or guidance produced by professionals' statutory regulators.

Again, principles of independent regulation and clarity of purpose and the appropriate role for Government are important to consider in this space.

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.

N/A

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.

We do not think there should be exemptions if a notifiable incident threshold has been met.

There may be more scope for debate in relation to reporting on the lower threshold of regulatory Duty of Candour around the areas described. However, such judgements would be made by regulators and/or their Fitness to Practise committees as part of the Fitness to Practise process – legislating for exemption scenarios would be extremely difficult.

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.

No

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.

In general, we are supportive of the content of the proposals in relation to the Being Open Framework. We again, however, point out that the comparable guidance in England, under its Statutory Organisational Duty of Candour, is produced by the CQC and not the DHSC and we seek clarity on the rationale behind the Department of Health producing the detailed guidance for Health and Social Care organisations and not the RQIA and/or other regulators. We note in paragraph 3.30 that it should be a statutory requirement that organisations must publish a report on the Duty of Candour as soon as practicable after the end of the financial year and that this report must be shared with DoH and the RQIA. What happens if DoH has concerns about the content of a report but the RQIA is content or vice versa? The principle of independent regulation needs to be explored more thoroughly.

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.

N/A

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.

Yes, the approach covers the necessary issues including capacity and participation. The development of this section of the guidance in particular should take cognizance of regulatory guidance for individuals and organisations (when relevant), which may cover similar ground to ensure they are complementary.

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.

N/A

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.

Yes – the approach covers the necessary issues and is in line with regulators' joint statement on reflective practice[7]. In developing the guidance, consideration will have to be given to ensuring it is adaptable by organisations of different sizes and resources, given the proposed scope of the legislation.

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.

N/A

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.

In general, we agree with the policy proposals at Level 1 of the Framework for Organisations. However, we retain concerns in relation to the fact that DoH will develop the guidance and provide 'support' to organisations, whilst simultaneously being the funding body with responsibilities for such issues as workforce planning.

[7] https://www.psni.org.uk/wp-content/uploads/2012/09/FINAL_Statement-IRG-on-reflective-practice-May-2019.pdf

The principle of independent regulation is at forefront of our thinking and we suggest that support, guidance, compliance and investigations should come from RQIA or another regulator, with DoH providing the necessary funding and support to RQIA or another regulator to achieve the legislative objectives.

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.

See above

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.

In general, we agree with the policy proposals at Level 2. Consideration may need to be given to the capacity of service users and carers to engage in the processes outlined and this may need to be considered as a stage in the engagement process between services users and organisations. The current definition of what qualifies as 'something untoward' is quite broad and, to ensure proportionality and consistency of application, the definition and application of Level 2 incidents may need to be further refined as the guidance is developed.

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.

N/A

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.

We agree in general with the policy proposals at Level 2 for staff. Further consideration may need to be given to whether the guidance covers protection for whistleblowers and the role of managers/leaders in relation to whistleblowing. Additionally, there are no accountability mechanisms under Level 2 for the failure of an organisation to meet its obligations to staff and service users. Again, we suggest that the regulation of HSC managers and leaders be explored as part of these proposals.

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.

See above.

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.

We agree in general with the proposals. However, we point out that there are no accountability mechanisms under Level 2 for the failure of an organisation to meet its obligations to staff and service users. Again, we suggest that the regulation of HSC managers and leaders be explored as part of these proposals, as relevant thresholds and investigations for failure to meet regulatory standards may be more readily pursued.

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.

See above.

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 – the policy proposals cover the necessary steps that need to be taken to inform and support service users and carers, including issues around capacity, participation and understanding. The requirements in relation to compassion, competence and seniority are extremely important in relation to ensuring apologies and engagement are appropriate to meet families' needs.

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.

N/A

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.

Yes – the proposals are correct in relation to ensuring service users and carers get the information they need in the appropriate manner, when a notifiable incident has occurred. The requirements in this area might better clarify issues relating to individuals not having to take any actions which may equate to an admittance of negligence or breach of a statutory duty to provide health and/or social care services, both in relation to an apology and meeting any of the other requirements outlined.

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.

N/A

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 - the proposals are correct in relation to ensuring service users and carers get the information they need in the appropriate manner, when a notifiable incident has occurred.

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.

N/A

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.

No

Consultation & Impact Screening (Section 6)

53. Do you have any feedback or data which may be relevant to the potential impact of the policy proposals within this consultation exercise, in particular in relation to the following areas:

- Equality;
- Human Rights;
- Rural Needs;
- Regulatory; and
- Economic Impact?

As outlined in our response to Question 4 and throughout the consultation response, there is a lack of clarity in relation to the scope of the Organisational Duty of Candour which brings into question the role the DoH will potentially play in relation to adherence and what impact this might have on the principle of independent regulation.

We would welcome more engagement on these issues and consideration of the professional and systems regulators that already exist within the proposed scope and what is the best mechanism for delivering the intent of the policy proposals.

54. Do you have any feedback in respect of the potential indicators that could be used in order to measure the effectiveness of this policy?

The RQIA could be tasked with producing a periodical compliance report which would assess compliance across all organisations within the scope of the legislation, which should be considered by the Health Committee and/or by the full Northern Ireland Assembly.

55. Do you have any feedback or suggestions on how best to engage and involve stakeholders on the development and implementation of this policy going forward?

We would recommend more focused engagement with the regulators of healthcare professionals and systems in Northern Ireland and the UK to ensure compatibility of approaches and clarity of purpose in relation to any Statutory Duty of Candour.