Response to the consultation on the Duty of Candour and Being Open in Northern Ireland

August 2021

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

2.1 We welcome the opportunity to respond to the Department of Health Northern Ireland's consultation on the policy proposals developed by the Duty of Candour Workstream and Being Open Sub-Group. We note that the proposals are intended to implement the relevant recommendations arising from the report of the Inquiry into Hyponatraemia-Related Deaths (IHRD). We commend the Northern Ireland Government for their committed, detailed, and thorough approach to this difficult area of policy.

2.2 We welcome the proposal to introduce a statutory duty of candour for organisations. This would the harmonise the arrangements in Northern Ireland with those in Scotland and England. We understand that the Welsh Government is in the process of developing the detail of their organisational duty of candour too.

2.3 Extending the duty to a range of bodies within healthcare is likely to be advisable, because successive inquiries have shown that responsibility for and involvement in mistakes – and occasionally their cover-ups – can extend far beyond the direct patient care context. The intention to mirror the threshold for other parts of the UK including England and Scotland also has

the benefit of minimising complexity. We recognise that there will be a need to develop country specific guidance and support for organisations to comply, however we would caution against unnecessary divergence from the other countries of the UK when developing the detail.

2.4 We have some queries and reservations about the proposals for the individual duty. We are aware that the move to introduce a criminal offence for non-compliance with the duty on individuals was a recommendation of the Hyponatraemia Inquiry, and that this proposal was further developed following significant amounts of engagement and policy work by the Northern Ireland Government.

2.5 We note however that this would set Northern Ireland apart from other UK jurisdictions, and appears to run counter to some of the thinking on developing open learning cultures in the workplace. For example, the Berwick Report *A promise to learn – a commitment to act, improving the safety of patients in England* highlighted the finding that 'fear is toxic to both safety and improvement'. It also recommended that 'recourse to criminal sanctions should be extremely rare and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.'[1]

2.6 The principles of Right-touch regulation[2] recommend using the minimum regulatory force to achieve the desired result, as well as checking for unintended consequences. We also understand that some of the professional regulators are concerned about these proposals. We would therefore recommend that, before introducing the full force of criminal sanctions, the Northern Ireland Government assure itself of the following:

- That the criminal sanction is proportionate to the offence, noting that there is a spectrum of lack of candour, and that instances at the lower end may be more appropriately dealt with through regulatory sanctions
- That the criminal sanction route would indeed result in greater openness, both to confirm that it would have the intended effect, and to ensure that it would not lead to unintended consequences that undermine the intended effect, or are otherwise detrimental to patient care. (*We provide more in-depth analysis of these issues under the relevant question*.)
- That there are no alternative, lighter-touch approaches that would be at least as effective.

2.7 Reserving criminal sanctions for the most egregious examples such as repeat offences and preventing others from speaking out, might be a more effective, proportionate approach.

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[1] National Advisory Group on the Safety of Patients in England 2013, *A promise to learn – a commitment to act, Improving the Safety of Patients in England*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

[2] Professional Standards Authority, *Right-touch regulation*. Available at: https://www.professionalstandards.org.uk/what-we-do/improving-regulation/right-touch-regulation

2.8 We support the requirement within the statutory organisational duty that professionals should be provided with the support, training and guidance they need to comply with the duty. We know that the absence of these elements represents a significant barrier to speaking up,[3] and simply raising the stakes for professionals does not mean that these barriers will disappear.

2.9 We also recommend that the Government checks the proposals would not lead to discrimination against particular groups, as registrants within the remit of equality legislation may find it harder to speak out in their workplace.

2.10 It would be helpful to know more about the status of the 'Being Open' framework outlined in the latter part of the consultation document. We understand that it will support the development of guidance for organisations, staff and patients around openness which we note is used to capture behaviours and actions broader than just the requirements around the proposed statutory duties.

2.11 However, as official guidance will also need to be produced specifically to support implementation of both the statutory organisational duty and the statutory individual duty, we would suggest further clarity may be required on the status of the framework to avoid confusion amongst stakeholders on the different guidance documents they should have regard to.

3. Answers to questions

3.1 We have provided answers to specific questions where we have a particular view or information or expertise to contribute. Where relevant we have expanded on views already outlined in our general comments which should be read alongside.

Terminology

Question 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.

3.2 We agree that it is helpful to draw a distinction between general expectations around openness in the health and care service and specific requirements relating to candour for both organisations and individuals.

3.3 We note that the term candour may not be well understood, however we agree with the conclusion that the benefits of aligning with other parts of the UK and using the terminology from major Inquiries including the IHRD and the Mid Staffordshire Inquiry suggests that this should be retained in NI also.[4]

[3] Professional Standards Authority 2013, Candour, disclosure and openness - Learning from academic research to support advice to the Secretary of State. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/candour-research-paper-2013.pdf?sfvrsn=5b957120_8

[4] We found in our 2019 report evaluating the professional regulators' approach to embedding the duty of candour that there is the potential for misunderstanding between lack of candour and dishonesty, both of which form separate charges within the fitness to practise process run by professional regulators. One professional body we spoke to also suggested that the duty could be better explained using more

Question 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.

3.4 N/A

Statutory Organisational Duty of Candour – Scope

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

3.5 We agree that the statutory organisational duty of candour should cover all the healthcare organisations listed. As noted in our general comments, past events demonstrate that responsibility for mistakes can go beyond those directly involved in the provision of care.

3.6 However, since not all of these organisations are regulated, consideration will need to be given to enforcement mechanisms for those organisations that fall outside of the current regulatory framework.

Question 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.

3.7 N/A

Statutory Organisational Duty of Candour – Routine requirements

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

3.8 No comments.

Question 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.

3.9 N/A

'everyday language'. However, there was also support for the cross-regulator approach to candour with one organisation commenting that 'there is strength in consistency of language and approach'. For more information, see *Telling patients the truth when something goes wrong - Evaluating the progress of professional regulators in embedding professionals' duty to be candid to patients,* Professional Standards Authority 2019. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6

Statutory Organisational Duty of Candour – Requirements – When Care Goes Wrong

Question 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.

3.10 The proposed definition to guide the threshold for application of the duty looks broadly appropriate. In particular we welcome the consideration given by the Workstream to ensuring that, as far as possible, the introduction of the statutory duty of candour in NI aligns with similar requirements elsewhere in the UK. This includes the decision to include 'moderate harm' within the threshold which mirrors the approach taken in England and Scotland.

3.11 In our review of the implementation of the professional duty of candour, we found that a common standard across the professional regulators would merit further consideration, as it would provide 'an opportunity to clarify expectations [*across regulators*] and thresholds between the organisational and professional duty of candour'. Confusion in this area was a barrier cited by some participants in our research.[5]

Question 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.

3.12 N/A

Statutory duty of candour procedure

Question 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.

3.13 No comments.

Question 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.

3.14 N/A

Statutory duty of candour – apologies

Question 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.

[5] Professional Standards Authority 2019, *Telling patients the truth when something goes wrong - Evaluating the progress of professional regulators in embedding professionals' duty to be candid to patients*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6

3.15 The value of the apology is consistently raised by patients and service users as a crucial aspect of redress when something has gone wrong. With regard to the proposal to create a legislative requirement for an apology, we note the potential here for unintended consequences, and in particular that it could lead to generic, meaningless apologies.

3.16 In our 2013 advice to the Secretary of State on the introduction joint statement on the duty of candour in England, one of the reasons that the HCPC gave for not feeling able to sign up to the joint statement on the professional duty of candour was the proposal to mandate an apology as it was felt that this could raise issues about its sincerity.[6] The HCPC also reported that this was the unanimous view of the working group of predominately lay stakeholders that they had established for the review of its standards of conduct, performance and ethics. Whilst this is not a direct parallel with what is being proposed here, we suggest that prior to taking this proposal forward it may be beneficial for the Northern Ireland Government to carry out further research to better understand the impact of statutory and voluntary apologies.

Question 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.

3.17 N/A

Question 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.

3.18 See answer to question 11.

Question 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.

3.19 N/A

Statutory organisational duty of candour – support and protection for staff

Question 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.

3.20 We agree with the proposals for support for staff under the statutory organisational Duty of Candour. If the proposed statutory individual duty is introduced, then it will be crucial to ensure that staff have the support they need to exercise this duty effectively.

3.21 This is likely to be particularly important to mitigate any potential additional impact on those registrants protected by equality legislation in Northern Ireland.

[6] https://www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/progress-on-strengthening-approach-to-candour-november-2014.pdf?sfvrsn=bbca7320_4

Question 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.

3.22 N/A

Statutory organisational duty of candour – Reporting and monitoring

Question 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.

3.23 No comments.

Question 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.

3.24 N/A

Statutory organisational duty of candour – criminal sanctions for breach

Question 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.

3.25 No comments.

Question 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.

3.26 N/A

Statutory organisational duty of candour – obstruction offence

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

3.27 No comments.

Question 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.

3.28 N/A

Statutory organisational duty of candour – additional feedback

Question 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?

3.29 No comments.

Statutory Individual Duty of Candour - Policy Proposal – Statutory Individual Duty of Candour with criminal sanction for breach

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

3.30 Please see our general comments for our overall view on the policy proposal for the statutory individual Duty of Candour with criminal sanction for breach.

3.31 A number of bodies, including the professional regulators and organisations representing registrants, have raised concerns, including possible unintended consequences, about the criminal sanctions element of the proposal. Matters that we believe may merit some consideration are:

- The risk that criminalising a lack of candour might encourage a culture of fear and cover-up
- The risk of giving rise to counter-productive defensive working practices, such as the introduction of paperwork that serves only to defend a decision against a potential challenge, and is not otherwise in the interests of patients
- The risk of giving rise to dishonest practices that work around the candour requirements, for instance classing an incident as a poor outcome from a risky procedure rather than avoidable harm, or as less harmful, to avoid it being captured by the duty.

3.32 Overall, we recognise that the arguments around these proposals are complex. There is a general lack of evidence about the effects that such a requirement might have, either positive or negative – as well as limited evidence of the benefits of a professional duty contained within professional codes and guidance, enforced through existing regulatory mechanisms.

3.33 We do share some of the widespread concern that introducing criminal sanctions for failing to be candid may still create a culture of fear and possibly even compound any existing cultural issues. It may also inadvertently encourage behaviours that are not in the public interest. There is little direct empirical evidence to draw on however. The examples we can look to, such as the negative impacts on practice of criminal sanctions for Gross Negligence Manslaughter[7] and dispensing errors,[8] relate to the original patient safety incident, rather than the institutional and professional response to it. There is perhaps some learning here nonetheless, as these examples do demonstrate that the threat of criminal sanction does not always have the intended effect of reducing instances of the behaviour in question, and can also have problematic unintended effects on practitioners as well as institutions.

3.34 One difficulty with the criminal sanction is that it is a fairly blunt instrument. There is a wide spectrum of lack of candour and criminalising all of it may be disproportionate. Low level instances (such as a professional panicking and not initially revealing all the facts to the patient) may be professionally wrong,

[7] https://www.gov.uk/government/publications/williams-review-into-gross-negligence-manslaughter-in-healthcare
[8] https://www.the-pda.org/pda-responds-to-proposals-on-decriminalisation-of-dispensing-errors/

though sometimes the circumstances may, on a human level, be understandable. They might, and often should, attract professional sanctions but not necessarily a criminal one. It is worth reflecting in these cases on what the criminal element would add to a regulatory sanction, particularly when you consider that a regulator is probably better placed to identify the seriousness of the matter than the criminal courts.

3.35 We note that some of the barriers we identified in our previous work on candour would not be addressed by a statutory individual duty alone. [9][10] We know for example that being candid can be a challenge for professionals in working environments that do not, for reasons that are often beyond their control, support this sort of openness. Lack of candour is often a result of concerns about the consequences and, particularly by the culture of an organisation.[11] The emphasis should perhaps be on encouraging organisations and senior managers to create a culture of candour, but this might not be achieved by criminalising individual practitioners working in a toxic culture. The full force of criminal sanctions should perhaps be reserved for the people who create that culture and discourage practitioners from being candid – see our comments on alternatives below.

3.36 If the policy is introduced as it is set out in the consultation, without wanting to absolve individuals of their own professional responsibility for speaking out, it will be essential that the Government provide reassurance that they will indeed receive the support they need, and that mitigations will be taken into account appropriately.

3.37 As explained briefly in our general comments, we recommend ensuring that the duty would not duplicate other requirements or legislation designed to hold to account individuals who cover up mistakes or tamper with records. This includes regulatory processes, noting that the likely effects of duplicating the fitness to practise processes on the professional include:

- prolonging the process because the regulator will normally await the outcome of the criminal process
- having the matter looked at by two bodies from different perspectives – this may be the right approach in serious cases, but we question whether it is helpful or necessary in the more minor ones, and
- the impression of being punished twice.

3.38 There may also be unintended consequences for how the regulators currently take forward fitness to practise cases involving non-compliance with the professional duty of candour. Regulators would be required to take forward a case in the event of a criminal conviction, and potentially two cases with similar

[9] Ibid. p.13 -21. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6
[10] Candour, Disclosure and Openness. Ibid.
[11] For an example, see West Suffolk Hospital where the management appeared more concerned about establishing the identity of the whistle-blowers than about the concerns they were raising. https://www.kingsleynapley.co.uk/insights/blogs/medical-negligence-and-personal-injury-blog/duty-of-candour-threatened-by-hunt-for-whistleblowers

facts, one from NI, and one from another UK country, would need to be treated differently. This would create the potential for differences in how the professional duty was applied in different parts of the UK by the professional regulators.

3.39 Finally, the main research carried out by the Workstream with patients and the public focussed on whether it should be a crime for individuals who work for Health and Social Care to withhold or alter information, cover-up events, or provide false information. Prior to introducing a criminal sanction for non-compliance with the statutory duty it may be helpful to explore further the perspective of patients and the public on making the wider aspects of the duty of candour a statutory requirement.

Statutory Individual Duty of Candour – Alternative policy proposals

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

3.40 Our views on these proposals are broadly captured in our comments on the primary policy proposal. Removing the criminal sanction for failing to comply with the statutory individual duty would remove the risk of unintended consequences, and avoid the use of disproportionate criminal action – see our discussion of this above.

3.41 However, without the addition of a criminal sanction for non-compliance it is less clear what alternative proposal *a)* adds to the pre-existing professional duty of candour, or who would be required to enforce such a duty.

3.42 Whilst we have not had the opportunity to fully consider all of the potential effects, we believe there may be benefit in further considering the second proposed alternative option *b)* – introduction of a statutory duty with separate and discrete criminal offences for: 'staff in the health and social care sector who are proven to have wilfully, intentionally, or maliciously:

- Suppressed or concealed information;
- Distorted or otherwise altered information; and / or
- Destroyed information.'

3.43 We note that this proposal has parallels with recommendation 183 in the report on Mid-Staffordshire where, following the proposed creation of a statutory duty of candour for organisations and individuals (recommendation 181) it was stated: 'It should be made a criminal offence for any registered medical practitioner, or nurse, or allied health professional or director of an authorised or registered healthcare organisation:

- Knowingly to obstruct another in the performance of these statutory duties;
- To provide information to a patient or nearest relative intending to mislead them about such an incident;
- Dishonestly to make an untruthful statement to a commissioner or regulator knowing or believing that they are likely to rely on the statement in the performance of their duties.

3.44 Whilst we do not have specific evidence to support this view, it seems likely that some of the unintended consequences which may arise from creating a specific criminal offence for non-compliance with the duty of candour may be less likely to arise when offences are focussed on the most serious and egregious instances of non-compliance with, or obstruction of compliance with the duty.

Question 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.

3.45 No comments.

Statutory Individual Duty of Candour – Scope

Question 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.

3.46 In theory, we support the principle of wide application of the duty, to avoid creating gaps in accountability. Without this, there is the potential to create false incentives to shift blame for non-compliance onto colleagues who are not covered by the statutory duty and criminal sanction.

3.47 However, the Northern Ireland Government may want to think carefully about how this would apply in practice to those less directly involved in the management or provision of care, and particularly those in more junior roles, such as hospital porters, or administrative staff. For example, it may seem disproportionate or unfair for these staff who may not be in a position to tell whether the duty is engaged, to be threatened with criminal sanctions for not speaking up.

Statutory Individual Duty of Candour – Routine Requirements & Requirements When Care Goes Wrong

Question 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.

3.48 No comments.

Question 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.

3.49 N/A

Statutory Individual Duty of Candour – Exemptions

Question 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.

3.50 No comments.

Statutory Individual Duty of Candour – Additional feedback

Question 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.

3.51 No further comments.

Being Open Framework

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

3.52 As noted in our general comments, it would be helpful to know more about the status of the 'Being Open' framework. We understand that it will support the development of guidance for organisations, staff and patients around openness which we note is used to capture behaviours and actions broader than just the requirements around the proposed statutory duties.

3.53 However, as official guidance will also need to be produced specifically on to support implementation of both the statutory organisational duty and the statutory individual duty, it will be important for there to be clarity on the status of this framework to avoid confusion amongst professionals and organisations on what they should have regard to.

Question 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.

3.54 N/A

Question 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.

3.55 No comments.

Question 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.

3.56 No comments.

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

3.57 No comments.

Question 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.

3.58 No comments.

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

3.59 No comments.

Question 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.

3.60 No comments.

Question 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.

3.61 No comments.

Question 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.

3.62 N/A

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

3.63 No comments.

Question 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.

3.64 N/A

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

3.65 No comments

Question 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.

3.66 N/A

Question 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.

3.67 No comments

Question 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.

3.68 N/A

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

3.69 No comments

Question 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.

3.70 N/A

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

3.71 No comments

Question 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.

3.72 N/A

Additional feedback

Question 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.

3.73 No further comments.

Consultation & Impact Screening

Question 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?*

3.74 As highlighted under our answer to question 24 relating to the proposed statutory individual duty of candour with criminal sanction there is the potential

for this proposal to have a greater impact on certain groups of registrants covered by equalities legislation.

3.75 Some people may find it more challenging to raise concerns and comply with such a duty in the workplace and therefore if this proposal is taken forward then there needs to be thinking about how best to mitigate this.

Question 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?

3.76 No comments.

Question 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?

3.77 We note that a great deal of work has been carried out already by the Department of Health NI in developing these proposals. We would suggest involvement from both patient and service user groups and those representing registrants will be important in considering further the practical implications of proposals to ensure that there can be adequate preparation for the effects that may result from changes to the regulatory framework.

3.78 It will also be important to ensure ongoing dialogue with professional regulators to prepare for any impact of the introduction of criminal sanctions on the existing regulatory regime including the professional duty of candour.

4. Further information

4.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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