# Deaprtment of Health – Ann Roinn Slainte Duty of Candour & Being Open



July 2021

# MPS response to the Department of Health consultation, Duty of Candour & Being Open

# **Opening Remarks**

Medical Protection Society (MPS) welcomes the opportunity to comment on the Policy proposals from the Department of Health on the Duty of Candour and Being Open.

MPS is the world's leading member-owned, not-for-profit protection organisation for doctors, dentists and healthcare professionals with over 300,000 members around the world, more than 8,000 of which are in Northern Ireland. Our in-house experts assist members with the wide range of legal and ethical problems that can arise from their professional practice. Our response to this consultation reflects both the view of Dental Protection and Medical Protection.

# Summary of our response

MPS fully supports a culture of openness in the healthcare sector and we advise members that they should apologise when something goes wrong. However, we have long standing concerns that we have long standing that codifying this ethical principle into legislation, such as a statutory Duty of Candour being proposed by the Department of Health, fail to provide the impetus necessary for behavioural change. We believe that the statutory Duty of Candour is unlikely to be effective in ensuring a genuinely open conversation with patients when things go wrong and can lead to unintended consequences.

MPS consistently raised concerns throughout the evolution of the statutory duty of candour in England and Wales, and Scotland. Similarly, we have concerns with the proposals of the Northern Ireland Department of Health.

A statutory duty could prove counterproductive to the development of an open learning culture in healthcare. For any statutory duty to be effective, a system will be required to monitor compliance and apply sanctions. Any such system will inevitably distract from the original objective of ensuring openness with patients and learning from mistakes. This is why cultural change rather than legislation is the appropriate way of creating safe, responsive, patient centred care and high-quality communication between professionals and patients. The legislation could instead result in a 'tick-box' reporting culture.

While MPS does not support the introduction of a statutory Duty of Candour; if the Department is minded and wishes to proceed, we believe that the Duty should be limited to healthcare organisations and not be imposed upon individuals. We believe the statutory individual Duty of Candour is unhelpful and impractical given how healthcare is currently delivered; involving multidisciplinary teams across the healthcare organisation; and our modern understanding of medical error which takes into account the system in which

practitioners operate. When something goes wrong in healthcare, the patient and/or the relatives want to not only seek information about what has occurred but also why and steps taken to mitigate this from happening again. It is the organization and not the individual practitioner which is best placed to address the range of factors leading to the adverse outcome, and to reflect on any changes introduced across the organization to stop this from happening again.

# **Consultation Questions**

**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.

MPS agrees with the terminology and definitions proposed.

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.

MPS has no comment on this question.

**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.

While MPS does not support a statutory Duty of Candour, as it could prove counterproductive to the development of an open learning culture in healthcare; if the proposals were to go ahead, then we understand that the statutory organizational Duty of Candour should apply to every healthcare organisation. We have concerns with the application of the Duty to some very small organisations, including small dental practices and general practices, which could face excessive form-filling and other administrative burdens, without adequate resources.

Dentistry is already heavily regulated and it is, in general terms, very compliant. Therefore, it is important that any duty is proportional to the risks posed. The potential for a simpler/streamlined process for smaller organisations such as dental practices possibly supported by the Health and Social Care Board (HSCB), should be considered.

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.

MPS would welcome clarity on what the Department means by 'regulated organisations' and in particular, the Department's understanding with respect to general practice, which is not regulated by the RQIA in the same way as general practice in England is regulated by the Care Quality Commission (CQC).

# 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.

MPS agrees with organisations having to act in an open and honest way in relation to the provision of health and social care to patients and service users. However, we do not fully agree with the routine requirements of the statutory organisational Duty of Candour.

In the consultation document, paragraph 3.10- indicates that "staff will be required to give full and honest answers to any question reasonably asked by a patient about their treatment." This proposition fails to recognize that in a limited number of cases, there is a 'therapeutic exception' to the general principle, as outlined by Lord Reed and the late Lord Kerr in the leading case on consent (Montgomery v Lanarkshire Health Board [2015] UKSC 11) as follows: "88. The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health".

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.

MPS has no comment on this question.

#### 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.

MPS does not agree with the proposed definition for the significant harm threshold. The threshold as defined will capture adverse outcomes which are not necessarily indicative of care having gone wrong -in the sense of an error having occurred-, within the context of medical/ surgical interventions that carry risks of significant harm. The Department should consider, by way of example, surgery which can carry risks such as damage to nerves and blood vessels. If nerve or vascular damage is sustained in any given case and moderate/ serious/ prolonged psychological harm occurs, the Duty of Candour is likely to be engaged by virtue of the definition proposed, because of the following factors:

1. The complication was unintended.

2. The complication related directly to the 'incident' (i.e. the surgical procedure) rather than to the natural course of the underlying condition/ illness.

In these circumstances, there are significant drawbacks to the Duty of Candour being triggered:

- The service user may be left with the impression that something has 'gone wrong'
  with their care when, in fact, the adverse outcome may have been a recognized
  complication (the risk of which had been accepted by the patient when they
  consented to the procedure).
- There will be an unnecessary bureaucratic burden on the health service provider.
- The Duty of Candour statistical returns of the healthcare organization may be skewed according to the types of procedure undertaken.

Furthermore, the definition of "moderate harm" as "harm that requires a moderate increase in treatment" is highly subjective.

We would like to see more details about the levels of harm as well as a list of sector- related examples accompanying this section, that relate to both medical and dental practice.

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.

We believe that the Department of Health in Northern Ireland could perhaps explore the Republic of Ireland Government's approach in the context of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019. While we have similar concerns about the legislation being developed in the Republic of Ireland, we note that their Government intends to adopt a more targeted approach by defining a 'notifiable incident' in Schedule 1 to the Bill, which specifies the types of incidents that require "open disclosure" such as "surgery performed on the wrong site", "patient death associated with a medication error", etc. The Bill also provides for the relevant Minister to make regulations that prescribe additional notifiable incidents within parameters laid down in the legislation.

### 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.

MPS supports open disclosure, and organisations should report on patient safety incidents. However, if the threshold for disclosure were to remain as proposed in the consultation document, MPS would be concerned about the application of the Statutory Duty to the category of adverse outcomes that are "unintended or unexpected" but nevertheless recognized risks of treatment -for the reasons set out previously in this response-.

We agree that where an error has occurred, patients should be notified and supported. However, the proposals fail to provide guidance on what will constitute 'reasonable support' for the person harmed and relatives and staff who may have been involved with the event. This could result in different organisations or practices applying varying interpretations to the definition of 'reasonable support'.

We are also concerned about the prospect of cases where the healthcare organization becomes aware of the "notifiable incident" long after the events giving rise to the incident. In some of these cases, the contact details of the patient may not be up-to-date, and the organization may not hold details of any "relevant person", if the patient is deceased. There will be uncertainty in these instances as to what will constitute "reasonable attempts" to contact the relevant person and any guidance issued by Department of Health, whilst helpful, will not be binding in law.

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.

MPS has no comment on this question.

# 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.

MPS has long supported the need for a genuine and sincere apology when things go wrong. We disagree with the legislative requirement to provide an apology, as we believe this may result in a tick box exercise, rather than a genuine and sincere apology for the patient, or their relatives.

Moreover, we are concerned with the prospect of an apology being understood as an admission of liability. We agree with paragraph 3.26 which recommends that there should be clarity 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.

However, currently in Northern Ireland there is no provision that affords legal protections for apologies, as there is in other jurisdictions, and the detail of this clarification would be important.

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.

MPS strongly believes and advises its members that they should apologise when something goes wrong. However, we are clear that doing so shouldn't be an admission of negligence or a breach of a statutory duty; and we would like the Department of Health to ensure that this is clear in the legislation in Northern Ireland.

As expressed above, we believe that providing an apology should not be a legislative requirement of the Duty of Candour procedure, as this could result in a tick box exercise rather than a genuine and sincere apology to patients and relatives.

Safeguards need to be put in place to ensure there is no unintended consequences of being open and does not lead to double jeopardy where being open in the context of the Duty of Candour is held against a healthcare professional in another forum.

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.

MPS agrees that an apology should not amount to an admission of liability.

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.

MPS has no comment on this question.

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.

While MPS believes a statutory Duty of Candour would be counterproductive to an open culture in healthcare, if the Department of Health is minded to proceed MPS agrees with the proposals that organization must ensure that all employees who carry out the Duty of Candour procedure receive training and guidance as well as support.

We are particularly concerned with how the training and support is conducted. Whilst it is obviously useful to have a policy document to refer to, practitioners need to have continuous and ongoing support, bearing in mind that there may be a significant time lag between initial training and the need to implement the Duty of Candour procedure following the occurrence of a 'notifiable incident'.

The introduction of a formal training program and relevant policies and procedures will promote clarity and consistency amongst organisations by reducing the scope for misinterpretation of the legislation. It will assist leaders within organisations in reaching the correct decisions to ensure compliance. Also, it will allow those affected by 'notifiable incidents' to understand how decisions are reached.

Since it has been recognized that being candid is an advanced communication skill, adequate training will be required to support healthcare professionals who discharge this duty. Significant resources will be required to ensure that patient care does not suffer as a result of complying with the proposed legislation. This is specially a concern for small dental practices, as many dental practitioners are self-employed.

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.

MPS has no comment on this question.

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.

While MPS believes a statutory duty of candour would be counterproductive to an open culture in healthcare, if the Department of Health is minded to proceed, it would seem sensible for the RQIA and the Department of Health to monitor it.

We also have concerns with the reporting of adverse incidents and how the Department -and potentially, the public- will interpret the statistical returns. The size of the healthcare organization and the complexity of the procedures undertaken will have an impact on the scale of 'notifiable incidents' that are reported. In general terms, one can assume that the larger the organization and the higher the complexity of the procedures, the higher the number of 'notifiable incidents' that will be reported. In the case of dentistry, for example, a practice that has a larger number of patients and undertakes more complicated procedures such as implant work is likely to have more 'notifiable incidents'.

If the RQIA and the Department of Health are to oversee the performance of healthcare organisations with respect to the Duty of Candour, then we believe it is essential that they are transparent about how the statistics will be interpreted and in particular, how the potential confounding factors outlined above will be taken into account.

We also believe the yearly report could place an additional administrative burden on some small dental and GP practices.

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.

As expressed responding to question 7, MPS has strong concerns with the harm threshold and as a result with what constitutes an incident that needs reporting. As a result of the Duty of Candour being triggered when a complication of a procedure was unintended or it related to the procedure rather than the natural course of the underlying condition, the patient could be left with the impression that something has gone wrong with their care when, in fact the adverse outcome was a recognized complication – accepted by the patient when consenting to the procedure-.

We are also concerned with the unnecessary bureaucratic burden that the reporting would place on healthcare providers, particularly in smaller GP and Dental practices when there may be only one or two people in charge of the whole practice.

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.

MPS does not agree with the proposed criminal sanctions as we believe in a culture of learning rather than blame. If the spirit of the legislation is truly about reflection, openness and learning rather than fostering a blame culture, then organisations ought to be given an opportunity to address any failings, without fearing criminal sanctions.

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.

MPS does not see a role for criminal sanctions and criminal law in relation to the Duty of Candour.

### 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.

MPS disagrees with the proposed obstruction offence under the statutory organisational Duty of Candour, as obstruction type offences exist elsewhere in legislation and we do not see the benefit in duplication.

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.

MPS has no comment on this question.

# 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?

MPS has long advocated for a culture of openness as it is essential to ensure quality and safety in healthcare. We offer training and educational programs to medical and dental professionals on the Duty of Candour, supporting them to fulfil their obligations to have an open and honest discussion with patients in the rare event that things go wrong. There is a risk that these proposals will encourage a bureaucratic, top-down, blame culture which undermines a culture of transparency and learning. Having studied the proposals closely, MPS does not believe that the Department of Health should proceed with its policy proposals for the statutory organizational Duty of Candour.

### **Statutory Individual Duty of Candour (Section 4)**

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

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

MPS does not agree with the introduction of the statutory individual Duty of Candour.

When things go wrong in healthcare, it is common for the patient, or their relatives, to seek information not only with respect to what has occurred, which is often obvious to the patient/ relative who has experienced the adverse outcome, but also the reasons why it has occurred and the steps that are being taken to reduce the risk of recurrence. The reasons why an adverse outcome has occurred are frequently complex and there has been increasing recognition of the role of human factors in healthcare over the past decades (i.e. the effects of teamwork, tasks, equipment, workspace, culture and organization on the performance of the practitioner). It is the organization and not the individual practitioner involved in the provision of care to the patient which is best placed to address the range of factors leading to the adverse outcome, following a significant event investigation using standardized methodology, and to reflect on any changes introduced across the organization. Therefore, in our view, if a statutory individual Duty of Candour imposes a legal obligation on an individual practitioner to provide a "full...explanation of the circumstances" surrounding the incident, in parallel to the obligation imposed on the organization; it is likely to lead to a suboptimal approach, because the individual practitioner is unlikely to be able to address the systemic and organisational factors that may have led to an adverse outcome, when discussing the incident with the patient or relative.

The consultation document highlights a number of important points in relation to the introduction of a statutory individual duty of candour with criminal sanction for breach: (i) comparable jurisdictions have decided not to implement similar policies (ii) such an approach could have unintended consequences where fear of litigation and a culture of blame could have the opposite effect, and lead to defensive practice (iii) this approach could have a negative impact both on the morale of existing staff and the recruitment and retention of staff.

MPS does not see why healthcare professionals in Northern Ireland could be deemed to be less open than healthcare professionals elsewhere, where there is no criminal sanction imposed on individual practitioners.

MPS is familiar with the impact of criminal investigations on healthcare practitioners through our support of members facing allegations of gross negligence manslaughter and in the context of other allegations. By virtue of their nature and potential implications, criminal investigations can have profound effects on practitioners, and frequently, on healthcare teams; in terms of their own health and their ability to continue to provide safe effective care to patients. We observe that in situations where the criminal law is concerned (such as gross negligence manslaughter), for each case where a decision to prosecute has been made by the relevant authority, there exists a significant number of cases which will have been subject to an investigation and which do not meet the threshold for prosecution. We also have concerns about the threshold for triggering an investigation in the first instance. It is possible that the existence of a criminal offence will be open to abuse by the category of complainants categorized as "unreasonably persistent" and/ or vexatious.

In conclusion, whilst we note that the intention of the policy proposal is to reserve criminal prosecution for the most serious cases, we believe that the Department of Health has not acknowledged that criminal investigations are likely to be triggered more frequently than suggested and potentially in circumstances that are not serious, leading to significant deleterious effects on individuals and teams across healthcare in Northern Ireland.

# Alternative Policy Proposals (paragraphs 4.23 – 4.35)

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

MPS disagrees with the proposals of a statutory individual Duty of Candour. While MPS fully agrees with the ethical principle of openness. Healthcare professionals are already under a professional obligation to be open and honest with patients if things go wrong.

While MPS does not support a Statutory Duty of Candour, we believe that the Duty, if enacted, should be limited to healthcare organisations and not be imposed upon individuals. However, the bureaucratic impact on small healthcare organizations such as GP and dental practices must be recognized and mitigated as far as possible.

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.

MPS believes that the key to achieve the policy proposals is cultural change, which can take time to achieve but it is possible by fostering a culture of learning and openness with enhanced oversight through contractual commitments and with professional regulation overseeing it, as most healthcare professionals are regulated professionals.

In order to create cultural change, individual healthcare professionals need to feel able and empowered to disclose when things go wrong, apologise to patients and learn from mistakes so that avoidable errors are reduced in the future, improving patient safety. This is contradictory to the principle of criminal sanctions, as it would only reinforce a culture of fear and blame in the healthcare sector possibly jeopardizing a culture of openness.

Individual healthcare professionals must be supported at management and organisational level so that they feel able to express candour, apologise and learn from mistakes. This is why we believe that cultural change has to come from an organisational level, and organisations will need time to embed this culture to individuals, so they should be allowed time to make these changes without imposing the statutory Duty of Candour upon individuals.

#### 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 expressed above, MPS does not support a statutory individual Duty of Candour and its application to all individuals in a healthcare setting. We agree with the statement that "[e]very healthcare organisation and everyone working for them must be open and honest in all their dealings with patients and the public". This is already part of healthcare professionals' duty as regulated professionals and therefore we do not believe there is a need for a Statutory Duty of Candour.

The Workstream would need to consider the fact that healthcare is increasingly delivered by teams across an organization and hence, an individual duty, if enacted, could apply to multiple individuals who are, or who have become aware of, a notifiable incident. The Department of Health would need to take into account both the impracticality of requiring multiple individual practitioners to make open disclosures to patients/ relatives with respect to the same notifiable incident and the fact that the professionals involved in patient care may have differing views regarding the factors involved in complex patient safety incidents. If there is a statutory obligation on each practitioner to convey a "full explanation" (which we submit is not made clear in the policy proposals), the patient/ relative could potentially be presented with a confusing array of explanations as to why their care has gone wrong. It is for these reasons that we emphasize the importance of an organizational approach to patient safety incidents, using standardized methodology to investigate the root causes and a coordinated approach to explaining the outcome of the investigation to the patient/ relative.

# 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.

We agree with the ethical principles (which are already subject to requirements outlined by professional regulators) but as has been made clear throughout this response, we do not agree with the concept of codifying the principles into legislation. We consider that the reporting of "notifiable incidents" by staff to their employers could be achieved by enhancing contractual obligations and by improving staff training, and clinical audit.

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.

MPS has no comment on this question.

# 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.

Although MPS disagrees with the introduction of a statutory individual Duty of Candour as expressed above, if the Department is minded to continue with the proposals we suggest the following exemption to the proposal requiring "openness in all circumstances", as per our response to question 5. Lord Reed and Lord Kerr in the leading case on consent outlines a 'therapeutic exception' to the general principle, (Montgomery v Lanarkshire Health Board [2015] UKSC 11) which is as follows: "88. The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be

seriously detrimental to the patient's health". We believe in these cases individual healthcare professionals should be exempt from the requirements.

# 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.

As with the statutory organizational Duty of Candour, MPS believes that the Department of Health should not proceed with this proposal. We believe that a culture of openness is essential to ensure quality and safety in healthcare, and that healthcare professionals should have an open and honest discussion with patients when things go wrong. However, there is a risk that these proposals will encourage a bureaucratic, top-down, blame culture which undermines a culture of transparency and learning; having the opposite effect of what it is intended to do, and increasing bureaucratic demands on already pressurized healthcare professionals.

### **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.

MPS understands that the policy proposals of the Being Open Framework are framed as guidance that will be applied simultaneously to the statutory Duty of Candour, but they will not be specifically codified in legislation. If this is the case, we cannot comment on the guidance until the legislation is finalized.

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.

MPS has no comment on this question.

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.

MPS has no comment on this 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.

MPS has no comment on this question.

# 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.

MPS has no comment on this 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.

MPS has no comment on this question.

# <u>Level 1 – Organisations (paragraphs 5.14 – 5.15)</u>

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

MPS has no comment on this 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.

MPS has no comment on this question.

# <u>Level 2 – Service Users and Carers (paragraphs 5.18 – 5.19)</u>

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.

MPS has no comment on this 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.

MPS has no comment on this question.

# 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.

MPS has no comment on this 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.

MPS has no comment on this question.

# <u>Level 2 – Organisations (paragraphs 5.22 – 5.23)</u>

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

MPS has no comment on this 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.

MPS has no comment on this question.

# 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.

MPS has no comment on this 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.

MPS has no comment on this question.

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.

MPS has no comment on this 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.

MPS has no comment on this question.

<u>Level 3 – Organisations (paragraphs 5.32 – 5.33)</u>

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

MPS has no comment on this 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.

MPS has no comment on this question.

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.

MPS supports the principles expressed in the proposals for the Being Open Framework. However, we remain concerned that the Statutory Duty of Candour is not the solution to achieve openness in healthcare.

We believe that the focus of the Department of Health should be on fostering a culture of openness and trust. This will be achieved with mentoring, training and supporting staff to communicate effectively and sensitivity with patients when things go wrong and ensuring senior clinicians lead by example.

#### **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?

There are many rural areas in Northern Ireland where many patients rely on a single handed dentist or GP. These single handed healthcare professionals are already under pressure having to see a lot of patients and dealing with the administration of the practice. These practitioners could be put under more pressure to deliver on the Duty of Candour requirements, and reporting while continuing with their daily duties.

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?

MPS suggests that the Department of Health monitors the impact of the new legislation on the rate of complaints, complaints to the Ombdusman and claims against Health Services in Northern Ireland. If the premise that people complain and litigate because of a lack of candour is true; then there should be a reduction in the number of complaints and claims as a result of the new legislation.

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?

MPS believes that if the Northern Ireland Department of Health is committed to introduce an organisational statutory Duty of Candour, formal training should be made available for healthcare professionals.

We believe that the introduction of a formal training programme and relevant policies and procedures will promote certainty and consistency amongst organisations by reducing the scope for misinterpretation of the legislation. It will assist leaders within organisations in reaching the correct decisions to ensure compliance. Also, it will allow those affected by disclosable incidents to understand how decisions are reached.

Since it is has been recognised that being candid is an advanced communication skill, it is vital that programmes are put in place to prepare health professionals on how to make disclosures and deal with a patient's reaction to that information. We believe that significant resources will be required to ensure that patient care does not suffer as a result of complying with the proposed legislation.

MPS believes that stakeholders should be informed at all times on next steps following this consultation and any plans the Department of Health may have if they consider to implement it in legislation.

#### **About MPS**

MPS is the world's leading protection organisation for doctors, dentists and healthcare professionals with more than 300,000 members around the world.

Our in-house experts assist with the wide range of legal and ethical problems that arise from professional practice. This can include clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

MPS is not an insurance company. We are a mutual non-for-profit organisation and the benefits of membership of MPS are discretionary as set out in the Memorandum of Articles of Association.

#### Contact

Should you require further information about any aspects of our response to this consultation, please do not hesitate to contact us.

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The Medical Protection Society Limited (MPS) is a company limited by guarantee registered in England with company number 36142 at 33 Cavendish Square, London, W1G 0PS. MPS is not an insurance company. All the benefits of membership of MPS are discretionary as set out in the Memorandum and Articles of Association. MPS is a registered trademark and 'Medical Protection' is a trading name of MPS.