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Being Open Framework

Consultation Response Form

RESPONSE FORM (IF NOT RESPONDING ONLINE VIA CITIZEN SPACE) Please indicate your answer to the questions by **circling** your selection. You can also provide further comments in the free text field.

Please send responses electronically using the response sheet below and email address below.

Responses to be sent by email to:

being.open@health-ni.gov.uk

or by post to:

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Consultation Response Form – Being Open Framework

CONSULTATION QUESTIONS

Please indicate in each section if you agree YES or NO and add comments in the box below.

Understanding Openness and Culture

These questions focus on how organisations can create a culture where being open and honest is the norm (further information is provided in Section 3 of the 'Being Open Framework').

Q1 The framework looks at openness at three levels:

- **Routine openness:** Being honest in everyday care and communication.
- **Learning from mistakes:** Reflecting on errors to improve and avoid repeating them.
- **When things go wrong:** Clear communication and accountability when harm is caused.

Do you think these levels are helpful and appropriate? YES NO

Q2 The framework focuses on three areas of culture in an organisation:

- Infrastructure (e.g., policies and systems to support openness).
- Behaviours (e.g., how staff interact and communicate).
- Beliefs and stories (e.g., shared values and lessons from the past).

Do you think it's helpful to also focus on three areas? YES NO

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Comments:

The Professional Standards Authority (PSA) welcomes the opportunity to respond to the Department of Health's consultation on the introduction of a Being Open Framework in Northern Ireland. We commend the Department's commitment on their co-production approach involving patients, services, staff and leaders across different sectors in the development of the draft Framework.

The PSA supports the aims of the Being Open Framework to deliver safe, effective and quality care. The levels of openness and components of culture (formal structures, accepted behaviours and agreed beliefs) provide an inclusive and accessible structure to support health and social care organisations to develop and embed routine cultures of openness to allow staff to respond in an open and appropriate manner when things go wrong.

The matrix on p21 of the Framework is a helpful tool to support staff at different levels within the organisation to understand how they can relate to the Framework in their area of responsibility.

Under the level of openness 'when things go wrong', we recommend there is absolute clarity for staff on when to involve external organisations, such as professional regulators. Clarity of the process and what to do next can help to alleviate any fear.

Supporting openness in everyday care

These questions focus on how organisations can make honesty and openness a natural part of daily care (further information is provided in Section 2, Section 3.3.1 and Section 7).

Q3 To support staff in being open it is proposed that organisations:

- Provide regular training for staff to promote openness.
- Share real-life examples of openness and what was learned.
- Recognise and celebrate examples of good practice in being open.
- Provide supervision that is supportive of openness.

Do you agree with these will help staff be open and honest every day?

YES NO

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Comments:

The PSA agree the areas highlighted above will help to support staff to be open and honest every day. However, this is a complex area and there are multiple factors that may act as a barrier to staff in being open and honest and can cause them to feel unsafe to speak up. It is important leaders of health and care organisations are aware of these factors when working to embed a learning and open culture.

The PSA has published a number of reports[1][2] reflecting the importance of cultures which support candour. The reports observed factors that encourage and discourage candour, together with points arising from a literature review on candour we carried out in 2013.

This work demonstrates that silence is often far from a neutral state, but rather, one which is conflictual and stressful for the individual, and that there are many different reasons for it. The workplace culture is a key factor in influencing the capacity of individuals to be candid. Other factors that could act as barriers to openness as a natural part of daily care could be career impact, fear of the regulator or litigation, and divided loyalties. Raising concerns can bring the prospect of both the uncomfortable admission of personal liability for mistakes, and the incrimination of colleagues, which may feel like a betrayal of long-standing professional relationships.

The literature suggests that employers can do the following to support a culture of openness, which could be added to the list highlighted in the Framework:

- Providing support to those who might raise concerns, including helping them to come to terms with their own mistakes
- Taking demonstrable action to prevent reoccurrence of mistakes highlights to both the individual and the wider workforce the organisation's commitment to improvement and the value of reporting
- Making the routes for raising concerns clear – what, how, who
- Emphasising the patient's right to information about their care
- Supporting and maintaining professionals' skills in disclosing difficult information sensitively and constructively, in particular in relation to communication with patients.

[1] Progress on strengthening professional regulation's approach to candour and error reporting | PSA
[2] https://www.professionalstandards.org.uk/publications/telling-patients-truth-when-something-has-gone-wrong-how-have-professional-regulators

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Openness with a focus on learning

These questions focus on how organisations learn from experience to improve care and avoid future harm (further information is provided in Sections 2 and 3).

Q4 To improve learning it is proposed that organisations should:

- Encourage staff to talk openly about mistakes without fear of unfair retribution.
- Understand the circumstances that may contribute to failures and mistakes.
- Share lessons across teams to improve safety and care.
- Make improvements visible to the public, so people know what has changed.

Do you agree that these will improve learning from experience? YES NO

Comments:

We agree the measures set out above will support learning to be instilled into the formal structures, accepted behaviours and agreed beliefs of organisations.

Education and training have an important part to play in equipping professionals with the skills they need to communicate confidently and well, including having candid conversations with patients and their families when things have gone wrong. Interprofessional education and training helps to prepare professionals to comply with an open culture in a multidisciplinary context.

It is also important to start training around openness at a pre-qualifying level to build awareness of the principles and expectations of an open culture as students prepare to transition into practise.

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Openness when things go wrong

These questions focus on when things go wrong, and how organisations and their staff handle these situations with openness, compassion, and clear communication (further information is provided in Section 3).

Q5 When things go wrong, it is proposed that organisations immediately:

- Inform patients and families as soon as possible after an incident.
- Offer apologies and explanations early.
- Provide emotional or therapeutic support to all those affected (patients; carers; staff).
-

Do you agree with the proposals for when things go wrong? YES NO

Q6 For all involved in serious incidents, it is proposed that they have:

- Timely access to information about the incident.
- Regular updates on progress and outcomes of any investigations.
- Counselling or emotional support as and when needed for all involved.
- Debriefs to discuss what happened and how to improve.

Do you think all involved in serious incidents should receive support?

YES NO

Comments:

Q5. The Framework acknowledges the impact on patient safety and quality of care if practitioners do not feel psychologically safe and are practising in an environment of fear where they feel there will be disproportionate or unfairly punitive responses when mistakes are made.

The PSA's Safer Care for All publication highlighted that practising in a culture of fear is not only bad for professional wellbeing, and impacts on recruitment and retention, but can also lead to defensive practice, or worse, cover ups. The prospect of regulatory and criminal or civil prosecution proceedings may discourage professionals from being candid. Professionals may worry that regulators will not be fair to those who have been candid and may perceive regulatory action as punitive or looking to apportion blame, with individuals being held responsible for organisation-wide problems.

Therefore, it is vital to encourage open cultures where staff feel safe to talk openly about mistakes without fear of unfair retribution and to share lessons that will improve the quality of care and patient safety. However, as the Framework sets out a Just Culture is about ensuring everyone is confident that they will be treated fairly when things go wrong but is not about an absence of responsibility and accountability and that staff will remain professionally accountable for their practice by their employer, regulator and the law.

In terms of public protection and confidence we need ways of holding individuals to account when things go wrong. These include, where possible, enabling a practitioner to address concerns about their competence or conduct, or removing the very small number of reckless, dangerous, dishonest practitioners from the workplace to prevent further harm.

Professional regulators' fitness to practise processes are one of the ways regulators can maintain public confidence in the profession. It is essential that professional regulators work collaboratively with health and social care organisations as the Framework is implemented to ensure that accountability mechanisms are not breeding fear-based cultures in health and care but also that culture changes to deliver open and learning working environments do not undermine individual accountability processes.

In Safer Care for All we recommended that professional regulators could do more, both collectively and individually, to clarify and explain their approach to fitness to practise cases where a professional has been involved in patient or service user safety incident. Greater clarity of professional regulator thresholds for fitness to practise referral and understanding on levels of seriousness could help reduce fear and defensive practice when things go wrong.

The PSA has started a programme of work called '*Refocusing regulation'* which aims to develop our understanding of how professional regulation and registration can be more preventative, by identifying concrete ways in which regulators can support compliance with their standards, while also limiting any negative unintended consequences. The start of this work is a public consultation to review the Standards we use to measure the

performance of regulators and registers to look at ways in which we could regulation and registration.

We agree with the Framework that timely action is essential when something has gone wrong, not least because a long delay can call into question the authenticity of an apology.

It is also essential that all staff involved understand the process for assessing patient safety incidents and when and how to involve external organisations. A project that may be useful for the Department to be aware of is NHS England's decision-making tool. The tool is currently being developed to support decision making for patient safety incidents to ensure the principles of just and learning culture are maintained. It supports staff if a learning response process begins to suggest a concern that an individual's actions may have been reckless, wilfully neglectful or malicious, and can help with decision making on next steps.

Finally, we welcome the fact that 'support' is referred to throughout this section. It is vitally important that all those involved, both staff and patients, receive timely and appropriate support when care goes wrong. We think that advocacy should be factored into the implementation plans for the Framework.

Duty of Candour to support Openness

These questions relate to the proposals for the introduction of a statutory organisational and individual Duty of Candour.

Q7 Do you think that the introduction of a statutory organisational Duty of Candour would support organisations in their development of a more open culture?

YES NO

Q8 Do you think that the introduction of a statutory individual Duty of Candour would support individuals to be more open?

YES NO

Q9 Do you think that including a "Duty of Candour" clause in staff contracts will improve openness?

YES NO

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Comments: We have detailed our positions on a statutory organisational and individual duty of candour below, but it would have been helpful to have more information on the Department's proposals in relation to statutory duties in order to comment further on how they would interact with the Framework to create a more open culture.

Q7. The PSA supports the introduction of a statutory organisational Duty of Candour. This would harmonise the arrangements in Northern Ireland with those in place in Scotland, Wales and England.

Extending the duty to a range of health and care organisations involved in patient safety is likely to be advisable, because successive inquiries have highlighted that responsibility for and involvement in mistakes can extend beyond the direct patient care context.

We would recommend mirroring the threshold for other parts of the UK to minimise complexity for patients and services users. We recognise that there will be a need for country-specific guidance and support for organisations to implement the Duty, however we would caution against unnecessary divergence from other countries of the UK when developing the detail.

Last year the Department for Health and Social Care in England reviewed the organisational duty of candour and therefore it may be useful to consider the lessons learnt through this review.

Q8. In line with our response to the Department's consultation in 2021 on Duty of Candour the PSA has concerns and reservations about the introduction of a statutory individual Duty of Candour as we believe it is unlikely to help address toxic cultures and could create unreasonable expectations on professionals.

We are aware that the move to introduce a criminal offence for non-compliance with the statutory duty on individuals was a consequence of a recommendation of the Hyponatraemia Inquiry, and that this proposal was further developed by the Northern Ireland Government. However, this proposal appears to run counter to some of thinking on developing open and learning cultures in the workplace[3]. It would also set Northern Ireland apart from other UK countries.

[3] 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:

The principles of Right-touch regulation[4] recommend using the minimum regulatory force to achieve the desired result, as well as checking for unintended consequences. We would therefore recommend that before introducing a statutory individual Duty of Candour with the full force of criminal sanctions, the Department assure itself of the following:

- That the criminal sanction is proportionate to the offence, noting that there is spectrum of lack of candour;
- That the criminal sanction route would result in greater openness and to ensure that it would not lead to unintended consequences that would undermine the intended effect of embedding an open culture, for example, encourage a culture of fear and defensive working practices; and
- That there are no lighter-touch approaches that would be as effective or more i.e. through employer and regulator approaches.

A statutory professional duty could potentially be appropriate for the most senior leaders in health and care organisations who by virtue of their role are expected to shoulder greater responsibility, however, we would also urge caution here, as the threat of criminal sanctions, for example, may not always deliver the intended behaviour required to embed an open and learning culture. In addition, there may be benefits to a phased approach to the introduction of different duties. It might be beneficial first to embed an organisational culture of openness and learning to create the conditions in which individuals are supported to meet the expectations of an individual duty. It may be that once a statutory organisational duty of candour is fully embedded, alongside the implementation of the Being Open Framework, a statutory individual duty would no longer be necessary. This could be ascertained through an evaluation of the statutory organisational duty and Being Open Framework.

It is worth acknowledging that there is also a professional duty of candour for regulated healthcare professionals, linked to their professional standards. In 2014 the professional health regulators introduced a joint statement on the professional duty of candour and since then all the regulators have made wide-ranging efforts to embed the duty. They have introduced candour-related standards, guidance and embedded candour into fitness to practise documents and education and training, as we identified in our 2019 report.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

[4] https://www.professionalstandards.org.uk/improving-regulation/right-touch-regulation

There has not to date been a thorough evaluation of the impact of the professional duty of candour, more than ten years on from its introduction, to establish whether it could be strengthened, and how it could work alongside any duties of candour placed on organisations. It should also be noted that this approach only covers regulated health practitioners.

Q9: We are not in a position to comment on the potential effectiveness of including the duty of candour in contracts, but on the face of it, it seems it could be a proportionate alternative to a statutory individual duty, as it provides a route for dealing with breaches as an employment/HR issue, rather than a criminal one.

Leadership and oversight to promote Openness

These questions consider the role of leaders in promoting and monitoring openness (further information is provided in Section 4).

Q10 Should Boards of organisations and Chief Executives, through their Board Patient Safety and Quality Committee, be held responsible for creating an open culture?

YES NO

Q11 Proposals for monitoring openness in organisations

- Organisations should report and publish regularly on their progress in being open.
- Organisations should be held accountable for supporting openness by the Department of Health and regulators.
- Independent audits should assess whether organisations are meeting openness standards.

Do you agree with the proposals to monitor openness?

YES NO

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Q12 Would the introduction of an Independent Patient Safety Commissioner improve openness and patient safety? (Further information is provided in Section 6.2).

YES NO

Comments:

Q10: Senior leaders are responsible for patient safety in their organisations, and open cultures should be considered part and parcel of the organisation's approach to patient safety.

Q11: We are not in a position to comment on the precise mechanisms for holding organisations to account for supporting culture, except to note that a statutory organisational duty of candour requires enforcement, a responsibility which in other parts of the UK, falls to the system regulator. Should such a duty be introduced for Northern Ireland, and most likely enforced by the RQIA, any other mechanisms for ensuring openness would need to work hand-in-hand with it.

Q12. We would support the introduction of an independent Patient Safety Commissioner (PSC) in Northern Ireland, however we would like to see more detail on the role and remit being proposed in order to make an assessment on whether it would improve openness and patient safety. We have commented that the Commissioner for England's role would benefit from being broadened to all patient safety issues, and not just those relating to medicines and medical devices, to give them the full overview of the patient safety system. This would be our recommendation for such a rule for Northern Ireland too.

We are conscious that the introduction of another body or role into the patient safety landscape has the risk of adding a further layer of complexity, however, we believe it is important to have an overarching patient and service user safety body.

Many health and care organisations have a specific role in patient safety which means there is no one body looking across the system through the eyes of the patient and service user and bringing about the necessary action. As the Cumberlege Review stated when describing the proposed PSC role in England: '*We are calling for a public spokesperson with the necessary authority and standing to talk about and report on, to influence and cajole where necessary without fear or favour on matters related to patient safety.*'[5]

[5] https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report

In England there is currently a review[6] of the bodies involved in the health and care patient safety landscape which is due to report at the end March 2025. The primary purpose of the review is to assess whether the current range and combination of organisations delivers effective leadership, listening, learning and regulation to the health and care systems in relation to patient and user safety. The Patient Safety Commissioners Office is one of the six organisations in scope of this review. There may be lessons to learn from the review's findings when looking at the structures and roles necessary to effectively implement the Being Open Framework.

Training and education to support openness

These questions focus on the training and support that is needed to help staff understand how to be open and honest in different situations (further information is provided in Sections 7 and 8).

Q13 Organisations should support and train staff in being open in different situations so they can:

- Be open and honest in everyday care.
- Learn from mistakes and failures to share lessons.
- Support patients and families when things go wrong.

Do you think all staff should be trained for these purposes? YES NO

Q14 Organisations should provide support and train staff at different times using a range of training methods

- Training for openness at induction and as refresher training for all staff.

[6] https://www.gov.uk/government/publications/review-of-patient-safety-across-the-health-and-care-landscape-terms-of-reference/review-of-patient-safety-across-the-health-and-care-landscape-terms-of-reference

- Provision of a range of different opportunities for learning such as online or in person.
- Provision of support through mentorship, coaching and supervision.
- Learning provided in way appropriate to the staff role and the most effective training method.

Do you think all staff should be trained for in these ways? YES NO

Comments:

Q13/14. We agree that organisations should train and support staff in being open and that this training and support should be delivered through a range of methods. The requirement for organisations to train and support could be a requirement of the statutory organisational Duty of Candour so that organisations have a duty to provide support, training and guidance to their staff. We know the absence of training and support presents a barrier to speaking up[7].

The Framework needs to be aligned to other professional guidance and standards around candour and openness.

Public Consultation on the Duty of Candour and Being Open Framework

Thank you for taking the time to respond to the consultation questions and in sharing your views. Your feedback is vital for shaping these proposals in improving honesty and openness in health and social care in Northern Ireland.

Any further comments on these proposals to improve openness?

We would like to highlight a point in relation to scope. The Framework applies to the sixteen HSC Arms-Length Bodies detailed in Appendix 2, this includes the Northern Ireland Social Care Council (NISCC). However, the health professional regulators are not included in this list of organisations but '*all registrants with professional health care regulators'* are. It would be helpful to understand how this would work in practice, with the professional regulator for social care workers being in scope but not, apparently the

[7] Can professional regulation do more to encourage candour when care goes wrong? | PSA

regulators of healthcare professions, including the regulator of pharmacists in Northern Ireland (Pharmaceutical Society of Northern Ireland). We appreciate the Northern Ireland Assembly may not be able to impose requirements on UK-wide regulators, therefore it would be helpful to understand more about how this would be managed in practice

In addition, we found the document unclear on what it means for the individual or organisation for the Framework to 'apply' to them.

Finally, we suggest that it would be helpful to clarify the status of the Being Open Framework, to avoid confusion among stakeholders.