Annex B
CONSULTATION QUESTIONNAIRE

Question 1 :
Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation ?

Yes ☒ No ☐

We agree with the principles of transparency, honesty and openness that a duty of candour supports. Putting a duty of candour on statutory footing will help close the gap between what is good practice and reality. By requiring and supporting those currently unwilling to disclose and discuss errors, it should prompt an organisational shift that will change organisational practices and procedures. This will encourage a culture of openness, learning and ongoing improvement. A statutory organisational duty should be more effective at achieving a consistent approach across all health and care services than the individual duties imposed by related guidance and codes of professional conduct.

We would like clarity on how the statutory duty of candour will fit in to the current legislative and policy framework. Will it be introduced through regulations as one of a number of measures, as the approach in England has been? There will need to be guidance on how the duty of candour will fit together with organisations' existing policies and procedures, for example on whistleblowing and grievances. In addition, how will the statutory duty fit with the proposed implementation of the National Patient Safety Agency (NPSA) Being Open principles in Scotland by Healthcare Improvement Scotland? It is important that there is consistency and a common understanding of the framework that staff are working within.

It is essential that staff receive the necessary training and institutional support to implement the legislation. Staff need to be provided with guidance and training on what an organisational duty of candour means, what action they are required to take and where they can access further advice and information regarding this duty. They need to be supported through any involvement in a disclosable event.

Individuals and organisations need clarity about the legal and other consequences of providing information and apologies to one another, patients and their families. The duty needs to be implemented in a way that discourages 'blame culture' and removes defensiveness associated with fear of individual blame and the threat of litigation. Cultural change will only come about through an organisational commitment to honesty, openness and transparency. Duty of candour must be seen in the context of a wider commitment to patient safety, learning and improvements in care. The factors known to inhibit disclosure (i.e. professional or institutional repercussion; legal liability; blame; lack of confidentiality; and negative family reaction) need to be addressed through the statutory duty and organisational arrangements.

Question 2:
Do you agree that the organisational duty of candour encompass the requirement that adequate provision be in place to ensure that staff have the support, knowledge and skill required ?

Yes ☒ No ☐

It is vital that organisations are under a duty to ensure staff have the required support, knowledge and skills to implement the duty of candour. As outlined above, staff will need guidance and training on what an organisational duty of candour means, what their actions are within this and where they can access further support and information. They will need support through any involvement in a disclosable event.

As part of this, there will need to be clear definitions and a common understanding by staff of what constitutes an 'adverse event resulting in harm', who is the 'relevant person' and what constitutes 'reasonable support', in order to take the required steps to comply with the duty without delay.

We note that the responsibility will rest with organisations to ensure that "*all staff who are asked to be involved with disclosure have access to the relevant training, supervision and support*". How would this work in practice? Will specific staff be given this training and assigned this role as a representative of the organisation, in addition to their existing role? Or will it be a new specific role? The person undertaking the disclosure may be different for each disclosure episode. Again, what would this mean in practice? In addition, could there be a scenario where the notification would be given by staff involved in the harm episode, who have an existing relationship with the relevant person, and what would the implications be of this?

Question 3a: Do you agree with the requirement for organisations to publically report on disclosures that have taken place ?

Yes ☐ No ☐

The RCN outlined its support for the principles of being open and encouraging learning from adverse events, and identified areas for further consideration, in its response to Healthcare Improvement Scotland's two recent consultations on *Learning from adverse events through reporting and review: Being Open in NHSScotland*[1] and *Data redaction and standardised*

[1] http://www.rcn.org.uk/__data/assets/pdf_file/0012/588684/Being_Open_-_RCN_Response_Form.pdf

adverse event review reports[2]. We suggest the Scottish Government looks at some of the issues raised through these consultations when considering its approach around requiring organisations to publically report disclosures, particularly around issues of confidentiality. There will be areas of commonality, and the two processes will also need to be aligned.

The requirement to report publicly on the nature of adverse incidents must take into account organisations' duties in relation to personal data under the Data Protection Act 1998. Even if it is just the 'nature' of adverse incidents that is to be disclosed publicly, individuals including staff and patients may be identifiable from this information and thus risks disclosing personal data. Personal data is also protected under Article 8 of the European Convention of Human Rights and Article 8 of the European Charter of Fundamental Rights. We would ask for clarity on what information would be required to be publicly disclosed and how the Scottish Government intends to address the issue of personal data. Given the privacy issues involved in any disclosure, the Scottish Government may wish to consider providing a specially adapted Privacy Impact Assessment (PIA) for use by staff. Although carrying out a PIA is not a legal requirement under the Data Protection Act it is best practice and can be an effective tool in informing the approach an organisation has taken. The Information Commissioner's Office has published guidance on conducting PIAs[3].

We welcome that guidance will be produced on implementing an organisational duty of candour, including resources to support the notification process, staff support and public reporting. Guidance and training on the legal framework should be provided to staff so that all those involved in adverse incidents are confident that their personal data will be managed accordingly. Similarly guidance and training must be provided to those making the decision as to whether an incident is a 'disclosable' event.

It would be helpful to know further detail on what format disclosures would be reported. Would the report be in the form of an adverse event review report, as recently consulted upon by Healthcare Improvement Scotland? If not, then these two separate approaches would need to clearly be aligned in order to prevent confusion.

We agree that organisations should publish their policies and procedures as this will encourage organisations to put these in place and provide guidance to those involved, both for staff or members of the public. Organisations may not update these annually, so we question whether there is a need to update these annually.

[2] http://www.rcn.org.uk/aboutus/scotland/professionalissues/influencing_scottish_health_and_social_care_policy/?a=603472

[3] http://ico.org.uk/for_organisations/data_protection/topic_guides/~/media/documents/library/Data_Protection/Practical_application/pia-code-of-practice-final-draft.pdf

Question 3b: Do you agree with the proposed requirements to ensure that people harmed are informed ?

Yes ☒ No ☐

We agree that the people harmed should be informed. This needs to be done in a professional, sensitive manner. Staff need to receive appropriate training on relevant communications skills and need to be clear about their role, how and what information to disclose to those that have been harmed. The necessary resources must also be made available to underpin this.

Question 3c: Do you agree with the proposed requirements to ensure that people are appropriately supported ?

Yes ☒ No ☐

There will need to be clarity about what constitutes 'reasonable support'. In order to support consistent and effective implementation of the duty of candour, organisations will need to have access to training resources and be equipped to provide training on how the duty applies within the particular context of their organisation. Organisations will need to be resourced to ensure appropriate support and training is fully available.

Question 4:
What do you think is an appropriate frequency for such reporting ?

Quarterly ☐ Bi-Annually ☐ Annually ☒ Other ☐ (outline below)

The frequency of reporting needs to balance the time and resources that reporting requires with the importance of reporting these events frequently, so that the issues are brought to light and addressed as soon as possible. Reporting requirements should be streamlined with other reporting duties organisations have.

We note that there may be some reporting restrictions on disclosable events that are subject to potential or ongoing litigation, which will need to be considered when determining the frequency of reporting.

Question 5:
What staffing and resources that would be required to support effective arrangements for the disclose of instances of harm ?

As outlined in our response to question 2, there needs to be clarity on who would be involved in the disclosure of harm. Would new staff roles be created for this purpose or would this role be added to the duties of existing members of staff?

Staff involved will require a detailed understanding of the legal framework and should have the expertise/training to identify what can and cannot be disclosed under the Data Protection Act 1998. High level training resources should be provided to ensure consistency in the approach being taken to this duty.

Question 6a:
Do you agree with the disclosable events that are proposed ?

Yes ☐ No ☐

The proposed definition is broad. This may cause difficulties with statutory interpretation and as well as with recognising such an event in practice. There may need to be clarity on the meaning of "unintended", "unexpected" and "prolonged". In relation to "prolonged" we note the proposal that this is a continuous period of 28 days. What is the basis for this proposal? Such a defined time period could exclude incidences that would otherwise merit disclosure. Prolonged pain or harm may differ depending on the harm incident.

Question 6b: Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings ?

Yes ☐ No ☐

The consultation document refers to specific care settings in its explanation, which indicates that the definition might not be clearly applicable and identifiable across all care settings. It is likely that further clarity and guidance on the definition and its applicability will be required. This is particularly relevant under the integration of health and social care, where care settings are likely to be increasingly flexible and less well defined. We have outlined further points to be clarified with respect to the duty of candour and integration in our response to question 8.

Question 6c:
What definition should be used for 'disclosable events' in the context of children's social care?

Question 7
What are the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred ?

There needs to be guidance and training for staff on the meaning of

disclosable harm and how to recognise such an incident in practice. The cost of implementing this duty and the provision of necessary resources also needs to be addressed.

Question 8:
How do you think the organisational duty of candour should be monitored ?

The consultation document outlines the roles of Healthcare Improvement Scotland and the Care Inspectorate and it would make sense for these two organisations to monitor the duty of candour responsibilities in the organisations that they have a scrutiny or regulatory function over. However there would need to be a joined up approach between the Care Inspectorate and Healthcare Improvement Scotland to ensure that there is a consistent interpretation and monitoring of the duty across different care contexts. They could also further work together to provide appropriate support and resources for the organisations they will monitor, and to support learning and improvement from the disclosures at a national level.

While the Care Inspectorate registers and regulates social care services, Healthcare Improvement Scotland does not have a regulatory function over the NHS (only independent healthcare providers). Therefore there is a risk that there will be a two-tier approach to monitoring – and enforcing – the duty of candour responsibilities in different sectors. The organisational duty of candour would need to also align with the performance management process of NHS Boards.

In addition, the impact of health and social care integration has not been considered within the consultation document. There needs to be clarity over the organisational roles and responsibilities in relation to duty of candour, and how these will be monitored, in services that have been delegated to integration authorities. If the delivery of these services has been delegated to the integration authority, will the duty of candour responsibilities also be delegated? Will these duties – and how they interact with the integration authorities' wider clinical and care governance arrangements - be monitored through joint inspections and scrutiny of the integration authority by the Care Inspectorate and Healthcare Improvement Scotland?

There also needs to be clarity over where responsibility for duty of candour lies if a disclosable event happens within a service that has been commissioned from a third or independent sector provider, and how this will fit with the duties of the integration authority, health board or local authority.

Question 9:
What should the consequences be if it is discovered that a disclosable event has not been disclosed to the relevant person ?

For duty of candour to be effective, it will need to be enforceable. We would like to see further details on the proposals for how the duty will be enforced. For example, will an organisation who has failed to comply with the duty be guilty of an offence and be subject to penalties for a breach of the duty? We do not think that there is a need for new criminal offences in relation to the statutory duty of candour. The evidence, in our view, does not support the further criminalisation of health care delivery. We doubt this will encourage greater openness and transparency by health professionals, rather, the opposite; it may lead to a culture of fear. We note in England, for example, it is an offence for a health service body to fail to notify the relevant person but it is a defence for a health service body, to prove that they took all reasonable steps and exercised all due diligence to prevent the breach.

What powers of enforcement will the monitoring body have if they discover a disclosable event has not been disclosed to the relevant person? Will this differ depending on whether this is the Care Inspectorate, who has a regulatory function, compared to Healthcare Improvement Scotland who has a scrutiny, but not regulatory function over NHS services. Are organisations likely to be 'named and shamed' by the monitoring body?

In terms of responsibility, the duty of candour is described as an organisational duty, therefore any breach of the duty of candour would be committed by the organisation as opposed to an individual. However we would ask for clarity on what the consequences may be for members of staff involved in any failure to disclose that may amount to a breach of the duty. Could this give rise to any disciplinary action, for example? How would the organisational duty of candour fit alongside the professional regulatory requirements of the Nursing and Midwifery Council (NMC), General Medical Council (GMC) and other regulatory bodies in relation to individuals disclosing when they have harmed people by their practice?
There will need to be assurances that disclosure will not jeopardise staff's position in the case of any further proceedings, disciplinary or otherwise. There will need to be clarity and training for all staff on their rights and obligations, with respect to disclosure, and clarity on how duty of candour interacts with existing policies and procedures on confidentiality, whistleblowing and grievances.

There will need to be more details on the recourse available to the relevant person, if they discover or suspect that a disclosable event has not been disclosed to them. For example, who do they complain or raise concerns to if they suspect an organisation has failed to comply with their statutory duty? Would this be the monitoring body, for example Healthcare Improvement Scotland or the Care Inspectorate, and what action would they need to take? Will they have any right to raise a court action?

End of Questionnaire