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 ☐

<table>
<thead>
<tr>
<th>Comments</th>
<th>[NB this is a different question from that which appears in the text of the consultation document – which asks whether the duty should be ‘specified in detail’]</th>
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<td>We welcome the intention behind introducing an organisational duty of candour outlined in legislation. We hope doing so will send a powerful message to organisations to be open and transparent, and to support and encourage healthcare professionals in discharging their existing professional duty to be open where those in their care suffer harm or distress. We do however understand the concern that the introduction of criminal sanctions could add to the culture of fear and blame rather than encouraging a culture of openness and learning, so recognise the importance of how the organisational duty will be implemented.</td>
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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 ☐

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<tr>
<th>Comments</th>
<th>It is crucial that staff who are ‘involved in disclosure’ are supported and that training is available where necessary. Organisations must support the development of a culture that values and supports staff to be candid. Being candid is an essential part of an open and transparent culture that puts patients first, learns from mistakes and supports doctors to deliver the best possible care.</th>
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<td>While the proposed obligations (and corresponding penalties) will be on the organisation, it is important to recognise that it will be doctors and other health professionals who are discharging these duties on behalf of the organisation and they must be supported to fulfil these duties and their professional obligations. It’s also important that the requirements don’t interfere with the exercise of professional judgement, and that the individual needs of patients are recognised when discharging the reporting requirements.</td>
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In our draft guidance *Openness and honesty when things go wrong: the professional duty of candour* (out for consultation until 5 January 2015), we recognise the importance of supporting those making the disclosure.
Question 3a: Do you agree with the requirement for organisations to publically report on disclosures that have taken place?

Yes ☒ No ☐

Comments: The requirement for organisations to publically report on disclosures would be a positive step to strengthen public confidence in the individual organisation, demonstrating a commitment to openness and transparency. However, there is a balance to be struck between reassuring the public and making sure the task of reporting does not become burdensome. Reporting disclosures publically, in addition to routinely reporting within the organisation, may add an extra layer of administration. It may be appropriate, for example, to publically report on disclosures for a trial period before reviewing whether continued regular reporting is justified.

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

Yes ☒ No ☐

Comments: The requirement to inform patients when they have been harmed is crucial to promoting an open and honest culture. Our position is set out in our core guidance *Good medical practice* where we say in paragraph 55:

*You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:*

a) put matters right  
b) offer an apology  
c) explain fully and promptly what has happened and the likely short-term and long-term effects.

This is reinforced in the *Joint statement on the professional duty of candour* as agreed by the eight UK healthcare regulators. And we expand on these principles in our explanatory guidance *Openness and honesty when things go wrong: the professional duty of candour* (currently out for consultation) where we offer guidance on saying sorry and speaking to those close to the patient.

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

Yes ☒ No ☐
Comments: It’s important the patient and those close to them are appropriately supported in what will inevitably be a stressful time. This may be having psychological care services available such as counselling but also supporting them to fully understand what has happened.

The communication skills of those disclosing the event to the patient must be good in order to minimise distress to the patient, and training must be in place to support this.

The needs of individual patients will be different and therefore the way that candour is communicated will vary depending on the individual circumstances, and the requirements should be flexible enough to accommodate this.

In setting the procedure for the discharge of the organisational duty of candour it will be important to ensure that, while being candid is never optional, professionals are empowered to use their professional judgement regarding the method of communication, apology and explanation, according to the circumstances.

It is important that organisations plan what additional resources may be needed to support patients, those close to them as well as healthcare professionals, so that the resources to support them are available as soon as the duty comes into force. This may be achieved through looking at the adequacy of the provision of psychological care services, such as counselling and occupational health.

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

Quarterly  □   Bi-Annually  □   Annually  □   Other  ☑  (outline below)

Comments: The frequency of reporting must be balanced between reassuring the public and making sure reporting isn’t too frequent so as to become a burdensome administrative task. It’s important that healthcare professionals are not unnecessarily distracted from delivering patient care. Therefore a frequency of reporting which fits with reporting mechanisms already in place would be desirable.

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

Comments This is not within our remit to comment on.
Question 6a:
Do you agree with the disclosable events that are proposed?

Yes ☒   No ☐

Comments
It would be helpful to have more information about the kinds of events that might fall under the category of an unexpected event that ‘was suspected to have occurred’. If by this it is meant that something has gone wrong with patient care, causing harm, but the precise cause of the harm is not yet known for certain, then we agree this should trigger the requirement to disclose to the patient.

It would be clearer if the events listed in paragraph 9.12 were preceded by, for example, ‘Harm has been caused to a patient by…’ so that it is clear that eg the cancellation of treatment is only a disclosable event if it results in harm to the patient.

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

Yes ☐   No ☐

Comments
It is not within our remit to comment.

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

Comments
It is not within our remit to comment.

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?

Comments
Organisations must ensure that staff are aware of the organisation’s duty of candour, and how it interacts with their own professional duty. The following must also be in place:

- A clear definition of a disclosable harm, including examples of events which do and don’t qualify as disclosable events.
- A place where healthcare professionals can seek immediate, independent (perhaps anonymous) advice about whether an event is disclosable.
• Continuity of care, eg follow up appointments with the same clinic (if eg the patient does not want to see the responsible healthcare professional) rather than handing over care eg to GPs immediately on discharge. Or at least ensuring the GP is fully aware of the event and the potential for harm which may yet mean the event will become disclosable (eg for someone suffering psychological harm which has not yet amounted to 28 days).
• Briefings for all healthcare professionals (eg through team meetings) so that they are aware of their responsibilities and the support available.

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

Comments
It seems reasonable that the organisational duty should be monitored using the existing regulatory mechanisms in Scotland such as Healthcare Improvement Scotland and The Care Inspectorate, as suggested in the partial business and regulatory impact assessment.

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

Comments
We don’t feel that this is within our remit to comment on, other than to say we feel it would be appropriate for any sanction to be imposed on the organisation responsible, rather than on the individual health or social care worker involved.

End of Questionnaire