## 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 □
Comments: The clear links with the national framework for the management of adverse events is welcomed; however any additional bureaucracy and processes should not undermine delivery of core business or patient care.
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?
Comments: The provision of adequate support, knowledge and skill for staff should form part of the existing organisational functional reporting system / policy for management of serious incidents / adverse events.  Point 6.7 – 8 The requirement for the organisation to provide an apology and a written record of the face-to-face meeting and any actions to be taken would require clear guidance to ensure any legal implications are taken into account.
Question 3a: Do you agree with the requirement for organisations to publically report on disclosures that have taken place?  Yes   No
Comments: Redaction will need to be robust to appropriate confidentiality is maintained.
Question 3b: Do you agree with the proposed requirements to ensure that people harmed are informed?  Yes   No
Comments: Currently this exists as part of UK professional codes of conduct and practice; any additional organisational requirements to support patients and carers being given all the information they ask for should reflect existing guidance and / or regulatory requirements.

Question 3c: Do you agree with the proposed requirements to ensure that people are appropriately supported?
Yes ⊠ No □
Comments: The provision of appropriate support to affected patients, carers and staff should form part of the existing organisational reporting system / policy for management of serious incidents / adverse events. The people harmed by adverse events can include staff as well as patients. An example would be an adverse event involving the unauthorised disclosure of staff members' personal identifiable information.
Question 4: What do you think is an appropriate frequency for such reporting?
Quarterly Bi-Annually Annually Other (outline below)
Comments: This should follow the existing organisational reporting system / policy for management of serious incidents / adverse events, taking account of annual NHSScotland review processes.
Question 5: What staffing and resources that would be required to support effective arrangements for the disclose of instances of harm?
Comments: Any resources required to support disclosure should be identified within the existing organisational reporting system / policy for management of serious incidents / adverse events. In NHS National Services Scotland, we believe that this could be accommodated within existing resources, although additional training might need to be commissioned. If additional independent review panels and or individuals were to be required this would have to be quantified and resourced.
Question 6a: Do you agree with the disclosable events that are proposed?  Yes  No
Comments: We share the concerns raised in 9.5; as described in points 9.6 – 7 where professional judgement is involved, organisations should define the arrangements in place in their reporting system / policy for management

of serious incidents / adverse events.

There would also be a need to consider other sources of harm e.g. loss of personal identifiable information (PII). The loss of PII has the potential for

anxiety, distress and embarrassment.
Question 6b: Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings?  Yes  No
Comments: No comment
Question 6c: What definition should be used for 'disclosable events' in the context of children's social care?
Comments: No 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: Consistency and clarity in definitions and recording of a serious

## Question 8:

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

adverse event or incident, with a standard reporting process.

Comments: Monitoring should be via existing processes where possible, including self-regulation and as part of the existing annual NHSScotland review processes.

## Question 9:

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

Comments: The principles of a just culture should apply i.e. support for genuine mistakes with additional training etc. provided. If the failure is found to be deliberate then organisational policies should apply e.g. capability or disciplinary policies. The organisation should define the management arrangements for any failures in their reporting system / policy for management of serious incidents / adverse events