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: there were mixed views across clinical staff but all respondents agreed there should be openness with patients when things have gone wrong, and this should be discussed as appropriate. However, there would presumably be sanctions applied for breaching legislation – these have not been identified. Concerns were raised by some staff groups that patients may be disadvantaged-as regardless of the aim of encouraging a more "open" culture, this may result in a more litigious approach by some patients and medicine being practised even more defensively and patients being denied riskier procedures where harm resultant from other factors (e.g. technical surgery difficulty due to obesity) out with the control of the treating team, contribute to poorer than average outcomes.

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 ☐

Comments Ensuring that all staff are sufficiently skilled to begin the conversation necessary with a patient or family member, and that a smaller number of staff are able to have more in depth conversations is an essential prerequisite to delivery of this policy but will be difficult to achieve in practice.

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

Yes ✔ No ☐

Comments It should be recognised that the public part of reporting on disclosures will need to be at a lesser level of detail than that required for successful organisational learning from episodes of harm.

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

Yes ✔ No ☐

Comments Honesty and open communication with patients and families is crucial. It does however need to be recognised that a system based definition of harm may differ from family's perception of harm. Regardless of the stated aspiration of a more open culture, opinion generally is that this is likely to result in increased legal action by patients with consequent personal/professional liability which has not been addressed.

A specific example that illustrates the complexity of this has been given by orthopaedic surgical colleagues:

> There is general agreement that if there has been obvious harm, it should be disclosed and dealt with promptly and openly. This must only apply to clear "harm" and not and should not automatically apply to "risk" OR "risk of harm"
>
> For example, a number of years ago we received a late notification that some ceramic femoral heads that had been implanted into FV patients earlier were from a batch that had an increased incidence of fracture as a result of a manufacturing error. This was not indication for surgical revision and the patients were all functioning well and were very happy with their outcomes at the time of notification. The FV medical director of the day and the surgeons involved agreed that we should not inform the patients involved, apart from letting them know that ceramic heads can occasionally fracture and be told the likely symptoms , should that occur. (Patients were warned of this potential complication from the outset.) As things transpired, none of those heads ever broke in the FV patients. The involved patients would have unnecessarily been subjected to anxiety for many years worrying about their "inferior" implant, had they been informed. Informing the patients, in this situation would have been the source of "harm". None of these patients clinical outcomes were compromised. In discussion with current colleagues, not everyone agrees that these patients should not have been told, so that if they had been living elsewhere, and their "inferior" head had failed, they could have been in a situation where some redress and cost compensation for revision, would have been a potential possibility.

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

Yes ✔ No ☐

Comments The amount of support required for staff as well as patients and families will be considerable. Adequate resources to support staff may be needed to prevent an adverse movement in the absence rates due to workplace stress

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

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

Comments This is to allow sufficient time for local investigation, addressing any identified actions and organisational issues, before a high level summary of the learning points is disclosed

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

Comments Staff members discussing events with families would require advanced communication skills, and this would need to include detailed knowledge of confidentiality and professional accountability. There would need to be adequate administrative support to ensure that investigation takes place in a structured and timely manner, with training of staff to do this. Good organisational knowledge and experience of working in partnership will be required to avoid any personalisation of blame or over commitment to undeliverable action. Training to support staff involved will also need to be augmented.

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

Yes ☐ No ✔

Comments The definition does not lend itself to being easily understood by families, particularly close to events that involve feelings of anger or grief. Immediate episodes of harm are usually obvious and we all have a professional, ethical and moral duty to disclose these fully. However, the definition of what requires disclosure is inadequate and belies a lack of understanding.

Specifically-
9.11 – who will determine this?
9.12 These are very wide categories with subjective definitions- e.g. extra time in hospital - as determined by whom? Transfer to intensive care can be an appropriate intervention, on a planned or unplanned basis. If a patient has an unexpected event leading to a severe compromise of physiology, which is promptly recognised, and appropriately managed by stabilisation and transfer to intensive care, how is this an adverse event?
9.13- these are subjective criteria
9.14- these are very broad categories
9.15- this is not clear

This section is written with insufficient regard to the detailed operational understanding required to make this proposal workable.
In addition, definitions of harm are dependent on the specialty and time course under discussion. For example, radiology and the following comments have been provided specifically by the Radiology department:

> How will we define "harm" physically or psychologically in radiology?
> Error is inherent in Radiology. Quoted error rates vary between 3 and 30% depending on examination type. A conservative estimate extrapolated from the UK estimate is of 83,000 errors a year in Scotland.
> The majority do not result in direct harm to patients, but many may have indirect/distant sequelae.
> Radiology is an interpretive process. Many "errors" are only detected in retrospect – subtle abnormalities initially very difficult to detect may be much more detectable in light of subsequent events. Failure to spot a subtle abnormality, which may be incidental to the reason for the initial imaging, can have severe consequences for the patient. On the other hand, missing a more obvious lesion may have little or no impact on the patient if it is picked up shortly afterwards on a different test or on review of imaging by another individual eg at an MDT. The degree of error therefore does not necessarily correlate with impact on patient.
> Patients, the public and many doctors have little understanding of the complexities of radiological interpretation, and have no idea how frequently initial reports require modification. The earliest signs of cancer are often extremely subtle and difficult to detect, but failure to appreciate them can have devastating consequences for the patient, sometimes years later eg a tiny lung nodule becoming a lung tumour, or a subtle colonic polyp becoming a bowel cancer many years later.

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

Yes ✔ No ☐

Comments They should be for consistency and the confidence of staff and public

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

Comments That depends on the purpose of disclosure, if it is for organisational transparency and to promote learning, it should mirror the level of disclosable events in health settings

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
Delivery of adequate training will be essential to effective recognition of the duty at an early stage and confidence of staff will reflect the training and the organisation's culture.
A consistent governance framework across organisations, with consistent definitions is required. Immediate episodes of harm are usually obvious and we all have a professional, ethical and moral duty to disclose these fully. However, the definition of what requires disclosure is inadequate and belies a lack of understanding.
The consultation does not address the gap between professional obligation and understanding of harm and the individual's understanding of harm (or of their family which may be different).

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

Comments . Monitoring/assessing/reviewing could become a new "industry" and divert funds away from clinical services.

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

Comments This should be covered by professional responsibilities already. It is unlikely that regulatory approach will be successful in developing an organisational culture that is open and discusses carefully with patients and families.

End of Questionnaire