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 X No ☐

Comments

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 X No ☐

This is absolutely essential otherwise poor communication and support will do more harm than good.

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

Yes X No ☐

If there is to be a statutory duty, there also has to be reporting.

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

Yes X No ☐

The definition of 'Harm' is crucial. It should be actual, not potential; it must be significant enough to have altered the outcome of a disease or event. This may not be evident for some time after the putative harm happened. Disclosure itself should not cause harm, particularly psychological, or affect compliance with agreed treatments. This is a real possibility. There should be a time limit after which harm need not be disclosed. This time limit will vary in different situations.

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

Yes X No ☐

This process will generate stress and anxiety in all parties, who will need considerable support. The support will have to be tailored to each situation; a blanket approach will not work.

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

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

Comments

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

This is an impossible question to answer. It depends upon the frequency of harmful events, the definition of a harmful event, the mechanism for identifying them, for investigating them before approaching the person possibly harmed, and for managing the consequences of disclosure, up to and including legal proceedings.

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

Yes ☐ No X

As set out, the disclosable events are too broadly defined to be applicable. Considerably more detail is required, for example in relation to the expected frequency of surgical complications requiring operative intervention, or the expected accuracy of a screening test in the context of the natural history of the disease. In particular, screening is a difficult area because, by definition, there will be false positive and negative tests. These may be many years previously, and it may be impossible to judge whether the natural history of the disease in that patient was altered as a result.

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

Yes ☐ No X

No. Each care setting – primary care, secondary care, social care, etc, will

need to generate data about putative harmful events in some detail as they will vary considerably between care settings.

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

I am unable to comment on this.

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 ?

Assessment of potentially harmful events – what are they; what harm might they cause.
Identification of such events – have they happened.
Identification of whether harm was actually caused – this should not involve approach to the person (potentially) harmed in the first instance because in so doing harm may be caused when none had previously been suffered.
Assessment of the degree of harm caused once it has been shown to have happened.

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

The proposals seem satisfactory

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

The appropriate Ombudsman should investigate the event.

End of Questionnaire