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 ☐

The College recognises that there is currently considerable public interest in patient safety, and open reporting, particularly in the wake of recent inquiries such as Vale of Leven. There is a need for the NHS to be recognised by the public as open and transparent about adverse incidents and poor quality, and in this regard the College supports the introduction of an organisational duty of candour.

The College would particularly emphasise that legislation needs to be accompanied by cultural change in organisations to be effective, and that the requirements should help to reinforce an open and transparent culture of learning and improvement where possible.

The legislation should identify a point of reference (a position or office holder) within the organisation to be responsible for overseeing the duty. There should also be an effective mechanism put in place to collate information relating to the duty from existing reports and provisions made for exploration of any gaps.

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 ☐

Significant cultural and organisational change will be required: a duty of candour requires highly developed communication skills and therefore there must be training for all stakeholders. It is necessary to have not only the relevant training available, but also the relevant support.

It is also essential that the budgetary impact of putting these provisions in place should be assessed ahead of the implementation of the duty and accounted for.

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

Yes **X** No ☐

Yes. However, an unanswered issue is how this is defined. Is it simply that the report is in the public domain, or that active steps have been made to disseminate the report?

Additionally, if the primary purpose is to obtain earlier redress for persons affected then there is arguably limited benefit - and a real risk of invasion of privacy - from public disclosure. Whilst the rights and responsibilities of the monitoring and enforcing agencies should be preserved, wholesale public disclosure could create a culture of negativity, in turn leading to under-reporting, so this must be managed carefully.

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

Yes **X** No ☐

Provided the information is imparted by appropriately trained people and any follow up support is available. However, people harmed need to be informed also about the steps which have been taken to prevent a recurrence with any other patient. Such information will help to alleviate their distress by offering a form of closure, even though it would be by proxy. Most importantly, it is the only single step which is certain to reduce the overall incidence of such adverse events in the future.

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

Yes **X** No ☐

That includes all stakeholders ie care staff as well as those who have suffered harm.

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

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

As a matter of routine, annually, but incidents should be reported as and when they occur.

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

The organisation would have to have on hand the availability of trained specialists when a disclosure is made and provide support for the recipients, and the appropriate organisational support to enable learning from any incident.

There are numerous precedents in industry for the disclosure, root cause investigation and remediation of adverse incidents, leading to enhanced quality assurance. The Six Sigma suite of techniques and tools is one such and is very well known, with a target quantifiable defect rate of fewer than 3.4 parts per million. A similar process in health and social care would require a dedicated quality assurance team within each participating organisation, with a brief to focus on patient outcomes rather than infrastructure or operational costs. It might be helpful if the legislation were to require organisations to have an accredited QA team in place. Industrial benchmarks suggest that an effective QA team size should be 3-5% of the total organisational manpower. Some of that number may already be in place and performing a compatible or identical role. The existing practice and dedicated headcount will vary enormously from one organisation to another.

The College would appreciate clarification around the percentage of current staff who would be required to cover these duties, and therefore what further costs as percentage of budget should be allowed in terms of provision of staff time, training etc, in order to ensure effective arrangements are established.

We would also appreciate clarification around the question of legal indemnity, and addressing the tension between transparency and culpability in terms of the duty.

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

Yes **X** No ☐

The list itself is adequate, but the consultation document does not address the fundamental definition of "unintended or unexpected". For example, if a given procedure carries a known 5% risk of an adverse outcome, is it "unintended or unexpected" when the risk materialises for a given patient?

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

Yes ☐ No ☐

Not necessarily. The complexity or number of care packages/interventions may make it difficult to extrapolate what is the primary catalyst and it may be the cumulative effect of actions/inaction that will lead to the disclosable event.

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

Rather than a definition, the underlying principle should be the best interest of the child. It should be considered whether children are at risk of a discrete set of adverse events which would not also apply to adults, and vice versa.

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?

Specialist training for those disclosing the information to individuals, as well as those who will have to deal with any follow up procedures, such as the QA team. There should be external verification of the QA process, coupled with an audit of selected events. It should also be part of the training of all care providers in their continuing professional development to be aware of the duty of candour.

There should also be a clear definition of "unintended or unexpected".

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

It should be done through the normal organisational monitoring arrangements, but these must be transparent and open to external, independent audit. The results of the audit should be publicly reported at a level of granularity which prevents the identification of individual instances.

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

At an organisational level there should be the possibility of sanctions but any civil or criminal penalties which may ensue must be intimated in the monitoring and regulation process.

End of Questionnaire