Annex B CONSULTATION QUESTIONNAIRE

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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 □

Before responding to the question asked, it is important to point out that the existing duty on doctors is to tell patients if something has gone wrong and a patient under their care has suffered harm 'or distress'. This existing duty is already wider than the one proposed in this consultation paper.

We can only speak about healthcare but in our view there is no need for an additional, statutory duty on organisations. Further, any duty on organisations that had a different and higher threshold than the existing duty upon clinicians would be likely to add confusion and delay while the clinical team worked out whether or not the statutory duty applied, and how the requirements of that duty differed from the existing duty which already falls on the doctors in the team (where it is usually the lead clinician who talks to the patient). We note at 2.9 in the consultation document there is a suggestion that schemes for requiring candour may undermine professionalism and/or may cause fear among healthcare professionals yet our experience in advising doctors (and other healthcare professionals) when something goes wrong suggests there is no basis for such fears. For over 50 years we have advised our members to tell patients as soon as they are aware that something has gone wrong and so far as we know that is what they do.

Our answer to the question is therefore that there is no need for a statutory duty upon healthcare organisations because a duty has existed for years for doctors. They are invariably going to be the clinician responsible for talking to the patient when something goes wrong because the senior doctor (or another doctor with appropriate skills and experience) is going to be the only member of the team who can fully explain what has gone wrong and

why and what options there are (if any) for putting it right, as well as answering fully all the patient's questions. If there is a statutory duty and if the threshold is as suggested higher than and different from the duty that already exists for doctors, there will need to be very clear instructions as to how that specific duty will apply in all clinical circumstances and how it will differ from the clinicians' existing duty so there is no room for doubt. If there is any doubt there is likely to be confusion which could delay or prevent the very actions the additional duty is apparently designed to facilitate.

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

With the proviso that with most healthcare cases it will be necessary for the person who talks to the patient to have appropriate skills and experience to provide a full explanation and answer all questions. It is about communication skills but even more important is the need to understand fully what happened and all that can be done to put it right. Often the only person who can do this will be, as it generally is now, the lead clinician.

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

Yes No x

More thought need to be given to the purpose of the disclosure and to how much information is provided in the report and to whom it is made available. The consultation document is silent on the purpose that any public disclosure is proposed to serve. If information is disclosed on a need to know basis to bodies that have a formal role in ensuring lessons are learned and incidents are not repeated, that will have a bearing on the information provided. However if it is intended for information to be disclosed more widely, there are a number of considerations that will limit the information that can be made available publicly. For example, there is a need to preserve patient confidentiality and there will be other legal considerations that will limit any disclosures if there are any other ongoing matters arising from the incident – which will happen in some cases. Information intended for a wider non-professional audience will need to be very limited.

Question 3b: Do you agree with the proposed requirements to ensure that people harmed are informed?
Yes x No
Patients who suffer harm or distress must be told as soon as a doctor becomes aware that this has happened to a patient within his or her care. If the incident is one that falls within the proposed statutory duty, or even if it doesn't but the organisation classifies such incidents as significant events that fall within the organisation's own procedure, we would expect the patient to be offered a copy of any report. The consultation document also mentions sharing such information with families but that will be entirely dependent on the patient's wishes in respect of confidentiality.
Question 3c: Do you agree with the proposed requirements to ensure that people are appropriately supported?
Yes No x
Of course patients who are harmed must be supported but there is not enough detail about what is proposed and the safeguards that need to be in place. For example, the extent of any information or support provided to a relative of the patient harmed must be determined by the patient's wishes in respect of confidentiality.
Question 4:
What do you think is an appropriate frequency for such reporting?
Quarterly Bi-Annually Annually Other x (outline below)
It is not clear from the consultation document what the purpose of reporting would be and to whom reports would be made and in what detail. This needs to be addressed before any decision is taken about frequency. For example, if reports are to be made to a body that has a proper role in ensuring healthcare organisations learn from incidents and put in place procedures to avoid future incidents, reporting might be necessary at the time the incident is recognised and the appropriate information becomes available. If, however, a report is prepared for other healthcare bodies that lists the type of incident and any action taken as a result in broadest terms, respecting patient confidentiality, this sort of report might be more useful if it contains annual aggregated information.

Question 5:

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

Our experience of assisting medical members with patient safety incidents is that the lead clinician usually takes the lead and is usually the person who talks to the patient.

Question 6a: Do you agree with the disclosable events that are proposed?
Yes □ No x
There will always be difficulty in defining a threshold for disclosable events because it will be a matter of judgement — which in healthcare will most likely fall upon the lead clinician. As we have explained earlier, the current duty upon doctors is that if a patient in their care has suffered harm or distress, doctors must explain to the patient what has happened and why and what the options are for putting it right (if any) as well as apologising. The proposed statutory duty will have a different threshold for disclosable events and we believe this will lead to confusion and could cause delay.
Question 6b: Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings? Yes No x
See our comments above
Question 6c: What definition should be used for 'disclosable events' in the context of children's social care?
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?

In healthcare settings it makes no sense to have a threshold for disclosable harm that is higher than the one that currently applies to doctors.

Question 8:

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

Our only comment relates to the need to ensure that patient information is

kept confidential and that any information disclosed for the purposes of monitoring is only done with explicit consent of identifiable patients.

Question 9:

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

It is impossible to define in advance all the types of incidents that would be disclosable in any satisfactory way and we are concerned this will cause dispute in many cases about whether an event is disclosable. We expect that in practice, if a statutory duty is imposed, organisations will err on the side of caution and 'over-disclose' as far as the duty is concerned. However, we repeat that the professional duty upon a doctor already requires the doctor to be candid after incidents that have a far lower threshold.

Further, there may be occasions when it is alleged that a disclosable incident under a statutory duty of candour has occurred when those responsible for the care or treatment of the patient do not agree. In some cases it might not be possible to reach agreement and we believe any guidance provided to explain the new duty should make this clear. It must be understood that it may be entirely legitimate, having carefully considered whether an incident qualifies for statutory disclosure, to determine that it does not. The clinical team/individual clinicians must be in a position to demonstrate that they have considered whether the statutory duty to disclose does apply and to describe the steps they took to reach that decision. This is different from the professional duty of a doctor that is triggered by the far lower threshold of a patient suffering any harm or distress and thus even if the clinical team determine the incident does not reach the statutory threshold, one of the doctors will have told the patient as is their current practice.

If it were to happen, after thorough investigation, that there had been a disclosable incident and a patient had not been told, any action taken should not be punitive but aimed at reinforcing the need for the duty and the steps that should be taken to identify whether an incident was disclosable. It should also explain the steps that need to be followed in order to comply with the duty. As the main aim of the duty is to ensure patients are always appropriately informed, any action taken is going to be most effective if it is remedial. The aim should be to provide additional information about the duty itself in order to promote a better understanding of why it is important to comply. Punitive action is unlikely to be effective in achieving these ends.

End of Questionnaire