

## 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** – We believe that this proposed legislation is in response to national reports following significant events in the NHS and independent hospitals. Any legislation needs to take into account existing arrangements in the Scottish NHS and in social care to avoid duplication of legislation or the potential for new legislation to conflict with existing requirements. NHS Boards have up-dated Significant Clinical Incidents Policies and these have greatly improved the openness in which communication with the patients and relatives now happens and this seen as an essential part of the Policy. As soon as a significant clinical incident has been identified it is essential that an appropriate person is identified to inform patients and relatives. Who this person is will depend on the individual circumstances but is likely to be the Consultant-in- Charge of the overall patient care, or where this person is not available a suitable senior clinician should be identified.

Any new legislation therefore should only be introduced if it provides additional protection or benefit to existing legislative or reporting requirements.

The consultation does not mention existing requirements for notifying the Mental Welfare Commission about adverse events and should provide a rationale if this legislation might duplicate these existing requirements.

In addition, in Scotland there are existing requirements for registered care providers to report adverse events and deaths to the Care Inspectorate and to report risk of harm under the Adult Support and Protection Act 2007.

It also helpfully recognises the need for strong support for staff.

While it may be viewed as likely to be the only way to guarantee progress in this area is via legislation it is important to acknowledge that “mandating” change has not always been sufficient to bring that change about.

There should however be caution not to conflate “non-disclosure” with “denial and dismissal of mistakes”.

The crux of whether the elements of a Duty of Candour are achievable or not will depend on the definition of a “disclosable event”. The list of events in the consultation document has some which are obvious (death, permanent harm and return to surgery) and some of which are vague and the potential volume would possibly make it unmanageable. How long would be regarded as extra time in hospital?

The principle of empowering staff to raise issues when things go wrong is welcome, particularly if the requisite support is in place for both individuals who do speak out and for the organisation to learn from such events.

How would it work in prison health services – high potential for misuse and significant implications for NHS staff working in prison health services.

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 – This will be key. Staff are likely to be affected emotionally if they are involved in any way with circumstances where the death of or harm occurs to a service user in their care.

Therefore there is obviously going to be a great training need and who has the skill to provide it and how staff are realised to access it.

The report quotes an article where a training programme for junior medical staff was developed. The key message in the article is that this type of training must be experiential so participants have the opportunity to practice the communication skills taught in a safe environment with feedback provided. This will be difficult to implement for the number of staff who would require this skill as it would require a face to face facilitated session.

Support is therefore required for the staff involved and also for the staff

members disclosing the event! Who will provide the support and what would this consist of?

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

Yes  No

Comments –What would be reported and where? What would be its purpose – would it be to show that a body was complying with the Duty of Candour or would it be to expose to the public the type of events that have required a Duty of Candour.

Consideration needs to be given when formulating new legislation that it does not duplicate or conflict with existing legislation, reporting and inspection requirements and care must be taken to ensure that service users and their families consent to the proposed level of personal information that will be in the public domain. Most important aspect of public reporting is the publicising of learning from incidents of harm that lead to practice change to avoid future harm. We do not currently report publically on adverse incidents. This would require a cataloguing of all events that would fall within the Duty of Candour and checked to ensure the process has been followed.

This would need to be dependent on the incident and may not be appropriate in all cases, particularly where there has been an honest error or where the reporting may cause patients/relatives unnecessary distress..

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

Yes  No

Comments - Need to consider the definition of “relevant person” – for example, to take account of those who lack capacity of understand.

It is however essential that people harmed are informed and an apology given together with assurances of any changes in systems and processes that demonstrate lessons learned. However we are not sure it needs to be in writing on every occasion.

There appears to be added bureaucracy in terms of dictating what requires to be written in terms of not only an apology but also a transcript of the disclosure event. This is not always necessary and adds an increased workload to the process. It would make more sense if as a

minimum for a disclosure event the patient received a written summary of the event and outcome. For other patients other written communication may be necessary but for patients that are being communicated with in person, following up every element in a letter appears to be too much.

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

Yes  No

Comments This is vital – an apology alone will not be sufficient. It will be necessary to provide the requisite support to people in order to ‘do the right thing’ and to reassure the public that measures have been put in place to avoid future errors. Just need to consider further the type of support, for how long and by whom. Therefore, essential that individuals experiencing harm as a result of care and treatment are properly supported in order that they can fully understand what has happened, the process of the investigation and how they contribute to it and are also supported in any formal investigation that results from the death of a relative e.g. FAI.

Question 4:

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

Quarterly  Bi-Annually  Annually  Other  (outline below)

Comments – Annually or link to HIS Adverse Events Policy. The most significant harm incidents are likely be infrequent, but will often require complex investigations , possibly multi agency and in some cases involve criminal proceedings or FAI so may take considerable time to investigate and conclude. Reporting more frequently than annually may therefore be difficult even in organisations as large as NHS GGC.

Annual reporting would also fit with the requirement for other reporting mechanisms however we are not entirely sure what is expected from this reporting and how difficult or otherwise it will be to comply.

Question 5:

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

Comments – This will depend on who has to get training, who does the training, who has to have what support, what that support its and who gives that support. Also – what monitoring would be required and who carries it out. More information will be needed but as a minimum training will be required from an external source. Also, it may be necessary to produce additional guidance to assist organisations in the implementation of organisational Duty of Candour.

Therefore, until the legislation is drafted it will be difficult to estimate exactly what resource will be required and whether there are existing resources, appropriately trained and skilled staff, currently working to support complaints, claims or clinical governance staff who might be able to develop effective arrangements to support the implementation of the new Duty of Candour. It is unlikely, in a period of financial constraint, that these small teams would be able to take on any additional work associated with this new legislation without it impacting on the duties they currently undertake. It is likely that staff involved in the disclosure of instances of harm will need special training in the new legislation and will require effective communication and counselling skills in order to deal effectively with those affected by harm and the staff involved in the incident of harm and any external agencies who may be involved in any investigation.

Question 6a:

Do you agree with the disclosable events that are proposed ?

Yes  No x

Comments – No. Some of the categories are too vague and open to interpretation that might lead to many incidents having to be investigated unnecessarily. In the first instance it would be better to stick to the descriptions in 9.9, 9.10 & 9.11. Some of the other descriptions may not even be incidents and add confusion. It would be better to monitor the higher end incidents until this is established and then introduce for others.

9.12 - is too all encompassing. If it said – “should be in the scope of what is considered as possibly causing sufficient harm”, then that would be more helpful.

In 9.15 – if a child is taken into care it may have unintended consequences in respect of psychological harm but such decisions are based on keeping children safe and the damage to the child may be even greater were he/she to remain with their parent(s). It would be very difficult to attribute psychological harm in such cases

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

Yes  No x

Comments – No. It is very difficult to imagine clear definitions of disclosable events that would apply in all care settings. Reference to the Mental Welfare Commission notification guidance in respect of definition of disclosable events in respect of care and treatment provided in different settings and across agencies maybe useful here.

Also, not sure how this will work for GP practices, Dental Practitioners, Opticians or Community Pharmacists. Some descriptions are too vague.

Also, not sure in terms of responsibility who would hold the governance for GP’s for example. Presumably each practice would be responsible for implementing this.

Question 6c:

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

Comments – Not entirely sure and will need further consideration – physical, psychological and sexual abuse of children and young people whilst in care are examples that should be included. The legislation therefore would need to have a clear rationale for having distinct and different definitions for disclosable events for adults and children's social care.

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 - The major issue for creating effective legislation will be having very clear definitions and thresholds for the incidents of harm that will be covered by the legislation. Therefore definitions need to be clearer and consistent with those already in place in existing legislation or within the Care Inspectorate and Mental Welfare Commission.

If they were clear when certain choices are made on Datix, a prompt with advice could appear about Duty of Candour, however there will still need to be monitoring to ensure this is not missed just as there is currently with Significant Clinical Incidents.

Question 8:

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

Comments – It will need to be monitored to provide the assurance that it is being followed especially if it has a legal standing. Access to these reports should be available to the public on those harm incidents where disclosure has taken place.

It should be monitored through existing performance/governance structures, regulation and/or scrutiny arrangements within respective organisations. It will also be necessary for the regulatory bodies (Care Inspectorate and Mental Welfare Commission) and the Scottish Government and Healthcare Improvement Scotland to be involved in monitoring and enforcement.

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 legislation needs to define "relevant person" and disclosure to the relevant person needs to comply with existing legislation on sharing of personal identifiable data in circumstances where the individual harmed has died or does not have capacity.

In addition, it will depend on who discovers the problem and when. If it is discovered internally there may be an opportunity to put the situation right however if this is on external inspection and the Board has no explanation for the lack of disclosure that is quite a different issue. Such breaches would require to be investigated, appropriate actions

taken by employers and, if necessary, the individuals involved held to account through their professional regulatory organisation.

Will the legislation identify a period following an incident at harm within which disclosure must have taken place? This may be challenging in those circumstances where the harm caused may only be identified some considerable time after the incident of harm occurred, e.g. where a swab is left in situ post operatively and not identified for some weeks, months or in some cases years following the initial procedures where the harm occurred.

**End of Questionnaire**