

General comments

Prior to and following the publication of the National Framework for Learning from Adverse Events, all NHS Boards have been and continue to work to improve how adverse events are managed and crucially, how we learn from them and improve services based on that learning. Our overall impression is that this document appears to be at odds with the spirit of the National Framework, particularly in recognising the significant role that the development of a culture in which openness is valued, encouraged and supported.

The focus should be on communicating openly and honestly with patients and families at all times, because it is the right thing to do rather than to discharge a statutory duty or meet a standard. In this way, 'disclosure' becomes a natural part of good clinical communication, rather than something separate. This is a critical point in creating the right culture such that staff are engaged in, confident and positive about the process and see adverse events as an opportunity for learning and improvement. The introduction of a statutory 'Duty of Candour' appears to be at odds with this vision.

It does raise the issue of fundamental belief in why we review adverse events i.e. is it for learning and improvement (and reviews often find that something in the journey could have been improved but not necessarily prevented the adverse event) or, to find out what went wrong?

The document does not appear to acknowledge the context of a spirit of open and honest communication, or on learning and improvement - quite the opposite in fact, with varied references focussing only on things 'going wrong' (as a result of omission or error).

'Being Open' should be part of what we do when managing an adverse (unexpected and unwelcome) event, not seen as an additional, separate process. NHS Lothian's values reflect this, expressed as 'Openness, honesty and responsibility' and our approach is one of empowering and supporting staff to have local ownership and resolve issues at the point of care.

The focus is on the discovery of an event which did or may have caused harm, rather than on the fact that the patient has experienced an unexpected and unwelcome event.

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

For the reasons outlined above, we do not believe that the introduction of legislation supports the development of a culture where open and honest communication with patients and families is seen as the norm. The focus on reporting and reviewing adverse events needs to remain on identifying opportunities for learning and service improvement and 'being open' with patients and families and involving them in that process is integral. In addition, health professionals already have an existing professional duty of candour and as noted in 4.11, further work is being undertaken to provide further guidance in this area.

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

It is essential. Ensuring that staff have the right support, knowledge and skill, again depends on having an open and honest culture, which values reporting of adverse events, focussing on learning and improvement. Significant time and resources are needed to equip staff to have such conversations and must be supported by reliable processes to embed. This cannot be underestimated and our experience in developing and testing approaches as part of the 'Being Open' work in NHS Lothian shows that using improvement methodology is essential and takes time. This is about cultural change and not simply a one day training course and for large organisations, a significant undertaking.

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

Yes No

Again, the creation of a separate system does not support the cultural change which is required to deliver open and honest communication reliably. Boards already record involvement of patients and families in adverse events of part of existing systems and reports on reviews of adverse events are frequently shared with the patient/family when that is

their wish. We do not believe that reporting over and above existing arrangements and those in development as part of monitoring implementation of the framework would be of any benefit.

It is not clear what the benefits in reporting as described in section 7 are in terms of learning and again, does not feel like something that supports development of an open culture. Surely the point is about identifying themes and improving services rather than reporting the numbers and individual events?

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

Yes No

This is already part of existing policies and procedures to implement the national framework. As outlined in our general comments we believe that ongoing, open and honest communication should be central to relationships between caregivers and patients/families and is essential to achieving meaningful partnerships. Informing people about adverse events in a caring and compassionate way is simply part of that relationship, not something separate. Informing people when harm has occurred is not a one-off conversation and it is essential that people have the opportunity to reflect and come back with questions they may wish to be considered as part of the review of the event and to receive feedback following review at a time and in a way that is appropriate and meaningful for them.

We do not therefore believe that the exact process of disclosure should be too prescriptive as the precise nature of exactly what happened and to whom, whether or not there is clear evidence of preventable harm will influence what is most appropriate. This is something we are learning from as we conduct tests of change as part of the 'Being Open' project.

There is no mention in the document of specialist support requirements that should be considered when informing individuals who are affected by mental illness, cognitive impairment associated for example with dementia, head injury or learning disability or those with communication difficulties who may find it hard to understand or talk about what has happened to them.

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

Yes No

In principle, yes, however, this needs further definition for Boards to be able to implement effectively. Does this refer to the process of disclosure or in relation to the impact of the harm suffered? This also needs to consider 'second victims' i.e. support for staff involved and indeed other patients and relatives.

Question 4:

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

Quarterly Bi-Annually Annually Other (outline below)

This should be part of the monitoring process of the implementation of the National Framework which is currently in development by HIS. It would be dangerous and misleading to separate as the context would be lost and simply become a meaningless counting exercise. The importance of the patient/families and staff experience of the process must not be lost and again, the focus on learning and improvement is central.

Question 5:

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

This would need to be scoped for each Board. However, from our experience of the 'Being Open' project in maternity and the neonatal unit, this would be significant. A team based training approach is needed and must address the specific services and patient groups as no one size will fit all. Without this approach, there is a great danger of tokenism. Definition of support arrangements as per question 4 also need to be considered.

Question 6a:

Do you agree with the disclosable events that are proposed?

Yes No

This is potentially the most difficult part in relation to implementing such a requirement and if a statutory duty is seen to be required then it is essential that the definitions are clear. The language throughout the document demonstrates the difficulty and potential for confusion very well. There are references to adverse incidents, patient safety, adverse events/significant events, safety and harm incidents and error without harm. Alignment and consistency with the National Framework is essential which defines an adverse event as :

'...an event that could have or did result in harm...'

'Harm is defined as an outcome with a negative effect...which may result

from worsening of a medical condition or the inherent risk of an investigation or treatment ...

All harm is not avoidable ...however; it is often not possible to determine if the harm caused was avoidable until a review has been carried out. ‘

The difficulty here will be in agreeing criteria for adverse events which would be disclosable and potentially infers that only when it is found following review that something has ‘gone wrong’ would the patient/family be told.

So, any definitions of ‘disclosable events’ must build upon the above definitions. Again, in line with our belief that open and honest communication is at the heart of all interactions with patients and families, this needs to be broad and not a closely defined list of ‘disclosable events’. This is something we have spent a lot of time discussing as part of the ‘Being Open’ project. Starting from the premise of an adverse event being something that a patient has experienced which was unexpected and unwelcome, all such events and the process of review would be openly discussed. Early personal communication is an essential element which cannot be delayed until the outcome of a review is known.

One of the examples given, re-admission to hospital, may be as a result of considered risk enablement rather than due to avoidable harm. Including all re-admissions may lead to risk aversion around admission/discharge from hospital thereby resulting in unnecessarily longer lengths of stay in hospital. The Self Directed Support Bill and the shift towards outcomes and personalisation all have their underpinnings on an emphasis on user choice, control, flexibility and participation and innovation – this could easily be inhibited by professional risk aversion which does not promote the cultural shift of risk enablement.

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

Yes No

For the reasons noted in response to 6a, this needs careful consideration and dialogue with professionals is needed to further develop.

Question 6c:

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

Requires further discussion with colleagues in 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 ?

As noted in previous responses, particularly 6a, this needs further discussion. The key is development of a culture whereby open and honest communication is the norm and therefore, the labelling of adverse events as 'disclosable' or not becomes of less importance.

Question 8:

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

'Being Open' is part of the implementation of the National Framework for learning from adverse events and as such, should be part of existing and developing systems to provide assurance on rather than creating a separate system. The danger of creating a separate system will be that it becomes a meaningless counting exercise without context.

Question 9:

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

The introduction of sanctions does not support the development of a culture in which open and honest communication can flourish and significantly detracts from the key purpose of reporting adverse events which is for learning and service improvement. The principles of taking a systems approach to reviewing adverse events, the consideration of contributory factors rather than causes aims to ensure a consistent, systematic and thoughtful approach. This will create a greater climate of openness and valuing opportunities to identify improvements and will positively influence communication with patients/families about adverse events in a far more meaningful way than sanctions.

End of Questionnaire