Consultation on proposals to introduce a statutory duty of candour for health and social care services

Healthcare Improvement Scotland response

January 2014

Introduction

Healthcare Improvement Scotland is the national healthcare improvement organisation for Scotland. We have a vital role in supporting healthcare providers to deliver safer, more effective and more person-centred care and to achieve Scotland's 2020 vision for health and social care.

Our key priorities are to work together with healthcare providers and the people of Scotland to:

- empower people to have an informed voice that maximises their impact in managing their own care and shaping how services are designed and delivered
- reliably spread and support implementation of best practice to improve healthcare, and
- comprehensively assess the quality and safety of healthcare.

Throughout everything we do, we value people, make best use of our resources and work effectively as one organisation.

Key points

Being open and honest with people about their care is a key part of existing processes of managing adverse events and is already a professional duty of all health professionals. The focus of openly reporting and disclosing events is for learning and improvement – understanding any weaknesses of the system so improvements can be made to prevent future events.

Openness about failures is one of the overarching principles set out in the National framework for learning from adverse events. We have been working with NHS boards to support them in applying the 'Being Open' principles so patients, families and carers are informed and involved in the adverse event review process, and that members of staff are equally supported through the process. We have primarily been focused on supporting NHS boards to implement the national framework, however the overarching principles are applicable to all health and care services.

We acknowledge that there is much more work to do to move to an open and transparent culture within NHSScotland, but we must also recognise the improvements that have already been made across NHS boards in recent years.

Fundamentally, we are trying to transform the culture of the NHS and we do not believe that legislation is necessarily the only or best way to achieve this. We note that the proposals do not currently include any sanctions such as those in place in NHS England, and we would strongly argue that any sanctions would be counterproductive to achieving the open, learning culture we are trying to achieve.

As the consultation paper sets out in the introduction, there are a number of known barriers to open disclosure and reporting of adverse events. One of these key factors is fear of the consequences of reporting an event. As the WHO guidance on adverse event reporting states, *'Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill-effects from reporting.'*

Whilst we do not believe legislation is absolutely necessary, if a statutory duty is to be introduced then we think this provides a good opportunity to set out in statute that individuals who report and disclose adverse events will be protected from disciplinary action. This follows

the example of the Danish Patient Safety Act introduced in 2004, which states '*A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, to supervisory reactions by the National Board of Health or to criminal sanctions by the courts.'*

The Act seeks to drive the reporting of, and learning from, adverse events by protecting people who report, rather than persecuting those who do not. Denmark therefore aims to deliver a cultural shift from 'blame and shame' to 'need to know'. We strongly believe this is what Scotland should be seeking to achieve.

This is not dismissing the importance of personal and professional accountability for actions, but rather supports the fostering of a culture where people feel supported and safe to identify and report errors.

As Don Berwick sets out in his report *A promise to learn - a commitment to act,* 'enforcement' and criminal sanction is necessary but rare and we share his concern that '*unintended errors must be handled very differently from severe misconduct'.* We must complement punitive measures with support for people who want to do the right thing. Introducing a statement similar to that in the Danish Patient Safety Act in legislation will send a clear message that we are focused on learning from errors and our emphasis is on making improvements to the systems of care we provide.

We have emphasised in our response to the Scottish Government consultation on proposals for an offence of willful neglect or ill-treatment in health and social care settings that there needs to be real clarity on what willful neglect is, how it should be distinguished from system-related harm and how learning systems and professionalism are key to minimising both. Otherwise we are very likely to reinforce a culture of fear, which again as Berwick said, is toxic to improving patient safety.

Consistency with these proposals for a statutory duty of candour and the professional duty of candour endorsed by the Professional Standards Authority (which oversees the nine professional regulatory bodies) is crucial. We must have a system where organisations support individual healthcare professionals, and any disconnect will result in confusion and duplication with no benefit to patient care.

We are continuing to work with NHS boards to support them in 'Being Open' with patients and families as part of effective management of an adverse event, and it is important that the duty of candour supports this work and avoids a system which descends into rigidly monitoring and counting disclosable events.

We are also continuing to support NHS boards in how they ensure people have a say in decisions about their care and in the development of local health services. The Participation Standard is a way of measuring how well NHS boards do this, with the first section of the Standard covering how well NHS boards focus on the patient – people should be involved in discussions about their own treatment and care; information about treatments and local health services should be available and easily accessible; people should be treated with dignity and respect; carers should be supported; and people should be encouraged and helped to give feedback and complaints about services.

All NHS boards should be recording the involvement of patients and families within their adverse event review processes, their Participation Standard assessment, and complaints and feedback annual reports. This should be sufficient to satisfy the duty of candour requirements, rather than separate reporting processes.

It is also important to note that from our experiences of supporting the Being Open pilot work in the maternity department at Edinburgh Royal Infirmary, it cannot be underestimated the time and resources required to ensure staff are appropriately skilled and supported to manage these open and honest conversations with patients and their families. Being open also very much requires a person-centred approach - there is no 'one-size fits all' approach. We need to trust professionals to use their judgement about when and how to disclose events taking into account the mental and physical needs of the people they are caring for.

Finally, many of our responses refer to the healthcare service as that is where our experiences and expertise lie. However, we see no reason why the high level principles we refer to cannot be applied to social care settings.

Our responses to each of the questions set out in the consultation document are provided below.

Questionnaire responses

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 ☒

We do not believe that legislation is necessarily the only or best way to achieve the cultural transformation we wish to see within health and social care services in Scotland.

However, any legislation must first and foremost state that the key focus of openly reporting and disclosing events is for learning and improvement so that people routinely receive high quality care. It is incredibly important that this is not lost within the details of the duty.

Being open and honest with people about their care is already a key part of existing processes such as managing adverse events and complaints handling. The organisational duty of candour must support these existing processes and the existing professional duty of candour for all health professionals.

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 ☐

We welcome that the paper emphasises the importance of ensuring staff have the appropriate skills to have open, honest and sensitive conversations with patients and their families, and supporting staff through this process. However, it cannot be underestimated the resources that are required to appropriately support staff.

We think organisations should be making their policies and procedures freely available via their website in line with our collective commitment to transparency, openness and public accountability. However, we were unsure of any benefit of submitting these policies and plans to 'the relevant organisation' (para 7.3) and indeed who these organisations may be.

In order to adequately support staff to openly report and disclose adverse events, they must first feel safe to do so. We believe that if legislation is to be introduced then there is an opportunity to set out in statute that individuals who report and disclose adverse events will be protected from disciplinary action. This follows the example of the Danish Patient Safety Act introduced in 2004 which seeks to drive the reporting of, and learning from, adverse events by protecting people who report, rather than persecuting those who do not. Denmark therefore aims to deliver a cultural shift from 'blame and shame' to 'need to know'. We strongly believe this is what Scotland should be seeking to achieve.

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

Yes ☐ No ☒

We are encouraging and supporting NHS boards to write adverse event review reports in a way that can be easily shared (with patients, their families, staff and other NHS boards) so that others can learn from the event and lessons learnt. We are also supporting NHS boards to share a one page learning summary with other NHS boards to maximise the opportunities to learn from each other.

NHS boards already publically report on complaints they have received. There is a legal requirement to produce an annual report on complaints and feedback, which stems from The Patients Rights (Feedback, Comments, Concerns and Complaints) (Scotland) Directions 2012 and the 'Can I help you?' guidance. There is also a requirement for NHS boards to complete the Participation Standard self assessment which supports measurement of how well NHS boards ensure people are involved in decisions about their care and in the development of local health services. These two requirements have now been streamlined and a single report will cover both areas for 2014-2015.

We believe that any reporting relating to the Duty of Candour should be as part of existing processes of adverse event management, complaints handling and Participation Standard assessment.

We are continuing to work with NHS boards to support them in 'Being Open' with patients and families as part of effective management of an adverse event, and it is important that the duty of candour supports this work and avoids a system which descends into rigidly monitoring and counting disclosable events. All NHS boards should be recording the involvement of patients and families within their adverse event review processes and this should be sufficient to satisfy the duty of candour requirements, rather than separate reporting processes.

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

Yes ☐ No ☐

We agree that as part of existing processes of managing adverse events people should be informed if they have been harmed.

Open and effective communication with people should begin at the start of their care and continue throughout all the care they receive. This should be no different when an adverse event occurs. Being open when things go wrong is key to the partnership between patients and those who care for them. As outlined in the consultation paper, openness about what happened and discussing adverse events promptly, fully and compassionately can help people cope better with the after-effects of adverse events.

In our Being Open guidance (adapted from the NPSA guidance) we have outlined that being open involves:

- Acknowledging, apologising and explaining when things go wrong
- If appropriate, conducting a thorough review into the adverse event which involves patients, families, carers and staff, and aims to identify lessons that will support improvements and help prevent the adverse event being repeated
- Providing support for those involved to address any physical and/or psychological consequences of what happened.

This is similar to that set out in Chapter 2 of the consultation paper. However, further clarity of some of the requirements set out in that chapter would be useful. For example, in paragraph 6.1 it outlines that when the person is notified a 'step by step account of the facts of what happened' should be provided. This is often difficult to provide until the event has been reviewed. The person who has been harmed should be informed of the event and should be part of a discussion about what will happen next and how they will be involved in the subsequent review process. We have developed information sheets for patients and their families which outline the significant adverse event review process and are encouraging all NHS boards to ensure this information is provided and explained to patients.

It is also unclear what 'reasonable support' (para 6.3) entails and further guidance would be helpful for organisations to implement this.

The adverse event review report should make up the record outlined in para 6.7, however, it is not always current practice to provide a written summary of all face to face meetings with patients as part of the adverse event review process. Although this seems sensible, it needs to be explored with NHS boards and patients as to whether this would be valuable and

useful while also considering the resource requirements to complete this.

Building on our experiences of adverse event reviews in mental health services, we feel it is also important that patients and their families have the opportunity of a follow-up meeting to discuss the event when they may be more mentally and physically ready to fully participate in the discussion and understand the actions that have taken place to prevent the event from recurring. It is important that the person harmed (and their family if appropriate) are involved in an ongoing process, not just notified at the time that they have been harmed.

While we aspire to an open and transparent culture where all errors or adverse events would be disclosed to people, there needs to be a recognition that there is no 'one-size fits all' approach. We need to trust professionals to use their judgement about when and how to disclose events taking into account the mental and physical needs of the people they are caring for. This is partly referenced in para 9.6 which states that '*each instance must be considered on its individual merits, taking account of the specific clinical and care elements of individual care episodes*.'

However, we can support professionals by providing decision-support tools to act as a guide for when events should be disclosed. Further work is required around this area and we would be happy to support these discussions.

There is also the question of whether adverse events that had the potential to cause harm, or 'near-misses', should be disclosed to the people involved. This may result in unnecessary distress to the individual concerned, but the revised professional duty of candour endorsed by the Professional Standards Authority states *'Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.'* Consistency across the duty on organisations and the professional duty is essential.

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

Yes ☐ No ☐

See answer above - it is unclear what 'reasonable support' (para 6.3) entails and further guidance would be helpful for organisations to implement this.

Question 4:

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

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

As outlined in our response to question 3a, we are continuing to work with NHS boards to support them in 'Being Open' with patients and families as part of effective management of

an adverse event, and it is important that the duty of candour supports this work and avoids a system which descends into rigidly monitoring and counting disclosable events.

If reporting is required then it is essential that the context surrounding the adverse event is also provided and the emphasis is on the improvements that were put in place as a result, how the people involved were engaged in the review process, and how the learning points were shared. This could potentially be part of an annual report that looks at learning from all types of feedback and encompasses the current activities around complaints reporting.

Question 5:

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

Patient-facing NHS boards will be able to provide more accurate information regarding the resource implications. However, from our experiences of supporting the Being Open pilot work in the maternity department at Edinburgh Royal Infirmary, it cannot be underestimated the time and resources required to ensure staff are appropriately skilled and supported to manage these open and honest conversations with patients and their families.

Although communicating effectively with people receiving care is a fundamental aspect for all health and social care professionals, this is a skill that needs to be continuously developed through team-based training.

Question 6a:

Do you agree with the disclosable events that are proposed?

Yes ☐ No ☒

Aspects of this are covered in our response to question 3b above, and a decision-support tool for professionals to determine if the event should be disclosed building on the National framework for learning from adverse events would be useful.

We feel that disclosable events must be completely aligned with the existing adverse event processes within NHS boards.

The definition of an adverse event and harm as outlined by the national framework is as follows

'An adverse event is defined as an event that could have caused, or did result in, harm to people or groups of people.

Harm is defined as an outcome with a negative effect. Harm to a people or groups of people may result from worsening of a medical condition, the inherent risk of an investigation or treatment, system failure, provider performance issues, service disruption, financial loss or adverse publicity.

All harm is not avoidable, for example the worsening of a medical condition or the inherent

risk of treatment. However, it is often not possible to determine if the harm caused was avoidable until a review is carried out.'

We think that clarity around the level of harm where the event must be disclosed would be useful and should build on the definitions above.

We interpreted the events described in paras 9.10 – 9.14 as examples of disclosable events, and found these examples helpful but were mindful of other events that would fall outside these examples. From our previous consultations with NHS boards, there were strong views that a list of events that must be reported/disclosed could potentially prevent events not on the list from being reported/disclosed.

As outlined in the national framework definitions, many of the harms listed in paras 9.10 – 9.14 will not be possible to determine if the event was unintended/unexpected/avoidable until a review is carried out, and this illustrates that the duty of candour should be part of existing adverse event review processes and not a separate standalone process.

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

Yes ☐ No ☐

We agree with the consultation paper that the *'definitions need to be developed and informed through dialogue with health and social care professions'.*

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

Our colleagues in social care are better placed to answer this question.

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?

This is covered in our responses to questions 3b and 6a.

Question 8:

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

We do not feel that an additional monitoring regime would be helpful either nationally or for NHS boards. We think that assurance that events resulting in harm are being disclosed to the individuals involved should be through existing mechanisms, such as ongoing scrutiny

programmes and the new quality of care reviews.

We should also be continuing to support NHS boards (and social care bodies) to openly publish their significant adverse event review reports which should contain the involvement of patients, families and carers in the process.

As outlined in the response to question 3a and 4, we are continuing to work with NHS boards to support them in 'Being Open' with patients and families as part of effective management of an adverse event, and it is important that the duty of candour supports this work and avoids a system which descends into rigidly monitoring and counting disclosable events.

All NHS boards should be recording the involvement of patients and families within their adverse event review processes, their Participation Standard assessment, and complaints and feedback annual reports. This should be sufficient to satisfy the duty of candour requirements, rather than separate reporting processes.

Question 9:

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

We note that the proposals do not currently include any sanctions such as those in place in NHS England, and we would strongly argue that any sanctions would be counterproductive to achieving the open, learning culture we are trying to achieve.

We think that if it is discovered a disclosable event has not been disclosed then it provides an opportunity to understand the process and where there is scope for improvement.

More consideration of the practicalities of applying the organisational duty of candour are required before this question can be considered in greater detail.

End of Questionnaire