4. Do you support the proposed duty of candour?

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, alongside the existing professional duty of candour for all health professionals. The duty of candour must therefore support these existing processes.

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. We acknowledge, however, that legislation can be an important lever for change. Therefore the reporting and disclosing of events for the purpose of learning and improvement should be explicit within the provisions of the bill. We note this is the intent from the Policy Memorandum but we feel it is important to include this in the bill itself.

We note that the proposals do not include any sanctions such as those in place in NHS England, and we would strongly argue that any sanctions would be counterproductive to achieving an open, learning culture. We support the use of existing performance management mechanisms, such as the annual review process of NHS boards, and the proposed monitoring arrangements, to uphold the principles of the bill.

We welcome the inclusion of a definition of an apology within the bill and the clear statement that an apology or anything else undertaken as part of the ‘duty of candour procedure’ does not of itself amount to an admission of negligence. This is an important part of the bill which will support staff to be open and compassionate with patients and their families when unexpected or unwelcome events occur.

The bill sets out the outcomes following an unintended or unexpected incident when the ‘duty of candour procedure’ must be activated. We have some concerns about how these outcomes will be interpreted in day to day practice, specifically around provision 21(4)(c)(i) ‘an increase in the person’s treatment’. We have assumed this would only apply to significant increases in the person’s treatment based on the other outcomes described in provision 21(4) as there are examples of treatment being increased where harm is not severe. For example, if a patient on an opiate becomes constipated (a significant harm for the person that could have been avoided) and their treatment is increased with the addition of stool softeners.

This example highlights that while we should be supporting staff to communicate openly with patients and service-users about their treatment and care, we should not create a system that descends into rigidly monitoring and counting disclosable events.

Statutory guidance, including case-studies, setting out the thresholds for activation of the ‘duty of candour procedure’ would therefore be welcome. In
addition, it may be useful to make reference to the important link between front-line review and local clinical or care governance arrangements. This is important for ease of reporting (both escalation and the flow of learning), supporting the duty of candour but minimising the requirement for exercising legislative action.

Additionally we think it would be helpful if the regulations or guidance would outline how the duty of candour will operate with other existing mechanisms that aim to support reporting and open disclosure of issues such as the National Confidential Alert Line, whistle-blowing policies and public interest disclosure.

We welcome within the financial memorandum that the regulations will set out that training, supervision and support will be required for staff who are involved in carrying out the duty of candour procedure. The financial memorandum also anticipates that ‘Health Boards will be able to incorporate the requirements for the duty of candour procedure within their existing processes to support staff training and induction programmes’. It does make provision for some non-recurring costs on the Scottish Administration based on previous costs of training developed to support complaints handling. However, there is a need to take into account the additional costs of supporting staff develop the necessary skills.

As part of implementation of the National Framework for Learning from Adverse Events we have supported the Being Open pilot work in the maternity department at Edinburgh Royal Infirmary. This has highlighted 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. The pilot work has delivered tailored workshops based on service-specific scenarios led by clinical communication educators. This specialist communication training was designed to build staff confidence and competence to have meaningful conversations with patients and families when adverse events happen and strengthen multi-professional team working.

This pilot has provided training for 46 members of the clinical team with an impressive impact on both staff and patient experience. The workshops and improvement changes have taken around 1 year and cost around £60,000 (around £1300 per member of staff). Once further developed and tested the costs are likely to reduce, however, it is clear to train and support staff to implement the duty of candour will require investment.

Much of our organisation’s work is aimed at promoting and supporting an effective safety and learning culture, including the Scottish Patient Safety Programme (SPSP). Scotland is the only country in the UK to have a co-ordinated safety programme across a range of clinical areas, all of which are underpinned by the development and use of safety climate survey tools and approaches to improve safety culture. This includes supporting staff to be open and speak up about safety issues. The use of these tools is also supported in contractual frameworks (e.g. GMS contract quality and safety domain), which further demonstrates the opportunities to embed these in
every day practice, incorporating openness and transparency at local team level. This will also support implementation of the duty of candour.

5. **Do you support the proposal to make wilful neglect or ill-treatment of patients a criminal offence?**

We are supportive of the policy intention behind the proposed legislation – that no measure of deliberate neglect or mistreatment is acceptable and that the criminal law should reflect this. There is a need, however, for greater clarity on how the proposals will be implemented in practice. This may be provided through guidance, definitions and case studies. The section below expands on specific areas of concern.

In our response to the Scottish Government consultation on the proposals, we noted the reasoning that the legislation and associated sanctions may have a deterrent effect (although also that it is not possible to quantify this). However, it is important to consider any possible unintended consequences in relation to efforts to establish a culture of openness, transparency and learning through the duty of candour and in our current work to support the reporting of and learning from adverse events.

The risk that legislation associated with wilful neglect would reduce the likelihood of reporting of harms, whether intended or not, may also undermine measurement work, a critical first step in improvement. For example, accurate reporting of the harms related to the Scottish Patient Safety Programme underpins the outcome measures that are essential to understand current state and the impact of improvement initiatives.

In considering both of the above aspects together i.e. recognition and action in relation to the criminal act of deliberately causing harm and the essential nature of openness to learning, we draw on Don Berwick’s *A promise to learn—a commitment to act*. Berwick sets out that ‘enforcement’ and criminal sanction is necessary but rare and we share his concern that ‘unintended errors must be handled very differently from severe misconduct’. Many of our comments are therefore attempting to seek clarity on what wilful neglect is, the role of system-related harm and how learning systems and professionalism are key to minimising both. It will be essential and challenging to define an act of ‘wilful neglect’ and separate this from system failures.

With the move towards integration of adult health and social care, we are supportive of proposals that cover both care settings. We also welcome the consistency of approach with the inclusion of voluntary organisations, as all services commissioned by health boards and local authorities should be expected to meet the same standards and commissioners should be satisfied of this.
6. **Is there anything you would add/remove/change in the Bill with regards to these provisions?**

**Duty of Candour**

The bill should make clear the aims of the duty of candour: to improve involvement of people in their own care, and to learn from and improve services following adverse events. This provides a good opportunity to set out in statute that the act of reporting an adverse event will not result in disciplinary action, censure or legal action against the reporter. This does not equate to a blame free culture, but rather a just culture.

This follows the example of the Danish Patient Safety Act introduced in 2004 which provides important protection of health care professionals: a health care professional cannot be subjected to disciplinary action as a result of reporting an adverse event. This protection has been crucial for the willingness of healthcare professionals to report events.

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. 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.

Healthcare Improvement Scotland is specified as the monitoring body in relation to independent healthcare services. We ask that the bill is amended to clarify that we are the monitoring body for those independent healthcare services that we regulate i.e. those independent healthcare services within the meaning of Section 10F(1) of the 1978 Act and where the legislative powers for regulation have been commenced.

**Wilful neglect**

While we do not have specific suggestions for amendments to the Bill, we have made the following observations:

**Care provider offence**

We agree that the offence should be in relation to committing the act rather than the outcome, and note that a required level of harm is not specified. The Bill states that a care provider commits an offence if their activities ‘are managed or organised in a way which amounts to a gross breach of a relevant duty of care’. We believe that the requirements on organisations in relation to safeguarding patients and service users need to be clarified. This can fall into two areas: safeguards against individuals (e.g. disclosure checks, supervision, responses to feedback and whistleblowing) and organisational responsibility to ensure safe, high quality care (e.g. risk assessment, training, provision of appropriate equipment). Clarification of what is expected of organisations would support consideration of whether an organisation can demonstrate that it has taken all steps that can reasonably be expected. It should be clear as to when failure to take such specific action can be classed as wilful neglect as well as any deliberate action taken.
As noted above, we also agree that the offence should apply to voluntary organisations; however we caveat this with the need to recognise that ways of working with volunteers may differ from paid staff. Arrangements for monitoring, supervision and feedback, for example, may be less prescriptive. The onus is therefore on the organisation to have appropriate governance and performance arrangements in place to safeguard against potential issues as far as can be reasonably expected.

Care worker offence
It is unclear as to how it will be established whether actions were wilful or constitute ill-treatment, as opposed to unintentional harm which may arise as a result of a lack of, for example, training or appropriate resources. This concept is difficult to determine. Whether this may then cause an offence to ‘transfer’ from a care worker to a care provider would also need consideration.

The NPSA has developed the Incident Decision Tree to help NHS managers determine a fair and consistent course of action toward staff involved in patient safety incidents. Such a mechanism may help to reduce fears of a ‘blame culture’ in relation to reporting adverse events and the potential risk that introducing the offence of wilful neglect may impede progress towards an open, safe, learning culture which the proposed Duty of Candour seeks to promote.

Penalties
It is also important to maintain a balance between legislation that will drive compliance and that which might lever positive change. We agree with the need to ensure that the worst cases of wilful neglect or ill-treatment can be dealt with effectively by the criminal justice system. However it is important to place any organisational penalties in the broader context of prevention, learning and service improvement rather than simply retribution. Additionally, focusing blame on individuals will not consider or address any systemic or organisational issues that can be improved.

General points
It is unclear as to the stage at which an action or situation formally becomes a possible instance of wilful neglect or ill-treatment. As noted previously, it will be important to determine how this will be differentiated from unintentional harm. How this is determined, and by whom, will need to be clarified.

It is important to recognise that people affected by any offence (patients, service users, carers and families) will be vulnerable, and this may impact more on people with particular protected characteristics more than others – for example, people with learning disabilities or dementia. It is important that people affected are supported to participate in the process (for example through access to advocacy, the Patient Advice and Support Service, Victim Support etc) and to understand their rights and responsibilities. Clear and accessible information for patients/service users and their carers is essential.

Healthcare Improvement Scotland