



## Proposals to Introduce a Statutory Duty of Candour for Health and Social Care Services: Consultation Analysis

**PROPOSALS TO INTRODUCE A STATUTORY DUTY  
OF CANDOUR FOR HEALTH AND SOCIAL CARE  
SERVICES: CONSULTATION ANALYSIS**

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## **EXECUTIVE SUMMARY**

1. Between October 2014 and January 2015, the Scottish Government undertook a consultation on proposals to introduce a statutory duty of candour for health and social care services.
2. The duty would create a legal requirement for health and social care organisations in Scotland to inform people (and / or their families) when they have been accidentally harmed (physically or psychologically) as a result of the care or treatment they have received. The duty would relate to more serious events (those resulting in death, injury or prolonged harm) – referred to in the consultation as ‘disclosable events’.
3. The proposals included that a duty of candour would involve: a review of the contributory factors to the event; efforts to put matters right; and the requirement to apologise. It would also include a requirement to provide training and support to staff in implementing the duty, and to offer support to those affected by an incident of harm. Finally, it proposed that organisations should publish a report outlining how the duty had been implemented, including the learning and improvements that have been identified and actioned.
4. The consultation paper contained nine questions, seeking views on a range of issues related to the requirements on organisations, the definition of ‘disclosable events’, and proposed monitoring arrangements. Around half of the consultation questions included a closed (yes / no, tick-box) component with space provided for further comments. The remaining questions were open.

### ***The consultation respondents***

5. The consultation received 109 responses – 7 from individuals and 102 from organisations. Organisational respondents included: NHS and local government organisations; third sector agencies; agencies responsible for the scrutiny and regulation of professional practice and / or services; and a range of organisations that support, train or represent health and social care professionals.

### ***Views on the introduction of a statutory duty of candour (Q1)***

6. Respondents were asked whether they agreed that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation. Eighty percent (80%) of respondents agreed and 12% disagreed.
7. Respondents who agreed with the proposal thought that legislation could be a useful lever in bringing about greater openness and transparency in services, and in addressing perceived failings associated with current arrangements based on ethical and professional codes. A legislative approach (and associated guidance) would also ensure that the duty was implemented in a clear and consistent way.
8. Respondents who disagreed with the introduction of a statutory duty of candour were generally supportive of the policy aims behind the proposals. However,

this group felt that openness with patients and service users would be best achieved through other means (staff training, guidance and professional codes), rather than through legislation. This group also argued that a case had not been made for establishing a duty of candour in law, and that such legislation would not address the issues of organisational culture which currently inhibit disclosure. In addition, there was a concern that the duty and its associated reporting requirements would result in a (potentially) costly and bureaucratic burden upon organisations, and would undermine the learning opportunities which can result from identification of more minor events and 'near misses'.

***Ensuring that staff have the required support, knowledge and skills to deal with disclosable events (Q2)***

9. The consultation proposed that the statutory duty of candour should include an organisational requirement to ensure that staff involved in disclosable events have the necessary support, knowledge and skills to respond effectively and confidently. Respondents were asked if they agreed with this proposal. Views in relation to this proposal were nearly unanimous – with 98% of respondents saying that they agreed.

***Informing and supporting people who have been harmed (Q3b and Q3c)***

10. The consultation set out proposed requirements for informing people who have been harmed as a result of an adverse event, and for offering 'reasonable support' to the individual, their relatives and to staff involved. Respondents were asked for their views on the proposals.
11. Ninety-three percent (93%) agreed with the requirements for informing people who are harmed. The requirement to inform was seen to be consistent with an open and honest approach to care and treatment. However, respondents also argued for a degree of flexibility, and commented that there could be exceptional cases where the disclosure of harm itself could be a source of further harm, and may not be in the best interests of the person affected. Respondents wanted clarification about a range of issues related to how to fulfil this requirement in practice.
12. Those who disagreed with the requirement to inform people who had been harmed were concerned about the resource implications of the requirement, and whether it might result in undermining public confidence in services.
13. In relation to the proposal to offer support to people following the disclosure of harm, again, most respondents (93%) agreed, and there was a general view that support should not only be offered but that its uptake should be actively encouraged. Respondents suggested that the provision of support would assist with communication; help people to understand the situation and participate in the process; and reduce the risk of the disclosure itself causing further harm. However, there were concerns about the potential resource implications of the requirement and how it would apply to small services in community settings.
14. These concerns were echoed by those who did not agree with the requirement to provide support. This group also thought that such a requirement would not

add value to existing professional duties or good practice, and they thought the requirement would be open to local interpretation.

#### ***Public reporting (Q3a and Q4)***

15. The consultation sought views on the public reporting of disclosures which have taken place. Two questions were posed: the first sought views about the proposed requirement for public disclosure, and second about the appropriate frequency for such reporting.
16. Three-quarters of respondents (75%) agreed that organisations should be required to publically report on disclosures, while 13% disagreed. Irrespective of whether respondents agreed or disagreed, there was a call for clarity about the *purpose* of public reporting and the *nature* of any reporting (in relation to, for example, the intended audience, or the form and level of detail of reporting).
17. Those who had indicated agreement with the requirement for public reporting generally saw it as being in line with openness, transparency and accountability in public services. There was a view that to *not* have such a requirement would be 'at odds with a duty of candour'. However, respondents also expressed some concerns related to: the need to protect the rights and privacy of those involved; how the information might be misinterpreted or misused; and the possible resource implications associated with public reporting.
18. Those who disagreed with the requirement for public reporting echoed these concerns and also thought that public reporting would provide no additional benefit – either to those who had been harmed, or to organisational learning.
19. In terms of the frequency of public reporting, the majority of respondents (62% of those who commented) favoured annual (rather than more frequent) reporting, as this was seen to be 'manageable' and 'proportionate'.

#### ***Staffing and other resources (Q5)***

20. Respondents were asked for their views on the staffing and resources required to support effective implementation of the duty of candour. In relation to staffing, respondents expected that a wide range of staff would need to contribute to meeting the obligations of the duty, and that this would have significant costs. They also identified needs in relation to: staff training; the resourcing of initial set-up activities (i.e. developing policies, procedures, etc.); the provision of support services for staff and for people affected by a disclosable event; and ongoing administrative support. There were concerns about the resource implications of the duty, particularly for small organisations.

#### ***Disclosable events (Q6)***

21. The consultation document set out a definition for 'disclosable events' and provided a list of events as examples. Respondents were asked if they agreed with the events that were proposed, and whether these events would be clearly applicable and identifiable in all care settings.

22. A majority of respondents (59%) agreed with the disclosable events proposed. However, over a quarter (26%) disagreed. This latter group included most of the local government organisations. Respondents who disagreed expressed a range of concerns about the disclosable events proposed, and these *same* concerns were also raised by those who agreed. The main point made by both groups was that the definition of a 'disclosable event' was 'not clear' and 'needed more detail'.
23. Respondents also queried, or explicitly disagreed with, the examples of disclosable events given in the consultation document. Some went on to describe scenarios in which such events would *not* be considered to be adverse but, rather, would be reasonable and appropriate responses in a clinical context.
24. In relation to the question about whether the disclosable events would be clearly applicable and identifiable in all care settings, nearly half of respondents (47%) said 'no', while a third (31%) said 'yes'. Respondents suggested that it would be difficult to define a set of disclosable events that would be applicable across all branches of medicine, and in both health and social care services.
25. Those who thought the disclosable events *would* be clearly identifiable in all care settings generally qualified their support by saying, 'as long as they are clearly defined'. Those who disagreed thought that the proposed events were too focused on acute healthcare services. This group also reiterated their views that the proposed definition lacked clarity, and suggested that not all of the proposed events would necessarily result in harm to a patient or service user.

#### ***Disclosable events in children's social care (Q6c)***

26. Respondents were asked for their views on the definition that should be used for 'disclosable events' in the context of children's social care services. There was disagreement among respondents about this issue. Some thought that any such definition should be developed by professionals and other experts who work in this area, while others argued that the *same* definition should be used for 'disclosable events' in adult and children's services.
27. Respondents thought that any definition or guidance about disclosable events for children's social care services should take into account and be consistent with the wider legislative and policy context in this area.

#### ***Supporting effective mechanisms to determine if disclosable harm has occurred (Q7)***

28. The consultation document asked respondents their views about the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred.
29. The main issues were the need for: clear definitions of 'disclosable event'; training and guidance for staff; access to advisors, both within and external to organisations; organisational policies and procedures to support the identification of disclosable events; adequate resourcing; an organisational

culture that supports transparency and openness; and awareness-raising among patients, service users and their carers about the duty of candour.

### ***Monitoring the statutory duty of candour (Q8 and Q9)***

30. Respondents were asked their views about how the organisational duty of candour should be monitored, and what the consequences should be when it is discovered that a disclosable event had not been disclosed. The consultation document also described how the existing roles of the Scottish Government, Healthcare Improvement Scotland and the Care Inspectorate would relate to monitoring the implementation of the duty of candour.
31. In general, respondents agreed that monitoring should take place through existing systems. Respondents were concerned that if a *new* monitoring system was set up, it would cause duplication and confusion. However, there were concerns that Healthcare Improvement Scotland and the Care Inspectorate have slightly different functions, and this could result in inconsistency in the way the duty of candour is monitored in health and social care services.
32. In general, respondents thought that consequences for not disclosing a disclosable event should be in line with existing procedures and processes, with staff subject to existing disciplinary or regulatory proceedings and organisations being required to put improvement plans in place. Others thought that the consequences should depend entirely on the circumstances.

### ***Cross-cutting issues***

33. Across all the questions, there were a number of recurring themes in the responses which could be seen both in the comments of those agreeing with the proposals and the comments of those disagreeing. These included: support for the continuing development of a culture of openness and honesty in health and social care services; the importance of taking account of the needs of different equality groups in communicating incidents of harm; repeated calls for clarification in relation to certain aspects of the proposed duty (and particularly regarding the definition of a 'disclosable event').
34. Respondents also frequently expressed concerns about: the unintended consequences of the duty which could encourage a 'blame' culture in services and lead to risk-averse decision-making; and the resource implications of the proposals. There was a general view that, as much as possible, existing procedures and systems should be used for identifying and reporting events.

# 1 INTRODUCTION

- 1.1 This is a report of the findings of a public consultation undertaken by the Scottish Government in relation to introducing a statutory duty of candour for health and social care services. The consultation document was published in October 2014 and the consultation closed in January 2015.<sup>1</sup>
- 1.2 Openness and transparency in relation to adverse events is increasingly recognised as an important element in establishing a culture of continuous improvement in health and care settings. The Scottish Government has a stated commitment to improving standards of care in health and social care settings, and a duty of candour in Scotland would sit alongside a range of other activities already being pursued in this area.<sup>2</sup>
- 1.3 The consultation document set out the Scottish Government's intention to introduce a statutory duty of candour for organisations providing health and social care services – i.e. a legal requirement for staff to tell people (and / or their families) when they have been accidentally harmed (physically or psychologically) as a result of the care or treatment they have received. A similar duty of candour came into force in England through new healthcare standards introduced in November 2014.<sup>3</sup>
- 1.4 The proposals included that a duty of candour would involve: a review of the contributory factors to the event; efforts to put matters right; and the requirement to apologise. It would also include a requirement to provide training and support to staff in implementing the duty, and to offer support to those affected by an incident of harm. In addition, it was proposed that organisations would need to publicise how they have implemented the duty of candour and the details of learning and improvements implemented as a result of episodes of harm. The consultation paper invited views on a range of issues related to the requirements on organisations, the definition of disclosable events, and the proposed monitoring arrangements, in order to help shape the detail of the new duty. The consultation contained nine questions. These are listed in Annex 1.
- 1.5 The consultation document was sent directly to all local authorities and NHS Boards in Scotland and to 50 other organisations with an interest in this area. The consultation paper was also available on the Scottish Government website and was promoted via a press release.

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<sup>1</sup> *Proposals to Introduce a Statutory Duty of Candour for Health and Social Care Services*. See <http://www.gov.scot/Publications/2014/10/9897>.

<sup>2</sup> See, for example, the NHS Scotland Quality Strategy (<http://www.gov.scot/Publications/2010/05/10102307/0>), the Scottish Patient Safety Programme (<http://www.scottishpatientsafetyprogramme.scot.nhs.uk/>), the Scottish Care Experience Survey Programme (<http://www.gov.scot/Topics/Statistics/Browse/Health/careexperience>) and the recent reforms to the care inspection regime (<http://www.scswis.com/>).

<sup>3</sup> See The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

## 2 THE CONSULTATION RESPONSES AND RESPONDENTS

2.1 This section provides information about the individuals and organisations that took part in the consultation.

### Number of responses received

2.2 The consultation received 109 responses – 7 from individuals and 102 from organisations. (See Table 2.1.)

**Table 2.1: Number of respondents**

Type of respondent	Number of responses	%
Individuals	7	6%
Organisations	102	94%
<b>Total</b>	<b>109</b>	<b>100%</b>

2.3 Most respondents (87 out of 109) submitted comments that addressed the consultation questions. However, 22 respondents (20%) submitted comments in free text – in the form of a letter or short report. These latter responses often related to the questions in the consultation questionnaire, but most also included additional material which did not directly address the questions.

2.4 Table 2.2 below provides a breakdown of the number and type of organisations that responded to the consultation. Organisational respondents included NHS and local government organisations; third sector agencies; agencies responsible for the scrutiny and regulation of professional practice and / or services; and a range of organisations that support, train or represent health and social care professionals. A complete list of organisational respondents is included at Annex 2.

**Table 2.2: Organisational respondents**

Type of respondent	Number of responses	%
NHS organisations	25	25%
Third sector organisations	23	23%
Professional associations, support agencies & trade unions	17	17%
Local government organisations	11	11%
Scrutiny / regulatory bodies	11	11%
Partnership bodies	7	7%
Other organisational respondents*	8	8%
<b>Total</b>	<b>102</b>	<b>100%</b>

Percentages do not total 100% due to rounding.

\* Other organisational respondents included: law organisations; research and academic organisations; campaign groups; and organisations in the private sector.

## Approach to the analysis

- 2.5 The consultation questionnaire included both closed and open questions and therefore both quantitative and qualitative analysis was undertaken.
- 2.6 In relation to the closed questions, descriptive analysis was carried out to identify the number of respondents who ticked 'yes' and 'no' to express their agreement or disagreement with the individual proposals. In cases where respondents submitted their views using the consultation questionnaire, if they did not tick 'yes' or 'no' to a particular question, but then went on to make comments in relation to that question, yes / no responses have been imputed on the basis of an analysis of the respondents' comments. However, if it was *not clear* from the respondent's comments whether they agreed or disagreed with the proposal, if they expressed uncertainty about their views, if they ticked *both* 'yes' and 'no', or if their comments discussed different aspects of a particular proposal, without stating their agreement or disagreement, their response was coded as 'Other'.
- 2.7 Similarly, for the 20% of respondents who did not submit their views using the consultation questionnaire form (see paragraph 2.3 above), if their comments explicitly stated that they agreed or disagreed with a particular proposal, then a yes / no response was imputed to the associated tick-box question. The figures in the tables in subsequent chapters therefore include some imputed responses. Details about the number of responses imputed for each question are included at Annex 3.

### 3 INTRODUCTION OF A STATUTORY DUTY OF CANDOUR (Q1)

3.1 The consultation paper proposed that such a duty would apply to health and care services provided by NHS boards, local authorities, all organisations providing services regulated by the Care Inspectorate, independent hospitals and hospices, general practices, community pharmacies, dental practices and optometry practices. Views were invited as follows.<sup>4</sup>

**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?

3.2 A total of 108 respondents replied to Question 1. Table 3.1 below shows that 80% agreed with the proposal and 12% disagreed. Eight percent (8%) neither agreed nor disagreed, but expressed mixed or unclear views.

**Table 3.1: Q1 – Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation?\***

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS	18	72%	5	20%	2	8%	25	100%
Third sector	21	91%	–	0%	2	9%	23	100%
Professional associations, support agencies and trade unions	11	69%	3	19%	2	13%	16	100%
Local government organisations	8	73%	3	27%	–	0%	11	100%
Scrutiny / regulatory bodies	10	91%	–	0%	1	9%	11	100%
Partnership bodies	6	86%	–	0%	1	14%	7	100%
Other organisational respondents	6	75%	1	13%	1	13%	8	100%
Individual respondents	6	86%	1	14%	–	0%	7	100%
<b>Total</b>	<b>86</b>	<b>80%</b>	<b>13</b>	<b>12%</b>	<b>9</b>	<b>8%</b>	<b>108</b>	<b>100%</b>

Percentages do not all total 100% due to rounding. \*Question wording as in the consultation questionnaire.

3.3 Altogether, 95 respondents made comments at Question 1, and their views are discussed further below. There was significant overlap in the points raised by different respondents, regardless of their degree of overall support for the introduction of a statutory duty of candour. In addition, all respondents stated

<sup>4</sup> Question 1 was worded differently in the consultation document (page 13) and in the accompanying questionnaire. The question in the questionnaire asked for views on the introduction of the duty *in legislation*; the question in the document asked whether arrangements *should be specified in detail*. Most respondents used the questionnaire. There was evidence, however, that people answering the second version of the question had answered somewhat differently.

clear support for the principles of openness and transparency in health and social care services when things go wrong.

### **Reasons for agreeing with the introduction of a statutory duty of candour**

3.4 Respondents who agreed with the introduction of a statutory duty of candour offered different explanations for their position, with some offering explicit support for the benefits of legislative action, while others expressed support for the underlying principles and policy aims which the legislation aimed to promote. The main themes from the comments were as follows:

- Legislation was seen to be a useful lever in bringing about changes in attitudes, practices and behaviour.
- A legislative approach with detailed requirements and guidance would ensure that the principle of candour was embedded in all health and social care organisations, and that it was implemented consistently.

3.5 Respondents also occasionally offered the following views:

- A statutory duty of candour would help to promote a positive culture in health and care services by encouraging openness, honesty and transparency, and facilitate learning from adverse events. In turn, it would enhance service quality and safety, help build trust and confidence among patients and service users, and may ultimately bring about savings through reductions in complaints and claims.
- A statutory duty of candour could support and complement current regulatory arrangements, and arrangements regarding the reporting of significant adverse events.

### ***Qualifications to support***

3.6 However, respondents who agreed with the introduction of a statutory duty of candour also often qualified their support in a range of ways, stating that legislation was helpful but, in isolation, would not be enough to bring about the desired policy outcomes. They stressed that any new organisational duty of candour would need to:

- Be implemented in a way that supports the continuing shift in organisational culture which values openness, transparency, and commitment to organisational learning
- Complement existing professional codes
- Take full account of existing disclosure, scrutiny and regulatory requirements and other current policy initiatives in the patient safety, service quality and service improvement fields

- Be aligned with other legislation relevant to the health and social care fields (including that relating to data protection and human rights, and any new approach to wilful neglect and ill-treatment)
- Minimise additional administrative burden and make use of existing procedures where possible – the importance of fully resourcing the implementation of the duty was also noted.

3.7 In addition, respondents highlighted the need to:

- Clarify how the duty related to the complaints system
- Take account of the needs of all groups, including children and young people and those with reduced mental capacity and mental health issues, and the full range of health and social care settings
- Learn from systems where a duty of candour was already in place.

### **Reasons for disagreeing with the proposed statutory duty of candour**

3.8 Respondents who disagreed with the introduction of a statutory duty of candour offered reasons which largely overlapped with the points raised by those who agreed with the proposal. While this group supported the Scottish Government's stated policy aims, they did not think that a legislative solution was the best way to achieve those aims. Instead, they thought that openness with patients and service users would be best promoted through staff training, guidance and professional codes. Their main concerns were that:

- A case had not been made for introducing a statutory duty of candour, particularly in relation to the social care sector. Respondents suggested that the nature of the social care sector – with long-term care arrangements often leading to the development of positive relationships, and with well-established inspection and reporting regimes already in place – reduced the need for a statutory duty of candour.
- A statutory duty of candour would not address the issues of organisational culture which currently inhibit disclosure: Respondents thought that the introduction of the new duty, with associated monitoring and reporting requirements, could be counterproductive in bringing about positive change in this area. They identified a range of possible unintended consequences including: negative impacts on team working, creating a culture of blame and fear, encouraging risk-averse behaviour, and discouraging openness in relation to less serious events.
- The duty and its related reporting requirements would represent a burden on organisations. Respondents were concerned that the legislation was inflexible, top-down and bureaucratic and risked duplicating many existing practices and requirements. It was suggested that an emphasis on monitoring and reporting could be detrimental to learning and

improvement, whereas a regulatory regime was seen to offer more flexibility in implementation and greater scope for practice to evolve.

- The focus on ‘harm’ and more serious adverse events was thought to be unhelpful. Respondents argued that all adverse events – including minor events and ‘near misses’ which would not be captured by the legislation – provided valuable learning opportunities.

3.9 Those who disagreed with the introduction of a statutory duty of candour nevertheless went on to respond to the subsequent consultation questions offering a range of views very much in line with those of other respondents.

### **Comments on the extent to which arrangements should be specified in detail**

3.10 There were mixed views among all respondents in relation to how detailed or prescriptive the legislation should be. Some welcomed specified arrangements and consistency in practice. Others favoured less restrictive legislation which allowed for local arrangements and discretion in responding to individual cases. Still others favoured legislation based on overarching principles which would then build on existing arrangements and processes.

### **Other points raised**

3.11 Other more specific points raised by all respondents included the following:

- The current proposals did not provide sufficient clarity or detail, particularly in relation to terms such as ‘harm’ and ‘disclosable event’; there was also a view that the term ‘disclosure’ was preferable to ‘candour’.
- The proposal was less relevant and presented difficulties for certain types of services / organisations (e.g. small community-based organisations and prison health services were both mentioned).
- Any new duty would need to operate in an integrated way across the health and social care sectors.
- The legislation should require a lead person within each organisation to take responsibility for implementation and operation. An advice body for staff involved in disclosable incidents might also be helpful.
- It would be important for the public to be made aware of the new duty and its implications, and how they could raise concerns.

## 4 ENSURING STAFF HAVE THE REQUIRED SUPPORT, KNOWLEDGE AND SKILLS (Q2)

- 4.1 The consultation proposed that the statutory duty of candour should include an organisational requirement to ensure that staff involved in disclosable events have the necessary support, knowledge and skills. Respondents were asked for their views on this proposal:

**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?

- 4.2 Altogether, 97 respondents replied to Question 2. Table 4.1 shows there was near unanimous agreement with this proposal, with 98% of respondents agreeing and just 1% disagreeing. One respondent made comments that neither agreed nor disagreed with the proposal.

**Table 4.1: Q2 – 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?**

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS	23	100%	–	0%	–	0%	23	100%
Third sector	22	100%	–	0%	–	0%	22	100%
Professional associations, support agencies and trade unions	13	93%	–	0%	1	7%	14	100%
Local government organisations	10	100%	–	0%	–	0%	10	100%
Scrutiny / regulatory bodies	8	100%	–	0%	–	0%	8	100%
Partnership bodies	6	86%	1	14%	–	0%	7	100%
Other organisational respondents	6	100%	–	0%	–	0%	6	100%
Individual respondents	7	100%	–	0%	–	0%	7	100%
<b>Total</b>	<b>95</b>	<b>98%</b>	<b>1</b>	<b>1%</b>	<b>1</b>	<b>1%</b>	<b>97</b>	<b>100%</b>

Percentages do not all total 100% due to rounding.

- 4.3 In total, 83 respondents made comments at Question 2, and the views of these respondents are explored in more detail below.
- 4.4 The consultation paper referred to (i) support for staff involved in a disclosable event (i.e. the original adverse event) as well as (ii) training, supervision and support for those involved in the disclosure process (i.e. the process of

disclosing to those harmed by the original adverse event), and respondents discussed both of these situations in their comments.

### **Reasons for supporting the requirement**

- 4.5 There was a clear consensus among respondents that it was 'essential' or 'vital' to the successful implementation of the legislation that staff had the necessary knowledge, skills and support, and that organisations should be responsible for providing this. Respondents also agreed that training and support were necessary for staff to be able to perform effectively and act confidently in dealing with adverse and disclosable events. It was also argued by some that, without adequate training and support for the staff involved, the introduction of a duty of candour could do more harm than good.
- 4.6 Respondents made the following points:
- Being involved in an adverse event could be a cause of anxiety and it was important that appropriate support was provided to safeguard staff welfare and to ensure the full benefit of organisational learning was achieved.
  - Disclosing adverse events to patients / service users and their families involved dealing with difficult situations and placed particular demands on staff in terms of communication skills (verbal and written) if their duties were to be carried out sensitively and effectively.
- 4.7 Respondents emphasised the importance of organisation-wide awareness raising in connection with the new duty and development of a common understanding of what the duty entailed for all those working in the health and social care sector.

### **Comments on the wider organisational culture**

- 4.8 Respondents saw training and support for staff as intrinsically linked to the issue of organisational culture. It was argued that successful implementation of the legislation could only be achieved if organisations were seen to value and support staff in being candid. This required a commitment, by management and throughout the organisation, to honesty, transparency, openness and learning, with appropriate governance arrangements in place.
- 4.9 Training and support services were seen as important in promoting cultural values of openness and transparency, and helping staff perceive the duty of candour as a positive contribution to that culture. They were not, however, seen as sufficient in isolation.

### **Comments on training**

- 4.10 Respondents also agreed on the need for good quality training for staff. There was a view that this should be developed at a national level as a way of supporting consistency (Scottish Social Services Council and NHS Education

for Scotland were both highlighted as having a potential role), and that multi-agency delivery of training might be helpful in developing an integrated approach. Respondents identified a range of ways in which training might be delivered, including through written guidance and information covering policies and procedures, online learning resources, and intensive experiential training for those seeking to acquire advanced communication skills.

- 4.11 Respondents also provided specific comments on training requirements (as opposed to support) focusing on what might be covered in training and who would need to receive training, as discussed below.

### ***Issues to be covered in training***

- 4.12 Respondents saw training as fulfilling several functions including: (i) disseminating information about the duty of candour; (ii) ensuring staff understood what the duty entailed for organisations and individual staff members, and how it related to their professional responsibilities; (iii) training staff in the procedures to be followed; and (iv) equipping people with the verbal and written communication skills and confidence required for disclosing incidents to service users and families and preparing reports and apologies. The need for specialist skills to deal effectively with particular groups such as children and young people and those with mental and cognitive disorders was also noted.

### ***Staff requiring training***

- 4.13 Respondents took a wide view on who would require training. It was argued that anyone within the organisation could potentially be involved in or be witness to a disclosable event and should therefore be aware of the duty and the related procedures, and the support available. Thus, training should be provided to board members and senior leaders as well as managers, frontline staff of all professions, and ancillary and support staff. Training for volunteers was also mentioned by some respondents. There was a suggestion that training should be mandatory for all staff.

### ***Comments on support for staff***

- 4.14 Although respondents often talked generally about the importance of a supportive organisational culture to the successful implementation of the duty of candour, there were also comments which outlined specific types of support that should be available to staff who were involved in disclosable events. These included counselling, occupation health services and trade union support. It was seen as important that the support needs of staff were recognised at an organisational level through the adequate resourcing of appropriate services.

## **Implementing the requirement**

- 4.15 A key concern for respondents in implementing the requirement related to resources, both in terms of time and money. There was a strongly expressed view that the extent and nature of training and support required could have significant resource implications for organisations, particularly at a time of budgetary constraint. Respondents identified costs relating to the development and delivery of the training and support itself; development of related guidance; review of existing arrangements; and staff time in attending training. It was noted that the provision of training would not be a one-off event but would need to be sustained and funded on an ongoing basis.
- 4.16 While the predominant view was that implementation would require significant training and support to be put in place, there was also a less commonly expressed view that meeting these requirements would have a more limited impact on organisations. Respondents commented that many staff already had relevant skills, that training was already provided, and that the new requirement would be able to build on existing arrangements for dealing with adverse events.
- 4.17 More generally, implementing the requirement was seen as an issue for smaller organisations. Respondents particularly queried the feasibility of community-based professionals such as GPs, dentists and pharmacists operating in small or single-handed practices meeting the requirement.

## **Views of those who did not agree with the requirement**

- 4.18 The two respondents who did not agree with the proposal (one disagreed in response to the tick-box question and one expressed mixed views in their comments) did not disagree with the benefit of training and support per se, but thought that existing arrangements were sufficient or that efforts should focus on the more fundamental issue of developing a culture of openness and trust.

## 5 INFORMING AND SUPPORTING PEOPLE WHO HAVE BEEN HARMED (Q3B AND Q3C)

5.1 The consultation paper proposed there should be a requirement for organisations to inform people who have been harmed as a result of an adverse event. This requirement would involve: reporting the incident to the person harmed and / or their relatives; providing information on the steps to be taken to review the event; offering the opportunity to be involved in the related investigation; providing an apology; and providing a written record of the events and summary of the face-to-face meeting. It would also involve making an offer of reasonable support to the person who had been harmed, to their relatives and to staff involved in the event.

5.2 Two questions sought views on the proposed requirements, as follows:

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

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

### Views on the requirements to inform people who have been harmed (Q3b)

5.3 Altogether 100 respondents replied to Question 3b. Table 5.1 shows that 93% agreed that the duty of candour should require that people who are harmed are informed, while 2% disagreed. Five respondents (5%) neither agreed nor disagreed and made comments which expressed mixed or unclear views.

**Table 5.1: Q3b – Do you agree with the proposed requirements to ensure that people harmed are informed?**

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS	24	100%	–	0%	–	0%	24	100%
Third sector	22	100%	–	0%	–	0%	22	100%
Professional associations, support agencies and trade unions	14	88%	1	6%	1	6%	16	100%
Local government organisations	10	91%	–	0%	1	9%	11	100%
Scrutiny / regulatory bodies	5	83%	–	0%	1	17%	6	100%
Partnership bodies	7	100%	–	0%	–	0%	7	100%
Other organisational respondents	5	63%	1	13%	2	25%	8	100%
Individual respondents	6	100%	–	0%	–	0%	6	100%
<b>Total</b>	<b>93</b>	<b>93%</b>	<b>2</b>	<b>2%</b>	<b>5</b>	<b>5%</b>	<b>100</b>	<b>100%</b>

Percentages do not all total 100% due to rounding.

5.4 Ninety (90) respondents made comments at Question 3b, as discussed below.

***Agreement with the proposed requirement that people harmed are informed***

5.5 In general, respondents supported the principle of informing people who had been harmed as a result of an adverse event. This was seen to be in line with an open and honest approach to service delivery and care and treatment.

5.6 It was argued that those harmed often wanted 'nothing more than an explanation of what had gone wrong and to know that lessons had been learnt', and that providing information, offering an apology and providing reassurance about remedial steps taken all played a part in this.

5.7 Respondents also articulated a range of benefits for the individuals and families concerned, including providing them with:

- Help to deal with the after-effects of adverse events
- Assurance that identified failings were being addressed
- Information to allow them to make informed choices about their response to the event
- The opportunity to seek help, advice and support, and to participate in the review process.

5.8 Respondents also felt that informing those involved would have a positive impact on professional practice, patient and service-user safety, and public confidence.

5.9 Respondents often referred to existing arrangements in health and social care (professional, regulatory, organisational and legal) to inform those harmed as a result of an adverse event. The value of a consistent approach was stressed:

- There was a general view that a requirement to inform people harmed as a result of an adverse event was already included within professional duties and regulatory guidance, and that any new duty would need to reflect this.
- Several respondents cited policies and practices within their own organisations (e.g. local health boards) which already promoted good practice relating to disclosure. It was also suggested that local policies may need to be strengthened in the light of any new statutory requirement.
- Respondents emphasised the need to ensure alignment with: *the Adults with Incapacity (Scotland) Act 2000*, the *Adult Support and Protection (Scotland) Act 2007* and the *Patients' Rights (Scotland) Act 2011*.

5.10 Respondents argued that the requirement to inform should be seen within a wider context of positive and ongoing communication between health and social care professionals and service users and patients.

### ***Views on the specific requirements outlined***

- 5.11 At a general level respondents offered two views on the requirements.
- Some argued for flexibility and proportionality. There was a view that the requirements should not be prescriptive but that there should be discretion in implementation to reflect the circumstances of any particular case.
  - Others argued for the need for consistency across settings and across the country and sought clarity on a number of issues in order to achieve this.
- 5.12 These two views were not presented as mutually exclusive, with many seeking a degree of flexibility as well attaching importance to consistency.
- 5.13 In relation to exercising discretion, respondents highlighted cases where disclosure itself could be a source of harm and might not therefore in the best interests of the person affected. This was seen as a difficult issue requiring professional judgement and experience. Respondents generally agreed that any decision to not disclose should be the exception but felt it should be allowed for in the requirements. It was suggested that any such decision should be taken by a senior member of staff, and should be recorded, and open to scrutiny. It was also suggested that there should be provision to disclose to a 'nominated other' in some circumstances.
- 5.14 Respondents also commented on the specifics of the requirements outlined in the consultation paper as noted below.

### ***Timing issues***

- 5.15 Respondents thought the term 'as soon as reasonably practical' was open to interpretation and clarity was sought. They also queried the implied sequence of events, and the practicality of providing a step-by-step account of what had happened as part of the process of informing the person when this may not be possible until after an investigation had been carried out.
- 5.16 There were also questions about the extent of an organisation's obligation to inform in cases where the adverse event did not come to light immediately. It was noted that there may be difficulties in contacting people if a significant amount of time had elapsed and clarification was sought about the requirement for organisations to trace a person to carry out the disclosure. There was a suggestion of a time limit, beyond which disclosure would not be required.

### ***The 'relevant person'***

- 5.17 Respondents called for clarification as to who might be regarded as a 'relevant person' or who should be informed of harm in particular circumstances. They drew attention to incidents involving children and young people, those with reduced capacity (permanent or temporary), those with communication difficulties, and cases involving the death of a patient or

service user. They also noted the importance of allowing provision for parents, appropriate adults, relatives, guardians or those with power of attorney to be regarded as relevant persons or to be present with the relevant person when disclosure took place. Respondents were clear that disclosure arrangements should meet the needs of all such groups.

- 5.18 A small number of respondents raised the issue of incidents involving harm to staff, and suggested that there may have to be provision for disclosure arrangements to encompass colleagues and managers.

*Providing a written record / summary of the face-to-face meeting*

- 5.19 Respondents called for more detail on what would be included in such a report, the form it would take and the point at which it would be provided. There was a specific view that the summary should record details of the adverse event and include information about available support, rather than just being a record of the disclosure meeting. There were calls for guidance to be provided or minimum standards to be prescribed. More commonly, though, respondents expressed concerns about the value, practicality and resource implications of providing such written reports in all cases.

- 5.20 There were also concerns about the implications of providing a written report (and apology – see below) should a case subsequently result in a complaint, or legal claim; the specific issue of criminal liability for pharmacists was also raised. However, there was also a view that protecting the rights of patients / service users and their families should always be the prime concern, and that the information provided should not be influenced by fear of a future claim.

*Respecting the person's wishes*

- 5.21 The consultation noted the need to respect the person's wishes with regard to how much information to provide. Respondents largely agreed, stating that while the presumption should be in favour of informing those harmed, people had a right *not* to be informed if that was their preference. However, it was also suggested that determining a person's wishes should not be regarded as a one-off event but should be kept under review, and there was a suggestion that a written record of the investigation should be maintained for anyone opting not to be informed, should they wish to access information later. The importance of seeking views and respecting people's wishes with regard to who should be informed (relatives, carers, etc.) was also noted.

*The appropriate person to disclose the harm episode*

- 5.22 Respondents emphasised the need for the person disclosing the episode to be adequately trained and supported in carrying out the task. More specific points focused on who the most suitable person might be in a particular case – there was support for the notion of flexibility and capitalising on existing staff / service-user or patient relationships. However, there was also a view that the

senior professional in charge of the care and treatment should be responsible for disclosing the episode.

- 5.23 Respondents recognised the ‘diverse nature of scenarios across health and social care which will come within the scope of the duty’ and the implications this had for determining the appropriate person to disclose the episode of harm. They highlighted cases where care is delivered by a range of organisations and professionals; where the cause of any harm is difficult to pinpoint; or where the harm is attributed to an element of care and treatment such as radiology that involves little or no direct contact with the person concerned. All these circumstances, it was suggested, may give rise to difficulties in identifying the most appropriate person to disclose the harm.

#### *Providing an apology*

- 5.24 The proposed new duty would involve providing an apology. Although this was generally endorsed, respondents also had reservations. Most frequently there was a concern that an apology could be construed as an admission of liability, and respondents requested guidance on how this should be handled. It was suggested that the legislation should stipulate that an apology did not on its own equate to an admission of liability, and that this should be made clear to those involved.

#### ***Disagreement with the requirement to ensure people harmed are informed***

- 5.25 Respondents who did not agree with the proposal thought it would be difficult to demonstrate compliance with the requirement; that the requirement would have significant resource implications; and it would risk undermining public confidence. Furthermore, since existing procedures related to adverse events already require people to be informed if they are harmed, the proposal would result in no further benefit to the individual or to the general public.

#### **Views on the requirement to ensure people are appropriately supported (Q3c)**

- 5.26 Question 3c asked respondents for their views about the proposed requirements to ensure that people who have been harmed are appropriately supported following the disclosure of harm. In total, 96 respondents replied to this question. Table 5.2 below shows that 93% agreed with the proposal and 2% disagreed. Five respondents (5%) neither agreed nor disagreed, but rather expressed unclear or mixed views.

**Table 5.2: Q3c – Do you agree with the proposed requirements to ensure that people are appropriately supported?**

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS	22	96%	–	0%	1	4%	23	100%
Third sector	22	96%	–	0%	1	4%	23	100%
Professional associations, support agencies and trade unions	12	86%	1	7%	1	7%	14	100%
Local government organisations	10	100%	–	0%	–	0%	10	100%
Scrutiny / regulatory bodies	5	83%	–	0%	1	17%	6	100%
Partnership bodies	7	100%	–	0%	–	0%	7	100%
Other organisational respondents	5	71%	1	14%	1	14%	7	100%
Individual respondents	6	100%	–	0%	–	0%	6	100%
<b>Total</b>	<b>89</b>	<b>93%</b>	<b>2</b>	<b>2%</b>	<b>5</b>	<b>5%</b>	<b>96</b>	<b>100%</b>

Percentages do not all total 100% due to rounding.

5.27 Altogether, 83 respondents commented at Question 3c, as discussed below.

### ***Views of those agreeing with the requirement***

5.28 There was widespread agreement with the principle of ensuring that people were appropriately supported – some noted that providing support in such circumstances should already be part of organisational procedures and practice. Respondents noted that being involved in a disclosable event was a potentially traumatic or stressful experience for all involved – and the provision of support was variously described as ‘vital’ or ‘essential’. It was further suggested that the obligation to provide support should also extend to carers and ‘named persons’. There was a view that support should not only be offered, but that uptake should be encouraged.

5.29 The provision of support was seen as fulfilling a range of functions including: assisting with communication; helping people to understand the situation and participate in the process; and reducing the risk of the disclosure itself causing further harm. From an organisational perspective it was suggested that offering support may have the added benefit of reducing complaints as a result of improving the experience of those involved in adverse events, and allowing concerns to be dealt with more effectively.

5.30 At a general level, respondents thought people should be able to access good quality information, and both practical and emotional support. There was also a range of more specific views on the types of support which should be provided, with people wishing to see:

- An individualised approach and access to a range of options – recognising that different people would have different support needs
- The availability of support throughout – and beyond – the disclosure and investigation process, with requirement that this be kept under review
- Support for relatives and carers as well as patients / service users (albeit the individual's wishes regarding confidentiality should be respected).

5.31 Respondents also highlighted the particular needs of vulnerable groups, children and young people, and those with communication difficulties and mental disorders, and proposed the use of specialist staff and / or appropriate third parties (e.g. parents, guardians, or 'named individuals' reflecting the provisions of the *Mental Health (Scotland) Act 2003*). It was also suggested information should be provided in an appropriate format for such groups.

5.32 Although respondents often focused on the importance of specialist support services and emphasised the value of third-party independence, there was also another perspective which emphasised local solutions to providing support. Specifically, respondents highlighted the value of building on existing arrangements and relationships or the role that well-trained, sympathetic frontline staff could play in supporting people involved in adverse events.

### ***Caveats and concerns***

5.33 Respondents who agreed with the proposed requirement nevertheless expressed some concerns. These focused on: the need for clarity in the legislation; resource implications; and the application to community settings:

- There was a view that the consultation paper lacked clarity about the type of support to be provided, by whom and for how long. To aid consistency, respondents called for: clear parameters; prescribed minimum levels of support; and examples to help in the planning of services.
- Respondents highlighted the potentially significant resource implications of providing support (which may continue for some time in any one case) and noted that there could be costs for training internal staff, backfilling for staff involved in providing support, or funding support from third-party providers.
- Some respondents from the pharmacy and dental sectors thought the requirement was not practicable or meaningful in small, community-based settings and was more relevant to large organisations.

### ***Views of those disagreeing with the requirement***

5.34 Respondents who disagreed, or who did not indicate clear agreement or disagreement, generally echoed the concerns of those agreeing with the requirement. They did not think the requirement would add value to existing professional duties or good practice, or expressed concern that it would be open to interpretation, and so requested further guidance.

## 6 PUBLIC REPORTING (Q3A AND Q4)

6.1 The consultation sought views on the public reporting of disclosures which have taken place. Two questions were posed: the first sought views about the proposed requirement for public disclosure, and second about the appropriate frequency for such reporting.

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

**Question 4:** What do you think is an appropriate frequency for such reporting?

### Views on the requirement for public reporting (Q3a)

6.2 In total, 96 respondents replied to Question 3a. Table 6.1 below shows that three-quarters of these (75%) agreed that organisations should have a requirement to publically report on disclosures that have taken place, while 13% disagreed. A further 12 respondents (13%) neither agreed nor disagreed with the proposal, or expressed unclear or mixed views.

**Table 6.1: Q3a – Do you agree with the requirement for organisations to publically report on disclosures that have taken place?**

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS	19	79%	3	13%	2	8%	24	100%
Third sector	20	95%	–	0%	1	5%	21	100%
Professional associations, support agencies and trade unions	8	50%	3	19%	5	31%	16	100%
Local government organisations	9	90%	1	10%	–	0%	10	100%
Scrutiny / regulatory bodies	3	60%	–	0%	2	40%	5	100%
Partnership bodies	4	57%	2	29%	1	14%	7	100%
Other organisational respondents	3	50%	2	33%	1	17%	6	100%
Individual respondents	6	86%	1	14%	–	0%	7	100%
<b>Total</b>	<b>72</b>	<b>75%</b>	<b>12</b>	<b>13%</b>	<b>12</b>	<b>13%</b>	<b>96</b>	<b>100%</b>

Percentages do not all total 100% due to rounding.

6.3 Altogether, 90 respondents made comments at Question 3a, and these are discussed below.

### *The need for clarity regarding reporting requirements*

6.4 A strong theme across the comments from all respondents – regardless of their stated agreement or disagreement with the requirement for public

reporting – was a perceived lack of detail in the consultation paper and / or a lack of clarity in the question posed about the purpose of public reporting, and the nature of any reporting (for example, in relation to the intended audience, or the form and level of detail of reporting). Some respondents stated that they felt unable to comment because of the lack of clarity provided.

- 6.5 Specifically, respondents wanted clarity on: (i) what the requirement to report publicly would cover (e.g. information on actual incidents; policies and procedures in relation to the duty; or information on compliance with the requirements); and (ii) whether the requirement meant public dissemination of reports primarily intended for regulatory, scrutiny or internal governance purposes or publication of information specifically for a wider public audience.

### ***Views of those supporting public reporting***

- 6.6 As noted above the balance of opinion was in favour of public reporting. Respondents saw public reporting as being in line with openness, transparency and accountability in public services. There was a view that to *not* have such a requirement would be ‘at odds with a duty of candour’.
- 6.7 Respondents identified specific benefits which they saw as accruing from public reporting, for both service users and organisations. For example, it was suggested that the requirement would:
- Support patient / service-user understanding of the health and social care environment, and help maintain confidence in services
  - Empower patients / service users by providing information for those seeking care and treatment, and encouraging organisations to involve people fully in investigating adverse events
  - Support learning and improvement within and across services
  - Reduce time spent responding to Freedom of Information requests.
- 6.8 However, respondents often qualified their overall support for public reporting. Comments mainly focused on the following issues:
- The rationale for public reporting: Respondents commented that the duty was intended to benefit patients and service users through disclosing adverse incidents. Once the incident was disclosed to the person harmed, further public disclosure provided no additional tangible benefit for those directly involved, and indeed may add to stress and psychological harm. It was thus seen as important that publication was seen to achieve public value. An initial trial period for public reporting was also suggested in order to assess whether it was justified.
  - Protecting the rights and privacy of those involved: Respondents noted the need to be mindful of the impact of public reporting on those involved (patients / service users, families, and staff). This was seen as a particular

issue in rural areas or where events, and the individuals involved, might be more easily identifiable. Guidance was sought on how personal data would be protected in the reporting process, and respondents put forward suggestions for how privacy might be protected, such as: having the option to exclude individual cases from public reporting requirements; developing a 'privacy impact assessment tool'; and ensuring that service user / family wishes were taken into account in reporting.

- Interpretation of published information: There was concern that information could be misleading if taken out of context. Respondents noted that cases were often complex, could involve more than one speciality and service, and that different services were not comparable and carried inherently different risks. There were also cases which may involve issues of contested liability. Respondents were concerned that publication could lead to a 'league table' culture, with services and / or individual staff targeted by the media. It was also suggested that staff may become vulnerable to disciplinary action if organisations felt they had to take action in the face of media scrutiny. It was stressed that any release of information should emphasise organisational learning, and that systems would need to be in place for dealing with the media.
- Accessibility of published reports: Respondents stressed that any reports should be easy to locate and designed to be easily understood by the general public. They should also be available in formats suitable for those with a range of special needs.
- Unintended consequences: There was a concern that public reporting could impact on the way the duty of candour was interpreted by frontline practitioners or managers. It was suggested that the fear of public reporting (or public / media reaction to such reporting) may deter people from being candid or encourage staff to classify events in a way that avoided the duty. Respondents thought this could ultimately impact on service delivery by encouraging risk-averse culture and practice.
- Resource implications: Respondents noted that there would be resource implications in terms of staff time and related training. There was a concern that the requirement should be proportionate and additional administration kept to a minimum. The importance of avoiding duplication by aligning with other reporting requirements was noted.

6.9 These caveats and concerns were repeated in comments made by those who did not indicate clear agreement or disagreement in relation to Question 3a.

6.10 At a practical level, respondents emphasised the importance of consistency in reporting (albeit that this may allow for flexibility), and called for clarity on issues such as the content, style and timing of reports. Some respondents suggested a reporting template would help achieve consistency, and there was a suggestion for reports to be independently reviewed prior to publication.

6.11 Clarity was also sought on how the requirement would be monitored and enforced, and what the sanctions for non-compliance would be.

### ***Views of those opposed to public reporting***

6.12 Those who opposed public reporting gave reasons which largely overlapped with the caveats and concerns put forward by those supporting the proposal:

- Public reporting of disclosures was of questionable value and would provide no additional benefit to those who had been harmed by an adverse event or in relation to organisational learning. Existing reporting requirements were already in place, or information could be requested under FOI rules. Therefore, there was no need for additional reporting as part of the new duty.
- Public reporting would have resource implications for organisations.
- Public reporting would be counterproductive in developing a culture of openness and continuous improvement, and could lead to individual staff or organisations classifying events in ways which avoided the requirement to report. Respondents thought public reporting should focus on identifying themes and implications for service improvement rather than the number or detail of individual cases.
- Public reporting could have a negative impact on public confidence in health and care services with the risk that information could be misinterpreted when taken out of context.

### **Views on the frequency of public reporting (Q4)**

6.13 Question 4 in the consultation paper sought views on the frequency of public reporting, inviting comment in relation to annual, bi-annual or quarterly reporting. Altogether 78 respondents replied to Question 4. Table 6.2 below shows that the majority (48 out of 78, 62%) were in favour of annual reporting.

**Table 6.2: Q4 – What do you think is an appropriate frequency for reporting?**

<b>Respondent type</b>	<b>Annually</b>	<b>Bi-annually</b>	<b>Quarterly</b>	<b>Other</b>	<b>Total</b>
NHS	13	2	–	5	20
Third sector	8	1	6	2	17
Professional associations, support agencies and trade unions	5	1	2	3	11
Local government organisations	9	–	1	–	10
Partnership bodies	6	–	–	–	6
Scrutiny / regulatory bodies	2	–	–	1	3
Other organisational respondents	1	–	1	3	5
Individual respondents	4	–	2	–	6
<b>Total</b>	<b>48</b>	<b>4</b>	<b>12</b>	<b>14</b>	<b>78</b>

### ***Support for annual reporting***

- 6.14 Annual reporting was, by and large, seen as ‘manageable’, ‘proportionate’ and ‘reasonable’. A key theme in the comments was the need to balance the potential resource implications of public reporting with the benefits of openness and effective scrutiny. Annual reporting was seen to deliver this.
- 6.15 On a more practical level, respondents believed that annual reporting would allow time for cases to conclude and, in some cases, for legal action to be resolved. It would also allow time for organisations to assess the incident and identify any learning points.
- 6.16 Some respondents suggested that annual reporting would align well with other reporting requirements – in particular, the NHS annual review process, and requirements regarding reporting of NHS complaints and feedback.
- 6.17 Others highlighted potential disadvantages of more frequent reporting which, it was suggested, may be perceived as punitive by staff involved in incidents; would make it harder to protect the identity of those involved; and would be too onerous for smaller organisations.
- 6.18 Some of the respondents who supported annual reporting nevertheless suggested that more frequent public reporting may sometimes be merited. It was suggested that this may depend on the type of organisation, while others suggested this may apply in more specific circumstances, for example:
- In ‘high-volume’ health settings
  - For incidents that merited speedy escalation to the public domain
  - On reaching a specified threshold for the number of incidents disclosed
  - On request, in response to particular circumstances.
- 6.19 Those who favoured annual public reporting often suggested that this could be supplemented by more frequent *internal* reporting – operating as part of organisational (or partnership) governance mechanisms. It was also pointed out that many incidents that might give rise to a duty of candour in the social care sector would be reported to the Care Inspectorate almost immediately.

### ***Support for bi-annual reporting***

- 6.20 Those favouring bi-annual reporting suggested that this would allow enough time for investigations to conclude, or would be ‘sufficient’ if public disclosure was required as part of the legislation.

### ***Support for quarterly reporting***

- 6.21 Comments made by those who favoured quarterly reporting were similar to the comments made by those who supported annual reporting, i.e. they suggested this was reasonable or proportionate without being overly

bureaucratic. Respondents also made reference to existing reporting requirements: several third sector respondents offered the requirement to report incidents in the social care field to the Care Inspectorate within 24 hours as a benchmark; while a professional body referred to the requirement for quarterly submission of complaints reports under the *Patients' Rights (Scotland) Act 2011*. However, two slightly different views offered by this group were that regular (i.e. quarterly) reporting was merited because it reflected the seriousness of the issue or because it would allow speedy identification of common themes.

### ***The view of those opposed to public reporting***

6.22 Several respondents opposed to, or with concerns about, public reporting nevertheless indicated a preferred frequency for reporting. The objective of aligning with other existing reporting requirements was a common theme in the views of this group, although those opting for annual reporting also thought that this was the most practical or least onerous option. Two respondents commented that the question assumed agreement with the principle of public reporting.

### ***Views of those not indicating a clear preference for frequency of reporting***

6.23 Respondents who did not indicate a clear preference for frequency of reporting offered comments which reflected those made by other respondents, focusing on: (i) the lack of clarity about the purpose of public reporting; (ii) the need to balance the burden on organisations with the benefits of openness and public confidence; and (iii) the benefits of aligning with existing local governance arrangements, and other sector-specific disclosure and reporting duties or scrutiny activities.

### ***Other points relating to frequency of reporting***

6.24 Additional points made by respondents in relation to frequency of reporting were as follows:

- Some called for a flexible approach to reporting, suggesting that frequency should take account of the level of harm experienced in any incident; the perceived level of risk; or the evidence of previous failure to disclose.
- Others suggested a two-stage approach, combining immediate reporting to a regulatory body in the first instance, followed by subsequent public reporting. There was also a suggestion that the regulatory body could collate reports for quarterly or annual reporting.
- There were also suggestions for: (i) a fixed timetable for reporting and (ii) a time lag (e.g. two months) to allow investigations to conclude prior to reporting being required.

## 7 STAFFING AND OTHER RESOURCES (Q5)

- 7.1 The consultation paper invited views on the staffing and resources which would be required if a statutory duty of candour was introduced:

**Question 5:** What staffing and resources would be required to support effective arrangements for the disclosure of instances of harm?

- 7.2 Altogether, 84 respondents provided comments at Question 5. Those not responding tended to be organisations such as professional associations and scrutiny bodies which do not have a service delivery function.

### **General views on resource implications**

- 7.3 Respondents frequently expressed concern about the potential resource implications of a statutory duty of candour. This issue was raised repeatedly across *all* the consultation questions, as well as in response to Question 5.
- 7.4 Respondents noted that health and social care organisations were already under financial pressure, and that there was little spare capacity within existing teams to take on additional duties. There was a concern that meeting the duty of candour requirements could impact on frontline services.
- 7.5 There was also, however, a less common view that the resource implications would be marginal, particularly beyond the initial set-up phase, and would be accommodated within existing budgets. Respondents who offered this view felt that: many of the activities envisaged as part of the duty of candour requirements were already undertaken within health and social care services; there was already substantial relevant experience and expertise within the health and care workforce so training requirements would be limited; and there was scope to make use existing mechanisms and systems.
- 7.6 A third, much less common view, was that the duty may in the longer term have a positive impact on costs as a result of a more open culture, reduced complaints, reduced legal claims, and service improvements achieved as a result of learning from disclosable events.

### ***Uncertainties in considering staffing and resource implications***

- 7.7 A key theme in the views put forward was the perceived difficulty in considering resource implications at this stage because of the number of 'unknown' factors and other influencing variables. These included:
- The detail of what would be required under the legislation: without this, respondents thought it was not possible to be sure about the types of

activities that staff would have to undertake or that organisations would have to fund, or the extent of any flexibility in meeting the requirements.

- A clear definition of what would constitute a 'disclosable event': without this it was not possible for organisations to estimate the number of cases they may have to deal with or the potential demands on staff
- Official guidance or expectations relating to staffing arrangements
- The possible impact on insurance premiums, legal claims and compensation pay-outs.

7.8 In addition it was felt that all cases would be different, each requiring different staff and other input on a case by case basis.

7.9 Some respondents also highlighted the fact that the resource implications would vary depending on the type of organisation. In particular, the requirements could have a disproportionate impact on smaller organisations, given that larger organisations were more likely to already have access to relevant expertise and systems. Thus, smaller organisations may need support in developing practices to meet their obligations under the legislation. In addition, the resources put in place would have to be service-specific, and in large organisations, tailored to individual specialities and departments.

### ***Involvement of non-frontline services***

7.10 Although respondents generally commented on the resource implications for frontline services, some also highlighted costs for other organisations that might have a role in supporting the delivery of the duty of candour. These included NHS Education for Scotland and the Scottish Social Services Council in relation to training and education, and regulatory bodies such as the Care Inspectorate. It was also suggested that Adult Protection Committees might take a role in supporting and monitoring duty of candour activities. Therefore, resource implications would be dependent on how the roles of these organisations / groups were specified.

### ***Suggestions for minimising costs***

7.11 Respondents suggested ways of minimising resource implications through: providing an online system for reporting incidents; sharing resources and developing joint solutions for smaller organisations; using existing systems and processes where possible (e.g. linking with those already in place for responding to adverse events); and providing national guidance, training resources and reporting templates.

### ***Specific staffing and resource requirements***

7.12 The most common resource issues highlighted were in relation to staffing and staff training. However, respondents also discussed the potential cost of initial

implementation activities; support services for service users and staff; and ongoing administrative costs. The main points raised are noted below.

### ***Implementation activities***

- 7.13 Respondents identified a range of set-up activities which would need to be undertaken and resourced if the legislation was introduced. These included reviewing and developing policies and procedures, producing information and guidance, developing and delivering training, and establishing IT systems.

### ***Staffing***

- 7.14 Respondents anticipated a wide range of staff contributing to meeting duty of candour obligations. These include: frontline clinical and service delivery staff, senior and supervisory staff and those at leadership level in organisations. There were suggestions that roles might include (at a senior-level) a duty of care 'lead'; a compliance officer; and a duty of candour 'champion'. The point was made that there would also be implications for backfilling posts where staff members were removed from normal duties to deal with adverse events.

### ***Training***

- 7.15 Most commonly respondents envisaged a combination of staff-wide and specialist training, but it was pointed out that training requirements would vary depending on whether a generic or specialist approach to duty of candour activities was adopted.
- 7.16 Respondents anticipated a significant requirement to invest in initial staff training to ensure that all employees were aware of the new duty and the roles and responsibilities associated with it. However, it was also thought that training would need to be provided on an ongoing (possibly annual) basis.

### ***Support services***

- 7.17 Views about the costs of providing support services have been covered in detail in earlier sections and are not repeated here. In summary, respondents thought that support for staff (e.g. trade union support, counselling and psychological services, occupational health services) and support for service users / patients and their families (e.g. counselling, advocacy, chaplaincy, independent medical advice) would need to be put in place.

### ***Ongoing administrative support and other costs***

- 7.18 Respondents noted the need for ongoing administrative support, particularly in relation to reporting. Other potential costs related to the needs for: (i) legal advice (i.e. regarding the development of apologies and responding to any subsequent claims made); (ii) communications support in publicising the new duty of candour; and (iii) accommodation for training and support sessions.

## 8 DISCLOSABLE EVENTS

8.1 The consultation document set out a definition for ‘disclosable events’ as follows: ‘an unintended or unexpected event that occurred or was suspected to have occurred that resulted in death, injury or prolonged physical or psychological harm being experienced by a user of health and / or social care services’. The consultation document also provided a list of events that might be considered to be disclosable events. However, it was noted that definitions would be developed and informed through dialogue with health and social care professions. The following questions were asked:

**Question 6a:** Do you agree with the disclosable events that are proposed?

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

**Question 6c:** What definition should be used for ‘disclosable events’ in the context of 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?

### Definition of ‘disclosable events’ (Q6a)

8.2 Question 6a asked respondents if they agreed with the ‘disclosable events’ proposed in the consultation document. Altogether, 97 respondents replied to this question. Table 8.1 below shows that 59% agreed, and just over a quarter (26%) disagreed. Fifteen respondents (15%) neither agreed nor disagreed with the proposed ‘disclosable events’ and made comments which were unclear or which expressed mixed views on the issue.

**Table 8.1: Q6a – Do you agree with the disclosable events that are proposed?**

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS organisations	14	58%	8	33%	2	8%	24	100%
Third sector organisations	16	80%	2	10%	2	10%	20	100%
Professional associations, support agencies and trade unions	7	44%	7	44%	2	13%	16	100%
Local government organisations	2	20%	7	70%	1	10%	10	100%
Scrutiny / regulatory bodies	4	50%	–	0%	4	50%	8	100%
Partnership bodies	6	86%	1	14%	–	0%	7	100%
Other organisational respondents	3	43%	–	0%	4	57%	7	100%
Individual respondents	5	100%	–	0%	–	0%	5	100%
<b>Total</b>	<b>57</b>	<b>59%</b>	<b>25</b>	<b>26%</b>	<b>15</b>	<b>15%</b>	<b>97</b>	<b>100%</b>

Percentages do not all total 100% due to rounding.

- 8.3 Most third sector respondents indicated agreement with the disclosable events proposed, while opinion was more divided among NHS organisations and professional associations, support agencies and trade unions. Most local government organisations did *not* agree with the events proposed.
- 8.4 Altogether, 80 respondents made comments at Question 6a. A number of recurring themes could be identified in these comments, and these were the same, irrespective of whether respondents had indicated agreement or disagreement with the question. People who answered ‘no’ to Question 6a expressed a range of concerns about the disclosable events proposed, and these *same* concerns were also raised by people who answered ‘yes’. It is therefore not entirely clear from respondents’ comments why some respondents agreed with this question and others did not.
- 8.5 Similarly, respondents whose comments were categorised as ‘Other’ in Table 8.1 above, frequently raised the same issues. This group suggested that they needed further clarification of the disclosable events before they could offer an opinion.
- 8.6 The key themes raised by all respondents are discussed below.

#### ***Aspects of the proposals with which respondents agreed***

- 8.7 Those who indicated agreement at Question 6a often prefaced their comments by saying that they welcomed the basic principle of having a definition of a disclosable event. Moreover, they supported the threshold for a disclosable event being set at a high level. Respondents thought that it was important to have greater transparency and openness with patients; but at the same time they also believed it was important that services should not worry patients about every minor service failure or ‘near miss’. Respondents were concerned that the introduction of a statutory duty of candour should not result in undermining public confidence in the care system.
- 8.8 Respondents welcomed the statement in the consultation document that definitions would be developed and informed ‘through dialogue with health and social care professions, taking due recognition of the different context, nature and requirements of health and social care settings’.

#### ***Comments and concerns about definitions***

- 8.9 However, irrespective of whether respondents ticked ‘yes’ or ‘no’ at Question 6a, they raised concerns about the definition given in the consultation document of a ‘disclosable event’. While many comments focused on the specific examples of disclosable events set out in the consultation document, respondents also made more general comments, including that the definition of a ‘disclosable event’ was ‘not clear’, ‘too vague’, ‘needed more detail’, was

'subjective' and was 'open to interpretation'. It was also common for respondents to state that the examples given in the consultation document were 'too health focused', or 'too heavily weighted to medical, as opposed to social care, events'.

- 8.10 Respondents called for greater clarity in relation to the definitions of 'unintended', 'unexpected', 'prolonged', 'injury' and 'harm'. Concerns were particularly voiced about how 'psychological harm' would be defined in the context of adults who lack capacity and / or those suffering from a mental illness. However, the definition of 'harm', in general, was also thought to require further clarification, and some respondents suggested that the Scottish Government should consider the definitions of different types of harm set out in the *Adult Support and Protection (Scotland) Act 2007*. Others commented on the difficulty of identifying and measuring 'harm', particularly in relation to adults who lack capacity, which could often be the subject of differences of opinion between clinicians, patients and carers.
- 8.11 Respondents also acknowledged the inherent difficulty of defining a set of disclosable events that would be applicable across all branches of medicine, and in both health and social care services. There was also a particular concern raised about the possible implications for social care settings where appropriate risk-taking among service users is encouraged.
- 8.12 Some respondents argued that any definition of a disclosable event must 'make sense to service users', as the proposed duty of candour is primarily for the benefit of service users, not service providers.

### ***Concerns and queries about the proposed disclosable events***

- 8.13 In general, respondents queried, or explicitly disagreed with, the examples of disclosable events given in the consultation document. Some went on to describe scenarios in which such events would *not* be considered to be adverse but, rather, would be reasonable and appropriate responses in a clinical context.
- 8.14 There was a suggestion that the inclusion of a timescale associated with each event would be necessary, and that it would be clearer that the events listed in the consultation document were 'disclosable events' if each one included the phrase: 'resulting from clinical error' (e.g. 'Return to surgery *resulting from clinical error*').

### ***Unintended consequences***

- 8.15 Respondents were concerned about the possible unintended consequences of the proposals. (Most of these were already raised in relation to Question 1 – see Chapter 3 above.) These could include the following:

- Depending on the definitions adopted, there could be a large volume of disclosable events which far exceed current complaints.
- The proposals could create ‘another layer of bureaucracy’ on top of current processes and remove healthcare professionals from frontline care.
- The result will be a ‘compliance and reporting culture’ rather than the open, transparent culture which the duty of candour seeks to foster.
- Health (and social care) professionals might be blamed for events that are outside their control.

### ***Other possible disclosable events***

- 8.16 There were also some suggestions that the loss of personal data should be included as a disclosable event, and that disclosable events should not only include those that resulted in *actual* harm to an individual, but also those that were *suspected* of having caused harm, or that have the *potential* to cause harm. However, it was more common for respondents to say that the duty of candour should focus on ‘high-threshold’ events in which an individual suffered actual harm.
- 8.17 Finally, there was a question about whether ‘neglect’ (in the context of an inappropriate level of care provided to an older person at home) should be considered to be a ‘disclosable event’.

### ***Other suggestions***

- 8.18 There was also a suggestion that a term other than ‘disclosable event’ should be used – to avoid confusion with the legal disclosure process in litigation, and to avoid implying that only certain events *can* be disclosed.
- 8.19 Finally, respondents saw the benefit of having a system to facilitate sharing of information about disclosable events between different areas, as this would support collective awareness and learning from these events.

### **Whether the disclosable events are applicable and identifiable in all care settings (Q6b)**

- 8.20 Question 6b asked respondents if the disclosable events proposed in the consultation document would be clearly applicable and identifiable in all care settings. Altogether, 89 respondents replied to Question 6b. Table 8.2 shows that around a third (31%) agreed, but nearly half (47%) disagreed. A fifth of respondents neither agreed nor disagreed, or made comments which expressed mixed or unclear views.

**Table 8.2: Q6b – Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings?**

Type of respondent	Yes		No		Other		Total	
	n	%	n	%	n	%	n	%
NHS	10	42%	11	46%	3	13%	24	100%
Third sector	6	32%	6	32%	7	37%	19	100%
Professional associations, support agencies and trade unions	4	24%	11	65%	2	12%	17	100%
Local government organisations	2	20%	7	70%	1	10%	10	100%
Partnership bodies	1	17%	4	67%	1	17%	6	100%
Scrutiny / regulatory bodies	–	0%	1	33%	2	67%	3	100%
Other organisational respondents	2	40%	2	40%	1	20%	5	100%
Individual respondents	3	60%	1	20%	1	20%	5	100%
<b>Total</b>	<b>28</b>	<b>31%</b>	<b>42</b>	<b>47%</b>	<b>18</b>	<b>20%</b>	<b>89</b>	<b>100%</b>

Percentages do not all total 100% due to rounding.

8.21 While NHS and third sector respondents were divided in their views on Question 6b, professional associations / trade unions, local government organisations and partnership bodies tended to disagree.

### ***Respondents' reasons for agreeing***

8.22 Not all respondents who agreed that the proposed disclosable events would be clearly applicable and identifiable in all care settings provided further comment. Only 16 respondents in this group did so, and in most cases, these comments offered no additional information about the respondent's views or their reasons for agreeing with the question.

### ***Respondents' reasons for disagreeing***

8.23 Respondents who disagreed that that the proposed disclosable events would be clearly applicable and identifiable in all care settings generally made fuller and more detailed comments than those who agreed. These respondents gave a range of reasons for disagreeing, including that:

- The proposed disclosable events lacked clarity, and would be interpreted differently by different people.
- Not all of the proposed events would result in harm to a patient or service user and therefore would not require disclosure. Moreover, the same event could have varying effects on different people.
- The proposed events were too focused on acute healthcare services. Respondents thought that further work was needed to identify events relating to social care, primary care, other health services, and third sector or independent sector services.

### ***Other comments on the definition and applicability of disclosable events***

- 8.24 While a few respondents believed that ‘when harm has occurred, this will be clearly identifiable’ whatever the care setting, it was far more common for respondents (particularly those in local authority and NHS settings, as well as those who work with adults with incapacity) to highlight the difficulties of: a) identifying harm; and b) attributing harm to a single specific cause. Respondents pointed out that events such as unplanned hospital readmissions or delayed discharges can result from a number of interconnected issues involving a range of agencies. These respondents queried which organisation would have the duty of candour in such cases.
- 8.25 The predominant view among respondents was that it is unlikely to be possible to create a single, exhaustive list of all disclosable events which would apply across all care settings. Respondents generally believed that disclosable events would have to vary between care settings, and that ‘context’ would be an important factor in determining whether a disclosable event had occurred.
- 8.26 Several respondents queried whether and how the duty of candour would apply to care settings such as:
- Third sector, independent agencies and personal assistants delivering care at home (through self-directed support arrangements)
  - Scottish Ambulance Service
  - Single-handed GP practices, where the responsibility would fall on an individual rather than an organisation
  - Dental practices
  - Opticians
  - Care homes (where service users are very frail and elderly and suffer from a range of complex conditions)
  - Foster care and child-minding services.
- 8.27 One pharmacy respondent suggested that pharmacists could easily define adverse events for their own profession. However, other professions, such as radiology, would find it difficult because of the inherent ‘error’ that exists in certain areas of medicine.
- 8.28 There was also a question about *who* within an organisation would be responsible for deciding when a disclosable event had occurred.

### ***Suggestions from respondents***

- 8.29 As noted above, some respondents suggested that an attempt to develop a list of disclosable events would be impossible. There were suggestions that the definition of a disclosable event should be linked to processes that health and social care professionals were already familiar with – for example, (as

previously noted) in health, this could be linked to 'adverse event' reporting, and in social care, it could be linked to notifications to the Care Inspectorate. The Mental Welfare Commission's notification guidance was also referred to as 'a useful example of how disclosable events may be consistently defined in relation to care and treatment delivered in different settings'.

- 8.30 Respondents thought it would be helpful if a 'decision tool' could be developed to assist with the process of identifying disclosable events.

#### **'Disclosable events' in children's social care (Q6c)**

- 8.31 Question 6c in the consultation document asked respondents for their views on what definition should be used for 'disclosable events' in the context of children's social care services. Around half of all respondents (n=54) answered this question, and there was disagreement among respondents about this issue.
- 8.32 Some thought that any such definition should be developed by professionals and other experts who work in this area (including Children's Panel members) – and with children and young people themselves. However, others argued that the *same* definition should be used for 'disclosable events' in adult and children's services. This latter group argued that many of the issues that arise in children's social care services are the same as those that arise in services for adults who lack capacity.

#### ***Defining 'disclosable events' in children's social care services vs defining principles***

- 8.33 Some respondents attempted to define a set of disclosable events for children's social care services. For example:
- 'Services being slow to react, resulting in a child's exposure to neglect being prolonged'
  - 'Undue delays in permanency planning and completion as a result of practice or resourcing decisions'
  - 'Incomplete implementation of a child's plan resulting in serious harm'
  - 'Physical, psychological and sexual abuse of children while in care'
  - 'Any instance where the child is left feeling vulnerable – where there are breaks in care'
- 8.34 Others suggested a set of principles or criteria that could be used to determine whether a disclosable event had taken place. For example:

- ‘Harm could be defined as anything not in the best interests of the child (where SHANARRI indicators are not being met)’<sup>5</sup>
- ‘The same criteria as for a significant case review... unintended or unexpected death of a child receiving health or social work services’<sup>6</sup>
- ‘Any incident which causes a child significant physical or psychological harm, or significant actual or anticipated material or other loss’
- ‘Should focus on harm resulting from corporate culpability rather than on unintended consequences resulting from decisions taken in good faith’.

8.35 Respondents thought that any definition or guidance about disclosable events for children’s social care services should take into account and be consistent with Getting it Right for Every Child (GIRFEC) and other child protection policies, children’s rights (UN Convention on the Rights of the Child), and legislation related to the Protecting Vulnerable Groups (PVG) scheme.

### ***Issues and concerns***

8.36 Respondents raised a range of issues and concerns about the attempt to define ‘disclosable events’ in the context of children’s social care services. In some cases, these echoed similar concerns expressed by respondents regarding disclosable events in other types of services. For example:

- There needs to be some consideration about whether disclosing information to the child – and / or their family – could result in an increased risk to the child’s safety. There was a view that the child’s opinion should be sought before disclosing certain information to parents / guardians.
- There are likely to be some difficulties in identifying any single cause for psychological trauma among children taken into care. There are also likely to be challenges in assessing pain in children who have communication difficulties, and the cause and effect of harm in children with serious long-term physical health problems.
- The proposed statutory duty of candour risks duplicating existing systems linked to child protection procedures.
- There was a question about which services the duty of candour would apply to, and a view that it would be anomalous if it applied to nurseries and after-school clubs, but not to primary or secondary schools.

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<sup>5</sup> SHANNARI: Safe, Healthy, Achieving, Nurtured, Active, Respected, Responsible and Included.

<sup>6</sup> See National Guidance for Child Protection Committees for Conducting a Significant Case Review (updated guidance presently out for comment).

## **Supporting effective mechanisms to determine if disclosable harm has occurred (Q7)**

- 8.37 Question 7 in the consultation document asked: 'What are the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred'?
- 8.38 Altogether, 88 respondents replied to this question, with the following issues identified as needing to be addressed. It should be noted that much of this has already been discussed in detail in relation to earlier questions.

### ***Need for clear definitions***

- 8.39 First and foremost, respondents wanted greater clarity about the definition of a 'disclosable event'. It was suggested that definitions and processes should be consistent with those in existing legislation (both child and adult protection legislation).

### ***Need for training and guidance for staff***

- 8.40 Staff training and clear (written) guidance were both seen to be key in helping staff to feel confident to recognise when an event needs to be disclosed. Respondents thought that specialist training should be provided to staff involved in disclosing information to patients / service users, and to staff responsible for managing follow-up procedures. It was also suggested that guidance should include: examples of disclosable events, examples of exclusions, case studies, and a decision tree.

### ***Need for advisors***

- 8.41 Respondents thought it would be helpful to have an individual within their own organisation (for example, a senior clinician, senior manager or a designated 'Disclosable Harm Officer'), or an independent, external organisation (for example, the Care Inspectorate or Healthcare Improvement Scotland) to provide advice about whether a disclosable incident had occurred. The benefit of having an independent organisation acting in this capacity is that it would ensure that agreed definitions were being interpreted consistently across different areas.
- 8.42 There was a view that there may also need to be some form of arbitration – for example in cases where there was disagreement among staff / teams about whether a disclosable event had occurred.

### ***Need for organisational policies and procedures to support the identification of disclosable events***

- 8.43 Respondents thought that there would need to be robust systems and processes in place, which are integrated with existing adverse events and risk management policies. Methods for measuring the impact of a disclosable

event on the patient (both the immediate and longer term impacts) were also thought to be needed.

- 8.44 There was a suggestion that it would also be helpful to have a framework to enable shared learning about disclosable events, both within and across organisations.
- 8.45 Respondents also raised issues about communication processes, since there is the possibility that a disclosable event could be identified, not by the service that caused the initial unintended harm, but rather by a different service. Respondents thought there would need to be mechanisms in place to ensure that communication with other relevant professionals takes place prior to the disclosure of the event. There was also a suggestion that the patient's GP should be informed about the event.
- 8.46 Finally, although not directly related to the question of mechanisms for determining if a disclosable event had taken place, respondents also thought there would be a need for standard systems and procedures for *reporting* disclosable events, as well as IT systems to support this. Several respondents referred to their experience of using the DATIX system for recording and reporting adverse events.
- 8.47 Related to the issue of reporting, respondents wanted clarification about *who* would have responsibility for reporting on disclosable events – i.e. which organisation and at what level of the organisation – particularly in the context of integrated services.

### ***Need for organisational capacity and resourcing***

- 8.48 Respondents commented that organisations would need to have both the capacity and the resources to ensure that disclosure takes place. The need for additional resources was identified – to develop and disseminate organisational policies on disclosable events, and to ensure that patient care does not suffer as a result of complying with the proposed duty of candour.

### ***Need for a culture of transparency and of learning from mistakes***

- 8.49 Respondents commented that an important factor in determining whether a disclosable event had taken place was the existence of a culture in which open and honest communication was the norm, and where there was no fear of disclosure. Some respondents suggested that a duty of candour would be part of a “Just Culture” ethos.<sup>7</sup> The point was made that the establishment of such a culture would require support from management at the very top level of organisations.

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<sup>7</sup> <https://www.justculture.org/getting-to-know-just-culture/>

8.50 However, there was also a contrasting view that the creation of legislation requiring professionals to demonstrate genuinely open communication would result in no more than 'a box-ticking exercise'.

***Need to inform and raise awareness among patients / service users and carers***

8.51 Finally, respondents saw a need for communication with members of the public. There were several aspects to this communication:

- Members of the public would need to be informed about the duty of candour
- There needs to be scope for service users to be involved in the process of identifying 'harm'.
- There needs to be some consideration about how to involve a service user's family or carers if the service user lacks capacity.
- Consideration will have to be given to continuity of care for individuals who have been inadvertently harmed if the individual does not wish to continue to receive care from the responsible healthcare professional.

8.52 There was a concern that communication with patients / service users about disclosable events would need to be done carefully, as there would otherwise be a risk of reinforcing a 'blame culture'.

## 9 MONITORING THE STATUTORY DUTY OF CANDOUR

- 9.1 The consultation document stated that the proposed duty of candour would apply to all providers of health and social care, and would be monitored through existing performance monitoring, regulation and / or scrutiny arrangements that apply to organisations. These differ for different organisations.
- 9.2 The consultation document then set out the existing roles of the Scottish Government, Healthcare Improvement Scotland and the Care Inspectorate as these would relate to monitoring the implementation of the duty of candour.
- 9.3 Respondents were asked two questions on these issues.

**Question 8:** How do you think the organisational duty of candour should be monitored?

**Question 9:** What should the consequences be when it is discovered that a disclosable event has not been disclosed to the relevant person?

### How should the duty of candour be monitored? (Q8)

- 9.4 Altogether, 91 respondents replied to Question 8, and in general, respondents agreed that the monitoring of the duty of candour should take place through existing arrangements. Respondents described this proposal as ‘pragmatic’ and ‘proportionate’, and suggested that it ‘would avoid additional burdens being placed on the health and social care sector or taxpayers’. Respondents were also concerned that if a *new* monitoring system was set up, it would cause duplication and confusion.
- 9.5 However, respondents also highlighted some issues in relation to this proposal. In particular, there were concerns that Healthcare Improvement Scotland (HIS) and the Care Inspectorate (CI) have slightly different functions, and this could result in inconsistency in the way the duty of candour is monitored in health and social care services. There were calls for greater clarity about how, exactly, the proposed monitoring function would fit within the remit of HIS specifically. There were a few respondents who thought it would be preferable to have a *single* organisation responsible for monitoring across health and social care (to ensure consistency).
- 9.6 The response from the Care Inspectorate raised a concern that the process of monitoring compliance with the duty of candour could have the potential to be very onerous for the organisation. Therefore, it was suggested that the requirement to monitor compliance should not be necessary at every inspection of a care service. There was also a concern that the CI may not be currently equipped or resourced to make judgements about the range of

complex medical issues that might be raised in monitoring compliance with a statutory duty of candour.

- 9.7 Some respondents suggested that other bodies should also (or instead) have a role in monitoring the duty of candour, including: the relevant regulators for each professional body, and a *new* body with representation from both professional and lay people. Finally, it was suggested that the role of the national Adult Protection Coordinator could be enhanced to assist with the task of monitoring.
- 9.8 Respondents made a range of suggestions about other ways in which the duty of candour could be monitored. These included:
- Through existing organisational governance arrangements, including adverse event reporting, performance management reporting, and through published (publicly accessible) reports – the development of a national audit tool was also suggested
  - Through staff appraisals and development reviews, and through regular anonymised staff surveys
  - Through patient / service user feedback, including the record of the discussion with patients / service users in adverse event reviews
  - Through the establishment of an external independent agency to whom dissatisfied patients / families could refer concerns about incidents of harm which had not been disclosed, or concerns about an organisation's handling of a disclosed event.
- 9.9 There were also suggestions about how compliance with the duty of candour could be measured, for example, through:
- Evidence of staff being trained and adequately supported
  - Having a named individual (or named individuals) with responsibility for ensuring compliance
  - Audits of random samples of complaints, claims and incident reports
  - Investigations into alleged breaches of the duty.
- 9.10 Finally, there was a view that it would be helpful if there could be an initial period of allowing organisations to become familiar with applying the duty of candour before any monitoring / enforcement arrangements are put in place.

### ***Concerns about monitoring compliance with the duty of candour***

- 9.11 Respondents raised a number of concerns about the monitoring and enforcement of the duty of candour. These largely related to the practicalities of enforcement, and the potential for unintended consequences

- 9.12 Some respondents suggested that the duty of candour would be difficult to enforce, and / or difficult to enforce consistently – particularly given the very wide range of ‘disclosable events’ proposed in the consultation document, and the requirement for a subjective assessment about whether harm had occurred.
- 9.13 Others felt that the statutory duty of candour had the potential to be counter-productive: that it would become a ‘box-ticking exercise’, that the task of monitoring and reviewing would result in the creation of ‘a new industry’ that would divert funds away from clinical services; and that it would undermine openness, transparency and candour because of the fear of possible negative consequences (sanctions or penalties) to individuals and organisations.
- 9.14 As noted previously in the discussion on Questions 6 and 7, there were also repeated requests for clarification about *who* the duty of candour would apply to in relation to: a) commissioned services delivered by the third or private sector; and b) integrated services delivered jointly by health and social care.

#### **The consequences of NOT disclosing a disclosable event (Q9)**

- 9.15 Question 9 asked respondents for their views on what the consequences should be when it is discovered that a disclosable event had not been disclosed to the relevant person. Altogether, 89 respondents answered this question.
- 9.16 In general, respondents thought that consequences for not disclosing a disclosable event should be in line with existing procedures and processes. Where an individual member of staff was responsible for a breach of the duty, it was thought that the individual should be subject to the organisation’s disciplinary procedures and, if a registered health or social care professional, referred to the appropriate professional regulator. It was thought that organisational accountability should be at chief executive / director level.
- 9.17 There was a view that, if it was discovered that a disclosable event had not been disclosed, then there should be an immediate disclosure (even if it relates to an historical event); a senior manager should meet with the relevant person or relatives; and an apology should be given.
- 9.18 It was less common for respondents to explicitly suggest that some form of investigation should take place, although this idea may have been implicit in the views of respondents who thought that existing procedures and processes should be followed. In general, those who discussed the idea of a formal investigation were concerned that there may be a deliberate attempt to hide or ‘cover up’ a disclosable event.
- 9.19 Respondents generally thought that the main consequence of a breach of the duty of candour should be for an improvement plan to be put in place – that the incident should be treated as a learning opportunity, and remedial action

taken to address the reasons for the failure to disclose. Some of those who suggested this course of action felt that the focus should be on the factors contributing to the breach of duty (i.e. inadequate staff training and support), rather than on the individual's failure to comply.

- 9.20 There was also a relatively common view that there should be increasing sanctions for persistent non-compliance – and moreover, that these sanctions could apply both to the organisation (i.e. fines, or cuts in public funding), or to the individual (criminal or civil penalties, loss of registration, etc.).
- 9.21 Other respondents thought that the consequences should depend entirely on the circumstances. For example, was this a one-off failure, or was there evidence of repeated and persistent non-compliance? Was the breach of the duty due to inadequate training and knowledge among staff, or was it a deliberate withholding of information?
- 9.22 Some respondents argued that the use of sanctions – either against the individual or the organisation – would be unhelpful and 'illogical'. This group thought that fines or other financial sanctions against the organisation would only disadvantage patients and risk safety. Similarly, the threat of legal action against individuals for a failure to comply with a duty of candour would be unlikely to encourage greater openness and transparency.

## 10 OVERVIEW OF CROSS-CUTTING THEMES

10.1 Chapters 3 to 9 of this report have presented respondents' views in relation to the questions set out in the consultation document. The questions sought views on the introduction of a statutory organisational duty of candour in health and social care settings in Scotland and on specific aspects of the introduction and implementation of such a duty. Across the questions, however, there were a number of recurring themes in the responses which could be seen both in the comments of those agreeing with the proposals and the comments of those disagreeing. These are drawn together in this final chapter of the report, providing an overview of the issues that respondents believed needed to be considered in any further policy development work.

### The wider context

10.2 In general, respondents of all types saw the (continuing) development of a culture of openness and honesty as key to ensuring safe, high-quality health and social care services in Scotland. It was this openness and honesty which would support organisational learning and service improvement. Some saw the proposed legislation as helpful in promoting and supporting such a culture, while others saw it as potentially counterproductive. However, the general consensus amongst those broadly supportive of the introduction of the new duty was that it could not, on its own, be an effective lever for change. Change would require a clear message from management at all levels that openness and honesty were valued and encouraged.

10.3 A key theme in the responses was the importance of taking account of existing legislation and regulatory and professional requirements, as well as current initiatives relating to the development of policy and practice in this area. Respondents generally supported the introduction of the new duty – seeing it as complementary to existing arrangements – but were clear about the need for learning and alignment wherever possible to support a consistency of approach.

10.4 There was a strong view that the proposals were too health-focused. Respondents thought the duty and its implementation had to take full account of the entire health and social care landscape, particularly in the light of moves towards service integration. This meant that the duty had to fit the circumstances of health *and* social care services; the primary and secondary sectors; large and small (included single-handed) organisations; and a full range of professions and specialisms.

### A person-centred approach

10.5 Respondents largely agreed that being candid with patients / service users when something went wrong should be inherent to a person-centred approach to service provision. It should reflect a positive relationship based on open

communication between professionals and service users at all stages of care and treatment (e.g. in explaining care options and treatment risks). The duty of candour, thus, had to be developed to meet the needs of patients and services users, and that it should not result in worrying people unnecessarily about minor incidents. It was stressed that it would be important for the public to be aware of the duty and what it entailed, that the disclosable events should be meaningful to non-professionals, that those harmed were actively involved and supported at all points in the disclosure process, and that public reporting took account of the needs of a wide audience.

### **Equality considerations**

- 10.6 The importance of taking account of the needs of different equality groups was raised by respondents in relation to a range of questions. The groups referred to most often were children and young people, those with communication difficulties and those who lacked mental capacity. It was argued that written information (e.g. summaries of disclosable events, information on sources of advice and guidance, public reports) should be provided in suitable formats for different groups, and that support should be provided by appropriately trained staff. It was further suggested that the provisions to inform 'relevant persons' should allow for carers, parents / guardians or 'named' persons to accompany or represent a harmed person. This would ensure that all groups understood and had the opportunity to be fully involved in proceedings.

### **Clarification and consistency**

- 10.7 There were repeated calls for clarification in relation to specific aspects of the proposed new duty, its requirements and its implementation. In particular, respondents called for clarity about the definition of a 'disclosable event'; this was seen as crucial to the operation of the duty. However, clear definitions were also sought for terms such as 'relevant person', 'as soon as reasonably practical', and 'reasonable support'. Further information was also sought on issues such as the detail and format of written summaries and public reporting requirements.
- 10.8 The need for consistent application (albeit this might involve a degree of flexibility) across organisations and settings was highlighted, with clarity of definitions seen as one factor in achieving this. Respondents also called for a range of resources which would assist in achieving consistent implementation. These included: accompanying guidance with examples and case studies; national training courses and materials; and the development of templates for recording and reporting disclosable events.

## **Unintended consequences**

- 10.9 Concern was expressed both by those in favour and those opposed to the proposed new duty about possible unintended consequences. These included the impact on professional practice and organisational culture; on compensation claims and litigation; and on public confidence in services.
- 10.10 In relation to professional practice and organisational culture, there was concern the new duty might lead to risk-averse decision-making in care and treatment, a tendency to classify events in ways which avoided the need for disclosure and the encouragement of a 'blame' culture with attention focused on the individuals involved in disclosable events. There was also concern that the definition of disclosable events might move attention away from the learning opportunities presented by less serious incidents and 'near misses'. In terms of claims and litigation, there was concern that any increase could impact on resources for services and in turn could impact on professional practice and organisational culture. Those concerned about undermining public confidence highlighted the need for careful handling of the public reporting requirements.

## **Resources**

- 10.11 The resource implications for organisations in implementing a duty of candour were raised by respondents across all the consultation questions. Frontline staffing and staff training were seen as the key resources issues, although respondents also highlighted the resource implications of administrative, communication and system support, management input, and the provision of support services. In general, respondents argued that the resource implications would be significant and ongoing, and would impact disproportionately on smaller organisations.
- 10.12 It was also argued by some that a poorly resourced duty would 'do more harm than good'. There was a general plea that minimising the burden on organisations should be a key objective in developing the proposed requirements further, for example, in making use of existing procedures and systems for recording events and in setting the frequency of reporting.

## **Development and implementation of the legislation**

- 10.13 Finally, across the consultation there were calls for further consultation with stakeholder groups – particularly in relation to the definition of disclosable events. A range of respondents noted interest in contributing to the further development and implementation of an organisational duty of candour.

## ANNEX 1: CONSULTATION QUESTIONS

- Q1 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)
- Q2 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)
- Q3a Do you agree with the requirement for organisations to publicly report on disclosures that have taken place? (Yes / No)
- Q3b Do you agree with the proposed requirements to ensure that people harmed are informed? (Yes / No)
- Q3c Do you agree with the proposed requirements to ensure that people are appropriately supported? (Yes / No)
- Q4 What do you think is an appropriate frequency for such reporting? (Quarterly / Bi-annually / Annually / Other)
- Q5 What staffing and resources would be required to support effective arrangements for the disclosure of instances of harm?
- Q6a Do you agree with the disclosable events that are proposed? (Yes / No)
- Q6b Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings? (Yes / No)
- Q6c What definition should be used for 'disclosable events' in the context of children's social care?
- Q7 What are the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred?
- Q8 How do you think the organisational duty of candour should be monitored?
- Q9 What should the consequences be if it is discovered that a disclosable event has not been disclosed to the relevant person?

## ANNEX 2: ORGANISATIONAL RESPONDENTS

### NHS (25)

- Child Protection Nurse Midwife and Allied Health Professionals Scotland Group
- Golden Jubilee National Hospital (NHS National Waiting Times Centre)
- Healthcare Improvement Scotland
- National Steering Group for Cervical Cytology
- NHS 24
- NHS Ayrshire and Arran
- NHS Ayrshire and Arran, Adult Community MH Services (9 staff members)
- NHS Borders, Area Nursing and Midwifery Committee (BANMAC)
- NHS Education for Scotland
- NHS Forth Valley
- NHS Forth Valley - Allied Health Professions Professional Support Group (short life working group )
- NHS Grampian, Mental Health & Learning Disability Services
- NHS Greater Glasgow & Clyde
- NHS Greater Glasgow and Clyde, Nursing and Midwifery
- NHS Health Scotland
- NHS Highland
- NHS Lanarkshire
- NHS Lothian (2 responses)
- NHS National Services Scotland
- NHS Scotland Directors of Pharmacy Group
- NHS Tayside
- NHS Tayside Pharmacy Service
- Scottish Ambulance Service
- The State Hospital

### Local government organisations (11)

- Aberdeenshire Council
- Argyll and Bute Council
- Convention of Scottish Local Authorities (COSLA)
- East Dunbartonshire Council
- Falkirk Council Social Work Services

- North Ayrshire Council
- North Lanarkshire Council and NHS Lanarkshire (joint response)
- Perth and Kinross Council
- South Ayrshire Council, Adult Community Care
- South Lanarkshire Council
- West Lothian Council

### Partnership bodies (7)

- East and Midlothian Public Protection Committee
- East Renfrewshire CHCP Clinical Governance Group
- Fife Health and Social Care Partnership
- Glasgow City Community Health Partnership and Glasgow City Council Social Work Services
- North Ayrshire Health & Social Care Partnership
- North Ayrshire Public Partnership Forum (PPF)
- Renfrewshire Child Protection Committee (RCPC)

### Professional bodies (17)

- British Association for Counselling and Psychotherapy
- British Dental Association
- British Medical Association (BMA) Scotland
- Community Pharmacy Scotland
- Council of Deans of Health & SHANAHP (Scottish Heads of Academic Nursing, Midwifery, and Allied Health Professions).
- Guild of Healthcare Pharmacists
- Institute of Chartered Secretaries and Administrators (ICSA)
- Medical and Dental Defence Union of Scotland
- Medical Defence Union
- Medical Protection Society
- Royal College of Nursing Scotland
- Royal College of Physicians & Surgeons of Glasgow
- Royal College of Physicians of Edinburgh

- Royal College of Radiologists
- Royal College of Speech and Language Therapists (RCSLT)
- Royal Pharmaceutical Society
- Unison

#### **Scrutiny / regulatory body (11)**

- Care Inspectorate
- General Chiropractic Council
- General Dental Council
- General Medical Council
- General Pharmaceutical Council
- Health Foundation
- Information Commissioner's Office
- Mental Welfare Commission for Scotland
- Professional Standards Authority
- Scottish Public Services Ombudsman
- Scottish Social Services Council (SSSC)

#### **Third sector service user care and support organisations (23)**

- Action against Medical Accidents (AvMA)
- Alzheimer Scotland
- British Red Cross
- CHILDREN 1ST
- Coalition of Care and Support Providers in Scotland (CCPS)
- CrossReach
- ENABLE Scotland
- Health and Social Care Alliance (the ALLIANCE)
- HUG (Action for Mental Health)
- Marie Curie
- National Carer Organisations
- National Pharmacy Association Ltd
- National Society for the Prevention of Cruelty to Children (NSPCC) Scotland
- PAMIS
- Parkinson's UK in Scotland
- Quarriers
- Royal Blind
- Salvation Army
- Scottish Care
- Scottish Infected Blood Forum
- Scottish Independent Advocacy Alliance

- Scottish Independent Hospital Association
- United Kingdom Homecare Association (UKHCA)

#### **Other (8)**

- Association of Personal Injury Lawyers (APIL)
- BLM
- The Company Chemists Association
- Law Society of Scotland
- Napier University, Centre for Mental Health and Incapacity Law Rights and Policy
- Patients First Scotland
- Picker Institute Europe
- WithScotland

### ANNEX 3: DETAILS OF IMPUTED RESPONSES

	Yes	Imputed yes	No	Imputed no	Other (not imputed as yes or no)	Total responses	Total responses imputed	% of responses imputed
Question 1	75	11	10	3	9	108	14	13%
Question 2	87	8	1	0	1	97	8	8%
Question 3a	65	7	11	1	12	96	8	8%
Question 3b	83	10	2	0	5	100	10	10%
Question 3c	80	9	2	0	5	96	9	9%
Question 6a	52	5	21	4	15	97	9	9%
Question 6b	27	1	37	6	18	89	7	8%

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