Consultation on Proposals to Introduce a Statutory Duty of Candour for Health and Social Care Services

October 2014

The Scottish Government
Riaghaltas na h-Alba

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1. INTRODUCTION

1.1. This consultation invites views on proposals to introduce legislation that will require organisations providing health and social care in Scotland to tell people if there has been an event involving them where the organisation has recognised that there has been physical or psychological harm as a result of their care or treatment.

1.2. "Transparency – especially when things go wrong is increasingly considered necessary to improving the quality of health care. By being candid with both patient and clinicians, health care organizations can promote their leaders' accountability for safer systems, better engage clinicians in improvement efforts, and engender greater patient trust"[1]

1.3. However barriers to being open after serious safety incidents have been identified to include fear, worry, embarrassment and lack of institutional support. [2]

1.4. Although much of the international evidence and current practice in this area has focussed on health services, it is proposed that in Scotland this duty will apply to providers of both child and adult social care services as well as health services.

2. Background

2.1. The Berwick Report[3] emphasised the importance of the requirement that people affected by serious incidents should be notified and supported.

2.2. It is internationally recognised that between 10-25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event.[4] However, it has been recognised that as few as 30% of incidents resulting in harm are disclosed to people who have been affected. Denial and dismissal of mistakes often results in distress and people spending several years seeking the truth, accountability and apology.[5]

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[1] Kachalia, A (2013) "Improving Patient Safety through Transparency", *New England Journal of Medicine*, 369, 18, 1677.

[2] Pinto, A., Faiz, O., & Vincent, C. (2012). Managing the after effects of serious patient safety incidents in the NHS: an online survey study. *BMJ quality & safety*, qhc-2012.

[3] Department of Health (2013). A promise to learn – a commitment to act: improving the safety of patients in England. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf (Accessed 03rd October 2014)

[4] The Health Foundation (2011). Evidence scan: Levels of Harm. Available at: http://www.health.org.uk/publications/levels-of-harm/ (Accessed 21st September 2014),

[5] Halligan, A. W. F. (2014). Implications for medical leaders of the proposed Duty of Candour. *Clinical Risk*, *20*(1-2), 29-31.

2.3. Improvements in arrangements to support the disclosure of harm, is a key element supporting a continuously improving culture of safety.[6] There are several healthcare systems and organisations worldwide that have introduced initiatives or arrangements to support open disclosure of harm. For example:

- In early 2002, the Michigan Healthcare System changed that way that it responded to instances of patient harm and injury. The public declaration on the requirement for honesty and transparency was subsequently associated with a steady reduction in the numbers and costs of clinical claims being made.[7] When claims were made, the time taken for processing or settlement of such claims was reduced. It has been suggested that this may also impact positively on psychological and physical recovery.

- The Australian Healthcare System has a National Open Disclosure Standard that requires all adverse incidents to be disclosed.[8]

- In the USA, Baystate Health[9] and the Veterans Health Administration[10] are two further healthcare systems who have implemented systems that required disclosure.

2.4. From November 2014 the Care Quality Commission in England will include the duty of candour among the standards to be met by healthcare providers in England. These will form part of the inspection and monitoring regime operating in England. This includes a range of new enforcement powers, including civil penalties and criminal proceedings for repeated failures. The duty of candour will also apply to adult social care services in England from April 2015.[11]

2.5. We want to introduce an organisational duty of candour in Scotland. This will require services to make sure that they are open and honest with people when something has gone wrong with their care and treatment resulting in harm. It will also require training and support to be provided for staff involved with disclosure and support to be available to people who have been affected by an instance of harm.

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[6] Etchegaray, JM., Gallagher, TH., Bell, SK et al. (2012). Error disclosure: a new domain for safety culture assessment. BMJ Quality and Safety, 21, 594-599.

[7] Boothman, R. C., Imhoff, S. J., & Campbell Jr, D. A. (2012). Nurturing a culture of patient safety and achieving lower malpractice risk through disclosure: lessons learned and future directions. *Frontiers of health services management*, *28*(3), 13.

[8] Fletcher, M, Barraclough, B., Bate, J. et al. (2003). New wine in old bottles: a national standard for open disclosure – the Australian experience. Clinical Risk, 9, 225-228.

[9] Peto, RR, Tenerowicz, LM, Benjamin, EM et al (2009). One System's Journey in Creating a Disclosure and Apology Program, The Joint Commission Journal on Quality and Patient Safety, 35, 10, 487-496.

[10] Eaves-Leanos, A., & Dunn, E. J. (2012). Open disclosure of adverse events: transparency and safety in health care. *Surgical Clinics of North America*, *92*(1), 163-177.

[11] The duty of candour applies only to adult social care services in England as the Care Quality Commission does not regulate child social care services.

2.6. The introduction of a statutory duty of candour would support a move toward a planned, co-ordinated and consistent approach that supported respectful disclosure of episodes of harm. This is a central element of good practice for adverse event management. Research in this area has identified that there is a gap between that which is regarded as good practice in respect of disclosure and reality. Statutory reform has been recognised as an important element that is likely to support improvements.

2.7. Any new duty will need to be reflective of and aligned with existing disclosure requirements. For example, social care services already work within a framework where statutory reporting requirements (e.g. for child protection, vulnerable adults) necessitate reporting of harm episodes. In addition people accessing social care services tend to have established longer term relationships with professionals that support candour in practice.[12]

2.8. It has been recognised that disclosure of harm requires advanced communication skills. Programmes have been developed to improve the preparation of doctors to make such disclosures, and to deal with emotional elements that are linked with this task.[13] The content of these programmes is equally relevant and applicable to other care professionals.

2.9. Healthcare professionals have raised concerns that schemes supporting disclosure may undermine their professionalism. Others have expressed concerns that introduction of requirements for candour to legislation would cause fear among healthcare professionals that would not be conducive to their work to improve the quality and safety of services. There are a range of factors that have been consistently shown to facilitate disclosure of harm and some that impede disclosure. The most commonly reported factors are outlined below:

Known Barriers to Disclosure[14]

Fear
Culture of secrecy and/or blame
Lack of confidence in communication skills
Fears that people will be upset
Doubt that disclosure is effective in improving culture

[12] 'Duty of Candour – An Adult Social Care Perspective. Think Local. Act Personal. http://www.thinklocalactpersonal.org.uk/_library/The_Duty_of_Candour_-_an_Adult_Social_Care_Perspective_March_2014.pdf (Accessed 26th September 2014)

[13] Bonnema, R. A., Gonzaga, A. M. R., Bost, J. E., & Spagnoletti, C. L. (2012). Teaching error disclosure: advanced communication skills training for residents. *Journal of Communication in Healthcare*, *5*(1), 51-55.

[14] Iedema, R., Allen, S., Sorensen, R., & Gallagher, T. H. (2011). What prevents incident disclosure, and what can be done to promote it? *Joint Commission journal on quality and patient safety*, *37*(9), 409-417.

Factors Facilitating Disclosure[15]

Accountability
Honesty
Restitution
Trust
Reduction re Risk of Claim

Factors Inhibiting Disclosure[16]

Professional or institutional repercussion
Legal liability
Blame
Lack of confidentiality
Negative family reaction

[15] Kaldjian, L. C., Jones, E. W., & Rosenthal, G. (2006). Facilitating and impeding factors for physicians' error disclosure: a structured literature review. *Joint Commission Journal on Quality and Patient Safety*, *32*(4), 188-198.
[16] Kaldjian, L. C., Jones, E. W., & Rosenthal, G. (2006). Facilitating and impeding factors for physicians' error disclosure: a structured literature review. *Joint Commission Journal on Quality and Patient Safety*, *32*(4), 188-198.

3. Proposals in this consultation paper

3.1. The Scottish Government intends to introduce a statutory requirement on organisations providing health and social care to have effective arrangements in place to demonstrate their commitment to disclose instances of physical or psychological harm. The proposals have been intentionally focused on an organisational duty. The introduction of this duty will form a further dimension of the arrangements already in place to support continuous improvements in quality and safety culture across Scotland's health and care services.

3.2. This consultation paper invites views on proposals that are intended to support a consistent approach to disclosure of events that have resulted in physical or psychological harm to users of health and social care services. In particular the proposals build on the progress made through the implementation across NHSScotland of the 'Learning from adverse events through reporting and review: A national framework for NHSScotland'[17] The testing that is currently ongoing within NHSScotland on 'Being Open' guidance is also likely to be helpful in framing stakeholder engagement and the further development of proposals.[18] There are also elements of the review of significant case reviews in Scotland regarding disclosure and involvement of families that will inform the scope and detail of proposed legislation.[19]

3.3. This paper has been divided into the following chapters:

Chapter 1 - Existing approaches regarding candour
Chapter 2 - Proposed requirements on organisations
Chapter 3 – Disclosable events
Chapter 4 - Monitoring of the statutory duty of candour
Chapter 5 - Responding to this consultation paper
Chapter 6 - The Scottish Government consultation process

[17] http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=3b248733-5f86-4379-9a28-35beae432004&version=-1 (Accessed 25th September 2014)
[18] http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=784df33e-be1a-4b63-9516-3d2edf31ada8&version=-1 (Accessed 26th September 2014)
[19] http://www.scotland.gov.uk/Publications/2012/10/5974/2 (Accessed 25th September 2014)

4. CHAPTER 1: Existing approaches regarding candour

4.1. There has been strong support for the benefits of improving organisational arrangements for disclosure of harm in recent years. The Dalton-Williams review[20] clearly outlined the expectations that all those involved in caring roles have a responsibility to be open and honest to those in their care. The recommendations from this review are summarised below from 4.2 to 4.4.

4.2. Organisations should support the development of a culture that values and supports staff to be candid. Providing health and social care services is associated with risk and things will inevitably go wrong from time to time. When this happens, people want to be told honestly what happened, what will be done in response, and to know how actions will be taken to stop this happening again to someone else in the future. This is one of a series of actions that should form part of organisational focus and commitment to learning, improvement and support of a culture where there is psychological safety.

4.3. Organisations must ensure that there is a clear commitment to ensure that a culture of candour is built as part of a wider culture of safety, learning and improvement. This includes the development of a process to ensure candour and open disclosure, systems and processes to assure that actions arising from learning are implemented and that staff are trained and support in work to improve a culture of candour.

4.4. The review recommended that there should be a statutory duty on organisations and that this would provide a powerful signal of what is considered essential and this should act as an important catalyst for care organisations to improve their systems and commit to a learning culture for their staff.

4.5. Healthcare Improvement Scotland have visited all NHS Boards in Scotland as part of the national programme supporting learning following adverse events. This confirmed that there is variation across the country in respect of the rigour and standard of open disclosure and support for families and staff when harm occurs.

4.6. Extracts from the review reports illustrate the variation that currently exists across the NHS in Scotland:

> "The three significant cases showed evidence of a consistent, robust approach to the involvement of patients and families throughout the process"

[20] https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf (Accessed 25th September 2014)

"…there was no consistent approach for involving patients, families and carers in the incident investigation, or a systematic process for documenting these events."

"Of the four cases we reviewed, only two documented some level of engagement with the family or relatives"

"We were unable to identify from the policy how NHS Board X actually involves patients, families or carers in investigations of adverse events"

"However the level of support provided to staff was sometimes variable"

"The level of engagement with the patient or family varied across the six cases"

"Most policies lacked guidance on how to involve stakeholders and there were significant inconsistencies in practice"

4.7. The observations made by Healthcare Improvement Scotland are consistent with observations from work that has shown that ethical and policy guidance has largely failed on its own to improve rates of disclosure.[21]

4.8. The 2013 Health and Care Survey[22] asked respondents whether they believed a mistake was made in their treatment or care by their GP practice. 6% of respondents believed such a mistake had been made in their treatment or care. Of those that felt a mistake had been made in their treatment or care:

7% indicated that it did not require a response

Of those that required a response:

19% were completely satisfied with how it was dealt with
44% were satisfied to some extent
38% of those where were not satisfied

4.9. The Care Inspectorate regulate around 14,000 care services including care homes, care at home, childminders, daycare of children, adoption and fostering, housing support, secure care, school accommodation, nurse agencies, and offender accommodation. All services are required to notify the Care Inspectorate of the death of a service user and the circumstances of the death under The Regulation of Care (Requirements as to Care Services) (Scotland) Regulations 2002. Additional requirements are placed on providers of care home services to notify the Care Inspectorate of any serious injury of a

[21] O'connor, E., Coates, H. M., Yardley, I. E., & Wu, A. W. (2010). Disclosure of patient safety incidents: a comprehensive review. *International Journal for Quality in Health Care*, , 22(5), 371-379..
[22] http://www.scotland.gov.uk/Resource/0045/00451272.pdf

service user, accident or any allegation of misconduct by the provider or any person who is employed by the care service.

4.10. For care services registered on or after 1 April 2011, additional notification requirements are in place. These are not specified in legislation, but are determined by Care Inspectorate under the terms of the Social Care and Social Work Improvement Scotland (Registration) Regulations 2011 and includes accidents, incidents or injuries to a person using a service. The Care Inspectorate regards accidents requiring notification as unforeseen events resulting in harm or injury to a person using the service which results in a GP visit or a visit or referral to hospital. An incident is defined as a serious, unplanned event that had the potential to cause harm or loss, physical, financial or material. The Care Inspectorate also requires notification of allegations of abuse in relation to a person using a service. These additional notification requirements relate to all services regulated by the Care Inspectorate except childminders.

4.11. Ethically and morally health and care professionals are already required to tell people about instances of harm. However of the eight UK wide professional regulatory bodies only the General Medical Council (GMC) and Nursing and Midwifery Council's (NMC) standards explicitly require their registrants to be candid with people harmed by their practice. The General Pharmaceutical Council has a standard that requires their registrants to respond 'appropriately' when care goes wrong however it does not specify that this involves being candid with the patient. As a result the NMC has been working with the GMC to develop guidance on candour on behalf of all of the regulators. The Professional Standards Authority is overseeing this work, with the intention that all the regulatory bodies will undertake to modify their codes of conduct and guidance to reflect a common position on candour.

5. CHAPTER 2: Proposed requirements on organisations

5.1. The statutory duty of candour would apply to health and care services provided by NHS Boards, Local Authorities, all organisations providing services regulated by the Care Inspectorate, independent hospitals, independent hospices, General Practices, community pharmacies, dental practices and optometry practices. As this is an organisational duty, it would not apply to individuals providing services, for example, childminders.

5.2. The statutory duty will require that an organisation must act in an open and transparent way with people when things go wrong. It will outline the minimum requirements that must be in place to support the duty of candour and require that reports are made to describe the implementation of arrangements.

6. What would be required of organisations?

6.1. As soon as it is reasonably practicable after becoming aware that there has been adverse event resulting in harm, the organisation must ensure that the relevant person is notified that this has happened. This will involve the provision of a step by step account of the facts of what happened, including as much or as little information as the person has expressed their wish for.

6.2. If an organisation becomes aware of an event that has resulted in harm after a period of more than a month after the index event, the relevant person should also be provided with an explanation for the delay and the organisation should identify the actions necessary to improve systems for the monitoring and reporting of harm.

6.3. There must be an offer of reasonable support provided to the person harmed, relatives and staff who have been involved with the event. The person undertaking the disclosure may be different for each disclosure episode. It is recognised that this flexibility will be required to reflect the importance of existing relationships with care professionals and the diverse nature of scenarios across health and social care that will come within the scope of the duty.

6.4. The responsibility will rest with organisations to ensure that all staff who are asked to be involved with disclosure have access to the relevant training, supervision and support before, during and after their involvement with disclosure communications.

6.5. The notification that is made to the relevant person should be given personally by a suitably trained representative of the organisation and should include an account of all of the facts known at the time of disclosure and the plans for the event to be reviewed. It will be for the organisation to determine who is most appropriate to disclose the harm episode.

6.6. The relevant person must be informed of the further steps to be taken to review the event and be given the opportunity to have their questions considered by the review process.

6.7. The organisation must provide an apology and must confirm all of the actions taken in a written record. The contents of this will inform the regular public reports of disclosable events and organisational response to these.

6.8. The relevant person must also receive a written summary of the face to face meeting.

7. Reporting on Disclosure Arrangements

7.1. All organisations would be required to report publically on the nature of adverse incidents that have been disclosed to people and confirm that requirements of the organisational duty of candour have been met.

7.2. Organisations would also be required to report on the ways in which they have supported staff in the development and maintenance of the skills required to ensure respectful disclosure by staff who are required to be involved with this.

7.3. Organisations should also publish annually their policies and procedures to support openness and transparency, this must include the arrangements in place to support staff training and development in these advanced communication skills. These reports should be submitted to the relevant organisation (which will differ for each care provider).

7.4. Organisations would be required to ensure that they have arrangements in place to ensure that if any adverse event/incident is reported that this is considered and a decision made whether this is a disclosable event.

7.5. Organisations would also be required to include a summary in their reports of the support that is available to patients, families and staff following an disclosable event. They would also need to describe the provision to ensure that training and development support has been implemented to ensure best practice in disclosure.

7.6. Guidance will be produced to assist organisations in implementation of the organisational duty of candour, which will include resources to support the process of notification, staff support and public reporting.

7.7. In many cases the requirements of organisations (disclosure, support and reporting periodically) will already be in place through local procedures for handling complaints or responding to adverse events/significant events, thereby minimising additional administrative demands on organisations. For example, NHS Boards already receive and monitor reports from GP practices on complaints and significant events. Social care services already have procedures in place to report on harm in respect of children and vulnerable adults.

8. Summary of Organisational Requirements for Duty of Candour

- Identify instances when there has been an event resulting in physical or psychological harm.
- Report the occurrence of these instances in person to the relevant person.
- Apologise.
- Offer the opportunity to be involved in review of the events.
- Offer access to emotional and practical support following the event (to staff, patients and relatives).
- Confirm in writing the details of the personal discussion.
- Have arrangements to ensure that those involved with disclosure have the necessary knowledge and skill to undertake this work.
- Identify and inform relevant person of the learning that was identified following the disclosure and review of the adverse event.
- Report publically (according to an agreed frequency) on all 'disclosable events', including on details of the organisational training and support arrangements in place to deliver the organisational duty of candour. The learning and improvement actions arising from disclosable events would also be included.
- If there have been delays in being notified of an instance of harm, organisations should report on actions being taken to improve on monitoring and reporting arrangements.

Question 1: Do you agree that the arrangements that should be in place to support an organisational duty of candour should be specified in detail ?

Question 2: Should 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 ?

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

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 ?

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

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

9. CHAPTER 3: Disclosable events

9.1. In order for organisations to implement effective arrangements for disclosure of episodes of harm, they need to be clear about the definition of harm that will be used to decide when disclosure is appropriate. The statutory duty of candour legislation would include a nationally agreed definition of the types of harm that would trigger the organisational duty of candour. These definitions need to be developed and informed through dialogue with health and social care professions, taking due recognition of the different context, nature and requirements in health and social care settings.

Definitions of Adverse Events Resulting in Harm

9.2. In healthcare, the National Framework for Adverse Events has proposed that it is possible to define episodes of harm considering events in accordance with the impact on the person who has experienced the event. The following definitions were proposed:

9.3. Category I – Events that may have contributed to or resulted in permanent harm, for example death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHSScotland risk assessment matrix, or category G, H or I from National Co-Ordinating Council for Medication Error Reporting (NCCMERP) index).

9.4. Category II – Events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as minor or moderate impact on NHSScotland risk assessment matrix).

9.5. These definitions rely on reference to the NHSScotland Risk Assessment Matrix and NCCMERP Index. These definitions are wider in scope than that proposed for the new legislation, for example an 'Extreme' event in the Risk Assessment Matrix would include an event that attracted national media coverage – which may not necessarily reflect that there had been an episode of physical or psychological harm. Equally these definitions may not work intuitively for social care provision.

9.6. It is recognised that there is not a consistent approach to definition of what constitutes an adverse event where disclosure should take place. We have also recognised that each instance must be considered on its individual merits, taking account of the specific clinical and care elements of individual care episodes.

9.7. Organisations would require to demonstrate through their reporting that they have arrangements in place to consider events in relation to the agreed definition of physical or psychological harm, and that when they have determined harm has not occurred the decision-making process that has informed this decision.

9.8. The issues that will need to be taken into account in considering what constitutes a disclosable event are outlined in this chapter. This will need to encompass the different contexts that influences safety and harm incidents within health and social care services.

Disclosable event

9.9. Disclosable events would be defined as 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.

9.10. Disclosable events in relation to health care would involve the death of someone receiving care where the death relates to the event itself (as opposed to the natural course of their illness or underlying condition).

9.11. Events involving harm that involve the permanent lessening of bodily, sensory, motor, physiological or intellectual functions (including removal of the wrong limb or organ or the occurrence of brain damage) would be disclosable.

9.12. Returns to surgery, an unplanned re-admission to hospital, a prolonged episode of care, extra time in hospital or as an out-patient, cancellation of treatment or transfer to intensive care should also be included within the scope of events that result in harm.

9.13. Prolonged pain and prolonged psychological harm also needs to be taken into account when framing definitions (e.g. prolongation for a continuous period of 28 days).

9.14. The shortening of the life expectancy of someone using social care services would be disclosable. If a user of social care services required treatment by a healthcare professional in order to prevent death this should come within the scope of the duty to disclose. The occurrence of an injury that, if left untreated would lead to death, impairment, harm or shortened life expectancy would also be within the scope of disclosable events for social care providers. This would not include a shortening of life expectancy as a result of a long-term condition where this is an expected outcome.

9.15. Children's social care services, alongside keeping children safe, are primarily focused on a child developing as well as it can and reaching his or her full potential. Decisions taken to that effect, such as taking children into care, may have unintended consequences, though it may not always be possible to attribute trauma to any particular action.

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 ?

10. CHAPTER 4: Monitoring of the statutory duty of candour

10.1. The proposed organisational duty of candour would be monitored through the existing performance monitoring, regulation and/or scrutiny arrangements that apply to the organisation. This will differ according to the organisation responsible for the provision of care. This has been proposed in recognition of the importance of embedding organisational requirements within existing mechanisms that are already familiar to providers of health and social care. The consequences that will be applied to those who do not demonstrate that they are implementing a duty of candour will vary depending on the organisation concerned.

10.2. The duty of candour is to apply to all providers of health and social care. The intention is to consider the extent to which such a duty can be monitored using the existing regulatory mechanisms in Scotland. These are outlined below in respect of Scottish Government, Healthcare Improvement Scotland and the Care Inspectorate. Disclosure, reporting and follow-up of harm episodes is regarded as a key dimension of good corporate governance and, as such, it is expected that the proposed new duty will support and enhance existing provisions already in place.

Scottish Government

10.3. National Health Service (Scotland) Act 1978 states that it shall be the duty of each Health Board to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals. This is referenced in regulations governing services provided by independent contractors such as General Practitioners (National Health Service (General Medical Services Contracts) Regulations 2004) and pharmacists (National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009).

Healthcare Improvement Scotland

10.4. Healthcare Improvement Scotland (HIS) was created through the Public Services Reform (Scotland) Act 2010, which amended the National Health Service (Scotland) Act 1978 ("the 1978 Act"), on 1 April 2011. The HIS strategic plan 2011-2014 sets out the purpose for the organisation as;

> "Our purpose is to support healthcare providers in Scotland to deliver high quality, evidence-based, safe, effective and person-centred care; and to scrutinise those services to provide public assurance about the quality and safety of that care."

10.5. The 1978 Act places a number of statutory duties upon HIS, including:

- a general duty of furthering improvement in the quality of healthcare
- a duty to provide information to the public about the availability and quality of services provided under the health service

- when requested by the Scottish Ministers, a duty to provide to the Scottish Ministers advice about any matter relevant to the health service functions of HIS

10.6. The 1978 Act sets out the functions of Scottish Ministers that HIS is to exercise:

- Functions in relation to supporting, ensuring and monitoring the quality of healthcare provided or secured by the health service including providing quality assurance and accreditations;
- Functions in relation to supporting, ensuring and monitoring the duty to encourage public involvement of each NHS board
- Functions in relation to supporting, ensuring and monitoring the duty to encourage equal opportunities of each NHS board
- Functions in relation to the evaluation and provision of advice to the health service on the clinical and cost effectiveness of new and existing health technologies including drugs

10.7. The 1978 Act also sets out the general principles in accordance with which HIS must exercise its functions, which includes that:

- the safety and well-being of all persons who use services provided under the national health service and independent health care services are to be protected and enhanced
- Good practice in the provision of those services is to be identified, promulgated and promoted
- Provision of those services taking account of guidance and information published or endorsed by HIS should be promoted and encouraged.

10.8. The 1978 Act provides HIS with powers to inspect any service provided by the National Health Service or independent health care services, in pursuance of its general duty of furthering improvement in the quality of healthcare in Scotland.

10.9. It also sets out that HIS must conduct joint inspections with other scrutiny authorities when requested by Scottish Ministers.

<u>The Care Inspectorate</u>

10.10. The Care Inspectorate (formal name Social Care and Social Work Improvement Scotland) was established on 1 April 2011 under the Public Services Reform (Scotland) 2010 Act as the new single improvement and scrutiny regulator in Scotland for social work and social care (taking over the functions of its predecessors, the Care Commission, the Social Work Inspection Agency and some of the functions of HMIE.

10.11. The Care Inspectorate's statutory duties include:

- Furthering improvement in the quality of social services.

- Undertaking joint inspections of services for adults and children.

- Providing information to the public about the availability and quality of social services.

- Providing advice to Ministers about any matter relevant to the functions of the Care Inspectorate.

- Taking into account standards and outcomes relating to care services and social work services and the Scottish Social Services Council's codes of practice in the performance of its functions.

10.12. The Care Inspectorate regulate around 14,000 individual care services. This includes registering/deregistering and inspecting services, supporting services improve, investigating complaints and undertaking enforcement action. The Care Inspectorate also scrutinise the delivery of local authority social work functions.

Monitoring of Organisational Duty of Candour

10.13. The introduction of a statutory duty of candour would require that monitoring of implementation be undertaken in accordance with the statutory provisions set out in this Chapter and operational arrangements set out in Chapter 2.

Question 8: How 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 ?

11. CHAPTER 5: Responding to this consultation paper

11.1. We are inviting written responses to this consultation paper between 15th October 2014 and 14th January 2015.

11.2. There are a number of consultation questions on which the Scottish Government would welcome views. Please do not feel obliged to answer all the questions. Equally, if you would like to comment on any other aspects of the proposals, the Scottish Government would welcome your views.

11.3. We would be grateful if you could use the separate consultation questionnaire provided to answer the questions posed throughout the consultation paper. The questions appear in full in the consultation questionnaire at Annex A and on the downloadable consultation response form (for electronic completion).

11.4. Please send your completed consultation questionnaire and Respondent Information Form (see "Handling your Response" below) to:

Dutyofcandourconsultation@scotland.gsi.gov.uk

or
The Quality Unit
Scottish Government
GER St Andrew's House
Regent Road
Edinburgh
EH1 3DG

11.5. If you have any queries contact Professor Craig White, Divisional Clinical Lead, Quality Unit on 0131 244 4049.

11.6. We would be grateful for responses to be completed electronically and sent by email where possible. This will aid handling and analysis of all responses.

11.7. This consultation, and all other Scottish Government consultation exercises, can be viewed online on the consultation web pages of the Scottish Government website at http://www.scotland.gov.uk/consultations.

11.8. You can telephone Freephone 0800 77 1234 to find out where your nearest public internet access point is.

11.9. The Scottish Government now has an email alert system for consultations (SEconsult: http://www.scotland.gov.uk/consultations/seconsult.aspx). This system allows stakeholder individuals and organisations to register and receive a weekly email containing details of all new consultations (including web links). SEconsult complements, but in no way replaces SG distribution lists, and is designed to allow stakeholders to keep up to date with all SG consultation activity, and therefore be alerted at the earliest opportunity to those of most interest. We would encourage you to register.

Handling your response

11.10. We need to know how you wish your response to be handled and, in particular, whether you are happy for your response to be made public. Please complete and return the Respondent Information Form (at Annex A and on the downloadable consultation response form) which forms part of the consultation questionnaire as this will ensure that we treat your response appropriately. If you ask for your response not to be published we will regard it as confidential, and we will treat it accordingly.

11.11. All respondents should be aware that the Scottish Government are subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Next steps in the process

11.12. Where respondents have given permission for their response to be made public and after we have checked that they contain no potentially defamatory material, responses will be made available to the public in the Scottish Government Library. (See the attached Respondent Information Form), these will be made available to the public in the Scottish Government Library and on the Scottish Government consultation web pages by 8 February 2015 . You can make arrangements to view responses by contacting the SG Library on 0131 244 4552. Responses can be copied and sent to you, but a charge may be made for this service.

What happens next?

11.13. Following the closing date, all responses will be analysed and considered along with any other available evidence to help us reach a decision on the terms of introducing a statutory duty of candour for health and social care services. We aim to issue a report on this consultation process by 27 March 2015

Comments and complaints

11.14. If you have any comments about how this consultation exercise has been conducted, please send them to Professor Craig White at the above address.

12. CHAPTER 6: The Scottish Government consultation process

12.1. Consultation is an essential and important aspect of Scottish Government working methods. Given the wide-ranging areas of work of the Scottish Government, there are many varied types of consultation. However, in general, Scottish Government consultation exercises aim to provide opportunities for all those who wish to express their opinions on a proposed area of work to do so in ways which will inform and enhance that work.

12.2. The Scottish Government encourages consultation that is thorough, effective and appropriate to the issue under consideration and the nature of the target audience. Consultation exercises take account of a wide range of factors, and no two exercises are likely to be the same.

12.3. Typically Scottish Government consultations involve a written paper inviting answers to specific questions or more general views about the material presented. Written papers are distributed to organisations and individuals with an interest in the issue, and they are also placed on the Scottish Government web site enabling a wider audience to access the paper and submit their responses[5]. Consultation exercises may also involve seeking views in a number of different ways, such as through public meetings, focus groups or questionnaire exercises. Copies of all the written responses received to a consultation exercise (except those where the individual or organisation requested confidentiality) are placed in the Scottish Government library at Saughton House, Edinburgh (K Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD, telephone 0131 244 4565).

12.4. All Scottish Government consultation papers and related publications (eg, analysis of response reports) can be accessed at: Scottish Government consultations (http://www.scotland.gov.uk/consultations)

12.5. The views and suggestions detailed in consultation responses are analysed and used as part of the decision making process, along with a range of other available information and evidence. Depending on the nature of the consultation exercise the responses received may:

- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

12.6. Final decisions on the issues under consideration will also take account of a range of other factors, including other available information and research evidence.

12.7. While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body**.**

Annex A Partial Business and Regulatory Impact Assessment

Title of Proposal

To Introduce a Statutory Duty of Candour for Health and Social Care Services

Purpose and intended effect

- **Background**

Improvements in arrangements to support the disclosure of harm, is a key element supporting a continuously improving culture of safety.[23] There are several healthcare systems and organisations worldwide that have introduced initiatives or arrangements to support open disclosure of harm. The Berwick Report[24] emphasised the importance of the requirement that a patient or carer affected by serious incidents should be notified and supported.

It is internationally recognised that between 10-25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event.[25] However, it has also been recognised that as few as 30 per cent of incidents resulting in harm are disclosed to people who have been affected. Denial and dismissal of mistakes often results in distress and people spending several years seeking the truth, accountability and apology.[26]

Healthcare Improvement Scotland have visited all NHS Boards in Scotland as part of the national programme supporting learning following adverse events. This confirmed that there is variation across the country in respect of the rigor and standard of open disclosure and support for families and staff when harm occurs. The Scottish Government wants to introduce an organisational duty of candour in Scotland. This will require services to make sure that they are open and honest with people when something has gone wrong with their care and treatment.

- **Objective**

The Scottish Government intends to introduce a statutory requirement on organisations providing health and social care to have effective arrangements in place to demonstrate their commitment to disclose instances of physical or psychological harm. The proposals have been intentionally focused on

[23] Etchegaray, JM., Gallagher, TH., Bell, SK et al. (2012). Error disclosure: a new domain for safety culture assessment. BMJ Quality and Safety, 21, 594-599.

[24] 'A promise to learn– a commitment to act. Improving the Safety of Patients in England National Advisory Group on the Safety of Patients in England', August 2013, Department of Health. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf (Accessed 25th September 2014).

[25] The Health Foundation (2011). Evidence scan: Levels of Harm. Available at: http://www.health.org.uk/publications/levels-of-harm/ (Accessed 21st September 2014),

[26] Halligan, A. W. F. (2014). Implications for medical leaders of the proposed Duty of Candour. *Clinical Risk*, *20*(1-2), 29-31.

organisational duties and specifically developed to ensure that this includes all of the elements that will need to be in place to support continuous improvements in quality and safety culture across Scotland's health and care services.
Ethically, morally and professionally health and care professionals are already required to tell people about instances of harm. The clear requirement for candour in professional standards and codes of conduct are complementary to the proposed introduction of a duty on organisations.

From November 2014 the Care Quality Commission in England will include the duty of candour among the standards to be met by healthcare providers in England. These will form part of the inspection and monitoring regime operating in England. This includes a range of new enforcement powers, including civil penalties and criminal proceedings for repeated failures. From April 2015 this will be extended to providers of adult social care services.

- **Rationale for Government intervention**

The observations made by Healthcare Improvement Scotland are consistent with observations from work that has shown that ethical and policy guidance has largely failed on its own to improve rates of disclosure[27]. There has been strong support for the benefits of improving organisational arrangements for disclosure of harm in recent years.

The 2013 Health and Care Survey[28] asked respondents whether they believed a mistake was made in their treatment or care by their GP practice. 6% of respondents believed such a mistake had been made in their treatment or care. Of those that felt a mistake had been made in their treatment or care:

7% indicated that it did not require a response

Of those that required a response:

19% were completely satisfied with how it was dealt with
44% were satisfied to some extent
38% of those where were not satisfied

The Dalton-Williams review[29] recommended that there should be a statutory duty on organisations and that this would provide a powerful signal of what is considered essential and this should act as an important catalyst for care organisations to improve their systems and commit to a learning culture for their staff.

[27] O'connor, E., Coates, H. M., Yardley, I. E., & Wu, A. W. (2010). Disclosure of patient safety incidents: a comprehensive review. *International Journal for Quality in Health Care*, , 22(5), 371-379..
[28] http://www.scotland.gov.uk/Resource/0045/00451272.pdf

[29] https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf (Accessed 25th September 2014)

The Scottish Government has five strategic objectives that underpin its core purpose - to create a more successful country, with opportunities for all of Scotland to flourish, through increasing sustainable economic growth. This proposal will contribute to the strategic objective of "healthier" by increasing the quality of health and social care that individual's experience.

Consultation

The legislation will be developed in a collaborative way involving colleagues from across and outside the Scottish Government.

- **Within Government**
  We are working with colleagues across the Scottish Government to develop this legislation. This includes, but is not restricted to the following teams: Primary Medical Services; Pharmacy, Integration and Reshaping Care; Children's Rights and Wellbeing; Chief Medical Officer, Chief Social Work Adviser, Chief Dental Officer and Chief Nursing Officer's Directorates. The nature and scope of the proposals have been shaped through dialogue with policy colleagues. This has also directly influenced the consultation questions that will be asked.

- **Public Consultation**
  The formal consultation will run for a period of 12 weeks from 15 October 2014.

- **Business**
  We will identify relevant organisations to meet with during the consultation period and update this section at Final BRIA stage.

Options

Option 1: do nothing. Ethically, morally and professionally, health and care professionals are already required to tell people about instances of harm. This duty would remain although there would be no statutory duty on organisations to ensure a culture and organisation that supports a consistent approach to disclosure of adverse events.

Option 2: to Introduce a Statutory Duty of Candour for organisations providing Health and Social Care The statutory duty will require that an organisation must act in an open and transparent way with people when things go wrong. It will outline the minimum requirements that must be in place to support the duty of candour and require that reports are made to describe the implementation of arrangements.

Requirements for Health and Social Care Organisations

1. As soon as it is reasonably practicable after becoming aware that there has been adverse event resulting in harm, the organisation must ensure that the relevant person is notified that this has happened. This will involve the provision of a step by step account of the facts of the event, including as much or as little information as the person has expressed their wish for.

2. There must be an offer of reasonable support provided to the patient, relatives and staff who have been involved with the event. The person undertaking the disclosure may be different for each disclosure episode.

3. The responsibility will rest with organisations to ensure that all staff who are asked to be involved with disclosure have access to the relevant training, supervision and support before, during and after their involvement with disclosure communications.

4. The notification that is made to the relevant person should be given in person by a suitably trained representative of the organisation and should include an account of all of the facts known at the time of disclosure and the plans for the event to be reviewed. It will be for the organisation to determine who is most appropriate to disclose the harm episode.

5. The relevant person must be informed of the further steps to be taken to review the event and be given the opportunity to have their questions considered by the review process.

6. The organisation must provide an apology and must confirm all of the actions taken in a written record, the contents of which will inform the quarterly report.

7. The relevant person must also receive a written summary of the face to face meeting.

Reporting on Disclosure Arrangements

1. All organisations would be required to report publically on a quarterly basis the nature of adverse incidents that have been disclosed to people and confirm that requirements of the organisational duty of candour have been met.

2. Organisations would also be required to report on the way in which they had supported staff in the development and maintenance of the skills required to ensure respectful disclosure by staff who are required to be involved with this.

3. Organisations should also publish annually their policies and procedures to support openness and transparency, this must include the arrangements in place to support staff training and development in these advanced communication skills. These reports should be submitted to the relevant organisation (which will differ for each organisation).

4. Organisations would be required to ensure that they have arrangements in place to ensure that if any adverse event is reported that this is considered and a decision made whether this is a disclosable event.

5. Organisations would also be required to include a summary in their reports of the support that is available to patients, families and staff following an disclosable event. They would also need to describe the provision to ensure that training and development support has been implemented to ensure best practice in disclosure.

Sectors and groups affected

The statutory duty of candour would apply to health and care services provided by NHS Boards, Local Authorities, all organisations providing services regulated by the Care Inspectorate, independent hospitals, independent hospices, General Practices, community pharmacies, dental practices and optometry practices.

Any or all patient/clients, and their families, treated in a formal healthcare setting could be affected. As this is an organisational duty, it would not apply to individuals providing services, for example, childminders.

Benefits

Option 1: do nothing

There would be no change to current policies and practice or to individual professional responsibilities. There would be no additional benefits.

Option 2: to Introduce a Statutory Duty of Candour for Health and Social Care

The legislation aims to make providers of health and social care increase transparency and openness in the organisation, facilitating a culture in which staff are supported to report incidents where harm may have been caused. Staff will be encouraged to speak candidly to service users and/or relatives in the event of harm (including death) resulting from treatment.

This will reduce the level of distress and frustration that people experience when they do not receive the information that they're seeking. This benefit is unquantifiable.

It is anticipated that, initially, there will be an increase in the level of reporting of incidences, providing an increase in learning opportunities. This should result in increased awareness of patient safety and ultimately a reduction in avoidable incidences of harm. This benefit is difficult to quantify.

Overall, a requirement which encourages openness and honesty across all organisations within the health and social care sector may increase both staff and patient satisfaction. This benefit is difficult to quantify.

Costs

Option 1: do nothing

Ethical, professional and policy guidance is generally insufficient in significantly improving rates of disclosure. Under current policies there may be a lack of support for professionals from their employer organisations resulting in a reluctance or failure to report adverse events. This in turn means patients and service users are not fully informed, nor do individuals and organisations have the opportunity to learn from any adverse event.

Option 2: to Introduce a Statutory Duty of Candour for Health and Social Care

Although ethically, morally and professionally health and care professionals are already required to tell people about instances of harm, by introducing an obligation on organisations which is intended to support a consistent approach to disclosure, it is likely to result in an increased number of incidents disclosed. It is also likely to significantly enhance staff wellbeing as a result of improved support and training for disclosure.

Although it is internationally recognised that between 10-25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event[30] and it has been recognised that as few as 30 per cent of incidents resulting in harm are disclosed to people who have been affected, it is not possible to quantify how many additional disclosures of harm this legislation might generate in Scotland .

There are likely to be a number of costs associated with the introduction of this legislation and any increase in reporting.

<u>Scottish Government</u>

The Government will need to consider whether it wishes to undertake a public education campaign to make people aware of any change in the law. There would also potentially be costs involved in providing literature/guidance for care providers including care homes and the range of health professionals. It is likely that this could be part of work to emphasise policy commitments on quality, safety and improvement work in health and social care.

[30] The Health Foundation (2011). Evidence scan: Levels of Harm. Available at: http://www.health.org.uk/publications/levels-of-harm/ (Accessed 21st September 2014),

SG/NHS Boards/providers: training

It has been recognised that being candid is an advanced communication skill. Programmes have been developed to improve the preparation of doctors to make such disclosures, and to deal with emotional elements that are linked with this task.[31] The Scottish Government in collaboration with NHS Education for Scotland (NES) would need to consider if and how to introduce any additional staff training. This might involve adding to existing training packages both for staff in training and those already qualified. Information on possible training content and focus will be obtained from stakeholders during the consultation period.

Within the NHS alone, there are approx 104,000 employees involved in delivering care (this excludes admin, support and health science workers) and there are over 192,000 employed in delivering social care services[32] across public, private and voluntary sectors. Different types/levels of training may be appropriate for different staff groups. For example although it will be everyone's responsibility to identify and report when an adverse event occurs, it may be appropriate to target training to particular senior staff groups who would then communicate with patients/clients.

All Providers

All health and social care providers will have to ensure that they have policies and procedures in place that reflect the statutory duty imposed to disclose adverse events. These will need to be communicated to staff. There will be a resource cost involved particularly in developing and disseminating these policies for the first time. These may be defined as transitional costs. It is anticipated that these activities would form part of routine management responsibilities.

Increased numbers of disclosure may result in an increased need for additional training for staff on specific issues. These will only be identified once incidents are reported.

There may be a small risk of increased litigation from an increased number of disclosures of adverse events although international evidence is that a statutory duty on disclosure results in a reduction in the number and costs of medical claims[33].

[31] Bonnema, R. A., Gonzaga, A. M. R., Bost, J. E., & Spagnoletti, C. L. (2012). Teaching error disclosure: advanced communication skills training for residents. *Journal of Communication in Healthcare*, *5*(1), 51-55.

[32] http://www.sssc.uk.com/

[33] Kachalia, A (2013) "Improving Patient Safety through Transparency", *New England Journal of Medicine*, 369, 18, 1677. & Boothman RC, Blackwell AC, Campbell DA Jr, Commiskey E, Anderson S. 'A better approach to medical malpractice claims? The University of Michigan experience' *Journal of Health and Life Sciences Law* 2009; 2: 125-159 & Kraman SS, Hamm G, 'Risk Management: Extreme Honesty May be the Best Policy' *Annals of Internal Medicine* 1999; 131(12): 963-967

All organisations would be required to report publically on a quarterly basis the nature of adverse incidents that have been disclosed to people and confirm that requirements of the organisational duty of candour have been met. Although this is an additional requirement it is assume that this could be incorporated into existing routine reporting.

Organisational Support for staff

For both staff who report incidents and those who communicate these to patients/carers it will be necessary for organisations to ensure that there are adequate supports in place and that staff are made aware of these. It is possible that additional resources will be required for larger organisations who might wish to enhance staff support available through specialists in psychological care, counselling and/or occupational health. Smaller organisations could incur costs associated with the provision of access to such support if this is not already in place.

Support for patients/clients/carers

There is evidence that honesty, openness and apologies are important to patients when there has been an error in treatment and that it may make them less likely to seek recompense through the courts. However it is important that not only are they given the information by an appropriately trained professional but that there is support available to them, should it be required, to deal with the information and any implications associated with that information. Additional demands for access to clinical psychologists, specialist nurses and/or counsellors could be made. Demands are likely to be met within existing services, though this will depend on the extent of service provision in place. This will be considered during the consultation period.

Monitoring & enforcement

It is proposed that the Scottish Government, Healthcare Improvement Scotland and the Care Inspectorate are involved in monitoring and enforcing. Although these would be additional responsibilities the Scottish Government considers that it would be a small increase in workload when integrated with existing monitoring, reporting and inspection arrangements and it is not anticipated that this would require significant additional staff or resource. Further information on this will be obtained throughout the consultation period.

Scottish Firms Impact Test

Throughout the formal consultation period officials will meet with a range of stakeholders, including organisations, businesses and patients/clients who are likely to be affected by any proposed legislation. The outcome of these meetings will be analysed and presented as part of the full BRIA.

Competition Assessment

Will the proposal directly limit the number or range of suppliers?

No, the proposal will not limit the range of suppliers within the market. It does not restrict the right to supply services in any way.

Will the proposal indirectly limit the number or range of suppliers?

No, the proposal will increase the standards of care expected but is not expected to indirectly affect the number of suppliers.

Will the proposal limit the ability of suppliers to compete?

No, the proposal will apply equally to all providers of health and social care.

Will the proposal reduce suppliers' incentives to compete vigorously?

No, it will reduce informational asymmetry between patients/clients and healthcare providers. Where a market exists, it will increase competition.

Test run of business forms

There are no new forms for businesses planned.

Legal Aid Impact Test

As part of the on-going development process we will liaise with the Scottish Government Legal Systems Division to gauge whether any proposals will have an impact on the legal aid system. This will be detailed within the full BRIA

Enforcement, sanctions and monitoring

Option 1: this option would require no additional monitoring or enforcement.

Option 2:

Monitoring and enforcement: organisations will be expected to report quarterly on all disclosable events including information on the arrangements in place to deliver duty of candour and the learning and improvement subsequent to these events.

It is intended to use the existing regulatory mechanisms within Scotland available through the Scottish Government, Healthcare Improvement Scotland and the Care Inspectorate. Particular sections of the health and social care market would report to assigned agencies. These proposed arrangements for reporting and monitoring are part of the consultation and the Scottish Government would welcome comments on these.

Sanctions: a decision on possible sanctions and/or penalties has yet to be reached. The Scottish Government invites, through the consultation, suggestions on possible sanctions for non-compliance with a duty of candour.

Implementation and delivery plan

15 October 2014 - 14 January 2015

- Consultation launch
- Publication of Partial BRIA & EQIA with consultation document October 2014
- Engagement with stakeholders including health professionals, health boards, care home providers

- **Post-implementation review**

Any review process will be considered as the legislation is developed.

Summary and recommendation

Option 2: to Introduce a Statutory Duty of Candour for Health and Social Care is the Scottish Government's preferred option. The Scottish Government is committed to improving the quality of all health and social care. This includes ensuring a culture in which staff are supported to report incidents where harm may have been caused. The statutory duty will complement the existing professional responsibilities of healthcare professionals. It will provide the structures in which staff can be supported to give clear explanations of events to patients/clients/carers and support providers to use the lessons learned.

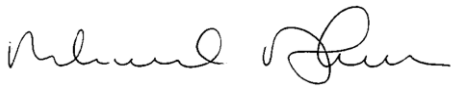
- **Summary costs and benefits table**

This information will be detailed in the full BRIA and financial memorandum that accompanies detailed proposals.

Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed:



Date: 13 October 2014

Minister's name Michael Mathieson
Minister's title Minister for Public Health

Scottish Government Contact point: Craig White, Divisional Clinical Lead, The Quality Unit

EQUALITY IMPACT ASSESSMENT

The purpose of carrying out an Equality Impact Assessment is to aid the Scottish Government in discharging its Public Sector Equality Duty under section 149 of the Equality Act 2010. The Scottish Government is required to assess the impact of applying a new or revised policy or practice against the needs in the public sector equality duty - to eliminate unlawful discrimination, to advance equality of opportunity and to foster good relations.

The protected characteristics that must be profiled against the policies are:

Age
Sex
Pregnancy and maternity
Disability
Race
Religion or belief
Gender Reassignment
Sexual Orientation

To help inform our Equality Impact Assessment of the policy proposals to reform FAI legislation, it would be helpful if you could answer the following question.

Please tell us about any potential impacts, either positive or negative, you feel any or all of the proposals in this consultation may have on a particular group or groups of people.

Comments

Annex B
CONSULTATION QUESTIONNAIRE

Question 1 :
Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation ?

Yes ☐ No ☐

Comments

Question 2:
Do you agree that the organisational duty of candour encompass the requirement that adequate provision be in place to ensure that staff have the support, knowledge and skill required ?

Yes ☐ No ☐

Comments

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

Yes ☐ No ☐

Comments

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

Yes ☐ No ☐

Comments

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

Yes ☐ No ☐

Comments

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

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

Comments

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

Comments

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

Yes ☐ No ☐

Comments

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

Yes ☐ No ☐

Comments

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

Comments

Question 7
What are the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred ?

Comments

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

Comments

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

Comments

End of Questionnaire

CONSULTATION ON PROPOSALS TO INTRODUCE A STATUTORY DUTY OF CANDOUR FOR HEALTH AND SOCIAL CARE SERVICES

RESPONDENT INFORMATION FORM
Please Note this form **must** be returned with your response to ensure that we handle your response appropriately

1. Name/Organisation
Organisation Name

Title **Mr** ☐ **Ms** ☐ **Mrs** ☐ **Miss** ☐ **Dr** ☐ **Please tick as appropriate**

Surname

Forename

2. Postal Address

Postcode	**Phone**	**Email**

3. Permissions - I am responding as…

Individual	/	**Group/Organisation**
☐	**Please tick as appropriate**	☐

(a) Do you agree to your response being made available to the public (in Scottish Government library and/or on the Scottish Government web site)?

Please tick as appropriate
☐ **Yes** ☐ **No**

(b) Where confidentiality is not requested, we will make your responses available to the public on the following basis

Please tick ONE of the following boxes

(c) The name and address of your organisation **will be** made available to the public (in the Scottish Government library and/or on the Scottish Government web site).

Are you content for your **response** to be made available?

Please tick as appropriate
☐ **Yes** ☐ **No**

Yes, make my response, name and address all available ☐

or

Yes, make my response available, but not my name and address ☐

or

Yes, make my response and name available, but not my address ☐

(d) We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

Please tick as appropriate ☐ **Yes** ☐ **No**

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