Marie Curie is the UK's biggest provider of high quality care for people who are terminally ill. In Scotland we treat close to 6,000 people each year through our community nursing services, hospices and other services.

We welcome the opportunity to respond to the consultation on proposals to introduce a statutory Duty of Candour for health and social care services.

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

We agree that legislation should outline arrangements to support an organisational duty of candour. The Scottish Government's 2020 Vision is committed to providing safe, high quality care whatever the setting. This is further emphasised in the Healthcare Quality Strategy for NHSScotland which has three quality ambitions to provide safe, effective, person-centred care. A statutory duty of candour will support the principles of openness, honesty and transparency that are fundamental to providing safe, consistent care across the country. This legislation should help to ensure an organisational shift towards a culture of learning and improvement, alongside stronger healthcare leadership.

The proposed legislation should also ensure that staff have the necessary training and support to be able to effectively implement the legislation. This should include ensuring that it does not unintentionally create a 'blame-culture' within health and social care settings through inadequate training or poor implementation. Systems should be in place within these settings to ensure improvements are driven forward and that staff are comfortable raising concerns. Likewise the legislation should ensure that it does not undermine public confidence in health and social care systems.

We would like to see further detail on how the legislation will align with pre-existing work and legislation, for example, the *Healthcare Improvement Scotland Learning from adverse events through reporting and review: Being Open in NHSScotland guide*[1]. We would also like further clarification on how the legislation will apply within integrated health and social care services, including integration joint boards, reporting and joint inspections.

[1] http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/adverse_events_consultation1.aspx?theme=default

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

Yes ☒ No ☐

We agree that the organisational duty of candour should require there is adequate provision to ensure that staff have the support, knowledge and skill required. It is crucial that all staff understand what an organisational duty of candour is, what this will mean for them and available support. This should be accompanied by clarity on how the duty interacts with existing policies and procedures on confidentiality, whistleblowing and grievances.

However, we have concerns over how this training will be designed, delivered and resourced. We would support the co-production of mandatory training to ensure there is a consistent approach to training, that it is applicable in all settings and that it is based upon good practice and evidence. It is also necessary to have appropriate support packages available alongside training.

We welcome further detail of how this training and support will be properly resourced across health and social care settings.

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

Yes ☒ No ☐

We agree that organisations should be required to publically report on disclosures that have taken place. This will ensure an open, honest and transparent culture.

However, we do have some concerns surrounding undermining public confidence in health and care systems if taken out of context, and around unintentionally creating a culture of negativity that may lead to underreporting. Requirements over reporting should take these considerations into account and be carefully managed. Annual reporting, available in the public domain might be more appropriate than a case-by-case basis.

In order to promote transparency and accountability, we would welcome a requirement for organisations to publically publish policies, procedures and guidance in relation to the duty.

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

Yes ☒ No ☐

We agree with the proposed requirement to ensure that people who are harmed are informed. However, this should only be undertaken by staff who have had the proper training and support to be able to do so.

Any feedback to patients should include the next steps and what action is being undertaken to prevent the same harm from happening again.

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

Yes ☒ No ☐

We agree with the proposed requirement to ensure that people are appropriately supported. This should include both staff and people who have suffered harm, and should be adequately resourced.

We would also welcome further definition on what is meant by 'appropriately supported'.

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

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

As detailed above, we agree that organisations should be required to publically report on disclosures that have taken place and how staff have been supported. Annual reporting may be appropriate in this instance.

However, reporting of disclosable events should be streamlined to co-ordinate with other reporting duties, for example, those required by Healthcare Improvement Scotland, Care Inspectorate and Health and Safety Executive. This will ensure that reporting will not cause additional strain on organisational resources and will aid monitoring processes.

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

Organisationally, there should be a process in place to disclose instances of harm. Training on this should be mandatory within the organisation, ensuring people are aware of the process and appropriately supported to

report. Organisational support to enable learning and development following an incident should also be identified.

We would welcome further clarification over how additional responsibilities will be resourced and adequate training delivered, to ensure consistency across all health and social care settings.

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

Yes ☒ No ☐

We agree that the legislation should include clear definitions of harm and the types of harm that would trigger the organisational duty of candour. We further agree that these need to be developed with, and informed by, engagement with representatives from all health and social care settings.

The definition provided in the consultation describes a disclosable event as 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'. We recommend further guidance on what is meant by the terms 'unintended', 'unexpected' and 'prolonged' to reduce issues surrounding statutory interpretation. This could be reinforced through clear case studies and examples.

We believe that the proposed system of reporting instances of harm will only work if it is reserved for significant events caused by the health or social care provider. Scottish Government is currently consulting on separate legislation for wilful neglect and ill-treatment in health and social care settings. Further guidance should be clear about the boundaries and any overlaps in legislation.

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

Yes ☒ No ☐

We agree that the events proposed should be applicable and identifiable in all care settings.

However, the disclosable events detailed within the consultation are weighted towards the incident happening in hospital. This should include people receiving care in other care settings including their own home or care home. Further consideration should also be given to ensuring consistency between public, third and independent sectors, which may be

subject to different regulatory functions.

We would also welcome guidance on definition and applicability specifically in relation to the integration of health and social care services and the interaction with integration joint boards.

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

No comment.

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

As detailed in question 2, appropriate training and support for staff is required in the identification and management of an instance of disclosable harm. This will include:

- Specialist training
- Quality assurance processes
- Audit
- Reporting

This will need to be properly resourced across health and social care settings and implemented consistently across the country.

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

We agree that the organisational duty of candour should be monitored through the existing performance monitoring, regulation and scrutiny arrangements that apply to the organisation. The organisation should then have a requirement to demonstrate to regulators that they are implementing the duty. We also agree that Healthcare Improvement Scotland and the Care Inspectorate should monitor organisational compliance, as detailed in the consultation documentation.

However, we have a number of concerns regarding consistency and how monitoring arrangements work alongside pre-existing arrangements. Healthcare Improvement Scotland and the Care Inspectorate have different regulatory functions, which could introduce differing systems of monitoring and enforcement. Further consideration should also be given to ensuring consistency between public, third and independent sectors who may also be subject to different regulatory functions. Clarification and guidance will also

be necessary in circumstances where an organisation reports to more than one regulatory/monitoring body.

We would also like clarification over the duty of candour within integrated health and social care arrangements. Will integrated joint boards be responsible for organisational duty of candour for both health and social care or will the responsibility remain separate?

Further guidance should also be developed for regulatory/monitoring bodies to ensure organisations are supported when reporting disclosable events. Systems should recognise where an organisation has a good duty of candour and those organisations should not be penalised for reporting disclosable events. There are concerns that existing monitoring systems could inhibit openness, transparency and candour for fear of negative sanction.

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

The duty of candour should be enforceable. When disclosable events are reported to the regulator/monitoring body, the organisation should be held responsible for developing an associated action plan for learning and improvement. Action plans should include methods to communicate any learning across the organisation. The regulator/monitoring body should have responsibility to ensure this is undertaken and make recommendations or requirements for further action, where necessary.

If it is discovered that a disclosable event has not been disclosed. The regulator/monitoring body should have authority to conduct an investigation. We would like further clarification as to whether the regulator/monitoring body will have powers of enforcement, with possible criminal or professional malpractice implications. Any such sanctions should be clearly stated within the legislation.

End of Questionnaire