Response to Welsh Government consultation on Statutory Guidance and Regulations required to implement the Duty of Candour

December 2022

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

2.1 We welcome the opportunity to respond to the Welsh Government consultation on Statutory Guidance and Regulations required to implement the duty of candour in Wales.

2.2 We responded to the 2019 consultation on the Health and Social Care (Quality and Engagement) (Wales) supporting the introduction of the statutory duty in Wales. We welcome this next step towards implementation of the duty from April 2023. Candour is extremely important for patients and families and a key part of providing person-centred care, respecting service users through being honest and involving them in their care.

2.3 Whilst we believe the guidance and regulations are broadly helpful in outlining how the duty will operate in Wales, we note that the implementation of the statutory duty in Wales signifies the introduction of yet another different threshold for the application of the duty of candour across the UK. This will sit alongside the existing thresholds for exercising the statutory duty in England and Scotland and the professional duty of candour which all regulated professionals across the UK are subject to through their professional registration.

2.4 As we stated in our response to the Scottish candour regulations[1], in our view it would improve clarity and understanding of the duty if a common threshold for candour was in use across the UK. Ideally this would include a common approach to the professional duty of candour and the statutory duties in each country.

2.5 Although we recognise that these differences are not fully within the gift of the Welsh Government to resolve, and there is a desire to ensure the threshold fits with existing incident reporting legislation for each country we believe that these variations could be more explicitly acknowledged in the guidance to ensure that any potential for confusion can be mitigated. This is particularly the case with the professional duty of candour which all healthcare professionals in Wales will be subject to. It is important to be clear on exactly how professional responsibilities will interact with the process for exercising the statutory duty in Wales.

2.6 Given the ongoing challenges in embedding a culture of candour across the UK with recent reviews of failings in NHS Trusts in East Kent and Shrewsbury and Telford as well as Cwm Taf Health Board in 2019 highlighting a lack of candour and openness, it would also be helpful for the guidance to address more explicitly some of the known barriers to candour. It will be important for healthcare providers to understand how they should seek to address these barriers to ensure staff feel able to exercise both the professional and statutory duty.

2.7 We note the duty of candour is already in place for social care in Wales and support the commitment to introduce an equivalent duty for independent providers from April 2024. It is important that patients and service users can expect the same level of openness and honesty regardless of where they access care, across both health and social care, the NHS and the independent healthcare sector.

3. Detailed comments

3.1 We have not answered all consultation questions but have instead provided general comments on each document referenced in the consultation.

Duty of Candour Guidance

3.2 The guidance is useful in elaborating on the process for how the statutory duty of candour should operate in Wales. However, there are some areas where we thought more detail would be helpful.

3.3 We note the ongoing challenges in embedding the duty in other parts of the UK. Whilst the reasons for this are complex the different thresholds for the different duties of candour across the UK may be a factor. In our 2019 report looking at the progress made by the professional regulators in embedding the

[1] Professional Standards Authority 2015, *Response to the Scottish Government consultation: Proposals to introduce a statutory duty of candour for health and social care services*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2015/scottish-government-duty-of-candour.pdf?sfvrsn=75a57f20_9

professional duty of candour, we heard from stakeholders that consistency in the application of thresholds in relation to the duty of candour was important in helping professionals to understand what is expected of them.[2] This included consistency between professional regulators but also greater clarity on the inter-relationship between the professional and statutory duty of candour.

3.4 As noted in our previous comments on the Health and Social Care (Quality and Engagement) (Wales) Bill[3], the threshold in Wales for exercising the duty of 'more than minimal' harm differs from the thresholds outlined for both the statutory duty of candour in England and the duty of candour in Scotland. In England the regulation refers to a 'notifiable safety incident' which could lead to the death of the service user (because of the incident rather than the natural course of the service user's illness or underlying condition) or 'severe harm, moderate harm or prolonged psychological harm to the service user.'[4] In Scotland the regulations refer to 'unintended or unexpected incidents' which result in certain specified outcomes.[5]

3.5 We recognise that each UK country, including Wales, has introduced the duty in a way which fits with existing adverse incident reporting requirements. However, we remain of the view that it would improve clarity and understanding of the duty if a common threshold was in use across the UK. Ideally this would include a common approach to the professional duty of candour and the statutory duties in each country.

3.6 Whilst we acknowledge that a common approach UK-wide would be a challenge to achieve, we would have liked to see more explicit reference to these differences in the guidance to help professionals navigate the variations and understand how to apply the duties effectively in Wales. In particular, although it references it, the guidance could be clearer on specifically how the professional and statutory duties interact. Although the guidance is for NHS bodies, the success of the implementation of the duty in Wales will nonetheless be reliant on healthcare professionals understanding how and when it should apply.

3.7 Although professionals will have access to guidance from their regulator on application of the professional duty it will be important for them to understand how this fits within the process for exercising the statutory duty in Wales. This relates both to process and timing as well as the differences in thresholds and

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[2] Professional Standards Authority 2019, *Telling patients the truth when something goes wrong - Evaluating the progress of professional regulators in embedding professionals' duty to be candid to patients*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6

[3] Professional Standards Authority 2019, *Comments to the Health, Social Care and Sport Committee on the Health and Social Care (Quality and Engagement) (Wales) Bill*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2019/professional-standards-authority-comments-health-and-social-care-(quality-and-engagement)-(wales)-bill.pdf?sfvrsn=4a477720_4

[4] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 – the duty of candour. Available at: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#full-regulation

[5] Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016, *Duty of candour procedure*. Available at: http://www.legislation.gov.uk/asp/2016/14/part/2/crossheading/duty-of-candour-procedure/enacted

application. This is particularly important in relation to the differences between the two duties, for example the fact that near misses are captured under the professional duty but not under the statutory duty.

3.8 We welcome the further clarity provided by the guidance on how the threshold for exercising the duty, of 'more than minimal' harm should be interpreted as moderate harm, severe harm or death. The examples provided in the levels of harm document are useful, however we suggest that it may be helpful to clarify that if in doubt the approach should be to err towards candour rather than not as there are still likely to grey areas in interpretation.

3.9 We support integrating the requirements for the duty of candour into existing requirements on incident reporting as this should help to ensure candour is seen as part of the normal process when adverse incidents occur. It seems logical to align reporting on the duty of candour with existing reporting requirements under Putting Things Right.

3.10 We welcome the references in the guidance to training for staff on providing an apology. However, we would also like to have seen more references to the need for providers to actively address the barriers that exist to candour in workplaces. Our 2013 advice for the Department of Health on implementing the professional duty of candour and research into candour, disclosure and openness, highlighted a number of barriers to health professionals doing the right thing.[6] It would be helpful if the guidance was able to explicitly address some of these challenges to ensure that providers are prepared to take the steps necessary within workplaces to make a culture of candour a reality.

Duty of Candour Procedure (Wales) Regulations 2023 ("the Candour Procedure Regulations")

3.11 We don't have detailed comments on the regulations and the process outlined looked broadly sensible and clear.

3.12 We agree that it is appropriate for the regulations to require an in-person communication initially to be followed up with in writing subsequently. We welcome the regulation clarifying that an apology isn't an admission of liability.

3.13 It is positive that the regulations include requirements for training to be provided to staff on the candour procedure and the guidance in Annex E should be helpful in supporting staff in making a meaningful apology.

3.14 We would suggest that a more explicit requirement on training for staff on how to apologise and have compassionate conversations might be helpful. Although guidance is helpful, as SANDs have highlighted in their principles for engaging parents in reviews/investigations following the death of a baby, 'clear sensitive and honest communication is essential in encouraging parental engagement'. It often requires a specific skillset to have these kind of

[6] Professional Standards Authority 2013, *Candour, disclosure and openness - Learning from academic research to support advice to the Secretary of State*. [Online] Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/candour-research-paper-2013.pdf?sfvrsn=5b957120_8

conversations and therefore additional training of this nature for staff may be helpful.[7]

Putting Things Right Guidance ("PTR Guidance") and regulations

3.15 We don't have detailed comments to the changes to the PTR regulations of guidance. It is logical to align PTR procedure with the duty of candour requirements and we support the shift to require the NHS to inform patients what has gone wrong in all circumstances where the duty is triggered.

3.16 Although there may be a perception that not telling someone may be in their best interests this is likely to be a subjective assessment and may not be appropriate.

Impact assessment

3.17 We welcome the assessment by the Welsh Government of the likely impact of the introduction of the duty of candour. We broadly agree that there is likely to be a net positive impact on patients and service users overall, although some groups might be more likely to be impacted by disclosure under the duty due to their level of contact with the health service.

3.18 It may be beneficial to consider any further impacts on groups of staff with protected characteristics. Although the aim of a culture of candour is admirable, there is evidence that toxic workplace cultures can have an inhibiting effect on candour and some evidence that staff with protected characteristics may face greater difficulties in raising concerns and speaking up. As this may extend to exercising the duty of candour, we suggest that consideration should be given to mitigating any effects of this nature.

3.19 We do not have a view on whether the introduction of the duty of candour is likely to have any effect on usage of the Welsh language.

4. Further information

4.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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[7] SANDs Principles for engaging parents in reviews/investigations: https://www.sands.org.uk/sites/default/files/Sands%20Principles%20of%20Parents%20Engagement%20in%20Review.pdf