General Medical Council

GMC Wales Feedback on Duty of Candour Statutory Guidance 2023

Overview

Thank you for the opportunity to provide feedback on the organisational duty of candour to be introduced in Wales, and on the draft statutory guidance.

The General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK.

- We decide which doctors are qualified to work here and we oversee UK medical education and training.
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

We welcomed the introduction an organisational duty of candour outlined in legislation when responding to the Quality and Engagement Bill in June 2019. We stated that we were in favour of the proposals as they would align Wales with legal requirements in England and Scotland. Alignment will help provide clarity to patients in terms of expectations, particularly in the delivering of cross-border care.

They would also support our existing guidance.

- Our core guidance for doctors, *Good medical practice* (GMP), states that doctors must be open and honest with patients if things go wrong and take prompt action if they think patient safety is or may be seriously compromised.
- Our joint guidance with the Nursing and Midwifery Council (NMC) on *The professional duty of candour* says that every healthcare professional must be open and honest with patients and people in their care when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. We also set out a duty for doctors, nurses, midwives and nursing associates to be open and honest with their employer, and to encourage a learning culture by reporting errors openly and honestly.

We believe the professional and organisational duties of candour are mutually reinforcing and should not be viewed in isolation. Fostering a working culture in which all staff and patients value the opportunity to put things right and learn from mistakes if things go wrong, in a non-punitive manner, will help support health professionals to be open and honest when such events arise.

Conversely, the act of individuals supporting and encouraging each other to raise concerns will help to support and nurture an open and honest culture across all levels of the organisation.

The GMC's Corporate Strategy 2021-2025 is designed to support all doctors in delivering high standards of care and moving away from acting only when things have gone wrong. Themes of openness, learning and reflection are key to this and we see our Corporate Strategy as a core reflection of the values of the health and social care system in which doctors work.

Professional duties of candour

Section 3 (page 11) of the duty of candour guidance covers the statutory duty of candour and existing professional duties of candour. We are pleased that the guidance says that the new duties on organisations will complement existing professional duties.

We also note that the draft document is closely aligned to our joint guidance with the NMC when it says that "Healthcare professionals who are subject to a professional duty of candour have to be open and honest with service users, colleagues, their employers and relevant organisations, and must take part in reviews and investigations when requested. They must support and encourage each other to be open and honest. They must also be open and honest with their regulators, raising concerns where appropriate."

However, we would encourage the Welsh Government to include the following additional wording (as highlighted) that appears at the relevant section of our guidance, as this is an important part of the professional duty: "They [professionals] must support and encourage each other to be open and honest, *and not stop someone from raising concerns*."

Lessons learned from implementation

Our outreach team works across the UK to improve understanding of our guidance. They explain how our processes work and promote our standards. They also collaborate with the service to understand the issues faced at local level.

Outreach are therefore in a good position to gather on-ground intelligence around the implementation of the organisational duty of candour in England and Scotland.

Below are some key takeaways from our Regional Liaison Services over the past few years:

- It took a while from launch for all doctors to become aware of the guidance
- It is useful that it applies to doctors and nurses as that enabled multidisciplinary training, which is helpful as whole teams are usually involved in incidents
- There was some confusion over the difference between the professional and organisational duty of candour, and it is useful to explain the difference (our professional guidance applies

in more situations than the organisational duty of candour and we therefore welcome the fact that the draft statutory guidance highlights this)

- Being clear on the difference between an apology and an admission of guilt/responsibility is key in enabling doctors to do the first without fear of the second
- Those involved in the organisational statutory response also need to be aware of the professional duty – we heard examples of cases where doctors said they were told not to speak to patients while an investigation was underway – this could put them in breach of our guidance.

Consultation document questions

This section covers our responses to the questions posed in the Consultation Document. We have included all questions for which we have specific comments to make.

Chapter one: Statutory Guidance Duty of Candour

Question 3: Are the guidance and case studies useful in determining what is meant by harm that "could" be experienced?

We think the explanation in the statutory guidance of harm a service user 'could experience' (paragraphs 5.3-5.6) is useful and that the illustrative case studies for these situations in Annex H are helpful. We also welcome the fact that the statutory guidance at paragraph 5.5 draws attention to the fact that our own joint guidance with the NMC applies in 'situations where a patient may yet suffer harm or distress as a result of something going wrong with their care'.

Question 7: Is the relationship between the professional duty of candour that many health - professionals are subject to and the statutory duty of candour clear?

We are pleased that the guidance states that the new duties on organisations will complement existing professional duties. As mentioned, we also welcome the fact that the guidance acknowledges that our joint guidance with the NMC covers a wider range of situations than the statutory duty of candour. While we believe that the draft guidance makes the distinction between the professional and statutory duties clear, adding an explicit encouragement for all registrants to familiarise themselves with information or guidance issued by their professional regulator about the professional duty of candour may also help increase understanding. Linked to this, we consider there's also an opportunity for the statutory guidance to highlight the GMC's and NMC's respective case studies on how the professional duty of candour applies in practice for our registrants.

Please also refer to the section above on 'Professional duties of candour'.

Question 12: Is the guidance clear when harm to Service Users that occurs whilst waiting for diagnostics and treatment triggers the duty of candour?

As the Welsh Government acknowledges in the statutory guidance, complex situations can be involved where service users suffer harm while waiting for diagnostics and treatment. While we don't have specific comments on the guidance between 8.77 and 8.83, we believe that it will be particularly important to understand the views of health and care professionals, and their representative bodies, on this issue. This includes whether they'd value further support or guidance in dealing with these situations.

Question 17: Is it reasonable to suggest the duty of candour report should be aligned to the existing annual PTR report already in place to avoid duplication?

Yes, it seems sensible to avoid duplication and prevent disproportionate burden on service providers.

Chapter two: Candour procedure regulations

Regulation 7(3) recognises that there will be situations where an NHS Body, despite taking reasonable steps, is unable to contact the Service User or person acting on their behalf to notify them the duty of candour has been triggered. It also caters for the possibility that a Service User or person acting on their behalf may decide they do not wish to communicate with the NHS Body about the duty of candour.

If this happens, the regulation requires the NHS Body to make a record of attempts to contact or communicate with the Service User/person acting on their behalf and provides that it is not required to communicate any further with the Service User/person acting on their behalf about the notifiable adverse outcome (i.e. the incident that triggered the application of the duty).

Question 20: Are the provisions at regulation 7(3) which allow an NHS Body to record when it will not be engaging with a Service User or a person acting on their behalf, either because:

(i) they have made reasonable attempts to contact them and failed; or

(ii) where the Service User has determined they do not wish to communicate about the duty, proportionate?

We believe these provisions are proportionate. In our joint guidance with the NMC (paragraph 13) we say that that patients will normally want to know more about what has gone wrong. But doctors should give patients the option not to be given every detail. If the patient does not want more information, doctors should try to find out why. If after discussion, the patient doesn't change their mind, their wishes should be respected and the potential consequences should be explained. Doctors must also record the fact that the patient doesn't want this information and make it clear that they can change their mind at any time.

Question 22: Do you agree that "in person" notification is appropriate and proportionate when informing a Service User or their representative that the duty of candour has been triggered?

Question 23: Do you agree that it is appropriate and proportionate that the NHS Body has the choice of which form of "in person" notification is most appropriate, taking into account these factors above?

We believe it is important to consider someone's preferred method of communication. A key principle in our guidance is that doctors must give patients (or those people with the legal authority to make healthcare decisions on a patient's behalf) the information they want or need to know in a way they can understand (*GMP*, paragraph 32). It's important to recognise that in some cases a person's preferred method may not be 'in person', but in writing via email, letter, or text. The Welsh Government may want to consider how a requirement for 'in person' notification will relate to situations where a person has agreed in advance with their service provider their preference for written communication. However, we welcome that the guidance highlights that NHS bodies must consider, among other issues, the personal circumstances of the service user and any known preferred method of communication, when deciding which form of 'in person' notification is most appropriate.

Question 24: Does the guidance on how to make a meaningful apology set out at section 7e and Annex E of the Guidance provide sufficient information and advice to ensure a personal, meaningful apology is conveyed?

We welcome the emphasis in the candour procedure and in Annex E on the importance of a meaningful apology, and the clear acknowledgement that saying sorry is not an admission of legal liability. Our own guidance on the professional duty of candour strongly emphasises both points.

Question 28: What type of training do you think would be required by NHS staff in addition to the current NHS training in order for the Duty of Candour to be successful?

As noted in the 'Lessons learned from implementation' section above, it is our experience that in England and Scotland, multidisciplinary training on the duty of candour proved helpful as whole teams are usually involved in incidents.

Our guidance (paragraph 30) notes that senior clinicians have an additional responsibility to lead by example and to actively foster a culture of learning and improvement, in relation to reporting on and learning from adverse incidents and near misses. The Welsh Government may therefore want to consider how it can address any training needs of such senior clinicians.

Question 29: Are the provisions related to staff support proportionate?

Our guidance (paragraph 27) notes that organisations should support staff to routinely report adverse incidents and near misses. We are pleased that the statutory guidance says that NHS bodies must provide staff who are involved in a 'notifiable adverse outcome' with details of

support services, and that these should take the circumstance of the incident and the staff member's own needs into account. However, we think there is also an opportunity to highlight the importance of staff raising concerns if they do not feel supported in reporting, or if they are discouraged or prevented from reporting a notifiable adverse outcome. The guidance could then signpost to relevant further guidance to support professionals in raising concerns, such as the GMC's guidance on this subject.

Chapter three: Further amendments to the PTR Regulations

"The Duty of Candour has a lot in common with Putting Things Right. Sometimes these laws will work together and impact one another.

Because of this some changes will need to be made to Putting Things Right, to make sure they work with the Duty of Candour. For example, Putting Things Right says that you can decide not to tell someone if harm was caused if it is in their best interest. The NHS would still need to write up details of this. And say why they decided not to tell the person.

Now Putting Things Right says that the person must be told if something went wrong with their care, in accordance with the objective behind the Duty of Candour

But they do not need to be involved in the process or the investigation, if that is what is best for them. Usually, people will be involved in investigations. But sometimes this may cause more stress or harm."

Question 33: Do you think changing the Putting Things Right rules like this will cause problems? For example, do you think it would be better to not tell the person what has happened if it is in their best interest?

It seems reasonable and helpful to change requirements in Putting Things Right (PTR) to make sure that it's compatible with the Duty of Candour.

The consultation document explains that, up to now, PTR has allowed NHS providers to decide not to tell someone if harm was caused, where this is in the person's best interest, although the provider is still required to write up the details of this and explain why they decided not to tell the person (for ease of reference we refer to this below as the existing approach).

The consultation document says that PTR will now say that a person must be told if something went wrong with their care, in accordance with the objective behind the Duty of Candour. But the person doesn't need to be involved in the process or the investigation, if that's what's best for them (for ease of reference we refer to this below as the proposed approach).

We understand the Welsh Government is asking whether the proposed change to PTR is the right approach or whether there is a case for continuing to permit NHS providers not to tell a person

what has happened where something has gone wrong with their care, if they judge that this is in their best interest (based on possible harm to the patient).

In our view, adopting the proposed approach to PTR, or retaining the existing approach after a statutory duty of candour is introduced, may not wholly support the Welsh Government's positive intentions around promoting candour and delivering the benefits of the open disclosure culture that the government wants to achieve.

We'd also point out that, if the organisational duty of candour includes scope not to disclose an incident and/or not to involve the person affected in the investigation of an incident, this may well come into conflict with the professional duty of candour that health professionals are expected to meet. We think the proposed approach is closer to the professional duty but please see what we say about the duty below.

In our guidance on the Professional duty of candour we set expectations on doctors, when they realise that something has gone wrong, to do what they can to put matters right, and then ensure that they or someone from the healthcare team speaks to the patient about what has happened. We say they should share all they know and believe to be true about what went wrong and why, and what the consequences are likely to be. They should explain if anything is still uncertain and must respond honestly to any questions (paragraphs 10 and 12).

We also deal with situations where people may not want to know the details of what has gone wrong (paragraph 13). We say that doctors should give the patient the option not to be given every detail. If the patient doesn't want more information, doctors should try to find out why. If after discussion, the patient doesn't change their mind, doctors should respect their wishes as far as possible, having explained the potential consequences. Doctors must record the fact that the patient doesn't want this information and make it clear to them that they can change their mind and have more information at any time.

Doctors would be faced with a dilemma, if the organisation in which they are working decides to withhold information from a patient based on a 'best interest' test, when in the same circumstances they have a professional duty to share the information with the patient.

It's not clear how organisations would assess the 'best interests' of a patient, in terms of receiving information related to their care. For example, what type of potential harm and how imminent or serious would it have to be to justify non-disclosure of relevant information? If the patient has capacity to decide what information they wish to receive (or refuse) about matters relating to their care could a 'best interest' judgement be made on their behalf? Or would best interest judgements only apply where a patient lacks capacity at that time to make their own decision? We think that if it is decided to permit information to be withheld in some circumstances, it will be vital for the Welsh Government to clearly define the factors to be taken into account in assessing a person's best interests. And given the implications for regulated professionals of such decisions, it would also be particularly important to explore and set out

how the organisational and professional duties would interact. We'd welcome the opportunity to discuss these issues further with the Welsh Government so we can better understand how both duties will interact and how any tensions can be best addressed.

We'd also want to see more advice for NHS professionals and other staff on how to share information in a sensitive and supportive way, which allows patients to manage the pace and nature of the information provided. In addition, where service providers decide not to disclose information to patients, it would be important to clearly record the details and reasons in the patient's record. Even if information isn't disclosed at the time of the events, or as part of the investigation, it's important to consider how the patient can find out at a later date what has happened and why their care provider decided not to share information with them.

Chapter five: Integrated Impact Assessments

Question 38: We would like to know your views on the effects that the Duty of Candour proposals would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favorably than English. For example, what effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Question 39: Please also explain how you believe the proposed Duty of Candour policy could have positive or negative effects on opportunities for people to use the Welsh language or treat it no less favorably than the English language?

As a regulator, we are committed to offering our services to the public in Wales in both Welsh and English. We believe that the Welsh Language Standards for Healthcare Regulators provide an opportunity to improve the services we offer.