Duty of Candour in the NHS and Primary Care – Frequently Asked Questions

1. **Does the Duty of Candour only apply if the NHS body or the Primary Care Provider was at fault?**

No. The presence or absence of fault on the part of the provider has no impact on whether or not a Duty of Candour is triggered. The trigger is if harm that is moderate, severe or death has occurred or may yet occur, and that the provision of health care may be or was a factor.

2. **Can the Duty of Candour procedure be triggered even if the patient has consented for a procedure to be carried out?**

Yes. Whether or not the patient has given consent does not affect the application of the Duty. If the patient experiences (or the circumstances are such that they could experience) any unintended or unexpected harm that is more than minimal and the provision of health care was or may be a factor, the Duty of Candour procedure would be triggered. This may include recognised and consented-for complications of a procedure if the level of harm is above that which is expected. The guidance provides definitions of the levels of "more than minimal harm", which are considered to constitute moderate harm, severe harm and death.

3. **How does the Duty of Candour work in Primary Care?**

The implementation of the Duty of Candour procedure should operate in Primary Care settings in the same way that it will be implemented across Health Boards, Trusts and Special Health Authorities with the exception of reporting. Primary Care providers are required to submit their Candour reports to the commissioning Health Board by the end of September for the preceding financial year. The Health Board will include the data in their annual Duty of Candour Putting Things Right (PTR) report, due at the end of every October.

Primary Care contractor staff should be aware that the Duty of Candour falls on the business owner/ contractor and not on individual staff in the business.

There is a Duty of Candour that applies to social care that is different from the Duty of Candour in health. Where treatment crosses health and social care – for example in mixed delivery models of care – it is important that health and social care providers work together and avoid duplication for patients and their families.

4. **Are we talking about an intervention that has gone wrong when we are defining a Duty of Candour incident?**

Possibly. Whether the Duty of Candour procedure is triggered will be decided through local discussions in respect of whether the service user suffered unintended or unexpected harm that is more than minimal (moderate and above) that is related (or may be related) to the provision of health care. There are occasions when a degree of harm is expected within treatment and this would not necessarily trigger

the duty. There are also times when an intervention goes wrong but does not cause harm, or does not cause harm that is more than minimal, and this would not trigger the duty.

5. If the incident occurred before the Act came into force, but has only been discovered recently, should the Duty of Candour procedure be carried out?

There is not a legal requirement to carry out the specific requirements laid out in the Act and Candour Regulations for something that happened before the Candour legislation was brought into force. However, the expectation is that care providers will behave in the spirit of the Duty of Candour regulations – i.e. to apologise and to be open and transparent with people about whatever has been discovered.

If the incident is discovered through a retrospective case review, and it occurred after the requirements of the Act had been formally brought into force, then this would trigger the Duty of Candour procedure. The reasons for the retrospective management of the duty of candour procedure would need to be clearly documented and explained to the individuals involved.

6. How will incidents be investigated?

Incidents giving rise to the Duty of Candour must be investigated in accordance with the existing 2011 Regulations i.e.in line with the Putting Things Right process. If the 2011 Regulations do not apply, the incident will be investigated in accordance with the health care provider's own incident investigation processes. The 2011 Regulations apply to Primary Care providers and independent health care providers under contract with the NHS, but do not apply to the NHS Blood and Transplant NHS trust except in terms of its functions in Wales.

7. How will Primary Care Practitioners report incidents?

The platform for capturing and recording instances where Duty of Candour is triggered is Datix Cymru, although it is not mandatory to use this system. Datix Cymru is a secure, cloud based, interactive system which enables Primary Care providers to make the necessary reports. Where accessing the system via a login, providers can see updates on cases. The Datix Cymru system is also used to notify patient safety concerns to the relevant Health Board.

Datix Cymru is available to all Primary Care providers. More information on Primary Care Incident Reporting, and a link to access the Datix system, can be found at this dedicated website.

8. What training on the Duty of Candour will be available to NHS staff and Primary Care Providers?

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The guidance is complemented by an online training package to support NHS bodies with the implementation of the Duty. Building on the work that has already been started as part of the PTR process to embed candid behaviour, the Welsh Government training programme considers how to encourage the cultural shift by making openness and transparency a normal part of the culture across NHS bodies in Wales. Please use this link to directly access the Duty of Candour e-learning module using the Digital Learning Wales platform. To access the platform you will need a username and password. Some email addresses can self-register for access to the platform - these include .ac.uk, .gov and .pnn If you don't already have a login and are unable to self-register, you can contact the All Wales E-learning Helpdesk on elearning@wales.nhs.uk or 01443 848636; or chat is available on Learning@Wales

There is a short awareness video for all staff to view with general principles and guidance on Candour, and an education package for individuals likely to be involved in processing Candour incidents or liaising with those patients affected.

9. How do NHS bodies and Primary Care providers report annually on the duty of Candour?

NHS bodies must submit a report outlining the number of times the Duty of Candour has come into effect and include those incidents from PCPs. The NHS body must also outline the lessons learned and what has been put in place to prevent this from occurring again.

Primary Care providers should complete an annual report on whether the Duty of Candour has come into effect in relation to NHS health care they have provided. The report should be submitted to the Health Board by 30 September each year.

If a Primary Care provider gives health care on behalf of two or more Health Boards, a separate annual report should be submitted to each Health Board.

The report must specify how often the Duty of Candour has come into effect during the reporting year. It should give a brief description of the circumstances, and specify any steps taken by the body with a view of preventing similar circumstances from arising in the future.

By 31 October each year, the Local Health Board must prepare a summary of reports received from Primary Care providers.

10. What are the oversight arrangements for Primary Care?

Regulation 10 requires NHS bodies to designate a person to be responsible for maintaining a strategic oversight of the operation of the Candour procedure. Primary Care providers have discretion in relation to whom to assign such roles.

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Regulation 11 requires NHS bodies to designate a person who has overall responsibility for the effective day-to-day operation of the procedure under the Candour Procedure Regulations. For Primary Care providers, it must be the person who acts as the Chief Executive of the body. If there is no Chief Executive, it is:

- the person who is the sole proprietor;
- in cases of a partnership, a partner; or
- in any other case a director or person responsible for management.

11. What about services commissioned by a Health Board with a Primary Care provider?

Where a Health Board enters into arrangements with a Primary Care provider for the provision of NHS services, it is the primary care provider who is subject to the duty.

Prison health

The majority of health services provided for His Majesty's Prisons and other Justice services are provided through Health Boards and commissioned services provided to the Health Board by other NHS services or Independent providers.

Community pharmacy

Registered pharmacists, pharmacy technicians and persons working under their supervision in a retail pharmacy should continue to be mindful of the provisions of the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 ("the Order") the requirements of the Order need to be considered alongside and in addition to the statutory duty of candour.

12. What about services commissioned by a Health Board or NHS Trust with an Independent Health Care provider?

Where a Health Board enters into arrangements with an Independent Healthcare provider for the provision of healthcare on behalf of NHS services, it is the Health Board or NHS Trust to whom the duty is applied.

13. Is triggering the Duty of Candour and providing an apology an admission of guilt or liability?

No – the law clearly allows for openness and transparency and the act of giving an apology does not mean liability has been admitted.