

Duty of Candour Internal Audit Report December 2024

Public Health Wales NHS Trust

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Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Chartered Institute of Public Finance & Accountancy in April 2023.

Acknowledgement

NHS Wales Audit and Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

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Executive Summary

Purpose

To review the operation of the Trust's Duty of Candour process.

Overview

We have issued reasonable assurance on this area.

The matters requiring management attention include the following recommendations:

- Consideration be given to adopt the Welsh Government statutory guidance on Duty of Candour as opposed to having a bespoke Trust Policy. The statutory guidance is more comprehensive.
- Implementation of Memorandums of Understanding or Service Level Agreements for Duty of Candour cases where responsibility for completeness of information is shared with other health organisations.

We have made some observations with regards to the functioning of the mandatory fields in the All Wales Datix system should be fed back to the system owner.

Report Opinion



Reasonable

Some matters require management attention in control design or compliance.

Low to moderate impact on residual risk exposure until resolved

Assurance summary¹

Objectives	Assurance
1 Process and procedures	Reasonable
2 Duty of Candour - training	Substantial
3 Operation and compliance	Reasonable
4 Monitoring and reporting	Substantial

¹The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

Key Matter Arising

	Objective	Control Design or Operation	Recommendation Priority	
1	Duty of Candour – supplementary guidance and checklists	1 & 3	Design	Medium

1. Introduction

- 1.1 This audit of the Duty of Candour arrangements was completed in line with the 2024/25 Internal Audit Plan for Public Health Wales NHS Trust (the 'Trust').
- 1.2 The Duty of Candour (the 'Duty or 'DoC') was introduced in April 2023 as part of the Health & Social Care (Quality and Engagement) (Wales) Act 2020 along with the Duty of Quality.
- 1.3 The Duty requires NHS organisations to be open and honest with people they are providing healthcare for and, if things go wrong and harm has occurred, they must recognise this and communicate with the service user. This builds upon the principles of the 'Putting Things Right Regulations' that were in place. The overall objective is to ensure that when a person receives healthcare from the NHS in Wales, they will be dealt with in an open and honest way by their care provider. The Duty ensures that NHS organisations are clear about avoiding a blame culture and supports those where mistakes and errors have been made.
- 1.4 When an incident occurs which meets the DoC criteria it should be investigated by the relevant NHS organisation within the required timeframes to understand what happened, with a view to identifying areas for improvement and lessons being learnt.
- 1.5 In April 2023, the Trust developed a DoC policy and procedure document to satisfy the requirements of the 2023 Duty of Candour statutory guidance. The policy and procedure describes the arrangements in place for managing incidents where it is suspected that the DoC has or may have been triggered. It also aims to ensure that appropriate structures and reporting mechanisms are in place to enable DoC incidents to be investigated and managed in a proactive and timely manner, as required by the statutory guidance.
- 1.6 The potential risk considered as part of this audit was as follows:
 - Strategic Risk 5: Failure to deliver excellent public health services on screening, infection, health protection and Emergency Planning Resilience and Response (EPRR) and comply with the Duty of Quality.

2. Detailed Audit Findings

Objective 1: Clearly defined procedures are in place for the management of Duty of Candour cases, which are in line with Welsh Government guidance and include the roles and responsibilities for identifying, investigating and monitoring cases.

- 2.1 The Trust has a policy and procedure document for the Duty of Candour. The policy and procedures are consistent with the All Wales statutory policy and procedure in relation to the definitions of roles and responsibilities for the process. However, it contains less information than the Welsh Government's statutory Duty of Candour policy and procedure document. The Trust's document describes what 'should happen', but does not provide operational guidance for delivery of the process. For example, a detailed 'how to' guide for a new employee or someone providing cover.

As such, the Trust should consider the need to further develop its own operational process guide. **(Matter Arising 1 – Medium Priority)**

- 2.2 During our fieldwork we identified that the All Wales statutory guidance paragraphs around incident review and investigation are not clear and may be contradictory. For example, one paragraph states that if an incident 'could cause harm' it should be considered, while a later paragraph specifically excludes 'near misses'. If the Trust reviews its policy and procedure, there is an opportunity to clarify its own position on such matters.

Conclusion:

- 2.3 The policy and procedure documentation supports the Trust's Duty of Candour processes including relevant definitions and clarity on the roles and responsibilities for identifying and monitoring of cases. We note that the Trust's version of DoC guidance contains less detail than the statutory guidance. In addition, there is an opportunity to develop process notes at an operational level. We have provided reasonable assurance for this objective.

Objective 2: Trust wide training and ongoing support is in place to help staff meet their Duty of Candour responsibilities

- 2.4 The Trust launched the Duty of Candour at the appropriate time and ensured staff were aware of the nationally available DoC e-learning (level 1) available on ESR.
- 2.5 Additionally, the Trust has created a bespoke DoC training course for staff involved in the review and management of incidents (level 2). We understand that this course has been delivered during 2023 and 2024 and is available as a refresher, or for new reviewers. The Trust has a record of staff that have completed DoC training. At the time of our fieldwork, 304/367 staff (84%) had completed it.
- 2.6 Duty of Candour guidance, *ad hoc* support and training to Trust staff is provided by the 'Putting Things Right' team. There is a dedicated DoC section on the Trust's intranet where staff can find DoC related information, such as upcoming training sessions and the relevant policies and procedures.

Conclusion:

- 2.7 The Trust has relevant training material and training records, as such we have issued substantial assurance for this objective.

Objective 3: Robust processes are in place to ensure that the Trust complies with requirements of the Duty of Candour.

- 2.8 The Duty of Candour is linked to the incident management process with incidents managed using the 'Once for Wales' Datix system. Our sample testing of cases from Datix revealed some inconsistencies in the use of Datix and how fields within it were completed.
- 2.9 Duty of Candour decision making requirements are part of the proscribed incident management and investigation process, which includes peer review and quality checking. The DoC trigger decision is made by the Quality, Safety and Putting Things Right team (QSPTR), who review incidents as part of that process.

Incidents, including those where the DoC has been triggered, are recorded on the QSPTR team tracker for control, monitoring and reporting purposes.

2.10 At the time of our fieldwork the Trust had a low volume of DoC cases. As such, we reviewed all of the cases selected from the Trust's incident tracking spreadsheet. We confirmed the completeness of the DoC cases using an 'all cases' Datix report and filtering using the DoC triggering criteria. We make the following observations:

- DoC cases were appropriately identified and managed within the Trust's process. However, we note that the Trust's guidance could go further by clearly defining the DoC critical date (first became aware date), as currently there is no distinction if this date should be when the matter is reported or when the review of the facts has been completed. **(See Matter Arising 1)**
- While the Trust has only a few DoC cases for which it has responsibility, there may be cases where the Trust may be a contributor to a case where responsibility lies with another NHS body. These cases could be significantly more complex. Our review of these cases highlighted there can be difficulties and differences communicating and resolving them, especially if third parties, such as solicitors, are involved. For these instances, it can be difficult to know which process to follow so the Trust should consider providing information on dealing with complex cases within its guidance. **(See Matter Arising 1)**
- We identified that the completion of the fields necessary for confirmation that the DoC has been properly considered is not consistent or enforced by the system logic within the All Wales Datix system. For example, an incident involving the service user can be closed without the two current key fields (healthcare question, and managers harm level) being completed. **(Observation 1)**
- We also note that when the DoC is triggered on Datix it requires a 30-working day target to be manually calculated. This is then set as the process completion date. This timeframe does not appear to be mandated in the statutory guidance and may not be achievable in complex cases. **(Observation 1)**

Conclusion:

2.11 Although we have found some weaknesses in the Datix system use we consider the Trusts QSPTR processes operating Duty of Candour with it to be effective and can award reasonable assurance for this objective.

Objective 4: Timely monitoring and reporting arrangements are in place at appropriate levels within the Trust, which include lessons learnt and contribute to a system of continuous improvement.

2.12 The Trust has an established routine for reporting of incidents, including DoC cases, through the executive management team to the Quality Safety and Improvement Committee (QSIC) and Board as appropriate.

2.13 Lessons learned are part of the incident management process and evidenced in the Datix system for each case, and summarised in the management and annual reports.

2.14 We note that the DoC annual report, as required by the statutory guidance, was presented to the business executive team and Board in May 2024.

Conclusion:

2.15 The Duty of Candour reporting process appears to operate effectively. As such, we have issued substantial assurance for this objective.

Appendix A: Management Action Plan

Matter Arising 1: Duty of Candour – supplementary guidance and checklists (Design)		Impact
<p>The Trust’s DoC policy and guidance is similar to the Welsh statutory versions, but has less detail. The Trust should consider reviewing its policy and provide greater detail around operational processes where appropriate, with the creation of specific and detailed process notes. This could further ensure consistency of operation across divisions of the Trust. In addition, there is an opportunity to provide localised clarity in relation to the parts of the All Wales guidance that are less clear.</p> <p>The critical date for DoC is the ‘first became aware’ date. The date is explained in the guidance, but not clearly and specifically defined. It would assist with the operation of the Duty if it was.</p> <p>The WG statutory guidance includes a section on complex cases, including where more than one NHS body is involved, or the NHS and other organisations. However, in the absence of detailed guidance notes or operating procedures, it is not clear what process should be followed. Given the Trust’s role across Wales it may be involved in more complex or ‘joint’ cases with other health organisations.</p>		<p>Potential risk of:</p> <ul style="list-style-type: none"> • Delay or failure to follow correct procedure • Misunderstanding and misdeclaration of complex cases
Recommendations		Priority
1.1	The Trust should create a guide for managers and reviewers to follow for DoC consideration, especially with regard to assessing harm correctly, completing their initial review, and properly recording these on the Datix system.	Medium
1.2	The Trust’s guidance should clearly define the DoC critical date (first became aware date) as currently there is no distinction if this date should be when the DoC is reported or if the date is when a review of the facts has been completed.	Medium
1.3	In order to prevent delays in taking required Duty of Candour actions, procedures that are developed should provide clear guidance on dealing with complex cases where more than one NHS body or another organisation is involved.	Low

Agreed Management Action	Target Date	Responsible Officer
1.1 The Trust will develop a guide for incident managers to support them with the initial review and actual levels of harm for incidents recorded as moderate. The Trust will also formalise the procedure for the meeting between the service area and PTR team should a moderate incident be recorded.	31/01/2025	Quality, Safety and PTR Manager
1.2 The Trust will update its guidance to be clearer on the DoC critical date to reflect triggering of the DoC once the review of the facts has been completed.	31/01/2025	Quality, Safety and PTR Manager
1.3 The Trust will develop an internal procedure for the management of joint DoC incidents with an internal escalation procedure. PHW will work with the Welsh Risk Pool Duty of Candour Network to request a joint process for investigation and support its development.	31/03/2025	Quality, Safety and PTR Manager

Observation 1: All Wales Datix system (Design)		Impact
<p>The logic used by the All Wales Datix system guides and supports the system user to make correct and completed declarations. We made a small number of observations:</p> <ul style="list-style-type: none"> Cases can be closed without defining the Healthcare, the harm level, and the managers initial review outcome field being completed. The nursing care involvement field can be answered 'yes' while the healthcare involvement question can be answered 'no'. This appears to be a contradiction. 		<p>Potential risk of:</p> <ul style="list-style-type: none"> Failure to support incident managers, reviewers, and the Duty of Candour process in general
Recommendation		Priority
2.1	We acknowledge that the Trust cannot directly change the Datix system. The Trust should raise the identified matters with the Datix system owner.	-
Agreed Management Action		Target Date
2.1	The Trust will work with the OfWCMS team to review the highlighted fields to support the identified issues.	31/03/2025
		Responsible Officer
		Quality, Safety and PTR Manager

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	Substantial assurance	Few matters require attention and are compliance or advisory in nature. Low impact on residual risk exposure.
	Reasonable assurance	Some matters require management attention in control design or compliance. Low to moderate impact on residual risk exposure until resolved.
	Limited assurance	More significant matters require management attention. Moderate impact on residual risk exposure until resolved.
	Unsatisfactory assurance	Action is required to address the whole control framework in this area. High impact on residual risk exposure until resolved.
	Assurance not applicable	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.



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