Internal Audit

Duty of Candour

November 2019

Internal Audit Assurance assessment:

Objective One	Objective Two	Objective Three	Objective Four
Significant Assurance	Significant Assurance	Significant Assurance	Significant Assurance

Timetable

Date closing meeting held: 10th October 2019

Date draft report issued: 14th October 2019

Date management comments received: 7th November 2019

Date Final report issued: 11th November 2019

Date presented to Audit and Risk Committee: 25th November 2019

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1. Introduction

1.1 An adverse event can be defined as an event that could have caused, or did result in, harm to people or groups of people. NHS Lothian acknowledge that the provision of healthcare is complex, and things can go wrong.

1.2 The Scottish Government have recently introduced statutory organisational Duty of Candour legislation (The Duty of Candour (Scotland) Regulations 2018) in Scotland on 1 April 2018. The purpose of this legislation is to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm, that is not related to the course of the condition for which the person is receiving care. The duty applies to a subset of adverse events where a defined level of harm has occurred, and the event was not expected as part of the care or service delivery plan

1.3 Following the introduction of this requirement, NHS Lothian has an Adverse Events policy which has incorporated the requirements of Duty of Candour as it is closely mapped against the significant adverse events process. Additionally, NHS Lothian have compiled a toolkit to support staff to follow the duty consisting of process maps and Duty of Candour guidance as well as updating DATIX fields to capture information for monitoring and reporting Duty of Candour.

1.4 NHS Lothian, as with other Health Boards and relevant organisations published an a report in August 2019 covering the first year of implementation of Duty of Candour, this will continue to be annual reporting requirement. It is recognised that there has been significant learning from the first year of implementation and that there may be improvements required to the processes as it becomes more embedded.

Scope

1.5 The objective of the audit was to review the procedures in place at NHS Lothian to ensure their processes align the requirements of the Duty of Candour legislation. The review considered NHS Lothian policies and operational procedures and what processes are in place to ensure staff identify when a case would trigger Duty of Candour and know how to implement the procedure once identified. Recognising that the process is new and has recently been established, we considered how process improvement is occurring and how lessons learned are being incorporated into the process going forwards.

1.6 It should be noted that the audit did not consider NHS Lothian's Adverse Events procedures. This is to reflect that Healthcare Improvement Scotland has recently undertaken a review into the Adverse Event procedures within the Board and internal audit did not want to duplicate this work.

Acknowledgements

1.7 We would like to thank all staff consulted during this review, for their assistance and cooperation.

2. Executive Summary

Summary of Findings

2.1 The table below summarises our assessment of the risks and the adequacy and effectiveness of the controls in place to meet each of the risk areas agreed for this audit. Definitions of the ratings applied to each action are set out in Appendix 2.

No.	Control Objectives	Assurance Level	Number of findings			
			Critical	High	Medium	Low
1	NHS Lothian's policies and processes align to the Duty of Candour requirements	Significant Assurance	-	-	-	-
2	There is a robust process in place for identifying adverse event cases which trigger Duty of Candour	Significant Assurance	-	-	-	1
3	Once identified, there is a robust process in place to implement the Duty of Candour procedures	Significant Assurance	-	-	-	-
4	There is a process in place to better improve the procedures for Duty of Candour, including incorporating lessons learned	Significant Assurance	-	-	-	1
TOTAL			**-**	**-**	**-**	**2**

Conclusion

2.2 There were clear processes in place across NHS Lothian, including at a service level, aligning to the Duty of Candour legislation with training being provided to appropriate staff, reporting of severe adverse events updated to reflect changes and a well-defined process for identifying and following Duty of Candour procedures.

2.3 A few minor areas for improvement (of a housekeeping nature) were identified during the audit, including the need to update the DATIX e-learning managing and reviewing adverse events module training and ensuring a formal action plan is put in place against identified improvements recognised by the Adverse Events Leadership Group.

Main Findings

2.4 Policies and procedures have been updated to reflect the Duty of Candour requirements and are available for all staff on the intranet. This has been supported through training provided at local level and updates to the reporting of adverse events to include a requirement to consider Duty of Candour. It was identified that whilst the majority of documents and training had been updated to incorporate Duty of Candour, the DATIX e-learning 'managing and reviewing adverse events' module had not been updated to reflect the new requirements and changes made to DATIX reporting as a result.

2.5 Recognising that the identification of a Duty of Candour event is subjective, clear processes are in place to ensure the decision is made by more than one individual. Acute Clinical Management Teams (CMT) and Health and Social Care Partnership's (HSCP) Senior Management Teams (SMT) are required to review all significant adverse events (defined as where major harm or death has occurred) and consider whether organisational Duty of Candour applies. The Medical Director will then validate all decisions to activate the Duty of Candour procedure to ensure consistency across the organisation.

2.6 Where a moderate harm has occurred, this is considered by local management teams within services (usually Clinical nurse managers/clinical director level staff) in line with established processes for managing adverse events. If agreed that organisational Duty of Candour applies, this is escalated to the relevant HSCP SMT/Acute CMT for agreement and validation sought from Medical Director as for significant adverse events. In these circumstances the Quality Improvement Support Team (QIST) perform an 100% audit of events to ensure a decision is not taken incorrectly and provide a second review.

2.7 There were generally well-defined processes in place for following the Duty of Candour processes once an event had been identified as occurring, including notifying the patient or their family and arranging a personal meeting with them, with these recorded on DATIX. An issue identified was in relation to completing the review process in a timely manner. For Duty of Candour, a review should ideally be completed within 90 of identifying the event. Of the 45 Duty of Candour events recognised in 2018/19, 62% took longer than 90 days to complete, with the longest time taken for one event being 327 days. This has been an area recognised for improvement across adverse events and Duty of Candour and actions have been agreed to improve this going forwards. Given this is a key focus of the QIST, we have not recorded an audit finding in relation to this, as a process is in place to address this.

2.8 A lessons learned exercise has been performed by the Adverse Event Leadership Group, which has representation from all service areas and QIST staff, to identify areas for improvement to the Duty of Candour process. Actions identified were split across QIST and service staff, however, a formal action plan and process for monitoring progress was not put in place following this.

3. Management Action Plan

Control objective 1: NHS Lothian's policies and processes align to the Duty of Candour requirements
We identified no issues in relation to this control objective. Policies and procedures have been updated to reflect the Duty of Candour requirements and are available for all staff on the intranet. The Duty of Candour requirements have been built into local flowcharts and processes to ensure these are considered.

Control objective 2: There is a robust process in place for identifying adverse event cases which trigger Duty of Candour	
Finding 2.1 – DATIX e-learning training should be updated to reflect the Duty of Candour reporting requirements	**Low**
Background Mandatory training is provided to all NHS Lothian staff on induction on adverse events and Duty of Candour in the form of a Health and Safety Module. In addition, non-mandatory training is available for staff on managing and reviewing adverse events within a DATIX e-learning reporting module. As part of the introduction of Duty of Candour, training was also undertaken at a local level by QIST staff and provided to Acute Clinical Management Teams, Team Leads, the Patient Experience Team among others. Observation and risk Whilst assurance was provided that appropriate training was put in place on introduction of Duty of Candour, it was identified that the DATIX e-learning module on managing and reviewing adverse events had not been updated to reflect the introduction of Duty of Candour and its requirements, as well as include the changes made to DATIX reporting as part of NHS Lothian's new processes. There is a risk that without this being updated, staff may not be aware of the new requirements and processes may not be followed.	
Recommendation The DATIX e-learning module on managing and reviewing adverse events should be updated to reflect the requirements of the Duty of Candour legislation and NHS Lothian's changed reporting processes.	
Management Response Agreed. Management Action Content of module currently being reviewed and changes will be forwarded by 31 December 2019 to Corporate Education and Training department to effect changes in the Learnpro system.	
Responsibility: Quality & Safety Assurance Lead	Target date: 31 March 2020

Control objective 3: Once identified, there is a robust process in place to implement the Duty of Candour procedures
We identified no issues in relation to this control objective. There were generally well-defined processes in place for following the Duty of Candour processes once an event had been identified as occurring, including notifying the patient or their family and arranging a personal meeting with them, with these recorded on DATIX. An issue identified was in relation to completing the review process in a timely manner. For Duty of Candour, a review should ideally be completed within 90 of identifying the event. Of the 45 Duty of Candour events recognised in 2018/19, 62% took longer than 90 days to complete, with the longest time taken for one event being 327 days. This has been an area recognised for improvement across adverse events and Duty of Candour and actions have been agreed to improve this going forwards. Given this is a key focus of the QIST, we have not recorded an audit finding in relation to this, as a process is in place to address this.

Control objective 4: There is a process in place to better improve the procedures for Duty of Candour, including incorporating lessons learned	
Finding 4.1 – A formal action plan should be put in place to ensure improvement areas identified are completed	**Low**
Background To support the implementation of the Duty of Candour processes, an Adverse Events Leadership Group was established, chaired by the Medical Director with representation from all service areas and QIST staff. This group meets bi-monthly throughout the year. At the end of the first year of implementation of Duty of Candour, a lessons learned exercise was undertaken and areas for improvement identified for both the service areas and QIST staff. Observation and risk It was identified that whilst improvements had been identified, this was not supported by a formal action plan, with defined ownership and timescales. There is a risk that without this in place, actions will not be addressed in a timely manner and progress against actions will not be monitored by the Group.	
Recommendation A formal action plan should be put in place to ensure improvements identified are addressed going forwards. This should be reported to the Adverse Events Leadership Group at their bi-monthly meetings.	
Management Response Agreed. Management Action Improvement plan in place for presentation to AE leadership group on 27 November 2019.	
Responsibility: Quality & Safety Assurance Lead	Target date: 30 November 2019

4. Internal Audit Follow-up Process

4.1 Approximately two weeks following issue of the final Internal Audit report, a member of the Audit Team will issue an ‘evidence requirements’ document for those reports where management actions have been agreed.

4.2 This document forms part of the follow up process and records what information should be provided to close off the management action.

4.3 The follow-up process is aligned with the meetings of the Board’s Audit & Risk Committee. Audit Sponsors will be contacted on a quarterly basis with a request to provide the necessary evidence for those management actions that are likely to fall due before the next meeting of the Audit and Risk Committee.

5. Appendix 1 – Staff Involved and documents reviewed

Staff Involved:

- Medical Director
- Associate Director for Quality Improvement and Safety
- Quality and Safety Assurance Lead
- Quality Information Facilitator
- Associate Nurse Director, Western General Hospital
- Associate Nurse Director, Royal Infirmary Edinburgh
- Associate Nurse Director, St John's Hospital
- Chief Nurse, Edinburgh Health and Social Care Partnership

Documents Reviews:

- Adverse Events Management Policy (26/06/18)
- Adverse Events Management Procedure (27/07/18)
- Duty of Candour excerpt
- The Duty of Candour Procedure (Scotland) Regulations 2018
- Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 – Part 2
- Documents available on Duty of Candour SharePoint including:
    - Duty of Candour Newsletter
    - Decision Tree
    - Process Map
    - A draft guide to good practice in communication with patients and families according to the level of harm
    - The role of the key contact
    - Organisational Duty of Candour Guidance (Healthcare Improvement Scotland, March 2018)
- DATIX fields (online)
- DATIX adverse event form (paper copy)
- Local Processes for Communication & Review of SAEs (for all sites)
- List of users who have completed training modules for
    - DATIX e-learning reporting module
    - Health and Safety Module – mandatory training covering adverse events
- Local training events held on DoC – including listing of events and slide pack presented
- NHS Lothian – Duty of Candour Annual Report 2018-19
- List of Duty of Candour Leads for sites
- Roles and responsibilities of Duty of Candour Leads
- Analysis of timescales to review Duty of Candour 2018-19
- Healthcare Governance Committee – Adverse Events Report 14th May 2019 including reflection on first year
- Various papers from the Adverse Events Leadership Group

6. Appendix 2 - Definition of Ratings

Findings and management actions ratings

Finding Ratings	Definition
Critical	A fundamental failure or absence in the design or operating effectiveness of controls, which requires immediate attention
High	A key control failure has been identified which could be either due to a failure in the design or operating effectiveness. There are no compensating controls in place, and management should aim to implement controls within a calendar month of the review.
Medium	A control failure has been identified which could be either due to a failure in the design or operating effectiveness. Other controls in place partially mitigate the risk to the organisation, however management should look to implement controls to fully cover the risk identified.
Low	Minor non-compliance has been identified with the operating effectiveness of a control, however the design of the control is effective

Report ratings and overall assurance provided

Report Ratings	Definition	When Internal Audit will award this level
No assurance	The Board cannot take any assurance from the audit findings. There remains a significant amount of residual risk.	The controls are not adequately designed and / or operating effectively and immediate management action is required as there remains a significant amount of residual risk (for instance one Critical finding or a number of High findings)
Limited assurance	The Board can take some assurance from the systems of control in place to achieve the control objective, but there remains a significant amount of residual risk which requires action to be taken.	This may be used when: • There are known material weaknesses in key control areas. • It is known that there will have to be changes that are relevant to the control objective (e.g. due to a change in the law) and the impact has not been assessed and planned for. The controls are deficient in some aspects and require management action (for instance one 'high' finding and a number of other lower rated findings)
Moderate assurance	The Board can take reasonable assurance that controls upon which the organisation relies to achieve the control objective are in the main suitably designed and effectively applied. There remains a moderate amount of residual risk.	In most respects the "purpose" is being achieved. There are some areas where further action is required, and the residual risk is greater than "insignificant". The controls are largely effective and in most respects achieve their purpose with a limited number of findings which require management action (for instance a mix of 'medium' findings and 'low' findings)
Significant assurance	The Board can take reasonable assurance that the system(s) of control achieves or will achieve the control objective. There may be an insignificant amount of residual risk or none at all.	There is little evidence of system failure and the system appears to be robust and sustainable. The controls adequately mitigate the risk, or weaknesses are only minor (for instance a low number of findings which are all rated as 'low' or no findings)