The Royal Wolverhampton NHS Trust

OP60

Being Open (Duty of Candour)

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1.0 Policy Statement (Purpose / Objectives of the policy)

Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare – this is the concept of being open also termed Duty of Candour ("DoC").

This policy aims to:

- enable and empower staff to apply principles of openness and honesty towards patients who have suffered harm from a patient safety incident.
- devise a formal being open process for instances where moderate harm, severe harm, death or prolonged psychological harm is caused by an adverse incident/event.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions

Apology: A sincere expression of sorrow or regret in respect of a notifiable safety incident.

Death: A death where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition.

Low harm: extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.

Moderate harm: Harm that requires a moderate increase in treatment, and significant but not permanent harm. [N.B. both conditions have to be met.]

Moderate increase in treatment: An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

No harm: Impact prevented – any patient safety incident that had the potential to cause harm but was prevented; or incident occurred but no harm was caused to patients receiving NHS-funded care.

Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.

Notifiable Safety Incident: a specific term defined in the duty of candour regulation. It refers to any unintended or unexpected incident that has occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, will result in, or appears to have resulted in: -

a) the death of the service user, where the death relates directly to the incident rather that to the natural course of the service user's illness or underlying condition; or
b) severe harm, moderate harm or prolonged psychological harm to the service user.

Severe (major) harm: A permanent lessening of bodily, sensory, motor, physiological

or intellectual functions, including removal of the wrong limb or organ, or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Prolonged psychological harm: psychological harm which the service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Please see Glossary attached as Appendix A.

3.0 Accountabilities

3.1 The Chief Medical Officer and Chief Nurse and responsible for ensuring the development, maintenance and monitoring of this policy.

3.2 Divisional and Directorate Management Teams are responsible for the local awareness, implementation and compliance with the requirements of the policy.

3.3 Healthcare Governance Managers (and their teams) are responsible for advising and supporting staff in the implementation of this policy. In the event of an incident they will ensure all staff within their division receive suitable and sufficient training / guidance / support in understanding and activating the Being Open policy.

3.4 The Complaints Team will screen complaints and investigations to identify any failure to disclose a reportable/ notifiable patient safety incident. The incident must be reported when identified and the DoC process applied.

3.5 All staff must comply with the requirements of this policy (refer Procedure 1).

3.6 The Quality and Safety Advisory Group (QSAG) is responsible for monitoring compliance with this policy.

4.0 Policy Detail

4.1 Being open about what happened and sharing information promptly, fully and compassionately can help patients cope better with the after-effects of adverse events. Openness and honesty can help prevent formal complaints or litigation claims being submitted. Many patients and / or their carers will often pursue these routes where they feel they have not received adequate and timely information, or an apology, from the healthcare team following an incident or poor experience.

4.2 In addition to the contractual duty under the NHS Standard Contract 2013, a statutory duty has been introduced by the Health and Social Care Act 2008 (Regulated Activities) Regulations in October 2014. The Act places a formal requirement on providers of health and social care to be open with their patients when they suffer harm relating to care or treatment.

4.3 Openness and honesty towards patients is supported and actively encouraged by many professional bodies, including the Medical Protection Society (MPS), the Medical Defence Union (MDU) and the General Medical Council (GMC), whose Good Medical Practice guide contains the following statement on a clinician's duty of candour:

"If a patient under your care has suffered harm or distress you should put matters right (if that is possible), offer an apology [and] explain fully to the patient what has happened and the likely short-term and long-term effects."

4.4 A joint statement from the Chief Executives of the statutory regulators of healthcare professionals sets out the professional duty of candour. It provides that *"Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress."* The duty also extends to the requirement *"to be open and honest with colleagues, employers and relevant organisations, and take part in reviews and investigations when requested."*

4.5 The Health & Care Professions Council Standards of Conduct, Performance and Ethics (Standard 8) require registrants to "be open and honest when something has gone wrong with the care, treatment or other services that [they] provide".

4.6 The Trust encourages all staff to report both actual incidents and near misses, regardless of whether harm has been caused (full instructions for reporting can be found in the Risk Management Reporting and Patient Safety Policy (OP10).

The 'gold standard' practice is for patients to always be informed if they have been the victim of a patient safety incident, regardless of the degree of harm they may have suffered. Less formal processes are required for incidents where no harm or low harm has occurred and can include consultations with patients and relatives following incident, concern or complaint.

4.7 Procedure 1 describes the process to be undertaken in implementing this policy.

4.8 From April 2013 the NHS Commissioning Board standard contract contains contractual Duty of Candour within its service conditions. Fines are levied against the Trust for breach of this duty. A contractual target is set as follows:

- that the patient is informed of the patient safety incident within 10 working days;
- that the patient is provided with the investigation report (within 10 working days). Commissioners have agreed that this is also satisfied by informing of the investigation outcome via a verbal communication, meeting or letter to the patient. The patient is to be consulted about their choice of communication;
- Where a complaint relates to or includes reference to a failure to disclose a reportable patient safety incident.

4.9 The NHS Resolution (NHSR) guidance directs that saying sorry when things go wrong is vital for the patient, their family and carers, as well as being the first step to learning from what has happened and prevent it recurring. It is not an admission of legal liability and the existence of a formal complaint or claim should never prevent or delay you saying sorry.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation revenue resources of this policy require additional revenue resources	No
3	Doe the implementation of this policy require additional manpower	No

4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments	

6.0 Equality Impact Assessment

An equality analysis has been carried out and it indicates that:

Tick	Options
	A. There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.
√	B. There is some likely impact as identified in the equality analysis. Two issues of low harm have been identified affecting personal protected characteristics for Disability and Ethnicity (relating to language). Redress action is available through the involvement of a patient advocate or interpreting services where appropriate.

7.0 Maintenance

This policy will be reviewed at least three yearly. More frequent review is possible if national guidance or local processes suggest the need.

8.0 Communication and Training

8.1 Trust-wide communication of this policy will be achieved via Trust Brief, local governance forum communication, newsletters and made available to all staff on the Trust intranet.

8.2 Being Open training will be via training information added to the OP60 Policy page on the intranet, bespoke booked sessions and incorporated into Risk Management training and Root Cause Analysis (RCA) investigation training.

8.3 Bespoke Being Open training is available through the Healthcare Governance Managers/ Governance Officers.

8.4 As a minimum each Division must ensure that the Directorate management teams or equivalent Department management receive Being Open training.

9.0 Audit Process

9.1 This policy will be monitored via 6 monthly reports to QSAG and commissioners which identifies whether the Trust has instigated the Being Open process for the appropriate harm events.

9.2 Datix alongside an internal spreadsheet will provide a monitoring record for incidents which trigger the formal Being Open (Duty of Candour) process and enable the necessary follow up.

Criterion	Lead	Monitoring method	Frequency	Committee
Staff acknowledge, apologise and explain when things go wrong.	Deputy Director of Assurance	Audit against policy	6 monthly	Quality & Safety Advisory Group Clinical Quality Review Meeting
Communication with patients, relatives or carers is recorded (for the formal process as a minimum).	Deputy Director of Assurance	Audit against policy	6 monthly	Quality & Safety Advisory Group Clinical Quality Review Meeting

10.0 References

Building a culture of Candour – A review of the threshold for the duty of candour and of the incentives for the organisations to be candid. Sir David Dalton, Professor Norman Williams (March 2014)

NHS Resolution Saying Sorry guidance (June 2017)

National Patient Safety Agency (NPSA) Saying sorry when things go wrong – Being Open, Communicating patient safety incidents with patients, their family and carers (November 2009)

NPSA Being Open Patient safety alert (NPSA/2009/PSA003).

Public Inquiry into Mid Staffordshire NHS FT – Francis reports 2010 and 2013.

Care Quality Commission (Registration) Regulations 2009.

Health and Social Care Act 2008 (Regulated Activities) Regulations October 2014.

The Future of NHS Patient Safety Investigation – Consultation document (March 2018)

CQC Updated guidance on meeting the duty of candour (March 2021)

GMC Good Medical Practice (April 2013; updated April 2019)

Joint Statement on the Professional Duty of Candour by GCC, GDC, GMC, GOC, GOsC, GPhC, NMC, PSNI (October 2014)

GMC & NMC Openness and honesty when things go wrong: the professional duty of candour (June 2015; updated February 2022)

HCPC Standard of Conduct, Performance and Ethics: Standard 8 (updated January 2016)

Part A - Document Control

Policy number and Policy version: **OP60 version 8.0**	**Policy Title** **Being Open (Duty of Candour)**	**Status:** **Final**		**Author:** Deputy Director of Assurance **Chief Officer Sponsor:** Chief Nursing Officer
Version / Amendment History	Version	Date	Author	Reason
	1.0	Jul 2006	Risk Manager	New Policy requirement
	2.0	Oct 2007	Risk Manager	Update
	3.0	Nov 2010	Head of Governance and Legal Services	National guidance update
	4.0	Nov 2011 Aug 2012	Head of Governance and Legal Services	NHSLA Audit update Minor Amendments
	5.0	Jun 2014	Head of Governance and Legal Services	National Guidance update
	6.0	Feb 2015	Head of Governance and Legal Services	Update in line with statutory duty under H&SC Act 2008 (Regulated Activity) Regulations 2014
	6.1	Jun 2015	Head of Governance & Legal Services	Update re moderate harm incidents to determine Duty of Candour responsibilities. Training delivery update & reinforced clarification on documentation.
	7.0	Jun 2018	Head of Governance & Legal Services	Review to include an approach to improve patient involvement in investigations.
	7.1	Oct 2020	Head of Governance	Minor amendments Appendix C – flowchart updated with formal sign off process for Duty of Candour letters. Appendix E – New letter templates for

				pressure ulcers and Maternity cases along with content checklist.
	7.2	Nov 2020	Head of Governance	Minor amendment made to 8.2.
	7.3	Jan 2021	Head of Governance	Extension to Policy.
	7.4	Nov 2021	Head of Governance	Extension to Policy
	7.5	Jan 2022	Head of Governance	Extension to Policy
	8.0	Apr 2022	Healthcare Governance Manager	Routine review includes: Updates to job titles, Committee/ Group names, definitions, references Removal of duplicated information DoC for HCAI Covid-19 deaths Updates to links and contact details of support groups Updates to template letters Update to policy title (virtually approved following review at TPG)

Intended Recipients: All staff groups	
Consultation Group / Role Titles and Date: Trust Policy Group – June 2022	
Name and date of Trust level group where reviewed	Trust Policy Group – June 2022
Name and date of final approval committee	Trust Management Committee – June 2022
Date of Policy issue	July 2022
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	June 2025 (full review) 3 yearly
Training and Dissemination: Refer section 8 in policy - Being Open training will be covered within Risk Management and Root Cause Analysis training. Specific Being Open training can be booked by contacting the	

Governance department on Ext 85114. A NPSA e-package is available on the intranet policies page.	
Publishing Requirements: Can this document be published on the Trust's public page: Yes (policy document; procedure and appendices redacted)	
To be read in conjunction with: OP10 Risk Management and Patient Safety reporting policy.	
Initial Equality Impact Assessment (all policies): Yes **Impact assessment (as required):** N/A If you require this document in an alternative format e.g., larger print please contact Policy Administrator 85887	
Monitoring arrangements and Committee	Quality & Safety Advisory Group will review a 6-monthly audit against the Policy.
Document summary/key issues covered. This policy covers the requirement to communicate to patients, their family and or carers when things go wrong (otherwise known as the Duty of Candour). The circumstances where this duty applies is explained and the steps to be taken by staff to discharge this duty. This duty imposes professional, contractual and statutory obligations upon individuals and the organisation therefore the internal process within Procedure 1 of this policy must be followed by all staff.	
Key words for intranet searching purposes OP60, Being, Open, Duty, Candour, Incident	
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.	**No** If Yes include the following sentence and relevant information in the Intended Recipients section above – In the event that this is policy is made available to the public the following information should be redacted:

Part B **Ratification Assurance Statement**

Name of document: OP60 Being Open (Duty of Candour)

Name of author: Maria Arthur Job Title: Deputy Director of Assurance

I, Maria Arhtur, the above named author confirm that:

- The Policy presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: Maria Arthur

Date: April 2022

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version OP60 version 8.0	**Policy Title** Being Open (Duty of Candour)	
Reviewing Group	Trust Policy Group	**Date reviewed:** June 2022
Implementation lead: Joanne Hughes joanne.hughes9@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N/A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	N/A – already existing	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	N/A – already existing	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	via Trust Brief	Healthcare Governance Manager (one month from approval)
Financial cost implementation Consider Business case development	N/A	
Other specific Policy issues / actions as required **e.g. Risks of failure to implement, gaps or barriers to implementation**	N/A	