Policy	NHS Worcestershire Acute Hospitals NHS Trust

Being Open (Duty of Candour) Policy

Department / Service:	Clinical Governance & Risk Management	
Originator:	Karen Apps Charlotte Merriman & Samantha Trigg	Head of Patient Safety Lead Patient Safety Incident Investigators
Accountable Director:	Dr Jules Walton	Chief Medical Officer
Approved by:	Patient Safety Incident Review Group (Formally Clinical Governance Group) ISAG	
Date of Approval:	01st July 2025	
Review Date: This is the most current document and is to be used until a revised version is in place	01st July 2028	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust	
Target Departments	All	
Target staff categories	All	

Policy Overview:

This document provides a framework for communication between healthcare professionals and patients and/or carers when a patient has been harmed as a result of a patient safety incident (moderate harm, severe harm or death). It describes the principles and process required to meet the statutory Duty of Candour.

Being Open & Candid involves apologising to patients and/or relatives following an incident that causes significant harm and explaining what happened. It ensures communication is open, honest and occurs as soon as possible following the incident. Being Open about what happened and discussing incidents promptly, fully and compassionately can help patients, and staff, cope better with the aftereffects and can prevent such events becoming formal complaints and legal claims. This communication is informed by information brought to light by review of the incident.

The Duty of Candour applies to incidents resulting in moderate (significant) harm, severe harm or death, including prolonged psychological harm experienced for a continuous period of at least 28 days.

The principles of this policy should also be applied during complaints resolution meetings where harm has occurred.

Key amendments to this Document:

Date	Amendment	By:
June 2025	Updated terminology and meeting titles in monitoring section. Removed references to Serious Incidents to reflect change to PSIRF	Clinical Governance

April 2021	Document approved for 3 years	Clinical Governance Group
April 2021	Document extended for 6 months as per Trust agreement 11.02.2021	
November 2020	Clarification regarding the sharing of findings from the investigation added for incidents that do not meet the threshold for formal incident investigation. Update of monitoring.	Dee Johnson
March 2019	Changes made to reflect lessons learned from audit and subsequent discussions at Serious Incident and Review Group Added flow chart to clarify roles in process. Clarified: role of Governance Team in supporting process and requirement to	Jo James
June 2018	Significant changes and shortening of policy to make it more succinct and clearer for staff on the process to be followed.	K Leach/ S Kapadia
Mar 2018	Document extended for 3 months as approved by TLG	TLG
Nov 2017	Document extended whilst under review	TLG
Dec 2016	Documents extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
Aug 2016	Minor amendments and change to the title to add clarity Responsibilities of committees and staff changed as required	C. Rawlings
April 2015	Republished with name change from 'Being Open and Candid Policy' to 'Being Open & Candid Following a Patient Safety Incident or Complaint Policy'	C. Rawlings
Aug 2014	Revision following audit of the Being Open process Inclusion of the Duty of candour elements & explicit inclusion of being open applied to complaints.	C. Rawlings
Jul 2012	Minor amendments to cover changes in structure and responsibilities. Monitoring section revised	C. Rawlings
Aug 2010	Transfer to new policy format Response to NPSA Safety alert and Being open Framework Addition of process flowchart, template letter, information leaflet.	C. Rawlings

Contents page:

1. Introduction

1.1. Worcestershire Acute Hospital NHS Trust is committed to a safety culture dedicated to learning and improving care, and striving to reduce avoidable harm. Being open and honest about patients' or service users' treatment and care is of paramount importance to promote good relationships with patients and their families or carers.

1.2. Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (implemented in October 2014) requires that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It sets out specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support and providing truthful information and an apology when things go wrong.

1.3. Clinicians have an ethical Duty of Candour to inform patients about mistakes. For example, the General Medical Council (GMC) states in the Good Medical Practice Guide the following:

45. You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you must follow our guidance on Openness and honesty when things go wrong: the professional duty of candour, and you should:

a. put matters right, if possible
b. apologise (apologising does not, of itself, mean that you are admitting legal liability for what's happened)
c. Explain fully and promptly what has happened and the likely short-term and long-term effects
d. Report the incident in line with your organisation's policy so it can be reviewed or investigated as appropriate – and lessons can be learnt, and patients protected from harm in the future.

1.4. The Nursing and Midwifery Council (NMC) exists to safeguard the health and wellbeing of the public by ensuring nurses and midwives consistently deliver high quality healthcare. The structure of the revised Code (2015) clearly outlines the responsibilities of all nurses and midwives in relation to public and patient safety in the UK. UK nurses and midwives must be open and candid with all patients about all aspects of care and treatment, including where mistakes or harm have taken place.

1.5. When things go wrong, you must:

- Act immediately to put right the situation if someone has suffered actual harm, for any reason or an incident has happened which had the potential for harm.

- Explain fully and promptly what has happened, including the likely effects and apologise to the person affected and where appropriate their advocate, family or carers.
- Document all these events formally and take further actions (escalate) if appropriate so they can be dealt with quickly.

It is important to understand that saying sorry is not an admission of liability. The Compensation Act 2006 s.2 states that ***"An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty".***

1.6. The Trust is committed to *Being Open* and the Duty of Candour and supports it by:

- Providing an open and honest structure across and at all levels of the organisation.
- Expecting that a person suffering significant harm is told in a timely manner when incidents have occurred and offered a written apology
- Providing reasonable support to the person after the incident
- Providing an environment where patients/carers receive the information they need to enable them to understand what happened and the reassurance that everything possible will be done to ensure that a similar type of incident does not recur
- Supporting patients/carers to ask questions and have their voices heard as part of a review/investigation.
- Creating an environment where healthcare professionals and managers feel supported when things go wrong and are encouraged to be open and honest.

2. Statement of intent

2.1 The aims of this policy are:

- To ensure that communication between health care providers, Trust staff and its patients or their families/carers, is open, honest and takes place within 10 working days of the Trust becoming aware of an incident that either has or could result in moderate harm, severe harm or death.
- To provide clear information for staff on what they must do when they are involved in such an incident and the support available to them to deal with the consequences of what happened, and how to communicate with the patients or service users, their families and carers.
- To fulfil contractual requirements with the local commissioners to demonstrate compliance with the Duty of Candour legislation.
- To clarify the principles of Being Open as part of the Patient Safety Incident Response Framework (PSIRF)

3. Scope of this document

3.1 This policy will ensure that patients, their families or carers receive verbal and written information, including an apology, within 10 working days of the reporting of an incident, when something has gone wrong causing **moderate harm, severe harm or death.**

3.2 Following a review of the incident the Trust will share the outcome of the review with the patient and/or their family (if they wish).

3.3 Where 'minor harm' has occurred, the legal Duty of Candour does not apply. However, communications with patients/carers will occur at local service delivery level. The principles of being open and honest and providing an apology are applied in these circumstances.

3.4 It should be recognised that patients/relatives do have the right to refuse to participate and this must be documented when expressed.

3.5 In the event of a Never Event Duty of Candour applies regardless of harm in order to ensure that the clinicians, managers and the Trust are open and transparent.

4. Definitions

4.1 Harm

The National Patient Safety Agency (NPSA) definitions for harm are as follows:

- **Moderate:** Any patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients
- **Severe Harm:** Any patient safety incident that resulted in permanent harm to one or more persons receiving NHS funded care
- **Death:** Any patient safety incident that directly resulted in the death of one or more persons receiving NHS funded care.

4.2 Duty of Candour Lead

This is determined on a case by case basis. The person responsible for discharging the duty of candour is the senior clinician in charge of the patient for the episode of care in which the incident happened, unless that duty is explicitly transferred and accepted by someone with expertise in the type of incident that has occurred. This must be an appropriate Senior member of staff.

The generation of correspondence following discussion may be delegated, but the DoC Lead has the responsibility to ensure delegated staff are aware of their roles and responsibilities, including deadlines.

Where there is any query or dispute as to who the appropriate person is, and it is not resolved at Divisional level, the final decision will be made at PSIRG.

*For falls resulting in harm or pressure ulcers resulting in harm, the Matron can delegate this responsibility to the ward manager.

5. Responsibilities and Duties

5.1. Committees with Overarching Responsibility for This Policy

5.1.1 Trust Board

Must ensure that mechanisms are in place to enable all staff to adhere to this policy.

5.1.2 Improving Safety Action Group

Chaired by the CNO/CMO this Group will receive updates from the Divisions on the application and effectiveness of the Being Open/Duty of Candour process. A bi-annual report on Duty of Candour will be provided to this meeting.

5.1.3 Patient Safety Incident Review Group (PSIRG)

The meeting is chaired by the Chief Medical Officer or Chief Nursing Officer and will monitor the application of the Being Open/Duty of Candour process for all significant harm incidents. It will take action where compliance with the process has either not been followed or is not effective.

5.1.5 Divisional Governance Meetings

Each Clinical Division will have a Governance meeting or section within its Divisional Board for Quality matters. The effectiveness of the Being Open process within the Division must be reviewed at least quarterly and, for individual cases where there has been a failure, take action where the process has not been followed.

5.2 Staff Members/Groups with Responsibility for This Policy

5.2.1 Chief Executive

The Chief Executive is required to ensure that the Trust meets the Duty of Candour and has suitable policies and procedures in place to support a culture of openness and transparency and that these are followed by all staff.

5.2.2 Chief Medical Officer

- The Chief Medical Officer is the delegated lead for Being Open and the Duty of Candour

5.2.3 Head of Clinical Governance and Risk Management

- To provide leadership and professional advice on the Duty of Candour
- To oversee the implementation of this policy
- To ensure adequate monitoring is in place and concerns are brought to the attention of the relevant governance group

5.2.4 Patient Safety Team and Divisional Quality Governance Teams

- To provide advice and support on a case by case basis, the application of Duty of Candour
- To ensure Duty of Candour processes within Divisions are congruent with and adhere to this policy
- To provide advice to clinical staff in undertaking the Duty
- To undertake regular audit and monitor the application of the process in their respective Divisions, reporting into the PSIRG Quarterly.

- To provide relevant reports to the monthly Divisional Governance Meetings and/or Improving Safety Action Group and to take appropriate action where areas for improvement are identified.
- Provide training in the Being Open and Duty of Candour processes
- To escalate to the Divisional Management Teams where barriers to this policy are identified

5.2.6 All Clinical Staff

- To familiarise themselves with this policy and understand their role in discharging the Duty of Candour to patients
- To ensure that the initial notification to the patient, service user, families or carers is undertaken by appropriate staff (Duty of Candour Lead)
- To address non-compliance via the appropriate management route

5.2.7 Duty of Candour Lead

- Responsible for ensuring contact with the patient and/or their relatives or delegating this where necessary
- When contact with patient and/or relatives is delegated following the initial contact, there should be a named individual responsible
- Responsible for ensuring timescales are met

6. Policy Details

6.1. Research has shown that:

- *Being Open* about what happened and discussing incidents promptly, fully and compassionately can help patients cope better with the after-effects
- Incidents can incur extra costs through litigation and further treatment. Openness and honesty can help prevent such events becoming formal complaints and litigation claims
- Many patients and/or their carers will often only make a litigation claim when they have not received any information or apology from the healthcare team following the incident

6.2 The Duty of Candour process involves:

- Acting in an open and transparent way with the relevant persons when things go wrong- this must initially be done verbally and in person, where possible.
- Notifying the patient and/or family and carers in a timely way (written notification within 10 working days of knowledge of incident or of the incident being identified as moderate or above harm)
- Providing an account of the known facts about the incident as at the date of the conversation
- Advising the relevant persons what further enquiries into the incident are required
- Offering an apology
- Keeping a written record of the actions taken throughout the process
- Providing support to the patient, and/or their families or carers to cope with the physical and psychological consequences of what happened. Examples of this could be a meeting with the family including signposting to available support, an offer of follow up review, referral to specialist service or another avenue

- Engaging with the patient and/or family throughout the review, providing opportunities for them to ask questions that they may have, keeping them updated with progress and notifying of any delays.
- Recording all details in the relevant Duty of Candour section on the Trust's incident reporting system and uploading all documentation/correspondence into the documents section (e.g. letters)

6.3. If the relevant person cannot be contacted in person or declines to speak to the Duty of Candour Lead, notification of the incident does not apply, and a written record must be kept of attempts to contact or speak the relevant person. This should be recorded on the Trust's incident reporting system.

6.4. If, in rare circumstances, it is considered that completing Duty of Candour may be more detrimental to the patient or their family than not completing it, this must be formally discussed at the Patient Safety Incident Review Group, decisions must be fully documented and, if necessary, legal advice sought. Concerns about causing families further distress are rarely sufficient justification in themselves for withholding information.

6.5. There are circumstances where Duty of Candour can be omitted. Regulation 20(5)5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 sets out that it is acceptable not to undertake Duty of Candour in the following circumstances:

6.5.1. If the relevant person cannot be contacted in person or declines to speak to the representative of the registered person. In these cases, the provider must make every reasonable attempt to contact the relevant person through all available modes of communication. All attempts to contact the relevant person must be documented.

6.5.2. If the relevant person does not wish to communicate with the provider, their wishes must be respected and a record of this must be kept.

6.5.3. If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.

6.5.4. Furthermore, it is acknowledged that there will be occasions when a patient has died and the incident for which Duty of Candour applies is not causative in the death. If the senior clinician feels that it would cause further distress to the family to undertake Duty of Candour it is acceptable to decide not to undertake the conversation or written follow up. For each case where this is applicable, a formal request not to undertake Duty of Candour should made to and formally discussed at the Patient Safety Incident Review Group. A formal documentation of this decision making will be documented within the electronic incident record on the Trust's incident reporting system.

6.6. It is NOT acceptable to omit Duty of Candour where the incident is considered to be or is possibly causative in that death, or where there is an ongoing legal proceeding at the point Duty of Candour becomes applicable.

6.7. In cases where the harm level does not meet the regulatory requirement for Duty of Candour to be completed, the principles of PSIRF and Being Open as part of Patient/Family engagement should still apply.

7. Action

7.1. STAGE 1- Notifying the Patient and/or Family

- The first priority is prompt and appropriate clinical care and the prevention of further harm
- Complete an incident form on the Trust's incident reporting system
- The incident should be reviewed and graded by the appropriate staff member as per the Incident Reporting Policy. If obvious moderate harm (or above) has occurred, senior management are to be contacted. This could be any senior member of the multi-professional team (e.g. Clinical Lead, Matron)
- A Duty of Candour Lead is appointed in accordance with section 4.2 of this policy
- Offer support and counselling for staff involved via Occupational Health referral if required
- Duty of Candour Lead to ensure that the incident on the Trust's incident reporting system is appropriately graded. Harm should be recorded using the CQC grades of insignificant/minor/moderate/severe harm
- Conduct an initial discussion with the patient and/or family within 10 working days of the incident, led by the Duty of Candour Lead
- Where the patient is deceased or does not have capacity, the Duty of Candour Lead to ensure the appropriate next of kin / family members are present
- Try to hold the meeting away from where the incident occurred if appropriate
- Duty of Candour Lead should introduce themselves and explain their role
- Apologise verbally for any suffering and distress the incident has had on the patient, and/or their families/carers, remembering an apology is not an admission of liability
- The Compensation Act 2006 s.2 states that ***"An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty".***
- The NHS Resolution fully supports and encourages Trusts to apologise to patients
- Provide factual details to date in straightforward language (no jargon/acronyms)
- Avoid disappointment and unrealistic expectations by being clear about what information you can tell them at that point in time
- Offer practical and emotional support
- Provide a Being Open leaflet (available on Datix home screen) with details of whom to contact if the patient, and/or their families and carers have further questions
- Write to the family, detailing what was discussed (template letter is on Datix home screen)- the facts known to date, what further enquiries are necessary (where indicated, including estimated timescales if known) and include an apology
- Duty of Candour Lead to ensure the Duty of Candour fields on the Trust's incident reporting system are completed
- Where, following on from Internal review it is agreed the harm level is minor or no harm, the Duty of Candour Lead should update the family regarding the situation, record the outcome and close the incident on the Trust's incident reporting system
- Where, after Duty of Candour has commenced, an initial review of the incident does not identify a basis for further investigation, this should be communicated via letter to the patient and/or family outlining the outcome of the review. This outcome should be recorded on the Trust's incident reporting system and a copy of the letter attached to the incident form.

7.2. STAGE 2 Maintaining Communication

If the incident is subject to a more detailed investigation

Rapid Reviews and After Action Reviews

- When a Lead Investigator is appointed, it is good practice for them to introduce themselves to the patient/family/carer and provide an opportunity for them to contribute to the investigation. Specifically, the patient and family should be asked whether they have any questions that they wish to be answered as part of the investigation; this may be done via phone, letter or in person.
- The Terms of Reference will be shared with the patient/family/carer, so they are aware of the scope of the investigation.
- The Lead Investigator should communicate with the patient/family/carer if there are delays during the investigation, or the scope of the investigation changes
- Where an incident is also the subject of a complaint, the investigation and complaint response will be handled as outlined in the Complaints Policy
- Respond to any queries from the patient or family as quickly and completely as possible

Patient Safety Incident Investigation (PSII) inc. Never Events:

- When the Patient Safety Incident Investigator is appointed, it is good practice for them to introduce themselves to the patient/family/carer and provide an opportunity for them to contribute to the investigation. Specifically, the patient and family should be asked whether they have any questions that they wish to be answered as part of the investigation; this may be done via phone, letter or in person.
- The Terms of Reference will be shared with the patient/family/carer, so they are aware of the scope of the investigation.
- The Patient Safety Incident Investigator will continue to engage with the Patient/family/carer during the investigation, as agreed on a case by case basis. Some investigations may take 6 months or longer. The Patient Safety Incident Investigator will update the patient/family/carer regarding the progress of the review and the anticipated completion date.
-
- Where an incident is also the subject of a complaint, the investigation and complaint response will be handled as outlined in the Complaints Policy
- Respond to any queries from the patient or family as quickly and completely as possible
- In the case of a Patient Safety Incident Investigation, the lead/investigator should arrange to meet with the patient/family/carer (in person if possible) to go through the draft report. This allows them a final opportunity to raise any unanswered concerns/questions.

7.3. STAGE 3 Sharing the Findings of the Investigation

Within 15 working days of the Report being approved as complete at the Patient Safety Incident Review Group :

- Duty of Candour Lead to telephone the patient/families or their carers to inform them that the report is complete. Ask them how they would like to receive the final report, e.g. either through the post or email, or whether they would like to come in for a meeting (or both). It may be appropriate to send an extract of the report for ease of understanding
- Duty of Candour Lead for the case to send out written correspondence to the patient/or their families and carers, with the outcome of the telephone conversation.

- If a meeting is requested this will be arranged as soon as possible by the Duty of Candour Lead with support from the Divisional Governance Team or Patient Safety Team. This support will include making a written record of the meeting for sharing with the family. The investigation lead may often be helpful in describing the findings of the report
- Ensure that the relevant people can be present at the meeting
- Consider the best way to provide the findings of the investigation to the patient, service user and/or their families and carers. Reasonable attempts must be made to ensure secure delivery to the correct recipient if sending via email or post. If unsure, please refer to the the Trusts IG Team.
- Provide a repeated apology, a chronology of facts and findings of the investigation including lessons learned and actions taken or planned. Where appropriate a copy of the report should be provided.
- Duty of Candour Lead to ensure that the patient record and electronic incident record is updated following the meeting, with the details of what has been discussed and noting if a copy of the report has been provided

8. Failure to disclose a reportable patient safety incident to the relevant person (patient/relative) or failure to meet the Duty of Candour

Regulation 20: The CQC guidance on the Duty of Candour states:

- Where a provider fails to inform the relevant person(s) within a reasonable amount of time of a notifiable incident, fails to provide a truthful account to relevant persons, fails to advise the relevant person of the enquiries and review process it will undertake, fails to offer reasonable support and/or fails to offer an apology, then CQC can move **directly to prosecution** without first serving a warning notice
- Where a provider becomes aware that **staff have not acted in accordance with** the requirements placed on them under the **Duty of Candour,** they must **refer the individual(s) concerned to their relevant professional regulator/body, police, other relevant body**

9. Being Open as part of the Patient Safety Incident Review Group

The Duty of Candour is a statutory obligation that applies in situations where an incident results in moderate harm or above. However, under the Patient Safety Incident Response Framework (PSIRF), the principles of being open and candid extend beyond statutory requirements and encompass a broader approach to promoting a safety culture and learning from all incidents.

As part of the PSIRF, it is encouraged to engage openly with patients and their families regarding incidents, regardless of the level of harm caused. The Trust is committed to fostering a culture of openness and learning, which underpins the continuous improvement of patient safety.

In line with this commitment, the Trust recognises that the Duty of Candour process may be appropriate in cases where the harm level does not meet the statutory threshold. This ensures that patients and their families are kept informed and supported, promoting trust

and transparency even in incidents that do not meet the legal criteria for statutory DOC, including near misses.

Worcestershire Acute Hospitals NHS Trust is dedicated to supporting a learning-focused culture through the promotion of an open and candid approach to patient safety incidents. This includes a proactive commitment to communication, engagement, and the ethical obligation to be transparent about incidents, irrespective of the harm level.

10. Implementation

10.1. Plan for dissemination

The *Being Open (*Duty of Candour Policy) will be accessible via the Trust's intranet. Access to supporting documents (leaflet and template letters) will be within the Datix home screen.

10.2. Implementation

This Policy will be implemented through the following means:

- The provision of training to Divisional Quality Governance teams to lead and support the process
- The promotion of the Being Open process by Patient Safety and Risk Team, Patient Services Team and Divisional Quality Governance support staff to the lead investigator and most senior clinician responsible for the care of the patient
- Monitoring of incident reports to check that the Being Open process has been commenced with alerts to Divisional / Directorate managers where it has not
- Inclusion of a requirement to record that the Being Open process was carried out on the electronic incident record and in investigation report templates
- Audit of significant harm incidents to test compliance with the Duty of Candour with reporting to the Patient Safety Incident Review Group for review and action by Corporate and Divisional teams to remedy and issues discovered. This will then be sent to Improving Safety Actions Group.

10.3. Training and awareness

The Duty of Candour will be covered as part of Trust Induction.

The Patient Safety mandatory training includes training staff in the principles and practice of Duty of Candour.

11. Monitoring and compliance

The recording of the Being Open process in each Patient Safety Incident Investigation Report will be monitored by the Patient Safety Incident Review Group.

Divisional Governance Teams will highlight to their Divisional Management Board when issues are identified.
For further information, please see section 14.

12. Policy Review

The *Being Open* Policy will be reviewed two years from the date of approval, unless any statutory or national guidance is introduced in the intervening period that requires revision of the documents before the planned review.

Changes to this document will be recorded and monitored in accordance with the Development, Management and Approval of Key Documents Policy.

13. References

Regulation 20: Duty of Candour – Information for all providers: NHS bodies, adult social care, primary medical and dental care and independent healthcare – March 2015: CQC http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf
Openness and honesty when things go wrong: the professional duty of candour – Nursing & Midwifery Council & General Medical Council 2015: http://www.gmc-uk.org/DoC_guidance_englsih.pdf_61618688.pdf
WAHT Claims Handling Policy & Procedure
WAHT Complaints and Concerns Policy & Procedure
Mental Capacity Act 2005 – Summary Guidance for Staff, January 2008
WAHT The Development, Approval and Management of Key Documents
WAHT Public Interest Disclosure (Whistleblowing) Policy
WAHT Investigation of incidents, complaints and claims Policy
WAHT Incident Reporting Policy
Supporting staff involved in incidents, complaints and claims
NPSA – Being Open resources: http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077
Mental Capacity Act 2005 – Code of Practice http://www.justice.gov.uk/protecting-the-vulnerable/mental-capacity-act
General Medical Council, Good medical Practice, 2006 www.gmc-uk.org/guidance/good_medical_practice/index.asp
National Patient Safety Agency, Seven Steps to Patient Safety, April 2004 http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/
NHS Litigation Authority, Litigation Circular No. 02/02 Apologies and Explanations, 11 February 2002 www.nhsla.com
Vincent CA and Coulter A, Patient safety: what about the patient? Quality and Safety in Health Care 11(1): 76-80, 2002
NHS Resolution – Saying sorry leaflet published June 2017 https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf
Crane M, What to say if you made a mistake, Medical Economics 78(16):26-8, 33-6, 2001
Department of Health, Building a Safer NHS for Patients, 2001 www.dh.gov.uk
Vincent CA, Pincus T & Scurr JH, Patients' experience of surgical accidents, Quality Health Care, 2920: 77-82, 1993

14. Background

14.1. Consultation

Consultation with the Divisional Management & Quality Governance Teams, Patient Services, Legal Services and the Clinical Governance & Risk Management Departments has been undertaken to ensure that the processes and responsibilities described here are reasonable and achievable.

14.2. Approval process

This policy will be approved by Patient Safety Incident Review Group and be forwarded to the NICE and Key documents Team for final checking and placing on intranet.

14.3. Equality requirements

The implementation of the *Being Open* Policy has been assessed against the Equality Impact Assessment Tool. The Trust's *Being Open* Policy does not affect one group less or more favourably than another.

14.4. Financial risk assessment

The Financial Risk Assessment reveals no imminent cost implications.

15. Monitoring

Being Open is a general concept and the specific delivery of 'Being Open' communications vary according to the severity, clinical outcome and arrangements for each specific event. In exceptional cases, information may need to be withheld or specific legal requirements might preclude disclosure. Equality records of communications with patients and families would not normally be shared in the public domain. Monitoring of compliance and effectiveness will be via a confidential planned audit using an appropriately sampled population. As a minimum the following elements will be monitored:

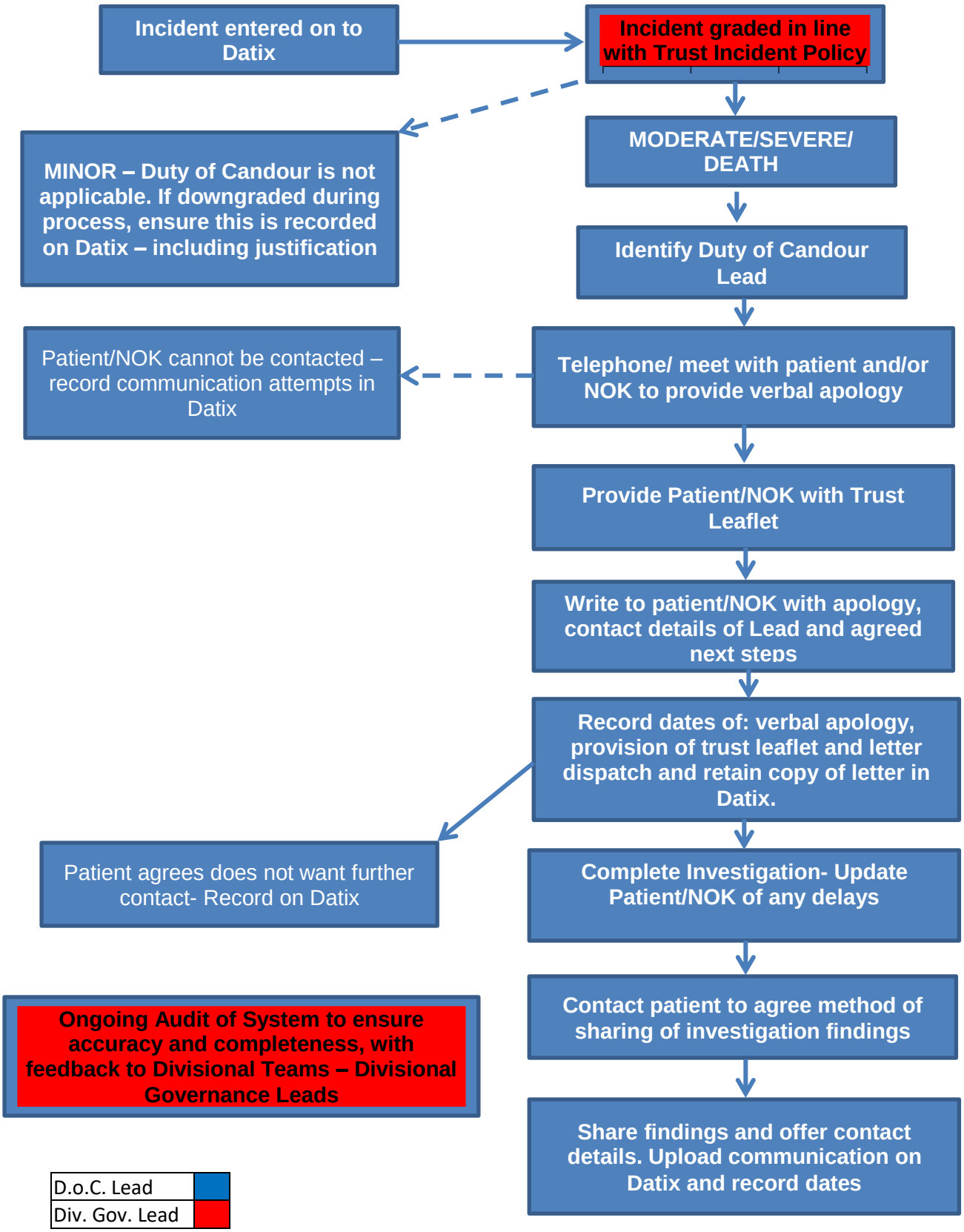
Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	Initial duty of candour discussion took place within 10 working days or, if not, valid reasons are recorded to failure to comply.	Via the Trust's incident reporting system	Monthly	Patient Safety Team	Improving Safety Action Group	Quarterly
	There is a written record of the initial duty of candour discussion in one of the following: • patient notes; • electronic incident record (on the Trust's incident reporting system, currently Datix); • included in the investigation report.	15% of applicable Patient Safety Incidents and Internal Investigations will consider paperwork detailing the application of Being Open.	Annually	Patient Safety Team	Patient Safety Incident Review Group Improving Safety Action Group	Annually
	The duty of candour discussion was with the patient, or, if not, there is a clear record confirming that the patient lacks capacity and appropriate patient representative was contacted	Via the Trust's incident reporting system	Monthly	Patient Safety Team	Patient Safety Incident Review Group	Quarterly
	There is evidence of a written follow up confirming duty of candour discussion sent to the patient or the appropriate patient representative) within 10 working days of the PSIRG discussion; or within 10 working days of knowledge of the incident; or of the	Via the Trust's incident reporting system	Monthly	Patient Safety Team	Patient Safety Incident Review Group	Quarterly

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	incident being identified as moderate or above harm					
	The initial letter includes: • account of the facts known at the time • an appropriate apology • how the incident will be investigated • results of any further enquiries.	15% of applicable Patient Safety Incidents will consider paperwork detailing the application of Being Open.	Annually	Patient Safety Team	Patient Safety Incident Review Group Improving Safety Action Group	Annually
	There is evidence of a written follow up after completion of the review within 15 working days of the Executive approval of the Patient Safety report.	Via the Trust's incident reporting system	Monthly	Patient Safety Team	Patient Safety Incident Review Group Improving Safety Action Group	Quarterly
	The second letter either: • includes information about the review findings • or has a report on the outcome of the review appended (evidenced by reference in the letter to appended investigation report).	15% of applicable Patient Safety Incidents will consider paperwork detailing the application of Being Open.	Annually	Patient Safety Team	Patient Safety Incident Review Group Improving Safety Action Group	Annually

Appendix 1: Determining When Duty of Candour Applies

The **Duty of Candour** applies to any incident causing **SIGNIFICANT HARM** i.e. **Moderate, Severe or Death**.			**Duty of Candour applies?**
No harm		• Incident prevented / near miss. • Incident not prevented but no harm was caused	**No**
Minor Harm		**Any patient safety incident that required extra observation or minor treatment and cased minimal harm to one or more patients** • e.g. first aid, additional therapy or additional medication **It does not include:** • any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; • nor does it include a return to surgery or readmission.	**No**, Provide a verbal apology
Significant Harm	**Moderate Harm**	**Any patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients** Moderate increase in treatment is defined as • a return to surgery, • an unplanned readmission, • a prolonged • episode of care, • extra time in hospital or as an outpatient, • cancelling of treatment, or • transfer to another area such as intensive care	**YES** **Duty of Candour applies** **Implement Being Open process**
	Severe Harm	**Any patient safety incident that appears to have resulted in permanent harm to one or more patients** Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as: • permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.	
	Death	**Any patient safety incident that directly resulted in the death of one or more patients** • **The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.**	

Appendix 2: Flowchart of Responsibilities for Duty of Candour Process


Incident entered on to Datix
Incident graded in line with Trust Incident Policy
MINOR – Duty of Candour is not applicable. If downgraded during process, ensure this is recorded on Datix – including justification
MODERATE/SEVERE/ DEATH
Identify Duty of Candour Lead
Patient/NOK cannot be contacted – record communication attempts in Datix
Telephone/ meet with patient and/or NOK to provide verbal apology
Provide Patient/NOK with Trust Leaflet
Write to patient/NOK with apology, contact details of Lead and agreed next steps
Record dates of: verbal apology, provision of trust leaflet and letter dispatch and retain copy of letter in Datix.
Patient agrees does not want further contact- Record on Datix
Complete Investigation- Update Patient/NOK of any delays
Contact patient to agree method of sharing of investigation findings
Ongoing Audit of System to ensure accuracy and completeness, with feedback to Divisional Teams – Divisional Governance Leads
Share findings and offer contact details. Upload communication on Datix and record dates
D.o.C. Lead
Div. Gov. Lead

Appendix 3: Being Open Leaflet

WAHT-PI-0007
V3.1.pdf

Supporting Document 1 – Equality Impact Assessment form

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page:

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	✓	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Charlotte Merriman	**Lead Patient Safety Incident Investigator**	**wah-tr.PatientSafety@nhs.net**
Date assessment completed	**02/07/2025**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Procedure			
What is the aim, purpose and/or intended outcomes of this Activity?	To provide guidance on the management of safety alerts			
Who will be affected by the development & implementation of this activity?	❑	Service User	✓	Staff
	❑	Patient	❑	Communities
	❑	Carers	❑	Other _____
	❑	Visitors	❑	
Is this:	✓Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, e.g. demographic information for patients / services / staff groups affected, complaints etc.	Not applicable			
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Representatives from Divisional Governance Teams, Corporate Nursing and Medical, and Patient Safety Team received copies of the changes to the policy for comment via email.			
Summary of relevant findings	Clarification regarding the sharing of findings from the investigation added for incidents that do not meet the threshold for formal incident investigation. Update of monitoring.			

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		✓		
Disability		✓		
Gender Reassignment		✓		
Marriage & Civil Partnerships		✓		
Pregnancy & Maternity		✓		
Race including Traveling Communities		✓		
Religion & Belief		✓		
Sex		✓		
Sexual Orientation		✓		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		✓		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		✓		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	Not applicable	.		
How will you monitor these actions?				
When will you review this EIA? (e.g. in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	**In line with Trust policy for review.**			

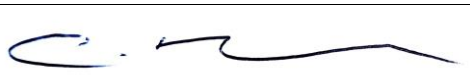
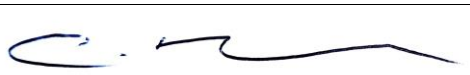
Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation.

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	02/07/2025
Comments:	
Signature of person the Leader Person for this activity	
Date signed	02/07/2025
Comments:	

Financial Risk Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Executive Team before progressing to the relevant committee for approval