Policy	Worcestershire Acute Hospitals NHS Trust

Being Open (Duty of Candour) Policy

Department / Service:	Clinical Governance & Risk Management	
Originator:	Dee Johnson	Head of Patient Safety
Accountable Director:	Mike Hallissey	Chief Medical Officer
Approved by:	Clinical Governance Group	
Date of Approval:	6th April 2021	
Review Date: This is the most current document and is to be used until a revised version is in place	6th April 2024	
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 after effects and can prevent such events becoming formal complaints and legal claims. This communication is informed by information brought to light by investigation of the incident.

The Duty of Candour applies to significant moderate harm, severe harm or death incidents, 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:
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	Dee Johnson

	incident investigation. Update of monitoring.	
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. The CQC's regulation 20 (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:*'55. You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress you should: a) put matters right (if that is possible), b) offer an apology, c) explain fully and promptly what has happened and the likely short term and long term effects.*

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
- 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, about their care or treatment, is open, honest and it takes place within 10 working days of the moderate or severe harm or death being reported.
- 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.

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, severe harm or death.**

3.2 Following an investigation of the incident the Trust will share the findings of the investigation with the patient and/or their family (if they wish) within 20 days of its approval.

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 a minimum of Consultant or Matron level.

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 question as to the most appropriate lead, this will be determined as a joint decision by a senior doctor (CMO/DCMO) and a Senior Nurse/Midwife (CNO/DCNO).

*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 Clinical Governance Group (CGG)

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 Serious Incident Review & Learning Group

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 SI&LG Quarterly.
- To provide relevant reports to the monthly Divisional Governance Meetings and/or Clinical Governance 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 be done 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 other avenue
- Writing to the relevant persons detailing the initial conversation, a further appropriate apology and outlining the next steps e.g. the plan for further investigation, if appropriate.

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 Datix.

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 Serious Incident Review and Learning 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 Serious Incident Review and Learning Group. A formal documentation of this decision making will be documented within the Datix record for that incident.

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.

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 Datix
- 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 Datix is appropriately graded. Harm should be recorded using the CQC grades of no/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
- Ensure that all members of staff who should attend the meeting can do so at the designated time as continuity is very important in building relationships
- 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
- At the meeting introduce everyone in the meeting, including their roles
- 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 Duty of Candour 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, explaining the outcome of the meeting (template letter is on Datix home screen)- the facts known to date, what further enquiries are necessary, where indicated and an apology
- Identify and agree next steps, explaining the investigation process (if an investigation is required) and the expected time taken (60 working days or more in some cases)
- Duty of Candour Lead to ensure Datix Duty of Candour fields are completed
- Where, following on from Internal investigation 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 Datix
- Where, after Duty of Candour has commenced, an initial review of the incident does not identify a basis for a formal or further investigation, this should be communicated via letter to the patient and/or family outlining that the investigation will not be continued and why. This outcome should be recorded in Datix 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 formal investigation:

- When the RCA/investigation Lead is appointed, it is good practice for the investigation lead 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 or letter
- If at 60 days, the investigation is incomplete the patient/family/carer will be contacted by the investigation lead to update them regarding the delay and provide assurance regarding the process
- 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

7.3. STAGE 3 Sharing the Findings of the Investigation

Within 15 working days of the investigation report being approved as complete at the Serious Incident Review and Learning Group (if the incident falls within the serious incident framework), or the Accountability Meeting for pressure ulcers:

- 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; either through the post 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 and Risk 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. Where the patient and/or NOK requests the findings are emailed to them, they should be made aware of the risks of sending a confidential report to an unencrypted email. They then should be asked to send an email to the Lead confirming they wish the report to be sent and they understand the risks involved. The lead will then use the email provided to send the password and the password protected document in separate emails requesting confirmation of receipt.
- Provide a repeated apology, a chronology of facts and findings of the investigation lessons learned
- Duty of Candour Lead to ensure that the patient record and Datix incident record is updated following the meeting, with the details of what has been discussed and noting if a copy of the RCA report or extract 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 investigation 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. Implementation

9.1. 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.

9.2. 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 Datix records 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 Datix file and in investigation report templates
- Audit of significant harm incidents to test compliance with the Duty of Candour with reporting to the Serious Incident Review and Learning Group for review and action by Corporate and Divisional teams to remedy and issues discovered. This will then be sent to Clinical Governance Group

9.3. Training and awareness

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

The Root Cause Analysis training includes training staff in the principles and practice of Duty of Candour.

10. Monitoring and compliance

The recording of the Being Open process in each Serious Incident Investigation Report will be monitored by the Serious Incident Review and Learning Group.

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

11. 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.

12. 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

13. Background

13.1. 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.

13.2. Approval process

This policy will be approved by Clinical Governance Group and be forwarded to the NICE and Key documents Team for final checking and placing on intranet.

13.3. 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.

13.4. Financial risk assessment

The Financial Risk Assessment reveals no imminent cost implications.

14. 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 Datix	Monthly	Patient Safety Team	Clinical Governance Group	Quarterly
	There is a written record of the initial duty of candour discussion in one of the following: • patient notes; • electronic incident record (Datix); • included in the investigation report.	15% of applicable Serious Incidents (SI) and Internal Investigations will consider paperwork detailing the application of Being Open.	Annually	Patient Safety Team	Serious Incident Review & Learning Group Clinical Governance 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 Datix	Monthly	Patient Safety Team	Clinical Governance 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 SIRLG discussion; or within 10 working days of knowledge of the incident; or of the incident being identified as moderate or above harm	Via Datix	Monthly	Patient Safety Team	Clinical Governance 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:
	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 Serious Incidents (SI) and Internal Investigations will consider paperwork detailing the application of Being Open.	Annually	Patient Safety Team	Serious Incident Review and Learning Group Clinical Governance Group	Annually
	There is evidence of a written follow up after completion of the investigation within 15 working days of the Executive approval of the investigation report.	Via Datix	Monthly	Patient Safety Team	Clinical Governance Group	Quarterly
	The second letter either: • includes information about the investigation findings • or has a report on the outcome of the investigation appended (evidenced by reference in the letter to appended investigation report).	15% of applicable Serious Incidents (SI) and Internal Investigations will consider paperwork detailing the application of Being Open.	Annually	Patient Safety Team	Serious Incident Review and Learning Group Clinical Governance Group	Annually

Appendix 1: Determining When Duty of Candour Applies

<table>
<tr><th colspan="3">The Duty of Candour applies to any incident causing SIGNIFICANT HARM i.e. Moderate, Severe or Death.</th><th>Duty of Candour applies?</th></tr>
<tr><td colspan="2">No harm</td><td>• Incident prevented / near miss.
• Incident not prevented but no harm was caused</td><td>No</td></tr>
<tr><td colspan="2">Minor Harm</td><td>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.</td><td>No,
Provide a verbal apology</td></tr>
<tr><td rowspan="3">Significant Harm</td><td>Moderate Harm</td><td>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</td><td rowspan="3">YES

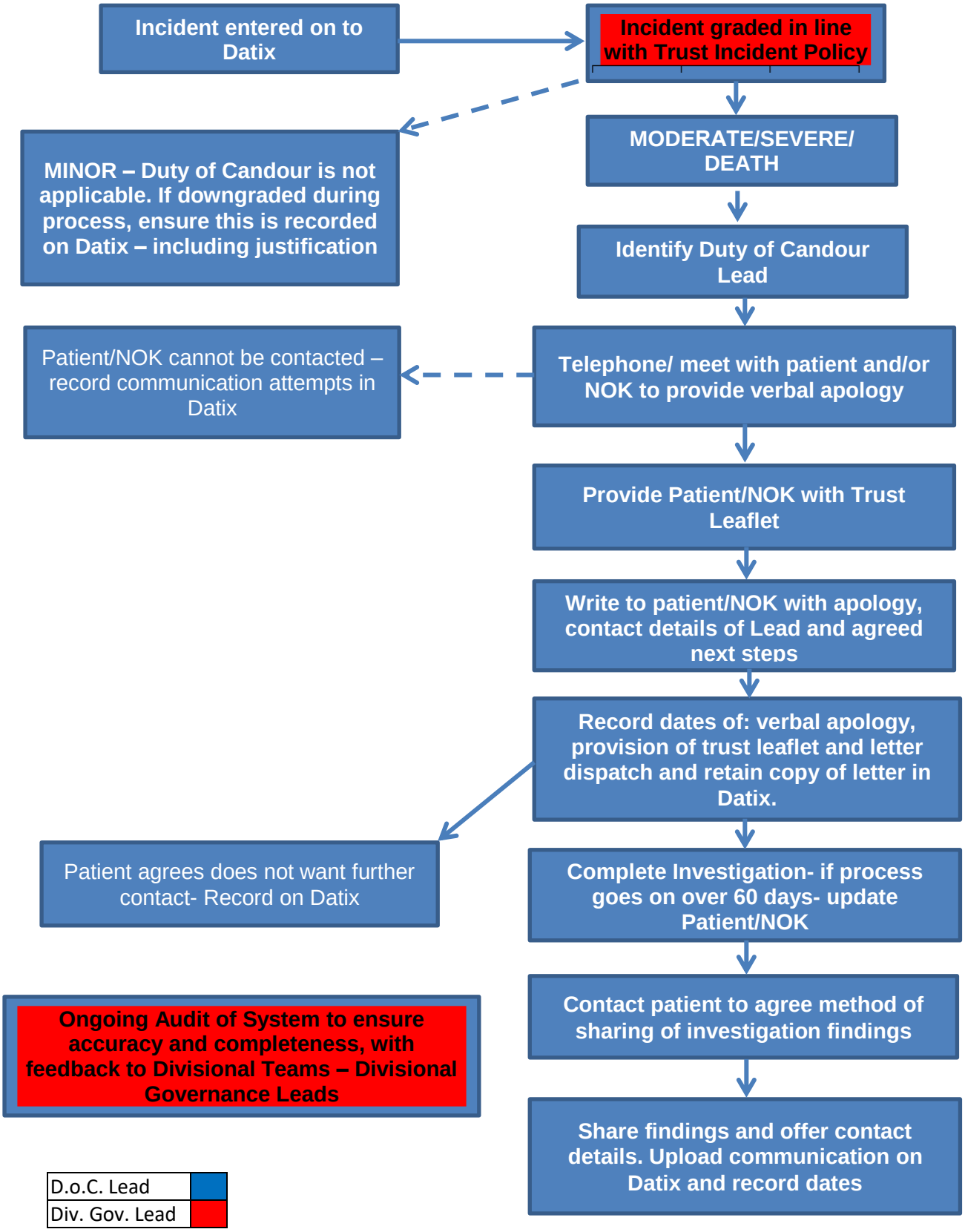
Duty of Candour applies

Implement Being Open process</td></tr>
<tr><td>Severe Harm</td><td>Any patient safety incident that appears to have resulted in permanent harm to one or more patients

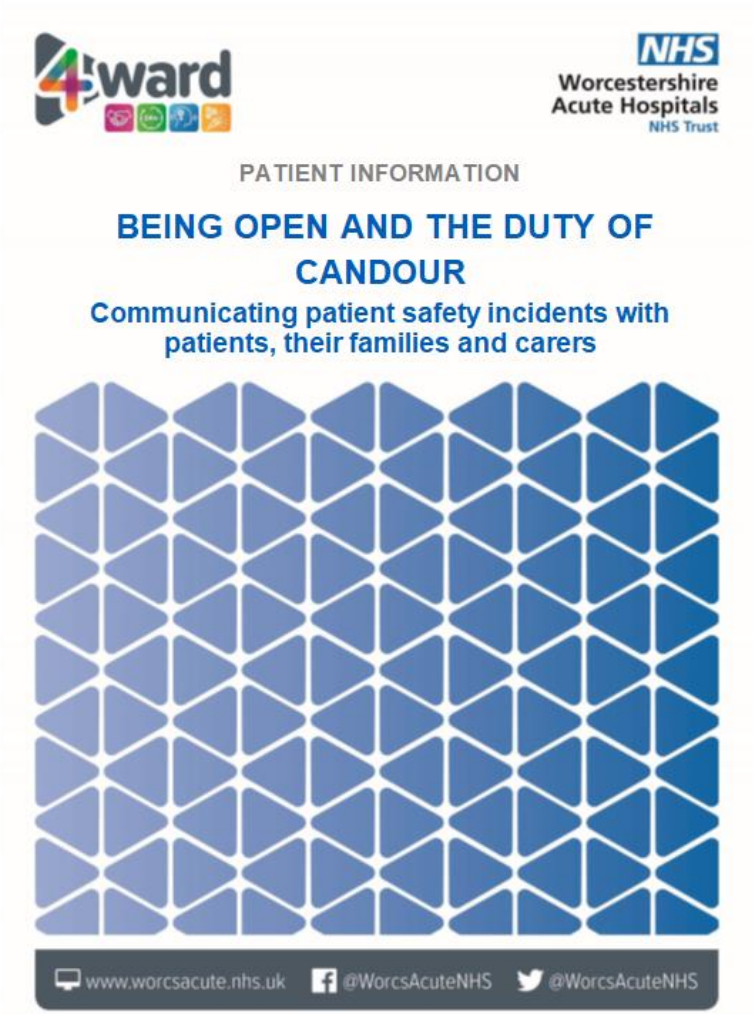
Permanent harm directly related to the incident and not related to the natural course of the patient’s illness or underlying condition is defined as:
• permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.</td></tr>
<tr><td>Death</td><td>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.</td></tr>
</table>

Appendix 2: Flowchart of Responsibilities for Duty of Candour Process



Appendix 3: Being Open and the Duty of Candour



Why have I been given this leaflet?
You have been given this leaflet as an incident has occurred, involving you or your family member, that may have affected the quality of care delivered.

What is 'being open'?
We are committed to delivering safe, high quality care. However, mistakes occasionally happen. Although there are numerous safety checks to ensure that these do not affect patients, sometimes these systems break down and patients may be harmed whilst in our care. Please be assured that this happens very rarely. In the unlikely event that this were to happen to you, we will be open and honest in telling you. We will share our understanding of why it happened and offer you involvement in how we plan to reduce the chances of the same mistake happening again.

A legal **Duty of Candour** reinforces the Being Open principles and means that healthcare providers must ensure that patients, and where appropriate their families, are told openly and honestly when unanticipated errors happen which cause significant harm.

Being open involves:

- Saying sorry, explaining what went wrong and why;
- Investigating why the incident happened and reassuring patients, their families and carers that lessons learnt will help to stop it happening again;
- Involving patients and their carers in the investigation from the outset so that any questions they may have can be addressed as part of the investigation;
- Hospital staff providing support to you and others involved or affected by the incident.

Our staff are encouraged to report all incidents when they believe that there may be lessons to learn. We may contact you at this stage before we know whether there have been any mistakes or gaps in care.

WAHT-PI-0007 Version 1 Approval Date: 02/04/2019 Review Date: 02/04/2022

Will my comments and suggestions be listened to?

Yes. Your views on what happened and why, are essential for us to understand and reduce the risk of the same mistake happening again. Please be open with us.

What treatment and care will I receive after the incident?

The Consultant in charge of your care will continue to treat you in accordance with your clinical needs.

You can expect to continue to receive all future treatment with respect, compassion and dignity. However, should you wish to receive treatment from another team or provider, we shall make arrangements for this.

What happens if the incident resulted in a patient's death?

A senior health care professional will meet with the patient's next of kin and ensure that they are informed of the incident. The process would be the same as described above but additionally may involve the coroner's officer.

If this is the case, the coroner's report will provide a key source of information that will help to complete the picture of events leading up to the patient's death.

Is support available if I need it?

Yes. Your named contact will help to identify specific support relevant to your needs.

Patients with different languages

The staff contact will arrange a translator to be available for the Being Open process.

What if I want to make a complaint or claim for compensation?

Being open with you and involving you in understanding what has happened does not affect your right to make a formal complaint or claim for compensation.

Any complaint would be managed by the Trust Complaints Team and your staff contact will continue with the investigation until an outcome has been reached. The outcome of any investigation would be included in the formal response to your written complaint. We would like to reassure you that your complaint will not affect the care and treatment you receive.

If, after the investigation has been completed, you wish to seek compensation, you should seek independent legal advice on your options.

Sharing your information

The Trust handles and shares your information to support your care and according to the law (General Data Protection Regulation 2018). For any further information please refer to the Privacy Notice on the Trusts website.

What happens next?

A senior health care professional will contact you and ensure that you are informed of the incident. If you want your family or other carers to also be involved in this discussion, please let us know. We think it is important that you the patient and your carers are supported in every way possible.

We will provide repeated opportunities for you and/or your family/ carer to obtain information about the incident. We will also provide information in a verbal and / or written format if required.

If our initial investigation finds that there are no concerns about the quality of care, we will let you know that a full investigation does not need to be carried out.

If a full investigation of the incident is required, it is important to note that it can sometimes take weeks or months to investigate an incident fully, so it might be that at the first meeting, no one can tell you exactly what went wrong.

You and your family will be informed if there are any delays in the process.
The final investigation findings will be shared with you in person and/or in writing.
You have a right to be informed as much or as little as you wish about the conclusions of the investigation.

The person named on this leaflet will meet you at agreed times, or keep in touch via phone or email, to keep you informed on progress, answer any questions you may have and offer any on-going support you require. Please contact them if you have any questions or concerns.

Contact details

Name:.....

Role:.....

Telephone:.....

Email:.....

Governance Team Contact details

Name:.....

Role:.....

Telephone:.....

Email:.....

WAHT-PI-0007 Version 1 Approval Date: 02/04/2019 Review Date: 02/04/2022

If your symptoms or condition worsens, or if you are concerned about anything, please call your GP, 111, or 999.

Patient Experience
We know that being admitted to hospital can be a difficult and unsettling time for you and your loved ones. If you have any questions or concerns, please do speak with a member of staff on the ward or in the relevant department who will do their best to answer your questions and reassure you.

Feedback
Feedback is really important and useful to us – it can tell us where we are working well and where improvements can be made. There are lots of ways you can share your experience with us including completing our Friends and Family Test – cards are available and can be posted on all wards, departments and clinics at our hospitals. We value your comments and feedback and thank you for taking the time to share this with us.

Patient Advice and Liaison Service (PALS)
If you have any concerns or questions about your care, we advise you to talk with the nurse in charge or the department manager in the first instance as they are best placed to answer any questions or resolve concerns quickly. If the relevant member of staff is unable to help resolve your concern, you can contact the PALS Team. We offer informal help, advice or support about any aspect of hospital services & experiences.

Our PALS team will liaise with the various departments in our hospitals on your behalf, if you feel unable to do so, to resolve your problems and where appropriate refer to outside help.

If you are still unhappy you can contact the Complaints Department, who can investigate your concerns. You can make a complaint orally, electronically or in writing and we can advise and guide you through the complaints procedure.

How to contact PALS:

Telephone Patient Services: 0300 123 1732 or via email at: wah-tr.PET@nhs.net

Opening times:
The PALS telephone lines are open Monday to Thursday from 8.30am to 4.30pm and Friday: 8.30am to 4.00pm. Please be aware that a voicemail service is in use at busy times, but messages will be returned as quickly as possible.

If you are unable to understand this leaflet, please communicate with a member of staff.

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:

NHS Worcestershire Acute Hospitals NHS Trust

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**
	Dee Johnson	**Head of Patient Safety**	**wah-tr.PatientSafety@nhs.net**
Date assessment completed	**28/01/2020**		

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, eg 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.**			

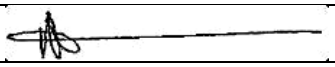
Section 5 - Please read and agree to the following Equality Statement

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	20/01/2021
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
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