Policy Document

Reference: RM12

University Hospitals of North Midlands NHS Trust

Duty of Candour

Version:	**10**
Date Ratified:	**May 2022 by Quality & Safety Oversight Group**
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To Be Reviewed Before:	**May 2025**
Policy Author:	**Head of Quality, Safety & Compliance Department**
Executive Lead:	**Medical Director**

Version Control Schedule

Version	Issue Date	Comments
1	October 2006	
2	February 2008	
3	August 2009	
4	October 2011	
5	May 2013	
6	February 2015	
7	March 2016	Amended to add in second template letter for recognised complications; add in roles of forums; take out being open principles from appendix
8	September 2018	Clarity added for term 'therapeutic non-disclosure'.
9	May 2019	Minor amendment. New paragraph added under 6.2.9
10	June 2022	Routine Review and update on guidance and 'Recognised Complications' (section 5.1) and revised flowchart

Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed here

University Hospitals of North Midlands NHS Trust

Review Form / Equality Impact Assessment (EIA)

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Analysis Form is designed to help consider the needs and assess the impact of each policy. To this end, EIAs will be undertaken for all policies.

Policy Reference, Title and Version Number	RM12 Duty of Candour Version 10
Summary of changes made on this review	Routine Review and update on guidance and 'Recognised Complications'
Please list which service users, staff or other groups have been consulted with, in relation to this	Quality, Safety & Compliance
Were any amendments made as a result? If yes, please specify	No
Does this policy involve the administration or control of medicines? If yes, have the Safe Meds Group been consulted with?	Not applicable
Which Executive Director has been consulted on?	Medical Director
Does this policy have the potential to affect any of the groups listed below differently - please complete the below. Prompts for consideration are provided, but are not an exhaustive list	

Group	Is there a potential to impact on the group? (Yes/No/Unsure)	Please explain and give examples	**Actions taken to mitigate negative impact** *(e.g. what action has been taken or will be taken, who is responsible for taking a future action, and when it will be completed by – may include adjustment to wording of policy or leaflet to mitigate)*
Age (e.g. are specific age groups excluded? Would the same process affect age groups in different ways?)	No		
Gender (e.g. is gender neutral language used in the way the policy or information leaflet is written?)	No		
Race (e.g. any specific needs identified for certain groups such as dress, diet, individual care needs? Are interpretation and translation services required and do staff know how to book these?)	No		
Religion & Belief (e.g. Jehovah Witness stance on blood transfusions; dietary needs that may conflict with medication offered)	No		
Sexual orientation (e.g. is inclusive language used? Are there different access/prevalence rates?)	No		
Pregnancy & Maternity (e.g. are procedures suitable for pregnant and/or breastfeeding	No		

Group	Is there a potential to impact on the group? (Yes/No/Unsure)	Please explain and give examples	**Actions taken to mitigate negative impact** *(e.g. what action has been taken or will be taken, who is responsible for taking a future action, and when it will be completed by – may include adjustment to wording of policy or leaflet to mitigate)*
women?)			
Marital status/civil partnership (e.g. would there be any difference because the individual is/is not married/in a civil partnership?)	No		
Gender Reassignment (e.g. are there particular tests related to gender? Is confidentiality of the patient or staff member maintained?)	No		
Human Rights (e.g. Does it uphold the principles of Fairness, Respect, Equality, Dignity and Autonomy?)	No		
Carers (e.g. is sufficient notice built in so can take time off work to attend appointment?)	No		
Socio/economic (e.g. would there be any requirement or expectation that may not be able to be met by those on low or limited income, such as costs incurred?)	No		
Disability (e.g. are information/questionnaires/consent forms available in different formats upon request? Are waiting areas suitable?) Includes hearing and/or visual impairments, physical disability, neurodevelopmental impairments e.g. autism, mental health conditions, and long term conditions e.g. cancer.	No		
Are there any adjustments that need to be made to ensure that people with disabilities have the same access to and outcomes from the service or employment activities as those without disabilities? (e.g. allow extra time for appointments, allow advocates to be present in the room, having access to visual aids, removing requirement to wait in unsuitable environments, etc.)			**Yes/No** **No**
Will this policy require a full impact assessment and action plan? (a full impact assessment will be required if you are unsure of the potential to affect a group differently, or if you believe there is a potential for it to affect a group differently and do not know how to mitigate against this - please contact the Corporate Governance Department for further information)			**Yes/No** No

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1. INTRODUCTION

The University Hospitals of North Midlands NHS Trust (UHNM) is committed to the provision of high quality healthcare.

As part of this objective, the Trust has a duty to limit the potential impact of clinical and non-clinical risks, and to put into place robust and transparent systems when managing patient safety incidents.

The Trust also has a statutory duty to ensure that it is open and transparent with patients and/or their relatives when certain incidents occur (in relation to the care and treatments provided) and may face criminal proceedings if it fails to discharge its statutory duties under the legislation. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 amend a framework created by the 2010 Regulations of the same name.

The statutory duty of candour is an important step towards ensuring an open, honest and transparent culture that was previously lacking and as highlighted in the Francis Inquiry (2013). In his report, Sir Robert Francis recommended the following definitions which are reflected in the legislation and central to the ethos of this policy:

1. Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

2. Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.

3. Candour – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

Since 1 April 2013 NHS bodies have been subject to a contractual duty of candour under the NHS Standard Contract; these contractual requirements are clearly set out in Standard Condition 35 (Appendix 5). The duty of candour conditions in this policy reflect the above mentioned contractual requirements together with the legislative requirements as set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The Care Quality Commission (CQC) propose to use the new powers as set out in the 2014 Regulations to encourage a culture of openness and it will therefore form part of their new inspection approach; monitoring of compliance will be undertaken by the CQC and they have statutory powers to deal with any breaches in practice.

2. SCOPE

This policy relates to all areas of the Trust and all individuals providing care in the Trusty including contractors, volunteers, students, locum, bank and agency staff and staff employed on honorary contracts.

The policy applies to communication by Trust staff with patients and/or their families/carers (relevant person) following notifiable safety incidents which fall into the following categories:

1. “moderate harm”

2. “severe harm”

3. “prolonged psychological harm”

4. “death”

Incidents that do not result in harm outlined in the categories above, or which could be classed as a ‘near-miss’ are not within the scope of this policy. It should be noted however that there are

some instances e.g. over exposure to radiation where no harm was caused but it would be appropriate to let the patient know of the incident. Trust policy RM07, encourages staff to report all patient safety incidents, including those deemed as a 'near miss' and those resulting in minor or no harm.

This policy aims to set out the required standard of communication when patients are involved in a notifiable safety incident, by ensuring that there is a consistent process for acknowledging, apologising and explaining when mistakes are made; this should be done in a timely and clear manner.

It also aims to ensure that patients and/or their carers receive further information in relation to what action the Trust will take to ensure that the risk of the same incident occurring again is minimised and that lessons are learned cross the organisation.

It should be remembered that any provision of information to patients and/or their carers must comply with, and in no way detract from, other relevant legislation, primarily Data Protection and the Access to Health Records Act 1990.

This policy should be read in conjunction with:

1. IT01 – Corporate Policy for Information Security

2. HS01 - Health and Safety Policy

3. RM02 - Policy and Procedure for Handling Complaints

4. RM07 - Trust Policy for Reporting and Managing Incidents (Including Notifiable Safety Incidents)

5. DSP10 – Data Security, Protection and Confidentiality Policy

6. RM06 - Claims Handling Policy

3. DEFINITIONS

This policy adopts the statutory definitions as follows:

1. "apology" means an expression of sorrow or regret in respect of a notifiable safety incident.

2. "moderate harm" means harm that requires a moderate increase in treatment and significant, but not permanent, harm.

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

4. "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a patient during the provision of a regulated activity, that in the reasonable opinion of a healthcare professional, could result in, or appears to result in:

a. the death of the patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition, or

i. an impairment of the sensory, motor or intellectual functions of the patient which has lasted, or is likely to last for a continuous period of at least 28 days,
ii. changes to the structure of the patient's body,
iii. the service user experiencing prolonged pain or prolonged psychological harm, or
iv. the shortening of the life expectancy of the patient; or

b. requires treatment by a healthcare professional in order to prevent

i. the death of the patient, or
ii. an injury to the patient which, if left untreated, would lead to one or more outcomes mentioned in above.

5. "prolonged psychological harm" means psychological harm which a patient has experienced, or is likely to experience, for a continuous period of 28 days.

6. "relevant person" means the patient, or in the following circumstances, a person lawfully acting on their behalf:

a. on the death of the patient; or

b. where the patient is under 16 and not competent to make a decision in relation to their care or treatment; or

c. where the patient is 16 or over and lacks capacity to make a decision in relation to their care or treatment.

7. "severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the patient's illness or underlying condition.

8. "therapeutic non-disclosure" means a decision is taken not to inform the patient or relevant person as this is deemed to be in their best interests, the reasons for this decision must be fully documented in the medical records and referenced in the Root Cause Analysis.

Whilst it is not anticipated, there will be justifiable reasons for exemptions from the process of Duty of Candour, if a senior clinician feels there are exceptional circumstances that necessitate it; this must be discussed with the Deputy Medical Director/Medical Director.

Information may be withheld or restricted where:

a. Communicating a certain piece of information may adversely affect the health of the patient
b. Information is held within legal privilege
c. Specific legal requirements preclude disclosure for specific purposes, for example, where formal safeguarding proceeding are in place or ongoing Police investigation; or
d. Disciplinary proceedings have been instigated following a Human Resources investigation, the details will usually be precluded from sharing with patients/families/carers.

Where information is withheld, the patient/family/carers will be informed of the reasons for the restrictions and when, if at all, the information will available.

4. ROLES AND RESPONSIBILITIES

All staff have a role to play in managing notifiable safety incidents. It is the responsibility of all staff to participate in the implementation of this policy when they become aware of a notifiable safety incident.

The culture of the organisation should encourage candour, openness and honesty at all levels as an integral part of a culture of safety that supports organisational and personal learning.

4.1 Role of all staff members

All staff working within the Trust will be expected to adhere to this policy and promote an open, honest and fair culture within the organisation. All staff have a responsibility for ensuring that notifiable serious incidents are acknowledged and reported as soon as they are identified. In cases where the patient and/or relatives inform healthcare staff that something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and concern by all healthcare staff.

4.2 Role of the Ward Manager / Line Manager

It is the role of the Ward Manager / Line Manager to escalate the notifiable safety incident to the Divisional Quality & Safety Manager and to support the treating clinician with their role of notifying the patient and their relatives / carers, where necessary.

4.3 Role of the Treating Clinician

Medical staff are responsible for promoting candour, openness and honesty within the organisation. It is the role of the patients treating clinician and/or nominated representative to be involved in discussions with the patient when a notifiable safety incident occurs, together with senior nursing support where necessary.

4.4 Investigating Officer for Notifiable Safety Incident

A lead will be identified in the early stages of the notifiable safety incident and this may be the patient's treating clinician or a nominated clinician (where applicable) together with a nominated investigating officer; as part of their investigation, they will ensure that the duty of candour statutory requirements have been met (this must be reflected in the Root Cause Analysis).

4.5 Role of the Matron / Divisional Quality & Safety Manager

Matrons and Divisional Quality & Safety Managers are responsible for promoting an open, honest and fair culture within the organisation making sure that the duty of candour policy is implemented throughout their area of responsibility.

4.6 Role of the Clinical Director / Associate Director

Clinical Directors and Associate Directors are responsible for promoting an open, honest and fair culture within the organisation and Divisions. They are responsible for ensuring that local management arrangements are suitable, and sufficient, to allow for all aspects of this policy to be implemented.

4.7 Role of the Corporate Quality, Safety and Compliance Department

The Quality, Safety and Compliance Department will act as champion for the Policy and Procedure for Duty of Candour; for leading on the implementation of the policy and preparing for CQC inspection.

The Head of Quality, Safety and Compliance Department will be responsible for preparing and disseminating Candour compliance reports for consideration at the Quality & Safety Oversight Group as part of the monthly Quality Performance Report.

4.8 Role of the Executive Directors

Executive Directors are responsible for promoting an open, honest and fair culture within the organisation.

4.9 Role of the Medical Director

The Medical Director is the identified lead for the development, implementation and promotion of the Policy and Procedure for Duty of Candour across the organisation.

4.10 Role of the Chief Executive

The Chief Executive is responsible for ensuring that there is the appropriate infrastructure to support candour between healthcare professionals and patients and/or their carers. In conjunction with the Trust Board, the Chief Executive is responsible for ensuring that there is a Board level commitment to being open and transparent in relation to care and treatment.

If there is a failure to explain that a notifiable safety incident has occurred, there is an immediate criminal sanction for the Trust under Regulation 22(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

5. DUTY OF CANDOUR STATUTORY REQUIREMENTS

The intention of the statutory requirements is to ensure that the Trust is open and transparent with patients who use our services and other 'relevant persons' (people acting lawfully on behalf of a patient) in general, in relation to care and treatment, and specifically, when things go wrong with their care and treatment.

It is a requirement that patients are provided with reasonable support, truthful information and an apology when things go wrong. The following processes should be followed when there has been a notifiable safety incident (see Appendix 1).

5.1 Acting in a Transparent Manner

The Duty of Candour process begins, or is triggered, with the recognition and acknowledgement that a patient has been involved in a notifiable safety incident (see Appendix 1). Application of the Trust Policy RM07 should be followed for all incidents reported and the Policy and Procedure for Duty of Candour should be applied alongside RM07.

The Duty of Candour extends to instances where the patient is appropriately consented for the risks of a treatment or procedure but a known and consented for complication has occurred, as a result of a specific act or omission which causes moderate harm, severe harm or death, (Refer to the CQC Duty of Candour Information for all Providers 2015). An example where the Duty of Candour would apply is where a blood vessel is nicked during surgery and the subsequent blood loss leads to a stroke. Conversely, an example of where the Duty of Candour would not apply would be the correct prescription of medication resulting in an unanticipated adverse drug reaction.

The first priority is to ensure prompt and appropriate clinical care for the patient involved with prevention of further harm. If additional treatment is required, it should be provided as soon as reasonably practicable following open and transparent discussions with the patient.

5.2 Notifying the Patient (or Relevant Person) of the Notifiable Safety Incident

5.2.1 When a notifiable safety incident has occurred, the patient (or relevant person) must be informed as soon as reasonably practicable after the incident has been identified – the NHS Standard Contract requires that the notification must be within 10 working days of the incident being reported on DATIX, and sooner where possible.

5.2.2 Notification of the notifiable safety incident, as set out in 5.2.1, should be given in person (face to face) by senior member of the treating clinical team in the clinical area, where practicable. In the absence of the treating team, this responsibility may be delegated to an appropriate nominated deputy.

5.2.3 Those persons outlined in 5.2.2 should provide an account which is true to the best of their knowledge at the time of the discussion with the patient. The patient should be given all of the facts that are available at the date of the notification. The information provided should include as much or as little information as the patient (or relevant person) wants to hear; it should be jargon free and complicated terms should be clearly explained.

5.2.4 The patient (or relevant person) should also be told what further investigations are being undertaken to look into the details of the incident.

5.2.5 An apology should be given at the time of notifying the patient (or relevant person) of the notifiable safety incident. Saying sorry is not an admission of legal liability but is an expression of sorrow and regret (see appendix 3 for NHS Litigation Authority guidance).

5.2.6 The discussion with the patient (or relevant person) should be documented in the patient's medical records. The record of the discussion should be written in detail (and must be legible) and should include the date and time of the discussion and the name of those involved in the discussions.

5.2.7 Where the patient lacks capacity (in accordance with sections 2 and 3 of the Mental Capacity Act 2005) or is under 16 years of age, the above steps should be followed with a person acting lawfully on behalf of the patient (family / parent).

5.2.8 Were the decision is taken not to inform the patient or relevant person (therapeutic non-disclosure) as this is deemed to be in their best interests, the reasons for this decision must be fully documented in the medical records and referenced in the Root Cause Analysis.

5.2.9 Whilst it is not a statutory requirement, the duty should be triggered in all cases where a patient has died in state detention (i.e. under section of the MHA) regardless of level of harm. This is due to the fact that such deaths are reportable to CQC and commissioners and a RCA is required in any event.

5.3 Provision of Support to the Patient

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, reasonable support should be offered to the patient (in relation to the incident) when discussing the details of the incident.

For guidance on what this support may involve, please refer to Appendix 4.

5.4 Follow-up with Written Notification

The face to face discussion with the patient (or relevant person) should be followed up in writing even though investigations may not be fully completed. The written correspondence must include all of the information that was provided to the patient (or relevant person) during initial discussions, an apology and the results of any investigations that have taken place since the notification in person.

This written correspondence should be sent within 10 days of the discussion with the patient unless there is a reasonable reason for not doing so documented.

The outcome of any investigations must also be provided in writing, through further written notifications, should the relevant person wish to receive them. Final written notification may be undertaken by a Trust forum best placed to approve such correspondence (i.e. following investigation):

Risk Management Panel
The Risk Management Panel will be responsible for signing off the written notification for those notifiable safety incidents which are presented corporately.

Tissue Viability Group
The Tissue Viability Group will be responsible for signing the written notification for those notifiable safety incidents which are presented to the Group.

Falls Group
The Falls Group will be responsible for signing the written notification for those notifiable safety incidents which are presented to the Group.

Acute Kidney Injury Group
The AKI Group will be responsible for signing the written notification for those notifiable safety incidents which are presented to the Group.

VTE
The VTE Group will be responsible for signing the written notification for those notifiable safety incidents which are presented to the Group.

Infection Prevention
Infection Prevention will be responsible for signing the written notification for those notifiable safety incidents which are presented to the Group.

5.5 Circumstances where Patient (or Relevant Person) cannot be Contacted

If the patient (or relevant person) cannot be contacted in person, or declines to speak the Trust representative, a written record of all attempts made, should be kept in the medical records. This includes those situations where the patient has died and there is nobody who can lawfully act on their behalf. If a face to face meeting is not possible, consideration should be given to whether or not contact should be made by telephone.

5.6 Record of Correspondence

There is a statutory duty to keep a record of the written notification shared with the patient, along with any investigations (Root Cause Analysis / RCA) and outcomes. The written notification should be uploaded and stored on DATIX and referenced in the RCA.

5.7 Therapeutic non-disclosure

When commencing an investigation, if the relevant officer feels it is not in the patient or relatives best interest to be informed the reasons for this decision must be discussed with the relevant Divisional Quality & Safety Manager, a Senior Clinician and agreed with the Deputy/Head of Quality & Safety.

If agreed the decision must be fully documented in the medical records and referenced in the Root Cause Analysis. The decision needs to be agreed within 10 working days of the incident being reported to fall in line with Duty of Candour requirements should the decision not be agreed.

Where the Duty of Candour process has commenced and the patient and/or relative has been informed of the incident and the investigation, Duty of Candour must be completed.

6. EDUCATION/TRAINING AND PLAN OF IMPLEMENTATION

All staff, clinical and non-clinical, will receive initial training on the duty of candour requirements which will be provided within the Trust Corporate Induction Programme. This will be reinforced again in the Statutory and Mandatory Training Programme. Training should be recorded within the personal staff record, ideally within ESR.

Further ad-hoc training will be provided by the Quality, Safety and Compliance Department as requested by the Medical Director or Chief Nurse, and in response to the follow-up of incidents which have identified learning needs and Root Cause Analysis training.

7. MONITORING AND REVIEW ARRANGEMENTS

7.1 Monitoring Arrangements

The Risk Management Panel will receive and review Root Cause Analysis (RCA) investigations and will advise and support investigating officers with the investigation, development and dissemination of action plans (see monitoring table below).

The compliance with Duty of Candour requirements will be reported in monthly Quality Performance Report which will provide assurance that the patients/families/carers involved in notifiable incidents have received both verbal and written confirmation of the incident and the written notification is within the agreed 10 working day timeframe following verbal notification.

The Quality Performance Report will be reviewed at Quality & Safety Oversight Group and quality Governance Committee.

7.2 Review

This policy will undergo formal review three years from date of ratification. On-going review will be undertaken as dictated by changes in statutory legislation or national guidance.

8. REFERENCES

References are as follows:

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

2. Care Quality Commission Guidance for NHS Bodies – Regulation 20: Duty of Candour (2014)

3. Mental Capacity Act (2005)

4. NHS Standard Contract 2014/15: Updated Technical Guidance (Appendix 5: Contractual requirements relating to Duty of Candour)

5. NPSA – Ten Principles of Being Open

6. Complaints Matter; Care Quality Commission 2014 http://www.cqc.org.uk/content/complaints-matter

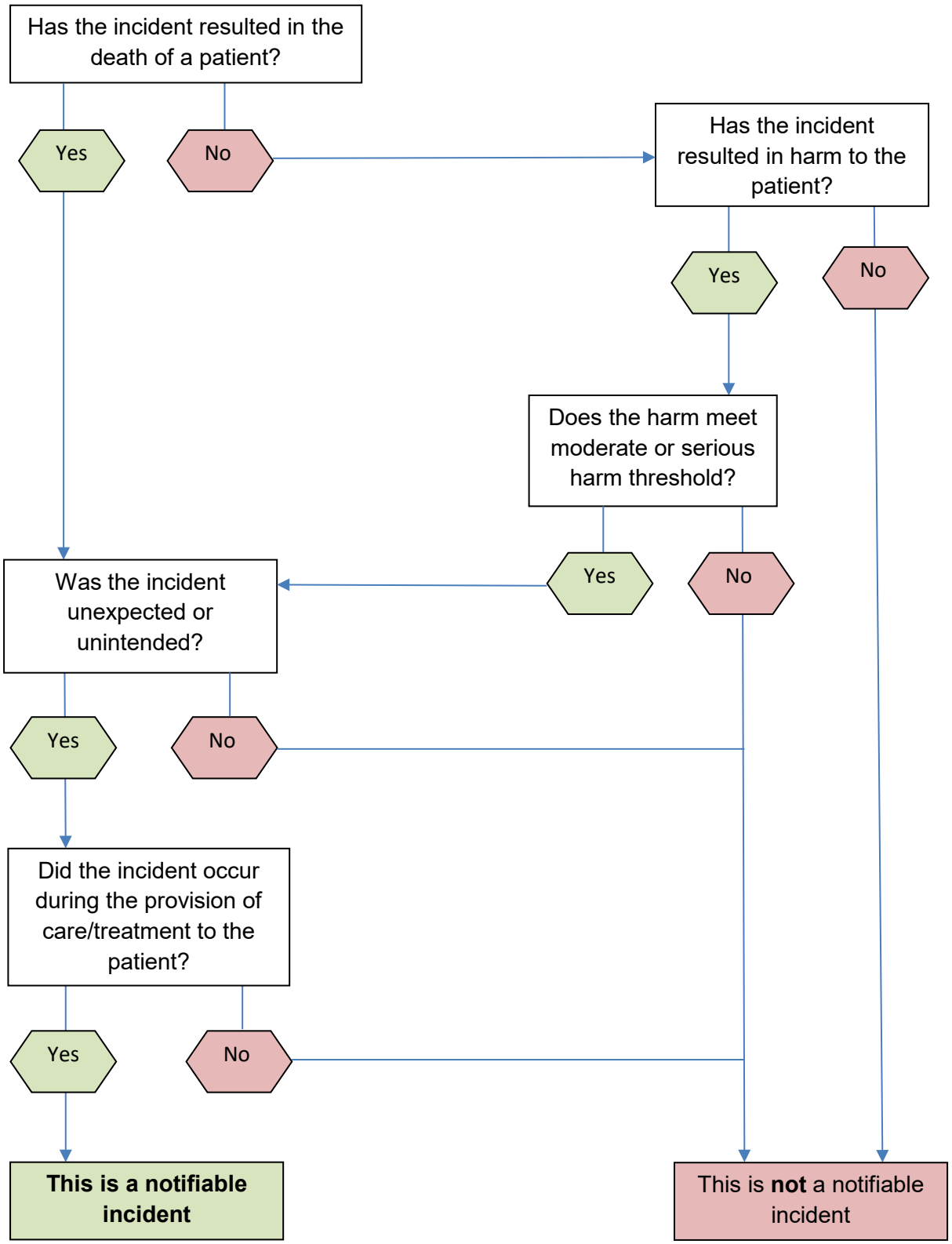
9. APPENDICES

APPENDIX 1: DUTY OF CANDOUR TRIGGERS
APPENDIX 2: DUTY OF CANDOUR TRIGGER FLOWCHART
APPENDIX 3: EXAMPLES OF HARM
APPENDIX 4: DUTY OF CANDOUT TEMPLATE LETTERS

Appendix 1: Duty of Candour Trigger

Duty of Candour Trigger	Statutory Definition
Incident resulting in moderate harm	Any unintended or unexpected incident that has occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, appears to result in a moderate increase in treatment and significant, but not permanent harm
Incident resulting in severe harm	Any unintended or unexpected incident that has occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, appears to result in permanent lessening of bodily, sensory, motor, physiologic or intellectual functions including the removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the patient's illness or underlying condition
Incident resulting in prolonged psychological harm	Any unintended or unexpected incident that has occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, appears to result in psychological harm which patient has experienced or likely to experience for a continuous period of at least 28 days
Incident resulting in death	Any unintended or unexpected incident that has occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, appears to result in the death of the patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition
Recognised Complication / Return to theatre following surgery or a transfer to another treatment area	The term 'moderate increase in treatment' does include situations such as a transfer or an unplanned return to surgery. But 'moderate increase in treatment' is only one part of the overall definition of 'moderate harm'. And it is the description of 'moderate harm' that helps define if something is a notifiable safety incident. To meet the 'moderate harm' threshold the harm must require a moderate increase in treatment **and** there must be significant, but not permanent, harm. So a transfer or unplanned return to theatre does not automatically qualify as a notifiable safety incident.

Appendix 2: Duty of Candour Trigger Flowchart



Appendix 3: Examples of Incidents Including Harm

Example 1: Maternity

What happened

A woman in an NHS hospital experienced pain during an elective caesarean section. She found this experience traumatic and subsequently had an acute episode of severe anxiety and depression that lasted more than 28 days. It was discovered that she had been not receiving enough anaesthesia from an epidural line.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?

Yes. The incident was both unexpected and unintended.

2. Did it occur during provision of a regulated activity?

Yes. The incident occurred while the woman was receiving care under the regulated activity 'maternity and midwifery services'.

3. Has it resulted in death or severe or moderate harm?

Yes. The incident has resulted in “prolonged psychological harm” (psychological harm lasting more than 28 days). The woman was receiving care in an NHS hospital so the harm definitions in Regulation 20(8) apply. If the maternity care had been delivered in an independent hospital, Regulation 20(9) would apply instead.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident.
And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 2: Surgery

What happened?

An elderly woman undergoes a coronary artery bypass operation. She has given appropriate consent for the risks of the operation, including for stroke and death. Unfortunately the woman suffers a large stroke during the operation and dies as a result.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?

Yes. The incident was a possible risk of the operation, and as such her consent was sought; however the incident was still unintended.

2. Did it occur during provision of a regulated activity?

Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.

3. Has it resulted in death or severe or moderate harm?

Yes. The incident resulted in death. The woman was receiving care in an NHS hospital so the definitions in Regulation 20(8) apply. The incident resulted in death.

Conclusion

Although the answers to all three questions are 'yes' this is a Known Complication of the surgery of which the patient was appropriately consented for. This type of incident would only be considered a notifiable safety incident had the patient not been appropriately consented for the procedure and risks associated.

Example 3: Medicine

A doctor unintentionally causes a perforation whilst carrying out an endoscopic procedure (a recognised complication). The patient attended the Emergency Department where it is identified that they require a further procedure to ‘clip’ the perforation. The patient makes a full recovery following an overnight stay on SAU

.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?

Yes. The incident was a possible risk of the procedure; however the incident was still unintended.

2. Did it occur during provision of a regulated activity?

Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.

3. Has it resulted in death or severe or moderate harm?

Yes. The incident resulted in moderate harm as the patient needed additional treatment and a readmission to hospital.

Conclusion

Although the answers to all three questions are 'yes' this is a Known Complication of the surgery of which the patient was appropriately consented for. This type of incident would only be considered a notifiable safety incident had the patient not been appropriately consented for the procedure and risks associated. However, the known complication of treatment letter should be provided

This would be an example where an incident appeared to have resulted in moderate harm.

Example 4: Maternity

A mother had significant post-partum bleeding after a difficult delivery, and there was some delay in obtaining blood for transfusion. As a result, she needed treatment in the high dependency unit for 24 hours before making a full recovery.

This would be an example where an incident appeared to have resulted in moderate harm.

Example 5: Patient Fall

A patient who is under the care of an NHS hospital falls on their way to the toilet and breaks their hip. As a result, the patient undergoes surgery to repair the fracture which increases their length of stay, morbidity and treatment.

This would be an example where an incident appeared to have resulted in severe harm.

Timescales

1. **Notify** the patient and/or relatives, documenting the discussion clearly in the medical notes and on the Datix.

2. Send a **letter** to the patient and/or relatives within 10 working days, confirming the conversation already held and investigation.

3. Maintain **communication**; where the patient and/or relatives wish to be kept informed of the outcome of the investigation, remember to advise them of any delays.

4. 4.If the patient and/or relatives wish to be informed of the **outcome** of the investigation, once the RCA has been closed by the CCG, they should be offered a meeting to discuss the findings, but can also be sent a copy of the investigation if they wish.

Appendix 4: Duty of Candour Template Letters

Private & Confidential- for addressee only

[Patient / Relatives Name]
[Address]

[Your Division]
[Your Department]
Royal Stoke University Hospital,
Newcastle Road,
Stoke on Trent,
ST4 6QG
Telephone: [Your contact number]
Email: [Your email address]
Date: [Date of the Letter]

Dear [*insert name of patient / relevant person*]

RE: Duty of Candour - Notifiable Patient Incident

I am writing to follow up the conversation which took place on date with xxxx and to express my sincere apologies that you/your relative were/was involved in an incident whilst under our care.

As discussed, the incident happened on xxxx [*insert a brief summary of the incident here*] which led to [*insert outcome for patient*].

As a Trust we are committed to being open and honest with patients, relatives and carers when events such as these occur so that we gain a shared understanding of what happened and how we can prevent such incidents occurring again in the future.

As discussed, we will be undertaking a full investigation into your/your relatives care which we would like the opportunity to discuss with you once complete and welcome your contribution to ensure any concerns or questions you may have are answered fully. The extent of your involvement is entirely your decision.

Once our investigation is complete, we will write to you again to provide feedback regarding the outcome, lessons learnt and actions we have put in place as a result. Following this, you may wish to have a copy of the full report for you to review. We can arrange to discuss the findings in a meeting with you if you would prefer.

If you have any concerns or questions at this stage, please contact me using the above details.

On behalf of the Trust I would again like to offer you my sincere apologies for any harm caused as a result of this incident.

Yours sincerely,

[Your Name]
[Your Title / Role]

Private & Confidential- for addressee only

[Patient / Relatives Name]
[Address]

[Your Division]
[Your Department]
Royal Stoke University Hospital,
Newcastle Road,
Stoke on Trent,
ST4 6QG
Telephone: [Your contact number]
Email: [Your email address]
Date: [Date of the Letter]

Dear [*insert name of patient / relevant person*]

RE: Duty of Candour - Notifiable Patient Incident

I am writing to follow up the previous letter which was sent to you in xxxx to advise that our investigation into the care provided to you/your relative is now complete.

Our investigation identified the causes and contributing factors for the incident are:

- List root causes & contributing factors from the RCA

We have also identified areas we would like to improve to prevent such incidents from occurring in the future. As a result of the investigation, we have identified the following areas where improvements will be made:

- List the learning/recommendations and the associated actions

As a Trust we are committed to being open and honest with patients, relatives and carers when events such as these occur so that we gain a shared understanding of what happened and how we can prevent such incidents occurring again in the future.

If you wish to see a copy of the full report please contact me using the details above; we can also arrange to discuss the findings in a meeting, if you wish.

On behalf of the Trust I would again like to offer you my sincere apologies for any harm caused as a result of this incident.

Yours sincerely,

[Your Name]
[Your Title / Role]

SAMPLE LETTER TO PATIENT / RELEVANT PERSON
RECOGNISED COMPLICATIONS

Private & Confidential- for addressee only

[Patient / Relatives Name]
[Address]

[Your Division]
[Your Department]
Royal Stoke University Hospital,
Newcastle Road,
Stoke on Trent,
ST4 6QG
Telephone: [Your contact number]
Email: [Your email address]
Date: [Date of the Letter]

Dear [*insert name of patient / relevant person*]

Notifiable Patient Incident - Recognised Complication

Further to your recent admission to the University Hospitals of North Midlands, you may recall that we discussed the fact that [*you / your relative*] [*were / was*] underwent an extended time in hospital.

From the discussions that we had, whilst [*you / your relative*] [*were / was*] in hospital, it was apparent that [*insert details of incident and discussions with the patient whilst in hospital*] which led to [*insert outcome ie. a return to theatre*].

We discussed that this was a recognised complication of the initial procedure for which [you / your relative] [were / was] consented. I am sorry that your [operation / procedure] was not as straight forward as one would have hoped. It is always regrettable that some people succumb to risks of a procedure despite care being taken to avoid such occurrences.

In this case, we do not feel that any further investigation is required and on behalf of the Trust, I extend my sincere apologies to [*you / your relative*] for the harm experienced as a result of this incident.

Yours sincerely,

[Your Name]
[Your Title / Role]