



Being Open (Duty of Candour) Policy

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Document Author = Rebecca Mallinder (Head of Investigations & Learning)

Associated Documentation:

- Incident & Serious Incident Management Policy
- Investigations & Learning Policy
- Compliments, Comments, Concerns and Complaints Management Policy
- Claims Management Policy

Section	Contents	Page No.
	Staff Summary	4
1	Introduction	4
2	Purpose/Scope	4
3	Process <ul style="list-style-type: none"> ▪ Principles of Duty of Candour ▪ Being open flow chart ▪ Principles of Communication 	6
4	Training Expectations for Staff	8
5	Implementation Plan	8
6	Monitoring compliance with this Policy	8
7	References	9
8	Appendices	10
A	Definitions	10
B	Roles & Responsibilities	11

Staff Summary

Robert Francis QC's report of the Mid Staffordshire Foundation Trust Public Inquiry included 12 recommendations relating to openness, transparency and candour. Recommendation 173 states the overarching requirement:

"Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful".

From 2013-14 the NHS Standard Contract (NHS Commissioning Board, 2013) includes a contractual duty of candour. These requirements are covered within this policy. The Health & Social Care Act 2008 Regulations 2014 sets out the new statutory duty of candour. The statutory duty came into force on the 27th November 2014.

The purpose of this Policy is to ensure that YAS has a clear system in place to identify when the Trust needs to be open about incidents where harm or potential for harm has occurred (including near misses).

A notifiable safety incident can be defined as:

"Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in –

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

However this only relates to patient safety incidents arising in the course of services delivered under the contract. As such, the contractual duty of candour is not applicable to any incidents which took place prior to April 2013.

Within 10 operational days of becoming aware of the incident the provider must conduct an investigation and notify the relevant person.

If there is a breach of the contractual duty of candour the commissioning body can recover from the provider either the cost of the episode of care, or up to £10,000 if the cost is unknown.

Lessons learned and action plans following the patient safety incident will be monitored via the processes outlined in the Incident and Serious Incident Management Policy. Learning arising from the Duty of Candour process will be recorded on the Datix record and reported to the Incident Review Group (IRG) when appropriate.

All staff will be made aware of the Trust's Being Open and Duty of Candour Policy through corporate induction and basic training. This will be part of the Trust's efforts to build a culture of openness, honesty, truthfulness and transparency.

The Significant Events Report to Trust Board and Quality Committee will include information on application of the Duty of Candour process.

1.0 Introduction

- 1.1 The National Patient Safety Agency (NPSA) advised all NHS organisations to implement a *Being Open* Policy in September 2005. The guidance was revised in November 2009 with the publication of its best practice *Being Open Framework* (National Patient Safety Agency, 2009). Robert Francis QC's report of the Mid Staffordshire Foundation Trust Public Inquiry included 12 recommendations relating to openness, transparency and candour. Recommendation 173 states the overarching requirement:

“Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful”.

- 1.2 From 2013-14 the NHS Standard Contract (NHS Commissioning Board, 2013) includes a contractual duty of candour. These requirements are covered within this policy. The Health & Social Care Act 2008 Regulations 2014 sets out the new statutory duty of candour and is one of the fundamental standards inspected by the Care Quality Commission (CQC). The statutory duty came into force on the 27th November 2014.

2.0 Purpose/Scope

- 2.1 The purpose of this Policy is to ensure that YAS has a clear system in place to identify when the Trust needs to be open about incidents where harm or potential for harm has occurred (including near misses). Discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after-effects. Openness and honesty can help to prevent such events becoming formal complaints and litigation claims.
- 2.2 This Policy applies to patient safety incidents that occur during care and associated activities, including patient related data, carried out by Yorkshire Ambulance Service that result in moderate harm, severe harm or death (see definitions in section 3.0) and that are reported via Trust risk management systems. It does not apply, automatically, to low/no harm incidents or near misses, but in some cases it may still be appropriate to report these incidents to the people involved.

3.0 Process

Principles for Duty of Candour

- 3.1 There are two elements to the Duty of Candour principles in order to satisfy both the contractual duty and the statutory duty. Under the contractual duty of candour the Trust is required to comply with obligations regarding candour if a notifiable safety incident occurs or is suspected to have occurred. A notifiable safety incident can be defined as:

"Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in –

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) severe harm, moderate harm or prolonged psychological harm to the service user."

However this only relates to patient safety incidents arising in the course of services delivered under the contract. As such, the contractual duty of candour is not applicable to any incidents which took place prior to April 2013.

- 3.2 Within 10 operational days of becoming aware of the incident the provider must conduct an investigation and notify the relevant person. Notification must be:
- Verbal and conducted by one or more representatives of the provider, including where possible the clinical responsible.
 - The relevant person must be given all known relevant facts.
 - An appropriate apology must be made and written notification must be offered.
 - Notification must be recorded in writing for audit purposes.
- 3.3 If there is a breach of the contractual duty of candour the commissioning body can recover from the provider either the cost of the episode of care, or up to £10,000 if the cost is unknown.
- 3.4 The statutory duty imposes similar implications on the organisation however does not hold the timescales that are enforced through the contract. It also requires that organisations offer reasonable support to those involved in the incident in contract to the contractual duty which requires all necessary support will be given. Both the contractual and the statutory duties fundamentally require Yorkshire Ambulance Service to act in an open, honest and transparent manner with patients and others involved in a notifiable safety incident.

Practical guidance

- 3.5 The Trust has a detailed Standard Operating Procedure which outlines the step-by-step process for application of the Duty of Candour to notifiable safety incidents. This can be found at Appendix C. The process is managed by the Quality & Safety Team with the Head of Investigations & Learning being the Trust's Being Open (Duty of Candour) Lead. No correspondence should be issued under the being open principles unless it has been coordinated and approved by the Head of Investigations & Learning (or appropriate deputy).
- 3.6 Patient safety incidents are identified and graded through the Trust Incident and Serious Incident Management Policy.
- 3.7 The Quality & Safety Team will keep full records of all correspondence, written and verbal, with the patient and/or others involved in the incident. These will be recorded

on the Datix record for each case. A Duty of Candour log is also utilised purely to track progress of cases with full information being available on the Datix record. This will include an archive of all closed cases.

3.8 Lessons learned and action plans following the patient safety incident will be monitored via the processes outlined in the Incident and Serious Incident Management Policy. Learning arising from the Duty of Candour process will be recorded on the Datix record and reported to the Incident Review Group (IRG) when appropriate.

3.9 Principles of Communication

- Patients and/or their carers/families/appointed advocate or representatives will be given a single point of contact for any questions or requests they may have throughout the process.
- Patients and/or their carers/families/appointed advocate or representatives will receive clear, unambiguous information which is free from medical jargon.
- Communication, including written communications will be tailored to the specific requirements and preferences of the individual and conform to Plain English standards as a minimum.
- Where an individual requires additional support, such as a translator, interpreter independent advocate or use of alternative methods of communication such as audio-recording or Braille, all reasonable measures will be taken to accommodate these requirements.
- All communications and records will be carried out and handled with full regard for patient confidentiality. Information will only be disclosed to third parties with the appropriate patient/next-of-kin consent.

4.0 Training expectations for staff

4.1 All staff will be made aware of the Trust's Being Open (Duty of Candour) Policy through corporate induction and basic training. This will be part of the Trust's efforts to build a culture of openness, honesty, truthfulness and transparency. Information on this policy and process will also be covered as part of the 1 day Serious Incident Investigation & Root Cause Analysis training day.

4.2. Staff within the Quality, Governance & Performance Assurance Directorate will receive guidance and support relating to their roles to ensure that they are able to carry out their duties effectively. The Deputy Director of Quality will ensure that this guidance and support is in place.

4.3 Senior managers responsible for taking part in 'being open' meetings will receive guidance and support on carrying out these responsibilities. This will be provided by (or on behalf of) the Head of Investigations & Learning.

5.0 Implementation Plan

5.1 The latest approved version of this Policy will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction’.

6.0 Monitoring compliance with this Policy

6.1 The YAS Being Open Log will maintain an up to date record of all current and archived cases of moderate harm, severe harm or death. Full details can be accessed via the Datix records.

6.2 Reports will be produced to inform the Quality Committee & Trust Board on the application of the Duty of Candour process as well as information being published within the Quality Account and Annual Report. Commissioners will receive updates on a case by case basis and through contract reports on the Duty of Candour.

6.3 An audit will be undertaken by the Head of Investigations & Learning monthly, quarterly, bi-annually and annually to ensure that all patient safety incidents with moderate or above recorded harm have been subject to the being open process.

7.0 References

- Being Open – Communicating patient safety incidents with patients, their families and carers, National Patient Safety Agency, London, 2009.
- Report of the Mid-Staffordshire NHS Foundation Trust Public Enquiry, Robert Francis QC, February 2013, HHC 947, London: The Stationary Office.
- Technical Guidance to NHS Contract 2013-14, Annex 4, available at: <http://www.england.nhs.uk/wp-content/uploads/2013/02/contract-tech-guide.pdf>
- Implementing a ‘Duty of Candour’; a new contractual requirement on providers - *Proposals for consultation*; Department of Health, 2011
- Introducing the Statutory Duty of Candour: A consultation on proposals to introduce a new CQC registration regulation, March 2014
- Health and Social Care Act 2008 (Duty of Candour) Regulations 2014
- CQC Regulations

8.0 Appendices

8.1 The following appendices are included within the policy:

Appendix A – Definitions

Appendix B – Roles & Responsibilities

Appendix C – Being Open (Duty of Candour) Standard Operating Procedure

Appendix A - Definitions

Apology (according to the standard contract)

Expression of sorrow or regret in respect of a notifiable safety incident.

Notifiable Safety Incident

"Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in –

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) severe harm, moderate harm or prolonged psychological harm to the service user."

No harm

Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.

Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.

Low Harm

Any patient safety incident that required extra observation or minor treatment and caused minimal harm to one or more patients receiving NHS-funded care.

Minor treatment is defined as 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.

Moderate Harm

Any patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.

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 as a result of the incident.

Severe Harm

Any patient safety incident that appears to have resulted in permanent harm to one or more patients receiving NHS-funded care.

Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.

Death

Any patient safety incident that directly resulted in the death of one or more patients receiving NHS-funded care.

The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.

Prolonged Psychological Harm

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

Relevant Person

The service user or in the following circumstances, a person lawfully acting on their behalf –

- a) on the death of the service user, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- b) where the service user is 16 or over and lacks capacity (as determined in accordance with the Mental Capacity Act 2005 in relation to the matter).

Appendix B - Roles & Responsibilities

The Trust Board is responsible for:

- Establishing a culture of openness and candour and making a public commitment to the principles of Being Open.

The Quality Committee is responsible for:

- Gaining assurance that the Policy on Being Open & Duty of Candour is being delivered effectively in practice.

The Incident Review Group is responsible for:

- Maintaining an overview of all Being Open cases and agreeing the decisions and proposed course of action.
- Supporting those involved in Being Open cases with clinical expertise and/or best practice on management of meetings.
- Highlighting cases not automatically within the Being Open system (i.e. those graded as Yellow or Green through the Trust Risk Management Procedures) which should be considered for Being Open.
- Closing Being Open cases at the appropriate stage of the process i.e. when contact has been made, findings shared and no further action required or when contact has not been established despite reasonable attempts being made by YAS.

All Staff

- Be aware and act upon guidance as outlined in this policy
- Identify potential incidents and report through agreed processes
- Provide statements if required, and participate in some feedback to patients where appropriate.
- At all times, act in an honest and transparent way.

Executive Director of Quality, Governance & Performance Assurance is responsible for:

- Being the ultimate lead within the Trust for Duty of Candour.
- Ensuring that the Being Open (Duty of Candour) Policy is fully integrated with other policies, specifically clinical governance risk management and complaints/concerns policies.
- Through attendance at the Incident Review Group, reviewing the notifiable safety incidents and confirming that agreed actions and next steps in line with this policy.

- Being accountable for decisions made in relation to the Duty of Candour process.

Executive Medical Director is responsible for:

- Chairing the Incident Review Group, reviewing notifiable safety incidents and confirming that agreed actions and next steps for current patient safety incidents are in line with this policy.
- Where required, nominating an appropriate individual to represent the Clinical Directorate at meetings with relevant persons.

Head of Investigations & Learning is responsible for:

- Acting as the Trust lead for Being Open for the management and application of the policy and representing the Trust with correspondence with relevant persons.
- Receiving notification of all new notifiable safety incidents resulting in moderate harm, severe harm or death and identifying how YAS will discharge its responsibility under this policy.
- Ensuring that each case has a nominated individual to act as a single point of contact and that communications are carried out by appropriately qualified and trained individuals.
- Ensuring that learning from Being Open cases is identified, triangulated with other sources of information and used to reduce future patient harm and inform the future development of this policy.
- Ensuring that staff involved in the Being Open process have the necessary skills and training to carry out their roles.
- Ensuring that there is an awareness by all Trust staff of the Duty of Candour and what this means in practice for working with honesty, openness and truthfulness.
- Presenting the Duty of Candour updates to the Incident Review Group and highlighting any cases that require discussion and action.
- Escalating any concerns relating to the Duty of Candour application to the Executive Director of Quality, Governance & Performance Assurance.
- Reporting to the commissioners under the standard contract updates on the Duty of Candour including any exceptions to the application of this process.

Quality and Risk Coordinator is responsible for:

- Maintaining the Duty of Candour log and the Datix records for each notifiable safety incident in relation to Duty of Candour application.
- Maintaining an archive of closed Being Open cases.
- Ensuring that full records are kept, and are accessible to appropriate parties, of Being Open cases.
- Acting as the single point of contact for the relevant persons throughout the Duty of Candour process where identified as appropriate.



YAS Quality, Governance & Performance Assurance Standard Operating Procedure

Managing Duty of Candour

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Response Lead: Steve Page (Executive Director of Quality, Governance & Performance Assurance)

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Aim

The aim of this document is to provide guidance to the members of the Quality, Governance & Performance Assurance team on the process for managing the Duty of Candour process.

1. Identification & Recording of Duty of Candour cases

Moderate & above harms

- All incidents with moderate or above patient harm are alerted to the Safety Governance Manager and coordination team. A review will be undertaken upon alert of the incident to assess whether the severity is accurate. This will be done by reviewing the information available and assessing the patient outcome. Where appropriate incident severity will be downgraded and rationale recorded on the Datix record.
- Where it is determined that the level of harm is accurate discussions will take place with the Executive Director of Quality, Governance & Performance Assurance and other appropriate colleagues to assess whether the incident meets the criteria for reporting as a Serious Incident and whether it meets the Duty of Candour criteria.
- Where a decision is made that Duty of Candour criteria has been met the Head of Investigations & Learning and Quality & Risk Coordinator will be notified to initiate the Duty of Candour process.
- Where further discussion is required or in instances where incidents with moderate or above harm are reported within 2 working days of Incident Review Group, the Safety Governance Manager will present these to the IRG.
- Discussion will be held at IRG to determine whether the level of harm is accurate. This is based on assessment of whether YAS contributed to this level of harm.
- If level of harm is determined to be less than moderate the incident should be downgraded on Datix with notes to explain the rationale for downgrade. This will be done by the Safety Governance Manager or nominated deputy. In these cases downgrading the level of harm from moderate or above will mean they will no longer meet Duty of Candour criteria.
- If the level of harm is determined to be accurate at moderate or above these cases will be added to the Duty of Candour log and documented within the Datix record by the Head of Investigations & Learning.
- On occasion where the criteria for Duty of Candour are not met following discussion at IRG (refer to the national Duty of Candour guidance for examples of when this might be relevant) these cases would not be added to the log but rationale for decision to be documented on the Datix record by the Head of Investigations & Learning.

Other cases

- On occasion IRG will request Duty of Candour to commence on cases unrelated to the degree of harm due to the nature of the case. This will follow the above process for recording on the Duty of Candour log and documented on the Datix record by the Head of Investigations & Learning.
- If other persons across the Trust identify cases for Duty of Candour consideration these will be flagged to the Head of Investigations & Learning and/or be taken through the above outlined process of discussion and decision making at IRG.

Audit & Monitoring

- On occasion there may be incidents that get upgraded to moderate or above level of patient harm outside of the IRG process following further information gathering.
- A monthly check will be conducted by the Head of Investigations & Learning & the Quality & Risk Coordinator to identify any cases that have not undertaken the IRG review process. These will be flagged to the Safety Governance Manager for review of the degree of harm.
- Where it is determined that the level of harm is accurate this case will be flagged to the Head of Investigations & Learning to commence the Duty of Candour process.
- Where it is determined that the level of harm is not accurate the Safety Governance Manager will downgrade the level of harm and record on Datix as outlined above.

2. Contact Details

Agreed Lead for Duty of Candour Process

- If identification of the incident was highlighted via a complaint from the patient/relative the Patient Relations Manager will lead the Duty of Candour process having already developed a relationship and contact with the patient / NOK. This communication will follow the 4Cs policy and practice.
- Where the case was highlighted via a service to service complaint or any other route the Head of Investigations & Learning will lead the Duty of Candour process.
- If the incident is a NHS 111 or LCD incident the NHS 111 Head of Nursing & Quality Assurance will lead on the Duty of Candour process in regular liaison with the central Quality Team.
- If the investigation is joint with another organisation, whoever is deemed the lead for that investigation should lead the Duty of Candour process. This needs to be explicitly stated and agreed at the start of the investigation. If another Trust is leading on the Duty of Candour process YAS will feed into their investigation and offer attendance at meetings or contact independent to the other Trust if requested by the family. Enquiry relating to this will be led by the lead organisation and regular updates will be provided to YAS throughout the duration of this contact.
- If the action of the other Trust is unclear YAS will initiate direct contact with the patient or family.

Obtaining Patient Contact Details

- If the patient is able to participate in the Duty of Candour process, the Quality & Risk Coordinator will obtain contact details for the patient.
- The Patient Care Record (PCR) would be obtained and reviewed to identify the correct contact details for the patient. If the PCR does not contain appropriate information (primarily phone number and/or address) and we cannot obtain this internally either via NHS 111 or Patient Relations, this information will be sought from the GP Practice or the receiving hospital.
- Contact details will be recorded on the Datix record by the Quality & Risk Coordinator.

Next of Kin Details

- If the patient is unable to participate, next of kin (NOK) details will be sought.
- As outlined above, these will be obtained from the PCR where recorded accurately and sufficiently. If the PCR does not include full relevant information and we cannot obtain this internally information will be sought externally.
- When the Trust declares a Serious Incident in which the patient has deceased the Legal Services department inform the Coroner. As part of this process they will also request NOK details to be returned to YAS. If the case has not been referred to the Coroner (i.e. when not reported as an SI) or if NOK details are not made available, attempts will be made to obtain the NOK details via the GP Practice and/or the receiving hospital.

If all of the above attempts have been unsuccessful the case will be closed on the basis of reasonable attempts having been made to obtain the contact details. All of the above attempts should be fully documented on the Datix record by the Quality & Risk Coordinator and presented to IRG for final decision to close the case on the basis of lack of contact details. Contact details should aim to be obtained within 5 working days of the being open process being initiated.

3. Making Contact

- Initial contact will be initiated by the Head of Investigations & Learning to the patient or NOK within 5 working days of the contact details being established. This should be done via letter (produced by the Head of Investigations) and should be sent recorded delivery. A letter template can be found in the Duty of Candour folder on the I Drive.
- If this cannot be done or if it is deemed more appropriate based on individual circumstances, a phone call should be made by the Head of Investigations & Learning. 3 attempts of a phone call will be made over a period of 5 working days. No voice messages will be left in line with information governance guidelines. A follow up letter after telephone call is required.
- Within the letter the patient or NOK will be invited to participate in the investigation if they wish to do so. As an alternative if they do not wish to participate they will be offered to receive the findings at the conclusion of the investigation. They will also have the choice not to be involved if they so wish. Contact details of the Quality & Risk Coordinator will be provided.
- Details will be recorded on the Datix record and reported to IRG by exception.
- If the case is being managed as a complaint, contact will be maintained following the 4Cs Policy

4. Participation

- The letter will advise the patient or NOK to contact the Quality & Risk Coordinator if they wish to participate in the investigation or receive feedback following investigation or if they do not wish to be involved.
- The letter will state that unless we receive specific instruction that the patient or NOK do not want to take part or be made aware of the findings from the investigation, a subsequent letter will be sent upon completion of the investigation to arrange a meeting to share the findings.

5. Investigation

- The investigation into the incident will now be underway. Please refer to the investigations guidance within the Quality & Risk Team for details of investigation process. Timescales outlined above to the patient or NOK are in line with the appropriate investigation timescales.
- If deemed appropriate by the Lead Investigator or if the patient or NOK request certain aspects to be covered as part of the investigation this will be built into the investigation and where appropriate further information may be sought from the patient or NOK if involved in the incident by the Lead Investigator.

6. Feedback

- Following conclusion of the investigation feedback will be provided to the patient or NOK.
- If the incident has been declared an SI, contact will be made by the Head of Investigations & Learning to the patient or NOK to arrange a meeting if one not already scheduled. Contact should be made within 5 working days of the investigation concluding. This contact will be made via telephone and in line with the above outlined process if contact is not made within 3 attempts, a letter will be sent if details available. If no communication is received within 4 weeks the case will be closed.
- The meeting will be offered within 4 working weeks of the investigation concluding however this is dependent on patient or NOK availability. If the patient or NOK does not wish to meet a telephone discussion can be offered or written findings from the investigation. This will be in the format of an investigation report.
- If a meeting is held to feedback the findings to the patient or NOK this will be led by the Head of Investigations & Learning (or appropriate deputy) and an appropriate senior manager from the service involved in the incident or the Lead Investigator). In the first instance the meeting should be offered at one of the Trust's 3 administration offices in Wakefield, York or Rotherham. Alternatively a local GP Practice may be sought. Travel expenses of the patient or NOK can be covered and if the meeting place is not suitable for the patient or NOK an alternative arrangement can be agreed. Lone working requirements must be considered as part of this alternative arrangement to ensure staff safety at all times.
- Where Patient Relations are leading the Duty of Candour process (when the event initiated as a complaint) a meeting will also be offered and details of this is outlined within the 4Cs policy.
- A recording of the meeting will be taken (with agreement from the participant) and a copy shared with them following the meeting should they wish to receive this. If sending a copy, a confidentiality agreement should be signed at the meeting. If they do not want the meeting to be recorded, notes should be taken that summarise the key discussion points and any actions. A follow up letter should be sent after the meeting. The investigation report should be shared with the participants and this can be before or after the meeting depending on what is agreed.

6. Closure & Learning

- Following the meeting the case is then closed and all records updated on Datix.
- Any learning relating to the Duty of Candour process is recorded on Datix and appropriate action taken for improvement and reported to IRG if identified. This could be highlighted within the meeting with the patient or NOK or via internal process.