



# Libertatem Healthcare Group

## Duty of Candour

### Policy and Procedure

Notice to employees using a paper copy of this policy  
The company Policies folder on the shared drive holds the most recent version of this document and all employees must ensure that they are using the most recent guidance.

## Document Control

<b>Document Name</b>	Duty of Candour
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## Introduction

It is the policy of Libertatem Healthcare Group to take an honest and open approach with users of our services, and when things go wrong with care or treatment to provide service users and other relevant persons with support, truthful information and a written apology.

It is broadly acknowledged that healthcare treatment is not risk free. Service users, families and carers usually understand this and want to know not only that every effort has been made to put things right, but every effort is made to prevent similar incidents from happening again to someone else. A critical test for service users' trust in Libertatem Healthcare Group is how we respond when things go wrong.

## Aim

Libertatem Healthcare Group will ensure an honest and open culture exists across all levels within the organisation, and it will ensure that systems are in place for reporting notifiable

safety incidents and informing relevant person(s) in a timely manner when such an incident has occurred.

### **Definition of candour**

**Candour** is defined by Robert Francis as: 'The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made'.

The Being Open principles and ethical duty of openness apply to all incidents and any failure in care or treatment (See Appendix 1). The Duty of Candour applies to incidents whereby moderate harm, significant harm or death has occurred.

It is a matter of judgment that needs to be exercised on a case by case basis to determine whether an incident that meets the Duty of Candour criteria has occurred. What may not appear to be such an incident at the outset may look very different once more information comes to light, and may therefore lead to an incident becoming notifiable under the Duty of Candour.

### **Purpose of Policy**

To ensure staff are aware of and abide by the Health and Care Social Care Act 2008

(Regulated Activities) Regulations 2014: Regulation 20, Duty of Candour.

- To ensure staff are made aware of legal responsibilities
- To ensure staff follow the procedure

### **Roles and Responsibilities**

#### **Clinical Director**

The Clinical Director is responsible for determining the governance arrangements of the group including effective risk management processes. They are responsible for ensuring that the necessary clinical policies, procedures and guidelines are in place to safeguard people we support and reduce risk. In addition they will require assurance that clinical policies, procedures and guidelines are being implemented and monitored for effectiveness and compliance. The Clinical Director has responsibility for safety of the people we support and ensuring that there are effective risk management processes within the group that meet all statutory requirements and adhere to guidance issued by the Department of Health.

#### **Managers**

Managers are responsible for ensuring that:

- This policy is made available to all staff
- The staff they are responsible for implement and comply with the policy
- That staff are updated with regards to any change in the policy

#### **Key Principles of the Duty of Candour**

The Health and Care Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 places the following requirements upon Libertatem Healthcare Group, as a provider organisation to promote:

- A culture that encourages candour, openness and honesty at all levels. Staff must feel that they work in an organisation that supports organisational and personal learning. The culture of openness and honesty must start at Board level

- A policy and procedures that support a culture of openness and honesty amongst all staff
- A zero tolerance approach to bullying and harassment (see Policy on Bullying and Harassment), including in relation to duty of candour. In any instance where it is alleged that a member of staff may have obstructed another in exercising their duty of candour, an investigation will be carried out. Furthermore, if a professionally registered member of staff is found, following investigation, to have breached their duty of candour, referral to the relevant professional body may be indicated.
- The provision of staff training in relation to the duty of candour, and support if they are involved in a notifiable safety incident

### **Procedure**

All staff employed at Libertatem Healthcare Group have a responsibility to adhere to the policy and procedures around duty of candour, regardless of seniority or permanency.

As soon as reasonably practicable after becoming aware that a safety incident has occurred that falls into the moderate harm or more serious categories the healthcare professional must-

1. Notify the 'relevant person' (this is usually the patient but may in some circumstances be the relative, carer or advocate) that the incident has occurred and;
2. Provide reasonable support to the relevant person in relation to the incident

The notification must:

- (a) Be given in person by one or more members of staff
- (b) Provide an account of all the facts known about the incident to date
- (c) Advise the person what further enquiries into the incident will be undertaken
- (d) Include an apology and/or a sincere expression of regret, and;
- (e) Be recorded in writing in the notes

This notification must be followed up in writing to the relevant person.

The member of staff should be clear in the first meeting that the facts may not yet have been established, tell the relevant person only what is known and believe to be true, and answer and questions honestly and as fully as they can.

The aim of the Duty is to ensure that patients are told when harm occurs as a result of the care they receive. Where the degree of harm is not yet clear but may fall into the moderate or above categories, then the relevant person must be notified.

- It is not necessary to inform a person where a 'near miss' (see Appendix 2) has occurred, so long as the incident has resulted in no harm to the person
- Arrangements must be in place to notify a person affected by an incident who lacks capacity to make a decision about their care, including ensuring that a person acting lawfully on their behalf is notified, as the relevant person (see Appendix 2)
- Other than in the exceptions outlined above, information should only be disclosed to family members or carers where the service user has given express or implied consent

### **Information to be provided**

The information to be provided should include a step by step account of all relevant facts known about the incident at the time.

The information should be given in person, by one or more appropriate staff members or 'representatives' of Libertatem Healthcare Group.

The information should be as detailed, or as simple, as the relevant person wants, and should be jargon free with any complicated terms explained.

The information must be given in a manner that the relevant person can understand, and if necessary, assisted by interpreters, advocates or other communication aids, having given due consideration to breaches of confidentiality.

The information should also include what further enquiries are to be made (if any).

Libertatem Healthcare Group will also ensure that a meaningful apology (see definitions) is given, in person, by the most appropriate representative of the group

Libertatem Healthcare Group will also ensure that all reasonable support is provided to the relevant person to help them overcome the physical, psychological and emotional impact of the incident, including:

- Treating the person with respect, consideration and empathy
- Offering direct emotional support during the process of notification, perhaps from a family member, friend, care professional or advocate
- Offering help to understand what is being said, perhaps through an interpreter, nonverbal communication aids, Braille etc.
- Providing access to treatment and care to recover from or minimize the harm caused if appropriate
- Providing details of specialist independent sources of practical advice and support, or emotional support / counselling
- Providing information about available impartial advocacy and support services
- Arranging for care and treatment from alternative care worker if possible and if the relevant person wishes
- Providing support to access the complaints procedure

### **Written notification**

Following the notification in person, written notification will also be provided, even though enquiries may not yet be complete. The written notification must contain all the information that was given in person, including an apology, as well as the results of any enquiries that have been made since the face to face meeting.

The outcomes or results of any further enquiries and investigations must also be provided in writing to the relevant person if they wish to receive them.

If the relevant person cannot be contacted in person or declines to speak to representatives of Libertatem Healthcare Group a documented record must be kept of all attempts to make contact.

In this situation, the wishes of the relevant person not to communicate with Libertatem Healthcare Group must be respected and a record kept. Also, if the relevant person has died and there is nobody who can lawfully act on their behalf, a record should be kept.

Libertatem Healthcare Group will maintain a record of the written notification, along with any enquiries and investigations and the outcomes or results of the enquiries or investigations.

All correspondence from the relevant person relating to the incident must be responded to in an appropriate manner and a record of communications should be kept.

### **Method**

Most individuals working in a healthcare setting will find themselves in the difficult position of having to discuss harm or potential harm with a patient at some time in their career. The following guidance provides a framework for staff to work to. It is recognised however that many scenarios do not always follow predetermined processes, and staff must use their own professional judgement in deciding, for example, when is the right time to talk to patients and families/carers. There is no substitute for clinical and professional expertise and compassionate care.

## Stage One

### Incident Identification and Reporting

Firstly any actions that can be taken immediately to reduce the risk of harm to the patient must be implemented.

The initial facts of the incident should be established and an assessment of the level of harm that has happened to the patient as a result of the incident (see table below) should be undertaken.

Incident	Action
No harm (including prevented patient safety incidents)	Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of the Duty of Candour. Openness remains best practice, but there is no requirement to follow the Duty of Candour processes.
Low harm	Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. <ul style="list-style-type: none"><li>• Communication should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers.</li><li>• Standard incident reporting will be undertaken. Openness remains best practice, but there is no requirement to follow the Duty of Candour processes for incidents that result in this level of harm. .</li></ul>
Moderate harm (see definitions)  Severe harm (see definitions) or death	The Duty of Candour policy is implemented. <ul style="list-style-type: none"><li>• It is necessary to inform the clinical director. For Never Events (see Appendix 3) a director must be informed immediately. The Group operates within openness principles with our commissioners and regulators, and we will inform these organisations of the incident and the management plans as soon as possible.</li></ul>

All incidents must be reported. The incident report must be completed as soon as possible after the incident has been discovered, and always within 48 hours of detecting the incident.

## Stage Two

### Being Open

There are a set of principles for being open (Appendix 1) that staff should refer to when communicating with the relevant person following an incident in which a service user was harmed.

### Mental Capacity

Where the patient or service user is assessed as not having the capacity to make a decision in relation to their care or treatment, or where the service user is under 16 and deemed not to have the necessary competency, then the most appropriate relevant person should be notified of the incident.

### Confidentiality

Details of a person's care and treatment should at all times be considered confidential. Where the Duty of Candour would include providing confidential information to family or carers, then

the consent of the individual concerned should be sought prior to disclosing information. This consent or denial of consent to share should be recorded in the clinical notes. Communication with parties outside of the clinical team should be on a strictly need-to-know basis and, where practicable, records should be anonymised.

### **The Relevant Person Cannot be Contacted or Declines to Have Further Information**

After discussion, if the patient says they do not want more information, then the possible consequences must be explained to them. It should be made clear that they can change their mind and have more information at any time.

All Duty of Candour conversations must be recorded in the logs including instances when the patient has declined the offer of further information.

Where a relevant person cannot be contacted, a clear written record must be kept of the attempts made to contact or speak to the relevant person. This should evidence that every reasonable effort was made to contact the person by stating how many attempts were made, who by and when.

All records are kept for 8 years in line with other healthcare records.

### **Stage Three**

The initial 'being open' communications will vary according to the individual needs of the relevant person, the severity grading of the incident, clinical outcome and family circumstances for each specific event. The care worker present, should initiate this initial communication, ensuring that the relevant person receives clear, unambiguous explanation of the event and the next steps to be taken. It is also vital that staff involved in the incident receive appropriate support from the outset. If the care worker is unable to initiate the initial communication this will be undertaken by the care manager as soon as is practically possible.

The following is intended as broad advice as it is recognised that the vast majority of staff have good communication skills.

### **Apology**

Where a patient safety incident has caused harm, an apology must be offered to the relevant person

– a sincere expression of sorrow or regret for any possible harm and distress caused.

### **Clarity of Communication**

The individual communication needs of the relevant person, for example, linguistic or cultural needs, learning disabilities, or sensory impairments must be considered and taken into full account before any discussion takes place. This involves consideration of circumstances that can include a patient requiring additional support, such as an independent patient advisor or a translator.

The relevant person should be fully informed of the issues surrounding the patient safety incident and its consequences in a face to face meeting.

The facts that are known should be explained. When talking to the relevant person about the incident staff must use clear, straightforward language and be honest with responses to any questions that are raised. The relevant person should be informed that an incident analysis will be carried out and more information will become available as this progresses.

It should be made clear to the relevant person that new facts may emerge as the incident analysis proceeds.

The relevant person's understanding of what happened should be established from the outset, as well as any questions they may have.

There should be consideration and formal noting of the relevant person's views and concerns, and demonstration that these have been heard and taken seriously.

An explanation should be given about what will happen next in terms of the long term treatment plan for the patient as well as the incident analysis findings.

Information on likely short and long-term effects of the incident (if known) should be shared.

An offer of practical and emotional support should be made to the relevant person.

Patients, family and/or carers might be anxious, angry and frustrated, even when the discussion is conducted appropriately. It is essential that staff are not drawn into speculation, attribution of blame, denial of responsibility or the provision of conflicting information.

## **Stage Four**

### **The Investigation**

Notifiable incidents may be classed as 'serious incidents' or 'significant events.' In either case an investigation of exactly what happened will be held by the Line Manager.

If the Line Manager is involved in the incident the investigation will be carried out by the next most senior and appropriate person.

The investigation will include a meeting with the employee(s) involved to establish the facts.

This will be followed by a letter to the patient/relatives with an offer of a meeting. This letter should be written by the most appropriate person (usually the Director of Care). This may be before the conclusion of the investigation.

Where appropriate this letter will advise the patient of an independent advocacy service available to support them.

## **Stage Five**

### **Communication with the Relevant Person – the Notification Meeting**

A meeting with the relevant person should be arranged as soon as possible after the incident has happened to notify them of the incident. This meeting should always take place within 10 working days of the incident being discovered.

It may be appropriate for more than one member of staff to meet with the relevant person for support or for additional information.

At the meeting the nominated member of staff should follow the procedure below:-

- If known, explain what went wrong and where possible, why it went wrong;
- Inform the service user and/or relative(s) and others what steps are being/will be taken to prevent the incident recurring;
- Offer an apology;

- Provide opportunity for the service user and/or relatives and others to ask any questions;
- Agree with the service user and/or relatives and others any future meetings as appropriate;
- Suggest any sources of additional support and counselling and provide written information if appropriate.
- Inform the relevant person that they will receive a written summary of the incident and that they will, if they wish, be informed of progress with the investigation. The relevant person will also receive a copy of the final investigation report.

Wherever possible a named contact should be provided who the relevant person can speak to regarding the incident. This can be a Member of the Board of Directors or another member of staff who has the skills and knowledge to undertake this role. It is vitally important that whoever is named as the contact is made aware of this, agrees to the role and is furnished with all of the information they may need to ensure clear and honest communication takes place.

The communication and outcome of the notification must be clearly recorded in the service user's electronic record by the person who has informed the patient/family.

A letter should then be written to the relevant person setting out what was explained at the notification meeting. The letter should be drafted immediately after the notification meeting and forwarded to the Clinical Director for approval prior to sending out. The letter must contain all the information that was provided at the initial notification meeting.

The regulations state that the notification given must be followed by a written notification given or sent to the relevant person containing—

- (a) the information provided,
- (b) details of any enquiries to be undertaken,
- (c) the results of any further enquiries into the incident, and
- (d) an apology.

Any Duty of Candour letters arising out of the notification meeting must be signed off by the Clinical Director and a copy kept in the electronic records.

If, for whatever reason, the patient cannot be contacted in person or declines to speak to anyone from the Group in relation to the incident, then the above processes do not apply but a written record must be kept of the attempts made to contact or to speak to the relevant person.

## **Stage Six**

### **Investigation, Closure and Learning**

A full report will be presented to Board of Directors. This will include details of how the Duty of Candour has been implemented.

Once the incident is signed off for closure by the Board of Directors, a letter should be sent to the relevant person together with the anonymised investigation report and action plan. The supporting letter should provide information in the event that the individual wishes to pursue legal action against Libertatem Healthcare Group. This letter will be signed off by the Clinical Director or their nominated deputy.

If the report is not available within the usual time frame for closure, a letter should be sent to the relevant person to provide an explanation as to when they can expect to be provided with additional details. This letter should clarify the information previously provided, reiterate key points, and record action points and future deadlines. This letter should also provide information

in the event that the individual wishes to pursue legal action against Libertatem Healthcare Group.

All learning from the incidents must be cascaded via the quarterly Board meetings to the staff meetings. This information will be recorded in the Clinical Directors Quality Report.

The outcome of reports must also be shared with any other healthcare organisation or relevant stakeholder as appropriate to optimise learning from the incident.

### Staff Training

All staff will be provided with training in relation to this policy.

### Audit

The policy will be audited at least every three years by tracking the method and timeliness of every incident that required the implementation of the duty of Candour.

### Brief Summary of the Stages in the Duty of Candour Process

Requirement under Duty of Candour	Responsible Person	Timeframe
For incidents where moderate harm, serious harm or death has occurred, the relevant person must be informed.	Senior carer or nurse for episode of care during which the incident occurred. The Clinical Director should be made aware and if appropriate, involved.	As soon as possible after the incident has been detected and reported but always within 10 working days of the incident
Initial notification of incident must be verbal (face-to-face, where possible) unless the relevant person declines notification or cannot be contacted in person. Sincere expression of regret or sorrow must be provided verbally. This must be recorded in the notes.	Senior Carer or nurse for episode of care during which the incident occurred. The Clinical Director should be made aware and if appropriate, involved.	As above
Step-by-step explanation of the known facts must be offered to the relevant person.	As above	As above
Written notification to the relevant person. The written notification should outline the facts discussed at the notification meeting and include a sincere expression of regret or sorrow.	As above. All letters must be approved by the Clinical Director or their nominated deputy.	As above
Maintain full written documentation of any meetings. If meetings are offered but declined this must be recorded	As above. All follow-up letters to patients/ relatives to be approved for release by the Clinical Director or their nominated deputy.	
Share incident investigation report	Investigating Officer or other nominated person.	As soon as reasonably practicable but always

(including action plans) with an accompanying letter	Letter to be approved and signed off by the Clinical Director or their nominated deputy.	within 25 working days of report being signed off as complete and incident closed by the Board of Directors.
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## **Appendix 1**

**The 10 Principles of Being Open** - Being open involves apologising when something has gone wrong, being open about what has happened, how and why it may have happened, and keeping the patient and their family informed as part of any subsequent review.

### **1. Principle of Acknowledgement**

All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare employees that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all employees. Denial of a person's concerns or defensiveness will make future open and honest communication more difficult.

### **2. Principles of Truthfulness, Timeliness and Clarity of Communication**

Information about a patient safety incident must be given in a truthful and open manner by an appropriately nominated person. Communication should be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. It will be explained that new information may emerge as the event investigation takes place. Patients, their families and carers and appointed advocates should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

### **3. Principle of an Apology**

Patients, their families and carers should receive a meaningful apology - one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety event or that the experience was poor. Both verbal and written apologies should be offered. Saying sorry is not an admission of liability and it is the right thing to do. Verbal apologies are essential because they allow face to face contact, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, should also be given.

### **4. Principle of Recognising Patient and Carer Expectations**

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face to face meeting with representatives from the organisation and/or in accordance with the local resolution process where a complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

### **5. Principle of Professional Support**

Libertatem Healthcare Group has set out to create an environment in which all employees are encouraged to report patient safety events. Employees should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the event. Where there is reason to believe an employee has committed a punitive or criminal act, the Board of Directors will take steps to preserve its position and advise the employee at an early stage to enable them to obtain separate legal advice and/or representation. Employees should be encouraged to seek support from relevant professional bodies. Where appropriate, a referral will also be made to the Independent Safeguarding Authority.

### **6. Principle of Risk Management and Systems Improvement**

Within Libertatem Healthcare Group the numbers of patient safety incidents are small and are all discussed at quarterly Board meetings. Investigations at any identified level will however focus on improving systems of care, which will be reviewed for their effectiveness. Being open is integrated into patient safety incident reporting and risk management policies and processes.

### **7. Principles of Multi-Disciplinary Responsibility**

Being open applies to all employees who have key roles in patient care. This ensures that the being open process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from actions of an individual. To ensure multidisciplinary involvement in the being open process, it is important to identify clinical and managerial leaders who will support this across the health and care agencies that may be involved.

## 8. Principles of Clinical Governance

Being open involves the support of patient safety and quality improvement through Libertatem Healthcare Groups clinical governance framework, in which patient safety incidents are investigated and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability to ensure that these changes are implemented and their effectiveness reviewed. Findings are disseminated to employees so they can learn from patient safety incidents. Audits are an integral process, to monitor the implementation and effects of changes in practice following a patient safety incident.

## 9. Principle of Confidentiality

Details of a patient safety incidents should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information. Libertatem Healthcare Group will anonymise any incident it publishes but still seek the agreement of those involved. Where it is not practicable or an individual refuses consent to disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of those involved in the investigation will be on a strictly need to know basis. Where possible, it is good practice to inform the patient, their family and carers about who will be involved in the investigations before it takes place, and give them the opportunity to raise any objections.

## 10. Principle of Continuity of Care

Patients will continue to receive all usual treatment and continue to be treated with respect and compassion.

## **Appendix 2**

### **Definitions**

1. **A notifiable safety incident:** is an 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

a. appears to have resulted in—

- I. 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,
- II. an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
- III. changes to the structure of the service user's body,
- IV. the service user experiencing prolonged pain or prolonged psychological harm, or

- V. the shortening of the life expectancy of the service user; or
- b. requires treatment by a health care professional in order to prevent—
- I. the death of the service user, or
  - II. any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned above.

**2. the relevant person:** means the service user or, in the following circumstances, a person lawfully acting on their behalf—

- a. on the death of the service user,
- b. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- c. where the service user is 16 or over but lacks capacity in relation to the matter

**3. moderate harm means:**

- a. harm that requires a moderate increase in treatment, and
- b. significant, but not permanent, harm

**4. moderate increase in treatment means:**

- a. an unplanned return to surgery
- b. an unplanned readmission
- c. a prolonged episode of care
- d. extra time in hospital or as an outpatient
- e. cancelling of treatment
- f. transfer to another treatment area (such as intensive care)

**5. prolonged pain** means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days

**6. prolonged psychological harm** means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days

**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 to the incident and not related to the natural course of the service user's illness or underlying condition

**8. an apology** means an expression of sorrow or regret in respect of a notifiable safety incident

**9. a 'never event'** is an incident classified by NHS England as so serious and so preventable that it should 'never' happen (see Appendix 3).

**10. a 'near miss'** is defined as a prevented patient safety incident (National Patient Safety Agency)

### **Appendix 3**

#### **Never Events**

The following is the list of 'never events' as defined by NHS England 2015/ 2016 list relevant to home care:

- wrong route of administration of medication
- Overdose of Insulin due to abbreviations or incorrect device
- Chest or neck entrapment in bedrails
- Misplaced naso- or oro-gastric tubes
- Scalding of patients

