Being Open Policy
- The Duty of Candour

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Part of:

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Background

Ozone Health Ltd is the overarching board and governance for Ozone Health Ltd (OHL) Clinical Partnership (CP) & The World Healthnet Ltd (WHN). As an organisation we are committed to the provision of high-quality care in a culture of openness and transparency for all people that access our clinical services.

Compliance with Statutory Requirements

- The Health and Social Care Act 2008, Regulation 20: Duty of candour
- The Health and Social Care Act 2008, Regulation 5: Fit and proper persons: directors
- Statutory Duty of candour 2014
- Public Interest Disclosure Act 1998

Summary

Duty of Candour can make an important contribution to creating a culture of openness and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

What is needed is a culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn, and we will improve.

The commitment to candour has to be about values and it has to be routed in genuine engagement of staff building on their own professional duties and their personnel commitments to their patients.

We have set out a commitment to transparency and being open and this document describes how the company will implement and monitor adherence to this commitment.

Introduction

We are committed to the provision of high-quality care in a culture of openness and transparency for all people that access our clinical services.

We do acknowledge that care and treatment is not harm free and mistakes do happen. If an error does occur, patients and their families will be offered an apology, truthful information and support. Learning from incidents will contribute to a culture of safety and improvement to prevent a similar incident happening to someone else.

Clinicians already have an ethical duty of candour as part of their professional registration to tell patients about errors and mistakes. This policy builds on individual professional duty and places an obligation on the organisation, to be open with patients when harm has been caused.

The impact and consequences of mistakes or errors can affect everyone involved and can be devastating for individual staff or teams; this policy aims to ensure there is sustained support for staff in reporting incidents and in being open.

This approach underpins a commitment to provide high quality care and truthful sharing of information when an incident of patient harm occurs both at an

organisational as well as an individual level and that any learning will be embedded into daily practice. The organisational values and clinical leadership aim to ensure a culture of candour by every member of staff and a continued commitment to patient safety.

Purpose of this Policy

Staff work hard to provide services which are safe and of a high quality. However, sometimesthings go wrong.

This policy has been developed to ensure that staff are aware of the processes and steps to follow in supporting patients and carers following an incident meeting the requirements for provision of Duty of Candour. It sets out specific requirements to follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.

Health professionals have a duty to be open and honest with patients when things go wrong as set out in the joint GMC / NMC document *Openness and honesty when things gowrong: the professional duty of candour*

The policy provides guidance to staff on how to undertake the Duty of Candour and support mechanisms available where staff are unsure how to proceed.

Illustrative examples of incidents that trigger the thresholds for duty of candour areprovided in Appendix A

Scope of this Policy

The Company's *Incident Reporting and Management Procedure* encourages staff to report all patient and service user safety incidents, including those where there was no harm or it was a'near miss' event.

This *'Being Open – The Duty of Candour'* policy only relates to those incidents where actual harm has occurred and the consequences are graded as Moderate, Major or Catastrophic. Implementation of this policy will be an integral part of the management and investigation of these incidents.

However, there is flexibility to discuss incidents resulting in a lower level of harm (including no harm) with patients on an individual basis depending on local circumstance and the best interest of the patient. Where this does occur details of all communication must be documented.

Other disciplinary processes are outside the scope of the *Being Open* policy. Immediate disciplinary action can create a barrier to open reporting. The root causes of an incident should be the focus of the investigation, rather than the last individual to provide care.

Definitions

NB: Definitions of openness, transparency and candour are those set out by Robert Francis inhis report. All other definitions are those set out within the CQC Regulation 20: Duty of Candour·

Openness – enabling concerns and complaints to be raised freely without fear and questionsasked to be answered.

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

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

Clinical Lead – The senior clinical professional responsible for undertaking the Duty of Candour communication.

Apology
An 'apology' is an expression of sorrow or regret in respect of a notifiable safety incident;It is not an admission of guilt.

Appropriate written records
Records are complete, legible, accurate and up to date. Every effort must be made to ensure records are updated without any delays.

Cancelling treatment
Where planned treatment is not carried out as a direct result of the notifiable safety incident.

Moderate harm
'Moderate harm' means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a "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 anoutpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

Prolonged pain
'Prolonged pain' means pain which a service user has experienced, or is likely to experience, for acontinuous period of at least 28 days;

Prolonged psychological harm
'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.

Relevant person
This is the person who is receiving services or someone acting lawfully on their behalf in the following circumstances: on their death, or where they are under 16 and not competent to make adecision in relation to their care or treatment, or are 16 or over and lack the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.

Severe harm
'Severe harm' means a permanent lessening of bodily, sensory, motor, physiologic or intellectualfunctions, including removal of the wrong limb or organ or brain damage, that is related directly tothe incident and not related to the natural course of the service user's illness or underlying condition.

Written Notification
A written notification is one given or sent to the relevant person in written form containing the information provided in any initial notification made in person, details of any enquiries to be undertaken, advise of any appropriate enquiries to be undertaken by the registered person, the results of any further enquiries into the incident, and an apology (as defined above).

Responsibilities

All staff
- Responsible for reporting patient safety incidents via the incident reporting procedure
- Documenting any conversation with the patient or other relevant person relating to the reported incident in the patient's health record.

Clinical Lead
- Responsible for providing an apology to the patient or other relevant person following areported notifiable incident according to the principles of the Duty of Candour.
- Documenting any conversation with the patient or other relevant person relating to the reportedincident in the patient's health record.
- Providing a written notification to the patient or other relevant person.

Governance Team
- Ensuring the Clinical lead is aware of the notifiable incident and their responsibility to providean apology and written notification.
- Monitoring completion of the Duty of Candour process using the relevant section of the incident reporting procedure.
- Escalation to the Clinical lead of any instance where the Duty of Candour process has not been adhered to.

Documentation

Throughout the Duty of Candour process it is important to record discussions with the patient or other relevant person in the health record.

Process for undertaking Duty of Candour

Meeting CQC Regulation 20

To meet the requirements of CQC Regulation 20, we will:

- Be open and transparent with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity.
- Tell the relevant person (in person) as soon as reasonably practicable after becoming aware that a safety incident has occurred and provide support to themin relation to the incident, including when giving the notification. (see appendix B)
- Provide an account of the incident, which, to the best of the company/services knowledge,is true of all the facts the service/company knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the company believes are appropriate.
- Offer an apology.
- Follow up by providing the same information in writing, and any update on the investigations.
- Keep a written record of all communication with the relevant person.

Recognising an incident

The relevance of the Duty of Candour begins with an acknowledgement that as the result of a safety incident, a patient has suffered moderate or major harm, or has died.

It is recommended the following are considered prior to notifying the relevant person:

- What member of the service team is already in contact with the relevant person
- What (if any) discussions have taken place?
- What is the relevant persons current understanding of the incident to date?
- Where will the conversation have taken place?
- Who will be present for the conversation
- What support is available to the relevant person pre, during and post conversation?

- Who is the company point of contact post discussion?

As soon as an incident has occurred or been identified, the company will ensure that the notification includes:

- An accurate account of the incident
- An explanation of the actions to be taken by the company as part of the procedure

Summary of CQC

CQC Inspections will report on "Duty of Candour" under the Key Question of Safety –

- Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
- Does the culture encourage candour, openness and honesty?

If the care provided does not reflect the required characteristics of "Good" (as defined in the CQC Provider Handbook), then inspections are recommended to assess whether the service "Requires Improvement" or "Inadequate", and whether there has been a breach of the regulation.

As this is an issue that affects patient safety, any information received from a member of the public or staff relating to Duty of Candour will be investigated in line with the CQC's Safeguarding and Whistleblowing protocols where relevant.

Arranging a meeting

When a notifiable safety incident has occurred, the relevant person must be informed as soon as reasonably practicable after the incident has been identified, up to a maximum of 10 working days (as per the NHS Standard Contract).

All staff must have responsibility to adhere to that organisations policies and procedures around duty of candour, regardless of their level of seniority or whether they are permanent, temporary/casual members of staff.

The 'Being Open Framework' provides guidance on how to ensure good communication with the patient, their families and carers.

Regulation 20 defines what constitutes a notifiable safety incident. It includes incidents that could result in, or appear to have resulted in, the death of the person using the service or severe harm, moderate harm, or prolonged psychological harm.

Where the degree of harm is not yet clear, the relevant person must be informed of the notifiable safety incident in line with the requirements of the regulation.

The company is not required by the regulation to inform a person using the service when a 'near miss' has occurred, and the incident has resulted in no harm to that person.

There must be appropriate arrangements place to notify the person using the service who is affected by an incident if they are;

- 16 years and over and

- lack capacity to make a decision regarding their care or treatment (as determined in accordance with sections 2 and 3 of the 2005 Mental Capacity Act)

This includes ensuring that a person acting lawfully on their behalf (e.g. persons acting as Carer) is notified as the relevant person.

A person acting lawfully on behalf of the person (e.g. persons acting as Carer) using the service must be notified as the relevant person where the person using the service is under 16 and not competent to make a decision regarding their care or treatment.

A person acting lawfully on behalf of the person (e.g. persons acting as Carer) using the service must be notified as the relevant person, upon the death of the person using the service.

Other than the situations outlined above, information should only be disclosed to family members or carers where the person using the service has given their express or implied consent.

A step-by-step account of all relevant facts known about the incident at the time must be given, in person, by one or more appropriate representatives of the company. This should include as much or as little information as the relevant person wants to know, be jargon free and explain any complicated terms.

The account of the facts must be given in a manner that the relevant person can understand. For example, the company should consider whether interpreters, advocates, communication aids etc. should be used, while being conscious of any potential breaches of confidentiality in doing so.

The company must also explain to the relevant person what further enquiries they will make.

The company must ensure that a meaningful apology is given, in person, by one or more appropriate representatives of the company to relevant persons. An apology is defined in the regulation as an expression of sorrow or regret. The NHS Litigation Authority has produced guidance on making an apology: https://resolution.nhs.uk/resources/saying-sorry/ which states that saying sorry is

not an admission of legal liability.

In making a decision about who is most appropriate to provide the notification and/or apology, the company should consider seniority, relationship to the person using the service, and experience and expertise in the type of notifiable incident that has occurred – therefore the board and or the business co-ordination manager in their absence shouldbe the nominated individuals. The Being Open Framework referenced below provides guidance on this.

The company must give the relevant person all reasonable support necessary to help overcome the physical, psychological and emotional impact of the incident.

This could include all or some of the following:

- Treating them with respect, consideration and empathy
- Offering the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate
- Offering access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille etc.
- Providing access to any necessary treatment and care to recover from or minimise the harm caused where appropriate
- Providing the relevant person with details of specialist independent sources of practical advice and support or emotional support/counselling
- Providing the relevant person with information about available impartial advocacy and support services, and other relevant support groups, to help them deal with the outcome of the incident
- Arranging for care and treatment to be delivered by another professional, team or provider if this is possible, should the relevant person wish
- Providing support to access its complaints procedure
- The Being Open Framework referenced below provides guidance on how to support patients, their families and carers when a patient safety incident has occurred

The company must ensure that written notification is given to the relevant person following the notification that was given in person, even though enquiries may not yet be complete.

The written notification must contain all the information that was provided in person including an apology, as well as the results of any enquiries that have been made since the notification in person.

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

The company must make every reasonable attempt to contact the relevant person through all available communication means. All attempts to contact the relevant person must be documented.
If the relevant person does not wish to communicate with the company/service, their wishes must be respected and a record of this must be kept.

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

Review process

Whilst the regulation does not specify the review process it is considered best practice if the review involves clinical professional with the relevant subject matter expertise and other individuals as deemed appropriate.

The written report of the review is to include the following:

- A description of the manner in which the review was carried out
- A statement of any actions to be taken by the organisation for the purpose of improving the quality of service it provides and sharing learning with other persons or organisations in order to support continuous improvement in the quality of health, care or social work services
- A list of actions taken for the purpose of the procedure in respect of the incident and the date each action took place

By including this information in the report, the Company/Group able to demonstrate that they have taken into consideration the views of the relevant person and, a review has been undertaken.

It is recommended that written reports are written in such a manner so that the need for redaction is minimalised.

The following will be to be sent the relevant person:

- A copy of the written report
- Details of supporting information about actions taken for quality improvement purposes
- Details of support services available to the relevant person

Record keeping

All correspondence should be held in accordance with Records Management Policy.

With specific relation to the Being Open/Duty of Candour the clinical records must:

- Record the sharing of any facts that are known and agreed with the relevant person;
- Record how it has been agreed that the relevant person will be kept informed of the progress and results of that investigation;
- Record, where appropriate, a full apology to the patient and their family/carers;
- Record any explanation given of the likely short and long-term effects of the incident;
- Contain copies of any letters sent to the relevant person;
- Record an offer of appropriate practical and emotional support.

Monitoring and review

The policy will be reviewed as a minimum every three years or sooner if legislation requires.

Appendix A Examples of incidents that trigger the thresholds for duty of candour

Taken from: Regulation 20: Duty of candour Information for all providers: NHS bodies, adult socialcare, primary medical and dental care, and independent healthcare (March 2015)

These examples have been developed with stakeholders to illustrate examples of notifiable safety incidents that triggerthe threshold for the duty of candour regulation. The examples presented are illustrative only and not an exhaustive list. Where possible the examples used in this guidance are sourced or adapted from the following two documents: 'Seven steps to patient safety for primary care' (National Patient Safety Agency 2006) and 'Duty of Candour Threshold ReviewGroup Review of Definitions' (Royal College of Surgeons 2014).

Examples	**Interpretation**
A patient arrived for planned surgery but had not been given the correctadvice to discontinue their Warfarin treatment. The surgery had to be postponed.	This would be an example where an incident appeared to have resulted in moderate harm
During a difficult appendectomy the patient's bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed and the patient made a full recovery.	This would be an example where an incident appeared to have resulted in moderate harm

Wrong site surgery: The identities of two patients on the list are mixed upand one patient undergoes the wrong operation on the incorrect site. Thepatient is permanently harmed as a result.	This would be an example where an incident appeared to have resulted in severe harm
An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result.	This would be an example where an incident resulted in death
A patient experienced pain during an elective Caesarean section due toincomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severeanxiety and depression which lasted more than 28 days	This would be an example where an incident appeared to have resulted in prolonged psychological harm

Appendix B - Actions and Timescales for Duty of Candour requirements

Requirement under Duty of Candour	Timeframe
Patient or their family/carer informed that incidenthas occurred (moderate harm, severe harm or death)	Maximum 10 working days from incident beingreported
A verbal notification of incident (preferably face-to-face where possible) unless patient or their family/carer decline notification or cannot be contacted in person. A sincere expression of apology must be providedverbally as part of this notification.	Maximum 10 working days from incident beingreported
Offer of written notification made. This must include a written sincere apology.	Maximum 10 working days from incident beingreported A record of this offer and apology must be made (regardless if it has been accepted or not)
Step-by-step explanation of the facts (in plainEnglish) must be offered.	As soon as practicable This can be an initial view, pending investigation, and stated as such to the receiverof the explanation.
Maintain full written documentation of anymeetings.	No timeframe If meetings are offered but declined this mustbe recorded.
Any new information that has arisen (whetherduring or after investigation) must be offered.	As soon as practicable
Share any incident investigation report (including action plans) in the approved format (Plain English)	Within 10 working days of report being signedoff as complete and closed
Copies of any information shared with the patientto the commissioner, upon request.	As necessary

Appendix C - Letter Template for Initial Notification Communication Letter in Accordance with Requirements of Duty of Candour.

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

Dear Mrs/Mrs xxxxxxxxxxx

I am writing to express my sincere regret that (you/your relative XXXXX) has been involved in an incident whereby ……(describe event here). As an organisation we are committed to being open with patients and carers when events such as these occur so that we gain a shared understanding of what happened, and what we can do to prevent such an incident occurring again in the future.

An investigation is already underway to try and establish the cause of the incident. If you would like to meet with a member of staff to discuss this, please let me know within the next two weeks, and we will arrange a mutually convenient time and place to meet.

There is an independent advocacy service available to support and assist you in this who can be contacted on XXXXXXX.

Staff member XXXXX is acting as your lead contact for the duration of the investigation. They can be contacted by email on xxxxxxxxxxxxxxx or on telephone number xxxxx xxxxxxx

Yours sincerely

Signed……..

Date……