**Meeting:**
Trust Board Public Meeting

**Date:**
6 May 2015

**Title of Paper:**
Duty of Candour Compliance Report & Procedure

**Key Issues:**

**A culture of openness, honesty and transparency**

Occasionally people in our care are involved in a safety incident. A small number of these incidents cause harm.

When things go wrong, we have a duty to inform our patients and their families what has happened. This is very much part of our culture.

We are committed to talking to patients and their carers at a very early stage to understand what happened and, where necessary, learn the lessons that will prevent it happening again to improve the safety of our future patients.

**Involving and informing you**

If something happens, we will investigate the incident and:

- ask how much the patient and their relatives or carers wish to be involved in the investigation process;
- review the patient’s medical and nursing notes;
- talk to the staff involved in the patient’s care;
- identify the cause(s) of the incident;
- share our findings with the patient, their family or carers;
- share learning and improvements across the Trust;
- let the patient and their family or carers ask any questions.

A member of the investigation team will meet with the patient to talk to them about what went wrong. This will usually be the consultant or nurse looking after them. The patient’s family or a friend can attend this meeting and be part of these conversations.

The level of investigation we do will depend on the seriousness of the incident and may take up to 45 working days (nine weeks). We will keep the patient and their family informed of our progress along the way.

We work in this way because it is the right thing to do for our patients, this way of working also ensures that the Trust is compliant with the new Duty of Candour legislation.

The new duty is described in more detail in the attached report and appendices.

The new Director of Nursing, Hilary Gledhill will lead this key work on behalf of the Trust Board ensuring that we not only meet but excel in being open and honest with our patients, families...
and the public. This work will include staff training and ensuring all of our policies and procedures meet the duty and promote a culture of openness, honesty and transparency. It should be noted that the Trust has been reporting on duty of candour compliance for the previous 12 months, however this paper lays out in simple terms the new duty, our procedure for how we will comply going forward, and the revised Serious Incident Reporting Procedure which supports it.

In addition to the work undertaken internally, a link has being posted on the Trust website, Twitter and Facebook and NHS Choices to provide the public with a single point of contact to raise concerns about duty of candour (the author) within the Trust.

As part of our continuing compliance a duty of candour declaration will be included monthly in Director of Nursing report, and a detailed report on compliance will also be provided as part of the serious incident report.

Links to Strategic Objectives:

- Provide services that are safe, person centred, delivered in appropriate environments and sensitive to the needs of the individual
- Retain the confidence of patients, carers and commissioners by upholding the principles of the NHS
- Use our positive reputation to develop new services and expand existing ones

Risk Issues:

- That the Trust will fail to comply with the duty of candour and face action from the Care Quality Commission (CQC), this is mitigated by the work that has been undertaken internally and externally to:
  - To develop a duty of candour procedure
  - Review and revise the Serious Incident Reporting process and procedure
  - Internal and external communications to raise awareness of the duty
- The commitment of the Trust Board and Senior Managers to uphold this key duty on behalf of people who use our services

Recommendations:

The Board is asked to approve the Duty of Candour procedure and accept this report

Author of Report:

Jules Williams, Care Quality & Compliance Director
Duty of Candour Compliance Report

The new CQC Regulations introducing a Duty of Candour in addition to the existing statutory duties of notification of deaths and serious incidents came into force in Foundation Trusts on 27/11/2014. The new regulations make it a statutory requirement for health service bodies to be open and transparent with service users and carers regarding care and treatment provided whilst carrying out a regulated activity. Humber NHS FT already has well developed incident and serious incident reporting and investigation processes in place, incidents have always been rated using a recognised national patient safety risk matrix. Our incident reporting procedures have been reviewed and a new procedure developed to specifically address the new Duty of Candour which is attached at appendix 1.

This procedure has been developed and approved by senior clinicians, corporate leads and Directors. This new Duty will be inspected by the CQC and failure to comply/ breach will lead directly to enforcement action bypassing the warning notifications.

The new regulated duty:

The duty of candour is triggered when there has been a notifiable safety incident involving a death, serious or moderate harm that has occurred. As per the NHS England definition below.

- “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinions of a health care professional, could result in, or appears to have resulted in:
  - the death of the service user, where the death relates to the incident rather than to the natural course of the service user’s illness or underlying condition, or
  - severe harm, moderate harm or prolonged psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

CQC Regulation 20(3) says - The notification to be given to service users) must

- be given in person by one or more representatives of the health service body,
- provide an account, which to the best of the health service body’s knowledge is true, of all the facts the health service provider knows about the incident as at the date of the notification,
- advise the relevant person what further enquiries into the incident are appropriate,
- include an apology, and
- be recorded in a written record which is kept securely by the health service body

There are two specific key lines of enquiry (KLOEs) which CQC inspectors will ask to assess duty of candour. These are: Are lessons learned and improvements made when things go wrong, and How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?

Our Procedure outlines five steps which must be taken

- Recognise an incident has taken place AND follow our serious incident reporting procedure report it via our usual Datix incident reporting system
- If a notifiable safety incident is triggered there are five stages to follow:
  - Incident Detection or Recognition.
Preliminary Team discussion and report to service manager
Initial Duty of Candour discussion
Follow up discussion
Process completion

CQC Enforcement Powers are outlined in two regulations. The first and fourth stages include an apology for what has happened.
- **Reg. 22(3) A breach of regulations 20(2)(a) and 20(3) is an offence.**
- **A person guilty of an offence is liable, on summary conviction, to a fine.**

But:
- **Reg. 22(4) it is a defence for the registered person or health service body to prove that they took all reasonable steps and exercised all due diligence to prevent the breach of regulations**

**Implementing the New duty of Candour**
- CQC guidance requires a Board level commitment to being open and transparent.
- In addition to the new Procedure, the Board of Directors must consider how it supports and endorses openness and transparency and conveys this commitment.
- When incidents are reported demonstrate they are taken seriously and how this is demonstrated to staff and patients. All serious untoward incidents are reported already through the serious incident report to the Integrated Audit & Governance Committee, as a sub committee of the Board. It is recommended this section is strengthened to include demonstrating how the Duty of Candour regulations are being met. Reporting on our Duty of Candour will also be reported in our Quality Account, Quarterly and Annually.
- Ensure staff accountability for Duty of Candour is recognised internally though internal communications and training as well as encouraging open reporting of all patient safety incidents. Information on how to raise a concern and performance will be available on the web site.
- The Complaints process is linked to the incident reporting process through the Weekly organisational risk management meeting. Our Complaints Policy has been updated to take account of the new Regulation.
- The claims management process has been reviewed and takes account of Duty of Candour.
- HR incidents such as Whistleblowing and disciplinary investigations must also take account of the new Duty and ensure incidents are reported routinely and the new standards apply.

**Recommendation**
The Board is asked to approve the new procedure which sets out how compliance with the CQC Regulation on Duty of Candour.
Appendix 1

Duty of Candour requirements and Duty of Candour Procedure

Regulation 20: Duty of Candour

The Health & Social Care Act 2008 (Regulated Activities) Regulations 2014 has made important changes to health and social care standards which are regulated by the Care Quality Commission. One core change is to introduce a statutory duty on all NHS provider bodies registered with the CQC. The Duty of Candour requires all NHS trusts to give patients accurate, truthful and prompt information when mistakes are made.

Whilst the Duty of Candour enforces the principles of being open we must recognise that the duty is a stand-alone duty and the Regulations specify the steps that we must take in order to comply with the law.

The intention of this regulation is to ensure that providers are open and honest with people who use our services and other ‘relevant persons’ (people acting lawfully on the behalf of service users) when things go wrong with care and treatment, and that they provide them with reasonable support, truthful information and a written apology as per NHS England and CQC guidance.

In addition to the duty being the right thing to do, failure to comply will incur financial penalties for the Trust.

This procedure should be read in conjunction with the pathway for the Management of Serious Incidents Requiring Investigation which is attached at appendix 1a

Steps required

The procedure consists of five stages which for the purposes of recording, retrieval and audit will be managed within the existing Datix Incident Management System.

Stage One - Incident Detection or Recognition

Immediate action will be taken to prevent further harm and ensure safety of patients and staff. Where additional treatment is required this should occur whenever reasonably practicable after a discussion with the patient/service user and with appropriate consent.

If at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act, the Medical Director/Director of Nursing should be notified immediately and referral made to the Serious Incident Pathway (see attached appendix 1)

Within 10 days, Relevant Persons (i.e. the Service User, family or carer for example) should be informed that the incident has occurred or is suspected to have occurred.

The incident should be reported in the normal way using the online Datix incident reporting system. Duty of candour will be triggered for all incidents rated moderate and above. When an incident is reported via datix the system will direct the reporter to complete a new drop down box. When the manager reviews the incident, and gives it an impact rating the duty of candour section will be mandatory to complete. The five stages can be recorded in the manager’s form and email reminders can be scheduled by the system administrators to ensure that the process has been completed as the regulation requires. The system will be maintained and supported by the Datix Team within Humber NHS Foundation Trust.

Care Group Directors will maintain responsibility for ensuring that Duty of Candour is followed.
Stage Two - Preliminary Team discussion

This stage includes an initial assessment, establishment of timeline and identification of the primary communication lead.

The multidisciplinary team, including the most senior health professional involved in the patient/service user safety incident, should meet within 72 hours of the event to agree any investigation and actions required, including for Duty of Candour:

- Establish the basic clinical facts and trigger an entry on datix.
- Assess for the level of immediate response required.
- Identify the lead responsible for consistent discussion with the patient/service user and/or their carer. The lead must have a good grasp of the facts relevant to the incident and be senior enough or have sufficient training, experience and expertise to be credible to patients/service user, carers and colleagues; be willing and able to offer an apology, reassurance and feedback to patients/service user and/or their carer; be able to maintain a medium to long term relationship with the patient/service user and/or their carer, where possible, and to provide continued support and information; be culturally and/or socially aware and informed about the specific needs of the patient/service user and/or their carer.

Junior or trainee healthcare professionals should not be expected to communicate patient/service user safety information alone or to be delegated the responsibility to lead a Duty of Candour discussion except when all of the following criteria have been considered:

- The incident resulted in low harm.
- That the junior staff have expressed a wish to be involved in the discussion.
- The senior healthcare professional responsible for the care is present for support.
- The patient/service user and/or their carers agree.
- Support needs for the service user/carer(s) and staff.

Stage Three - Initial Duty of Candour discussion

The initial Duty of Candour discussion with the patient/service user and/or their carers should occur as soon as possible after recognition of the patient/service safety incident. It should wherever possible be face to face. The notification must where possible:

- Be verbal, and conducted in person by one or more representatives of the Trust, including where possible the clinician responsible for the episode of care.
- Provide all facts known about the incident.
- Include an appropriate apology.
- Be accompanied by the offer of a written notification including an apology
- Provide the named contact details.

Where the relevant person cannot be contacted in person, or declines to speak to the representative of the service provider, a record should be kept of all attempts to contact or speak to the relevant person. The manager’s form in the Datix incident report will enable capture of this information.

The initial conversation should be recorded in writing, uploaded to the incident form and shared with the service user/relevant other. The senior member of staff leading the Duty of Candour discussion is responsible for maintaining complete records, a copy of which should be recorded on Datix.

The written records of the Duty of Candour discussion should include:

- The time, place, date, as well as the name and relationships of all attendees.
• The plan for providing further information to the patient/service user and/or their carer.
• Offers of assistance and the patient's/service user's and/or carer's response.
• Questions raised by the family and/or carers or their representatives and the answers given.
• Plans for follow-up as discussed.
• Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient/service user and/or their carer.
• Copies of letters sent to patients/service users, carers and the GP for patient/service user safety incidents not occurring within primary care.
• Copies of any statements taken in relation to the patient/service user safety incident.
• A copy of the incident report.

Stage Four - Follow-up discussion

More than one meeting may be needed to ensure that all information has been communicated and understood and updates provided as further information becomes available. The lead contact should also respond to queries in a timely manner. As with Stage three all communications should be recorded in the patient's records and in the Duty of Candour section within the Datix incident report.

Stage Five - Process Completion

After completion of the incident investigation, feedback should take the form most acceptable to the patient/service user; this may be achieved through the RCA report feedback process. Whatever method is used, the communication should include:

• The chronology of clinical and other relevant facts.
• Reiterated apology for the harm suffered and any shortcomings in the delivery of care that led to the incident.
• A summary of the factors that contributed to the incident.
• Information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

Within 10 days following the investigation being signed off as being complete, provide the Relevant Person with a copy or summary of the investigation report.

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases information may be withheld or restricted. For example, where communicating information will adversely affect the health of the patient/service user, where there are ward security issues raised in the report, where investigations are pending coronial processes, or where specific legal requirements preclude disclosure for specific purposes e.g. performance action taken with a named member of staff. In these cases the patient/service user will be informed of the reasons for the restrictions.

It may be appropriate to share information with other relevant people. It may be helpful to send a brief communication to the patient’s GP describing what happened. When the patient/service user leaves the care of the Trust, a discharge letter should also be forwarded to the GP or appropriate community care service. It should contain summary details of:

• The nature of the safety incident and the ongoing care and treatment if applicable.
• The current condition of the patient/service user.
• Key investigations that have been carried out to establish the patient’s/service user’s clinical condition.
• Recent results.
Additional considerations

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient/service user, their family and carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Duty of Candour process. In this case, the following strategies may assist:

- Deal with the issue as soon as it emerges;
- Where the patient/service user agrees, ensure their family and carers are involved in discussions from the beginning;
- Ensure the patient/service user has access to support services;

All cases of unexpected or unexplained death need to be reported to the Coroner. A Coroner may request the case is not discussed with other parties until the facts have been considered. However, this should not preclude a verbal and written apology or expression of regret where appropriate. It should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties after the Coroner’s process is finished and in some instances, Police investigations.

It should also be recognised that Coronial investigations may be stressful for patients/service users, families, carers and staff. Bereavement counselling and advice on professional support groups should be offered at the outset of a Coroner’s investigation.

After completion of the incident investigation, further feedback to the patient/service user and/or their carer should include information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored. As above, there should be a written record that this follow up has been completed with the patient/service user.

To learn effectively from patient safety incidents, Root Cause Analysis (RCA) techniques should be applied to the incident investigation process. Relevant staff should be trained to undertake appropriate incident investigations that will identify the underlying causes.

The Chief Operating Officer will ensure each care group should establish a system to ensure that learning and notable practice is disseminated within and across services. This can be achieved either through the governance routes or additionally through newsletters, staff forums and/or training sessions.

References


Jules Williams
Care Quality Director
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