Rotherham Doncaster and South Humber NHS Foundation Trust

Being Open Policy

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1. Document summary

1.1 What is this policy about?

- Sometimes something goes wrong with a person's care. This policy explains what RDaSH colleagues must do when this happens.
- Colleagues must be open and honest with the patient. The patient may choose to involve a family member, carer or another person they trust.

1.2 What colleagues must do

- Colleagues must make sure everyone is safe. They must report the incident on the Trust's incident reporting system as soon as possible.
- Colleagues must tell the patient or relevant person what is known. They must use clear words, listen to questions and say sorry. Saying sorry does not mean that a colleagues or the Trust has accepted legal responsibility.
- Colleagues must explain what will happen next. They must provide one named contact and keep the person updated if new information becomes available.

1.3 When duty of candour applies

Duty of candour applies to notifiable patient safety incidents that cause moderate or severe harm, death, or prolonged psychological harm. Near misses are not notifiable incidents, although the principles of being open still apply. A named duty of candour lead must oversee the process and remain involved until it is complete.

1.4 Key timescales

The patient or relevant person should be told as soon as possible. Written confirmation, including an apology and information about the review, must normally be provided within 10 working days. Review findings and written feedback should normally be offered within 60 working days, unless an agreed investigation or external review needs longer.

1.5 Records, learning and support

Colleagues must keep clear records of discussions, contact attempts, letters, support offered, review findings and outcomes. The patient or relevant person must be kept informed and given a single point of contact. Care must continue safely and respectfully, and patients may ask to receive care from another team where this is practical. Colleagues involved in an incident must also be offered appropriate support. Learning from incidents must be shared to improve patient safety and reduce the risk of the same thing happening again.

Remember
If you are unsure what to do, speak to your manager or the Patient Safety Team.

2. Introduction and aim

This policy explains how colleagues must communicate openly and honestly after an incident, complaint or claim. It sets out the Trust's arrangements for following the principles of being open and meeting the duty of candour.

Clear communication is an important part of responding to incidents and errors. Healthcare professionals have a legal and professional duty to speak openly and honestly with patients and, where appropriate, their families or carers when something goes wrong with care or treatment.

This policy applies to all clinical colleagues and colleagues who have a key role in sharing information with the relevant people following an incident.

Incidents which come under the patient safety incident investigation (PSII) criteria are investigated under the incident management policy and are therefore not specifically covered by this policy.

Being open refers to the processes for communicating adverse events with patients, families, and carers. It is the opportunity to say sorry at the onset.

Duty of candour means giving all relevant information, without waiting to be asked, to a person who has been or may have been harmed by the care provided. This applies whether or not the person has made a complaint or submitted a report.

The principles of being open and the duty of candour provide a clear process for communicating after an incident. NHS healthcare providers must meet the standards in Regulation 20, Duty of Candour.

Hard Truths (DH, 2014) acknowledges that the professional values of individual clinicians are critical in ensuring an open culture. This means that along with incidents being reported, we should act in an open and transparent way when an incident has occurred.

All Rotherham, Doncaster and South Humber NHS Foundation Trust (RDaSH) colleagues should be aware of their professional and statutory roles and responsibilities when an incident occurs, and this means being open and honest with the relevant people.

The trust recognises that a culture of openness and honesty creates a positive learning environment where teams and individuals can be involved in improving care and sharing those improvements. Transparency is key in producing an open-minded safety culture.

2.1 The 10 principles of being open and actions

When something goes wrong, patients value openness and honesty. Being open is the right thing to do and is an ongoing process, not a single event. Colleagues must follow the 10 principles in Appendix A for all patient safety incidents. NHS Resolution's Saying Sorry leaflet also provides guidance.

2.2 Duty of candour, an introduction

The more serious the incident, the more important it is to complete all required being open actions. NHS bodies have a statutory duty to be open, honest and candid when a patient is harmed. Colleagues must not provide false or misleading information. The Care Quality Commission (CQC) oversees this duty.

RDaSH has integrated the process for capturing, recording and managing the duty of candour within the on the incident reporting system.
The criteria that must be met to fulfil the duty are listed in appendix B, duty of candour criteria and requirements.

2.3 The relevant person

The regulation defines the relevant person as the patient, the patient may also request that a suitable person acts on their behalf making them both relevant people. This person may or may not be a relative but will be a person the patient has trust in and who they have agreed to be involved in their care.

In certain situations, such as when a patient dies or is incapacitated, this extends to people acting lawfully on their behalf.

3. Procedure

3.1 Reporting the incident

The required process is outlined in the flow chart at appendix D duty of candour step by step and appendix E.

When any incident occurs, the colleagues involved are to complete an incident report using the incident reporting system. This report identifies whether the incident is a patient safety incident, and the level or harm that occurred as a result of the event (actual impact).

In some cases, the incident may not initially involve RDaSH colleagues, or the incident may be reported to colleagues by someone else; such as a patient, visitor or other organisation. These are also to be reported on the incident reporting system, including in the report all information that is available.

3.2 Being open actions

The actions required to comply with the being open process can be found in appendix A, the 10 principles of being open.

3.3 Notifiable patient safety incident

A notifiable patient safety incident is an unintended or unexpected incident during NHS care which, in the reasonable opinion of a healthcare professional, has caused or could cause moderate harm, severe harm, death or prolonged psychological harm. Near misses are not notifiable safety incidents.

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

More detail can be found in the actual harm grading scale at appendix F which includes psychological harm.

RDaSH records and manages duty of candour actions through the incident reporting system. Colleagues responsible for duty of candour or an incident review must know how to record and complete the process in the system.

Within the incident reporting form is a record of the perceived actual impact (harm) caused. If this is recorded as moderate harm or above for a patient safety incident, then the incident has triggered the duty of candour.

In some cases, the presence of psychological harm caused by the incident will not be recognised until after the 28-day period. In these cases, a new incident report is required documenting the presence of psychological harm from the original incident.

Moderate patient safety incidents that are also safeguarding concerns will follow the usual safeguarding enquiry process so that patient safety remains the priority. A police investigation may take priority over the usual duty of candour process where the investigation is being led outside the Trust.

3.4 Duty of candour actions

All patient safety incidents require the being open actions to be carried out. If, however, the incident is of such a severity that the duty of candour applies, then further actions are required. These further actions follow on from the being open actions and are as follows.

3.4.1 As soon as possible after the incident

- Offer and provide support to the relevant people after the incident, throughout the review and ongoing as required.
- The duty of candour lead is to meet the relevant person, in person (if possible), and inform them that the incident has occurred, apologise, inform them what happened as far as we are aware and what actions are to be taken next.
- The date and details of this contact are recorded on the incident reporting system in the duty of candour 'relevant person contacted' section by the duty of candour lead.
- If contact is not possible, for example, there is no relevant person or the person is clinically unwell, this is entered onto the incident reporting system.

3.4.2 First letter within 10 working days of the incident

Share with the patient and, or relevant person, in writing, the original notification and the results of any further enquiries.

This should include:

- all the information given verbally during the face-to-face meeting

- an apology
- any further information that has come to light since the meeting
- an outline of the review that is in progress
- any relevant support details

The duty of candour letter template available at appendix G reflects a scenario and can be adapted to meet individual needs. These templates are guides only and the letter should be personal and relevant to the case.

The date the letter was sent or given to the relevant person should be recorded on the incident reporting system in the duty of candour 'Written Explanation' section by the duty of candour lead. If contact is not possible, for example, there is no relevant person or the person is clinically unwell, this is entered onto the incident reporting system.

On rare occasions, it may not be possible for the letter to be sent within 10 working days. In these instances, an explanation must be given for reporting purposes, and a record of the reason should be made. This will be reported to the care group directors and the integrated care board by the patient safety, carer and community lead.

3.4.3 Review and feedback within 60 working days of the incident

Feedback should be facilitated by the duty of candour lead with the lead investigator as they will have had the most recent contact with the relevant people.

- Written feedback should be offered to the relevant person. The final investigation report should be concise, in an appropriate format to meet the requirements of the relevant person and should be restricted to the incident.
- The findings from the review can fed back in letter format. This is the responsibility of the duty of candour lead. A template for this is available in appendix H If colleagues have not been in recent contact with the patient or family, a query letter can be used to determine if they require the report (see appendix I)
- If the incident has undergone a full patient safety incident investigation (PSII), the feedback may be provided as either a full copy of the PSII report, a redacted version if necessary, or a shorter version may be preferrable. A covering letter template is available in appendix K.
- The final duty of candour report should be concise, easy to understand by the relevant person and restricted to the incident. If the patient/family have made a complaint, the Duty of Candour feedback may be given in the form of a complaints response to reduce duplication.
- This can be a distressing time for patients, families and carers especially where a death has occurred. It is acknowledged that those involved may not wish to receive a report in any format. Where this is the case, a record of the conversation should be made, and the incident reporting system should be updated to acknowledge this.
- The date actions were taken, notifications given, letters sent and outcomes are to be recorded with the initial incident on the incident reporting system by the duty of candour lead or the lead investigator.

The timescales for each review will follow the standard requirements as identified in the incident management policy unless agreement to extend the timeframe has been accepted by all concerned.

See the flow chart at appendices D and E.

3.5 Mortality Review

In the event of a death being logged on a mortality form, an appraisal will take place by the Mortality Operational Group (MOG). Any incidents where the Trust may have caused harm are then escalated to the weekly LFPSE Group for discussion and Duty of Candour can be triggered if appropriate. If Duty of Candour is triggered, the mortality form will be re-entered as an incident form. The Duty of Candour letter is required within the usual timeframe of 10 working days from the LFPSE meeting date.

3.6 Specific guidance

3.6.1 Provide an explanation

In keeping with the principles of being open, for non-notifiable incidents the colleague(s) involved should provide the patient or significant other with a full explanation of what is known at the time, including what further action is to be taken. This can be given by another colleague if it is decided that this would be more beneficial. Colleagues should speak to their manager for advice about how to approach this if they are unsure.

The relevant person should be kept abreast of what will happen and should be given the opportunity to be involved as much as they wish.

3.6.2 Information to be shared

Communication should be timely, informing the patient and, or their carer what has happened as soon as is practicable.

A step-by-step account of all relevant facts known about the incident at the time should be given, in person, by one or more appropriate representatives of the trust. This should:

- include as much or as little relevant information as the relevant person or people want to hear
- be jargon-free and explain any complicated terms in line with the accessible information standards
- include an explanation of any further planned enquiries and reviews
- be given in a manner that relevant person or people can understand, for example, colleagues should consider if appropriate interpreters, advocates, communication aids and so on, should be present, but should be conscious of any potential breaches of confidentiality in doing so

3.6.3 Review of the DOC incident

An appropriate manager must review each relevant incident using a systems-based approach. The review must consider the care provided, actions taken and learning identified. The depth of the review must match the seriousness of the incident.

Where a patient safety incident investigation is required, a lead investigator from the patient safety team will carry it out in line with the incident management policy.

This appropriate manager becomes the duty of candour lead.

In many cases the review will be immediate and short with the apology, explanation and results of the review being delivered all at the same time.

In other cases, these may be three distinct stages, the apology, the explanation, and the results of the review.

The process for reviewing the incident should be explained to the patient and, or their carer informing them that they will be kept up to date as any new information emerges as a result of any review.

The manager or investigator for the incident is responsible for liaising with and providing information in a timely, truthful and open manner to the patient and, or carer in line with the agreed review process.

3.6.4 De-logging patient safety incident investigations

An incident that requires review is logged on the incident reporting system. There will be occasions where the incident and report will be de-logged, for example when a patient safety incident investigation or other review finds that the trust caused no harm to the patient. Where the duty of candour process has begun, it should always be followed through with the relevant people and letter outlining the findings should be provided.

3.6.5 Provision of additional support as required

Patients and or their carers should also be provided with support in a timely manner to meet their needs. This may involve an independent advocate or an interpreter. Information on the patient advisory and liaison service (PALS) and other relevant support groups should be given as soon as possible. The offer of additional support and the outcome should be recorded. It should be borne in mind that the need for support may change throughout the review process.

There should also be recognition of the traumatic effect that adverse outcomes and their aftermath might have on NHS colleagues as well as patients and their relatives.

3.6.6 Patients who do not agree with the information provided

Sometimes, despite the best efforts of colleagues, the relationship between the patient, their family and carers and the healthcare professional breaks down.

They may not accept the information provided, may desire a higher level of review, or may not wish to participate in the process. In this case, the following strategies may assist:

- where the patient consents, ensure their family and carers are involved in discussions from the beginning
- write a comprehensive list of the points that the patient, their family, and carers disagree with and reassure them you will follow up these issues

- offer the patient, their family and carers another contact person with whom they may feel more comfortable, this could be another member of the team or a manager from another team or service
- use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution
- ensure the patient, their family and carers are fully aware of the formal complaints' procedure

3.7 Special considerations

The being open approach may need to be modified according to the individual patient or personal circumstances, for example (but not restricted to):

- when a patient dies
- patients who have a cognitive impairment and may lack capacity
- patients with a different language or cultural considerations
- patients with different communication needs
- children and young people
- when there is a corresponding criminal enquiry

3.7.1 When a patient dies

When an incident has resulted in a patient death it is crucial that communication is sensitive, empathetic, and open. A verbal apology will be given as soon as possible after the patient's death. It is particularly important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened.

A written notification and apology from the duty of candour lead should follow (see letter template, appendix G)

Usually, the being open discussion and any review will occur before the coroner's inquest. In some circumstances the trust may consider it more appropriate to wait for the coroner's inquest before holding the being open discussion with the family and or carers. It is important to explain that they will be kept informed as information is released from the coroner's office.

In most instances where someone dies it can be unclear if the services provided by the trust were at fault and whether duty of candour should be applied. See below for further detail:

- if death is reported to be due to natural causes, duty of candour is not applicable
- the main provider of care is not the trust; duty of candour is not applicable.

Where a suicide or child death has taken place, these incidents will always trigger the duty of candour. Where the child death is due to natural causes, duty of candour does not apply.

N.B. In all cases, duty of candour is only applicable if the death occurs while the patient is receiving regulated care (NHS funded care) or within 6 months of them being discharged from care.

3.7.2 Where there is no identified relevant person

Where no contact details have been recorded or updated in the clinical record and, or the relevant person cannot be easily identified, colleagues should ask the coroner, general practitioner or other official body if they can provide contact details. This can then be recorded on the incident reporting system as 'other relevant person not identified' but it should later be recorded on the incident reporting system if contact is made. A clear record should be made of the attempts to contact the relevant person along with any reasons why contact has not been made.

Where colleagues are unclear, they should seek advice from management.

3.7.3 Patients who have a cognitive impairment and may lack capacity

Wherever possible the patient will be involved in communications about what has happened. An advocate with appropriate skills should be available to the person to assist in the communication process.

It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using 'unofficial translators' and or the patient's and, or carers as they may distort information by editing what is communicated.

3.7.4 Patients with different communication needs

Some patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating a process, focusing on the needs of individuals and their families and being personally thoughtful and respectful.

3.7.5 Children and young people

The trust's Safeguarding Children team can provide advice related to assessing and managing risks in relation to children and young people and child protection, including information-sharing with other agencies See also trust safeguarding children policy and multiagency safeguarding children procedures.

The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children and young people to involve their families in decision-making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent (known as Gillick competence). Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he or she should be involved directly in the being open process after an incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

Where children and young people are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is

provided to the parents alone or in the presence of the child. In these instances, the parents' views on the issue should be sought.

3.8 Documenting all communication

Colleagues must keep a clear record, made at the time or as soon as possible afterwards, of all communication. This includes discussions with the patient or relevant person and records of the incident review.

The initial apology and explanation given should be documented in the incident reporting system, and in-depth detail recorded in the patient's record.
The incident reporting system will be the main record repository for duty of candour processes, with copies of letters and written notes being scanned and uploaded into the system.

Once the relevant person has been informed in person about the notifiable or patient safety incident, the trust must provide the relevant person with a written note of the discussion, and copies of all correspondence must be kept by the trust, along with any enquiries or reviews, and the outcome or results of those enquiries or reviews. A record of such communications should also be included in the patient record, incident reporting system and complaints and patient safety incident investigation files where applicable.

Any routine day to day 'being open' communication such as an incident outside the duty of candour and the remit of the above policies will be recorded in the patient's health record.

Colleagues should make every reasonable effort to contact the relevant people through various communication means. All attempts to contact the relevant people should be documented. If the relevant person declines to contact the trust, their wishes should be respected and a record of this kept.

Good documentation is crucial. Discussions around the time of an incident should be recorded in the patient records. Any subsequent meetings should have minutes taken and followed up by letter.

The outcomes or results of any enquiries and reviews should also be provided in writing to the relevant people, should they wish to receive them. Any correspondence from relevant person(s) relating to the incident should be responded to in an appropriate and timely manner and a record of communications kept.

3.9 Next steps

The relevant person should be advised on what further enquires are appropriate and they should be given all reasonable opportunities to be involved as much as they wish to be in the progress of any enquiries.

New information may emerge during the course of any review into the incident, and the relevant people must be informed of new information as it arises. The trust must keep the relevant people informed about the conclusions of our enquiries, and provide them with a single point of contact for any questions and further opportunities to discuss the case:

- on an ongoing basis throughout the course of their continuing recovery and, or treatment, and during any review or inquiry
- at times and amounts of their choosing until they are satisfied that all relevant information has been disclosed

3.10 Continuity of care

Patients are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive the treatment elsewhere.

Patient or service users, their families and carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the team involved in the incident.

When a patient or service user has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the ongoing clinical management plan.

3.11 Practical support

In line with the expectations of all colleagues regardless of any incident, patients will be provided with all reasonably practical and emotional support necessary to help overcome the physical, psychological and emotional impact of the incident. At a direct level this will include:

- treating all patients and their families with respect, consideration and empathy
- offering the option of immediate emotional support during the notifications, for example from a family member, a care professional or a trained advocate
- offering access to help with understanding what is being said, for example, via interpretative services, non-verbal communication aids, written information, Braille
- in line with the accessible information standards

In addition, colleagues will be supported by relevant process and individuals within the trust to:

- offer access to any necessary remedial treatment to minimise the harm caused
- provide information about available impartial advocacy and support services, local health watch and other relevant support groups, such as cruse bereavement care and action against medical accidents (AvMA), to help them deal with the outcome of the incident
- arrange for care and treatment to be delivered by another professional or team or provider as far as reasonably practical, should the relevant people wish.

3.12 Support for colleagues

During the course of their duties, RDaSH colleagues may find themselves involved in an incident. This can be distressing, and colleagues may require support. This

should be provided via the team manager who will identify the relevant level of support and assist the colleagues member to access this in a timely manner. This could be via occupational health, or informal arrangements within the trust.

4. Responsibilities

4.1 The trust

The Trust must have policies and procedures that support good practice, effective services and safe management of risk. These arrangements must meet NHS requirements and relevant legal duties.

Ensuring that there are systems in place that do not obstruct anyone from exercising the duty.

4.2 Executive director, with lead responsibility

The Chief Nurse is the executive lead for this policy and is responsible for the effective management of clinical risk. They work with care group directors, who manage clinical risk within the Trust's clinical services.

This will include responsibility for ensuring being open principles and duty of candour are appropriately applied to the review and management of incidents, complaints, and claims.

They will also ensure that there are appropriate systems in place to share learning.

4.3 Care group directors, nurse directors, service managers and modern matrons

All care group directors, care group nurse directors, deputy care group directors, heads of corporate service and matrons are responsible for the dissemination and implementation of this policy within their departments.

They are also responsible for creating an environment within their services where open, timely and clear communication and information sharing is encouraged in line with the being open principles and duty of candour requirements. This includes ensuring colleagues are aware of the system for reporting incidents and ensuring that appropriate colleagues are trained in the principles and procedure relating to being open and the duty of candour.

4.4 Patient safety, carer and community lead (medical devices safety officer and patient safety specialist)

The patient safety, carer & community lead is responsible for providing support to directors, care group nurse directors, deputy care group directors, head of corporate services and matrons to facilitate the effective implementation and monitoring of this policy.

They will ensure that the principles of being open, and requirements of the duty of candour are discussed and embedded as part of the learning process for incidents.

Any breaches in the duty will be reported to care group directors and the integrated care board (ICB).

4.5 Duty of candour lead

When an incident is identified, a named person must lead the duty of candour process. This is usually the manager of the team or service involved. The modern matron, deputy care group director or head of corporate service will confirm who will take this role. The duty of candour lead must remain involved throughout and ensure that findings are shared with the relevant person.

4.6 Lead investigator (PSIIs)

Any colleagues nominated to investigate an incident should comply with this policy and where appropriate, involve the patient and, or their carers and other relevant teams and organisations (for example where patient care extends beyond RDaSH) investigation. For further information see the RDaSH incident management policy.

The lead investigator should maintain contact with the duty of candour lead throughout the investigation. The team manager or service manager has a key role in ensuring the findings are shared.

4.7 Medical devices and duty of candour officer (MDDCO)

The MDDCO is responsible for the day-to-day monitoring of the duty of candour process and will monitor the incident reporting system for incidents which trigger the duty of candour. They will produce reports and provide colleagues with advice about the process. See appendix L for further information.

4.8 All colleagues

All colleagues should comply with the principles of being open and the requirements of the duty of candour with patients and, or their carers as outlined in this policy.

Colleagues should report all incidents promptly and clearly to ensure that the appropriate actions can be taken to ensure an open and honest culture.

5. Training

Whilst there are no mandatory training needs in relation to this policy, the CQC set out expected standards required by healthcare providers in Regulation 20 ‘Duty of Candour’ (Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014). Training is required for:

- lead investigators who will have contact with patients, their families and carers during the course of their review
- any other individual or group with a responsibility for implementing the contents of this policy
- all clinical colleagues who during the course of their work will have direct contact with patients their carers

Training sessions will be delivered through the learning and development department to raise awareness of the duty of candour for managers, including how to record duty of candour compliance on the incident reporting system. All training attended should be recorded on the NHS electronic colleagues record (ESR)

As a trust policy, all colleagues need to be aware of the key points that the policy covers. Colleagues can be made aware through a variety of means such as:

- one to one or supervision
- team brief
- weekly newsletter
- team meetings
- trust wide email notices
- group supervision

6. Monitoring Arrangements

This section is about how we will know that the policy is working effectively.

6.1 Number of duty of candour incidents

- How and who by: Incident reporting system output report by MDDCO
- Reported to: Trust Patient safety, carer and community report to Quality Committee.
- Frequency: Monthly

6.2 Open duty of candour incidents

- How and who by: E-mail feedback by MDDCO.
- Reported to: Care group directors.
- Frequency: Monthly

7. Related documents

- Listening and responding to concerns and complaints policy (formally complaints handling policy)
- Freedom to speak up policy: raising concerns (whistleblowing) policy
- Healthcare record keeping policy
- Healthy workplaces staff support and stress at work policy
- Incident management policy
- Interpreters policy (provision, access and use of, for patients, service users and carers)
- MCA Mental Capacity Act 2005 policy
- Patient advice and liaison service (PALS) policy
- Safe and secure handling of medicines manual
- Hard Truths (2014) Department of Health.
- NHS Resolution (NPSA) (2017) Saying sorry when things go wrong: Being Open.
  The 10 Principles Of 'Being Open' Adapted From National Patient Safety Agency NPSA (2009). NPSA (2009) Being Open: Communicating Patient Safety Incidents with patients their families and carers following a patient safety incident. Report of the Mid Staffordshire NHS Foundation Trust Public Enquiry (2013). CQC guidance Regulation 5 and regulation 20, November 2014.https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

8. Appendices

8.1 Appendix A 10 Principles of being open

8.1.1 Acknowledgement

All patient safety incidents must be acknowledged and reported as soon as they are identified. Colleagues must tell the patient or relevant person and offer an apology, face to face where possible. This does not apply if the person cannot be contacted or does not want to be told. If a patient, family member or carer tells colleagues that something has gone wrong, colleagues must take the concern seriously from the start and respond with compassion and understanding.

8.1.2 Truthfulness, timeliness and clarity of communication

A suitable named colleagues must give information about a patient safety incident in an open and honest way. They must explain, step by step, what is known and adapt the discussion to the person's needs. Information must be shared as soon as practical and must be based only on the facts known at the time. Colleagues must explain that more information may become available during the review and must keep the patient or relevant person updated. The information must be clear, consistent and free from unexplained medical terms. A single point of contact must be provided for questions or requests.

8.1.3 Apology

Patients, their families and carers must receive a meaningful apology. This should be a sincere expression of sorrow or regret for the harm caused by the incident and should be given as early as possible. An apology is not an admission of legal liability or poor professional performance.

The Trust must decide who is best placed to give the verbal and written apologies. This decision should consider the person's seniority, relationship with the patient and experience of the type of incident. A verbal apology should be given as soon as colleagues know that an incident has happened. A written apology must also clearly say that the Trust is sorry for the suffering and distress caused. The apology must not be delayed while a formal meeting is arranged, because delay can increase anxiety, anger or frustration.

8.1.4 Recognising patients, families, and carers 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 healthcare organisation. They should be treated sympathetically, with respect and consideration. They should also be provided with support if they require it, in a manner appropriate to their needs.

When communicating with relatives and when appropriate, the issue of consent should also be considered and any discussion in relation to the patient wishes should be clearly documented.

8.1.5 Professional support

All colleagues, whether directly employed or independent contractors, should report patient safety incidents and colleagues should feel supported throughout the incident. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk, or any threat to their registration.

The Just Culture Guide (NHS Improvement, 2018) supports a conversation between managers about whether a colleague involved in a patient safety incident requires specific individual support or intervention to work safely.

8.1.6 Risk Management and systems improvement

The trust investigation process will be used to identify any causes of a patient safety incident.

8.1.7 Multidisciplinary responsibility

Most healthcare provision is through multidisciplinary teams. This should be reflected in the way that patients, their families, and other relevant people are communicated with when things go wrong. This will ensure that the being open process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

8.1.8 Clinical governance

Being open requires the support of patient safety and quality improvement processes through clinical governance frameworks in which patient safety incidents are investigated and analysed to find out what can be done to prevent their recurrence. These findings should be disseminated to healthcare professionals so that they can learn from patient safety incidents.

Within the trust, monitoring and reporting is carried out through the incident reporting system.

8.1.9 Confidentiality

Colleagues must protect the privacy and confidentiality of patients, relevant people and colleagues throughout the being open process. Information about an incident must be treated as confidential. Consent should be obtained before information is shared beyond the colleagues involved in the patient's care, unless there is a clear lawful reason to share it.

Communications with parties outside the clinical team should also be on a strict need to know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient, their family and carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections.

8.1.10 Continuity of care

Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team or person, the appropriate arrangements should be made for them to do so.

8.2 Appendix B Duty of candour criteria and requirements

In order to meet this duty, the trust must:

- act in an open and transparent way with relevant persons in relation to care and treatment provided to people who use our services in carrying on a regulated activity
- tell the relevant person, in person, as soon as reasonably practicable after becoming aware that a notifiable patient safety incident (PSI) has occurred and provide support to them in relation to the incident, including when giving the notification
- provide an account of the incident, which to the best of its knowledge is true, of all the facts that it knows about the incident as at the date of notification
- advise the relevant person what further enquiries it believes are appropriate
- offer an apology
- follow this up by giving the same information in writing and providing an update on the enquiries
- keep a written record of all communication with the relevant person.
- the CQC will monitor compliance with the key requirements with respect to the duty of candour
- there should be a board-level commitment to being open and transparent in relation to care and treatment
- candour, openness and honesty should be encouraged at all levels, as an integral part of a culture of safety that supports organisational and personal learning
- providers should take action to tackle bullying, harassment and undermining, and must investigate any instances where a colleague may have obstructed another in exercising their duty of candour
- colleagues should receive appropriate training, and there should be arrangements in place to support colleagues who are involved in a notifiable patient safety incident
- there is no formal deadline under the regulation for notifying the relevant person of an incident, but the guidance refers to the NHS standard contract provision which requires notification within ten working days of the incident being reported and sooner where possible
- where the degree of harm is not yet clear but may fall within the criteria in the regulation (death, severe harm, moderate harm or prolonged psychological harm) the relevant person must still be informed of the incident in line with the regulations
- although there is a requirement to investigate incidents which ‘could result in’ harm as described above, the CQC state that there is no need to inform a person under the regulation when a ‘near miss’ has occurred, resulting in no harm to that person
- where the incident relates to care delivered by another provider, RDaSH would work with others, and that provider would then be responsible for notifying the relevant person of the incident
- there is guidance as to what constitutes ‘reasonable support’, for example, third party emotional or advocacy support, arranging further treatment, where necessary by a different team or provider, and providing support to access RDaSH complaints procedure

- where, despite reasonable attempts, the relevant person cannot be contacted, or does not wish to communicate with the provider (including historic incidents) a written record should be kept of the attempts to contact or speak with them

8.3 Appendix C Duty of candour colleague flow diagram

- Please refer to the duty of candour colleagues flow diagram (colleagues access only)

8.4 Appendix D Duty of candour step by step

1. Provide initial verbal apology and explanation of what happened as far as is known at that time.
2. Report as an incident on the incident reporting system and record the conversation in the relevant section of the form.
3. Inform manager as soon as practicable.
4. Offer patient or relevant person support during and after the process, including, but not limited to, interpreters, advocates, counselling, self-help groups, transfer of care to another team, and so on.

8.4.1 Within 10 working days the manager must:

- Nominate a Lead to comply with the duty of candour.
- Notify patient that incident has occurred, this must be:
    - in person (if possible)
    - include an apology, what happened and what is going to happen next, review
    - be delivered by a suitable manager from the service involved
    - be followed by written notification
    - be recorded in the duty of candour section on the incident reporting system

8.4.2 Within 60 working days of the incident (extend if PSII or similar) the line manager must:

- Carry out a review and provide an explanation of the events and circumstances which resulted in the incident.
- Provide and maintain written records of the interactions with the patient or relevant person.
- Provide a copy of the review report to the patient or relevant person, this report has to be approved for release and suitably redacted if required.
- Offer patient or relevant person support after the process, including, but not exclusively, counselling, self-help groups, transfer of care to another team, and so on. Also, the patient feedback and complaints process.

8.5 Appendix E Process flow chart

1. Patient safety incident occurs.
2. Being open at the time of the Incident.
3. Ensure the safety of those involved and the area, assist as required.
4. Provide verbal apology and explanation of what happened as far as is known at that time.
5. Advise and, if possible, agree with the patient what further enquiries are appropriate.
6. Report as an incident on the incident reporting system and record the conversation in the relevant section of the form.
7. Provide reasonable support to the patient or service user, their families, or carers.
8. Was the severity of harm moderate, major, catastrophic or death? or psychological harm over 28 days?
9. No, duty of candour does not apply, but being open initiative applies to all patient safety incidents.
10. Yes, Within 10 working days the allocated manager must Notify patient that incident has occurred. This should be:
    - delivered by a suitable manager from the service involved
    - in person
    - include all known facts about the incident
    - include a repeat apology
    - include next steps
    - be followed by written notification
    - be recorded in the duty of candour section of the incident reporting system
    - commence a review into the incident
11. Within 60 working days (If the incident is being reviewed as an PSII, or an external review, then the 60-day limit may be exceeded) of the incident the manager must:
    - carry out a review to provide an explanation of the events and circumstances which resulted in the incident
    - keep the patient or relevant person informed of progress during the review
    - provide and maintain written records of the interactions with the patient or relevant person
    - provide an explanation and offer a copy of the investigation report to the patient or relevant person, this report has to be approved for release and suitably redacted if required
    - offer patient or relevant person support during and after the process, including, but not exclusively, counselling, self-help groups, transfer of care to another team, and so on. Also, the patient feedback and complaints process, incident is now complete

8.6 Appendix F Actual harm grading scale

8.6.1 Actual harm grading scale: Physical harm

8.6.1.1 No harm (1)

- 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.
- Minimal injury requiring no or minimal intervention or treatment.
- No time off work.

8.6.1.2 Minor (2)

- Minor injury or illness, requiring minor intervention.
- Minor treatment is defined as first aid, additional therapy, or additional medication.
- Increase in length of hospital stay by 1 to 3 days.
- Requiring time off work for greater than 3 days.

8.6.1.3 Moderate (3)

- Injury requiring 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.
- Semi-permanent injury taking up to 12 months to recover.
- Increase in length of hospital stay by 4 to 15 days.
- Requiring time off work for 4 to 14 days.

8.6.1.4 Major (4)

- Major injury leading to long-term incapacity or disability.
- Increase in length of hospital stay by greater than 15 days.
- Requiring time off work for greater than 14 days.

8.6.1.5 Catastrophic (5)

- 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.
- Multiple permanent injuries or irreversible health effects.

8.6.1.6 Death (6)

- The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.
- Death as a result of an incident classified as a 'never event'.

8.6.2 Specific harm grading scale

8.6.2.1 Minor (2)

Pressure ulcers:

- patient develops trust acquired pressure ulcer category 1 or 2 or a moisture lesion

Falls:

- fall causing harm that resolves within one month, for example, scalp laceration

Medication errors:

- medication error resulting in patient harm which resolves within 1 month, for example, increased dose of antihypertensive administered in error which requires additional BP monitoring

8.6.2.2 Moderate (3)

Pressure ulcers:

- trust acquired category 3 or 4 pressure ulcer, multiple trust acquired category 2 pressure ulcers causing significant affects judged to be moderate

Falls:

- fall causing harm that takes 1 to 12 months to resolve, for example, fractured humerus, seriousness of the incident or affects is judged to be moderate

Medication errors:

- medication error resulting in patient harm that takes 1 to 12 months to resolve seriousness of the incident or affects is judged to be moderate

8.6.2.3 Major (4)

Pressure ulcers:

- multiple trust acquired category 3 or 4 pressure ulcer

Falls:

- as moderate, but judged to be a major harm

Medication errors:

- as moderate, but judges to be a major harm

8.6.2.4 Catastrophic (5)

Pressure ulcers:

- pressure ulcer resulting in sepsis and sepsis recorded on death certificate

Falls:

- fall causing an injury which contributes to patient death, for example, recorded on part 2 of death certificate or causes permanent harm or permanent disability, for example, fractured neck of femur

Medication errors:

- medication error which contributes to patient death, for example, failure to reconcile cardiac medication contributing to patient death

8.6.2.5 Death (6)

Falls:

- fall leading to injury that directly causes death of patient

Medication errors:

- medication incident directly resulting in patient death, for example, medication administered to which the patient had a known allergy and administration results in death

8.6.3 Psychological Harm

No psychological harm: Distress is inherent in being involved in any patient safety incident, but please select this option if there is no specific psychological harm over and above this.

Low psychological harm: Low psychological harm is when at least one of the following apply:

- distress that did not, or is unlikely to affect the patient's normal activities for more than a few days
- distress that did not, or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit
- distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition

Moderate psychological harm: Moderate psychological harm is when at least one of the following apply:

- distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months
- distress that did or is likely to need a course of treatment or therapy sessions that extends for less than six months
- distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months

Severe psychological harm: Severe psychological harm is when at least one of the following apply:

- distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months
- distress that did or is likely to need a course of treatment or therapy sessions that continues for more than six months
- distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months.

8.7 Appendix G Letter template: general

- Please refer to the letter template general (colleague access only)

8.8 Appendix H Letter template: pressure ulcer

- Please refer to the letter template: pressure ulcer (colleague access only)

8.9 Appendix I Report template

- Please refer to the report template (colleague access only)

8.10 Appendix J Query Letter Template

- Please refer to the query letter template (colleague access only)

8.11 Appendix K Cover letter for PSII report template

- Please refer to the cover letter for PSII report template (colleague access only)

8.12 Appendix LMonitoring and management process

Day numbers refer to days after the incident is reported.

1. The incident is reported.
2. System emails manager, Patient Safety, Carer and Community Lead (PSCCL), and medical devices and duty of candour officer (MDDCO).
3. Manager moderates the incident report.
4. DOC incident added to DOC monitoring spreadsheet (MDPO). Exceptions to be raised with Patient Safety, Carer and Community Lead (PSCCL).
5. If DOC section on incident reporting system is not commenced, notification email to be sent to DOC lead or manager to inform that it is a DOC and what is required (MDDCO).
6. Day 10 incident marked as RED on spreadsheet if no contact or letter. Phone to remind manager or DOC lead if no contact and, or letter recorded on the incident reporting system (MDDCO). Reason for delay is recorded. If still not completed, this would be escalated to care group director and ICB (PSCCL)
    - PSII (or external report), PSII report due date entered onto the incident reporting system as target date for report (MDDCO). Once known, PSII investigator is entered on incident reporting system as DOC lead for the incident (MDDCO). Weekly check of live PSII cases to confirm progress of report (MDDCO). Once PSII report completed and reviewed by ICB, email PSII investigator to chase up final feedback to patient or family. (MDDCO) If report is not forthcoming escalate to PSCCL (MDDCO). Escalate to PSCCL, care group director, or head of quality and promises in monthly report.
    - Not PSII, after action review or SWARM etc day 60 email DOC lead to remind about report (MDDCO). Chase on a monthly basis (MDDCO). Escalate to PSCCL, care group director, or head pf quality and promises in monthly report (MDPO).

Assistance and advice can be called for at any time in this process from the patient safety, carer and community lead (PSCCL) or medical devices and duty of candour