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SELDOC
DOCTORS COOPERATIVE

"Being Open" and Duty of Candour Policy

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Contents

1.INTRODUCTION

This document describes how SELDOC implements the Being Open Framework 2009 "Being Open – Saying Sorry When Things go Wrong" (National Patient Safety Agency (NPSA), Safety Alert 2009 and the Duty of Candour requirement 2013 (Department of Health)).

Being Open is a fundamental process affecting integrated governance throughout SELDOC. This document is integral to the Incident, Serious Incident and Complaints processes and Clinical Governance framework. Being Open is part of the "no blame" culture which is required throughout all health care providers. This culture is fundamental to being a learning organisation.

This document provides a framework for:

- patients/relatives to receive the open, accurate and timely communication, apology and support they need;
- staff to be encouraged to admit shortcomings and mistakes and learn from errors whilst being supported; and
- root cause analysis, investigation and systematic leaning.

All moderate harm, severe harm and death incidents must have documented evidence of the Being Open process. This is referred to as the Duty of Candour and is a contractual requirement reflecting the Francis Report (2013) following the Mid Staffordshire Enquiry. A key aim of the Francis Report is to help all health professionals to feel they can be open and honest whenever mistakes are made, and to not be reluctant to apologise to patients.

The NHS Litigation Authority (NHSLA) litigation circular 02/2002 encourages health care staff to apologise and clarifies that doing so is not an admission of liability:

"It seems to us that it is both natural and desirable for those involved in treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives and to express sorrow or regret at the outcome. Such expressions of regret would not normally constitute an admission of liability, either in part or in full, and it is not our policy to prohibit them, not to dispute any payment, under any scheme, solely on the grounds of such an expression of regret."

The principles of this policy apply to all communications with patients and their families when errors have been made. This applies to incidents as well as complaints. It applies in personal explanations and apologies, as well as in local resolution meetings which are arranged to try to resolve remaining concerns following a formal complaint investigation. The principles also apply to internal inquiry meetings.

The NPSA website www.npsa.nhs.uk/advice contains the NPSA Being Open Framework 2009, on which this policy is based. Information on Duty of Candour can be found on the Department of Health website www.dh.gov.uk.

2. CONTEXT

Openness - It is important that openness is shown whenever things go wrong with treatment and care. Without openness about incidents, patient consent for treatment can be made invalid.

The NPSA‟s Being Open policy does not require potential patient safety incidents that have been prevented or “no harm” incidents to be reported to patients/relatives.

Communications with Patients/Families - All communications with patients/families must be timely, using understandable language. Being Open meetings must allow sufficient time for discussion and questions. Staff must demonstrate that they are approachable through written communications, the way they speak and their body language. Openness is promoted by staff showing they are caring and sympathetic, and providing several opportunities for patients/relatives to ask questions and gain information.

Disclosing to the patient that an incident has occurred, which they may be unaware of, has to occur as soon as possible (and within 10 working days of the incident) by a member of staff with understanding and experience/support as part of a planned process. Face to face communication is best.

It is usual to share the findings of investigations with the patient/family afterwards in a letter and a meeting. Patients/families should be asked how they would prefer this to occur.

Being Open is based on evidence that this approach means patients/relatives have better outcomes following errors and reduces their trauma. It also helps SELDOC to prevent and resolve complaints, and reduces the risk of patients/relatives escalating their complaints to the Public Health Service Ombudsman.

SELDOC’s approach to complaints supports Being Open, with a flexible approach focused on addressing the complainant’s concerns and making real service improvement.

Being Open is supported by the 7 Steps to Patient Safety (NPSA, 2003) initiative which describes a methodical approach to developing a patient safety culture in healthcare organisations.

Results of surveys of patients and relatives show that receiving an apology, followed by investigation and support, are more important than financial compensation or disciplinary action (MORI – Making Amends DoH 2003).

In addition to this, there are benefits to staff from increased satisfaction as they can be confident that communication with patients and relatives has been handled appropriately and that the experience has contributed to their own professional development.

3. DEFINITION OF TERMS

Being Open - Being Open is a specific process of actions and behaviours that have to be followed following any incident causing harm to a patient. These are determined by the Ten Principles of Being Open which can be found at Appendix A.

Organisations are said to be "open" when the prevailing culture visibly encourages key behaviours. These include honesty, openness, appropriate sharing of information and a willingness to learn from experience to change how the organisation functions.

No Harm Incidents - Any patient safety incident that had the potential to cause harm but was prevented resulting in no harm to people receiving NHS-funded care.

Local Resolution Meetings - Meetings arranged with patients and their relatives to address complaints. The purpose of the meeting is to address issues and concerns raised in the complaint and to provide answers to questions. The meeting is held in an honest and open manner and support provided to the patient and family.

Duty of Candour - A contractual duty requiring hospitals to ensure that patients/families are informed of medical errors causing moderate, severe harm or death and provided with support. This includes receiving an apology, as appropriate, and the investigation findings and actions to prevent recurrence are shared.

Gillick (or Frazer) Competent - Children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention.

4. ROLES AND RESPONSIBILITIES

SELDOC Board:

- To demonstrate SELDOC's commitment to Being Open principles and standards in their own behaviour.
- To make a public commitment to Being Open.
- To require all staff to meet Being Open standards and to learn from incidents.
- To ensure arrangements are in place for implementation of the Duty of Candour.

Medical Director:

- To facilitate the Being Open/Duty of Candour and learning process.

Deputy Medical Director:

- To promote the Being Open culture.
- To ensure overall implementation of this document is supported, where appropriate, by the organisation.

Governance Quality Team:

- To facilitate implementation of this document.
- To facilitate inclusion of Being Open and Duty of Candour in appropriate training e.g. induction and in training programmes for all staff involved in the follow up of incidents.

- To facilitate the planning of Duty of Candour discussions with investigators and clinicians, as required.
- To provide administrative support to ensure accurate records are maintained of all meetings with patients and their families involving complaints and/or incidents.
- To encourage learning and openness following incidents.
- To monitor the effectiveness of this document on an ongoing basis and report on this in routine governance reports and raise any concerns.
- To monitor assurance of implementation of this document.

All Staff:

- To be aware of and apply the principles of Being Open and the Duty of Candour.
- To report incidents using SELDOC's Incident Policy.
- To address concerns or complaints openly and honestly.
- To communicate with patients/families in line with this document.

5. PROCESS

The principles of Being Open are detailed in Appendix A and the Duty of Candour process is described in a simple flow diagram in Appendix B.

Staff are encouraged to apologise when things go wrong, offering sympathy and caring. Apology is not an admission of liability. There is no requirement to report prevented or "no harm" incidents to patients and relatives.

The Duty of Candour will apply to moderate, severe harm or death incidents (SELDOC Risk harm scores of 3, 4 and 5).

"Requirements of Truthfulness, Timeliness and Clarity of Information"
The NPSA's Being Open policy does not require prevented patient safety incidents or "no harm" incidents to be reported to patients/relatives (SELDOC Risk harm scores of 1 & 2 – "no physical harm"). The decision as to whether to communicate these to patients depends on local circumstances and advice should be sought from the Medical Director or Deputy Medical Director. Low harm incidents should always be communicated to patients/relatives.

All communications with patients should have the underlying principle of health care being a partnership between the professional and the patient, based on respect. It is most important that communication with the patient and their family is open, honest, comprehensive, timely and not delayed due to investigations etc. All communications should adhere to the Being Open Principles. It is paramount that communication of moderate, severe harm or death incidents occurs as soon as possible with patients/families as part of the Duty of Candour.

Meetings convened as a result of complaints are designed to be nonintimidating and relatives/patients should be given the opportunity to express themselves fully. The purpose of the meetings is to meet their needs for information, apology and acknowledgement.

In internal inquiry meetings, openness and a readiness to identify and learn from mistakes are fundamental principles.

SELDOC is aware and emphasises the importance of communication. The Governance Quality Team provides support to staff and clinicians where difficulties are identified.

As part of the Duty of Candour process, records must be made of all conversations, whether face to face, by telephone or letter in the health records.

Complaint investigations are recorded separately in the complaint file – not in the health records. This is to avoid discrimination against patients.

When investigating any complaints and incidents with a SELDOC Risk score of 3, 4 or 5, the Governance Quality Team will undertake the following actions:

- Identify how the patient and/or family will be informed of the incident and given an apology. Face to face discussion is best or a telephone call if the patient is not in hospital. Verbal communication should always occur before a letter is sent. It is useful to identify an appropriate senior staff member to be a single point of contact.
- Make Initial Disclosure and Apology with the Patient/Family as Soon As Possible and Within 10 Working Days of Incident. Delay in disclosure must be avoided. The initial communication must occur even if details are not yet clear. This communication can occur by any appropriate means – face-to-face is best, but it can be a telephone call or invitation to a meeting. Reference should be made to the investigation which may provide different or further information.
- This initial communication must be recorded in the Complaint or Incident file with a heading “Duty of Candour meeting” – Date, time, people present (including patient and family names), apology, what was discussed, concerns raised by the family, arrangements for further communication/support etc. See Appendix D for more information on Being Open meetings.
- The communication is mainly disclosing that an incident has occurred and offering apology and sympathetic support. It is important to avoid giving too much detail about the incident until the incident investigation has been completed. The patient/family can be told they will be invited to a meeting to discuss details either during or after the investigation, as preferred by the patient/family. Patient/family concerns, preferences etc. should be recorded and considered in the investigation.
- An offer to meet again should be made to the patient/family. This is usually at the end of the investigation so the findings can be shared and discussed, but may also occur before the investigation starts or during the process. The approach is agreed with the patient/family. The patient/family may require meetings at any stage during the investigation.
- The patient must be given sufficient time before the meeting so they can arrange to have a family member present, if they wish. It is often not appropriate for staff involved in the incident being present and this should be carefully considered. The Medical Director or Deputy Medical Director would be more appropriate.

In the case of a Serious Incident, a note of the “Duty of Candour” communication will be made in the Serious Incident file and provide evidence of SELDOC’s contractual duty.

6. MONITORING COMPLIANCE AND AUDIT

This document will be monitored using the following indicators:

1. All Serious Incidents and moderate incidents will have Duty of Candour disclosures and offers of Duty of Candour meetings.
2. Feedback from patients/families involved in Duty of Candour meetings.

Implementation of this document will be reported to the Quality Committee and thence to the Board.

8. DISSEMINATION, IMPLEMENTATION AND ACCESS TO THIS POLICY

This policy and procedure is available on the SELDOC intranet.

All clinical staff will be notified via email of the policy and procedure and any subsequent amendments.

7. REFERENCES

NPSA Being Open Framework 2009 “Being Open – Saying Sorry When Things go Wrong”
Safe care: The National Patient Safety Agency (NPSA) 'Being open' framework: NHS Midlands and East
NPSA Safety Alert 2009: Being Open – Supporting Information
NHSLA 2009: Apologies and Explanations
NPSA 2004: Incident Decision Tree
NPSA 2010: Medical Error: What to do if things go wrong: A guide for junior doctors
Royal College of Surgeons 2010 Openness and Transparency in Surgery Medical error.
NPSA 2003 - Seven Steps to Patient Safety
NHS Litigation Authority (NHSLA) litigation circular 02/2002
MORI – Making Amends DH 2003
Implementing a “Duty of Candour” - A new contractual requirement on providers – DoH 2012

Appendix A - The Principles of Being Open

A summary of the key actions of the NPSA‟s Being Open Framework. This can be used in planning meetings with staff and patients following incidents, complaints or claims. Actions are grouped under the Ten Principles of Being Open.

1. Principle of acknowledgement

- Acknowledge and report all incidents, complaints promptly as per Incident Reporting Procedure and Complaints Policy and Procedure.
- Take seriously any reports of incidents/concerns from patients/carers.
- Take notice of a patient's concerns.

2. Principle of truthfulness, timeliness and clarity of communication

- Be truthful and give information in an open manner.
- Person giving information to be appropriately nominated.
- Give a step by step explanation of events.
- Timely communication – as soon as possible.
- Information to be based on known facts at the time.
- Explain that investigation may reveal more information.
- Tell patients how they will be updated on the progress of investigation.
- Provide a single point of contact for information, avoiding conflicting information from different staff.

3. Principle of apology

Express sincere regret or sorrow as soon as possible and make an apology verbally and in writing. Written apology must clearly state SELDOC is sorry for the suffering and distress caused.

The most appropriate member of staff to make apology must be identified considering seniority, relationship to patient, experience and expertise regarding incident.

4. Principle of recognising patient and carer expectations

- Patients/carers expect a face-to-face meeting with representatives of the organisation.
- Maintain confidentiality.
- Identify names of people who can provide support to patient and whom patient has agreed can receive information e.g. a friend, Cruse Bereavement Care etc.

Patient issues:

- Identify any restrictions of openness the patient wants you to observe e.g. may not want to know all the details of what went wrong. In this case, respect wishes but say they can ask for full details later.
- Give several opportunities for patient/carer to gain information about incident.
- Provide verbal or written information.
- Develop on going care plan, tell patient/carers that care will be unaffected by any dispute.
- Take steps to make sure that carers etc. are involved in discussions about incident, with patient's consent.

- Provide access to information, observing confidentiality and patient instructions, to carers and those close to the patient. Information should assist decision making e.g. if patient cannot participate or has died.
- Ensure the patient understands the situation fully. Determine whether they need this information at different times.
- Provide carers with known information, care and support if a patient has died.
- Refer carers to the coroner for more detailed information.
- Document discussions with patients/carers. Share information with them.
- Provide patients/carers with information on the complaints procedure and how to give positive or negative feedback to staff.
- Provide patients/carers with information on the incident reporting process.
- When appropriate, ensure the incident investigation e.g. through root cause analysis, includes the patient or relative's account of events leading up to the incident.
- Provide patients/carers with information on how improvement plans from root cause analysis will be implemented and monitored.

5. Principle of professional support

For staff:

- Encourage reporting of incidents by all staff.
- Help staff feel supported throughout process as they may have been traumatised.
- Provide formal and informal debriefing of clinical team, separate from the requirement to provide statements for the investigation. Support your staff.
- Provide individual feedback on the final outcome of the investigation.
- Avoid disciplinary action and use the NPSA's Incident Decision Tree if suspension considered.
- Provide advice and training on managing incidents.
- Provide information on support systems for staff distressed by incidents e.g. counselling, stress management, mentoring. Include staff who lead discussions and the Being Open/Duty of Candour process.

For patients:

- Discuss, assess and meet individual needs of patients/carers for practical and emotional help and support.
- Provide information on services offered by relevant support agencies and community services.
- Identify a staff member to provide timely, practical and emotional support, maintaining an ongoing relationship with the patient.
- Provide contact details to patient/carers.

6. Principle of risk management and systems improvement

- Carry out Root Cause Analysis to uncover underlying causes of an incident.
- Focus on improving systems of care.

- Review the changes made to ensure they are effective.
- Share learning to all staff and report to Quality committee
- Serious risks should be entered on Risk Register.

7. Principle of multi-disciplinary responsibility

- Involve all staff who had key roles in patient's care in root cause analysis and investigation.
- Communicate findings throughout SELDOC at all levels.

8. Principle of clinical governance

- Investigate and analyse incidents that are moderate, severe or lead to death.
- Identify clear accountabilities from all levels, from Board level to all staff to ensure investigations, and action plans are implemented and the effectiveness of the process reviewed.
- Give information to health care staff on findings/learning from investigations.
- Audit the patient's experience of Being Open.
- Monitor the implementation and effects of changes following an incident.

9. Principle of confidentiality

- Details of an incident are confidential.
- Seek consent of individual before disclosing information to others.
- Need to know basis for communications outside the Quality team.
- Information Governance principles for records.
- Inform the patient/carers who will be undertaking the investigation before it takes place to allow them the opportunity to raise any objections.

10. Principle of continuity of care

- Continue giving patient all usual treatment, with compassion and respect.
- Make arrangements for alternative provision of care, if requested.

Appendix B - Duty of Candour Flow Diagram

1. Incident occurs – report as Complaint or Incident

2. Incident reviewed by DMD or MD and rated as Moderate/Severe Harm/Death → Duty of Candour applies
All other incidents causing harm apologise and explain

3. Agree how disclosure discussion will occur with patient – urgent preliminary Quality team discussion.
Involve MD or DMD as soon as possible.

4. Initial disclosure and apology
DO NOT DELAY – As soon as possible; must be within 10 days of incident being flagged within SELDOC.
Disclosure, apology, information and support. Given outline of investigation. If a complaint and SI – complaint is handled through SI investigation process.
Identify when/if patient or relatives would like to meet.

5. Record communication in health records
"Being Open – Duty of Candour" – Date, time, names present, issues apology, plan for further communication.

6. Maintain contact, as agreed with patient/family
On approval of investigation report – letter and summary sent to patient/family

Appendix C - Patient Issues – Being Open/Duty of Candour

The points below summarise action points from the NPSA Being Open document.

Patients who do not agree with the information provided:

- If the relationship with the healthcare professional breaks down, consider these strategies:
- Deal with the issue as soon as it emerges.
- Where patient agrees, involve carers in discussions from the start.
- Ensure access to support services.
- Provide alternative mechanisms for communication e.g. patient expressing concerns to other members of clinical team where senior health professional is unaware of difficulties.
- Offer a different contact person.
- Use a mutually acceptable mediator to help identify issues and solutions.
- Ensure awareness of formal complaints procedure.
- Write a comprehensive list of points disagreed upon.
- Reassure patient/carers you will follow these up.

Patients with different language or cultural considerations:

- Plan the need for translation and advocacy services and dealing with special cultural needs, e.g. cultures that make it difficult for a woman to talk to a male about intimate issues.
- Obtain advice from an advocate or translator before the meeting on a sensitive approach.
- Avoid using unofficial translators or the patient's family or friends.

Patients with different communication needs:

- Plans for meetings should consider particular communication difficulties e.g. hearing impairment.

If patient dies as result of incident:

- Maintain sensitive and empathetic communication.
- Involve bereaved in deciding when to discuss events.
- Provide emotional support.
- Open channels of communication so bereaved can indicate if they need counselling at any stage.
- Issue apology as soon as possible after patient's death, including an explanation that the coroner's process has been started. Include realistic timeframe for provision of more information.
- In most circumstances, have the meeting with the bereaved before the coroner's inquest. Also, conduct any investigation before the coroner's inquest.

Children affected by an incident:

- If possible, encourage children under 16 to be involved in decision making and in the Being Open process.
- Apply “Gillick competence” or Frazer guidelines.
- Provide opportunity for parents to be involved unless child asks for them not to be present.
- If children do not have sufficient maturity or ability to understand, provide information to parents, alone or in presence of the child, seek their views.

Patients with mental health issues:

- Follow normal procedures unless patient also has cognitive impairment or you are advised to withhold incident information by consultant psychiatrist. A second opinion by another consultant psychiatrist would be needed.
- Do not discuss incident information with a carer/relative without the express permission of patient (unless in exceptional circumstances).

Patients with cognitive impairment:

- Involve patients with cognitive impairment directly in communications about the incident, making an advocate available to assist in the communication process.
- Where patients have an authorised person to act on their behalf by lasting power of attorney, ensure this extends to decision making and the medical care and treatment of the patient. Hold discussions with the holder of power of attorney.
- If there is no such person, clinicians should act in patient’s best interests. They should decide who the appropriate person is with whom to discuss the incident. Discussion should take regard of patient’s welfare as a whole.

Patients with learning disabilities:

- If a patient has difficulty expressing their opinion verbally, assess whether they are also cognitively impaired.
- If they are not cognitively impaired, provide alternative communication methods (e.g. written questions) and agree with them appointment of an advocate.
- Ensure the patient’s views are considered and discussed.

Appendix D Being Open/Duty of Candour – Points to Consider

Includes communication, documentation and meeting requirements

Anyone involved in the process needs to read and use these practical guidelines and see www.npsa.nhs.uk/advice for further information.

1. Communication

- Open and effective communication with the patient and family is likely to include the following aspects:
- Early on identify and seek to meet patient's practical and emotional needs e.g. the names of people who can provide assistance and support to the patient (patient's consent would be required before information can be given).
- Any special restrictions on openness that the patient would like the healthcare team to respect.
- Identifying whether the patient does not want to know every aspect of what went wrong: respect their wishes and reassure them this information will be made available later on should they change their mind.
- Provide repeated opportunities for the patient and family to ask for information about the incident.
- Provide information in written and verbal form.
- Provide assurance that an ongoing care plan will be formulated with the patient.
- Facilitate inclusion of the patient's family in discussions, if the patient wishes.
- Information may need to be given more than once and at different times to allow the patient and family to understand.
- Ensure the patient's account of events leading up to the incident is fed into the incident investigation.
- Provide information on how improvements will be made as a result of learning from the incident.

Before the meeting, a Governance Quality Team discussion should be held as soon as possible after the event, including the most senior health professional involved. Basic plans should be made about role allocation and how patient needs will be met.

The timing of the Being Open discussion should be planned, holding it as soon as possible after the incident whilst considering relevant factors. An appropriate individual should be chosen to communicate with patients/carers and inform them about the incident. This should be a senior clinician, so either the Medical Directory or Deputy Medical Director. They should have the training and skills needed and be acceptable to those involved.

The Medical Directory or Deputy Medical Director leading the discussion should be able to nominate a colleague to assist them with the meeting. If it is clear the patient would rather speak to someone else, a substitute should be provided. Normally, the clinicians involved in the incident should not lead the Being Open process. If they ask to be involved, they should be accompanied and supported by a senior team member.

Where the incident relates to the environment of care (e.g. an injury), a senior manager of the relevant service should communicate with the patient/carers. The discussion should include a senior member of the multi-disciplinary team and the health care professional responsible for treating the injury.

Regarding incidents arising from errors by healthcare staff, the involvement of the staff involved must be considered individually balancing the needs of the patient/carers with those of the healthcare professional concerned. Guidelines are given on meeting both sets of needs and the use of written apologies.

The incident must be reported via the Trust incident reporting system. The NPSA are then notified through the National Reporting and Learning System (NRLS).

The patient's General Practitioner should be informed by the Medical Directory or Deputy Medical Director. The coroner should be informed of all cases of untimely, unexpected or unexplained death and suspected unnatural death. Involvement of the coroner should not prevent apologies where appropriate. Other statutory bodies may need to be informed.

2. The meeting

The content of the Being Open discussion should include:

- Those involved.
- Expressions of sympathy or regret or apologies.
- Handling the facts and when disagreement about them occurs.
- Understanding and noting the views of patients and carers.
- Appropriate language and terminology.
- Explaining what happens next in terms of treatment plan and incident analysis findings.
- Information on effects of the incident.
- Offering practical and emotional support.
- Recognising that patients/carers may be angry or frustrated.
- Avoiding speculation, attribution of blame, denial of responsibility and conflicting information.
- Arrangements for subsequent discussions.
- Copy of investigatory report, or significant incident report, may be offered once available.

3. Documentation

All staff managing Being Open meetings must be aware of the following document requirements:

- Copy of incident report or complaint and root cause analysis,
- A written record of all Being Open – Duty of Candour discussions/meetings is made in the patient records. "Being Open – Duty of Candour meeting" – heading in health records
- Date, time, place, date and name and relationships of all attendees
- Plan for providing further information to patient and family
- Offers of assistance and the patient's and family's response

- Questions raised by the patient and family/issues for consideration in the investigation
- Plans for follow up meetings
- Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and family
- Copies of letters sent to the patient and family and the GP for patient safety incidents.
- Written record of the discussions (a summary should be shared with the patient).

4. Preliminary Follow-Up

Follow-up discussions should be planned, carried out and recorded. These should occur at the earliest practical opportunity.

5. Completing the Process Feedback

This should be given in a form acceptable to the patient after completion of the incident investigation, usually through discussion. Communication should include a chronology, details of concerns and complaints, apology and any shortcomings, factors that contributed and what has been and will be done to prevent recurrence, with monitoring arrangements.

Arrangements for continuity of care need to be made and information should be given to patients on their clinical management plan. Reassurance should be given that the dispute will not affect their care and their right to continue their treatment elsewhere.

Communication with the GP and other community care service providers is required including a description of the implications of the incident.

An action plan should be made for monitoring the implementation of changes to prevent recurrence. This should be recorded with the complaint or incident file in SELDOC's Governance Quality Team management reporting system.

Changes as a result of learning must be communicated with staff. This is a vital step to prevent recurrence.