BrisDoc Patient care by people who care

NHS

Being Open – A duty to be candid.

Version:	Owner:	Created:
4	Clare-Louise Nicholls	1st September 2011
Published:	**Approving Director:**	**Next Review**
14/04/2025	Dr Kathy Ryan Medical Director	01/04/2025

Contents

1. PROCESS STATEMENT

The effect on patients, relatives, carers (relevant person(s)) and staff, when things go wrong, can be devastating. ‘Being Open- a duty to be candid’ outlines the principles that BrisDoc staff should use when communicating with relevant person(s) following a patient safety incident, complaint or claim where a patient was harmed. The term “relevant person” is now used with respect to the person(s) with whom duty of candour communications are held. ‘Being Open- a duty to be candid’ supports a culture of openness, honesty and transparency, and includes apologising and explaining what happened after reflection and with knowledge of all the facts. This policy incorporates Regulation 20 ‘Duty of Candour’, (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and reinforces the legal obligation to be open and honest in the event of an incident where patient harm has occurred. Although a rare event, when a clinically related incident occurs in which a patient suffers harm or dies, entering into an open dialogue with the patient, their carers or their representatives can significantly reduce the impact, stress and worry for all concerned. An essential part of handling patient related incidents effectively is following an established procedure of honest and open communication with them, their carers and/or their families. Staff providing health care have a legal and professional duty of candour to be open and transparent with patients when things go wrong. In line with BrisDoc’s Incident Policy, staff must report incidents, and as part of having an “open, strong culture for patient and staff safety” BrisDoc will ensure that staff are fully supported throughout any investigation and resolution. It is also the case that patients, family and staff can experience significant distress with “lesser impact” issues. The statutory duty of candour applies to notifiable safety incidents as set out in Regulation 20 (appendix 1). However, the importance of being open, honest and using sensitive communication is high irrespective of the “weight” of the case. Openness and honesty at the point of an incident occurring can help prevent all such events becoming complaints or litigation claims. This policy addresses BrisDoc’s response to the national best practice guidance regarding Being Open and legal duty of candour when a patient safety incident occurs, using the 10 principles underpinning ‘Being Open’ as supported by the National Patient Safety Agency (NPSA). These are (see appendix 2 for a full description):

The effects of harming a patient can have devastating emotional and physical consequences for relevant person(s). It can also be distressing for the professionals involved. Being open and honest about what happened; discussing the incident/complaint/potential claim fully, openly and compassionately can help the relevant person(s) cope better with the consequences of harm, whether potential or actual, in managing the event, and also in coping in the longer term. In addition, being open and candid when things go wrong ensures that the investigation gets to the root cause of the event and promotes individual and organisational learning. The purpose of this policy is to set out BrisDoc's standards and expectations for having an open and candid conversation in accordance with BrisDoc's values for patient, workforce and quality care. These standards are based on the guidance of the NPSA, and are intended to create an environment where patients, their representatives and staff feel supported, have the confidence to act in accordance with their duty, and for ensuring that all communications with relevant people are open, honest and occur as soon as possible after an event.

2. DEFINITION

Being open means to acknowledge, appropriately apologise and explain; and to record the incident including the investigation, lessons learnt and actions implemented that may help prevent the incident happening again. BrisDoc believes the active management of incidents (adverse events, patient safety incidents and near misses) through the timely and appropriate provision of information to those affected is an essential prerequisite to improving patient safety and the quality of health care systems. THE DUTY OF CANDOUR is a statutory (legal) duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused, or could lead to, significant harm in the future.

3. EXPECTATIONS

All healthcare professionals have a duty of candour – a professional responsibility to be honest with patients, colleagues and employers at all times and especially when things go wrong. BrisDoc expects its professional staff to honour this and will support them in exercising this duty. BrisDoc seeks to ensure it has a learning culture by reporting adverse incidents that lead to harm (or would have led to harm), as well as near misses, whether minor or major. However, any discussion with a relevant person regarding these matters must be arranged in conjunction with the relevant Deputy Medical Director and the Medical Director. Where there has been a patient death or serious harm, then a Deputy Medical Director or Medical Director will hold the

conversation unless there are exceptional circumstances. BrisDoc considers all professionals should set an example and encourage openness and honesty in reporting adverse incidents and near misses. Clinical leaders should actively foster a culture of learning and improvement. Through robust clinical audit, internal intelligence, complaints and incidents, and review of patient experience feedback, BrisDoc encourages early warnings of any failure, or potential failure, in the clinical performance of individuals or teams to be identified and remedied through support, learning, practice and process change. This process will include 1:1 line management/clinical supervision meetings, team meetings if appropriate, and if required through performance management in accordance with BrisDoc's policy for managing performance. For self-employed GPs the expectation of openness also applies and BrisDoc has separate avenues of support and performance management for this cohort. BrisDoc must notify its medical malpractice insurers of any circumstance of which BrisDoc is aware, or should reasonably have become aware, that may reasonably be expected to give rise to a claim where legal support may be required. This would potentially include any incident that triggers the threshold for the statutory duty of candour. Failure to do so could affect the validity of the insurance policy. Notification to NHS Resolution may also be appropriate and self-employed clinicians should be advised to notify their medical defence organisation.

4. RISKS AND BENEFITS OF A BEING OPEN PROCESS

Mistakes and errors can occur and the aim of following this policy is to assist relevant person(s) to acknowledge and, where possible, accept this;

• Helping relevant person(s) understand how and why a specific mistake or error took place;

• Helping to ensure that the communication procedure has been appropriate to the situation;

• Enhancing the clinician's understanding of how the incident affected the patient, their family and carer;

• Improving the clinician's ability to handle difficult situations effectively;

• Reducing the likelihood of a formal complaint and of costly legal action;

• Ensuring BrisDoc is able to fulfil its contractual and regulatory duty to report incidents that resulted in moderate harm, severe harm or death to patients.

• Ensuring relevant person(s) receive high quality care and a positive experience. The following elements should be part of implementing an effective Being Open Policy:

• BrisDoc staff and clinicians likely to be involved in investigating such incidents should have appropriate communication skills e.g. NVC, to ensure that they have the ability to act in a professional and effective way with the relevant person(s),

• The process itself has been carefully designed to incorporate a realistic response timeline (in accordance with duty of candour standards); an effective investigative, analysis, feedback and follow-up system; as well as appropriate counselling support should this be required,

• Guidance on the procedure to be followed is clear and all relevant BrisDoc staff and clinicians have been made familiar with its processes and understand its requirements,

• Effective working with BrisDoc's insurer to ensure there is no risk of prejudice to its indemnity cover. The relevant person(s) have confidence in the process because:

• It is fair, open and honest,

• An appropriate apology is offered as soon as it is practically possible to do so,

• The clinician(s) involved in the incident are actively involved in the discussions with the patient, their carer or their families,

• The concerns of the relevant person(s) are always respected and heard.

5. STEPS IN IMPLEMENTING A BEING OPEN PROCESS

A diagrammatic overview of the process is set out in appendix 3.

5.1 RECOGNISE AND REPORT THAT AN INCIDENT HAS OCCURRED AS SOON AS POSSIBLE.

Where the incident is categorised as a serious incident (SI) then the statutory duty of candour will most likely apply. If not an SI, then a judgement call should be made regarding contact with the relevant person(s). When BrisDoc management is advised of an incident through its reporting processes, or by a relevant person, it must be always be taken seriously, with all expressed concerns expressed being met and responded to with compassion and understanding, as well immediate action being taken to avert additional harm or such an event being repeated, if possible. Any additional required treatment should take place as soon as possible, after discussing the situation and, where needed, obtaining consent from the relevant person. If the incident relates to a third party, consent must be obtained before proceeding, unless the third party lacks capacity, in which case appropriate action should be taken.

5.2 CONDUCT A THOROUGH, IMPARTIAL INVESTIGATION INTO THE INCIDENT

As soon as possible after the incident, convene the appropriate team which could include a Service/Practice Manager, Lead GP, Lead Nurse, Governance Team member (involve all other relevant parties), to establish and record the known clinical and non-clinical facts in an impartial manner. An SI will be investigated using Root Cause Analysis methodology.

As part of the investigation consideration will be given to the following:

• the severity / scale of the incident and the appropriate level of immediate response by performing a risk assessment,

• allocating responsibility to the most suitable member of staff for being the point of contact with the relevant person and supporting them to arrange the initial discussion,

• deciding whether initiating third party patient liaison and support (who would identify the patient's needs and feed them back to BrisDoc Team) would be appropriate and helpful,

• ensure that BrisDoc staff involved in the incident are supported appropriately (section 5.5),

• in exceptional circumstances exclude the individual should the incident decision tree (appendix 4) and risk assessment indicate this (exclusion is a neutral act that keeps the person and others free from further harm).

5.3 HOLD AN INITIAL DISCUSSION WITH THE PATIENT AND FAMILY – THE FIRST STAGE IN THE COMMUNICATION PROCESS

• Liaise with the relevant person to ensure the initial discussion takes place, via a medium of the person's choice and within relevant covid guidance, as soon as possible (and within 10 working days of the incident), at a mutually convenient time, at a suitable venue, with convenient access and where privacy is assured,

• This should be led by the senior nominated staff member, but other BrisDoc staff can attend if relevant. If this is the case, before the discussion takes place, ensure the relevant person know the identity and role of all people who propose to attend, and encourage them to state their own preferences about which staff they would prefer to be present, or not,

• The discussion should be delivered at a level that is clearly understood by the relevant person(s), avoiding jargon and using appropriate lay rather than medical terminology, • It should be a truthful, factual explanation of exactly what happened.

• Any areas where events are unclear should be identified and an undertaking given to explore and clarify them, • Explain what is likely to happen next, both in the investigation and any treatment plan, • Confirm that they will be kept up to date as the investigation progresses and new information comes to light. Advise them of the name of BrisDoc member of staff who will do this.

• Explain the probable short (and long-term effects if known at this time) of the incident. This is especially important if the incident has resulted in death as the procedure(s) to identify the causes of death will probably need to be fully explained,

• Treat the relevant person(s) with respect, compassion and consideration. Ensure that their views are taken into account and try to ascertain any expectations they have from the resolution process,

• Consider offering the relevant person appropriate additional support (e.g. help from charities or voluntary organisations, or bereavement counselling in the event of a death), as well as more direct assistance,

• Offer genuine empathy and make a face-to-face (or telephone apology if appropriate and if the relevant person has specified, they do not wish to meet face to face).

• The content of the apology should be carefully considered beforehand, documented and may be discussed with the indemnity insurer before being given,

• Ideally the apology will be made by the most senior person actively involved in the patient's care (or alternatively someone with experience of this type of incident) as they are known and trusted, and best placed to maintain a relationship with the relevant person,

• The duty of candour specifies that a face to face apology is made (although note previous point) and this should be followed up with a written apology, reiterating the conversation and explaining the next steps. If a face-to-face apology is not possible, the relevant person must be contacted and asked how they would like to proceed,

• Make accurate and comprehensive written records of the initial and any subsequent discussions including the details discussed, questions and answers, offers of assistance, plans for follow-up and feedback. Provide copies to all the relevant person(s) ensuring the language used meets lay understanding,

5.3.1 SPECIAL CONSIDERATIONS

Patients who do not wish to participate or who disagree with the information provided.

Sometimes, despite the best efforts of staff, the relationship between the relevant person(s) and the healthcare professional is difficult or breaks down altogether. They may not accept the information provided, may desire a higher level of investigation or may not wish to participate in the process. In this case, the following strategies may assist:

• Make prompt contact after the incident;

• where the relevant person(s) consents, ensure their family and carers are involved in discussions from the beginning;

• write a comprehensive list of the points that the relevant person(s) disagree with and reassure them you will follow up these issues.

• offer the relevant person(s) 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 relevant person(s) are fully aware of the formal complaints procedures. The incident may impact on relevant person(s) to such an extent that relations between the two parties may be strained or may collapse; they may decline to take part in any discussion. Should this situation arise:

• Try to resolve it as soon as possible;

• Offer access to support services;

• Consider an alternative member of the healthcare team with whom they may feel more comfortable;

• Consider a postponement of the discussion;

• Consider using an impartial, suitably qualified person to act as a mediator;

• Prepare a comprehensive list of the points of disagreement and reassure the patient these will be followed up;

• Document that BrisDoc has carried out its statutory duty as far as was possible

• Ensure you provide details of the NHS complaints procedure, including PALS, Independent Health Complaints Advocacy services e.g. The Advocacy People, should the relevant person wish to complain.

Making a complaint - The NHS in England- NHS Choices

http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx

Young people

A young person aged 16years or above has reached the legal age of maturity to give consent to treatment. They may therefore be seen alone. If such a young person has learning disability, then this usual “rule of thumb” should be considered and amended if necessary. Good practice would involve parents/carer/guardians with the young person’s consent.

People with mental ill-health problems

Where a Consultant Psychiatrist advises it would cause adverse psychological harm to inform a relevant person(s) with mental illness about a clinical safety incident it may be appropriate to withhold that information. It is advisable to obtain a second opinion to justify withholding the information. In these circumstances it is not usually appropriate to inform a carer/relative as to do so would require the patient’s express consent The Mental Capacity Act should be followed and a capacity assessment undertaken as required.

People who lack capacity

Where a relevant person(s) lacks the mental capacity to make a decision regarding their care or treatment the person acting lawfully on the patient’s behalf must be notified of patient safety incident that triggers the duty of candour. Where possible the patient should also be involved in this discussion. An advocate with appropriate skills should be used to assist the patient in the communication process. This may be a family member or Independent Mental Capacity Advocate (IMCA). Some patients may have authorised a person to act on their behalf as a lasting power of attorney. In these cases, steps must be taken to clarify the extent of this authority and the Being Open discussion would be held with the holder of the power of attorney. This person would be the relevant person with regard to the Duty of Candour requirements. Where there is no such person staff may act in the patient’s best interest in deciding who the appropriate person is to discuss information with, regarding the welfare of the patient as a whole and not simply their medical interests.

Translation and Communication Needs

The need for translation services will be met for any relevant person(s) where English is limited and formal translation support is considered appropriate. Plans for a meeting should carefully consider any communication difficulties, and appropriate measures taken or support put in place, to enable or enhance communication that meets people’s needs.

Cultural needs

Cultural needs will be taken into consideration where feasible, for example, where it may be difficult for a woman to discuss certain issues with a male member of staff. 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’ (which includes family/friends etc.) as they may distort information by editing what is communicated.

Bereavement

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 where appropriate. Sincere condolences should always be offered. The emotional state of bereaved relevant person(s) will be taken into consideration when deciding when and how to

discuss and review an incident. They will be involved in deciding when this might appropriately take place. Ensuring open communication with the relatives may allow for the identification of emotional support needs. In cases in which the coroner is involved, the aim will be to have a discussion and investigation before a Coroner's Inquest, whilst noting the coroner's report on post-mortem findings is a key source of information that will help complete the picture of events leading up to the patient's death. In some circumstances it may be appropriate to wait until after the coroner reports to hold a discussion. It is important to explain that they will be kept informed as information is released from the coroner's office. The relatives/carer may be supported to access the Coroner's Office.

5.4 AN APOLOGY

Apologising to a relevant person(s) does not mean that legal liability for clinical negligence is being admitted. This is set out in legislation in parts of the UK (Compensation Act 2006). NHS Resolution also advises that saying sorry is the right thing to do. Extending an apology does not mean that person is taking personal responsibility for something going wrong that was not their fault e.g. a system error or a colleague's mistake. However, the apology must not be a legal admission of negligence and therefore needs to be planned as set out in 5.3.

An apology needs to include:

• what happened,

• what can be done to deal with any harm caused,

• what will be done to prevent someone else being harmed.

5.5 PROVIDING SUPPORT TO BRISDOC STAFF

As well as supporting the relevant person(s), it is essential that BrisDoc staff are themselves actively supported throughout the investigation, because they may be suffering conditions such as stress/anxiety as a result of the incident. Where applicable, staff may be offered external counselling support and/or occupational health advice in addition to supportive meetings with their Line Manager and/or HR. In cases in which the staff involved are self-employed, the senior nominated manager will make a judgement about ongoing support for that individual.

BrisDoc will operate an open culture where staff feel able to:

• Receive and report patient safety incidents without undue worry,

• Be accountable for their actions,

• Discuss an incident they have been involved in with colleagues (whilst considering confidentiality requirements).

If disciplinary action is deemed necessary, BrisDoc's Disciplinary Policy & Procedure (available on the intranet) should be invoked. If the member of staff's action is proved and gross misconduct is concluded, summary dismissal may arise. In instances where there is sufficient reason to consider that a member of staff might have committed a criminal act, BrisDoc should offer support by advising them of the possibility as soon as possible, to enable them to source and arrange independent legal advice / representation. Police advice should be sought and insurers should be informed.

5.6 GOING FORWARD - REDUCE RISK AND IMPROVE SYSTEMS

After an incident that triggers the duty of candour has been identified and necessary short-term action taken to rectify the problem, BrisDoc will:

• Undertake a root cause analysis to determine the extent of the problem and influencing factors that will enable the identification of remedial solutions, the implementation of which will ensure the risk of the incident recurring is removed or reduced,

• Consider using the support of clinical governance frameworks through which patient safety incidents can be investigated and analysed,

• Record and formalise all necessary procedural changes and ensure relevant staff undergo appropriate training to meet the knowledge gaps identified, so that they are competent to implement them,

• Advise the relevant person(s) when staff training has been completed and the revised system is operational.

5.7 ENSURE COMPLIANCE WITH GDPR AND DPA 2018

The “Being Open” Policy should comply with both the relevant person(s) rights, and BrisDoc staff rights, to privacy and confidentiality. As the details of every medical related incident in which a patient suffers harm or dies should be considered as confidential, the consent of the person concerned should be obtained prior to disclosing identifiable information to clinician(s) other than those directly involved in treating the patient or in the investigation.

BrisDoc policies for confidentiality of patient data apply.

5.8 CONTINUITY OF CARE

If the incident occurs within a BrisDoc GP practice and results in a patient expressing a preference for any future healthcare need to be managed by a different person within BrisDoc, or indeed at a completely separate GP Practice, BrisDoc will be responsible for making the appropriate arrangements to facilitate this request and to ensure that the patient continues to receive all their usual treatment without interruption in so far as it can.

6. EXTERNAL REPORTING

In addition to the internal reporting of incidents that caused, or had the potential to cause harm there may be a requirement to report to an external body. For example:

• Suspect adverse drug reaction to the UK-wide yellow card scheme run by the medicines and Healthcare Products Regulatory Agency (MHRA),

• Medical devices to the MHRA,

• Care Quality Commission,

• National Reporting and Learning System,

• Relevant Commissioner.

7. RELATED POLICIES

Complaints Procedure

Disciplinary Policy & Procedure

Incident Reporting Policy

Data Protection, Confidentiality and Disclosure Policy

Consent Policy Audit Framework

8. Change register

Date	Reviewed and amended by	Revision details	Issue number
27/11/13	CLN	Change of author, change to reflect root cause analysis, updated for new role titles, equality and diversity inclusion.	1
29/3/17	CLN, GW	Updated CQC standards, values slide, related policy list. Change ICAS to SEAP. Change policy Director owner to Medical Director and change reviewer from Project Manager to Head of Out of Hours. Inclusion of expectations of professionals, a definition of an apology, external reporting. Inclusion of the need to liaise with BrisDoc's indemnity insurance provider. Inclusion of diagrams/tools from the NPSA/NRLS.	2
05/01/2021	CLN	Change language throughout to relevant persons, map to new policy template, change SEAP to The Advocacy People, and incorporate policy recommendations from CNA. Addition of appendix 1.	