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Guide for adult patients and their families about investigations of unexpected events and incidents

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This leaflet has been written for adult patients and their families who have been involved in an unexpected event or incident. For most people who use our services, things go well and they receive the best treatment we can offer in a way that meets or exceeds their expectations. However, sometimes unexpected events happen and unfortunately sometimes things do not go to plan.

We cannot always prevent unexpected events or things going wrong even though we do everything possible to ensure the safety of our patients. It is important we can still learn from looking at these events and incidents, including identifying good practice that can be shared across the organisation.

This guide is designed to give you some basic information about each of the processes used to look at such unexpected events or incidents.

There are some processes that will always take place and some that will happen only in specific circumstances. There can also be some occasions where more than one process happens at the same time.

What do we mean by an unexpected event?

Provision of healthcare often involves a balance of risks and benefits of one kind of treatment or another, or indeed doing nothing. When you need to make a decision about whether or not to have a particular treatment offered, the risks and benefits will be explained to you. If formal consent is required for a particular treatment such as an operation, the main risks will be documented on a consent form which is signed by the patient and medical professional explaining the treatment.

A risk is simply something that might happen in the course of an action. For example: for operations which involve making a cut in the skin, we know that there is a risk of bleeding and infection because a hole in the skin's protective barrier and underlying tissues is made. How big the risk is will depend on the type of operation and the individual patient. In many, but not all, cases we know that there are steps that can be taken which are effective in reducing risks and which form a routine part of healthcare provision.

If one of these risks happens to you or your family, this can be what is called a "known complication" of the procedure, and therefore may not be considered "unexpected". The difference between a "known complication" and an unexpected event or incident is not always easy to determine.

This guide includes information on how we look at unexpected events and "known complications".

What do we mean by an incident?

A patient safety incident is something unexpected or unintended that happened during yours or a member of your family's care or treatment which could have or did cause harm.

Sometimes we miss an opportunity to stop an incident occurring, and we need to learn from this.

Sometimes someone simply makes a mistake. We need to understand why this happened and act on our findings to reduce the risk of it happening again.

Sometimes when something goes wrong, this can cause serious harm to you or a member of your family. An incident causing serious harm is one example of what is called a serious incident.

The guide includes information on how we investigate patient safety incidents.

What happens when someone has died?

The death of someone, even if expected, can be a very distressing and difficult time for family and loved ones. Sometimes a death is likely or inevitable due to a patient's medical condition, advanced illness or frailty. Sometimes, it is tragically sudden and unexpected. On occasions a death may be related to an incident or known complication.

This guide includes information about how we review all adult deaths and investigate further and when other processes such as a Coroner's inquest is to take place.

Being open

The need to be open and honest with patients and families goes without question, even if something has gone wrong, and is a requirement of all healthcare professionals. We are committed to this principle in all aspects of the care we provide. We would like to share information with you as much as you want to know and respect that you may not want to know certain things. In our experience, people may be ready to ask for or be given information at different times after something has happened, particularly if there has been a bereavement, and we will do our best to respond to your needs.

Incident investigations

Who is responsible for this process?

The hospital is responsible for reporting and investigating incidents in a way that is set out by NHS Improvement. It is a requirement that incidents are investigated by someone outside of the team directly caring for the patient and to obtain independent opinions or ask for an independent investigation external to the Trust where required. We are also required to report incidents to the Care Quality Commission, our regulator, and to report certain kinds of incidents to other external bodies. We are held to account by NHS England or the relevant Clinical Commissioning Group for the objectivity and robustness of our investigations.

Why are incidents reported and investigated?

Patient safety incidents are reported by staff so we know when things have gone wrong or the quality of care provided did not meet our standards and expectations.

They are investigated:

- to find out what happened and why
- to make improvements to stop them happening again
- so we can share this information with you if you want to know
- to look for patterns that may alert us to a wider problem.

If an incident involves a death, the investigation is not designed to establish the cause of death but may include reviewing events surrounding the death.

Duty of candour

Duty of candour is a specific requirement for 'being open' about patient safety incidents. We strive to tell patients and their families when things haven't gone to plan and will give an honest account of the facts as we know them. We will apologise for what happened and how this affected the person or people involved. It is now a statutory requirement for us to tell you if you have been involved in certain kinds of patient safety incidents.

What can I initially expect under being open/duty of candour?

If you have been involved in a patient safety incident that has resulted in moderate harm (or a more serious level of harm), you can expect:

- to be told as soon as possible when we know the incident has happened
- to receive an apology in writing

- to be given an explanation about any enquiries and investigations we will make
- to be offered a written and truthful account of the incident
- to be offered reasonable support if you were directly affected by the incident
- giving feedback on your experience of the incident investigation process

How will the incident be investigated?

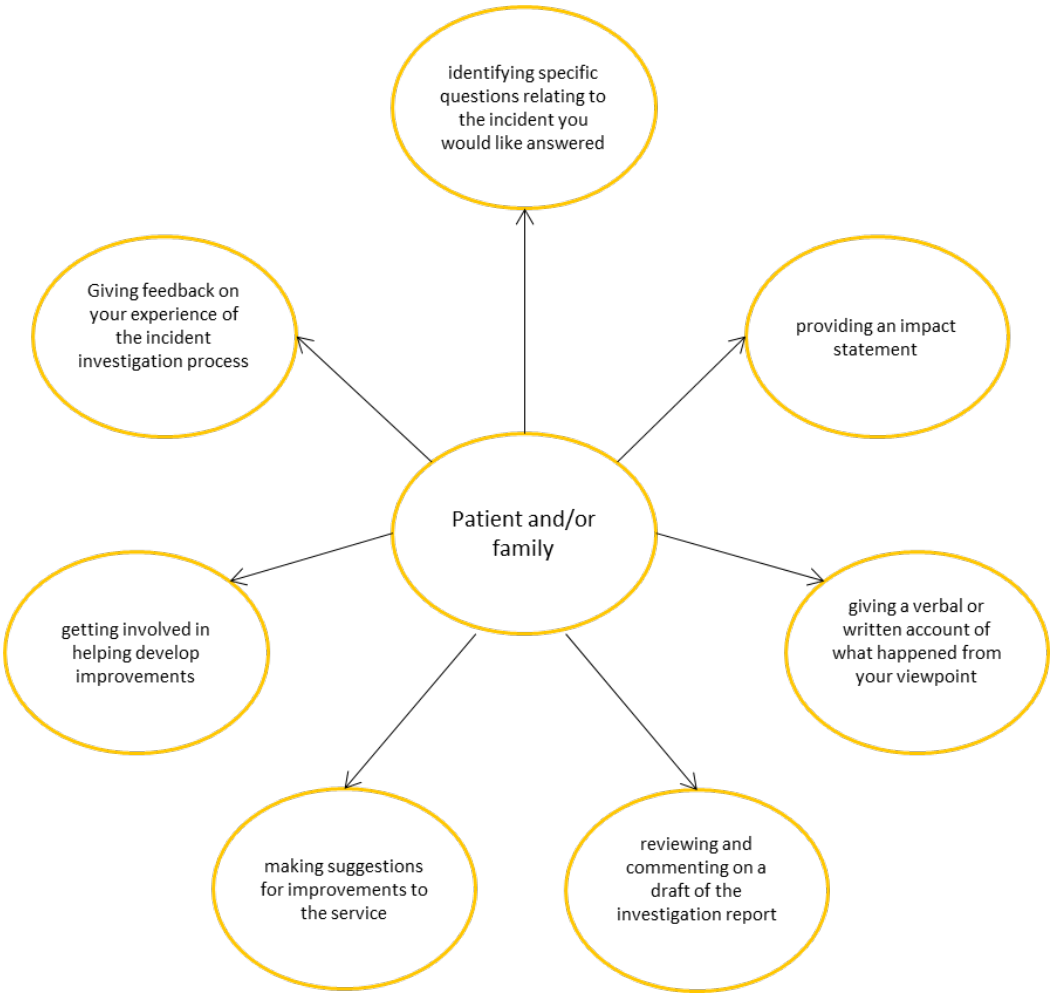
In some cases it is clear what happened from an initial review of the facts and any improvements needed can be quickly put into place. Some incidents are complicated and need a more detailed investigation. For these incidents, there is an identified lead investigator who will have received training to undertake incident investigations (sometimes called a root cause analysis). The lead investigator will work with a small team to establish the facts and understand what happened. They will produce a written report of the investigation findings and make recommendations for improvements.

Detailed incident investigations usually take several weeks to investigate thoroughly, and can take several months. In a few cases, the investigation may find that there is no direct cause as to what went wrong, despite having all the appropriate information.

What if I want to be more involved in the investigation of an incident that affected me or my family member?

You can chose to be more involved in an incident investigation in a number of ways. If you are a family member of an adult patient, you will need the consent of the patient concerned

to become involved in the investigation on their behalf. If the person involved in the incident has died, their next of kin should provide consent. If an adult involved in the incident does not have capacity to consent, we will follow the requirements of the Mental Capacity Act. If you want to, you could contribute to an investigation by:



We will support you to be able to contribute in one or more of the ways outlined above if you want us to.

What can I expect during or after an investigation?

The team completing the investigation will remain in touch with you throughout this process and once complete will ask to meet with you to give detailed feedback, unless you do not want this. You will be given a copy of the report to take away with you at this meeting.

Root Cause Analysis investigations are a well-recognised tool for investigations of this type, they are designed as a learning tool around a particular event and are shared with external organisations such as the local commissioners, NHS England and Public Health Wales and so the tone and the language used can feel somewhat impersonal. For example your relative will be referred to anonymously throughout; hence we understand that these reports can be distressing for you or your family to read. Also it is helpful for us to explain any complex and technical aspects of the report which are sometimes difficult to get across in writing and may sound worrying and cause you further unnecessary distress. For this reason we always give an open ended offer of feedback and support following sharing the report.

You may wish to receive the report before a meeting to give you time to read it in advance or you may wish to just receive the report and not meet with the investigation team. We do not recommend this for the reasons outlined above but will respect your wishes if that is what you want.

What support is available for patients and families?

If you have any worries or questions about what happened, please ask your doctor, nurse or other relevant healthcare professional to give you the information you need in the first

instance. If you need further support, the contact details of our patient support and complaints team (adult patients) and LIAISE service (child patients) are at the end of this guide.

What happens to the staff involved in the incident?

It is common for staff involved in an incident to be affected by what happened and to need extra support from their managers or other sources. Most incident investigations show that unintended flaws in systems and processes have caused or contributed to the incident or staff made a genuine mistake through no fault of their own and did not intend to cause harm. We use a widely recognised systematic tool to identify if there is any individual culpability for what happened and will take action under our human resources policies where necessary.

Where can I get more information?

You can talk to your doctor or nurse in the first instance. If you would prefer to talk to someone not involved in your care, we can give you the details of a member of the patient safety team or a member of the investigation team. You can write their details in the space at the end of this booklet.

Reviewing unexpected events and known complications

Who is responsible for this process?

Teams of doctors and nurses and other healthcare professionals in our hospitals are responsible for reviewing the individual care of patients which has included an unexpected event or known complication. This happens in what is called a Mortality and Morbidity meeting.

What is the purpose of this process?

The purpose of this process is similar to that for incidents, to learn and make improvements so we can provide better care in the future.

Sometimes an incident will be identified and reported through this process and will follow the incident investigations process described in this guide.

We also use quality intelligence information about complications and unexpected events to look for patterns and conduct further investigations if we need to.

Mortality (death) review

Who is responsible for this process?

The hospital is responsible for reviewing deaths of adult patients. Some deaths will meet the criteria for involvement of the coroner as set out in the 'Coroner's inquest' section of this guide. From April 2017 we have started a new and improved adult mortality review process in accordance with guidance from NHS England and the Royal College of Physicians.

When does this happen?

This process applies to deaths of adult patients which meet the criteria within the guidance from NHS England such as: all sudden or unexpected deaths, deaths in patients with learning disabilities or on-going mental health problems and deaths associated with a planned admission, along with a sample of other deaths.

For 16 and 17 year olds, who may be treated in our adult services, a separate Child Death Review Process applies to all such patients. There is a further guide available for deaths involving children and those under the age of 18 years.

What is the purpose of this process?

The purpose of this process is similar to that for incidents. The aim is to identify themes where the organisation could improve, as well as identifying areas of good practice. The process will involve initial screening of the healthcare records of adult in-patients who have died followed by a senior clinician reviewing the case notes of a subset of these patients as in the examples mentioned above.

Sometimes an incident will be identified and reported through this process and will follow the incident investigations process described in this guide.

Coroner's inquest

When does this happen?

The law in England and Wales requires a coroner to hold an inquest into any death which is considered to be sudden, violent or unnatural. An inquest will also be held where, after an initial investigation, including a post-mortem examination, the cause of death is still unknown. Inquests must also be held when a person dies in state detention (this includes people who die in prison, police custody or if they are detained in hospital under the provisions of the Mental Health Act).

What is the purpose of this process?

An inquest is a legal investigation to establish who the deceased was, as well as when, where and how the death occurred.

Unlike criminal trials or civil cases, inquests do not apportion blame or try to establish whether anyone was responsible for a person's death. Evidence is presented either through written documents, or sometimes witnesses are called to explain issues

to the coroner, but there is no prosecution or defence.

After a death family members can have many questions. It is important to note that the scope of the inquest is limited and the coroner will only look into issues which he or she considers are directly linked to the death.

The involvement of the family

When an inquest is held, the coroner must inform the deceased's family. This is usually the partner or nearest relative. It is usually helpful to the coroner if the family nominate one person through whom all communication should be conducted.

Who is responsible for this process?

This process is entirely managed by the coroner who is responsible for the area in which the person died. Occasionally an inquest will be transferred to another coroner if, for example, the person died in hospital but the incident giving rise to the death occurred in a different part of the country. However this is not a common occurrence and inquests in Bristol are usually managed by the Avon Coroner (see on page 14 for contact details).

The coroner is responsible for deciding whether there needs to be an inquest, what evidence needs to be gathered and who, if anyone, is to be called to the inquest. The coroner will seek the views and involve the family in the process.

How long does this process take?

Changes in the law governing inquests expects coroners to conclude inquests within six months of the date of death, and indeed when the coroner opens the inquest a provisional date will be given for the final inquest to be heard. Some inquests, however, including on occasion those involving

deaths in hospital can require more detailed investigations and in these circumstances the time scale can extend beyond that. The coroner's office will keep the family fully informed of developments and progress.

The coroner will normally wait until any other investigations, including internal hospital investigations, health and safety investigations and police investigations have been concluded before holding the inquest. It is suggested that families fully engage with these other processes because they may address issues that the coroner will not cover in the inquest.

The length of the inquest itself will depend on the type and volume of evidence the coroner wishes to hear. Some inquests where no witnesses are called, may last no more than 30 minutes. Others can run into hours or days.

Where do I go for more information on this process?

More information about the process is available online at https://www.gov.uk/after-a-death/overview.

The Avon Coroner's Court is extremely helpful and can be contacted for more information on 01275 461920.

If the inquest is being managed in a different area you can find contact details through the local authority website for that area.

Safeguarding Serious Case Review for an adult

When does this happen?

This may happen if an adult (with additional care and support needs), has died, has suffered or thought to have suffered significant harm, and there are concerns about the way in which agencies have worked together. This may also include Domestic Homicide Reviews.

What is the purpose of this process?

The main purpose of a case review is for agencies and individuals to learn lessons to improve the way they work together to safeguard and promote the welfare of children and adults.

Who is responsible for this process?

Serious Case Reviews are part of a national process led by the Local Safeguarding Adult Board. Any professional or agency may refer a case to the Local Safeguarding Board if they believe there are important lessons to be learnt from the case.

The decision to conduct a serious case review should be made within one month of the notification of the incident. The Local Safeguarding Board must notify the national panel of independent experts and Ofsted of this decision.

How does the serious case review take place?

The Local Safeguarding Board should appoint one or more reviewers to lead the Serious Case Review. The lead reviewer must be independent of the Local Safeguarding Board and any organisations involved with the case.

The Local Safeguarding Board should make sure there is appropriate representation from the different professionals and organisations who were involved with the patient and the family. The Local Safeguarding Board may decide to ask them to give written information or may talk to them directly about their involvement with the patient.

How long does this process take?

The Local Safeguarding Board should aim to complete a safeguarding adult review within six months of the date of

death. The final report, and the Local Safeguarding Board's response to the findings, must be published on the Local Safeguarding Board's website for a minimum of 12 months and should be available on request. This is important for sharing lessons learnt and good practice in writing and publishing safeguarding adult reviews.

Where do I go for more information on this process?

Detailed information about the process will be available on the Local Safeguarding Board websites. You can find out more about this process by contacting your Local Safeguarding Board via your local authority. In some circumstances, an unexpected event investigation may form part of a Local Authority Safeguarding investigation. If so, Bristol City Council Safeguarding Adults team would be the contact for further information regarding their involvement.

What if I have more general concerns?

If you have wider questions about your relatives or your care or are looking for additional guidance or support, please see further contacts below.

Useful contacts

For adults: the Patient Support and Complaints Team:

- Call on 0117 342 1050 (confidential voicemail)
- Email psct@uhbristol.nhs.uk
- Call in at our office in the Welcome Centre at the front of the Bristol Royal Infirmary between 9.00am and 4.30pm, Monday to Thursday, and 9.00am to 3:30pm on Fridays.

For children: the LIAISE family support team

- Call on 0117 342 8065 (confidential voicemail)
- Email bchinfo@uhbristol.nhs.uk
- Drop in to the Family Information Room, Level 2 of the Bristol Royal Hospital for Children.

Notes and queries

Notes and queries

Please note that if for any reason you would value a second opinion concerning your diagnosis or treatment, you are entirely within your rights to request this.

The first step would usually be to discuss this with the doctor or other lead clinician who is responsible for your care.

As well as providing clinical care, our Trust has an important role in research. This allows us to discover new and improved ways of treating patients.

While under our care, you may be invited to take part in research. To find out more please visit:
www.uhbristol.nhs.uk/research-innovation
or call the research and innovation team on
0117 342 0233.

For access to other patient leaflets and information please go to the following address:

www.uhbristol.nhs.uk/patients-and-visitors/information-for-patients/.

Hospital Switchboard: 0117 923 0000

Minicom: 0117 934 9869

www.uhbristol.nhs.uk

For an interpreter or signer please contact the telephone number on your appointment letter.

For this leaflet in large print, audio or PDF format, please call the patient information service:
0117 342 3728 / 3725

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Statutory Duty of Candour

Professional Context:

"Good medical practice" and the "Code of Conduct for nurses and midwives" both say that doctors, nurses and midwives must:

- be open and honest with patients if something goes wrong with their care
- act immediately to put matters right if that is possible
- promptly explain to patients what has gone wrong and the likely long-term and short-term effects.

Why introduce a Statutory Duty of Candour ?

The Mid Staffordshire public inquiry identified the principles of openness, transparency and candour as the cornerstone of healthcare.

In his report, Sir Robert Francis QC acknowledged that doctors and nurses are required by their professional bodies to be open with patients. But he stated clearly that the current requirements for candour are not enough.

- They do not adequately cover the necessary areas: ‘individual clinical and managerial professionals, provider organisations and their collective leadership, in the NHS and the private sector, commissioners, regulators and political leaders’.

- The ways in which the requirement is currently recognised are ‘piecemeal and disjointed’.

The Department of Health (England's) response to the recommendations in the Francis report:

- *'the General Medical Council and the Nursing and Midwifery Council will be working with the other regulators to agree consistent approaches to candour and reporting of errors, including a common responsibility across doctors and nurses and other health professions to be candid with patients when mistakes occur whether serious or not'*

- As well as working with the other healthcare regulators on the joint statement, the GMC and NMC have been jointly developing guidance that expands on the advice given in "Good medical practice" and "the Code". The draft guidance can be found here.

What is a Duty of Candour?

There is a general duty on all health service bodies and registered healthcare professionals to act in an open and transparent way in relation to the care and treatment provided to service users. This will apply at all times.

When a service is meeting the Duty of Candour our patients should expect:

- A culture within the service that is open and honest at all levels.
- To be told in a timely manner when certain safety incidents have happened.
- To receive a written and truthful account of the incident and an explanation about any enquiries and investigations that the service will make.
- To receive an apology in writing.
- Reasonable support if they were directly affected by the incident.

What are the existing requirements for Duty of Candour?

If a patient is involved in an incident which causes moderate or severe harm, a senior clinician should:

1. Inform the patient (or family), ideally face to face, within 10 working days
2. Provide an appropriate apology
3. Impart the facts as know at the time
4. Ask the patient (or family) if they want any specific questions answered as part of the investigation.
5. Offer them a written outcome of any further investigation
6. Document all of the discussion in the patient's notes
7. Follow through the patient's (or family's) wishes as discussed using templates on Connect.

What do we need to do to comply with statutory Duty of Candour?

The organisational duty of candour does not apply to individuals, but organisations providing healthcare are expected to implement the new duty throughout their organisation by ensuring that staff understand the duty and are appropriately trained.

What does statutory duty of candour mean in practice?

"*…as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred*" a health service body must notify the "*relevant person*" that that the incident has occurred.

What is a notifiable safety incident?

In respect of NHS bodies, a "*notifiable safety incident*" means any "*unintended or unexpected incident that occurred in respect of a service user during the provision of regulated activity that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in:*

- *Death*
- *Severe harm*
- *Moderate harm*
- *Prolonged psychological harm*

What is the definition of severe harm and death?

- **Severe harm** is defined as "*a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb, or organ or brain damage*."
- The definitions for both death and severe harm are qualified in that they only apply to the extent that the death or severe harm is "*related directly to the incident rather than the natural course of the service user's illness or underlying condition*."

What is the definition of moderate harm?

Moderate harm is defined as "*harm that requires a moderate increase in treatment; and significant, but not permanent, harm.*" A moderate increase in treatment includes:

- An unplanned return to surgery
- An unplanned re-admission
- A prolonged episode of care
- Extra time in hospital or as an outpatient
- Cancelling of treatment
- Transfer to another area such as intensive care

Moderate harm is not qualified in the same way as severe harm in terms of having to be "related directly to the incident" and could cover recognised complications if they are "unintended or unexpected".

What is the definition of prolonged psychological harm?

The definition of prolonged psychological harm is also limited, being taken from the Care Quality Commission (Registration) Regulations 2009:

"*psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days*.''

What are my individual professional responsibilities for informing the patient?

It is recognised that care is often provided by multidisciplinary teams and that you may be one of several healthcare professionals involved in a patient's care. We would not expect every member of a healthcare team to talk to the patient.

- But you must make sure that an appropriate person – usually the lead or accountable clinician –takes responsibility for speaking to the patient or those close to them if something goes wrong.
- This should include as much or as little information as the relevant person wants to hear, be jargon free and explain any complicated terms.
- The account of the facts must be given in a manner that the relevant person can understand. For example, you should consider whether interpreters, advocates, communication aids etc. should be used
- You must also explain to the patient/relative what further enquires you will make.

What are my individual professional responsibilities regarding an apology?

- You must ensure that a meaningful apology is given, in person, by one or more appropriate representatives of the provider to relevant persons. An apology is defined as an expression of sorrow or regret.

- The NHS Litigation Authority has produced guidance on making an apology, which states that saying sorry is not an admission of legal liability Being Open framework

- In making a decision about who is most appropriate to provide the notification and/or apology, the provider should consider seniority, relationship to the person using the service, and experience and expertise in the type of notifiable incident that has occurred.

What are my individual professional responsibilities to follow up initial action?

- You must ensure the patient/family are given all reasonable support necessary to help overcome the physical, psychological and emotional impact of the incident.
- You must ensure that written notification is given to the patient/family following the notification that was given in person, even though enquiries may not yet be complete(draft letter template on Connect)
- The written notification must contain all the information that was provided in person including an apology, as well as the results of any enquiries that have been made since the notification in person.

What are my individual professional responsibilities to follow up initial action?

- The outcomes or results of any further enquiries and investigations must also be provided in writing to the patient/family through further written notifications, should they wish to receive them.
- You must keep written records (in the patient's notes) of all verbal and written correspondence that relates to compliance with duty of candour

What if you can't contact the patient, or they do not want to communicate or have died?

- You must make every reasonable attempt to contact the patient/family through all available communication means. All attempts to contact the relevant person must be documented.
- If the patient/family does not wish to communicate with a representative of the Trust, their wishes must be respected and a record of this must be kept.
- If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.

What happens if we don't comply?

- From mid-November 2014 it will be a criminal offence not to notify a service user of a notifiable safety incident or to fail to meet the requirements for such a notification. If the organisation is found guilty of the offence, they will be liable, on conviction, to a fine not exceeding £2,500.

- However, if the registered* person can prove that they took all appropriate steps and exercised all due diligence to ensure that they complied with the duty, this will be a defence. A fixed penalty notice of £1,250 may be offered by the CQC as an alternative to prosecution.

*The registered person in this context is the accountable person named on the Trust's registration with the Care Quality Commission.

How does this work in practice over and above existing requirements?

Key issues:

- In relation to “unintended or unexpected known complications” there may be a need for a change in culture to report such complications as incidents and being open with patients when these cause moderate or severe harm or death.
- More inclusion of patients/families in incident investigations if they wish to be
- Importance of documentary evidence of compliance with Duty of Candour in the patient’s notes (including unsuccessful attempts to make contact).

What help is available?

- Draft joint professional guidance from the GMC and NMC is here

http://www.gmc-uk.org/Openness_and_honesty___Draft_guidance.pdf_58423740.pdf

- Basic letter template on Connect to follow up initial verbal disclosure of an incident /unintended or unexpected complication.
- Advice available from the Associate Medical Director for Patient Safety and Head of Quality (Patient Safety)

Where can I find out more?

- Staff Support and Being Open Policy on the DMS
- Duty of Candour pages on Connect
- Guidance on Being Open is here Being Open framework
- Guidance from the Care Quality Commission is here

http://www.cqc.org.uk/content/fit-and-proper-persons-requirement-and-duty-candour-nhs-bodies

University Hospitals Bristol NHS
NHS Foundation Trust

Staff Support and Being Open Policy (Duty of Candour)

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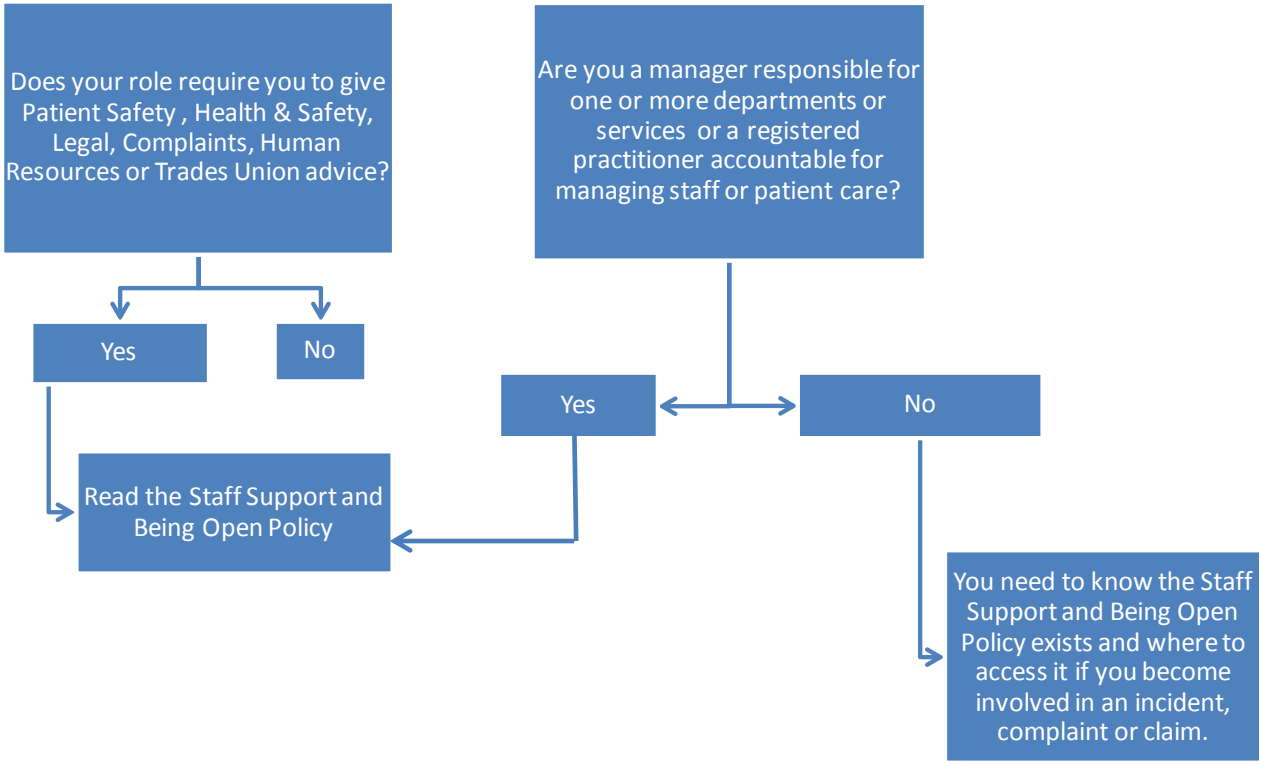
Document Abstract
The Trust has as duty of care to look after the psychological as well as the physical well-being of staff that have been exposed to a traumatic incident, complaint or claim. The policy sets out what support is available to staff in the short and longer term, internally and externally, and details of how to access these. The Trust also has a legal duty to communicate honestly and sympathetically with patients and their families when things go wrong. This is reflected in the Duty of Candour Regulations (Care Quality Commission 2015) for all NHS organisations as shown in Appendix E Clearly it is right to express regret when things go wrong, such as in adverse incidents, complaints or claims and staff should not worry that any expression of regret constitutes an admission of liability. In being open, the Trust can mitigate the trauma suffered by patients and potentially reduce complaints and claims.

[1] Divide number of words (5,747) by 240 for average reading time and add 25% for specialist content.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
July 2007	1	Jonathan Sheffield	Major	Additional guidance for staff required
July 2008	2	Jonathan Sheffield	Major	Review for comparison with new NHSLA risk management standards
January 2012	2.1	Sean O' Kelly	Minor	Interim update by author in response to Histopathology Inquiry 2010 pending full update for NHSLA Level3 March 2012.
June 2012	2.2	Anne Reader	Minor	Updated for NHSLA Level 3 and to reflect the Duty of Candour 2011.
March 2013	2.3	Anne Reader	Minor	New Appendix E added to reflect 2013/14 contractual requirements for Duty of Candour. Monitoring table updated.
June 2016	3	Barry Howarth	Major	Updated Policy to reflect Duty of Candour legislation.

Do I need to read this Policy?



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1. Introduction

1.1 Effective communication with patients begins at the start of their care and should continue throughout their time with the healthcare organisation. This should be no different when an incident[2] occurs. Openness about what happened and discussing incidents honestly, promptly, fully and compassionately can help patients cope better with the after-effects.

The Statutory Duty of Candour came into force in November 2014. This involves giving patients accurate, truthful, prompt information when mistakes are made and treatment does not go to plan.

Whilst the statutory duty of candour requirement is directly linked to a providers' Care Quality Commission (CQC) registration requirement, the principles sitting behind the new duty are wholly aligned to the wider drive around transparency and also entirely endorsed by the NHS Litigation Authority in terms of health providers " being open" when errors are made and harm caused.

Saying sorry when things go wrong is vital for the patient, their family and carers, as well as to support learning and improve safety. Patients, their families and carers should receive a meaningful apology; one that is sincere expression of sorrow or regret for the harm that has occurred.

This guidance is intended for use as an integral part of existing policies which deal with the management of incidents[3]. It is also based upon the National Patient Safety Agency policy.[4]

The same principle of 'Being Open' applies where there is a potential/actual complaint or claim relating to treatment or care. There are separate procedures to be followed for the investigation of complaints and claims.

1.2 Rationale

The honest sharing of information with patients and families is important in reducing uncertainty, suspicion or anger. This principle was reinforced in the Francis Report on the failing at the Mid-Staffordshire NHS Foundation Trust which was published in February 2013which explicitly recommended that it is a requirement for clinicians to be candid with patients about avoidable harm and for safety concerns to be reported openly and truthfully[5]. It has long been recognised that patients are more likely to resort to formal complaints or pursuing litigation in the absence of appropriate explanation[6]. Openness with patients and families could reduce the number of formal complaints or potential litigation.

The policy ensures that the Trust complies with Regulation 20 of the Health and Social Care Act (Regulated Activity) Regulations 2014

2. Purpose and Scope

2.1 Scope:

2 Also known as a patient safety incident
3 The Policy for the Management of Incidents also applies Health & Safety, Information Governance and Operational incidents
4 Being Open Framework (2009) National Patient Safety Agency (NPSA) http://www.npsa.nhs.uk/nrls/
5 Francis Report into the failings at Mid-Staffordshire NHS Foundation Trust February 2013 Chapter 22
6 Vincent C, Young M, Phillips A, Why do people sue doctors? A study of patients and relatives taking legal action, The Lancet vol 343, 1609-13 (1994)

(a) This policy applies to all staff including permanent and temporary staff employed by the Trust. The policy also applies to students, bank and locum staff, contracted staff and volunteers. Every healthcare professional in the Trust must be open and honest with patients when something goes wrong with their treatment or care which causes , or has the potential to cause harm or distress.

The Being Open principles and ethical duty of openness applies to all incidents and any failure in care or treatment. The Duty of Candour applies to incident whereby moderate, significant harm or death has occurred.

2.2 The purpose of this guidance is three-fold:

(a) To ensure that staff understand their role in applying the statutory requirements in relation to Duty of Candour.

(b) To encourage the adoption of the principles of being open in disclosing information to patients and families following an incident;

(c) To recognise the need for staff support in following this guidance and involvement with an incident, complaint or legal enquiry including negligence actions and inquests[7].

3. Definitions

3.1 Being Open

(a) Acknowledging, apologising and explaining when things go wrong and, in the case of incidents, recording this in the patient's clinical records and the incident root cause analysis investigation report. Conducting a thorough investigation and reassuring families that lessons learned will help prevent the incident happening again.[7]

3.2 Duty of Candour

(a) Candour is defined in the Francis Report :

" The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not information has been requested and whether or not a complaint or report about that provision has been made."

Unlike the existing professional and ethical duty which applies to all circumstances where a patient is harmed when something goes wrong, the statutory Duty of Candour only applies to incidents where a patient suffered (or could have suffered) unintended harm resulting in moderate or severe harm or death or prolonged psychological harm.

(b) The person best suited to meet the requirements of Duty of Candour and be the key contact for the patient and/or family in this respect should be identified by the relevant division guided by the complexity of the incident. Key contacts need to have sufficient experience in having difficult conversation with the families and have the

[7] Chief Medical Officer. Making Amends – Clinical Negligence Reforms. DoH (2003)

appropriate clinical knowledge to respond to any initial questions from the patient and/or family.

4. Duties, Roles and Responsibilities

4.1 Staff member directly involved in the incident

(a) Report the incident as per the Policy for the Management of Incidents and the Trust's Serious Incident Policy and guidelines

(b) Determine with their line manager how the patient and/or their carer is to be informed. This should include an explanation of what happened and the likely harmful impact

(c) Depending on the nature of the incident if the manager deems appropriate for the member of staff, they should inform the patient and/or their carers what happened in an incident that led to low harm, moderate harm, severe harm or death

(d) Apologise to patients harmed as a result of healthcare treatment as early as possible. Staff involved in patient care or treatment which results in an incident, for whatever reason, should sympathise with the patient or the patient's relatives and express sorrow or regret at the outcome

(e) Such expressions of regret would not normally constitute an admission of liability, either in part or in full, solely on the grounds of such an expression. The importance of openness is also emphasised in the National Health Service Litigation Authority *(NHSLA) Saying Sorry* Guidance.[8] (appendix

(f) It is *not* however a requirement for prevented clinical and 'no harm' incidents to be discussed with patients and/or their carers due to potential:

(i) added stress to patients;

(ii) loss of confidence in the standard of care;

(iii) negative effects on staff confidence and morale;

(iv) decreased public confidence in the NHS.

(g) It is important that duty of candour related discussions with the patient and/or family are documented in the patient's notes.

4.2 Line or Department Manager/Designated Senior Clinician.

(a) Ensure incident has been appropriately reported and that patient/carer has been informed

(b) Depending on the nature of the incident, if it is not appropriate for the staff member directly involved in the incident to do so, inform the patient and/or their carers what happened in an incident that led to low harm, moderate harm, severe harm or death

[8] National Health Service Litigation Authority *(NHSLA) Saying Sorry* Guidance

(c) Apologise to patients harmed as a result of healthcare treatment as early as possible if the staff member involved is unable to do so.

(d) Such expressions of regret would not normally constitute an admission of liability, either in part or in full, solely on the grounds of such an expression. The importance of openness is also emphasised in the National Health Service Litigation Authority (NHSLA) standards

(e) Confirm with the patient/relative if they would like feedback on the outcome of the incident investigation

(f) Follow sections 5.2-5.7 for management of the feedback to the patient

(g) Follow section 5.1 to ensure all relevant staff members receive suitable support depending on the particular circumstances

4.3 Divisional Patient Safety Lead/Advisor

(a) Identify particular staff support requirements as per section 5.1

(b) Ensure patient/family feedback has been provided as per sections 5.2-5.7

(c) Ensure incident database is updated with full details including feedback provided to patient/family. This database is also used for complaints and claims

(d) Ensure incident is reported to relevant divisional committee

4.4 Patient Safety Manager/Head of Health and Safety/Complaints Manager/Legal Advisors

(a) Ensure incident, complaint or claim is investigated appropriately and reported to the relevant management group

(b) Ensure staff members involved have received feedback on the outcome of the investigation of the incident, complaint or claim

5. Policy Statement and Provisions

University Hospitals Bristol NHS Foundation Trust is committed to the principles of openness and this policy and guidelines detail the meaning of these principles in practice. Clearly it is right to express regret when things go wrong, such as in adverse incidents, complaints or claims and staff should not worry that any expression of regret constitutes an admission of liability.

The policy seeks to reflect the ethical and legal obligations relating to candour in relation to patients, visitors and staff members.[9] It is also recognised that a culture of openness is a

[9] Shipman Inquiry, 5th Report. Safeguarding patients: Learning from the Past – Proposals for the Future. Command Paper Cm 6394 (2004)

prerequisite condition to improving patient safety and the quality of the healthcare provided by this Trust.[10]

5.1 How staff acknowledge, apologise and explain when things go wrong

(a) Near miss and no harm incidents: no requirement to inform or discuss with patient or family

(b) Low harm incidents: inform patient or family verbally and offer appropriate apology

(c) Moderate and severe harm incidents and catastrophic incidents where death was avoidable: Within 10 working days of the incident being identified, verbally and in person, the clinician responsible for the patient's care informs the patient or family of the incident including all facts known at the time and provides an appropriate apology.

(d) Offer the patient or family written confirmation of the discussion. If a formal incident investigation is to be conducted ask the patient or family if they have any questions they would specifically like answered as part of the investigation. Offer the patient or family the opportunity to receive the outcome of the investigation.

(e) Document the discussion and outcome in the patient record. If offer for written confirmation is accepted, follow up initial discussion in writing using Trust template. (NB: if the patient or family cannot be contacted or decline a discussion this should also be recorded in the patient record)

(f) No formal incident investigation: As soon as practicable and if patient/family wish to take up the offer, the clinician responsible for the patient's care should provide a step by step explanation of events and circumstances which led up to the incident. Document in the patient record.

(g) Formal incident investigations e.g. RCAs: Include the patient's or family's questions in the scope of the investigation and document Being Open and Duty of Candour requirements in the RCA report using the Trust RCA template.

(h) Formal incident investigations: within 10 working days of completion and sign off of formal investigation report (in accordance with Trust Policy for the Management of Incidents) provide patient or family with a copy of the incident investigation report. Unless the patient or family decline, this should be done at a face to face meeting to provide opportunity to answer questions which may arise.

(i) This policy provision is provided in a flow chart in Appendix E. The following guidance provides a framework for staff to follow when a patient safety incident has occurred resulting in harm:

5.2 Involving staff who made an error and staff support

(a) Some patient safety incidents will result from errors made by healthcare staff while caring for the patient:

[10] Manchester Patient Safety Framework – National Patient Safety Agency (2006)

(i) The member(s) of staff involved may or may not wish to participate in the discussion with the patient/family/carer;

(ii) Consider each case, balancing the needs of the patient/family/carer with those of the healthcare professional concerned;

(iii) Where a healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting;

(iv) In cases where the patient/family/carer prefers the healthcare professional not to be present, an offer of a personal written apology could be made to the patient/family/carer during the first discussion.

(b) Healthcare professionals involved in the patient's clinical care which involved a patient safety incident may require emotional or practical support and advice:

(i) Immediate Support;

(A) Clinicians who have been involved directly in the incident and those with the responsibility for discussions should be given access to assistance, support and any information they need to fulfil this role, e.g. details of what happened and when;

(B) These must be the objective facts as known at that time, not subjective opinions;

(C) Relevant policies;

- Policy for the Management of Incidents and Serious Incident Policy
- Claims Handling Policy
- Complaints and Concerns Policy

(ii) Further support may be required from peers, managers for staff to discuss the incident. To determine if this is necessary use the triggers for consideration of work related pressures from the Work Related Stress Policy

(iii) Consider self-referral to the relevant professional or union representative organisation.

(c) On-going support

(i) Manager's role:

(A) Assistance with the preparation of witness statements and oral evidence. Follow links to claims and incident policies above;

(B) Offer face to face debrief to individual staff member or team;

(C) Refer or provide information about Occupational Health Services;

(D) Consider reassignment as a temporary measure;

(E) Consider special leave or relevant Human Resources Policies (Capability, Special Leave, Link between Incident & Disciplinary, Work Related Stress Policy);

(F) Further support may be required from the Patient Safety Team (x23710);

(G) Advice and support may be sought from the Occupational Health Department including counselling services (x22333);

(H) Consider referral to the relevant professional or union representative organisation;

(I) Where necessary refer to relevant Executive Director for referral to professional regulatory authority.

5.3 Timing of the discussion

(a) The initial discussion with the patient/family/carer should occur as soon as possible after recognition of the patient safety incident but with 10 working days. The following factors should be considered when timing this discussion and include:

(i) clinical condition of the patient

(ii) availability of key staff involved in the incident

(iii) availability of the patient's family/ carer

(iv) availability of support staff, for example a translator or independent advocate (if required)

(v) patient preference (when and where the meeting takes place and which healthcare professional leads the discussion)

(vi) privacy and comfort of the patient

(vii) identifying and availability of a suitable location offering privacy and comfort

5.4 Which healthcare professional should inform the patient or carer

(a) This should be the most senior clincian responsible for the patient's care and/or someone with experience and expertise in the type of incident that has occurred, e.g. the patient's consultant, nurse consultant, or other healthcare professional with a designated caseload of patients. They should demonstrate effective communication skills or have received training (e.g. 'Breaking Bad News' training). Consideration also needs to be given to the characteristics of the person nominated to lead the process. They should:

(i) be known to, and trusted by, the patient/family/carer;

(ii) have a good grasp of the facts relevant to the incident;

(iii) have excellent interpersonal skills, including the ability to communicate with patients/family/ carer in a way they can understand and avoiding excessive use of medical jargon;

(iv) be willing and able to offer an apology, reassurance and feedback to patient/family/carer;

(v) maintain a medium to long term relationship with the patient/family /carer, where possible and provide continued support and information;

(vi) be culturally aware and informed about the specific needs of the patient/family /carer.

(b) Use of a substitute healthcare professional for the discussion:

(i) In exceptional circumstances, if the healthcare professional who would lead the discussion cannot attend, they may delegate to an appropriate substitute. The qualifications, training and scope of responsibility of this person should be clearly delineated. This is essential for effective communication with the patient and/or carers. The substitute may be the clinician responsible for patient safety (for example, Divisional Patient Safety Lead) or someone of similar experience.

(c) Assistance with the initial discussion:

(i) The healthcare professional communicating information about a patient safety incident should be able to nominate a colleague to assist them with the meeting. Ideally this should be someone with experience of such situations.

(d) Consultation with the patient/carer regarding the healthcare professional leading the discussion:

(i) If it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected. A substitute with whom the patient is satisfied should be provided.

5.5 Patient Issues

(a) Overall Principal:

(i) Offer repeated opportunities for the patient/family/ carer to obtain information about the patient safety incident;

(ii) Provide information to patients initially verbally and face-to-face and offer confirmation of discussion in writing

(iii) Provide assurance that an on-going care plan will be developed in consultation with the patient and will be followed through;

(iv) No bias assurance i.e.: provide assurance that the patient will continue to be treated according to their clinical needs and that the prospect of, or an actual dispute between, the patient and/or their carers' and the healthcare team will not affect their access to treatment.

(b) When a patient dies:

(i) Consider the emotional state of bereaved relatives or carers and involve them in deciding when it is appropriate to discuss what has happened;

(ii) The patient's family and/or carer will probably need information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support;

(iii) Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage;

(iv) Ensure the notification of relevant community health care staff including the patient's GP takes place;

Usually, the discussion and any investigation occur before the Coroner's Inquest. In certain circumstances the Trust may consider it appropriate to wait for the Coroner's Inquest before the discussion with the patient's family and/or carers. Advice can be sought from the Legal Department on (x23612).

The Coroner's report on post-mortem findings is a key source of information that will help to complete the picture of events leading up to the patient's death. A copy is provided to the patient's GP. Expressions of sympathy and regret, where appropriate, should be offered as soon as possible after the patient's death. An information leaflet outlining the coroner's process should be offered. Referral of the family to the Coroner's office should facilitate further details of the likely timeframe of when the family and/or carers will be provided with more information.

(c) Children:

(i) The legal age of maturity for giving consent to treatment is 16 when a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality overrides their parents or guardians. Therefore it is possible to discuss a patient safety incident with a teenage patient alone, but, it is usually preferable to involve parents/carers with the child's permission.

(d) Patients with mental health problems:

(i) Follow normal procedures, however, it may be appropriate to withhold patient safety incident information from a patient when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient;

(ii) A second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient;

(iii) Apart from exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer /relative without the express permission of the patient;

(iv) For an initial assessment of capacity to understand the details of the incident, consult the Capacity Assessment Tool**.**

(e) Non competent adult patients (assessed as lacking capacity). Some individuals have conditions that limit their ability to understand what is happening to them:

(i) Another person may be authorised to act on their behalf by use of a lasting power of attorney. However, steps must be taken to ensure this extends to decision making relating to the medical care and treatment of the patient. The discussion would be held with the holder of the power of attorney;

(ii) Where there is no such person the clinicians may act in the patient's best interest in deciding who is the appropriate person with whom to hold a discussion regarding the incident;

(iii) However, any patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened;

(iv) An advocate with appropriate skills should be available to the patient to assist in the communication process. This could be a family member or Independent Mental Capacity Advocate (IMCA).

(f) Patients with different language or cultural considerations:

(i) When planning the information meeting with the patient and or family, the need for translation and advocacy services must be taken into account. Inclusion of the services of a translator may assist the communication of information and avoid misunderstanding;

(ii) In some circumstances consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues) will be relevant;

(iii) It could be helpful to involve an advocate, which can be sought through the Patient Support and Complaints team or family member.

(g) Patients who disagree with the information provided:

(i) Sometimes, patients may not accept the information provided or may not wish to participate in the discussion. In this case the following strategies may assist:

(A) Offer the patient access to support services which they will accept;

(B) Provide the opportunity for the patient to meet with another member of the health care team or refer to the Patient Support and Complaints team see above;

(C) Offer the patient and/or carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for Patient Safety in the Department or Division;

(D) Use a mutually acceptable mediator to help identify the issues between the healthcare team and the patient, and to look for a mutually agreeable solution;

(E) Ensure the patient and/or their carers are fully aware of the formal complaints procedures;

(F) Prepare a comprehensive list of the points of disagreement and reassure the patient/family/carer you will follow up these issues.

5.6 Content of the Discussion

(a) Advise the patient and/or carers of the identity and role of all those attending the discussion before it takes place;

(b) Express genuine sympathy, regret and an apology for the harm that has occurred;

(c) The facts that are known are agreed in advance by the multidisciplinary team. Inform the patient/carers that an incident investigation is being carried out and more information will become available as it progresses;

(d) The patient/carer's understanding of what happened should be explored, as well as answering any questions they may have;

(e) Document the patient/carer's views and concerns, and demonstrate that these are being heard and taken seriously;

(f) Use appropriate language and terminology which the patient/carer can understand and consider translation services;

(g) Provide an explanation of the long term treatment plan and incident analysis findings;

(h) Provide information of the likely short and long term effects of the incident (if known). This may need to be delayed until the incident is fully investigated;

(i) Offer practical and emotional support. This may involve getting help from third parties such as charities and voluntary organisations as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without their consent;

(j) Patients/carers may be anxious, angry and frustrated even when the meeting is conducted appropriately;

(k) It is essential the following does not occur:

(i) Speculation;

(ii) Attribution of blame;

(iii) Denial of responsibility;

(iv) Provision of conflicting information from different individuals.

5.7 Documentation

(a) Documentation should include the following:

(i) The time, place, date + name and relationships of all attendees;

(ii) The agreed plan for providing further information to the patient and/or their carers;

(iii) Offers of assistance and the response from the patient/carer;

(iv) Questions raised by the family and/ or representatives, and the answers given;

(v) Plans for follow-up and feedback as discussed;

(vi) Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient/carers;

(vii) Copies of letters sent to patients, carers and the GP for patient safety incidents not occurring within primary care;

(viii) Copies of any statements taken in relation to the patient safety incident[11];

(ix) A copy of the incident report which will include a record confirming that the patient/relative has been informed the incident;

(x) A copy of the discussion should be offered to the patient - avoid jargon.

5.8 Completing the Process

(a) Within 10 working days after completion of the incident investigation and its sign off in accordance with the Policy for the Management of Incidents, a copy of the incident investigation report should be provided if the patient or family have taken up this offer. Feedback should ideally occur in a face to face meeting and a copy of the report provided, but may be in another form if more acceptable to the patient. Whatever method is used, the communication should include:

(i) The chronology of clinical and other relevant facts;

(ii) Details of the patient/carer's concerns and complaints;

(iii) A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident;

(iv) A summary of the factors that contributed to the incident;

(v) Information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

(b) There will be a complete discussion of the findings of the investigation and analysis.

[11] Advice on preparing statements and recollections of events is available on the Patient Safety Intranet

(c) In some limited cases information may need to be withheld or restricted:

(i) Where communicating information is likely to adversely affect the health of the patient;

(ii) Where investigations are pending coronial processes unless the Coroner gives permission. Consult Legal Services team for advice;

(iii) Where specific legal requirements preclude disclosure for specific purposes. In these cases the patient will be informed of the reasons for the restrictions. Consult Legal Services team for advice.

(d) On-going care:

(i) Patients/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 healthcare team;

(ii) They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident.

6. Standards and Key Performance Indicators

6.1 Applicable Standards

(a) Compliance with the Duty of Candour will be monitored through incident investigation root cause analyses report.

6.2 Training

(a) Training on all aspects of incident investigation can be found on the **Patient Safety Training** pages of Connect

7. References

7.1 Kaplan C, Hepworth S. *Supporting Health Service Staff Involved in a complaint, Incident or Claim – an NHSLA Initiative.* NHSLA Journal, issue 3, 11 -13 (2004)

7.2 Francis Report into the failings at Mid-Staffordshire NHS Foundation Trust February 2013

7.3 Chief Medical Officer. Making Amends – Clinical Negligence Reforms. DoH (2003)

7.4 National Health Service Litigation Authority *(NHSLA) Saying Sorry* Guidance

7.5 National Patient Safety Agency. *Being Open Communicating Patient Safety Incidents with Patients and their Carers.* London: (2005)

7.6 Walker S. *Apologies and Explanations, Chief Executive letter to NHS Trust Chief Executives*, August 2007. http://www.nhsla.com

7.7 National Health Service Litigation Authority (2008) Risk Management Standards for Acute Trusts

7.8 Vincent C, Young M, Phillips A, *Why do people sue doctors? A study of patients and relatives taking legal action*, The Lancet vol 343, 1609-13 (1994)

7.9 Chief Medical Officer. *Making Amends – Clinical Negligence Reforms*. DoH (2003)

7.10 Shipman Inquiry, 5th Report. *Safeguarding patients: Learning from the Past – Proposals for the Future*. Command Paper Cm 6394 (2004)

7.11 Manchester Patient Safety Framework – National Patient Safety Agency (2006) www.npsa.org.uk

7.12 University Hospitals Bristol Policies:

(a) Policy for the Management of Incidents

(b) Serious Incident Policy

(c) Complaints and Concerns Policy

(d) Claims Handling Policy

(e) Work Related Stress Policy

(f) Special Leave

(g) Capability (2007)

(h) Protection of Vulnerable Adults From Abuse Policy (2008)

(i) Advice on preparing statements and recollections of events on the Patient Safety intranet

8. Associated Documentation

8.1 The relationship between incident reporting and disciplinary action is found at appendix D.

9. Appendix A – Monitoring Table for this Policy

Standard	How these will be monitored	Monitoring Group
How staff acknowledge, apologise and explain when things go wrong.	Local quarterly audit will be undertaken to measure compliance with Duty of Candour legislation and guidance	The results of the audits will be reported on an annual basis to the Patient Safety Group who will also be responsible for ensuring the action plan is completed
Action for managers or individuals to take if the staff member is experiencing difficulties associated with the event		

10. Appendix B – Dissemination, Implementation and Training Plan

10.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Head of Quality (Patient Safety)
This document replaces existing documentation:	Yes
Existing documentation will be replace by:	Rescinding of superceding document
This document is to be disseminated to:	Trust wide
Training is required:	Not Applicable
The Training Lead is:	Not applicable

Additional Comments
Not applicable

11. Appendix C – Document Checklist

11.1 The checklist set out in the following table confirms the status of 'diligence actions' required of the 'Document Owner' to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The 'Approval Authority' will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Title	The title is clear and unambiguous:	Yes
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Yes
Content	The document uses the approved template:	Yes
	The document contains data protected by any legislation (e.g. 'Personal Data' as defined in the Data Protection Act 2000):	Not Applicable
	All terms used are explained in the 'Definitions' section:	Not Applicable
	Acronyms are kept to the minimum possible:	Yes
	The 'target group' is clear and unambiguous:	Yes
	The 'purpose and scope' of the document is clear:	Yes
Document Owner	The 'Document Owner' is identified:	Yes
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	Yes
	The following were consulted:	Divisional Patient Safety Leads and Advisors, Assistant Director of Human Resources, Head of Health and Safety, Trust Solicitor, Patient Safety Manager (Incidents), Staff Side.
	Suitable 'expert advice' has been sought where necessary:	Yes
Evidence Base	References are cited:	Yes
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	Reducing patient harm
Equality	The appropriate 'Equality Impact Assessment' or 'Equality Impact Screen' has been conducted for this document:	Yes
Monitoring	Monitoring provisions are defined:	Yes

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
	There is an audit plan to assess compliance with the provisions set out in this procedural document:	Yes
	The frequency of reviews, and the next review date are appropriate for this procedural:	Yes
Approval	The correct 'Approval Authority' has been selected for this Procedural Document:	Yes

Additional Comments
Not applicable

12. Appendix D - Relationship between Incident Reporting and Disciplinary Action

12.1 Our assurance to employees

(a) A culture of "fair blame" will operate.

(b) The Trust believes that the emphasis must be on taking corrective action, learning from the experience and improving practice accordingly.

(c) An open and thorough investigation may reveal that it is the system or process at fault which resulted in an individual(s) making a mistake.

(d) It is assumed that in discharging their responsibilities staff act in good faith and within their sphere of professional practice and competence.

(e) However, the actions of an individual, in the event of an incident, may be tested against the NPSA Incident Decision Tree which is a standardised assessment tool.

(f) All new members of staff will be informed of this policy at induction.

12.2 Incident Reporting

(a) The aim of incident reporting is not to apportion blame. The purpose of incident reporting is to ensure mistakes or potential mistakes [near misses] are highlighted and reported to the Trust, so that they can be avoided in future or the risk of their occurrence minimised. Thus, the system is an essential part of improving patient care and safeguarding the patient from harm. The Trust has adopted a proactive approach to risk management by identifying risks, assessing risks and reducing or where possible eliminating risks to patients.

(b) Staff are encouraged to report any incidents or near misses and consider them as an opportunity to learn from errors and ultimately improve patient care. A report by a staff member may either involve them as an individual or a colleague. The individual needs to be assured that the Trust does not take a punitive approach, but needs to find out what happened to prevent a reoccurrence. An individual's actions therefore, may be assessed using the standardised Incident Decision Tree assessment tool.

(c) Where an incident is considered to be serious, managers will explicitly ensure that, during the investigation into an incident or near miss, staff members involved will be given specific personal support.

(d) All incidents are investigated using a 'systems' approach that looks at a number of contributory factors e.g. system faults, catalyst events, as well as human error.

12.3 Relationship between Disciplinary Action and Reporting Incidents

(a) The Trust is clear that the incident reporting system is not to be used for highlighting issues of capability and/or suboptimal performance. However, disciplinary action will be taken in accordance with the Trust's Disciplinary Policy if in the course of an investigation and the application of the Incident Decision Tree:

(i) There is clear evidence of intended malpractice;

(ii) There is clear evidence of intended harm;

(iii) There is clear evidence of intended disregard of trust policies and procedures;

(iv) There is clear evidence that staff are found to be deterring others from using the incident reporting system and reporting incidents.

Managers are expected to investigate all incidents in an open and constructive manner. The focus of an investigation should be on 'What is wrong?', rather than 'Who is wrong?' Managers should not, therefore, assume that disciplinary action will be the outcome but should use the Incident Decision Tree in order to establish a clear picture of what happened and what went wrong.

12.4 Relationship between Reporting Incidents and other Policies:

(a) The Trust policy for Managing Performance will be used if an individual repeatedly makes the same mistake / error and fails to learn from the support / training provided by the organisation, or where serious issues of capability are evident;

(b) If there is evidence of ill health the Supporting Attendance Policy should be used;

(c) If there is evidence of substance abuse then the Trust's Substance Misuse Policy should be consulted;

(d) Staff must be clear to differentiate between incident reporting and raising a grievance via the trust Grievance Policy. Grievances relate specifically to employment related matters;

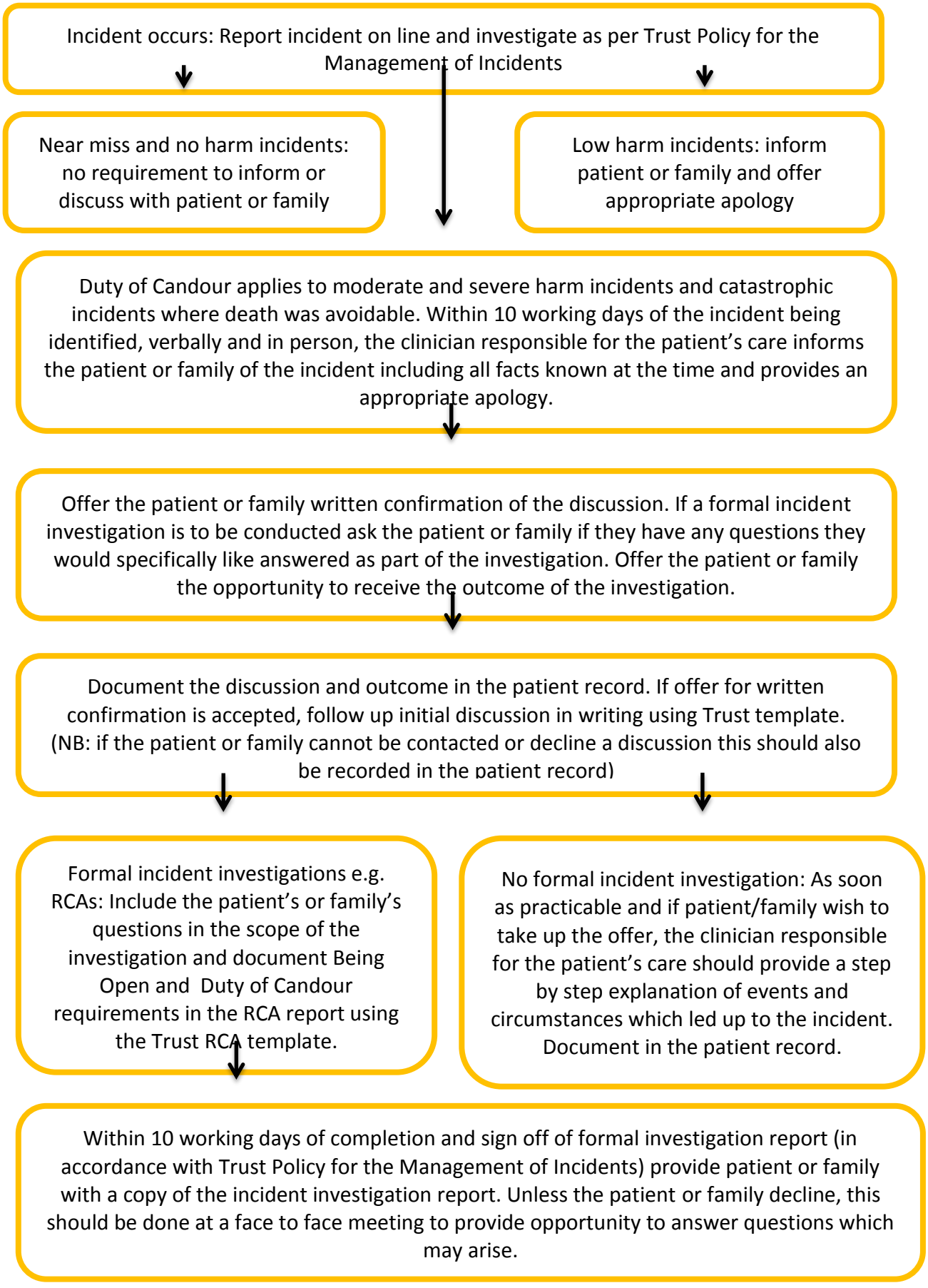
(e) The Trust's Speaking Out Policy provides a mechanism for staff to raise a general concern, but should a specific incident be reported under this policy this will be investigated using a systematic approach;

(f) The Work Related Stress Policy is designed to help Managers consider possible sources of work related pressure amongst their staff which should be considered as part of an incident investigation.

12.5 External agencies:

(a) Managers will ensure that; where external agencies are involved in such incidents and reporting e.g. Radiation Protection, they are made aware of the Trust policy and do not unilaterally pursue recommendations for disciplinary action. The latter is a decision for the Trust, unless there is re-course by law when an illegal act has been identified.

13. Appendix E- Duty of Candour/Being Open Flow Chart



14. Appendix F Principles of Being Open

The 10 Principles of Being Open - Being open involves apologising when something has gone wrong, being open about what has happened, how and why it may have happened, and keeping the patient and their family informed as part of any subsequent review.

1. Principle of Acknowledgement

All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare employees that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all employees. Denial of a person's concerns or defensiveness will make future open and honest communication more difficult.

2. Principles of Truthfulness, Timeliness and Clarity of Communication

Information about a patient safety incident must be given in a truthful and open manner by an appropriately nominated person. Communication should be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. It will be explained that new information may emerge as the event investigation takes place. Patients, their families and carers and appointed advocates should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

3. Principle of an Apology

Patients, their families and carers should receive a meaningful apology - one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety event or that the experience was poor. Both verbal and written apologies should be offered. **Saying sorry is not an admission of liability and it is the right thing to do.** Verbal apologies are essential because they allow face to face contact, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, should also be given.

4. Principle of Recognising Patient and Carer 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 organisation and/or in accordance with the local resolution process where a

complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

5. Principle of Professional Support

The Trust has set out to create an environment in which all employees are encouraged to report patient safety events. Employees should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the event. Resources available are referred to within the respective Trust policies, to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the practice of individual employee the Trust's Human Resources department must be contacted for advice. Where there is reason to believe an employee has committed a punitive or criminal act, the Trust will take steps to preserve its position and advise the employee at an early stage to enable them to obtain separate legal advice and/or representation. Employees should be encouraged to seek support from relevant professional bodies. Where appropriate, a referral will also be made to the Independent Safeguarding Authority.

6. Principle of Risk Management and Systems Improvement

Root Cause Analysis (RCA) or similar techniques should be used to uncover the underlying causes of patient safety events. Investigations at any identified level will however focus on improving systems of care, which will be reviewed for their effectiveness. Being open is integrated into patient safety incident reporting and risk management policies and processes.

7. Principles of Multi-Disciplinary Responsibility

Being open applies to all employees who have key roles in patient care. This ensures that the Being open process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the Being open process, it is important to identify clinical and managerial leaders who will support this across the health and care agencies that may be involved. Both senior managers and senior clinicians will be asked to participate in the patient safety incident investigation and clinical risk management as set out in the respective Trust policies and practice guidance.

8. Principles of Clinical Governance

Being open involves the support of patient safety and quality improvement through the Trust's clinical governance framework, in which patient safety incidents are investigated and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability to ensure that these changes are implemented and their effectiveness reviewed. Findings are disseminated to employees so they can learn from patient safety incidents. Audits are an integral process, to monitor the implementation and effects of changes in practice following a patient safety incident.

9. Principle of Confidentiality

Details of a patient safety incidents should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. The Trust will anonymise any incident it publishes but still seek the agreement of those involved.

Where it is not practicable or an individual refuses consent to disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of those involved in the investigation will be on a strictly need to know basis. Where possible, it is good practice to inform the patient, their family and carers about who will be involved in the investigations before it takes place, and give them the opportunity to raise any objections.

Consent and duty to inform for incidents involving patients in Offender Health will be dealt with in accordance with the normal prison protocol.

10. Principle of Continuity of Care

Patients will continue to receive all usual treatment and continue to be treated with respect and compassion.

15. Appendix G NHS LA Saying Sorry Leaflet

NHS Litigation Authority

Saying Sorry

Saying sorry when things go wrong is vital for the patient, their family and carers, as well as to support learning and improve safety. Of those that have suffered harm as a result of their healthcare, fifty percent wanted an apology and explanation. Patients, their families and carers should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has occurred.

How should this happen?

Verbal apologies are essential because they allow face-to-face contact between the patient, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given.

Who should say sorry?

Information about a patient safety incident must be given to patients and their families in a truthful and open manner by an appropriately nominated person. Staff may be unclear about who should talk to patients when things go wrong and what they should say; there is the fear that they might upset the patient, say the wrong things, make the situation worse and admit liability. Having a local policy that sets out the process of communication with patients and raising awareness about this will provide staff with the confidence to communicate effectively. The local policy should state who is the most appropriate member of staff to give both verbal and written apologies to patients and their families; the decision should consider seniority, relationship to the patient, experience and expertise. Most healthcare provision is through multidisciplinary teams so any local policy on openness should apply to all staff that have key roles in the patient's care.

What if there is a formal complaint or claim?

Poor communication may make it more likely that the patient will pursue a complaint or claim. It is important not to delay giving a meaningful apology for any reason, including where there is a formal complaint or claim. It is also essential that any information given is based solely on the facts known at the time. Healthcare professionals should explain that new information may emerge as an investigation is undertaken, and that patients, their families and carers will be kept up-todate with the progress of an investigation.

Is an apology the same as an admission of liability?

Saying sorry is not an admission of legal liability; it is the right thing to do. The NHS LA is not an insurer and we will never withhold cover for a claim because an apology or explanation has been given. The NHS LA claims teams are always happy to provide support and advice where there is a potential claim.

What about the staff involved?

Healthcare organisations must create an environment in which all staff, whether directly employed or independent contractors of NHS care, are encouraged to report patient safety incidents. Staff should feel supported throughout the investigation process because they too may have been traumatised by being involved. Sometimes patients can suffer significant harm. In these circumstances, the member(s) of staff involved may find it hard to participate in the discussion with the patient and their family. Every case needs to be considered individually, balancing the needs of the patient and their family with those of the healthcare professional concerned. In cases where the healthcare professional responsible wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. In cases where the patient and their family express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient, their family and carers during the initial Being Open discussion.

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Key Messages

Timeliness: The initial discussion with the patient and their family should occur as soon as possible after recognition that something has gone wrong.

Explanation: Patients and their families should be provided with a step -by-step explanation of what happened, that considers their individual needs and is delivered openly.

Information: Patients and their families should receive clear, unambiguous information. They should not receive conflicting information from different members of staff. The use of medical jargon and acronyms, which they may not understand, should be avoided.

On-going support: Patients and their families should be given a single point of contact for any questions or requests they may have. They should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.

Confidentiality: Policies and procedures should give full consideration of, and respect for privacy and confidentiality for the patient, their family and staff.

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, the appropriate arrangements should be made for them to receive treatment elsewhere.

"Achieving timely and fair resolution, enhancing learning and improving safety."

16. Appendix H Draft letter template following conversations with patients.

PRIVATE AND CONFIDENTIAL
(insert date)
(insert name and address)

Dear

I am writing to follow up on the conversation that we had on (insert date).
Again I would like to express my sincere apologies that you/ your ….'s has been involved in a patient safety incident (provide appropriate factual details here).
I would like to assure you that the Trust aims to provide a quality service to all our patients. As explained we are therefore, undertaking a full investigation into you/your ….'s care and treatment in an effort to understand exactly what happened and, we would like the opportunity to discuss our investigation with you and describe how we can share our findings with you.
The initial investigation will take up to xxxx weeks to complete and there may be a number of actions that come out of the investigation. As discussed there may also be additional information that comes to light as the investigation proceeds and we have agreed that we will …….. to ensure that you are kept informed.
When our investigation is completed we will write to you again to ask how you would like us to provide feedback regarding the outcome of the investigation, if you feel able to arrange a mutually convenient time to meet (in advance of the completion of the investigation) please let us know.
XXXXX is acting as your lead contact for the duration of the investigation and they can be contacted on telephone number xxxxx xxxxxxx, email xxxxxxxx or on the address at the top of this letter.
I also recognise that you may not feel any further communication would be of any help and if this is the case I again, would be grateful if you could contact xxxxxxxxxxxx to let them know.
Just as importantly, if there is anything else you would like to mention at this stage to assist with the investigation then please do contact us.

Yours sincerely

17. Appendix I Draft letter template following investigation conclusion.

PRIVATE AND CONFIDENTIAL

(insert date)
(insert name and address)
Dear xxxxxxx

I am writing to let you know that we have now conducted the investigation, which is known as a Root Cause Analysis, into (give details of the incident).

Either

As discussed earlier we have arranged to meet on (date & time) and the meeting has been planned to take place at (insert venue). I would be grateful if you could contact xxxxxxxxxxxxxxx on number xxxxxxxxxx, email xxxxxxxxxxx or at the address above to confirm that you are still able to attend, Xxxxxxxxxxx can also explain who would be present at the meeting. You may also wish to consider whether you would like to bring a friend or family member along with you.

Or

I would, therefore, like to invite you/your ….'s to meet with me to discuss the findings of the investigation and would be grateful if you would contact xxxxxxxxxxx on number xxxxxxxxx, email xxxxxxxxxxx or at the address above, so that we can organise an appropriate day, time & venue should you wish to meet, Xxxxxxxxxxx can also explain who would present at the meeting. You may also wish to consider whether you would like to bring a friend or family member along with you.

If however you do not wish to attend a meeting, I can arrange for the final report to be sent directly to you.

Finally I and the staff at University Hospitals Bristol NHS Foundation Trust are very sorry for any suffering and distress caused as a result of this incident. I wish to assure you that we have learnt from the events surrounding xxxxxxx care and have agreed/ or are in the process of changing (insert relevant information here)

University Hospitals Bristol NHS
NHS Foundation Trust

University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
BS1 3NU
Department: xxx
Phone: xxx
E mail: xxx

Date: xx/xx/xxxx

Dear [name of patient/next of kin]

Re: [Name of patient] Date of birth: xx/xx/xxxx NHS number: xxxxxxxxxxxxx
Incident number: xxxxxx

I am writing to follow up our discussion on xx/xx/xxxx when I informed you of an incident which occurred involving your/your [relationship of patient to recipient]'s care in the [name of hospital].

I would like to offer my sincere apology that [headline description of the incident which occurred] happened and to assure you that we are taking this seriously. The organisation seeks to learn lessons when things go wrong and to take action to reduce the risk of such events happening again.

The initial facts of what happened have shown that:

- xxxx
- xxxx

A more detailed investigation will be undertaken including the points below you have requested:

- xxxx
- xxxx

We expect to have concluded our investigation within [x] months. Once this has been completed you will be offered the opportunity to discuss the findings and receive a copy of the investigation outcome; I will contact you again once the report is completed.

Please be aware that sometimes incident investigations turn out to be more complex than originally anticipated and it takes longer to complete a thorough investigation, if this proves to be the case I will contact you and let you know.

If you have any questions about this incident or would like further information please do not hesitate to contact me using the details at the top of this letter.

Yours sincerely

[Name]
[Job title]