Duty of Candour

Statutory duty of candour

Extract from the NHS Constitution for England 2009: "…when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively"

The Duty of Candour has been introduced as a direct result of the Francis Inquiry Report into the Mid Staffordshire NHS Foundation Trust, which recommended that a statutory "duty of candour" be imposed on all healthcare providers, which defined "Openness", "Transparency" and "Candour";

Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.

Candour – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

The intention is that there is a culture of openness and truthfulness to improving the safety of patients, staff and visitors to the Practice, as well as raising the quality of healthcare systems. If patients or employees have suffered harm as a result of using their services, a Practice should be able to confidently investigate, assess and if necessary apologise for and explain what has happened.

Being Open

A culture of "being open" should be fundamental in a Practice's relationships with (and between) patients, the public, Practice Staff and other healthcare organisations.

The Duty of Candour is the contractual requirement to ensure that the Being Open process is followed when an incident that affects patient safety results in moderate or severe harm, or death.

What is a Patient Safety Incident?

The National Patient Safety Agency defines a Patient Safety Incident as: "Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care".

"Being open" and "Duty of Candour"

Practices must:

- Acknowledge, apologise and explain when things go wrong;
- Carry out investigations into incidents affecting Patient Safety;

- Provide support for those involved in the incident (patients and staff) to cope with the physical and emotional impact.
- Reassuring patients, families and carers that lessons learned will prevent any patient safety incidents happening in future;

Definition of “Levels of Harm”

No harm

- Impact prevented – any incident that had the **potential** to cause harm but was prevented and resulted in no harm to staff or patients.
- Impact not prevented - any incident that has occurred, but resulted in **no harm** to people receiving care.

Low
An incident that required extra observation or minor treatment and caused **minimal harm**, to one or more persons receiving care.

Moderate
An incident that resulted in a moderate increase in treatment (e.g. increase in length of hospital stay by 4-15 days) and which caused **significant but not permanent harm**, to one or more persons receiving NHS-funded care.

Severe
An incident that appears to have resulted in **permanent harm** to one or more persons receiving care.

Death
An incident that directly resulted in the death of one or more persons receiving care.

A “Sincere Apology”

The Duty of Candour states that an apology does not constitute an admission of liability. Patients and relatives will request detailed explanations of what led to the incident(s) occurring (and their adverse outcomes), and an apology and acknowledgement of the impact it has on them helps to understand that there are lessons that the Practice can learn to ensure this does not happen again in the future.

To meet the requirements of **CQC Regulation 20**, a Practice must be:

- Open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity.
- Tell the relevant person (in person) as soon as reasonably practicable after becoming aware that a safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the Practice’s knowledge, is true of all the facts the Practice knows about the incident as at the date of the notification.

- Advise the relevant person what further enquiries the Practice believes are appropriate.
- Offer an apology.
- Follow up by providing the same information in writing, and any update on the investigations.
- Keep a written record of all communication with the relevant person.

Recognising an Incident

The relevance of the Duty of Candour begins with an acknowledgement that as the result of a safety incident, a patient has suffered moderate or major harm, or has died.

As soon as an incident has occurred or been identified;

- Clinical care must be administered to prevent further harm.
- If any additional treatment is necessary, it should happen as soon as reasonably practicable after discussing with the patient (or carer if the patient is unable to participate in discussion) and with the appropriate consent.

Summary of CQC Regulation 20 : Duty of Candour

All staff must have responsibility to adhere to that organisation's policies and procedures around duty of candour, regardless of their level of seniority or whether they are permanent, temporary/casual members of staff.

Regulation 20 defines what constitutes a notifiable safety incident. It includes incidents that could result in, or appear to have resulted in, the death of the person using the service or severe harm, moderate harm, or prolonged psychological harm.

Where the degree of harm is not yet clear, the relevant person must be informed of the notifiable safety incident in line with the requirements of the regulation.

The Practice is not required by the regulation to inform a person using the service when a 'near miss' has occurred, and the incident has resulted in no harm to that person.

There must be appropriate arrangements place to notify the person using the service who is affected by an incident if they are;

- **16 years and over** and
- **lack capacity to make a decision regarding their care or treatment** (as determined in accordance with sections 2 and 3 of the 2005 Mental Capacity Act)

this includes ensuring that a person acting lawfully on their behalf (e.g. persons acting as Carer) is notified as the relevant person.

Other than the situations outlined above, information should only be disclosed to family members or carers where the person using the service has given their express or implied consent.

A step-by-step account of all relevant facts known about the incident at the time must be given, in person, by one or more appropriate representatives of the Practice. This should include as much or as little information as the relevant person wants to know, 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, the Practice should consider whether interpreters, advocates, communication aids etc. should be used, while being conscious of any potential breaches of confidentiality in doing so.

The Practice must also explain to the relevant person what further enquiries they will make.

The Practice must ensure that a meaningful apology is given, in person, by one or more appropriate representatives of the Practice to relevant persons. An apology is defined in the regulation as an expression of sorrow or regret. The NHS Litigation Authority has produced guidance on making an apology (http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf), which states that saying sorry is not an admission of legal liability.

In making a decision about who is most appropriate to provide the notification and/or apology, the Practice should consider seniority, relationship to the person using the service, and experience and

expertise in the type of notifiable incident that has occurred. The Being Open Framework referenced below provides guidance on this.

The Practice must give the relevant person all reasonable support necessary to help overcome the physical, psychological and emotional impact of the incident.

This could include all or some of the following:

- Treating them with respect, consideration and empathy.
- Offering the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate.
- Offering access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille etc.
- Providing access to any necessary treatment and care to recover from or minimise the harm caused where appropriate.
- Providing the relevant person with details of specialist independent sources of practical advice and support or emotional support/counselling.
- Providing the relevant person with information about available impartial advocacy and support services, their local **Healthwatch** and other relevant support groups, for example **Cruse Bereavement Care and Action against Medical Accidents (AvMA)**, to help them deal with the outcome of the incident.
- Arranging for care and treatment to be delivered by another professional, team or provider if this is possible, should the relevant person wish.
- Providing support to access its complaints procedure.
- The Being Open Framework referenced below provides guidance on how to support patients, their families and carers when a patient safety incident has occurred.

The Practice must ensure that written notification is given to the relevant person following the notification that was given in person, even though enquiries may not yet be complete.

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.

The outcomes or results of any further enquiries and investigations must also be provided in writing to the relevant person through further written notifications, should they wish to receive them.

The Practice must make every reasonable attempt to contact the relevant person through all available communication means. All attempts to contact the relevant person must be documented.
If the relevant person does not wish to communicate with the Practice, 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.

Appendix 1 : Actions and Timescales for Duty of Candour requirements

Requirement under Duty of Candour	Timeframe
Patient or their family/carer informed that incident has occurred (moderate harm, severe harm or death)	**Maximum 10 working days** from incident being reported
A verbal notification of incident (preferably face-to-face where possible) unless patient or their family/carer decline notification or cannot be contacted in person. A Sincere expression of apology must be provided verbally as part of this notification.	**Maximum 10 working days** from incident being reported
Offer of written notification made. This must include a written sincere apology.	**Maximum 10 working days** from incident being reported A record of this offer and apology must be made (regardless if it has been accepted or not)
Step-by-step explanation of the facts (in plain English) must be offered.	As soon as practicable This can be an initial view, pending investigation, and stated as such to the receiver of the explanation.
Maintain full written documentation of any meetings.	No timeframe If meetings are offered but declined this must be recorded.
Any new information that has arisen (whether during or after investigation) must be offered.	As soon as practicable
Share any incident investigation report (including action plans) in the approved format (Plain English) With patient/relative/carer.	**Within 10 working days** of final report being signed off as complete and closed
Copies of any information shared with the patient to the commissioner, upon request.	As necessary