Duty of Candour
Key Principles

This Key Principles document has been developed with the legal input and support of DAC Beachcroft LLP
1. Objective

This document is intended to summarise the key legal and regulatory issues that arise in relation to the statutory Duty of Candour, enforced by the Care Quality Commission (CQC). The intention is to prompt and support AIHO member organisations into considering this key issue, by highlighting the central principles and to help to signpost some common strengths and weaknesses of local policy. AIHO members are encouraged to develop local, organisation specific policies to address the principles in this document.

2. Context - Overview of Duty of Candour in England

The statutory Duty of Candour was introduced for all health and social care providers registered with the CQC with effect from 1 April 2015. It arose as a result of growing concern that health and social care bodies were not culturally as transparent and open with patients and service users as they should be, when incidents resulting in harm arose in the context of care or treatment being provided. After much debate, a statutory Duty of Candour was introduced in England, as an express element within the Fundamental Standards regulated by the CQC. (Scotland, Wales and Northern Ireland have set out their own intentions to introduce a statutory Duty of Candour).

All providers of healthcare registered with the CQC must therefore be able to demonstrate compliance with this Duty of Candour, which will be checked at all inspections by the regulator, as well as being specifically tracked following statutory notification of an incident.

The detail of how to comply with the duty is set out below, but in principle, a provider needs to ensure it can achieve the following:

- a. Recognise when a notifiable safety incident has occurred
- b. Tell the patient the truth about what has happened
- c. Apologise for the incident and support the patient.

It is important to also be aware of the existence of other Duties of Candour, as the precise definitions are not identical, albeit the principles are. There is a contractual Duty of Candour contained within the standard NHS commissioning contract, and therefore any AIHO member delivering services commissioned by the NHS will need to consider its contractual duties around candour in addition to the regulatory duties set out in this document.

In addition, every doctor or nurse registered with the General Medical Council (GMC) or Nursing & Midwifery Council (NMC) already has an individual, professional Duty of Candour as part of his or her professional conduct requirements through that registration. Following the introduction of the ‘corporate’ level statutory Duty of Candour by the CQC for providers, both the GMC and NMC revisited the individual Duty of Candour for their registrants, and co-authored a guidance document http://www.gmc-uk.org/guidance/ethical_guidance/27234.asp to improve awareness of the individual duty for registrants, and to achieve greater consistency with the corporate Duty of Candour.
Please note:

- Corporate compliance with the statutory Duty of Candour at provider level should broadly ensure compliance with the contractual Duty of Candour (if contracting with NHS commissioners in any given care related incident arising)

- Corporate compliance does not however automatically deliver individual professional compliance for the GMC or NMC, and individual practitioners must also ensure they have dealt with transparency in the event of an incident causing harm, in a way that meets their individual professional obligations too

- Independent sector providers must ensure clinicians with practising privileges are aware of their role in ensuring candour at a corporate provider level is delivered (i.e. through training, through incident reporting and cooperation with incident investigations and, where appropriate, taking part in notification meetings – see point 6.)

3. What is the statutory Duty of Candour?

The general principle is clear, honest and effective communication with patients, their families and carers throughout their treatment, in particular when things go wrong. All healthcare providers have a general duty to act in an open and transparent way, however the statutory Duty of Candour mandates a particular approach to incidents causing harm.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires that, in the event a registered provider becomes aware of a notifyable safety incident which in the reasonable opinion of a health professional appears to have resulted in certain defined levels of harm, the provider must as soon as reasonably practicable after becoming aware:

a. Notify the relevant person (i.e. the patient, or someone lawfully acting on their behalf, if they are deceased or do not have capacity to engage on the issue, based on the test for capacity contained in the Mental Capacity Act 2005)

b. Provide reasonable support to the relevant person (i.e. in relation to the incident, any investigations, any harm suffered, and the process of engagement with the patient around Duty of Candour).

How the above is achieved is very specific within Regulation 20, and key operational steps must be built into any local policies (for example, incidents management policy, claims policy, complaints policy etc.) to ensure compliance. See also point 6.
4. When is the duty triggered?

A simple formula that can be applied is:

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<th>Unexpected/unintended incident during the provision of care</th>
<th>PLUS harm to the patient that meets the defined threshold</th>
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Providers should be aware that if an incident occurs, but there is no harm caused to the patient, this does not technically trigger the statutory Duty of Candour. Similarly, if a patient suffers harm, but it does not arise as a result of a notifiable safety incident, then this particular duty is not triggered. The incident also has to arise in the context of the treatment or care provided (i.e. in the course of delivering the regulated activities for which you as a provider are registered with the CQC).

It is however, right to note that the key driver for the statutory Duty of Candour in the sector was to ensure openness and transparency with patients, through an improved culture of care. Therefore, many providers will choose to adopt the same transparent and open approach to incidents or harm to patients, even if the statutory duty has not technically been triggered. Whist this can result in some resource implications around managing such situations, taking a broader view of candour can ensure (a) that your organisation will be compliant from a regulatory perspective, even if the case is borderline or you have misjudged whether the statutory duty is triggered and (b) may deliver far greater cultural change than taking a more limited approach to the duty.

5. What does it mean for the Independent sector?

Duty of Candour is a Fundamental Standard and therefore forms part of the CQC (NHS and independent acute hospitals) Key Lines of Enquiry for the domains of safe and well led:

- **Safe** – Are people who use services told when they are affected by something that goes wrong, given an apology and informed of actions taken as a result
- **Well Led** – Does the culture encourage candour, openness and honesty?

There are currently two separate definitions associated with notifiable safety incident, and the associated level of harm that will trigger the statutory duty of candour. NHS Bodies (defined as NHS Trusts, Foundation Trusts and Special Health Authorities) have a broader definition to follow, such that when considering harm linked to the incident, NHS bodies have to also include whether the incident “could result in, or appears to have resulted in” the list of harm described.

For AIHO members, a narrower definition is given, which does NOT include the words “could result in”, and therefore the independent sector currently does not need to consider the potential for harm arising, but simply whether harm (as defined) has, in the reasonable opinion of a healthcare professional, occurred.

The existence of two definitions is generally regarded as unhelpful in the sector, particularly where there is increasing integration of health services and care pathways. Despite proposing a consultation on creating a single definition for all providers, the CQC have yet to pursue this, and AIHO members should therefore consider the following wording as applying to them:
Notifiable incident description for independent sector providers

Where there has been an unintended or unexpected incident to a patient or service user during the provision of a regulated activity;

AND

This incident, in the reasonable opinion of a healthcare professional, results in

- Death of a service user (where it arises as a result of the incident, not simply the underlying condition)
- Impairment of sensory, motor or intellectual functions lasting > 28 days
- Changes to the structure of the body
- Prolonged pain or psychological harm lasting > 28 days
- Shortening of life expectancy, or
- Treatment to prevent any of the above occurring.

6. What do AIHO members have to do, practically, to comply?

a. Tell the patient (or other relevant person) that the incident has happened. This must be in person by one or more representatives of your organisation

b. Provide a true account (to the best of your knowledge at the time), of the facts of the incident

c. Tell the patient (or other relevant person) how you will investigate the incident (including involving them – a best practice point rather than a regulatory requirement)

d. Apologise to the patient (or other relevant person) for the incident occurring

e. Create a written record of the above notification meeting and keep it securely

f. Follow up the above meeting by repeating the key elements in writing

g. Offer support and information.

If a face to face meeting is not possible or appropriate, agree with the patient/other relevant person, alternatives – for example, written or telephone discussion. Keep a record of attempts to engage the patient in the above, if the patient does not engage or indicates they do not wish to meet. The CQC will need to see that every effort was made to comply with this duty.

At a practical level, this notification meeting is crucial – not only for the provider but also for the patient. Choosing who holds the meeting is essential, and it is important to be mindful of personal involvement in the incident itself (which may introduce bias, tone or secondary victim issues if the healthcare professional is effected by what has happened). It is also important to have someone present who knows the clinical context sufficiently well to answer questions the patient may have. Offering the patient someone to support them in the meeting is also prudent.

Providers will also need to be aware of the parallel rights of employees in the event disciplinary investigations are ongoing, or indeed the sensitivities of external agencies if a coroner’s investigation or a police investigation is ongoing. Realistically, only a police investigation may impede the provider’s ability to engage the patient or other relevant person in this notification meeting.
7. What the statutory duty is not – dispelling common ‘urban myths’:

a. Duty of Candour does not apply to near misses

b. Culpability or otherwise is not part of the equation

c. It can include recognised complications and risks the patient has consented for (for example, a major bleed might be a recognised complication, but what if the cause of the bleed was poor surgical technique? This would also trigger most providers own incident reporting requirements in any event)

d. An apology under Duty of Candour does not amount to an admission of civil liability/medical malpractice etc.

8. What does compliance with the Duty of Candour currently look like?

a. Hard evidence:
   i. Ability to consistently identify that an incident and particular levels of harm have occurred
   ii. Evidence that you tell patients in a timely manner when notifiable safety incidents have occurred
   iii. Evidence to support the patient after the incident
   iv. Evidence that you provide the patient with an apology in writing
   v. Keeping a written record of all communication with the patient/relevant person.

b. Soft evidence:
   i. Demonstrating an open and honest culture across and at all levels within your organisation
   ii. Promoting a culture that encourages candour
   iii. Ensure staff have adequate training – including Board level
   iv. Demonstrating Board level commitment to candour, such that openness comes from all that you do as an organisation (part of a well led provider)
   v. Having a positive reporting culture, with effective incident investigation and feedback
   vi. Taking lack of candour seriously, including consideration of reporting to professional bodies.

9. What happens if a provider gets this wrong?

The most common impact of a provider not having robust processes in place to satisfy the statutory Duty of Candour, is negative commentary within an inspection report, impact on ratings and potentially a requirement notice.

If corporate providers find non-compliance with candour amongst their health care professionals, they must consider whether this triggers referral to the individual’s professional body.
10. Key references and sources of information for AIHO Duty of Candour – Key Principles

CQC Regulation 20
http://www.cqc.org.uk/content/regulation-20-duty-candour

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Mental Capacity Act 2005

11. Document review date

September 2019 or reactive in the event of regulatory change
AIHO is the trade association for independent healthcare hospitals across the UK. It provides a voice for the sector to stakeholders, media and government.

AIHO represents over 250 hospitals that provide services to insured, self-pay and NHS funded patients. AIHO members are a wide range of private and charitable providers. Members vary from large hospital groups to smaller, specialist providers of specific surgeries and treatments.

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