

## Candour - what is a Notifiable Patient Safety Incident?

The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014 introduces the statutory duty of candour. While the terms used in those regulations are slightly different, they are based on the requirements of the contractual duty of candour and the *Being Open* framework.

The most important point is that the term “reportable patient safety incident” has been changed to “notifiable safety incident” and given the following definition:

“Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in –

- (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
- (b) severe harm, moderate harm or prolonged psychological harm to the service user.”

Note that the key measure is the level of harm that has occurred and not on the scale of any incident. The duty also now applies to “prolonged psychological harm” as well as physical harm.

### The regulations themselves offer little help in defining “incident”

The regulations do not define what constitutes an “incident”. On one level an incident is simply the occurrence of harm. Many serious incidents are first reported on the basis of a patient being harmed (such as a patient falling on the ward) before the organisation is aware of whether or not there is any failure in care. On another level it is where something

has very obviously going wrong during a procedure or episode of care.

A strict interpretation of the regulations could mean that the duty of candour applies to any “unintended or unexpected” occurrence of harm (if that harm meets the threshold) even if it is a recognised complication and occurred despite the best of care. Even where the harm may not be “unexpected”, it is still caught by the definition because it is “unintended”.

However, it is difficult to see that this is really what was intended by Robert Francis QC or the Government, when they recommended and introduced the duty.

### The regulator’s guidance suggests a “mistake or error” interpretation.

As a provider of regulated activity, an NHS body is required to have due regard to guidance issued by the Care Quality Commission (CQC). In November 2014 the CQC issued a new guidance document addressing both the fit and proper persons test and the duty of candour. In the overview relating to duty of candour they explain the approach they will be taking to assess whether a provider is complying with the new regulation:

“During the inspection process, we will assess whether the provider is delivering good quality care. Two specific key lines of enquiry (KLOEs) under the safe and well-led questions are relevant to the duty of candour:

**S2:** Are lessons learned and improvements made when things go wrong?

Prompt: Are people who use services told when they are affected by something that goes

wrong, given an apology and informed of any actions taken as a result?

**W3:** How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?

Prompt: Does the culture encourage candour, openness and honesty?"

The implication of this is that the inspectors will be assessing whether services users are told about "things [that] go wrong". The CQC appears to envisage that the duty will be triggered when there has been a "notifiable safety incident" where it can be said that there has been a "deviation, error or mistake" in respect of the care or treatment. There must be something that can be pointed to as the "incident" rather than simply the occurrence of a recognised complication or consequence of correct treatment given.

This is supported by the guidance provided under the "summary of regulation" section at p29:

"The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on behalf of them) in general in relation to care and treatment, and specifically when things go wrong with care and treatment, and that they provide them with reasonable support, truthful information and an apology when things go wrong."

This guidance suggests the duty is triggered "when things go wrong with care and treatment".

For example, a patient may report a chemotherapy burn in the days after attending for treatment and be asked to return to hospital for further care. It may be, in the reasonable opinion of a healthcare professional, that this meets the definition of moderate harm (it is significant and requires a moderate increase in treatment) but may not be considered an "incident" in the absence of suggestion that anything "went wrong" when the chemotherapy was administered.

When it is unclear if there is a mistake, you should consider investigating.

There will be many cases where a patient reports harm that may or may not have occurred because of an error or mistake in the treatment they received.

A dementia patient may fall on the ward for example, sustaining significant injuries that require a moderate increase in treatment. Everything may have been done appropriately to care for that individual and the fall may simply be an accident. However, this is almost certainly going to be something that you would want to discuss with the "relevant person" be that the patient or a relative. It is certainly appropriate to treat the incident as though the duty of candour applied and it is possible that a detailed investigation reveals that more could have been done to prevent it – in which case the incident may then meet the definition of a notifiable patient safety incident.

The same may be true of any number of recognised complications, from the relapse of a mental health patient who starts new therapy, a patient who suffers serious side effects from medication or the patient who develops a serious complication.

Therefore, it is a matter of judgment that needs to be exercised on a case by case basis to determine whether a notifiable patient safety incident has occurred. What may or may not appear to be an incident at the outset may look very different once more information comes to light. Providers should ensure that notifiable patient safety incidents are reported retrospectively when necessary.

It should be remembered that the whole point of the duty of candour is to ensure patients are told when harm occurs as a result of the care they receive.

## Get in touch

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