Secondary care providers registered with CQC in England are now subject to a statutory duty of candour, introduced in November 2014. Dr Michael Devlin, head of professional standards and liaison at the Medical Defence Union, explains the new law, which sits alongside the existing contractual and ethical duties of candour.

For over 50 years the MDU has advised doctors to tell patients when things have gone wrong, to apologise and to try and put things right. This is in addition to the ethical requirement to be open and honest, and the more recent contractual duty of candour.

Now the government has introduced a further duty of candour on secondary care organisations registered with CQC – one required, and enforceable, by law.

**Ethical guidance**

Doctors have had a professional duty of candour for many years. In its core guidance for doctors, *Good medical practice (2013)* paragraph 55, the GMC says:

“You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

a. put matters right (if that is possible)
b. offer an apology
c. explain fully and promptly what has happened and the likely short-term and long-term effects.”

**Contractual duty of candour**

NHS organisations whose services are commissioned under a post-April 2013 standard NHS contract, with the exception of primary care services, already have a contractual duty of candour.

**Statutory duty of candour**

The new statutory duty of candour was introduced for NHS bodies in England (trusts, foundation trusts and special health authorities) from 27 November 2014, and will apply to all other care providers registered with CQC from 1 April 2015.

The obligations associated with the statutory duty of candour are contained in regulation 20 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The key principles are:

1. Care organisations have a general duty to act in an open and transparent way in relation to care provided to patients. This means that an open and honest culture must exist throughout an organisation.

2. The statutory duty applies to organisations, not individuals, though it is clear from CQC guidance that it is expected that an organisation’s staff cooperate with it to ensure the obligation is met.

3. As soon as is reasonably practicable after a notifiable patient safety incident occurs, the organisation must tell the patient (or their representative) about it in person.
4. The organisation has to give the patient a full explanation of what is known at the time, including what further enquiries will be carried out. Organisations must also provide an apology and keep a written record of the notification to the patient.

5. A notifiable patient safety incident has a specific statutory meaning: it applies to incidents where a patient suffered (or could suffer) unintended harm that results in death, severe harm, moderate harm or prolonged psychological harm. Severe and moderate harm definitions are derived from the NPSA’s Seven Steps to Patient Safety. Prolonged psychological harm means that it must be experienced continuously for 28 days or more.

6. There is a statutory duty to provide reasonable support to the patient. Reasonable support could be providing an interpreter to ensure discussions are understood, or giving emotional support to the patient following a notifiable patient safety incident.

7. Once the patient has been told in person about the notifiable patient safety incident, the organisation must provide the patient with a written note of the discussion, and copies of correspondence must be kept.

Doctors, who are used to having candid discussions with their patients, are most likely to be the organisation’s representative under the statutory duty. It is important that you cooperate with your organisation’s policies and procedures, including the requirement to alert the organisation when a notifiable patient safety incident occurs.

An area of difficulty may be deciding whether an incident reaches the threshold for notification under the statutory duty. This may be confusing, as the threshold is low for the doctor’s ethical duty (any harm or distress caused to the patient) while the thresholds for the contractual and statutory duties are higher and slightly different (with the inclusion of prolonged psychological harm in the statutory duty).

Where an organisation’s clinical governance procedures for reporting and investigating incidents are followed, it is unlikely that a notifiable patient safety incident will be overlooked. And in any event, doctors must always follow their ethical duty, irrespective of whether the statutory duty applies.
Case study

Bowel perforation

After a difficult appendicectomy, the patient became increasingly unwell the following day and was reviewed by the consultant. Investigations suggested a perforated viscus, which was not noted during the operation. The consultant and core trainee (who had carried out the surgery) both went to see the patient. They explained that it was probable the bowel had been damaged while separating adhesions during surgery. Although the patient had been told of this risk before surgery, the doctors apologised for what had happened, in keeping with their ethical duty of candour.

After surgery to repair the perforation, the patient recovered well, but her hospital stay was longer than it might otherwise have been. When the patient had recovered from the anaesthetic, and comfortably settled on the ward, the consultant went back to speak to her. She was told that a bowel perforation was confirmed, treated, and it was anticipated she would make a full recovery. The consultant reiterated his apology. The nursing team caring for the patient supported her emotionally, and ensured she had fully understood what she had been told. The senior member of the healthcare team made contemporaneous notes in the clinical records of discussions with the patient on each occasion she was seen.

The consultant notified the trust manager responsible for duty of candour arrangements in the hospital and also followed the trust’s clinical governance procedures for reporting patient safety incidents. Referring to CQC guidance, the manager and consultant agreed that it was a notifiable patient safety incident, and that the discussions that had taken place were appropriate and sufficient under the statutory duty of candour obligations. It was also noted that the way in which the consultant had addressed the incident complied with the trust’s contractual duty and a report was made to the commissioners in line with the contractual obligations. They agreed the consultant would write to the patient, summarising what had happened.

The consultant personally delivered a letter to the patient, summarising all that was known about what had happened, and which repeated the earlier apologies. The patient was recovering well, and appreciated the consultant’s personal touch and professionalism. She said she believed that the complication had not been anyone’s fault — so far as she was concerned the matter was satisfactorily resolved.

The consultant made a final note in the clinical records of the discussion, relaying this to the manager so that the trust’s notification process was complete.
Healthcare organisations (other than health service bodies) registered with CQC in England are now subject to a statutory duty of candour, introduced in April 2015. Organisations who are not health service bodies include general practices and doctors working in independent practice.

Dr Michael Devlin, head of professional standards and liaison at the Medical Defence Union, explains the new law, which sits alongside the existing ethical duty of candour.

For over 50 years the MDU has advised doctors to tell patients when things have gone wrong, to apologise and to try and put things right. This is in addition to the ethical requirement to be open and honest.

Now the government has introduced a statutory duty of candour on general practices and independent providers registered with CQC – one required, and enforceable, by law.

**Ethical duty**

Doctors have had a professional duty of candour for many years. In its core guidance for doctors, *Good medical practice* (2013) paragraph 55, the GMC says:

“You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

a. put matters right (if that is possible)
b. offer an apology
c. explain fully and promptly what has happened and the likely short-term and long-term effects.”

**Statutory duty of candour**

The obligations associated with the statutory duty of candour are contained in regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The key principles are:

1. Care organisations have a general duty to act in an open and transparent way in relation to care provided to patients. This means that an open and honest culture must exist throughout an organisation.

2. The statutory duty applies to organisations, not individuals, though it is clear from CQC guidance that it is expected that an organisation’s staff cooperate with it to ensure the obligation is met.

3. As soon as is reasonably practicable after becoming aware of a notifiable patient safety incident, the organisation must tell the patient (or their representative) about it in person.

4. The circumstances that give rise to a requirement to tell the patient or their representative about something that has gone wrong are the same as those that are required to be notified without delay to the CQC. This notification to CQC is separate from and in addition to the statutory duty of candour which requires the organisation to keep copies of correspondence with the patient.

5. The organisation has to give the patient a full explanation of what is known at the time, including what further enquiries will be carried out.
Organisations must also provide an apology and keep a written record of the notification to the patient. Failure to make that notification may amount to a criminal offence.

6. A notifiable patient safety incident has a specific statutory meaning: it applies to incidents where something unintended or unexpected has occurred in the care of a patient and appears to have resulted in:
   a. their death, where this relates to the incident and is not simply due to the natural progression of the illness or condition;
   b. impairment (of sensory, motor or intellectual function) that has lasted or is likely to last for 28 days continuously;
   c. changes to the structure of the body (for example, amputation following arterial occlusion);
   d. prolonged pain or prolonged psychological harm. The pain or psychological harm must be, or likely to be, experienced continuously for 28 days or more;
   e. shortening of their life expectancy;
   f. or where the patient requires treatment by a healthcare professional in order to prevent death, or the adverse outcomes listed above.

7. There is a statutory duty to provide reasonable support to the patient. Reasonable support could be providing an interpreter to ensure discussions are understood, or giving emotional support to the patient following a notifiable patient safety incident.

8. Once the patient has been told in person about the notifiable patient safety incident, the organisation must provide the patient with a written note of the discussion, and copies of correspondence must be kept. Following the initial notification the patient must be given written notification including details of any further enquiries into the incident and their results and an apology.

Although the statutory duty of candour applies to organisations, doctors, who are used to having candid discussions with their patients, are most likely to be the organisation’s representative under the statutory duty. It is important that you cooperate with your organisation’s policies and procedures, including the requirement to alert the organisation when a notifiable patient safety incident occurs.

An area of difficulty may be deciding whether an incident reaches the threshold for notification under the statutory duty. This may be confusing, as the threshold is low for the doctor’s ethical duty (any harm or distress caused to the patient) while the threshold for the statutory duty is higher and complex.

Where an organisation’s clinical governance procedures for reporting and investigating incidents are followed, it is unlikely that a notifiable patient safety incident will be overlooked. And in any event, doctors must always follow their ethical duty, irrespective of whether the statutory duty applies.

Reference

1. Care Quality Commission (Registration) Regulations 2009, regulations 16 and 18.
Case study

Delayed diagnosis of malaria

A young man, who had just returned from East Africa after working as a volunteer in a school, attended a GP’s surgery feeling unwell. The patient said that he had a temperature, felt like he had flu with aches all over and that he was very tired. He had also been increasingly restless and had vomited several times. On questioning, the patient said that he had taken all his anti-malarials and not missed a dose. The GP wondered if the patient might have developed hepatitis A and took some blood for serology and a full blood count. A malarial parasite screen was not specifically requested. The patient was advised to come back if he felt worse and in any event to call again after 48 hours to discuss the results of the blood tests.

Thirty six hours later a message was received from the out-of-hours service to say that they had been called to see the patient who was febrile, drowsy and had signs of meningo-encephalitis. The patient had been admitted to hospital. Concerned that he had missed a serious condition in the patient, the GP contacted the physician under whose care the patient had been admitted. The consultant said that the patient had cerebral malaria and was comatose and that there had been seizures. The GP was very concerned that the patient might not recover, or might suffer neurological damage. As was required under the statutory duty of candour, the GP practice wrote to the patient to summarise what had happened and that they planned to review the case in detail to see what lessons could be learned. The letter summarised the investigation the practice had carried out, including details of enquiries undertaken and their results, and reiterated the treating GP’s earlier apology and confirmed that they would write again after the case had been discussed under their clinical governance procedures.

The patient did survive, but was unfortunately left with cerebellar ataxia. He had seen a neurologist, who advised that although it may improve slightly, it was likely to be permanent. The doctor had not been able to see the patient until he had been discharged, but he then did so straight away. He had a full and frank discussion with the patient, explained that he should have suspected the possibility of malaria when he first attended the surgery, and arranged the necessary diagnostic tests or sought the urgent opinion of a consultant. The doctor apologised to the patient.

As was required under the statutory duty of candour, the GP practice wrote to the patient to summarise what had happened and that they planned to review the case in detail to see what lessons could be learned. The letter summarised the investigation the practice had carried out, including details of enquiries undertaken and their results, and reiterated the treating GP’s earlier apology and confirmed that they would write again after the case had been discussed under their clinical governance procedures.

The practice arranged for an early significant event audit of the incident, and invited the hospital consultant, who attended. The outcome was that the GP had been falsely reassured by the history given by the patient of having taken his anti-malarials and that the diagnosis should have been considered. But the consultant said that it was by no means certain that the patient would not have developed cerebral malaria even if the diagnosis had been made earlier.

All correspondence and discussions with the patient were carefully documented and retained in the clinical records. At a practice meeting it was decided that the statutory duty had been complied with and nothing further was required. There was correspondence with the COC who had been notified about the incident and the actions taken by the practice. The COC was satisfied that all necessary action had been taken and that the matter was concluded.