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.

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.

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.”
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 meningism. 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. 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.

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.

In addition to the written notification required by the duty of candour, a further letter was sent to the patient which detailed all the discussions of the significant event audit meeting and again apologies were given about what had happened. The patient came to see the treating GP shortly after receiving the letter. He said that he had been giving thought to speaking to a solicitor about the delay in diagnosis, but on reflection he had been struck by the openness, the apologies and the care and support of the GP and the rest of the practice. He had noticed his ataxia was improving and he felt that the most important thing to happen was for the doctors to learn from the incident, and he was satisfied that had happened.

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.

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.

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.

At the practice the GP met with his colleagues and the practice manager. They all agreed that what had happened was a notifiable patient safety incident and that the statutory duty of candour would apply. As this was the case, it was also necessary to notify the COC without delay under their registration requirements, which was done that same day.
For individual medico-legal advice:

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