The key principles are:

1. Regulations 2014 (as amended).
2. Health and Social Care Act 2008 (Regulated obligations are set out in regulation 20 of the registered care providers (such as dental authorities) in November 2014. Since 1 April 2015, it was extended to all other CQC-registered care providers (such as dental practices in England).

3. The GDC, along with other healthcare regulators, recognises a common professional duty to be open and honest when things go wrong. The professional duty of candour means that when something goes wrong with patients’ treatment or care and which causes (or could cause) harm or distress, dental professionals must:
   - tell the patient (or their representative) when something has gone wrong
   - apologise to the patient
   - offer an appropriate remedy or support to put matters right, if that is possible
   - explain fully to the patient the short- and long-term effects of what has happened.

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 in addition to the statutory duty of candour.

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.

6. 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.

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.

Statutory duty of candour

A statutory duty of candour was first introduced for NHS bodies in England (trusts, foundation trusts and special health authorities) in November 2014. Since 1 April 2015, it was extended to all other CQC-registered care providers (such as dental practices in England).

The statutory duty of candour and its obligations are set out in regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended). It applies regardless of whether a complaint has been made or a question asked about it. The key principles are:

1. 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, although it is expected that an organisation’s staff will 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 in addition to the statutory duty of candour.

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.

6. 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.

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.

The position in devolved nations

Wales

The Welsh Government is looking to update the NHS regulations to make clear the organisational duty to be open when harm occurs.

Northern Ireland

The Health Minister announced in January 2015 that a statutory duty of candour will be introduced in Northern Ireland. A date for this to be implemented has not yet been announced.

Scotland

The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 received Royal Assent on 1 April 2016 and introduced a new organisational duty of candour on health, care and social work services. This is due to come into effect on 1 April 2018.

Notifiable patient safety incidents

NHS body (trust, foundation trust, etc)

In relation to a health service body, a notifiable safety incident means 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:

- 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
- severe harm, moderate harm, moderate increase in treatment or prolonged psychological harm to the service user.

‘Severe harm’ means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition.

‘Moderate harm’ means harm that a) requires a moderate increase in treatment, and b) significant, but not permanent, harm.

‘Moderate increase in treatment’ means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

‘Prolonged psychological harm’ means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Non-NHS body (dental practices)

In relation to a registered person who is not a health service body, a notifiable safety incident means 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:

- appears to have resulted in:
  i. 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
  ii. an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days.
Case study: Damage to lingual nerve
A 26-year old woman attended her general dental practitioner for removal of an impacted lower right third molar that was causing recurrent pericoronitis. The dentist was experienced in removing wisdom teeth and proceeded with the extraction under local anaesthetic.

However, the procedure was not as straightforward as the dentist had hoped and took 25 minutes to complete. The woman, although anxious about the procedure, was otherwise well and was given advice on surgical aftercare and told to come back if she had any problems.

The woman returned 10 days later, reporting tingling and a loss of sensation on the right side of the tongue and floor of the mouth, with occasional throbbing. On examination, the dentist found reduced sensation to pinprick. The dentist realised that the right lingual nerve had been damaged, possibly when using the periosteal elevator during the extraction.

He explained what had happened to the patient and, although he had warned about the possibility of nerve damage before undertaking surgery, he nonetheless apologised that it had occurred. The dentist offered to refer her to a maxillo-facial surgeon with a particular interest in nerve damage, to which the patient agreed.

Later that day the dentist discussed the adverse incident with two of his partners and the practice manager. They concluded that although the neural symptoms may well resolve, they were likely to persist for at least 28 days continuously. Therefore, it was a situation where the statutory duty of candour would apply. It was also necessary to notify COC without delay to comply with registration requirements. The partners agreed that the initial notification to the patient had been entirely appropriate, and that they should write to her as well.

Although he understood that the statutory duty of candour falls on the organisation, not the individual, the dentist believed it was right for him to write personally to the patient, on behalf of the organisation, reiterating his initial apology. The practice manager notified COC.

Several weeks later, the practice reviewed the case as a significant event audit. By that time the woman had seen the maxillo-facial surgeon who believed the prognosis was good and that she could be expected to recover. The discussions, which took into account comments from the maxillo-facial surgeon, reached the conclusion that although it had been reasonable to offer removal of the third molar in the practice, with hindsight there were some features on the X-ray which may have merited referral for hospital removal.

The dentist wrote again to the patient detailing the further discussions, and apologising once again. He also offered her a meeting to discuss the matter, which she accepted. Her lingual nerve symptoms began to improve, and she was optimistic that she would recover totally. She was pleased that the dentist and practice had been so open about what had happened, and had immediately offered an apology for what had been a distressing and worrying experience. As she expected to recover, the patient said she considered the matter closed.

COC asked the practice manager to update them when there were further developments. This was duly done and COC informed the practice that it noted the incident had been notified promptly and that the duty of candour had been followed. No further action was required.