Duty of candour
Judith Davison, Juliette Mellman-Jones and Jane Lang explain what dentists need to know

Following Sir Robert Francis’s report into the events at Mid Staffordshire NHS Foundation Trust, openness and transparency have been identified as fundamental principles of healthcare

Dentists will now find themselves subject to both a statutory and a professional duty of candour. Whilst a professional duty of candour has applied for many years, a joint statement from all of the healthcare regulators was issued in October 2014. The statutory duty of candour was introduced by regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and came into force for health service bodies (including dentists in NHS hospital practice) on 27 November 2014 and for primary dental care providers (and other non-health service body CQC-registered providers) on 1 April 2015.

The statutory duty
Regulation 20 effectively requires dentists in hospital practice and primary care dentists in practices registered with the CQC to act in an open and transparent way in relation to dental care and treatment provided to patients. This has been interpreted by the CQC to mean “clear, honest and effective communication with patients, their families and carers throughout their care and treatment, including when things go wrong”.

The statutory duty does not apply to individuals within the dental practice, or to individual dentists in hospitals, but to the organisation or hospital trust itself, namely – the provider registered with the CQC.

When will it apply and what must be done?
If a provider becomes aware of a “notifiable safety event”, it is required to:

• Notify the relevant person (usually the patient) that the incident has occurred;
• Provide reasonable support;
• Provide an account, true to the best of the provider’s knowledge, of all the facts known about the incident at the time;
• Advise about other relevant enquiries;
• Include an apology – which is considered to be an expression of sorrow or regret. It is explicitly stated not to include an admission of liability or guilt; and
• Record the account in writing and keep it securely.

What is a “notifiable safety incident”?
The definition of a “notifiable safety incident” for primary care dentists is subtly different to that which applies to dentists in NHS hospital practice.

It is defined as “any unintended or unexpected incident” which appears, to a reasonable healthcare professional, to have resulted in:
• Death;
• Impairment of sensory, motor or intellectual functions;
• Changes to the structure of the body;
• Prolonged pain or prolonged psychological harm; or
• Shortening of life expectancy.

There is also a duty to notify patients where any of the above types of harm would have arisen without the intervention of a health care professional.

The definition applicable to dentists in NHS hospital practice is whether an unintended or unexpected incident occurred which could result in, or appears to have resulted in:
• the patient’s death; or
• severe harm;
• moderate harm; or
• prolonged psychological harm.

The duty for dentists in NHS hospital practice to be candid about near misses is therefore subtly wider than that for primary care dentists.

The CQC has produced guidance for providers on the duty of candour. This sets out the CQC’s approach, which is to apply the duty proportionately to different providers, taking into consideration the size and type of the service and how relevant the regulation is to the provider’s regulated activity.

What are the consequences of non-compliance?
If a dentist does not comply with the duty of candour, the CQC has the power to issue fixed penalty notices and to prosecute registered providers for a breach. Non-compliance could also affect a provider’s continued registration with the CQC.
The professional duty
The professional duty is set out in a joint statement by the eight regulators of healthcare professionals in the UK. It requires all healthcare professionals to:
“be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress”.

The joint statement expanded upon this duty, requiring all healthcare professionals to:
• Tell the patient when something has gone wrong;
• Apologise to the patient;
• Offer an appropriate remedy or support to put matters right (if possible);
• Explain fully to the patient the short and long term effects of what has happened.

In addition to the requirements for openness and honesty with patients, healthcare professionals must also be open and honest with:
• Colleagues, employers and relevant organisations – taking part in reviews and investigations as requested; and
• Regulators – raising concerns where appropriate. They must support and encourage each other to be open and honest and, importantly, must not stop someone from raising concerns.

GDC draft guidance
The GDC recently consulted on its draft guidance on the duty of candour, which is expected to be published in early 2016. The guidance will reiterate the requirements of the joint statement and will provide further advice on telling the patient and apologising when things go wrong.

The guidance makes reference to the duty of a dental care provider (DCP) to raise concerns about patient safety and emphasises the need for those employing, managing or leading a team to ensure that staff members understand the need to be open and honest with patients and that the culture of the practice or workplace supports this.

The guidance does not provide any advice or assistance on how dentists or DCPs should manage differences of opinion within a practice and where there are conflicting views around whether there has been a trigger for a notification in accordance with the statutory or professional duty of candour. Practice principals may wish to consider how such issues will be dealt with and whether a policy or procedure should be implemented to address such a situation, before any conflict arises. Regular and open communication, plus frequent staff meetings to discuss any potential areas of concern, will minimise the likelihood of any conflict arising.

What are the consequences of non-compliance?
The Indicative Sanctions Guidance used by the Professional Conduct Committee (PCC) in fitness to practise hearings provides that the PCC should take very seriously, when considering what sanction to impose, any finding that the dental professional “took deliberate steps to avoid being candid with a patient or to prevent someone else from being so”.

Case study 1
Patient A attends the XY Dental Practice to have her wisdom teeth removed under conscious sedation. The dentist uses Midazolam for the procedure. Unfortunately, the dentist realises that patient A has been given too much sedation, resulting in an overdose. Patient A is admitted to hospital and makes a full recovery.

Both patients make a full recovery – are the statutory or professional duties of candour triggered in either case?
Yes – in both cases further treatment was required to prevent death, so the incidents would be classed as a “notifiable safety incident”, triggering the statutory duty of candour. The patients both suffered harm (and most likely distress as well) as a result of something going wrong with their treatment, so the professional duty of candour would also be triggered.

Case study 2
Patient B has a severe allergy to latex, which she stated in the medical history questionnaire she completed at XY Dental Practice. Patient B attended the practice for a dental procedure, but the dentist failed to check the patient’s medical history before starting the procedure and was wearing latex gloves. Patient B developed an anaphylactic reaction and required hospitalisation. She made a full recovery.

What steps must the dentists and/or the dental practices take to comply with the professional and/or statutory duty of candour?
The dentists should explain to the respective patients, at the earliest opportunity what went wrong. They should also provide an apology, initially a verbal apology, but followed up with a written one if the patient wishes to receive one (or if the practice policies require it). Any short or long term effects of what happened should be explained and the patients should be offered support. All discussions and apologies should be carefully recorded in the patients’ notes.

In addition, the dental practice should update the patients regarding any investigations into what went wrong and any steps that will be taken to prevent a repeat of the incident.
Case study 3
Patient C attends the XY Dental Practice for root canal treatment. Once satisfactory local anaesthesia is established, the dentist commences the endodontic treatment. She takes appropriate preventative measures, including wearing appropriate personal protective equipment, ensuring the use of a well-sealed rubber dam and instructing her dental nurse to use high volume suction. Initially the endodontic treatment progresses uneventfully, until the dentist is in the process of irrigating the root canal with sodium hypochlorite. The practice has recently switched dental suppliers and the concentration of sodium hypochlorite the practice recently received is 5.25% (as opposed to the 0.5% concentration provided by the previous supplier).

Whilst the root canal is being irrigated, patient C becomes distressed and reports a sudden extreme pain in the area of the treatment. The dentist realises she has inadvertently wedged the tip of the irrigation syringe into the root canal preventing the passive flow of irrigant. Patient C tells the Dentist he can smell and taste bleach, from which the dentist discerns that there may have been extrusion of the sodium hypochlorite into the soft tissues and quite possibly the maxillary antrum.

The dentist explains that she needs to conduct a thorough clinical and radiological assessment in order to determine the degree and extent of the injury. The dentist subsequently refers patient C to a maxillofacial surgeon at the local NHS Trust. The surgeon’s investigations confirm there has been extravasation of sodium hypochlorite resulting in irreversible tissue and nerve necrosis. Patient C has suffered a sensory disturbance of the maxillary hypochlorite resulting in irreversible tissue and nerve necrosis.

The dentist should apologise to patient C and explain the short and long term effects of what has happened. The discussions, apology and action should be recorded in patient C’s notes and a written apology provided as required.

The Practice should advise patient C about any investigations into the incident and the discrepancy in the concentration of sodium hypochlorite and should keep a written record. It would also be prudent for the Practice to raise the issue with the dental supplier to ensure that they are aware of the situation and can investigate as necessary.

At a glance comparison

<table>
<thead>
<tr>
<th>Statutory Organisational</th>
<th>Professional Individual</th>
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<tbody>
<tr>
<td>Care and treatment during performance of regulated activity</td>
<td>Care or treatment</td>
</tr>
<tr>
<td>Notifiable safety incident (note different definitions for health service body and for other registered persons)</td>
<td>When something goes wrong</td>
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<tr>
<td>Causes severe or moderate harm or prolonged psychological harm</td>
<td>Causes or has the potential to cause harm or distress</td>
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<tr>
<td>As soon as reasonably practicable - notify, support, apologise and record</td>
<td>As soon as dentist/DCP realises something has gone wrong - notify, support, apologise and record</td>
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<td>Apology is an expression of sorrow and regret</td>
<td>Apology more likely to be meaningful if personal and relevant to the patient and to the incident</td>
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<td>Notification and apology must be verbal and written</td>
<td>Notification and apology may be written</td>
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<tr>
<td>Openness and transparency with the patient/representative</td>
<td>Openness and transparency with the patient/representative, colleagues, employers, relevant organisations and the regulators</td>
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<tr>
<td>Silent on duty to raise concerns</td>
<td>Incorporates duty to raise concerns where appropriate and to allow/not to impede others from raising concerns</td>
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<tr>
<td>Monitored by CQC</td>
<td>Monitored by GDC</td>
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Is either the statutory or professional duty of candour triggered?
Yes – Patient C has suffered a change in the structure of his body so the incident is a “notifiable safety event” and the statutory duty of candour is triggered. Patient C suffered harm as the result of something going wrong with his treatment, so the professional duty of candour will also be triggered.

What steps need to be taken to comply with the statutory and/or professional duty?
The dentist has already partially complied with the duty of candour requirements by having explained to patient C what went wrong and taking steps to remedy the situation and minimise any detrimental effects.