Royal College of Surgeons
ADVANCING SURGICAL CARE

The Royal College of Surgeons

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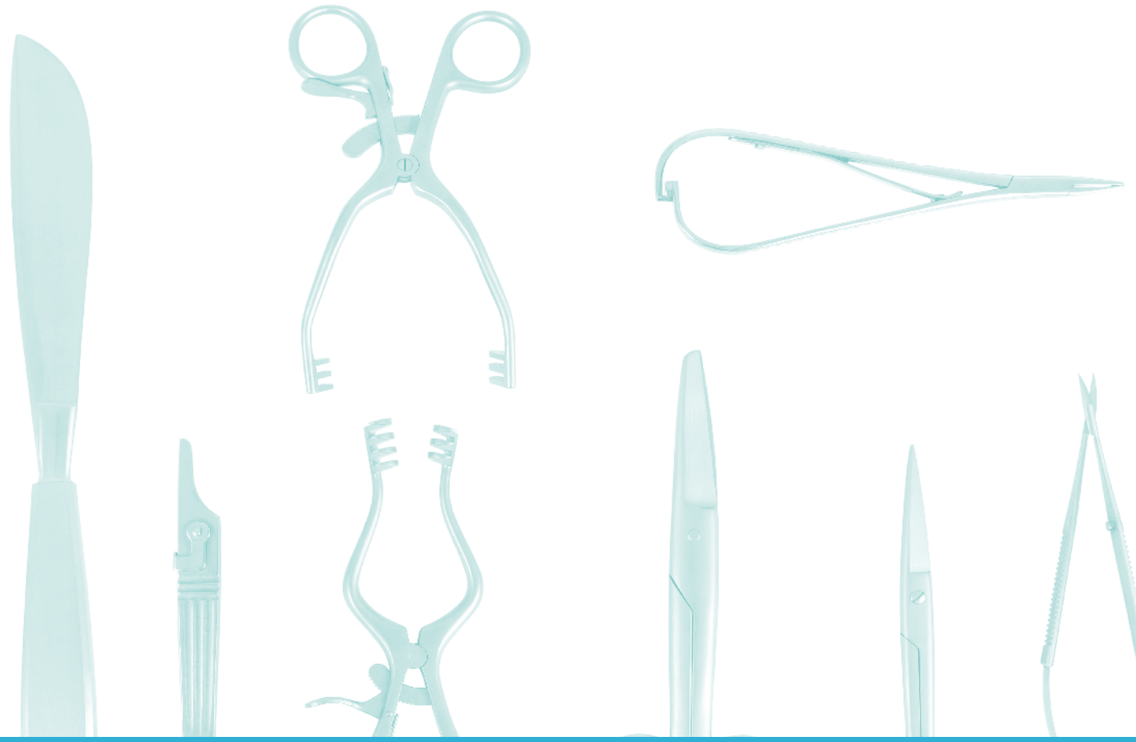

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DUTY OF CANDOUR

DUTY OF CANDOUR

Guidance for surgeons and employers

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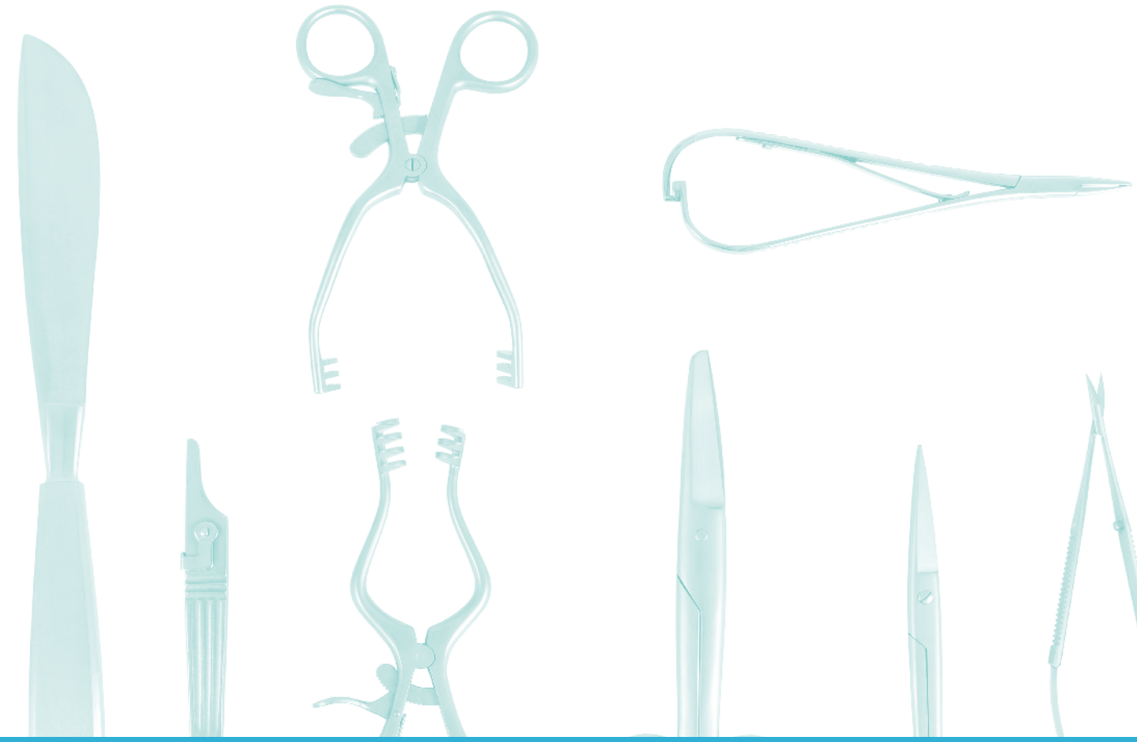

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Contents

A. Overview of the duty of candour

In late 2014, new legislation (*Health and Social Care Act 2008 (Regulated Activities), Regulations 2014, Regulation 20*) introduced a statutory duty of candour for healthcare providers in England, to ensure that they are open and honest with patients when things go wrong with their care. This means that any patient harmed through the provision of a healthcare service should be informed of the fact and offered an appropriate remedy, regardless of whether a complaint has been made or a question asked about it. Although the statutory duty applies specifically to organisations, individual doctors are the representatives of those organisations in their interactions with patients and therefore need to understand and cooperate with relevant policies and procedures.

Surgeons already have a professional duty to be open to their patients when harm occurs, set out in *Good Medical Practice* (GMC, 2013), and *Good Surgical Practice* (RCS, 2014). The introduction of the statutory duty provides an opportunity for surgeons to reaffirm the good practice of having a detailed postoperative discussion with each of their patients, explaining fully the course of their operation and all events that occurred between the first and last surgical contact. When an incident takes place that reaches the threshold of the statutory duty of candour, surgeons will be required to follow a defined process of disclosure, over and above their own professional duty, which is led and facilitated by their trust. It should be emphasised that the statutory duty of candour refers to safety incidents caused through the provision of care. It does not refer to recognised complications or undesirable outcomes that occur as part of the natural course of the patient's illness or their underlying condition.

B. Purpose of this guidance

This document provides guidance on both the professional and the statutory duty of candour for surgeons and their employers. It makes recommendations on how to communicate with patients who have suffered harm and how to support them. It also highlights the need to provide early support to surgeons and surgical teams who have been involved in harm, as a vital part of safety management and avoiding harmful incidents in the future. A full explanation of terms that underpin the duty of candour is provided in the last section of the document. Although this guidance has been developed mainly for surgeons and their employers, most of its recommendations are applicable to all medical specialties.

C. The professional duty of candour for all doctors

1. CURRENT GUIDANCE

The professional duty of candour for all doctors is broadly set out in the GMC's *Good Medical Practice* (GMC, 2013, page 18): "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 put matters right (if that is possible), offer an apology, and explain fully and promptly what has happened and the likely short-term and long-term effects."
In addition, the GMC, jointly with the Nursing and Midwifery Council, developed the document *Openness and Honesty When Things Go Wrong* (GMC, 2015) to elaborate on the professional duty of candour for all healthcare professionals.

When it comes to surgeons, the main principles of the professional and ethical duty to be open and honest are also outlined in the College's *Good Surgical Practice* (RCS, 2014, page 42):

- Inform patients promptly and openly of any significant harm* that occurs during their care, whether or not the information has been requested and whether or not a complaint has been made.
- Act immediately when patients have suffered harm, promptly apologise and, where appropriate, offer reassurance that similar incidents will not reoccur.
- Report all incidents where significant harm has occurred through the relevant governance processes of your organisation.

2. WHAT DO SURGEONS HAVE TO DO?

All surgeons should have an open discussion with patients about a safety incident that resulted in harm. In practice, this means that surgeons should:

- Notify patients (or, where appropriate, their supporters) of the incident as soon as possible once it is established that something has gone wrong with their care.
- Provide a factual explanation of all the facts known about the incident at the date of notification. Share all relevant information known to be true, explaining if anything is still uncertain and respond honestly and fully to any questions.
- Provide a verbal apology. The verbal apology may also need to be provided in writing if this is required by local policy or the patient requests it.
- Explain fully to the patient the short- and long-term effects of the incident.
- Offer an appropriate remedy or support to put matters right (if possible).
- Explain the steps that will be taken to prevent recurrence of the incident (where relevant).
- Record details of the discussion in the patient's clinical record.

3. LOW HARM AND NEAR MISSES

At the level of individual doctors, the duty of candour consists of an open and honest disclosure to patients about all safety incidents that have resulted in harm or have the potential to result in harm or distress regardless of their severity, including low harm.

There is no expectation to disclose to patients near misses or incidents that have resulted in no harm. However, surgeons may decide to do so if they think that the patient may want to know this information and that the lack of disclosure may undermine the relationship of trust between surgeon and patient. Local trust policies may also require doctors to disclose no-harm incidents and near misses, depending on circumstances and the patient's best interest.

In every case, low-harm incidents as well as near misses and incidents that resulted in no harm must be reported through the trust's local reporting systems to support learning and service improvement, and to avoid future harm.

4. PARALLELS BETWEEN CONSENT AND CANDOUR

Good Surgical Practice emphasises the importance of establishing and maintaining effective partnerships with patients. Evidence provided in the 2014 Dalton/Williams review *Building a Culture of Candour* (DH, 2014) suggested that having a candid conversation when something goes wrong is far easier when it forms part of an ongoing clinical relationship in which issues of risk and consent have been clearly discussed from the outset.

Prior to a surgical procedure, and as part of the consent discussion, surgeons are required to provide information on the procedure and its implications, including the risks inherent in the procedure and any side effects and complications. Correspondingly, after the surgical procedure, the surgeon has a duty towards his or her patient to give an account of what happened during the operation.

Surgeons should aim to have a detailed postoperative discussion with every patient as a matter of course, offering a full explanation of all events that happened between the first and last surgical contact. As with the consent process, the duty to be open and honest when things go wrong is not a one-off event, but a process that may require more than one meeting to ensure that all necessary information has been made available and that patients have had the opportunity to reflect on it, and to give patients the opportunity to ask questions.

5. SURGEONS' DUTY TOWARDS THEIR EMPLOYERS AND REGULATORS

As part of their professional duty of candour, all surgeons must also be open and honest with their colleagues and employers, and take part in reviews and investigations when requested. They have the responsibility to familiarise themselves with their organisation's relevant policies and comply with local disclosure processes around the duty of candour. They must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.

D. The statutory duty of candour

1. CURRENT LEGISLATION

The statutory duty of candour for healthcare organisations, is described in the new legislation and the Care Quality Commission's *Regulation 5 and Regulation 20: Guidance for NHS Bodies* (CQC, 2014). It is triggered when a safety incident has occurred that meets the threshold of a 'notifiable safety incident', ie an incident that has resulted or has the potential to result in moderate harm, severe harm or death.

An example of incidents of varying severity

It is expected that there will be a degree of interpretation and professional judgment as to what constitutes moderate harm. However, the National Patient Safety Agency, in its guidance *Seven Steps to Patient Safety* (NPSA, 2004) attempts a useful illustration of different incidents based on their severity, through an example of perforation of the bowel during surgery:

- **Low harm** – If the perforation of the bowel is repaired at the time of the surgery and the area is appropriately washed out and requires only antibiotic therapy, it would be classed as low harm. As a matter of his or her professional duty the surgeon should disclose this incident to the patient and report it in accordance with trust policy.
- **Moderate harm** – If the perforation was not picked up at the time and resulted in septicaemia and a return to theatre for repair, this would be classed as moderate harm. This incident should be managed in accordance with the statutory duty of candour.
- **Severe harm** – If the perforation of the bowel required a temporary colostomy and subsequent major operations, this would constitute severe harm. This incident would therefore be managed in accordance with the statutory duty of candour.

Again, it should be noted that the statutory duty of candour does not refer to recognised complications or undesirable outcomes that occur as part of the natural course of the patient's illness, but rather to safety incidents caused through the provision of care.

2. DIFFERENCE BETWEEN THE DUTY OF INDIVIDUALS AND THE DUTY OF ORGANISATIONS

The statutory duty is a duty on health providers. However, individual doctors and surgeons are relied on to discharge it on behalf of their organisations, and therefore need to have a clear understanding of the differences between the common professional duty and the statutory duty for organisations.

The organisational duty requires health providers to act in an open and transparent way towards patients. It includes all aspects of the professional duty of candour for individual doctors as described in the previous section. In addition, however, providers must also undertake the following actions when the threshold of a 'notifiable safety incident' has been reached:

- Carry out a thorough investigation into the causes of the incident and share relevant details with the patient.
- Provide an apology in writing, following the verbal apology in person.
- Provide reasonable support to the patient in relation to the incident.
- Establish a formal and defined process of harm disclosure as part of the provider's clinical governance processes.

3. THE STATUTORY DUTY OF CANDOUR ACROSS THE UK NATIONS

The legislation introducing the statutory duty of candour in 2014 applies specifically to healthcare providers in England. However, at the time of publication of this guidance, all UK nations either had similar duties in place, or were considering their formal introduction. In Wales the existing regulations – *The NHS Concerns, Complaints and Redress Arrangements Wales Regulations 2011* – already include a generic duty for organisations to be open when harm has occurred. In Northern Ireland, it is currently a requirement to disclose to patients if their care has been the subject of a serious adverse incident report. In addition, a review conducted on behalf of the Department for Health, Social Services and Public Safety in 2014 recommended that a more comprehensive, organisational duty of candour should be introduced, consistent with the English legislation. The Scottish Government is also considering the introduction of a duty of candour for organisations providing health and social care, including health boards.

The professional duty of candour for individual doctors and surgeons, as set by the GMC (*Good Medical Practice*, GMC, 2013) and the RCS (*Good Surgical Practice*, RCS, 2014) is applicable across all UK nations.

E. Outline of a disclosure process

An outline of a proposed disclosure process covering the requirements of the duty of candour for both individuals and organisations is presented below. This is an adaptation of the *Being Open* process (NPSA, 2009) and the *Open Disclosure Framework* (Australian Commission on Safety and Quality in Healthcare, 2013).

Disclosure process for low-harm incidents (professional duty of candour)

Step 1: Incident detection and assessment	• Detect safety incident. • Where possible, act immediately to put things right for the patient and to prevent harm. • Make an assessment of the severity of harm and report the incident through local processes.
Step 2: Notification and open disclosure	• Notify the patient about the incident as soon as possible with a factual explanation of all facts known at the time of the notification. • Provide an apology. • Explain fully the short- and long-term effects of the incident. • Offer an appropriate remedy or support to put matters right (if possible). • Explain the steps that will be taken to prevent recurrence of the incident (where relevant). • Record details of the discussion in the patient's clinical record. For low-harm incidents the disclosure process can conclude here.

Disclosure process for notifiable safety incidents (statutory duty of candour)

Step 1: Incident detection and initial response	• Detect safety incident. • Where possible, act immediately to put things right for the patient and to prevent harm. • Make an initial assessment of the severity of harm and report the incident through local processes. • Acknowledge the incident to the patient with an explanation of facts known to you at the time and a verbal apology. • Explain that you will follow up with more information after further investigation.

Step 2: Team discussion

- The MDT should meet as soon as possible after the incident to:
  - Get the facts straight.
  - Assess the severity of harm and notify the risk manager or equivalent.
  - Identify any investigations required to determine the cause of the incident.
  - Where relevant, identify further treatment required for the patient.
  - Identify options for further support to the patient.
  - Identify support for the staff involved in the incident.
  - Nominate the individual who will communicate with the patient.
  - Arrange a meeting for open disclosure in a sensitive location.

Step 3: Notification and open disclosure

- Provide an apology to the patient and his or her supporters.
- Give a truthful and clear account of the facts of the incident.
- Explain fully the short- and long-term effects of the incident.
- Provide an explanation about the enquiries and investigations that will be undertaken.
- Assure the patient that you will share with him or her the relevant details of the outcome of any investigations.
- Give the patient and his or her supporters the opportunity to tell their stories, exchange views and observations about the incident and ask questions.
- Offer practical and emotional support to the patient in relation to the incident.
- Discuss what can be done to deal with any harm caused, eg options for further treatment and alternative courses of action.
- Explain what will be done to prevent a recurrence of similar incidents in the future.
- Record details of the discussion in the patient's clinical record.

Step 4: Follow-up actions and process completion

- Provide a written notification with all information that was provided in person including an apology as well as the results of any enquiries that are known since the initial notification in person (even if the enquiry is still incomplete).
- Where relevant, identify the appropriate management plan that ensures the patient's continuity of care.
- Arrange follow up discussions with the patient and his or her supporters as necessary to:
  - inform them of the final outcome of enquiries and investigations, and of actions taken to prevent recurrence;
  - explain the next steps about their care and assure them that they will continue to be treated according to their clinical needs; and
  - answer any questions.
- Record details of follow-up discussions and maintain all documentation in the patient's clinical record.

F. What to consider when carrying out the duty of candour

1. WHO SHOULD HAVE THE DISCUSSION WITH THE PATIENT?

- Notification of the safety incident to the patient and a meaningful apology is undertaken by one or more representatives of the trust.
- Most surgery takes place through multidisciplinary teams, so any local policy on candour should apply to all staff with key roles in the care of the patient.
- In making the decision about the most appropriate person to notify the patient and apologise, factors that should be considered are seniority of the healthcare professional, relationship to the patient, as well as experience and expertise in the type of the notifiable incident that has occurred.
- The nominated healthcare professional should have the opportunity to further nominate a colleague to be present and assist him or her with the meeting. This colleague may be someone with experience or training in communication and disclosure procedures.
- In cases where the harm occurred owing to the environment of care or organisational systems, a senior manager of the relevant service should be responsible for communicating with the patient and his or her supporters. The healthcare professional responsible for treating the person should also be present to assist in the initial discussion, and to provide clinical information around the likely effects on the patient and next steps in his or her treatment.

2. APOLOGY AND LIABILITY

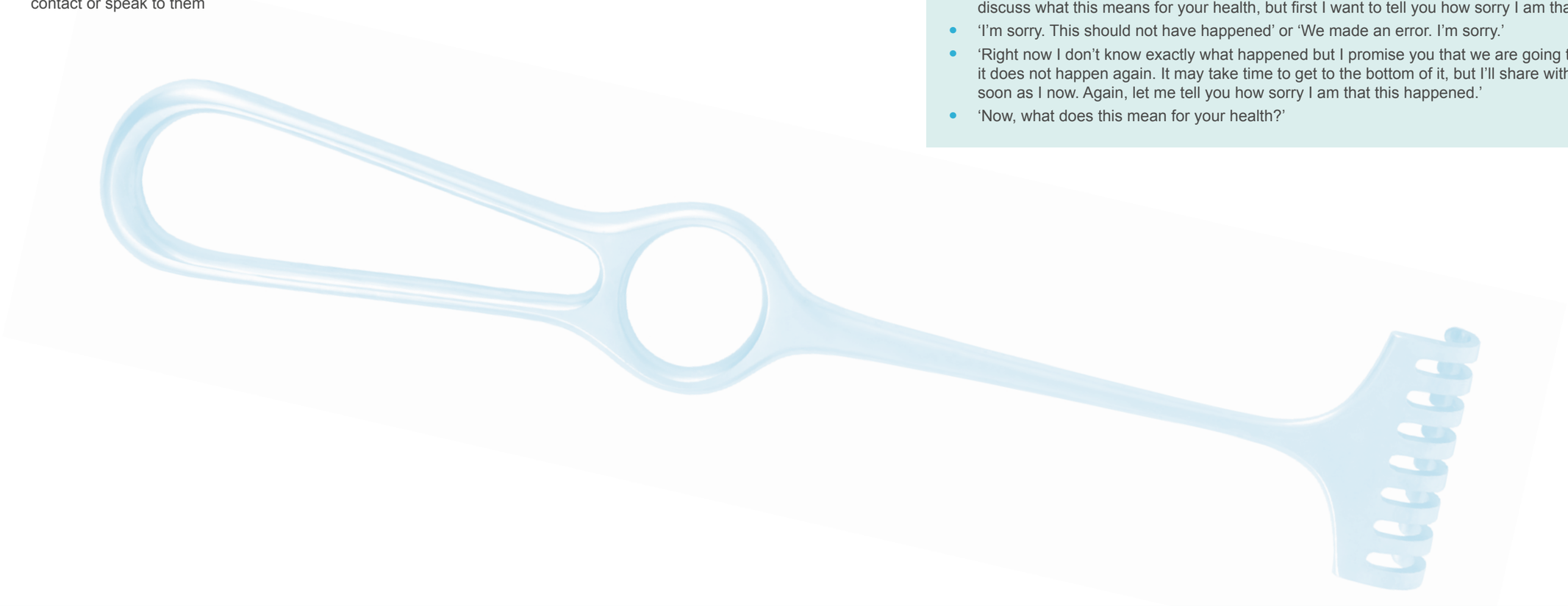
- Providers and healthcare professionals should not wait until the outcome of the investigation to apologise, but they should make clear to the patient that the facts have not yet been established. They should share only what they know and believe to be true, and answer any questions honestly and fully.
- At the stage of an initial disclosure meeting, it is likely that all that can be offered is a genuine expression of regret for what happened. A full explanation and therefore a fuller apology with an acceptance of responsibility may be appropriate when the investigation is concluded.
- One of the barriers towards candour is the fear of litigation. However, the NHS Litigation Authority has made it clear that an apology and an explanation is not an admission of liability and it will continue to indemnify organisations that apologise and explain to patients.
- Early apology is not only the right thing to do, but it is also likely to prevent drawn-out cases where legal action is an expression of the desire to know what happened and to receive an acknowledgment of harm and a reassurance that action will be taken to prevent a recurrence of similar incidents in the future.

3. TIMING, LOCATION AND WHO SHOULD BE NOTIFIED

- The initial discussion with the patient and his or her supporters should take place as soon as possible after the realisation that something has gone wrong. When it comes to the full notification, the Care Quality Commission suggests that this should take place within ten working days of the incident being reported to local systems, and sooner where possible.
- The meeting should be arranged in a sensitive location taking into consideration the patient's privacy and comfort.
- According to the legislation, the notification should normally be directed to the patient. In the following circumstances however, the notification should be directed to those lawfully acting on the patient's behalf:
  - on the death of the patient;
  - where the patient is under 16 years of age and not competent to make a decision in relation to their care or treatment; or
  - where the patient is 16 years of age or older and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Mental Capacity Act) in relation to the matter.
- If the patient or their representative cannot be contacted or they decline to speak to the nominated representative of the trust, then a written record must be kept of attempts to contact or speak to them

4. SUPPORTING PATIENTS

- As part of the disclosure process, surgeons and healthcare providers should offer reasonable support to the patient and his or her supporters in relation to the incident. This can include:
  - Offering the option of direct emotional support during the notification, eg from a family member, friend, advocate or care professional.
  - Where appropriate, providing access to any necessary treatment to recover from harm or to minimise the harm that has occurred.
  - Where possible, arranging for care to be delivered by another professional team or organisation, if the patient wishes that.
  - Providing the patient with details of specialist independent sources of practical advice and support or emotional support /counselling.
  - Providing information about available impartial advocacy and support services, such as their local Healthwatch and other relevant support groups (eg Action Against Medical Accidents), to help them deal with the outcome of the incident.
  - Offering a single point of contact for any questions or requests they may have.
  - Providing support to access the organisation's complaints procedure.



5. OPEN COMMUNICATION

- Surgeons should take advantage of any training opportunities offered in their trust to develop communication skills and experience around the duty of candour and the local disclosure process.
- Below are some key considerations to bear in mind when communicating with the patient:
  - Disclose harm in a sensitive and compassionate manner, and in a way that is appropriate for the individual concerned.
  - Speak in a language that the patient can understand. Do not overwhelm with information, but do not oversimplify either.
  - Be factual. Information should be based solely on the facts known at the time of the discussion. Explain that new information may emerge as an investigation is undertaken, and that patients will be kept up to date with the progress of an investigation.
  - Give clear and unambiguous information. Do not provide conflicting views from different members of staff. If there is disagreement, communication about these events should be deferred until after the investigation has been completed.
  - Allow time for questions and do not monopolise the conversation.
  - Remind patients that you will return to follow up.
  - Do not avoid the patient or his or her supporters, even if you do not have all the answers yet.
  - Respect the patient's wishes if he or she insists that he or she does not want more information, explaining potential consequences. Give the patient the opportunity to say that he or she does not want to be given any more information and document this in the patient's record.
- Open communication does not include:
  - Speculation
  - Attribution of blame or criticism of the care or response of other professionals or providers
  - Claiming liability
  - Denial of responsibility
  - Provision of conflicting information from different individuals
  - Making excuses, being misleading, defensive or evasive

Some examples of appropriate language have been suggested by the Washington University School of Medicine:

- 'Let me tell you what I know about what happened. Instead of receiving x we gave you y instead. I want to discuss what this means for your health, but first I want to tell you how sorry I am that this happened'.
- 'I'm sorry. This should not have happened' or 'We made an error. I'm sorry.'
- 'Right now I don't know exactly what happened but I promise you that we are going to find out and make sure it does not happen again. It may take time to get to the bottom of it, but I'll share with you what we find out as soon as I now. Again, let me tell you how sorry I am that this happened.'
- 'Now, what does this mean for your health?'

6. DOCUMENTATION

- Written records of the disclosure discussions should include:
  - The time, date and place of the discussion as well as the name and relationships of those present.
  - The plan for providing further information to the patient and his or her supporters.
  - Offers of support and the responses received.
  - Questions posed by the patient and his or her supporters and the answers given.
  - Plans for follow-up meetings.
  - Progress notes relating to the clinical situation and accurate summaries of all the points explained to the patient and his or her supporters.
  - Copies of letters sent to the patient and his or her supporters as well as the patient's GP.
  - A copy of the incident report.
- The original incident report, along with a record of the investigation and analysis process should be filed separately as part of the trust's clinical governance reports.

7. NOTIFIABLE SAFETY INCIDENT OCCURRING ELSEWHERE

- If a safety incident is identified as having occurred in a different organisation, the patient should not be at a disadvantage. The guidance *Being Open* (NPSA, 2009), suggests that the individual who first identifies the possibility of an earlier incident should notify the risk manager of their own hospital in the first instance, and then contact their equivalent at the hospital where the incident occurred to establish whether:
  - The safety incident has already been recognised.
  - A process of open disclosure and an investigation of the event are already underway.
- The process around the duty of candour, including the investigation and analysis of a safety incident, should be pursued in the organisation where the incident took place.

G. Supporting surgeons and surgical teams when a safety incident has occurred – recommendations for employers and surgeons

- The impact of safety incidents can be devastating not only for patients but also for individual doctors and teams. According to a recent study published in the *British Journal of Surgery*, surgeons reported that the stress associated with serious complications can reduce their capacity to concentrate on other patients. Some surgeons experience a crisis of confidence in their skills or judgment, and many become more risk averse. Providing early support after safety incidents to surgeons who have been involved in harm is therefore a vital element for safety management and employers should put in place arrangements to support staff who find themselves in this position.
- Consideration should be given to developing structured peer-support programmes which include one-to-one discussion with experienced peers following safety incidents. Reflection on the clinical aspects of the case with a knowledgeable peer can build resilience, avert destructive self-blame and enhance learning. Any peer-support programme should include training for peer supporters.
- Additional arrangements should include mentoring, open opportunities for discussion and formal arrangements for operating in pairs. Operating alongside a respected colleague may afford guidance, companionship and a period of practice without the burden of full responsibility. Through providing impartial and objective assessment of capability, it can also help restore organisational confidence in the surgeon's technical skills. In some cases counselling support should also be considered.
- In morbidity and mortality meetings, during case reviews and the assessment of safety incidents, all factors should be carefully considered, both surgeon-related and system-related. Jumping to critical conclusions about the performance of colleagues may lead to systems factors going unnoticed. Overlooking individual performance and focusing on systems factors alone is equally dangerous.
- Organisations should support staff by providing training in communication skills and in local policies that will help them understand their individual responsibilities in relation to the duty of candour. This will reinforce the importance of being open when safety incidents occur and will provide staff with the skills and confidence they need to communicate openly and effectively with patients, with support from their peers and their employers.
- All relevant support services within the organisation should be signposted for staff members who have been involved in harm.

H. Building a culture of learning, openness and safety – recommendations for employers

1. INCIDENT REPORTING AND INVESTIGATION

- Organisations need to have accurate systems and processes in place for detecting and reporting safety incidents.
- Errors should be reported at an early stage to put matters right and to learn any lessons so that future patients may be protected from harm. All incidents should be reported for learning purposes, even no-harm incidents and near misses.
- Past studies have identified that surgeons tend to under report safety incidents, sometimes referring them instead to morbidity and mortality meetings. This has created a distorted picture of the rate and nature of surgical safety incidents both at local and at national level. Barriers to reporting have been identified as lack of time, lack of feedback, uncertainty about what constitutes an incident, and doubt that learning follows reporting. The statutory duty of candour requires organisations to demonstrate they have fulfilled their obligation to inform patients about safety incidents and many will build upon existing reporting systems to do this. One way forward therefore may be to integrate incident reporting with referral of cases to morbidity and mortality meetings, and to streamline reporting systems such as Datix to make them more amenable to consistent and informative surgical incident reporting.
- Incidents of harm provide vital information for improvement so organisations should strive to identify the underlying causes of safety incidents by using methods such as Root Cause Analysis. Incidents should be investigated and analysed to find out what can be done to prevent their recurrence.
- Investigations should not focus exclusively on the last individual to provide care. Individual errors are often underpinned by organisational factors. Therefore, such errors should be seen as a consequence of flaws in the healthcare systems, not just the individual, and any learning should consider the human factors in the context of team, organisation and system factors.
- The findings of investigations should be disseminated to healthcare professionals so that they can learn from safety incidents and mistakes. These should be used as the basis for organisational learning and not for criticism of individuals.

2. LEARNING AND APPLYING LESSONS TO PRACTICE

- There should be willingness to learn and apply lessons to practice. Organisations should ensure that concrete action follows on from learning. There should be a system of accountability through the chief executive to the board to ensure that changes are implemented and their effectiveness reviewed through learning programmes and audits.
- At an individual level, appraisal presents an opportunity to record and reflect on individual actions and organisational processes that have followed a safety incident. The appraisal cycle leading to revalidation requires surgeons to produce supporting information about their involvement in such incidents, including reflection. Such reflection can help increase individual learning, and when included in appraisal it may help draw attention to gaps in the organisational management of incidents.

3. DEVELOPING A CULTURE OF SAFETY

- The *Dalton/Williams* review (DH, 2014) stressed the importance of organisational commitment to a culture of safety that understands the inevitability of harm even as it tries to do all it can to avoid it. Medical care is not risk free, and so the aim should not be to eliminate harm completely, but to provide swift, thoughtful and practical response when harm does occur.
- The effective application of the duty of candour is not a matter of compliance to legislation and regulatory guidance. It can only be part of a wider commitment to safety, learning and improvement.
- Leadership is vital for the implementation of the duty of candour. It is essential to have consistent and visible commitment at all levels in the organisation, including at board level, and to support a culture of transparency and safety.
- Organisations should actively promote an open and fair environment that encourages the reporting of safety incidents, fosters peer support and discourages the attribution of blame.
- There should be a step-by-step process for open disclosure, policies and procedures to support staff throughout the investigation process and to ensure all relevant policies are followed.
- Organisations should take action to tackle bullying, harassment and undermining in relation to the duty of candour, and investigate any instances where a member of staff may have obstructed another in exercising their professional responsibilities. They should have processes in place for breaches of the duty of candour, including obstruction of colleagues to exercise their responsibilities. This should include a process of investigation and escalation that may lead to referral to their professional regulator.

I. Explanation of terms

The following terms from (1) to (7) are referred to in the new legislation, (*Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 20*) and underpin the statutory duty of candour.

1. Notifiable safety incident for health service bodies

In relation to a health service body, 'notifiable safety incident' means any unintended or unexpected incident that occurred in respect of a patient's care that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in:

- the patient's death,
- severe harm,
- moderate harm, or
- prolonged psychological harm.

This definition of the notifiable safety incident (and the whole duty of candour) refers to harm caused directly by the incident, and not by the natural course of the patient's illness or underlying condition. Identifying something as a notifiable safety incident does not automatically imply error, negligence or poor-quality care. It simply indicates that an unexpected and undesirable clinical outcome resulted from some aspect of the patient's care, rather than the patient's underlying condition.

The CQC *Regulation 5 and Regulation 20: Guidance for NHS Bodies* (CQC, 2014) further clarifies that the term 'notifiable safety incident' does not refer to near misses where an incident has resulted to no harm to the patient. The words 'could result in' in the definition of a notifiable safety incident suggest that the unintended incident is likely to manifest harm in the future, even if no harm is immediately evident at present.

2. Severe harm

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, which is related directly to the incident and not to the natural course of the patient's illness or underlying condition.

3. Moderate harm

Moderate harm means:

- significant harm, which is defined as the temporary lessening of bodily, sensory, motor, physiologic or intellectual functions, that is related directly to the incident and not to the natural course of the patient's illness or underlying condition; and
- moderate increase in treatment, which is an unplanned return to surgery, an unplanned readmission, 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).

Based on the regulation, moderate harm occurs when both significant harm and moderate increase in treatment occur. If there is only a moderate increase in treatment and no significant harm, this does not fall under the statutory duty of candour, although it might still be appropriate for the individual surgeon to apologise to the patient depending on local policies and the specific circumstances.

4. Prolonged psychological harm

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

5. Apology

Apology means an expression of sorrow or regret in relation to an unexpected incident that resulted in patient harm. Apology does not imply acceptance of responsibility for the incident and the resulting harm. In some cases, however, where harm is linked to an error in the care of the patient, then an apology should also include an acknowledgment and acceptance of responsibility – this is not an admission of legal liability.

6. Notifiable safety incident for registered persons

In April 2015, amendments to the legislation (*The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015*) introduced a second definition of a notifiable safety incident for registered persons, extending the statutory duty of candour to all providers of an independent or private service. According to this second definition, a notifiable safety incident for registered persons is an incident that:

a. appears to have resulted in

- the patient's death,
- an impairment of the sensory, motor or intellectual functions of the patient that has lasted, or is likely to last, for a continuous period of at least 28 days,
- changes to the structure of the patient's body,
- the patient experiencing prolonged pain or prolonged psychological harm, or
- the shortening of the patient's life expectancy; or

b. requires treatment by a health care professional in order to prevent

- the patient's death, or
- any injury to the patient which, if left untreated, would lead to one or more of the outcomes mentioned under (a).

This different definition of a notifiable safety incident for a registered person as opposed to a health service body implies that, for a registered person, the threshold of a notifiable safety incident is met only when an unintended incident appears already to have resulted in harm, whereas for a health service body the threshold of a notifiable safety incident is also met when an unintended incident is likely to manifest harm in the future, even if harm is not immediately evident.

7. Prolonged pain

Prolonged pain means pain which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.

The following terms under (8) and (9) are described in the guidance *Being Open* (NPSA, 2009). They are not part of the legal duty of candour for healthcare providers, which requires a formal process for disclosing and investigating a notifiable safety incident. However, in some cases they may be relevant as part of the professional and ethical duty of the individual doctor to be open to patients about incidents that happened during their care.

8. Low harm

Low harm means any incident that required extra observation or minor treatment, and caused minimal harm to the patient.

9. No harm

No harm means:

- Any incident that had the potential to cause harm but was prevented and therefore no harm occurred to the patient (near miss).
- Any incident that was not prevented but resulted in no harm to the patient.

References and further reading

Legislation and Department of Health

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 20: Duty of Candour.
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- Kumar, M et al. Adverse outcome reporting in surgery: identification of the problem and implementation of an integrated reporting system in surgery. *Qual Saf Health Care 2006*; **18:** 116–120.