Introduction:

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 and Wales, to ensure that they are open and honest with patients when things go wrong with their care.

This was introduced as a response to recommendations in the Francis report (2013) on the investigation into standards of care and excessive deaths (several hundred) at the Mid Staffs Foundation Trust between 2005 and 2009.

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. The Royal College of Surgeons in England produced a new guidance **-** Building a culture of candour - in March 2014 to better define what is required from surgical specialities.

Please note that the requirements of DOC outside of England and Wales are different. Please refer to the following for more details.

Scotland: https://www.legislation.gov.uk/ssi/2018/57/made, https://www.legislation.gov.uk/asp/2016/14/contents/enacted.

Republic of Ireland: https://www.gov.ie/en/collection/e29900-open-disclosure/

The situation in Northern Ireland is currently the subject of a legal consultation.

DOC requirements are:

All surgeons should have an open discussion with patients about any unintended or unexpected incident that has resulted in significant (moderate, severe or prolonged psychological) 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 within 10 days of the incident. 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 these discussions in the patient's clinical record.
- Feedback results of any formal investigation in writing within 10 days of incident being closed.

Definition of Harm:

Severe harm (includes patient death)

Severe harm is defined as a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, and includes removal of the wrong limb or organ or brain damage, which is related directly to the unexpected incident and not to the natural course of the patient's illness or underlying condition.

Suggested thoracic surgery categories for severe harm:

- Death
- Permanent stroke / cognitive impairment.
- Loss of limb.
- Permanent organ failure: long-term need for dialysis, respiratory support.
- Unexpected complication that moves patient from an active to a palliative care pathway.

Moderate harm

Based on the regulation, moderate harm occurs when both significant harm and a moderate increase in treatment occur. Significant harm is defined as the temporary (rather than permanent) 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. Examples of a moderate increase in treatment would include 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 ITU).

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.

Suggested thoracic surgery categories for moderate harm:

- Return to theatres for any unplanned reason during initial inpatient episode
- Unplanned ITU admission for > 72 hours +/- organ support
- Complication requiring unplanned inpatient stay > 2 weeks or one that adversely impacts on the delivery of necessary adjuvant treatment.
- Significant delirium / temporary cognitive decline e.g. TIA.
- Re-admission for a direct complication of surgery – empyema, recurrent pneumothorax, wound infection, wound hernia.
- *Un-expected* incomplete cancer resection requiring further treatment.
- Intra-operative vascular injury requiring initiation of emergency transfusion protocols / massive transfusion even if full recovery / no harm by any other criteria.

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.

Thoracic Surgery Never Events – may be covered by other category definitions but should potentially be considered to require DOC even if the level of harm doesn't fit into severe or moderate harm categories?

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Unplanned retained foreign object post procedure
4. Mis-selection of a strong potassium solution
5. Overdose of insulin due to use of abbreviations or incorrect device
6. Transfusion or transplantation of ABO-incompatible blood components or organs
7. Unrecognised misplaced naso- or oro-gastric tubes
8. Burning / Scalding / intra-operative fire injuring patients due to LASER or diathermy use.