Cite this article as:
Strickland NH. Duty of candour: implications for radiologists. *Br J Radiol* 2019; **92**: 20190063.

REVIEW ARTICLE

Duty of candour: implications for radiologists

NICOLA HILARY STRICKLAND, MA Hons (Oxon), BM, BCh, FRCP (UK), FRCR

Imperial College Healthcare NHS Trust, London, UK

Address correspondence to: Dr Nicola Hilary Strickland
E-mail: nicola.strickland@nhs.net

ABSTRACT

This article addresses duty of candour in relation to radiologists. The legislation underpinning duty of candour, definition of terms and the requirements for its application are explained. Consideration is given as to the differences between duty of candour and openness of discussion. The issue of how duty of candour should apply to radiologists (both diagnostic and interventional) is then addressed.

INTRODUCTION

This article addresses duty of candour in relation to radiologists. The legislation underpinning duty of candour and its application is considered first. The issue of how duty of candour should apply to radiologists (both diagnostic and interventional) is then addressed.

THE STATUTORY DUTY AND ITS BACKGROUND

Duty of candour is defined as Regulation 20(1) of The Health and Social Care Act (HSCA) 2008 (Regulated Activities) Regulations 2014,¹ which states that “A health service must act in an open and transparent way with relevant persons in relation to the care and treatment provided to its users in carrying on a regulated activity”. This was introduced as part of a new culture based upon the mid-Staffordshire Francis report. The General Medical Council (GMC) is responsible for the interpretation of the legislation, and the Care Quality Commission (CQC) is responsible for its implementation.²

Definitions are offered to explain the terms used in these regulations:

Candour means that any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked.

Openness means enabling concerns and complaints to be raised freely without fear, and any questions that have been asked, to be answered.

Transparency means allowing information about the truth relating to performance and outcomes to be shared with staff, patients, the public and regulators.

Regulation 20(2) goes on to state that: “As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must ... notify the relevant person that the incident has occurred....” The NHS Standard Contract requires that the notification must be within at most 10 working days of the incident being reported to local systems, and sooner where possible. It is important to note that these notifiable safety incidents are retrospective as well as current, with the Regulation stating that “A provider may discover a notifiable safety incident that happened sometime ago, or that relates to care that was delivered by another provider”, and advises that “The provider that discovers the incident should work with others who are responsible for notifying the relevant person of the incident”.

A definition of a *notifiable safety incident* is any unintended or unexpected incident that occurred in respect of a service user during the provision of regulated activity that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in: death, severe harm, moderate harm or prolonged psychological harm. The word *incident* is not defined. Any “unintended or unexpected incident” will include instances where harm has occurred even though there may not have been a mistake in the care provided. It therefore includes instances of recognized complications, even where a patient has been warned in advance and there has been no failure of care. The words “could result in” are intended to capture incidents where the expectation of a reasonable healthcare professional is that the patient will suffer harm, even if that harm has not yet materialized. However there is no requirement to report “near misses” where no harm has resulted.

The four possible outcomes of the notifiable safety incident are further defined:

Death is only where the death relates directly to the incident, rather than to the natural course of the service user's illness or underlying condition.

Severe harm is a permanent lessening of bodily, sensory, motor, physiological 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 (a) harm that requires a moderate increase in treatment, and results in (b) significant, but not permanent harm. A 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 is not defined, but the patient must have experienced, or be likely to experience, this psychological harm for a continuous period of at least 28 days.

The reporting requirements are defined in Regulation 20(3) and 20(4) as a vital checklist of how the notification must be given. This is shown as a flowchart of the steps in the duty of candour process in [Figure 1](#). The notification must be given in person. It must provide an account of the facts as known at the date of notification. It must advise the relevant person (which is usually the patient him/herself) what further enquiries into the incident will be undertaken. It must include an apology. It must be recorded in writing to be kept securely by the health service body, and confirmed in writing to the relevant person. Reasonable support should be offered to the relevant person throughout this process. *An account of the facts* is defined further: it should include as much or as little information as the relevant person wants. It should be jargon-free, with any complicated terms explained. It should be neutral, so the account should stick to the known facts and not stray into speculation or the provision of an opinion. The fact that there will be an investigation can be communicated. The

account of the facts should be given in a manner that the relevant person can understand, which may require an interpreter, advocate and/or communication aid whilst being conscious of any possible breaches of confidentiality these may incur.

Regulation of duty of candour is by the CQC, which is responsible for inspecting compliance with duty of candour. The CQC must assess whether the Trust's culture encourages candour, openness and honesty. The CQC is expected to test that staff understand the requirement of the duty of candour, and will assess if lessons are being learned and improvements are being made when things go wrong.

HOW DOES ALL THIS AFFECT THE RADIOLOGIST?

For radiologists, as for all doctors, duty of candour represents a balance between complying with the law and acting in a manner which is truly in the best interest of the patient and his/her family. Inevitably, deciding what is in the best interest of the patient is, to some extent, a value judgment in each case. Applying duty of candour legislation with a sledge hammer approach to every possible case where it could be applied, whilst doubtless complying with the letter of the law, would often be unkind, unnecessary and impractical. It would be unkind to create unnecessary stress for the patient and the patient's family, by initiating a full duty of candour process when it is clear that the patient's outcome would have been the same, even if the incident under consideration for a possible duty of candour procedure (which might be a radiological "miss") had not occurred.

It is, however, sensible and morally right, always to aim for openness with the patient and the patient's family. Being open involves a judgment of what it is appropriate to tell the patient, whereas a formal duty of candour procedure hinges on the degree of harm the patient has suffered. Duty of candour requires an apology and a letter to the patient, openness does not. An example might be the case of a missed lung cancer on a chest X-ray or a scan which had the same radiological staging, and therefore is likely to have the same clinical outcome when it was later picked up on subsequent imaging as it would have had if it had been noticed and reported on the original imaging study. In this case, since no serious or moderate harm has resulted from the original miss, there is no legal obligation for a duty of candour procedure to be invoked. However, openness with the patient in this case would be highly advisable—*i.e.* telling the patient that, in retrospect his/her lung cancer was visible on the earlier imaging study, but that even if it had been spotted at that stage it would not have made any difference to the clinical outcome/management of the cancer. Openness is essential in the interests of honesty, and to maintain a trusting relationship between the patient and his/her doctor and medical team. Imagine, in the case cited above, if the fact that the lung cancer had in fact been visible on an earlier imaging study had been withheld from the patient, and if s/he were subsequently to ask "Was my lung cancer there on the previous chest X-ray/scan I had done?" the doctor answering the question would be obliged to admit that it was and the patient would inevitably lose all faith in the doctor and in the treatment s/he was receiving,

which would be in nobody's best interest, and would certainly be psychologically harmful to the patient.

In the example used above, had the lung cancer grown by the time it was picked up to an extent which altered its radiological staging, and therefore changed the treatment options available adversely, then clearly the patient would have suffered moderate or severe harm and a duty of candour procedure has to be invoked.

There are several reasons why radiologists in general are reluctant to start a duty of candour process when they come across a significant error made by one of their colleagues (or themselves) in the report on an earlier imaging study. The most potent is the fear that the radiologist who missed or misinterpreted the first imaging study will be sued medicolegally for his/her miss/error. Such a medicolegal investigation could call into question the competence of that radiologist, with the perceived threats of an investigation into his/her fitness to practice, notification of the General Medical Council and theoretical concern about erasure from the Medical Register. Contrary to expectation perhaps, there is no evidence that being open, or having duty of candour conversations with patients about radiological errors leads to a greater likelihood of being sued by the patient, or the patient's family, although such an outcome remains a risk obviously. Equally it could cogently be argued that a radiologist is at far greater risk of being sued by a patient if the patient were to find out that such a radiological "miss" was already known about, but that fact had not been communicated to the patient. The patient, with some justification, is likely to view such behavior as secretive and dishonest. It is generally true that openness and honesty build trust, and that patients who trust their doctors respect them, and are less likely to want to sue them.

Another reason for radiologists' reluctance to initiate a duty of candour process is that it involves initially telling a colleague that s/he has made an error in a previous report, which is never a pleasant task. Nevertheless we all know that we all make mistakes in our reports, with a frequency which has been variably measured in the literature as between 3–30%^{3–10} depending upon the design of the study. We also know that we can only hope to learn from our mistakes if they are pointed out to us, in the context of a blame-free culture, and this is the tenet underlying radiological "discrepancy meetings" and the Royal College of Radiologists' READ (radiological errors and discrepancies)" publication. (These are now known as "learning meetings", and "REAL"—radiological excellence and learning—respectively).¹¹

WHO SHOULD HOLD THE DUTY OF CANDOUR CONVERSATION?

This should not be lead by the diagnostic radiologist. It should be the doctor (consultant) who has current contact with the patient, and who has become aware of the miss/harm in question. Usually the duty of candour lead will be the consultant physician or surgeon whose care the patient is under. It is essential that the patient has trust in the communicating doctor, and a patient is unlikely to trust a doctor whom they have never seen before, and generally the reporting radiologist (or pathologist)

has had no previous relationship with the patient. It would be sensible, and courteous to the patient, if the radiologist involved were also present at the face to face duty of candour meeting with the patient. When the duty of candour incident relates to patient harm arising from an interventional radiological procedure, then it may well be most appropriate for the interventional radiologist involved to take charge of the duty of candour process if s/he already knew the patient from a clinic appointment, and if not leading the duty of candour process at least be present during these meeting(s) with the patient. Obviously taking ownership of a duty of candour procedure is not popular, and the administrative burden is fairly onerous.

AMBIGUITIES IN DUTY OF CANDOUR FOR RADIOLOGICAL PRACTICE

The definition of serious or moderate harm leading to the need for duty of candour includes recognized complications of a procedure leading to escalation of care or an additional procedure or admission, even if these possible complications were properly consented for prior to the procedure. At some time in their careers this is theoretically likely to affect radiologists performing a procedure as seemingly trivial as a CT-guided core lung biopsy, since the risk of a pneumothorax due to image-guided lung biopsy is relatively common—25.3% (in a large meta analysis), with 5.6% of those requiring a chest drain: an additional procedure, and possible overnight hospital admission.¹²

A further ambiguity for radiologists arises in deciding for which possible complications of a procedure they should consent their patients. Again taking the example of a patient about to undergo a CT guided lung biopsy, should that patient be consented for death as a possible complication? The risk of death from a lung biopsy has been quoted in the literature as 0.15%¹³ (mainly from air embolism and haemorrhage) *i.e.* well over a hundred times lower than the risk of a pneumothorax, but a risk nevertheless. Most radiologists do not consent for death from lung biopsy (although some do) believing that it is stressful, and possibly even cruel, to do so when the patient clearly clinically requires, and will benefit from, having a lung biopsy definitively to confirm or refute an imaging diagnosis of lung cancer.

In radiology it is important to remember that overdiagnosis can lead to moderate or serious patient harm, particularly when this leads to a surgical procedure which ultimately turns out to have been unnecessary. A well known example in chest CT is the spiculated lung lesion with equivocal histology, masquerading as a lung cancer, for which a thoracotomy and lobectomy is performed, and then the final histology on the entire surgical specimen reveals that it was benign organizing pneumonia. Assuming there are no surgical complications, the patient has still suffered severe harm in having an unnecessary major operation, and thus merits a duty of candour discussion despite all doctors involved having acted in the best interests of the patient in their clinical decision-making, and potentially acting in the same way subsequently if presented with a similar clinical scenario.

THE RADIOLOGIST AS A VICTIM IN DUTY OF CANDOUR AND MEDICOLEGAL SEQUELAE

There is no doubt that the radiologist is placed at a disadvantage compared with the physician or surgeon when it comes to reviewing the evidence of a particular case in retrospect, since all the diagnostic imaging study evidence is archived on the PACS (picture archiving and communication systems) with a written report on that imaging study archived on the RIS (radiological information system). There is no such rigorous, indisputable documentation of exactly what was observed or performed during a physical examination of the patient, or a surgical operation.

It is well known that any abnormalities visible on an imaging study are more obvious when reviewed in retrospect, especially in the artificial setting of a case review. Also the judgment of others upon the conspicuity or interpretation of any missed or misinterpreted radiological findings is inevitably subject to bias – particularly hindsight bias (where knowing in advance that there is an abnormality on the images makes it easier to spot) and outcome bias (where a known poor patient outcome as a result of an error leads to a more severe assessment of the gravity of that error).¹⁴ Unfortunately radiological “expert opinion” in any medicolegal case is always going to be exposed to hindsight and outcome bias. The only way of avoiding such biases would be for the imaging study in question to be slipped into a normal reporting worklist of another radiologist in a clinical setting and disguised as a current case for routine reporting, with only the same information available as was provided for the original reporting radiologist, and comparing whether the same error was made in the report issued by this second radiologist.¹⁵

It is difficult for the lay public (including the legal profession) and even for any non-radiological clinician, to appreciate that error is inherent in diagnostic radiology, and that radiologists record their best radiological opinion (which is a combination of observation and informed interpretation) on an imaging study. This rarely yields a binary “yes/no” answer, as would be expected with the print out from an automated blood test. It is also worth appreciating that in many instances radiological diagnoses only emerge over time, as more information on the patient becomes available with further investigation, and thus a potentially reasonable diagnosis proffered on an early imaging examination becomes “erroneous” as further patient data become available.

The literature on radiological error rate is extensive and varied, with a plethora of methodologies and criteria for judging “error” and categorizing its seriousness. A number of studies⁷ have shown an error rate of 1–5% when assessing unselected radiological practice, although figures as high as 26%⁴ have been reported in studies where images have been subjected to subspecialist radiological review to assess error rate. The potential scale of the problem can be appreciated by a simple calculation: in excess of 40 million radiological examinations a year are performed in the NHS in England; a 3% error rate would mean there are 1.2 million errors in reporting those examinations, which equates to approximately 90 errors a week in an average sized radiology department. Clearly 90 duty of candour, or even 90 openness discussions per week would be unnecessary and untenable, which further emphasizes that the duty

of candour pathway should only be invoked when it is truly necessary and appropriate.

Duty of candour procedures can lead to patients who have suffered harm (or their families) instigating medicolegal proceedings against the radiologist (or reporting radiographer or other reporting non-doctor) concerned, and it is difficult for the radiological profession to defend itself against this. Perceptual errors are particularly difficult to defend, since when pointed out in retrospect, they are generally visible even to the lay viewer. Clearly better education of the public as to what a radiologist does, in terms of issuing reports that are considered opinions but not infallible statements of fact; and making it clear that radiological reporting and intervention, like every other human act, is subject to error, will go some way to raising general awareness and understanding of why such errors inevitably occur. If possible the working environment should be optimized to decrease unforced errors, by reducing the number of interruptions to the reporting radiologist, guarding against tiredness whilst reporting and improving the ergonomic comfort of the reporting workplace.

The individual radiologist can exonerate him/herself to some extent by documenting evidence that his/her normal practice is of an acceptable standard, and that s/he undertakes professional activity aimed at reducing error, learning from any previous mistakes, keeping up to date with current radiological knowledge, performing self-testing activity and engaging in peer review. Unfortunately the current underfunding of the NHS and in particular the serious shortage of radiologists in the UK,¹⁶ leading to severe pressure upon radiologists to produce more reports more quickly despite the ever increasing complexity of their workload, is not conducive to undertaking and documenting such continuous self-improving activity. The yearly appraisal goes some way to satisfy and document this activity. The radiologist's appraisal should record audit studies undertaken – particularly audits into personal error rate, participation in “radiological learning and excellence, REAL”¹⁷ meetings (formerly known as “radiological learning and discrepancy, READ” meetings) where anonymised cases are reviewed for learning purposes, and the accumulation of continuous professional activity CPD points with associated documented reflection. Incidentally it should be emphasized that such “discrepancy” or, rather, “learning” meetings are aimed at being exactly that: a private means of radiologists being able to improve their future performance by learning from errors or excellence in diagnosis of their peers and themselves. To protect the radiologists and to encourage their participation in such meetings, it is essential that all the imaging studies and reports reviewed are fully anonymised, that the learning experience is conducted in a blame-free environment, and that there should be no written/computer documentation of the cases reviewed, nor of the reflection thereon. These learning meetings are completely separate from the duty of candour legislation and process, and should never be a vehicle for identifying cases suitable for the initiation of a duty of candour process. Cases requiring a duty of candour discussion should already have been identified and acted upon before being submitted to a “learning/discrepancy” meeting, which is internal to the radiology department.

The pressurized environment of NHS radiology rarely permits the luxury of formal radiology peer review activity, routine double reporting or formal annual self-testing against a national standard outside the subspecialty of breast radiology, where double reporting is the UK norm for breast screening and breast radiologists are expected to test themselves annually on the national PERFORMS dataset.¹⁸

SUMMARY

Duty of candour is legally required when an unintended or unexpected incident (even if consented for) could/has result(ed) in death, severe or moderate harm, or prolonged psychological harm. There is a set duty of candour process to be followed under these circumstances, including a written

apology and an investigation. Openness is different, and is encouraged, but only when it is truly in the patient's best interest, which is a judgment call. It is important not to cause patients futile distress by officiously applying a policy of openness or duty of candour when it is unnecessary. However, appropriate openness with the patient can avert medicolegal action. The radiologist is an inevitable target for medicolegal blame, due to the long-term archiving of digital image and report data, and the hindsight and outcome biases, which come into play when these data are subsequently reviewed. Perceptual errors are difficult to defend, but mitigating factors include education of the public about the nature of radiological error, and lifelong documentation by the radiologist of his/her efforts to maintain a high standard of radiological practice.

REFERENCES

1. <https://www.legislation.gov.uk>
2. <https://www.cqc.org.uk>
3. FitzGerald R. Radiological error: analysis, standard setting, targeted instruction and teamworking. *Eur Radiol* 2005; **15**: 1760–7. doi: <https://doi.org/10.1007/s00330-005-2662-8>
4. Abujudeh HH, Boland GW, Kaewlai R, Rabiner P, Halpern EF, Gazelle GS, et al. Abdominal and pelvic computed tomography (CT) interpretation: discrepancy rates among experienced radiologists. *Eur Radiol* 2010; **20**: 1952–7. doi: <https://doi.org/10.1007/s00330-010-1763-1>
5. Robinson PJ, Wilson D, Coral A, Murphy A, Verow P. Variation between experienced observers in the interpretation of accident and emergency radiographs. *Br J Radiol* 1999; **72**: 323–30. doi: <https://doi.org/10.1259/bjr.72.856.10474490>
6. Garland LH. Studies on the accuracy of diagnostic procedures. *Am J Roentgen Radium Ther Nucl Med* 1959; **82**: e38.
7. Wong WS, Roubal I, Jackson DB, Paik WN, Wong VKJ. Outsourced teleradiology imaging services: an analysis of discordant interpretation in 124,870 cases. *J Am Coll Radiol* 2005; **2**: 478–84. doi: <https://doi.org/10.1016/j.jacr.2004.10.013>
8. Jordan YJ, Jordan JE, Lightfoote JB, Ragland KD. Quality outcomes of reinterpretation of brain CT studies by subspecialty experts in stroke imaging. *AJR Am J Roentgenol* 2012; **199**: 1365–70. doi: <https://doi.org/10.2214/AJR.11.8358>
9. MZ W, McInnes MD, Macdonald DB, et al. CT in adults: systematic review and meta-analysis of interpretation discrepancy rates. *Radiology* 2014; **270**: 717e35..
10. Armato SG, Roberts RY, Kocherginsky M, et al. Assessment of radiologist performance in the detection of lung nodules: dependence on the definition of “truth”. *Acad Radiol* 2009; **16**: 28e38.
11. <https://www.rcr.ac.uk/clinical-radiology/being-consultant/read/submit-case>
12. Heerink WJ, de Bock GH, de Jonge GJ, Groen HJM, Vliegthart R, Oudkerk M, et al. Complication rates of CT-guided transthoracic lung biopsy: meta-analysis. *Eur Radiol* 2017; **27**: 138–48. doi: <https://doi.org/10.1007/s00330-016-4357-8>
13. Manhire A, Charig M, Clelland C, et al. British Thoracic Society guidelines for radiologically guided lung biopsy. *Thorax* 2003; **58**: 920–36.
14. Busby LP, Courtier JL, Glastonbury CM. Bias in radiology: the how and why of misses and misinterpretations. *Radiographics* 2018; **38**: 236–47. doi: <https://doi.org/10.1148/rg.2018170107>
15. Semelka RC, Ryan AF, Yonkers S, Braga L. Objective determination of standard of care: use of blind readings by external radiologists. *AJR Am J Roentgenol* 2010; **195**: 429–31. doi: <https://doi.org/10.2214/AJR.09.3987>
16. https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr185_cr_census_2017.pdf
17. <https://www.rcr.ac.uk/clinical-radiology/being-consultant/read>
18. Esserman L et al. Improving the accuracy of mammography: volume and outcome relationships. *CancerSpectrum Knowledge Environment* 2002; **94**: 369–75. doi: <https://doi.org/10.1093/jnci/94.5.369>