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Clinical Radiology

The Royal College of Radiologists

Professional duty of candour

Guidance for radiologists

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Contents

Foreword

Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. They must also be open and honest with their colleagues, employers, and relevant organisations, taking part in reviews when required. This is our professional duty of candour. In addition, we should support and encourage each other to be open and honest, and not prevent others from raising concerns.

The Faculty of Clinical Radiology has developed this document with the aim of providing radiologists with guidance and real-world examples on the implementation of the duty of candour. The document recognises the unique circumstances faced by radiologists and all who work in imaging. It is not possible to provide guidance for every situation, but the aim is to provide an approach which will help colleagues navigate an unfamiliar process in the best possible way for our patients and the professionals who care for them.

My thanks go to Professor Mark Callaway, Dr Giles Maskell, Dr Christopher Hammond, Dr Robin Evans and Mr Carl Flint (lay representative) for leading on this work.

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1 Introduction

Patients and their families expect openness and honesty from healthcare providers. It is no longer considered acceptable for doctors to keep information from patients that patients themselves might consider important. It is incumbent on the radiology community to ensure that future relationships with patients and their families are built on trust and mutual understanding.

In producing this document, the working party struggled to balance the competing demands of a practical and implementable policy; providing support and guidance for departments and radiologists undertaking duty of candour processes, with the ethical and moral principles of openness and transparency and the rights of patients to be informed about all aspects of their clinical care.

The working party therefore decided to outline the following:

- The principles of candour
- Why this can be difficult in a radiological context
- Candour in different situations (reactive and proactive candour) and departmental disclosure policies
- Candour processes in practice
- The difference between discrepancy assessment and education/Radiology Events and Learning Meetings (REALM)
- Specific considerations (interventional radiology and remote reporting within an imaging network).

2 Recommendations

Hospitals, radiology reporting organisations and regulatory and professional bodies should where appropriate:

- Take reasonable steps to ensure that patients undergoing medical imaging are informed in advance of the limitations and risks, as well as the benefits of imaging (including the risks of missed-, mis- and overdiagnosis).
- Ensure as far as possible that all professionals requesting or reporting medical imaging are aware of the frequency and nature of error in radiological practice and of the effect of hindsight and other cognitive biases when reassessing imaging retrospectively.
- Create a formal enterprise-wide policy document stating the process to follow in the event of the discovery of a radiological discrepancy. This document should be:
  - Created jointly by the radiology governance team and the organisation's risk management department
  - Regularly reviewed.
- Ensure that all its professionals are aware of the policy document and the procedure to follow in the event of the discovery of a possible radiological error.
- Establish, support and maintain a *discrepancy assessment process* (as described in section 7 of this document) to allow independent review of radiological discrepancy. This should be *distinct from* and *in addition to* an educational and learning process such as REALM.
- Have an agreed governance mechanism for discussing discrepancies with external providers and recipients of reporting, radiological and clinical services.
- Acknowledge that error is inevitable. An approach rewarding candour, rather than highlighting instances of lack of candour, will foster an organisational culture of openness where individuals do not fear being candid.
- Ensure individuals understand that '*offering an apology is an important part of being candid as it shows that you recognise the impact of the situation on the patient, and you empathise with them*'.

Individuals reporting medical imaging should engage with their local radiology duty of candour process in accordance with General Medical Council (GMC) guidance and good medical practice.[1]

3 The principles of candour

The professional duty of candour

All medical professionals are expected to comply with the professional duty of candour which states:[1]

Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. This means that healthcare professionals must:

- Tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong.
- Apologise to the patient (or, where appropriate, the patient's advocate, carer or family).
- Offer an appropriate remedy or support to put matters right (if possible).
- Explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short- and long-term effects of what has happened as far as can be ascertained.

The statutory 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.

Duty of candour within the wider governance framework

The Francis report[2] identified three necessary characteristics of an organisational culture committed to patient safety and the avoidance of substandard care:

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Transparency** – allowing true information about performance and outcomes to be shared with staff, patients, the public and regulators.
- **Candour** – 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 about it.

Candour is therefore only one aspect of a safety culture. Arrangements to comply with the statutory duty of candour are complementary to, but different from other governance processes such as:

- The management of complaints (both formal and informal) and queries.
- Assurance of compliance with fundamental care quality standards and relevant statutory regulation and rapid correction when these standards or regulations are breached.
- Effective investigation of, and learning from, complaints and incidents.

- Management and mitigation of risk.
- Effective appraisal.

It is essential that all clinicians contribute to and engage with a culture of openness and transparency with their patients.

4 Definitions and assessment

Statutory definitions relevant to duty of candour

The Care Quality Commission (CQC) requires a statutory duty of candour notification for notifiable patient safety incidents in England.[3]

Notifiable patient safety incident

'Any unintended or unexpected incident … that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in harm … where the harm results from the incident, rather than from the natural history of the patient's disease.'

Similar definitions are found in statute of the other home nations.[4,5]

Within this definition, an error (as defined above) is an 'unintended or unexpected incident'.

Harm

Harm is defined (by the CQC) as:

- Death
- A moderate increase in treatment, ie:
  - Unplanned return to surgery
  - Unplanned readmission
  - A prolonged episode of care
  - Extra time in hospital or as an outpatient
  - Cancelling of treatment
  - Transfer to another treatment area (such as intensive care).
- Psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.

Discrepancy and error definitions

For the purposes of this document, and from this point on, the following terms are defined.

Discrepancy

A discrepancy is defined as where the contemporaneous interpretation of an imaging study (usually in the form of a report) is different from (ie, discrepant with) a *retrospective reinterpretation of that study*, sometimes occurring in light of further information which might include further imaging.

Discrepancy assessment

A discrepancy assessment is a process to assess a discrepancy against an audit standard. An appropriate audit standard is that the contemporaneous interpretation of the imaging (usually in the form of a report) is *as complete and comprehensive as would be reasonably expected given information available* at the time the report was issued.

Error

An error is a discrepancy for which the contemporaneous report (after discrepancy assessment) is deemed **not to have met the audit standard** as *complete and comprehensive as would be reasonably expected given the information available* at the time. In other words, the contemporaneous interpretation of the imaging study would reasonably have been expected to be different from that offered.

Relationship between discrepancy, error and errors that have resulted in harm

Not all discrepancies are errors, and not all errors result in harm. The number of errors that have resulted in harm will therefore be substantially less than the number of discrepancies identified within a department.

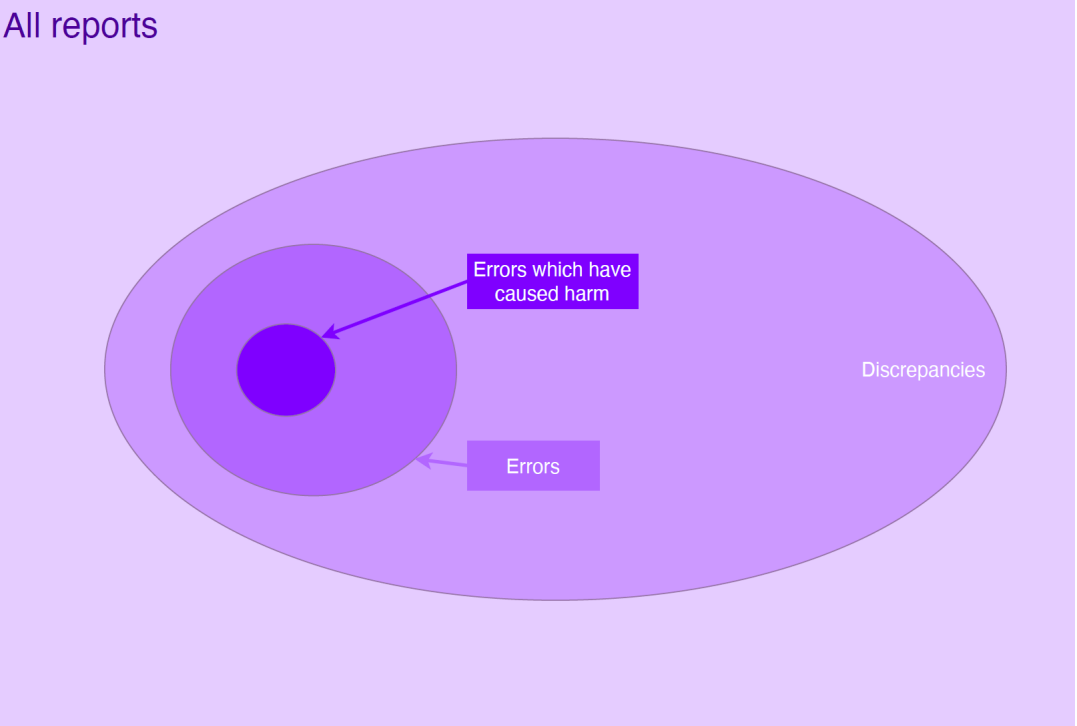

Figure 1: Relationship between discrepancy, error and errors that have resulted in harm (not drawn to scale).

Thus, the statutory duty requires two determinations to be made in the case of a reporting discrepancy:

1. Does the discrepancy constitute an error (as defined above)?
2. Did this error lead to harm?

Assessing harm

Experience suggests that the assessment of whether a radiological error has led to harm is complex. Radiologists will not usually have seen or examined the patient personally and will need time to gather all information relevant to the patient's care. It is therefore extremely difficult for radiologists to assess the level of harm an error has caused.

Making a harm assessment solely based on information available to the radiology department is not advised and **dialogue between the radiology governance lead or relevant radiology lead clinician and the relevant clinical team is essential** before triggering a candour discussion with the patient.

There may well be factors related to the patient's general condition or availability of treatment options which mean that a delay in diagnosis, for example, has not resulted in harm.

It may be helpful for radiologists to be present at candour discussions with patients or their carers when there has been a discrepancy or error, as they are best placed to discuss the complexities of these issues. Where a radiologist is a planned participant in such a meeting, prior evaluation and discussion is essential to ensure both radiological and clinical perspectives about a discrepancy or error and the associated harm (if any) are properly understood. Radiologists involved in such meetings may require additional communication skills training to ensure such discussions are conducted sensitively and fairly. They may also require mentoring and support.

Examples of the difficulty in harm assessment are offered in box 1 (below) and box 4.

Box 1: Harm assessment

An 80-year-old man presents with cough and haemoptysis. A chest radiograph demonstrates a 5cm mass in the left lower lobe. On review of previous imaging, it is noted that he had undergone thoracic computed tomography (CT) for breathlessness five years earlier and that a 7mm nodule was evident in the left lower lobe at the site at which the tumour had subsequently developed.

A discrepancy assessment process is undertaken, and all the reviewing radiologists identify the nodule. The consensus is that the contemporaneously issued report was incomplete as the nodule should have been commented upon.

A respiratory physician reviews the case to determine whether harm had resulted from this error. In her opinion, the patient had significant co-morbidities which even five years earlier would have prevented radical treatment. The conclusion was that no harm had resulted and in accordance with local policy, a duty of candour notification was not triggered.

5 Why is duty of candour difficult in radiology?

Duty of candour in radiology is problematic for several reasons:

Defining an 'incident'

The GMC guidance discusses duty of candour being required 'when something has gone wrong'. The CQC guidance on the statutory duty defines a 'notifiable patient safety incident' (as defined in section 4).[3] Devolved nation guidance references similar concepts.[4,5] These concepts are predicated on some 'incident' occurring or something not occurring which should have occurred (an omission). That is, an identifiable point at which 'something has gone wrong'.

However, the concept of an 'incident' is not easily applied to diagnostic radiological practice. Discrepant interpretation of a radiographic image is not only commonplace but cannot immediately be identified as an 'incident' in the way that administration of the wrong medication, omission of a necessary intervention or complication of a surgical procedure can be defined.

Most diagnostic radiology discrepancies only become evident in hindsight. It is usually not immediately clear that they represent 'something [that] has gone wrong' because:

- The digital image forms a permanent record (subject to satisfactory digital storage arrangements) which can be reviewed at any point in the future when hindsight may well affect interpretation. It is impossible to recreate the exact circumstances under which the original interpretation was made. Even restricting a later reader to only the same clinical information as was originally available does not allow for the environmental, circumstantial, and other cognitive factors that will have influenced the original interpretation. For some examinations (for example, ultrasound) the dynamic nature of the examination may not be fully reflected in the stored imaging.
- The interpretation of radiographic images is a subjective process and different observers may come to different conclusions about a particular image that are equally valid at the point at which interpretation is made but some of which will subsequently be shown to have been 'wrong'. Moreover, the variation in imaging appearances between individuals is so great that it is impossible to define 'normal' for any but the simplest tests. The skill of the radiologist is not so much in detecting 'abnormalities' but in determining which of the myriad variations demonstrated on any set of images is significant for the patient's health.
- Review of previous imaging is inherent in- and fundamental to- the practice of radiology (just as the taking of a clinical history is central to clinical practice). Such review offers continuous ongoing opportunity for reinterpretation (and reassessment) of prior clinical evidence that is unusual elsewhere in medical practice outside of clinical audit. This *routine retrospective reinterpretation* of subjective interpretations of medical imaging results in a ready identification of discrepancies in diagnostic radiological practice. Most of these will not have resulted in harm to patients but some will.

Relationships with the patient and with clinicians

It is standard diagnostic radiological practice that image interpretation is carried out at a distance from the patient. The primary relationship is generally between radiologist and referring clinician rather than directly with the patient. If a discrepancy or error is identified, the radiologist is not usually immediately at hand to discuss possible reasons. Explanation may therefore have to be through the intermediary of the clinician. This can result in misunderstanding and miscommunication, especially if the clinician does not understand the nature of radiological discrepancy. It is *never* appropriate for a radiologist or clinician to state at the point of discovery that a different interpretation *should* have been made on the earlier occasion.

It is not the purpose of this document to proscribe the nature and limits of conversations clinicians have with their patients. However, radiologists should encourage their clinical colleagues to be sensitive to the issue of hindsight bias when reinterpreting imaging and discussing its reporting. Clinicians should be encouraged to seek radiology advice and if necessary, ask for a discrepancy assessment prior to discussing discrepancies in detail with patients.

Public and professional expectation

There is a gap between public and professional understanding of the nature of radiological interpretation. Experience suggests that patients generally have a level of trust in the accuracy of medical imaging and expect that if they have a serious condition, it will be detected. Most radiology professionals regard this as unrealistic: all our tests have limitations. Some fractures are not visible on X-ray, and some breast cancers are not visible on mammography. Even when a fracture or cancer is visible on the image, it will not always be detected. There are many possible reasons for such a failure, some of which we have come to understand better in recent years.

Additionally, while for many medical processes there are interventions that can be undertaken to mitigate recurrence of error, in radiology this rarely applies. For example, a level of perceptual error is inevitable.

The potential unforeseen consequences for radiology departments

Reporting discrepancies are common (between 3 and 30% of reports in published literature) and have many causes.[6] Given that around 100,000 studies are performed each day in the UK, there will inevitably be a very large number of discrepancies. Although most of these will not result in harm to patients, some will.

While committed to improving patient care by learning from discrepancy, radiologists have legitimate concerns about the difficulty in making the distinction between discrepancy and error and about the potential suppression of learning opportunities (see section 9) and the impact of additional work (see section 4).

6 Candour in different situations and radiology departmental disclosure policies

Reactive candour

See example in box 2. In situations where a patient is aware of (or queries the presence of) a discrepancy, the moral and ethical requirements for openness and transparency necessitate that the outcome of any discrepancy assessment (including that such an assessment has taken or will take place) is communicated to the patient *irrespective of the outcome of this assessment*.

Patients who raise queries or complain rightly expect to have those queries or complaints investigated thoroughly and the outcome of this investigation communicated to them whatever the outcome.

Reactive candour is akin to the concept of openness in the Francis report.[2]

Box 2: Example of reactive candour

A patient is diagnosed with a right renal cell carcinoma on a contrast enhanced CT scan performed after investigation for microscopic haematuria. He had undergone an unenhanced CT abdomen 20 months earlier for non-specific bloating.

During the course of a urology clinic consultation, the patient asks how long he has had the tumour and mentions the prior CT scan. The urologist, in attempting to answer this query, reviews the prior CT scan and notes a slight contour abnormality in the outline of the right kidney. This was not reported at the time. Given the direct query, the urologist feels uncomfortable not disclosing this to the patient, even though she is not sure whether the lesion would have been prospectively identified. She discusses the discrepancy with the patient and also raises the discrepancy via the uro-radiology multidisciplinary team (MDT).

The CT scan is reviewed via a discrepancy assessment process. The consensus is that the contemporaneously issued report was reasonable and that no error has occurred.

This outcome is reported back to the patient via the urology clinic. The patient remains dissatisfied, and a meeting is offered with representatives from uro-radiology, radiology governance and the urologist.

Proactive candour:

This applies when an incident is identified in the patient's care *of which the patient (or their carer) is not aware*. The Francis report and the GMC and CQC guidance are clear that candour is required (by which they mean proactive candour) when things have gone wrong and harm has occurred 'whether or not a complaint has been made or a question asked about it'.

Most duty of candour in diagnostic radiology practice is likely to fall into this category as discrepancies are usually identified in hindsight, geographically and temporally distant from the patient and their imaging study.

Audits of care take place throughout healthcare. If an audit identifies failings or errors in care, it is good practice to notify the patient(s) involved, and if harm has occurred this is a statutory requirement. By analogy, a discrepancy assessment can be considered an audit of an aspect of a single patient's care. If the discrepancy assessment identifies an error (ie, that something has gone wrong), it is good practice to notify the patient(s) involved, and if harm has occurred this is a statutory requirement.

A fundamental question is at what stage, if at all, a patient should be notified of a discrepancy of which they are unaware. Should a patient be informed:

- That a discrepancy in their imaging has been identified and has triggered an audit of the accuracy of the contemporaneous (prior) report?
- Only if the audit identifies an error in the prior report?
- Only if the audit identifies an error in the prior report ***and*** the error has resulted in harm (ie, that a notifiable patient safety incident has occurred)?

This is a difficult ethical and practical dilemma. Individual committee members advocated different approaches. Representative arguments presented to the committee are outlined in the appendix.

Radiology departmental governance leads and committees will need to consider these arguments and conclude policy decisions with their hospital risk management teams about if and when patients should be informed of discrepancies or errors during a proactive candour process. Notifiable patient safety incidents require a statutory notification.

Circumstances may vary and a policy decision reached in one department may be different from that reached in another.

Policy decisions should be documented, and the policy reviewed regularly. Policy decisions may require a relevant risk register entry to be created.

Box 3: Example of proactive candour

A patient is diagnosed with a right renal cell carcinoma on a contrast enhanced CT scan performed after investigation for microscopic haematuria. He had undergone an unenhanced CT abdomen 20 months earlier for non-specific bloating.

On reviewing prior imaging immediately before a clinic consultation, the urologist reviews the prior CT scan and notes a slight contour abnormality in the outline of the right kidney. This was not reported at the time. The patient makes no reference to the prior CT in the clinic appointment and the urologist does not raise the issue with him. However, she raises the discrepancy via the uro-radiology MDT.

The CT scan is reviewed via a discrepancy assessment process. The consensus is that the contemporaneously issued report was reasonable and that no error has occurred.

The discrepancy with the prior report is not an error. The agreed hospital policy is that only discrepancies assessed as errors that have caused harm require disclosure. The patient is not informed of the assessment or its outcome.

Box 4: Example of proactive candour and harm assessment

A patient undergoes a chest X-ray for chest pain and breathlessness on which marked right sided lobular pleural thickening is identified. A CT scan confirms advanced mesothelioma. The patient had complained to his GP of right shoulder pain 12 weeks previously and had a shoulder radiograph which was reported as normal. The radiologist reporting the current chest X-ray reviews the prior shoulder radiograph and notes that, while the shoulder joint itself was normal, the lobular pleural thickening was visible.

The shoulder radiograph is reviewed via a discrepancy assessment process. The consensus is that the contemporaneously issued report was incomplete and that the pleural thickening should have been commented upon. The referring clinical team review the patient's notes and conclude that the delay to diagnosis is unlikely to have resulted in harm as the pleural malignancy was already incurable at the time of the shoulder radiograph.

However, on reviewing the patient in clinic, a chest physician ascertains that the patient has been suffering significant right sided shoulder and chest pain for some time which has been an increasing source of distress for him. They consider that the delay to diagnosis caused by the radiology error has resulted in harm even if the prognosis had been unaffected by it, and therefore that a statutory duty of candour disclosure is required.

7 Discrepancy assessment in practice

When identifying a discrepancy, it is important for radiologists to remember that their primary responsibility is to the ongoing care of the patient whose imaging they are reporting. They should issue a report in the usual manner and ensure time-sensitive, urgent or unexpected findings are alerted to the referring team. If necessary, when describing a discrepancy with previous imaging, the use of subjective terms (such as 'unfortunately') or making value judgements about the previous report (such as 'previously missed', 'incorrectly') should be avoided. Instead, a neutral form of words such as '...has become apparent' is recommended.

Discrepancy assessment is difficult and mechanisms for achieving it will vary according to local practice and organisational arrangement. An audit standard (that the contemporaneous interpretation of the imaging (usually in the form of a report) is *as complete and comprehensive as would be reasonably expected given information available* at the time the report was issued) may be subject to interpretation dependent on the context in which the original report was issued. For example, it may not be appropriate for a neuroradiologist with a subspecialty interest in paediatric imaging to assess a discrepancy made by a general radiologist reviewing an on-call paediatric head CT.

The first step in 'discrepancy assessment' is often carried out by the reporting radiologist – if they don't think that an error has occurred, they won't trigger the assessment process.

Radiology governance leads should create appropriately resourced processes for discrepancy assessment locally.

Recommendations for the design of a discrepancy process

- Discrepancies should be assessed by forwarding the imaging in question *together with the clinical information provided to the original reporter and relevant prior imaging* to a panel of reviewers. It is helpful to ask reviewers to commit to one of a series of options, as well as being able to make a narrative comment.
- Reviewers' opinions should be collated in confidence.
- Once all (or a sufficient number) of reviews have been submitted, a named person (usually the radiology department governance lead or their nominated representative) should review the responses and determine whether the discrepancy be classified as an error.
- In some circumstances it may not be possible to conclusively determine whether the discrepancy be classified as an error. This may be the case if the reviewers consider it impossible to make a judgement, or comment that their assessment of the case is somehow compromised. For example, by prior knowledge of it or an inability to overcome the inherent biases of retrospective imaging review (see below) or if there are significant differences in opinion between reviewers. In this circumstance the assumption should be toward openness and possible proactive disclosure.
- The outcome of all discrepancy panel reviews should be recorded in the imaging record as an addendum to the verified report of the discrepant imaging. The outcome of the review should be fed back to the original reporter and consideration should be made whether the case is shared anonymously at an education meeting (for example, if there are learning points that need emphasis).

- If a discrepancy meets the threshold for error, the original reporter should create an entry in their appraisal portfolio and reflect appropriately.
- Once a review is complete, all reviewers should have the outcome of the review and the anonymised responses of their fellow reviewers fed back to them. This will allow reflection on their opinion in the context of those of their colleagues.

Avoiding bias in discrepancy assessment

It should be recognised that by its very nature discrepancy review is a biased process. It is impossible to recreate the exact circumstances under which the original imaging interpretation was made. Even restricting a later reader to only the same clinical information as was originally available does not allow for the environmental, circumstantial, and other cognitive factors that will have influenced the original interpretation.

Reviewers undertaking discrepancy assessment need to be aware of the substantial risk of bias when making comments on prior imaging. Hindsight bias, outcome bias, information bias, selection bias, presentation bias and reinterpretation of expected normal variation biases are difficult to overcome. While some discrepancies will be obvious errors, some will be very subtle and be the subject of legitimate differences of opinion. In designing and taking part in the process for reviewing discrepant imaging, organisations and individual radiologists need to consider the following:

Prior case awareness

Every effort should be made to ensure that those reviewing discrepant imaging are unaware of the case and the circumstances in which the discrepancy was identified. Knowledge of subsequent outcome, information or imaging may substantially bias interpretation and correcting for this is almost impossible.

This may be a particular issue for small departments, or in subspecialist imaging teams where cases are informally discussed between colleagues as a normal part of professional practice. In this circumstance, neighbouring or affiliated organisations might liaise to create processes facilitating mutual review of each other's cases.

Blinding to subsequently available further information

Reviewers should ideally be blinded to subsequent imaging or other information arising since the date of the imaging they have been asked to review. They should review only the potentially discrepant imaging, relevant priors and the clinical information available at that time.

Blinding to the opinions of other reviewers

Reviewers should comment individually and in isolation and should not have access to the opinions of their fellow reviewers. Electronic resources such as Google forms (see figure 2) should be made available to support this.* A 'candour review meeting' is not recommended as non-verbal and other cues can easily sway opinion.

***Note:** No patient identifiable information should be entered when using commercially available electronic resources, though this is easily achieved by assigning the case an ID number. Google forms can be run from any device including a smartphone, which makes the process of a reviewer entering their opinion very easy.

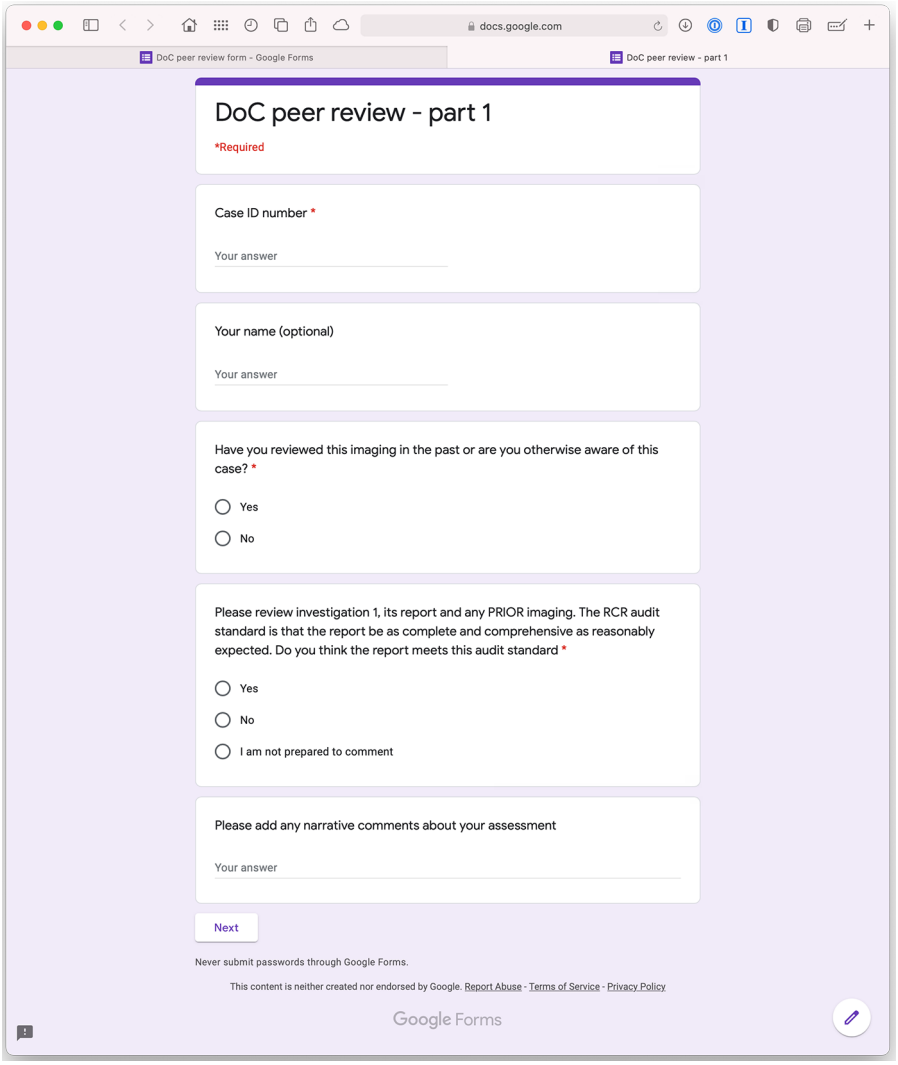

Figure 2: an example of an online form for duty of candour assessment.

Anonymity

Reviewers should be blinded to the identity of the original reporter of the imaging.

Circumstances of review

Reviewers should be aware of the bias introduced by the fact that they have been asked to review a case. It is likely that imaging review in this context will be more thorough, and reviewers more vigilant than imaging review during the course of normal work. Correcting for this entirely is extremely difficult.

An ideal scenario would involve a case being 'dropped' into the worklist of a reviewer without them being aware that the case was for a discrepancy review. It is acknowledged that for most NHS organisations such an ideal is aspirational given workload and information technology constraints, though some teleradiology companies have processes approximating this. Where this is not possible, reviewers should make efforts to ensure the opinion offered is a genuine assessment of how they would have acted had they reviewed the imaging as part of their normal workload.

Appropriate selection of reviewers

Where possible, the reviewers should be chosen from the pool of people who report the discrepant imaging in the course of their normal practice. Appropriate selection of reviewers is important to ensure their skill sets and areas of subspecialty interest are concordant as far as possible with those of the original reporter, subject to minimum standards.

'Hawks' and 'Doves'

There will be a natural variation in baseline opinion about whether a discrepancy meets a threshold for classification as an error. Some radiologists will have a relatively lower threshold ('Hawks') than others ('Doves'). Radiologists should bear their baseline in mind and try to ensure that the opinion offered is a genuine assessment of how they would have acted had they reviewed the imaging as part of their normal workload.

8 Performance management, appraisal and reflection

Assessments of discrepancy against an audit standard are not an assessment of professional performance and **should not** be used as a mechanism for performance management. A full analysis and discussion of circumstances in which errors are made is out of the scope of this document, but error is frequently multifactorial[6] and a focus on individual performance is reductionist and less likely than a holistic approach to error to improve patient care.[7] Furthermore, if the process of assessment of discrepancy is known (or even understood or suspected) to be associated with performance management, this may undermine the ability or willingness of reviewers to give an objective or fair opinion.

Discrepancies classified as errors should be highlighted to the original reporter for inclusion in their appraisal portfolio for appropriate reflection.

The Royal College of Radiologists (RCR) has published guidance to support appraisal and revalidation[8] and has produced a template for reflection on discrepancies and errors. A formative approach to discussion of errors within an appraisal meeting is essential with the emphasis on learning from (and possibly sharing the circumstances of) the error, rather than as a judgement of the performance of the clinician making the error.

9 Education, REALM and sharing

Learning from errors and discrepancies is an essential part of quality assurance in radiology. The RCR has published guidance on learning from discrepancy meetings[6] which emphasises the formative and educational aspects of such meetings. The use of scoring systems for discrepancies within an educational meeting is not recommended as this can fuel a defensive or blame culture. Imaging review in a meeting does not replicate the circumstances in which the discrepant imaging report was originally produced.

For these reasons, assessment of discrepant imaging against the audit standard described earlier **should not** take place in an education or REALM meeting. The necessary forming of a judgement about the original discrepant report is at odds with the purpose and culture of an education or REALM meeting (see table 1). Information about whether a discrepancy has been classified as an error should not be made available to an education meeting. The purpose of an education meeting should be solely about understanding, sharing and learning.

All discrepancies, whether errors or not, and whether or not harm has been caused, should be considered for discussion at a departmental education meeting.

Table 1: Comparison of an Education / REALM meeting and discrepancy assessment against threshold process

	Educational cases meeting	Discrepancy assessment
Purpose	To learn from interesting cases. Focus is on education	To decide if discrepant imaging meets the threshold for error. Education is not an aim
Anonymity	Patient and reporter anonymised	Patient identifiable, reporter anonymised where possible
Decision-making	Non-judgemental	Judgement (on whether the discrepancy meets the threshold for error) is necessary
Outcome recording	Outcome does not routinely form part of medical record	Outcome forms part of the patient's medical record
Professional driver	RCR	RCR, GMC, CQC
Frequency	Recommended six meetings attended per year	No recommendation

Nature	Inclusive, open, formative, discursive	Confidential, closed
Quorum	None set	None set
Target group	Multidisciplinary	Not usually appropriate for anyone but consultants or reporting radiographers with established expertise
Sharing	Narrative outcomes widely disseminated for learning	Binary outcome (error or not) shared with original reporter, documented in the patient's record and where there is error, progressed to an assessment of harm

10 Specific considerations

Candour in interventional radiology

The Royal College of Surgeons of England has published guidance on candour relating to surgical procedures.[9] The RCR considers that this applies equally to invasive radiological procedures.

If there has been an event that has resulted in harm in the course of an interventional radiological procedure, the radiologist should have an open discussion with a patient about the event, including a clear explanation of what happened and why. They should offer an apology and discuss the likely consequences. This discussion should be recorded.

Complications of a procedure, *including recognised complications for which the patient was appropriately consented*, are included in the definition of an event and if harm is caused, should be discussed and documented as above.

Unlike reporting errors (where the radiologist usually has no direct relationship with a patient), harm is usually apparent to an interventional radiologist following a procedural complication and it is reasonable for the radiologist to make a harm assessment, rather than delegating this assessment to the non-radiology clinician with responsibility for the patient's care.

It is essential that interventional radiologists reflect on incidents occurring during procedures they undertake (including formal reflection in their appraisal portfolio). Incidents should be submitted to an appropriate forum for discussion, education and the sharing of learning. Whether this forum constitutes the departmental education meeting, or a more focused morbidity and mortality meeting, will depend on local departmental organisation.

Teleradiology

The principles outlined in this document apply equally to reporting undertaken remote from the organisation obtaining the imaging. This includes teleradiology providers, another NHS trust, a private hospital, within an NHS regional radiology network or where imaging is transferred between organisations for the purposes of tertiary or quaternary care.

These circumstances provide challenges in the effective application of duty of candour. For example, awareness of an identified radiology error may not be shared between providers. Appropriate candour decisions may not occur because a patient outcome is unknown or incorrect assumptions are made that another organisation is conducting an incident investigation.

The CQC duty of candour guidance is that when a notifiable patient safety incident is discovered involving a different provider, that provider must be informed.[3] Duty of candour procedures must be conducted by the provider caring for the patient. If multiple providers contributed to an incident, they should liaise and work together in its investigation.

In a radiology context:

- If a discrepancy is discovered by one provider on imaging reported in another, the radiology clinical governance lead in the originating provider must be informed. Conversely, a reporting provider should inform a client provider's radiology clinical governance lead of errors that are identified within the reporting provider's service.
- There must be agreement on which provider is conducting a discrepancy assessment, harm assessment (if needed) and duty of candour notification (also if needed). Usually this should be the provider with primary responsibility for the patient's management.

- If there are contributing factors involving multiple providers, then they must cooperate fully, openly, respectfully and without bias in these assessments. Investigations should be led by the radiology clinical governance lead from one or the other provider. Usually this should be the provider with primary responsibility for the patient's management.
- Assessments of harm (if needed) must be made by a patient-facing clinician, usually at the request of the relevant provider's radiology clinical governance lead. The outcome of harm assessments should be shared with the reporting provider.
- The processes of discrepancy assessment, harm assessment and duty of candour notification should be undertaken using the principles and processes described earlier in this document irrespective of the type of reporting provider involved.
- If a statutory duty of candour notification is required, a local candour conversation with a patient and/or their family may be needed. The external reporting provider should provide input into this process, although personal representation is not mandated.
- Remotely reporting radiologists should be supported through these processes in an identical manner to onsite radiologists. Arrangements for appraisal, reflection, education and REALM described above apply equally to all radiology reporting organisations and providers.

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Appendix 1.

Arguments advocated by committee members about timing of patient notification when a proactive candour process is undertaken.

A governance lead's perspective

Radiologists make judgements all the time about imaging report discrepancies. These judgements are often made informally. Occasionally, more formal departmental review processes are undertaken. These, and the extent to which their outcomes are shared, are very variable.

The statutory duty of candour necessitates a formal approach to the assessment of discrepancy. Formal processes have advantages for patients in assuring them that healthcare is transparent and honest, but also for healthcare organisations so risks associated with non-disclosure after informal assessment are minimised.

The difficulty comes in the practical implementation of a formal process. The risk is that radiologists and radiology departments, already stretched, are overwhelmed by formal discrepancy assessments, notification processes and associated patient query. Equally undesirable is that formal processes are ignored by staff if they are considered cumbersome, naive or unimplementable.

Ultimately a binary decision needs to be made. In each individual case of discrepancy, either the patient is to be notified of a discrepancy or they are not. A balanced approach requires that learning from discrepancy is not compromised, and that workload associated with formal discrepancy assessment is minimised.

A discrepancy assessment is essentially an audit of a single patient's care. A desire for openness surely does not require proactive disclosure of every audit and audit detail of someone's healthcare journey.

A radiologist's perspective

Doctors have a duty to be open and honest with patients which is enshrined in guidance from the GMC and has become known as the professional duty of candour. The statutory duty of candour requires organisations to inform patients when harm has resulted from an error in their care and sets out in regulation a process which must be followed.

Radiologists recognise that discrepancies in image interpretation occur frequently and have resisted moves to make us decide which of these discrepancies constitute errors. This is partly because we recognise the inevitably subjective nature of any such determination and the many factors which might influence it, and also because we fear that the introduction of a process requiring us to make such an assessment will lead to the conscious or unconscious suppression of discrepancies and a loss of learning opportunities as a result.

The introduction of the statutory duty has effectively compelled us to devise a way of making this distinction. Although we have concerns about the impact of this, both on professional practice and on patient care, there is little doubt that radiologists are better placed to make this determination than anyone else. Clinicians on the other hand are much better placed to decide whether harm has resulted in a particular case.

A satisfactory process for implementing duty of candour with regard to radiology requires close co-operation between radiologists and clinical colleagues.

A patient's perspective

It is reasonable to reflect that the majority of patients undergoing imaging have little or no medical training. The process can result in a stressful and worrying time for the patient. From the initial consultation the patient is totally dependent on the expertise of the health professionals who administer, examine, test and feedback on their findings. This unspoken dependency defines the trust the patient places on the medical professionals who determine their prognosis.

Following feedback from the health professional there is, for the vast majority of patients, little or no option of being able to seek an alternative expert opinion. You do trust and have to trust what you have been told. Therefore, it is crucially important that the patient is informed of the variables and validity inherent in the examination process. It cannot be over emphasized that the chances of identifying a health problem from an image is always less than 100%. The patient needs this explained such that they understand that the imaging process is not a perfect science.

If at a later stage during the medical process or at a time in the future an error is found to have been made which would have adversely affected the original prognosis, then the patient must be informed.

A clinical ethicist's perspective

When ethical practices are institutionalised, we run the risk of losing sight of why they matter. A sound discrepancy disclosure framework will rest on clarity about why candour is morally important.

Patients have a deep moral interest in what happens to their own body. It is theirs, no one else, and it respects patients' personhood to share information gathered about their body. Vitally, when there are decisions to be made, providing relevant information is the foundation of respect for patients' autonomy.

Looking purely from the perspective of consequences, candour is important because it sustains trust between patients, professionals and organisations. Patients and their families have deeply felt moral expectations that treatment effects, untoward outcomes, unfortunate discoveries and errors will be explained. When these expectations are not met it generates hurt, distrust, fear and often anger. Additionally, candour supports a culture of improvement. Being honest with patients and carers requires care providers to be honest with themselves, which is in turn the foundation of a culture of improvement.

Differently, and following arguments made by philosopher W.D. Ross, prima facie duties of non-maleficence (doing no harm), fidelity (acting according to explicit and implied promises), and reparation (the duty to make up for wrongful acts done to others) all underpin the necessity of disclosure. There is a duty to be honest about harm, to act in ways consistent with what we have promised, and to make reparation when it is due.

Finally, a narrative ethical approach points compellingly towards the need for disclosure to be done with care and compassion. Patients and their families tell and retell the feelings of disorientation and destabilisation that follow in the wake of care going awry.

Disclosure systems should be responsive to the needs of patients and their bereaved. Imaging is done for differing reasons, each of which may affect what patients or bereaved should be told and when. So radiologists working with risk management teams to develop local systems for discrepancy disclosure should consider these questions:

1. Would withholding this information be respectful of patients as persons?
2. Could this information be relevant to life decisions by patients or their families?
3. Would we be seen as trustworthy if we withheld this information?
4. Would sharing this information with patients help make care safer?
5. What should we promise to patients in advance of their imaging procedure?
6. What have we (explicitly or impliedly) promised in relation to imaging?
7. Could withholding any information infringe our duty of reparation?
8. How will we support clinicians and others to share information in an empathetic way?

Responding to question 2 it could be argued that only advising patients when a discrepancy assessment has identified harm could be too narrow, because an acknowledged discrepancy might also give rise to new treatment decisions. Responding to question 5 suggests that patients should be properly informed about what their imaging procedure is intended to achieve. And answering question 7 suggests that on grounds of natural justice a discrepancy assessment by a provider should be open to third party review. Hence, in cases where there is any margin of doubt about either the nature of the discrepancy, or its possible consequences, patients or their families should be made aware of the discrepancy assessment.

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