The Royal College of Radiologists
Faculty of Clinical Radiology

Response to:

NMC and GMC – Consultation on Openness and honesty when things go wrong: the professional duty of candour

Question 1: Is it helpful to have additional guidance on this issue?

It is helpful to have additional guidance, especially as the application of the duty of candour in a diagnostic specialty such as radiology is not a simple matter.

Our principle concern stems from the fact that the tone of the guidance appears to perpetuate the myth that healthcare-related harm is an infrequent event.

Error is inherent in radiology. The available evidence suggests an error rate in unselected radiology practice of between three and five percent. For certain types of specialist examination, where review by sub-specialists has occurred, the quoted error rate exceeds 30%. About 36 million radiological examinations take place in the NHS in England each year, the great majority of which receive a radiologist’s report. A conservative estimate therefore would suggest that close to one million radiological errors occur each year in the NHS. This equates to approximately 4500 a year in an average sized radiology department ie 90 a week. Near misses are even more common.

While some of these are minor, a great many could fall within the definition of causing ‘moderate harm’ as defined in the new Regulations.

Radiological diagnosis is an interpretive process and not a binary activity. Indeed radiological diagnosis is only a component, if an important one, in diagnosing what is wrong with many patients. For many patients, their diagnosis often emerges over hours/days/weeks/months as more information from various sources becomes available, and the natural history of disease evolves. This being the case, it is commonplace for the initial recorded interpretation of an imaging test to be considered “erroneous” on later review. Moreover, the fact that an abnormality is visible in retrospect does not mean that the failure to report it constituted an error. An example would be the presence of a 2mm pulmonary nodule visible in retrospect on a cardiac CT at a site at which lung cancer is subsequently diagnosed.

The magnitude of the harm suffered by a patient is completely unrelated to the size of the “error” made in radiological interpretation. The greatest harm could result from failure to make the most subtle observation, for example in a patient with the earliest signs of cancer. There is no benchmark for what constitutes an “acceptable error” in diagnostic radiology. Indeed on the rare occasions when this has been tested in the Courts, the judicial view has been that no failure of observation or interpretation should be considered “acceptable”.

It is better to consider many Radiological diagnostic “errors” as discrepancies in reporting, understandable given many factors. Radiological detection and/or interpretation of a lesion is influenced by:

- the quality of the clinical history given to the reporting Radiologist
- the stage of disease eg 3 mm lung nodule v 3cm mass
- trade off of sensitivity v specificity, undercall v overcall, benign scar versus early tumour
• location of disease,
• misdirection eg small renal tumour found incidentally on one slice out of hundreds in an MRI spine examination carried out for investigation of back pain
• distracting co-morbidity eg innumerable abnormal findings
• confounding co-morbidity eg subclinical colon cancer in a patient with diverticulitis, ovarian cancer in a patient with severe endometriosis
• clinically silent/benign abnormalities on imaging
• hundreds, sometimes thousands of images to interpret for a single CT scan… and to be compared with one or more previous CT scans in an oncology patient to determine if there is response to a particular chemotherapeutic agent
• factoring in type of treatment into radiological diagnosis
• physique of patient, eg abdominal pathology more obvious on CT in an obese patient, but less obvious with ultrasound
• technical factors eg radiographic quality, number and type of imaging sequences used, patient movement blur
• the imaging technique used eg MR and CT much more sensitive that plain x-rays but routine MRI for every patient in A&E who presents following an injury is unaffordable (and unnecessary) in any healthcare system
• system factors eg reporting overnight on call and again next day
• remote teleradiology reporting without access to previous imaging/reports/electronic patient records/easy phone liaison with clinicians
• nature of disease reported, clinician receiving report, and actionability of report wording
• workforce crisis in UK Radiology with 1 in 7 Consultant Radiologist posts vacant overall across the UK, some hospitals 1 in 4 or worse.
• IT issues with workflow inefficient/poorly designed reporting RIS [Radiology Information Systems] or work stations
• lack of training/IT support with new scan applications/scanners/reporting location.

However in the very human desire to apportion blame when there has been delayed diagnosis of cancer or lifelong disabling conditions, the report of an x-ray or scan can be a tempting, simple, managerially convenient, but unfair explanation/scapegoat.

Moreover interpretation of the seriousness of a radiological error is confounded by hindsight bias, outcome bias, information bias, selection bias, presentation bias, expected variation, etc. Lesions are often much more obvious in retrospect when asked to look at one image out of hundreds, with additional information and the artificial setting of a case review.

That is not to say that radiologists should not apply due knowledge, skill and diligence in their diagnostic activity for every patient……or that, on occasion, a radiologist’s performance is below acceptable and /or has long term serious consequences for a patient.

Guidance is also needed as to who should explain to the patient the combination of factors that usually apply when a radiological error is made. Radiologists usually will not have met the patients whose imaging they report, and if reporting by teleradiology, they may be a long distance away in the UK or abroad. Also, if the report in question was produced a number of years before, the radiologist may have retired, moved away etc.

Many radiologists currently have little training or experience in breaking bad news. Moreover they are not in a position to advise as to the change in prognosis, or treatment options, some of which may be necessary years in the future.

What threshold criteria principles for moderate harm would the GMC advise re Duty of Candour in diagnostic radiology?

A culture of learning from error has gradually become established in UK radiology departments in recent years with the almost universal adoption of a system of “discrepancy meetings” at which errors identified in radiology practice are presented in such a way as to facilitate group learning by all the radiologists in a department. This culture could be put at risk by over-zealous interpretation of the duty of candour. It may also deter doctors from a career in radiology.
There is considerable collective learning and patient benefit from discussion of radiological errors and near misses at Radiological Discrepancy Meetings, which typically are held every month.


In addition, The Royal College of Radiologists encourages its members to provide feedback to colleagues on their reports to promote more accurate reporting for patients.


However, workflow, efficient IT and better staffing is required to maximise this practice.

Moreover, unlike Australian, American and Canadian doctors, British radiologists have no legal protection for healthcare related quality improvement activity like discrepancy meetings. Radiologists in Ireland are seeking new legislation in this respect.

Overall we consider this guidance needs to include specific reference as to how the duty of candour applies to diagnostic specialties like clinical radiology. We would be happy to work with the GMC further on this.

**Question 2: How easy is this guidance to understand?**

Very easy.

**Question 3: Do you think there is anything else that the guidance should cover?**

The emphasis in this guidance is on how the duty of candour applies in treatment but it is less clear how the process should be applied in diagnostic and interpretive specialties such as clinical radiology. Greater clarity is required in how the guidance also covers these aspects of healthcare.

Specific GMC guidance will also be required on how the duty of candour applies to telediagnosis and teleradiology, teleconsultation and telemedicine.

**Question 4: Is there anything you think could be removed from the guidance?**

Yes. We do not feel that near misses should be the subject of candour with patients, particularly as regards radiological diagnosis. Patients’ justifiable trust and confidence in radiologists and healthcare in general would be undermined by candour about near misses. This would also cause much unnecessary distress for patients and relatives.

**Question 5: Do you have any ideas about how we could illustrate how the guidance works in practice (eg case studies or decision tools)?**

It may be useful to link to the following documents:

- The Australian Open Disclosure Framework is an important reference with a detailed meeting planning and preparation template

- The Irish National Guidelines on Open Disclosure is another important reference with detail on the support that doctors in management should establish for healthcare professionals involved in open disclosure and “second victims”.
The experience of the Australian and Irish Medical Councils could also be considered concerning their experience of regulating open disclosure by doctors in their jurisdictions.

**Question 6: Do you think there is anything else that doctors, nurses or midwives should consider when apologising to patients or those close to them?**

Offer to help patients access faster diagnosis and treatment than would usually occur and/or facilitate their diagnosis and treatment elsewhere if the relationship with that provider has been damaged.

**Question 7: To what extent do you agree that patients should always be told about near misses?**

Strongly disagree. Please see comments to question 4.

**Question 8: Do you have any other comments or suggestions about the draft guidance?**

No.

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