The Royal College of Radiologists

Response to:

Care Quality Commission Consultation - Guidance for NHS bodies on the fit and proper person requirement for directors and the duty of candour

1. Is it clear what NHS providers should do to meet the fit and proper person requirement for directors? If not, how could it be made clearer?

Yes

2. Is it clear what NHS providers should do to fulfil their duty of candour? If not, how could it be made clearer?

No – although the regulations and requirements may be fairly clear for some types of incident such as surgical complications, there is a great deal of misunderstanding and a lack of clarity as to how they should be interpreted when it comes to errors in diagnosis.

The terms ‘moderate harm’ and ‘prolonged psychological harm’ in relation to radiology are not clear and subject to interpretation.

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 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.

The majority of these do not result in direct harm to patients but a large number could fall within the definition of “moderate harm”.

Radiology is an interpretive process. Many “errors” are only apparent in retrospect – the review of previous imaging may reveal subtle abnormalities which would have been difficult or impossible to identify at the time of reporting but which are all too easy to detect when the later course of events is known. Failure to spot a very subtle abnormality (as clearly occurs with great frequency) can have devastating consequences for the patient. Correspondingly, failure to identify an obvious lesion may have no impact at all if by chance a different reader identifies the abnormality very soon afterwards or the patient undergoes further tests. In other words the impact on the patient is unrelated to the magnitude of the error.

Patients and the public have very little understanding of the complexities of radiological interpretation and certainly have no idea of the frequency with which the final interpretation may differ from the original report. A common view is that “if it’s serious, it must be obvious” whereas nothing could be further from the truth. The earliest signs of cancer, for example - at the point at which the disease is most readily treatable - may be extremely subtle. Failure to make the most subtle observations may have the most devastating consequences. There is a risk that increased public awareness of the fallibility of radiological interpretation may lead to a plethora of inappropriate complaints and lawsuits, diverting clinical resource from where it is best spent, and a further risk that there may be a general undermining of confidence in medical imaging. Set
against this is the potential for a valuable increase in public understanding of the limitations of imaging in medical diagnosis.

The position as regards “near misses” is even more difficult. It is commonplace for example for diagnosis and/or staging to be changed in the context of a Multidisciplinary team (MDT) meeting. The inference may be that the initial radiological report could have led to harm as it was not accurate and might have resulted in the wrong treatment. The reality is that the MDT acts as a safety net designed to avoid this so this should not be considered as a near miss. A near miss applies where there is no safety net in place and harm is averted by quick thinking or the circumstances.

Some “errors” are corporate where lack of investment results in delays in diagnosis that may impact and lead to harm. An example would be delayed reporting of an imaging investigation which turns out to reveal significant pathology. This occurs commonly due to lack of investment in radiology reporting capacity. How much of a delay would be considered to constitute a cause of “moderate harm” – two weeks, four weeks, 12 weeks?

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.

We also foresee certain practical difficulties in respect of radiology. To whom does the responsibility fall to communicate to the patient (or relative) that an error in radiological interpretation may have occurred? The radiologist in most cases has no direct relationship with the patient and it would seem inappropriate for him or her to contact a patient out of the blue to tell them that an error in their care occurred at some point in the past. It is not uncommon for radiological error to become apparent years after the event. Failure to detect a colonic polyp may lead to a patient presenting with bowel cancer 10 years or more later. The original reporting radiologist may no longer be contactable.

3. Is the format and layout of the guidance easy to follow and understand?

Yes

4. Are the links to key legislation and guidance helpful? How could we promote these links better?

Yes

5. Is there anything missing from the guidance?

The link to ‘Please see below for guidance regarding ‘reasonable attempts’ on page 28 could be made clearer.

6. Is there anything that should be taken out of the guidance?

No

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