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THE ROLE OF IMAGING IN SCREENING SPECIAL FEATURE: COMMENTARY

Commentary on duty of candour and cancer screening

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ABSTRACT

English law mandates a duty of candour (DOC) for all healthcare providers. They must be open and honest when something goes wrong with care causing harm. Providers must apologize to those affected and investigate what happened. Screening is not 100% accurate and false positive and false negative results are inevitable. Guidance on DOC assists providers to judge when something has gone wrong in screening and the DOC legislation applies. DOC guidance helps distinguish such incidents from harms that are an expected and inevitable consequence of the imperfections of screening tests. For breast cancer screening the classification of interval cancers has been updated to take account of DOC. This guidance on DOC and classification of prior films of those presenting with interval cancers has relevance to other areas of diagnostic imaging. Review of prior examinations after a significant diagnosis has been made may reveal a previously overlooked abnormality.

Healthcare involves a balance of harms and benefits. When offering screening to an asymptomatic population the benefits must outweigh the harms. We should be clear and open about both. Duty of candour (DOC) legislation¹ followed the Francis enquiry into failings in care in the NHS. DOC places a legal requirement on healthcare providers to be open and transparent about harm. When a notifiable safety incident (NSI) causing harm has occurred it must be investigated, an apology given and the outcome of the investigation shared with the affected individual.

Healthcare providers have found it difficult to judge how this seemingly simple directive should be applied to the harms arising from screening. For instance, screening tests are not 100% accurate; there are both false positive and false negative results. False negative tests in the cervical cancer screening programme may result in invasive cancers and may result in interval cancers in breast and bowel screening programmes. Should these all be considered as NSIs? Some trusts have interpreted the legislation as meaning that they should.

In order to clarify the application of DOC to screening programmes, guidance has been published jointly from the Care Quality Commission (CQC) and Public Health England (PHE) with representation from all the English screening programmes.² This guidance recognizes that

there are a number of circumstances in which a person may be harmed by screening which include

- failure to recognize and treat the condition screened for early enough to improve the outlook (e.g. interval cancer)
- harm caused by the procedure for detecting the condition (e.g. bowel perforation during colonoscopy)
- psychological harm from being told they are screen positive when this is not confirmed on further tests.

These, however, are recognized risks and harms of screening, part of the known balance between harm and benefit. They should not automatically trigger DOC when the programme is working within agreed standards.

This leads to the question of which harms should trigger DOC processes. The guidance advises that possible harms should be looked at to judge whether “something has gone wrong”. This might be due to a failure in systems or process or individual or team performance falling below expected standards. In this case DOC should be applied, with the affected individuals being told as soon as practicable about the safety incident, and an apology being given.

DOC does not stop screening programmes being open with individuals who have suffered recognized harms because of the known limitations of screening, which therefore have not triggered DOC. Guidance encouraging transparency, the disclosure of audit (DOA), was published in 2006 and

incorporated into the new guidance. This advises on audit of all interval cancers and on offering the results of that review to affected individuals. DOA provides detailed advice on communication and on how to offer the results sensitively to those who wish to have it and on ascertaining what information they want. DOA also recognizes that conversations about interval cancers can be distressing for both affected individuals and professionals and discusses when and how to communicate, akin to advice on handling “bad news” interviews. It touches on the medicolegal aspects of disclosure citing evidence that openness and a demonstrable willingness to learn when things have gone wrong reduce the likelihood of subsequent litigation.

For imaging-based cancer screening programmes such as breast screening the requirement to decide which interval cancers are NSIs poses a problem not covered in the published DOC guidance. There is a need for a robust, consistent and sustainable way of classifying large numbers of screening images of females who have subsequently presented with interval cancers. How many interval cancers are there? In 2014–2015, 2.11 million females were screened for breast cancer in England and 18,015 had cancers detected by screening. National data reports that for every 1000 females screened 8.6 (0.86%) are diagnosed with cancer and of the 997 given a normal result, 3 (0.3%) will present with an interval cancer before their next screening invitation is due in 3 years. This means that nationally about 6000 previous mammograms of females presenting with interval cancer each year require careful review and classification. This allows

- (a) the individuals affected to be offered the results of review
- (b) screening staff to learn from review and improve the quality of screening
- (c) the effectiveness of the programme in detecting cancer to be monitored

The breast cancer screening programme has now updated its system of interval cancer image classification to align with DOC legislation. This classification is designed to distinguish between cases where prior mammograms were normal or showed subtle changes seen in retrospect (satisfactory or satisfactory with learning points) from cases where a cancer was missed in error and is clearly seen on review of the screening images (unsatisfactory). (Table 1) For cases in the unsatisfactory category DOC should be applied. These are expected to be the minority of interval cancers, around 7%. For the rest, expected to be the majority, affected individuals should have access to the review if they wish following disclosure of audit processes.

Ensuring a consistent system for interval cancer classification also requires definition of the five key steps in the process for screening units:

- (1) ascertaining when an interval cancer is diagnosed
- (2) obtaining diagnostic films and pathology for review
- (3) ensuring review of prior screening films by a minimum of two readers
- (4) ensuring wider review in cases where there is discrepancy between first reviewers
- (5) disseminating learning from the review process among film readers.

The updated classification and review process for interval cancers are covered in new guidance from PHE.³ This guidance also covers those cases where an individual has been previously assessed following a recall from screening, given a normal result and has then presented with a cancer at the same site within 3 years. Presentation may be as an interval cancer or as a cancer diagnosed on the next screening round. Most cases that are reviewed will be found to be either satisfactory or satisfactory with some learning points. Within the group of females with previously assessed cancers, however, there will be some cases where on review the original assessment was found to be unsatisfactory and errors have been made. DOC should be applied in these cases. Identification of and change in an inadequate assessment process may prevent further incidents.

Individuals with harms arising from screening, such as interval cancers, commonly present to services outside screening. Females with breast interval cancers will be diagnosed in symptomatic units that may be geographically remote from the unit where they were screened. Ensuring that all these females are aware of the offer of access to a review and that DOC is applied appropriately can be complex. Communicating with these females sensitively, consistently and reliably throughout all of England's symptomatic services is a challenge. The breast screening programme in England, working with the Association of Breast Surgeons and British Society of Breast Radiologists, has developed a toolkit⁴ to support understanding and implementation of DOC and DOA for affected females. Implementing this toolkit reliably will require dissemination to and training of multidisciplinary team members.

Implementing DOC in the screening programmes raises the question of its application more widely in other areas of imaging. At the moment, systematic review of previous imaging may or may not happen when a significant diagnosis is made. There is no

Table 1. Interval cancer classification: update 2017

Category	Radiological appearance	Action warranted	DOA/DOC
1 Satisfactory	Normal or benign mammographic features	No reason to recall	DOA
2 Satisfactory, learning possible	Seen with hindsight, difficult to perceive, not clearly malignant	May provide learning, not all readers would recall	DOA
3 Unsatisfactory	Appearance clearly suggests malignancy	Should have been recalled, all readers reviewing the films would recall	Classify as notifiable safety incident under DOC process

DOA, disclosure of audit; DOC, duty of candour.

clear guidance around the process of undertaking such reviews or classifying the findings with respect to DOC. Reviews of previous images may happen as part of learning from discrepancy meetings in radiology departments. The Royal College of Radiologists guidance notes that, when judging the impact of an error in reporting, the setting where management is solely dependent on the imaging is different from that where other factors feed into the clinical decision-making process. They recommend discussion between radiologists and the clinical team caring for the patient to assess possible harm.⁵

In conclusion, DOC mandates compliance with a simple set of principles:

- (1) to identify when something has gone wrong and the patient has been harmed
- (2) to investigate what happened
- (3) to share this with those affected
- (4) to apologize

They are reasonable principles and most health practitioners would want this openness in their own care if affected by errors. Application of these principles, however, in a routine and robust way in screening is complex. It involves different teams and will only happen consistently if clear practical guidance is produced and disseminated widely. The process developed by the screening programmes for DOC may have wider applicability in imaging.

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