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Discharging the duty of candor following delayed post-endoscopy cancer diagnosis

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ABSTRACT

Endoscopic examination is not risk free. Not only are there well-known complications associated with the procedure, but malignant and pre-malignant lesions can be missed due to human factors or failures in organizational process. Duty of candor (DoC) is a legal requirement if significant harm occurs in delivery of healthcare. Post-colonoscopy colorectal cancer (PCCRC) and post-endoscopy upper gastrointestinal cancer (PEUGIC) audits have identified missed diagnoses that are associated with harm and require consideration of DoC. This article explores the new and unique challenges associated with DoC in endoscopy audits. There are unresolved questions around the place of DoC in retrospective audits, agreement of harm thresholds, and constitution of review teams. Involved departments must be committed to transparency and trained in governance processes. Fear of institutional and personal reputational damage, as well as future litigation, may influence decisions. Patient expectations need to be clarified, as do supportive structures for individual endoscopists who will be involved in DoC processes when significant lesions have been missed. Further consensus around DoC is required so that clear guidance can be given to endoscopy units.

Introduction

The duty of candor (DoC) has been a legal requirement since October 1, 2014 for NHS bodies. That followed the inquiry into poor medical care at Mid Staffordshire NHS Foundation Trust and subsequent reports by Don Berwick and the Royal College of Surgeons [1, 2, 3, 4]. The DoC encourages transparency and full disclosure to patients who come to harm (through commission or omission) in the delivery of healthcare. It poses clinical and organizational challenges. For example, verbal and written communication that contains an apology and a commitment to investigate the incident are required within 10 days of recognition of harm. Endoscopy services have developed strategies and administrative infrastructure to ensure that the DoC is discharged in a timely and complete way.

In endoscopy, two national audits have been introduced to detect potential missed upper and lower gastrointestinal cancers at colonoscopy and gastroscopy. The Post-Colonoscopy Colorectal Cancer (PCCRC) audit was launched in 2020 following recommendation by the World Endoscopy Organization (WEO) and it is funded by Bowel Cancer UK [5]. The window is 6 to 48 months post procedure. This program references an audit by Anderson et al which identified “shortcomings in

quality of procedure, decision making, documentation of decisions and booking" [6].

The Post-Endoscopy Upper Gastrointestinal Cancer (PEUGIC) audit, which was launched in 2023, was built on lessons learned from PCCRC audit and is supported by a NIHR Research for Patient Benefit Grant [7]. Both the audits are Joint Advisory Group (JAG) requirements for endoscopy services. Their intention is to detect avoidable cancers, i. e. those that could and should have been diagnosed at the initial endoscopy. It will lead to identification of contributary factors and processes and will inform development of quality improvement initiatives to improve standards. The process is not intended to find fault with individual endoscopists.

Both PCCRC and PEUGIC audits have raised the question of whether patients should be informed if the diagnosis of malignancy was missed or delayed and was avoidable. Guidance has been circulated by the audit team addressing the principles of the DoC in this context (unpublished). It is made clear that a cancer must have been "probably or definitely avoidable" and was associated with significant harm for the DoC to be invoked. It also proposed a three-tiered structure by which cases can be found clearly avoidable at first review (in obvious cases), more ambiguous cases then being discussed anonymously by a group of expert endoscopists (at least three), and then by involvement with the trust's safety or legal team if consensus cannot be reached. This is based on the process used by the Royal College of Radiologists for missed lesions. We believe there are several considerations that need to be worked through before individual departments begin to write to patients.

Principle of disclosing harm discovered during audits

The role of the DoC in retrospective audits remains unclear. The DoC was designed to ensure patients are informed if a mistake was made in their care or harm was avoidable; the intention was that this be undertaken in a prospective way, and the legislation did not anticipate that DoC would be invoked after quality improvement exercises. Nationally, countless audits take place in the NHS, and these often produce examples of variability in care which had adverse consequences. For instance, a hepatology audit discovers that x% of patients did not have ascitic taps following diagnosis, and several patients deteriorated due to late diagnosis. Should we contact them? We do not usually require investigators to follow through with DoC in audits, unless the terms of reference clearly stated that it was a harm review. Instead, it is accepted that detection of harm should lead to learning, improvement, and better care in the future. There is a precedent in the breast cancer screening program, which has issued guidelines on DoC which apply to cancers discovered after November 2014. This involves a letter being sent to the affected patient to ask if they want the outcome of interval cancer review [8]. This is an adaptation of the DoC as described in law. It appears, therefore, that individual specialties are adapting DoC law according to their own requirements, and this does demand further discussion.

Grading harm

"Significant harm" includes moderate or severe harm (physical or mental) as judged by governance teams, with reference to National Health Service England general guidance [9]. These categories are largely focussed on the duration of change in function or quality of life. In each clinical area, teams have had to apply these general principles to specific scenarios. The Northern Cancer Alliance (NCA), which authored recent guidance, gives the following suggestions:

1. Minor harm - Prolongation of symptoms
2. Moderate harm - Increase in symptoms, increase in medication or treatment
3. Major harm - Progression of cancer, contributes to death from condition
4. Catastrophic - Directly causes death

For illustration, available guidance for PCCRC cases suggests that if a patient's treatment would have been radical/curative surgery but ended up being radiotherapy or chemotherapy or even best supportive care, then significant harm has occurred. This seems clear-cut. However, often there is considerable debate among senior governance and patient safety staff as to which level of harm occurred in a patient safety incident. Typically, discussions take place soon after the event, with the benefit of contemporaneous information regarding patient experience and outcome. Retrospective audits on missed cancer cases pose a new challenge, given the extended time period under review and the likely complexity of the care pathway.

In a series of examples that were forwarded to endoscopy leads by NCA, each case was discussed by an expert panel, and in four of 22 (18%) of these, the final decision regarding DoC was "debatable" (DoC was "not recommended" in 10 [45%]). According to guidance, these four ambiguous cases would then be referred to the trust's legal/safety team. We believe such teams will not have the expertise to be confident in making a DoC judgement, and will need to be guided by endoscopy teams. Therefore, we need to agree whether ambiguous cases should default to "no DoC", by reason of uncertainty.

The membership of the review group will need careful thought and selection. The 36% of "DoC required" cases included in the recently circulated examples will, if replicated nationally, lead to a significant burden of work and follow up. Endoscopy department members will need to be committed to the principle of transparency and be both willing and prepared to meet with patients who have further questions.

Preparing for investigations and their consequences

One of the obligations that comes with the DoC is to listen to affected patients' concerns and invite them to be involved in the parameters of any subsequent investigation (if undertaken). Patients also have the right to read the final investigation report. Therefore, departments must be ready to undertake such engagement and to demonstrate what lessons have been learned, and more importantly, what changes are made organi-

zationally. Experience has shown that many PCCRCs are related to organizational or administrative factors (e. g. delayed follow up, misplaced referrals). To fully discharge DoC according to legislation, departments must be prepared to describe what measures they have taken to remove or reduce risk of future occurrences.

Related to this topic is the issue of litigation. Although experience in the United States suggested that increased transparency ultimately led to reduced litigation [10], the authors have noted cases in which the DoC process (after perforation, for example) appeared to result in litigation [11]. Trusts should be aware, at a senior level, that DoC letters are going out as a result of these audits. It is inevitable that some will stimulate claims for damages. In cases in which death has resulted, a decision must be made as to the appropriateness of contacting families. DoC communications may be made available to coroners prior to inquests; it is instructive to note that structure judgement reviews (SJRs), which were implemented as an internal learning exercise, are now routinely called for by coroners. Although PEUGIC and PCCRC audits are primarily intended to promote quality improvement, we should be aware that DoC letters may be interpreted as admissions of fault, despite clear CQC guidance about DoC that "apologizing is not an admission of liability" [12].

Informing and supporting endoscopists

Although endoscopists have been aware of PCCRC and PEUGIC audits for over 5 years (information was circulated to all endoscopists prior to commencement in 2020), it may come as a surprise to individuals when they are told that patients who they have performed procedures on are going to receive letters of apology due to a missed cancer. Emotional effects on individuals when they learn patients they have performed endoscopy on have come to severe harm and death need to be considered. It should be noted that missed cancers are sufficiently common to be included as a potential complication on consent forms [13]. The missed cancer rate was around 9.4% at gastroscopy in a recent meta-analysis [14]. The degree of association with individual endoscopists needs to be clarified, and appropriate support put in place if individuals have an adverse psychological reaction.

Communications about DoC in this context have emphasized the need to manage it at a departmental level, rather than hand responsibility for communication to individuals. There is a spectrum of opinion among endoscopists (authors' observation) regarding their desire to be informed if they were personally involved in a missed cancer case. Patients themselves may ask for details about the particular individual who performed the procedure. Endoscopists will need to understand that during their career, it is likely that a PCCRC or PEUGIC will occur, and they will need to be prepared to handle this. Experienced endoscopists are likely to have been involved in patient safety incidents, especially if they perform therapeutic procedures or have high volumes of diagnostic work. Therefore, they would not be completely naïve to the concept of DoC and the downstream effects that it can have on the individual. However, some endoscopists, especially those in training (albeit "signed off"), junior consultants, and clinical/nurse endoscopists are often unprepared to deal with complications/missed lesions; this can have a significant psychological impact on clinician performance and confidence and lead to long-term negative effects on the person's career [15]. Robust arrangements for support of staff need to be made. Current training models do not include this aspect in endoscopy training and new consultants are often unprepared for these situations. Going forward, this needs to be included in gastroenterology training curriculum to prepare trainees for these inevitable incidents in the course of their career.

Patient understanding, expectation and support

It is important to realize that behind these numbers and cases there are actual patients and families who will be hearing for the first time through a DoC communication that there was a healthcare-associated harm. If this led to severe harm or death, we will be subjecting them to the emotional trauma of reliving the ordeal. This could lead to psychological fallout and organizations need to be ready to deal with this. Being transparent about harm comes with its set of challenges and implications for patients, families and organizations.

Although patients expect and have a right to know if a procedure has led to harm, they may be surprised to learn that historical procedures are being analyzed to see if there was a missed diagnosis. Therefore, before or when they receive DoC letters, a certain amount of education is required so that they understand how this was discovered. When adverse events have occurred that were covered by informed consent processes, the DoC obligation becomes a more challenging concept. There are parallels in other areas of medicine, such as surgery. For instance, if the patient consents to a bowel cancer resection, complications including anastomotic breakdown and sepsis will be discussed. If this occurs, it is still unclear whether the DoC is invoked. In diagnostic colonoscopy, if a polyp is missed despite the endoscopist's best efforts, the need for transparency remains unclear.

Regarding patient and public involvement (PPI), although there are established national guidelines and toolkits to support clinicians in disclosing missed lesions to patients diagnosed with breast cancer between screening appointments, there are no published data reporting patient views on how this should be managed. The authors understand that there was PPI in development of guidance in post-endoscopy cancers (unpublished). Further research is needed to understand patient views on investigation of cases found in retrospective audits.

Conclusions

Since the Mid Staffordshire health care scandal and the passing of DoC into statute, the NHS has made huge strides toward transparency, and the current drive to demonstrate this in endoscopy is welcome. However, the challenges and lessons

encountered in other areas of medicine could usefully be applied to this area. These include reaching agreement around harm thresholds, organizational changes to create expert panels, and preparing the workforce for the practice of disclosure (given the potential for further escalation to formal complaint or litigation). Importantly, the involvement and education of patients will help to minimize any unintended emotional consequences related to large-scale endoscopic surveillance programs.

Conflict of Interest

The authors declare that they have no conflict of interest.

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