

# Colonoscopy is not mammography: Challenges of applying the Duty of Candor



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## Key words

Endoscopy Upper GI Tract, Endoscopy Lower GI Tract

received 25.9.2024

accepted after revision 9.10.2024

## Bibliography

Endosc Int Open 2024; 12: E1342–E1344

DOI 10.1055/a-2451-8572

ISSN 2364-3722

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Post-endoscopy cancer (PEC) presents unique challenges, both clinically and legally. Despite endoscopy being the most effective tool for detecting and preventing gastrointestinal cancers, PEC can still occur due to missed or incompletely resected lesions, raising questions about accountability and transparency under the Duty of Candor (DoC). These situations can lead to complex legal and professional challenges for healthcare providers.

Every year, millions of people across Europe undergo screening colonoscopies and gastroscopies, contributing to a high volume of procedures. The purpose of these screening procedures is to identify and manage precancerous lesions, such as diminutive polyps and advanced adenomas, rather than to diagnose full-blown cancers.

On the one hand, we are aware of the effectiveness of endoscopy in reducing cancer incidence and mortality among not only moderate-high risk population but also for the average-risk population [1, 2, 3]. On the other hand, we know that silent errors are probably more common than might believe.

Considering colonoscopies, the adenoma miss rate is calculated to be around 26%, specifically around 9% for advanced adenomas and 27% for serrated polyps. Regarding gastroscopy, as mentioned in the article, the missed cancer rate is around 9.4%, as shown in a recent meta-analysis [4, 5].

So, how is it possible that so many lesions are missed every day and post-endoscopy colorectal cancer is not so commonly encountered in everyday clinical practice? There may be differ-

ent reasons, the first and foremost of which is epidemiological. Besides the large number of lesions missed, the estimated rate ratios for colorectal cancer (CRC) by colonoscopy screening are 0.77 in women and 0.66 in men [6]. The risk of having carcinomatous lesions following a positive fecal immunochemical test is estimated to be between 3% and 4.6% [7, 8]. We are dealing with small numbers. Therefore, even if an endoscopic examination is suboptimal, epidemiology is in our favor. Second, post-index procedure surveillance programs often mitigate the impact of these initial oversights.

Yet missed colorectal neoplasia remains the most common cause of post-colonoscopy CRC, which occurs at a rate of 1% within 10 years of screening or surveillance colonoscopy. Studies suggest that 52% to 57% of post-colonoscopy CRC cases are due to missed neoplastic lesions at the index colonoscopy [9, 10, 11, 12, 13]. Data for gastroscopy and gastric cancer are not more encouraging, with 10.7% of upper gastrointestinal cancers, including esophageal and gastric, being diagnosed within 3 years of index procedure [14]. Thus there is a moral duty to admit the truth when such unfortunate cases happen.

However, as highlighted by the article, DoC and its application in gastrointestinal endoscopy is much more complicated than a simple “obligation to tell the truth”, because the truth about and the etiology of PEC are often hard to establish. First, not all post-endoscopy cancers are the same. The most frequent scenario occurs when cancer develops shortly after an endoscopy, within what is considered a reasonable timeframe

to be defined as a potentially preventable cancer, i.e. up to 48 months, as suggested by the 2018 World Endoscopy Organization Consensus Statement [10]. It is likely that these cases represent cancers that had already developed or advanced adenomas that were missed during the index examination. The second scenario is occurrence of an interval cancer between 48 months and the next recommended rescreening/surveillance examination, which is typically in the following 5 to 10 years. In that case, PEC may have developed due to de novo carcinogenesis or to suboptimal detection of precancerous lesions during the previous endoscopy, where a missed lesion evolved over time. A completely alternative third scenario involves development of cancerous lesions following polypectomy, likely due to incomplete lesion resection. Possibly, we could consider a fourth scenario, in which a patient was advised to undergo follow-up endoscopy, but for reasons related to the hospital, the patient, or the endoscopist, the follow-up did not take place, leading to development of a cancerous lesion and sequelae.

A second key aspect that should be considered is the strict relationship between endoscopy quality and development of PEC. The pivotal study in 2006 by Barclay et al. led to establishment of a minimum 6-minute withdrawal time (WT) for colonoscopies by the American College of Gastroenterology. This benchmark has since been validated by numerous observational studies. Considering colonoscopy, Kaminski et al. and Corley et al. reported an inverse association between adenoma detection rate (ADR) during colonoscopy and occurrence of interval colorectal cancer. Kaminski et al. demonstrated that patients who were examined by endoscopists with an ADR of less than 20% had more than 10 times the risk of developing interval CRC during the follow-up period compared with those examined by endoscopists with an ADR of 20% or higher [15, 16]. In addition, emerging artificial intelligence technologies, and in particular computer-aided detection (CADe), are showing promise in improving both WT and overall colonoscopy outcomes, offering a new tool for gastroenterologists [17, 18]. However, even if it is of the uttermost importance to demonstrate that an endoscopist has been properly trained and regularly performs good-quality examinations respecting guidelines criteria, suboptimal examinations may still occur. Even the best endoscopist may miss lesions and implementation and regulation of CADe systems into endoscopy rooms presents us with a valuable mitigation strategy.

A third relevant aspect is the peculiarity of endoscopic examinations that distinguishes them from other medical screening procedures like mammography: a thorough retrospective review of a previous endoscopy - at the moment - is not feasible. Given the limited number of images available and the operator-dependent nature of the procedure, it is difficult to determine from the report alone whether the endoscopist definitively missed a lesion. This may suggest future perspective, with the help of CADe systems, of registering endoscopic examinations, also for reasons of accountability.

However, accountability is not what DoC is about. It is about apologizing when it is reasonable to believe that PEC is linked to missed diagnosis. But when is that belief reasonable? A consensus must be reached. A reasonable timeframe would be to consider a gastrointestinal cancer developing within 48 months post-index endoscopic examination, as suggested by the 2018 World Endoscopy Organization Consensus Statement [10]. Paradoxically, the etiology of PEC may be even more evident after a polypectomy if the lesion develops at the site of resection.

DoC may appear more as a rightful duty within the hospital. The goal should be review sessions and recordkeeping about PEC to improve the endoscopy service and work toward a reduction in such cases. The effort also should include introduction of a clear checklist with verbal and written communication about endoscopic examination results and follow-up programs. PECs are often the result of missed communication about follow-up surveillance, which leads to suboptimal care. However, if proper follow-up instructions were provided to the patient but they skipped the scheduled surveillance program and then developed a cancerous lesion, DoC should not be applied.

An intriguing consideration arises when reflecting on DoC, especially in healthcare systems like Italy's, which are facing delays and work overload. In these scenarios, patients scheduled for a surveillance examination may experience delays, potentially allowing carcinogenesis to progress. In such cases, should DoC extend to include the healthcare system or the government? This raises a critical question about accountability within public health services and is an issue deserving of further debate.

Moreover, we should be careful about the fact that imposing DoC without conducting a proper investigation first may come across as shifting responsibility rather than taking responsibility. Patients might feel lost and uncertain, particularly in such sensitive times, thinking they were victims of medical errors without clearly knowing what happened.

## Conclusions

In conclusion, DoC presents complex challenges in managing PECs, where missed lesions are a key concern. Although endoscopy is highly effective, accountability and transparent communication are essential, particularly in cases involving healthcare system delays or missed follow-up care. This calls for further discussion of the role of the healthcare system and the need for continuous quality improvement.

## Conflict of Interest

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The authors declare that they have no conflict of interest.

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