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Issues of informed consent for non-specialists conducting colorectal cancer screenings

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Abstract: The United States is currently facing a physician shortage crisis including a lack of specialist providers. Due to this shortage of specialists, some primary care providers offer colorectal cancer screenings in communities with few gastroenterologists, especially in under-resourced areas such as rural regions of the United States. However, discrepancies in training and procedural outcomes raise concerns regarding informed consent for patients. Because osteopathic physicians play a critical role in addressing the physician shortage in these under-resourced communities, this commentary may be especially useful because they are likely to encounter these ethical complexities in their day-to-day practice.

Colorectal cancer (CRC) is one of the nation’s most common types of cancers and is a leading cause of cancer-related deaths for both men and women [1]. It is a disease that primarily affects older adults, but in recent years, studies have revealed that the rates of CRC in the United States have increased in prevalence and age of onset, and it is now the leading cause of cancer-related death in men under the age of 50 [2]. Screening for CRC via colonoscopy has been shown to be an effective method to lower the incidence and mortality of CRC [3]. This commentary highlights inequities due to the overreliance on non-specialists to conduct a colorectal cancer screenings (CRCS) and the ethical issues raised by nondisclosure of elevated risks.

Typically, CRCS is conducted by specialists in the treatment of gastrointestinal diseases known as gastroenterologists. After medical school, these providers complete a 3-year Internal Medicine residency followed by a 3-year Gastroenterology fellowship. Such 3-year fellowships include extensive training on how to properly conduct CRCS, as fellows complete at minimum 275 colonoscopies as recommended by the American Society for Gastrointestinal Endoscopy [4]. Some studies even suggest that fellows should complete at least 500 colonoscopies over the span of the fellowship in order to obtain procedural competency in CRCS [5]. Although these are recommended minimums to achieve competency, the average gastrointestinal fellow completes over 1,000 colonoscopies during his or her fellowship [4].

Although gastroenterologists receive the greatest level of training in CRCS, general practitioners also sometimes perform colonoscopies. This includes primary care physicians (PCP) in family and internal medicine, as well as some general surgeons. However, discrepancies exist in the level of training received by these Nongastroenterologist Providers (NGPs) during their postgraduate training. Rather than undergoing fellowship training dedicated to gastrointestinal diseases, NGPs receive only supplemental CRCS training in residency. Family medicine physicians, for example, undergo a 3-year residency and on average complete 42.6 colonoscopies during this time [6]. This is less than 10% of Spier’s recommended amount of colonoscopies for procedural competency and less than 5% of the average number of colonoscopies that a gastrointestinal fellow completes during training [4, 5]. Despite this training discrepancy, the American Academy of Family Physicians (AAFP) maintains that family medicine physicians are equally as qualified to perform routine CRCS as their gastroenterologist counterparts and should participate in the delivery of colonoscopies to the patient population at large [7].

Advocates of NGPs performing CRCS point to studies that claim there is no difference in patient outcome based on what type of provider conducts the CRCS [8, 9]. A plethora of competing studies, however, show that patient outcomes are reduced when they receive CRCS completed by NGPs compared to CRCS performed by gastroenterologists. For example, CRCS performed by NGPs have higher average levels of early repeat colonoscopies compared to those conducted by gastroenterologists [10]. NGP management of patients after initial CRCS is also worsened because NGPs
are more likely to deviate from widely accepted guidelines as to when a patient should receive follow-up CRCS [11]. Patients who receive their CRCS from NGPs are also more likely to suffer from life-threatening complications such as colonic perforations [12, 13]. For example, studies have demonstrated that general and colorectal surgeons conducting CRCS have a perforation rate 121.8 % higher than gastroenterologists [12]. Despite surgical interventions to treat colonic perforations, the mortality rate of patients suffering from this complication is 30 % [14]. If colonic perforations are compounded by diffuse peritonitis, the mortality rate of patients rises to 70 % [14].

NGPs also have significantly worse quality metrics that are utilized as a benchmark to assess individual provider competency in CRCS. The cecal intubation rate (CIR), a measurement utilized to quantify the completion rate of a colonoscopy, is significantly lower for NGPs compared to gastroenterologists [15]. Providers should on average achieve a CIR of 95 %, a standard consistently achieved by gastroenterologists. NGPs, on the other hand, have an average CIR of 83.5 % [16]. Additionally, the adenoma detection rate (ADR), a measurement that is inversely related to the rate of CRC, is significantly lower among NGPs compared to gastroenterologists [17, 18]. The minimum ADR threshold for providers conducting colonoscopies is 30 and 20 % for men and women age 45–50, respectively [19]. Overall, providers should achieve an ADR of at least 25 % for their patients, yet studies show NGPs on average miss this threshold [17, 18]. These worsened quality metrics for NGPs are likely to blame for the findings in studies that show that the CRC mortality rate for patients who receive CRCS from NGPs is significantly higher for all non-specialist physician types compared to gastroenterologists [20]. This raises serious concerns about patient safety.

While only 2 % of all CRCS are performed by family medicine physicians, this number may not accurately depict the prevalence of the practice in under-resourced areas such as rural communities, meaning that osteopathic physicians may be more likely to encounter these issues than their allopathic counterparts because many osteopathic physicians practice within these communities [21]. Advocates argue that allowing NGPs to perform CRCS will increase the availability of screenings to patient populations that do not have access to gastroenterology specialists, such as those who live in rural areas [8]. While balancing quality and access represents an inherent tension in all healthcare systems, compromised quality of CRCS among already-disadvantaged populations raises multiple ethical concerns. Thus, while unequal outcomes of CRCS by specialty may represent a critical ethical issue, in the case of CRCS, compromises to patients’ informed consent raise additional worries.

Findings show that there is a significant knowledge gap in patient understanding regarding the risks and benefits of CRCS. Although there is a general lack of understanding surrounding CRCS in the population as a whole, individuals of lower education levels and lower income have an even poorer understanding of CRCS [22]. This is especially problematic because marginalized communities are on average of lower socioeconomic status, meaning that they are particularly susceptible to exploitation because there is likely a greater lack of understanding of CRCS within these groups.

Moreover, access to specialist care, including CRCS, is often dependent on primary care provider referral. When CRCS is among the suite of procedures offered by a PCP, they are naturally disincentivized from referring the patient elsewhere for that screening. This conflict of interest, of which the patient likely remains unaware, is exacerbated by disproportionate reimbursement rates for procedures, relative to many other kinds of primary care services [23].

When explaining the risks and benefits of CRCS to patients, these providers should be compelled to explain the discrepancies in the training they received compared to that of gastroenterologists. Additionally, patients should be made aware of the elevated risks associated with NGP-performed colonoscopies, such as higher rates of life-threatening complications and greater overall risk of death from CRC [12, 13, 20]. To the benefit of the NGP, they may also provide their patient with their individual professional experience conducting CRCS to better convey their competency in performing CRCS. This will ensure that the patient is able to make a decision with an understanding of the differences in training while also taking into account a physician’s individual CRCS quality metrics. Additionally, when citing the frequency of complications in CRCS, providers should make clear to patients that this data has largely been collected from patients who underwent CRCS performed by gastroenterologists because it is misleading to apply these statistics that were based on providers who received more training than the gastroenterologists.

For NGPs practicing in an area that has significant barriers in access to gastroenterology care, noninvasive CRCS options such as fecal immunochemical tests (FIT) or multi-target stool DNA testing are viable alternatives that NGPs can utilize for select patient populations. These screening options test for hemoglobin and certain DNA mutations that are
known to be associated with CRC in patients’ stool samples [24]. Although these options may increase CRC surveillance, these screening methods are associated with lower accuracy and specificity compared to colonoscopies [25]. Although these options are not a replacement for colonoscopies, they do represent a treatment option that could expand access to supplemental screening methods that eliminates the risk of procedural complications such as colonic perforations.

At-risk populations with access to relatively few specialists deserve the same quality of care as the rest of the United States. At minimum, at-risk populations must be afforded the ability to make informed decisions regarding their own healthcare. This is very dependent on the transparency of their PCP to honestly and adequately educate their patients on the differences in training of the various types of physicians offering CRCS. Additionally, patients must be made aware of outcome disparities when receiving CRCS performed by NGs. Only then can a patient accurately weigh the risks and benefits associated with having an NG perform their CRCS in order to make an informed decision regarding their healthcare. Osteopathic physicians in under-resourced communities should take special note of these issues because they are likely to encounter these practices and can serve to help advise their colleagues on these matters. It is our hope that the insight provided in this commentary helps guide PCPs through the ethical complexities of offering CRCS to their patients to ensure that patient outcome and informed consent are prioritized.

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References


