Abdominal Radiology

Published online: 19 November 2016

Abdom Radiol (2017) 42:1268–1275
DOI: 10.1007/s00261-016-0971-9

Predictors of primary care provider adoption of CT colonography for colorectal cancer screening

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Abstract

Purpose: To examine factors influencing primary care provider (PCP) adoption of CT colonography (CTC) for colorectal cancer (CRC) screening.
Materials and methods: We performed a retrospective cohort study linking electronic health record (EHR) data with PCP survey data. Patients were eligible for inclusion if they were not up-to-date with CRC screening and if they had CTC insurance coverage in the year prior to survey administration. PCPs were included if they had at least one eligible patient in their panel and completed the survey (final sample $N = 95$ PCPs; $N = 6245$ patients). Survey data included perceptions of CRC screening by any method, as well as CTC specifically. Multivariate logistic regression estimated odds ratios and 95% confidence intervals for PCP and clinic predictors of CRC screening by any method and screening with CTC.
Results: Substantial variation in CTC use was seen among PCPs and clinics (range 0–16% of CRC screening). Predictors of higher CTC use were PCP perceptions that CTC is effective in reducing CRC mortality, higher number of perceived advantages to screening with CTC, and Internal Medicine specialty. Factors not associated with CTC use were PCP perceptions of less organizational capacity to meet demand for colonoscopy, number of perceived disadvantages to screening with CTC, PCP age and gender, and clinic factors.
Conclusion: Significant variation in PCP adoption of CTC exists. PCP perceptions of CTC and specialty practice were related to CTC adoption. Strategies to increase PCP adoption of CTC for CRC screening should include emphasis on the effectiveness and advantages of CTC.

Key words: Colorectal cancer screening—CT colonography—Primary care providers

Colorectal cancer (CRC) screening decreases morbidity and mortality from this deadly disease. CRC incidence has been decreasing largely due to screening efforts [1–3]. Yet, it remains the second leading cause of cancer deaths in the United States for men and women combined with ~50,000 deaths per year [4]. Despite improvements in national CRC screening rates, adherence remains relatively low with only two-thirds of eligible individuals being screened by any method [5]. Cancer screening has recently received national attention with the American Cancer Society (ACS) call for 80% of eligible patients being screened for CRC by 2018 and the US Vice President's cancer moonshot call to action [6]. A moonshot is much more than a single researcher finding the magic

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bullet to cure all cancer; it involves a multi-pronged effort that includes a focus on prevention and recognition that we have not yet optimized screening for cancer.

One way to optimize cancer screening is to enhance the choices available for CRC screening. Recent studies have shown that when patients are given options, overall CRC screening rates increase [7–9]. Inadomi et al. [7] found that when providing patients with a choice between colonoscopy and fecal immunochemical testing (FIT), the rates of both FIT completion and colonoscopy completion were higher among the group who had a choice. The importance of CRC screening by any method has also been recognized in the recently updated USPSTF guidelines [10], which highlights that CRC screening by multiple methods substantially reduces deaths from CRC in adults aged 50 to 75.

CT colonography (CTC) is a screening examination that structurally evaluates the entire colon. Several multicenter trials have demonstrated the ability to accurately detect precursor polyps and early cancer, similar to the abilities of colonoscopy [11–13]. This has led to inclusion in the most recently revised ACS guidelines as one of the preferred modalities for CRC screening and prevention [14]. Despite the data supporting its use and consensus that it outperforms the imaging screening modality of barium enema, it remains widely underutilized. Even where economic reimbursement exists, utilization of CTC for CRC screening remains minimal [15]. Given the relative newness of the technology, the slowness of adoption by primary care providers (PCPs) has been theorized as a major cause. The purpose of this study was to examine the factors influencing CTC adoption by PCPs as a CRC screening option, including demographic factors, attitudes about CTC specifically, and attitudes toward CRC screening in general.

Materials and methods

Study setting

We retrospectively analyzed CRC screening data from one of the 12 largest multi-specialty academic physician groups in the US where services are delivered by over 300 PCPs in more than 40 multi-specialty and community-based primary care clinic sites owned and managed by either the hospital or the physician group practice. In addition, our healthcare system has one of the largest and longest running CTC-based screening initiatives in the US. PCPs have been exposed to multiple educational efforts on CTC-based screening through departmental lectures, interactions with radiology, and promotions through our system-wide colon cancer prevention initiative. Our study takes advantage of a unique feature where significant numbers of patients are enrolled in commercial health plans that cover CTC as a screening modality. The three largest third-party payers in our area have covered CTC for CRC screening since its introduction to our healthcare system in 2004 with most of the remaining commercial insurance plans following suit by 2009. During the period of this study, Medicare and Medicaid did not cover CTC for initial CRC screening. Each year, on average, 70% of patients within our healthcare system are covered by commercial insurance plans, 25% are covered by Medicare, and the rest are covered by Medicaid or are uninsured [16]. This creates an invaluable opportunity to examine the adoption of CTC in actual clinic practice.

Study population

All PCPs in the healthcare system were administered a survey of CRC screening beliefs and practices with a response rate of 70% ($N = 226/322$). The healthcare system tracks CRC screening rates for public reporting based on PCPs and clinics from Internal Medicine, Geriatrics, and Family Medicine. Subspecialty clinics are not included in this performance metric, so the survey was not sent to providers in subspecialty medical clinics. The survey was adapted from the National Cancer Institute Survey of Colorectal Cancer Screening Practices developed in collaboration with the CDC and Centers for Medicare and Medicaid Services which has been used extensively in prior studies [16–20]. Survey items were divided into four sections: (1) cancer screening beliefs and practices; (2) attitudes toward CRC screening; (3) CRC screening modalities; and (4) provider characteristics. PCPs who completed the survey were eligible for inclusion.

Electronic health record (EHR) data were used to identify the pool of patients eligible for CRC screening. All EHR data were abstracted from our Epic-based EHR by our Data Operations Team who have received training directly from Epic. The criteria used to define the pool of eligible patients matches the definition used for our public reporting of CRC screening metrics [21]. Patients aged 50–75 years at the start of the study period were included if they were "medically homed" by the physician group, defined as having at least two primary care office visits in an outpatient, non-urgent care setting within the previous 36 months, with at least 1 visit in the prior 24 months. This definition has been used in previous studies and ensures that patients who have a single visit to a clinic but seek the majority of their care elsewhere are not included in our screening measures [16, 22]. Patients were excluded if they had a history of a total colectomy based on ICD-9 codes (45.8x) and CPT codes (44150, 44151, 44155–44158, 44210-44212, and 44799).

Patients were eligible for CRC screening with CTC by two measures: (1) they had not been previously screened in the last year with a fecal occult blood test (FOBT), in the last 5 years with a CTC, flexible sigmoidoscopy, or double contrast barium enema (DCBE), or in the last 10 years with a colonoscopy; and (2) they had insurance coverage for CTC in the year prior to survey administration. The denial rate for screening CTC exams in our

Table 1. Sample characteristics for primary care providers and primary care clinics

Primary care provider (PCP) characteristics	$N = 95$
Age (mean, SD)	47.6 (9.8)
Gender (%)	
Female	55.8
Specialty (%)	
Family medicine	47.4
Internal medicine/geriatrics	52.6
Practicing in hospital-owned clinics (%)	31.6
Practicing in physician-owned clinics (%)	68.4
Primary care clinic characteristics	$N = 20$
Clinic management (%)	
Hospital-owned	30
Physician-owned	70

SD standard deviation

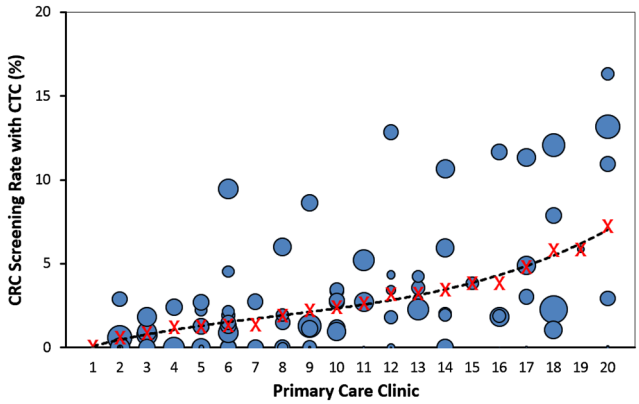

Fig. 1. Variation in CRC screening rates with CTC by primary care provider within primary care clinics in 2009. Each *blue bubble* represents an individual primary care provider and the size of the bubble corresponds to the relative size of that provider's eligible patient population. Providers within the same primary care clinic are arranged *vertically*. The *red X* represents the average CRC screening rate with CTC for that clinic.

healthcare system was 14% in the year before survey administration. Patients were assigned to PCPs with the plurality provider algorithm [23]; PCPs were assigned to clinics by identifying the clinic at which the provider billed the majority of their Evaluation & Management (E&M) visits during the year before the survey. In our healthcare system, all PCPs have open access to colonoscopy and CTC. In addition, most local third-party payers cover CTC as a CRC screening modality as described above in the Study Setting [15]. The final sample included PCPs who had at least one patient in their panel eligible for CRC screening by CTC in the year before the survey and who completed the survey ($N = 95$) and eligible patients ($N = 6245$).

Explanatory variables

The survey questions included in the study addressed perceptions of CRC screening overall, as well as screening specifically using CTC. Questions with a natural scale were translated to have the neutral category centered at 0. Questions with the option of multiple responses (e.g., number of perceived advantages and disadvantages to screening with CTC compared to colonoscopy) were added into a final score. For questions with a category representing uncertainty (e.g., "Don't Know"), an indicator variable was created (1 = uncertain, 0 = a positive or negative answer). Additional PCP and clinic level variables were obtained from the EHR. PCP variables included gender, age, and specialty. Clinic management was defined as hospital-owned vs. physician-owned. Differences in clinic management within our healthcare system are associated with varied clinic infrastructure and populations served.

Statistical analysis

For descriptive purposes, we calculated CRC screening rates for PCPs and primary care clinics in the year prior to survey administration. We determined the total numbers of eligible patients who completed CRC screening by each modality (colonoscopy, CTC, FOBT, flexible sigmoidoscopy, and DCBE) and those who did not complete CRC screening in each PCP's panel.

Logistic regression was used to determine the association between PCP survey responses, PCP/clinic characteristics, and completion of CRC screening by any method, as well as specifically by CTC (compared to all other modalities). Each model included random effects to account for potential variation in PCP patient panels.

Each survey question was fitted one at a time and assessed with a likelihood ratio test (LRT) to evaluate a potential association with CRC screening by any method and specifically with CTC. A question was retained for potential inclusion in a final model when the LRT p value was <0.2 [24]. Multivariate models were then fit using all combinations of the retained survey questions, as well as PCP and clinic characteristics as predictors. The Akaike Information Criterion (AIC) was used to select a final parsimonious model, from which we obtained odds ratios and 95% confidence intervals [25]. Analyses were carried out with Stata 13.1 (StataCorp, College Station, TX) and SAS 9.3 (SAS Institute, Cary, NC). Tests of significance in the final model used two-sided p values at a significance level of 0.05.

Results

Sample characteristics

Ninety-five PCPs were included in this study based on criteria previously described in the Methods section. They practiced at 20 different primary care clinics

Table 2. Survey questions and distributions of responses ($N = 95$ PCPs)

Question	Answer choice (score)					
	Not at all (%)	Slightly (%)	Moderately (%)	Very (%)	Extremely (%)	Don't know (%)
Effectiveness of CTC						
Perceived effectiveness of CTC on reducing CRC mortality	1	1	16	52	26	4
Guideline influence on CRC screening recommendations						
Influence of ACS guidelines	5	11	35	24	9	16
Influence of USPSTF guidelines	0	3	20	35	37	5

Question	Answer choice (score)			
Screening capacity	Inadequate (%)	Just about right (%)	More than enough (%)	Don't know (%)
Perceived organizational ability to meet demand for colonoscopy	75	21	1	3
Perceived organizational ability to meet demand for CTC	7	57	19	17

Question	Answer choice (score)		
Education on CRC screening	No (%)	Yes (%)	Don't know (%)
CME course on CRC screening in past 3 years	68	29	2

Question	Answer choice (score)						
	0 (%)	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	6 (%)
Number of perceived disadvantages to screening with CTC compared to colonoscopy[a]							
Respondents could select as many of the following choices that applied:	8	22	26	21	8	11	3
–too expensive/insurance coverage inadequate							
–false-positive colonic findings							
–following up on extra-colonic findings							
–need for a second test if a polyp is found							
–radiation exposure if follow-up imaging is necessary							
Number of perceived advantages to screening with CTC compared to colonoscopy[b]							
Respondents could select as many of the following choices that applied:	11	5	15	23	24	22	
–patient comfort and tolerability							
–availability of appointments							
–patients on anticoagulation/anti-platelet therapy							
–patient sedation risk							
–there are no advantages over colonoscopy							

Question	Answer choice (score)			
Tolerability/comfort of screening with CTC	Less tolerable than colonoscopy (%)	Equivalent to colonoscopy (%)	More tolerable than colonoscopy (%)	Don't know (%)
Perceived tolerability/comfort of CTC compared to colonoscopy	15	37	34	15

Question	Answer choice (score)			
Complexity of screening with CTC	More complex than colonoscopy (%)	Equivalent to colonoscopy (%)	Less complex than colonoscopy (%)	Don't know (%)
Perceived complexity of using CTC compared to colonoscopy	27	49	15	8

PCP, primary care provider; CTC, computed tomographic colonography; CRC, colorectal cancer; ACS, American Cancer Society; USPSTF, United States Preventive Services Task Force; CME, continuing medical education

[a] Additive score: 1 point for each "checked" response

[b] Additive score: 1 point for each "checked" response, except for "There are no advantages over colonoscopy," where 1 point was awarded for "unchecked"

and cared for 6245 patients who were eligible for CRC screening with CTC in 2009. PCP mean age was 47.6 years, 56% were female, and a little over half practiced Internal Medicine/Geriatrics (Table 1). The majority of primary care clinics were physician-owned compared to hospital-owned (70% vs. 30%).

Variation in CTC use among primary care providers and clinics

CTC use for CRC screening varied substantially across our healthcare system. CTC use by PCPs ranged from 0% to 16% (of total CRC screening) in the clinic with the

Table 3. Adjusted associated between PCP perceptions/characteristics and CRC screening

PCP perceptions and characteristics	Any vs. No CRC screening (N = 95 PCPs; 6245 patients)			Screening by CTC vs. other modalities[a] (N = 84 PCPs; 1906 patients)		
	Odds ratio	95% CI	p value	Odds ratio	95% CI	p value
Effectiveness of CTC			0.42			**0.02**
Not at all, slightly, or moderately	(ref)			(ref)		
Very	1.10	(0.86, 1.41)		1.34	(0.55, 3.26)	
Extremely	0.94	(0.72, 1.23)		**2.86**	(**1.13**, **7.25**)	
Don't know	1.01	(0.67, 1.52)		0.66	(0.12, 3.74)	
Perceived organizational capacity for colonoscopy			**0.03**			0.39
Just about right or more than enough	(ref)	–		(ref)	–	
Inadequate	**1.23**	(**1.02**, **1.48**)		1.59	(0.8, 3.17)	
Don't know	0.68	(0.32, 1.42)		2.38	(0.19, 29.8)	
Advantages to CTC compared to colonoscopy			0.89			**0.01**
None	(ref)	–		(ref)	–	
1–3 advantages	1.05	(0.79, 1.39)		1.85	(0.57, 6.04)	
4–5 advantages		(0.76, 1.34)		**3.79**	(**1.2**, **11.97**)	
Age (years)	1.01		0.72			0.88
<40	(ref)	–		(ref)	–	
41–59	1.01	(0.84, 1.22)		0.92	(0.49, 1.75)	
<59	0.92	(0.7, 1.21)		1.12	(0.44, 2.83)	
Gender			0.47			0.54
Male	(ref)	–		(ref)	–	
Female	0.94	(0.78, 1.12)		0.82	(0.44, 1.53)	
Specialty			**<0.01**			**< 0.01**
Family medicine	(ref)	–		(ref)	–	
Internal medicine/geriatrics	**1.41**	(**1.16**, **1.71**)		**2.66**	(**1.41**, **5.03**)	
Clinic management			0.51			0.10
Hospital-owned	(ref)	–		(ref)	–	
Physician-owned	1.08	(0.87, 1.34)		1.79	(0.9, 3.53)	

Bold values are statistically significant
CRC, colorectal cancer; PCP, primary care provider; CI, confidence interval
[a] Other modalities include fecal occult blood testing, flexible sigmoidoscopy, double contrast barium enema, and colonoscopy

largest spread and from 0% to 2% in the clinic with the smallest spread (Fig. 1). During this time period, CTC accounted for 8% of screening efforts by the entire multispecialty group. The majority of screening was accomplished by colonoscopy at 86% with FOBT used infrequently (4%) and flexible sigmoidoscopy and DCBE used rarely [16].

PCP perceptions of CTC and CRC screening

The survey questions considered for inclusion in the final model addressed: (1) perceived effectiveness of CTC, (2) guideline influence on CRC screening recommendations, (3) screening capacity, (4) PCP education on CRC screening, (5) number of perceived disadvantages to screening with CTC compared with colonoscopy, (6) number of perceived advantages to screening with CTC compared to colonoscopy, (7) tolerability/comfort of screening with CTC, and (8) complexity of screening with CTC. Seventy-eight percent of PCPs perceived CTC as being very or extremely effective in reducing CRC mortality (Table 2). More PCPs felt that the USPSTF guidelines [26] were very or extremely influential on their CRC screening recommendations compared to the ACS guidelines [14] (72% vs. 33%). Three-quarters of respondents believed that the organizational capacity to meet the demand for colonoscopy was inadequate. In terms of capacity for CTC, the majority (57%) felt the capacity was just about right to meet the demand for CTC. With respect to education on CRC screening, 68% of PCPs reported that they had not attended a continuing medical education course on CRC screening in the previous three years.

For perceived disadvantages to screening with CTC compared to colonoscopy, respondents could indicate that CTC is too expensive or insurance coverage is inadequate; false-positive colonic findings, following up on extra-colonic findings, need for a second test if a polyp is found on CTC, and radiation exposure if follow-up imaging is necessary. The results were calculated into a score with 30% perceiving none or just one disadvantage, 26% perceiving two disadvantages, and the remainder reporting three or more perceived disadvantages. For perceived advantages to screening with CTC compared to colonoscopy, respondents could indicate patient comfort and tolerability, availability of appointments for CTC, use of CTC for patients on anticoagulation/anti-platelet therapy, sedation risk, and the choice of no advantages to using CTC over colonoscopy. The results were again calculated into a score with 16% perceiving none or just one advantage, 15% perceiving two advantages, and 69% reporting three or more advantages (Table 2). One-third of PCPs reported that patient tolerability and

comfort of screening with CTC was greater than screening with colonoscopy. On the other hand, about one-quarter of PCPs felt the process of screening with CTC was more complex than the process of screening with colonoscopy.

Predictors of overall CRC screening and screening by CTC

Significant predictors of completing CRC screening overall by any method (i.e., colonoscopy, CTC, flexible sigmoidoscopy, FOBT, and DCBE) were PCP specialty, with Internal Medicine/Geriatrics more likely to complete CRC screening over Family Medicine (OR 1.41; 95% CI 1.16–1.71, $p < 0.01$) and PCP perceptions of organizational capacity to meet demand for colonoscopy. PCPs who perceived that capacity for colonoscopy was inadequate were more likely to screen their patients for CRC (OR 1.23, 95% CI 1.02–1.48, $p = 0.03$). This result is counterintuitive; however, at the time of survey administration, there was a shortage of gastroenterologists in the participating healthcare system to perform colonoscopies leading to inadequate capacity to meet the demand for colonoscopies. We hypothesize that high-performing PCPs were able to accurately identify this issue because they are more engaged in the CRC screening process and therefore, encounter and are more attuned to the barriers to CRC screening in our healthcare system. Interestingly, PCP age and gender, and clinic management were not significant in this model (Table 3).

Among the subset of patients who completed CRC screening, significant predictors of being screened with CTC compared to any other method were PCP perceptions that CTC is effective in reducing CRC mortality, number of perceived advantages to screening with CTC compared to colonoscopy, and PCP specialty. PCPs who perceived CTC as extremely effective in reducing CRC mortality were more likely to use CTC compared to those who felt it is not at all, slightly, or moderately effective (OR 2.86; 95% CI 1.13–7.25, $p = 0.02$). PCPs who perceived more than three advantages to CTC were more likely to use CTC compared to those who perceived no advantages to CTC over colonoscopy (OR 3.79; 95% CI 1.2–11.97, $p = 0.01$). Internal Medicine/Geriatrics providers were more likely to use CTC for CRC screening (OR 2.33; 95% CI 1.41–5.03, $p < 0.01$). Perceived organizational capacity to meet the demand for colonoscopy, PCP age and gender, and clinic management were not significant predictors of CRC screening by CTC compared to other modalities (Table 3). Also of note, number of perceived disadvantages to screening with CTC compared to colonoscopy, tolerability of screening with CTC, and complexity of screening with CTC were not included in the final parsimonious model based on the AIC.

Discussion

Our research shows that even in a healthcare system with widespread insurance coverage for CTC as a CRC screening modality, substantial variation in early PCP adoption of CTC can be seen. CTC screening rates within even a single clinic may vary from 0 to 16%. We showed that PCPs who believe that CTC is effective in reducing CRC mortality are more likely to screen with CTC and that the number of perceived advantages to using CTC over colonoscopy was also associated with higher CTC use. Interestingly, the number of perceived disadvantages to CTC compared to colonoscopy was not significant. This knowledge will be helpful to increase adoption of this technology. The results of our study can help direct efforts to improve CTC adoption among PCPs. Given the poor adherence rates with current tests, improved adoption of an effective modality such as CTC may make a large impact on future CRC incidence. This is especially important in the light of the recently updated USPSTF guidelines on CRC screening which highlight the effectiveness of CRC screening by multiple methods [10].

The fact that the number of perceived disadvantages to CTC compared to colonoscopy was not significant is surprising. Since its introduction, opponents to CTC-based screening have been very concerned about the perceived disadvantages. They argued extra-colonic findings, radiation exposure, and decreased performance in various polyp subtypes as reasons against use of this modality. Over the past decade, a substantial body of literature has emerged addressing these issues [27]. Many of these areas of perceived deficiency at CTC are nuanced. For example, extra-colonic findings have been shown to hold both benefits and drawbacks, ultimately requiring 6–8% additional workup for findings outside of the colon, yet leading to the unsuspected identification of extra-colonic cancers in 0.3–0.6% and abdominal aortic aneurysms in 0.1–0.8% [28–35].

We should focus on the fact that a significant predictor of higher CTC use for CRC screening was the perceived advantages to screening with CTC over colonoscopy. This can be explained by research which has shown that organizations are more likely to be willing and able to adopt technologies that offer relative advantages, especially when the "innovation is [perceived to be] technically superior (in terms of cost, functionality, image, etc.) than the technology it supersedes" [36]. Thus, a potential strategy for CTC adoption should concentrate on disseminating the effectiveness of this test which has a sensitivity of 96.1% for cancer detection in a large meta-analysis [37] and 90% for polyps ≥10 mm (a benign precursor) which has the potential to progress to cancer [11]. The emerging data on the effectiveness of serrated polyp detection at CTC should be an educational priority for the radiology community to provide to

PCPs [38]. Similarly, education regarding patient comfort and tolerability, ability to perform CTC without cessation of anticoagulation, lack of need for sedation, and lack of perforation risk should also be areas of emphasis.

Our study does have some limitations. The provider group included in the study represents a large, academic practice with multi-specialty, and community-based primary care clinics which could impact the generalizability of our findings. However, large multi-specialty systems are becoming a preferred way to provide high-quality health care and are increasingly recognized as critical to the understanding and improvement of health care delivery [39]. Another potential limitation is selection bias when relying on survey data; however, we believe this impact is minimal in our study due to the high overall response rate (70%) and our inclusion criteria that counted all PCPs who had at least one patient eligible for CRC screening with CTC based on insurance coverage. A third source of bias is that a number of our variables are obtained from the EHR which could result in misclassification of CRC screening status due to missing data. This is unlikely to result in systematic bias across our healthcare system since all clinics have used a fully integrated EHR populated with all data going back to 1991 (including scanned documents that are manually reviewed to assess completion of CRC screening outside the system). A fourth limitation is that patients with inflammatory bowel disease, a history of CRC, and patients with a known hereditary colon cancer syndrome were not excluded from this study. These patients were not excluded due to our eligibility criteria that aligned with our definition for public reporting of CRC screening metrics [21]. This could lead to an underestimate of CTC utilization by PCPs for CRC screening; however, there is no reason to suspect a systematic bias across PCPs or primary care clinics with respect to this issue. A final limitation that will impact generalizability of our results is the issue of insurance coverage. Insurance coverage for CTC has been available for several years in our healthcare system, and this is a common knowledge among our PCPs. However, with the recently updated USPSTF CRC screening guidelines, we are optimistic that insurance coverage for CTC for CRC screening will be expanding across the country.

In conclusion, significant variation in PCP adoption of CTC exists even in a healthcare system where insurance coverage is not a major barrier. Potential effective strategies to increase PCP adoption of CTC for CRC screening should include emphasis on the effectiveness and advantages of this test as opposed to addressing the perceived disadvantages.

Compliance with ethical standards

Funding This work was supported by the National Cancer Institute (Grants R01 CA144835 and P30 CA014520); the National Center for Advancing Translational Sciences (Grant UL1TR000427); the American Cancer Society (Grant MRSG-13-144-01-CPHPS); and the UW Health Innovation Program.

Conflict of interest Perry J. Pickhardt is co-founder of VirtuoCTC and shareholder in SHINE, Elucent, and Cellectar Biosciences. David H. Kim is co-founder of VirtuoCTC, consultant for Viatronix, on the Medical Advisory Board for Digital ArtForms, and shareholder in Cellectar and Elucent. Patrick R. Pfau serves on the Scientific Advisory Board of Exact Sciences. The other authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Informed consent Statement of informed consent was not applicable since the manuscript does not contain any patient data.

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