#### American College of Radiology ACR Appropriateness Criteria® Colorectal Cancer Screening

<u>Variant: 1</u> Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen.

| Procedure  | Appropriateness Category | Relative Radiation Level |
|--|--------------------------|--------------------------|
| CT colonography without IV contrast screening      | Usually Appropriate      |                          |
| Fluoroscopy barium enema double-contrast           | Usually Not Appropriate  | <b>૽ ૽</b>               |
| Fluoroscopy barium enema single-contrast           | Usually Not Appropriate  | <b>૽ ૽</b>               |
| CT abdomen and pelvis with IV contrast             | Usually Not Appropriate  | <b>૽ ૽</b>               |
| CT abdomen and pelvis without IV contrast          | Usually Not Appropriate  | <b>૽</b>                 |
| CT abdomen and pelvis without and with IV contrast | Usually Not Appropriate  | ***                      |

# <u>Variant: 2</u> Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

| Procedure  | Appropriateness Category | Relative Radiation Level |
|--|--------------------------|--------------------------|
| CT colonography without IV contrast screening      | Usually Appropriate      |                          |
| Fluoroscopy barium enema double-contrast           | Usually Not Appropriate  | <b>**</b>                |
| Fluoroscopy barium enema single-contrast           | Usually Not Appropriate  |                          |
| CT abdomen and pelvis with IV contrast             | Usually Not Appropriate  | <b>⊗ ⊗</b>               |
| CT abdomen and pelvis without IV contrast          | Usually Not Appropriate  | <b>૽ ૽</b>               |
| CT abdomen and pelvis without and with IV contrast | Usually Not Appropriate  | <b>∵ ∵ ∵</b>             |

#### **Variant: 3** Adult. Colorectal cancer screening. High-risk individual.

| Procedure  | Appropriateness Category | Relative Radiation Level |
|--|--------------------------|--------------------------|
| Fluoroscopy barium enema double-contrast           | Usually Not Appropriate  | <b>૽ ૽</b>               |
| Fluoroscopy barium enema single-contrast           | Usually Not Appropriate  | <b>૽ ૽</b>               |
| CT abdomen and pelvis with IV contrast             | Usually Not Appropriate  | <b>૽ ૽</b>               |
| CT abdomen and pelvis without IV contrast          | Usually Not Appropriate  | <b>⊗ ⊗</b>               |
| CT abdomen and pelvis without and with IV contrast | Usually Not Appropriate  | <b>⊗⊗</b> ⊗              |
| CT colonography without IV contrast screening      | Usually Not Appropriate  | <b>⊗⊗⊗</b>               |

## <u>Variant: 4</u> Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy.

| Procedure  | Appropriateness Category | Relative Radiation Level |
|--|--------------------------|--------------------------|
| CT colonography without IV contrast screening      | Usually Appropriate      |                          |
| Fluoroscopy barium enema double-contrast           | Usually Not Appropriate  |                          |
| Fluoroscopy barium enema single-contrast           | Usually Not Appropriate  | <b>*</b>                 |
| CT abdomen and pelvis with IV contrast             | Usually Not Appropriate  |                          |
| CT abdomen and pelvis without IV contrast          | Usually Not Appropriate  | <b>€</b>                 |
| CT abdomen and pelvis without and with IV contrast | Usually Not Appropriate  | <b>⊗⊗⊗</b>               |

#### **Panel Members**

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#### **Summary of Literature Review**

#### Introduction/Background

Colorectal cancer (CRC) is the second leading cause of cancer mortality in the United States [1] and the second highest treatment cost of any cancer, with the cost of medical services and prescription treatment over \$24 billion in 2020 [2]. Because of advances in cancer prevention, earlier detection of precancerous lesions and advances in treatment, overall incidences of CRC are decreasing. CRC screening rate among United States adults > 50 years of age has increased from approximately 38% in 2000 to 66% in 2018, leading to decreases in CRC mortality [3]. However, the incidence rates of colon and rectal cancers in adults <50 years of age have been increasing by approximately 2% per year since 2003 [1]. In 2016, the US Preventive Services Task Force (USPSTF) commissioned a report from the Cancer Intervention and Surveillance Modeling Network Colorectal Cancer Working Group to provide information from comparative modeling on how many estimated lifeyears gained, CRC cases averted, and CRC deaths averted vary by different starting and stopping ages for various screening strategies. It concluded with high certainty that screening for CRC in adults 50 to 75 years of age has substantial net benefit [4]. In addition, the USPSTF concluded with moderate certainty that screening for CRC in adults 45 to 49 years of age has moderate net benefit [5]. Given the updated recommendations from the USPSTF and current imaging practices, the ACR Appropriateness Criteria aligned its variants for CRC screening in those at average risk for CRC to begin at age 45 years [1].

This document covers CRC screening by imaging procedures and does not include modalities outside of imaging such as colonoscopy, flexible sigmoidoscopy, fecal immunochemical test (FIT), and stool DNA. This document has divided screening scenarios into 4 variants: 1) average-risk individuals (45-75 years of age without CRC risks factors), 2) individuals (45-75 years of age) with elevated risk; not average risk nor high risk, 3) high-risk individuals defined as a diagnosis of a hereditary syndromes such as hereditary nonpolyposis CRC (HNPCC) or familial adenomatosis polyposis (FAP) or a personal history of ulcerative colitis or Crohn colitis, and 4) individuals (average risk, elevated risk or high risk) after incomplete colonoscopy or unable to tolerate colonoscopy.

#### **Special Imaging Considerations**

CT colonography (CTC) is a defined imaging procedure distinct from standard abdomen pelvic CT in which there is a dedicated protocol to optimize the colorectum for the detection of polyps and masses. This includes a bowel preparation, colonic distention, and imaging in multiple patient positions. A low-dose technique is undertaken with resultant overall doses of 3 to 5 mSv per examination [6]. It is typically performed without intravenous (IV) contrast but can be added when combined with extracolonic indications such as CRC staging. When IV contrast is given, the prone series is typically conducted as a noncontrast series and the supine series is undertaken with IV

contrast. For details, please refer to the <u>ACR-SABI-SAR Practice Parameter for the Performance of Computed Tomography (CT) Colonography in Adults [7].</u>

Regarding MR colonography, its use in the United States is generally considered an investigational test and has not been adequately validated as an acceptable test for CRC screening. Furthermore, there has been no recent literature that documents routine use of MR colonography in CRC screening. As a result, MR colonography has been removed from the current AC guidelines.

#### **Discussion of Procedures by Variant**

### Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen.

This clinical scenario involves screening of individuals between 45 and 75 years of age without known risk factors that would elevate the likelihood of developing CRC over their lifetime. Risk factors include a personal history of adenomas or a family history of CRC. In addition, this scenario would also exclude individuals with symptomatology concerning for possible CRC such as abdominal pain, change in bowel habits, or a positive fecal occult blood test/FIT test. Over an individual's lifetime, the risk of CRC with no known risk factors is 4.1% [1].

## Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen. A. CT abdomen and pelvis with IV contrast

Several studies have evaluated the use of standard or routine CT abdomen and pelvis (not CTC protocol) in the detection of CRC. Ozel et al [8] found standard CT moderately effective for the detection of invasive carcinomas with a sensitivity of 72.4% but insensitive for polyps with a sensitivity of 14.5%. Mangat et al [9] evaluated 207 patients with histologically proven CRC who underwent CT before biopsy. The initial sensitivity of CT for detecting CRC in the unprepared large bowel was 66%; upon rereview, the sensitivity increased to 86.5%. Ye et al [10] likewise found suboptimal sensitivity for detection of CRC in a small group of patients, with a sensitivity of 45.5%. A small study of 209 patients published by Johnson et al [11] found half of colorectal tumors in the study were not diagnosed prospectively on routine CT. Additionally, a meta-analysis from Koo et al [12] evaluated CT with minimal preparation with oral contrast, without insufflation showed a pooled sensitivity of 83% (95% confidence interval [CI], 76%-89%) and pooled specificity to be 90% (95% CI, 85%-94%).

A meta-analysis by Yu et al [13] included 4,797 patients and found a pooled overall sensitivity of 74% (95% CI, 71%-77%) and a specificity of 86% (95% CI, 85%-87%) for colorectal tumors. The subgroup analysis revealed the following results: a) for IV contrast use only, the pooled sensitivity and specificity were 63% (95% CI, 56%-69%) and 89% (95% CI, 86%-92%), respectively, and b) for oral contrast use, the pooled sensitivity and specificity were 78% (95% CI, 74%-81%) and 86% (95% CI, 84%-87%), respectively.

Although the above studies showed that conventional CT without a dedicated CTC protocol can detect some cancers, it is imperative to note that most studies did not focus on detection of precancerous lesions (ie, polyps). Currently, there is insufficient evidence to support the use of routine abdomen pelvis CT with IV contrast as a standard screening test for CRC.

Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial

### screening, then follow-up every 5 years after initial negative screen.

#### B. CT abdomen and pelvis without and with IV contrast

Although standard or routine CT of the abdomen and pelvis with IV contrast may detect some CRC, there is no data to support the role of CT abdomen and pelvis without and with IV contrast for screening.

## Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen.

#### C. CT abdomen and pelvis without IV contrast

There is no data to support the use of routine CT abdomen and pelvis without IV contrast for CRC screening.

## Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen.

### D. CT colonography without IV contrast screening

In the American College of Radiology Imaging Network (ACRIN) National CTC Trial [14], perpatient sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were 90%, 86%, 23%, and 99%, respectively, for detecting  $\geq$ 10 mm adenomas or cancers. The perpatient sensitivity for detecting adenomas  $\geq$ 6 mm was 78% [14]. The per-polyp sensitivity for  $\geq$ 10 mm adenomas or cancers was 84% [14].

In another large study of average-risk individuals undergoing CRC screening, the sensitivities of CTC and colonoscopy for detecting adenomatous polyps  $\geq 10$  mm were 94% and 88%, respectively [15]. A trial performed with 307 asymptomatic subjects using 64 multidetector-row CT demonstrated a CTC sensitivity and specificity of 91% and 93%, respectively, for polyps  $\geq 6$  mm and 92% and 98%, respectively, for polyps  $\geq 10$  mm [16]. Two meta-analyses of CTC performance in detecting  $\geq 10$  mm polyps showed pooled sensitivities by patient of 85% and 93%, with pooled specificities of 97% [17,18]. Some older studies have shown poorer performance of CTC (sensitivity of 55%-59%) [19,20]. These discrepant results were likely related to differences in study design and CTC technique (eg, no fecal tagging) in these older studies.

The diagnostic yields of CTC and colonoscopy for advanced neoplasia have also been compared in parallel screening programs [20]. Primary CTC screening in 3,120 patients was compared with primary colonoscopy screening in 3,163 subjects. Similar detection rates were found for CTC and colonoscopy screening, which identified 123 and 121 advanced neoplasms, respectively [21]. The total numbers of polyps in the CTC and colonoscopy groups were 561 and 2,434, respectively. A multicenter randomized trial of 1,610 patients assigned to undergo either colonoscopy (n = 1,072) or CTC (n = 538) found an 11% detection rate for cancers and polyps  $\geq$ 10 mm with both techniques.

A review of a 1-year CTC screening experience for colorectal neoplasia showed that 3.9% of individuals had 1 polyp  $\geq 1$  cm, and 6.9% had  $\geq 1$  polyp(s) 6 to 9 mm [22]. Of the 71 patients who chose colonoscopy for further evaluation of these polyps, concordant lesions were found with colonoscopy in 65 (91.5% PPV) [22]. In addition, the outcomes of patients with negative CTC screens have also been reported. A longitudinal follow-up of 1,011 patients over nearly 5 years demonstrated a single-interval cancer (crude cancer incidence of 0.2 cancers per 1,000 patient years), leading to the conclusion that a 5-year routine screen interval and nonreporting of diminutive lesions ( $\leq 5$  mm) were appropriate strategies [23].

CTC performance has been evaluated in senior patient cohorts (≥65 years of age) [24]. A retrospective analysis of 577 subjects found an excellent CTC concordance rate of 91% [24]. Based on a 6-mm threshold, there was an overall patient referral rate of 15% for colonoscopy. Considering only adenomas, the per-patient positivity rates for 6- and 10-mm thresholds were 11% and 7%, respectively. When comparing 204 nonsenior (14%) and 250 senior patients (13%) undergoing CTC, another study found no statistically significant difference in the percentage of individuals with at least 1 polyp ≥6 mm [25]. A post hoc analysis of 477 senior patients from the ACRIN National CTC Trial demonstrated that, for large neoplasms, sensitivity and specificity among the older cohort were 82% and 83%, respectively [26]. There was no statistically significant difference when compared with the sensitivity and specificity of 92% and 86%, respectively, for lesions ≥10 mm in the younger patient cohort. For lesions >6 mm, the sensitivity and specificity were 72% and 86%, respectively, for older patients, and 81% and 89%, respectively, for younger patients, with no statistically significant difference. Another study reporting outcomes of 1,400 senior patients who underwent CTC found a 15% frequency for referral to colonoscopy at a polyp threshold of 6 mm [27]. Colorectal neoplasia was identified in 9% of patients, and advanced neoplasia was found in 3%.

Similar to colonoscopy, evidence supporting serrated polyp detection at CT is emerging. Despite a subtle, flat nature to sessile serrated polyps, these lesions can be detected at CTC likely because of a phenomenon of polyp coating. It appears that the adherent mucin elaborated by these lesions mix with the tagging agents to form a contrast coat. In an observational CTC screening study (n = 8,289), CTC demonstrated a prevalence of 3.1% for serrated lesions ≥6 mm in size. As seen by the colonoscopy experience, these lesions tended to be large (>10 mm in size), flat, and right sided. The presence of a contrast coat markedly improved lesion detection with an odds ratio of 40.4 (95% CI, 10.1-161.4) [28].

In the updated evidence report and systematic review for the USPSTF, a review of 7 studies with a total of 5,328 participants found CTC had a sensitivity of 86% to 100% (95% CI, 21%-100%) for CRC, a sensitivity of 89% (95% CI, 83%-96%), and a specificity of 94% (95% CI, 89%-100%) for adenomas  $\geq$ 10 mm, and a sensitivity of 86% (95% CI, 78%-95%) and specificity of 88% (95% CI, 83%-95%) for adenomas  $\geq$ 6 mm [29].

## Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen. E. Fluoroscopy barium enema double-contrast

Fluoroscopic barium enema with high-density barium and air sufflation to create a double-contrast technique has fallen out of use with the emergence of CTC. The literature has confirmed clinical consensus that the fluoroscopic modality is not as sensitive as the CT-based examination. In the Special Interest Group in Gastrointestinal and Abdominal Radiology (SIGGAR) trial, a randomized prospective multicenter trial for screening symptomatic patients (n = 3,838 randomized to barium enema or CTC in a 2:1 ratio), the detection rate for barium enema was 5.6% compared to 7.3% at CTC (P = .039) [21]. Furthermore, a meta-analysis involving 11 studies of double-contrast barium enema (DCBE) (5,995 patients, 1,548 polyps) and 30 studies of CTC (6,573 patients, 2,348 polyps) concluded that the sensitivity and specificity of barium enema were both less than that of CTC at the 6-mm polyp threshold [30].

There is no evidence to suggest that DCBE should be used for routine screening, and one study

found DCBE is no longer justified as a backup examination for an incomplete colonoscopy [31].

### Variant 1: Colorectal cancer screening. Average-risk individual. Age 45 to 75 years. Initial screening, then follow-up every 5 years after initial negative screen.

#### F. Fluoroscopy barium enema single-contrast

Single-contrast barium enema (SCBE) studies are performed by administration of liquid barium without insufflation with air. A preponderance of the literature has demonstrated a markedly inferior performance profile for SCBE. A retrospective evaluation of 139 patients who underwent barium enema and had 1 or more colonic polyps diagnosed endoscopically found sensitivity of SCBE for polyps <1 cm to be 72% and for polyps  $\geq$ 1 cm to be 94% [32]. In the same study, the sensitivity of DCBE was 88% for polyps <1 cm and 96% for polyps  $\geq$ 1 cm [32].

# Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

This variant covers colorectal screening in individuals at elevated risk, which is increased from average-risk persons. However, these persons are not in the high-risk group, which is specifically defined by several disease states. This degree of elevated risk may be a result of a personal history of adenomas or a family history of CRC. Alternatively, the patient may be experiencing occult blood in stool or a positive stool DNA test or be symptomatic raising suspicion for CRC.

# Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

#### A. CT abdomen and pelvis with IV contrast

Several studies have evaluated the use of standard or routine CT abdomen and pelvis (not CTC protocol) in the detection of CRC. Ozel et al [8] found standard CT moderately effective for the detection of invasive carcinomas with a sensitivity of 72.4% but insensitive for polyps with a sensitivity of 14.5%. Mangat et al [9] evaluated 207 patients with histologically proven CRC who underwent CT before biopsy. The initial sensitivity of CT for detecting CRC in the unprepared large bowel was 66%; upon rereview, the sensitivity increased to 86.5%. Ye et al [10] likewise found suboptimal sensitivity for detection of CRC in a small group of patients, with a sensitivity of 45.5%. A small study of 209 patients published by Johnson et al [11] found half of colorectal tumors in the study were not diagnosed prospectively on routine CT. Additionally, a meta-analysis from Koo et al [12] evaluated CT with minimal preparation with oral contrast, without insufflation showed a pooled sensitivity of 83% (95% CI, 76%-89%) and pooled specificity to be 90% (95% CI, 85%-94%).

A meta-analysis by Yu et al [13] included 4,797 patients and found a pooled overall sensitivity of 74% (95% CI, 71%-77%) and a specificity of 86% (95% CI, 85%-87%). The subgroup analysis revealed the following results: a) for IV contrast use only, the pooled sensitivity and specificity were 63% (95% CI, 56%-69%) and 89% (95% CI, 86%-92%), respectively, and b) for oral contrast use, the pooled sensitivity and specificity were 78% (95% CI, 74%-81%) and 86% (95% CI, 84%-87%), respectively.

Although the above studies showed that conventional CT without a dedicated CTC protocol can detect some cancers, it is imperative to note that most studies did not focus on detection of precancerous lesions (ie, polyps). Currently, there is insufficient evidence to support the use of routine abdomen pelvis CT with IV contrast as a standard screening test for CRC.

Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

#### B. CT abdomen and pelvis without and with IV contrast

Although standard or routine CT of the abdomen and pelvis with IV contrast may detect some CRC, there is no data to support the role of CT abdomen and pelvis without and with IV contrast for screening.

Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

#### C. CT abdomen and pelvis without IV contrast

There is no data to support the use of routine CT abdomen and pelvis without IV contrast for CRC screening.

Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

#### D. CT colonography without IV contrast screening

The performance of CTC is well established with multiple studies and trials demonstrating ability to detect both precancerous polyps and cancerous masses [14-16,24-26,33-39]. An updated evidence report and systematic review by the USPSTF in 2018 reported a sensitivity of 86% (95% CI, 78%-95%) and specificity of 88% (95% CI, 83%-95%) at the 6 mm threshold for adenomatous polyps based on 7 published studies comparing CTC and colonoscopy [29]. The sensitivity and specificity values were noted to be similar to colonoscopy based on moderate strength of evidence. CTC has also been shown to be able to detect flat sessile serrated lesions, which typically arise in the right colon and is another recognized polyp precursor [28]. Regarding cancers, a meta-analysis of 49 studies (n = 11,151 patients) showed a sensitivity for CTC at 96.1% (n = 398 of 414; 95% CI, 93.8%, 97.7%) for cancerous masses [40].

CTC with a sized-based selective polypectomy strategy ( $\geq 10$  mm resect, 6-9 mm surveillance or resect,  $\leq 5$  mm ignore) demonstrates an important filtering aspect where polypectomies for pseudodisease are limited. One study demonstrated nearly a 5-fold decrease (P < .001) in the number of polypectomies in a CTC-based screening program compared against a colonoscopy-based program yet with the same yield of high-risk polyps from the polypectomies within each program [41]. Longer-term outcomes from large observational cohorts have shown this to be a safe approach without high incident cancers between screening [23,42,43].

The following trials have documented similar test performances values specifically for patients with elevated risk (Variant 2). A large multicenter prospective Italian trial (n = 937 participants) evaluated patients with either a positive family CTC history, prior history of adenomas, or positive fecal occult blood test and reported a sensitivity and specificity at the 6-mm polyp threshold of 85.3% and 87.8%, respectively [44]. A single institution cohort series (n = 304) examining patients with a positive family history reported sensitivities of 77% and 89% at the 6- and 10-mm thresholds, respectively [45]. And a study looking at individuals with a personal polyp history or positive family CRC history (n = 249) showed a sensitivity of 84% and specificity of 92% at the large 10-mm polyp threshold [46]. The SIGGAR trial (large, multicenter prospective trial; n = 1,610) involved 21 centers in the United Kingdom and investigated CTC in patients with symptomatology

suspicious for CRC. They concluded that although "guidelines are needed to reduce the referral rate after CTC in this group, for most patients, however, CTC provides a similarly sensitive, less invasive alternative to colonoscopy" [21]. A small study (n = 31) included suspicious symptomatology such as change in bowel habits, bleeding, pain in addition to personal history of polyps, or family history of cancer and reported a sensitivity of 92% at the 10-mm threshold with a specificity of 95% [47].

Populations with elevated risk raise the possibility of leading to excessive polypectomy referral rates for positive examinations, diminishing the usefulness of CTC as a screening filter. This was shown specifically not to be the case for patients with a family history in which a large observational cohort (n = 8,857) showed only a mild increased rate of 16% versus 10.5% (P = .035) for the general population [48]. However, referral rates may be substantially increased in other risk settings as suggested in the SIGGAR trial, which can be mitigated by size thresholding [21].

# Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

#### E. Fluoroscopy barium enema double-contrast

Fluoroscopic barium enema with high density barium and air sufflation to create a double-contrast technique has fallen out of use with the emergence of CTC. The literature has confirmed clinical consensus that the fluoroscopic modality is not as sensitive as the CT-based examination. In the SIGGAR trial, a randomized prospective multicenter trial for screening symptomatic patients (n = 3.838 randomized to barium enema or CTC in a 2:1 ratio), the detection rate for barium enema was 5.6% compared to 7.3% at CTC (P = .039) [21]. Furthermore, a meta-analysis involving 11 studies of DCBE (5.995 patients, 1.548 polyps) and 30 studies of CTC (6.573 patients, 2.348 polyps) concluded that the sensitivity and specificity of barium enema were both less than that of CTC at the 6-mm polyp threshold [30].

# Variant 2: Colorectal cancer screening. Individuals 45 to 75 years of age with elevated risk (not average risk nor high risk). Initial screening, then follow-up every 5 years after initial negative screen.

#### F. Fluoroscopy barium enema single-contrast

SCBE studies are performed by administration of liquid barium without insufflation with air. A preponderance of the literature has demonstrated a markedly inferior performance profile for SCBE. A retrospective evaluation of 139 patients who underwent barium enema and had 1 or more colonic polyps diagnosed endoscopically found sensitivity of SCBE for polyps <1 cm to be 72% and for polyps  $\geq$ 1 cm to be 94% [32]. In the same study, the sensitivity of DCBE was 88% for polyps <1 cm and 96% for polyps  $\geq$ 1 cm [32].

#### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

A high-risk individual is defined as having a hereditary syndrome such as HNPCC/Lynch syndrome or FAP or a personal history of ulcerative colitis or Crohn colitis.

The cumulative probability of CRC in an ulcerative colitis patient is 2% by 10 years, 8% by 20 years, and 18% by 30 years [49]. The risk for individuals with Crohn colitis may be comparable. Individuals with HNPCC, also known as Lynch syndrome, are at increased risk for CRC. CRCs tend to occur at a younger age and with a shorter dwell time in individuals with HNPCC [50]. CRC screening recommendations for individuals with HNPCC or at risk (first-degree relatives) are colonoscopy

every 1 to 2 years beginning at 20 to 25 years of age or earlier if familial diagnosis of CRC before 25 years of age [50].

Colonoscopy is preferred in this patient population because of the high prevalence of polyps in this clinical scenario and its ability to obtain biopsies to look for dysplasia. A systematic review performed in 2022 found imaging techniques are unsuitable for colon surveillance in Lynch syndrome [51].

### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

#### A. CT abdomen and pelvis with IV contrast

Although several studies have evaluated the use of standard or routine CT abdomen and pelvis (not CTC protocol) in the detection of CRC, none have specifically focused on high-risk patients. Whereas patients with hereditary cancer syndromes are at risk of malignancy in several other organs, the specific role of routine CT with IV contrast for CRC screening in this population is not supported by evidence.

#### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

#### B. CT abdomen and pelvis without and with IV contrast

There is no data to support CT abdomen and pelvis without and with IV contrast (non–CTC protocol) is effective in detecting polyps or colorectal carcinoma in high-risk individuals.

#### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

#### C. CT abdomen and pelvis without IV contrast

There is no data to support CT abdomen and pelvis without IV contrast (non–CTC protocol) is effective in detecting polyps or colorectal carcinoma in high-risk individuals.

### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

#### D. CT colonography without IV contrast screening

Colonoscopy is preferred over CTC in this patient population because of the high prevalence of polyps in this clinical scenario and its ability to obtain biopsies to look for dysplasia. A recent systematic review performed in 2022 found imaging techniques are unsuitable for colon surveillance in Lynch syndrome [51].

### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

#### E. Fluoroscopy barium enema double-contrast

Limited evidence is available regarding the performance of DCBE in individuals with a family history of CRC. An older investigation of screening with colonoscopy or sigmoidoscopy and DCBE compared to no screening found a reduction in CRC incidence with screening in families with HNPCC [52].

Colonoscopy is preferred over barium examinations because of the high prevalence of polyps in this clinical scenario and its ability to obtain biopsies to look for dysplasia. There is no data to support the use of DCBE for colon polyp or colon carcinoma detection in high-risk individuals.

#### Variant 3: Adult. Colorectal cancer screening. High-risk individual.

#### F. Fluoroscopy barium enema single-contrast

Colonoscopy is preferred over barium examinations because of the high prevalence of polyps in this clinical scenario and its ability to obtain biopsies to look for dysplasia.

There is no data to support the use of SCBE for colon polyp or colon carcinoma detection in high-risk individuals.

### Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy.

Incomplete colonoscopy is defined as the inability to visualize the entire colon from the rectum to the cecum. The reported incidence of incomplete colonoscopy ranges from 4% to 25% [53]. In one study in which severe luminal narrowing was observed due to CRC, automated pressure-controlled CO<sub>2</sub> insufflation was found to be as efficient in colonic distention as it is in patients without severe luminal narrowing [54]. The prevalence of synchronous CRC varies from 1% to 7% [55,56]; a study involving nearly 5,900 patients revealed that the prevalence of synchronous CRC is 2.2% [57]. However, it is known that the presence of synchronous neoplasm can be higher in the setting of obstructive CRC [58-60].

In some other scenarios, patients are not able to tolerate colonoscopy due to higher risk of complications related to the sedation, such as American Society of Anesthesiology of III or IV and Mallampati class III or IV should be given additional consideration., and alternative modalities without sedation should be considered; see the <u>ACR–SIR Practice Parameter For Minimal and/or Moderate Sedation/Analgesia</u> [61].

# Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy. A. CT abdomen and pelvis with IV contrast

Several studies have evaluated the use of standard or routine CT abdomen and pelvis (not CTC protocol) in the detection of CRC. Ozel et al [8] found standard CT moderately effective for the detection of invasive carcinomas with a sensitivity of 72.4% but insensitive for polyps with a sensitivity of 14.5%. Mangat et al [9] evaluated 207 patients with histologically proven CRC who underwent CT before biopsy. The initial sensitivity of CT for detecting CRC in the unprepared large bowel was 66%; upon rereview, the sensitivity increased to 86.5%. Ye et al [10] likewise found suboptimal sensitivity for detection of CRC in a small group of patients, with a sensitivity of 45.5%. A small study of 209 patients published by Johnson et al [11] found half of colorectal tumors in the study were not diagnosed prospectively on routine CT. Additionally, a meta-analysis from Koo et al [12] evaluated CT with minimal preparation with oral contrast, without insufflation showed a pooled sensitivity of 83% (95% CI, 76%-89%) and pooled specificity to be 90% (95% CI, 85%-94%).

A meta-analysis by Yu et al [13] included 4,797 patients and found a pooled overall sensitivity of 74% (95% CI, 71%-77%) and a specificity of 86% (95% CI, 85%-87%). The subgroup analysis revealed the following results: a) for IV contrast use only, the pooled sensitivity and specificity were 63% (95% CI, 56%-69%) and 89% (95% CI, 86%-92%), respectively, and b) for oral contrast use, the pooled sensitivity and specificity were 78% (95% CI, 74%-81%) and 86% (95% CI, 84%-87%), respectively.

Although the above studies showed that conventional CT without a dedicated CTC protocol can detect some cancers, it is imperative to note that most studies did not focus on detection of precancerous lesions (ie, polyps). Currently, there is insufficient evidence to support the use of routine abdomen pelvis CT with IV contrast as a standard screening test for CRC.

Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy.

#### B. CT abdomen and pelvis without and with IV contrast

Although there is some evidence to support that routine CT with IV contrast can detect cancer, there is no data to support a CT abdomen and pelvis without and with IV contrast (non–CTC protocol) as an effective screening tool in the detection of polyps or colorectal carcinoma after incomplete colonoscopy or in patients unable to tolerate colonoscopy.

# Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy. C. CT abdomen and pelvis without IV contrast

There is no data to support the use of CT abdomen and pelvis without IV contrast (non–CTC protocol) has been effective in the detection of polyps or colorectal carcinoma after incomplete colonoscopy or in patients unable to tolerate colonoscopy.

## Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy.

#### D. CT colonography without IV contrast screening

Several studies have demonstrated the usefulness of CTC in individuals who have undergone an incomplete colonoscopy [62-65]. In a study of 546 patients who underwent CTC after an incomplete colonoscopy, 13% were found to have lesions ≥6 mm. Per-patient and per-lesion PPVs of CTC for masses and large polyps were 91% and 92%, respectively [66]. In a prospective study of 100 patients who underwent CTC after incomplete colonoscopy, CTC was found to have a PPV of 86% and 100% for polyps ≥6 mm and ≥10 mm, respectively [49,67]. CTC following incomplete colonoscopy detected CRC in 9% and adenomatous polyps in 20% [68]. Performing a dedicated CTC bowel preparation on a later date following incomplete colonoscopy results in much higher examination quality compared to same-day CTC [69]. If same-day CTC is performed following incomplete colonoscopy, the patient should ingest a fecal tagging agent (eg, 30 mL oral diatrizoate) after recovery from sedation with imaging performed at least 2 hours after ingestion [69].

Noncathartic CTC also has been assessed in recent years and does not perform as well as conventional CTC. In a prospective study of 605 adults at average to elevated risk for colon cancer who underwent both laxative-free CTC and colonoscopy, per-patient sensitivity and specificity of CTC were 91% and 85% for adenomas  $\geq$ 10 mm, 70% and 86% for adenomas  $\geq$ 8 mm, and 59% and 88% for adenomas  $\geq$ 6 mm [36]. In a prospective study of 564 asymptomatic adults who underwent noncathartic CTC with fecal tagging, the sensitivity, specificity, NPV, and PPV of noncathartic CTC for adenomatous polyps or cancer  $\geq$ 6 mm was 76%, 92%, 98%, and 38%, respectively [38].

Overall, CTC without IV contrast offers a reliable alternative for CRC screening in patients with incomplete colonoscopy or those unable to tolerate colonoscopy.

# Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy. E. Fluoroscopy barium enema double-contrast

Limited historical data have been published on the accuracy of DCBE following incomplete colonoscopy. In a study of 233 patients who underwent DCBE following incomplete colonoscopy, polyps were reported in 2.1% of patients (5 patients; 5 of 6 polyps >5 mm) [70]. However, 2 patients with 4- and 10-mm polyps reported on DCBE underwent repeat colonoscopy, and no polyps were found. The remaining 3 patients with polyps reported on DCBE refused repeat

colonoscopy. Thirteen patients whose DCBE studies were reported as of suboptimal quality underwent repeat colonoscopy, and 5 patients were found to have polyps (one 1-cm tubular adenoma, 4 <5 mm hyperplastic polyps). In a study of 103 patients who underwent DCBE performed immediately after incomplete colonoscopy, the entire colon was visualized in 94% of subjects [71]. Five malignant neoplasms (size not reported) were identified at DCBE [71]. Further, one study found DCBE is no longer justified as a backup examination for incomplete colonoscopy [31].

## Variant 4: Adult. Colorectal cancer screening. Average, elevated, or high risk after incomplete colonoscopy or unable to tolerate colonoscopy.

#### F. Fluoroscopy barium enema single-contrast

Very limited data are available regarding the accuracy of SCBE performed after incomplete colonoscopy. In a study of 118 patients who underwent barium enema following incomplete colonoscopy (103 double-contrast, 15 single-contrast), 2 polyps were found (4 and 5 mm) and removed at subsequent repeat colonoscopy [72]. Repeat colonoscopy findings were not available for the vast majority of study subjects [72].

#### **Summary of Highlights**

This is a summary of the key recommendations from the variant tables. Refer to the complete narrative document for more information.

- Variants 1,2, and 4: For colorectal cancer screening for individuals of average risk 45 to 75 years of age or those with elevated risk (ie, family history of cancer, personal history of polyps, symptomatology, positive FIT), CTC without IV contrast is usually appropriate, whereas all other imaging studies including all CT abdomen/pelvis options and fluoroscopy (single/double contrast) are usually not appropriate. For incomplete colonoscopy or for those who cannot tolerate colonoscopy in individuals at average, elevated, or high risk, CTC without IV contrast is usually appropriate whereas other imaging options are usually not appropriate.
- **Variant 3:** For CRC screening for individuals at high risk, which is defined as having familial adenomatosis polyposis, hereditary nonpolyposis colorectal cancer, or inflammatory bowel disease, and can undergo colonoscopy, no imaging option including CTC without IV contrast should be used and falls in the usually not appropriate category.

#### **Supporting Documents**

The evidence table, literature search, and appendix for this topic are available at <a href="https://acsearch.acr.org/list">https://acsearch.acr.org/list</a>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, please go to the ACR website at <a href="https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria">https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria</a>.

#### **Gender Equality and Inclusivity Clause**

The ACR acknowledges the limitations in applying inclusive language when citing research studies that predates the use of the current understanding of language inclusive of diversity in sex,

intersex, gender, and gender-diverse people. The data variables regarding sex and gender used in the cited literature will not be changed. However, this guideline will use the terminology and definitions as proposed by the National Institutes of Health.

#### **Appropriateness Category Names and Definitions**

| Appropriateness Category Name        | Appropriateness<br>Rating | Appropriateness Category Definition  |
|--------------------------------------|---------------------------|--|
| Usually Appropriate                  | 7, 8, or 9                | The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable riskbenefit ratio for patients.   |
| May Be Appropriate                   |                           | The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal. |
| May Be Appropriate<br>(Disagreement) | 5                         | The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.                   |
| Usually Not Appropriate              | 1, 2, or 3                | The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.  |

#### **Relative Radiation Level Information**

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria Radiation Dose Assessment Introduction document.

### **Relative Radiation Level Designations**

| Relative Radiation Level*                    | Adult Effective Dose Estimate Range | Pediatric Effective Dose<br>Estimate Range |
|--|-------------------------------------|--|
| О  | 0 mSv                               | 0 mSv                                      |
| •  | <0.1 mSv                            | <0.03 mSv                                  |
| <b>②</b>                                     | 0.1-1 mSv                           | 0.03-0.3 mSv                               |
| <b>* *</b>                                   | 1-10 mSv                            | 0.3-3 mSv                                  |
| <b>※                                    </b> | 10-30 mSv                           | 3-10 mSv                                   |



\*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

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#### **Disclaimer**

determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

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