STATE OF MARYLAND

DHMH

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April 22, 2013

Dear Colleague,

Maryland continues to be a national leader in Public Health Screening for Colorectal Cancer.

- Between January 2000 and December 31, 2012 in the Cigarette Restitution Fund Program:
  - **23,196** people have been screened for CRC by one or more methods;
  - **8,356** FOBTs have been done (7% positive);
  - **181** sigmoidoscopies have been performed; and
  - **21,354** colonoscopies have been performed:
    - Adenoma(s) were found in 5,074 of the colonoscopies (24% of the total); and
    - 243 colonoscopies have found confirmed or suspected colorectal cancer and 88 have found adenoma(s) with high grade dysplasia.

Thanks to your ongoing help in screening patients from the public health programs and from the community, we continue to decrease Maryland's colorectal cancer incidence and mortality rates. **Maryland was #1 in the US for the rate of decrease in CRC incidence from 2003—2007** (Morbidity and Mortality Weekly Report. July 8, 2011 / Vol. 60 / No. 26).

Attached is your copy of the **revised March 2013 Minimal Elements for the Screening, Diagnosis, Treatment, Follow-up, and Education of Colorectal Cancer**, and a list of the major updates to the document. This update includes updates to the screening and surveillance guidelines and recall intervals (Attachments 1A and 1B).

Bowel Preparation

We are continuing to review the adequacy of bowel preparation as it is one of the most important factors in the detection of colorectal neoplasia. The Standards for Colonoscopy Reporting and Data System (CoRADS)* state that if a provider's rate of inadequate bowel prep is >10%, then "this may reflect a quality-control issue and indicate that special attention should be given to the method of patient instruction and the type of bowel preparation."

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Data in the past two years disclose that **420 (9.4%) of 4,485** colonoscopies in the screening program had **bowel prep considered <u>inadequate</u>** (Client Database 2/14/2013). While statewide our programs have achieved the goal of <10% inadequate, individual county CRF Programs ranged from **2.0% to 20.5%** of colonoscopies reported as having inadequate bowel prep. Variation among providers is also wide.

In order to assure that each person has been adequately screened for CRC, we ask that you evaluate your bowel preps and your rate of inadequate bowel prep. This may include reviewing the data that the programs provide you in the quality reports. Other information regarding bowel prep in our program:

1. **Our programs *WILL* pay for a repeat colonoscopy (or other indicated procedure, such as double contrast barium enema) right away if the endoscopist considers the colonoscopy to have been inadequate (either inadequate prep or not reaching the cecum).**
2. Attached is an information sheet on bowel preparation regimens for colonoscopy. We encourage you to consider prescribing the **split-dose regimen** where appropriate.

Serrated Polyps/ Lesions/Adenomas

We encourage you to speak with your pathologists concerning the diagnosis of serrated lesions such as sessile serrated polyps/adenomas and traditional serrated adenomas. The defining characteristics of these lesions have evolved, and they appear to lead to a number of colorectal cancers, especially right sided colon cancers. **The current Minimal Elements have updated recall intervals for serrated lesions including hyperplastic polyps, sessile serrated polyps, and traditional serrated adenomas.**

If you have questions or comments, please contact Dr. Diane Dwyer at 410-767-5088 or ddwyer@dhmh.state.md.us. Thank you again.

Sincerely,

Stanley Watkins, M.D.
Chairman, Medical Advisory Committee

Attachments

1. CRC Minimal Elements--Updates
2. CRC Minimal Elements, revised April 2013
3. Attachment 1A - Guidelines for Screening for Early Detection of Colorectal Polyps and Cancer
4. Attachment 1B - Guidelines for Recall Interval or Surveillance Interval following Colonoscopy
5. Fact Sheet on Colonoscopy Bowel Prep Regimens

Maryland Department of Health and Mental Hygiene
Colorectal Cancer: Updates to
Minimal Elements for Screening, Diagnosis, Treatment, Follow up, and Education
Updated April 2013

Summary of Major Updates by the Medical Advisory Committee in this version:

A. Updated the Minimal Elements

1. Pages 1 and 2: Includes information about not screening minors <18 funded by the program

2. Various sections and Attachment 1A include changes to risk based on family history.

   Screening at **40 years old (or 10 years before the earliest diagnosis in the FDR**, **whichever is earlier**) for those at increased risk due to family history should be performed for those who have one first degree relative[@] (FDR) at **<60** years old or two or more FDRs at any age who had:
   - colorectal cancer (CRC); or
   - adenoma(s) (see Note below); or
   - sessile serrated polyp(s); or
   - polyp(s) with unknown histology.

   And we added the note: "Note: A person who has one FDR at <60 years or two or more FDRs at any age who had a few small tubular adenoma(s) may be considered average risk and begin screening **at age 50** after shared decision making discussion with provider."

   Screening **at 50 years** for a person who has **one** FDR who was diagnosed at age **≥60 years** with CRC or adenomatous polyp(s) (or polyp of unknown histology).

3. Page 5, Histology, and Attachment 1B includes more information about serrated lesions

4. Page 5, Treatment, includes a statement about patients diagnosed with cancer that is consistent with the Maryland Comprehensive Cancer Plan:
   The local program or the medical care providers(s) may refer the patient to a cancer multidisciplinary team or may offer referral to another provider for a second opinion regarding treatment of the cancer diagnosed. The Maryland Comprehensive Cancer Control Plan (Chapter 9 Page 10: Goal 1, Objective 2, Strategy 1) has as a strategy: "Educate primary care providers to refer patients initially diagnosed with CRC to high volume surgeons and centers that have multidisciplinary cancer treatment teams, when possible."

5. Page 6-7, Education/Information, has new information including a link to American College of Surgeons Commission on Cancer accredited cancer programs

B. Attachment 1 has been revised and split into two documents:

1. Attachment 1A is the **Guidelines for Screening for Early Detection of Colorectal Polyps and Cancer**

a. Includes new information about what constitutes increased risk of colorectal cancer because of family history. (See A. 2., above.)

2. Attachment 1B is the **Guidelines for Recall Interval or Surveillance Interval following Colonoscopy for Early Detection of Colorectal Polyps and Cancer**

a. Specifies recall and surveillance intervals in a separate chart
b. Gives revised categories of findings and their recall intervals, for example for serrated lesions such as sessile serrated polyps
c. Gives revised recall intervals for hyperplastic polyps

C. Deleted Attachment 2 about staging of CRC. Staging is complex and beyond the scope of the Minimal Elements

Colorectal Cancer--Minimal Elements for Screening, Diagnosis, Treatment, Follow up, and Education

Center for Cancer Surveillance and Control, Maryland Department of Health and Mental Hygiene
November, 2000—Most Recent Update: April 2013

I. Screening

A. Detection for those at AVERAGE RISK of colorectal cancer (CRC):

Anyone age 50-75 years WITHOUT other personal, or family risk factors, and WITHOUT symptoms suggestive of CRC may be screened (see page 2 for testing those with increased risk or with symptoms).

Anyone >age 75 years may be screened if provider recommends screening after taking into account comorbidities, longevity, and past CRC screening results. Patients < age 18 years are not eligible for the CRF CRC program.

1. Screening with/by:

a. Colonoscopy (see Attachment 1A for initial screening and Attachment 1B for recall and surveillance intervals)

- Repeat colonoscopy in **10 years** for an average risk individual who has **a negative initial colonoscopy** that was considered "adequate" and who remains at **average risk**.

  This 10-year interval for those at average risk is recommended by the American Cancer Society, the American College of Gastroenterology, and the American Gastroenterological Association.

  > "This [10-year] interval is based on estimates of the sensitivity of colonoscopy and the rate at which advanced adenomas develop. The dwell time from the development of adenomatous polyps to transformation into cancer is estimated to be at least 10 years on average." *Winawer S, Fletcher R, Rex D, et al. CRC Screening and Surveillance: Clinical guidelines and rationale—Update based on new evidence. Gastroenterology 2003;124:544-560.*
  >
  > "There is now even stronger evidence to support the 10-year interval after negative findings on baseline colonoscopy for average-risk individuals, assuming that the baseline colon examination is complete with a good bowel preparation." *Lieberman DA, Rex D, Winawer SJ et al. Guidelines for colonoscopy surveillance after screening and polypectomy: A consensus update by the US Multi-Society Task Force on colorectal cancer. Gastroenterology 2012;143:844-857.*

- At about 5 years after the colonoscopy, asking an individual at average risk who had a negative colonoscopy about changes in family history, personal risk history, and symptom history may help determine whether the individual should have a colonoscopy **sooner** than the 10-year interval.

- Repeat colonoscopy in a **shorter interval** (see Attachment 1B for details) for a person who is **at increased risk (moderate or high risk)**--based on the colonoscopy findings (e.g., a large adenomatous polyp, villous histology, high grade dysplasia, sessile serrated polyp), or the family and personal risk or symptom history. (These follow up colonoscopies on people with prior neoplastic findings are called "surveillance" colonoscopies.)

- Repeat colonoscopy right away or in a **shorter interval,** or recommend a different screening method **if the colonoscopy was inadequate to visualize the entire colon** (e.g., poor bowel preparation; inability to reach the cecum, etc.).

OR

b. High sensitivity fecal occult blood tests (FOBT) (see IV.C., below) annually

OR

c. Flexible sigmoidoscopy (every 5 years) combined with a high sensitivity FOBT (every 3 years).

- If either the FOBT or sigmoidoscopy is positive, proceed to colonoscopy for diagnosis or treatment or both. If FOBT is positive, proceed directly to colonoscopy without doing a sigmoidoscopy.

2. Special situations

a. If the individual refuses a colonoscopy and sigmoidoscopy, offering screening with a high sensitivity FOBT is preferable to not screening.

- If FOBT is positive, proceed directly to further recommendation for colonoscopy; no need to repeat FOBT.
- If FOBT is negative, encourage a colonoscopy or sigmoidoscopy, and, if refused, encourage again at the time of the next annual FOBT.

b. **Fiscal Limitations:** Although screening with colonoscopy or FOBT/sigmoidoscopy are the most sensitive and specific methods for CRC screening, if Program monies are limited, annual FOBT, followed by colonoscopy if positive, is a less effective but acceptable strategy.

B. Detection for those at INCREASED RISK of colorectal cancer; namely, anyone with:

- Family history of genetic syndromes (familial adenomatous polyposis, hereditary non-polyposis colorectal cancer);
- Family history of colorectal cancer or certain adenomatous polyp(s) in one or more first degree relatives (i.e., parent, sibling, or child) (see Attachment 1A); or
- Personal history of adenomatous polyps (including serrated adenomas and sessile serrated adenoma/polyps), cancer of the colon, inflammatory bowel disease (ulcerative colitis, Crohn's disease), or woman with cancer of the ovary or endometrium diagnosed at <50 years of age. (Note: This group may include people who had a colonoscopy in which the polyp(s) was lost, polyp was not biopsied, or pathology was not available).

1. Screen with Colonoscopy at an age and on a schedule depending on risk category and prior findings (see Attachment 1A or 1B)

2. For individuals age 18, 19, or 20 years, consult with the person's primary care provider and the gastroenterologist regarding timing of initial screening and subsequent screenings (those <18 are not eligible for the program).

II. Testing those WITH SIGNS or SYMPTOMS of CRC:

Anyone with signs or symptoms suggestive of colorectal cancer (see Education/Information, page 6, below) should have a medical evaluation with further testing for CRC based on the history, symptoms, and physical examination and results of current or prior CRC testing.

III. Notes on Screening and Screening Procedures:

A. Colonoscopy is a screening test, but it is also a diagnostic test and/or a treatment procedure when lesions are identified and biopsied or removed.

B. The goal during colonoscopy is that all lesions identified as cancer or polyps (sessile or pedunculated) be excised and sent for pathologic examination.

The only exception to complete removal of polyps or lesions is

1) If the lesion is too large for excision
   Biopsy the lesion(s) and send for pathology; and
2) When numerous (>20) small polyps are encountered:
   Remove all polyps >= 1cm; Remove, if possible, all polyps 5 mm-9mm; Remove at least half the polyps < 5 mm; **and**
   Send all removed polyps for pathologic exam.

Pathology is necessary to determine whether cancer or adenomas were found; the pathology influences the individual's risk category for CRC, the individual's family members' risk of CRC, and the interval for repeat CRC testing (colonoscopy, etc.).

C. Tattoo the colon (e.g., at the site of removal of large sessile polyps, funny-looking pedunculated polyps) at the time of original colonoscopy. If pathology returns that the lesion was cancer or needs surgery and the area was *not* tattooed at the time of original colonoscopy, repeat the colonoscopy and tattoo the area before the colonic mucosa has healed so that the area can be identified at surgery.

D. CT colonography ("virtual colonoscopy") and stool DNA tests are now available, but there is insufficient evidence to recommend these as screening modalities. The MAC will review these emerging technologies on an annual basis.

E. Reserve double contrast barium enema (DCBE) or CT colonography for case-by-case situations (such as patient refusal of colonoscopy, anticoagulation, inability of the colonoscopy to reach the cecum) where patient and provider discuss and determine that DCBE or CT colonography is indicated for the individual. Client, provider, and payer should discuss the additional procedures needed to follow up on findings and the timing and type of future screenings recommended/covered.

F. Digital rectal exam (DRE) should be performed at the time of colonoscopy or sigmoidoscopy. A DRE may also be a component of other screening such as prostate screening in men or pelvic exams in women.

- Findings suggestive of CRC on DRE mean that the person needs referral for colonoscopy, etc. for evaluation of a palpated finding.

G. In-office fecal occult blood testing is **not recommended**.

IV. Results (for purposes of the public health screening program):

A. Colonoscopy

1. Adequacy of Colonoscopy:

a. "Adequate" colonoscopy is defined as reaching the cecum AND having bowel preparation sufficient to visualize polyps >5mm.

b. The **colonoscopist's report** should detail whether the cecum was reached and whether the endoscopist visualized the colonic mucosa "adequately," in the judgment of the endoscopist, for repeat in an interval specified by the endoscopist (e.g., 1 year, 3, 5, 10, years, etc.). The Quality Assurance Task Group and the Multi-Society Task Force-CRC recommend a simple method of reporting based on the *adequacy of examination for the detection of lesions larger than 5 mm*.

2. Findings of Colonoscopy:

a. Colonoscopist Report:

Colonoscopist's report of optical colonoscopy findings including polyp(s), mass, lesion/tumor, other lesions (hemorrhoids, diverticular disease, varices, inflammatory bowel disease [ulcerative colitis, Crohn's colitis])

- **Including**:
  - Number of lesions
  - **Description** (e.g., flat, raised, pedunculated, bleeding, irregular, etc.), **size**, and **location** of lesion(s) seen
  - Whether there was:
    - biopsy during colonoscopy *with* removal of entire lesion(s);
    - biopsy *without* removal of entire lesion(s);
    - no biopsy during colonoscopy; and
    - other management of polyp/lesion (tattoo of site; saline lift prior to biopsy, etc.)
  - Whether additional surgery or procedure is needed at this time (specify what is needed), or that there is no need for additional surgery or procedure at this time
  - Whether referral for genetic testing is recommended

3. **Colonoscopist's recommendation for date of next colonoscopy** or other testing based on the adequacy of the colonoscopy, the optical findings, the results of pathology, and the client's risk category.

   Note: Findings, such as adenomas, Crohn's colitis, or ulcerative colitis, will change the risk category of the patient and he/she will need more frequent screening (see Attachment 1B).

4. **Pathologist Report:**
   - Pathologist report of histologic findings on specimen(s) submitted (see VII. Histologic Classification, below)

B. Flexible Sigmoidoscopy:

See Colonoscopy, above regarding Adequacy and Findings.

Note: Biopsy during flexible sigmoidoscopy is not required because any patient with findings suggestive of polyps or colorectal cancer should be referred for colonoscopy, at which time a biopsy will be performed; therefore, whether a polyp is adenomatous or not will be determined based on biopsy during future colonoscopy. However, if a biopsy *is* performed during sigmoidoscopy and the polyp(s) is (are) hyperplastic, further colonoscopy may not be necessary, but an FOBT is necessary to screen the remainder of the colon, if not already performed. If an adenoma is found, then a complete colonoscopy is indicated as follow up.

Note: Diagnosis of Crohn's colitis or ulcerative colitis will change the risk category of the patient and he/she will need more frequent screening (see Attachment 1B).

C. High sensitivity fecal occult blood stool test (FOBT) such as Hemoccult SENSA or Fecal Immunochemical Test (FIT)

Positive = one or more test is positive for fecal blood
Negative = each test in the kit is negative for fecal blood

V. Follow up of screening findings:

A. If result of the FOBT/FIT is positive or if sigmoidoscopy has findings other than hemorrhoids/diverticula perform colonoscopy promptly for diagnosis, treatment, or both.

B. If colonoscopy is positive or possibly positive, proceed with additional diagnosis and treatment, per clinician and guided by Attachment 1B recommendations.

C. If results are negative for polyps and colorectal cancer, the individual may need to be referred for follow up of other medical conditions found on FOBT/FIT, colonoscopy, or flexible sigmoidoscopy that are not covered by the local cancer program.

VI. Diagnosis / Further Evaluation

A. Excise or, if too large for excision, biopsy all suspicious lesions/polyps during colonoscopy (an exception is when numerous [>20] small polyps are encountered, obtain representative biopsies [see III. B., above]), retrieve, submit for pathologic diagnosis, and manage based on findings.

B. If numerous polyps found, consider referral for genetic testing and, potentially, colectomy.

C. Based on the findings of above testing, the **following *may* be indicated** for evaluation and staging:

History and Physical Exam including pelvic exam
Blood testing
Carcinoembryonic antigen (CEA)
HIV testing (esp. anal cancers)
Chest X-ray
Genetic Testing
Other tests including CT scan, MRI, endoluminal ultrasonography, cystoscopy

D. Note: An individual with other findings/conditions identified on screening or diagnostic evaluation that are **not** covered by the local cancer program may need to be referred for follow up or linked to care.

VII. Histologic Classification of Polyp or Tumor

A. Specimens should be classified as: normal; polyp; carcinoma; or other finding (specify).

B. A polyp or lesion should be classified by:

1. Type of polyp or lesion: tubular adenoma; villous adenoma; tubulovillous adenoma; serrated polyp or lesion; sessile serrated polyp, traditional serrated adenoma, other (hyperplastic polyp, mucosal polyp, inflammatory, pseudopolyp, submucosal polyp [variety of lesions], lipoma, carcinoid, lymphoma, metastatic tumor, etc.).
2. Degree of dysplasia for adenomas: low grade dysplasia (mild dysplasia, moderate dysplasia), high grade dysplasia (including severe dysplasia, carcinoma in situ, and intramucosal carcinoma). Please identify degree of dysplasia (if present) in sessile serrated polyps/serrated adenomas.
3. Presence of involvement of stalk/margin: If neoplasia is present, determine whether the stalk or margin of the specimen is free of involvement.

C. An invasive carcinoma on biopsy or polypectomy specimen should be classified as follows:

1. Differentiation: Note whether the carcinoma is well, moderately, or poorly differentiated
2. If carcinoma is **arising in adenomatous polyp**:
    a. Presence or absence of lymphatic/vascular invasion
    b. Margins: Note whether the margin is involved; distance of the carcinoma from the margin/stalk, or distance of the carcinoma from the cauterized margin of the specimen.

VIII. Staging

Stage of disease: Based on biopsy results, diagnostic tests, surgical findings, and pathology, the stage of disease should be determined for the individual patient. This should include the American Joint Committee on Cancer (AJCC) staging by TNM classification of the tumor, nodes, and metastases.

IX. Treatment

Based on the findings on colonoscopy or other screening/diagnostic tests and the further evaluation, the usual and customary treatments will be recommended by the medical care provider(s) on a case-by-case basis. These treatments include:

No further treatment necessary
Ablation or excision of lesions during colonoscopy
Surgery
Chemotherapy
Radiation Therapy

The local program or the medical care providers(s) may refer the patient to a cancer multidisciplinary team or may offer referral to another provider for a second opinion regarding treatment of the cancer diagnosed. The Maryland Comprehensive Cancer Control Plan (Chapter 9 Page 10: Goal 1, Objective 2, Strategy 1) has as a strategy: "Educate primary care providers to refer patients initially diagnosed with CRC to high volume surgeons and centers that have multidisciplinary cancer treatment teams, when possible."

X. Follow-Up Recall and Surveillance Intervals (see Attachment 1B)

A. Follow-up colonoscopy and other testing when no colorectal cancer found

1. Inadequate colonoscopy (or other procedure):

If a provider determines that the colonoscopy (or other procedure) is "inadequate," the provider should determine whether additional procedures are necessary to complete this screening for CRC (e.g., repeating the colonoscopy, doing a DCBE, having the client submit an FOBT to screen the remainder of the colon in a person with average risk and no symptoms, etc.). Based on the findings and the type of "inadequacy," determine how soon the additional testing is needed, notify the client, and work with the program to determine when the client and provider can arrange the additional testing.

2. **Average Risk:**

   An individual of average risk who had a **negative** screening colonoscopy (including individuals who had few rectal or sigmoid hyperplastic polyps) should have a follow up colonoscopy in 10 years (unless symptoms develop or family history changes during the interval) (see page 1 and Attachment 1B).

   An individual at average risk choosing to be screened with high sensitivity FOBT and/or sigmoidoscopy should have one of the following screening regimens; either a high sensitivity FOBT every year **OR** sigmoidoscopy every 5 years and high sensitivity FOBT every 3 years, from age 50. Clients should be re-interviewed at each encounter to see if symptoms developed or risk category changed.

   An individual screened **only** with high sensitivity FOBT should receive and complete an **annual** high sensitivity FOBT. S/he should be encouraged to complete screening with visualization of the colon (colonoscopy or flexible sigmoidoscopy); **if colonoscopy is performed, annual FOBT testing is unnecessary.**

3. **Increased Risk:** See Attachment 1B for the recommended interval for follow-up colonoscopies for individuals at increased risk of colorectal cancer based on risk category and prior findings.

4. **Symptoms:** An individual who develops signs or symptoms of colorectal cancer should be evaluated by a health care provider and should not wait for the next scheduled screening to receive medical evaluation.

B. Colorectal cancer: Follow up visits and examinations per medical case manager and Attachment 1B.

XI. Education / Information

Education about colon cancer to a patient or to the public should include information about:

A. Risk factors:

- Age (increased risk with age especially 50 years and above)
- Family history of colorectal cancer or certain adenomatous polyp(s), especially in first degree relative under age 60 years
- Personal history of inflammatory bowel disease (ulcerative colitis, Crohn's colitis); colorectal cancer; adenomatous polyps; or cancer of the ovary or endometrium diagnosed under age 50 years
- Diets high in total fat, protein, calories, alcohol, and meat (both red and white meat) and low in calcium and folate are associated with an increased incidence of CRC
- Cigarette smoking is associated with an increased tendency to form adenomas and to develop CRC

B. Symptoms/signs:

- Microcytic (iron deficiency) anemia not explained by other condition (e.g., menstruation, blood donation, etc.)
- Unexplained abdominal mass
- Bleeding from rectum or blood in stool
- Occult blood in stool identified by fecal occult blood tests
- Abdominal cramps or pain
- Change in bowel habits including "penciling" of stools (narrowing of stool caliber)
- Note: these symptoms can also be caused by something other than colorectal cancer like an ulcer, or hemorrhoids. If person has these symptoms for the first time, advise them to talk to their doctor

C. Screening and diagnostic tests available:

- Tests that detect adenomatous polyps and cancers: colonoscopy; flexible sigmoidoscopy; double contrast barium enema; CT colonography (virtual colonoscopy)

- Tests that primarily detect cancer: high sensitivity fecal occult blood testing (guaiac FOBT or fecal immunochemical test [FIT]); stool DNA

D. Prevention:

- The following are excerpts from the Everyday Choices from the American Cancer Society, the American Heart Association, and the American Diabetes Association (2013 http://www.everydaychoices.org/index.html) (not specific to CRC):
  - Eat Healthy
  - Get Active
  - Don't Smoke
  - See Your Doctor

E. Available medical services and telephone numbers to call for referral are available from local programs; the American College of Surgeons, Commission on Cancer (CoC) Web site, http://www.facs.org/cancerprogram/index.html, offers the ability to find a CoC accredited cancer program near the person

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Attachment 1A: Guidelines for Screening for Early Detection of Colorectal Polyps and Cancer

Attachment 1B: Guidelines for Routine Recall Interval or Surveillance Interval Following Colonoscopy for Early Detection of Colorectal Polyps and Cancer

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Colorectal Cancer Medical Advisory Committee - - 2013

The following members participated in the formulation of the Minimum Elements and its current Update:

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Attachment 1A: Guidelines for Screening for Early Detection of Colorectal Polyps and Cancer+
Colorectal Cancer (CRC) Medical Advisory Committee, Maryland Department of Health and Mental Hygiene
March 2013

Begin screening based on a person's CRC Risk Category (Column 1)

CRC Risk Category	Screening Recommendation	Age to Begin**	Interval for Next Colonoscopy	References
Average Risk				
A person who is asymptomatic and **not** at increased risk because of family or personal history (as noted below)	Colonoscopy (preferred) or Alternative CRC screening such as annual fecal immunochemical test (FIT) or high sensitivity guaiac fecal occult blood test (FOBT) or sigmoidoscopy with FOBT/FIT, followed by colonoscopy if positive*	Age 50 years	See Attachment 1B	1, 2, 5
Increased Risk: Family History				
A person who has one first degree relative[@] (FDR) at **<60** years old or two or more FDRs at any age who had: • colorectal cancer (CRC); or • adenoma(s) (see Note below); or • sessile serrated polyp(s); or • polyp(s) with unknown histology. **Note:** A person who has one FDR at **<60** years or two or more FDRs at any age who had a few small tubular adenoma(s) may be considered average risk and begin screening at age 50 after shared decision making discussion with provider	Colonoscopy	Age 40 years or 10 years before the youngest case in the family, whichever is earlier Age 50 years[@@]	See Attachment 1B	2, 5
A person who has **one** FDR who was diagnosed at age **≥60 years** with CRC or adenomatous polyp(s) (or polyp of unknown histology)	Colonoscopy	Age 50 years	See Attachment 1B	2, 5

CRC Risk Category	Screening Recommendation	Age to Begin**	Interval for Next Colonoscopy	References
Increased Risk: Personal history of endometrial/ovarian cancer or personal history of radiation to colon or rectum				
A woman with a personal history of cancer of the ovary or endometrium diagnosed at <50 years old[&]	Colonoscopy	At time of diagnosis of ovarian or endometrial cancer	See Attachment 1B	5
A person with a personal history of radiation to colon or rectum (that is radiation to pelvis, prostate, cervix, or uterus that involved the colon or rectum, or radiation directly to colon or rectum)	Colonoscopy	Age appropriate for CRC risk category, or begin 3-5 years after radiation, whichever is earlier.	See Attachment 1B	5
Increased Risk: High Risk				
A person diagnosed with familial adenomatous polyposis (FAP) or who is at risk of FAP based on family history (and genetic testing has not been performed)	Early surveillance with flex sig or colonoscopy, counseling to consider genetic counseling and testing, and referral to a specialty center	Age 10-12 years	See Attachment 1B	1, 2, 3, 5
A person with a family history of hereditary non-polyposis colon cancer (HNPCC) or family history consistent with HNPCC	Colonoscopy and counseling to consider genetic testing	Age 20 to 25 years, or 10 years before the youngest case in the immediate family	See Attachment 1B	1, 2, 3, 5
A person with a personal history of inflammatory bowel disease (IBD): ulcerative colitis (pancolitis/left-sided colitis); or Crohn colitis	Colonoscopy with biopsies for dysplasia	8-10 years after the start symptoms of IBD	See Attachment 1B	1, 4, 5
Personal history of **CRC--curative-intent resection of invasive colorectal adenocarcinoma**	Colonoscopy if not performed at the time of diagnosis		See Attachment 1B	5
Personal history **of anal cancer** (for example, squamous cell carcinoma)	Colonoscopy if not performed at the time of diagnosis		See Attachment 1B	5
Personal history of **carcinoid, cloacogenic carcinoma, squamous cell cancer of rectum,** or other non-adenocarcinomas of colon or rectum	Colonoscopy if not performed at the time of diagnosis		See Attachment 1B	5

References for Recommendations:

1. American Cancer Society. Colorectal cancer early detection. Last revised January 24, 2013. Available at http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/index. Accessed February 13, 2013.
2. Rex DK, Johnson DA, Anderson JC, et al. American College of Gastroenterology guidelines for colorectal cancer screening. Am J Gastroenterol 2009:104;739-750.
3. Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA Cancer J Clin*. 2008;58;130–160.
4. Itzkowitz SH, Present DH; Crohn's and Colitis Foundation of America Colon Cancer in IBD Study Group. 2005. Consensus conference: Colorectal cancer screening and surveillance in inflammatory bowel disease. Inflamm Bowel Dis. 2005 Mar; 11(3):314-21.
5. Recommendations from the Maryland Colorectal Cancer Medical Advisory Committee, 2013 or prior years.

***** Each positive fecal blood test (FIT or gFOBT) needs to be followed up with a colonoscopy to complete the screening. In-office FIT or gFOBT using stool from the digital rectal exam are NOT recommended. Reserve double contrast barium enema (DCBE) and CT colonography for screening in situations where client and provider discuss and determine that the DCBE or CT colonography is indicated for the individual client; client, provider, and payer should discuss the additional procedures needed to follow up on findings and agree to the timing and type of future screenings recommended/covered based on risk and findings. See Minimal Elements Section I. A. for more details on tests and schedules.

@ A "first degree relative" is a mother, father, sister, brother, or child of the person.

@@ Age to begin screening may be individualized based on the strength of the family history, whether the details of the findings are known or unknown, the endoscopist's clinical judgment, and shared decision making with the patient and provider.

& Women with ovarian or endometrial cancer diagnosed at age 50 years or older should be considered average risk for screening unless they have other risk factors.

** The program funded by Cigarette Restitution Fund only screens adults 18 years and older. If screening is recommended for a person under age 18, the person should be referred outside of the program.

Attachment 1B: Guidelines for Routine Recall Interval or Surveillance Interval following Colonoscopy for Early Detection of Colorectal Polyps and Cancer
Colorectal Cancer (CRC) Medical Advisory Committee, Maryland Department of Health and Mental Hygiene
March 2013

Identify the person's *Most Advanced Findings* on Last Colonoscopy (first column), and read across for the Recommendation for Recall Interval or Surveillance Interval for next Colonoscopy

Last Colonoscopy: Most Advanced Findings	Recommended RECALL or SURVEILLANCE Interval	References
No adenomatous, serrated, or hyperplastic polyp(s) or findings as specified in the categories below, *and* **adequate** colonoscopy	Colonoscopy in **10 years** if **Average Risk***. **If *family history*** of CRC or adenoma(s) (especially large [≥1 cm] adenomas and those with high grade dysplasia, villous histology, or serrated features) then repeat colonoscopy in **5 years**. **If *personal history*** of colonoscopy findings but *this most recent colonoscopy* is negative, consult with endoscopist on interval recommended for next colonoscopy.	1, 9
New symptoms or change in symptoms suggesting CRC, *regardless* of prior screening or colonoscopy findings	Test for CRC based on clinician judgment.	
"**Inadequate colonoscopy**," that is, colonoscopy did not reach cecum or one in which the patient had inadequate bowel preparation regardless of CRC risk category	Repeat colonoscopy within one year; assure adequate bowel preparation before repeat test or other procedure. If client has symptoms suggestive of CRC or has increased risk of CRC, repeat as soon as reasonably possible. Based on patient's risk, the adequacy of the colonoscopy through the sigmoid, and the findings, the clinician(s) may recommend an alternate CRC screening method and interval, such as annual FIT/gFOBT until colonoscopy is repeated.	1, 9
Uncertain removal, that is: Sessile (broad based) or flat adenoma(s) that are removed piecemeal OR Pathological evidence of incomplete removal of an adenoma OR Where endoscopist is uncertain that the polypectomy was complete	Consider colonoscopy at **short interval (2-6 months)** to verify complete removal. Once complete removal has been established, the subsequent surveillance interval should be individualized based on the histologic diagnosis and the endoscopist's clinical judgment.	2, 3, 9

Last Colonoscopy: Most Advanced Findings	Recommended RECALL or SURVEILLANCE Interval	References
Findings of Polyp(s) on Prior Colonoscopy		
Polyp(s) of unknown size or unknown histology (e.g., ablated polyps, polyps that were lost; or polyps with histology "unknown" after attempts to obtain the information from prior endoscopist or patient's primary care provider)	Colonoscopy **within 5 years** of initial polyp(s) removal (number of years based on information on number, size, etc. and judgment of the clinician(s)) If subsequent colonoscopy normal or only hyperplastic polyps found, then screening as per Average Risk* recommendations	9
1-2 small (<10 mm) tubular adenomas	Colonoscopy in 5-10 years (timing within the 5-10 year interval should be based on other clinical factors such as prior colonoscopy findings, family history, and preferences of the patient and judgment of the physician)	1,9
3-10 small (<10 mm) tubular adenomas	Colonoscopy in no more than 3 years	
>10 adenomas, any size or histology	Colonoscopy in <3 years based on endoscopist's clinical judgment	
Tubular adenoma(s), ≥10 mm size	Colonoscopy in no more than 3 years	
Villous adenoma(s) (or tubulovillous)	Colonoscopy in no more than 3 years	
Adenoma(s) with high grade dysplasia^	Colonoscopy in no more than 3 years	
Sessile serrated polyp(s), <10 mm with no dysplasia	Colonoscopy in no more than 5 years	
Sessile serrated polyp(s), ≥10 mm OR Sessile serrated polyp(s) with dysplasia OR Traditional serrated adenoma(s)	Colonoscopy in no more than 3 years	
Serrated polyposis syndrome** (multiple or large **hyperplastic polyps** suggestive of serrated polyposis syndrome (formerly called hyperplasic polyposis syndrome))^	Colonoscopy every 6-12 months. These clients are best referred to a center with experience in the management of this syndrome)	9
Hyperplastic polyp(s), any number, <10 mm in size, in rectum or sigmoid	Colonoscopy in 10 years	1, 4, 9

Last Colonoscopy: Most Advanced Findings	Recommended RECALL or SURVEILLANCE Interval	References
Hyperplastic polyp(s), few (~1-3) in number, < 6 mm in size, **proximal** to the sigmoid	Colonoscopy in 10 years	9
Hyperplastic polyp(s)**, few (1-3) in number, 6-9 mm in size, proximal to sigmoid; OR Hyperplastic polyp(s), four or more, <10mm in size, proximal to sigmoid colon	Colonoscopy in 5 years	4, 9
Hyperplastic polyp(s) one or more, large (>= 10 mm) hyperplastic polyp(s) anywhere in colon	Colonoscopy[&] **in no more than 3 years** after initial polyp removal	9
Increased Risk: Personal history of endometrial or ovarian cancer, or personal history of radiation to pelvis, colon, or rectum		
Personal history of cancer of the ovary or endometrium diagnosed at <50 years old	If no CRC or adenomas on screening, **repeat colonoscopy every 3-5 years** (or sooner if findings). Consider genetic testing for Lynch Syndrome (HNPCC)	9
Personal history of radiation therapy to colon or rectum (e.g., radiation to pelvis, prostate, cervix, uterus, colon, rectum, etc.)	If no CRC or adenomas on screening, **repeat colonoscopy in 3-5 years** (or sooner if findings)	9

Baseline or Last Colonoscopy--Most Advanced Findings, or Genetic Syndrome	Recommended RECALL or SURVEILLANCE Interval	References
Increased risk—High Risk		
Patients with known familial adenomatous polyposis (FAP)	**These clients are best referred to a center with experience in the management of FAP who will make the recommendations**	9
Family history of hereditary non-polyposis colon cancer (HNPCC) or family history consistent with HNPCC	If genetic test positive or if client has not had genetic testing, colonoscopy every 1-2 years until age 40, then every year. **These clients are best referred to a center with experience in the management of HNPCC who will make the recommendations**	5, 9
Personal history of inflammatory bowel disease (IBD): ulcerative colitis and Crohn's colitis	**Clients are best referred to a center with experience in the surveillance and management of IBD, number of biopsies needed, frequency of repeat colonoscopy, etc.** Colonoscopy every1-2 years if left sided colitis OR every year if pancolitis Colonoscopy every 5 years if client is found to have *only* proctitis or proctosigmoiditis with biopsies negative for colitis proximal to 35 cm	6, 9
Personal history of **CRC--curative-intent resection of invasive colorectal adenocarcinoma**	a. Make sure the colon and rectum are clear of other existing neoplasia during the perioperative period (if non-obstructed, check the entire colon with colonoscopy; if obstructed, check the entire colon with DCBE or CT colonography pre-operatively and with colonoscopy 3-6 months post op) b. After clearing the colon of other existing lesions and treating the CRC, perform colonoscopy in **1 year** c. If normal at that time, perform colonoscopy[&] in **3 years** d. If still normal, perform colonoscopy[&] in **3-5 years** e. If **rectal** cancer, consider endoscopic ultrasound or flexible sigmoidoscopy at 3-6 month intervals for the first two years after resection in addition to the above. Shorter intervals may be indicated based on findings or on patient's age, family history, or tumor testing indicating possible HNPCC	7, 3, 9

Baseline or Last Colonoscopy--Most Advanced Findings, or Genetic Syndrome	Recommended RECALL or SURVEILLANCE Interval	References
Personal history **of anal cancer** (for example, squamous cell carcinoma)+	**Surveillance for CRC** a. Make sure the colon and rectum are clear of other existing neoplasia during the perioperative period (if non-obstructed, check the entire colon with colonoscopy; if obstructed, check the entire colon with DCBE or CT colonography pre-operatively and with colonoscopy 3-6 months post op) b. Full colonoscopy should be repeated every 5 years or earlier based on findings other than anal cancer (that is, family history or personal history of adenocarcinoma, adenomas, etc.) **Surveillance for further anal cancer** c. Perform digital rectal exam (DRE) between 8-12 weeks after completion of primary treatment with chemotherapy. d. If complete remission, perform DRE, anoscopy, and inguinal node palpation every 3-6 months for 5 years. If T3-T4 or inguinal node positive, consider chest x-ray, pelvic CT annually for 3 years. e. If persistent disease or progressive disease after treatment, treatment and follow up per Medical Case Manager.	8, 9
Personal history of **carcinoid, cloacogenic carcinoma, squamous cell cancer of rectum,** etc.+ [&]	Surveillance for CRC and surveillance for the carcinoid, cloacogenic carcinoma, or squamous cell cancer of rectum per Medical Case Manager recommendation+	9

References for Recommendations:

1. Lieberman DA, Rex DK, Winawer SJ, et al. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on CRC. Gastroenterol. 2012:143;844-857.
2. Winawer SJ, Zauber AG, Fletcher RH, et al. Guidelines for colonoscopy surveillance after polypectomy: A consensus update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society. CA Cancer J Clin 2006; 56:143-159. Note: The US Multi-Society Task Force guidelines have been endorsed by the Colorectal Cancer Advisory Committee of the American Cancer Society and by the governing boards of the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.
3. American Cancer Society. Colorectal cancer early detection. Last revised January 24, 2013. Available at http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/index. Accessed February 13, 2013.
4. Rex DK, Ahnen DJ, Baron JA, et al. Serrated lesions of the colorectum: Review and recommendations from an expert panel. Am J Gastroenterol. 2012:109;1315-29.
5. Rex DK, Johnson DA, Anderson JC, et al. American College of Gastroenterology guidelines for colorectal cancer screening. Am J Gastroenterol 2009:104;739-50.
6. Itzkowitz SH, Present DH; Crohn's and Colitis Foundation of America Colon Cancer in IBD Study Group, 2005. Consensus conference: Colorectal cancer screening and surveillance in inflammatory bowel disease. Inflamm Bowel Dis. 2005 Mar; 11(3):314-21.
7. Rex DK, Kahi CJ, MD, Levin B, et al. Guidelines for colonoscopy surveillance after cancer resection: A consensus update by the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer. CA Cancer J Clin 2006;56:160–7.
8. National Comprehensive Cancer Network. NCCN Clinical practice guidelines in oncology. Anal Carcinoma. V.2 2013.
9. Recommendations from the Maryland Colorectal Cancer Medical Advisory Committee, 2013.

* "Average Risk" (see Attachment 1A) is a person **without** any of the following: a family history of CRC or advanced adenomas, or a personal history of CRC, adenomas, inflammatory bowel disease, genetic syndrome, ovarian/endometrial cancer before age 50.

** Definition of serrated polyposis syndrome (formerly called hyperplastic polyposis) is: (1) at least five histologically diagnosed hyperplastic and/or serrated polyps proximal to the sigmoid colon of which 2 are greater than 1 cm in diameter, or; (2) any number of serrated and/or hyperplastic polyps occurring proximal to the sigmoid colon in an individual who has a first-degree relative with serrated (or hyperplastic) polyposis, or; (3) greater than 20 serrated and/or hyperplastic polyps of any size distributed throughout the colon.

+ Recommendations for rescreening intervals for adenocarcinoma of the colon and rectum and counseling of risk for cancer that is *other than adenocarcinoma* should be made by the Medical Case Manager (examples include squamous cell carcinoma of rectum/anus, carcinoid, cloacogenic carcinoma)

^ "High grade dysplasia" includes severe dysplasia, carcinoma in situ, and intramucosal carcinoma.

& In some cases when only the rectum and sigmoid need examination to view the site of prior findings, a sigmoidoscopy is sufficient for screening instead of a full colonoscopy.

Bowel Preparation Regimens for Colonoscopy:

Information for the Provider

Maryland Dept. of Health and Mental Hygiene, Center for Cancer Prevention and Control

March 2013

Colorectal cancer is the third most common cancer and the second leading cause of cancer-related deaths in the United States. Through the use of colonoscopy and other screening techniques, many colorectal cancers can be prevented or treated at an early stage. A 2012 study published in the *New England Journal of Medicine* estimated a 53% reduction in mortality from colorectal cancer with colonoscopic polypectomies of adenomas[1].

The goal of Bowel Preparation is to prepare the colon for colonoscopy by removing all fecal material. Prior to the procedure, liquid coming from the bowel should look like clear water.

"Traditional Bowel Preparations Dosing" refers to:

- A patient typically consumes 3-4 liters of a bowel prep solution
- The preparation acts as an oral lavage
- It is consumed in entirety on the **night prior** to the procedure
- Side effects secondary to the large volume include nausea, vomiting, and bloating.

Reports about Traditional Bowel Preparation estimate that up to:

- 15% of patients do not complete the regimen[2]
- 25% of patients have poor bowel preparation resulting in missed lesions, increased cost, and adverse events[3]

In order to improve the quality of colonoscopy and the tolerability of regimens, NEW dosing schedules including Split-Dose and Same-Day dosing regimens have been investigated.

A "Split-Dose Regimen" is defined as:

- A regimen in which the patient consumes **half** the preparation the **night prior** to the procedure
- The **second half** of the preparation is taken the **morning of the colonoscopy**, **3-5 hours before the procedure**

A "Same-Day Regimen" is defined as:

- A regimen ***for afternoon colonoscopies*** in which the patient starts and finishes the **entire** bowel preparation the **morning of the colonoscopy, 4-5 hours before the procedure.**
- No preparation is taken the day prior to the procedure

A meta-analysis found that **Split-Dose Regimen is superior to Traditional Dosing regimen with respect to colon cleansing, patient compliance, patient willingness to repeat the same bowel preparation in the future,**

[1] Zauber et al., Colonoscopic polypectomy and long term prevention of colorectal-cancer deaths. *N Engl J Med* 2012; 366:687-696.

[2] Atreja A, Nepal S, Lashner BA., Making the most of currently available bowel preparations for colonoscopy. *Cleveland Clinic Journal of Medicine* 2010; 77(5):317-326;doi 10.3949/ccjm.77a.09122

[3] Dongen, M.V., Enhancing Bowel Preparation for Colonoscopy. *Gastroenterology Nursing* (2012) 35;36-44.

and reduction of nausea[4]. One study found that this dosing produced better mucosal cleaning with fewer side effects and less impact on ADLs[5].

Additional recent findings and recommendations:

- In 2008, the American College of Gastroenterology guidelines were updated to include Split-Dose regimens as a key measure for improving the quality and cost effectiveness of colonoscopies.[6] However, endoscopists have been hesitant to transition to Split-Dose regimen for fear of patient inconvenience and the potential risk of aspiration from oral ingestion 4-5 hours before the use of anesthesia.
- Individuals were surveyed about their willingness to awaken early to take the Split-Dose; 85% of those surveyed stated they would be willing to get up during the night to take a second dose of the preparation[7].
- One study showed that patients using Split-Dose were no more likely to stop to find a restroom on the way to their colonoscopy compared to their counterparts who used a Traditional Dosing Regimen[8].
- The American Society of Anesthesiologists states that a patient can ingest clear liquids 2 hours prior to a colonoscopy and a light meal 6 hours before the procedure with no increased risk of aspiration.[9]

Conclusion:

To ensure consistently good bowel preparation prior to colonoscopy, please consider Split-Dose and Same Day bowel preparation regimens.

Sample patient education materials can be found by Google searching "split dose colonoscopy prep instructions" to get examples such as this from University of Virginia
http://www.virginia.edu/uvaprint/HSC/pdf/03042.pdf

[4] Kilgore et al., Bowel Preparation with split-dose polyethylene glycol before colonoscopy: a meta-analysis of randomized controlled trials. *Gastrointestinal Endoscopy* (2011) 73:1240-1245.
[5] Longcroft-Wheaton G and Bhandari P., Same-Day Bowel Cleansing Regimen is Superior to a Split-Dose Regimen over Two Days for Afternoon Colonoscopy. *J Clin Gastroenterol* (2012)46:57-61
[6] Rex DK, FACG1 , Johnson DA, Anderson JC. American College of Gastroenterology guidelines for colorectal cancer screening 2008. *Am J Gastroenterol* 2009; 104:739-750
[7] Unger RZ et al., Willingness to Undergo Split-Dose Bowel Preparation for Colonoscopy and Compliance with Split-Dose Instructions. *Dig Dis Sci* (2010) 55:2030-2034.
[8] Khan MA, Piotrowski Z, Brown MD. Patient acceptance, convenience, and efficacy of single-dose versus split-dose colonoscopy bowel preparation. *J Clin Gastroenterol.* 2010;44:310-311
[9] Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration. Application to healthy patients undergoing elective procedures: a report by the American Society of Anesthesiologist Task Force on Preoperative Fasting. *Anesthesiology.* 1999;90:896–905.