STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

Family Health Administration
Russell W. Moy, M.D., M.P.H., Director – Joan H. Salim, Deputy Director

March 30, 2009

Dear Colleague,

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

- Between January 2000 and December 31, 2008 in the Cigarette Restitution Fund Program:
  - **16,737** people have been screened for CRC by one or more methods;
  - **8,328** FOBTs have been done (7% positive);
  - **148** sigmoidoscopies have been performed; and
  - **13,552** colonoscopies have been performed:
    - Adenoma(s) were found in 2,994 of the colonoscopies (22% of the total); and
    - 152 colonoscopies have found confirmed or suspected colorectal cancer and 53 have found adenoma(s) with high grade dysplasia.
- Between June 2005 and December 31, 2008, in the Baltimore City CDC CRC Screening Demonstration Program:
  - **578** people have been screened for CRC with colonoscopy
  - **616** colonoscopies have been performed
    - Adenomas found in 114 of the colonoscopies (19%)
    - 3 cancers and 1 high grade dysplasia have been identified.
- The Maryland Cancer Fund (*funded through donations on your Maryland Tax Form*) has additionally awarded funds for enhanced CRC screening to four programs in Maryland beginning in 2008.

Thanks to your ongoing help in screening patients from the public health programs and from the community, we will decrease Maryland's colorectal cancer incidence and mortality rates.

Attached is your copy of the revised March 2009 Minimal Elements for the Screening, Diagnosis, Treatment, Follow-up, and Education of Colorectal Cancer, and a list of the major updates.

Adequacy of bowel preparation is of ongoing interest to the program. 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."

Data in the past two years disclose that **637 (8.7%) of 7,311** first colonoscopies in the screening programs had **bowel prep NOT adequate** (Client Database 12/1/2008). Overall, our programs have achieved the goal of <10%. However, individual county CRF Programs ranged from **2.9% to 19.9%** of colonoscopies reporting inadequate prep on the first colonoscopy in a cycle. 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. Other information regarding bowel prep:

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.**
2. On December 11, 2008 the FDA released an alert regarding oral sodium phosphate (OSP) products and additional reports of acute phosphate nephropathy, a rare, but serious form of kidney failure, has been associated with the use of OSP products. The FDA noted that:
   - over-the-counter laxative OSP products should not be used for bowel cleansing; and
   - consumers should only use OSP products for bowel cleansing when prescribed by a healthcare professional.
3. Various other bowel preparation products are available. A consensus document on bowel preparation before colonoscopy is available at: http://www.guideline.gov/summary/summary.aspx?doc_id=9619&nbr=5139&ss=6&xl=999

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

*Standards for colonoscopy reporting and data system: Report of the Quality Assurance Task Group of the national Colorectal Cancer Roundtable were published in Gastrointestinal Endoscopy 2007;65:757-766.

Maryland Department of Health and Mental Hygiene
Colorectal Cancer: Updates to
Minimal Elements for Screening, Diagnosis, Treatment, Follow up, and Education
Updated March 2009

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

A. Updated the Minimal Elements

- Added note about screening people >75 years of age
- Added "serrated adenomas" with other types of adenomas
- Added information about the approach to patients who have large numbers of polyps (removal or sampling)

B. Updated Attachment 1

- Updated section on interval for repeat screening for people with inflammatory bowel disease
- Additional categories and screening/surveillance information added to Risk Category:
    - Personal history of anal cancer
    - Personal history of carcinoid, cloacogenic carcinoma, squamous cell cancer of the rectum

C. Deleted the former Attachment 2 (CRC Screening Tests) and renumbered Attachment on CRC Staging

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: March 2009

I. Screening

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

Anyone 50-75 years old 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 symptoms).

Anyone >75 years old may be screened if provider recommends screening after taking into account comorbidities, longevity, and past CRC screening results.

1. Screening with/by:

a. Colonoscopy

- 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.*

  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 1 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), or the family and personal risk or symptom history.

- 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. Fecal occult blood tests (FOBT) annually, and, if FOBT negative, flexible sigmoidoscopy every 5 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 an FOBT is preferable to not screening.

- If FOBT is positive, proceed directly to further recommendation for colonoscopy.
- 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 adenomatous polyp(s) in one or more first degree relatives (i.e., parent, sibling, or child);
- 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 1)**

2. **For individuals < 21 years old**, consult with the person's primary care provider and the gastroenterologist regarding timing of initial screening and subsequent screenings.

II. Testing those WITH SIGNS or SYMPTOMS of CRC:

A. Anyone with signs or symptoms suggestive of colorectal cancer (see Education/Information, page 6, below) should **NOT** be "screened;" rather the person needs a medical evaluation with further testing and screening intervals as indicated after history and physical examination.

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 or, if too large for excision, biopsied, and sent for pathologic examination

The only exception to complete removal is 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 these for pathology.

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.

G. A single in-office FOBT should **not** serve as the only screening for CRC but may be done using the stool remaining on the glove after a DRE, especially in situations where the client is unlikely to return.

- If in-office FOBT is positive, refer for colonoscopy.
- If in-office FOBT is negative (and DRE not being done in conjunction with colonoscopy,) give home FOBT or Fecal Immunochemical Test (FIT) kit (multi specimen tests) that tests defecated stools.

IV. Results (for purposes of this 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 disease of the colon])
   - **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 1).
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.

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

C. Guaiac FOBT (Home test kit; three fecal specimens with two samples "windows" from each specimen)

Positive FOBT = at least one test window is positive
Negative FOBT = all FOBT test kit windows (usually 6 windows) are negative

D. Immunochemical FOBT (Fecal Immunochemical Test, FIT)

Positive FOBT = at least one specimen is positive
Negative FOBT = all specimens are negative

V. Follow up of screening findings:

A. If result of the FOBT/FIT is positive or if sigmoidoscopy has findings other than hemorrhoids/diverticuli, perform colonoscopy for diagnosis, treatment, or both. If colonoscopy is positive or possibly positive, proceed with additional diagnosis and treatment, per clinician and guided by Attachment 1 recommendations.

B. 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. If results of the FOBT/FIT and/or sigmoidoscopy are positive, perform colonoscopy for diagnosis or treatment or both.

B. 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.

C. If numerous polyps found, consider genetic testing and, potentially, colectomy.

D. 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

E. 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; villo-tubular adenoma; serrated adenoma; sessile serrated adenoma/polyp, 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).
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. (See Attachment 2.)

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:

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

X. Follow Up (see Attachment 1)

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

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 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 1);

An individual at average risk choosing to be screened with FOBT/FIT and sigmoidoscopy should have an FOBT/FIT every year and sigmoidoscopy every 5 years from age 50 on, i.e., those who had a negative FOBT/FIT and negative flexible sigmoidoscopy in year 1, should have annual FOBTs/FITs for the following four years. Five years after the flexible sigmoidoscopy, the person should have an FOBT/FIT and another flexible sigmoidoscopy (unless symptoms develop or risk category changes).

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

3. **Increased Risk:** See Attachment 1 for the recommended interval for follow-up colonoscopies in 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 1.

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 and above)
- Family history of colorectal cancer or adenomatous polyps, especially in first degree relative <60
- Personal history of inflammatory bowel disease (ulcerative colitis, Crohn's disease), colorectal cancer, adenomatous polyps, or cancer of the ovary or endometrium under age 50
- 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 less serious than colorectal cancer like an ulcer, or hemorrhoids. If you have these symptoms for the first time, talk to a 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: fecal occult blood testing—guaiac-FOBT; fecal immunochemical test (FIT); stool DNA

D. Prevention:

- The following are excerpts from the General Prevention Guidelines for All Average Risk Adults from the American Cancer Society, the American Heart Association, and the American Diabetes Association (2004) (not specific to CRC):
    - Avoid all forms of tobacco.
    - Achieve and maintain a healthy weight.
    - Exercise for at least 30 minutes on 5 or more days a week.
    - Eat at least 5 servings of vegetables and fruits daily.

E. Available medical services and telephone numbers to call for referral

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Attachment 1: Guidelines for Screening and Surveillance for Early Detection of Colorectal Polyps and Cancer
Attachment 2: Staging—Classification of Colon/Rectal Cancer

Colorectal Cancer Medical Advisory Committee - - 2009

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

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Attachment 1: Guidelines for Screening and Surveillance for Early Detection of Colorectal Polyps and Cancer+ Colorectal Cancer (CRC) Medical Advisory Committee, Maryland Department of Health and Mental Hygiene March 2009

Identify the person's *most advanced* Risk Category (first column), and read across for the Recommendation

Risk Category	Recommenda-tion	Age to Begin	Interval[&]	Reference[+]
Inadequate Colonoscopy				
"Inadequate colonoscopy," that is, colonoscopy didn't reach cecum or paitent had inadequate bowel preparation; any risk category	Repeat colonoscopy or perform other screening, as recommended by provider		As soon as indicated by colonoscopist; assure adequate preparation before repeat test or other procedure [&]	
Average Risk[++]				
All people who are asymptomatic and **not** in the categories below[++]	Colonoscopy*	Age 50 years	Colonoscopy[&] **every 10 years**	Winawer-- US Multi-Society Task Force, Gastro 2003 Maryland CRC Medical Advisory Committee, 2006
People with small and limited number of rectal hyperplastic polyps^ [++]	Colonoscopy	At time of initial polyp diagnosis	Colonoscopy[&] **every 10 years**	Winawer-US Multi-Society Task Force and ACS, 2006
Increased Risk of Adenocarcinoma of the Colon or Rectum—Moderate Risk: Family History				
Colorectal cancer (CRC) or adenomatous polyp(s) (or polyp of unknown histology) in first degree relative[@] (FDR) at **<60** years old or in **two or more** FDRs of any ages	Colonoscopy	Age 40 years or 10 years before the youngest case in the family, whichever is earlier	Colonoscopy[&] **every 5-10 years**	ACS, 2003
CRC or adenomatous polyp(s) (or polyp of unknown histology) in **one** FDR who was diagnosed at age **≥60 years**	Colonoscopy	Age 40 years	As for Average Risk persons if no CRC or adenomas found	ACG, 2000

Risk Category	Recommendation	Age to Begin	Interval[&]	Reference[+]
Increased Risk: Personal history of endometrial or ovarian cancer				
Personal history of cancer of the ovary or endometrium diagnosed at <50 years old[@@]	Colonoscopy	At time of diagnosis of ovarian or endometrial cancer	If no CRC or adenomas on screening, **repeat every 3-5 years** (or sooner if findings)	Maryland CRC Medical Advisory Committee 2007
Increased Risk: Personal history of radiation therapy to colon or rectum				
Personal history of radiation therapy to colon or rectum (e.g., radiation to prostate, cervix, uterus, rectum, etc.)	Colonoscopy [&&]	Age appropriate for CRC risk category, or begin 3-5 years after radiation, whichever is earlier.	If no CRC or adenomas on screening, **repeat in 3-5 years** (or sooner if findings)	Maryland CRC Medical Advisory Committee 2007
Increased Risk—High Risk				
Family history of familial adenomatous polyposis (FAP)	Early surveillance with colonoscopy, counseling to consider genetic testing, and referral to a specialty center	Puberty	If polyposis is confirmed by genetic testing *and* colonoscopy or by colonoscopy alone, colectomy is indicated. These clients are best referred to a center with experience in the management of FAP	ACS, 2003
Family history of hereditary non-polyposis colon cancer (HNPCC)	Colonoscopy and counseling to consider genetic testing	Age 21	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.	**ACS, 2003**

Risk Category	Recommendation	Age to Begin	Interval[&]	Reference[+]
Personal history of inflammatory bowel disease (IBD): ulcerative colitis--pancolitis/left-sided colitis; and Crohn's colitis	Colonoscopy with biopsies for dysplasia	8 years after the start of pancolitis; 12-15 years after the start of left-sided 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 (every year if pancolitis) If client is found to have *only* proctitis or proctosigmoiditis with biopsies negative for colitis proximal to 35 cm, then colonoscopy every 5 years.	IBD Study Group, 2005[7] Maryland CRC Medical Advisory Committee, 2008
Increased Risk: Personal history of polyps—"Surveillance Colonoscopies"				
People with **sessile or flat adenomas that are removed piecemeal**; people with pathological evidence of **incomplete removal of an adenoma** or where endoscopist is uncertain that the polypectomy was complete	Colonoscopy	At time of initial polyp diagnosis	Consider follow-up at **short intervals (2-6 months)** to verify complete removal. Once complete removal has been established, subsequent surveillance should be individualized based on the endoscopist's judgment.	Winawer-US Multi-Society Task Force and ACS, 2006, Maryland CRC Medical Advisory Committee, 2008
People with **>10 adenomas** of any size	Colonoscopy	At time of initial polyp diagnosis	Colonoscopy at **less than 3 years**; interval based on clinical judgment	Winawer-US Multi-Society Task Force and ACS, 2006
People with • **one or more large adenoma(s) (>=1 cm);** • **3-10 adenomas of any size or histology; OR** • **1 or more adenomas of *any size* with:** o **villous or tubulovillous histology;** o **serrated adenoma histology; or** o **high grade dysplasia^^**	Colonoscopy	At time of initial polyp diagnosis	Colonoscopy[&] **in 3 years** after initial polyp removal; if this colonoscopy is negative for adenomas or CRC, or shows only 1-2 small tubular adenomas without high grade dysplasia then repeat colonoscopy **in 5 years**; if no adenomas then, the patient can thereafter be screened as per average risk guidelines	Winawer-US Multi-Society Task Force and ACS, 2006

Risk Category	Recommenda-tion	Age to Begin	Interval[&]	Reference[+]
People with **1-2 small (<1 cm), tubular adenomas with NO villous histology and NO high grade dysplasia**	Colonoscopy	At time of initial polyp diagnosis	Colonoscopy[&] **5-10 years** after initial polyp removal (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)	Winawer-US Multi-Society Task Force and ACS, 2006
People with multiple or large **hyperplastic polyps** suggestive of hyperplasic polyposis syndrome^	Colonoscopy	At time of initial polyp diagnosis	Colonoscopy every **6-12 months**. These clients are best referred to a center with experience in the management of this syndrome	Maryland CRC Medical Advisory Committee, 2006
People with one or more polyps of unknown size or histology (e.g., ablated polyps, polyps was lost; or histology still unknown after attempts to obtain the information from prior endoscopist or patient's primary care provider)	Colonoscopy	At time of initial polyp diagnosis	Colonoscopy **within 5 years** of initial polyp(s) removal (number of years based on information on number, size, etc. and judgment of the physician); if normal or only hyperplastic polyps found on that colonoscopy, then screening as per average risk recommendations, above	Maryland CRC Medical Advisory Committee, 2006

Risk Category	Recommenda-tion	Age to Begin	Interval[&]	Reference[+]
Increased Risk: Personal history of colorectal cancer—"Surveillance Colonoscopy"				
Personal history of **CRC--curative-intent resection of invasive colorectal adenocarcinoma**	Colonoscopy	At time of diagnosis	a. Clear colorectum of synchronous neoplasia in the perioperative period (if non-obstructed, clear with colonoscopy; if obstructed, DCBE or CT colonography pre-operatively and colonoscopy 3-6 months post op) b. After clearing for synchronous disease and treatment of CRC, perform colonoscopy in **1 year**. c. If normal, perform colonoscopy in **3 years** d. If still normal, colonoscopy in **5 years**[&] e. If **rectal** cancer, consider endoscopic ultrasound or flexible sigmoidoscopy at 3-6 month intervals for the first two years after resection. Shorter intervals may be indicated based on findings or on patient's age, family history, or tumor testing indicating possible HNPCC.	Rex--US Multi-Society Task Force and ACS, 2006

Risk Category	Recommenda-tion	Age to Begin	Interval[&]	Reference[+]
Increased Risk: Personal history of *other* cancers—"Surveillance Procedures"				
Personal history of anal cancer (for example, squamous cell carcinoma)	Colonoscopy	At time of diagnosis	**Surveillance for CRC** a. Clear colorectum of synchronous neoplasia in the perioperative period (if non-obstructed, clear with colonoscopy; if obstructed, DCBE or CT colonography pre-operatively and 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** a. Perform DRE between 8-12 weeks after completion of primary treatment with chemotherapy. b. 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. c. If persistent disease or progressive disease after treatment, perform inguinal node palpation and CT scan every 3-6 months for 5 years.	NCCN v,1,2008 http://www.nccn.org/professionals/physician_gls/PDF/anal.pdf and per Medical Case Manager surgeon/oncologist/ radiation oncologist Maryland CRC Medical Advisory Committee, 2008
Personal history of carcinoid, cloacogenic carcinoma, squamous cell cancer of rectum, etc.			Surveillance for CRC and for the other cancer(s) per Medical Case Manager recommendation+++	Maryland CRC Medical Advisory Committee, 2008

+ **References for Recommendations:**

1. Smith RA, Cokkinides V, Eyre, HJ. American Cancer Society guidelines for early detection of cancer, 2003. CA Cancer J Clin 2003; 53:27-43.
2. Rex DK, Johnson DA, Lieberman DA, Burt, RW, and Sonnenberg A. Colorectal cancer prevention 2000: screening recommendations of the American College of Gastroenterology. Am J Gastroenterology 2000; 95: 868-877.
3. Rex DK, Bond JH, Winawer S, et al. Quality in the Technical Performance of Colonoscopy and the Continuous Quality Improvement Process for Colonoscopy: Recommendations for the US Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterology 2002; 97:1296-1308.
4. Winawer SJ, Fletcher R, Rex D, et al. Colorectal cancer screening and surveillance: Clinical guidelines and rationale—Update based on new evidence. Gastro 2003; 124:544-560.
5. 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 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.
6. Rex DK, Kahi CJ, Levin B, et al. Guidelines for colonoscopy surveillance after cancer resection: A consensus update by the American Cancer Society and US Multi-Society Task Force on Colorectal Cancer. CA Cancer J Clin 2006; 56:160-167. 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.
7. 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.

& Interval is based on the findings of an ***adequate*** colonoscopy and asymptomatic client. If the endoscopist either fails to reach the cecum ***or*** determines that the preparation of the colon was inadequate for visualization, the colonoscopy should be considered ***inadequate*** and the colonoscopy repeated as soon as feasible. Symptomatic patients should be screened for CRC based on clinician judgment. If there are findings, shorter screening intervals are allowed under CRF funding (e.g., per Medical Advisory Committee: people with family history of CRC in multiple FDR or <60 years of age may be screened every **5 years**; people with 2 small tubular adenomas may return **within 3** years; people with 1 small tubular adenoma may return at 5 years; people with large, multiple, or villous adenomas may return **within 3** for surveillance; and people with past CRC could continue colonoscopy at another 3 year interval).

++ Average risk includes those people found to have limited number of small **hyperplastic** (or serrated hyperplastic polyps) but not found to have adenomatous polyps or CRC.

***** 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. If chosen for screening and no findings, DCBE should be repeated in 5 years. Digital rectal exam should be performed at the time of colonoscopy or sigmoidoscopy.

^ Definition of hyperplastic polyposis suggested is: (1) at least five histologically diagnosed hyperplastic polyps proximal to the sigmoid colon of which 2 are greater than 1 cm in diameter, or; (2) any number of hyperplastic polyps occurring proximal to the sigmoid colon in an individual who has a first-degree relative with hyperplastic polyposis, or; (3) greater than 20 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.

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

&& In some cases when only the rectum and sigmoid need examination, a sigmoidoscopy is sufficient for screening.

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

Attachment 2

Classification of Colon/Rectal Cancer

References:

- Colon and rectum. In: American Joint Committee on Cancer: AJCC Cancer Staging Manual. 6th ed. 2002. Editors: Greene FL, Page, DL, Fleming ID, et al., Springer-Verlag, New York, Berlin, Heidelberg pp 113-119.
- Maryland Cancer Registry classification.
- Rex DK, Bond JH, Winawer S, et al. Quality in the Technical Performance of Colonoscopy and the Continuous Quality Improvement Process for Colonoscopy: Recommendations for the US Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterology 2002; 97:1296-1308.

AJCC/UICC				Comparison to Duke' or Modified Astler-Coller classifications	Comparison to SEER and Maryland Cancer Registry classification
Stage	**Tumor**	**Regional Lymph Nodes**	**Distant Metastasis**		
Stage 0*	Tis*	N0	M0	--	In situ
Stage I	T1	N0	M0	Dukes A or Modified Astler-Coller A	Localized
	T2	N0	M0	Dukes A or Modified Astler-Coller B1	
Stage IIA	T3	N0	M0	Dukes B or Modified Astler-Coller B2	Localized
Stage IIB	T4	N0	M0	Dukes B or Modified Astler-Coller B3	Regional
Stage IIIA	T1-T2	N1	M0	Dukes C or Modified Astler-Coller C1	
Stage IIIB	T3-T4	N1	M0	Dukes C or Modified Astler-Coller C2/C3	
Stage IIIC	Any T	N2	M0	Dukes C or Modified Astler-Coller C1/C2/C3	
Stage IV	Any T	Any N	M1	Dukes – or Modified Astler-Coller D	Distant

TNM Definitions

Primary tumor (T)

TX: Primary tumor cannot be assessed
T0: No evidence of primary tumor
*Tis: Carcinoma in situ: intraepithelial or invasion of the lamina propria
T1: Tumor invades submucosa
T2: Tumor invades muscularis propria
T3: Tumor invades through the muscularis propria into the subserosa, or into nonperitonealized pericolic or perirectal tissues
T4: Tumor directly invades other organs or structures, and/or perforates visceral peritoneum**, ***

*Note: Tis includes cancer cells confined within the glandular basement membrane (intraepithelial) or lamina propria (intramucosal) with no extension through the muscularis mucosae into the submucosa.
(Note: Carcinoma in situ and intramucosal carcinoma are now included with severe dysplasia as "high-grade dysplasia" (Rex at al.). Future AJCC Staging Manuals may reflect this change and may eliminate the category Tis.)

**Note: Direct invasion in T4 includes invasion of other segments of the colorectum by way of the serosa; for example, invasion of the sigmoid colon by a carcinoma of the cecum.

***Tumor that is adherent to other organs or structures, macroscopically, is classified T4. However, if no tumor is present in the adhesion, microscopically, the classification should be pT3. The V and L substaging should be used to identify the presence or absence of vascular or lymphatic invasion.

Regional Lymph Nodes (N)

NX: Regional nodes cannot be assessed
N0: No regional lymph node metastasis
N1: Metastasis in 1 to 3 regional lymph nodes
N2: Metastasis in 4 or more regional lymph node

A tumor nodule greater than 3 mm in diameter in the pericolorectal adipose tissue of a primary carcinoma without histologic evidence of a residual node in the nodule is classified in the pN category as a regional lymph node metastasis if the nodule has the form and smooth contour of a lymph node. If the nodule has an irregular contour, it should be classified in the T category and also coded as V1 (microscopic venous invasion) or as V2 (if it was grossly evident), because there is a strong likelihood that it represents venous invasion.

Distant metastasis (M)

MX: Distant metastasis cannot be assessed
M0: No distant metastasis
M1: Distant metastasis