Take Home Messages from Dr. Choti’s Talk on Rectal Cancer

Maryland Department of Health and Mental Hygiene
Prevention and Health Promotion Administration

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Why is Rectal Cancer Different?

- Defined as <12 cm from the anal verge by rigid proctoscopy.
- Distinct clinical management issues:
  - Increased local recurrence with rectal cancer
  - Use adjuvant radiation therapy to treat rectal cancer (don’t use radiation therapy for colon cancer)
  - Need to stage rectal cancer prior to surgery
  - Use neoadjuvant (before surgery) therapy

Following the Results of the Biopsy-

Work-up for appropriate clinical staging includes:

a) CT scan of chest, abdomen & pelvis
b) Endorectal ultrasound
c) pelvic MRI

Clinical stage helps determines treatment
Goals of Rectal Cancer Surgery

- Improved local control
- Improved overall survival
- Maintaining quality of life
- Sphincter preservation
- Satisfactory bowel function
- Maintain genitourinary function
- Maintain sexual function

What is the “Mesorectum?”

- The “mesorectum” is the fatty tissue envelope around the rectum that contains:
  - Blood and lymph vessels
  - Lymph nodes
  - Nerves

Goal of Surgery:
Total Mesorectal Excision

Low Anterior Resection (LAR)
Preoperative vs. Postoperative Adjuvant Therapy for Rectal Cancer:

**POTENTIAL ADVANTAGES TO PREOPERATIVE TX:**
- Able to preserve sphincter
- Less irradiated small bowel
- Improved late bowel function
- Earlier systemic therapy

**POTENTIAL DISADVANTAGES TO PREOPERATIVE TX:**
- Staging uncertainty
- Overtreatment in some patients
- Delay in surgical therapy
- Increased operative complications?

Management of Rectal Cancer:

- Endorectal Ultrasound--ERUS
- T1N0 no adverse pathologic features → Local Excision
- T2N0 or T1N0 w/adverse features
- T3/T4 and/or N1 → Preop CRT
- T1 w/o adverse pathologic features
- T1 with adverse pathologic features
- T1-2, N0 → Observe
- T1-2, N1 → CRT
- Radical resection
- Observe vs radical resection

Take Home Messages:

- Multidisciplinary team of physicians needed:
  - Colorectal surgeon
  - Radiation therapist
  - Medical oncologist
  - Pathologist
- Lymph node examination is very important
Considerations for the Local Program Case Manager

- How do you advocate for the client?
  - Has a Multidisciplinary Team prepared a treatment plan?
  - When should a second opinion be suggested?
  - When do you involve your Health Officer?
- Does the Local Program have a point of contact/working relationship with providers/facilities to assist the client to make application for charity care?
- Does the Local Program have contracts in place to pay for services?

http://ideha.dhmh.maryland.gov
http://fha.dhmh.maryland.gov
Serrated Polyps of the Colorectum

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9/10/2012

Overview

• Polyp Types
• Clinical Features of Serrated Polyps
• Molecular Features of Serrated Polyps
• Problems with Serrated Polyps
• Follow-Up of Serrated Polyps

Colon Polyp Screening

• Cancer detection / prevention

Colon Polyp Screening

• Cancer detection / prevention
• Removal of precursor lesions (polyps)
• Pathologic identification of polyps
  – Allows risk stratification/appropriate follow-up
Polyps

- Masses of tissue projecting from the normal surface
- Mesenchymal polyps (lipomas, smooth muscle tumors, etc.)
- Lymphoid tissue
- Pseudopolyps
- Epithelial Polyps - overgrowth of epithelium

Normal Features: Histology

- Straight, narrow crypts
- Small nuclei, at base of cell
- ‘Moderate’ amount of mucin

Normal

Epithelial Polyps: Histologic Findings

- Bigger nuclei, ‘picket fence’ or ‘cigar-shaped’
- Decreased mucin
- Larger crypts with epithelial overgrowth extending into lumen → star-shaped or serrated lumens
- Increased mucin
- Small nuclei
Polyp Types: Then

- Adenomatous: less mucin, big nuclei
  - Tubular adenoma
  - Villous adenoma

- Hyperplastic Polyp:
  increased growth, mucin; stellate/serrated lumens

Serrated Polyps

- Traditionally all serrated polyps were defined as hyperplastic polyps, dismissed as benign

- Increasing recognition of some polyps with ‘serrated’ look, with associated adenomatous features, that were associated with malignancy
Overgrowth of epithelium with serrated shape

Polyp Types: Then

- **Adenomatous**: less mucin, big nuclei
  - Tubular adenoma
  - Villous adenoma
- **Serrated adenoma**: less mucin, big nuclei; serrated
- **Hyperplastic Polyp**: increased growth, mucin; stellate/serrated lumens

Sessile Serrated Polyps

- Little change in nomenclature / categorization for ~ 10 years
- Starting around 2000, rapidly increasing interest in serrated polyps
  - Superficially resemble hyperplastic polyps (mucin-rich, without ‘adenomatous’ features) but otherwise atypical for hyperplastic polyps (size, location, etc).
  - Many different names applied to these:
    - hyperplastic polyposis
    - giant hyperplastic polyyp
    - giant hyperplastic polyposis
    - large hyperplastic polyposis
    - hyperplastic-adenomatous polyposis syndrome
    - mixed epithelial polyyp
    - mixed hyperplastic/adenomatous polyyp
    - serrated adenoma

Sessile Serrated Polyps

- Differences in morphology substantiated by differences in behavior and molecular features
  - Recognition based on molecular data that most of these represent a distinct neoplastic pathway

- (Gradual) reorganization of nomenclature to account for this
Polyp Types: Now

- Adenomatous
  - Tubular adenoma
  - Villous adenoma

- Serrated
  - Hyperplastic
  - Sessile serrated adenoma/polyp
  - Serrated adenoma (traditional)

Adenomatous Polyps

- Traditionally, the polyp type that we worry about

- Marked increase in frequency with increasing age

- Neoplastic (chromosomal instability) with malignant potential

- Villous (if mostly growing out) or tubular (if mostly growing in)
Serrated Polyps

- Hyperplastic polyp
- Sessile serrated adenoma / sessile serrated polyp
- Serrated adenoma / traditional serrated adenoma

Hyperplastic Polyps (HPs)

- Most common serrated subtype (70-95%)
- Predominantly left-sided
- Usually small (< 5 mm)
- Benign
  - May contribute to serrated polyposis syndrome
**HP Appearance**

- Straight, simple, symmetric crypts
  - No branching
- Wider and more serrated at the top
- Bland cytology, i.e., individual cells look basically normal
- Several different subtypes
  - No clear clinical difference between subtypes

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**Sessile Serrated Adenoma / Sessile Serrated Polyp**

  - Concept is somewhat older
  - Slow and somewhat uneasy adoption into general pathology practice
- Malignant potential
SSA Appearance

- Serrated, mucin-rich appearance
  - May have mucin coating the surface
- Distorted architecture
  - Branching and dilation, ‘boot-like’ shape
- Increased maturation at base
- Increased proliferation

- May have increased cellular atypia (low- or high-grade dysplasia)
- May have areas that look like HP

Serrated Adenoma / Traditional Serrated Adenoma

- Least common type
- Not well defined
  - Studies probably contaminated with other polyp types
- Malignant potential
TSA Appearance

- Stellate/serrated appearance
  - Decreased mucin production
- Variably dysplastic epithelium (low, high)

Unclassifiable Serrated Lesions

- Reasons you may get this diagnosis:
  - Overlapping histologic features
  - Technical problems with specimen or processing
Conventional Adenoma with Serrated Features

- Usually occur in patients with other serrated lesions
- Substantial proportion share molecular features with serrated polyps

Serrated Polyp Types: Review

- HP - prototype
  - Common, distal
  - Small
  - Benign

- SSA – branching crypts
  - Common, proximal
  - Large
  - Malignant potential

- SA – decreased mucin
  - Rare, proximal
  - Large
  - Malignant potential

Epidemiology of Serrated Lesions

- Increase with increasing age

- Location:
  - More numerous in distal colon
  - More significant in proximal colon

Risk Factors for Serrated Lesions

- Distal (relatively less important, clinically)
  - Increased risk: cigarette smoking
  - Decreased risk: folate, exercise
  - Unclear: EtOH, fiber, NSAID, family CRC history, BMI

- Proximal (less data)
  - Increased risk: cigarette smoking
### Molecular Features of Serrated Lesions

- **Molecular Pathways of Carcinogenesis**
  - Chromosomal instability (traditional, most adenomas)
  - Mismatch repair defects (MSI)
  - CpG island methylator phenotype (CIMP)

### CIMP

- **CIMP-high** (methylation of an extensive set of genes)
  - Usually set of 5 promoters
- Present in some HPs, most SSAs
  - SAs more heterogeneous; possibly not a pure group

### Other Molecular Alterations

- CIMP is strongly associated with BRAF mutations
  - ~50-70% of serrated polyps
- KRAS mutations less common (~15-30%)
- CIMP-high lesions often associated with microsatellite instability

### Proposed Serrated Lesion Progression

SSA $\rightarrow$ dysplasia $\rightarrow$ carcinoma

- Although HPs share some molecular features with SSA, no evidence that they're premalignant
  - CIMP cancer risk increases progressively towards the proximal colon; HPs most common in the distal colon
Serrated Polyposis Syndrome / Hyperplastic Polyposis Syndrome

- Predisposition to serrated polyps
- Relatively younger age of onset
- Family history of serrated polyps or colon cancer
  - Many cases are sporadic

SPS: Definition

1) At least 5 serrated polyps proximal to the sigmoid colon, with at least 2 > 10mm, or
2) Any serrated polyp proximal to the sigmoid colon, in someone with a 1st degree relative with SPS, or
3) More than 20 serrated polyps, of any size, in any site in the colon

Fundamentally arbitrary definition

SPS: Significance

- Increased risk of colon cancer
  - Uncertain degree
- If undergoing resection for carcinoma, also resect segments with large polyps
- Annual colonoscopy with removal of proximal polyps
- Screening for 1st-degree relatives starting at age 40.
Problems With Serrated Lesions

- **Diagnostic**
  - Recognition of serrated lesion
  - HP versus Everything Else
  - Use of appropriate nomenclature

- **Management**
  - Diagnostic variability
  - Guidelines?

Diagnostic Problems

1. **Lack of clear nomenclature; inconsistent application of established nomenclature**
   - What is it?

2. **Lack of specific criteria**
   - How do we know what it is?

3. **Pathologist disagreement**
   - Knowledge of nomenclature/criteria
   - Pathologists may just disagree anyway

1. **Nomenclature**

- Should be less of a problem, as concept of HPs / SSAs / TSAs is fairly well-established by now
  - Education

- Can’t tell / want to play it safe
  - May be related to lack of clear diagnostic criteria
  - Sign-out as ‘serrated polyp’ or ‘serrated lesion’
    - Because some are benign, some have malignant potential: not really a useful diagnosis

2. **Diagnostic Criteria**

- **Good news:**
  - Some guidelines emerging

- **Bad news:**
  - Guidelines are recent; will probably take a while to catch on
  - Some entities still not well defined (TSA)
  - Data lacking for many of these decisions
    - Tendency to ‘play it safe’ and overdiagnose to ensure adequate follow-up
SSA vs HP

• Biggest problem (common polyps, with very different follow-up implications)

• Recommendation (as of 6/2012):
  Even one distorted / ‘boot-like’ crypt is sufficient for SSA

3. Pathologist Disagreement

• Historically, a lot of interobserver variability
  – Improved when pathologists given clear rules

• Should improve as problems with nomenclature and diagnostic criteria are resolved

Management Problems

1. Diagnostic variability/vagueness
   • Should (hopefully) continue to improve in the future

2. Lack of clear guidelines

Follow-Up: Guidelines

• Recent consensus statement (Rex et al, Am J Gastroenterol, 2012)

• Important considerations include:
  – Number
  – Location
  – Size
  – Histologic subtype

• Not a lot of evidence regarding natural history to guide follow-up guidelines
Follow-Up: Basic Principles

Follow-Up: HP

Follow-Up: SSA/SA

Take Away

- Accurate characterization of the number, size and location of lesions is dependent on the endoscopist.

- Accurate characterization of histology is dependent on the pathologist.
  - Can be quite variable
  - Advent of clear-cut guidelines may help in the future
What Your Report Says
(And what to do about it)

• Hyperplastic polyp: Benign
  – However, look for size/number/location: may indicate closer follow-up
• SSA/SSP: Malignant potential, closer follow-up
• TSA: Malignant potential, closer follow-up
• ‘Serrated lesion’:
  – Look for the reason that it’s unclassifiable
  – If you don’t see it, call pathologist & pin them down
  – No guidelines for follow-up
• Conventional adenoma with serrated features
  – No specific guidelines for follow-up

References

Kang GH. Arch Pathol Lab Med. 2011; 135: 698-703
Lane, N. Cancer Res. 1976, 36(7 part 2); 2669-72
Rex DK et al, Am J Gastroenterol, 2012 (advance online publication)
**Stool Blood Testing for Colorectal Cancer**

September 10, 2012

Maryland Department of Health and Mental Hygiene
Prevention and Health Promotion Administration

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**Molecular ‘Cartoon’ of Hemoglobin**

Fe-Iron
Protein-Globin

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**Heme Portion of Hemoglobin**

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**How the Guaiac-Based Fecal Occult Blood Test (FOBT) Works**

- Paper for stool test is impregnated with a chemical called, alpha-guaiaconic acid
- Adding hydrogen peroxide (H₂O₂) to the paper the chemical to a blue color slowly
- The heme component of hemoglobin increases the peroxidase activity and speeds up this reaction
  - Blue color appears more quickly
Medical Literature Supporting FOBT

- 1990s—several randomized clinical trials examining guaiac-based FOBT for colorectal cancer (CRC) screening
- Supported the use of FOBT for CRC screening as a means to decrease mortality from CRC

False Positives and False Negatives with Guaiac-Based FOBT

- False positives—(test may be positive (‘blue color’) when a lesion is not present)
  - Foods with peroxidase activity (some uncooked fruits and vegetables such as broccoli, cauliflower, radishes, turnips, and cantaloupe)
  - Aspirin and NSAIDs can cause upper GI bleeding
  - Non-human hemoglobin (red meat)
- False negatives (test may be negative in the presence of a lesion)
  - Vitamin C
  - Intermittent bleeding of lesion
  - Degradation of hemoglobin by colonic bacteria

Fecal Immunochemical Test (FIT)

- More recent test; been tested and in use since late 1990s
- Uses antibodies that attach to the protein or globin portion of the hemoglobin molecule
- Specific for human hemoglobin
- Less likely to be positive for gastric bleeding as heme protein is broken down in GI tract
- Dietary restrictions are not necessary
- Detects lower amounts of blood in stool

Comparison of FOBT and quantitative FIT (qFIT) with Follow-up Colonoscopy in Screening Population in Korea

- 770 completed study
  - 3 Hemoccult II test cards and 3 OC-SENSA (FIT)
  - All participants underwent colonoscopy
- Sensitivity was higher for qFIT for both cancer and advanced adenomas
  - Sensitivity - measures the ability of a test to be positive when disease is present
- Specificity was similar
  - Specificity - measures the ability of a test to be negative when disease is absent
Editorial*

- Discussed technical/reporting difficulties in interpreting medical literature on FIT topic
  - Different tests from different companies
  - Using different techniques and reagents
  - Qualitative tests have different cut points for positive
- Makes comparisons across articles difficult


Randomized Clinical Trial Comparing Colonoscopy and FIT, Spain

- Compared one time colonoscopy (n=26,703) to FIT every 2 years (n=26,599) in adults 50-69 years.
- Colonoscopy was recommended to FIT participants who had stool hemoglobin >= 75 ng/ml
- Outcome: Death from colorectal cancer at 10 years.
- Results after first 2 years:
  - No difference in cancer diagnosis (0.1%)
  - Prevalence of advanced and non-advanced adenomas were higher in colonoscopy group

Fecal Immunochemical Test (FIT)

- Widely used in Europe for screening
- Organized screening program vs. opportunistic screening (in doctor's office)
- Kaiser-Permanente

Convenience and Cost of FIT

- FIT: fewer samples (fewer days collection)
- FIT: collection technique may be easier
- Cost of FIT is higher per test
  - If it is a better test, cost-effective analysis needs to include more than just the cost of the test
What is the Best CRC Screening Test?

- The one that gets done
- Should FIT be offered in CRF program?
- What is the experience in Maryland jurisdictions that used/have offered FIT?

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http://fha.dhmh.maryland.gov
Anesthesia Care for Colonoscopy: What are the Options? September 10, 2012

Maryland Department of Health and Mental Hygiene
Prevention and Health Promotion Administration

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Definitions of Sedation

- Moderate sedation (‘conscious sedation’)
  - Drug induced depression of consciousness
  - Patient can respond purposefully to verbal commands (either alone or with light touch)
  - Patient maintains own airway and spontaneous breathing is adequate
- Deep sedation
  - Purposeful response following repeated or painful stimulation
  - Airway assistance/intervention may be required
  - Spontaneous breathing may be inadequate

Moderate Sedation

- Moderate sedation
  - Physician service where he/she administers or supervises the administration medications
    - Sedative drugs to allay anxiety (midazolam)
    - Analgesic drugs to control pain (fentanyl or demerol)
  - These drugs depress the level on consciousness
  - Physician responsibilities
    - Assess cardiac and respiratory function during procedure
    - Be able to recognize ‘deep sedation,’ manage its consequences, and bring patient up to a level or moderate sedation

Monitored Anesthesia Care (MAC)

- Does not describe the depth of sedation
- Describes a service provided by an anesthesiologist when patient undergoes a diagnostic or therapeutic procedure
  - Medical assessment by anesthesia personnel
  - Management of a patient’s actual or anticipated medical problems
  - Sedative drugs are generally used
- Anesthesiologist/certified registered nurse anesthetist (CRNA)
  - Able to support patient’s airway, if necessary
  - ready to convert to general anesthesia as circumstances warrant
- Propofol seems to be the sedation drug of choice with MAC for colonoscopy
What is Propofol?

- Propofol (dripivan) is included in the class of drugs as general anesthetic
- Package insert says: “should be administered by persons trained in the administration of general anesthesia”
  - Suppresses respiratory drive and cardiac output
- Advantages for colonoscopy
  - Rapid onset of action
  - Rapid offset (patients are alert and feel well shortly after procedure)
  - Reduces need for opioids, decreasing nausea and vomiting

Propofol for Colonoscopy

- Based on a recent review of 20 studies that compared Propofol to benzodiazepine and opioid sedation for colonoscopy*
  - Propofol resulted in faster recovery and discharge times;
  - Increased patient satisfaction;
  - However, the rates of cecal intubation, procedure completion, and adverse events were comparable.

Two Questions Being Debated in Medical Community

- Is MAC appropriate for colonoscopy?
  - Average risk (ASA class I-II) vs. high risk patients
  - Additional costs vs. benefit
- Can Propofol be administered by non-anesthesia personnel?
  - Patient safety vs. cost savings

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# Hoda KM, Holub JL, Eilaan GM. More large polyps are seen on screening colonoscopy with deep sedation compared with moderate sedation.
Gastrointest Endosc. 2009;69:AB119-AB120.
How Does the Use of MAC Add to the Cost of Colonoscopy?

- Different perspectives
- Medicare - MAC increases costs about $155
- Policies vary across Medicare providers
  - Some will not pay for average risk patients, some will
- Private insurance is higher - $400
  - Estimated MAC costs from endoscopy procedures - $5 billion/year
- Patients with co-pays and deductibles might be charged even higher costs

MEDICARE Rules for Deep Sedation

- In December, 2009 Centers for Medicare and Medicaid Services (CMS) said deep sedation should be provided by:
  - Anesthesiologist,
  - Certified Registered Nurse Anesthetist (CRNA), or
  - Trained physician or osteopath not involved in procedure
- In January, 2011, CMS allowed emergency physicians to administer deep sedation
  - Policy also allows hospitals to create policies on procedural sedation based on national guidelines

Utilization of Anesthesia Services for Outpatient Endoscopy and Colonoscopy

- Number of procedures increased for commercial insurance, stayed stable for Medicare
- The proportion of procedures using anesthesia services increased 14% in 2003 to more than 30% in 2009
- Two-thirds of anesthesia services were delivered to low-risk patients
- Regional variation-Northeast>South>Midwest>West
- Medicare - $150  Commercial - $500

Five Models for Sedation for Colonoscopy-- Position Paper on Non-Anesthesiologist Use of Propofol

- Standard (moderate, conscious) sedation provided by endoscopist (goal of moderate sedation)
- Monitored anesthesia care
- Non-anesthesiologist administered Propofol (NAAP)--either alone or in combination with other agents (goal of moderate to deep sedation)
- Nurses-administered Propofol sedation (NAPS)--under the direction of a non-anesthesiologist trained physician (goal of deep sedation)
- Balanced Propofol sedation (BPS)--includes an opioid and a benzodiazepine along with small doses of propofol under the direction of a non-anesthesiologist physician to achieve moderate sedation.

Non-anesthesiologist physicians need advanced training in the use of Propofol and airway management

Discussions with Your Providers

- Who determines whether MAC is used?
- Contract arrangements for MAC?
- Budget considerations?
- Health officer input in the discussion/decision?
New Employee Orientation
Procedures for Paying for Clinical Services
September 2012

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Purpose of Presentation

- To ensure that local Cigarette Restitution Fund Program (CRFP) Funds are expended appropriately
- To ensure local CRFP fund expenditures are made with sufficient “paper trail” to meet audit requirements

Learning Objectives

At the end of this training, staff will know the:
- Key definitions, background, and procedures for paying for clinical services
- Guidance documents (e.g. Health Officer Memos) for bill paying procedures
-Templates on bill paying procedures and letters to providers
-Relevant forms (HCFA 1500, ICD 9, Explanation of Benefits - EOB)
-CDB billing component
-Reference websites

Procedures for Determining Eligibility

- Determine client eligibility for the program:
  - Residence
  - Income: Equal to/less than 250% current Federal Poverty Guidelines
  - Uninsured (an individual has no health insurance); screen these clients
  - Underinsured (an individual has health insurance that does not cover a portion of the services needed to complete the cancer screening); may screen these clients as noted in programs approved grant
Procedures for Determining Eligibility (cont.)

- Prior to screening individuals with limited insurance benefits
  - The program needs to get Explanation of Benefits (EOB) from client’s insurance company that states the amounts for co-payment, deductibles, and covered services. (An EOB is not available until the provider submits a bill for services. The program can have the client contact their insurance company for written documentation of covered screening services.
  - Medicare Part A does not cover colonoscopy
    - Screen these patients
  - Medicare Part B covers some of the cost for colonoscopy
    - Get EOB prior to screening these patients
  - Some commercial insurance plans do not cover colonoscopy; Get EOB prior to screening these patients

Key Definitions

- Local Health Department Funding System (LHDFS) Manual
  - Administrative and fiscal policy for funding from the Department of Health and Mental Hygiene (DHMH) to the Local Health Department (LHD)
    - Processed by Division of Program Cost and Analysis (DPCA) and are reflected on the Unified Funding Document (UFD) (Note: Home rule jurisdictions are not reflected in the UFD.)

Key Definitions (cont.)

- CPEST
  - Cancer Prevention, Education, Screening, and Treatment
- CPT (Current Procedure Terminology) Code
  - Provides codes for clinical procedures (e.g., office visit, screening, diagnosis, and treatment)
- Conditions of Award
  - Enclosed with the Grant Award Letter to the Health Officer and Program Coordinator/Manager
  - Conditions accepted by the LHD as binding upon the LHD upon receipt of UFD awards from DHMH
- Encumbrance
  - Obligation to expend funds supported by contract or purchase order which are to be furnished in the subsequent Fiscal Year
  - Not recognized as expenditures in the current Fiscal Year
- Explanation of Benefits (EOB)
  - A statement sent by a health insurer to patient that lists medical services paid and unpaid
Key Definitions (cont.)

- Fixed Price & Unit Price Funding Agreement
  - Contract is required for services and the rate is market rate in the region or set in law or regulation
  - Payment is made only after services are delivered
  - Original documentation is required to pay bills

- Health Services Cost Review Commission (HSCRC)
  - A part of DHMH that is responsible for reviewing and approving the rates for hospitals in Maryland

Key Forms (cont.)

- HCFA 1500 (Health Care Financing Administration)
  - The official standard form submitted by the Provider for reimbursement to Medicare or Medicaid for health services
  - Contains dates of services, demographics, diagnostic codes, CPT/HCPCS codes, physician name (CPEST Program receives these as bills from the provider)

Key Forms (cont.): Explanation of Benefits

- Explanation of Benefits (EOB)
  - A statement sent by a health insurer to patient that lists medical services paid and unpaid
  - Date of the service, the description and/or insurer’s code for the service, the name of the person or place that provided the service, and the name of the patient
  - Doctor’s fee, and what the insurer allows—the amount initially claimed by the doctor or hospital, minus any reductions applied by the insurer
  - The amount the patient is responsible for and possibly a brief explanation of any claims that were denied, along with how to appeal. (The patient responsibility may include co-pays or amounts applied to the patient’s deductible and/or co-insurance.)
Example of an EOB

Prevention and Health Promotion Administration
09/10/2012

ICD: International Statistical Classification of Diseases and Health Related Problems

- ICD-9
  - A medical classification list for the coding of diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases, as maintained by the World Health Organization
  - Used by physicians to bill insurance and to determine health services patients can receive

Relevant Health Officer Memos

- Health Officer (HO) Memo 02-26 Sample Templates of Operational Procedures and Billing Procedures—Final Version (DD provided modified template in e-mail of 10/24/11)
  - A list of components that are commonly seen in client medical records that is also attached for your information and more tools for client flow and client processing.
- HO Memo 03-40 Reimbursement for Multiple Biopsies Taken During Colonoscopy; includes example of HCFA 1500 and notation of approval
  - Guidance on how to reimburse providers who obtain and bill for multiple biopsies during a single colonoscopy procedure

Relevant Health Officer Memos (cont.)

- HO Memo 04-27 Reimbursement of the “Facility Fee” when billed for multiple CPT codes during one colonoscopy
  - Medicare reimbursement is 100% of the allowable Medicare rate of the first colonoscopy facility fee CPT code.
  - For each of the second, third, etc. facility fee by CPT codes during the same colonoscopy, Medicare allows 50% percent of the Medicare amount to be reimbursed for each one.
  - Programs may make arrangements with the facility to accept a rate less than this Medicare rate
Relevant Health Officer Memos (cont.)

- HO Memo 08-17 Reimbursement rates and procedures for office visits for women who are patients of both the BCCP and CRF programs
  - For example, a bill might come in from Dr. Smith for Jane Doe charging $250.00 for CPT 99203.
    - The BCCP should write on the bill: "F676N--$44.78" for a CPT code of 99203 in region 99 and the CRF should write "FCO2N--$44.79" for the CRF share of the same bill.
    - The local program sends the bill to the local fiscal office for payment.
    - The fiscal office reimburses the provider the entire amount, $89.57 or the full Medicare amount for that CPT code in that region, and would charge the two LHD accounts as indicated.

Relevant Health Officer Memos (cont.)

- HO Memo 11-07 Pathology Laboratory Reimbursement for Colonoscopy Biopsy Specimen Processing in the CRF Program.
  - Programs should have at hand both the pathology invoice and the corresponding pathology results when they are approving and processing the pathology invoices.
  - Programs should review the pathology results and note the number of specimens submitted for processing and then match that number to the pathology bill.
  - Programs generally should approve payment for the number of specimens processed.
  - If the invoice bills the program for each fragment processed, then the program would deny the additional bills over and above the number of specimens processed.

Relevant Health Officer Memos (cont.)

- HO Memo 12-03 or most recent date - CPT codes and 2012 Medicare, Medicaid and Dental Reimbursement Schedule
  - Includes worksheets on colorectal, oral, prostate and skin cancer amounts by CPT codes, with their Medicare and Medical Assistance reimbursement rates.
- HO Memo 11-38 - Fiscal Year 2012 Non-Chargeable List for the following services regardless of client income and do not need to be billed to third party payers:
  - Fecal Occult Blood Test (FOBT) kits (guaiac or immunochemical) for colorectal cancer screening
  - Oral cancer screening and oral brush biopsy
  - Skin cancer screening.

Procedures for approving and paying invoices

- Program can pay up to the Medicare rate for screening services and up to the Medicaid rate for diagnosis and treatment services.
- Program must receive and maintain an original invoice, not a copy.
- Date stamp the invoice and confirm that:
  - Program has a contract with the provider.
  - The services on the invoice are stated in the contract.
  - Services on the invoice have been received by the client and all relevant reports (e.g., office visit, procedure, pathology, treatment, recall date) have been received.
  - The amount on invoice matches the amount stated on the CPT Code reimbursement sheet. If the amount on the invoice is greater than the CPT Code Rate of Reimbursement, reduce the amount manually on the invoice. Program may call CRFP Unit when CPT Code is not listed for further guidance.
- Administrative Case Manager reviews and approves the invoice for reimbursement before it is given to local fiscal office for payment.
Procedures for approving and paying invoices (cont.)

- Notify provider and client of CPT code/items that are not reimbursed by the local CRF-CPEST program.
- Administrative Case manager should write in the amount that their grant approves for payment.
- Invoices for services that will be split between programs, each program (BCCP/CRF) should write in the amount their grant will contribute toward the bill and the grant number.
- Program should keep a copy of the “approved” bills for their records.
- Enter billing information in the Client Database (optional).

Resources

- Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Fee Schedule: [https://www.cms.gov/ClinicalLabFeeSched/02_clinlab.asp#TopOfPage](https://www.cms.gov/ClinicalLabFeeSched/02_clinlab.asp#TopOfPage)
- CMS Anesthesiologists Center: [https://www.cms.gov/center/anesth.asp](https://www.cms.gov/center/anesth.asp)
- HCPCS Manual (American Medical Association Healthcare Common Procedure Coding System Level II Codes): [https://www.cms.gov/MedHCPCSGenInfo/02_HCPCSCODINGPROCESS.asp#TopOfPage](https://www.cms.gov/MedHCPCSGenInfo/02_HCPCSCODINGPROCESS.asp#TopOfPage)
- Health Services Cost Review Commission: [http://www.hscrc.state.md.us/](http://www.hscrc.state.md.us/)

Please take the quiz (Procedures for Paying Clinical Services) and email or fax it to:

Cynthia Walker
cynthia.walker@maryland.gov
Phone: 410-767-0787
Fax: 410-333-5210

For questions on updated information, call 410-767-5123
Latest Cancer Screening Recommendations
September 10, 2012

Maryland Department of Health and Mental Hygiene
Prevention and Health Promotion Administration

Annette Hopkins, RN, MS
Nurse Consultant
Surveillance and Evaluation Unit
Center for Cancer Prevention and Control

Current Screening Recommendations for Targeted Cancers

- Breast
- Cervical
- Colorectal
- Lung
- Skin (Melanoma)
- Oral
- Prostate

Sources for Recommendations

- ACIP - CDC’s (Advisory Committee on Immunization Practices)
- ACS – (American Cancer Society)
- CDC – (Centers for Disease Control and Prevention)
- CRF (Cigarette Restitution Fund) Cancer Report 2012
- DHMH MAC –(Medical Advisory Committees)
- NCI – (National Cancer Institute)
- PDQ – NCI’s (Physician Data Query)
- USPTF – (U. S. Preventive Services Task Force)

Breast Cancer Screening
CRF Cancer Report 2012
Public Health Intervention for Breast Cancer
Source: DHMH Breast Cancer Medical Advisory Committee, 2009

Early detection of breast cancer:
- Screen using mammography and a clinical breast examination by a health professional, every 1-2 years for women age 40 years and older.
Public Health Intervention for Cervical Cancer  
CRF Cancer Report 2012  
Sources: USPSTF and ACIP

- Screen women age 21-65 years who have a cervix with the Pap test every 3 years, or for women age 30-65 years who want to lengthen the screening interval, screen with Pap test and HPV testing every 5 years.
- Vaccinate females and males according to ACIP recommendations.

Cancer and Human Papillomavirus (HPV)  
Source: NCI*

- Virtually all cervical cancers are caused by HPV infections, with just two HPV types, 16 and 18, responsible for about 70 percent of all cases.
- HPV also causes anal cancer, with about 85 percent of all cases caused by HPV-16. HPV types 16 and 18 have also been found to cause close to half of vaginal, vulvar, and penile cancers.

*http://www.cancer.gov/cancertopics/factsheet/risk/HPV

Cancer and Human Papillomavirus (HPV)  
Source: NCI*

- Most recently, HPV infections have been found to cause cancer of the oropharynx, which is the middle part of the throat including the soft palate, the base of the tongue, and the tonsils.
- In the United States, more than half of the cancers diagnosed in the oropharynx are linked to HPV-16.
- The incidence of HPV-associated oropharyngeal cancer has increased during the past 20 years, especially among men. It has been estimated that, by 2020, HPV will cause more oropharyngeal cancers than cervical cancers in the United States.

*http://www.cancer.gov/cancertopics/factsheet/risk/HPV

HPV Vaccines

- The Food and Drug Administration (FDA) has approved two HPV vaccines:
  - Gardasil® for the prevention of cervical, anal, vulvar, and vaginal cancer, as well as precancerous lesions in these tissues and genital warts caused by HPV infection.
  - Cervarix® for the prevention of cervical cancer and precancerous cervical lesions caused by HPV infection.
- Both vaccines are highly effective in preventing infections with HPV types 16 and 18.
- Gardasil also prevents infection with HPV types 6 and 11.
- These vaccines have not been approved for prevention of penile or oropharyngeal cancer.
Colorectal Cancer Screening  
Public Health Intervention for CRC  
CRF Cancer Report 2012  
Sources: USPSTF 2008; DHMH CRC Medical Advisory Committee, 2009

- For those age 50 to 75 years at average risk, screen with colonoscopy or with FOBT and flexible sigmoidoscopy. Persons older than age 75 years may also be screened if there are considerations to support screening after taking into account comorbidities, longevity, and past CRC screening results. The harms likely outweigh the benefits of CRC screening for persons older than age 85 years.
- For those unable or unwilling to undergo colonoscopy or sigmoidoscopy, FOBT is an alternative initial screening method.
- Reserve other CRC screening tests as alternatives for situations where the patient and the provider discuss and determine that such tests are indicated for the individual.

Lung Cancer Screening  
Public Health Evidence  
CRF Cancer Report 2012  

- Based on solid evidence, screening with chest x-ray (CXR) and/or sputum cytology does not reduce mortality from lung cancer.
- Screening with CXR and/or sputum cytology or with low-dose helical computed tomography (LDCT) would lead to false-positive tests and unnecessary invasive diagnostic procedures and treatments.
- There is evidence that screening persons age 55-74 years who have 30+ pack-years smoking history (either current smokers or former smokers who quit within the last 15 years) with LDCT decreases mortality from lung cancer.

Center for Cancer Prevention and Control--9/10/12--Page 37
A type of CT scan known as low-dose spiral CT (or helical CT) has shown some promise in detecting early lung cancers in heavy smokers and former smokers. 

- Spiral CT of the chest provides more detailed pictures than a chest x-ray and is better at finding small abnormalities in the lungs.
- The type used for lung cancer screening uses lower amounts of radiation than a standard chest CT and does not require the use of intravenous (IV) contrast dye.

The National Lung Screening Trial (NLST) compared two ways of detecting lung cancer: low-dose helical computed tomography (LDCT) and standard chest X-ray (CXR).

- NLST launched in 2002 and enrolled 53,454 current or former heavy smokers from 33 sites across the United States.
- On June 29, 2011, the primary results were published online in the New England Journal of Medicine.
- There was a statistically significant 20% reduction in lung cancer mortality in the LDCT group compared to the CXR group.
- The LDCT group had not experienced a rate of unforeseen, adverse screening effects that would lead to uncertainty about the balance of benefits and harms.

Eligibility Criteria for the National Lung Screening Trial

- Age 55-74, with no signs of symptoms of lung cancer
- Active or former smoker with a 30 pack year history.
- If active smoker, should also be vigorously urged to enter a smoking cessation program
- If former smoker, must have quit within 15 years
- General health exclusions:
  - Metallic implants or devices in the chest or back
  - Requirement for home oxygen supplementation
  - Prior history of lung cancer or other lung cancer symptoms

- Adults between the ages of 55-74 who meet the eligibility criteria of the NLST may consider screening for early lung cancer detection.
- With their primary provider, individuals interested in screening should weigh the currently known benefits of LDCT screening with the currently known limitations and risks and make a shared decision as to whether they should be screened for lung cancer.
- At this time, adults who do not meet the NLST entry criteria should be informed that there is uncertainty regarding the balance of benefits and harms for individuals at younger ages and/or with less lifetime exposure to tobacco smoke and therefore screening is not recommended.
ACS Interim Guidance for Lung Cancer Screening (continued)

- Adults who choose to be screened should follow the NLST protocol of annual screening.
- Adults who choose to undergo lung screening should enter an organized screening program at an institution with expertise in LDCT screening, with access to a multidisciplinary team skilled in the evaluation, diagnosis, and treatment of abnormal lung lesions.
- Active smokers entering a screening program should be vigorously urged to enter a smoking cessation program. Screening should not be viewed as an alternative to smoking cessation.

Public Health Intervention for Lung Cancer
CRF Cancer Report 2012


- Prevent tobacco use among youth and young adults.
- Promote cessation among adults and young people.
- Eliminate exposure to secondhand smoke.
- Identify and eliminate tobacco-related disparities.

Skin Cancer Screening
Public Health Evidence
CRF Cancer Report 2012

Sources: NCI PDQ, 1/26/2012 and 1/26/2012, and USPSTF, 2/2009

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of using a whole-body skin examination by a primary care clinician or a patient skin self-examination for the early detection of melanoma of the skin, basal cell cancer, or squamous cell skin cancer in the adult general population.

Public Health Intervention for Skin Cancer Prevention
CRF Cancer Report 2012

- Reduction of exposure to the sun and other UV light by practicing sun-protective and UV-protective behaviors:
- Avoiding sun exposure, especially between 10 a.m. and 4 p.m.
- Wearing sun-protective clothing, hat, and sunglasses when exposed to sunlight.
- Avoiding artificial sources of UV light (e.g., tanning booths).
- If sun cannot be avoided, using sunscreen with a SPF of 15 or higher.
Legislation re: Tanning Devices

- Maryland General Assembly passed HB1358 in 2008 which provided authority to DHMH to adopt regulations on parental informed consent and age verification for minors’ use of tanning devices.
- In 2012, Maryland legislature did not pass legislation banning commercial tanning bed use for minors.
- The Maryland Secretary of Health is considering whether the regulations or consent form should be updated.
- Is the current law being enforced?
- Is the current law working?

Oral Cancer Screening
Public Health Evidence
CRF Cancer Report 2012
Source: NCI PDQ, 1/26/2012 and 1/26/2012, and USPSTF, 2/2004

- The routine examination of asymptomatic and symptomatic patients can lead to detection of earlier stage oral cancers and premalignant oral lesions.
- Incorporating routine oral cancer examinations (and other screening methods for oral cancer) into the daily practice of healthcare practitioners can increase the likelihood of earlier detection of oral cancer.
- However, the USPSTF concluded that the evidence is insufficient to recommend for or against routinely screening adults for oral cancer.

Public Health Intervention for Oral Cancer
CRF Cancer Report 2012
(DHMH Oral Cancer Medical Advisory Committee, 2005)

- Avoidance or cessation of smoking and other tobacco use.
- Avoidance or reduction of alcohol consumption.
- Avoidance of sun exposure; use of ultraviolet light-blocking lip balm.
- Screening for oral cancer targeted to individuals age 40 years and older.

Prostate Cancer Screening
Public Health Evidence
CRF Cancer Report, 2012

- The evidence is insufficient to determine whether screening for prostate cancer with prostate-specific antigen (PSA) or digital rectal exam (DRE) reduces mortality from prostate cancer.
- The USPSTF recommends against PSA-based screening for prostate cancer.
- Screening tests are able to detect prostate cancer at an early stage, but it is not clear whether this earlier detection and consequent earlier treatment leads to any change in the natural history and outcome of the disease.
Prevention and Health Promotion Administration

Prostate Cancer Screening

Public Health Evidence Continued

CRF Cancer Report 2012


- Based on solid evidence, screening with PSA and/or DRE detects some prostate cancers that would never have caused important clinical problems. Thus, screening leads to some degree of overtreatment.
- Based on solid evidence, current prostate cancer treatments, including radical prostatectomy and radiation therapy, result in permanent side effects in many men, including erectile dysfunction and urinary incontinence. The screening process itself can lead to adverse psychological effects in men who have a prostate biopsy but not prostate cancer; prostate biopsies are associated with complications.

Public Health Intervention for Prostate Cancer

CRF Cancer Report 2012

- The decision to be screened for prostate cancer should be an individual one involving shared decision-making.
- If a patient raises the issue of PSA screening, or the clinician believes his individual circumstances warrant consideration of PSA screening, the clinician should discuss with the patient the benefits and harms thoroughly so he can make an informed decision.
- The decision to start or continue PSA screening should reflect the patient’s understanding of the possible benefits and expected harms and should respect his preferences.

Hepatitis C and “Baby Boomers”

- In the United States, hepatitis C is the leading cause of liver transplants and primary liver cancer, which is the fastest-rising cause of cancer-related deaths.
- People born from 1945 through 1965 currently account for more than 75% of adults infected with hepatitis C in the U.S. and are five times more likely to be infected than other adults.
- Each year, more than 15,000 Americans, most of them baby boomers, die from hepatitis C-related illness, such as cirrhosis and liver cancer.
- The new recommendations from the CDC calls for all Americans born from 1945 through 1965 or “baby boomers” to get a one-time blood test for the hepatitis C virus (HCV).

American Red Cross Tests Done on Donated Blood

- Chagas disease (T.cruzi)
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV 3.0)
- Human Immunodeficiency viruses, Types 1 and 2 (HIV 1,2)
- Human T-Lymphotropic virus (HTLV-I/II)
- Syphilis (Treponema pallidum)
- West Nile virus (WNV)
Cancer Prevention

Best Way to Reduce Your Risk for Cancer is to Maintain Your Health

- Exercise
- Eat a healthy diet
- Maintain a healthy weight
- Protect yourself from excessive sun exposure
- Don’t smoke
- Don’t drink alcohol excessively
- If you’re sexually active, practice safe sex and limit the number of partners you have
- Get regular check-ups with your health care provider

Maryland Prevention and Health Promotion Administration

http://ideha.dhmh.maryland.gov
http://fha.dhmh.maryland.gov

CRFP Funded Programs are Currently Approved to Screen for the Following Cancers if Specified in the Program’s Annual Grant Award

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Age*</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>40+</td>
<td>Mammogram and CBE every 1-2 years</td>
</tr>
<tr>
<td>Cervical</td>
<td>40-65</td>
<td>As per current Minimal Elements recommendations</td>
</tr>
<tr>
<td>Colorectal</td>
<td>50+</td>
<td>FOBT or FIT annually, Sigmoidoscopy every 5 years or Colonoscopy every 10 years</td>
</tr>
<tr>
<td>Oral</td>
<td>40</td>
<td>Oral cancer screening exam at intervals recommended by the Medical Case Manager (Provider)</td>
</tr>
<tr>
<td>Skin</td>
<td>40</td>
<td>Whole body skin exam at intervals recommended by the Medical Case Manager (Provider)</td>
</tr>
</tbody>
</table>

* Age is for average risk asymptomatic individuals