Washington State Health Care Authority

Health Technology Assessment Program

Health Technology Clinical Committee
CT Colonography

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Colorectal Cancer
CT Colonography (CTC)

- Estimated 153,000 new cases and 55,000 deaths per year
  - The cancer has an identifiable precursor lesion, so there is an opportunity for prevention rather than cancer detection alone.
  - targeted detection and removal of advanced adenomas may be the most effective approach to cancer prevention
- CT Colonography
  - CTC uses computer generated images to examine colon for lesions
  - Bowel cleansing/preparation is necessary, a rectal tube is inserted to insufflate colon with air/gas prior to radiographic imaging
  - No sedation required

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CT Colonoscopy (CTC) Context

- **Technology is not new, but this application is emerging**
  - pressure to screen asymptomatic patients at average risk of colon cancer
- **Potential Benefits**
  - Compliance is issue with CR screening - New test that is less invasive may increase screening rates
  - Decrease in time
  - Decrease risk related to bowel perforation and anesthesia
- **Potential Drawbacks**
  - Test is additive (doesn't replace optical colonoscopy or others)
  - Test must be done more often and clinical uncertainty over findings (legion size, disease progression, extra-colonic findings)
  - Cost is higher
  - Not as sensitive/specific
  - Uncertainty of radiation risk where used for routine, repeat screening

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Selection Ranking CT Colonoscopy

Primary Criteria	
Potential patient **harm/safety** concerns:	Low
Concerns about therapeutic **efficacy or diagnostic accuracy** and appropriateness of outcomes for patients:	Med
Estimated total direct **cost** per year (estimated increase/decrease):	Med
Secondary Criteria	
Number of persons affected per year:	High
Severity of condition treated by technology:	High
Policy related urgency/diffusion concern:	Med
Potential or observed variation:	Med
Special populations/ethical concerns:	Low

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CTC Medicare Coverage

- **National Medicare Coverage**
  - Medicare covers colorectal cancer screening tests, but not CTC
- **Medicare Coverage Colon Cancer Screening (2004)**
  - (1) annual fecal occult blood tests (FOBTs);
  - (2) flexible sigmoidoscopy over 4 years;
  - (3) screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years;
  - (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer;
  - (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.
- All other indications for colorectal cancer screening not otherwise specified above remain noncovered.

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CTC Guidelines

SUMMARY TABLE OF GUIDELINES

Organization	Date	Outcome	Evidence Cited?
US Preventive Services Task Force	2002	Insufficient evidence that CTC improves health outcomes	Y
National Cancer Institute	2008	Evidence summarized, no recommendations	Y
American Cancer Society	2007	CTC not recommended	N
American Gastroenterological Association	2007	CTC evolving, not recommended for primary screening	Y
American College of Radiology	2006	CTC indications listed, including screening for colorectal cancer	Y
American Society for Gastrointestinal Endoscopy	2006	CTC not ready for widespread screening	Y

Further summary in report and guidelines included in appendix.

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CT Colonography

Questions

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Agency Medical Director Comments

Health Technology Clinical Committee
CT Colonography

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CT Colonoscopy (CTC) Background

- **AMDG Perspective**
  - **Technology is not new, but this application is emerging**
    - Rapid dissemination, marketing, literature advocating use as CRC screening method for "average risk" over 50 population
    - Scientifically (intellectually) and esthetically appealing
  - **Prevention is a shared agency focus: increased number of individuals screened for colon cancer results in better health**
    - **Screening compliance nationally ~ 50% percent**
    - **For state agencies ~ 40% percent**
  - **A key question: Will this additional method increase or simply shift individuals from other tests?**
    - Critical if CTC is higher cost or less effective – net result would be worse health outcome at higher agency cost

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Current State Agency Policy

Colorectal Cancer Screening Summary		
Procedure	**Medicaid Policy**	**UMP Policy**
Flexible Sigmoidoscopy	Clients age 50 and older who are not at high risk Once every 48 months	Flexible sigmoidoscopy once every 48 months; 50 + years, or younger if at risk
High Risk Colonoscopy Screening	Clients at high risk for colorectal cancer One every 24 months (Certain diagnosis codes only)	
Fecal occult	No limits	Fecal occult blood test for colorectal cancer at each annual physical; 50 + years
Colonoscopy	Clients age 50 and older Once every 10 years	Colonoscopy once every 10 years, but not within 48 months of screening sigmoidoscopy; 50 + years, or younger if at risk
*Barium Enema	Clients age 50 and older Once every 5 years	Barium enema, once every 5-10 years; 50 + years, or younger if at risk
Labor and Industries		
Average risk cancer screening services are not within the scope of services provided under worker's compensation benefits. These technologies may be covered if reasonable and necessary for a work place related disease or injury.		
CTC	Investigational	Investigational

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CT Colonography

- **State Agencies Conclusions (ICER Report for Colorectal Cancer Preventive Screening)**
  - **Safety**
    - Less invasive but same bowel prep and "smaller" perforation risk
    - Reduces but does not eliminate risks of a 2nd procedure (true and false positives)
    - Radiation exposure, uncertain lifetime risk
    - Benefit vs Harms ? (identification of extra-colonic findings; unnecessary interventions)
    - Potential of failed follow-up (compliance) of mid-sized lesions

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CT Colonography

- **State Agencies Conclusions (ICER Report for Colorectal Cancer Preventive Screening)**
  - **Effectiveness**
    - Evidence of sensitivity, specificity, and reliability is worrisome
      - User and site specific (training/experience), tech specs/protocol variations
      - Still evolving (ICER cites: technology, bowel cleansing, fecal tagging, computer assisted interpretation)
    - Screening vs. colonoscopy (screening, diagnostic, and therapeutic in one procedure)
      - Doesn't allow polypectomy (6–9 mm **"polyp dilemma"**)
    - No evidence of enhancing screening compliance rates
  - **Cost**
    - Higher testing frequency, higher cost/test
    - Added tests if suspicious lesions, equivocal results or poor study add to cost

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State Agency Utilization (SFYs 2006 and 2007)

Procedure	Patients	Cost
Conventional Colonoscopy	27,655	$20,231,011
Sigmoidoscopy	1,548	$262,475
Barium Enema	0	$0
Virtual Colonoscopy (CTC)	25	$22,824

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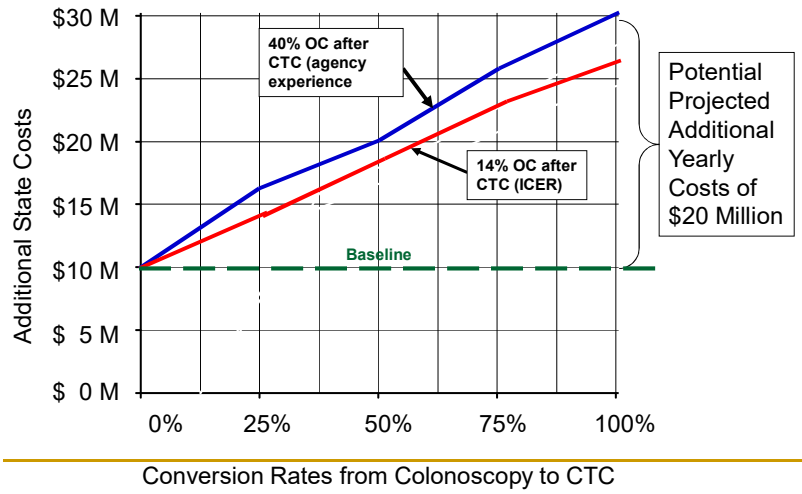
Potential Cost Change

One Year State Cost Changes for Same Number Screenings



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CT Colonography

- **Agency Conclusions**
  - ICER Report findings consistent with other HTAs
    - **Hayes Inc.** (06) - Potential but unproven benefit
    - **BCBS TEC** (04) – CTC does not meet TEC criteria
    - **ICSI** (04) - "unclear . . . sensitivity and specificity . . . limited available data" and ". . . not been proven. . . superior to (OC)"
    - **OHTAC** (03) – ". . . CTC cannot be proposed for population-based colorectal cancer screening."
    - **NZHTA** (07) – ". . . CTC is not currently recommended for generalized screening."
    - **ECRI** (05) – ". . . no published evidence of the effect of CT colonography on colorectal cancer incidence and mortality."
  - ICER Report findings consistent: Professional Society, College and Association position statements

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CT Colonography

- **State Agencies Summary View**
  - CT Colonography screening diffusion in current "real world" settings not controlled as in ICER report
    - High variability: equipment, training, experience (quality) is problematic
  - Safety Issues not resolved
    - No evidence on radiation exposure
    - Extra-colonic findings, polyp size and poor compliance present dilemmas
  - Costs increase because not a replacement
    - Costs for referral to optical
    - Tests performed twice as often
    - Costs for extra-colonic findings and poor compliance undetermined
  - No evidence of increase in screenings or improved health outcomes

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CT Colonography

- **State Agencies Summary View**
  - CT Colonography for CR cancer screening is promising but limited benefit and high cost
  - State Agencies already cover recommended colorectal cancer screening tests
    - FOBT
    - Flexible Sigmoidoscopy
    - Barium Enema
    - Colonoscopy (Optical) – [screening; diagnostic; therapeutic]

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CT Colonography

Questions

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Appraisal of CT colonography versus optical colonoscopy

Presented by
Steven D. Pearson, MD, MSc, FRCP

ICER

The Institute for Clinical
and Economic Review

Scope

- Patient population: primary screening
- Comparators
- Key questions
  - Technical issues
  - Sensitivity and specificity vs. OC
  - Safety
  - Patient acceptance
  - Extracolonic findings
  - Impact on population screening rates
  - Cost-effectiveness vs. no screening and vs. alternatives

Background

- Colorectal cancer screening
  - ~50% of eligible get screened
  - Non-invasive methods
  - Invasive methods: screening = prevention
  - Lack of infrastructure for universal colonoscopy
  - Polyps
    - ≥ 10 mm
    - 6-9 mm
    - ≤ 5 mm

Previous HTA on CTC

- MSAC (2006)
- ICSI (2006)
- NICE (2005)*
- BCBSA TEC (2004)
- CTAF (2004)

- Consensus: “Variable findings of sensitivity across studies”

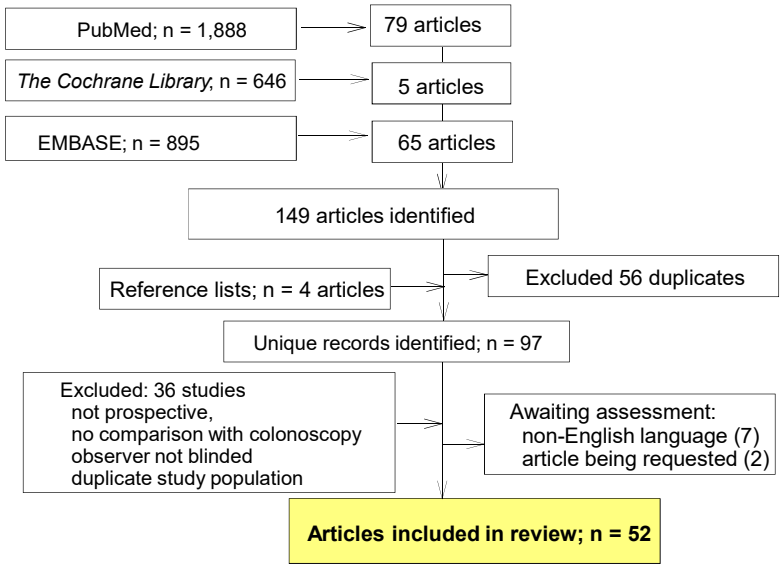
Key Ongoing Research

- ACRIN Trial
  - Preliminary results announced September, 2007
  - Results in line with findings of ICER appraisal

Systematic Review Criteria

- Prospective diagnostic accuracy studies of CTC
- Colonoscopy used as reference standard
- Endoscopists unaware of index test results; CT readers unaware of reference test results
- Study participants:
  - Adults who have undergone CT colonography and colonoscopy
  - No active bowel disease (e.g., Crohn's disease, irritable bowel syndrome, etc.)

Search Results



Technical criteria

- Multi-detector CT scanners with collimation < 5 mm
- Scan acquired within a single breath hold of ≤ 30 seconds
- Reference standard of combined CT colonoscopy and colonoscopy results (segmental unblinded colonoscopy or second look colonoscopy)
- Observers had read at least 30 CT scans and/or received CTC training before study start.

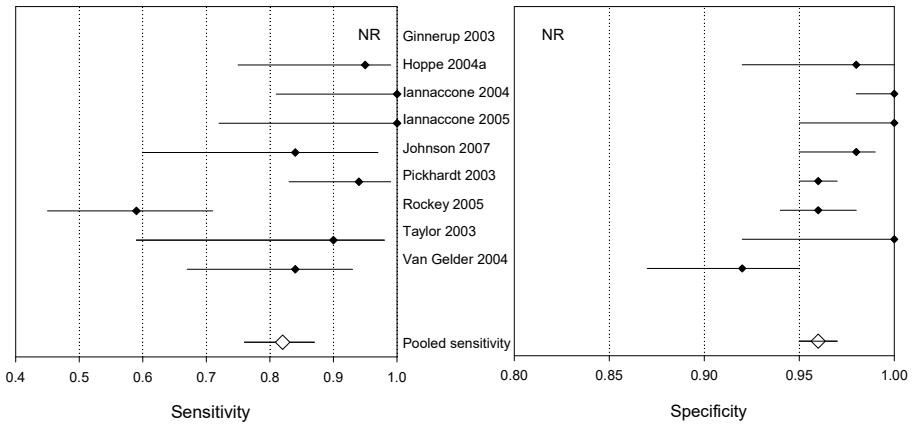
Included studies

Author	Scanner	Time	Training
Ginnerup 2003	Marconi M x 8000, Marconi Medical Systems	2 x 17 s	approximately 100
Hoppe 2004	Asterion 4- channel multi-detector	30 s	30-60
Iannaccone 2004	Somatom Plus 4 Volume Zoom, Siemens Medical Solutions.	12-18 s	> 300, 200, 100
Iannaccone 2005	Somatom Plus 4 Volume Zoom, Siemens Medical Solutions	14-20 s	> 400, 200, 100
Johnson 2007	Lightspeed Ultra, GE Healthcare	28 s	> 1,000
Pickhardt 2003	GE Lightspeed or LightSpeed Ultra, GE Medical Systems	NR	> 25 for training or > 1,000 scans
Rockey 2005	4- or 8-slice multi-detector CT scanners	NR	> 50 or training module
Taylor 2003	Lightspeed Plus, GE Medical Systems	NR	NR
Van Gelder 2004	Mx8000, Philips	22 s	> 50

Study Quality

- QUADAS Tool
  - Used to assess diagnostic accuracy studies
  - 14 items assessing internal validity
- 5 “high” quality studies
  - Ginnerup 2003; Iannaccone 2004 & 2005; Pickhardt 2003, Taylor 2003
- 4 “fair” quality studies
  - Hoppe 2004, Johnson 2007, Rockey 2005, Van Gelder 2004

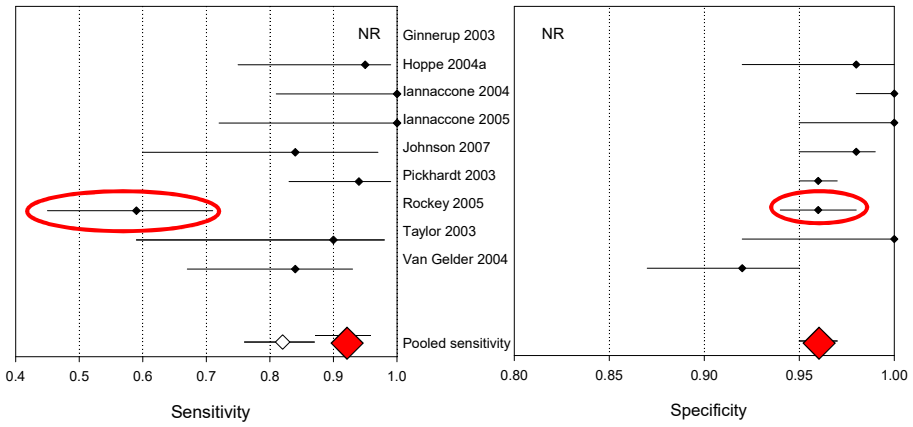
Sensitivity & specificity per patient for polyps ≥ 10 mm



82%, (95% CI, 76-87%)

96%, (95% CI, 95-97%)

Sensitivity & specificity per patient for polyps ≥ 10 mm



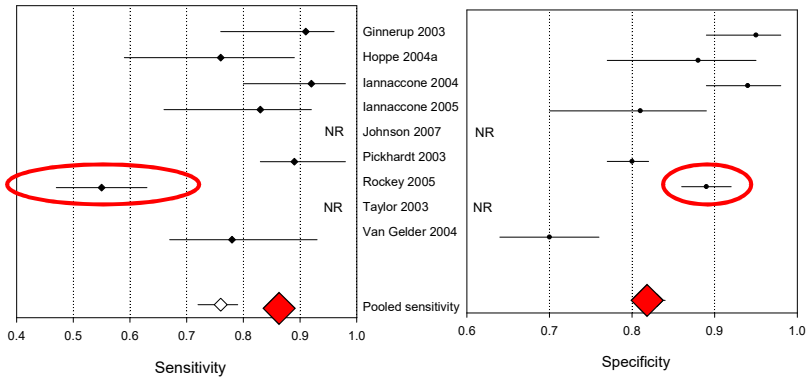
82%, (95% CI, 76-87%)

92%, (95% CI, 86-95%)

96%, (95% CI, 95-97%)

96%, (95% CI, 95-97%)

Sensitivity & specificity per patient for lesions ≥ 6 mm



77% (95% CI, 73-80%)

86%, (95% CI, 83-90%)

83% (95% CI, 81-84%)

81%, (95% CI, 79-83%)

Harms: Perforation

- Rate of perforation in a survey of 50 institutions = 0.08%
- Rate in largest US cohort = 2 out of 21,000
- Rate of perforation in colonoscopy = 0.13%
- Rate of perforation per biopsy = 0.2 – 0.3%

Harms: radiation exposure

Radiation exposure scenario	Approximate mean individual dose (mSv)
Chest x ray	0.02
Round-trip flight, New York-Seattle	0.06
Low-dose CT colonography (Van Gelder, 2004)	**0.5**
Lumbar spine x-ray	1.3
Head CT	2.0
Single-screening mammogram (breast dose)	3
Background dose caused by natural radiation	3 per year
Adult abdominal CT scan	10
Typical dose to A-bomb survivor at 2.3 km distance from ground zero Hiroshima	13
Radiation worker annual exposure limit	20 per year
Exposure on international space station	170 per year

Extracolonic Findings

- Pooled results: 6%-8%
- “Benefits”
  - 0.3% of patients had extracolonic cancers
  - Other lesions: AAA, adrenal adenomas, cysts
- “Harms”
  - Most lesions will not be clinically consequential
  - No data on complications of investigation
  - $2 - $34 per patient for f/u
- Importance of reporting protocols

Patient Acceptance

- After having experienced both CTC and colonoscopy, of 1883 patients in 4 included studies:
  - 48.7% preferred CTC
  - 41.3% preferred colonoscopy
  - 9.9% had no preference
- No data on impact of availability of CTC on population screening rates

Modeling of Comparative Clinical Effectiveness and Value

- No screening
- Annual FOBT
- Annual FIT
- SIG 5y
- Annual FOBT + SIG 5y
- Annual FIT + SIG 5y
- Colonoscopy 10y

4 CTC Strategies

Strategy	Finding Triggering Colonoscopy Referral	Intervals
CTC-M	≥ 6 mm	Every 5y, Every 10y
CTC-L	≥ 10 mm	Every 5y, Every 10y

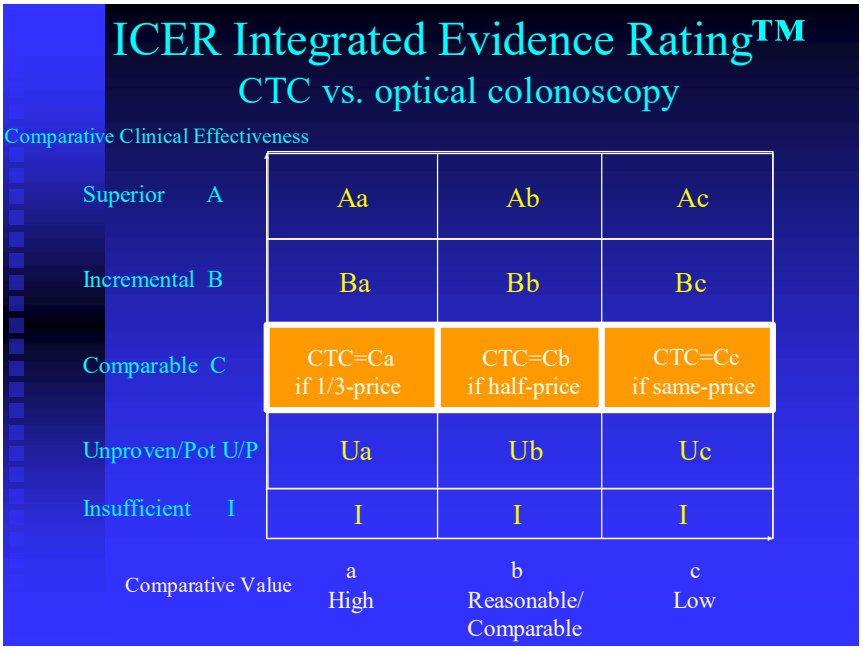
Cases & Deaths Prevented*

Strategy	Cases	Deaths
CTC-L 10y	**32.7**	**17.8**
SIG 5y	38.3	18.9
FOBT 1y	38.5	19.7
CTC-L 5y	**41.6**	**22.2**
FIT 1y	46.3	24.6
CTC-M 10y	**46.9**	**23.5**
FOBT 1y + SIG5y	49.0	24.3
FIT 1y + SIG 5y	51.7	25.9
Colonoscopy 10y	**52.3**	**25.6**
CTC-M 5y	**52.9**	**26.0**

* Per 1,000 screened; 64.1 cases & 29.9 deaths expected without screening

Cost-effectiveness

- CTC-M and price = $522
- Versus *no screening*
  - Cost to prevent one case of cancer = $19,000
  - Cost to prevent one death = $37,000
  - Cost to gain one year of life = $1,500
- Versus *optical colonoscopy*
  - Cost to gain one year of life = $630,700



ICER ERG Key Issues

- The relevance of smaller polyps
- System use of other screening methods
- Integration with colonoscopy
- Impact of extra-colonic findings
- Impact on population screening rates

ICER ERG conclusions

- Assuming:
  - Technical criteria used for this review
  - CTC protocols that do not report polyps ≤ 5 mm and refer polyps ≥ 6 mm for colonoscopy
- CTC has “superior” comparative clinical effectiveness to no screening
- CTC has “comparable” comparative clinical effectiveness to colonoscopy
- Test characteristics compare favorably to all other alternative screening methods
- CTC has “high” comparative value vs. no screening
- CTC comparative value vs. colonoscopy depends on reimbursed price ratio
- Important considerations for which evidence is limited include system integration, extracolonic findings, and the impact on population rates of screening.

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
- Bowel Perforation	
- Radiation Exposure (accumulation)	
Efficacy/Effectiveness Outcomes	**Efficacy/Effectiveness Evidence**
Specificity (true negative, false negative)	
Sensitivity – - Small Polyps - Med Polyps - Large Polyps	
Equipment Variation	
Reader training	
Bowel Preparation	
Cost Outcomes	**Cost Evidence**
-Procedure Fee and timing	
- Referral to optical colonoscopy	
- Extra-colonic findings	
Other Factors	**Evidence**
- Patient preference	
- Impact on screening rate	

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	2004	Colorectal Cancer Screening covered tests: FOBT, sigmoidoscopy, colonoscopy, barium enema. Tests not specified are non-covered.	Y	N/A
US Preventive Services Task Force	2002	Insufficient evidence that CTC improves health outcomes	Y	Insufficient evidence
National Cancer Institute	2008	Evidence summarized, no recommendations	Y	N/A
American Cancer Society	2007	Colorectal Cancer screening recommended; CTC not included in listed methods	N	N/A
American Gastroenterological Association	2007	CTC is not endorsed as a primary screening modality for CRC in asymptomatic adults evolving	Y	N/A
American College of Radiology	2005 (u2006)	CTC indications listed, including screening for colorectal cancer	Y	N/A
American Society for Gastrointestinal Endoscopy	2003 (u2006)	CTC is an evolving technique and is not currently recommended as the primary method of screening	Y	N/A

Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Inconclusive (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not covered. _____ Covered Unconditionally. _____Covered under certain conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover With Conditions
If covered with conditions, the Committee will continue discussions.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence of a diagnostic tests' accuracy
    - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does the scientific evidence confirm that use of the technology can effectively replace other tests?
- Does use of the test change treatment choices
- What is the evidence that use of the technology results in a more beneficial outcome
    - Direct outcome or surrogate measure
    - Short term or long term effect
    - Magnitude of effect
    - Impact on pain, functional restoration, quality of life
    - Disease management

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?