



CT Colonography: Is it Inevitable?

St. Louis University Symposium on GI Cancers



Joel V. Brill, MD

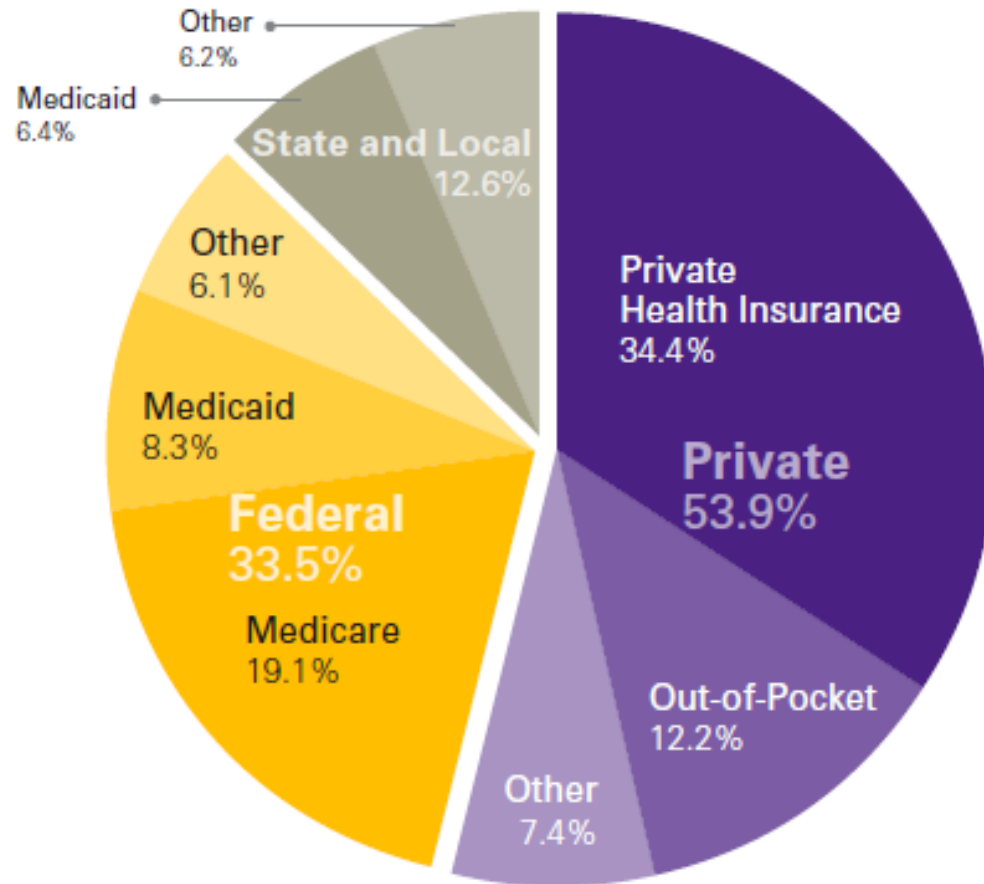
Gastroenterology is Facing a Challenge...

- ▶ Are you solely in the endoscopy business?
 - ▶ *“I scope, therefore, I am”*
- ▶ Or are you in the colorectal cancer screening, detection and prevention business?
 - ▶ *“Our practice is the referral center for all your CRC needs.”*
- ▶ The average Gastroenterologist spends:
 - ▶ 70% of his/her time performing colonoscopy
 - ▶ 70% of colonoscopies are for screening
 - ▶ Which leaves you vulnerable



Who Pays for Care?

Total Health Spending: \$2.1 trillion



Gastroenterology is under CMS attack

- ▶ Linked ASC reimbursement to hospital outpatient (OPPS) payment (2008)
- ▶ Proposes to eliminate payment for Consultations (2010)
- ▶ The reduction in procedure time and increasing use of anesthesia professional raises potential for review of colonoscopy reimbursement (2011)

CTC: Barbarians at the Gate



ACRIN 6664 study

▶ Per-patient analysis

| | Sensitivity | Specificity | Positive predictive value | Negative predictive value |
|--------|-------------|-------------|---------------------------|---------------------------|
| ≥ 6mm | 0.78 | 0.88 | 0.40 | 0.98 |
| ≥10 mm | 0.90 | 0.86 | 0.23 | 0.99 |

- ▶ Per-polyp analysis, sensitivity for lesions ≥ 5 mm of 0.70 and for lesions ≥ 10 mm of 0.84.
- ▶ Extracolonic findings were observed in 66% of the participants; however, only 6% were deemed to require either additional evaluation or urgent care.

Johnson CD, et al *N Engl J Med* 2008;359:1207-1217

Microsimulation Model Analysis

- ▶ “Screening for CRC with CT colonography every 5 years with referral of individuals with a 6 mm or larger lesion to colonoscopy provides a benefit in terms of life-years gained that is comparable to that of five-year flexible sigmoidoscopy with annual FOBT and slightly lower than colonoscopy screening every 10 years.”

Zauber AG, et al <http://www.cms.hhs.gov/determinationprocess/downloads/id58TA.pdf>



US Preventive Services Task Force

- ▶ “In settings with sufficient quality control, CT colonography is as sensitive as colonoscopy for large adenomas and colorectal cancer.
- ▶ Uncertainties remain for smaller polyps and frequency of colonoscopy referral.”
- ▶ “Potential radiation-related harms, the effect of extracolonic findings, and the accuracy of test performance of CT colonography in community settings remain uncertain.
- ▶ Evidence is insufficient to assess the benefits and harms of computed tomographic colonography”

Whitlock EP, et al *Ann Intern Med* 2008;149: 627-637 and 638-658

Munich

- ▶ CT colonography, per polyp sensitivity
 - ▶ 70.1% for all adenomas
 - ▶ 59.2% for adenomas < 6mm
 - ▶ 90.2% for 6-9mm
 - ▶ 93.9% for > 9mm.
- ▶ For all adenomas, per person sensitivity was 84.1% and specificity was 47.4%.
- ▶ “High resolution and low dose CTC is feasible for colorectal cancer screening and reaches comparable sensitivities to colonoscopy for polyps >5 mm.”

Graser A, et al *Gut* 2009;58:241-248

BCBSA Technology Assessment

- ▶ Objective: To determine whether there is adequate evidence to demonstrate that CT colonography screening is effective in reducing mortality from colon cancer.
- ▶ Main results: A test that approaches the sensitivity of optical colonoscopy for the detection of clinically relevant polyps should logically approach the clinical effectiveness of optical colonoscopy, as optical colonoscopy is considered to be the most effective techniques for cancer screening and prevention.
- ▶ Findings: CT colonography for the purpose of colon cancer screening meets the TEC criteria

<http://www.bcbs.com/blueresources/tec/press/ct-colonography-virtual.html>



Medicare: Screening services

- ▶ Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.
- ▶ If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test.

CMS Transmittal I769, July 10, 2009

<http://www.cms.hhs.gov/transmittals/downloads/R1769CP.pdf>

CAG-00396N

- ▶ National Coverage Analysis Tracking Sheet for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)
- ▶ “The evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under §1861(pp)(1) of the Social Security Act.
- ▶ CT colonography for colorectal cancer screening remains noncovered.”

<http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=220>

Why Medicare non-coverage?

- ▶ The evidence was not sufficient to determine that CT colonography is a valuable screening test for colorectal cancer for average risk Medicare individuals compared to optical colonoscopy.
- ▶ The evidence was not sufficient to conclude that the use of CT colonography improves health outcomes for colorectal cancer screening in average risk individuals compared to optical colonoscopy.



What factors did CMS consider

- ▶ Radiation Risk
- ▶ Extracolonic findings
- ▶ Impact of CTC coverage on CRC screening rates for the Medicare population
- ▶ Cost effectiveness
- ▶ Whether data on commercial patients can be generalized to the Medicare population
- ▶ Variable precision for polyps < 10mm
- ▶ Was coverage with evidence development (CED) available



Coverage with Evidence Development

- ▶ CMS makes National Coverage Determinations (NCDs) based on requests for national coverage from individuals or entities that identify an item or service as a potential benefit (or to prevent potential harm) to Medicare beneficiaries.
- ▶ Guided by Section 1862(a)(1)(A) of the Social Security Act

http://www.cms.hhs.gov/CoverageGenInfo/03_CED.asp

The NCD process may result in

- ▶ No change in coverage. Current coverage, whether local or national, will remain unchanged.
- ▶ Non-coverage. The medical evidence is not adequate to conclude that the item or service is reasonable and necessary for Medicare beneficiaries.
- ▶ Coverage without special conditions. The item or service is reasonable and necessary.
- ▶ Coverage with special conditions. The item or service is reasonable and necessary only under one or more of the following circumstances:
 - ▶ Patients with specific clinical or demographic characteristics.
 - ▶ When provided by physicians and/or facilities that meet specific criteria.
 - ▶ When specific data are submitted in addition to claims data to demonstrate that the item or service was provided as specified in the NCD (Coverage with Appropriateness Determination)
- ▶ Coverage with Study Participation. Under section 1862(a)(1)(E), the NCD process may result in coverage if the item or service is provided within a setting in which there is a pre-specified process for gathering additional data, and in which that process provides additional protections and safety measures for beneficiaries, such as those present in certain clinical trials.

Why a CED for CTC?

- ▶ Questions that could be answered through Coverage with Study Participation:
 - ▶ Natural history of small and intermediate sized polyps
 - ▶ Clarification of radiation risks
 - ▶ True rate and cost of extracolonic findings
 - ▶ Health-related benefits of colonoscopy and polypectomy
 - ▶ Accurate and real world cost-effectiveness



Cost-Effectiveness (Cost/Year Life Saved)

- | | |
|--------------------------------|-------------|
| ▶ Mandatory motorcycle helmets | \$2,000 |
| ▶ Colorectal cancer screening | \$25,000 |
| ▶ Breast cancer screening | \$35,000 |
| ▶ Dual airbags in cars | \$120,000 |
| ▶ Smoke detectors in homes | \$210,000 |
| ▶ School bus seat belts | \$1,800,000 |
-
- ▶ If an intervention can save one year of life for less than \$50,000, it is cost-effective
 - ▶ In economic terms, screening for colorectal cancer is very cost-effective

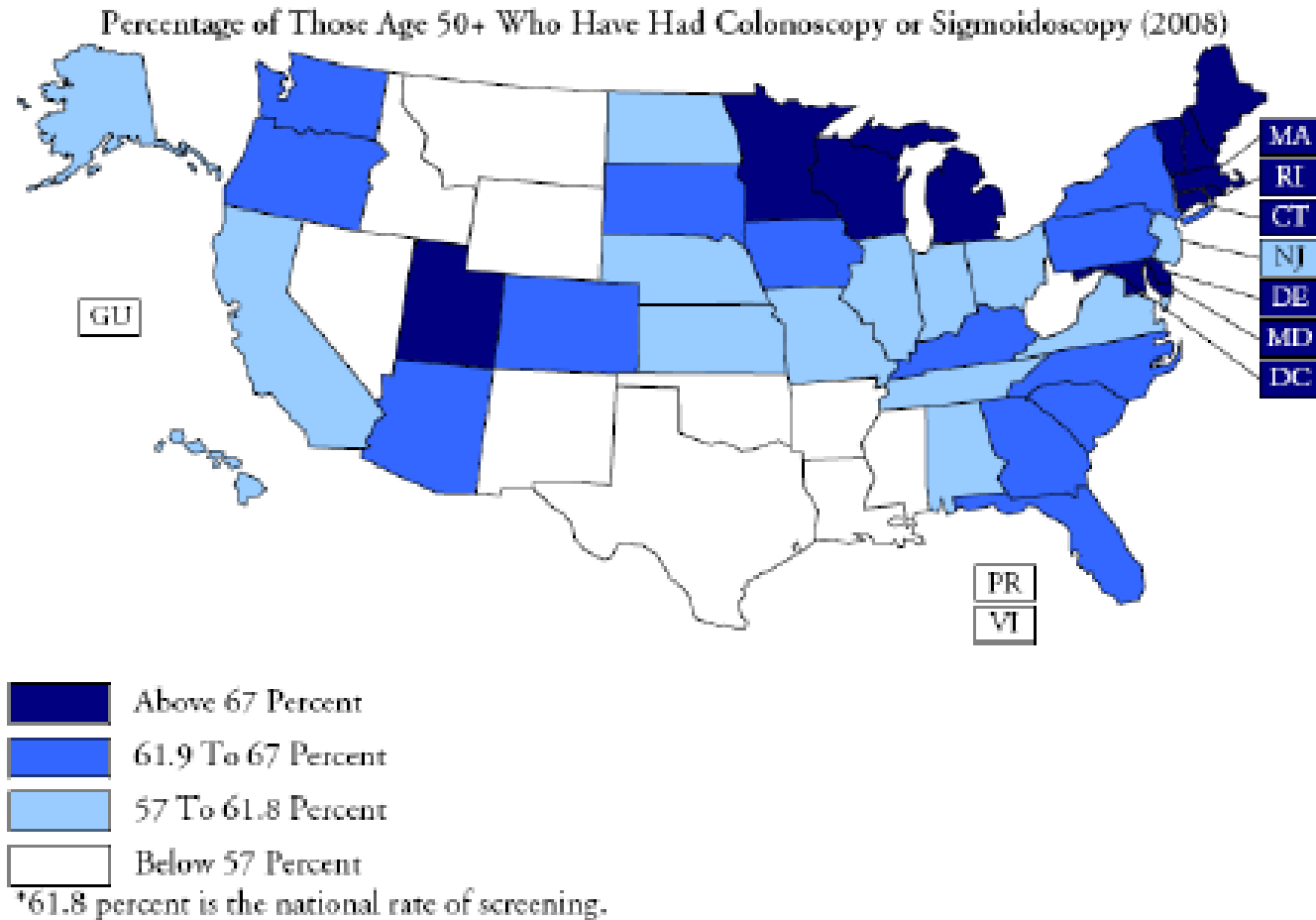


States with CRC screening mandates

- ▶ Alabama
- ▶ Arkansas
- ▶ Delaware
- ▶ Colorado
- ▶ Connecticut
- ▶ District of Columbia
- ▶ Georgia
- ▶ Illinois
- ▶ Indiana
- ▶ Kentucky
- ▶ Louisiana
- ▶ Maine
- ▶ Maryland
- ▶ Minnesota
- ▶ Missouri
- ▶ Nebraska
- ▶ Nevada
- ▶ New Jersey
- ▶ New Mexico
- ▶ North Carolina
- ▶ Oklahoma
- ▶ Oregon
- ▶ Rhode Island
- ▶ Tennessee
- ▶ Texas
- ▶ Virginia
- ▶ Washington
- ▶ West Virginia
- ▶ Wyoming

<http://www.ncsl.org/default.aspx?tabid=14328>

% of those 50+ who have been scoped



Source: CDC, 2008 Behavioral Risk Factor Surveillance System

Why are CRC Screening Rates Low?

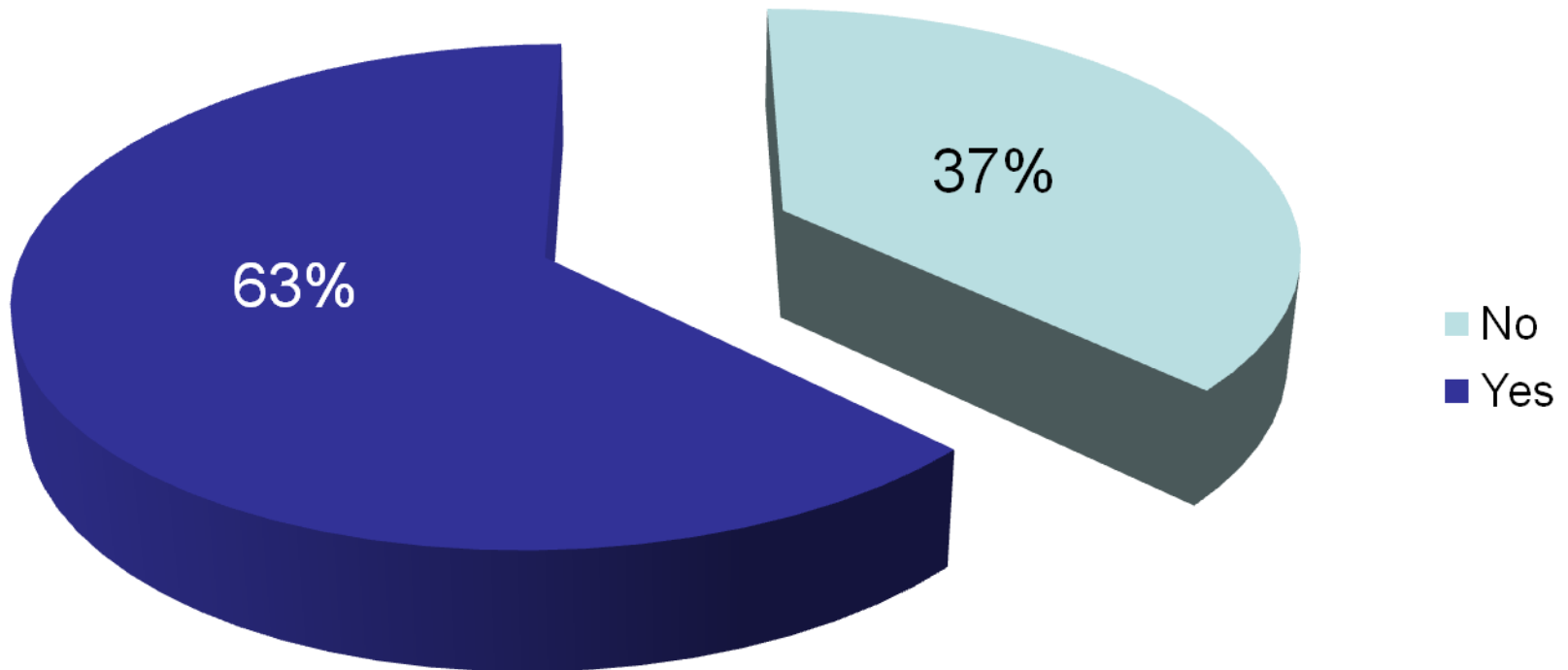
(According to Patients)

- ▶ Low awareness of CRC as a *personal* health threat
- ▶ Lack of knowledge of screening benefits
- ▶ Fear, embarrassment, discomfort
- ▶ Hate the prep
- ▶ “Will it hurt, doc?”
- ▶ “You’re going where no man has ever gone before!”
- ▶ Time
- ▶ Cost
- ▶ Access

American Cancer Society

Does CTC Increase Compliance?

**Would you get screened if CTC not offered?
250 Consecutive Patients at NNMC (free care)**



Cash BD, unpublished data collected Jan-Feb 2009

Insurers and Screening CTC

▶ Cover screening

- ▶ Cigna
- ▶ CareFirst BCBS
- ▶ BCBS Delaware
- ▶ Independence Blue Cross
- ▶ Horizon BCBS
- ▶ Anthem BCBS
- ▶ BCBS North Carolina
- ▶ Physicians Plus of WI
- ▶ BCBS Rhode Island
- ▶ BCBS Arkansas
- ▶ Wellmark BCBS
- ▶ United Healthcare

▶ Not Covered

- ▶ CMS
- ▶ Aetna
- ▶ BCBS Florida
- ▶ BCBS IL/NM/OK/TX
- ▶ BCBS South Carolina
- ▶ Health Net
- ▶ Highmark BCBS
- ▶ Humana
- ▶ Harvard Pilgrim
- ▶ Premera Blue Cross
- ▶ Regence BCBS
- ▶ Priority Health
- ▶ UPMC Health Plan

As of August 27, 2009

Reimbursement for non-radiologists

- ▶ **Gastroenterologists who read CTC should:**
 - ▶ Demonstrate their proficiency through training, certification, mentoring, and ongoing education programs
 - ▶ Address who will read the extra-colonic findings
- ▶ **Facility owners:**
 - ▶ Need to be accredited by ACR or Intersocietal Commission for the Accreditation of Computed Tomography Laboratories (www.icactl.org or www.intersocietal.org)
 - ▶ United Healthcare – 2009
 - ▶ Medicare – 2012



Should Your Practice Add a CT Now?

- ▶ Is it better to own the facility or interpretation revenue?
- ▶ Partnership opportunities:
 - ▶ TC/PC model
 - ▶ Gastroenterologist owns the facility (TC)
 - ▶ Radiologist performs the interpretation (PC)
 - ▶ IDTF model
 - ▶ Physicians and non-physicians can own the facility (TC)
- ▶ Can you offer CTC screening to patients with whom the practice does not have a pre-existing physician – patient relationship?
 - ▶ No absolute requirement under Stark that a group have a pre-existing physician-patient relationship with a patient to whom they furnish a designated health service.






Costs: CTC vs. Colonoscopy

- ▶ **Proposed rule devastating to imaging:**
 - ▶ Increasing equipment utilization = decreased TC
 - ▶ AMA PPIS survey shifts \$\$ from imaging to primary care
- ▶ **Anticipate CTC reimbursement less than colonoscopy**
 - ▶ “The cost of CT colonography relative to the benefit derived and to the availability and costs of other CRC screening tests, would need to be in the range of \$108 to \$205 to be a cost-effective alternative to all other available screening modalities, and in the range of \$179 to \$237 to be cost-effective compared to colonoscopy screening with CMS payment of approximately \$500 for colonoscopy without polypectomy and \$650 for colonoscopy with polypectomy.” (Zauber)
- ▶ **CMS to release the 2010 Fee Schedule in November**



Shift in CRC Screening Utilization

Medicare

| | 2000 | 2002 | 2005 | 2012 |
|--------------------|------------------|------------------|------------------|---|
| Flex Sig | 543,502 | 236,139 | 170,222 |  |
| Colonoscopy | 2,211,925 | 3,150,738 | 3,307,176 |  |
| CTC | | | |  |



Thank you!

Joel V. Brill, MD

P: 602.418.8744

F: 480.452.0424

joel.brill@verizon.net

Chief Medical Officer
Predictive Health, LLC
6245 N. 24th Parkway
Suite 112
Phoenix AZ 85016



*"Give it to me straight, Doc.
How long do I have to ignore your advice?"*