Blood Tests To Screen For Colorectal Cancer

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The Appeal of a Screening Blood Test is Obvious

- Many people, probably most people, love the idea of a blood test that tells you if you have cancer.
- Far and away, the simplest initial approach to CRC screening.
- Freenome and Guardant have both demonstrated very high participation rates, even in people who previously chose not to have a CRC screen.

Just Don’t Lose Sight of the Basic Truth of CRC Screening

- ALL of the benefit of CRC screening derives from finding pre-cancerous lesions or early cancers during colonoscopy.
- Having a positive initial screen that does not lead to colonoscopy is a tragedy.
- Will people who opt for the simplicity of the blood test be willing to accept the complexity of colonoscopy?
- If not, the blood tests will have far less benefit than they might achieve.

Multi-cancer Detection vs. Single-cancer Detection

Both technologies rely on detecting cell-free DNA, proteins, or other blood markers of cancer. The differences between the two approaches reflect both differences in technology and differences in strategies pursued by the various companies involved in this work.

MCED's Will Not Have a Major Role in Screening for Colorectal Cancer Anytime Soon

- They are not intended to replace screening strategies that are proven to be effective.
- They are not as sensitive as existing CRC screening options.
- No data at all regarding screening for polyps.

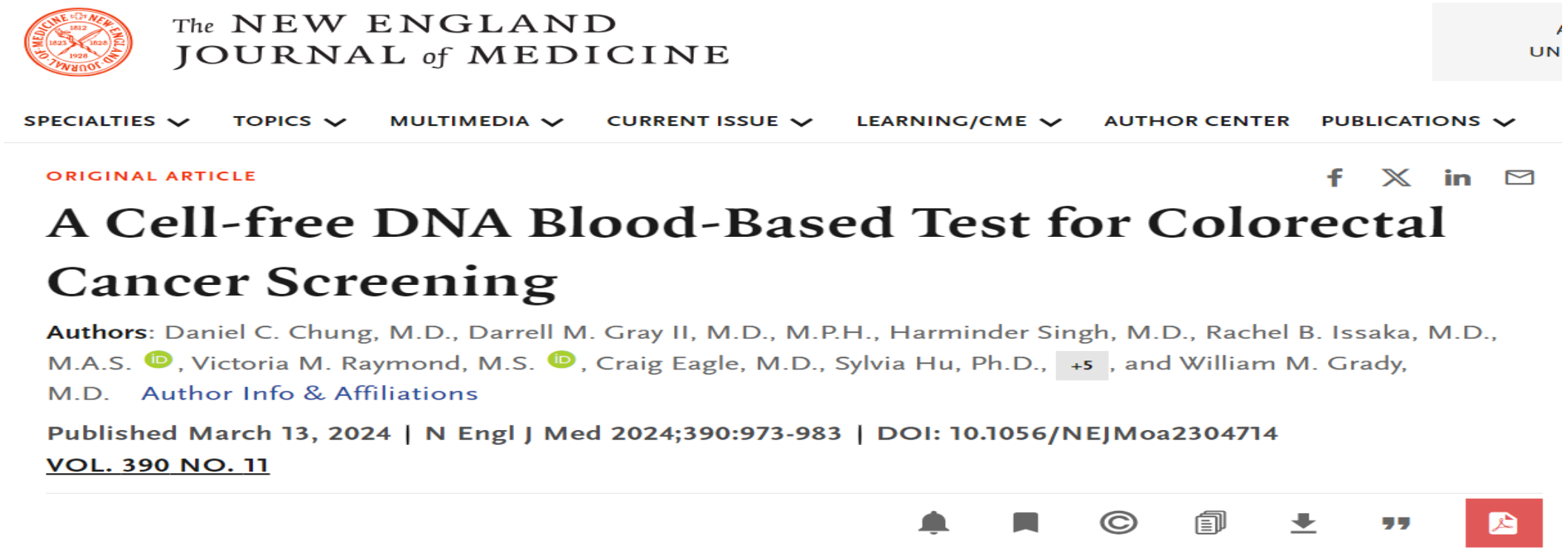
Epi proColon Was the First Blood Test to Screen for CRC

- Detected the methylated Septin-9 gene.
- Earned FDA approval for those who refused first line CRC screening.
- Low sensitivity for colon cancer, (around 50%), precluded inclusion in guidelines and the Epi proColon test is no longer available.

Motivated Medicare to Set Thresholds for Coverage of a CRC Screening Blood Test

- Medicare thresholds for coverage:
  - Sensitivity of at least 74%
  - Specificity of at least 90%

Blood Tests for Colorectal Cancer Screening



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ORIGINAL ARTICLE

A Cell-free DNA Blood-Based Test for Colorectal Cancer Screening

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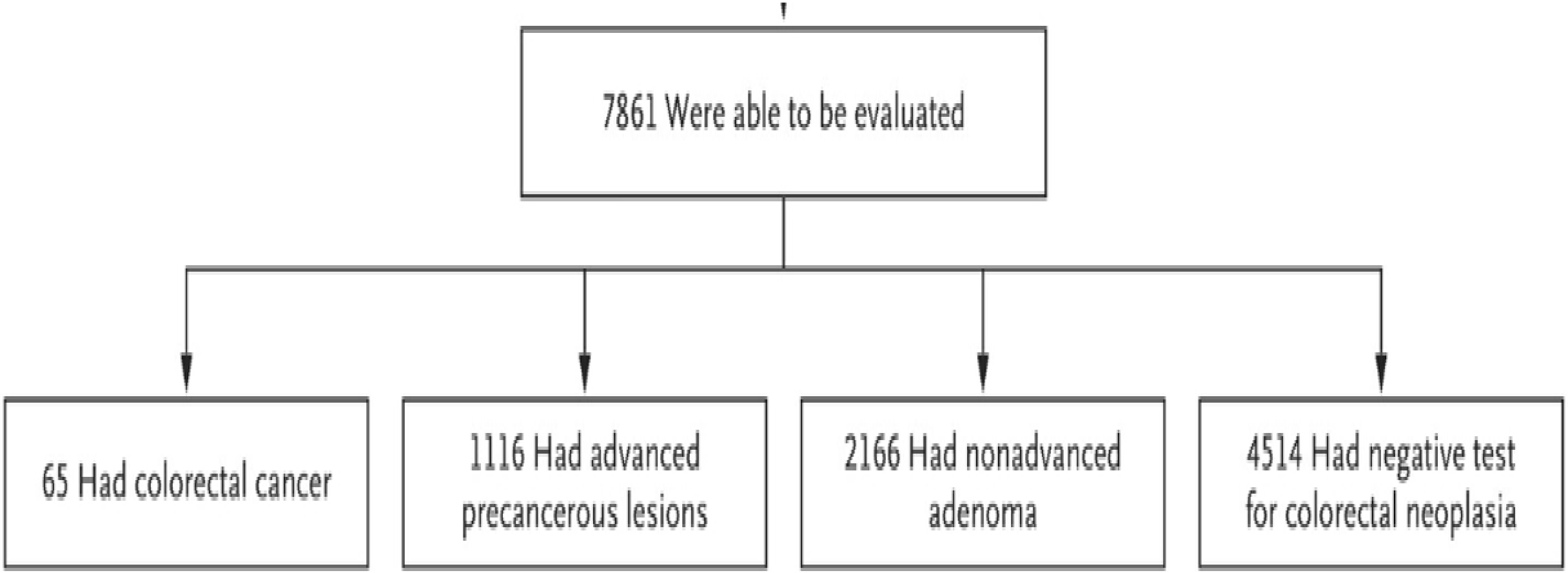
Results:


7861 Were able to be evaluated
65 Had colorectal cancer
1116 Had advanced precancerous lesions
2166 Had nonadvanced adenoma
4514 Had negative test for colorectal neoplasia

Guardant CRC Blood Test Trial: Sensitivity

- For any stage of cancer: 83.1%
- For Stage I, II, or III: 87.5%
- For Stage I: 55-65%
- For Advanced precancerous lesions : 13.2 %

Specificity of 89.6%

SHIELD Cost and Reimbursement

- The test is approved by the FDA and covered by Medicare.
- Medicare reimburses $1,495 for the test!
- Medicare Advantage patients may have deductibles or co-pays.
- Individuals not on Medicare can have the test ordered by a physician for the out-of-pocket expense of $895.

Freenome is Developing a CRC Blood Test

- Sensitivity, CRC Overall: 79.2%
  - Stage I: 57.1%
  - Stage II: 100%
  - Stage III: 82.4%
  - Stage IV: 100%
- Advanced precancerous lesions: 12.5%

Specificity of 91.5%

Characteristics of a cost-effective blood test for colorectal cancer screening

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Abstract

Cost-Effectiveness of Available Blood Test for CRC Screening

- “Conclusion: Blood tests that only meet CMS coverage requirements should not be recommended to patients who would otherwise undergo screening by colonoscopy or fecal immunochemical testing because of lower benefit. Blood tests need higher advanced adenoma sensitivity (above 40%) and lower costs (below $125) to be cost-effective.”

In Other Words . . . .

- **"The best test is the one that gets done"** may no longer be our best guide.
- **"The best test is the option other than a blood test that the patient is willing to do."**
- The new SHIELD blood test is best reserved for individuals who won't do any other screening option – and only if the patient can afford the test and is willing to undergo colonoscopy.

Blood Test Future – My Synthesis

- Sensitivity for cancer will be higher than FIT for **one-time testing.** Probably not better than FIT annually for three years vs. one blood test in three years.
- Relatively low sensitivity for Advanced Precancerous Lesions (APL's) will temper enthusiasm for these tests.
- Shield ™ can be ordered now at a cost of over $900. Cost could be a real limiting factor.
- **But high acceptability of blood tests could enable us to reach more people.**