



Innovative Health Diagnostics

Amey Wood

CDC's Colorectal Cancer Screening Statistics

67.4% → **68.8%**
2016 2018

The percentage of adults aged 50 to 75 years who were up-to-date with colorectal cancer (CRC) screening increased by **1.4%** from 2016 to 2018.

That means
4.2 million

more adults aged 50 to 75 years were screened for CRC.



21.7 million

Adults aged 50 to 75 years who have never been screened for CRC.



81%

Of adults who have never been screened are people aged 50 to 64 years.

About **one-quarter** of adults have not been screened as recommended.

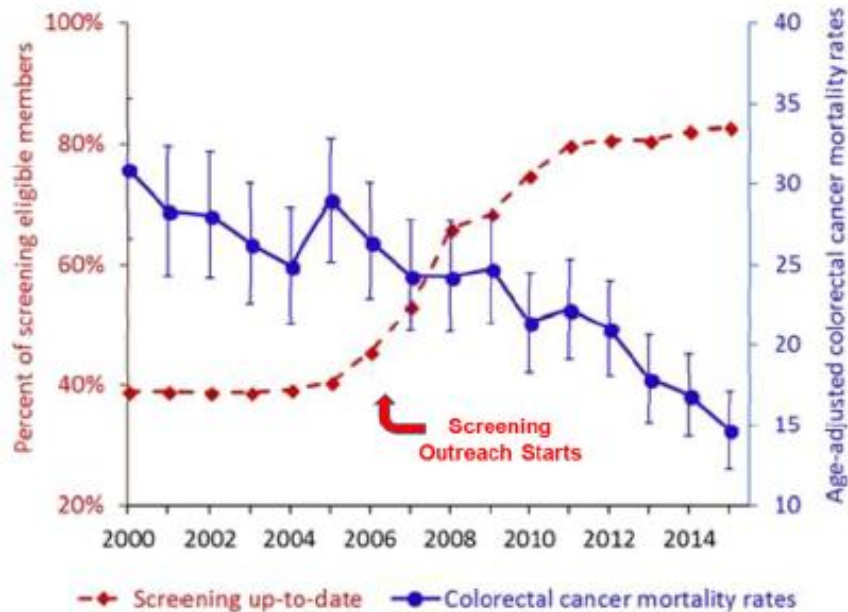
More Information

- [Colorectal Cancer \(CDC\)](#)
- [Behavioral Risk Factor Surveillance System \(CDC\)](#)



OC FIT CLINICAL EVIDENCE

Colorectal Cancer Screening and Mortality Rates at Kaiser Permanente Northern California



Gastroenterology

Initiation of organized CRC screening (annual fecal immunochemical testing and colonoscopy) increased the up to date status of screening, from 38.9% in 2000 to 82.7% in 2015, and was associated with a 25.5% reduction in annual CRC incidence and a 52.4% reduction in cancer mortality.

OC FIT

Over 100
published peer
reviewed studies
documenting OC
FITs test
performance



"The OC-Light and the OC FIT-CHEK family of FITs (Polymedco, Inc., Cortlandt Manor, NY) have the best test performance characteristics (i.e., highest sensitivity and specificity)."



"At this time, the brand of FIT that has been most extensively tested and is available in the United States is OC FIT-CHEK® (Polymedco)."



"These data are consistent with an overall impression that the fecal immunochemical test product by Eiken (marketed in the U.S. by Polymedco) is the FIT test with the best clinical evidence to support its use."

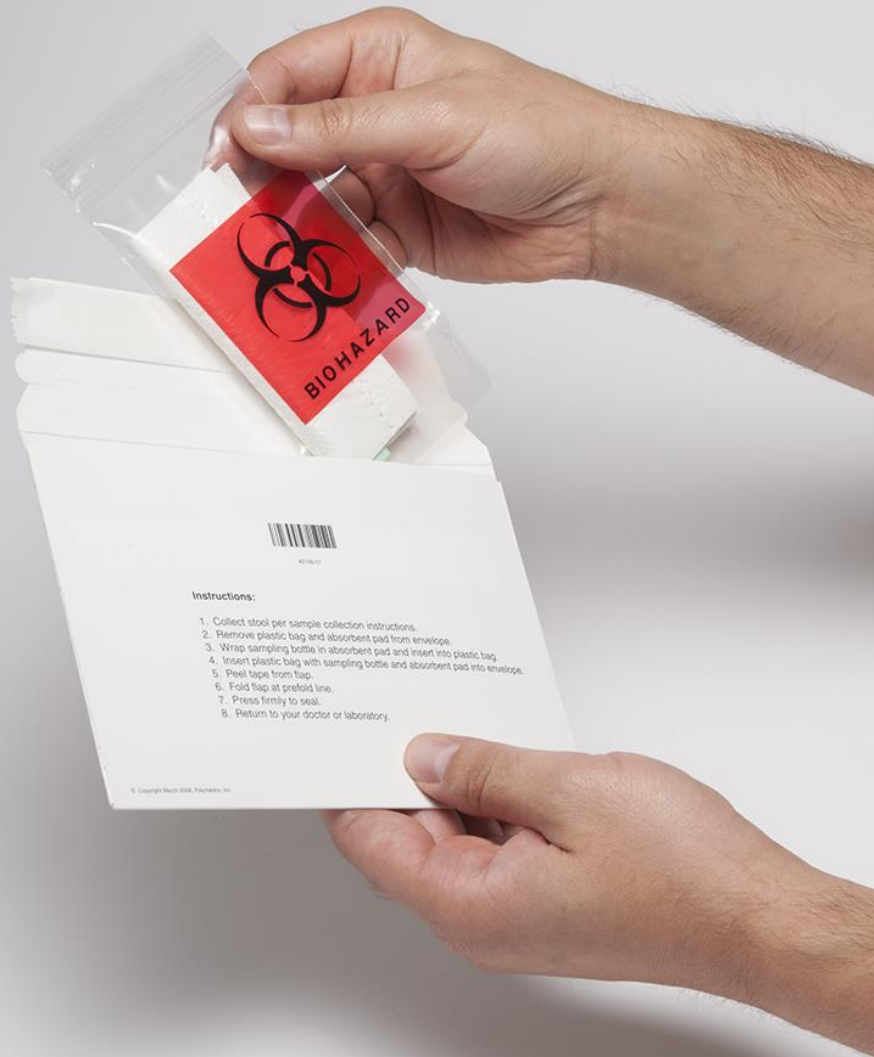
CLINICAL BENEFITS OF POLYMEDCO'S OC FIT

Clinical Performance

- Sensitivity 86-93%
- Specificity 93-96%


Patient Pack Optimizes Patient Compliance

- Pre-addressed & Postage Pre-Paid
- 15 Day Inoculated Stability
- Collection Vial Design Prevents Buffer from Spilling




Product Ease of Use


1. Unfold the collection paper.



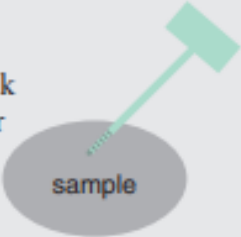
2. Lay the collection paper flat inside your toilet on top of the water. Have a bowel movement on top of the paper.




3. Twist and lift the cap on the sample bottle. **Keep the liquid in the bottle.** We need it for the test.



4. Scrape the stool with the sample stick a few times to cover the grooved tip of the stick.



5. Push the stick back into the sample bottle until the cap clicks. (Collection paper will flush easily.)



1. Wrap your sample bottle in the small shipping pad.



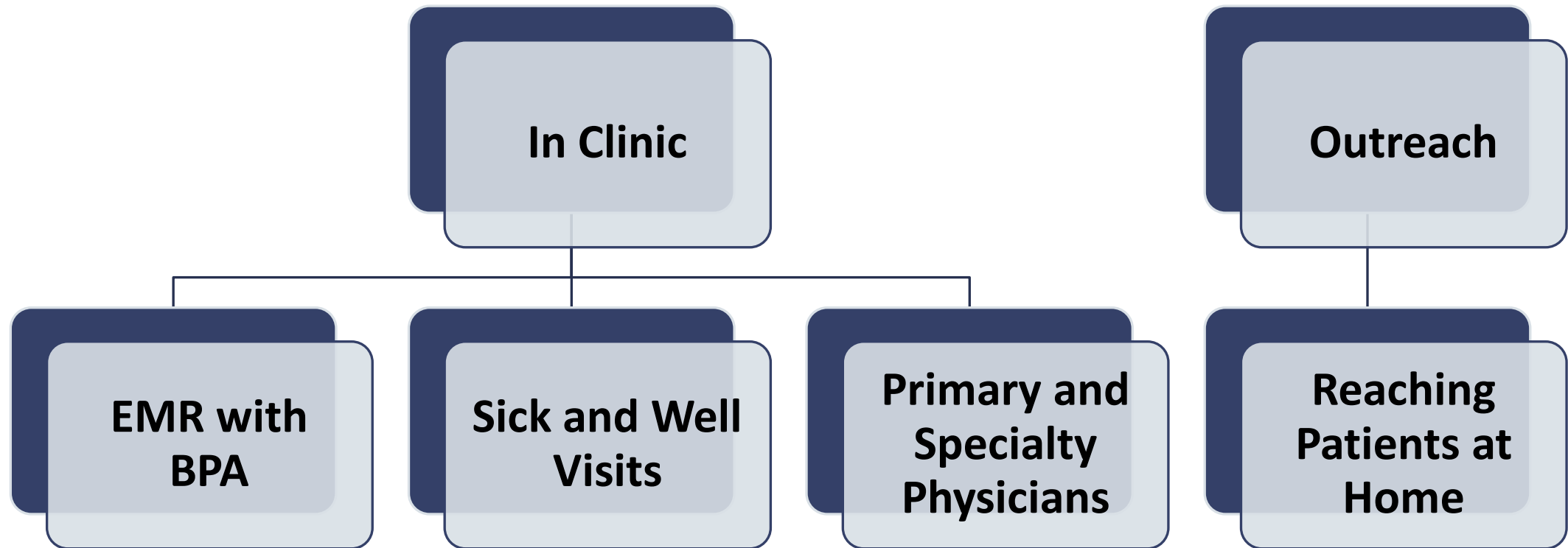
2. Put the sample bottle and the pad inside the plastic bag. Seal the bag.



3. Mail the envelope within 24-48 hours.



Standardized Programmatic Approach

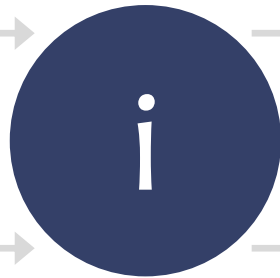


OUTREACH PROCESS



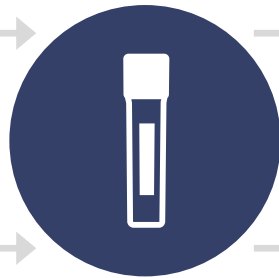
IDENTIFY/ EMR

Patients in need of CRC screening



EDUCATE

Through patient website portal, pre-call reach-out, emails, texts or written letters.



DISTRIBUTE

OC-FIT patient packs to patient via the mail



REMIND

With a reminder phone call, text, email, etc...



PROCESS

50-60% return via mail resulted in your laboratory. Positives are diligently contacted by Primary Care Teams instructed and scheduled for colonoscopies



RESULTS

Most critical patients are first to be scheduled for colonoscopy as soon as endoscopy is screening patients again

OC FIT Vs. OTHER FIT

CDC Meta-Analysis

The CDC did a meta-analysis showing the importance of FIT for CRC screening but stressed **“not all FITs are the same and you should only use a FIT method with peer reviewed evidence of efficacy”**. They set the bar very low at 50% detection for CRC with documentation required via peer reviewed studies.

The only one sample method that met this minimum requirement is Polymedco's OC FIT, with a sensitivity of 93%. No other FIT methods met this minimum requirement of performance.

Cologuard Vs. FIT

US Preventive Services Task Force Recommendation Statement

- sDNA-FIT ‘specificity is lower than that of FIT, resulting in more false-positive results, more follow-up colonoscopies, and **more associated adverse events per sDNA-FIT.**’
- ‘Modeling suggests that **screening every 3 years does not provide a favorable balance of benefits and harms compared with other stool-based screening options.**’
- ‘**No direct evidence evaluating the effect of sDNA-FIT on colorectal cancer mortality.**’

2020 ACP Guidance Statements

- Screening reduces CRC greatest benefit in patients older than 60 years.
- The ACP recommends screening average-risk patients with one of the following: colonoscopy every 10 years, flexible sigmoidoscopy every 10 years with biennial FIT, biennial guaiac FOBT, or biennial FIT.
- **Because of limited evidence of benefit and increased harms, neither FIT with stool DNA testing nor CT colonography is a recommended screening method.**

ACG Clinical Guidelines: Colorectal Cancer Screening 2021

- ‘We recommend **colonoscopy and FIT as the primary screening modalities for CRC screening.**’
- ‘We suggest consideration of the following screening tests **for individuals unable or unwilling to undergo colonoscopy or FIT: flexible sigmoidoscopy, multitarget stool DNA test, CT colonography or colon capsule.**’

USMSTF CRC Screening Tier Recommendations

- ‘The first-tier tests are colonoscopy every 10 years and annual fecal immunochemical test (FIT). **Colonoscopy and FIT are recommended as the cornerstones of screening regardless of how screening is offered.**’

The New England Journal of Medicine

- **Multitarget Stool DNA Testing for Colorectal-Cancer Screening: “The specificity of FIT (94.9 to 96.4%) was superior to that of the DNA test (86.6 to 89.8%) with false positive rates of 3.6 to 5.1% and 10.2 to 13.4% respectively”.**

Center for Medicaid and Medicare Services

- New CMS Report Casts Doubt on Cologuard: But those projections were made before the new research report finding that **Cologuard is “less effective and considerably more costly” than alternatives.** “At its current reimbursement rate, triennial mtSDNA testing also has **higher costs than all other strategies, making it an inefficient screening option,**” according to the paper published in the Sept. 4, 2019, issue of PLOS ONE.

OC FIT Sales

Target Types

1. IDNs that employ Primary Care Physicians
2. IPAs
3. Primary Care Medical Groups
4. OBGYN Offices

Key Contacts

1. Chief Medical Officer or Medical Director of Primary Care
2. Chief of Gastroenterology
3. Office Manager

Thank You

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awood@polymedco.com

Technical Support / Service

- ▶ Polymedco's Technical Services Department can be reached at 914-739-5400 x 285:
 - Monday – Friday, 8:00 a.m. – 6:00 p.m. EST Regular Office Hours
 - Monday – Friday, 6:00 p.m. – 9:00 p.m. EST after hours on call telephone support service
 - ▶ Calls come into Technical Services (T/S)
 - ▶ T/S troubleshoots and determines if the issue is reagent or hardware related
 - ▶ If the issue is hardware related, the call is referred to Biomedical Engineering (BME) (during regular office hours)
 - ▶ If BME cannot resolve the issue over the phone, a service call will be dispatched (during regular office hours)
 - ▶ Engineering's response time is 24 hours from the time of dispatch

