

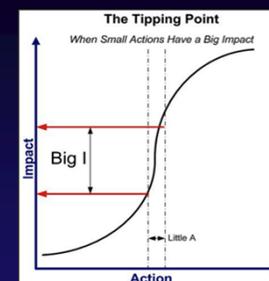
80% National CRC Screening Rate by 2018
A goal we can reach by getting FIT!



James E. Allison, MD, FACP, AGAF
Clinical Professor of Medicine Emeritus
University of California San Francisco
Emeritus Adjunct Investigator
Kaiser Division of Research



2012 – The Tipping Point



Source: Malcolm Gladwell. *The Tipping Point: How Little Things Can Make a Big Difference*.
Little, Brown and Company, 2000

Summary of Messages
2000 - 2012

- Colonoscopy every 10 years, beginning at age 50, remains the preferred CRC screening strategy because it is the best test.
- Relying on flexible sigmoidoscopy is as clinically logical as performing mammography of one breast to screen women for breast cancer.
- If fecal tests are used the opportunity for CRC prevention is limited and incidental.
- Fecal occult blood tests have been proven to be inherently insensitive and nonspecific markers for screen relevant neoplasia.
- FOBT require repeated testing that is unlikely to be done.

The New Messages
2012 – 2018 and beyond

- No CRC screening strategy has been shown to be superior but, colonoscopy is the predominant method for CRC screening in the U.S.
- Primary-care providers are the most common source for a CRC screening recommendation. Many providers believe that colonoscopy is the best test option and do not offer other screening tests to their patients.
- The potential to increase screening rates exists if health-care providers identify the test that their patient is most likely to complete and consistently offer **all** recommended screening tests.

CDC MMWR January 2012 & November 2013

The new NCCRT messages Tweets and FB posts

- There are several ways to get screened for CRC including simple take home options. Talk to your doc about **#savinglives**
- Preventing colon cancer, or finding it early, doesn't have to be expensive. There are simple, affordable tests available. Get screened. **#80by2018**
- A colonoscopy isn't the only way to get screened for CRC. Your doctor can even give you a kit to take and use at home! Read more and talk to your doctor.
<http://ow.ly/HY99v>

GIE 2013 Screening and Surveillance for CRC: state of the art

- Colonoscopy remains the dominant CRC screening strategy in the U.S. but is less effective at preventing right-sided CRC than previously thought.
- FIT has emerged as an effective low cost alternative to colonoscopy and is considered by some an equivalent or superior approach to screening as compared to colonoscopy.

Kahi CJ, Anderson JC, Rex DK GIE 2013 77:335-350

JAMA PATIENT PAGE Options for CRC Screening

Evidence does not yet support any one screening test over another, so in deciding which screening option is best for you, consider your personal health situation and talk with your doctor.

JAMA August 14, 2013 Volume 310, Number 6

Take Home Message: Time To Get FIT

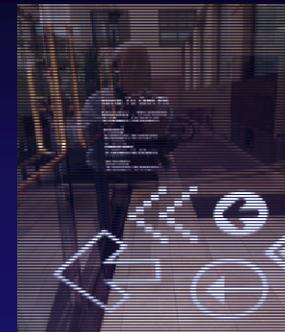




Photo: ALEX GOODLETT / New York Times

Available on Amazon.com - Price: \$22.99
Second Generation FIT for Colorectal Cancer

- Features
 - ◆ Amazingly accurate with 98% sensitivity and 96% specificity.
 - ◆ Easy to use with results in 5 minutes in the privacy of your home.
 - ◆ This is the same test as physicians, hospitals, and labs use for colorectal cancer screening, now available without a prescription or visit to the doctor.
 - ◆ 93% as effective as colonoscopy when performed annually. This is the same test used by physicians to effectively diagnose diverticulitis, colitis, ulcerative colitis and irritable bowel syndrome.
 - ◆ FDA-cleared for over-the-counter (home) use and CLIA-waived.

FIT and the FDA – the issues

- Only qualitative FIT are FDA approved & available for use in the U.S.
 - ◆ The approved FIT are CLIA-waived
 - CLIA-waived tests are defined as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”
 - Laboratories with a Certificate of Waiver are not subject to a routine inspection (survey) under the CLIA Program.
 - ◆ In 2013 it was reported that 93% of the FIT reported on by U.S. proficiency labs with available data were CLIA-waived FIT.
 - ◆ As of September, 2014, there were one hundred and sixteen FDA approved CLIA-waived FOBT for sale and very few of them had evidence of a published peer-reviewed independent demonstration of their performance characteristics and quality control.