

Introduction

Since 1997, the members of the National Colorectal Cancer Roundtable (NCCRT) have united to increase the use of evidence-based colorectal cancer screening tests among the entire population for whom screening is appropriate. As part of this mission, the NCCRT along with its 150 member organizations launched the <u>80% in Every Community</u> initiative, which aims to ensure that colorectal cancer screening rates reach or exceed 80% in communities and organizations across the nation. From 2012 to 2018, due to improved screening rates, <u>9.3 million more individuals</u> were up to date with screening.

Yet, many communities lag behind, and the COVID-19 pandemic has challenged efforts to address inadequate screening and inequities in colorectal cancer outcomes, hindering the progress toward our *80% in Every Community* goals. In the early stages of the COVID-19 pandemic, leading agencies, such as the <u>Centers for Medicare & Medicaid Services</u> (CMS) and the <u>American Cancer Society</u>, made recommendations to delay all non-urgent procedures. Colonoscopies to detect colorectal cancer have been delayed or cancelled and patient fears about contracting COVID-19 have led to further <u>reductions in screening</u>. This drop has raised concern that COVID-19 related screening delays will lead to missed and advanced stage colorectal cancer diagnoses and to <u>excess deaths from colorectal cancer</u>. Moreover, this burden will likely not be evenly distributed as screening disparities may be exacerbated in communities and populations that are disadvantaged by both old and new challenges in the COVID-19 era.

The colorectal cancer fighting community stands prepared and well-positioned to respond to and overcome the difficult task ahead. This document provides an action-oriented playbook for how NCCRT members, 80% pledged partners, and colorectal cancer screening advocates across the nation can work together to reignite our screening efforts appropriately, safely, and equally for all communities.

Overarching Messages to Guide Our Response to Delays in Screening:

- 1. There are several safe and effective tests to screen for colorectal cancer, including stool tests (fecal immunochemical test [FIT], guaiac fecal occult blood test [FOBT], multi-target stool DNA [mt-sDNA]), and tests which provide a structural exam of the colon and rectum including colonoscopy, sigmoidoscopy, and CT colonography (also called virtual colonoscopy).
- 2. Screening disparities are already evident and, without deliberate focus, are likely to increase as a result of the COVID-19 pandemic. Efforts to promote screening in populations with low screening prevalence must be at the forefront of our focus and accelerated immediately.
- **3.** For those at the highest risk, access to colonoscopy should be prioritized. While multiple screening options are now available to those at average risk, people at above average risk or high risk for colorectal cancer due to family history or a positive initial screening test should be given priority to complete colonoscopy.
- 4. Overcoming the screening barriers and delays resulting from the pandemic is urgently needed and will demand that organizations work creatively to find new solutions. Close collaboration between every partner in the health care system and critical policy changes will help us accomplish this critical preventive health goal.



It is critical to ensure that patients with signs or symptoms of gastrointestinal illness, including colorectal cancer, undergo colonoscopy as soon as possible. Many people with symptoms that might be due to colorectal polyps or cancer – such as blood in bowel movements, change in bowel habits, abdominal pain, weight loss or unexplained anemia – have avoided medical care due to fears of infection with the SARS-CoV-2 virus. Colonoscopy is being safely provided throughout the country and diagnostic colonoscopies for patients with symptoms need not and should not be delayed.

JUNE 2020 SNAPSHOT: IMPLICATIONS OF THE COVID-19 PANDEMIC ON COLORECTAL CANCER SCREENING

The <u>direct impact from COVID-19</u> on the US is devastating, with over 2.6 million reported cases and more than 129,000 deaths as of June 30, 2020. However, the larger health-related consequences from the COVID-19 pandemic will certainly not end there and we face a challenging battle ahead in our efforts to prevent and screen for cancer and other diseases. In the early stages of the COVID-19 pandemic, the <u>Centers for Medicare & Medicaid Services</u>, the American Cancer Society, and <u>gastroenterology associations</u> made a recommendation to delay all non-urgent procedures. The following snapshot depicts the challenges ahead due to delays in screening and missed diagnoses of colorectal cancer.



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RECOVERY THROUGH ALIGNMENT

Adopting the following statements of alignment will better coordinate our national response to screening delays and declines by synthesizing the latest data and information available as well as consolidating key recommendations from leading organizations on the front lines.

Aligning Statement 1: Despite the challenges we face during the pandemic, colorectal cancer remains a public health priority, and we must provide the public with safe opportunities to prevent and detect colorectal polyps and cancer.

Colorectal cancer is the second leading cause of cancer death in the US when men and women are combined, but is largely preventable through screening. Approximately <u>30% of adults</u> aged 50 to 75 are past due for screening and the burden of colorectal cancer is not equally distributed. <u>Black Americans</u> have the highest overall mortality from colorectal cancer followed closely by American Indian / Alaska Natives. Further, Hispanics are less likely to complete a screening colonoscopy compared to non-Hispanic whites. It is conceivable that the impact of procedural delays will disproportionately affect Blacks, American Indian / Alaska Natives, Hispanic communities, and low socioeconomic individuals, mirroring observed patterns in colorectal cancer incidence and mortality. Thus, as COVID-19 cases begin to taper, it is imperative to quickly and safely resume existing programs intended to reduce colorectal cancer mortality and implement new initiatives to recover missed diagnoses in a way that addresses persistent colorectal cancer inequities.

On April 19th, <u>CMS</u> updated its recommendation to encourage resumption of non-urgent preventive procedures following a reduction in local COVID-19 infections, increased availability of personal protective equipment (PPE), and broader access to COVID-19 testing. Still, <u>79% of primary care practices are reporting limited chronic and wellness visits</u>. Gastroenterology visits that decreased at the height of the pandemic to <u>39% of pre-COVID-19 levels are now up to 62%</u>, still under two-thirds the volume of gastroenterology visits prior to the pandemic. Fewer primary care visits as well as limits to gastroenterology clinic and endoscopy volumes are likely to persist due to a combination of patient fear of contracting COVID-19, a rise in uninsured rates, shifting patterns of COVID-19 infection, and evolving local policies on essential vs. non-essential services (*Read more in Aligning Statement 4*).

<u>A multi-pronged approach</u> can help regain momentum in reducing the public health impact from colorectal cancer. As proponents of colorectal cancer prevention, we should confidently reassure patients about the safety and importance of colorectal cancer screening, including the unique advantage of stool-based colorectal cancer screening tests which can be completed at home. Individuals who test positive (abnormal) on a non-invasive stool test have a higher likelihood of prevalent polyps or cancer. These individuals should therefore be assigned very high priority for completing colonoscopy *(Read more in Aligning Statements 2 and 3)*.

COVID-19 has already drastically added to the number of lives that will be lost in 2020, and we don't know how impacts from the virus will evolve over the remainder of 2020 and beyond. Meanwhile, effects from other chronic diseases and public health risks, including cancer and cardiovascular disease, persist. **However, due to the availability of multiple** screening test options, colorectal cancer screening presents a unique opportunity to limit pandemic-related excess mortality and to address health care inequities both caused and accentuated by the pandemic.

Aligning Statement 2: Colonoscopy remains safe, is a good option for screening, and is quickly reopening around the country, but identifying patients who should receive higher priority for colonoscopic screening is a critical step.

At the start of the COVID-19 pandemic, government authorities, the American Cancer Society, and <u>gastroenterology</u> <u>associations</u> rightfully recommended delaying non-urgent procedures, including screening colonoscopy. Now, colonoscopy is becoming easier to access in most communities. Two trends are helping to increase access to colonoscopy. First, in many states, COVID-19 cases and deaths are declining, and the likelihood of being exposed to someone with infection is now lower. This decrease in cases allows resources and personal protective equipment (PPE) to be dedicated to facilitating safe return to routine medical procedures. Second, protocols to ensure safe provision of services, including endoscopy, are now well defined. Having said that, local policies and recommendations may not only vary, but change depending on community needs, given that COVID-19 cases are increasing in some states and will likely continue to fluctuate.

Endoscopy units need to be aware of and follow the guidance being provided by their local and state governments. As a general guideline, elective endoscopic procedures may be resumed when there has been a sustained reduction in new COVID-19 cases in the relevant geographic area for at least 14 days. Most non-urgent colonoscopy procedures have been deferred or rescheduled over the past several months. **As endoscopy facilities start performing colonoscopies again**, **prioritization of the patient population will be essential**, with patients at higher risk for adenomas or cancers given prioritized access. Once every effort has been made to accommodate emergency and urgent colonoscopy indications, elective screening colonoscopy exams can also be made available, following a clear priority order. Higher priority for access to screening colonoscopy should be assigned to patients at higher risk for colorectal cancer and polyps, such as those with abnormal stool-based cancer screens, patients with a family history of adenomas or cancer, patients with inflammatory bowel disease, and patients with a genetic syndrome that elevates risk for colorectal cancer. Patients at average risk for colorectal cancer or those due for surveillance colonoscopy should be assigned lower priority. Although screening colonoscopy or other options (e.g. CT colonography) are now available in many communities, in locales experiencing a high burden of COVID-19 related illness the average risk group should predominately be screened using non-invasive stool test screening options.

Many people are reluctant to come to a health facility to receive health care of any kind. Endoscopy units must be committed to a plan to address and allay patient fears. The key to reassuring patients is to adopt best practices to reduce the risk that anyone will become infected during a procedure. The United States Multi-Society Task Force recommends measures to reduce the risk of transmitting COVID-19 infection during endoscopic procedures include the following: PCR testing of patients for COVID-19 prior to endoscopy, daily temperature check and survey for COVID-19 exposure for all patients and staff, and instituting social distancing practices. These practices include requiring masks for all individuals, providing space between patients and staff, restricting visitors, individualizing workspace, reducing procedure volume if necessary, avoiding crowding in recovery areas, and enhanced cleaning techniques to minimize cross contamination of equipment and facilities. While PCR testing is appropriate in most communities for now, as infection rates fall, indications for COVID-19 PCR testing prior to endoscopy are certain to evolve.

Lastly, both clinical and non-clinical colorectal cancer screening stakeholders need to communicate within their communities about any hindrances or access limitations in health systems. Primary care providers will need to be aware of the level of burden experienced by local endoscopy facilities. Community organizations and cancer coalitions will need to understand the communication priorities and recommendations from local health systems and facilities to better disseminate messages that promote colorectal cancer screening options through community outreach and public awareness.

More on Resuming Elective Procedures

<u>CMS</u> American Gastroenterological Association American College of Gastroenterology <u>American Society of Gastrointestinal Endoscopy</u> <u>American College of Radiology</u> Joint Statement: American College of Surgeons, et al

Aligning Statement 3: During a time when availability of elective screening colonoscopy may be limited by the COVID-19 pandemic, colorectal cancer screening can be safely offered through at-home stool-based tests.

Due to delays in cancer screening caused by the pandemic-related shutdowns, our nation faces an urgent priority to help everyone who needs to be screened for colorectal cancer to get up to date with screening as soon as possible. **Fortunately, not only is colonoscopy completely feasible to perform, we also have a unique opportunity to take advantage of all universally endorsed screening test options.** One practical and widely available strategy to overcome delays and barriers to screening resulting from the COVID-19 pandemic is to offer and implement stool-based screening tests. The NCCRT's <u>Clinicians Reference</u> provides guidance on high-quality stool testing.

The two main stool-based screening tests are fecal immunochemical testing (FIT) and multi-target stool DNA testing (mt-sDNA); high-sensitivity guaiac-based fecal occult blood tests are an acceptable third option. The chief advantage of stool tests is that each one can be completed at home and returned to the lab, thereby limiting in-person engagement with the healthcare facility and avoiding loss of time from work or family duties. Stool-based testing can also reach individuals living in communities with limited access to endoscopy or other healthcare resources, or in those under restrictions due to COVID-19. Which stool test to offer depends not only on patient preference and health insurance coverage or cost, but, to a large extent, on the tracking systems in place at the healthcare practice. To ensure effective screening, systems must be able to track whether the patient received the selected stool test, returned a properly collected and labeled specimen to the lab, and followed through with diagnostic colonoscopy, when a positive result is obtained. For FIT tests, mail-based outreach can be implemented and is a successful approach but requires an organized program of tracking and follow-up to be in place. For mt-sDNA, all tests are shipped directly to and from a patient's home and a patient navigation system is in place to facilitate most of these steps. For either testing option:

- A negative test (the most likely outcome) must be tracked and repeated at the appropriate time interval.
- A positive (abnormal) test must be <u>referred promptly for colonoscopy</u> because <u>a delay of six months</u> or longer after an abnormal FIT result is associated with higher rates of advanced adenomas and late-stage colorectal cancer.
 - » Patients with an abnormal stool-based test should be carefully tracked and given priority as colonoscopy capacity remains below pre-COVID levels.
 - » Acting on an abnormal stool test requires close cooperation and communication between primary care and colonoscopy providers.

Stool-based tests are covered by the vast majority of insurers, including Medicare and many Medicaid plans. Both FIT and mt-sDNA tests must be ordered by a clinician, most commonly the patient's primary care clinicians, although the tests can be ordered through urgent care centers, retail clinics, or <u>independent telehealth providers</u>.

It is important to note that there is evidence that SARS-CoV-2 virus is shed in the stool, although most evidence suggests that it is not shed in a viable, infectious form. Regardless, these tests are designed so that patients do not physically handle a stool sample, and risks to clinic or laboratory staff are extremely low as long as standard specimen handling protocols are observed.

Aligning Statement 4: Gaining momentum and reigniting screening activities and public messaging will be highly dependent upon local regulatory requirements, public health priorities, and policy change.

In most areas around the U.S., the resumption of non-urgent services, including colorectal cancer screening via colonoscopy, has occurred with a variety of new policies and processes in place to substantially decrease the risk of contracting COVID-19. These additional safeguards are highly effective in protecting both patients and medical staff (as discussed in preceding sections of this report).

- 1. A first requirement in reigniting screening activities across the U.S. is realizing that simply re-opening facilities and offering screening will not be enough. Informally, endoscopists are reporting a significant number of patients who are refusing or delaying endoscopy appointments, and in many instances, this appears to be based on patient concerns about visiting medical facilities and the associated fears of exposure to COVID-19. These fears may be amplified by some of the new procedures put in place to lower risk, such as symptom assessment, fever checks, and required use of PPE. While health and safety procedures are meant to protect patients and medical staff, some of these measures may exacerbate patient fears and create the impression that these environments are "crawling with COVID-19." It will require a few months operating within these new realities to better understand patient behaviors and perceptions, but these enhanced patient protections, while necessary, will create added barriers for already apprehensive unscreened patient populations. For patients who were already procrastinating about getting screened, these added precautions are likely to reinforce their inclination to delay screening. Providers and facilities will need to find compelling messages to remind patients that these measures are designed to protect everyone and are not in place because of any identified risk in the facility.
- 2. A second key requirement for local response efforts is recognizing the need to develop new approaches to recommend and complete colorectal cancer screening in a COVID-19-aware environment. Some practice changes implemented in response to the pandemic will likely remain a permanent element of our healthcare environment. Chief among these is the increased consideration toward offering and using telehealth/telemedicine visits. Implementation of screening via telehealth requires new approaches to arranging and tracking screening consultations and referrals and for disseminating stool tests for screening. In many practices, specimen collection kits are traditionally kept in exam rooms or storage areas and nurses or medical assistants hand the kits to patients and then explain how to use the test during an office visit. Thus, telehealth encounters will require new processes to enable kit distribution, to educate patients on specimen collection, to provide follow-up, and to help reduce any anticipated barriers for patients to complete the test. Arranging for patients to pick up stool test kits at a local laboratory offers one possibility. However, many other opportunities and evidence-based practices are also available through the utilization of existing mailed specimen options (mt-sDNA testing) or the development of mailed FIT programs (see Aligning Statement 3).
- **3.** A third consideration relates to addressing the large number of missed colorectal cancer screenings due to the COVID-19 pandemic by seeking critical and high-impact policy changes. First, finding ways to provide continued access to care including colorectal cancer screening for the millions of individuals who have lost their jobs and the associated employer-sponsored health care is an important area of focus and policy consideration for the public health community. A second essential policy opportunity to aid our recovery efforts is the elimination of financial barriers to the completion of screening such as co-pays for patients in the Medicare system who have biopsies during an exam that was initially ordered as a screening colonoscopy, and the requirement by many insurers that a patient pay a deductible or co-pay for a colonoscopy performed following an abnormal stool test. Failure to define the colonoscopy following an abnormal stool test as a continuation of the screening process results in patient cost-sharing (hundreds of dollars in many instances) and serves as a major barrier to receipt of follow up colonoscopy. Due to the consequences of the pandemic, including a potentially greater adoption of stool-based testing as well as a growing number of newly unemployed and uninsured individuals, it is imperative that this type of short-sighted and harmful payment policy be urgently corrected.

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