Network for Excellence in Health Innovation

Addressing Persistent Disparities in Colorectal Cancer Screening Among Racially and Ethnically Diverse Populations

A NEHI Report

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About NEHI

NEHI is a non-profit, unbiased organization with members, including providers, hospitals and health systems, pharmaceutical and biotech companies, medical device, and technology providers, as well as associations and consultants. Through interdisciplinary collaboration and with our members' guidance, we research and examine tough and timely health care innovation issues from multiple, often divergent, perspectives. We then address policy and adoption challenges to promote the value of innovative products and processes.

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Executive Summary

Colorectal cancer (CRC) is the second leading cause of cancer death in the US. According to the American Cancer Society, in 2023, more than 50,000 people will die from the disease. This figure, while staggering, fails to recognize the continued differences in CRC incidence and mortality that certain populations face. For example, non-Hispanic Black individuals have higher CRC incidence (41.7 per 100,000) and mortality (17.6 per 100,000) than non-Hispanic White individuals (35.7 and 13.1 per 100,000, respectively).¹ Moreover, it does little to elevate to what degree disparities in preventive screenings account for these differences.

Timely and consistent screenings are a proven method for lowering CRC incidence and mortality. Early screenings help identify CRC before it has progressed. Moreover, screenings can be preventive in nature: practitioners can remove potentially cancerous polyps found during colonoscopies. Racial disparities in access to CRC screening, however, have persisted for decades. While recent data suggests that gaps are closing, as we will discuss in this report, the data do not present the full picture.

Through this work, NEHI sought to propose recommendations that, if adopted, may help to better illuminate and subsequently close disparities in CRC screenings. We used peer-reviewed research, gray literature, and qualitative interviews with CRC experts to arrive at our final recommendations, which we present in two sets. The first set are recommendations that, in the short term, would help make progress in closing gaps. The second set focuses on solutions that are more complex in nature. Several of these recommendations would require federal or state legislative solutions, which we acknowledge can be time consuming and more challenging, especially in states where the legislative bodies are balancing many competing priorities and budget constraints.

Experts generally agreed that the extent of disparities in CRC screening are not well defined—it is difficult to identify populations in need of more targeted interventions. Most experts interviewed said they seek more data on hard-to-reach, average-risk patients who could benefit from greater use of stool-based testing and higher-risk patients who have received a positive stool test result and need a follow-up colonoscopy. Combining in a dashboard (or similar tool) the many disparate datasets that contain data on CRC screenings to create more transparency and clarity around trends is one potential solution. Potential aggregators of this data cited by the experts include the American Cancer Society (ACS), National Colorectal Cancer Roundtable, National Committee for Quality Assurance (NCQA), and/or Centers for Disease Control and Prevention (CDC). The other short-term recommendation is that NCQA should amend its CRC screening quality measure to require reporting of follow-up colonoscopies after a positive stool test.

In the longer term, a more complex, multifaceted approach to correcting disparities in CRC screening will be required. Recommendations identified include: Passing federal and state solutions aimed at Medicaid quality measurement and reimbursement for navigation services; ensuring the Affordable Care Act's (ACA) preventive services provision extends to more patients and to follow-up colonoscopies after a positive stool-based test; and creating stricter standards for community health needs assessments and subsequent implementation plans created to mitigate identified issues.

One notable development occurred during this project that could have a significant impact on future CRC screening rates. The *Braidwood v. Becerra* case, in which a U.S. District Court Judge ruled that US Preventive Services Task Force (Task Force) recommendations made under the ACA's preventive services provision since 2010 violated federal law, is not resolved yet. If the ruling were upheld, it could unwind decades of progress in improving overall CRC screening rates and in helping to close disparities.

As disparities in CRC screenings—and thus CRC incidence and mortality—continue, new policy approaches and programmatic solutions will be required. This report elevates a set of recommendations that, if adopted, could help to close these gaps. The challenges in this area—and the solutions required to tackle them—are complex and multifaceted.

Background

Colorectal cancer (CRC) is the second leading cause of cancer death in the US. According to the American Cancer Society (ACS), in 2023, "approximately 153,020 individuals will be diagnosed with colorectal cancer (CRC)." More than 50,000 people will die from the disease.²

Screening is an important step in the cancer control continuum.³ Timely and consistent screenings are a proven method for lowering CRC incidence. Early screenings help identify CRC before it has progressed. Moreover, screenings can be preventive in nature: screening tests can help detect potentially cancerous polyps which can be removed during colonoscopy. Today, however, CRC screening rates fall far below the National Colorectal Cancer Roundtable's goal of reaching 80% screening in every community. Data from the 2021 National Health Interview Survey indicates that only 59% of all individuals recommended for CRC screening (ages 45 to 75) are up to date.⁴

Disparities in CRC screening have persisted for decades. While national data on CRC screening across several modalities (colonoscopy, stool tests, etc.) indicates that some disparities in CRC screening rates have narrowed over the last decade, these data do not reveal the full picture. There are continuing differences by race and ethnicity, income, age, and insurance type. For example, while 59% of individuals ages 45 and older are up to date with screenings, only 20% of individuals ages 45-49 and 21% of uninsured individuals are up to date.⁵

In the last several years, there has been notable progress in identifying and adopting policies and approaches that can close these gaps. As an example, the 2016 US Preventive Services Task Force (Task Force) recommendations for CRC screening stated that "follow-up colonoscopy after a positive fecal test is a diagnostic colonoscopy." This led many insurance companies to apply cost-sharing to follow-up colonoscopies. Advocacy organizations pushed for changes and, in 2021, the Task Force revised its recommendations to remove the reference to diagnostic colonoscopies.⁶ It also lowered the recommended screening age to 45 after research and analysis of CRC screening modalities and outcomes indicated that screenings should occur at a younger age.⁷

As disparities continue, additional solutions—both in policy and in program—will be required. This report elevates a set of recommendations that, if adopted, could help to close these gaps.

Methodology

NEHI used a three-phased approach to identify these recommendations. We launched the project in January 2023 and completed it in May 2023.

Phase 1: Literature review

We scanned peer-reviewed literature using search terms such as: "strategies to improve colorectal cancer screening diversity" and "CRC screening guidelines." This literature search uncovered 25 articles. In parallel, we scanned gray literature—publications and resources from many sources, including ACS, National Colorectal Cancer Roundtable, Fight CRC, Colorectal Care Alliance, NCQA, CDC, Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Administration (HRSA), and more.

Phase 2: Qualitative interviews with CRC experts

Using an interview guide we developed based on the literature scan, we interviewed CRC experts in the fields of patient-centered outcomes and programmatic research, screening, diagnostics, and advocacy. These interviews focused on identifying gaps not uncovered in the literature search and uncovering policy and program solutions that might help address disparities in CRC screenings.

Phase 3: Discussion of the findings

After summarizing the literature and qualitative research, we drafted a set of recommendations. We then convened the experts we connected with in Phase 2 to discuss these recommendations and seek their feedback. We integrated applicable feedback throughout this report.

Short-Term Solutions:

Narrowing – or eliminating altogether – CRC screening disparities will require a multifaceted approach. This cannot be overstated. However, our research uncovered two recommendations that, in the short term, would help to make progress in closing gaps.

Data aggregators: Create a tool or dashboard that exposes gaps in screening

We heard reasonable consensus among the subject matter experts that we have failed to fully define the problem as it pertains to disparities in CRC screening—both between and within different populations. Data on CRC screenings comes from several different sources (e.g., Behavioral Risk Factor Surveillance System [BRFSS], National Health Interview Survey [NHIS]), and analysis of that data is led by several different entities (e.g., ACS, CDC).⁸

While data lag is a constant issue, more can be done to explore and uncover trends from what does exist. Most experts we interviewed said they seek more data on hard-to-reach, average-risk patients who could benefit from greater use of stool-based testing and on higher-risk patients who have received a positive stool-based test result and need a follow-up colonoscopy. Creating such a tool would allow all stakeholders interested in and responsible for closing gaps—providers, insurers, public health agencies, Medicaid agencies, community health systems, and more—understand specific trends and identify populations in need of targeted intervention. Achieving this will only be possible if all of the data sources that contain information on CRC screenings are made transparent and available for public use. It will also require collaboration between many entities that hold different data elements.

The tool should have the following characteristics:

1. Stratification by certain patient characteristics, including, but not limited to, race and ethnicity, age segments (e.g., 45-50, 50-55), geography, insurance coverage type, and risk level. As previously noted, the data on CRC screenings comes from several different sources. In addition to national data sets such as BRFSS and NHIS, other sources should be considered, including electronic health record (EHR), the Uniform Data System (UDS), health plan data, and large clinical research networks such as PCORnet[®]. Information about risk should include family history, genetics, and prior advance adenoma. These sources would need to be combined with one another to show this aggregated view.

- 2. The ability to identify which populations had a positive stool test then received a followup colonoscopy (or conversely, who failed to receive one). Analysis of this issue has been piecemeal to date. For example, Mohl et al. examined trends in follow-up colonoscopies using data from the Optum Labs Data Warehouse, which includes administrative claims and EHR data on 100 million US lives that received care through 39 health care organizations. The researchers found that the median organization had a follow-up colonoscopy rate of 53.4% within one year.^{9*} We go into more detail on the importance of tracking this figure in the next recommendation.
- **3.** Data uncovering trends over time. Experts expressed the need to understand how the COVID-19 pandemic impacted, and continues to impact, screening rates for different populations. A recent analysis of BRFSS data suggests that overall CRC screening rates were not impacted by the pandemic due to the availability of home-based screening methods (e.g., FIT and multi-target stool DNA [mt-sDNA] tests). The researchers say that "stool testing counterbalanced decreases in colonoscopy during 2020."¹⁰ It is still unclear, however, whether this trend is true for all patient populations and whether there remains a backlog in screening among certain patient populations.

The experts we interviewed generally supported this concept. As one interviewee noted, "We're struggling to find some of that more robust data ourselves. We are using some of what ACS has reported out, but we recognize that some of the sources that may be capturing this have a lag in the data reporting." This person also observed that the issue is not that this data does not exist, but that the issue is with accessibility. Yet another interviewee explained that "there's this huge backlog of colonoscopies. No one really seems to have taken a deep dive to understand what that means and what that means for the population at large."

^{*}Additional findings from this study: The best performing health care systems failed to achieve the 80% target recommended by the US Multi-Society Task Force on CRC. Examined health systems had significant variation in followup rates. The likelihood of timely follow up colonoscopy also varied significantly based on factors including race, insurance type, and type of stool test used (mt-sDNA vs FIT). Follow-up rates significantly declined during the early days of the COVID-19 pandemic, suggesting a potential backlog of patients who received a positive result from a stool-based sample and failed to obtain a follow-up colonoscopy.

There's this huge backlog of colonoscopies. No one really seems to have taken a deep dive to understand what that means and what that means for the population at large. – Durado Brooks, Exact Sciences

NCQA: Amend the CRC screening measure to require plans to report how many patients received a follow-up colonoscopy after a positive FIT or FIT-DNA test

As the saying goes, "We cannot improve what we do not measure." Quality measurement plays an important role in identifying gaps in health care more broadly. NCQA is a key stakeholder in quality measurement, as it is the measure steward for the Healthcare Effectiveness Data and Information Set (HEDIS[®]). HEDIS[®] "is the basis for nearly all value-based and performance measurement systems in the nation."¹¹

NCQA has revised its CRC screening quality measure as the Task Force has updated its screening recommendations. For example, in 2022, NCQA lowered the recommended age to begin screening to 45 after the Task Force made that revision (which followed a 2018 ACS recommendation to lower the age to 45).

Another revision made by the Task Force was to emphasize the importance of follow-up colonoscopies after positive stool-based tests. Stool-based tests are only recommended for patients with average risk. The Task Force has clarified its recommendations to say, "to achieve the benefits of screening, abnormal results from stool-based tests, CT colonography, and flexible sigmoidoscopy *should be followed up with colonoscopy.*"¹² Recent evidence indicates that this is not consistently done. We reference earlier in this report the findings from Mohl et al. that many patients who should have received a colonoscopy after a positive stool-based test did not get one. The patients in this study were predominantly covered by commercial (67.4%) and Medicare (23.7%) insurance.¹³ Lower rates were documented in patients with Medicaid coverage. While this study did not assess follow-up rates for uninsured patients, work from other investigators suggests that rates are even lower in this group.^{14, 15}

This theme emerged in our interviews, as well. To quote from one interview, "This what we do on a daily basis—we try to get follow-up colonoscopies reported. I believe policy needs to be created to report the follow up colonoscopies to abnormal FIT tests. We're working with a lot of clinics that just stop at FIT knowing that it checks that box." They went on to say, "A lot of clinics, especially rural ones, not only cannot identify who their eligible patients due for screening are, but cannot identify those with an abnormal FIT in need of a follow-up colonoscopy." Another interviewee said, "There are so many other structural barriers to the follow-up colonoscopy. We need to understand what needs to be mitigated when we're looking at unique populations."

This is what we do on a daily basis—we try to get these followup colonoscopies reported. I believe policy needs to be created to report the follow-up colonoscopies to abnormal fit tests because we're working with a lot of clinics that just stop at FIT knowing that it checks that box. – Amanda Petrik, Kaiser Permanente Center for Health Research

NCQA has been a leader in efforts to close disparities in health care by raising quality reporting standards. It is important to note one important effort NCQA has led in this space: It announced in 2021 that it would begin requiring certain HEDIS quality measures be stratified by race and ethnicity beginning with the 2022 measurement year. CRC screening is one of the five measures with which it is piloting this program.¹⁶

In April 2023, NCQA then announced it had created the Race and Ethnicity Stratification Learning Network to Advance Health Equity. NCQA created the Learning Network to help stakeholders collecting this data better leverage it. In addition to creating a dashboard that displays initial results from the data collection effort, NCQA also partnered with 14 health plans that committed to being transparent about learnings from this process. NCQA's interviews with these health plans revealed early findings in how they have collected the data and best practices in integrating the stratified data into their quality improvement work.¹⁷ Monitoring ongoing progress with this work will be an important step to identifying and closing disparities.

Long-term solutions:

As we highlighted earlier, tackling this problem will require a multifaceted set of changes. Our research uncovered many additional changes, both in policy and in practice, that would help close gaps in CRC screening rates among historically marginalized populations. These solutions are more complex in nature. Several would require legislative solutions, which we acknowledge can be time consuming and much more challenging, especially in states where legislative bodies are balancing divided power, many competing priorities, and budget constraints.

Congress: Pass legislation to extend the SUPPORT Act provisions to require state Medicaid programs to report the full Adult Core Set of quality measures

Significant gaps in CRC screening exist, both among different populations of Medicaid beneficiaries and between Medicaid beneficiaries and individuals with other types of insurance. Only 52% of the Medicaid population are up to date on their screening (compared with 63% of individuals who have commercial insurance).¹⁸ While the ACA required CMS to create a core set of Medicaid quality measures—now called the Adult Core Set—state reporting of the full set is voluntary.¹⁹

CMS added CRC screening starting at age 50 to the Medicaid Adult Core Measure Set starting in the 2022 measurement year.³ In early 2023, CMS lowered that quality measure to the recommended screening age of 45.²⁰ CMS does not have authority to require states to report the full Adult Core Set, however, and only a handful of states opt to use the full Adult Core Set for their Medicaid quality measurement reporting. Some states have "home grown" measurement sets that include CRC screening.

Congress passed the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act in 2018. The SUPPORT Act included a requirement that all states must begin reporting the Child Core Set and the behavioral health measures in the Adult Core Set in 2024. However, this legislation did not extend the requirement to the full Adult Core Set.²¹ Extending the requirement to the full set would ensure that all states report CRC screening rates for their Medicaid population.

How was CRC screening added to the Medicaid Adult Core Set?

A group of 27 experts called the Core Set Review Voting Members leads the process of reviewing and revising the Medicaid quality measure set. They represent different stakeholders across the US health care system. Each year, this group convenes to introduce, discuss, and decide on measures that should be added or removed from the Adult Core Set. Over the course of several years, advocacy organizations including the California Colorectal Cancer Coalition (C4), Fight CRC, the National Association of Chronic Disease Directors, and Leavitt Partners worked closely with members of this panel to push for this measure to be added to the Adult Core Set. In 2021, the proposed measure was put in front of the voting members, and in December 2021, they voted unanimously to adopt it as part of the Adult Core Set.

Source: Fight Colorectal Cancer. (2022). Increasing Access to Colorectal Cancer Screening. Retrieved from https://fightcolorectalcancer.org/blog/increasing-access-to-colorectal-cancer-screening/

States: Pass legislation and create other policies to fund training for and encourage more use of navigators

Navigators are professionals (often community health workers [CHWs]) hired to assist patients with navigating the health care system. The navigation services they provide are critical for reaching historically marginalized populations. Navigators are frequently hired from the community within which they provide services and are often part of a larger intervention designed to help patients overcome barriers to accessing care, including preventive services and screenings.

In many cases, what we think from a health care system perspective, a researcher, a clinician, or whatever our role is, is often very different from what the described barrier is for the patient. – Freda Lewis Hall

In a systematic review of 34 studies, researchers concluded that employing navigators has helped "increase breast, cervical, and colorectal cancer screenings among historically disadvantaged racial and ethnic populations and people with lower incomes."²² In one study, an intervention designed to increase CRC screening among the economically disadvantaged population, multilingual navigators helped increase the number of patients who received CRC screenings significantly over the control population who did not receive navigation assistance.²³

State Medicaid programs can be an influential partner in increasing the use of navigators such as CHWs, especially among hard-to-reach populations. As of July 1, 2022, over half of states that responded to a survey (29 of 48) reported allowing Medicaid payment for services provided by CHWs. A number of states reported plans to implement Medicaid coverage/payment of CHW services under state plan authority or through other coverage pathways, including under Section 1115 authority.²⁴

Examples of states that have updated state plan amendments that include CHW services:

- **California's** state plan amendment provides that CHWs may conduct many services, including health education to promote beneficiary health or address barriers to care; health navigation services to support access and connection to community resources; screening and assessment to help identify need for services; and individual support or advocacy services.
- In **Nevada**, CHW services must be related to disease prevention and chronic disease management and follow national standards of care and guidelines (e.g., Task Force A and B recommended services and screenings).

In addition to supporting reimbursement for CHWs and navigation services they provide, states must also ensure these professionals receive appropriate training to ensure they are providing culturally competent care to the populations they serve.

States: Pass legislation requiring health plans to follow current recommendations for CRC screenings

According to Fight CRC, most states (34) have a colorectal cancer statute.²⁵ What is included in these statutes varies widely across states, however. We recommend states adopt the following legislative priorities:

- States with a statute:
 - Ensure that it includes language that waives cost-sharing for all CRC screening modalities.
 - Ensure the cost-sharing language extends to follow-up colonoscopies after a positive stool-test result.
 - Ensure that it includes an age at which individuals should start screening, and that the age mirrors the Task Force recommendation of age 45.
- States without a statute should adopt one and ensure that it includes the above language.

Cost sharing

As of this publication, only eight states have a statute in place that requires health plans to waive costsharing for follow-up colonoscopies.²⁶ Strong evidence exists that indicates removing cost sharing for screenings and other preventive services leads to better patient access. Indeed, the US Department of Health and Human Services (HHS) published data earlier this year supporting the notion that the ACA's preventive services provision helped increase CRC screening rates.²⁷ However, there are still populations covered by plans that require cost sharing for preventive services.

Setting aside the fact that it does not protect the uninsured population, Section 1001 of the ACA – the preventive services provision (see call out box) – also does not extend to all insured populations. In Medicaid, the provision applies only to Medicaid expansion enrollees and other Medicaid enrollees in Alternative Benefit Plans.²⁸ Individuals who are in "traditional" Medicaid plans are not covered by this provision unless their state has passed legislation to require it.

Another population that is not covered by this provision is individuals who have coverage through grandfathered plans – plans that were in place prior to the ACA and were granted an exemption from those provisions. The number of people enrolled in these plans is difficult to estimate, but a survey from the Kaiser Family Foundation found as recently as 2020, 19.1 million people were enrolled in a self-funded plan that was grandfathered or were offered benefits with a grandfathered option. It also estimated that 4.6 million people were enrolled in grandfathered plans offered through state or local governments.²⁹

Section 1001 of the Affordable Care Act requires most health plans to cover preventive services with no cost sharing – copays or deductibles

Section 1001 of the ACA states: "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force."

Source: United States Congress. (2010). Patient Protection and Affordable Care Act, Pub. L. No. 111-148. Retrieved from https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf In addition to ensuring that patients do not have cost-sharing for initial screening methods, state legislation should also include language that extends this policy to follow-up colonoscopies after a positive stool-based test result." As Fight CRC states, "for those who receive a positive result, screening is not complete until they undergo a colonoscopy."³⁰ This is codified for individuals in private insurance coverage through guidance from HHS, the United States Department of Labor, and the US Department of the Treasury, which clarified that these policies must cover follow-up colonoscopies after a positive noninvasive stool test.³¹

A final note about cost-sharing that arose during our interviews is the fact that there are many additional costs associated with screening that are not the target of the preventive services provision. Stakeholders, such as providers, health plans, and state Medicaid agencies should explore this issue more deeply to understand the additional cost burden associated with screening their patients may face. For example, patients who undergo colonoscopy screening are prescribed a stool-prep medication. If a patient is in a high-deductible health plan, they may be fully exposed to the costs associated with that prescription. As one interviewee observed, "Even though we have had policies to make these changes, we still have some ways to go to make the procedure truly cost-neutral for patients."

Noninvasive, home-based stool testing, which are recommended only for average-risk patients, has helped reduce or eliminate some of these barriers. However, for many patients, such as those who are high-risk, colonoscopies are the only recommended screening modality. In addition to the sometimes-hidden health care costs associated with colonoscopy, there are also social, environmental, and economic barriers for many patients. As one interviewee stated, "For some individuals, there are transportation challenges. There are childcare challenges. There are things that we don't always expect insurers to take care of—but they are cost burdens that fall on patients. We need to think about how we're going to address if we really want to get everybody screened."

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Recommended screening age

Sixteen of the states that have CRC screening statutes lack language that mentions an age at which screening should begin. Of the states that do include age in the statute, only six have lowered it to age 45. While ACS and the Task Force have lowered the recommended screening age for a first test to 45, as described in the previous section, these recommendations are not automatically applied to all health insurance plans. States that do have CRC screening statutes in place should review the language to 1) ensure that it references the age at which screenings should start and 2) ensure that the recommended screening age has been updated to the latest Task Force recommendation.

Regulators: Create a "floor" for community health needs assessments

The ACA requires non-profit hospitals and health systems to conduct community health needs assessments (CHNAs) every three years and to adopt an implementation strategy to address the identified needs.³² The Internal Revenue Service (IRS) is the regulating body for CHNAs.

CHNAs are not standardized, however, nor are they required to be. Many hospitals and health systems have identified screenings, and more specifically, CRC screenings, as a need in their community. In identifying gaps in their surrounding community, health systems are well positioned to prioritize programs and other interventions that may close disparities in more difficult to reach populations. They are also well positioned to identify and connect patients with services that fall outside of traditional health care services (e.g., transportation) that could support patients in accessing more regular screenings.

Creating a floor—or a core set of issues that all CHNAs must assess—could help to standardize this process and ensure that a basic set of needs is addressed in every community. This floor should include requiring non-profit hospitals and health systems to:

- Assess overall cancer screening rates (including CRC) in their community and identify specific populations that have lower rates than others (racial and ethnic groups, residents of specific neighborhoods/wards, age groups).
- Identify common access barriers to preventive screenings and services in their community (e.g., transportation, lack of providers, distance to closest facility with a colonoscopy service).
- Develop a plan targeted at closing identified gaps and barriers, including identifying social services organizations that could address barriers that fall outside of the traditional health care system (e.g., transportation, caregiving duties).

Monitoring Court Case Proceedings

One important development occurred during our research that could have a significant impact on CRC screening rates. The *Braidwood v. Becerra* case is not yet resolved and continues to face appeals in higher courts. If the ruling were to be upheld, however, it could unwind decades of progress in improving overall CRC screening rates and in helping close disparities.

Braidwood v. Becerra case background

On March 30, 2023, Judge Reed O'Connor of the US District Court of the Northern District of Texas issued a ruling on *Braidwood Management Inc v. Becerra*. In his ruling, he states that "compulsory preventive care coverage requirements in response to an "A" or "B" rating by the Task Force made on or after March 23, 2010, violates the Appointments Clause." This ruling would have a broad-sweeping impact on the progress made around preventive services and screenings, including CRC screenings. As the Kaiser Family Foundation said, "It would effectively lock in place coverage requirements based on evidence from 13 years ago."

Sources:

United States District Court Northern District of Texas Fort Worth Division. (2023, March 30). Second memorandum opinion & order on remedies in relation to plaintiff's motion for summary judgment. https://aboutblaw.com/7jg

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If the *Braidwood v. Becerra* ruling were to stand, significant legislative and regulatory changes would need to be made to ensure already existing inequities do not worsen. The ruling would reverse any recommendations made by the Task Force after 2010 (see call out box). This would have a broad-sweeping impact on CRC screenings, as well as other types of cancer screenings and preventive services. USPTSF rulings on CRC screenings made since 2010 include:

- Lowering the recommended screening age to 45.
- Adding new screening methods (e.g., mt-sDNA testing).
- Including follow-up colonoscopies after a positive stool test as "fully screened".
- Removing "diagnostic" from the recommendation so that colonoscopies that detect a polyp are considered a part of the screening process.

Additionally, many state and federal statutes refer to Task Force guidelines.³³

The interim impact from the ruling could be significant even though the U.S. 5th Circuit Court of Appeals temporarily blocked U.S. District Court Judge Reed O'Connor's ruling in May 2023. As one expert we interviewed observed, "[this ruling] gives the implementers, facilitators, and mediators the grounds to call into question whether they should as aggressively implement the current recommendations even if the policy hasn't changed. Now, philosophically, the policies that we've worked so hard to get into place are called into question."

Some experts have offered what might be quick fix solutions to this issue if the ruling were to be upheld. In a *Health Affairs* article covering the aftermath of this decision, a set of authors outlined three steps the Administration could take to protect the authority given to Task Force to issue recommendations for preventive services and screenings:

- 1. Authorize the director of a federal authority such as the Agency for Health Care Research and Quality (AHRQ) or the CDC to review and adopt all of the recommendations.
- 2. Require the Task Force publish and solicit comments on all of its recommendations through the Federal Register (the authors acknowledge this may not sufficiently protect the Task Force against this ruling).
- 3. Establish an additional body in HHS to review, oversee, and approve all Task Force recommendations.³⁴

Future Innovation will Depend on Today's Policy Foundation

Today's policies may need to be updated in the future to accommodate emerging screening modalities. While stool-based tests to screen for CRC have made strides in closing gaps in screening rates in the US, innovators continue to test new screening methods.

One emerging method is the multi-cancer early detection (MCED) test. As we described in <u>our 2022</u> <u>report</u>, MCED tests are an emerging class of innovative devices and analytical services that will detect many types of cancer based on the initial detection of blood-borne markers of cancer, such as cancer tumor DNA circulating in a patient's blood.³⁵ Companies like GRAIL and Exact Sciences, have been conducting clinical trials on MCED tests that could change how we screen for CRC in the future. The ACA's provision ensured that updates to screening recommendations to account for emerging science and new modalities have broad implications for coverage and cost-sharing. The experts we interviewed identified several potential issues that could arise in this area in the future, including:

- Different approaches based on different types of "originating sites" for cancer: Today, screenings are focused on different body parts and a person's likelihood to develop cancer focused there (e.g., lung, prostate, breast). These tests would necessitate a move away from that, which may cause confusion both for clinicians and patients in making recommendations on when and how often patients should seek screenings.
- Differences in risk profiles of patients: For example, if a patient is at high-risk for CRC, but not lung or breast cancer, should they have an MCED done early based on their CRC risk profile? And will their insurance cover it?

Conclusion

Individuals from historically marginalized populations continue to be screened for CRC at lower rates. As a result, these populations continue to have higher CRC incidence and mortality rates. Solutions to this problem will not be simple, as is indicated by the set of recommendations we outline in this report. Additional solutions to these issues will also be required. NEHI sought to identify solutions that are feasible and have the greatest potential reach. Most will require significant resources—people, political will, and/or funding—to achieve the potential benefits.

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