

Toward the Elimination of Colorectal Cancer Disparities Among African Americans

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Abstract

Background In the USA, race and socioeconomic status are well-known factors associated with colorectal cancer incidence and mortality rates. These are higher among blacks than whites and other racial/ethnic groups.

Methods In this article, we review opportunities to address disparities in colorectal cancer incidence, mortality, and survivorship among African Americans.

Results First, we summarize the primary prevention of colorectal cancer and recent advances in the early detection of the disease and disparities in screening. Then, we consider black-white disparities in colorectal cancer treatment and survival including factors that may contribute to such disparities and the important roles played by cultural competency, patient trust in one's physician, and health literacy in addressing colorectal cancer disparities, including the need for studies involving the use of colorectal cancer patient navigators who are culturally competent.

Conclusion To reduce these disparities, intervention efforts should focus on providing high-quality screening and treatment for colorectal cancer and on educating African Americans about

the value of diet, weight control, screening, and treatment. Organized approaches for delivering colorectal cancer screening should be accompanied by programs and policies that provide access to diagnostic follow-up and treatment for underserved populations.

Keywords African Americans · Cancer survivorship · Colorectal cancer · Health status disparities · Prevention · Screening

Colorectal cancer is the third leading cause of cancer-related death among both men and women in the USA and in many other developed countries. In 2015, there are an estimated 122,700 cases of colorectal cancer and 49,700 deaths from the disease in the USA [1]. Race and socioeconomic status are known factors associated with colorectal cancer incidence and mortality patterns [2, 3]. Although colorectal cancer incidence rates have declined in recent decades due to increases in routine screening and changes in risk factors, mortality rates have been consistently higher among African Americans than whites [1]. During 2006 through 2010, the colorectal cancer mortality rates for black men (29.4 per 100,000 population) were more than 50 % higher than those for non-Hispanic white men (19.2) or Hispanic men (16.1) and more than twice as high than that for Asian/Pacific Islander men (13.1) [4]. Similar disparities were obtained among women [4]. Possibly accounting for colorectal cancer disparities are a higher prevalence of risk factors among African Americans, decreased access to and lower utilization of health-care services, and genetic or microbiomic influences [5].

Challenges experienced by economically disadvantaged African Americans in receiving colorectal cancer prevention and treatment services include a variety of social determinants, not the least of which is poverty itself. Specific barriers

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include locations of diagnostic and treatment facilities outside of the patient's neighborhood, lack of transportation, lack of understanding of colorectal cancer, unavailability of support resources needed to access colorectal cancer treatment services, lack of health-care insurance, lack of access to primary care, and lack of familiarity with resources available from cancer support organizations. Factors that likely contribute to the relatively high colorectal cancer death rates for African Americans include low health literacy, lack of knowledge about colorectal cancer, attitudes, beliefs, cultural factors, and lack of access to services (Table 1). African Americans are more likely to have fatalistic attitudes toward cancer [5]. Other barriers to receiving colorectal cancer services include fear and mistrust, denial, uncertainty, lack of information, and unfamiliarity with providers [6]. Misperceptions about cancer and mistrust of the health care system can interfere with cancer treatment. In many communities, these challenges are worsened by the disjointed, categorical nature of service provision and the lack of a coordinated effort to address cancer treatment challenges [7]. In addition to social, environmental, and structural factors, genetic and microbiomic factors may be a factor in black-white disparities in colorectal cancer.

In this expert review, we consider opportunities to address disparities in colorectal cancer incidence, mortality, and survivorship among African Americans. The current article extends beyond previous reviews of colorectal cancer among African Americans by capturing recently published articles and by having a broader scope that extends from primary prevention and early detection to treatment and cancer survivorship (Table 2.) We first discuss modifiable risk factors and then summarize recent advances in the early detection of colorectal cancer and identify disparities in screening. Next, we consider black-white disparities in treatment including factors that may contribute to such disparities and the important roles played by cultural competency, patient trust in one's physician, and health literacy in addressing colorectal cancer disparities, including the need for culturally competent colorectal cancer patient navigators. Finally, we discuss remaining challenges in this area and summarize the findings.

Methods

Our review incorporated some elements of a systematic review; for example, it is based upon several bibliographic searches in PubMed and CINAHL. We used MeSH terms for "colorectal cancer" and for "African Americans" and used the Boolean algebra AND command to identify articles published in English in recent years (2000–2015). An initial sample of 806 articles was identified in the bibliographic search; of these, 691 were published since January 1, 2000 (Fig. 1). From this initial sample, many articles were excluded because they were beyond the scope of the current review. The search

was not limited to studies with positive findings. Nor was it limited to words appearing in the title of an article. Information obtained from PubMed and CINAHL (title and topic of article, information in abstract, geographic locality of a study, and key words) was used to determine whether to retain each article identified in this way. We gave priority to recent studies and to studies that included African Americans. For example, we were interested in the most recent articles on colorectal cancer screening rates among African Americans as rates can change over time. We reviewed key reports (for example, those released by the US Institute of Medicine and the Guide to Community Preventive Services) and reviewed the references of reports and review articles.

Modifiable Risk Factors for Colorectal Cancer

Modifiable risk factors for colorectal cancer include obesity and physical inactivity [1]. The prevalence of obesity and physical inactivity is higher among African Americans than among whites [8]. Cigarette smoking also increases the risk of colorectal cancer. Dietary factors such as moderate to heavy alcohol consumption; high consumption of red or processed meat; low calcium intake; and low intake of whole-grain fiber, fruits, and vegetables may also increase the risk [5]. Consumption of beef and pork is higher among African Americans than among other racial groups in the USA [9]. High consumption of animal products has been associated with increased proliferation of intestinal mucosal and increased populations of bile salt-producing bacteria in the colon [10]. Results from microbiomic studies suggest that gut flora, high fecal bile acid concentrations, and levels of short chain fatty acids influence risk of colorectal cancer in African Americans and other groups [10–12]. Although dietary and lifestyle factors have been associated with colorectal cancer risk and may contribute to the disparity in African Americans versus whites, the contribution of these factors to the overall burden of colorectal cancer remains to be clarified [5]. In the Polyp Prevention Trial, the adoption of a low-fat, high-fiber, high fruits and vegetables diet did not reduce the recurrence of adenomas [13].

Regular use of nonsteroidal anti-inflammatory drugs, such as aspirin, also reduces risk. However, these drugs are not recommended for the prevention of colorectal cancer among average risk individuals because they can have adverse health effects, such as gastrointestinal bleeding [1]. Menopausal hormone therapy (particularly combined estrogen and progesterone) also lowers risk. However, such therapy is not recommended for the prevention of colorectal cancer because it increases risk of breast cancer, stroke, heart attack, and blood clots [1]. Although the focus of this review is on black-white disparities in colorectal cancer, men and women have substantial differences in risk factors, effectiveness of cancer

Table 1 Factors that contribute to colorectal cancer disparities among African Americans across the cancer continuum

	Primary Prevention	Early detection	Treatment	Survivorship	End-of-life care
Patient factors	Low health literacy Obesity and physical inactivity Dietary factors	Lack of information, low health literacy Attitudes, beliefs, cultural factors Mistrust, denial, unfamiliarity with providers	Lack of information, low health literacy Attitudes, beliefs, cultural factors Mistrust, denial, unfamiliarity with providers Poverty, lack of health insurance Lack of transportation	Lack of information, low health literacy Obesity and physical activity Attitudes, beliefs, cultural factors Mistrust, denial Poverty, lack of health insurance Decreased access to quality care Comorbid conditions Possible differences in tumor biology	Lack of information, low health literacy
Provider-related factors		Failure to recommend screening to patients Inadequate knowledge of screening guidelines Poor patient-provider communication Lack of cultural competency Lack of timely follow-up	Under use of cancer care plans Poor patient-provider communication Lack of cultural competency		
Health care system-related factors			Disjointed, categorical nature of service provision Lack of a coordinated effort to address cancer treatment challenges Socioeconomic disadvantages Location of treatment facilities outside of patient neighborhoods		
Structural factors	Socioeconomic disadvantages Lack of safe or convenient recreational areas to exercise Lack of affordable healthy foods				

Table 2 Addressing colorectal cancer disparities among African Americans at the patient, provider, health care system, and community level

	Primary prevention	Early detection	Treatment	Survivorship	End-of-life care
Patient	Health education	Health education, one-on-one education Tailored interventions Patient navigation	Health education Patient navigation	Health education Support groups Cancer care plans	Patient and family health education Support groups
Provider	Provider counseling and education for patients Provider education in patient-physician communication Cultural competency skills	Provider counseling and education for patients Provider recommendation to get screened Continuing professional education Provider assessment and feedback Quality assurance of screening Provider education in patient-physician communication Cultural competency skills	Quality assurance of treatment Continuing professional education Provider education in patient-physician communication Cultural competency skills	Provider counseling and education for patients Quality assurance of survivorship care Continuing professional education	Quality assurance of palliative treatment
Health care system	Patient education	Reducing structural barriers Enhanced access Health care reform Integrated health care systems Accountable care organizations Quality assurance of screening	Reducing structural barriers Enhanced access Health care reform Integrated health care systems Accountable care organizations Quality assurance of treatment Cancer registration Cancer coalitions Support groups	Enhanced access Quality assurance of survivorship care Integrated health care systems Accountable care organizations	Enhanced access Quality assurance of palliative treatment
Community	Cancer coalitions Public health programs	Cancer coalitions Public health programs	Cancer coalitions Support groups	Cancer coalitions Support groups	Support groups

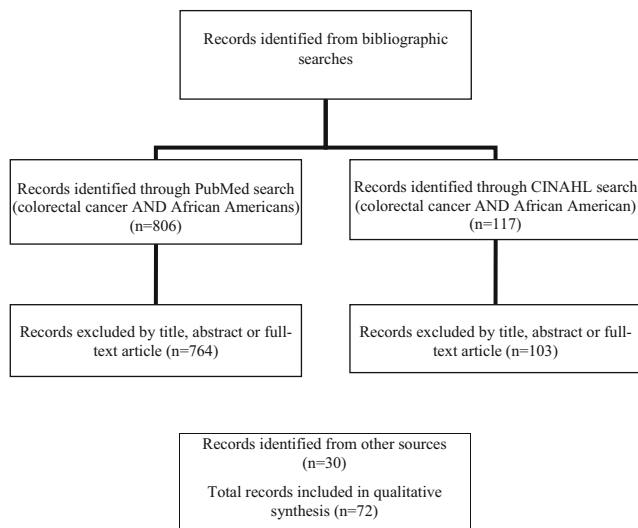


Fig. 1 Summary of search and exclusion process

prevention services, and tumor biology [14]. For women, colorectal cancer risk factors such as diet, obesity, and smoking may have disparate effects related to gender differences in estrogen exposure, body fat distribution, and tumor biology [16]. The benefit from colorectal cancer screening is lower in women than that in men [15].

Early Detection of Colorectal Cancer

Disparities in colorectal cancer screening contribute to the relatively high incidence and mortality from colorectal cancer among African Americans as compared with whites [17]. A meta-analysis of four randomized controlled trials found that biennial guaiac-based FOBT screening was associated with a 15 % reduction in the relative risk of colorectal cancer mortality [18]. Newer fecal immunochemical tests or fecal DNA tests may have a greater effect. Randomized controlled trials of flexible sigmoidoscopy have also shown a reduction in colorectal cancer mortality [19]. Observational studies suggest that screening colonoscopy is associated with a 50 % reduction in colorectal cancer mortality. Other screening modalities include double-contrast barium enema (rarely used) and computed tomographic (CT) colonography (not approved for reimbursement by Medicare and most insurance plans).

Shapiro et al. [20], using data from the 2010 National Health Interview Survey, examined the age-standardized percentage of respondents aged 50 to 75 years reporting FOBT, sigmoidoscopy, or colonoscopy within the recommended time interval. The age-standardized rate of colorectal cancer test use was 59.2 % (95 % confidence interval [CI] 57.8–60.6) among whites and 55.6 % (95 % CI 52.6–56.6) among blacks. Steele et al. [21] examined colorectal cancer screening rates by race and other factors using data from the 2010 Behavioral Risk Factor Surveillance System. Among respondents aged

50 to 75 years, 64.5 % reported being up-to-date with colorectal cancer screening. The proportion of respondents who reported having had any of the test options was greater among persons aged 65 to 75 years compared with those aged 50 to 64 years, and among persons with health insurance relative to those with no health insurance [21]. The disparity in reported test use by health insurance status was evident for all three test types (FOBT, sigmoidoscopy with FOBT, and colonoscopy). Rates of test use increased with increasing education level and household income. The prevalence of respondents who were up-to-date with CRC screening was 66.4 % among non-Hispanic whites and 64.8 % among non-Hispanic blacks [21]. Racial disparities in screening colonoscopy have been observed among persons with a positive family history of colorectal cancer. Almario et al. [22] examined data from the 2009 California Health Interview Survey. Among persons aged 40 to 49 years with a positive family history, African American men were 71 % less likely to have had a colonoscopy than white men (95 % confidence interval 13 to 96 %).

Racial disparities in colorectal cancer screening arise from a variety of individual-, provider-, and health care system-related barriers including differences in income, education, and health insurance coverage. The introduction of health insurance coverage for colorectal cancer screening and other routine preventive services through the Affordable Care Act (ACA) has opened up new opportunities for addressing disparities. However, people who choose FOBT or sigmoidoscopy as their initial test could face high, unexpected, out-of-pocket costs because the ACA does not mandate that Medicaid and insurance plans cover needed follow-up colonoscopies after positive tests [23]. A further issue is that African Americans and low-income persons often have additional barriers to screening beyond inadequate health-care insurance including lack of knowledge about colorectal cancer and the importance of screening, fear, distrust of doctors, poor knowledge of colorectal cancer risk or perceived benefits of screening, and less time available to practice preventive health behaviors [17, 24]. Although receiving a doctor's recommendation is the most important predictor of cancer screening, African Americans are less likely than whites to receive a recommendation to get screened for colorectal cancer [7, 25]. Ahmed et al. [26] in a study of data on 5900 adults eligible for endoscopic screening from the National Health Interview Survey found that African Americans were 26 % less likely ($P < 0.05$) to receive this recommendation than whites. Having a regular health-care provider, continuity of primary health care, and good communication with a provider improves screening participation [7, 17, 26].

Although addressing health care system and structural barriers to colorectal cancer screening is important, studies have not consistently found that the provision of insurance coverage alone reduces inequities in screening uptake [17, 27]. Comprehensive programs aimed at increasing colorectal

cancer screening and addressing disparities in screening may benefit from client and provider interventions [28]. The Guide to Community Preventive Services recommends one-on-one education, provider assessment and feedback, and reducing structural barriers for increasing FOBT [28]. In primary care, tailored interventions for patients are especially likely to be effective in increasing colorectal cancer screening in primary care [29–31]. The use of lay or nurse cancer screening navigators is also likely to be helpful [32–35]. Horne et al. [36] examined the effect of patient navigation on increasing colorectal cancer screening among older African Americans. The participants were randomized to either a control group, receiving printed education materials or to an intervention group in which they were assigned a patient navigator in addition to receiving printed educational materials [36]. Relative to controls, the intervention group was more likely to report being up-to-date with colorectal cancer screening in the exit interview (odds ratio = 1.55, 95 % confidence interval 1.07–2.23).

Black-White Disparities in Colorectal Cancer Treatment

Relative to whites, African Americans tend to be diagnosed with colorectal cancer at younger ages, are more likely to be diagnosed with more advanced stage cancer, and are more likely to be diagnosed with tumors of the proximal colon [5–37]. From the Surveillance, Epidemiology, and End Results (SEER)-Medicare linked database, Simpson et al. [38] identified 9935 non-Hispanic white and 1281 black patients aged 66 years and older with stage IV colorectal cancer. In an unadjusted survival analysis, black patients had a 15 % higher chance of dying relative to white patients (hazard ratio = 1.15, 95 % confidence CI 1.08–1.22, $P < 0.001$). After adjustment for differences in treatment (surgery, chemotherapy, or radiotherapy) and patient and tumor variables, however, the increased risk of death for black patients disappeared [38].

The survival of patients with colorectal cancer differs based upon race/ethnicity and socioeconomic status. Racial differences in cancer outcomes may be due to several factors including decreased access to quality care, differences in tumor biology resulting in increased aggressiveness or resistance to treatment, socioeconomic factors influencing treatment options, increased comorbid conditions, and/or suboptimal patient-physician interactions [39].

The causes of racial differences in colorectal cancer treatment and survival include patient, provider, and health care system factors. Racial disparities in the quality of care among colorectal cancer patients may contribute to differences in outcomes, and patient misperceptions about cancer and mistrust of the health care system can interfere with cancer treatment. African Americans are less likely to receive surgery for colorectal cancer than whites; racial differences in cancer staging

have also been noted [5]. African Americans may be less likely to receive cancer surgery because of patient refusal, because it was not recommended or because of a higher prevalence of comorbid conditions [40].

Structural problems, such as lack of transportation, may also be involved. When patients receive appropriate, timely care, there are few racial differences in colorectal cancer survival rates. For example, in their systematic review of published studies, Bach et al. [41] found no important differences in cancer-specific survival between African American and white patients when treatment was comparable for cancers of similar stage. Black-white differences in patient refusal rates, as well as patient attitudes, beliefs, and knowledge about colorectal cancer, may contribute to racial differences in receipt of appropriate treatment. Patient attitudes such as fatalism and denial can lead to delays in presenting for follow-up care. In addition, there are differences in the understanding of colorectal cancer among different racial/ethnic and socioeconomic groups. Individuals from disadvantaged backgrounds may be more likely to have misperceptions about their risk of colorectal cancer or the benefits of surgical resection, although results have been inconsistent across studies [42].

Cultural Competency, Patient Trust, and Health Literacy

Patient's trust in his or her physician is essential for desirable treatment outcomes such as satisfaction and adherence [43]. This is especially true in oncology due to the life-threatening nature of cancer. Patient trust is enhanced by the physician's technical competence, honesty, and patient-centered behavior. A trusting relationship between patients and their physicians can result in improved communication and medical decision-making, decrease patient fear, and improve treatment adherence [43, 44]. Effective patient-physician communication is related to improved adherence to medical regimens, better decision-making, and increased satisfaction with the patient-physician relationship [45, 46]. Cultural competency skills can assist patient-provider communication. Cultural competency influences how health messages are transmitted and perceived, how illness is defined, how symptoms are described, when and where care is obtained, and how treatment options are considered [44].

Low health literacy has been associated with decreased use of preventive services such as smoking cessation programs, increased risk of having a chronic disease such as cancer, increased use of emergency services, poorer treatment adherence, and poorer health outcomes [47, 48] and with decreased likelihood of seeking cancer information from a health-care professional, increased sense of fatalism about cancer, decreased participation in cancer control programs, and later stage at diagnosis [49]. Health literacy also influences

patient-provider communication. Individuals with low health literacy are more passive when interacting with providers, less likely to engage in shared decision-making, and are less likely to ask questions [50]. The ability to communicate effectively with providers is particularly important due to the complexity of cancer care. Furthermore, cancer prevention and control messages are often written at a reading level too high for individuals with marginal literacy skills, and health professionals often overestimate the health literacy skills of patients, possess inadequate awareness about health literacy issues, and do not routinely use recommended communication strategies [51, 52].

Identification of differences in the quantity and quality of health care provided to African American men and women, including the nature and quality of cultural competency interventions, is necessary to find the basis for cancer disparities. Various constructs have been utilized as targets of such interventions designed to increase access to care and decrease health disparities in racial/ethnic or disadvantaged groups [53, 54]. These interventions should include methods for defining and operationalizing social constructs (culture, family, and community) as well as measuring behavior-related constructs associated with culture including psychosocial factors such as fear, isolation, fatalism, trust, and respect.

Colorectal Cancer Patient Navigators

Patients who are newly diagnosed with colorectal cancer must not only cope with the emotional trauma of a cancer diagnosis but are expected to digest complicated and often threatening information about their illness and treatment procedures [46]. Many cancer patients, especially those who are socioeconomically disadvantaged, leave their health-care visit confused about their diagnosis, prognosis, options for treatment, and next steps [55]. The challenges of navigating the health care system can be overcome with the assistance of patient navigators (e.g., oncology nurses, social workers, or lay health advisors) who are trained to help patients through the processes of care. The linkage of colorectal cancer patients with patient navigators at the time of diagnosis could help ensure treatment completion and improve survival rates. Potential benefits include a reduction in fear of cancer, increased trust in oncologists and other health-care providers, improved patient satisfaction, increased knowledge of colorectal cancer treatment options, and better adherence and completion of treatment regimens. Much of the evidence supporting the use of patient navigators is based upon studies of women with breast cancer. Studies involving women with breast cancer and men and women with colorectal or lung cancer have demonstrated that cancer patients can experience better outcomes if they have patient navigators that provide services that are culturally appropriate, confidential, respectful, and compassionate

[55, 56]. Despite the increasing number of studies of patient navigators, there is a paucity of nurse-patient navigator interventions that are culturally appropriate for colorectal cancer patients who are low-income African Americans [56]. Current evidence supporting the use of patient navigators for low-income African Americans with colorectal cancer is promising but still not clear.

Patient navigation includes support and guidance offered to vulnerable persons with a colorectal cancer diagnosis, with the goal of facilitating receipt and completion of timely and appropriate staging and treatment and maximizing quality of life [57, 58]. Patient navigators can provide emotional and support services to patients and their families and assist them with the coordination of care among health care and other community service care providers. To address disparities in colorectal cancer, navigators should not only be knowledgeable about cancer diagnosis and treatment but should also understand the barriers to care and have communication skills, cultural competency, and local networks of resources to support patients. Nurse-patient navigators can explain why follow-up tests are needed and coordinate scheduling; be available to speak with the patient and his or her family about a cancer diagnosis; provide colorectal cancer education, including general information about the nature of various treatment options, and assist with appointment scheduling once the treatment process has been decided upon by the patient and his or her physician.

The American College of Surgeons Commission on Cancer (CoC) recognizes the importance of patient navigation in improving patient outcomes and reducing disparities. In hospitals with accredited cancer programs, the CoC requires that facilities have a process to navigate patients that addresses health-care disparities and other barriers that may impede patient care [59].

Discussion

Disparities in colorectal cancer among African Americans should be understood within the context of disparities among other groups identified by race, ethnicity, culture, and place of residence. Pronounced health disparities exist across population groups defined by race/ethnicity, socioeconomic factors, urban versus rural residence, place of birth, language, and other factors [60, 61]. The determinants of health disparities are complex and multifactorial in nature. They include biologic and behavioral individual factors, provider-, and health care system-related barriers including differences in income, education, and health insurance coverage. Racial differences in colorectal cancer treatment may be due to differences in tumor biology resulting in increased aggressiveness or resistance to treatment, socioeconomic factors influencing treatment options, increased comorbid conditions, suboptimal patient-physician interactions, and structural problems such as lack

of transportation and decreased access to quality care. The use of community coalitions is a valuable approach for addressing colorectal cancer disparities in African American and other minority communities [62–64]. Improving the cultural competence of health-care providers and the health care system are other examples of evidence-based approaches for reducing health disparities.

A comprehensive approach is needed to reduce or eliminate disparities in colorectal cancer that includes increased access to and utilization of screening, timely follow-up of abnormal results, and treatment of colorectal cancer [5]. Health-care providers should be involved in the primary, secondary, and tertiary prevention of colorectal cancer. Interventions at the health care system and provider levels are important part of efforts to address disparities in colorectal cancer among African Americans [35]. Cultural competency and patient-provider communication training are likely to be helpful for providers who care for African American patients.

Hospitals can play a key role in identifying potential disparities by looking at cancer registry data within the hospital. Data from the registries can readily identify treatment by stage of disease, race, ethnicity, age, comorbidities, provider, and other factors. By conducting quality review of colon cancer cases for adherence to quality guidelines such as those provided by the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology may help the hospital's quality management department identify and address disparities in colon cancer care. The NCCN provides a patient-friendly version of their guidelines, complete with diagrams that can serve as a source document for patients for discussion with their provider [65].

Addressing colorectal cancer disparities among people who are socioeconomically disadvantaged, including many African Americans, will require leveraging recent developments in health care reform and extensions of insurance coverage under Medicare and the ACA. In view of the fragmented nature of health care for many Americans, integrated health care systems and accountable care organizations are likely to improve cancer outcomes and be helpful for addressing colorectal cancer disparities [66]. Additional research is needed to identify best practices for effective colorectal cancer screening and treatment at community clinics including federally qualified health centers [67]. These centers offer primary and preventive care, including colorectal cancer screening, for the nation's most vulnerable populations [68]. Organized approaches to increase screening and to reduce disparities in screening participation, such as the Centers for Disease Control and Prevention Colorectal Cancer Prevention and Control Program, which currently funds programs in 25 states and four tribal organizations [69], are effective ways to increase screening at the population level through provision of financial resources, evidence-based interventions, and quality assurance measures. Approaches for delivering colorectal cancer

screening should be accompanied by programs and policies that provide access to diagnostic follow-up and treatment for underserved populations [70]. Monitoring of quality indicators of colorectal cancer screening is necessary for improving screening quality [71].

With respect to limitations, the current article is not a systematic literature review as recently published articles were given priority and the article does not speak to the weight of the evidence. A summary of the literature is provided rather than an evaluation of the weight of the evidence.

As colorectal cancer and other diseases become more preventable and survivable due to advances in medical knowledge, individuals with greater access to resources tend to benefit more, a factor that can lead to the worsening of health disparities [72]. Public health interventions are therefore needed to facilitate a more equitable distribution of medical advances and improved uptake and utilization of colorectal cancer treatment among lower socioeconomic groups such as economically disadvantaged African Americans and other at-risk populations.

Compliance with Ethical Standards

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Conflict of Interest The authors declare that they have no competing interests.

Ethical Approval This article does not contain any studies with human participants performed by any of the authors.

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