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Race-based Clinical Recommendations in Gastroenterology

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Introduction

The use of race and ethnicity in clinical decision-making has been under scrutiny, in light of greater awareness that race is a social construct with limited biological basis.¹ Population genomic studies have found more variation within than between racial groups.¹ Thus, racial/ethnic differences found in large studies more likely reflect differences in exposure, healthcare access, and delivery than race/ethnicity itself.² The use of broad racial/ethnic categories in research studies is also problematic due to the high-degree of heterogeneity in ancestry and cultural practices within such groups, and limited consideration of the rapidly growing number of people who self-identify as being of mixed racial and ethnic background. The inherent problems with commonly used racial/ethnic categories along with growing support in the medical community to proactively tackle health inequities have increased the imperative for reconsidering existing practices.

The use of race/ethnicity is pervasive in clinical practice.³ Adjustment for an individual's race/ethnicity in diagnostic and predictive algorithms may lead to biases in individualized risk assessment and clinical decision-making, or create and perpetuate health inequities. Such algorithms are embedded in clinical guidelines. Those concerns have led to major recent shifts in how race/ethnicity is used in clinical algorithms and guidelines.⁴ Recently, new equations which remove race/ethnicity from well-established models, including estimated glomerular filtration rate (eGFR) and Vaginal Birth After Cesarean Section (VBAC) calculators, have been proposed.^{5–6}

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Within gastroenterology (GI), there is a need to further examine, critique, and reconsider the use of race/ethnicity in clinical decision-making. In this article, we aim to define the extent to which race/ethnicity is used in current GI guideline recommendations. We propose recommendations for guideline developers on considering race/ethnicity in the context of clinical recommendations and provide examples for incorporating health equity into the guideline development process.

Race/ethnicity-based recommendations in gastroenterology clinical guidelines

We conducted a comprehensive search of clinical guidelines or guidance from US-based GI professional societies (e.g. the American Gastroenterological Association [AGA], American College of Gastroenterology [ACG], American Association of Liver Diseases [AASLD], and American Society of Gastrointestinal Endoscopy [ASGE]), published between January 1, 2010 and September 1, 2021. The full protocol is in Supplementary Table 1, and the PRISMA diagram is shown in Supplementary Figure 1. There were seven guidelines which included a total of eight race/ethnicity-based recommendations (Table 1).

Screening for Hepatocellular Cancer in Individuals Living with Hepatitis B Virus (HBV)

The 2018 AASLD guidance endorsed earlier screening for hepatocellular carcinoma (HCC) for Asian and Black individuals with chronic HBV based on higher incidence of HCC in those racial groups, and subsequent cost-effectiveness.⁷ The recommendation endorses ultrasound screening for Asian or Black men over 40 years and Asian women over 50 years of age every six months. Other factors such as chronicity of disease, source of transmission, recent immigration status, viremia, and prevalence of HBV in country of origin or acquisition were not incorporated into the recommendation.

Helicobacter pylori (H. pylori)

A 2015 ASGE guideline focused on race/ethnicity considerations recommends screening for and treating *H. pylori* in all non-White racial/ethnic groups.⁸ Prior studies have shown that socioeconomic variables such as education, employment and property values correlate with *H. pylori* sero-prevalence.⁹ However in some populations, such as those with African ancestry, socioeconomic factors alone may not fully explain differences in prevalence.⁹ This guideline cited purposefully the use of race/ethnicity as a means to help reduce inequities in access to care while acknowledging heterogeneities within racial/ethnic groups.

Gastric intestinal metaplasia (GIM):

Three current guidelines on GIM utilize race and/or ethnicity in recommendations (Table 1).^{8,10–11} All three utilize non-specific definitions of non-White racial and/or ethnic groups as one category. Both ASGE guidelines suggest surveillance for individuals from racial/ethnic backgrounds at increased risk for gastric cancer, without an explicit definition of which groups fall within these recommendations.^{8,10} The AGA 2019 GIM guideline has a conditional recommendation against routine use of endoscopic surveillance for all individuals.¹¹ However, the conditional recommendation indicates that some populations

may be reasonable to screen based on specific rationale, including racial/ethnic background. The authors included a careful and transparent explanation for this recommendation, based on a meta-analysis that acknowledges the differences amongst racial/ethnic groups were not statistically significant differences, but could not exclude the possibility of clinically meaningful differences.¹¹

Barrett's esophagus (BE):

White race has been cited as a risk factor for the development of BE and has been incorporated into recommendations in three current guidelines (Table 1), based on the observed higher prevalence rates of esophageal adenocarcinoma (EAC) in White individuals relative to other racial/ethnic groups.^{12–14} In these three guidelines, recommendations include White race as a risk factor, amongst others, to screen for BE with upper endoscopy.

Challenges with the use of race/ethnicity in clinical recommendations

The use of broad groups of racial categories, such as in the current HBV guidance for HCC surveillance, in race-based recommendations poses challenges in clinical contexts, particularly when more accurate variables are present for risk stratification. For example, should a US-born healthcare worker of Asian ancestry who has chronic HBV from needlestick injury be surveilled identically as an individual who immigrated from Asia without a clear source of exposure and presumed to have acquired HBV via vertical transmission? These clinical scenarios convey different risks of developing HCC. In this scenario, variables such as chronicity of disease to encompass suspected vertical transmission, viremia, and presence of fibrosis, define risk more accurately and appropriately than race/ethnicity. Similarly, factors such as country of origin and living environment may more appropriately identify people who may benefit more from *H. pylori* screening.

In the GIM-related guidelines, the current clinical recommendations group all non-White racial/ethnic groups together which is problematic as it encourages clinicians to treat all non-White individuals in the same manner without clear assessment of environmental factors (including country of origin or recent immigration status) which may predict risk. Additionally, one guideline with an accompanying systematic review reported 3-year cumulative risks for gastric cancer as 1.0% (95% CI, 0.4%–1.7%) among Hispanic individuals, 0.3% (95% CI, 0.1%–0.8%) among Asian individuals, 0.4% (95% CI, 0.0%–1.4%) among Black individuals, and 0.3% (95% CI, 0.1%–0.6%) among non-Hispanic White individuals.¹¹ The authors express concern regarding whether there may be clinically meaningful differences in gastric cancer risk between Hispanic individuals and non-Hispanic White individuals (1.0% vs. 0.3%) despite the absence of a statistically significant difference, and therefore incorporate race/ethnicity in the recommendation. The broad racial/ethnic category grouped Asian individuals with other racial/ethnic minorities despite having similar cumulative risk for gastric cancer as non-Hispanic White individuals.

For BE screening, the association between White race and BE is not fully understood with some studies postulating a genetic basis for comparing American individuals of European and African descent.¹⁵ However, more research is needed to determine whether associations

are specific to certain groups. Specifically, identification of specific risk factors, including environmental and genetic mechanisms, are needed. While three guidelines incorporate White race into recommendations on BE, a newer 2019 ASGE guideline on BE does not.¹⁶ The updated systematic review for this guideline cited family history of EAC or BE, age>50, obesity/central adiposity, history of smoking, and male gender as risk factors for BE.¹⁷ Clarification regarding whether the removal of race was purposeful or not, along with a discussion on the potential impact on health equity, would aid in transparency of this shift in guideline recommendation. Also, clarification is needed regarding whether the ASGE 2019 BE guideline, which has the non-race-based recommendation, is meant to replace the ASGE 2015 GERD guideline with the race-based recommendation, in order to avoid confusion from practitioners.^{13,16}

Shifting away from race/ethnicity-based recommendations

There are several recent examples of replacing or removing race/ethnicity in GI clinical guideline recommendations in addition to the example above regarding the removal of race from the ASGE 2019 BE screening guideline.¹⁶ Another example is in colorectal cancer (CRC) screening, in which there are higher incidence and mortality rates in Black compared to White individuals. In an effort to tackle these inequities, prior ACG guidance suggested screening Black individuals at an earlier age than White individuals.²³ However, there was not strong evidence that initiating screening earlier in Black individuals would reduce the disparities. Subsequent modeling studies also do not support earlier screening in Black individuals alone. Therefore, current guidelines recommend initiating screening at age 45 for all average-risk people across all racial/ethnic groups on account of the rise in early onset CRC that impacts all racial/ethnic groups.²¹ As emphasized in the 2021 ACG CRC screening guideline, evidence-based efforts are still needed to reduce disparities among Black individuals.²¹ Finally, a prior guideline by AASLD and the Infectious Disease Society of America on HCV treatment recommended a longer course of antiviral therapy (12 weeks instead of 8 weeks) for Black individuals.²⁴ An updated guidance in 2019 now recommends 12 weeks for all individuals with HCV, regardless of race/ethnicity.²⁵ These changes are examples of race-conscious medicine, which acknowledges that race is a social risk factor rather than a biological risk factor and promotes mindful use of race/ethnicity in healthcare.

Considerations for the guideline development process

There are many considerations for US-based GI professional societies regarding the inclusion of race/ethnicity into clinical guidelines. This is a vital step in addressing health inequities. Clinical guidelines should be based on a full systematic review, utilizing rigorous methodology with *a priori* criteria and not be based on expert opinion, which is more subject to bias. Additionally, conflict of interest assessment should be conducted and reported in a transparent manner. Guideline panels should also consider whether there was adequate representation of all racial/ethnic groups in studies. If the evidence base clearly indicates differences in outcomes by race/ethnicity, it is important for guideline developers to consider whether, in that context, race/ethnicity is a proxy for social risk factors and related variables. If more precise variables can be utilized, such as ancestry or local prevalence, these variables should be considered instead of race/ethnicity. For any replacement variable, the impact

on health inequities must be examined. It is also important that to recognize that broad recommendations encompassing all racial/ethnic groups other than White individuals have the potential to ignore important differences among groups in treatment decision-making. When there are unexplained differences among racial/ethnic groups, guidelines should call for research to test plausible assumptions. When racial/ethnic differences are felt due to structural barriers or differential environmental exposures, guidelines can consider implementation strategies to target these exposures and barriers to address inequities.

In summary, guideline panels should:

- Consider the racial/ethnic diversity of relevant existing research and examine any existing inequities
- Avoid the use of race/ethnicity in clinical recommendations and utilize more precise variables than race/ethnicity when feasible
- Be transparent about why race/ethnicity is (or is not) used and the implications for care and health equity if race/ethnicity is used in a contemporary guideline and/or removed from a previous recommendation
- Call for future research to understand the role of social determinants of health on disease incidence, outcomes, and response to treatment.

Acknowledging race/ethnicity, as well as the implications of recommendations on existing health inequities, is important across all guidelines. Examples of some of these recommended best practices are shown in Table 2.

Conclusion

We identified eight recommendations across seven clinical guidelines or guidance documents published since 2010 that suggest or recommend that providers tailor clinical decisions based on race and/or ethnicity.^{7-8,10-14} The recommendations were focused on four main topic areas: surveillance for HCC in individuals with chronic HBV, surveillance for GIM, screening for *H. pylori*, and surveillance for BE. In these guidelines, individuals are either screened or surveilled for a clinical condition based on the incidence or risk of the condition within a racial or ethnic group. Racial/ethnic categories are amorphous and do not adequately capture many groups including multi-racial individuals. Additionally, inappropriate racial/ethnic-based recommendations could have the unintended consequence of increasing, rather than mitigating, health inequities. In this vein, it is prudent for GI societies to re-examine existing guidelines and current guideline development processes to avoid race/ethnicity-based recommendations when possible, utilize more precise variables in place of race/ethnicity, and transparently rationalize the use of race/ethnicity and its potential impact on health equity.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1: Race and ethnicity-based recommendations in GI professional society clinical guidelines

Topic	Guidance/Guideline (Society, Year)	Race/ethnicity variable definition	Race/ethnicity-based recommendation(s)	Race/ethnicity variable potential proxy	Potential implications on health disparities
Hepatitis B	Update on Prevention, Diagnosis and Treatment of Chronic Hepatitis B (AASLD 2018) ⁷	Not explicitly defined	“HBsAg-positive adults at high risk for HCC (including Asian or black men over 40 years and Asian women over 50 years of age), persons with a first-degree family member with a history of HCC, or persons with HDV should be screened with US examination with or without AFP every 6 months.”	Chronicity of disease (incl. factors such as suspected/confirmed vertical transmission), active viremia, prevalence of HBV in country of origin/acquisition	Associated harms and cost of ultrasound and blood testing
	Race and ethnicity in GI endoscopy (ASGE 2015) ⁸	Caucasian, Hispanic, and African American * individuals	“We suggest screening for and treating H pylori in racial and/or ethnic groups at high risk for gastric cancer.”	Environmental factors that may be related to socioeconomic factors, including living conditions and diet	Associated harms and cost of H. pylori testing, potentially through stool testing, breath testing, or upper endoscopic biopsies
Gastric Intestinal Metaplasia (GIM)	The role of endoscopy in the management of premalignant and malignant conditions of the stomach (ASGE 2015) ¹⁰	Not explicitly defined	“We suggest surveillance endoscopy for patients with GIM who are at increased risk of gastric cancer due to ethnic background or family history. Optimal surveillance intervals have not been extensively studied and should be individualized.”		
	Race and ethnicity considerations in GI endoscopy (ASGE 2015) ⁸	Not explicitly defined	“We suggest EGD for surveillance in patients with gastric atrophic gastritis or intestinal metaplasia coupled with an increased risk of gastric cancer because of ethnic background, extensive anatomic distribution, or family history.”	Environmental factors such as dietary habits potentially linked to socioeconomic status, smoking, and H. pylori prevalence. Potential genetic basis.	Associated harms and cost of routine endoscopy with biopsy
	Gastric Intestinal Metaplasia (AGA 2019) ¹¹	Non-Hispanic White individuals	“In patients with GIM, the AGA suggests against routine short-interval repeat endoscopy for the purpose of risk stratification. Comment: Based on shared decision-making, patients with GIM and high-risk stigmata, concerns about completeness of baseline endoscopy, and/or who are at overall increased risk for gastric cancer (racial/ethnic minorities, immigrants from regions with high gastric cancer incidence, or individuals with family history of first-degree relative with gastric cancer) may reasonably elect for repeat endoscopy within 1 year for risk stratification.”		
Barrett’s Esophagus (BE)	Management of Barrett’s Esophagus (AGA 2011) ²	White vs non-white individuals	“In patients with multiple risk factors associated with esophageal adenocarcinoma (age 50 years or older, male sex, white race, chronic GERD, hiatal hernia, elevated body mass index, and intra-abdominal distribution of body fat), we suggest screening for Barrett’s esophagus.”	Potential genetic basis (genomic variants at the GSTT2 locus) in European Americans	White individuals have greater access to screening and early detection for BE
	The role of endoscopy in the management of GERD (ASGE 2015) ¹³	White vs non-white individuals	“We suggest that endoscopy be considered in patients with multiple risk factors for Barrett’s esophagus.” Described risk factors include: older than 50 years of age, male sex, white race, a family history of BE or EAC, prolonged reflux symptoms, smoking, and obesity.”		
	Diagnosis and Management of	Caucasian, African	“1. Screening for BE may be considered in men with chronic (>5 years) and/or frequent (weekly or more) symptoms of gastroesophageal reflux		

Topic	Guidance/Guideline (Society, Year)	Race/ethnicity variable definition	Race/ethnicity-based recommendation(s)	Race/ethnicity variable potential proxy	Potential implications on health disparities
	Barrett's Esophagus (ACG 2016) ¹⁴	American, Hispanic individuals	(heartburn or acid regurgitation) and two or more risk factors for BE or EAC. These risk factors include: age >50 years, Caucasian race, presence of central obesity (waist circumference >102 cm or waist-hip ratio >0.9), current or past history of smoking, and a confirmed family history of BE or EAC (in a first-degree relative) (strong recommendation, moderate level of evidence). 2. Given the substantially lower risk of EAC in females with chronic GER symptoms (when compared with males), screening for BE in females is not recommended. However, screening could be considered in individual cases as determined by the presence of multiple risk factors for BE or EAC (age >50 years, Caucasian race, chronic and/or frequent GERD, central obesity: waist circumference >88 cm, waist-hip ratio >0.8, current or past history of smoking, and a confirmed family history of BE or EAC (in a first-degree relative)).*		

Included clinical guidelines and guidance documents with race/ethnicity-based recommendations published between January 1, 2010 and September 1, 2021.

* Specific racial and ethnic groups were not outlined as part of the recommendation; this is extracted from the guideline text.

Abbreviations: American Gastroenterological Association (AGA), American College of Gastroenterology (ACG), American Society for Gastrointestinal Endoscopy (ASGE), American Association for the Society of Liver Diseases (AASLD), Gastric Intestinal Metaplasia (GIM), Gastrointestinal (GI), Barrett's Esophagus (BE), Esophageal Adenocarcinoma (EAC), Gastroesophageal Reflux Disease (GERD).

Table 2:

Best practice examples of approaching race and ethnicity

Best Practice	Guideline	Example
Consideration of the impact of a clinical recommendation on health equity (e.g. including equity as an explicit outcome)	COVID testing (AGA 2021) ¹⁸	“Our search did not yield any direct evidence on equity issues in the context of preprocedure testing. However, our guideline panel acknowledges the widespread indirect data supporting health disparities in access to testing, clinical care, and vaccines during the COVID-19 pandemic. Given this, our guideline panel discussed and acknowledged the potential for testing to serve as an additional barrier to care for underserved populations who may already have disparities in care.”
Report diversity (or lack thereof) in patient cohorts	Intra-gastric balloons (AGA 2020) ¹⁹	“In the vast majority of studies included in the Technical Review, patients were either White with little inclusion of individuals from other racial and ethnic backgrounds, or there was no reporting of race or ethnicity within the studies. Future research must concentrate on studying a more diverse patient population, identifying whether disparities exist in weight-loss treatment interventions offered to patients and assessing whether such disparities affect outcomes of weight-loss interventions.”
	Malnutrition, Frailty, and Sarcopenia in Patients with Cirrhosis (AASLD 2021) ²⁰	“Standardized, feasible assessment of frailty and sarcopenia in diverse populations of patients with cirrhosis with respect to sex/gender, race/ethnicity, and clinical acuity: The literature has been lacking on detailed comparisons of frailty and sarcopenia by not only biological sex but also by self-identified gender. Cohorts should be enriched with patients of diverse racial/ethnic backgrounds to better understand variation in race/ethnicity differences in manifestations of malnutrition, frailty, and sarcopenia and the implications on clinical outcomes.”
Outline and acknowledge existing health disparities in the field	Colon cancer screening (ACG 2021) ²¹	“Nationally, screening rates in blacks are lower than in whites, suggesting an unmet need for efforts to improve screening in this group. Recent trends from Surveillance Epidemiology and End Results (SEER) show a decline in CRC incidence and mortality for black men and women. Based on recent SEER data, modeling studies show similar benefit of CRC screening in African Americans and whites starting at age 45 years. Special efforts and outreach programs are needed to boost screening in African Americans to reduce the disparities in screening rates and reduce incidence rates.”
	Alcoholic Liver Disease (ACG 2018) ²²	“Subjective variables like...race...and adherence to treatment are some of the barriers for referral of patients, who otherwise may be potential LT candidates.”
Utilize country of origin or ancestry instead of broad racial/ethnic groups	Race and ethnicity considerations in GI endoscopy (ASGE 2015) ⁸	“Screening EGD for gastric cancer may be considered in new U.S. immigrants from high-risk regions around the world including Korea, Japan, China, Russia, and South America, especially if there is a family history of gastric cancer in a first-degree relative.”