



animal reproduction studies with intravenous administration of vedolizumab to rabbits and monkeys at dose levels 20 times the recommended human dosage (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and miscarriage is 15 to 20%, respectively.

#### Clinical Considerations

##### *Disease-associated maternal and embryo/fetal risk*

Published data suggest that the risk of adverse pregnancy outcomes in women with inflammatory bowel disease (IBD) is associated with increased disease activity. Adverse pregnancy outcomes include preterm delivery (before 37 weeks of gestation), low birth weight (less than 2,500 g) infants, and small for gestational age at birth.

##### *Fetal/Neonatal adverse reactions*

ENTYVIO administered during pregnancy could affect immune responses in the in utero exposed newborn and infant. The clinical significance of low levels of ENTYVIO in utero-exposed infants is unknown. The safety of administering live or live-attenuated vaccines in exposed infants is unknown.

#### Data

##### *Animal Data*

A reproduction study has been performed in pregnant rabbits at single intravenous doses up to 100 mg/kg administered on gestation Day 7 (about 20 times the recommended human dosage) and has revealed no evidence of impaired fertility or harm to the fetus due to vedolizumab. A pre- and post-natal development study in monkeys showed no evidence of any adverse effect on pre- and post-natal development at intravenous doses up to 100 mg/kg (about 20 times the recommended human dosage).

#### Lactation

##### *Risk Summary*

Available published literature suggests the presence of vedolizumab in human milk. The effects of local gastrointestinal exposure and expected low systemic exposure to vedolizumab on the breastfed infant are unknown. There are no data on the effects of vedolizumab on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ENTYVIO and any potential adverse effects on the breastfed infant from ENTYVIO or from the underlying maternal condition.

#### Pediatric Use

Safety and effectiveness of ENTYVIO in pediatric patients have not been established.

#### Geriatric Use

Clinical trials of ENTYVIO did not include sufficient numbers of subjects aged 65 and over (46 Crohn's and ulcerative colitis patients aged 65 and over were treated with ENTYVIO during controlled Phase 3 trials) to determine whether they respond differently from younger subjects. However, no overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Manufactured by:

**Takeda Pharmaceuticals America, Inc.**

Deerfield, IL 60015

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Revised: March 2020

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For more information, go to [www.ENTYVIO.com](http://www.ENTYVIO.com) or call 1-877-TAKEDA-7 (1-877-825-3327).

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# GASTROENTEROLOGY

## DATA TRENDS 2020

### 8 Long-Term Impact of COVID-19 on the Practice of Gastroenterology and Endoscopy

**John I. Allen, MD, MBA, AGAF**

### 10 Consolidation Trends in Gastroenterology

**Michael Weinstein, MD, AGAF**

### 12 IBD Management Amid COVID-19

**Kim L. Isaacs, MD, AGAF**

### 14 Racial and Social Disparities in Gastroenterology

**Sandra M. Quezada, MD, MS**

### 16 Impending Physician Shortages in Gastroenterology

**Michael Weinstein, MD, AGAF**

### 18 Recommendations for Colonoscopy and the Management of Large Polyps

**Aasma Shaukat, MD, MPH, AGAF**

### 20 Nonalcoholic Steatohepatitis (NASH): Identifying Patients with High-Risk Disease

**Brent Tetri, MD, AGAF**

### 22 Esophageal Adenocarcinoma: Geographical Clustering and Time Trends

**Joel Rubenstein, MD, MSc**

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# LONG-TERM IMPACT OF COVID-19

## *on the Practice of Gastroenterology and Endoscopy*

John I. Allen, MD, MBA, AGAF

The COVID-19 pandemic has had a swift, broad impact on clinical operations and finances of gastroenterology practices in the United States. During the first quarter of 2020, elective procedures were universally deferred in many parts of the country and clinic visits shifted to telehealth options. The in-person visits that did occur often required previsit viral testing, more personal protective equipment, slower room turnover, and alterations to facilities to reduce the potential exposure of staff and patients to SARS-CoV-2.<sup>1,2</sup>

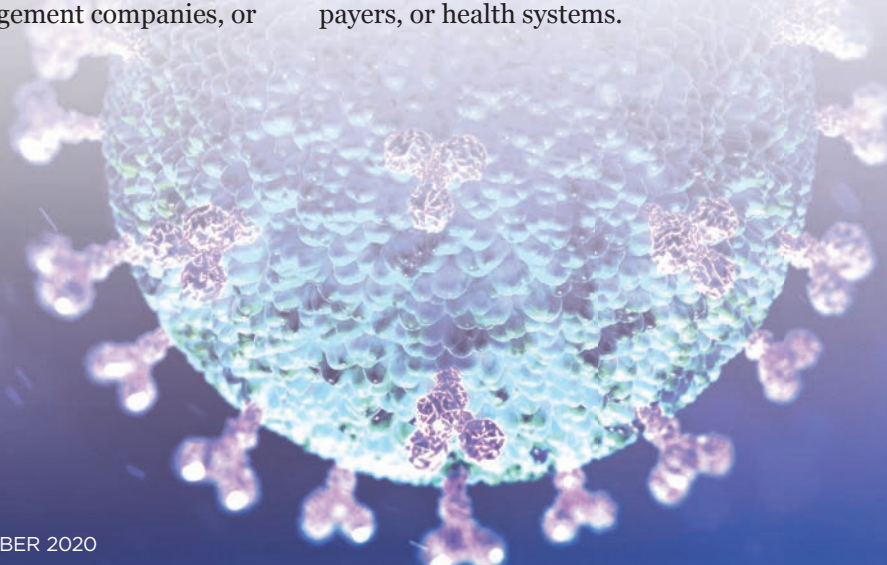
The switch to virtual care had disparate effects on patient populations. Large areas of the country, particularly rural communities, lack adequate broadband access for individual households, and patients may depend on internet connectivity at libraries or businesses that also shut down. Clinical practices had to adapt quickly to newer remote patient monitoring and engagement technology where available. Clinical practices also faced difficulties in triaging and risk-stratifying patients whose care was deferred. Unfortunately, deferral of screening and diagnostic exams led to a sharp reduction in the number of GI cancers that were diagnosed during this period.<sup>3</sup>

Declines in procedural volume and facility use led to difficult decisions about staff furloughs, layoffs, and permanent reductions. For practices that had been acquired by private equity (PE) firms, management companies, or

health systems, these difficult decisions often were made without direct physician input, which led to frustration and renewed feelings about loss of practice autonomy.

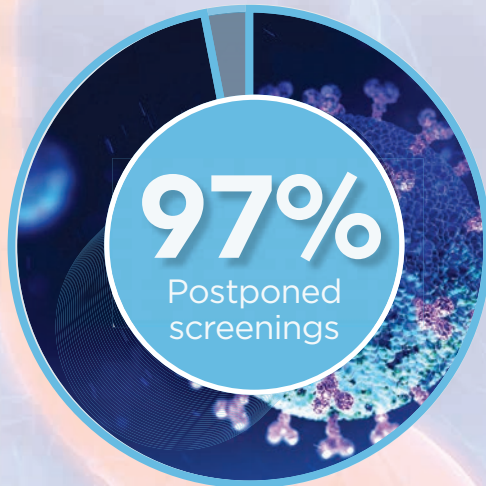
Financial vulnerabilities were most apparent for practices heavily dependent on one service line – colonoscopy (often 60%-80% of practice income) – for continuous cash flow. Practices suddenly needed rapid access to external sources of income, such as bank credit lines, or capital that might only come from PE or large health system sources. Practices with ongoing financial commitments such as debt or PE contractual obligations were the most vulnerable. Financial stresses affected community practices, academic medical centers, and health systems differently, however. For example, while many larger health systems rebounded to prepandemic patient numbers rapidly after the initial shutdown, smaller private practices may not have been able to rehire staff and resume pre-COVID volumes as quickly and did not have capital reserves to help weather the downturn.

The future brings more uncertainty. There are ongoing concerns about rehiring staff, long-term financial recovery, implementation and management of new patient/visitor policies, payer shifts caused by changes in patient employment status, and continuing consolidation of practices, often coupled with acquisition by PE companies, payers, or health systems.

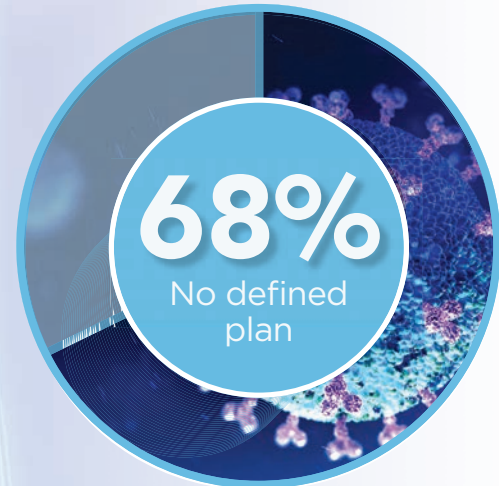




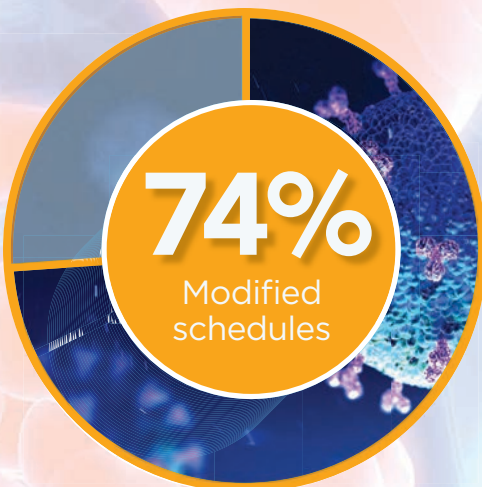
Based on a survey of 73 gastroenterology/endoscopy practices in North America:<sup>1</sup>



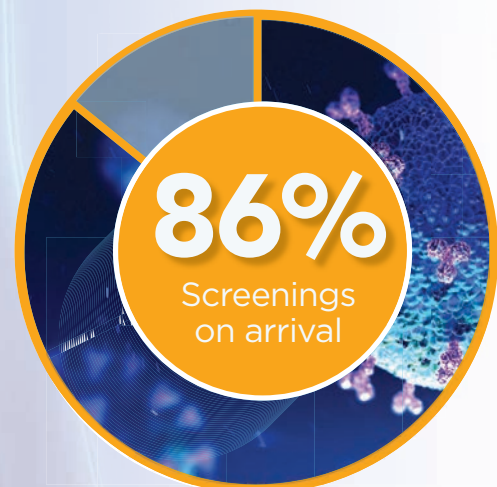
during the height of  
the COVID-19 pandemic



to address the backlog of procedures  
once restrictions were lifted



limiting the number of attending  
physicians on-site at one time



for COVID-19 symptoms, sometimes  
resulting in canceled appointments

Between March 1 and April 18, 2020,  
the mean weekly number of  
**newly diagnosed** colorectal  
cancer cases

**fell from**  
946 to 625.<sup>3</sup>

Sources:

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# CONSOLIDATION TRENDS

## *in Gastroenterology*

Michael Weinstein, MD, AGAF

A primary driver behind the consolidation of gastroenterology practices is following the current trend toward consolidation throughout health care, including physician groups in all specialties, hospitals, accountable care organizations, and payers. Factors include the adoption of increased regulatory requirements, such as the move toward EMRs, transparency, and interoperability, which are more difficult for smaller practices, especially because of the high cost of information technology.

A newer factor is the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which is moving health care toward a value-based payment system that in turn requires practices to measure outcomes, comfortably take risks, and consider forms of alternative payment systems including bundled care. Practice groups need to coordinate physicians, facilities, pathology, anesthesia, infusions—all of the components needed to assume risk—which can be performed well in larger groups in which analytics can be applied to outcomes and the risk of adverse selection is minimal. Finally, there's the capital needed to build a central infrastructure. Raising significant amounts of money is very challenging for small groups.

Consolidation provides immediate, midrange, and long-term benefits. Immediate benefits include the security of belonging to a larger group, with less competition for consults, referrals, and patients, as well as the reduction in overhead costs related to administrative functions, office staffing, malpractice rates, and health insurance. The switch to a shared practice management system with specifically educated administrative staff is also an immediate benefit. Midrange benefits include the improved ability to negotiate for better contracts with payers and the opportunity to build ancillary revenue through ambulatory surgery centers, pathology laboratories, infusion centers, and anesthesia services. Long-term benefits include improved ability to attract employees and new associates with better benefits, as well as use of centralized services such as a call center, human resources department, and employee training. A switch to a better EMR system may be part of a mid-range or long-term change.

We will continue to see consolidation, and I anticipate that, within 10 years, it will be very uncommon to find gastroenterology groups of fewer than 5 physicians except in small rural communities.

In **2018**, there were only **2** private equity deals for gastroenterology practices.

In **2019**, there were **16**. As of July, there have been 5 in 2020.<sup>3</sup>

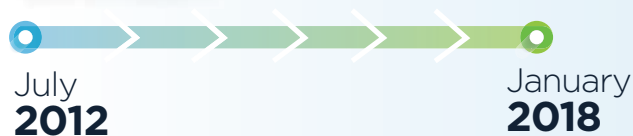
Between



Hospitals acquired  
**8,000 medical practices.**

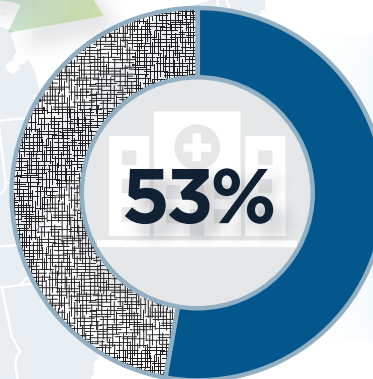
**14,000 physicians** left private practice to work in hospitals.<sup>1</sup>

Between



The number of hospital-owned practices **increased by 128.7%** across the United States.<sup>1</sup>

**Of the nearly 14,500** gastroenterologists in the United States: About **6,000** are in private practice.



are employed at hospitals or other health care organizations.<sup>2</sup>

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# IBD MANAGEMENT AMID COVID-19

Kim L. Isaacs, MD, AGAF

The COVID-19 pandemic has complicated the care of patients with inflammatory bowel disease (IBD). Concerns have arisen about diagnosis and relative risks of COVID-19 and the role these factors play in the management of IBD.<sup>1-3</sup>

Patients with IBD who take immune modulators such as anti-tumor necrosis factor therapies, thiopurines, and/or tofacitinib have an increased risk of certain viral infections, such as herpes zoster or reactivation of hepatitis B. Initially concern was raised over potential increased risk of infection with SARS-CoV-2. While reports from Italy, Spain, and the United States have confirmed that patients with IBD do not face an increased risk of infection with SARS-CoV-2, compared with the general population, there are certain factors associated with IBD that complicate a COVID-19 diagnosis.<sup>4-8</sup>

For example, diarrhea is a key symptom of IBD flare, but it is also present in 10.6% of patients with COVID-19 – and

in some cases presenting before any respiratory symptoms.<sup>9</sup> In such instances, early indications of COVID-19 could be mistaken by the patient for regular IBD symptoms, potentially delaying proper self-quarantine to help reduce the spread of the virus.

Factors associated with more severe COVID-19 in patients with IBD include increasing age, multiple comorbidities, and corticosteroid or aminosalicylate use.<sup>6,10,11</sup> TNF antagonists are not associated with more severe COVID-19. Moderate to severe IBD activity and a higher Charlson Comorbidity Index (CCI) score are significantly related with COVID-19–related death, even when the data are adjusted for steroid use.<sup>6,10</sup>

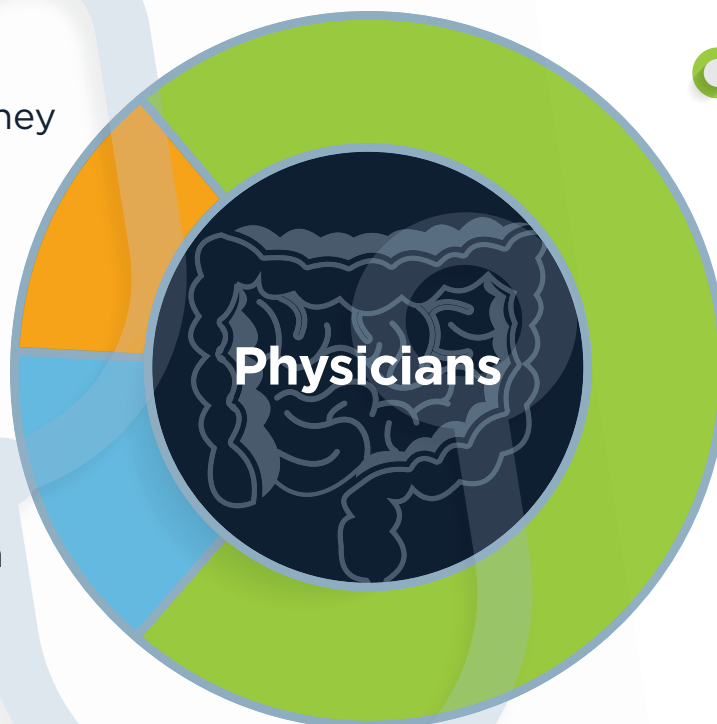
Once a patient tests positive for COVID-19, it is recommended that IBD therapies stop for a minimum of 10 days and resume at least 3 days after recovery from symptoms (this timeframe should be closely monitored and increased in more severe COVID-19 cases).<sup>3,12,13</sup>

13%

Did not feel they knew how to appropriately manage IBD patients with COVID-19

14.5%

Felt uncertain

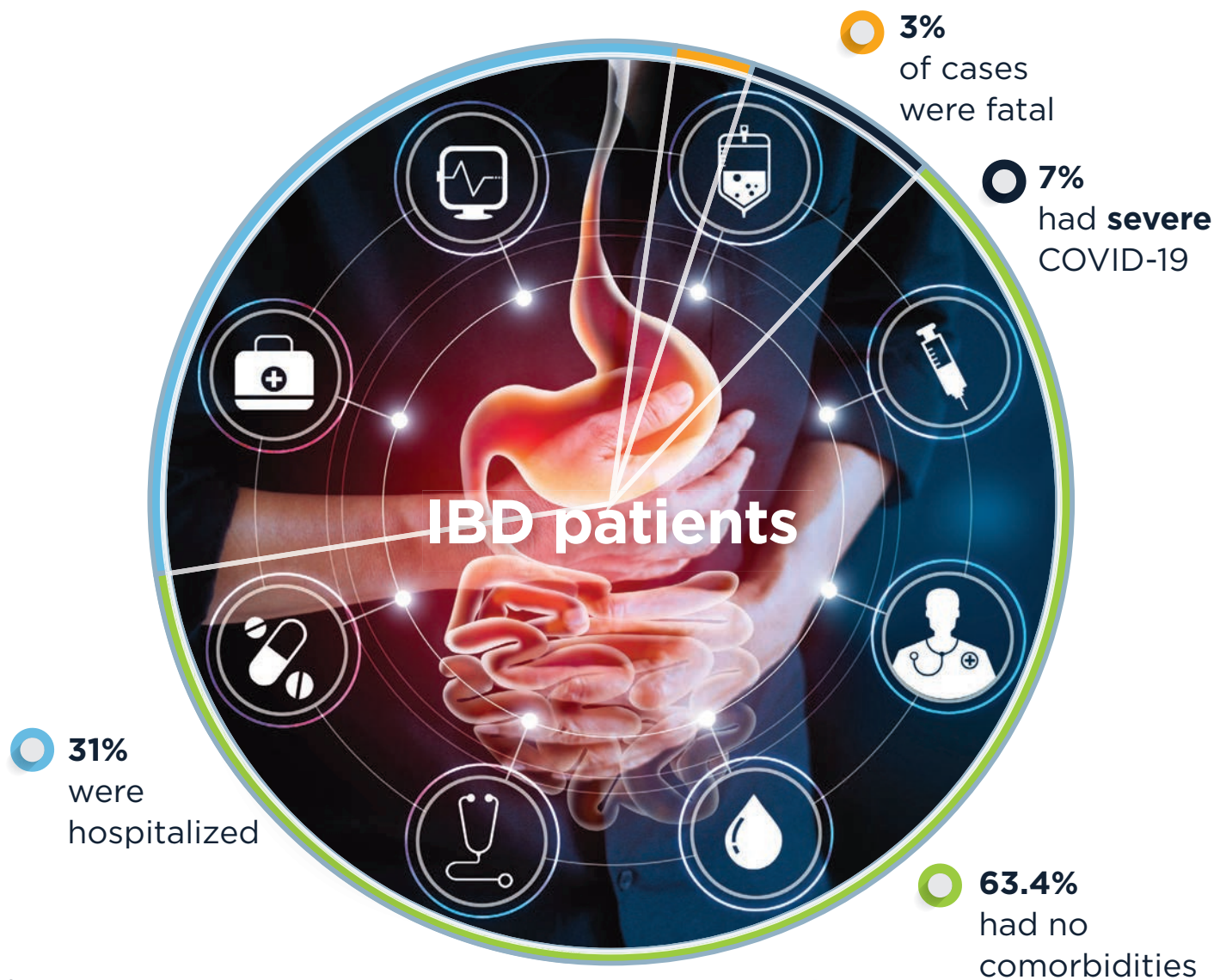


72%

Thought they knew how to properly manage patients with possible COVID-19 symptoms

Based on a survey of European Crohn's and Colitis Organization members

## Characteristics of 525 patients with IBD and COVID-19<sup>6</sup>



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# RACIAL AND SOCIAL DISPARITIES

## *in Gastroenterology*

Sandra M. Quezada, MD, MS

Race is a social, rather than biological, construct, and disparities in disease incidence and care across race reveal underlying social differences and inequities. Racial disparities have been identified in outcomes of gastrointestinal cancers.<sup>1</sup> For esophageal cancer, the age-adjusted incidence in and age-adjusted mortality for Black patients is shown to be twice that of Whites.<sup>2</sup> Incidence and death rates for gastric cancer also differ by race and ethnicity, with Asian/Pacific Islander males having the highest incidence and mortality, and with Black patients having a similar rate.<sup>1</sup> Hispanic females have the highest incidence for gastric cancer among women, while non-Hispanic White females have the lowest incidence. Compared with Whites, African Americans have higher incidence and death rates for colorectal cancer (CRC), are diagnosed with CRC as much as 5-8 years earlier in age, and have a higher prevalence of both proximal precursor adenomas and CRCs.<sup>3,4</sup> Poorer CRC outcomes are also linked to lower socioeconomic status (SES).<sup>3</sup>

Disparities across race/SES and type of medical insurance exist in CRC care as well. Compared with Whites, non-Hispanic Blacks and Native American/Alaskan Natives have lower odds for completing CRC screening, while Hispanics had similar odds and Asian/Pacific Islanders had higher odds of completing CRC screening.<sup>5,6</sup>

Blacks are also less likely than Whites to receive regular care for inflammatory bowel disease (IBD) from a gastroenterologist or IBD specialist.<sup>7</sup> There was no significant disparity by race in patients with Medicaid insurance, however, which suggests that disparities in IBD treatment may be driven by SES or other issues affecting access to care.<sup>8</sup> These screening disparities underscore the need to increase awareness among patients and referring providers, and to advocate for policies that increase CRC screening access.

Minorities continue to be underrepresented in clinical trials of cancer therapies.<sup>9</sup> Prospective, multicenter approaches will be needed to discover methods to eliminate these race- and SES-based disparities in GI health care.<sup>10</sup> Given the historical mistreatment of minority communities in clinical research trials,<sup>11,12</sup> investigators must develop partnerships with underserved communities to build trust and increase awareness of how inclusion in clinical research can lead to improved care for these populations. Additionally, investigators must clarify their intent in studying communities of color along with social determinants of health to elucidate the inextricable linkage of these factors—and to educate the scientific community that race, and particularly racism, is a social determinant of health, and not a genetic or biological one.



## CRC incidence rates

African American



Non-Hispanic White



Asian/Pacific Islander



Though overall trends for CRC death have decreased in the last 25 years, **African Americans have lower 5-year survival**, compared with non-Hispanic Whites.<sup>3</sup>



**86% vs. 90%** localized disease  
**65% vs. 72%** regional disease  
**10% vs. 14%** distant disease



Among **Black patients with IBD**, **77%** report seeing an IBD subspecialist regularly (at least once a year) **versus 92% of White patients.**



Compared with **5% of White patients**, **12% of Black patients** reported difficulty obtaining specialist referrals.

Compared with **7% of White patients**, **18% of Black patients** expressed concerns over health care-related costs.<sup>7</sup>



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# IMPENDING PHYSICIAN SHORTAGES

## *in Gastroenterology*

Michael Weinstein, MD, AGAF

The US Department of Health & Human Services and the Association of American Medical Colleges have each released reports projecting impending physician shortages across many specialties in the next decade.<sup>1,2</sup> Both reports cite changes in health care demand and physician supply, largely because of an aging population and increased use of health care services caused by national expansion of insurance coverage.

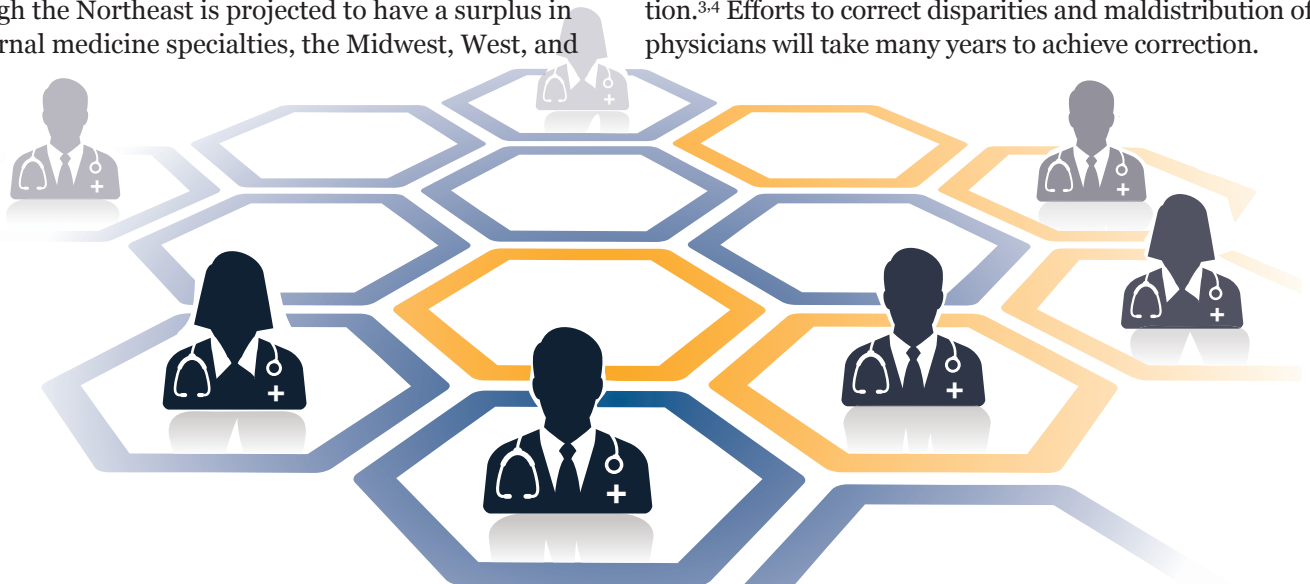
Between 2018 and 2033, the number of adults 65 years and older in the United States is expected to grow by 45.1%, resulting in an increased need for physician specialties that treat older populations.<sup>2</sup> The supply of gastroenterologists is not expected to keep pace with this demand. Factors influencing supply include not only the projected number of new gastroenterologists entering the workforce, but also the decisions made by those currently in practice. A growing population of aging patients also means many physicians will be making decisions about decreasing hours and/or retirement during this period.<sup>1</sup>

The US Department of Health & Human Services has estimated a shortage of 1,630 gastroenterologists by 2025. Although the Northeast is projected to have a surplus in all internal medicine specialties, the Midwest, West, and

South of the country are expected to be hit hardest, with estimated shortages of 810, 690, and 680 gastroenterologists, respectively.<sup>1</sup>

It is critical to continually assess workforce projections because there are several factors that may impact the latest predictions (such as changes in practice regulations or technical advances). For example, increased colorectal screening and detection of Barrett's esophageal dysplasia using nonendoscopic diagnostic approaches could potentially decrease GI demand, while a growing need for nonalcoholic steatohepatitis and nonalcoholic fatty liver disease treatment options may increase GI demand. Most notably, these reports were largely put together prior to the start of the COVID-19 pandemic, and we have yet to see what the long-term effects may be on physician supply and demand.

These reports were also put together prior to the national movement to recognize the problems with racial disparities in health care delivery and underrepresented minorities amongst providers. This is particularly evident in gastroenterology, where only 4-5% of providers are Black or African American compared with 13.4% of the general population.<sup>3,4</sup> Efforts to correct disparities and maldistribution of physicians will take many years to achieve correction.



A shortage of **33,700 to 86,700** non-primary care specialty physicians is projected by 2033.<sup>2</sup>

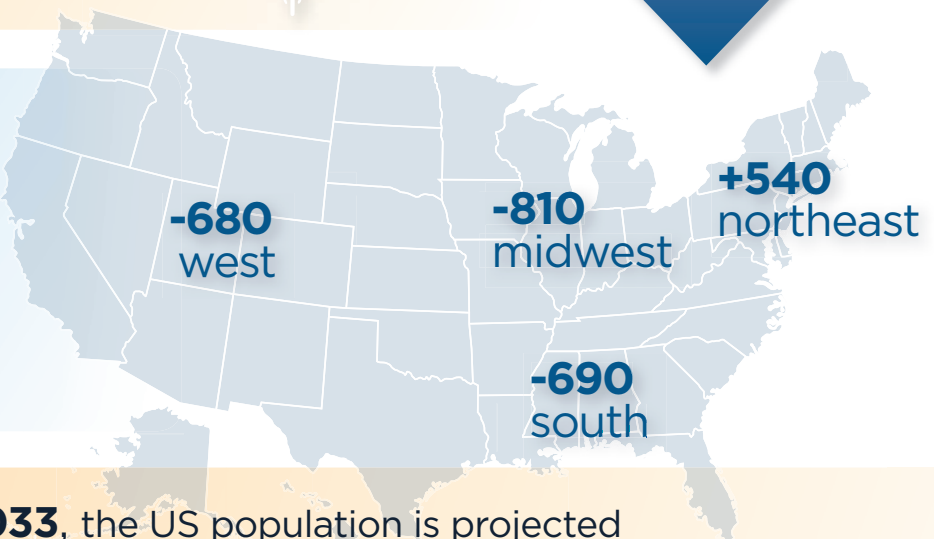
**This includes:**

- ✓ Between 17,100 and 28,700 surgical specialists
- ✓ Between 9,300 and 17,800 medical specialists
- ✓ Between 17,100 and 41,900 other specialists



**A shortage of 1,630**

US gastroenterologists is expected by 2025 though a surplus is expected in the Northeast.<sup>1</sup>



Between **2018 and 2033**, the US population is projected to grow by **10.4%** (from about 327 million to 361 million).<sup>2</sup>

• The population **65 years and older** is projected to **grow by 45.1%**.



• The population **under age 18 years** is projected to **grow by only 3.9%**.



• More than 2 in 5 currently active physicians will be 65 years or older within the next decade.



**Sources:**

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# RECOMMENDATIONS FOR COLONOSCOPY

## *and the Management of Large Polyps*

Aasma Shaukat, MD, MPH, AGAF

The prevalence of cancer in colorectal polyps larger than 20 mm ranges from 2%-5%, and residual neoplastic tissue remains a relatively common occurrence even after polypectomy is judged as “complete” by the endoscopist.<sup>1,2</sup>

Polyps may have superficial submucosal invasion (involving the first third of the submucosa or a depth of 1,000 microns) or deep invasion (extending beyond the first third of the submucosa or >1,000 microns deep). Submucosally invasive polyps present several challenges.

The endoscopist must recognize features that indicate deep submucosal invasion with the need for endoscopic biopsy and referral directly to surgery without an attempt at endoscopic resection. Key descriptors of the polyp (including location, size, and shape) should be recorded in the colonoscopy procedure report. The Paris and NICE classification systems should be consulted to accurately assess the polyp.<sup>3,4</sup> Specific features of pedunculated and sessile polyps portend higher risk for deeper invasion and a need for surgery.<sup>5</sup>

Another challenge is the application of special resection techniques – such as “en bloc” resection – that allow most patients to avoid surgical resection. Additionally, when cases arise in which the pathology report indicates evidence of submucosal invasion in an endoscopically resected polyp, the physician must make decisions of whether to proceed with surgery to resect potential residual cancer at the site of endoscopic resection or nearby lymph nodes.<sup>6</sup>

Endoscopic mucosal resection can provide curative resection and obviate the higher morbidity, mortality, and cost associated with alternative surgical treatment for non-polypoid and sessile serrated lesions. It is the preferred treatment method of large ( $\geq 20$  mm) nonpolypoid and sessile serrated colorectal lesions, with resection of all visible neoplastic tissue in a single session. The postresection management of submucosally invasive lesions optimally involves a multidisciplinary approach, with input from the pathologist, surgeon, and sometimes an oncologist and/or radiation oncologist.<sup>7</sup> However, the endoscopist often plays the central role in informed decision-making, frequently serving as the point of contact for the patient and their family.

### NBI International Colorectal Endoscopic (NICE) Classification of Colorectal Polyps

	Type 1	Type 2	Type 3
<b>Color</b>	Same or lighter than background	Browner relative to background (verify color arises from vessels)	Brown to dark brown relative to background; sometimes patchy whiter areas
<b>Vessels</b>	None, or isolated lacy vessels may be present coursing across the lesion	Thick brown vessels surrounding white structures*	Has area(s) with markedly distorted or missing vessels
<b>Surface pattern</b>	Dark spots surrounded by white	Oval, tubular, or branched white structures* surrounded by brown vessels	Distortion or absence of pattern
<b>Most likely pathology</b>	Hyperplastic or sessile polyp (adenoma)	Adenoma**	Deep submucosal invasive cancer

This classification can be applied using colonoscopes both with or without optical (zoom) magnification.

\*These structures (regular or irregular) may represent the pits and the epithelium of the crypt opening.

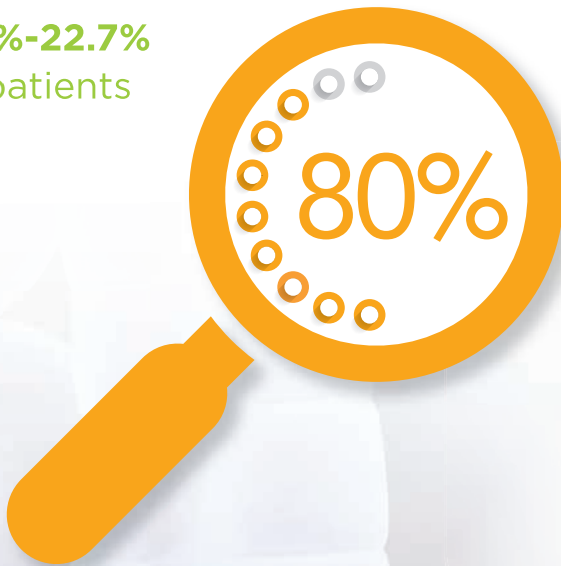
\*\*Type 2 consists of Vienna classification types 3, 4, and superficial 5 (all adenomas with either low- or high-grade dysplasia or with superficial submucosal carcinoma).

The presence of high-grade dysplasia or superficial submucosal carcinoma may be suggested by an irregular vessel or surface pattern and is often associated with atypical morphology (eg, depressed area).



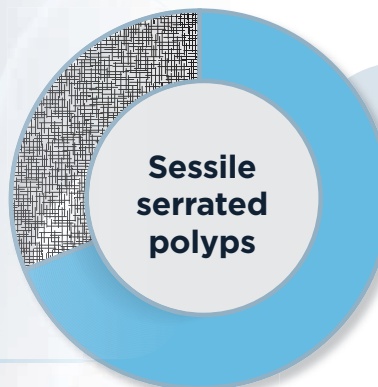
6.5%-22.7%  
of patients

**Residual neoplastic tissue** has been reported in **6.5%-22.7%** of patients following a polypectomy judged by the endoscopist to be **“complete.”**<sup>6</sup>

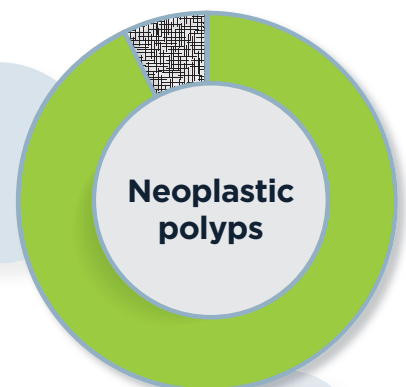


**Missed lesions** can account for **70%-80%** of **interval cancers**, while **incompletely resected lesions** during earlier colonoscopy may explain **10%-27%** of such cancers.<sup>2</sup>

**Sessile serrated polyps** are more likely to be **incompletely resected** than other neoplastic polyps (**31% vs. 7.2%**).<sup>2</sup>



**31%** Incomplete



**7.2%** Incomplete

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# NONALCOHOLIC STEATOHEPATITIS (NASH)

## *Identifying Patients with High-Risk Disease*

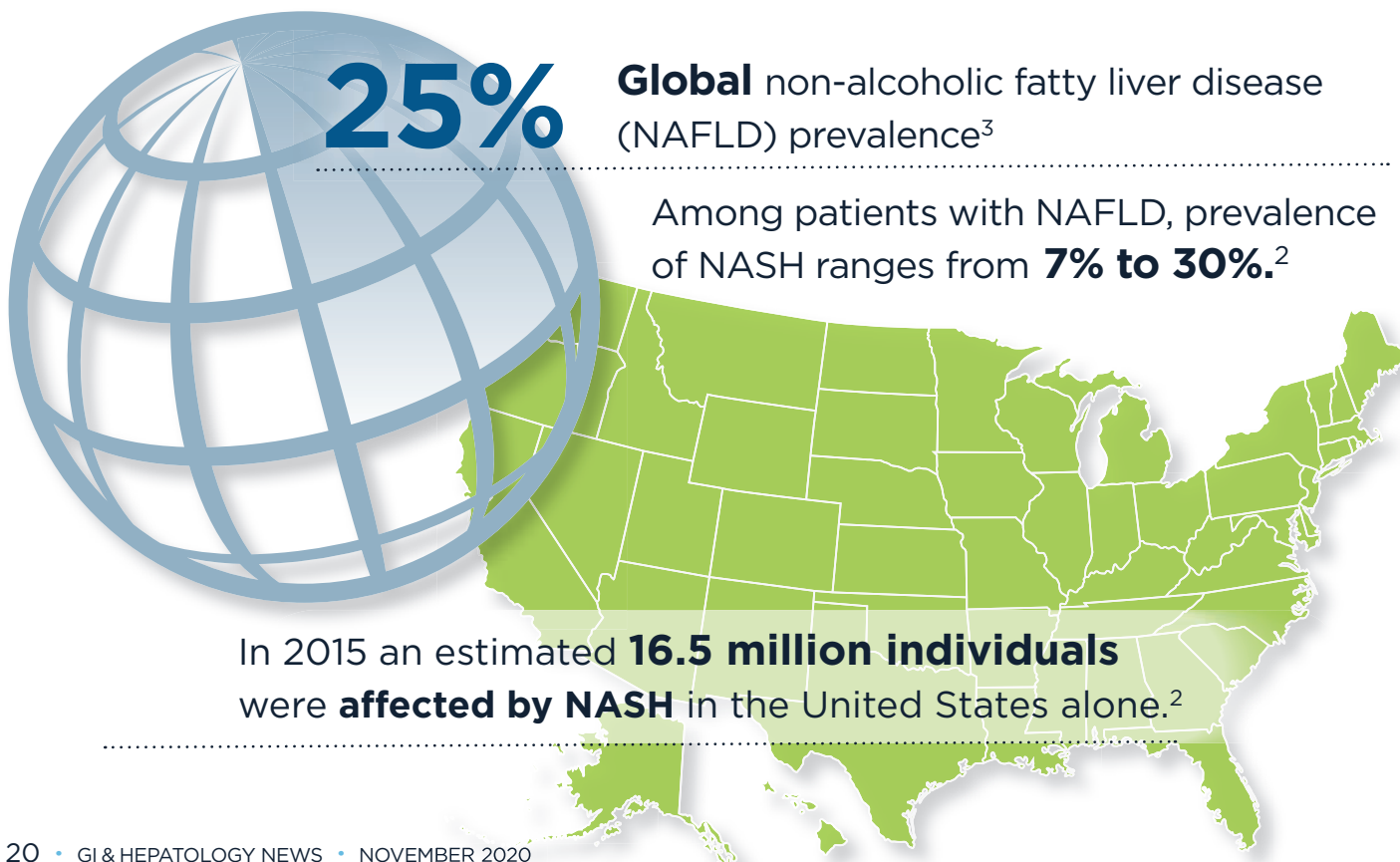
**Brent Tetri, MD, AGAF**

About one-third of adults in the United States have too much fat in their livers, and approximately 3%-5% have nonalcoholic steatohepatitis (NASH). Importantly, about 1% of the adult population has NASH with fibrosis, and these individuals are at high risk of progression to cirrhosis and its complications.<sup>1</sup> Type 2 diabetes also has a clear impact on the progression with an increased probability of cirrhosis and poorer outcomes.<sup>1,2</sup>

Progression of NASH cirrhosis is becoming one of the most common reasons for doing liver transplants, second only to alcohol-related liver disease.<sup>2,3</sup> The prevalence of hepatocellular carcinoma (HCC) in liver transplantation candidates with NASH increased approximately 12-fold between 2002 and 2016, and in the United States, NASH is the most rapidly growing cause of HCC in patients awaiting liver transplantation.<sup>3,4</sup>

It is important to identify patients with high-risk NASH and screen those with cirrhosis for HCC. Noninvasive markers for liver fibrosis provide helpful prognostic information and have demonstrated a high degree of accuracy in excluding a diagnosis of advanced disease. These include the Fibrosis-4 index, Aspartate Aminotransferase to Platelet Ratio Index, and FibroScan, an ultrasound-like instrument that combines vibration-controlled transient elastography with controlled attenuation parameter to estimate fibrosis and steatosis.<sup>2,5,6</sup>

Clinicians should also take the time to counsel and educate patients with NASH with fibrosis about the importance of lifestyle modifications, including healthy eating and exercise. These changes in lifestyle have been shown to improve NASH and reduce fibrosis over time.<sup>7,8</sup>







The incidence of NASH as an underlying etiology for HCC in patients listed for liver transplantation has increased **7.7-fold (from 2.1% to 16.2%)** in the United States.<sup>2</sup>

In a retrospective study of US liver transplant recipients **from 2002 to 2012, NASH** was the **second leading etiology of HCC-related liver transplantation.**



If this trend continues, it will become the leading cause.<sup>3</sup>

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# ESOPHAGEAL ADENOCARCINOMA

## *Geographical Clustering and Time Trends*

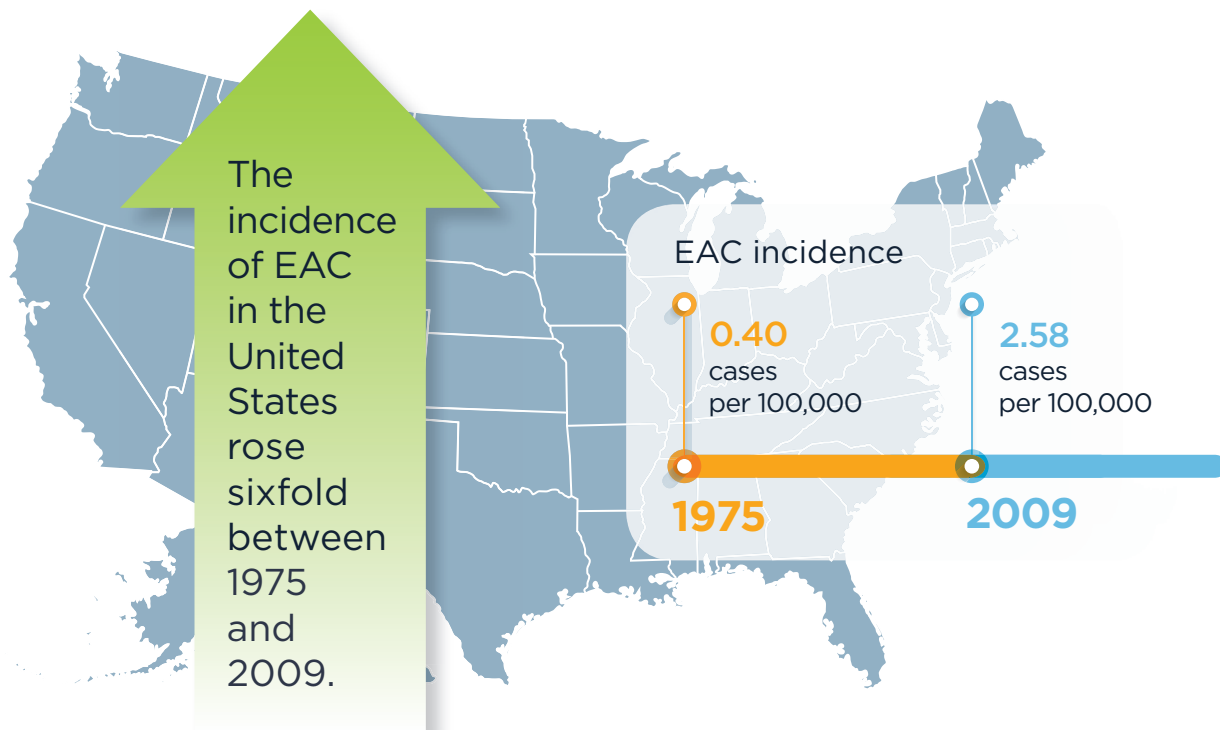
Joel Rubenstein, MD, MSc

The incidence of esophageal adenocarcinoma (EAC) in the United States has risen sixfold over 4 decades.<sup>1</sup> Most of the increase in incidence is from cohorts born between 1900 and 1930 (those born later than 1930 have fairly similar incidence to those born in the 1930s).<sup>2</sup> Risk factors for EAC include male sex, advancing age, obesity, tobacco use, and symptoms of gastroesophageal reflux disease (GERD).<sup>3-7</sup> Although obesity prevalence has been rising, changes in the prevalence of obesity accounts for less than 10% of the rise in EAC incidence.<sup>8</sup> Changes in GERD prevalence, tobacco use, and alcohol use do not seem to explain the trend, either.<sup>9,10</sup>

The geographical distribution of EAC cases suggests that there may be an unknown environmental exposure that is responsible for this rise in incidence. In the United States, the incidence of EAC is greatest in the Great Lakes region extending to New England, as well as in the Pacific Northwest, and is lowest in the Southeastern

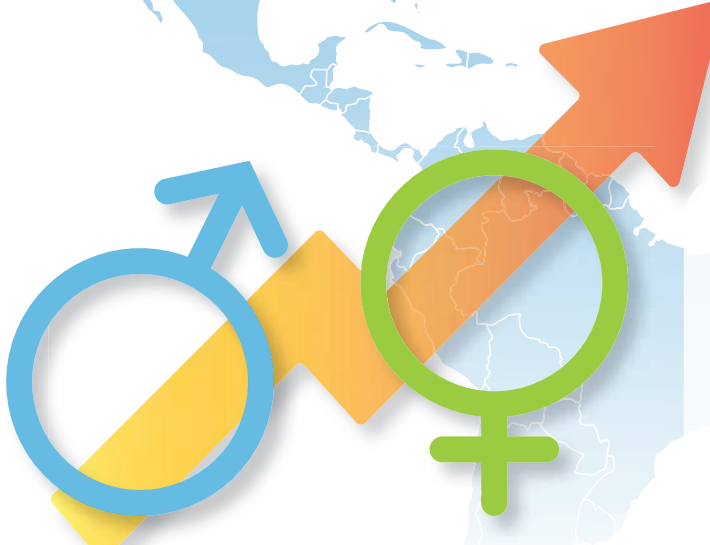
states. These clusters are not explained by factors such as race, obesity, or tobacco use.<sup>11</sup> In Canada, there are similar clusters of high incidences bordering the high cluster US regions along the shore of Lake Ontario, in Nova Scotia, and in British Columbia.<sup>12</sup> In Europe, the incidence is greatest in the northern countries. Meanwhile, EAC is rare in Africa and Asia.<sup>13</sup>

The incidence of EAC began to level off in the late 1990s, before the widespread introduction of effective endoscopic therapy for neoplastic Barrett's esophagus but a decade after the release of proton pump inhibitors (PPI). High doses of PPI have been shown to prevent the progression of Barrett's esophagus to EAC in a randomized controlled trial, which suggests that the widespread use of PPIs may have led to this leveling off in cases.<sup>14</sup> Further research into the environmental factors that contribute to the time trends and geographic clustering of EAC could improve our ability to control the burden of this illness.





## EAC Incidence Worldwide



**Although annual EAC incidence is much higher in men**, cases rose at proportionally similar rates among men and women during this period **(6.1% and 5.9%, respectively)**.

### Obesity has a smaller than expected impact:

In a modeling study, the rise in obesity prevalence between 1973 and 2005 accounted for **only 6.5%** of the increase in EAC incidence.



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