

# GI & Hepatology News

March 2020

Volume 14 / Number 3



Dr. Gil Y. Melmed reported on a quality improvement initiative that also reduced hospitalizations and opioid use.

## GALAD score predicts NASH-HCC

*More than a year in advance*

BY WILL PASS  
MDedge News

For patients with nonalcoholic steatohepatitis (NASH), the GALAD score may accurately predict hepatocellular carcinoma (HCC) as early as 560 days before diagnosis, according to investigators.

The GALAD score, which combines sex, age, alpha-fetoprotein-L3 (AFP-L3), alpha-fetoprotein, and des-gamma-carboxyprothrombin (DCP), could improve cancer surveillance among NASH patients whose obesity limits

sensitivity of ultrasound, reported lead author Jan Best, MD, of the University Hospital Magdeburg (Germany), and colleagues.

"The limitations of ultrasound surveillance alone for early detection of HCC are particularly evident in patients with NASH," the investigators wrote in Clinical Gastroenterology and Hepatology. "Serum-based biomarkers might be more effective, with or without ultrasound surveillance, for HCC surveillance in NASH patients, although data in this patient population are

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## IBD quality initiative slashes ED utilization

BY RICHARD MARK KIRKNER  
MDedge News

REPORTING FROM CROHN'S & COLITIS CONGRESS

AUSTIN, TEX. – A quality improvement initiative aimed at patients with inflammatory bowel disease (IBD) has reduced emergency department visits and hospitalizations by 20% or more and slashed opioid use by half, according to study results presented at the Crohn's & Colitis Congress®, a partnership of the Crohn's & Colitis Foundation and the American Gastroenterological Association.

After 15 months, the quality improvement program showed emergency depart-

ment visit rates decline from 18% to 14%, a 22% relative decrease, Gil Y. Melmed, MD, AGAF, of Cedars-Sinai Medical Center, Los Angeles, said. Additionally, the study documented a similar decrease in the rate of hospitalization, declining from 14% to 11%, while narcotic utilization rates declined from 8% to 4%. "We also found decreases in special-cause variation in other measures of interest, including CT scan utilization as well as corticosteroid use, which was reduced 29% during the course of the program," he said.

The quality initiative was conducted through

See **Quality** · page 13

## IBD: Inpatient opioids linked with outpatient use by IBD patients

BY WILL PASS  
MDedge News

Patients with inflammatory bowel disease (IBD) who receive opioids while hospitalized are three times as likely to be prescribed opioids after discharge, based on a ret-

rospective analysis of more than 800 patients.

Awareness of this dose-dependent relationship and IBD-related risks of opioid use should encourage physicians to consider alternative analgesics, according to lead author Rahul S. Dalal, MD, of Brigham and Wom-

en's Hospital, Boston, and colleagues.

"Recent evidence has demonstrated that opioid use is associated with severe infections and increased mortality among IBD patients," the investigators wrote in Clinical

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## LETTER FROM THE EDITOR:

# Crohn's & Colitis Congress has passed, DDW ahead

In late January, the Crohn's & Colitis Foundation teamed with AGA to present the Crohn's & Colitis Congress® in Austin, Tex. Each year, this is the premier gathering for IBD experts and the rest of us to catch up on the substantial progress we are making in treating patients with IBD. This month, we highlight a number of articles from the Congress, including results showing how a focused IBD quality initiative reduced emergency department visits, an article about the effects of IBD on fertility, and the link between stress and ulcerative colitis flares. All of these articles are worth reading, since they can help our care of patients. On [agau.gastro.org](http://agau.gastro.org), you can access slides from the Congress.

Several more articles deserve mention. Three articles from the AGA journals highlight new information about colorectal cancer prevention and the U.S. Multi-Society Task Force on Colorectal Cancer has updated colonoscopy follow-up



Dr. Allen

guidance. In our practice management section, we provide a step-by-step guide to changes in evaluation and management (E/M) coding – these changes are the most im-

pactful since the Medicare E/M documentation specifications first appeared.

We have 2 months left before Digestive Disease Week® (DDW). Each year, DDW marks the end of our AGA Institute President's term and the beginning of another's epoch. Hashem B. El-Serag will pass the gavel to Bishr Omary – both great friends and great gastroenterologists. I am happy to see that Gail Hecht follows me as this year's AGA Julius Friedenwald Medal recipient (AGA's highest honor). She, too, is a great friend and role model for me and many others. DDW returns to Chicago in early May, and once again will be the world's best gathering of physicians and scientists dedicated to digestive diseases.

**John I. Allen, MD, MBA, AGAF**  
**Editor in Chief**

## DDSEP<sup>9</sup> Digestive Diseases Self-Education Program Quick quiz

**Q1.** A 45-year-old man has recently been diagnosed with leukemia. The chemotherapeutic regimen will include rituximab and high-dose steroids. He is a former IV drug user but has been sober for 20 years. His lab work is as follows: ALT 25 U/L, HAV total antibody positive, HBs antibody positive, HBs antigen negative, HBc total positive, HCV antibody positive, HCV RNA undetected.

Which of the following is true?

- A. The patient is at risk of HCV reactivation because of prior exposure.
- B. The patient should receive prophylaxis against HBV reverse seroconversion through his chemotherapy.
- C. The patient should receive prophylaxis against HBV reverse seroconversion through his chemotherapy and for 12-18 months afterward.
- D. The HBV reactivation is not a concern in this patient.
- E. A watchful waiting approach is reasonable with q 3-month

monitoring of the ALT and HBV DNA.

**Q2.** An 18-year-old woman presents for evaluation of chronic diarrhea, fatigue, and abdominal cramping. She was recently in Puerto Rico for 6 months visiting family and returned a few weeks ago. Her labs are significant for a hemoglobin of 11 g/L with an MCV of 109 fL. Her albumin is 3.6 g/dL. She had stool studies which ruled out infection, including parasites. TtG IgA and total IgA were within normal limits. EGD with multiple duodenal biopsies showed villous blunting with increased intraepithelial lymphocytes.

What is the preferred treatment for this patient?

- A. Gluten-free diet
- B. Ceftriaxone IV followed by Bac-trim PO
- C. Low FODMAP diet
- D. Tetracycline and folic acid
- E. Rifaxmin

*The answers are on page 6.*

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## Detects HCC separate from cirrhosis

NASH-HCC from page 1

currently lacking. The current study assessed the performance of the GALAD score for early HCC detection in patients with NASH-related liver disease.”

The study consisted of two parts: first, a retrospective case-control analysis, and second, a phase 3 prospective trial that implemented the GALAD score in a real-world population.

The retrospective component of the study involved 126 NASH patients with HCC (cases) and 231 NASH patients without HCC (controls), all of whom were treated at eight centers in Germany. The median GALAD score was significantly higher among NASH patients with HCC than in those without (2.93 vs. -3.96; *P* less than .001). At an optimal cutoff of -1.334, the GALAD score predicted HCC with a sensitivity of 91.2% and a specificity of 95.2%. Each component of the GALAD score aligned with previously published findings, as patients with HCC were predominantly older men with elevated serum AFP-L3, AFP, and DCP. But a closer look at the data showed that the GALAD score more accurately predicted HCC than any of its constituent serum measurements in isolation. For any stage of HCC, GALAD had an area under the curve (AUC) of 0.96, compared with significantly lower values for AFP (0.88), AFP-L3 (0.86), and DCP (0.87). Similarly, for early-stage HCC, GALAD score AUC was 0.92, compared with significantly lower values for AFP (0.77), AFP-L3 (0.74), and DCP (0.87).

The accuracy of the GALAD score – for detection of both

any-stage and early-stage HCC – remained high regardless of cirrhosis status. Among patients with cirrhosis, the AUC for any-stage HCC was 0.93, and 0.85 for early-stage HCC. For patients without cirrhosis, GALAD was slightly more predictive, based on AUC's of 0.98 and 0.94 for detection of any-stage and early-stage HCC, respectively. Again, these accuracy values significantly outmatched each serum measurement in isolation.

“These data on NASH-HCC patients demonstrate that GALAD can detect HCC independent of cirrhosis or stage of HCC,” the investigators wrote. “Indeed, even early noncirrhotic NASH-HCC seems clearly separable from NASH controls, as even small groups resulted in robust performance.”

The prospective component of the study involved screening 392 patients with NASH at a single treatment center in Japan. From this cohort, 28 patients developed HCC after a median of 10.1 years. Many patients in this group had significantly higher GALAD scores for 5 or more years before being diagnosed with HCC, and scores rose sharply in the months preceding diagnosis. Depending on selected cutoff value, the GALAD score predicted HCC from 200 to 560 days prior to diagnosis.

“While this specific result has to be confirmed in further prospective studies, it is a promising observation for potential use of GALAD as a screening tool in NASH patients,” the investigators wrote.

“In conclusion, our data confirm that the GALAD score is superi-

There has been increasing recognition that ultrasound-based HCC surveillance in patients with cirrhosis has suboptimal sensitivity and specificity for early HCC detection, particularly when applied to those with nonalcoholic steatohepatitis (NASH). These data highlight the critical need for



Dr. Singal

novel biomarkers to improve early HCC detection and reduce mortality. The study by Dr. Best and colleagues evaluated a blood-based biomarker panel, GALAD, in patients with NASH and found that it was able to detect HCC at an early stage with a sensitivity of 68% and specificity of 95% – performance comparable, if not superior, to that of abdominal ultrasound. In an accompanying pilot prospective cohort study, the authors also found GALAD may detect HCC more than 1 year prior to diagnosis. Although earlier studies had similarly demonstrated high performance of GALAD for early HCC detection, this study specifically examined patients with NASH – a cohort that increas-

ingly accounts for HCC cases in the Western world but has been underrepresented in prior studies. Therefore, it is reassuring to know that GALAD appears to have high sensitivity and specificity in this patient group. However, while the data by Best et al. are promising, validation of these results in larger cohort studies is needed before routine adoption

in clinical practice. Fortunately, maturation of phase 3 biomarker cohorts, including the Early Detection Research Network Hepatocellular Early Detection Strategy (EDRN HEDS) and Texas HCC Consortium, will facilitate this evaluation in the near future and will hopefully translate promising biomarkers into clinical practice.

*Amit G. Singal, MD, is an associate professor of medicine, medical director of the liver tumor program, and chief of hepatology at UT Southwestern Medical Center, Dallas. He has served as a consultant for Wako Diagnostics, Glycotest, Exact Sciences, Roche Diagnostics, and TARGET Pharmaceuticals.*

or to individual serum markers for detection of HCC in NASH, independent of tumor stage or cirrhosis,” the investigators wrote. “The findings suggest that GALAD should be investigated as a potential tool for screening of NASH individuals to detect HCC at a resectable stage in a sufficiently large prospective study to identify a cutoff.”

The study was funded by Deutsche Forschungsgemeinschaft, the Wilhelm-Laupitz Foundation, and the Werner Jackstaedt Foundation. The investigators declared no conflicts of interest.

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**SOURCE:** Best J et al. Clin Gastro Hepatol. 2019 Nov 8. doi: 10.1016/j.cgh.2019.11.012.

## Mailed fecal tests may catch more cancer than endoscopic testing

BY WILL PASS

MDedge News

On a population level, mailed fecal immuno-histochemical tests (FITs) may catch more cases of advanced neoplasia than endoscopic methods, based on a Dutch screening study that invited more than 30,000 people to participate.

The relative success of mailed FIT screening was largely due a participation rate of 73%, compared with participation rates between 24% and 31% among those invited to undergo endoscopic screening, reported lead author Esmée J. Grobbee, MD, of Erasmus University Medical Centre in Rot-

terdam, the Netherlands, and colleagues.

In addition to high participation, previous research has shown that successful FIT screening depends upon continued adherence to the screening program, the investigators wrote in Clinical Gastroenterology and Hepatology. They noted that, in the present study, just two rounds of FIT were needed to outperform endoscopic methods, and that these comparative findings are a first for the field.

“No literature is available on the comparison between endoscopic screening strategies and multiple rounds of FIT screening,” the investigators wrote. “It is of key importance for policy makers to know the impact of different screen-

ing programs over multiple rounds with long-term follow-up.”

To this end, the investigators invited 30,052 screening-naïve people in the Netherlands to participate in the present study. Each invitation was for one of three groups: once-only colonoscopy, once-only flexible sigmoidoscopy, or four rounds of FIT. All individuals received an advanced notification by mail followed 2 weeks later by a more substantial information kit (and first FIT test when applicable). If these steps received no response, a reminder was sent 6 weeks later.

Participants in the FIT group received one test

*Continued on following page*

# Large study probes colonoscopy surveillance intervals

BY WILL PASS

MDedge News

Compared with patients who have normal baseline colonoscopy findings, those with low-risk adenomas may not have elevated risks of colorectal cancer (CRC) or CRC-related death, based on a retrospective analysis of more than 64,000 patients.

In contrast, patients with high-risk adenomas at baseline had significantly elevated rates of both CRC and CRC-related death, reported lead author Jeffrey K. Lee, MD, of Kaiser Permanente San Francisco and colleagues.

With additional research, these findings may influence colonoscopy surveillance intervals, the investigators wrote in *Gastroenterology*.

“Current guidelines recommend that patients with a low-risk adenoma finding ... receive surveillance colonoscopy in 5-10 years, although in practice, clinicians often use even more frequent surveillance ... in this low-risk group,” they wrote. “The rationale for continued support of shorter-than-recommended surveillance intervals for patients with low-risk adenomas is unclear, but could stem from a lack of long-term population-based studies assessing colorectal cancer incidence and related deaths following low-risk adenoma removal or randomized

The current CRC surveillance paradigm stratifies adults into high- and low-risk groups based on index findings. However, there are few data on postcolonoscopy CRC incidence to support this approach. Lee et al. provided valuable long-term data in their retrospective analysis of data from an integrated health organization. While index high-risk adenomas were associated with an increased CRC risk, compared with no adenomas, low-risk adenomas (LRA; 1-2 tubular adenomas less than 1 cm) had no increased risk. A lower CRC mortality in those with LRAs decreased the likelihood that CRCs resulted from overdiagnosis or lead time bias caused by differences in exposure among the three groups to subsequent surveillance colonoscopies, a common issue in long-term studies. These data add to growing evidence, such as that from the Prostate, Lung, Colorectal and Ovarian Cancer Trial, that support lengthening current surveillance intervals for LRAs.

Study strengths include a large sample and inclusion of quality measures such as adenoma de-

tections rates. However, to examine conventional adenoma risk, individuals with serrated polyps were excluded and thus the impact of these lesions is unclear. Since New Hampshire Colonoscopy Registry data demonstrate a higher risk of metachronous advanced adenomas for those with both sessile serrated polyps and high-risk adenomas, long-term CRC data for serrated polyps is crucial. In addition, data from short-term studies suggest that there may be heterogeneity in risk for LRAs, a higher risk for an 8-mm lesion than a 3-mm one. Thus, we await more long-term studies to address these and other issues.



Dr. Anderson

Joseph C. Anderson, MD, MHCDS, is an associate professor of medicine at White River Junction VAMC, Dartmouth College, Hanover, N.H., and the University of Connecticut Health Center, Farmington, Conn. The contents of this work do not represent the views of the Department of Veterans Affairs or the United States Government. He has no relevant conflicts of interest.

patients remained. Among these patients, the mean age was 61.6 years, with a slight female majority (54.3%). Almost three out of four patients (71.2%) had normal colonoscopy findings, followed by smaller proportions who were diagnosed with low-risk adenoma (17.0%) or high-risk adenoma (11.7%), based on United States Multi-Society Task Force guidelines.

After a median follow-up of 8.1 years, 117 patients who had normal colonoscopy findings developed CRC, 22 of whom died from the disease. In comparison, the low-risk adenoma group had 37 cases of CRC and 3 instances of CRC-related death, whereas the high-risk adenoma group had 60 cases of CRC and 13 instances of CRC-related death.

*Continued on following page*

*Continued from previous page*

every 2 years. Patients who had a positive FIT (hemoglobin concentration of at least 10 mcg Hb/g feces) were scheduled for a colonoscopy. Similarly, colonoscopies were performed in patients who had concerning findings on flexible sigmoidoscopy (e.g., sessile serrated adenoma). This sequential system reduced the relative number of colonoscopies in these two groups; colonoscopy rates in the FIT group and flexible sigmoidoscopy group were 13% and 3%, respectively, compared with the 24% participation rate in the colonoscopy group.

At a population level, FIT screening had the highest advanced neoplasia detection rate, at 4.5%, compared with 2.3% and 2.2% for screening by sigmoidoscopy and colonoscopy, respectively.

“In the intention-to-screen analysis, FIT already detected significantly more advanced neoplasia and colorectal cancer (CRC) after only 2 rounds of FIT, and this difference increased over rounds,” the investigators noted.

Again in the intention-to-screen population, mailed FIT detected three times as many cases

of CRC than either of the other two groups (0.6% vs. 0.2% for both). In contrast, colonoscopy and sigmoidoscopy had higher detection rates for nonadvanced adenomas, at 5.6% and 3.7%, respectively, compared with 3.2% for FIT, although the investigators noted that nonadvanced adeno-

**At a population level, FIT screening had the highest advanced neoplasia detection rate, at 4.5%.**

mas are “of uncertain clinical importance.” Sessile adenoma detection rates were similar across all three groups.

The as-screened analysis revealed higher detection rates of advanced neoplasia for colonoscopy (9.1%), compared with sigmoidoscopy (7.4%) and FIT (6.1%). In the same analysis, detection rates of colorectal cancer were comparable across all three groups.

According to the investigators, the CRC-related

findings require careful interpretation.

“Comparing CRC detection rates of FIT and endoscopic screening is complex ... because CRCs detected in FIT screening could in theory have been prevented in a once-only colonoscopy by the removal of adenomas,” they wrote.

Still, the key takeaway of the study – that FIT screening was the most effective strategy – may have practical implications on a global scale, according to the investigators.

“Because many countries are considering implementing screening programs, the findings of this study aid in deciding on choice of screening strategies worldwide, which is based on expected participation rates and available colonoscopy resources,” they wrote.

The study was funded by the Netherlands Organization for Health Research and Development. The investigators disclosed no conflicts of interest.

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**SOURCE:** Grobbee EJ et al. *Clin Gastro Hepatol*. 2019 Aug 13. doi: 10.1016/j.cgh.2019.08.015.



Continued from previous page

In the no-adenoma and low-risk groups, trends in age-adjusted CRC incidence rates were similar; in both cohorts, CRC incidence increased gradually over the decade following colonoscopy, with each group reaching approximately 50 cases per 100,000 person-years by year 10. In contrast, CRC incidence climbed rapidly in the high-risk adenoma group, ultimately peaking a decade later at almost 220 cases per 100,000 person-years. Average incidence rates per 100,000 person-years were similar among patients with no adenoma (31.1) and low-risk adenoma (38.8), but markedly higher among those with high-risk adenoma (90.8). At the end of the 14-year follow-up pe-

**Average incidence rates per 100,000 person-years were similar among patients with no adenoma (31.1) and low-risk adenoma (38.8). In contrast, CRC incidence climbed rapidly in the high-risk adenoma group, ultimately peaking a decade later at almost 220 cases per 100,000 person-years.**

riod, absolute risks of CRC among patients with no adenoma, low-risk adenoma, and high-risk adenoma were 0.51%, 0.57%, and 2.03%, respectively.

Based on covariate-adjusted Cox regression models, patients with low-risk adenoma did not have a significantly higher risk of CRC or CRC-related death than did patients with no adenoma. In contrast, patients with high-risk adenoma had significantly higher risks of CRC (hazard ratio, 2.61) and CRC-related death (HR, 3.94).

"These findings support guideline recommendations for intensive colonoscopy surveillance in [patients with high-risk adenomas at baseline]," the investigators wrote.

Considering similar risks between patients with low-risk adenomas and those with normal findings, the investigators suggested that longer surveillance intervals may be acceptable for both of these patient populations.

"Guidelines recommending comparable follow-up for low-risk adenomas and normal examinations, such as lengthening the surveillance interval to more than 5 years and possibly 10 years, may provide

comparable cancer incidence and mortality benefits for these two groups," they wrote.

Still, the investigators noted that study limitations – such as disparate rates of subsequent colonoscopy between groups – make it difficult to draw definitive, practice-changing conclusions.

"Additional studies, potentially including randomized trials, on the natural history of low-risk adenoma and normal findings without intervening surveillance exams before 10 years are needed to help guide future surveillance practices," they concluded.

The study was supported by the

National Cancer Institute and the American Gastroenterological Association. The investigators disclosed no conflicts of interest.

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**SOURCE:** Lee JK et al. *Gastroenterology*. 2019 Oct 4. doi: 10.1053/j.gastro.2019.09.039.

## It's time for a different approach to combat *H. pylori*

### The FDA classifies *H. pylori* as a potential public health threat<sup>1</sup>

# 90%

of noncardia gastric cancers are *H. pylori*-related<sup>2</sup>

# >30%

resistance found in a 2016 U.S. multicenter study analysis of *H. pylori* strains<sup>3</sup>

# ≈3x

likelihood of treatment failure of clarithromycin triple therapy with clarithromycin-resistant strains<sup>3</sup>

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1. U.S. Food & Drug Administration. CFR—Code of Federal Regulations Title 21. Section 21CFR317.2. 2. Moss S. The clinical evidence linking *Helicobacter pylori* to gastric cancer. *Cell Mol Gastroenterol Hepatol*. 2017;3(2):183-191. 3. Park JY, Dunbar KB, Mitui M, et al. *Helicobacter pylori* clarithromycin resistance and treatment failure are common in the USA. *Dig Dis Sci*. 2016;61:2373-2380.

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# U.S. Multi-Society Task Force publishes polypectomy guidance

BY WILL PASS

MDedge News

The U.S. Multi-Society Task Force (USMSTF) on Colorectal Cancer recently published recommendations for endoscopic removal of precancerous colorectal lesions.

According to lead author Tonya Kaltenbach, MD, of the University of California, San Francisco, and fellow panelists, the publication aims to improve complete resection rates, which can vary widely between endoscopists; almost one out of four lesions (22.7%) may be incompletely removed by some practitioners, leading to higher rates of colorectal cancer.

“[A]lthough the majority (50%) of postcolonoscopy colon cancers [are] likely due to missed lesions, close to one-fifth of incident cancers [are] related to incomplete resection,” the panelists wrote in *Gastroenterology*, referring to a pooled analysis of eight surveillance studies.

The panelists’ recommendations, which were based on both evidence and clinical experience, range from specific polyp removal techniques to guidance for institution-wide quality assurance of polypectomies. Each statement is described by both strength of recommendation and level of evidence, the latter of which was determined by Grading of Recommendations, Assessment, Development, and Evaluation Ratings of Evidence (GRADE) criteria. Recommendations were written by a panel of nine experts and approved by the governing boards of the three societies they represented – the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. The recommendations were copublished in the March issues of the *American Journal of Gastroenterology*, *Gastroenterology*, and *Gastrointestinal Endoscopy*.

Central to the publication are recommended polypectomy techniques for specific types of lesions.

“Polypectomy techniques vary widely in clinical practice,” the panelists wrote. “They are often driven by physician preference based on how they were taught and on trial and error, due to the lack of standardized training and the paucity of published evidence. In the past decade, evidence has evolved on the superiority of specific methods.”

“Optimal techniques encompass effectiveness, safety, and efficiency,” they wrote. “Colorectal lesion characteristics, including location, size, morphology, and histology, influence the optimal removal method.”

For lesions up to 9 mm, the panelists recommended cold snare polypectomy “due to high complete resection rates and safety profile.” In contrast, they recommended against both cold and hot biopsy forceps, which have been associated with higher rates of incomplete resection. Furthermore, they cautioned that hot biopsy forceps may increase risks of complications and produce inadequate tissue samples for histopathology.

For nonpedunculated lesions between 10 and 19 mm, guidance is minimal. The panelists recommended cold or hot snare polypectomy, although this statement was conditional and based on low-quality evidence.

Recommendations were more extensive for large nonpedunculated lesions (at least 20 mm). For such lesions, the panelists strongly recommended endoscopic mucosal resection (EMR). They emphasized that large lesions should be removed in the fewest possible pieces by an appropriately experienced endoscopist during a single colonoscopy session. The panelists recommended the use of a viscous injection solution with a contrast agent and adjuvant thermal ablation of the post-EMR margin. They recommended against the use of tattoo as a submucosal injection solution, and ablation of residual lesion tissue that is endoscopically visible. Additional recommendations for large lesions, including prophylactic closure of resection defects and coagulation techniques, were based on low-quality evidence.

For pedunculated lesions greater than 10 mm, the panelists recommended hot snare polypectomy. For pedunculated lesions with a head greater than 20 mm or a stalk thickness greater than 5 mm, they recommended prophylactic mechanical ligation.

Beyond lesion assessment and removal, recommendations addressed lesion marking, equipment, surveillance, and quality of polypectomy.

Concerning quality, the panelists recommended that endoscopists participate in a quality assurance program that documents adverse events, and that institutions use standardized polypectomy competency assessments, such as Cold Snare Polypectomy Competency Assessment Tool and/or Direct Observation of Polypectomy Skills.

“Focused teaching is needed to ensure the optimal endoscopic management of colorectal lesions,” the panelists wrote. They went on to suggest that “development and implementation of polypectomy quality metrics may be necessary to optimize practice and outcomes.”

“For example, the type of resection method used for the colorectal lesion removal in the procedure report should be documented, and the inclusion of adequate resection technique as a quality indicator in colorectal cancer screening programs should be considered,” they wrote. “Adverse events, including bleeding, perforation, hospital admissions, and the number of benign colorectal lesions referred for surgical management, should be measured and reported. Finally, standards for pathology preparation and reporting of lesions suspicious for submucosal invasion should be in place to provide accurate staging and management.”

The investigators reported relationships with Covidien, Ironwood, Medtronic, and others.

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**SOURCE:** Kaltenbach T et al. *Gastroenterology*. 2020 Jan 18. doi: 10.1053/j.gastro.2019.12.018.



## Quick quiz answers

**Q1.** Correct answer: C

### Rationale

This patient has been exposed to HBV in the past and has cleared the virus. The HBVcore total Ab is indicative of prior exposure while the HBV surface Ab is detectable and gives immunity against reinfection under most routine clinical scenarios. Patients who have been exposed to HBV still have HBV ccc DNA within their hepatocytes that is dormant, but under extreme combined B- and T-cell immunosuppression, the patients are at risk for reverse seroconversion where they can lose HBV surface Ab and manifest HBV surface antigen and present as an acute HBV infection. Prophylaxis is required during therapy and for at least 12-18 months after therapy because of the long-lasting effects of anti-B cell monoclonal antibodies like rituximab. Reactivation of HCV in HCV Ab–positive, RNA-negative patients has not been reported.

### Reference

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**Q2.** Correct answer: D

### Rationale

This patient has tropical sprue based on her travel to an endemic country, negative celiac serologies, labs revealing a macrocytic anemia and low albumin, and characteristic histology (villous blunting, increased intraepithelial lymphocytes). Treatment is with tetracycline and folate. Diagnosis of tropical sprue is ultimately confirmed by a response to treatment. A gluten-free diet is not appropriate, as the patient does not have celiac disease, confirmed by normal celiac serologies. Ceftriaxone IV followed by Bactrim PO is the correct treatment for Whipple’s disease. A diet low in fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs) is beneficial treatment in some patients with IBS with abdominal bloating or pain. Rifaximin is the correct treatment for small-intestine bacterial overgrowth or IBS-D.

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# CRC task force updates colonoscopy follow-up guidance

BY WILL PASS

MDedge News

The U.S. Multi-Society Task Force on Colorectal Cancer (CRC) recently updated recommendations for patient follow-up after colonoscopy and polypectomy.

The new guidance was based on advancements in both research and technology since the last recommendations were published in 2012, reported lead author Samir Gupta, MD, AGAF, of the University of California, San Diego, and colleagues.

“[Since 2012,] a number of articles have been published on risk of CRC based on colonoscopy findings and patient characteristics, as well as the potential impact of screening and surveillance colonoscopy on outcomes, such as incident CRC and polyps,” the investigators wrote in *Gastroenterology*. “Further, recent studies increasingly reflect the modern era of colonoscopy with more awareness of the importance of quality factors (e.g., adequate bowel preparation, cecal intubation, adequate adenoma detection, and complete polyp resection), and utilization of state of the art technologies (e.g., high-definition colonoscopes).”

The task force, which comprised the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, identified key topics using PICO (patient, intervention, comparison, and outcome) questions before conducting a comprehensive literature review that included 136 articles. Based on these findings, two task force members generated recommendations that were further refined through consensus discussion. The recommendations were copublished in the March issues of the *American Journal of Gastroenterology*, *Gastroenterology*, and *Gastrointestinal Endoscopy*.

According to Dr. Gupta and colleagues, some of the new recommendations, particularly those that advise less stringent follow-up, may encounter resistance.

“Patients, primary care physicians, and colonoscopists may have concerns about lengthening a previously recommended interval, and will need to engage in shared decision making regarding whether to lengthen the follow-up interval based upon the guidance here or utilize the recom-

mendation made at the time of the prior colonoscopy,” the task force wrote.

The most prominent recommendations of this kind concern patients who undergo removal of tubular adenomas less than 10 mm in size. For patients who have one or two of these adenomas removed, the task force now recommends follow-up

**‘Importantly, the observed risk for fatal CRC among individuals with 1-10 adenomas less than 10 mm is lower than average for the general population.’**

after 7-10 years, instead of the previously recommended interval of 5-10 years.

“[This decision was] based on the growing body of evidence to support low risk for metachronous advanced neoplasia,” the task force wrote. “In this population, the risk for metachronous advanced neoplasia is similar to that for individuals with no adenoma. Importantly, the observed risk for fatal CRC among individuals with 1-10 adenomas less than 10 mm is lower than average for the general population.”

Along similar lines, patients who undergo removal of three to four small adenomas now have a recommended 3-5 year follow-up window, instead of the previously strict recommendation for follow-up at 3 years.

But not all of the new guidance is less stringent. While the task force previously recommended a follow-up period of less than 3 years after removal of more than 10 adenomas, they now recommend follow-up at 1 year. This change was made to simplify guidance, the investigators wrote, noting that the evidence base in this area “has not been markedly strengthened” since 2012.

Compared with the old guidance, the updated publication offers more detailed recommendations for follow-up after removal of serrated polyps. On this topic, 10 clinical scenarios are presented, with follow-up ranging from 6 months after piecemeal resection of a sessile serrated polyp greater than 20 mm to 10 years after removal of 20 or fewer

hyperplastic polyps less than 10 mm that were located in the rectum or sigmoid colon. Incidentally, these two recommendations are strong and based on moderate evidence, whereas the remaining recommendations for serrated polyps are weak and based on very-low-quality evidence.

Because of such knowledge gaps, the investigators emphasized the need for more data. The publication includes extensive discussion of pressing research topics and appropriate methods of investigation.

“Our review highlights several opportunities for research to clarify risk stratification and management of patients post-polypectomy,” the task force wrote. “In order to optimize risk-reduction strategies, the mechanisms driving metachronous advanced neoplasia after baseline polypectomy and their relative frequency need to be better understood through studies that include large numbers of patients with interval cancers and/or advanced neoplasia after baseline polypectomy. Mechanisms may include

new/incident growth, incomplete baseline resection, and missed neoplasia; each of these potential causes may require different interventions for improvement.”

The task force also suggested that some questions beyond risk stratification remain unanswered, such as the impact of surveillance on CRC incidence and mortality.

Other suggested topics of investigation include age-related analyses that incorporate procedural risk, cost-effectiveness studies, and comparisons of nonendoscopic methods of surveillance, such as fecal immunochemical testing.

The study was funded by the National Institutes of Health and the Department of Veterans Affairs. The investigators reported relationships with Covidien, Ironwood, Medtronic, and others.

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**SOURCE:** Gupta S et al. *Gastroenterology*. 2020 Feb 7. doi: 10.1053/j.gastro.2019.10.026.



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# GI leaders honored by AGA's prestigious recognition prizes

**A**GA has announced the 2020 recipients of the annual Recognition Prizes, given in honor of outstanding contributions and achievements in gastroenterology.

"AGA Recognition Prizes allow members to honor their colleagues and peers for outstanding contributions to the field of gastroenterology," said Hashem B. El-Serag, MD, MPH, AGAF, president of the AGA Institute. "The 2020 AGA Recognition Prize winners are just a few of the distinguished and talented members who help make AGA such an accomplished organization. We are honored that such esteemed individuals are representatives of AGA."

The AGA Recognition Prizes will be presented during Digestive Disease Week® 2020, May 1-5, 2020, in Chicago, Ill.

## Julius Friedenwald Medal

AGA bequeaths its highest honor, the Julius Friedenwald Medal, to Gail Hecht, MD, MS, AGAF, for her substantial contributions to the field of gastroenterology and AGA. The Julius Friedenwald Medal, presented annually since 1941, recognizes a physician for lifelong contributions to the field of gastroenterology.

Dr. Hecht is internationally renowned for her pivotal contributions to the understanding of the important diarrheal pathogen, enteropathogenic *E. coli*. She is also a passionate advocate for the science and practice of gastroenterology, including serving as AGA Institute President. Dr. Hecht's collegial and generous spirit, her past and continued leadership roles in AGA, her passion for and contributions to science and clinical medicine, and her dedication to both her patients and trainees have strengthened the specialty of gastroenterology, and also inspired and shaped the next generation of investigators and gastroenterologists. Dr. Hecht is currently assistant dean, medical student research and professor of medicine and microbiology/immunology at Loyola University Chicago Stritch School of Medicine, and a staff physician at Hines VA Medical Center, Chicago, Ill.

## Distinguished Achievement Award in Basic Science

AGA recognizes R. Balfour Sartor, MD, with the AGA Distinguished Achievement Award in Basic Science, for his major accomplishments in basic science research, which

have significantly contributed to the understanding of the pathogenesis of inflammatory bowel diseases (IBD). Dr. Sartor's seminal observations throughout his career helped launch the area of inquiry that led to the recognition that the microbiome is a key to metabolic disease, IBD, intestinal neoplasia, and hepatic disorders. Dr. Sartor is the Margaret W. and Lorimer W. Midgett Distinguished Professor and a professor, departments of medicine, microbiology and immunology, University of North Carolina, Chapel Hill.

## William Beaumont Prize

AGA honors two individuals with the William Beaumont Prize in Gastroenterology, which recognizes individuals who have made unique, outstanding contributions of major importance to the field of gastroenterology.

Dennis Ahnen, MD, AGAF, had made many contributions to the field of gastroenterology that have significantly advanced the care of patients through clinical and translational research into the pathobiology of colorectal cancer and its prevention. Dr. Ahnen, has provided exemplary service to AGA. He is director of genetics at Gastroenterology of the Rockies and Professor Emeritus of medicine at the University of Colorado Anschutz Medical Campus School of Medicine, Aurora.

Peter Kahrilas, MD, AGAF, has worked tirelessly and creatively to characterize the function and pathophysiology of the esophagus and has written the esophageal papers upon which a large portion of current research is based. Dr. Kahrilas has also dedicated many years of service to AGA and is currently the Gilbert H. Marquardt Professor of Medicine in the division of gastroenterology at the Feinberg School of Medicine, Northwestern University, Chicago, Ill.

## Distinguished Educator Award

AGA honors Robert Fontana, MD, with the Distinguished Educator Award, which recognizes an individual who has made outstanding contributions as an educator in gastroenterology on both local and national levels. Dr. Fontana's greatest teaching impact has been the establishment of one of the most highly successful transplant hepatology fellowship training programs in the country. He has taught countless medical students, residents, and fel-

lows, as well as faculty members via his clear, concise, and well-organized lectures and presentations. Dr. Fontana is a professor of medicine, medical director of liver transplantation, and director of transplant hepatology fellowship ACGME-accredited training program at the University of Michigan, Ann Arbor.

## Distinguished Clinician Awards

The AGA Distinguished Clinician Awards recognize members of the practicing community who, by example, combine the art of medicine with the skills demanded by the scientific body of knowledge in service to their patients.

AGA presents the Distinguished Clinician Award in Private Practice to Kimberly Persley, MD, AGAF. Dr. Persley made a huge impact on patient care in her community as the first IBD-specialty trained private practice gastroenterologist in the Dallas-Fort Worth, Tex., region. She was sought out by gastroenterologists and patients throughout the region for her thorough, kind and holistic care. Dr. Persley is a partner at Texas Digestive Disease Consultants and assistant clinical professor of medicine at the University of Texas Southwestern Medical School, Dallas, Tex.

AGA is honored to present the Distinguished Clinician Award in Clinical Academic Practice, to Gary Lichtenstein, MD, AGAF. Dr. Lichtenstein is a renowned physician, educator, and investigator whose local, regional, and national prominence is remarkable. Patients and physicians throughout the country seek his consultation and advice in IBD. Dr. Lichtenstein is a professor of medicine and director of the IBD Center at the University of Pennsylvania, Philadelphia.

## Distinguished Mentor Award

AGA bestows the Distinguished Mentor Award to Juanita Merchant, MD, PhD. This award recognizes an individual who has made a lifelong effort dedicated to the mentoring of trainees in the field of gastroenterology and for achievements as outstanding mentors throughout their careers. Dr. Merchant is an exceptional mentor, providing guidance to multiple learners to jump start, enhance, and guide their careers as scientists in gastroenterology. Many of her trainees are faculty in institutions around the world who

have also stimulated young learners to pursue careers in science. Dr. Merchant is professor and chief of gastroenterology and hepatology at the University of Arizona, Tucson.

## Research Service Award

AGA honors Peter Perrin, PhD, with the Research Service Award, which recognizes individuals whose work has significantly advanced gastroenterological science and research. As a program director at the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), Bethesda, Md., Dr. Perrin has had a huge impact on NIH-funded digestive diseases research. At NIDDK, he has the largest portfolio of grants that have high impact in digestive diseases, in topics including immunology, microbiology, infectious diseases, and IBD, barrier and transport functions, and AIDS/HIV.

## Outstanding Service Award

AGA honors the Funderburg family with the Outstanding Service Award, which was created in 1972 to honor an individual(s) who has contributed significantly to society's health and welfare. The family, which includes Rob and Cathy, Alex and Patty, and Hugh and Gail, has significantly contributed to the AGA Research Foundation through their personal philanthropy. Their parents established the AGA - R. Robert and Sally Funderburg Research Award in Gastric Cancer in 1992. In total, the family has given \$3 million and with their most recent gift, they have permanently endowed their research award in gastric cancer.

The family encourages collaboration and communication between and among the Funderburg recipients and as a result, AGA established the annual Funderburg Symposium at DDW. This symposium allows leaders in the gastric cancer field, many of whom are past Funderburg recipients, to come together and learn about the latest advances and findings in gastric cancer research.

## Young Investigator Awards

The AGA Young Investigator Awards recognize two young investigators, one in basic science and one in clinical science, for outstanding research achievements.

AGA honors Jennifer Lai, MD, MBA, with the Young Investigator

*Continued on following page*



## Now open: Registration for DDW® 2020 and the AGA Postgraduate Course

**D**igestive Disease Week® (DDW) is taking place May 2-5, 2020, at McCormick Place in Chicago, Ill. Featuring clinical care updates – presented nowhere else during DDW – the AGA Postgraduate Course will be held in conjunction with DDW on May 2 and 3. You can register for both together. Visit [DDW.org](http://DDW.org) and [AGA University, agau.gastro.org](http://AGA University, agau.gastro.org), to learn more about each.

### Improve patient care

The AGA Postgraduate Course is a comprehensive 1.5-day program highlighting ground-breaking advances in the delivery of high-quality, patient-centered GI care. Attendees will participate in dynamic case-based sessions, learning lunches, and panel discussions, and will walk away with best practices for treating a variety of disease states and digestive disorders.

### The brightest ideas and breakthroughs in digestive disease

DDW continues to improve

and consolidate its reputation as the meeting that brings the brightest ideas and breakthroughs in digestive disease. Prepare to be blown away in the Windy City by all that DDW has to offer:

More than 400 scientific sessions, organized by educational tracks and presented in a wide range of session formats. New sessions include an AGA Clinical Plenary, Topic-Focused Workshops on hypnosis techniques and nutrition, and expanded programming in the DDW Trainee and Early Career Lounge.

Opportunities to connect with over 14,000 attendees from around the world, including top GI experts. New Continuing Conversation blocks, immediately following select invited-speaker sessions, allow you time to network with presenters and fellow attendees.

An Exhibit Hall spotlighting new innovations and technologies that you can implement in your practice. [ginews@gastro.org](mailto:ginews@gastro.org)

*Continued from previous page*

Award in Clinical Science. Dr. Lai has pioneered a research program in frailty in hepatology that is changing the way that gastroenterologists and hepatologists manage patients with liver disease. She has carved out a niche at the junction of aging and hepatology research that is particularly timely given the influx of older patients with cirrhosis being seen in clinical practice, as well as the rapid rise in cirrhotic patients with multiple co-morbidities and frailty seeking liver transplantation. Dr. Lai is an associate professor of medicine in residence and director of the Advancing Research in Clinical Hepatology Group in the division of gastroenter-

ology and hepatology, at the University of California, San Francisco.

AGA honors Nobuhiko Kamada, PhD, with the Young Investigator Award in Basic Science. Dr. Kamada is known for his innovation combining fields examining the microbiota and the immune system in IBD, specifically, the interplay between diet, commensal and pathogenic microbes, and the immune system. He has published stellar findings that have been highly cited within short periods of time because of their innovation. Dr. Kamada is an assistant professor in the division of gastroenterology at the University of Michigan Medical School, Ann Arbor.

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## AGA honors today's luminaries in gastroenterology

**C**elebrate with the AGA Research Foundation.

To honor the lifelong contributions and achievements of some of our most esteemed members, we are pleased to present the AGA Research Foundation's newest program, **AGA Honors: Celebrating Difference Makers in Our Field**.

Our honorees have been chosen for their pivotal role in shaping the future of gastroenterology and hepatology. Honorees span the gamut from mentors and researchers to administrators and clinicians and educators across a myriad of disciplines:

John I. Allen, MD, MBA, AGAF  
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Martin Brotman, MD, AGAF  
Michael Camilleri, MD, AGAF  
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Sheila Crowe, MD, AGAF  
Francis M. Giardiello, MD, AGAF  
Fred S. Gorelick, MD  
Gail A. Hecht, MD, AGAF  
Wayne I. Lencer, MD, AGAF

Rodger A. Liddle, MD  
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Anil K. Rustgi, MD, AGAF  
Robert S. Sandler, MD, MPH, AGAF  
Michael L. Weinstein, MD  
C. Mel Wilcox, MD



We invite you to learn more about our honorees and to celebrate their contributions to the field by making a donation to the AGA Research Foundation. Visit our website at <http://foundation.gastro.org/aga-honors-celebrating/>.

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## Diversify GI: Mayra Sanchez

**W**e're celebrating diversity in our field with a new series spotlighting members of the AGA Diversity Committee and AGA FORWARD Program.

Born and raised in Cuba, Mayra Sanchez, MD, came to this country as an adult, with little money in her pocket and no recognition of her previous medical training. Unfortunately, she explains, her story is not uncommon.

"I first got involved with the AGA Diversity Committee to ensure there is recognition of those who come to our field from nontraditional paths such as this."

Her professional hero is Dr. Guadalupe Garcia-Tsao, a senior hepatologist at Yale.

"She is inspiring as an engaging teacher and as a role model for practicing cutting-edge medicine, but she also is my hero because she was able to rise to a leadership position despite the challenges of being a minority."

An issue affecting underrepresented minorities at the top of her radar is the need for more mentorship.

While serving on the committee, she also wants to stimulate a deeper understanding among colleagues of the value people bring by virtue of their different backgrounds, both in the gastroenterology and hepatology fields, and in GI patients.

"The practice of gastroenterology allows me to understand mind-body interactions and to appreciate how each person's life experiences and emotional well-being contributes to her or his digestive health."

### Let's get personal

What are you most proud of in your career? "I am proud that I built a very large, very busy, state-of-the-art motility practice at Yale University. Despite the fact that we have one of the biggest motility practices on the East Coast, we also pride ourselves on our dedication to patient care and patient satisfaction."

... In your personal life? "In my personal life, I am proud to have two beautiful children and a wonderful husband who serve as constant reminders of the importance of life outside of the workplace."

What's your favorite part of your job? "Making a difference in people's lives, especially when others have not been able to."

What do you know now that you wish someone told you when you started your career? "The importance of persistence cannot be overstated."

If I weren't in gastroenterology, I would be ... "a writer."

In my free time I like to ... "travel with my family to experience new cultures."

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## Top AGA Community patient cases

Physicians with difficult patient scenarios regularly bring their questions to the AGA Community (<https://community.gastro.org>) to seek advice from colleagues about therapy and disease management options, best practices, and diagnoses. In case you missed it, here are the most popular clinical discussions shared in the forum recently:

1. Adherence to noninvasive CRC screening (<http://ow.ly/6eng30qfUKq>).
2. eQ&A with Guideline authors: Management of gastric intestinal metaplasia (GIM) (<http://ow.ly/Cxsl30qfUYm>).
3. IBD patient: Crohn's colitis (<http://ow.ly/DsOg30qfUNT>).
4. Patient with intractable abdominal pain (<http://ow.ly/EPFi30qfU5i>).
5. IBD patient: Ulcerative colitis (<http://ow.ly/d6e730qfUVZ>).

Access these clinical cases and more discussions at <https://community.gastro.org/discussions>.

## AGA congressional champion Phil Roe announces retirement

Long-term AGA congressional champion and fierce physician-community advocate Congressman Phil Roe (R, Tenn.), MD, announced that he will not seek re-election in the upcoming 2020 election. Following his retirement announcement, Congressman Roe communicated to AGA and fellow health care organizations that he is still committed to ensuring the success of the prior authorization bill, H.R. 3107, before leaving Congress.

**Congressman Roe served both his constituents and his colleagues in the House of Representatives as a valued and respected leader on health care issues.**

Congressman Roe, who was first elected to Congress in 2008 and is currently serving his sixth term, is an OBGYN by trade who practiced for thirty years before running for office. He originally ran for Congress on a platform touting his experience as a practicing physician to drive and positively impact health care policy. Upon entering Congress, he did just that – focusing his legislative attention and efforts on policies that protect patients, ease administrative burdens, and protect fair reimbursements for specialty physicians. Throughout his tenure, Congressman Roe served both his

constituents and his colleagues in the House of Representatives as a valued and respected leader on health care issues. He currently serves as the top-ranking Republican on the Veteran's Affairs Committee and as co-chair of both the House Doctor's Caucus and the Congressional Academic Medicine Caucus. His primary focus as a member of Congress has always been on health care issues – many of which include AGA's top policy priorities.

### GI wins with Roe

Sustainable Growth Rate (SGR). Congressman Roe was an instrumental figure in the bipartisan victory to repeal the flawed Medicare physician payment formula, in 2015. Throughout the deliberation of SGR repeal legislation, he stayed in close contact with physician groups and actively whipped House members for support.

Independent Payment Advisory Board (IPAB). Congressman Roe was a key ally in the fight to repeal the IPAB, which was created under the Affordable Care Act and which AGA and all of organized medicine long opposed since its sole purpose was to make budgetary cuts to Medicare if it reached a certain threshold of spending. Largely because of Congressman Roe's leadership on this issue, the IPAB was successfully repealed after years of



Congressman Phil Roe

advocacy on the issue.

Through AGA PAC, AGA staff was afforded the opportunity to cultivate a strong working relationship over the years with Congressman Roe and his staff. While his leadership and commitment to pro-patient, pro-physician policies will be missed following his retirement from Congress, AGA staff looks forward to working with Congressman Roe through the remainder of his term on issues that impact our patients and our practice.

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## ► IBD AND INTESTINAL DISORDERS

## FDA approves fidaxomicin for treatment of *C. difficile*-associated diarrhea in children

BY LUCAS FRANKI

MDedge News

The Food and Drug Administration has approved fidaxomicin (Dificid) for the treatment of *Clostridioides difficile*-associated diarrhea in children aged 6 months and older.

Approval was based on results from SUNSHINE, a phase 3, multicenter, investigator-blind, randomized, parallel-group study in 142 pediatric patients aged between 6 months and 18 years with confirmed *C. difficile* infection who received either fidaxomicin or vancomycin for 10 days. Clinical response 2 days after the

conclusion of treatment was similar in both groups (77.6% for fidaxomicin vs. 70.5% for vancomycin), and fidaxomicin had a superior sustained response 30 days after the conclusion of treatment (68.4% vs. 50.0%).

The safety of fidaxomicin was assessed in a pair of clinical trials involving 136 patients; the most common adverse events were pyrexia, abdominal pain, vomiting, diarrhea, constipation, increased aminotransferases, and rash. Four patients discontinued fidaxomicin treatment because of adverse events, and four patients died during the trials, though all deaths were in patients aged younger than 2

years and seemed to be related to other comorbidities.

"*C. difficile* is an important cause of health care- and community-associated diarrheal illness in children, and sustained cure is difficult to achieve in some patients. The fidaxomicin pediatric trial was the first randomized, controlled trial of *C. difficile* infection treatment in children," Larry K. Kociulek, MD, associate medical director of infection prevention and control at Ann & Robert H. Lurie Children's Hospital of Chicago, said in the press release from Merck, manufacturer of fidaxomicin.

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# No biopsy to diagnose most pediatric celiac disease

BY ERIK GREB

MDedge News

In most cases, a biopsy is no longer required to diagnose celiac disease in children, according to new guidance from the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). The authors recommend that the diagnosis be established with a two-stage blood test instead of an endoscopy, which children often find distressing.

The guidance was published in the Journal of Pediatric Gastroenterology and Nutrition. The document is an update of ESPGHAN's 2012 guidance.

About half of children with suspected celiac disease undergo a biopsy to confirm the diagnosis. With reduction of the number of biopsies, and the anesthesia required to perform them, the new guidelines could reduce European health care costs.

Steffen Husby, MD, of Odense (Denmark) University Hospital, and colleagues recommend testing for total IgA and anti-intestinal transglutaminase 2 (TGA-IgA) antibodies as initial screening in children with suspected celiac disease. An IgG-based test is indicated only when total IgA is low or undetectable, according to the authors. Physicians should refer children with positive results to a pediatric gastroenterologist. If the level of TGA-IgA is 10 or more times the upper limit of normal, and the family agrees, the physician may diagnose celiac disease without a biopsy, provided that endomysial antibodies test positive in a second blood sample, according to the guidance. For children with a positive TGA-IgA level of less than 10 times the upper limit of normal, however, at least four biopsies from the distal duodenum and at least one from the bulb are required to establish the diagnosis.

Physicians can diagnose celiac disease in children with no symptoms without the need for a biopsy using the same criteria as they use for symptomatic children, wrote Dr. Husby and colleagues. Clinicians, parents, and, when appropriate, children should participate in the decision about whether to perform a biopsy.

Celiac disease is the most prevalent food-related chronic disease in European children, but as much as 80% of children with celiac disease are undiagnosed. The prevalence of celiac disease is increasing, and undiagnosed children with this disease are at risk of nutritional and developmental problems, as well as long-

term health complications. Although celiac disease is easy to detect and treat, 10-13 years may elapse between symptom onset and the time of diagnosis. The new guidelines are intended to facilitate diagnosis and increase its accuracy, thus enabling earlier diagnosis and improved detection, according to ESPGHAN.

"These new guidelines mean that

more than half of all children being investigated for celiac disease will no longer need to have an invasive biopsy," said Luisa Mearin Manrique, MD, PhD, professor of pediatrics at Leiden (the Netherlands) University and senior author of the guidelines, in a press release. "This is a big step forward in our mission to ensure that children can be diagnosed and effec-

tively treated for celiac disease. It is scandalous that so many children go so long, often up to 10 years, without diagnosis."

No conflicts of interest were reported.

egreb@mdedge.com

**SOURCE:** Husby S et al. J Pediatr Gastroenterol Nutr. 2020;70(1):141-56.

## 2020 AGA Postgraduate Course

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EDU20-004

# ERAS takes its place in IBD surgery

BY RICHARD MARK KIRKNER

MDedge News

REPORTING FROM THE CROHN'S  
& COLITIS CONGRESS

AUSTIN, TEX. – Enhanced recovery after surgery (ERAS) protocols have been around for decades, but typically excluded patients having surgery for inflammatory bowel disease (IBD). However, recent studies have shown strategies to optimize these patients, including presurgery carbohydrate loading and early postsurgery feeding, can improve outcomes, according to a review of evidence presented at the Crohn's & Colitis Congress®, a

partnership of the Crohn's & Colitis Foundation and the American Gastroenterological Association.

"It's really important that we implement strategies to help mitigate the impact that malnutrition is going to have on our perioperative patients, and one of the ways we do that is by using an ERAS or enhanced recovery after surgery protocol," said Kelly Issokson, MS, RD, of Cedars-Sinai Medical Center, Los Angeles. She noted that patients with IBD are five times more likely to be malnourished than non-IBD patients, and those with fistulizing Crohn's disease and bowel resections are at greatest risk (*Inflamm Bowel Dis.* 2008;14:1139-46).

"I constantly see patients who are kept NPO [nothing by mouth] 12 or 24 hours before surgery, maybe even longer sometimes, unfortunately," she said. "We should really be minimizing that NPO to help mitigate the catabolic effect that surgery has on our patients and help them recover more quickly."

To screen surgery patients for nutrition risk, Ms. Issokson said that gastroenterologists can ask two questions from the malnutrition screening tool: Did the patient have recent unintentional weight loss, and is the patient eating less because of poor appetite? A yes to either question merits referral to a registered dietician. Malnutrition, weight loss of 5%-10% of total

body weight, and sarcopenia are predictors of surgical complications for IBD patients, the latter an independent predictor in patients aged 40 years and older.

The ERAS protocol involves optimizing preoperative and postoperative nutrition, she said. It has been linked with improved outcomes in elective colorectal surgery (*World J Surg.* 2014;38:1531-41), although the evidence in IBD isn't as robust. She cited a retrospective study reported at the 2019 annual Digestive Disease Week® of patients with Crohn's disease that found no difference in readmissions, complications, or reoperations between ERAS and standard-care patients.

Preoperative nutrition optimization in ERAS involves anemia and fluid management, oral nutrition supplementation, and – based on European Society for Clinical Nutrition and Metabolism (ESPEN) 2017 guidelines – delaying the operation where possible if the patient is malnourished. "Patients who receive preoperative nutrition support have been shown to have better outcomes postoperatively," Ms. Issokson said, citing a meta-analysis of 1,111 Crohn's disease patients that reported the complication rate was 20% in patients on nutrition support versus 60% for those on standard care; in those on enteral nutrition, the disparity was more pronounced: 21% versus 73% (*Eur*

*J Gastro Hep.* 2018;30:997-1002).

Gastroenterologists should not be afraid of implementing total parenteral nutrition (TPN) perioperatively in these patients, Ms. Issokson said. "This can really help to improve outcomes and quality of life in our patients, and it's something that we really should not shy away from," she added in an interview. "If our patients are malnourished and meet the criteria for TPN, then we should really not be withholding it." Patients with severe IBD who are not absorbing from their gut and can't meet 60% of their needs by mouth are prime candidates for TPN, she said, referencing a 2019 study that reported that preoperative TPN in malnourished IBD patients resulted in a rate of overall noninfectious complications half that of no-TPN patients: 8.3% versus 16.8% (*Gastroenterol Rep.* 2019 Apr;7:107-14).

Carbohydrate loading before surgery is a big part of ERAS in these patients. "Surgery has a huge impact on the catabolic state of a patient," Ms. Issokson said. "It's similar to running a marathon; you wouldn't go out and run a marathon without fueling up the night before with a whole bunch of carbohydrates. So we use this same strategy in our surgical patients."

ERAS society guidelines call for 100 g of carbohydrates the night before and 50 g 2 hours before surgery in the form of a clear-liquid beverage, along with permitting a light meal up to 6 hours before, with exceptions in gastroparesis, motility disorders, and emergency surgery.

Another key component of ERAS in IBD is early postoperative feeding. "Postoperatively we want to feed our patients as soon as possible," Ms. Issokson said. ESPEN guidelines call for feeding patients with new nondiverted colorectal anastomosis within 4 hours. "Studies show that patients aren't able to eat enough calories to help them recover postoperatively, so implementing an oral nutrition supplement might be helpful there," she added.

Ms. Issokson is a Crohn's & Colitis Foundation board member, and disclosed financial relationships with Orgain, RMEI, and Medscape.

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**SOURCE:** Issokson K et al. Crohn's & Colitis Congress 2020, Session Sp83.



Kelly Issokson

RICHARD MARK KIRKNER/MDEDGE NEWS

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# Provides quick care improvement

Quality from page 1

the Crohn's & Colitis Foundation as an outgrowth of its IBD Qorus quality improvement program. The 15-month study involved 20,392 patient visits at 15 academic and 11 private/community practices from January 2018 to April 2019. "This specific project within Qorus is fo-



Dr. Gil Y. Melmed

cused specifically around the concept of improving access during times of urgent care need," Dr. Melmed told this news organization. The goal was to identify practice changes that can drive improvement. The intervention consisted of 19 different strategies, called a "Change Package," and participating sites could choose to test and implement one or more of them, Dr. Melmed said. Some examples included designating urgent care slots in the clinic schedule, installing a nurse hotline, a

weekly "huddle" to review high-risk patients, and patient education on using urgent care. One of the drivers of the program was to provide immediate care improvement to patients, Dr. Melmed said in the interview. "As opposed to investments into the cure of IBD that we need, but which can take years to develop, this research has immediate, practical applicability for patients today." "The fact that we were able to demonstrate reduction in emergency room utilization and hospitalization, steroid use, and narcotic use has really energized the work that we were doing. We can now show that very-low-cost process changes at a site level lead to robust improvement in patient outcomes. These changes are potentially implementable in any practice setting," Dr. Melmed said in the interview. After Dr. Melmed's presentation, Maria T. Abreu, MD, AGAF, director of the Crohn's and Colitis Center at the University of Miami, asked about the cost of the interventions. Dr. Melmed said the costs were nominal, such as paying for a new phone line for a patient hotline. "But overall the cost really involved in the program was the time that it took to review the high-risk list on a weekly basis with the team, and that is essentially a 15-minute huddle," he said. Later, Dr. Abreu said in an interview that the program was "a terrific example of how measuring outcomes and sharing ideas can make huge impacts in the lives of patients." She

## Changes in outcome measures after quality initiative

Outcome measure	Baseline rate (February 2018)	Final rate (April 2019)	Relative change
Clinical remission	42%	45%	+7%
Perceived need for urgent care in prior 6 months	26%	21%	-19%
Emergency room use	18%	14%	-22%
Hospitalization	14%	11%	-22%
CT-scan use	22%	18%	-18%
Corticosteroid use	14%	10%	-29%
Narcotic use	8%	4%	-50%
>4 phone calls to clinic in prior month	11%	10%	-9%
Proportion of patients with "high risk"	14%	6%	-57%

Note: Based on data for 20,392 patient visits at 26 practices.  
Source: Dr. Melmed

added, "An enormous amount of money is spent on clinical trials of expensive biologics which have revolutionized treatment, yet the humanistic aspects of our care have just as great of an impact. In this study, each center focused on ways they could lower ER visits and hospitalizations. One size did not fit all, yet they could learn from each other. The very platform they used to conduct the study is a model for all of us." Corey A. Siegel, MD, of the Dartmouth-Hitchcock Medical Center, Lebanon, N.H., and Dr. Melmed's co-principal investigator on Qorus, said the quality initiative now includes 49 GI practices across the country with plans to grow to 60 by the end of the year. "We have created this 'collaboratory' for providers from across the country to work together to learn how to best deliver high-quality care for patients with IBD," he said. Another feature of the quality initiative allowed participating sites to

see how they compared with others anonymously, Dr. Melmed said. "Using the data, we called out high-performing sites to teach the rest of us what they were doing that enabled them to improve, so that all of us could learn from their successes," he said. The researchers are aiming to evaluate costs and identify the most successful interventions, with the plan to present the latter at Digestive Disease Week® and use them to develop a toolkit practices can use. Dr. Melmed disclosed financial relationships with AbbVie, Boehringer-Ingelheim, Celgene, GSK, Janssen, Medtronic, Pfizer, Samsung Bioepis, Takeda, and Techlab; IBD Qorus receives support from Abbvie, AMAG, Helmsley Charitable Trust, Janssen, Nephroceuticals, Pfizer, Takeda, and UCB. ginews@gastro.org

**SOURCE:** Melmed GY et al. Crohn's & Colitis Congress 2020, Session 28.

# Demonstrates more education is needed

Opioids from page 1

Gastroenterology and Hepatology. "Despite these concerns, opioids are commonly prescribed to IBD patients in the outpatient setting and to as many as 70% of IBD patients who are hospitalized." To look for a possible relationship between inpatient and outpatient opioid use, the investigators reviewed electronic medical records of 862 IBD patients who were treated at three urban hospitals in the University of Pennsylvania Health System. The primary outcome was opioid prescription within 12 months of discharge, including prescriptions at time of hospital dismissal. During hospitalization, about two-thirds (67.6%) of patients received intravenous opioids. Of the total population, slightly more than half (54.6%) received intravenous hydromorphone and about one-quarter (25.9%) received intravenous mor-

phine. Following discharge, almost half of the population (44.7%) was prescribed opioids, and about three out of four patients (77.9%) received an additional opioid prescription within the same year. After confounders such as IBD severity, pre-admission opioid use, pain scores, and psychiatric conditions were considered, data analysis showed that inpatients who received intravenous opioids had a threefold (odds ratio, 3.3) increased likelihood of receiving postdischarge opioid prescription, compared with patients who received no opioids while hospitalized. This association was stronger among those who had IBD flares (OR, 5.4). Furthermore, intravenous dose was positively correlated with post-discharge opioid prescription. Avoiding intravenous opioids had no impact on the relationship between inpatient and

outpatient opioid use. Among inpatients who received only oral or transdermal opioids, a similarly increased likelihood of postdischarge opioid prescription was observed (OR, 4.2), although this was a small cohort (n = 67). Compared with other physicians, gastroenterologists were the least likely to prescribe opioids. Considering that gastroenterologists were also most likely aware of IBD-related risks of opioid use, the investigators concluded that more interdisciplinary communication and education are needed. "Alternative analgesics such as acetaminophen, dicyclomine, hyoscyamine, and celecoxib could be advised, as many of these therapies have been deemed relatively safe and effective in this population," they wrote. The investigators disclosed relationships with Abbott, Gilead, Romark, and others. ginews@gastro.org

**SOURCE:** Dalal RS et al. Clin Gastro Hepatol. 2019 Dec 27. doi: 10.1016/j.cgh.2019.12.024.

# IVF, surgery, education have improved IBD fertility

BY RICHARD MARK KIRKNER

MDedge News

REPORTING FROM CROHN'S  
& COLITIS CONGRESS

AUSTIN, TEX. – Patients with inflammatory bowel disease (IBD) who want to have children can benefit from better education about recent findings that disease control, laparoscopic surgery, and in vitro fertilization (IVF) have improved their chances of conceiving, according to a review of published reports presented here at the Crohn's & Colitis Congress®, a partnership of the Crohn's & Colitis Congress Foundation and the American Gastroenterological Association.

"Decreased fertility in IBD is due to voluntary childlessness, which we can change with education; surgery for IBD, which we can improve with laparoscopic surgery; and increased disease activity, which we can also make a difference in," Sonia Friedman, MD, of Harvard Medical School, Boston, said in an interview.

Dr. Friedman and coauthors last year published an analysis of the Danish National Birth Cohort, which showed women with IBD had a 28% greater relative risk of taking a year or more to get pregnant than controls without IBD, and that the relative risk was even higher in women with Crohn's disease – 54% (Clin Gastroenterol Hepatol. 2019. doi: 10.1016/j.cgh.2019.08.031). "We found that women with



Dr. Sonia Friedman of Harvard Medical School discussed advances in IBD fertility.

Crohn's surgery had decreased fertility by 2.54 times greater relative risk," she said.

"Fertility, pregnancy is the most important thing to patients," Dr. Friedman said in an interview. "That's what people ask me about the most. In the population of IBD patients, the onset is age 15-35, and these people are in the prime of their reproductive years." Sexual function, known to be decreased in men and women with IBD, is also an overriding concern in these patients, she said. "There needs to be a lot more information out there about it."

She said gastroenterologists should keep in mind that much of the evidence documenting reduced fertility after ileo-pouch anal anastomosis is dated and focused on open surgery, which caused profound scarring of the pelvis and fallopian tubes, thus hindering conception. Laparoscopic ileoanal J-pouch surgery (IPAA) has yielded much improved outcomes in women of child-bearing age, she said, citing a study late last year that reported women who had laparoscopic IPAA had a median time to pregnancy of 3.5 months versus 9 months for women who had open IPAA (Surgery. 2019;166:670-7).

"It's really important to discuss the issues of fertility, especially for patients contemplating surgery," Dr. Friedman said. "Emphasize that there are good outcomes with laparoscopic surgery, and they can have assisted reproductive technology [ART], or in vitro fertilization, if needed. Never withhold surgery based on fear of infertility."

Her practice is to refer women with IBD in remission for IVF if they've tried to get pregnant every month for a year or more and to refer women with IBD surgery for IVF after trying to get pregnant for 6 months. Dr. Friedman coauthored two studies of the Danish National Birth Cohort of ART in women with Crohn's disease and ulcerative colitis (UC) along with controls (Gut. 2016;65:767-76; Gut. 2017;66:556-

8). "We found that women with Crohn's and UC had a decreased chance of having a clinical pregnancy, but they had no problem carrying the pregnancy to term," she said.

Those findings raised questions about the etiology of decreased fertility in IBD patients, which could include factors such as IVF technique, reproductive hormone and microbiome changes, or IBD medications. "How can we carry that forward to all women with IBD?" she said. Women with IBD have less chance of conceiving with each IVF treatment cycle than do women without IBD, she said. "The most interesting thing is that the reduced chance of live birth after IVF treatment in Crohn's and UC is related to the stages of implantation and not to the ability to maintain the fetus throughout pregnancy," she said.

Dr. Friedman has no financial relationships to disclose.

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**SOURCE:** Friedman S. Crohn's & Colitis Congress, Session Sp86.

## AGA Resource

The AGA IBD Parenthood Project can help guide your patients with IBD throughout their pregnancy, from trying to conceive through postpartum care. Learn more at [IBDParenthoodProject.org](http://IBDParenthoodProject.org).

# High stress responsiveness linked to UC flare risk

BY RICHARD MARK KIRKNER

MDedge News

REPORTING FROM CROHN'S & COLITIS CONGRESS

AUSTIN, TEX. – Early results from a cohort study that aims to characterize the brain-gut relationship in ulcerative colitis (UC) have identified potential structural and functional brain changes consistent with the effect chronic bowel inflammation has on the brain and found two subgroups of patients that differed in how they respond to stress.

These findings may provide further insight into the role of the brain in symptom flares, the study leader reported at the Crohn's & Colitis Congress®, a partnership of the Crohn's & Colitis Foundation and the American Gastroenterological Association.

So far, the study has shown that, based on validated measures of perceived stress or neuroticism, patients with UC in clinical remission are

clustered on two ends of the stress spectrum, with high and low stress responsiveness, said Emeran A. Mayer, MD, who is co-principal investigator of the study with Jenny Sauk, MD, both of the University of California, Los Angeles.

The goal of the longitudinal follow-up study is to identify brain, gut microbiome, and stress signatures that predict the risk of flares for up to 2 years in UC patients in clinical remission, he said. Patients' clinical, microbiome, and stress-psychological measures are evaluated quarterly. The intent is to enroll 100-120 patients between ages 18 years and 65 years. Questionnaire and symptom data on 70 patients have been analyzed so far.

"What we found so far is that, at baseline using the questionnaire data and clustering analysis, you can identify two distinct subgroups: one characterized by stress hyperresponsiveness and one that does not have that feature," Dr. Mayer said in an interview. "Then we found in the stress hyperres-

Continued on following page



Dr. Emeran A. Mayer, of UCLA, found two subgroups of UC patients that differ in how they respond to stress.



# Colorectal cancer cases spike after start of routine screening at 50

BY HEIDI SPLETE  
MDedge News

Incidence of colorectal cancer (CRC) spiked among adults in the United States between the ages of 49 and 50 years, the age when many have routine screening colonoscopies, based on data from a cross-sectional study of 165,160 patients.

"We would expect to see some degree of CRC incidence increase from 49 to 50 years of age owing to screening uptake and diagnosis of preexisting CRCs that may have been clinically undetected," wrote Wesal H. Abualkhair, MD, of Tulane University, New Orleans, and colleagues.

In a study published in JAMA Network Open, the researchers reviewed data from the Surveillance, Epidemiology, and End Results (SEER) registries from 2000 to 2015 on colorectal cancer incidence in 1-year intervals for adults aged 30-60 years, focusing on the year between ages 49 and 50.

Overall, the incidence of colorectal cancer

increased by 46.1% from 49 to 50 years of age, and 93% of these cases were invasive.

The increase in cancer rates occurred across geographical regions, sex, and race, and likely

**'We would expect to see some degree of CRC incidence increase from 49 to 50 years of age owing to screening uptake and diagnosis of preexisting CRCs that may have been clinically undetected.'**

reflects the impact of screening rather than advancing age, the researchers said.

They also found a significant increase in 5-year relative survival (6.9% absolute increase, 10% relative increase) for the transition between 49 and 50 years of age; no other age transitions showed a significant change.

The findings were limited by several factors, including the lack of specific outcomes data and inability to determine the number of years that the cancers existed before diagnosis, the researchers said. However, the results were strengthened by the large study population and detailed yearly assessment.

"Our analysis of the transition from 49 to 50 years provides new, registry-based data regarding risk among individuals younger than 50 years, which can add to preexisting modeling studies to help inform decision-making on the age at which to initiate screening," the researchers said.

The study did not receive outside funding. Lead author Dr. Abualkhair had no financial conflicts to disclose.

ginews@gastro.org

**SOURCE:** Abualkhair WH et al. JAMA Network Open. 2020 Jan 31. doi: 10.1001/jamanetworkopen.2019.20407.

Continued from previous page

ponsive group there are more flares reported and documented during a mean follow-up of 8.1 months."

The findings so far have also determined that the differences in stress responsiveness and flare frequency don't seem to be related to baseline fecal calprotectin levels, said Dr. Mayer, who is director of the G. Oppenheimer Center for Neurobiology of Stress and Resilience and codirector of the CURE: Digestive Diseases Research Center.

Early findings show the incidence of clinical flares in the high stress-responsiveness group was 27.4% vs. 9.3% in the low-stress group, and the rate of symptomatic flares was 11.8% vs. 4.6%, respectively.

With regard to baseline biological measures, there were no significant differences in cardiovascular tone or morning salivary cortisol measures between the two clusters, Dr. Mayer noted, although the high stress-responsiveness cluster had higher sympathetic tone before, during, and after a brief psychological stress.

He noted that the same clustering into low and high stress responsiveness was confirmed in a different data set of 66 UC subjects and that the two clusters showed significant differences in anatomical connectivity of the default mode network in the brain, a set of regions involved in chronic pain and emotion regulation.

By identifying factors that con-

**The findings so far have also determined that the differences in stress responsiveness and flare frequency don't seem to be related to baseline fecal calprotectin levels.**

tribute to inflammatory bowel disease, the study may ultimately simplify the process of identifying IBD patients in remission who are at highest risk of flares, Dr. Mayer said. "Patients won't need to undergo brain imaging or assessment of microbiome parameters; they

can just answer a short questionnaire," he said. Another potential benefit of the study would be to identify changes in the brain-gut microbiome interactions associated with flares, he said.

Full study results would be available in about 2 years, Dr. Mayer

said, with more data on biological parameters expected next year.

The study is funded with a Crohn's & Colitis Foundation grant. Dr. Mayer disclosed financial relationships with Amare, Axial Biotherapeutics, Bloom Science, Danone, Mahana Therapeutics, Pendulum, Ubiome, and Viome.

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**SOURCE:** Mayer EA et al. Crohn's & Colitis Congress 2020, Session Sp74.

# Multiomics blood test outperforms others for CRC

BY SUSAN LONDON

MDedge News

SAN FRANCISCO – A blood-based test that integrates data from multiple molecular “omes,” such as the genome and proteome, performs well at spotting early-stage colorectal cancer (CRC), the AI-EMERGE study suggests.

At a specificity of 94%, the multiomics test had a sensitivity of 94% for detecting stage I and II CRC. Moreover, the test netted better sensitivity than a fecal immunochemical test (FIT), a circulating tumor DNA (ctDNA) test, and a carcinoembryonic antigen (CEA) test.

Findings were reported in a poster session at the 2020 GI Cancers Symposium, which is co-sponsored by the American Gastroenterological Association, American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology.

“Today, about a third of age-appropriate adults are not up to date with [CRC] screening,” lead study investigator Girish Putcha, MD, PhD, chief medical officer of Freenome in San Francisco, noted at the symposium. “A noninvasive blood-based screening test having high sensitivity and specificity for [CRC] generally, but especially for early-stage disease, could help improve adherence and ultimately reduce mortality.”

Dr. Putcha and colleagues evaluated a blood-based multiomics test in 32 patients with CRC of all stages and 539 colonoscopy-confirmed negative control subjects.

The test uses a multiomics platform to pick up both tumor-derived signal and non-tumor-derived signal from the body’s immune response and other sources. The test uses machine learn-

ing, and entails whole-genome sequencing, bisulfite sequencing (for assessment of DNA methylation), and protein quantification methods.

At 94% specificity, the test had a 94% sensitivity for spotting stage I and II CRC, 91% sensitivity for stage III and IV CRC, and 91% sensitivity for CRC of any stage. By location, sensitivity was 92% for distal tumors and 88% for proximal tumors.

The multiomics test outperformed a ctDNA test, a CEA test, and a FIT. At a specificity of 96% for both tests, the multiomics test yielded a higher sensitivity than a commercially available FIT stool test



Dr. Putcha

(OC-Auto FIT, Polymedco) for stage I and II disease (100% vs. 70%), stage III and IV disease (100% vs. 50%), and any-stage disease (100% vs. 67%).

When set at 100% specificity, the multiomics test outperformed a commercially available plasma ctDNA test (Avenio, Roche) set at 75% specificity. The multiomics test yielded a higher sensitivity for

stage I and II disease (94% vs. 38%), stage III and IV disease (91% vs. 55%), and any-stage disease (90% vs. 47%).

At a specificity of 94% for both tests, the multiomics test yielded a higher sensitivity than plasma CEA level for stage I and II disease (94% vs. 18%), stage III and IV disease (91% vs. 45%), and any-stage disease (91% vs. 31%).

“Although there were many exciting aspects to this study, the test’s ability to detect cancers without loss of sensitivity for early-stage cancers was striking to me,” said Michael J. Hall, MD, of Fox Chase Cancer Center in Philadelphia, who

was not involved in the study. “The loss of sensitivity in early tumors has been a limitation of other tests – FOBT [fecal occult blood test], FIT – so if this is replicable, this is exciting.”

Although the study was small for a CRC screening assessment, “the preliminary results presented in the poster were certainly compelling enough to support more research,” Dr. Hall said.

Dr. Putcha said that the test will be validated in a prospective, multicenter trial of roughly 10,000 participants at average risk, expected to open later this year. Further research will also help assess the test’s performance among patients with inflammatory bowel disease, for whom false-positive results with some screening tests have been problematic.

The study was sponsored by Freenome. Dr. Putcha is employed by Freenome and has a relationship with Palmetto GBA. Dr. Hall disclosed relationships with Ambry Genetics, AstraZeneca, Caris Life Sciences, Foundation Medicine, Invitae, and Myriad Genetics, and he shares a patent with institutional colleagues for a novel method to investigate hereditary CRC genes.

ginews@gastro.org

**SOURCE:** Putcha G et al. 2020 GI Cancers Symposium, Abstract 66.

## AGA Resource

Visit the AGA GI Patient Center for education to share with your patients about currently available CRC screenings at <https://www.gastro.org/practice-guidance/gi-patient-center/topic/colorectal-cancer-crc>.

## CLINICAL CHALLENGES AND IMAGES

### What is your diagnosis?

By Diogo Turiani Hourneaux de Moura, MD, MSc, PhD, Kelly E. Hathorn, MD, and Christopher C. Thompson, MD. Published previously in *Gastroenterology* (2019;156:2139-41).

We describe three unique presentations of patients with a prior history of Roux-en-Y gastric bypass who were referred for endoscopic treatment of weight regain. All of the patients had failed prior attempts at lifestyle modifications and pharmacologic weight loss treatment. On physical examination, their body mass indexes ranged from 27 to 30 kg/m<sup>2</sup>, but examination and complete laboratory evaluation, including thyroid-stimulating hormone, were otherwise normal. During the first upper gastrointestinal esophago-gastroduodenoscopies, the pouch

and the gastrojejunal anastomosis (GJA) were characterized by healthy-appearing mucosa. In all three cases, the pouch size measured between 3 and 5 cm and the GJA was dilated, with diameters of more than 20 mm (Figure A). Laser resurfacing of the stoma by argon plasma coagulation (APC) at 0.8 L/min and 70 watts was successfully performed in a 1-cm concentric ring fashion around the gastric side of the GJA (Figure B). Three months after the initial APC, the patients returned for reevaluation. The pouch mucosa again seemed to be normal, but there was persistent, albeit improved, dilation of the GJA. Repeat APC sessions were performed without any adverse events.

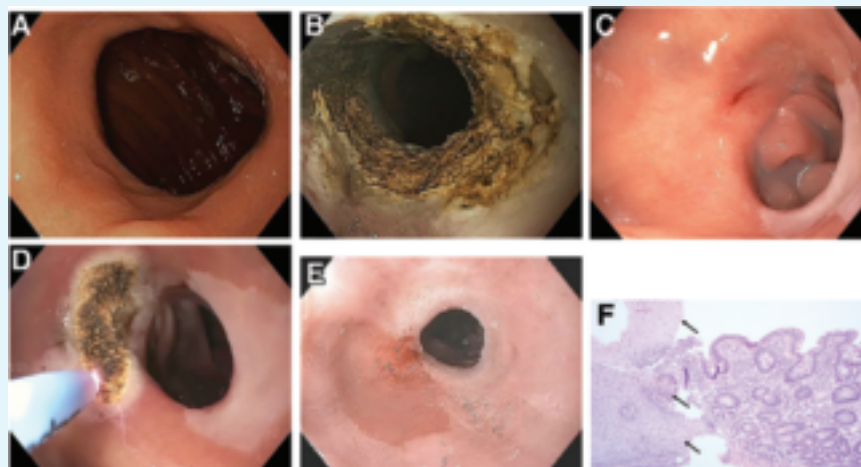
On their next follow-up esophago-gastroduodenoscopies, all patients were noted to have an

abnormal color of approximately 25% of their gastric pouch epithelium, which seemed to be more similar to the esophageal epithelium (Figure C). The GJAs remained dilated, measuring more than 14 mm, and their third APC sessions were performed (Figure D). The patients did well after the procedures, with significant weight

loss. A 1-year follow-up endoscopy showed a 10-mm GJA, but the gastric pouch was now approximately 80%-100% covered with this abnormal epithelium (Figure E). A forceps biopsy was performed for histologic evaluation (Figure F).

What is the histopathologic diagnosis of this finding?

*The diagnosis is on page 19.*



AGA INSTITUTE



# Sociodemographic disadvantage confers poorer survival in young adults with CRC

BY SUSAN LONDON

MDedge News

SAN FRANCISCO – Young adults with colorectal cancer (CRC) who live in neighborhoods with greater disadvantage differ on health measures, present with more advanced disease, and have poorer survival. These were among key findings of a retrospective cohort study reported at the 2020 GI Cancers Symposium.

The incidence of CRC has risen sharply – 51% – since 1994 in individuals aged younger than age 50 years, with the greatest uptick seen in those aged 20-29 years (J Natl Cancer Inst. 2017;109[8]. doi: 10.1093/jnci/djw322).

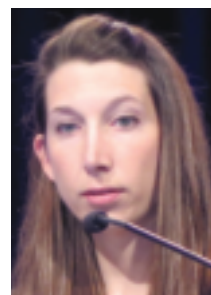
“Sociodemographic disparities have been linked to inferior survival. However, their impact and association with outcome in young adults is not well described,” said lead investigator Ashley Matusz-Fisher, MD, of the Levine Cancer Institute in Charlotte, N.C.

The investigators analyzed data from the National Cancer Database for the years 2004-2016, identifying 26,768 patients who received a CRC diagnosis when aged 18-40 years.

Results showed that those living in areas with low income (less than \$38,000 annually) and low educational attainment (high school graduation

rate less than 79%), and those living in urban or rural areas (versus metropolitan areas) had 24% and 10% higher risks of death, respectively.

Patients in the low-income, low-education group were more than six times as likely to be black and to lack private health insurance, had greater comorbidity, had larger tumors and



Dr. Matusz-Fisher



Dr. Carethers

more nodal involvement at diagnosis, and were less likely to have surgery.

Several factors may be at play for the low-income, low-education group, Dr. Matusz-Fisher speculated: limited access to care, lack of awareness of important symptoms, and inability to afford treatment when it is needed.

“To try to eliminate these disparities, the first step is recognition, which is what we are doing – recognizing there are disparities – and then making people aware of these disparities,” she commented. “More

efforts are needed to increase access and remove barriers to care, with the hope of eliminating disparities and achieving health equity.”

## Mitigating disparities

Several studies have looked at mitigating sociodemographic-related disparities in CRC outcomes, according to session cochair John M. Carethers, MD, AGAF, professor and chair of the department of internal medicine at the University of Michigan, Ann Arbor.

A large Delaware initiative tackled the problem via screening (J Clin Oncol. 2013;31:1928-30). “Over 50, you can essentially eliminate this disparity with navigation services and screening. How do you do that under 50? I’m not quite sure,” he said in an interview, adding that some organizations are recommending lowering the screening age to 45 or even 40 in light of rising incidence in young adults.

However, accumulating evidence suggests that there may be inherent biological differences that are harder to overcome.

“There are a lot of data ... showing that polyps happen earlier and they are bigger in certain racial groups, particularly African Americans and American Indians,” Dr. Carethers elaborated. What is driving the biol-

ogy is unknown, but the microbiome has come under scrutiny.

“So you are a victim of your circumstances,” he summarized. “You are living in a low-income area, you are eating more proinflammatory-type foods, you are getting your polyps earlier, and then you are getting your cancers earlier.”

## Study details

Rural, urban, or metropolitan status was ascertained for 25,861 patients in the study, and area income and education were ascertained for 7,743 patients, according to data reported at the symposium, sponsored by the American Gastroenterological Association, the American Society of Clinical Oncology, the American Society for Radiation Oncology, and the Society of Surgical Oncology.

Compared with counterparts living in areas with both high annual income (greater than \$68,000) and education (greater than 93% high school graduation rate), patients living in areas with both low annual income and education were significantly more likely to be black (odds ratio, 6.4), not have private insurance (OR, 6.3), have pathologic T3/T4 stage (OR, 1.4), have positive nodes (OR, 1.2), and have a Charlson-Deyo comorbidity score of 1 or greater (OR, 1.6). They also were less likely to undergo surgery (OR, 0.63) and more likely to be rehospitalized within 30 days (OR, 1.3).

After adjustment for race, insurance status, T/N stage, and comorbidity score, relative to counterparts in the high-income, high-education group, patients in the low-income, low-education group had an increased risk of death (hazard ratio, 1.24;  $P = .004$ ). And relative to counterparts living in metropolitan areas, patients living in urban or rural areas had an increased risk of death (HR, 1.10;  $P = .02$ ).

In patients with stage IV disease, median overall survival was 26.1 months for those with high income, high education, but 20.7 months for those with low income, low education ( $P$  less than .001).

Dr. Matusz-Fisher reported no conflicts of interest. The study did not receive any funding.

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**SOURCE:** Matusz-Fisher A et al. 2020 GI Cancers Symposium, Abstract 13.



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FND19-40

# Serum keratin 18 promising as AAH biomarker

BY M. ALEXANDER OTTO  
MDedge News

**S**erum keratin 18, an epithelial protein released from dying hepatocytes, identifies patients with severe acute alcoholic hepatitis (AAH) at high risk for death, according to an investigation of 173 subjects.

Standard biomarker scores – Model for End-stage Liver Disease (MELD), age, serum bilirubin, International Normalized Ratio, and serum creatinine (ABIC) – predict prognosis and severity of alcoholic liver disease, but they don't reflect "the magnitude of cell death nor the form of cell death (apoptosis/necrosis), which may be important in distinguishing various

forms of liver injury" and guiding therapy, explained investigators led by Vatsalya Vatsalya, MD, of the division of gastroenterology, hepatology, and nutrition at the University of Louisville (Ky.).

It's important to identify people with alcoholic cirrhosis but not active hepatitis, as they "would likely not benefit from anti-inflammatory

agents such as steroids or [interleukin]-1 receptor antagonists, but would incur their side effects." For those and other reasons, "new biomarkers are needed for diagnosing AAH, assessing the degree of hepatocyte death, and predicting mortality," they said.

Keratin 18 – both the cleaved form (K18M30) and the uncleaved protein (K18M65) – have been suggested before as a marker for AAH, so the investigators took a closer look.

They analyzed serum from 57 people with severe AAH (MELD score above 20), 27 people with moderate AAH (MELD score 12-19), 34 with nonalcoholic steatohepatitis, 17 healthy controls, and 38 people with

**Serum levels of K18 also identified patients who died within 90 days with greater accuracy than did MELD, ABIC, and other scores.**

alcohol use disorder and either mild or no liver injury. Patients were in their mid 40s, on average; there were more men than women.

Overall, 51.9% of moderate AAH cases and 38.9% of severe cases had K18M65 levels between 641 and 2,000 IU/L; 25.9% of moderate and 61.1% of severe cases had K18M65 levels greater than 2,000 IU/L. All severe cases had levels above 641 IU/L. Serum levels of K18 also identified patients who died within 90 days with greater accuracy than did MELD, ABIC, and other scores.

The K18M65:ALT ratio distinguished AAH from nonalcoholic steatohepatitis with a sensitivity of 0.971 and specificity of 0.829. Findings were similar for the K18M30:ALT ratio.

Levels of K18M65 and K18M30 increased significantly as liver disease worsened, as did the degree of necrosis as indicated by the K18M65:K18M30 ratio. Meanwhile, although k18 levels correlated with MELD scores, levels of ALT, AST, and the ratio of AST:ALT did not.

The National Institutes of Health supported the work; the investigators had no disclosures.

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**SOURCE:** Vatsalya V et al. Clin Gastroenterol Hepatol. 2019 Dec 4. doi: 10.1016/j.cgh.2019.11.050).



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FND19-38



# Telehealth helps speed front end of liver transplant

BY GREGORY TWACHTMAN

MDedge News

The incorporation of telehealth in the liver transplantation process is demonstrating the potential to expedite the evaluation of patients and get them added on the transplant wait list.

New research shows “a transplant hepatologist evaluation using telehealth was associated with significantly reduced time to evaluation and listing without adversely affecting pretransplant mortality compared to the current standard of care of in-person evaluation at a transplant center,” Binu V. John, MD, of McGuire VA Medical Center, Richmond (Va.), and colleagues wrote in a report published in *Clinical Gastroenterology and Hepatology* (2019 Dec 27. doi: 10.1016/j.cgh.2019.12.021).

Researchers looked at 465 patients who had evaluations for liver transplants at the Richmond Veterans Affairs Medical Center from 2005 through 2017. Nearly half (232 patients) were evaluated via telehealth, with the remaining 233 evaluated with traditional in-person evaluations.

“Patients in the telehealth group were evaluated significantly faster than patients in the usual care

group (22 vs. 54 days,  $P$  less than .001),” Dr. John and colleagues wrote, adding that, after conducting a propensity-matched analysis, “telehealth was associated with an 85% reduction in time from referral to evaluation.”

**Patients ‘who underwent the initial evaluation by telehealth were listed significantly earlier than the usual care group,’ the authors stated, adding that ‘telehealth was associated with a 74% reduction in time to listing.’**

Additionally, patients “who underwent the initial evaluation by telehealth were listed significantly earlier than the usual care group (95 vs. 149 days;  $P$  less than .001),” the authors stated, adding that “telehealth was associated with a 74% reduction in time to listing” after conducting a propensity-matched analysis.

However, while speeding up time to referral and listing, “the median time to transplant was not significantly different between the two groups on unadjusted (218 vs. 244 days;  $P$  = .084) or adjusted analysis

(325 vs. 409 days;  $P$  = .08),” they added.

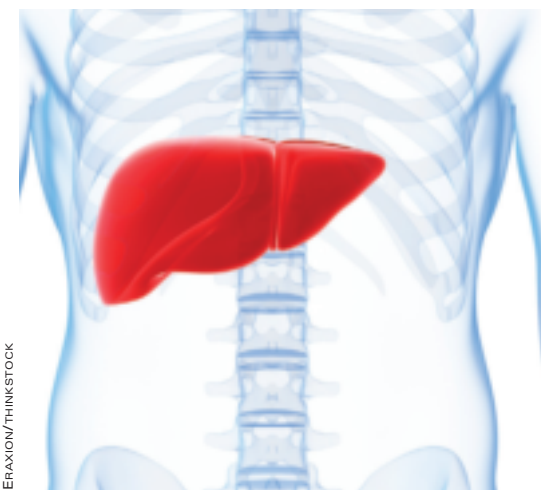
Additionally, “there was no difference in pretransplant mortality between [those] evaluated by telehealth or usual care in unadjusted analysis,” Dr. John and colleagues observed, noting that 169 of 465 patients (51 on the waiting list for a transplant and 118 who were not listed) who were referred died without receiving a liver transplant.

Researchers suggested that, while evaluation times may have been shorter with the use of telehealth, they did not translate to shorter transplantation times “likely because the latter is a complex metric that is driven primarily by organ availability.”

Dr. John and colleagues cautioned that the centralized nature of the VA medical system could make the results of this study not generalizable across private care settings, particularly when care needs to cross state lines, which does not present an issue within the VA medical system.

That being said, the “ability to successfully evaluate and list patients via telehealth and obtain the same outcomes in terms of time to transplant and pretransplant mortality is significant because of the numerous advantages that tele-

health offers to improve overall access to transplantation,” they stated, adding that more studies are needed, both in and out of the VA sys-



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tem, “to confirm that telehealth is a safe and effective way to expand access for patients undergoing evaluation for liver transplantation.”

Lead author Dr. John serves on medical advisory boards for Gilead and Eisai and received research funding from a number of pharmaceutical manufacturers. No conflicts of interest were reported by the other authors.

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**SOURCE:** John BV et al. *Clin Gastroenterol Hepatol*. doi: 10.1016/j.cgh.2019.12.021.

## CLINICAL CHALLENGES AND IMAGES

### The diagnosis

**Answer to “What is your diagnosis?” on page 16: Squamous metaplasia**

Weight regain can accompany re-emergence of obesity-related comorbidities and, thus, early intervention is important. Although diet, exercise, and behavior modifications are fundamental, they can have limited efficacy. Thus, endoscopic management is important, with specific evaluation for gastrogastroic fistulae, pouch dilation, and GJA dilation, all of which can be successfully intervened upon endoscopically. For GJA dilation in particular, APC has been used with promising results.<sup>1</sup>

In the normal GI tract, the esophagus is lined with squamous epithelium, and the stomach is lined with columnar epithelium. One of the most well-known and well-documented scenarios in which the typical mucosal lining is replaced by abnormal mucosa is Barrett’s esophagus (BE). BE is defined by the replacement of the normal distal squamous epithelial lining with columnar epithelium with a minimum length of 1 cm (tongues or circum-

ferential) containing specialized intestinal metaplasia on histopathologic examination. It is well documented that treatment of BE with thermal ablation and acid-suppression therapy results in re-epithelialization of the esophagus with neosquamous mucosa.<sup>2</sup> In contrast with this, in our patients, after we burned the gastric columnar mucosa with APC to treat their dilated GJA, the gastric pouch mucosa has been replaced with squamous epithelium, which we have termed “reverse BE.” To our knowledge, there are no reports of this condition in the literature, nor do we know the precise cause.

There is a series of patients without a history of bariatric surgery who developed squamous metaplasia in the proximal gastric cardia.<sup>3</sup> The authors hypothesized that this condition may be due to chronic mucosal injury owing to hiatal hernia, reflux, caustic ingestion, chronic gastritis, or pyloric stenosis. We suggest two potential mechanisms for this condition in our patients: 1) extending the ablation to the Z-line on the medial aspect of the pouch may allow for the distal extension of squamous mucosa during the healing process; and 2) acid-suppression therapy with proton pump inhibitors

after the procedure, in combination with a postoperative decrease in acid production, allows for a shift in the cell proliferation and differentiation in the pouch. Notably, although there are well-defined guidelines for surveillance of BE, owing to the risk of progression to esophageal adenocarcinoma,<sup>2</sup> it is unclear what clinical significance this reverse BE may have in the future. It is important to continue to monitor these patients and clarify the natural history of this finding.

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*Christopher C. Thompson is a consultant for Boston Scientific and Medtronic, a consultant for and has institutional grants from USGI Medical, Olympus, and Apollo Endosurgery.*

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# Prepare for major changes to E/M coding starting in 2021

BY BRADEN KUO, MD, JOSEPH LOSURDO, MD,  
SHIVAN J. MEHTA, MD, MBA, AND PATRICIA  
GARCIA, MD

**E**valuation and Management (E/M) coding and guidelines are about to undergo the most significant changes since their implementation in the 1990s. For now, the changes are limited to new and established outpatient visits (CPT codes 99202-99205, 99211-99215) and will take place as of Jan. 1, 2021. Changes to all E/M codes are anticipated in the coming years.

The changes to the new and established office/outpatient codes will impact everyone in health care who assigns codes, manages health information, or pays claims including physicians and qualified health professionals, coders, health information managers, payers, health systems, and hospitals. The American Medical Association (AMA) has already released a preview of the CPT 2021 changes as well as free E/M education modules. They are planning to release more educational resources in the near future.

## Why were changes needed?

The AMA developed the 2021 E/M changes in

response to interest from the Centers for Medicare & Medicaid Services (CMS) in reducing physician burden, simplifying documentation requirements, and making changes to payments for the E/M codes. CMS's initial proposal was to collapse office visit E/M levels 2-5 to a single payment. While the new rates would have provided a modest increase for level 2 and 3 E/M codes, they would have cut reimbursement for the top-level codes by more than 50%. There was concern that these changes would adversely affect physicians caring for complex patients across medical specialties. There was an outcry from the physician community opposing CMS's proposal, and the agency agreed to get more input from the public before moving forward.

The AMA worked with stakeholders, including the AGA and our sister GI societies, to create E/M guidelines that decrease documentation requirements while also continuing to differentiate payment based on complexity of care. CMS announced in the 2020 Medicare Physician Fee Schedule (MPFS) final rule that it would adopt the AMA's proposal as well as their recommended relative values for 2021 CPT E/M codes. Of note, there will be modest payment increases for

most office E/M codes beginning Jan. 1, 2021, which may benefit those who manage patients with complex conditions.

## In sum, what are the 2021 E/M changes

While there will be many changes to office/outpatient E/M visits, the most significant are deletion of code 99201 (Level 1 new patient visit), addition of a 15-minute prolonged services code that can be reported with 99205 and 99215, and the following restructuring of office visit code selection:

### 1. Elimination of history and physical as elements for code selection:

While obtaining a pertinent history and performing a relevant physical exam are clinically necessary and contribute to both time and medical decision making, these elements will not factor in to code selection. Instead, the code level will be determined solely by medical decision making or time.

### 2. Choice of using medical decision making (MDM) or total time as the basis of E/M level documentation:

- **MDM.** While there will still be three MDM sub-components (number/complexity of problems,

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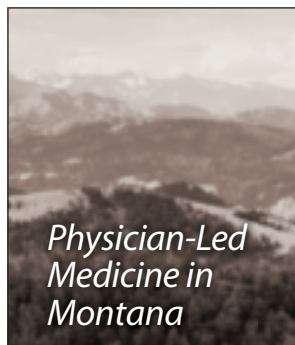


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# CMS's new rule for antibiotic stewardship: *H. pylori*

BY DAVID Y. GRAHAM, MD, AND  
HASHEM B. EL-SERAG, MD, MPH, AGAF

The Centers for Medicare & Medicaid Services (CMS) finalized a new regulation requiring all hospitals participating in its programs to establish antimicrobial stewardship programs by March 30, 2020 (<https://federalregister.gov/d/2019-20736>). This welcome action was prompted by the rise in antimicrobial resistance; recent Centers for Disease Control and Prevention estimates more than 2.8 million antibiotic-resistant infections with more than 35,000 deaths occur in the United States each year ([www.cdc.gov/drugresistance/biggest-threats.html](http://www.cdc.gov/drugresistance/biggest-threats.html)). CMS recommended that hospitals follow stewardship guidelines established by CDC, and other nationally recognized sources ([www.cdc.gov/](http://www.cdc.gov/)

antibiotic-use/healthcare/pdfs/hospital-core-elements-H.pdf). Antibiotic stewardship includes optimization of several aspects of antimicrobial therapy including the drugs, formulations, doses, and dosing intervals. It also includes obtaining and updating local, regional, and national susceptibility data to provide regularly updated guidance regarding diagnosis and therapy.

How does this new CMS rule affect gastroenterologists and what role, if any, do we play in the epidemic of antibiotic resistance? The one infectious disease that gastroenterology effectively owns is *Helicobacter pylori*. Treatment of this infection has the potential to be involved in the epidemic of antimicrobial resistance. Current *H. pylori* therapies were largely devised without considering the principles of antibiotic steward-

ship. Therapies for *H. pylori* have largely been developed using trial and error, antimicrobial susceptibility testing is rarely available, and local and regional susceptibility are not readily available or updated. Current

**Therapies for *H. pylori* have largely been developed using trial and error, antimicrobial susceptibility testing is rarely available, and local and regional susceptibility are not updated.**

national treatment recommendations are most often based on comparisons of regimens grouping trials containing different drugs, doses, and durations of therapy performed in populations in whom resistance was neither assessed nor taken into ac-

count. Finally, some of the most highly recommended effective regimens inevitably contain at least one antibiotic unnecessary for the outcome, and inadvertently serve to increase population antibiotic exposure.

Clarithromycin-amoxicillin-PPI triple is still the most often used legacy therapy in the United States with an average cure rate of 70%. Recent guidelines have suggested adding a fourth drug, metronidazole, to produce a quadruple therapy (concomitant therapy); the premise is that, although both clarithromycin and metronidazole resistance are common, dual resistance is not. However, this benefit comes at the price of every patient receiving at least one unnecessary antibiotic, and patients with treatment failures receiving three unnecessary antibiotics. The

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data, and risk), extensive edits were made to the ways in which these elements are defined and tallied.

- **Time.** The definition of time is now minimum time, not typical time or "face-to-face" time. Minimum time represents total physician/qualified health care professional time on the date of service. This redefinition of time allows Medicare to better recognize the work involved in non-face-to-face services like care coordination and record review. Of note, these definitions only apply when code selection is based on time and not MDM.

**3. Modification of the criteria for MDM:** The current CMS Table of Risk was used as a foundation for designing the revised required elements for MDM.

- **Terms.** Removed ambiguous terms (e.g., "mild") and defined previously ambiguous concepts (e.g., "acute or chronic illness with systemic symptoms").
- **Definitions.** Defined important terms, such as "independent historian."
- **Data elements.** Re-defined the data elements to move away from simply adding up tasks to focusing on how those tasks affect the management of the patient (e.g., independent interpretation of a test performed by another provider and/or discussion of test interpretation with another physician).

CMS also plans to add a new Healthcare Common Procedure Coding System (HCPCS) add-on code as of Jan. 1, 2021, that can be used to recognize additional resource costs that are inherent in treating complex patients.

- **GPCX1 - Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing**

*care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established.).*

GPC1X can be reported with all levels of E/M office/outpatient codes in which care of a patient's single, serious, or complex chronic condition is the focus. CMS plans to reimburse GPC1X at 0.33 RVUs (about \$12).

## Who do these changes apply to?

The changes to the E/M office/outpatient CPT codes and guidelines for new and established patients apply to all traditional Medicare and Medicare Advantage plans, Medicaid, and all commercial payers. E/M HCPCS codes apply to Medicare, Medicare Advantage plans, and Medicaid only; commercial payers are not required to accept HCPCS codes.

## What should you do?

Visit the AMA E/M Microsite; there you will find the AMA's early release of the 2021 E/M coding and guideline changes, the AMA E/M learning module and future resources on the use of time and MDM that are expected to be released in March.

**AMA E/M Microsite:** <https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management>

**2021 E/M changes:** <https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf>

**AMA E/M learning module:** <https://edhub.ama-assn.org/interactive/18057429>

**AMA MDM table:** <https://www.ama-assn.org/system/files/2019-06/cpt-revised-mdm-grid.pdf>

Connect with your coders and/or medical billing company to create a plan for training physicians and staff to ensure a smooth transition on Jan. 1, 2021.

Contact your Electronic Health Records (EHR) vendor to confirm the system your practice uses will be ready to implement the new E/M coding and guidelines changes on Jan. 1, 2021.

Run an analysis using the new E/M office/outpatient payment rates recommended by the AMA for 2021 (<https://www.ama-assn.org/about/rvs-update-committee-ruc/ruc-recommendations-minutes-voting>) for each of your practice's contracted payers to determine if your practice will benefit from the new rates. While CMS has proposed to accept the AMA recommended rates, this will not be finalized until CMS publishes the 2021 proposed rule in early July 2020.

Once CMS confirms its decision, reach out to your payers to negotiate implementing the new E/M rates starting in 2021.

With changes this big, we encourage you to prepare early. Watch for more information on the 2021 E/M changes in Washington Insider and AGA eDigest.

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cumulative effect given the approximately 2 million treatments annually is tens of thousands of kilograms of inappropriate antibiotic use annually with the likely consequence of increasing resistance.

How to move forward? The CDC documents regarding antimicrobial stewardship in hospitals with limited resources ([www.cdc.gov/antibiotic-use/core-elements/resource-limited.html](http://www.cdc.gov/antibiotic-use/core-elements/resource-limited.html)) suggest creation and promotion of evidence-based treatment guidelines for common clinical syndromes, tracking of antibiotic dispensing using available data, setting of national targets for improvement, and description of resistance patterns to improve treatment guidelines and identify priority pathogens. The CDC documents require creating and promoting of evidence- and susceptibility-based treatment guidelines, tracking antibiotic dispensing, and setting targets for improvement (i.e., monitoring and reporting). It is important to note that the CMS rule focused on hospitals as they have traditionally been the sites where local susceptibility data are obtained and gathered to provide the regional data and updated treatment guidelines used to treat most infectious diseases.

The Houston Consensus Conference on Testing for *Helicobacter pylori* Infection in the United States in 2017 had several recommendations that would effectively address the CMS rule and CDC recommendations. For example, statement 15: that empiric eradication therapy for *H. pylori* be based on region or population-specific antibiotic susceptibility data (Grade 1B); statement 17: that validated diagnostic testing of stool or gastric mucosal biopsy by culture and susceptibility, or molecular analysis be universally available (Grade 1); statement 18: that antibiotics that may be routinely evaluated for susceptibility include amoxicillin, clarithromycin, levofloxacin, metronidazole, and tetracycline (Grade 2C); and statement 19: that professional societies provide the research needed to support evidence-based reimbursement decisions for antibiotic susceptibility testing for *H. pylori* (Grade 1).

Organized gastroenterology needs to join with the infectious disease community to make *H. pylori* an infection of joint interest. Mass eradication of *H. pylori* worldwide offers the promise of elimination of gastric cancer. The CMS rule should result in significant changes in the approach to treating *H. pylori* infections that includes improved testing and availability and implementation of knowledge

of local susceptibility and resistance patterns. Therapies that reliably cure *H. pylori* without unnecessary antibiotics need to be used whereas regimens that fail to reliably achieve high cure rates should be abandoned. We should consider establishing quality metrics related to appropriate diagnostic testing for both the initial

infection as well as posttreatment evaluations. We must add our voice to advocate for hospitals and central laboratories to offer susceptibility testing locally or as a send out for clinicians to provide locally relevant antimicrobial therapy for *H. pylori* infections. The CMS rule provides both the impetus and the methods to move

forward and deal with *H. pylori* like other infectious diseases.

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