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Gastrointestinal Cancer™

UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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ABIM CME MOC ACCREDITED

CME Certified

Gastrointestinal Cancer™

UPDATE

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Gastrointestinal Cancer Update
A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Colorectal cancer (CRC) is a common and potentially lethal type of cancer, and its clinical management is continuously evolving. Although "non-CRC" gastrointestinal (GI) tumors are less frequently encountered individually, the cancer-related deaths in that subcategory surpass those attributed to CRC. Published results from ongoing trials continuously lead to the emergence of novel biomarkers and new therapeutic targets and regimens, thereby altering existing management algorithms. In order to offer optimal patient care — including the option of clinical trial participation — the practicing medical oncologist must be well informed of these advances. To bridge the gap between research and patient care, *Gastrointestinal Cancer Update* uses one-on-one discussions with leading GI oncology investigators. By providing access to the latest scientific developments and the perspectives of experts in the field, this CME activity assists medical oncologists with the formulation of up-to-date management strategies.

LEARNING OBJECTIVES

- Appraise recent data on therapeutic advances and changing practice standards in colorectal and gastric cancer, and integrate this information, as appropriate, into current clinical care.
- Develop a long-term care plan for individuals diagnosed with metastatic CRC, considering the patient's biomarker profile, exposure to prior systemic therapy, symptomatology, performance status and personal goals for treatment.
- Use HER2 status, clinical factors and patient perspectives to optimize the selection and sequence of systemic therapy for locally advanced or metastatic gastric/gastroesophageal cancer.
- Appraise the rationale for and clinical data with investigational anti-PD-1 and/or anti-PD-L1 antibodies in patients with CRC or gastric cancer.
- Assess available data with currently approved and investigational agents with documented activity in gastroesophageal cancer, and develop a clinical algorithm for optimal patient care, including the option of participating in clinical research.
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials.

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FACULTY — **Dr Mayer** had no relevant conflicts of interest to disclose. The following faculty (and his spouse/partner) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Ajani** — Advisory Committee: Amgen Inc, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Genentech BioOncology, Lilly, Novartis Pharmaceuticals Corporation, Roche Laboratories Inc; Contracted Research: Amgen Inc, Bristol-Myers Squibb Company, Genentech BioOncology, Lilly, Merck, Novartis Pharmaceuticals Corporation, Roche Laboratories Inc, Takeda Oncology; Other Remunerated Activities: Genentech BioOncology.

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Interview with Robert J Mayer, MD

Tracks 1-16

Track 1 **Case discussion:** A 29-year-old man with a family history of colon cancer presents with de novo, widespread metastatic colon cancer with mismatch repair deficiency and Lynch syndrome

Track 2 Mismatch repair deficiency and response to anti-PD-1/PD-L1 antibodies

Track 3 Evaluation for mismatch repair deficiency in patients with metastatic colorectal cancer (mCRC)

Track 4 Interim results of the Phase II CheckMate 142 study: Nivolumab with or without ipilimumab for mCRC with or without high microsatellite instability (MSI-H)

Track 5 **Case discussion:** A 64-year-old woman with BRAF-mutant mCRC whose disease progresses on multiple lines of therapy receives TAS-102 and then regorafenib

Track 6 Efficacy of the MEK inhibitor trametinib, BRAF inhibitor dabrafenib and anti-EGFR antibody panitumumab in combination for BRAF V600E mutation-positive mCRC

Track 7 Activity of and clinical experience with TAS-102 for mCRC

Track 8 Dosing and clinical utility of regorafenib for patients with mCRC

Track 9 Cavitation and hoarseness as potential prognostic markers of response to regorafenib

Track 10 Dealing with stress and burnout in the practice of oncology

Track 11 Investigation of methods for converting mismatch repair-proficient tumors to mismatch repair deficient

Track 12 Incidence of HER2 amplification in patients with CRC and the use of anti-HER2 agents

Track 13 Activity of the cancer stemness inhibitor napabucasin (BBI608) in combination with FOLFIRI for mCRC

Track 14 **Case discussion:** A 52-year-old man with newly diagnosed pan-wild-type rectal cancer with substantial liver metastases experiences an excellent response with FOLFIRI/bevacizumab

Track 15 Resection of the primary tumor in patients presenting with mCRC

Track 16 Role of EGFR monoclonal antibodies in pan-wild-type mCRC

Interview with Jaffer A Ajani, MD

Tracks 1-20

Track 1 Joint ASCO/College of American Pathologists/American Society of Clinical Pathology guidelines on HER2 testing for gastric or gastroesophageal cancer

Track 2 Epidemiology and prognosis of HER2-positive gastric cancer (GC)

Track 3 GATSBY: Results of a Phase II/III trial of T-DM1 versus a taxane as second-line therapy for HER2-positive metastatic gastric or gastroesophageal junction (GEJ) cancer

Track 4 Clinical experience with and tolerability of T-DM1 in HER2-positive GC

Track 5 Approach to second-line therapy for HER2-positive GC

Track 6 **Case discussion:** A 53-year-old man with HER2-positive metastatic GEJ cancer experiences a durable response with oxaliplatin/5-FU/trastuzumab and continues to receive maintenance trastuzumab

Track 7 Activity of immune checkpoint inhibitors in squamous cell carcinoma of the esophagus

Track 8 The Cancer Genome Atlas study of the molecular biology of squamous cell carcinoma and adenocarcinoma

Track 9 **Case discussion:** A 63-year-old man with HER2-negative metastatic GEJ cancer experiences disease progression after 11 months of anti-PD-L1 antibody therapy and receives ramucirumab/paclitaxel

Interview with Dr Ajani (continued)

Track 10 Microsatellite instability status and response to anti-PD-1 treatment in GC

Track 11 BRIGHTER: A Phase III trial of napabucasin and weekly paclitaxel versus placebo and weekly paclitaxel for previously treated gastric or GEJ adenocarcinoma

Track 12 Incorporating ramucirumab into the treatment of metastatic GC (mGC)

Track 13 Ramucirumab monotherapy for HER2-negative mGC

Track 14 Perspective on ramucirumab-associated toxicities

Track 15 Investigation of ramucirumab in combination with immune checkpoint inhibitors for mGC

Track 16 **Case discussion:** A 41-year-old Asian woman with GC who received neoadjuvant chemoradiation therapy

Track 17 Postoperative chemotherapy versus chemoradiation therapy after neoadjuvant therapy for GC

Track 18 Perspective on HER2 testing and use of neoadjuvant anti-HER2-based therapy for patients with GC

Track 19 Quality indicators in the management of Barrett's esophagus, dysplasia and esophageal adenocarcinoma

Track 20 Viewpoint on the current landscape of treatments for GC

Bonus Audio: Access the web tracks at
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Related Video Program

Visit www.ResearchToPractice.com/GICU116/Video to view video highlights of the interviews with Drs Mayer and Ajani and earn up to 2.25 additional *AMA PRA Category 1 Credits™*.

Topics covered include:

- First-line therapy for mCRC
- Mismatch repair deficiency and response to anti-PD-1 treatment
- First-line treatment for patients with BRAF-mutant mCRC
- Tolerability and predictors of response with TAS-102
- Dosing of regorafenib
- Cancer stemness inhibitors in mCRC and other GI cancers
- Use of EGFR monoclonal antibodies in pan-wild-type mCRC
- HER2 testing in gastric and GEJ cancer and treatment options for HER2-positive disease
- Immune checkpoint inhibitors in gastric and esophageal cancers
- Use of ramucirumab in mGC
- New understanding of Barrett's esophagus

SELECT PUBLICATIONS

A Phase III study of pembrolizumab (MK-3475) vs chemotherapy in microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) Stage IV colorectal carcinoma (KEYNOTE-177). NCT02563002

Al-Shamsi HO et al. **Continuation of trastuzumab beyond disease progression in patients with metastatic gastric cancer: A retrospective analysis of 25 cases — The MD Anderson experience.** *Proc ASCO* 2016;**Abstract e15560**.

Atreya CE et al. **Updated efficacy of the MEK inhibitor trametinib (T), BRAF inhibitor dabrafenib (D), and anti-EGFR antibody panitumumab (P) in patients (pts) with BRAF V600E mutated (BRAFm) metastatic colorectal cancer (mCRC).** *Proc ASCO* 2015;**Abstract 103**.

Bendell JC et al. **Clinical activity and safety of cobimetinib (cobi) and atezolizumab in colorectal cancer (CRC).** *Proc ASCO* 2016;**Abstract 3502**.

Corcoran RB et al. **Combined BRAF and MEK inhibition with dabrafenib and trametinib in BRAF V600-mutant colorectal cancer.** *J Clin Oncol* 2015;33(34):4023-31.

Diaz LA et al. **Programmed death-1 blockade in mismatch repair deficient cancer independent of tumor histology.** *Proc ASCO* 2016;**Abstract 3003**.

Ganesh K et al. **Somatic tumor profiling of DNA mismatch repair deficient (MMR-D) colorectal cancers (CRC).** *Proc ASCO* 2016;**Abstract 1528**.

Grothey A et al. **Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): An international, multicentre, randomised, placebo-controlled, phase 3 trial.** *Lancet* 2013;381(9863):303-12.

Janjigian Y et al. **Clinical next generation sequencing (NGS) of esophagogastric (EG) adenocarcinomas identifies distinct molecular signatures of response to HER2 inhibition, first-line 5FU/platinum and PD1/CTLA4 blockade.** *Proc ESMO* 2016;**Abstract 612O**.

Kelly CM, Janjigian YY. **The genomics and therapeutics of HER2-positive gastric cancer — From trastuzumab and beyond.** *J Gastrointest Oncol* 2016;7(5):750-62.

Le DT et al. **PD-1 blockade in tumors with mismatch-repair deficiency.** *N Engl J Med* 2015;372(26):2509-20.

Mayer RJ et al; RECOURSE Study Group. **Randomized trial of TAS-102 for refractory metastatic colorectal cancer.** *N Engl J Med* 2015;372(20):1909-19.

Melero I et al. **Safety and preliminary efficacy of nivolumab (nivo) in patients (pts) with advanced hepatocellular carcinoma (aHCC): Interim analysis of the phase 1/2 CheckMate-040 study.** *Proc ESMO* 2016;**Abstract 615O**.

Muro K et al. **Pembrolizumab for patients with PD-L1-positive advanced gastric cancer (KEYNOTE-012): A multicentre, open-label, phase 1b trial.** *Lancet Oncol* 2016;17(6):717-26.

O'Neil BH et al. **Phase 1b extension study of cancer stemness inhibitor BBI608 (napabucasin) administered in combination with FOLFIRI +/- bevacizumab (bev) in patients (pts) with advanced colorectal cancer (CRC).** *Proc ASCO* 2016;**Abstract 3564**.

Overman MJ et al. **Nivolumab ± ipilimumab in treatment (tx) of patients (pts) with metastatic colorectal cancer (mCRC) with and without high microsatellite instability (MSI-H): CheckMate-142 interim results.** *Proc ASCO* 2016;**Abstract 3501**.

Pavlakis N et al. **Regorafenib for the treatment of advanced gastric cancer (INTEGRATE): A multinational placebo-controlled phase II trial.** *J Clin Oncol* 2016;34(23):2728-35.

Shah MA et al. **The BRIGHTER trial: A phase III randomized double-blind study of BBI-608 + weekly paclitaxel versus placebo (PBO) + weekly paclitaxel in patients (pts) with pretreated advanced gastric and gastro-esophageal junction (GEJ) adenocarcinoma.** *Proc ASCO* 2016;**Abstract TPS4144**.

Shinozaki E et al. **Timing of adverse events (AEs) in the Phase 3 RECOURSE trial of TAS-102 versus placebo in patients (pts) with metastatic colorectal cancer (mCRC).** *Proc ECC* 2015;**Abstract 2151**.

Smyth EC et al. **Correlation between mismatch repair deficiency (MMRd), microsatellite instability (MSI) and survival in MAGIC.** *Proc ASCO* 2016;**Abstract 4064**.

Yoshino T et al. **TAS-102 monotherapy for pretreated metastatic colorectal cancer: A double-blind, randomised, placebo-controlled phase 2 trial.** *Lancet Oncol* 2012;13(10):993-1001.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **A recent study published in *The New England Journal of Medicine* and subsequently updated at ASCO 2016 demonstrated that patients with mCRC and _____ responded to treatment with the immune checkpoint inhibitor pembrolizumab.**
   a. Microsatellite stable tumors
   b. MSI-H tumors
   c. Both a and b
   d. Neither a nor b

2. **In a study for patients with BRAF V600E mutation-positive mCRC, the triplet combination of the BRAF inhibitor dabrafenib, the MEK inhibitor trametinib and the anti-EGFR antibody panitumumab demonstrated improved and promising activity compared to the doublet combination of panitumumab with either dabrafenib or trametinib.**
   a. True
   b. False

3. **Interim results of the Phase II CheckMate 142 study presented at ASCO 2016 evaluating nivolumab with or without ipilimumab for patients with mCRC with or without high microsatellite instability demonstrated encouraging clinical activity in patients with MSI-H mCRC with nivolumab alone and in combination with ipilimumab.**
   a. True
   b. False

4. **Which of the following is the mechanism of action of TAS-102?**
   a. Anti-angiogenic
   b. Antibody-drug conjugate
   c. Anti-PD-1 antibody
   d. Oral nucleoside

5. **Approximately what proportion of patients with GC have HER2-amplified disease?**
   a. 5% to 20%
   b. 35% to 50%
   c. >50%

6. **Results of a Phase Ib study presented at ASCO 2016 evaluating the cancer stemness inhibitor napabucasin (BBI608) in combination with FOLFIRI with or without bevacizumab for mCRC demonstrated that napabucasin _____ be safely combined with FOLFIRI with or without bevacizumab.**
   a. Could
   b. Could not

7. **Side effects typically associated with TAS-102 therapy include which of the following?**
   a. Hepatic dysfunction
   b. Neutropenia
   c. Rash
   d. Renal dysfunction
   e. Vomiting
   f. All of the above

8. **The Phase III BRIGHTER trial is evaluating _____ with weekly paclitaxel versus placebo with weekly paclitaxel for previously treated gastric or GEJ adenocarcinoma.**
   a. Napabucasin
   b. Nivolumab
   c. Regorafenib
   d. TAS-102

9. **Side effects which may be associated with ramucirumab include _____.**
   a. Hypertension
   b. Nosebleeds
   c. Bowel perforation
   d. Thromboembolism
   e. All of the above

10. **Approximately what proportion of patients with squamous cell carcinoma of the esophagus exhibit PD-L1 expression?**
    a. 10%
    b. 25%
    c. 50%
    d. 100%

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Gastrointestinal Cancer Update — Issue 1, 2016

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Ongoing evaluation of mismatch repair deficiency and its implications for response to immune checkpoint inhibitors in GI cancers	4 3 2 1	4 3 2 1
Factors affecting the sequencing of TAS-102 and regorafenib in the later-line treatment of mCRC	4 3 2 1	4 3 2 1
Biologic rationale for and preliminary clinical data with anti-PD-1/PD-L1 antibodies for patients with mCRC or advanced GC	4 3 2 1	4 3 2 1
The concept of "stemness" and emerging clinical data with the cancer stem cell inhibitor napabucasin in advanced GI cancers	4 3 2 1	4 3 2 1
Efficacy of the MEK inhibitor trametinib, BRAF inhibitor dabrafenib and anti-EGFR antibody panitumumab for BRAF V600E mutation-positive mCRC	4 3 2 1	4 3 2 1

Practice Setting:

⬭ Academic center/medical school ⬭ Community cancer center/hospital ⬭ Group practice

⬭ Solo practice ⬭ Government (eg, VA) ⬭ Other (please specify).....

Was the activity evidence based, fair, balanced and free from commercial bias?

⬭ Yes ⬭ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

⬭ This activity validated my current practice

⬭ Create/revise protocols, policies and/or procedures

⬭ Change the management and/or treatment of my patients

⬭ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

.....

The content of this activity matched my current (or potential) scope of practice.

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4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Appraise recent data on therapeutic advances and changing practice standards in colorectal and gastric cancer, and integrate this information, as appropriate, into current clinical care. . . . . 4 3 2 1 N/M N/A
- Develop a long-term care plan for individuals diagnosed with metastatic CRC, considering the patient's biomarker profile, exposure to prior systemic therapy, symptomatology, performance status and personal goals for treatment. . . . . 4 3 2 1 N/M N/A
- Use HER2 status, clinical factors and patient perspectives to optimize the selection and sequence of systemic therapy for locally advanced or metastatic gastric/gastroesophageal cancer. . . . . 4 3 2 1 N/M N/A
- Appraise the rationale for and clinical data with investigational anti-PD-1 and/or anti-PD-L1 antibodies in patients with CRC or gastric cancer. . . . . 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Assess available data with currently approved and investigational agents with documented activity in gastroesophageal cancer, and develop a clinical algorithm for optimal patient care, including the option of participating in clinical research. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials. . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

. . . . . .

Would you recommend this activity to a colleague?

☐ Yes ☐ No

If no, please explain: . . . . . .

Additional comments about this activity:

. . . . . .

PART 2 — Please tell us about the faculty and editor for this educational activity

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Faculty	Knowledge of subject matter	Effectiveness as an educator
Robert J Mayer, MD	4 3 2 1	4 3 2 1
Jaffer A Ajani, MD	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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