

TOPIC INFO – 1ST DRAFT

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|--------------------|---|
| <b>TOPIC:</b>      | MANAGING INFLAMMATORY BOWEL DISEASE IN THE ERA OF PERSONALIZED MEDICINE |
| <b>SPEAKER:</b>    | TIMOTHY L. ZISMAN, MD, MPH  |
| <b>TITLE:</b>      | GASTROENTEROLOGIST  |
| <b>AFFILIATION</b> | DIGESTIVE DISEASE INSTITUTE, VIRGINIA MASON MEDICAL CENTER              |
| <b>TIME:</b>       | 30 minutes  |

**PRACTICE GAP ANALYSIS:** MANAGING INFLAMMATORY BOWEL DISEASE IN THE ERA OF PERSONALIZED MEDICINE

Describe the problems or gaps in practice this activity will address:

What are you trying to change?

Inflammatory bowel disease (IBD) is growing on a worldwide scale and is a chronic, frequently progressive condition that affects approximately 1.6 million people in the United States. Substantial room for improvement in the care of patients with IBD is needed. The outcomes of patients with IBD are diminished by multiple factors, including uncertainty about approaches to diagnosis, assessment, and treatment, as well as, a lack of knowledge about available therapies. To meet the persistent challenges associated with IBD management, health care professionals must be knowledgeable about the evidence-based and expert-recommended strategies for the treatment of patients with IBD to avoid disease flares, prevent structural damage and disability, and restore quality of life

Current therapies for IBD have not, yet, been able to prevent the need for surgical intervention in more than 50% of patients with IBD. Education for clinicians who manage patients with moderate-to-severe IBD about the immunopathophysiology of IBD and the latest available options to individualize IBD treatment can reduce the use of corticosteroids and need for hospitalizations or surgery, resulting in improved quality of life for these patients.

What is the problem?

Care of the inflammatory bowel disease (IBD) patient presents unique challenges, as decisions regarding therapy must consider numerous distinct characteristics of each patient. Beyond the dichotomy between Crohn’s disease (CD) and ulcerative colitis (UC), which may be difficult to ascertain in some patients, several distinct phenotypes exist within these diseases. IBD can be categorized by existing severity, location and extent, and potential for complications. It may be further categorized according to responsiveness to medical therapy. A number of individualized markers of disease, however, may allow for better prediction of response to therapy and disease course. Decisions for therapy must also be tailored to the comorbidities or risks of an individual patient, such as the risk of hepatosplenic T-cell lymphoma among men younger than 35 years.<sup>1</sup> As such, IBD constitutes an opportunity for personalized medicine, and strategies should be tailored to maximize the success of the current treatment, minimize loss of response to therapy or relapses in the future, and address the risks associated with specific medications for given patients.

How did you assess and/or measure these issues?

How was the educational need/practice gap for this activity identified? Place an X by each source utilized to identify the need for this activity.

Attach copies of documentation for each source indicated (REQUIRED)

\* please make sure when selecting your needs assessment data and references that you highlight applicable components.

**Method**

**Example of required document**

Previous participant evaluation data

Copy of tool and summary data

|   |                                 |                                |
|---|---------------------------------|--------------------------------|
|   | Research/literature review      | Abstract(s) or articles        |
| x | Expert Opinion                  | Summary                        |
|   | Target audience survey          | Copy of tool and summary data  |
|   | Regulatory body requirements    | Requirements summary           |
|   | Data from public health sources | Abstract, articles, references |
|   | Other (describe)                |                                |

Describe the needs of learners underlying the gaps in practice: What are the causes of the gaps in practice? Check all that apply

What are the causes of the gaps in practice? Check all that apply

|   |   |   |
|---|---|---|
| x | Lack of awareness of the problem,       | Poor self-efficacy,   |
|   | Lack of familiarity with the guideline, | Inability to overcome the inertia of previous practice, and |
|   | Non-agreement with the recommendations, | Presence of external barriers to perform recommendations    |
|   | Other                                   |   |

Why does the gap exist? Check all that apply

|   |  |  |
|---|--|--|
| x | Lack of Knowledge competence                 | Lack of time to assess or counsel patients |
|   | Performance-based.                           | Cost / Insurance/reimbursement issues      |
|   | Lack of consensus on professional guidelines | Patient Compliance Issues                  |
|   | Other:                                       |  |

What do learners need to be able to know or do to be able to address the gaps in practice?

- Need to have a proper understanding of the natural history and complications of IBD and how they impact treatment approach.
- Be knowledgeable of considerations in selecting therapy for patients with IBD
- Aware of strategies to optimize short- and long-term response to medication in IBD

#### CME OBJECTIVES MANAGING INFLAMMATORY BOWEL DISEASE IN THE ERA OF PERSONALIZED MEDICINE

State at least three or more things that participants should be able to do after they participate in this CME activity. Please note these objectives should be measurable, specific, actionable and timely.

**Upon completion of this activity, attendees should be able to:**

- 1 Review natural history and complications of IBD and how they impact treatment approach.
- 2 Describe considerations in selecting therapy for patients with IBD
- 3 Discuss strategies to optimize short- and long-term response to medication in IBD

**The ACCME does not want you to use the words** - think, understand, know, appreciate, learn, comprehend, be aware of, be familiar with, etc. as they are not measurable.

**You can use words such as** Analyze, Categorize, Classify, Compare, Conclude, Construct, Critique, Define, Demonstrate, Describe, Discuss, Evaluate, Identify, List, Name, Outline, Show

#### COMPETENCIES: MANAGING INFLAMMATORY BOWEL DISEASE IN THE ERA OF PERSONALIZED MEDICINE

What ACGME or IOM related competency is associated with this activity? (check all that apply)

|   |                   |   |   |                            |
|---|-------------------|---|---|----------------------------|
| x | Patient Care      | Practice-Based Learning and Improvement | x | Medical/Clinical Knowledge |
|   | Procedural Skills | Interdisciplinary Teams                 |   | Teams and Teamwork         |

|  |                      |                            |                         |
|--|----------------------|----------------------------|-------------------------|
|  | Communication Skills | Professionalism            | Systems-based Practice  |
|  | Quality Improvement  | Utilization of Informatics | Evidence-based Practice |

**What is the activity designed to change**

- Competence** - (knowing how to do something)  
Selecting this option requires the CME activity being planned provide participants with an opportunity to:
  - hear information related to advances or best practice
  - hear examples of application in practice of information presented
- Performance**- (actually doing something)  
Selecting this option requires the CME activity being planned provide participants with an opportunity to:
  - practice what they have learned during the CME activity
  - receive feedback about doing what they have learned during the CME activity
- Patient Outcomes**- (actually measure change in patients)  
Selecting this option requires the CME activity track change in patient outcomes:
  - provide tangible improvements and data to support overall change to patient outcomes

**What potential barriers do you anticipate attendees may encounter when incorporating new objectives into their practice?**

- |                                     |  |                   |
|-------------------------------------|--|-------------------|
| <input checked="" type="checkbox"/> | Lack of time to assess or counsel patients | Other – describe: |
|                                     | Cost                                       |                   |
|                                     | No perceived barriers                      |                   |
|                                     | Lack of administrative support/resources   |                   |
|                                     | reimbursement issues                       |                   |
|                                     | Insurance/                                 |                   |

**Describe how will this educational activity address these potential barriers and the strategies used?**

**RESULTS:** MANAGING INFLAMMATORY BOWEL DISEASE IN THE ERA OF PERSONALIZED MEDICINE

please describe the results expected (outcomes) for this activity in terms of specific improvements in patient care and/or other work related to the practice of medicine.

- Your description
- Improvements in patient care based on evidence-based treatment
  - Reduce Health care costs
  - Streamline care of patients

**MEASURING YOUR SUCCESS:** MANAGING INFLAMMATORY BOWEL DISEASE IN THE ERA OF PERSONALIZED MEDICINE

Will use pre-and post CME activity questionnaire to measure success.  
Please provide 3 questions and answers that will asked to the audience before and after your talk. The answer to these questions should be in your presentation. Please highlight the correct answer and limit your possible answers to a maximum of 4 with only one correct answer. The others can be partially correct or wrong

**Question 1. Which of the following is a risk factor for developing hepatosplenic T cell lymphoma among patients with inflammatory bowel disease?**

- Answers
- 1 Female sex
  - 2 Age > 65
  - 3 Azathioprine use
  - 4 Methotrexate use

**Feedback:**  
1. Female sex : correct Answer.

The correct answer is azathioprine (C). Hepatosplenic T cell lymphoma is a rare malignancy that has been associated with thiopurine immunosuppressants, including azathioprine and 6-mercaptopurine. Additional risk factors include male sex and age < 35. There is no association with methotrexate use.  
Reference: Kotlyar DS, Clin Gastroenterol Hepatol 2011

2. Age > 65: Wrong Answer.
3. Azathioprine use: Wrong Answer.
4. Methotrexate use: Wrong Answer.

Question 2: Which of the following factors improves response to infliximab in patients with Crohn's disease?

Answers

- 1 Long duration of disease
- 2 Combination therapy with azathioprine
- 3 Severe disease activity
- 4 Obesity

Feedback: Please provide a detail feedback (MOC)

1. Long duration of disease: Wrong Answer.
2. Combination therapy with azathioprine: Correct Answer.

The correct answer is combination therapy with azathioprine (B). The SONIC study demonstrated that combination therapy with infliximab and azathioprine was superior to either infliximab or azathioprine alone in treating Crohn's disease. Other factors that are associated with improved response to infliximab include shorter disease duration, less severe disease (as assessed by lower CRP and higher albumin). Obese patients have lower response rates to therapy than average weight patients.

References: Colombel JF, N Engl J Med 2010  
Ordas I, Clin Gastro and Hepatol 2012

3. Severe disease activity : Wrong Answer.
4. Obesity: Wrong Answer.

Question 3: A patient with Crohn's disease initially respond to infliximab but then develops a secondary loss of response. A trough infliximab level is drawn and shows an undetectable infliximab level with no antibodies to infliximab. Which of the following strategies is recommended to recapture response?

Answers

- 1 Increase infliximab dose
- 2 Switch to another medication in the same class (TNF antagonist)
- 3 Switch to another class of medication (vedolizumab or ustekinumab)
- 4 Add methotrexate

Feedback:

1. Increase infliximab dose: Wrong Answer.
2. Switch to another medication in the same class (TNF antagonist): Wrong Answer.
3. Switch to another class of medication (vedolizumab or ustekinumab): Correct Answer.

The correct answer is to increase the infliximab dose (A). Current guidelines recommend reactive therapeutic drug monitoring in patients with initial response to therapy who subsequently lose response. Those patients who have inadequate levels of infliximab with no antibodies to infliximab benefit from dose escalation. If the low infliximab level is associated with antibodies to infliximab, then increasing the dose is not likely to be effective. In this case, since the patient initially improved with a TNF antagonist it is advised to switch within the same drug class to another TNF antagonist. Patients who already have therapeutic levels of infliximab are not likely to improve with more infliximab or with another TNF antagonist so these patients should switch to another drug class to control their disease.

References: Feuerstein JD, Gastroenterol 2017  
Afif W, Am J Gastro 2009

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|--|--|------------------------------------|
|  |  | 4. Add methotrexate: Wrong Answer. |
|  |  |                                    |