

**2021**

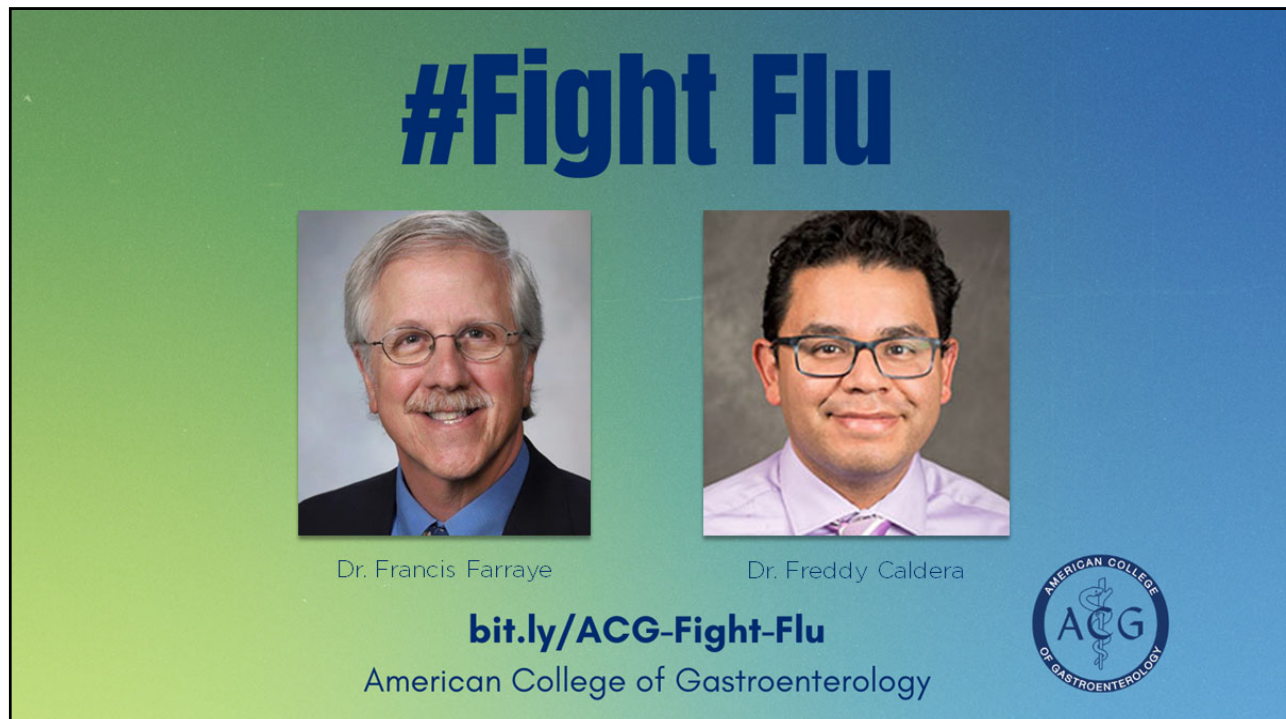
**ACG / LGS REGIONAL POSTGRADUATE COURSE**

**MARCH 5-7, 2021** | HILTON NEW ORLEANS RIVERSIDE  
NEW ORLEANS, LOUISIANA

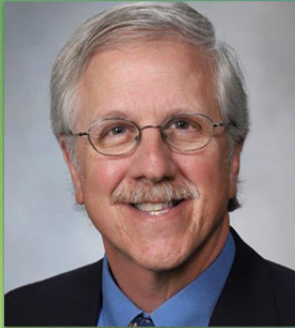
Register online: [meetings.gi.org](https://meetings.gi.org)

Welcome to the Virtual Grand Rounds Waiting Room – The educational activity will begin promptly at 12 Noon Eastern.


1



**#Fight Flu**




Dr. Francis Farraye



Dr. Freddy Caldera

[bit.ly/ACG-Fight-Flu](https://bit.ly/ACG-Fight-Flu)

American College of Gastroenterology



2



**2021**  

# ACG/FGS ANNUAL SPRING SYMPOSIUM

**FEBRUARY 26-28, 2021** | NAPLES GRANDE BEACH HOTEL  
NAPLES, FLORIDA

 Register online: [meetings.gi.org](https://meetings.gi.org)

Welcome to the Virtual Grand Rounds Waiting Room – The educational activity will begin promptly at 12 Noon Eastern.

3



# #Fight Flu

GI AND LIVER PATIENTS:  
WILL YOU FIGHT FLU?



[bit.ly/ACG-Fight-Flu](https://bit.ly/ACG-Fight-Flu)  
American College of Gastroenterology



4



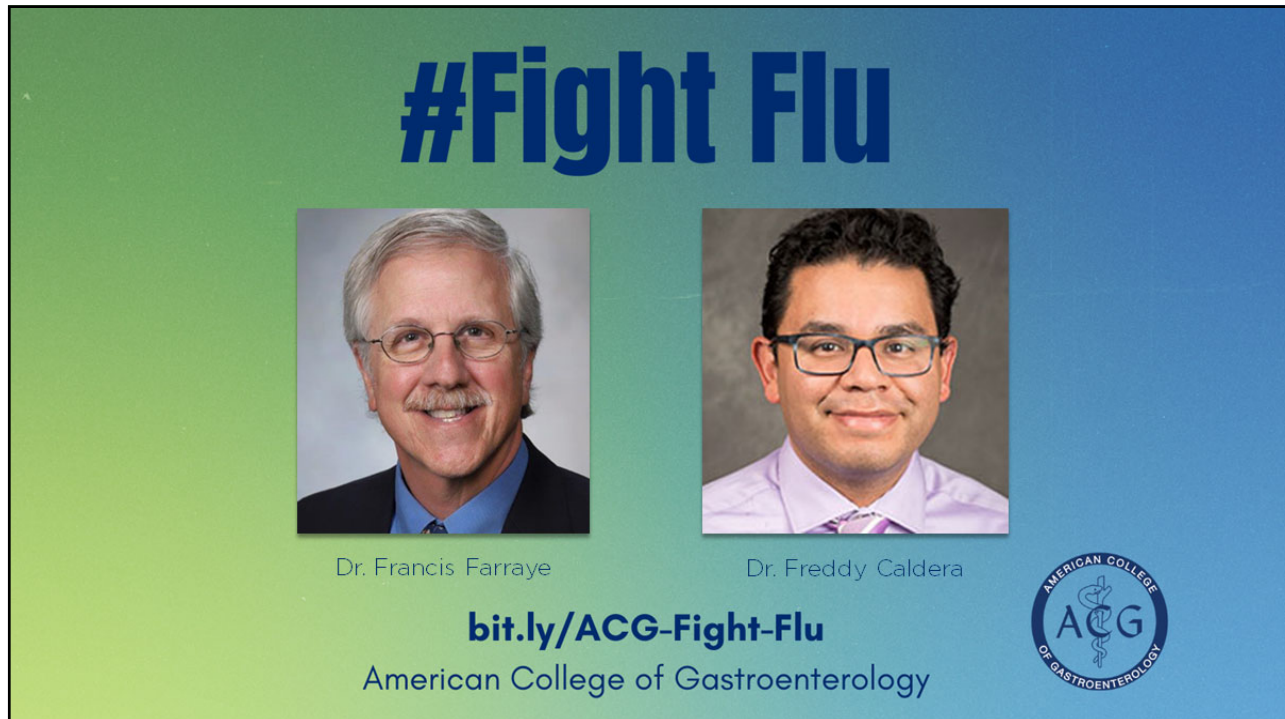


**2021**  
**ACG'S IBD SCHOOL**  
 JANUARY 30, 2021 | *Virtual!*

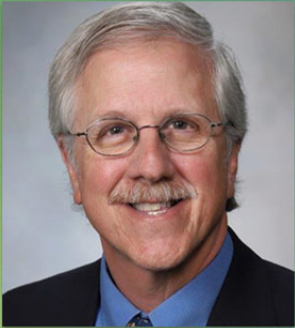

Register online: [meetings.gi.org](https://meetings.gi.org)

Welcome to the Virtual Grand Rounds Waiting Room – The educational activity will begin promptly at 12 Noon Eastern.

5




# #Fight Flu

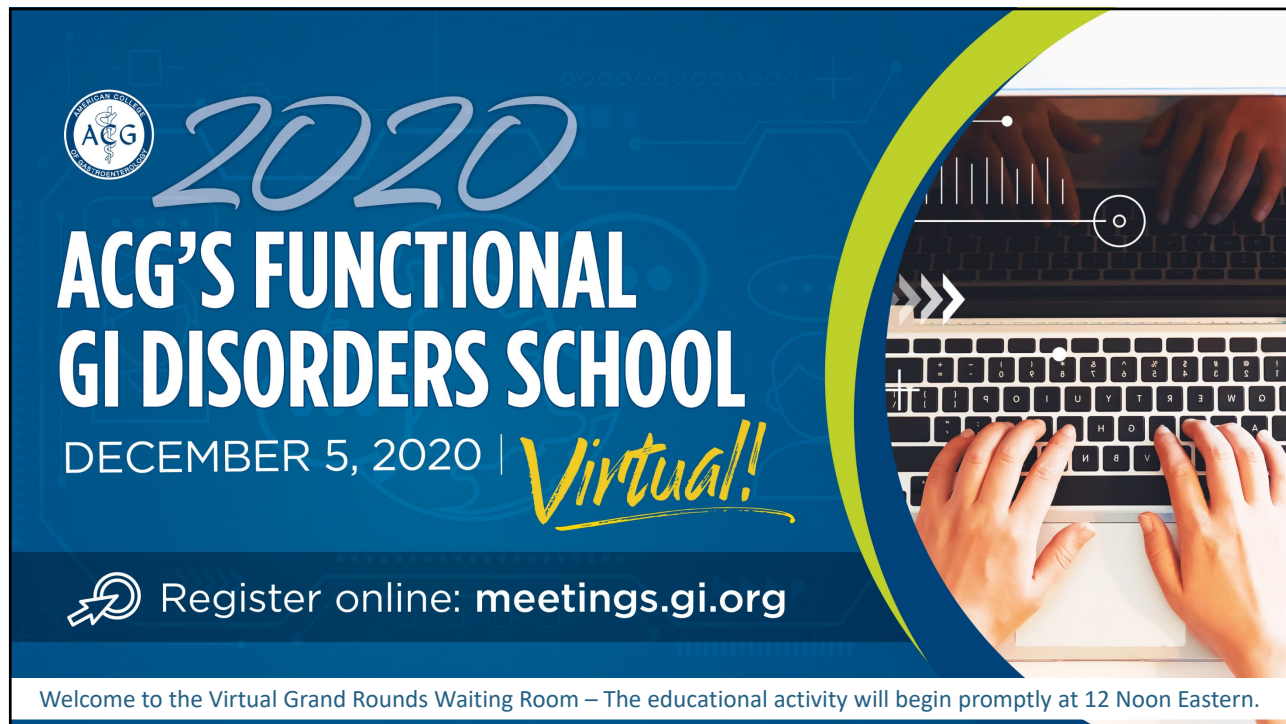
Dr. Francis Farraye


Dr. Freddy Caldera


**[bit.ly/ACG-Fight-Flu](https://bit.ly/ACG-Fight-Flu)**  
 American College of Gastroenterology



6



 **2020**  
**ACG'S FUNCTIONAL  
 GI DISORDERS SCHOOL**  
 DECEMBER 5, 2020 | *Virtual!*

 Register online: [meetings.gi.org](https://meetings.gi.org)

Welcome to the Virtual Grand Rounds Waiting Room – The educational activity will begin promptly at 12 Noon Eastern.

7



**#Fight Flu**  
 GI AND LIVER PATIENTS:  
 WILL YOU FIGHT FLU?



[bit.ly/ACG-Fight-Flu](https://bit.ly/ACG-Fight-Flu)  
 American College of Gastroenterology



8



**ACG INSTITUTE RESEARCH GRANTS AND AWARDS 2021**

SEVEN different award types; INCREASED Junior Faculty FUNDING;  
NEW Mid-Career Bridge Funding; Med Resident and Student Awards

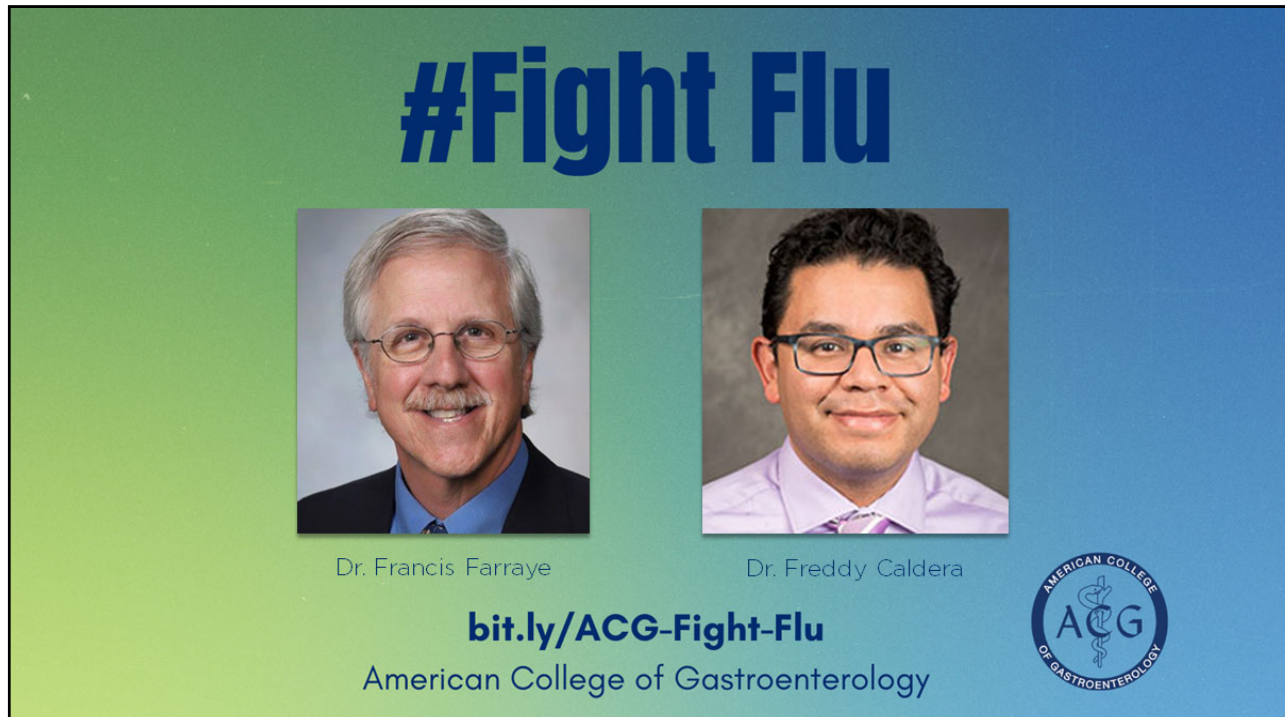
**[www.gi.org/research-awards](http://www.gi.org/research-awards)**

**Application Deadline: December 4, 2020**

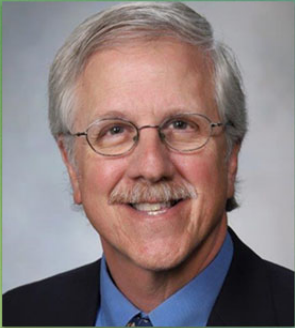

Read the [Grant Flyer](#), [FAQs](#), or visit the webpage for the RFAs.

Welcome to the Virtual Grand Rounds Waiting Room – The educational activity will begin promptly at 12 Noon Eastern.

9



# #Fight Flu





Dr. Francis Farraye

Dr. Freddy Caldera

**[bit.ly/ACG-Fight-Flu](https://bit.ly/ACG-Fight-Flu)**

American College of Gastroenterology



10



ACG Virtual Grand Rounds universe.gi.org

## Participating in the Webinar

All attendees will be muted and will remain in Listen Only Mode.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.

Meridith Test  
Webinar ID: 998-321-123  
This session is being recorded.  
GoToWebinar

11

ACG Virtual Grand Rounds universe.gi.org

## How to Receive CME and MOC Points

### LIVE VIRTUAL GRAND ROUNDS WEBINAR

ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

**ABIM Board Certified physicians need to complete their MOC activities by December 31, 2020 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2021 for this activity.**

12

ACG Virtual Grand Rounds universe.gi.org

## MOC QUESTION

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

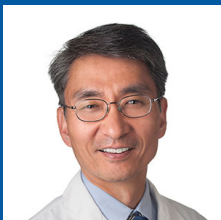
Include specific strategies or changes that you plan to implement.  
**THESE ANSWERS WILL BE REVIEWED.**

13


ACG Virtual Grand Rounds universe.gi.org

## ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!



**Week 36: New Therapeutic Options for EoE and EGIDs on the Horizon**  
 Ikuo Hirano, MD, FACG  
*December 10, 2020 at Noon EDT*



**Week 37: Choledochal Cysts: Recognition and Management**  
 Laith H. Jamil, MD, FACG  
*December 17, 2020 at Noon EDT*

**PLEASE NOTE:** There will be no ACG Virtual Grand Rounds on December 24 or 31 due to the holidays. We will begin again on Thursday, January 7, 2021.

**Visit [gi.org/ACGVGR](https://gi.org/ACGVGR) to Register**

14

ACG Virtual Grand Rounds universe.gi.org

## Disclosures:



**Speaker:**  
**Francis A. Farraye, MD, MSc, MACG**  
**Consulting Fee:** BMS, Braintree Labs, Gilead, GI Reviewers, GSK, Janssen, Pfizer, Sebela  
**Stockholder:** Innovation Pharmaceuticals  
**DSMB:** Lilly, Theravance

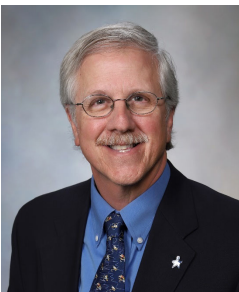


**Moderator:**  
**Samir A. Shah, MD, FACC**  
**Dr. Shah has no conflicts of interest related to this talk.**

15

ACG Virtual Grand Rounds universe.gi.org

## Vaccinations for Immunocompromised Patients with Inflammatory Bowel Disease and Chronic Liver Disease During the Covid Pandemic



**Francis A. Farraye, MD, MSc, MACG**  
**Professor of Medicine**  
**Department of Gastroenterology and Hepatology**  
**Director, Inflammatory Bowel Disease Center**  
**Mayo Clinic, Jacksonville, FL**  
**farraye.francis@mayo.edu**  
**@FarrayeIBD**

MAYO CLINIC

16



## Objectives

1. Appreciate the increased risk of infections in patients with IBD and chronic liver disease
2. Review necessary vaccinations for these patients
3. Review the status of Covid vaccines in 2020

17

## First “Vaccination” in 1796 by Dr. Edward Jenner

- Smallpox was rampant throughout the world and killed 10-20% of infected individuals and left 1/3<sup>rd</sup> of survivors blind
- Jenner’s observation: Cowpox is a mild disease; Milkmaids who contracted cowpox were subsequently immune from smallpox
- Dr. Jenner inoculated scrapings from cowpox skin lesions into a 8-year-old boy who developed mild symptoms
- When the 8-year-old was injected with smallpox skin scrapings 2 months later, no disease developed



Jenner coined the word “vaccine” from the Latin “vacca” or cow

18

## Health Maintenance in the Patient with IBD

- Patients with IBD do not receive preventive services at the same rate as general medical patients
- Patients with IBD often only see their GI MD, NP or PA and will identify these clinicians as their primary care provider
- Clarify the limits of your responsibilities with the patient; Delegate routine health care issues to the primary care team
- Offer guidance on the unique health maintenance needs in patients with IBD on immunomodulators and biologic agents
- Should certain health maintenance tasks such as vaccinations be the responsibility of the treating gastroenterologist?

Selby L, et al. Dig Dis Sci. 2011;56(3):819-24; Melmed GY. Inflamm Bowel Dis. 2012;18(1):41-2;  
Reich JS, et al. Dig Dis Sci. 2016 Aug;61(8):2205-16.

19

## Why are the Initial Visits with a Patient with IBD so Important?

**As many as 70% of IBD patients require immunosuppressive therapy at some time in their course**

Selby L, et al. Dig Dis Sci. 2011;56(3):819-24; Reich JS, et al. Dig Dis Sci. 2016 Aug;61(8):2205-16.

20

## Why Vaccination?

- Immunomodulators and biologics used to treat IBD puts patients at increased risk for infections
  - Multiple case reports of infections including fulminant hepatitis or fatal varicella
  - Risk of infection increases with the number of immunosuppressive therapies
  - Several of these are vaccine preventable
- IBD patients, like other patients on immunosuppressive therapy, are not being vaccinated appropriately **though we are doing better**

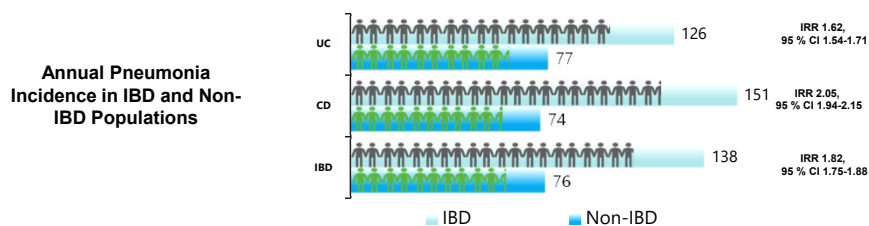
Keene JK, et al. JAMA. 1978;239:45-6.  
Domm S, et al. Br J Derm. 2008;159:1217-28.

21

## Patients With IBD Are at an Increased Risk of Pneumonia

Crude and Multivariate Analyses of Medication Use Within the Previous 120 Days and Pneumonia in Patients with IBD (N=108,361)

Medication	Crude OR, 95% CI	Adjusted OR, 95% CI
Biologic	2.83 (2.04-3.93)	1.32 (1.11-1.57)
Thiopurine	1.77 (1.49-2.11)	1.13 (1.00-1.27)
Corticosteroid	3.59 (3.14-4.10)	1.91 (1.75-2.12)



Long MD, et al. Am J Gastroenterol. 2013 Feb;108(2):240-8.

22

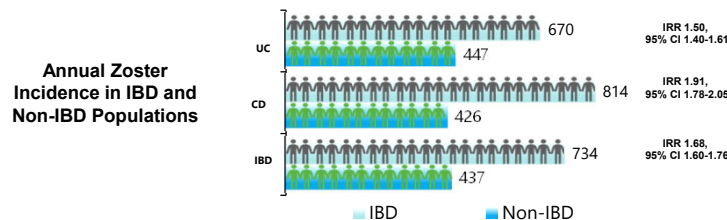


## Patients With IBD Are at an Increased Risk of Herpes Zoster

Crude and Multivariate Analyses of Medication Use Within the Previous 120 Days and Zoster in Patients with IBD (N=108,361)

Medication	Crude OR, 95% CI	Adjusted OR, 95% CI
Biologic	3.85 (2.47-6.00)	1.81 (1.48-2.41)
Thiopurine	2.20 (1.73-2.78)	1.85 (1.62-2.13)
Corticosteroid	2.83 (2.34-3.43)	1.73 (1.52-1.99)

Anti-TNF and thiopurine therapy  
(OR: 3.29, 95% CI: 2.33-4.65)



Long MD, et al. Aliment Pharmacol Ther. 2013;37(4):420-9.

23

## Best Practices in Vaccinations

- The ideal time to obtain a vaccination history is during the initial office visit(s)
- Patients should be vaccinated prior to starting immunosuppressive therapy
- If vaccinations are not offered in your office, write a prescription for your patient to take to their local pharmacy
- Necessary IBD therapy should never be delayed in order to administer vaccines

Reich J, et al. Gastro Hepatol. 2017;13(12):717-50.

24

# Vaccinating the IBD Patient

25

## Who Owns Vaccinations?

### •Survey of 109 Gastroenterologists (2011)

- Only 50% of GI providers ask about vaccinations always or most of the time with associated poor knowledge of appropriate vaccinations
- Poor knowledge regarding the appropriate vaccines to recommend
- Majority thought PCP was responsible for determining which vaccinations to give (65%) and administering the vaccine (83%)

### •Survey of 61 PCPs (2010)

- Only 30% felt comfortable coordinating vaccinations for the immunosuppressed IBD patient

Wasan SK, et al. Inflamm Bowel Dis. 2011;17(12):2536-40; Selby L, et al. Dig Dis Sci. 2011;56:819-824.

26

## IDSA Guidelines 2013

**“Specialists who care for immunocompromised patients...**

***...share responsibility with the primary care provider for ensuring that appropriate vaccinations are administered to immunocompromised patients.”***

***...share responsibility with the primary care provider for recommending appropriate vaccinations for members of immunocompromised patients’ household.”***

Rubin L, et al. Clin Infect Dis. 2013;58(3):1-57.

27

## ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease

Francis A. Farraye, MD, MSc, FACP<sup>1</sup>, Gil Y. Melmed, MD, MS, FACP<sup>2</sup>, Gary R. Lichtenstein, MD, FACP<sup>3</sup> and Sunanda V. Kane, MD, MSPH, FACP<sup>4</sup>

Recent data suggest that inflammatory bowel disease (IBD) patients do not receive preventive services at the same rate as general medical patients. Patients with IBD often consider their gastroenterologist to be the primary provider of care. To improve the care delivered to IBD patients, health maintenance issues need to be co-managed by both the gastroenterologist and primary care team. Gastroenterologists need to explicitly inform the primary care provider of the unique needs of the IBD patient, especially those on immunomodulators and biologics or being considered for such therapy. In particular, documentation of up to date vaccinations are crucial as IBD patients are often treated with long-term immune-suppressive therapies and may be at increased risk for infections, many of which are preventable with vaccinations. Health maintenance issues addressed in this guideline include identification, safety and appropriate timing of vaccinations, screening for osteoporosis, cervical cancer, melanoma and non-melanoma skin cancer as well as identification of depression and anxiety and smoking cessation. To accomplish these health maintenance goals, coordination between the primary care provider, gastroenterology team and other specialists is necessary.

**SUPPLEMENTARY MATERIAL** is linked to the online version of the paper at <http://www.nature.com/ajg>

Am J Gastroenterol advance online publication, 10 January 2017; doi:10.1038/ajg.2016.537

Farraye FA, et al. Am J Gastroenterol. 2017 Feb;112(2):241-258.

28



ACG Virtual Grand Rounds universe.gi.org

**Annals of Internal Medicine** CLINICAL GUIDELINE

**Recommended Adult Immunization Schedule, United States, 2020\***

Mark Freedman, DVM, MPH; Andrew Kroger, MD, MPH; Paul Hunter, MD; and Kevin A. Ault, MD; for the Advisory Committee on Immunization Practices†

Freedman M, et al. Ann Intern Med. 2020 Mar 3;172(5):337-34.

29

ACG Virtual Grand Rounds universe.gi.org

**Vaccines to Consider**

**IBD is rare before age 5 so most patients have received all their childhood vaccines**

**In adults, consider hepatitis A, hepatitis B, HPV, influenza, pneumococcal, herpes zoster and varicella vaccinations**

30

## Will the Vaccine Work or Worsen the IBD?

- **Diminished immune response in patients on anti TNFs alone or with immunomodulators but not with vedolizumab**
- **No evidence that vaccination exacerbates IBD**

Melmed GY, et al. Am J Gastroenterol. 2010; 105:148–154; Dotan I, et al. Inflamm Bowel Dis. 2012;18(2):261-8; Fiorino G, et al. Inflamm Bowel Dis. 2012;18(6):1042-7; Wyant T, et al. Gut. 2015 Jan;64(1):77-83.

31

## Safety of immunizations for the patient with IBD: A systematic review and meta-analysis

- **The primary outcome of interest was the incidence of adverse events and IBD flares among vaccinated patients in a literature review of studies evaluating the safety of vaccinations**
- **Out of 2438 articles reviewed, 13 studies with 2116 participants were included**
- **Ten studies reported local adverse events with a pooled incidence of 24% (95% CI: 9-42%), similar to those reported in clinical trials in non IBD patients**
- **Systemic adverse reactions were mostly mild, without resulting in hospitalizations or deaths with a pooled incidence of 16% (95% CI: 6-29%) for all vaccines**
- **Increased activity after immunization was found with pooled incidence of 2% (95% CI: 1-4%) for all vaccines**

Desalermos A, et al. ACG 2020, S0736

32



## New Adjuvant Recombinant Hepatitis B Vaccine (Heplisav-B)

- FDA approved 2-dose hepatitis B vaccine in November 2017, given over one month instead of 6 months
- HepB-CpG vaccine is a yeast-derived vaccine prepared with a novel adjuvant recommended for use in all patients over the age of 18
- Seroprotective anti-HBs after two doses of HepB-CpG versus three doses of Engerix-B were 95.4 versus 81.3 percent, respectively
- Potentially immune-mediated adverse events 0.1%-0.2% (HEPLISAV-B) vs. 0.0%-0.7% (comparator)
- To date, there have been no published studies examining this new vaccine in patients with IBD

Schillie S, et al. Morb Mortal Wkly Rep. 2018 Apr 20;67(15):455-458.

33



## Zoster Vaccine Recombinant, Adjuvanted (Shingrix)

- Zoster Vaccine Recombinant, Adjuvanted indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older
- Administer 2 doses IM (0.5 mL each) at 0 and 2 to 6 months
- After a mean follow-up of 3.2 years, the overall vaccine efficacy was 97.2% (95% CI, 93.7%-99.0%), compared with placebo
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)
- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)

Lal H, et al. N Engl J Med. 2015;372(22):2087-96.

34



## Recommendations for the Use of Herpes Zoster Vaccines

### Zoster Vaccine Recombinant, Adjuvanted (Shingrix)

In October 2017, the Advisory Committee on Immunization Practices (ACIP) made the following three recommendations:

1. Recombinant zoster vaccine (RZV) is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged  $\geq 50$  years.
2. RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL).
- ~~3. RZV is preferred over ZVL for the prevention of herpes zoster and related complications.~~
4. ZVL is no longer available in the United States

Dooling KL, Guo A, Patel M, et al. Morb Mortal Wkly Rep 2018;67:103–108.

35

## Safety of Recombinant Vaccine (RZV) in Patients with IBD

- RZV administered between February 2018 and July 2019
- Sixty-seven patients received at least one dose of RZV
- Of these, 55 (82%) receive two doses
- Median duration of follow-up was 207 days and no cases of herpes zoster identified
- Local and systemic adverse reactions reported in 74.6 and 56.7% of patients respectively c/w reported rates in clinical trials
- One patient flared (1.5%) several days after 2<sup>nd</sup> Shingrix dose

Satyam VR, et al. Dig Dis Sci. 2020 Oct;65(10):2986-2991.

©2020 MYMER | slide 36

36



[universe.gi.org](https://universe.gi.org)