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Virtual Grand Rounds

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Application Deadline: November 10, 2023
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Request for Applications

GRADE Methodologists
for **ACG** Guidelines

APPLICATION DEADLINE:
➔ December 15, 2023


Those selected will be required to participate and complete the International Guideline Development Credentialing & Certification Program through McMaster University. The onsite training will be in Spring 2024 and is sponsored by the ACG. Applicants must agree to a 5-year term as a GRADE Methodologist.

Want to Learn More?
GRADE INFORMATION SESSION IN VANCOUVER:
Sunday October 22 3:30-4pm Room 111-112

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Participating in the Webinar



Moderator:
Francis A. Farraye, MD, MS,
MACG

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.

A handout with the slides and room to take notes can be downloaded from your control panel.

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ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!




Week 45 – Thursday, November 9, 2023
 Pharmaceutical and Device Clinical Research in the GI Practice: A Win-Win for Your Patients and Your Practice
 Faculty: Deepinder Goyal, MD, MSCR
 Faculty: Shajan Peter, MD, FACP
 Moderator: Sapna Thomas
At Noon and 8pm Eastern



Week 46 – Thursday, November 16, 2023
 Hemochromatosis
 Faculty: Manida Wungjiranirun, MD
 Moderator: Rebecca G. Kim, MD
At Noon and 8pm Eastern

Visit gi.org/ACGVGR to Register

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ACG Standard Slide Decks

Colorectal Cancer Screening and Surveillance Slide Deck

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Disclosures



Freddy Caldera, DO, MS, FACG:
 Research support from Novavax, Janssen, and Takeda Pharmaceuticals. He has been a consultant for Takeda, Arena Pharmaceuticals, GSK, and Celgene.



Francis A Farraye, MD, MSc, MACG:
 Consulting Fee: AbbVie, Avalo Therapeutics, BMS, Braintree Labs, Fresenius Kabi, GI Reviewers, GSK, IBD Educational Group, Iterative Health, Janssen, Pharmacosmos, Pfizer, Sandoz Immunology, Sebela, Viatrix
 DSMB: Lilly
 Research Support to Mayo: BMS, Creatics, Janssen, Takeda


*All of the relevant financial relationships listed for these individuals have been mitigated

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2023 Vaccine Update for Gastroenterologist

Freddy Caldera, DO, MS, FACG
Associate Professor of Medicine
Division of Gastroenterology & Hepatology
University of Wisconsin-Madison, School of
Medicine & Public Health
[@dr_fcalderaibd](#)



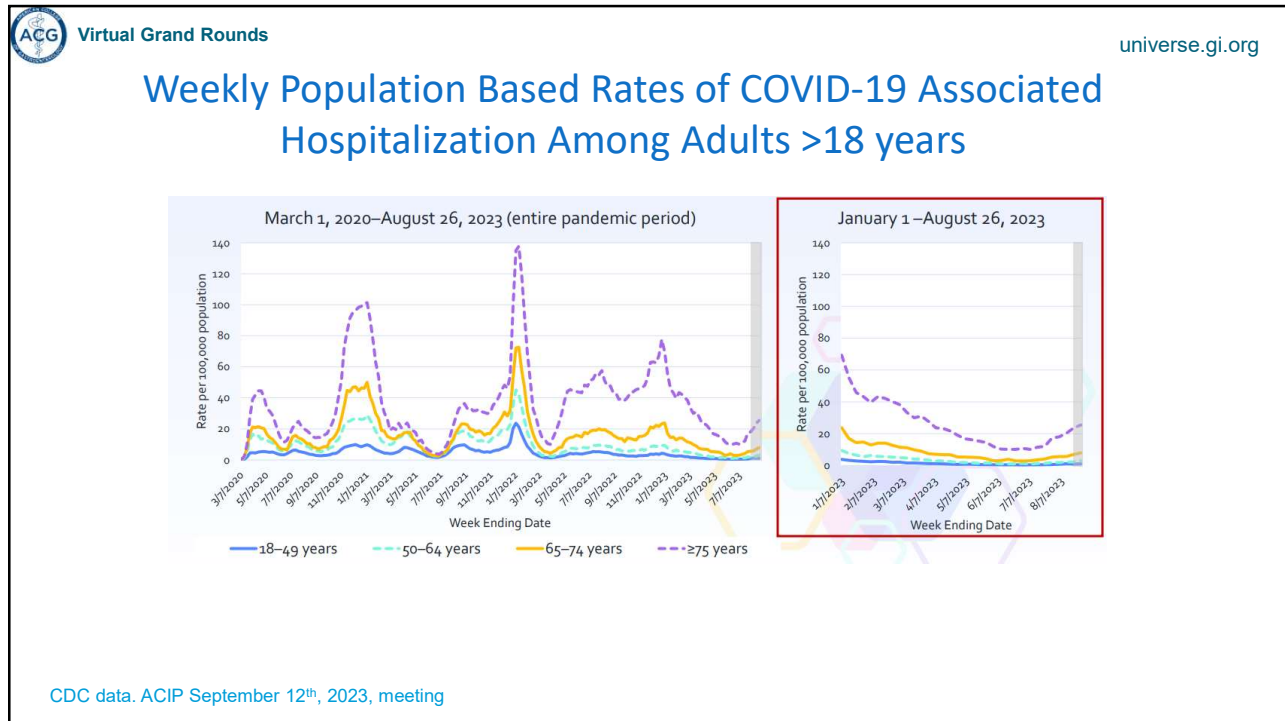
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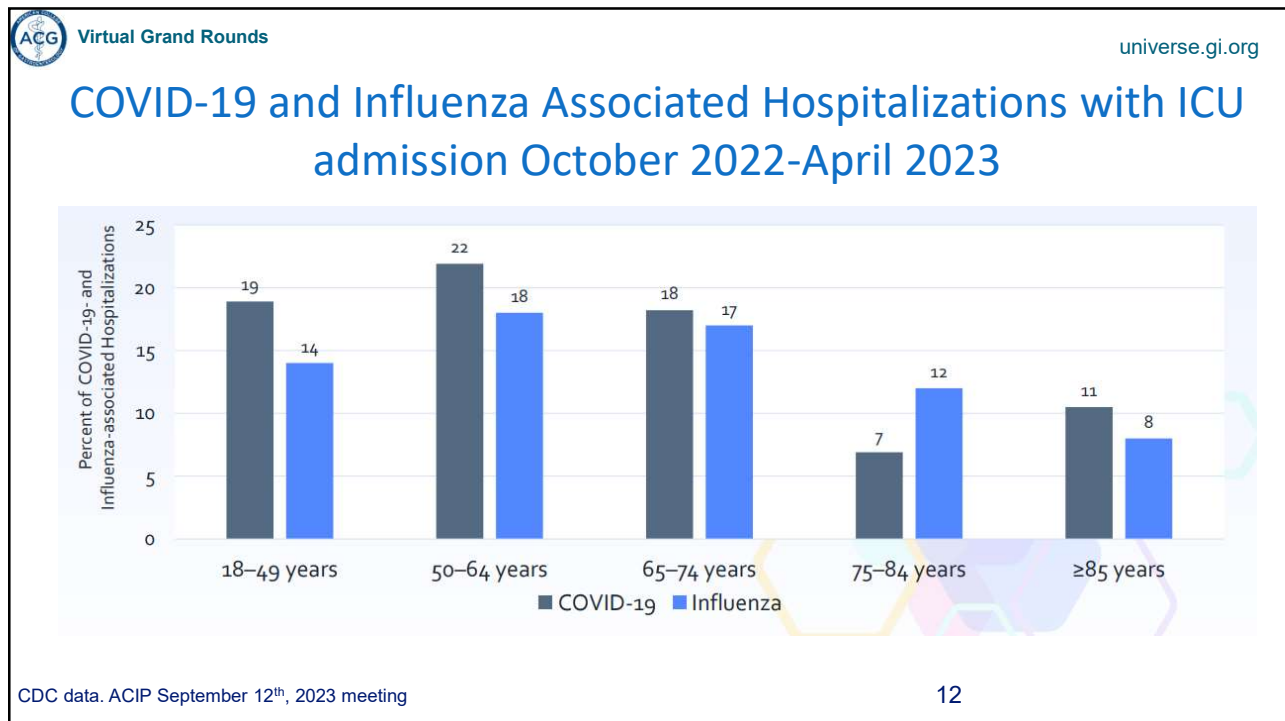
Objectives

- Educate gastroenterology providers on new vaccine recommendations from the Advisory Committee on Immunization Practice
- Discuss new COVID-19 vaccine Recommendations
- Discuss RSV vaccine
- Optimal immunization schedule for patients with IBD

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Post COVID-19 Conditions among Adults

Approximately **1 in 5 adults** ages 18+ have a health condition that might be related to their previous COVID-19 illness, such as:

- Neurologic and mental health conditions*
- Cardiovascular conditions
- Kidney failure
- Respiratory conditions
- Musculoskeletal conditions
- Blood clots and vascular issues

Talk to your health care provider if you have symptoms after COVID-19

bit.ly/MMWR7121 MAY 24, 2022 * Adults aged 65 and older at increased risk **MMWR**

Bull-Otterson L, et al. MMWR Morb Mortal Wkly Rep 2022;71:713–717

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Increased Risk of Herpes Zoster in Adult Patients with Inflammatory Bowel Disease After SARS-CoV2 Infection

Era	Overall IBD	Overall UC	Overall CD
Pre-vaccine era	3.49 (1.92-6.36), p<0.0001	2.16 (1.05-4.43), p=0.03	2.51 (1.28-4.93), p=0.005
Post-vaccine era	3.04 (1.48-6.24), p=0.001	2.67 (1.32-5.39), p=0.004	2.16 (1.15-4.04), p=0.01

↑ risk of HZ →

aOR (95% CI)

Desai A, et al. Inflamm Bowel Dis. 2023. OXFORD UNIVERSITY PRESS

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Current COVID-19 vaccine Monovalent COVID-19 vaccine booster

The 2023–2024 formulation for all COVID-19 vaccines licensed or authorized in the United States (Moderna, Novavax, and Pfizer-BioNTech) has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2.

The Original monovalent and bivalent (Original and Omicron BA.4/BA.5) formulations should no longer be used.

Three vaccines are available (none of the vaccines are preferred over another)

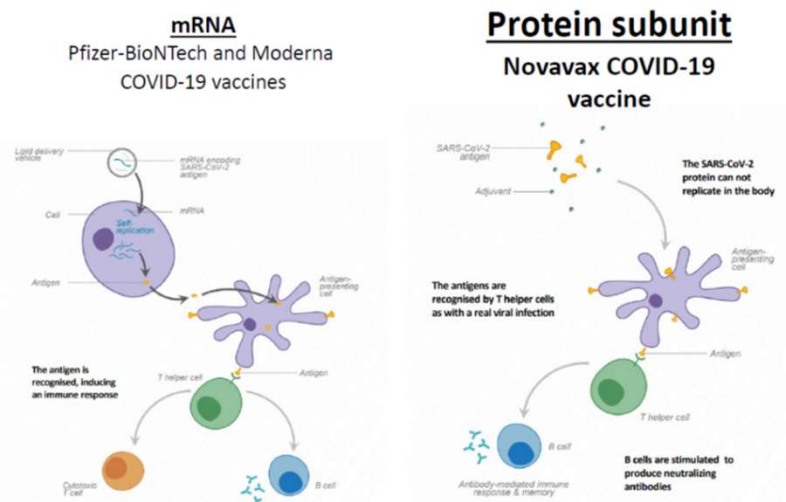
- Moderna (mRNA)
- Pfizer (mRNA)
- Novavax (recombinant vaccine)

<https://www.cdc.gov/vaccines/acip/recommendations.html>

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Mechanism of action of authorized COVID-19 vaccines



<https://www.cdc.gov/vaccines/acip/recommendations.html>

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Mechanism of action of Novavax COVID-19 Vaccines

- Components of Novavax COVID-19 vaccine, Adjuvanted, include:
 - SARS-CoV-2 recombinant spike (rS) protein is purified, full-length, and stabilized in its prefusion conformation
- Matrix-M™ adjuvant facilitates activation of the cells of the innate immune system, which enhances the magnitude of the spike protein-specific immune response
- These two vaccine components elicit B- and T-cell immune responses to the spike protein, including neutralizing antibodies, which protect against COVID-19

Dunkle LM, et al. N Engl J Med. 2022 Feb 10;386(6):531-543.

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Randomized clinical trials evaluating efficacy of COVID-19 vaccines

Incidence of Symptomatic Covid-19 in the Per-Protocol Population

	Vaccine Efficacy (95% CI)	Placebo	NVX-CoV2373
Per-Protocol Population	89.7% (80.2 to 94.6)	96/7019	10/7020
Non-B.1.1.7 Variant	96.4% (73.8 to 99.5)	28/7020	1/7020
B.1.1.7 Variant	86.3% (71.3 to 93.5)	58/7020	8/7020

NVX-CoV2373 Vaccine

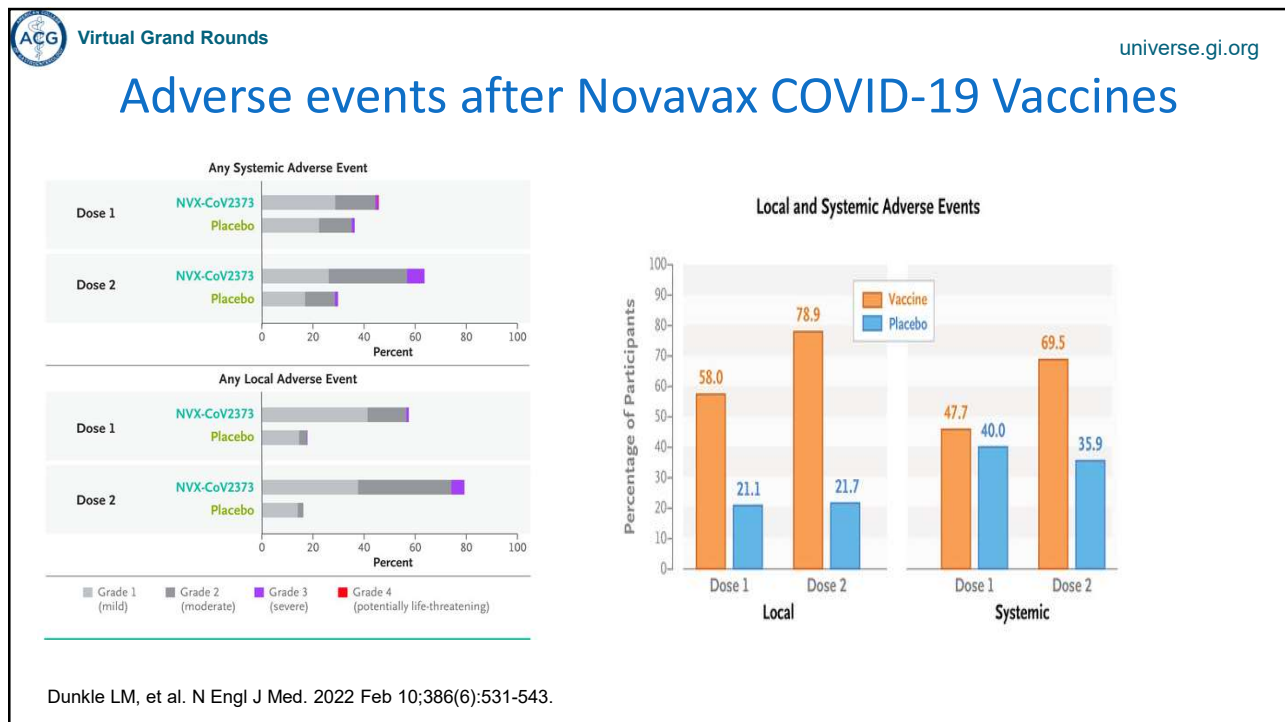
Vaccine Efficacy
90.4%
95% CI, 82.9 to 94.6
P<0.001

Placebo

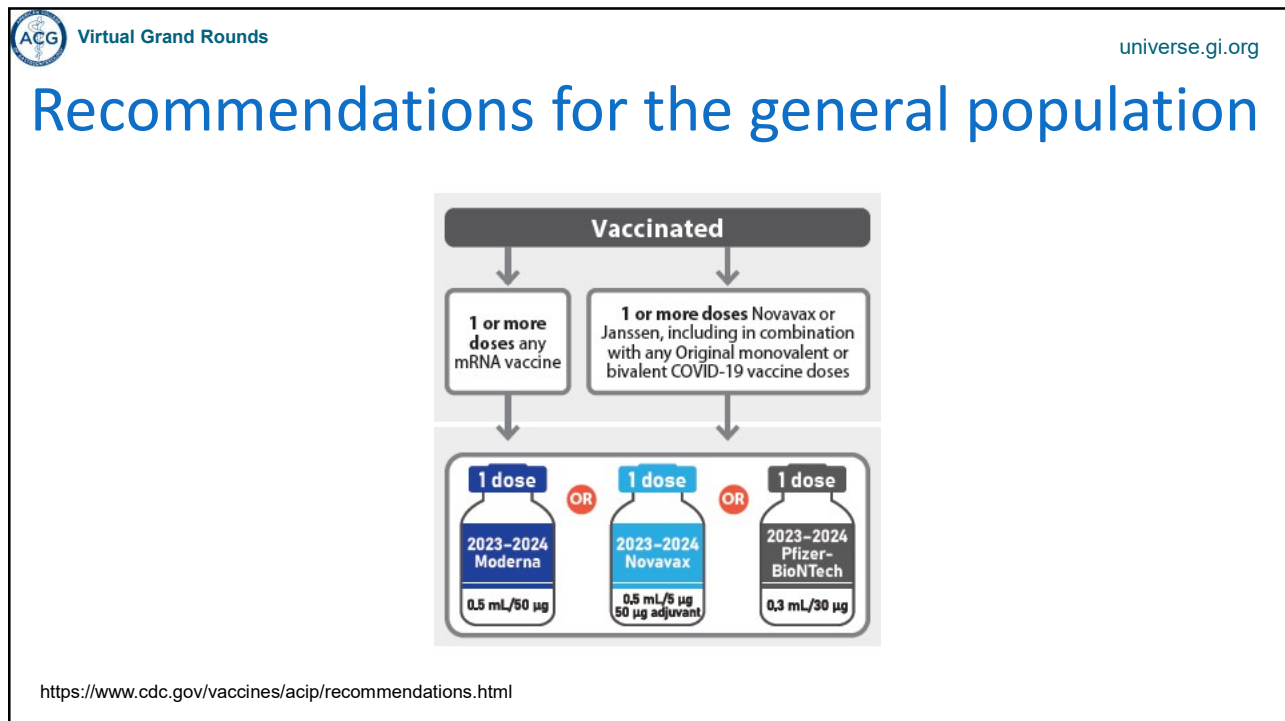
Confirmed, Symptomatic Covid-19 (at least 7 days after the second dose)

Dunkle LM, et al. N Engl J Med. 2022 Feb 10;386(6):531-543.

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Recommendations for immunosuppressed populations

- Previously vaccinated individuals with a primary COVID-19 series should receive 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Additional doses: May receive 1 or more additional doses of an updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) following the last recommended updated (2023–2024 Formula) COVID-19 vaccine dose at least 8 weeks from last dose.

<https://www.cdc.gov/vaccines/acip/recommendations.html>

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Moderate to Severely Immunocompromised People

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that

*General Best Practice Guidelines for Immunization, CDC Yellow Book, IDSA 2013 guidelines

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Summary of studies evaluating antibody response and after COVID-19 vaccination in patients with IBD

- Majority of patients are seropositive
- Patients with IBD have lower antibodies than non-IBD patients
- Vedolizumab, ustekinumab not associated with lower antibodies
- Increased antibody responses are seen after three doses or boosters of COVID-19 vaccines.
- Response is sustained for six months
- Response is higher after SARS-CoV2 infection
- Lower antibody Response
- Antibody response may be blunted in some groups
- On >20mg of steroids for >2 weeks
- Those on Anti-TNF therapy
- Tofacitinib
- Ozanimod?
- Limited data on
 - Upadacitinib
 - Rizankizumab
 - Etrasimod

Caldera F, et al. ACG. 2022;117(1):176-179.
 Lin S, et al. Nat Commun. 2022;13(1):1379
 Long MD, et al. Clinical gastroenterology and Hepatology (2022)
 Schell TL, et al. Inflamm Bowel Dis. 2022
 Li D, et al. Inflamm Bowel Dis. 2022

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Timing considerations for Patients with Current or Prior SARS-CoV-2 Infection

- Consider delaying any COVID-19 vaccination by 3 months from symptom onset or positive test (if asymptomatic)

ACIP: Interim Clinical Considerations

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Coadministration of COVID-19 vaccines with Other Vaccines

- Routine administration of all age-appropriate doses of vaccine
- Offer influenza and COVID-19 vaccines at the same visit
- Remember new recommendations for influenza vaccines in patients >65 years of age.
 - Get an influenza vaccine that is recommended for all adults.

ACIP: Interim Clinical Considerations

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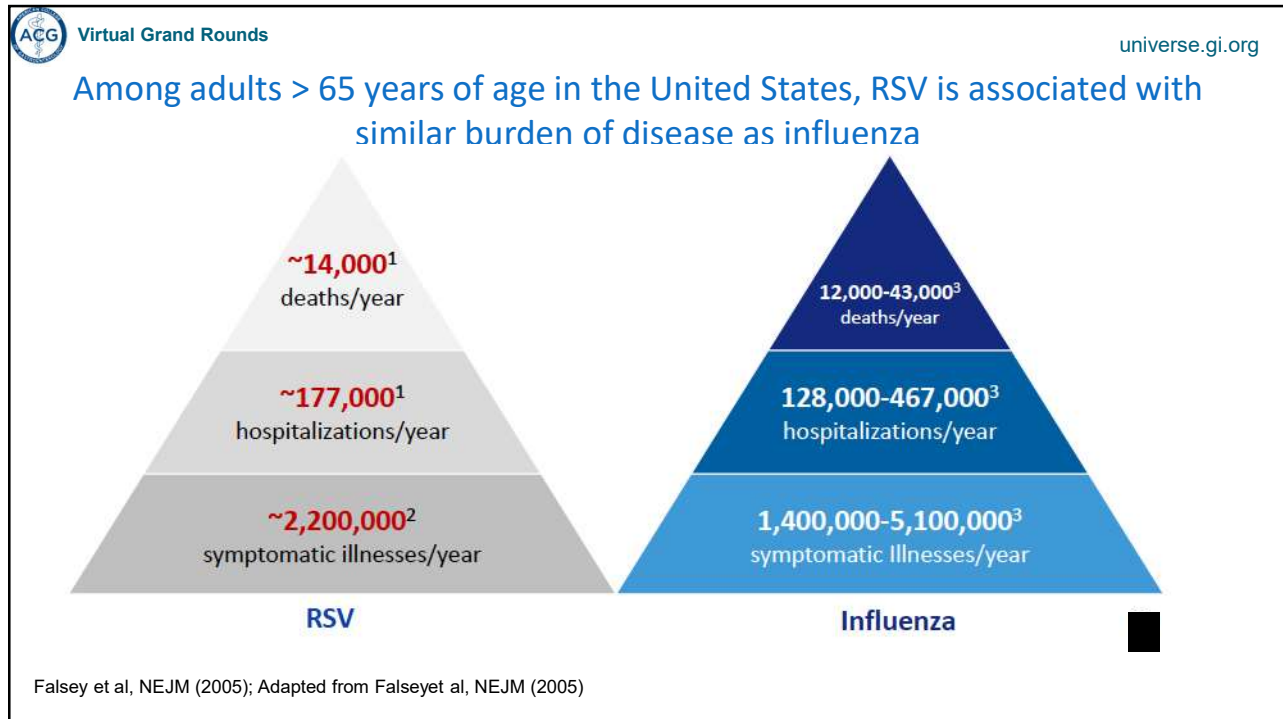


Respiratory Syncytial Virus Epidemiology

- Frequent cause of severe respiratory illness in older adults
- Lower awareness of RSV in adults among healthcare providers and the public
- Under detection: RSV testing often not performed
- No specific recommended vaccine or treatment

Falsey et al, NEJM (2005); Adapted from Falsey et al, NEJM (2005)

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Underlying medical conditions and other factors associated with increased risk for severe RSV disease

- **Chronic underlying medical conditions associated with increased risk**
 - Lung disease (such as chronic obstructive pulmonary disease and asthma)
 - Cardiovascular diseases (such as congestive heart failure and coronary artery disease)
 - Moderate or severe immune compromise*
 - Diabetes mellitus
 - Neurologic or neuromuscular conditions
 - Kidney disorders
 - Liver disorders
 - Hematologic disorders
 - Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease
- **Other factors associated with increased risk**
 - Frailty
 - Advanced age
 - Residence in a nursing home or other long-term care facility
 - Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease

Melgar M., et al. MMWR Morb Mortal Wkly Rep 2023;72:793–801

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Respiratory Syncytial Virus Vaccines

- Two RSV vaccine currently approved for adults 60 years and older
- The two vaccines are non-live recombinant vaccines.
- Shared clinical decision-making recommendation from ACIP.
- Arexvy is adjuvanted recombinant subunit vaccine GSK
- Abrysvo unadjuvanted bivalent recombinant subunit vaccine Pfizer

Smith R. et al. Inflammatory Bowel Diseases 2023

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Patients with IBD are at Increased Risk for Serious Infections due to RSV

Analyses	Risk for Hospitalization				
	IBD cohort N (%)	Control cohort N (%)	aOR	95% CI	p value
Age groups					
≥ 18 years old	318 (47.3%)	267 (39.7%)	1.36	1.09-1.69	0.005
18-49 years old	82 (36.7%)	56 (25.1%)	1.73	1.15-2.60	0.007
≥ 50 years old	236 (52.6%)	212 (47.3%)	1.23	0.95-1.61	0.10
≥ 60 years old	195 (54.1%)	173 (48%)	1.27	0.95-1.71	0.10
≥ 65 years old	162 (56.4%)	136 (47.3%)	1.43	1.03-1.99	0.02

- Cases requiring hospitalization: 317 in IBD, 30,466 in non-IBD cohorts
- Youngest and oldest cohorts at risk for hospitalization
- No difference in complications during hospitalization
- Mortality rate of IBD cohort was 4.7%

Smith R. et al. ACG 2023

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Patients with IBD and RSV vaccination

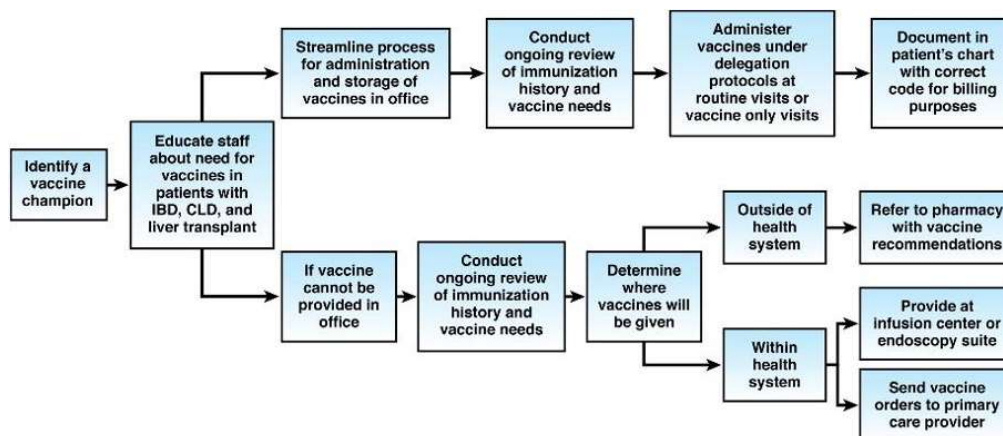
- Gastroenterology providers should educate patients on their increased risk from RSV and serious infections due to RSV.
- Strongly recommend vaccination to all eligible patients

Smith R. et al. ACG 2023

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How to Implement a Successful Vaccination Program in Outpatient Gastroenterology Practices



Bhat S, et al Gastroenterology 2023 Jun;164(7):1047-1051

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Evidence-based Strategies for Increasing Immunization in Gastroenterology and Hepatology Clinics During COVID-19

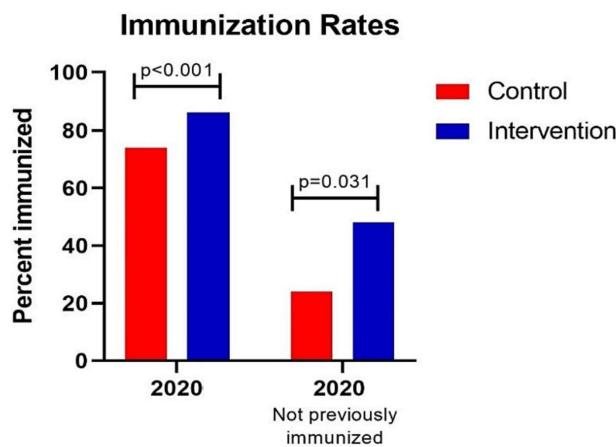
Intervention	Level of evidence	Example
Client reminder and recall systems	Strong	Reminder letter or message to patient
Provider assessment and feedback	Strong	Evaluate provider or practice performance
Provider reminders	Strong	Prompt in electronic health record to administer vaccine
Standing orders	Strong	Delegation protocols so medical assistant, nurses, or pharmacist can provide vaccines
Immunization information systems	Strong	State immunization registries
Home visits	Strong	Healthcare worker administering vaccine during routine home visit
Healthcare system-based interventions implemented in combination	Strong	Multiple proven interventions including standing orders, provider reminders, assessment and feedback, client reminders, and expanded access
Increase access	Strong	Immunization in infusion center, blood draws, local pharmacies

Lutz M, et al. Clin Gastroenterol Hepatol. 2020 Dec;18(13):2868-2872

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Providing influenza vaccines at endoscopy visits increases influenza vaccine uptake



Golovkina MI, et al. Vaccine. 2023 Oct 13;41(43):6403-6405.

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Optimized Immunization Schedule for patients with IBD

Vaccine	Recommendations
COVID-19 vaccine	Follow Recommendations for General population- new monovalent booster
Influenza vaccine	All patients Older adults >65 years of age High Dose, Recombinant or Adjuvant Vaccine Those on Anti-TNF monotherapy High dose influenza vaccine
PCV 15, PCV 20 or PPSV 23	All patients with IBD 19 years of age and older on immunosuppressive therapy
Recombinant Herpes Zoster Vaccine	All patients with IBD 19 years of age and older
Hepatitis B vaccine	All adult patients with IBD not previously up to age 60.
HPV vaccine series	All adults up to age 26 27-45* shared clinical decision
Respiratory Syncytial Virus (RSV)	All adult patients 60 years of age and older

Caldera F, et al . Am J Gastroenterol. 2020 Sep;115(9):1356-1361.

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

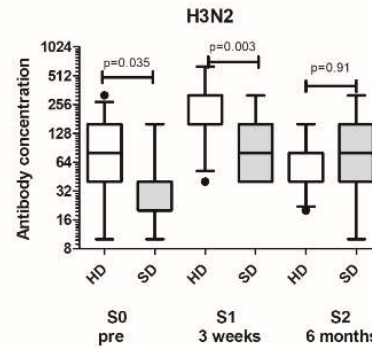
- A total of 13 with 2116 patients
- Ten studies reported local adverse events with a pooled incidence of 24% (95% CI: 9-42%)
- Systemic adverse reactions were mostly mild, a pooled incidence of 16% (95% CI: 6-29%) for all vaccines
- IBD flares 2% (95% CI: 1-4%) for all vaccines

Desalermos A, et, al Inflamm Bowel Dis. 2022 Sep 1;28(9):1430-1442..

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Which Influenza vaccine?

- Influenza vaccine for all patients
- Older Adults >65
 - HD dose, recombinant or adjuvanted.
- Consider HD dose influenza vaccine for those anti-TNF monotherapy
- Use local pharmacy, infusion centers, & GI or PCP clinic to provide vaccines.



Caldera F, et al. *Inflamm Bowel Disease*. 2020 Mar 4;26(4):593-602
 Grohskopf LA, et al. *MMWR Recomm Rep* 2022;71

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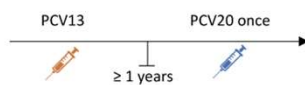
Simplified Immunization Scheduled for Pneumococcal

Patient with IBD and age 19-64 years on immunosuppressive therapy

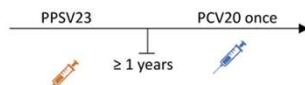
A. Patients not previously vaccinated or whose previous vaccination status is unknown:



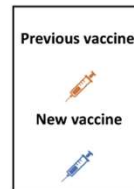
B. Patients previously vaccinated with PCV13:



C. Patients previously vaccinated with PPSV23:



D. Patients previously vaccinated with both PCV13 and PPSV23:



Mazen A, et al. *Crohn's Colitis* 360 2023 (in-press)


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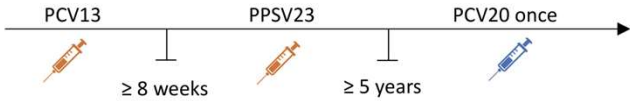
Pneumococcal Immunization adults 65 years and older


Patient with IBD and age ≥ 65 years


A. Patients not previously vaccinated or whose previous vaccination status is unknown:



B. Patients previously vaccinated with both PCV13 and PPSV23:



Previous vaccine 

New vaccine 


Mazen A, et al. Crohn's Colitis 360 2023 (in-press)

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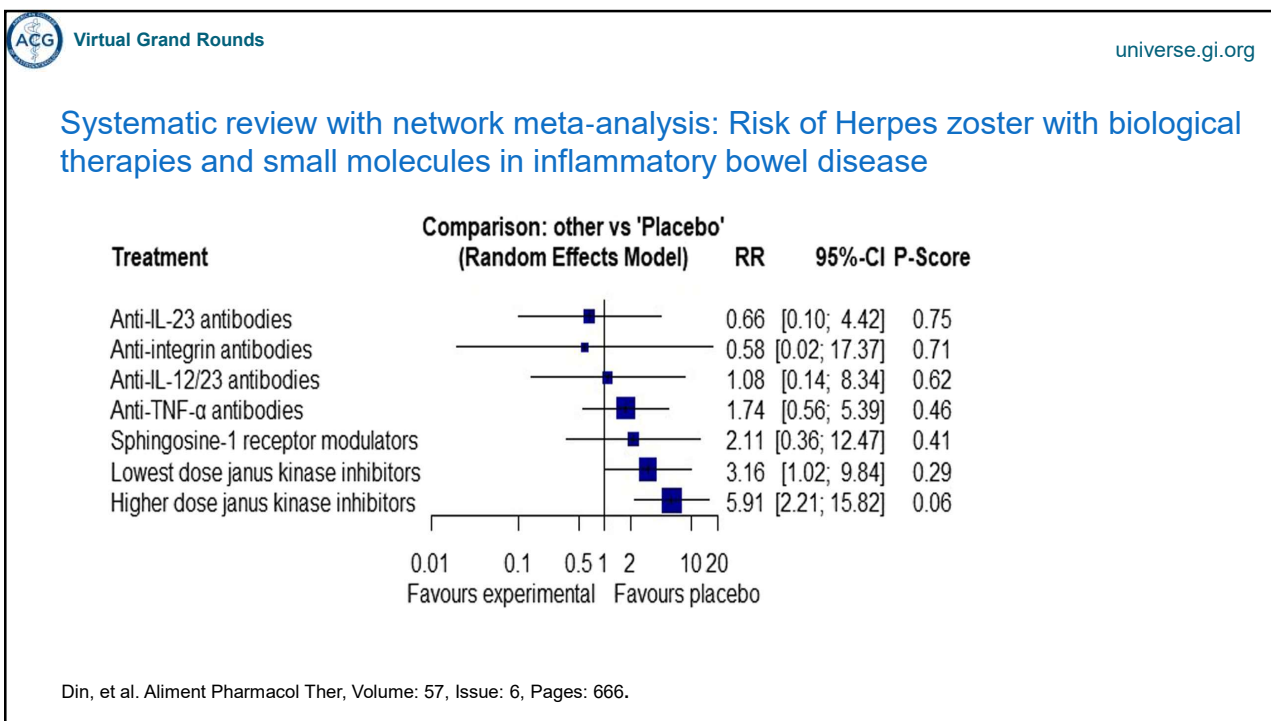
Prevention of HZ: Recombinant HZ vaccine

- Recombinant herpes zoster vaccine (RZV) is a two-dose series
- All adults 50+
- Adults 19 > years who are or will be immunodeficient or immunosuppressed because of disease or therapy.
 - Different dosing schedule for immunosuppressed 1 month after 1st dose
 - Do prior authorization process and appeal letter with MMWR to get coverage
 - Use pharmacies for patients with Medicare



Anderson TC, et al. MMWR Morb Mortal Wkly Rep 2022;71:80.

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Cost-Effectiveness of an Adjuvanted Recombinant Zoster Vaccine in Adults with Inflammatory Bowel Disease

In our model, vaccination with Recombinant Zoster Vaccine (RZV) was cost effective for all adult patients with Inflammatory Bowel Disease.

In our model vaccination with RZV improved quality adjust life years for all patients. Vaccination also reduced morbidity from herpes zoster by preventing these events and complications due to herpes zoster.

Caldera F, et al. Aliment. Pharmacol. Ther 2023 Jun57(11)1326

AP&T

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Thank you! Questions?

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- [dr_fcalderaibd](#)


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Questions



Freddy Caldera, DO, MS, FACG:



Francis A Farraye, MD, MSc, MACG:

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A Partnership of the American College of Gastroenterology
and the Crohn's & Colitis Foundation



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