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2022
**ACG'S ENDOSCOPY SCHOOL
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POSTGRADUATE COURSE**

DECEMBER 2-4, 2022 | GRAND HYATT
NASHVILLE, TENNESSEE

Register online: meetings.gi.org

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2023 **ACG HEPATOLOGY SCHOOL & WESTERN**
REGIONAL POSTGRADUATE COURSE
JANUARY 27-29, 2023 | CAESARS PALACE
LAS VEGAS, NEVADA

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ACG AMERICAN COLLEGE OF GASTROENTEROLOGY

The banner features a circular inset image of the Caesars Palace fountain in Las Vegas. The background is white with blue and orange accents.

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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.

The screenshot shows a GoToWebinar interface. The audio settings are set to 'MUTED' for 'Microphone Array (Realtek Audio)'. The 'Questions' section is visible with a text input field and a 'Send' button. The webinar title is 'Meridith Test' and the ID is '998-211-123'. A recording indicator is present at the bottom.

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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, 2022 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, 2023 for this activity.

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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.

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ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!

There is not Virtual Grand Rounds next week- Have a Happy Thanksgiving!



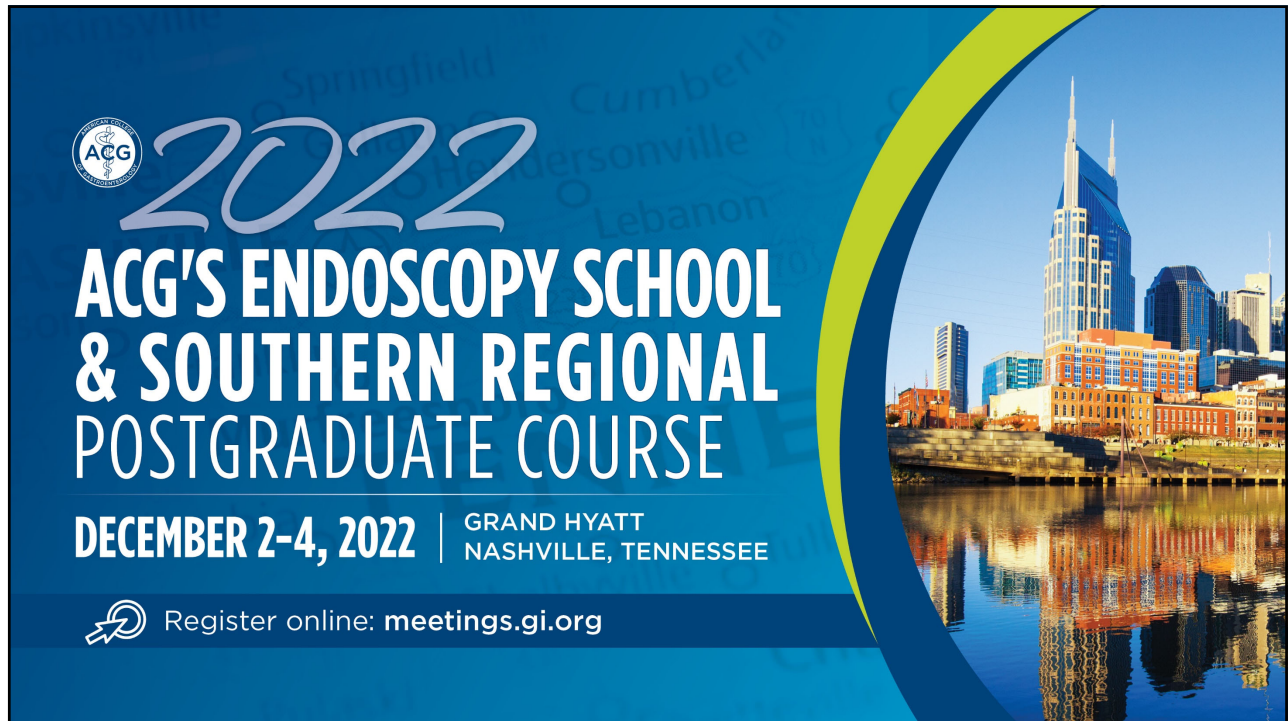
Week 48 – Thursday, December 1, 2022
ACG's Clinical Guideline on Gastroparesis
 Faculty: Michael Camilleri MD, MACG
 Moderator: Linda Anh Nguyen, MD
At Noon Eastern and NEW! 8pm Eastern!




Week 49 – Thursday, December 8, 2022
ADR, PDR, or IRR: What Are My Quality Metrics for Colonoscopy?
 Faculty: Aasma Shaukat, MD, MPH, FACG
 Moderator: Asmeen Bhatt, MD
At Noon Eastern and NEW! 8pm Eastern!

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ACG'S ENDOSCOPY SCHOOL & SOUTHERN REGIONAL POSTGRADUATE COURSE

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Disclosures





Freddy Caldera, DO
 Research Support: Takeda and Janssen
 Consultant: GSK, Celgene, and Takeda

Daniel J. Pambianco, MD, FACP
 Dr. Pambianco has no relevant disclosures with ineligible companies.


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

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COVID-19 Vaccine Update

Freddy Caldera, DO, MS, FACP
 Associate Professor of Medicine
 Division of Gastroenterology & Hepatology
 University of Wisconsin-Madison, School of
 Medicine & Public Health
 @dr_fcalderaibd



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- A 55-year-old male with a 15-year history of pan-ulcerative colitis is currently on infliximab and azathioprine. He has been in clinical and endoscopic remission for the past 2 years.
- He comes for a routine follow up appointment. He expresses concerns that his medications will increase his risk for a SARS-CoV-2 infection?
- What is your recommendation?

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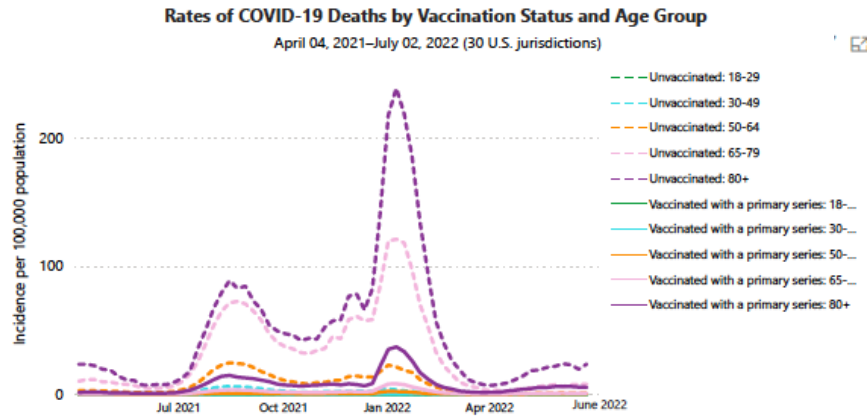
Objectives

- Provide an update from recent ACIP meetings
- Review the impact of IBD therapy and therapy used by liver transplant recipients on COVID-19 vaccine response
- Discuss the new bivalent booster recommendations.

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Goals of COVID-19 Vaccination

PREVENTION OF SEVERE DISEASE (HOSPITALIZATION, ICU, MECHANICAL VENTILATION)

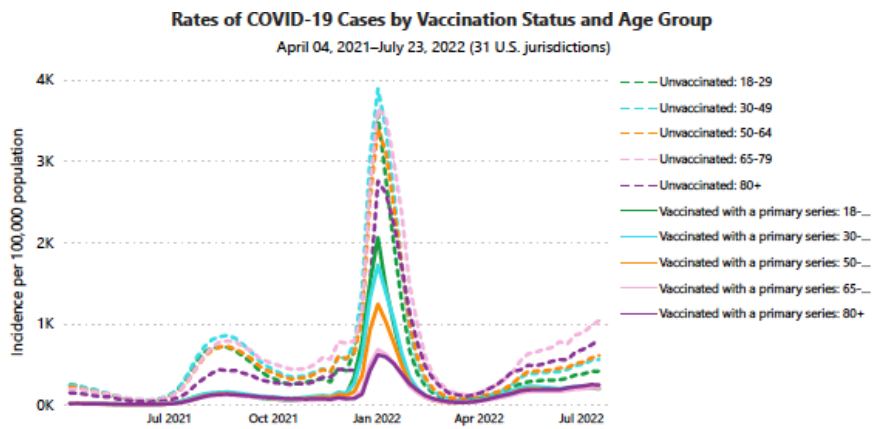


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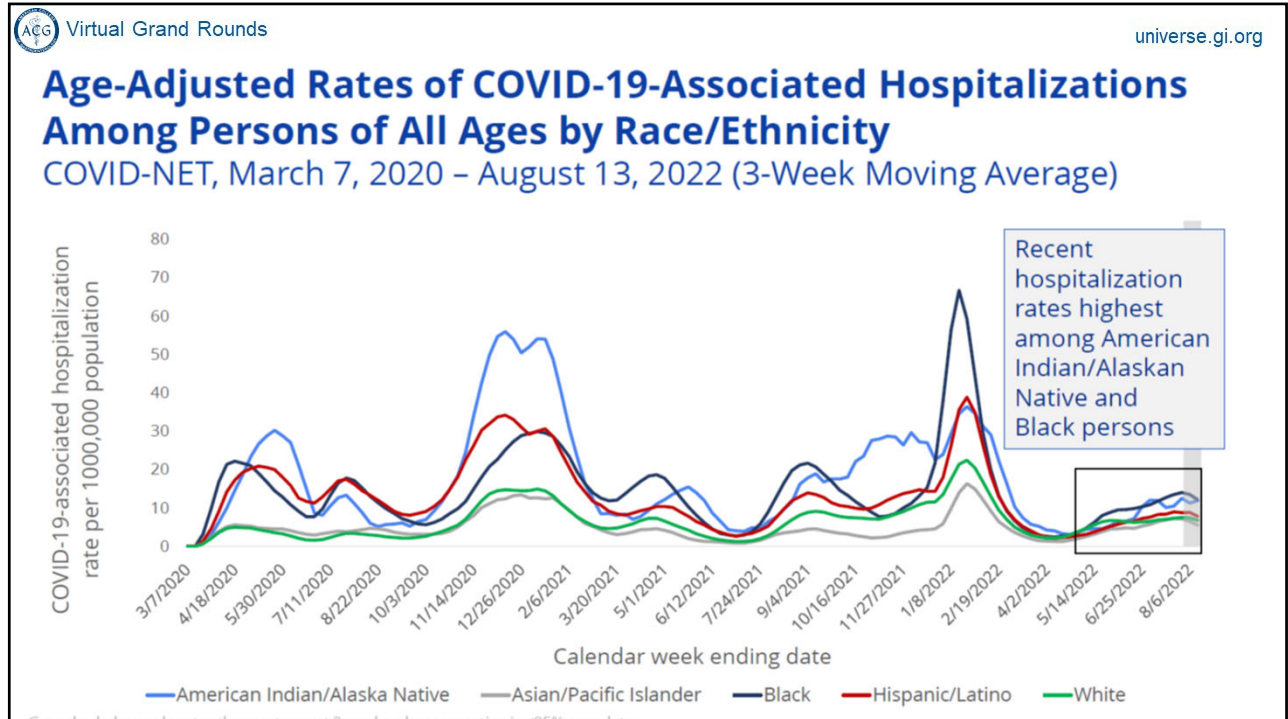
Goals of COVID-19 Vaccination

CURRENT VACCINES DO NOT HAVE THE ABILITY TO PREVENT BREAKTHROUGH INFECTIONS

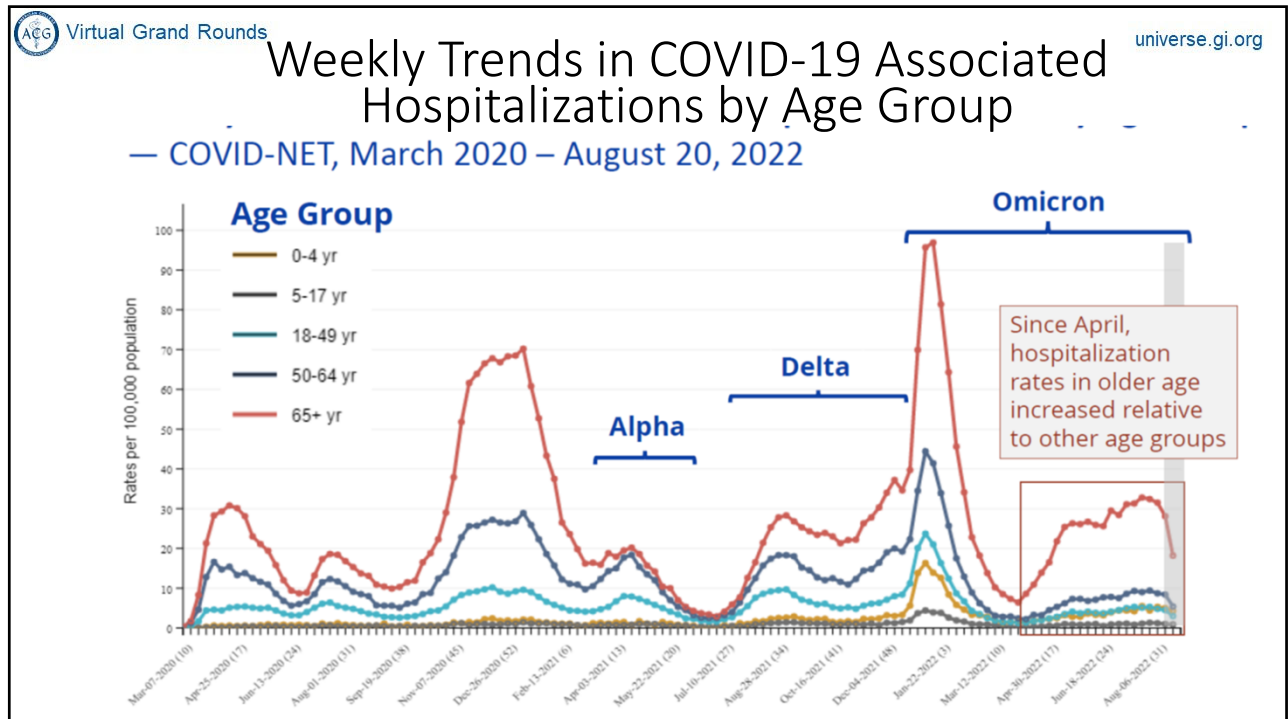


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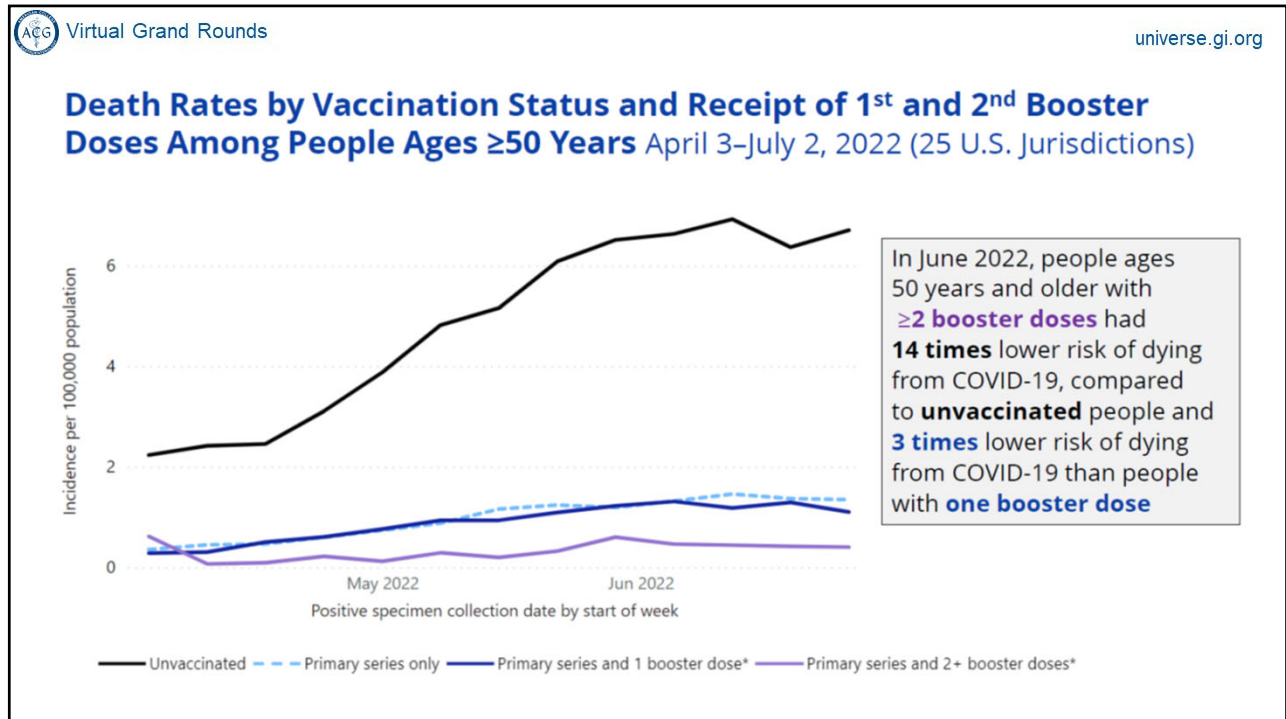
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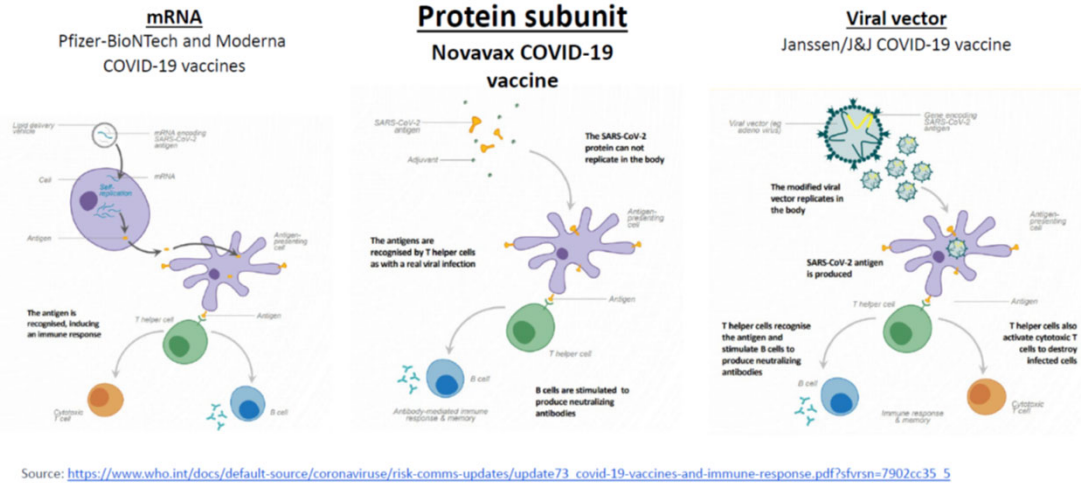
Risk of SEVERE COVID-19 Illness

- Unvaccinated people at higher risk of severe illness compared with vaccinated people
- Most (75%) vaccinated people with severe COVID-19 illness have multiple risk factors:
 - Older age (most ≥65 years, but with risk increasing with age)
 - Underlying medical conditions (with risk increasing with number of underlying conditions)
 - Immunosuppression
 - Diabetes mellitus
 - Chronic kidney disease
 - Chronic lung disease
 - Chronic cardiovascular disease
 - Chronic neurologic disease
- Antiviral drugs can help reduce risk of severe illness in people at higher risk, regardless of vaccination status

Yek et al. MMWR 2022;71:19–25. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7101a4.htm>; Taylor et al. MMWR 2022;71:466–473. [https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm](http://dx.doi.org/10.15585/mmwr.mm7112e2and unpublished COVID-NET data, as described here; Malden et al. MMWR 2022; 71(25):830–833; <a href=); Gold et al. MMWR 2022; 71(25):825–829; <https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm>; Najjar-Debbinyet al. CID 2022; ciac443, <https://doi.org/10.1093/cid/ciac443> Dryden-Peterson et al. medRxiv2022.06.14.22276393; <https://doi.org/10.1101/2022.06.14.22276393>

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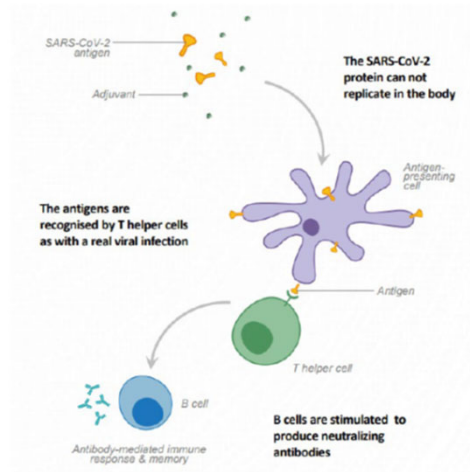
Mechanism of action of authorized COVID-19 vaccines



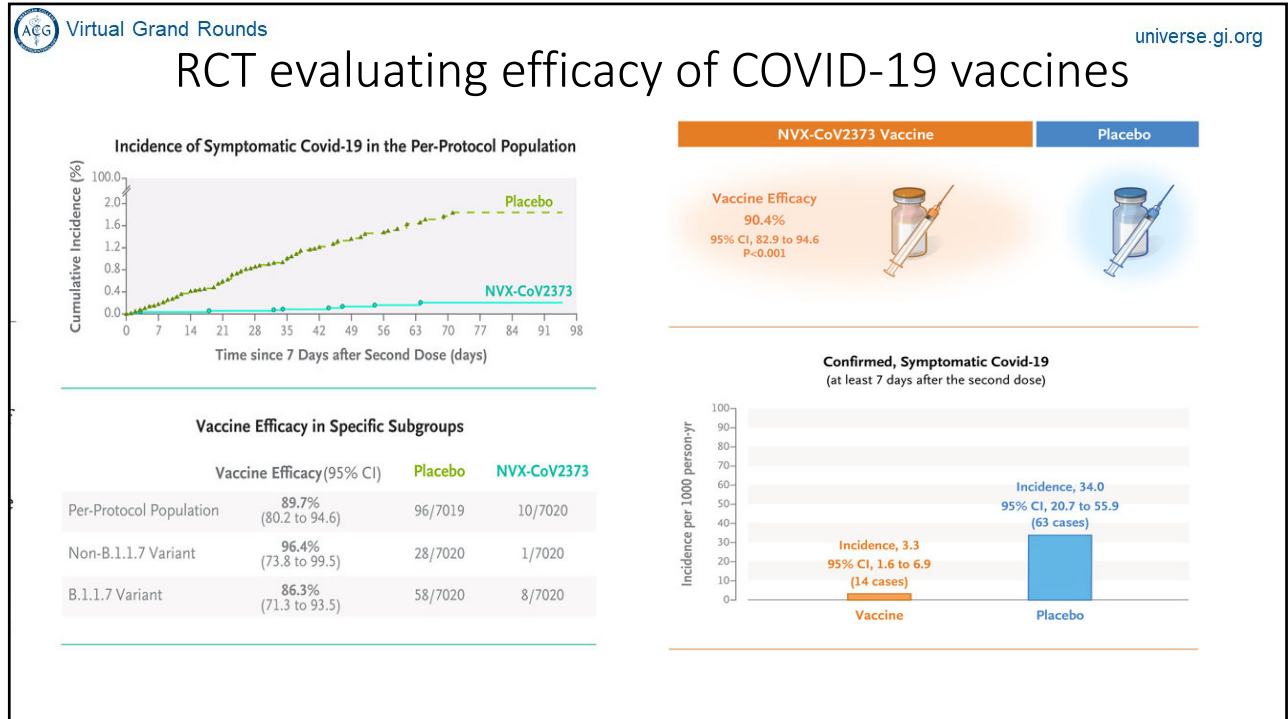
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Mechanism of action of Novavax COVID-19 Vaccines

- 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



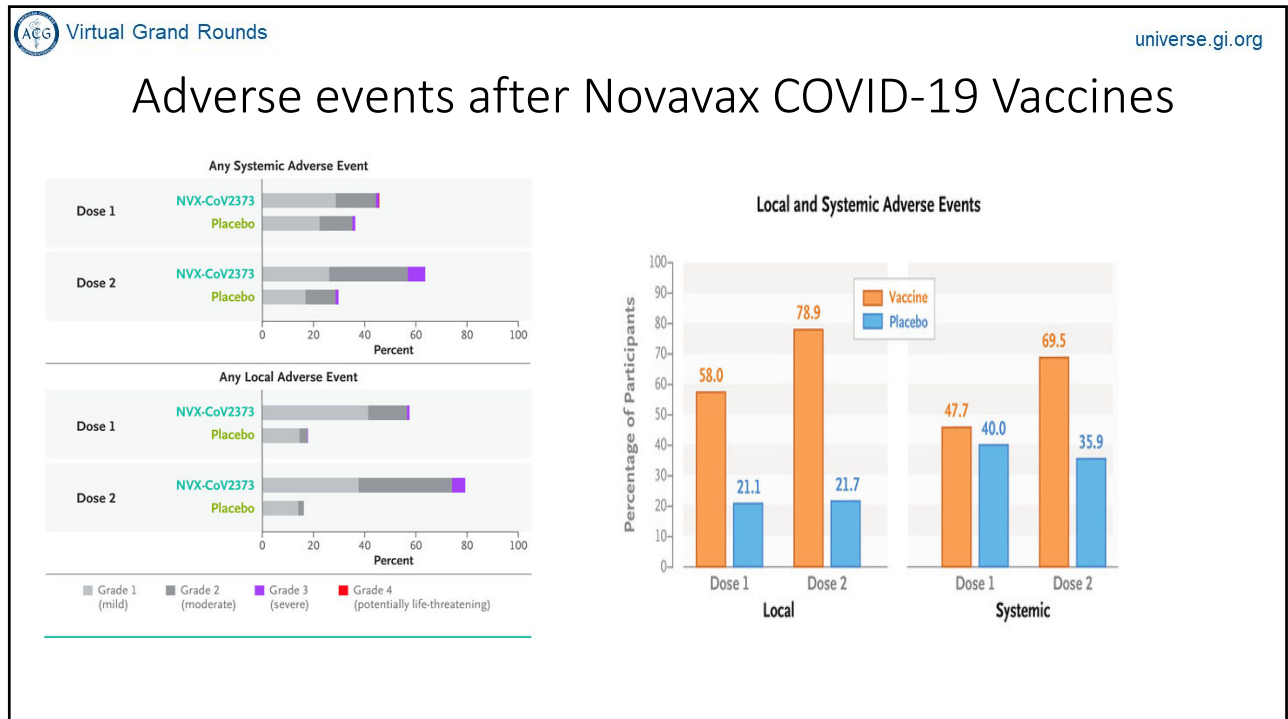
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Vaccine Efficacy in Specific Subgroups

	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

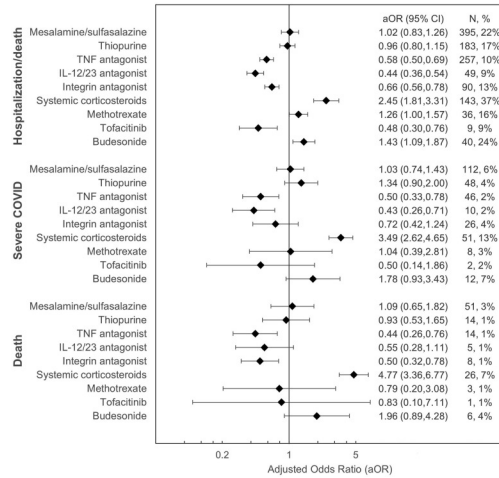
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Corticosteroids Associated with Increased Risk of Severe COVID-19

- 6144 patients with IBD
- IBD itself does not increase the risk of severe COVID-19 disease
- Those who are older, have additional comorbidities and are on oral corticosteroids appear to be at increased risk of adverse outcomes from COVID-19.
- Those on combination thiopurines with TNF antagonists are not at increased risk



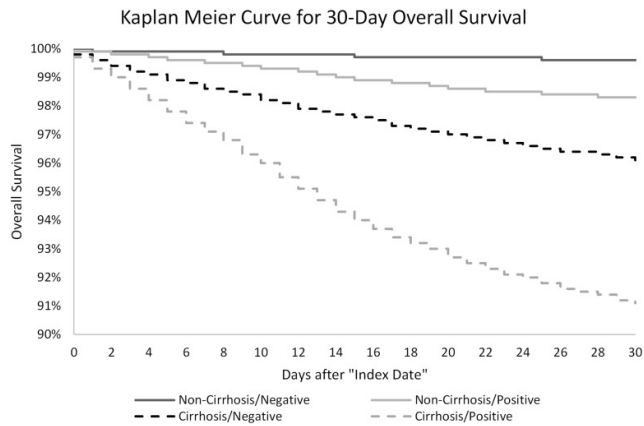
Ungaro RC, *Gastroenterology*. 2022;162(1):316-319

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Patients with CLD are more likely to die from COVID-19 infection

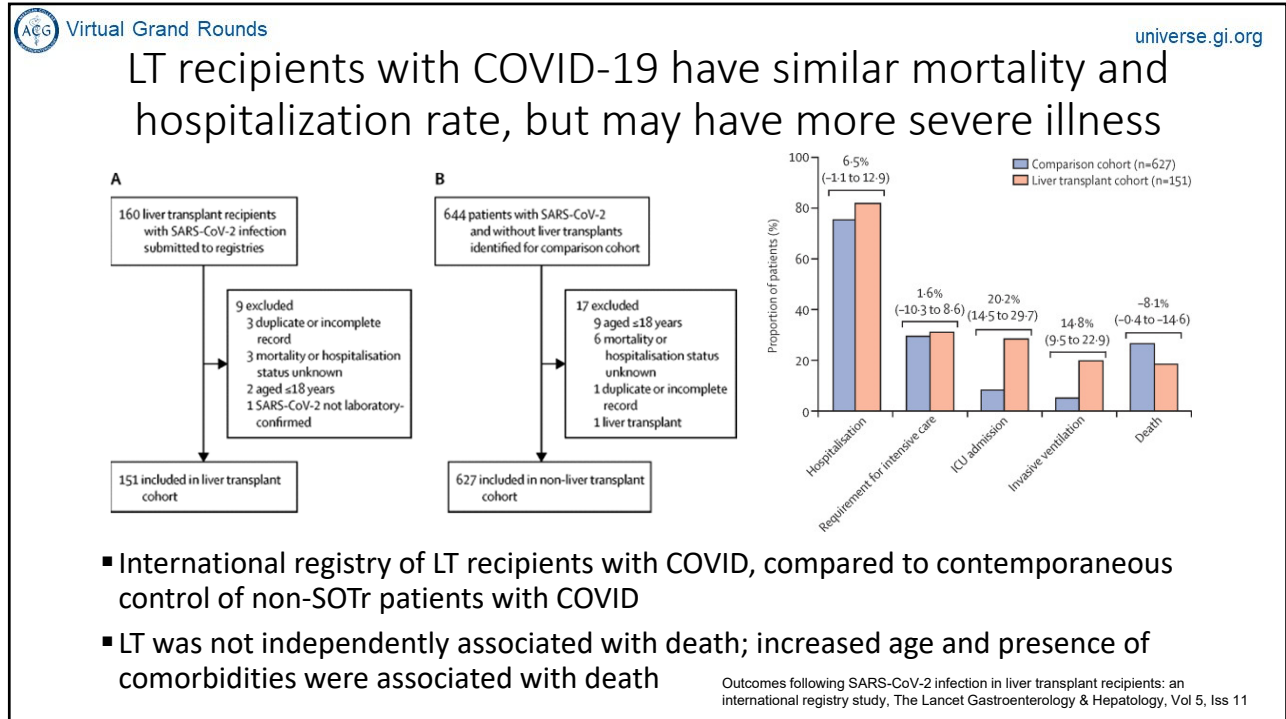
CLD appears to be a risk factor for COVID-19 mortality

- 2780 patients (pts), 250 with CLD:
12 vs 4% rate of death, RR 4.6
- NAFLD, NASH, cirrhosis likely increase mortality
- Independent of age, race, BMI, hypertension, diabetes
- Affected by CLD severity:
 - Cirrhosis vs no cirrhosis
 - CP class A vs B or C



Gastroenterology. 2020;159(2):768. Epub 2020 May 4. *Gastroenterology*. 2021;161(5):1487. Epub 2021 Jul 18.

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Who makes vaccine recommendations? Advisory Committee on Immunization Practices

- The ACIP is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.
- The Centers for Disease Control and Prevention (CDC) sets the U.S. adult and childhood immunization schedules based on recommendations from the ACIP.

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Recommendations for immunosuppressed populations

Advisory Committee on Immunization Practice (ACIP)

Immunocompromised people comprise 2.7% of US adults including

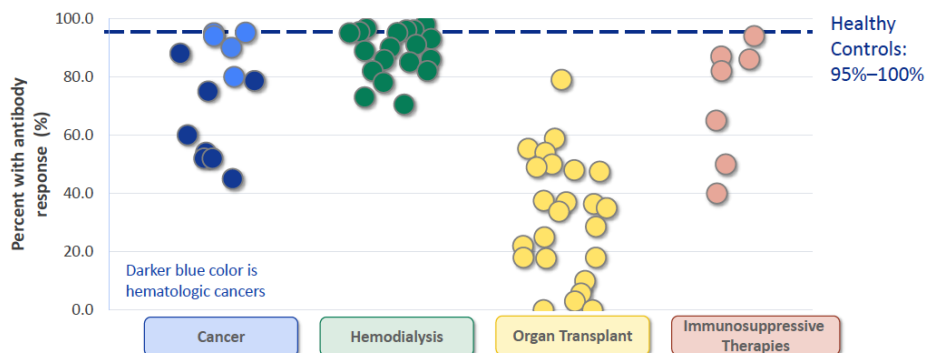
- Solid tumor and hematologic malignancies
- Receipt of solid-organ or hematopoietic stem cell transplant
- Severe primary immunodeficiencies
- Persons living with HIV
- Treatment with immunosuppressive medications such as cancer chemotherapeutic agents, TNF blockers, certain biologic agents (e.g., rituximab), and high-dose corticosteroids

ACIP has provided special recommendations regarding vaccine in the past

- Pneumococcal 13 serotype vaccine
- Zostavax vaccine

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Percent of subject with antibody response after two mRNA vaccine doses by condition



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Additional dose of COVID-19

On August 13, 2021, the CDC Advisory Committee on Immunization Practice (ACIP) recommended an additional dose of mRNA COVID-19 vaccine for moderate to severe immunocompromised individuals (solid transplant recipients) and to individuals on the following therapies:

- High-dose corticosteroids (defined at ≥ 20 mg / day of oral prednisone)
- Anti-TNF biologics and biosimilars or immunomodulators (azathioprine, methotrexate, etc.)

This additional dose was intended for people who likely did not mount a protective immune response after initial vaccination.

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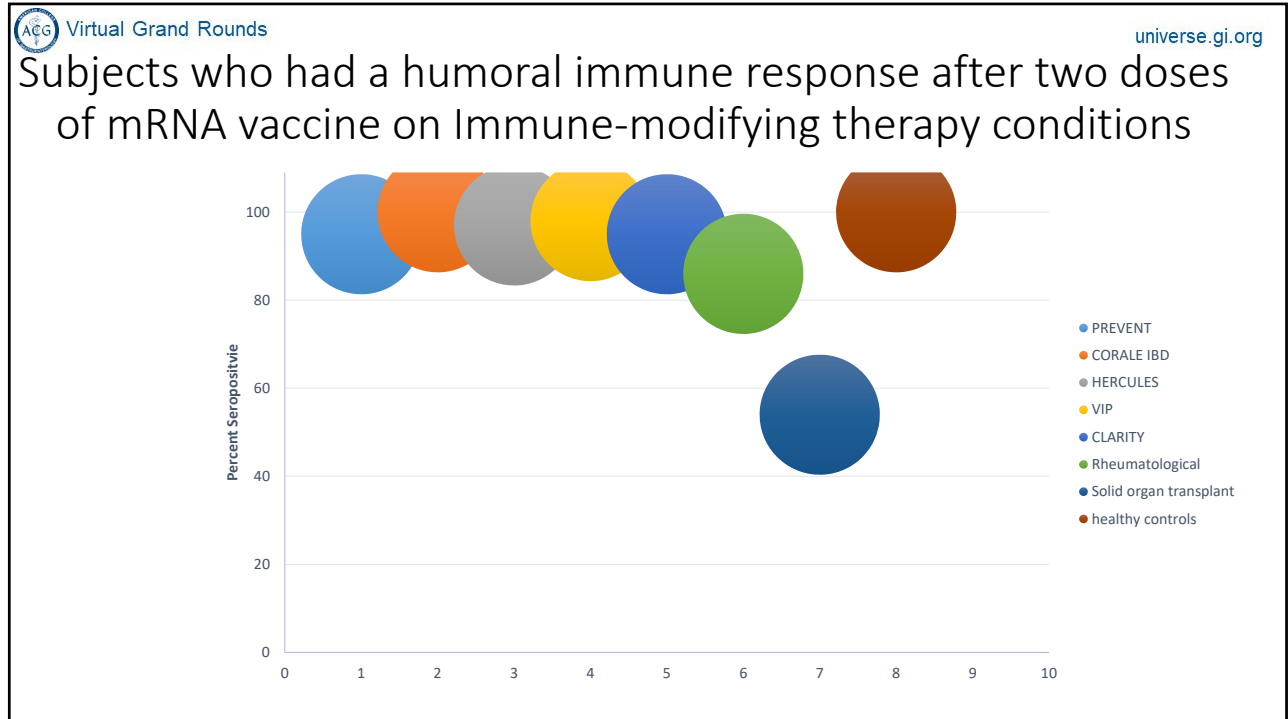
Moderate to Severely Immunocompromised People

- 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 are immunosuppressive or immunomodulatory

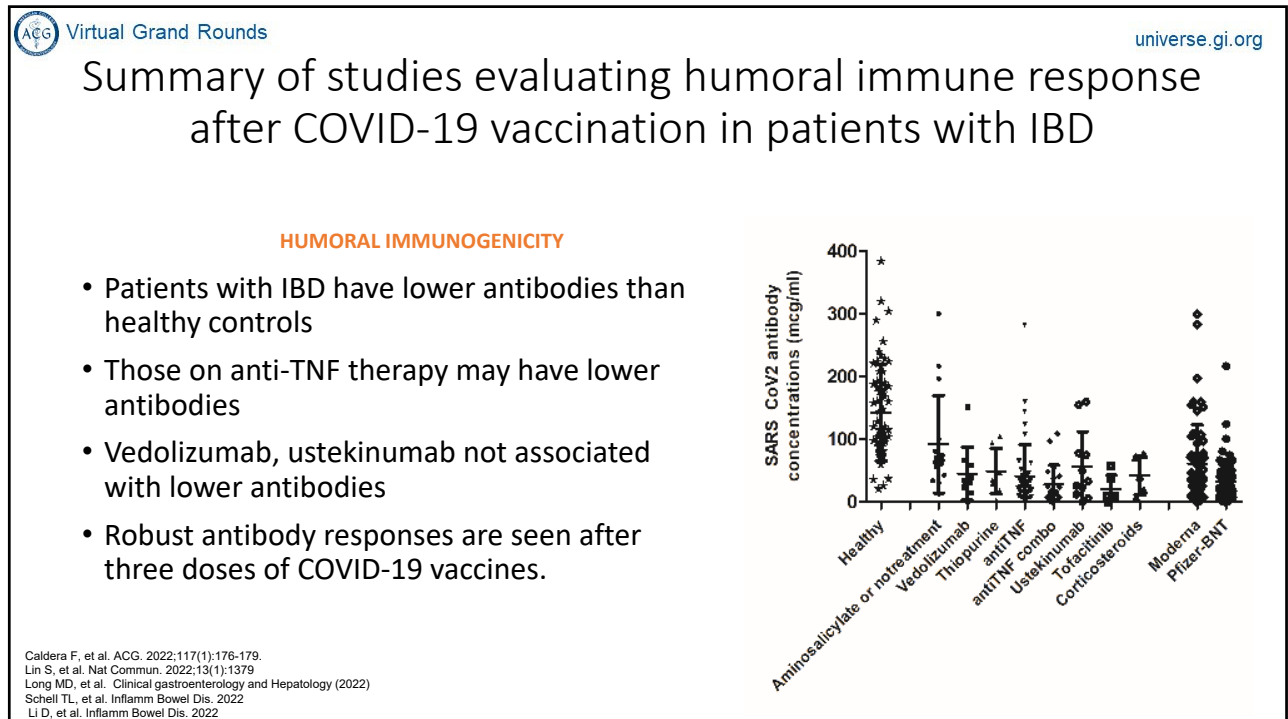
*General Best Practice Guidelines for Immunization, CDC Yellow Book, IDSA 2013 guidelines

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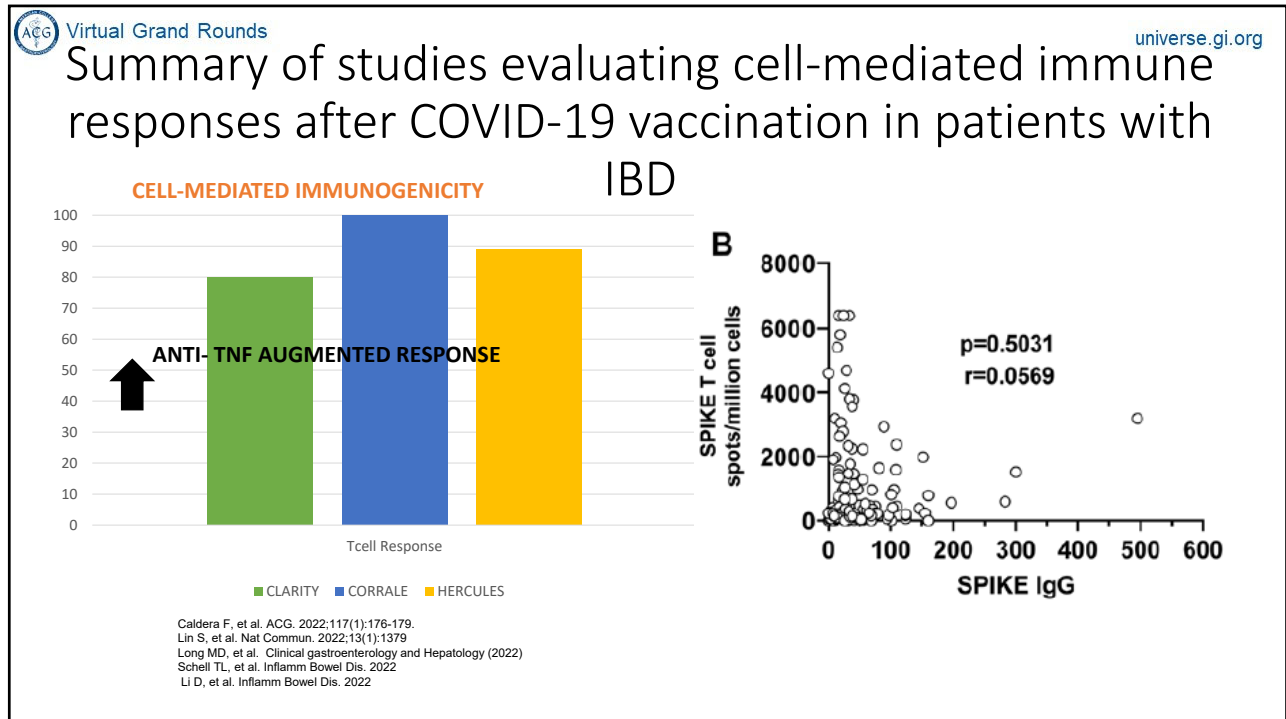
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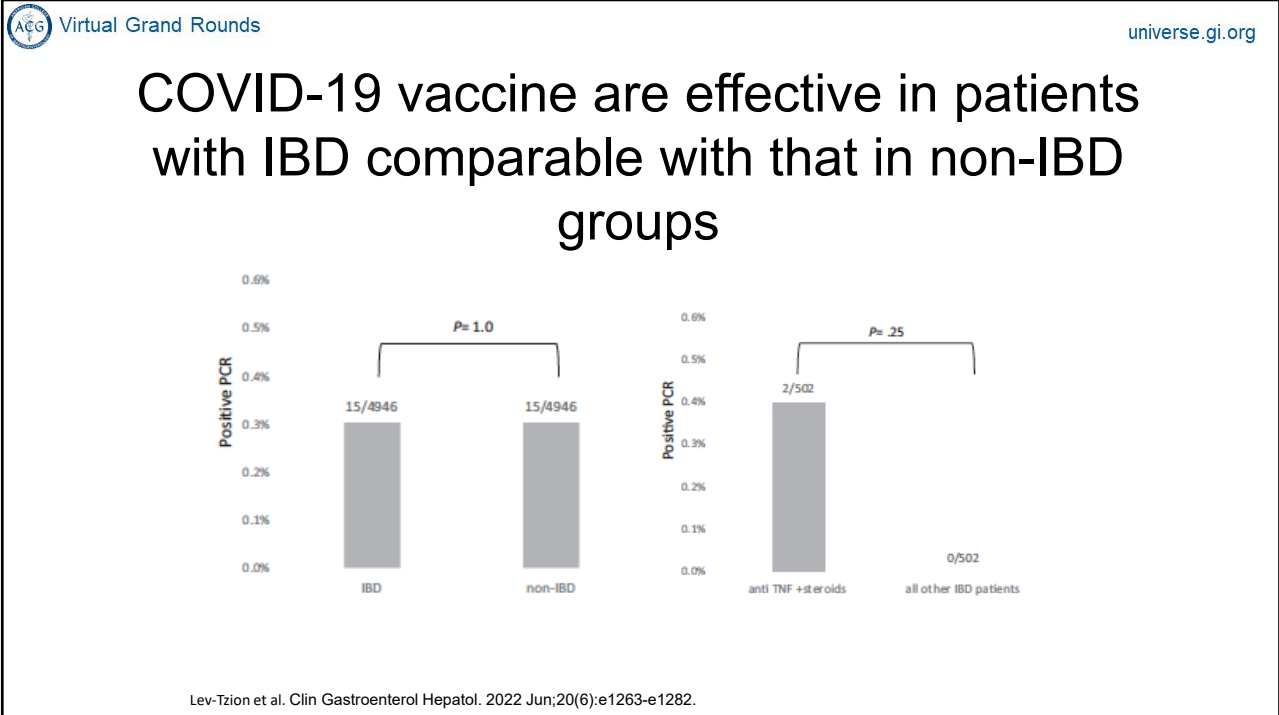
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COVID-19 vaccines are safe in patients with IBD

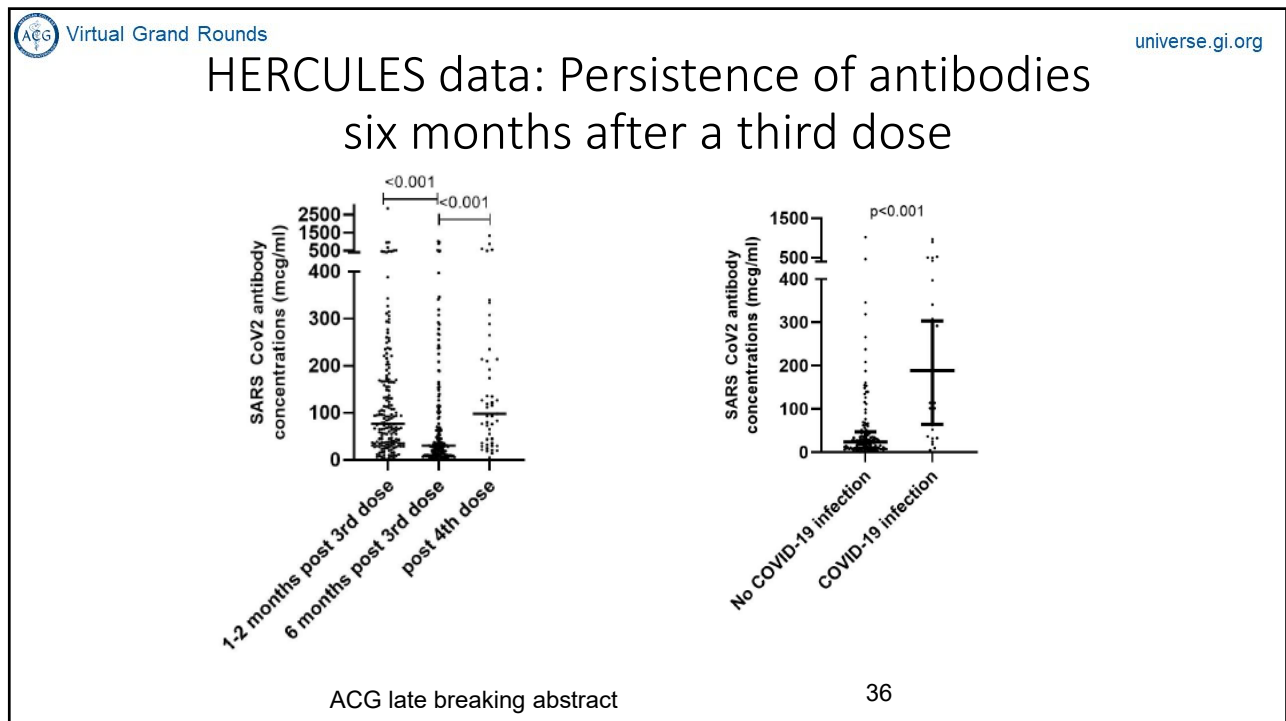
- Previous studies have shown the vaccines are safe and not associated with disease flares.
- In 3316 individuals with IBD
 - Risk of flares is rare less than 2% of patients had a flare
 - Injection site tenderness (68%) and fatigue were the most common reported localized and systemic adverse events.

Desalermos A, et al. Inflamm Bowel Dis. 2022 (9):1430-42.
Weaver KN, et al. Inflamm Bowel Dis. 2021 Dec 6

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SOTr have an altered immune response and lower vaccine immunogenicity

- SOTr have lower antibody responses to many vaccinations
- mRNA COVID vaccines response ranges 30-58%
- Antimetabolite-containing immunosuppression (IS) (mycophenolate), age, eGFR, appears to negatively influence immune response

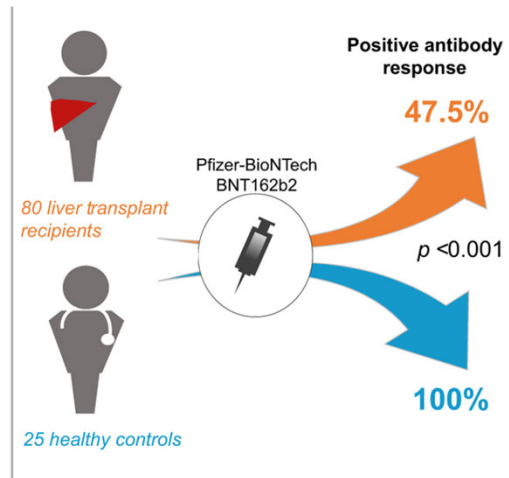
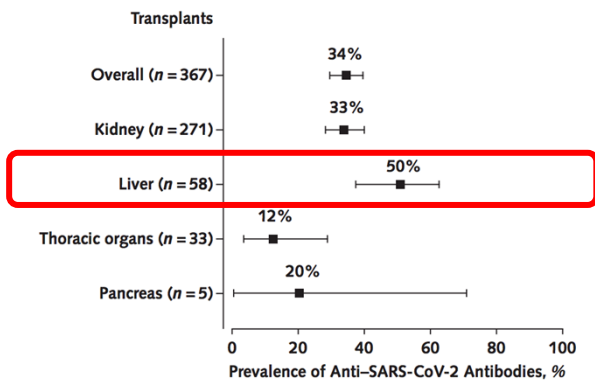


¹Chavarot et al, Transplantation 2021. ²Holden et al, J Int Med 2021. ³Benotmane et al, Kidney Intern 2021. ⁴Mazzola et al, CID 2021. Rabinowich et al. J Hepatology. Aug 2021 ⁵Marinaki et al, Am J Transplant 2021. ⁶Miele et al, Am J Transplant May 2021. ⁷Olivier et al, Annals of Int Med 2021. ⁸Rashidi-Alavijeh J et al. Vaccines (Basel). 2021 Jul.

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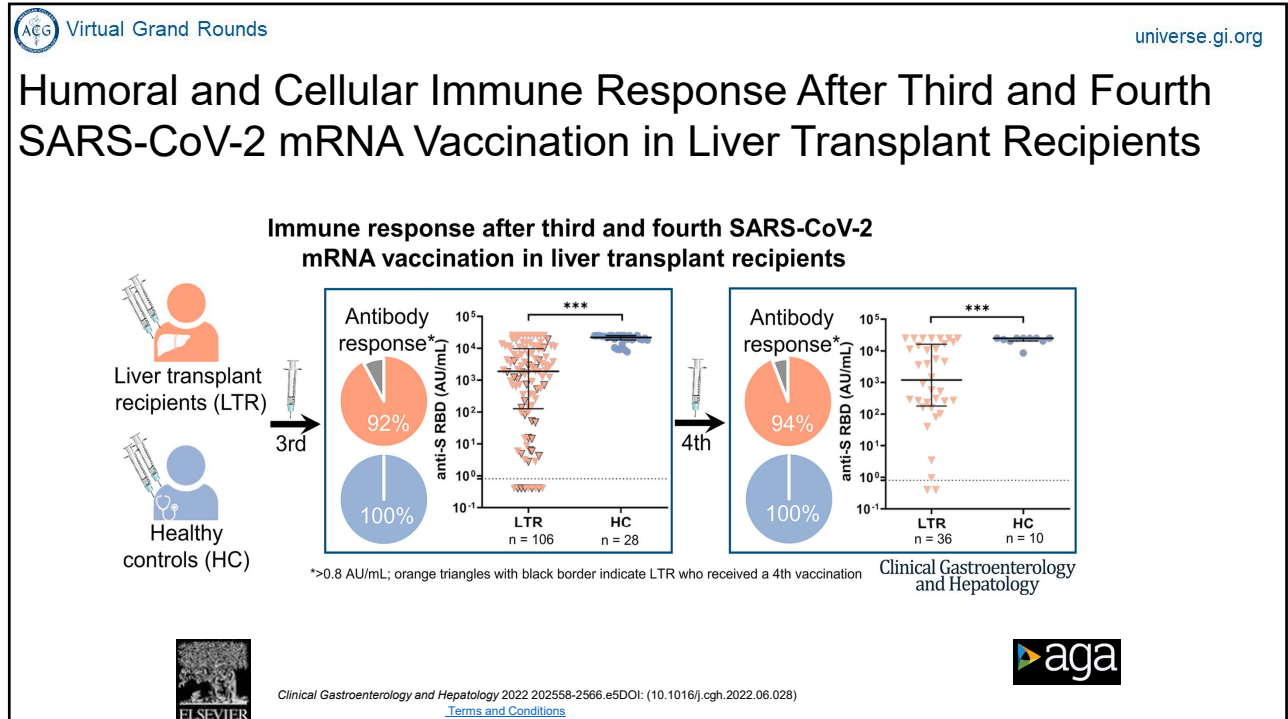
Immunogenicity is decreased in liver transplant recipients (LTr), but less so than other SOTr

Figure. Prevalence of anti-SARS-CoV-2 antibodies at 4 wk after the second vaccine dose in all transplant patients and by type of organ transplant.



Rabinowich et al. J Hepatology. Aug 2021

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Bivalent COVID-19 vaccine booster

- Bivalent vaccine based on the original (ancestral) strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 (BA.4/BA.5) variants of SARS-CoV-2.
- New booster recommendation for people ages 5 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series; it replaces all prior booster recommendations
 - bivalent Moderna or Pfizer-BioNTech booster dose in people ages 5 years and older
- Monovalent Novavax booster available in limited situations
 - People age 18 and older who are unable to receive an mRNA vaccine.

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COVID-19 Vaccination Schedule General Population

People ages 5 years and older*

Regardless of previous booster doses given

Ages and vaccines as authorized by FDA and recommended by ACIP/CDC

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COVID-19 Vaccination Schedule for Moderate to Severely Immunocompromised

People ages 12 years and older

Moderna or Pfizer-BioNTech

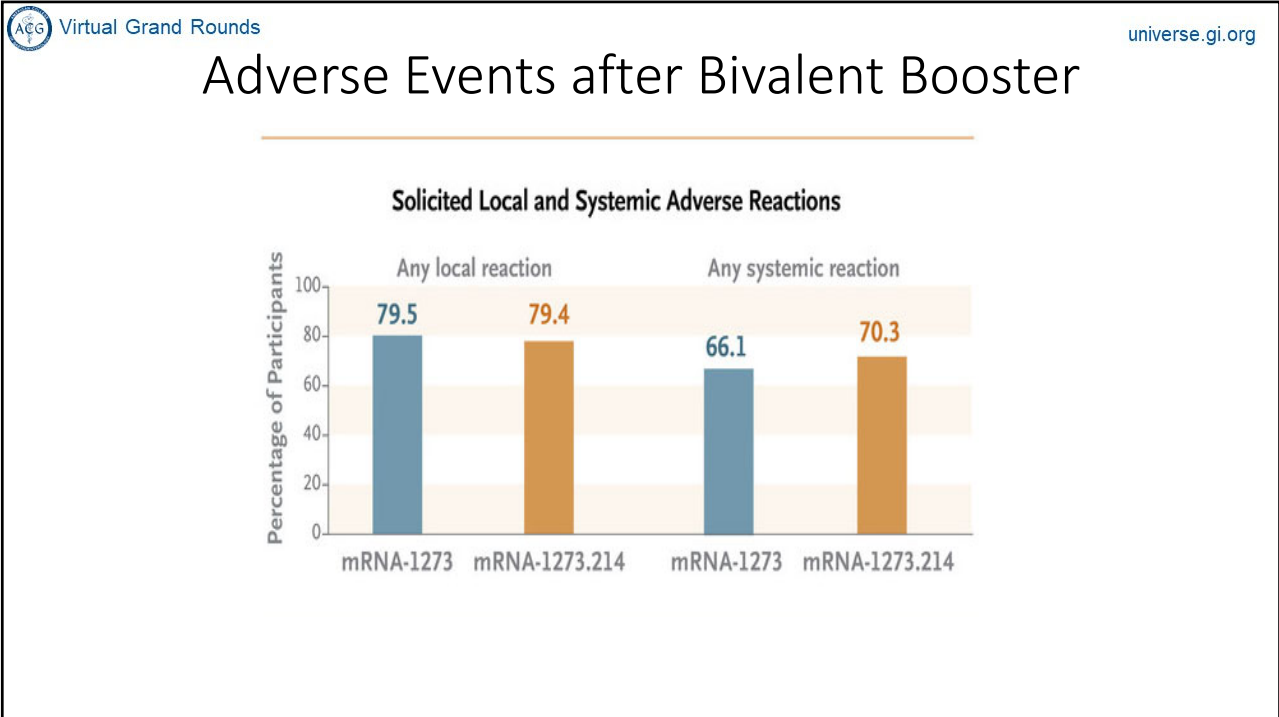
Novavax

-OR-

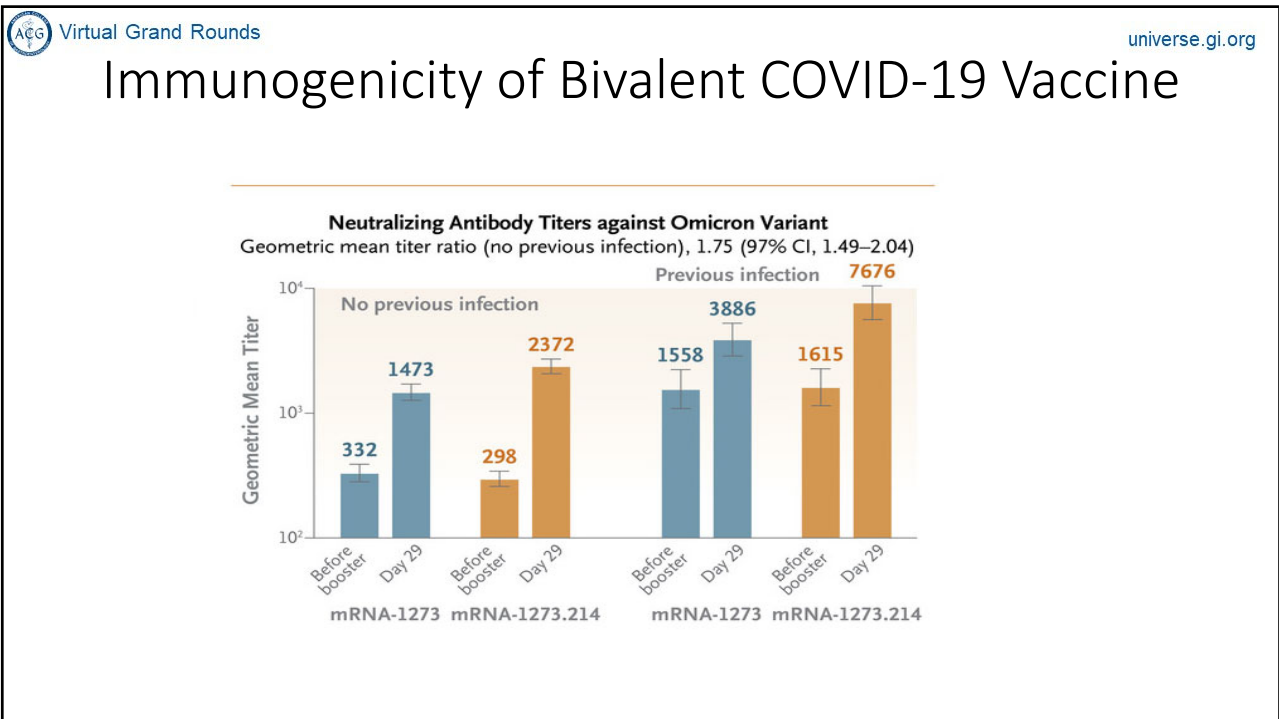
People ages 18 years and older who previously received Janssen primary series dose†

ACIP: Interim Clinical Considerations 42

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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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Timing considerations for Patients with recent COVID-19 vaccine booster

- ACIP recommended at least 2 months since last booster dose.
- Could not be extended because needed to follow recommendation in FDA EUA
 - Depends on number of boosters +/- SARS-CoV-2 infection

CS0

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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.

CS0

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Summary on Myocarditis and Pericarditis

- Risk of myocarditis and pericarditis has been identified after COVID-19 vaccines
 - Risk is rare and primarily observed in adolescent and young males
 - Among VAERS risk is lower after booster dose compared to primary series
- Most individuals have fully recovered
- The risk of adverse cardiac outcomes were 1.8-5.6 higher after SARS-CoV-2 infection than after mRNA COVID-19 vaccination among males ages 12-17 years

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Provider Recommendation on COVID-19 vaccine acceptability

- A poll from the University of Michigan found that **77%** of older adults say their provider's recommendation about COVID-19 vaccination is very or somewhat important to their decision to get vaccinated
- It was very important to those who were:
 - Black (**79%**),
 - over age 65,
 - retired or have incomes under \$30,000

Institute for Healthcare Policy and Innovation. University of Michigan. August 9, 2022. Most older adults are ready to roll up sleeves this fall for updated COVID-19 boosters, U-M poll shows. <https://ihpi.umich.edu/news/most-older-adults-ready-roll-sleeves-fall-updated-covid-19-boosters-u-m-poll-shows> Accessed August 24, 2022

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Provider Recommendation on COVID-19 vaccine acceptability

- All health care workers: Physicians, nurses and nurse practitioners, pharmacists and physician's assistants should start communicating to their patients now about the importance of getting a dose of one of the updated (bivalent) COVID-19 boosters when they become available



Institute for Healthcare Policy and Innovation. University of Michigan. August 9, 2022. Most older adults are ready to roll up sleeves this fall for updated COVID-19 boosters, U-M poll shows. <https://ihpi.umich.edu/news/most-older-adults-ready-roll-sleeves-fall-updated-covid-19-boosters-u-m-poll-shows> Accessed August 24, 2022

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What else?

Health Maintenance Checklist

 Screening	<input type="checkbox"/> Skin Cancer <input type="checkbox"/> Colorectal Cancer <input type="checkbox"/> Cervical Cancer <input type="checkbox"/> Osteoporosis <input type="checkbox"/> Anxiety/ Depression <input type="checkbox"/> Latent TB	 Vaccines	<input type="checkbox"/> Influenza <input type="checkbox"/> Pneumococcus <input type="checkbox"/> Zoster <input type="checkbox"/> Varicella immunity <input type="checkbox"/> MMR immunity
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Please see the full checklist for specific recommendations.
www.crohnscolitisfoundation.org/science-and-professionals/education-resources/health-maintenance-checklists


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Take Home Points: back to case

- Certain patients are still at risk for SEVERE COVID-19 disease
- Patients with IBD are not at increased risk for SEVERE disease and able to mount immune response to COVID-19 vaccine
- Liver transplant recipients can mount a response to a third dose of a COVID-19 vaccine
- Bivalent boosters are safe and boost the immune response.

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Thank you! Questions?

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- dr_fcalderaibd

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Questions?



Freddy Caldera, DO



Daniel J. Pambianco, MD, FACP

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