Disclosures

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There are no relevant conflicts of interest for any speakers or moderators.
COVID-19 Vaccines
Where are we today?

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Where We Are Today

Vaccine Distribution

42.4 million people have received at least one dose of a COVID-19 vaccine in US as of 2/9/2021

135 million people have received at least one dose of a COVID-19 vaccine worldwide as of 2/9/2021
Dear Colleagues,

As we write this, vaccinations against coronavirus are becoming available to combat COVID-19, and the FDA and CDC advisory panels have deemed these vaccines to be safe and highly effective.

Public health officials tell us that a successful vaccination program will require 70-80% of the U.S. population to be vaccinated. We know there is significant mistrust and vaccine hesitancy amongst the population.

As a community of gastroenterologists and other GI-related healthcare providers, we are well positioned to lead by example. For the vast majority of patients, the benefits of vaccination overwhelmingly outweigh the risks. While we each have our own personal choice about whether to be vaccinated, the decisions we make will be followed closely by our colleagues, coworkers and, most importantly, our patients.

We urge you to share your decision to be vaccinated with others, and to have open discussions with your patients about this critically important topic. The availability of SARS-CoV-2 vaccines is a historic opportunity that we must act on promptly — to help our patients and our peers best take advantage of the scientific breakthroughs which, if applied widely, will help control the COVID-19 pandemic.

COVID-19 Management: Pearls for the Gastroenterologist

Moderator & Speakers

Francis A. Farraye, MD, MSc, MACG

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Top 5 GI Consultations for COVID-19 Complications
(Tips from a GI Hospitalist)

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Director, Inpatient GI Services Tisch/Kimmel
Director, Enteral Access Team
NYU Langone Health
🐦📸: @mlatorremd

GI Consults To Be Covered:

• Gastrointestinal Bleeding (GIB)
• Nausea / Vomiting, Diarrhea & Abdominal Pain
• Abnormal Liver Function Tests (LFTs)
• Ileus & Acute Colonic Pseudo-obstruction (ACPO)
• Enteral Nutrition & Gastrostomy Tube Placement
ACG Task Force – PMC Survey

<table>
<thead>
<tr>
<th>ANSWER CHOICES</th>
<th>RESPONSES</th>
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<tr>
<td>I continued to provide only the same specialty-specific care to patients as</td>
<td>82.62%</td>
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<td>before.</td>
<td>328</td>
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<tr>
<td>In addition to my specialty-specific care I also provided services to patients</td>
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<tr>
<td>outside of my usual specialty.</td>
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GASTROINTESTINAL BLEEDING (GIB)
Background

• GIB is estimated to occur in 2-13% of patients hospitalized with COVID-19.

• The most common etiologies include PUD (80%) and rectal tube trauma (60%).

• There are NO identifiable risk factors for GIB including anticoagulation and antiplatelets.

• No difference in initial presentation or severity of COVID-19 symptoms.

• One large study showed higher mortality in patients with COVID-19 and GIB (OR 1.58 p=0.02).

Martin TA et al. Am J Gastroenterol 2020

Tips:

• Use all available tubes and data to risk assess your patients.

• Initiate aggressive and immediate medical management as indicated.

• Consider endoscopic evaluation if there is:
  • Persistent hemodynamic instability
  • Inappropriate response to transfusion
  • Ongoing overt bleeding
  • There is a need for long-term anticoagulation or antiplatelets

• Be proactive - it is best to perform endoscopy in a controlled environment with adequate staff and tools.
NAUSEA / VOMITING, DIARRHEA & ABDOMINAL PAIN

Background:

• SARS-CoV-2 enters and replicates by binding to ACE2 receptors which are abundant in epithelial cells of the stomach and intestine.

• Estimated pooled prevalence of GI symptoms from 2 meta-analyses were: diarrhea (8-9%), nausea/vomiting (6-8%) and abdominal pain (3%).

• GI symptoms may develop in advance of respiratory symptoms and are associated with more severe disease course and infection (OR 2.96, p=0.02).

Galanopoulos M et al. World J Gastroenterol 2020
Sultan S et al. Gastroenterology 2020
Mao R et al. Lancet Gastroenterol Hepatol 2020
Tips:

• Exclude alternative sources of GI symptoms upon admission (history, imaging, stool studies, prior GI endoscopy).

• Monitor electrolytes and fluid status closely.

• For diarrhea - if symptoms are due solely to COVID-19, initiate anti-diarrheal medication titrated to diarrhea frequency.

• For N/V - aggressive use of scheduled IV antiemetics with a plan for de-escalation to PO and PRN as needed.

Tips:

• In patients who develop diarrhea during hospitalization, consider alternative sources:
  • Hospital acquired infection (CDIFF)
  • Medication induced (antibiotics; oral contrast)
  • Opportunistic infections from medically induced immunosuppression (CMV)
  • Overflow

• Cross sectional imaging and endoscopic evaluation as needed to rule out alternative etiologies of GI symptoms.
ABNORMAL LIVER FUNCTION TESTS (LFTs)
Background:

- ACE2 receptors are present in hepatocytes and cholangiocytes permitting a retrograde entrance of virus from biliary tree.

- Viral RNA has been confirmed in liver biopsies along with evidence of viral injury:
  - Cell apoptosis and ballooning
  - Acidophilic bodies and lobular inflammation

- Liver injury may occur due to the massive release of pro-inflammatory cytokines, tissue hypoxia and thrombosis.

Galanopoulos M et al. World J Gastroenterol 2020

Background:

- The pooled prevalence of Abnormal LFTs was estimated between 15-19%.

- Predominant hepatocellular > cholestatic.

- Higher abnormal LFTs at admission were associated with more severe COVID-19 infection (OR 2.73, 95% CI 1.19-6.30).

- Emergence of post-COVID cholangiopathy akin to secondary sclerosing cholangitis of the critically-ill patient (SSC-CIP).

Sultan S et al. Gastroenterology 2020
Mao R et al. Lancet Gastroenterol Hepatol 2020
Roth NC et al. Am J Gastroenterol 2021
**Tips:**

- In hospitalized patients with suspected or known COVID-19, obtain baseline LFTs at admission and monitor throughout treatment.

- Consider alternative sources of elevated LTFs:
  - Pre-existing or undiagnosed liver disease (viral hepatitis; steatosis)
  - Thrombotic (AUS with doppler)
  - Medication induced (remdesivir; antibiotics) – livertox.org
  - Critical illness / ischemic injury
  - Concomitant infection

- If abnormalities persist, consider imaging, EUS/ERCP and/or biopsy to further elucidate the etiology.
Background:

- Paralytic ileus and acute colonic pseudo-obstruction (ACPO) can occur in critically ill patients including those with severe COVID-19.

- One study of 141 COVID-19 ICU patients showed an incidence of ileus (56%); ACPO (2%) and bowel ischemic in (4%).

- One study showed significantly higher ileus and complications in patients with COVID-19 ARDS compared to non-COVID ARDS:
  - Severe ileus (48% vs 22%; P < .001)
  - Bowel ischemia (4% vs 0%; P = .04).

Key Features:

- Small and/or large bowel distention
- No obvious obstruction/transition
- Minimal toxicity
- Faint bowel sounds
- Paucity of bowel moments
- Inability to tolerate feeds

Paralytic Ileus:

Hwabejire J et al. ACS Case Reviews in Surgery 2020

Kaafarani HMA et al. Annals of Surgery 2020
El Moheb M et al. JAMA 2020
**Tips for Treatment:**

- IV fluid and electrolyte repletion (potassium; magnesium)
- Mobilization as tolerated
- Nutritional support: oral/enteric feeding v. TPN
- Reversal of offending agents (narcotics; sedation)
- Gastrointestinal decompression (NG tube, rectal tube; colonoscopy)
- Symptomatic relief (anti-emetics)
- Laxatives (polyethylene glycol BID-TID)

**Acute Colonic Pseudo-Obstruction (Ogilvie’s):**

**Key Features:**

- Acute massive dilation without obstruction.
- CONCERN when cecum > 9cm
- The incidence of colonic ischemia or perforation 15% and when these occur, mortality rises to ~40%.
- Highest risks of perforation are those with a cecal diameter greater than 12 cm and colonic distension over six days.

Kaafarani HMA et al. Annals of Surgery 2020
Hwabejire J et al. ACS Case Reviews in Surgery 2020
Tips for Decompression:

NEOSTIGMINE:
• Reversible acetylcholinesterase inhibitor that enhances muscarinic receptors.

• 2 mg SLOWLY IV over five minutes, with continuous monitoring of vital signs and rhythm for 30 minutes and continuous clinical assessment for 15 to 30 minutes. (Atropine at bedside)

• Relative contraindications: Recent MI, acidosis, asthma, bradycardia, peptic ulcer disease, and therapy with beta-blockers. Consider lower doses of 0.5 – 1 mg.

Decompression:
• Neostigmine effectiveness to resolve ACPO with only one dose averaged was 89.2% (ranging from 84.6 to 95.2%) versus 14.8% (from 0.0 to 45.0%) of control group (NNT = 1 [95% CI 1–2]).

• If partial success, a second dose can be tried.

• Colonic decompression should be considered if medical management is ineffective or contraindicated.
ENTERAL NUTRITION & PERCUTANEOUS GASTROSTOMY TUBE PLACEMENT

What best describes your current approach for placement of percutaneous gastrostomy tubes (PEG tubes) on patients infected with COVID 19?

- Do not place PEG tubes on patients infected with COVID: 11.62% (46 responses)
- Perform PEG placement on patients infected with COVID 19 based on clinical need: 37.37% (148 responses)
- PEG placement for patients infected with COVID 19 is delayed or deferred until after contact precautions are lifted and other means of nutritional access are recommended: 21.87% (87 responses)
- Gastrostomy placement in patients infected with COVID 19 is referred to interventional radiology or surgery: 2.78% (11 responses)
- This issue does not apply to my practice: 26.28% (104 responses)

TOTAL: 394 responses
Tips:

• Gastrostomy tube placement should be considered when the patient is nearing discharge and respiratory status is optimized:
  • Afebrile
  • Off of vasopressors
  • Stable respiratory status
  • After appropriate management/bridging of anticoagulation/antiplatelets
  • Optimization of concomitant medical issues

• Decision for long term enteral access should be based on prognosis and discharge planning.


Tips continued:

• Consider cross sectional imaging or review prior abdominal / chest imaging to ensure an adequate placement window prior to the procedure.

• Optimize issues that may interfere with placement (i.e. ileus / constipation; disseminated intravascular coagulation).

• On the day of exam, perform a thorough abdominal exam prior to attempting placement.
Using CT Imaging to Guide Placement:

GI Placement

IR Placement

Conclusions:

- Hospitalized patients with COVID-19 are at high risk for GI complications that may require co-management with a gastroenterologist.

- GI manifestation may develop as a direct consequence of infection or of prolonged hospitalization.

- It is important to exclude alternative causes of GI illness such as medications and non-COVID infections.

- Careful consideration should be given to the timing of endoscopic procedures in order to optimize patient outcomes and ensure a safe environment for the endoscopist and staff.
COVID-19 Treatment

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Acknowledgement: Brian Metzger, MD

What Are We Going To Talk About Tonight

• General management issues
• Medical management of CoViD-19
• Antimicrobial stewardship
• IBD drugs and CoViD-19
• Famotidine
• PPIs (are the worst drugs known to mankind!!)
General Management Issues

- Empiric treatment for Influenza during Influenza season
- Empiric treatment for bacterial pneumonia in select patients
- Avoiding nebulizing medications
- NSAIDs – Uncertain
- Thromboembolism – Prevention and evaluation
- Managing chronic medications:
  - ACEI/ARBs
  - Statins
  - Immunomodulatory agents

Hydroxychloroquine

- In vitro properties against SARS, MERS and... SARS-CoV-2
- Used early in the pandemic
- Five non-randomized studies failed to identify an association between persons treated with HCQ and mortality
- IDSA – recommends against its use
Lopinavir/ritonavir (Kaletra) – Cao et al.

- Randomized 199 hospitalized patients with severe COVID-19 lopinavir/rit and standard of care (n=99) or SOC alone (n=100)
- 14 days of therapy
- No difference from SOC in the time to clinical improvement (HR for clinical improvement, 1.31; 95% CI, 0.95 to 1.80)
- 28-day mortality
  - 19.2% lop/rit vs. 25.0% standard care
  - RR 0.67 [0.38-1.17]

Remdesivir

- Inhibitor of viral RNA-dependent, RNA polymerase
- Causes premature termination of viral RNA transcription
- Inhibitory activity against SARS-CoV and the MERS-CoV
- Shown to inhibit SARS-CoV-2 \textit{in vitro}
- In rhesus macaques, treatment with remdesivir showed reduction in SARS-CoV-2 viral loads, pathologic changes and progression of clinical disease
Remdesivir – ACTT-1

- **Adaptive Covid-19 Treatment Trial** – NIH funded
- Remdesivir vs. placebo up to 10 days
- Primary outcome – time to recovery
- April 27th – Data and safety monitoring board -> early unblinding
- Prelim results from 1059 patients (538 remdesivir, 521 placebo)
- Median recovery time of 11 days (remdesivir) vs. 15 days (placebo)
  - Rate ratio of recovery 1.32; 95% CI, 1.12 – 1.55; p<0.001


Remdesivir

- Kaplan-Meier estimates of mortality by 14 days
  - 7.1% with remdesivir vs. 11.9% with placebo
  - HR for death, 0.70; 95% CI, 0.47 – 1.04
- KM estimates of mortality by 28 days not reported “given the large number of patients that had yet to complete day 29 visits”

Remdesivir – SIMPLE Trial

- Randomly assigned remdesivir for 5 or 10 days
- Patients receiving mechanical ventilation excluded
- Primary endpoint – clinical status on day 14 using a 7-point scale
- 200 patients assigned 5 days, 197 assigned 10 days
- By day 14, a clinical improvement of 2 points or more occurred in 64% of patients in the 5-day group and in 54% in the 10-day group


Dexamethasone – RECOVERY Trial

- Randomized, controlled, open label trial in UK
- Dexamethasone (IV or PO) 6 mg daily up to 10 days, or receive usual care
- 28-day mortality:
  - Dexamethasone group: 482/2104 (22.9%)
  - Usual care group: 1110/4321 (25.7%)
- Age-adjusted RR: 0.83; P<0.001

Dexamethasone – RECOVERY Trial

- Mortality among patients receiving mechanical ventilation:
  - 29.3% vs. 41.4%; RR, 0.64
- Mortality among patients receiving oxygen without mechanical ventilation:
  - 23.3% vs. 26.2%; RR, 0.82
- Mortality among patients receiving no respiratory support:
  - 17.8% vs. 14.0%; RR, 1.19


Anticoagulation

- Elevated rates of thrombotic complications in COVID-19
- Thrombotic complications lead to increased morbidity and mortality
- We know patients should be anticoagulated, don’t know to what degree
- Prophylactic dose anticoagulation for all inpatients
- Intermediate or therapeutic dose anticoagulation for critically ill individuals (e.g., in the ICU)
- Possible continued thrombo-prophylaxis following discharge
Antimicrobial Stewardship and COVID-19

• Too many patients receiving antibacterial agents at COVID admission
• WHO – overprescribing of antibiotics for COVID-19 patients may be creating resistance to antibiotics used to treat common infections
• “Evidence shows that only small proportion of COVID-19 patients need antibiotics to treat subsequent bacterial infections” – WHO
• Bacterial superinfection or post-viral pneumonia presents days later
• Of 1705 patients with COVID-19, 56.6% were prescribed early empiric antibacterial therapy; 3.5% (59/1705) had a confirmed community-onset bacterial infection


Others Being Studied

• Actemra (tocilizumab)
• Kevzara (sarilumab)
• Calquence (acalabrutinib)
• Xeljanz (tofacitinib)
• Jakafi (ruxolitinib)
• Olumiant (baricitinib) – EUA (1 day)
• Kineret (anakinra)
• Ilaris (canakinumab)
• Otezla (apremilast)
• Mavrilimumab
• Avigan (favipiravir)
• Arbidol (umifenovir)
• Galidesivir
• Merimepodib
• Colchicine
• Ivermectin - stay tuned
• Famotidine
• etc., etc., etc.
Convalescent Plasma

• Passive antibody transfer from patient recovered from COVID-19
• Neutralizing antibodies are thought to be the main active component; other immune mediators may also contribute
• Antibodies bind to circulating virus in COVID-19 patient
• Optimal characteristic of CP – High Ab titer
• FDA Expanded Access Program (April 2020)
• Mayo Clinic Protocol
  • US Government-sponsored, national, pragmatic intervention conducted as a multicenter, open-label protocol in hospitalized adults with COVID-19

Convalescent Plasma – Mayo Protocol

• Between April 4 and July 4, 36,226 patients transfused through the EAP
• 7-day mortality rate reduced in patients transfused within 3 days (8.7%) of diagnosis compared to transfused >= 4 days after diagnosis (11.9%; P<0.001)
• Decrease in mortality associated with antibody levels at both 7- and 30-days (p<0.05)
Convalescent Plasma – FDA EUA

• August 23rd, FDA granted Emergency Use Authorization
• Hospitalized patients with COVID-19
• “Given that the clinical evidence supporting this EUA was not obtained from prospective, well-controlled randomized clinical trials (RCTs), additional RCTs are needed. Convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. Ongoing clinical trials of convalescent plasma should not be amended based on the issuance of the EUA. Providers are encouraged to enroll patients in those ongoing clinical trials.”

Monoclonal Antibodies

• Convalescent plasma limitations
  • batch-to-batch variability
  • requirement for blood type matching
  • screening for blood-borne pathogens, including hepatitis viruses, HIV etc.
• Mechanisms available to rapidly produce antiviral monoclonal Ab
• Can be rapidly scaled up (see mAb114 and REGN-EB3 for Ebola)
• Several candidates in trials potently neutralize SARS-CoV-2
• Generally target spike protein

Bamlanivimab and Casirivimab-imdevimab aka "Trump cocktail"

- FDA EUA for **non-hospitalized** CoViD-19 patients with mild to moderate illness who have risk factor for severe disease, any one of the following:
  - BMI of 35 or more
  - CKD
  - DM
  - Immunosuppression (Disease or treatment)
  - Age 65 or more
  - Age 55 or more with CAD and/or HTN and/or COPD
- Antibodies need to be given as soon as possible in a single dose within 10 days.

Adjusting IBD Medications

- **Therapies requiring no interruption:**
  - Budesonide
  - Aminosalicylates
  - Topical rectal therapy

- **Therapies requiring temporary adjustments:**
  - Glucocorticoids:
    - Mild to moderate disease: reduce dose to 20mg or less
    - Severe disease: continue at the same dose
  - Immunomodulators: Hold thiopurines and MTX in patients with active symptoms, until symptoms resolve
Adjusting IBD Medications

- Tofacitinib:
  - Consider holding or reduce dose to 5mg po bid in patients with active symptoms till the symptoms resolve
- Biologics:
  - Consider delaying therapy in patients with active symptoms until the symptoms resolve

Does PPI Use Increase The Risk of COVID-19?

- PPIs increase the risk of enteric infections
- Online survey: 53,310 participants, 3,386 (6.4%) reported positive CoViD-19 test
- Regression analysis showed individuals using PPIs up to once daily (aOR 2.15, 95% CI 1.9-2.44) or twice daily (aOR 3.67; 95% CI 2.93-4.6) had increased odds for reporting a positive CoVid-19 test when compared to those not taking PPIs
- H-2 receptors antagonists were not implicated

Spiegel and Chey et al. AJG Aug 2020
Famotidine and COVID-19

- Associated with improved clinical outcomes in hospitalized COVID-19 patients – Gastroenterology 2020;159:1129-1131
- Famotidine use in hospitalized patients with COVID-19 is associated with a lower risk of mortality, lower risk of combined outcome of mortality and intubation, and lower levels of serum markers for severe disease in hospitalized patients with COVID-19 – Mather et al AJG Aug 2020
- Territory-wide retrospective cohort analysis of 952 patients from Hong Kong showed no effect of Famotidine or PPIs on the severity of Covid-19 illness – Cheung et al, Gastro May 2020

Top 5 Take Home Pearls

- Hydroxychloroquine and Lopinavir/ritonavir has no role in the medical management of COVID-19 patients (this is not a political statement)
- Remdesivir has limited role in non-ventilated hospitalized patients requiring supplemental oxygen
- Dexamethasone has a role in hospitalized patients with severe respiratory complications of COVID-19 requiring supplemental oxygen including mechanical ventilation
- Anticoagulation is recommended in all patients (prophylactic versus full-dose)
- IBD meds need adjustments as discussed
Top Clinical Questions Regarding COVID-19 Vaccines

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Objectives

- Discuss vaccine safety update from CDC
- Provide an update on anaphylaxis following COVID-19 vaccinations
- Review consensus statements regarding providing vaccine in immunosuppressed patients
- Review statements regarding providing vaccines to pregnant patients and lactating women

COVID-19 Cases and Vaccination in U.S.

- COVID-19 Cases in US 26,852,809 and 462,037 Deaths
- Total Doses Vaccines Administered 42,417,617

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<thead>
<tr>
<th></th>
<th>COVID cases</th>
<th>Severe COVID</th>
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<tbody>
<tr>
<td>Pfizer vaccines</td>
<td>43,555</td>
<td>Vaccine 8</td>
</tr>
<tr>
<td>administered</td>
<td></td>
<td>Placebo 162</td>
</tr>
<tr>
<td>Moderna vaccine</td>
<td>28,207</td>
<td>Vaccine 11</td>
</tr>
<tr>
<td>administered</td>
<td></td>
<td>Placebo 225</td>
</tr>
</tbody>
</table>

American College of Gastroenterology
How Do I Get a Vaccine?

We got our COVID-19 vaccines. Can we go back to normal?

• Getting vaccinated and following CDC recommendations to protect yourself and others offers the best protection from COVID-19.
  • Wear a mask.
  • Avoid close contact. Maintain social distancing.


https://www.cdc.gov/vaccines/covid-19/index.html
Should COVID-19 + patients get vaccinated?

• Due to the risk of COVID-19 and potential reinfection immunization is recommended
• Unknown how the length of natural immunity
• No recommended minimum interval between infection and vaccination
• Standard dose of COVID-19 vaccines

MMWR Morb Mortal Wkly Rep 2021;70:46–51

Update on Vaccine Safety from V-safe program
Will the shot hurt or make me sick? What about the side effects?

- Explain that they cannot get COVID-19 from the vaccine.
- Explain what the most common side effects from vaccination are and how long they last.

### Vaccine Safety Update - V-Safe Data

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
<th>All COVID-19 Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>People receiving 1 or more doses in the United States</td>
<td>12,153,536</td>
<td>9,689,497</td>
<td>21,843,033</td>
</tr>
<tr>
<td>Registrants completing at least 1 v-safe health check in</td>
<td>997,042</td>
<td>1,083,164</td>
<td>2,080,216</td>
</tr>
<tr>
<td>Pregnancies reported to v-safe</td>
<td>8,633</td>
<td>6498</td>
<td>15,131</td>
</tr>
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</table>

As of 1/20/2021 v-safe data
Local and systemic reactions

<table>
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<tr>
<th>Reactions, day 0-7</th>
<th>All vaccines %</th>
<th>Pfizer-BioNTech dose 1%</th>
<th>Pfizer-BioNTech Dose 2%</th>
<th>Moderna dose 1%</th>
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<tbody>
<tr>
<td>Pain</td>
<td>70.7</td>
<td>67.7</td>
<td>74.8</td>
<td>70.1</td>
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<tr>
<td>Fatigue</td>
<td>22.4</td>
<td>28.6</td>
<td>50.0</td>
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<tr>
<td>Headache</td>
<td>29.4</td>
<td>25.6</td>
<td>41.9</td>
<td>26.0</td>
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<tr>
<td>Myalgia</td>
<td>22.8</td>
<td>17.2</td>
<td>41.6</td>
<td>19.6</td>
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<tr>
<td>Chills</td>
<td>11.5</td>
<td>7.0</td>
<td>26.7</td>
<td>9.3</td>
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<tr>
<td>Fever</td>
<td>11.4</td>
<td>7.4</td>
<td>25.2</td>
<td>9.1</td>
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<tr>
<td>Swelling</td>
<td>11.0</td>
<td>6.8</td>
<td>26.7</td>
<td>13.4</td>
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<tr>
<td>Joint pain</td>
<td>10.4</td>
<td>7.1</td>
<td>21.2</td>
<td>8.6</td>
</tr>
<tr>
<td>Nausea</td>
<td>8.9</td>
<td>7.0</td>
<td>13.9</td>
<td>7.7</td>
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Update on anaphylaxis following COVID-19 vaccine
Is it safe to get a COVID-19 vaccine if I have allergies?

- Ask what kind of allergies they are concerned about.
- Explain that people should not get vaccinated if they are allergic to any ingredient in COVID-19 vaccines.

### Anaphylaxis reports to VAERS following COVID-19 vaccines

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pfizer-BioNTech (N=50)</th>
<th>Moderna (N=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years</td>
<td>38.5 (26-63)</td>
<td>39 (24-63)</td>
</tr>
<tr>
<td>Female</td>
<td>47 (94)</td>
<td>21 (100)</td>
</tr>
<tr>
<td>Minutes to symptom onset, median (range)</td>
<td>10 (&lt;1-1200)</td>
<td>10 (&lt;1-45)</td>
</tr>
<tr>
<td>Symptom onset &lt; 15 minutes (%)</td>
<td>37 (74)</td>
<td>18 (86)</td>
</tr>
<tr>
<td>Symptom onset &lt; 30 minutes (%)</td>
<td>45 (90)</td>
<td>19 (90)</td>
</tr>
<tr>
<td>Document h/o of allergies or allergic rxn (%)</td>
<td>40 (80)</td>
<td>18 (86)</td>
</tr>
<tr>
<td>Document h/o of prior anaphylaxis (%)</td>
<td>12 (24)</td>
<td>5 (24)</td>
</tr>
</tbody>
</table>
Estimated anaphylaxis reporting rates following COVID-19 vaccines

<table>
<thead>
<tr>
<th>Reported vaccine doses administered</th>
<th>Anaphylaxis cases</th>
<th>Reporting rate (analytic period Dec 14-Jan 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech 9,943,247</td>
<td>50</td>
<td>5.0 per million doses admin</td>
</tr>
<tr>
<td>Moderna 7,581,429</td>
<td>21</td>
<td>2.8 per million doses admin</td>
</tr>
<tr>
<td>H1N1 influenza</td>
<td></td>
<td>10.8 per million doses administered</td>
</tr>
<tr>
<td>Influenza</td>
<td></td>
<td>1.35 cases per million per doses administered</td>
</tr>
</tbody>
</table>


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Can I proceed with vaccination?

<table>
<thead>
<tr>
<th>ALLERGIES</th>
<th>ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of allergies that are unrelated to components of an mRNA COVID-19 vaccine, other vaccines, injectable therapies, or polysorbate such as...</td>
<td>History of any immediate allergic reaction to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccine or polysorbate, as these are contraindicated)</td>
</tr>
<tr>
<td>• Allergy to oral medications (including the oral equivalent of an injectable medication)</td>
<td>• Risk assessment</td>
</tr>
<tr>
<td>• History of food, pet, insect, venom, environmental, latex, etc, allergies</td>
<td>• Consider deferral of vaccination and/or referral to allergist/immunologist</td>
</tr>
<tr>
<td>• Family history of allergies</td>
<td>• 30-minute observation period if vaccinated</td>
</tr>
<tr>
<td>ACTIONS</td>
<td>ACTIONS</td>
</tr>
<tr>
<td>30-minute observation period for persons with a history of anaphylaxis (due to any cause)</td>
<td>History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines:</td>
</tr>
<tr>
<td>15-minute observation period for all other persons</td>
<td>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components</td>
</tr>
<tr>
<td></td>
<td>• Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polysorbate 80)*</td>
</tr>
<tr>
<td></td>
<td>• Immediate allergic reaction of any severity to polysorbate 80**</td>
</tr>
<tr>
<td></td>
<td>ACTIONS</td>
</tr>
<tr>
<td>Do not vaccinate*</td>
<td></td>
</tr>
<tr>
<td>Consider referral to allergist/immunologist</td>
<td></td>
</tr>
</tbody>
</table>

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My patient had an allergy to a biologic. Can they get the vaccine?

### Reaction History

<table>
<thead>
<tr>
<th>Reaction History</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of allergies unrelated to injectable therapies, vaccines, or mRNA vaccine components</td>
<td>Proceed with COVID-19 vaccine with 15-minute observation</td>
</tr>
<tr>
<td>History of anaphylaxis due to any cause</td>
<td>Proceed with COVID-19 vaccine with 30-minute observation</td>
</tr>
<tr>
<td>History of immediate reaction* to vaccine or injectable therapy</td>
<td>Risk assessment, consider vaccine deferral or referral to Allergy/Immunology May proceed with COVID-19 vaccination with 30-minute observation</td>
</tr>
</tbody>
</table>

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Update on Recommendations for Pregnant Patients and Lactating Women
Is it safe to get a COVID-19 vaccine if I am pregnant or breastfeeding?

• Limited data about the safety of COVID-19 vaccines during pregnancy and breastfeeding, but that experts do not believe it poses a risk.
• Clarify that patients may choose to get vaccinated if they are part of a recommended group.
• Emphasize that vaccination is a personal decision and offer to discuss it in more depth.

Should my pregnant patient or lactating women get a COVID-19 Vaccine?

• WHO
  • Use mRNA vaccines in pregnancy only in health workers or those with comorbidities
• ACOG & ACIP
  • Recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
  • Lactating Women
  • COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
Update on Recommendations for COVID 19 Vaccination in Immunosuppressed Patients

Should I vaccinate my immunosuppressed patient?

- Immunosuppressed patients with IBD should receive a COVID 19 vaccine.
- COVID-19 vaccination is recommended for all SOT recipients including liver transplant recipients.
Do I need to hold immunosuppression?

- Patients with IBD, Liver transplant recipients and those with chronic liver disease should not hold or interrupt their therapy to receive a vaccine.
- Certain immunosuppressant may blunt vaccine response of certain vaccines.

Do I need to check for antibody pre-or post immunization?

- Serum antibody testing against SARS-CoV-2 is NOT recommended pre- or post-vaccination to confirm immunity.
- Over 60 commercial assays to detect IgG and/or IgM antibodies to SARS-CoV-2 spike glycoprotein and/or nucleoprotein under EUA.
  - They are high sensitivity, specificity, and negative predictive value but variable positive predictive value.
  - They do not reflect protect immunity.
Which vaccine should I get?

- Pfizer
- Moderna
- J & J
- Get the one that is offered to you

Recommending COVID-19 Vaccine

- Start from a Place of Empathy and Understanding
- Assume Patients Will Want to Be Vaccinated but May Not Know When to Expect It
- Give Your Strong Recommendation
- “I strongly recommend you get a COVID-19 vaccine once it is widely available…”

https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html
Thank you

Fcaldera@medicine.wisc.edu
@dr_fcalderaibd

Questions & Answers
1 FACT/1 MYTH COVID-19 VACCINE INFORMATION
FROM THE AMERICAN COLLEGE OF GASTROENTEROLOGY

#1FACT1MYTH

FOR MORE INFO BIT.LY/ACG-COVIDVACCINE
#1FACT1MYTH #COVIDVACCINE #MYCOVIDVAX #COVID19