2021 ACG'S IBD SCHOOL
JANUARY 30, 2021 | Virtual!
Register online: meetings.gi.org

2021 ACG/FGS ANNUAL SPRING SYMPOSIUM
FEBRUARY 26-28, 2021 | NAPLES GRANDE BEACH HOTEL
NAPLES, FLORIDA
Register online: meetings.gi.org
ACG/VIRTUAL NAVIGATING, NETWORKING AND NEGOTIATING YOUR FIRST JOB WORKSHOP

MODERATORS

Dr. Kara De Felice
Dr. Shivangi Kothari
Dr. Judy Trieu

PANELISTS

Dr. Daniel Raines
Dr. David Greenwald
Dr. Harish Gagneja
Dr. Margaret Schiessow
Dr. Amy Oxentenko
Dr. Mark Pochapin
Dr. Ripple Sharma
Dr. Samir Sheh
Dr. Vivek Kaul

Saturday, January 16, 2021 at 10 am to 1 pm EST

Fellows interested in gaining valuable insight on what he or she faces at the start of their career will find this workshop a must-attend event.

This event is hosted by the ACG Women In GI Committee and supported by Medtronic.
ACG Virtual Grand Rounds
Join us for upcoming Virtual Grand Rounds!

Week 1, 2021: Management of Acute Kidney Injury in Patients with Cirrhosis
Paul Y. Kwo, MD, FACC
January 7, 2021 at Noon Eastern

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.

Week 2, 2021: Management of Barrett’s Esophagus
Prateek Sharma, MD, FACC
January 14, 2021 at Noon Eastern

Visit gi.org/ACGVGR to Register

Disclosures
According to ACCME guidance, because there are no current preventive or specific treatments for coronavirus infection, there are no relevant conflicts of interest for any speakers or moderators.

Speakers:

Freddy Caldera, DO, MS
Francis A. Farraye, MD, MSc, MACG
David A. Greenwald, MD, FACC (Moderator)

Mary Hayney, RPH, PharmD, MPH, BCPS
Jonathan L. Temte, MD, PhD, MS
COVID-19 Vaccines
Where are we today?

David A. Greenwald, MD, FACP
ACG President
Director of Clinical Gastroenterology and Endoscopy
Mount Sinai Hospital
New York, NY

Worldwide COVID-19 Cases as of 12/22/2020 at 10:22am

Global Cases: 77,556,703
Global Deaths: 1,706,513
U.S. COVID-19 Cases as of 12/22/2020 at 10:22am

DAILY CONFIRMED NEW CASES (7-DAY MOVING AVERAGE)
Outbreak evolution for the current 10 most affected countries

Categories of data: New cases, Incidence rate, Case fatality rate, 30-day survival

Click any country below to hide/show from the graph:
- United States
- Brazil
- United Kingdom
- Russia
- India
- Turkey
- France
- Colombia
- Germany

12/21/2020 https://coronavirus.jhu.edu/data/new-cases
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 decision we make will be followed closely by our colleagues, co-workers 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.
Outline for this lecture:

- **COVID-19 vaccine development**
  - Traditional vaccine development
  - Operation Warp Speed Accelerated Vaccine Development
- **m-RNA vaccine**
  - What are m-RNA vaccine
  - How they work
- **The Role of the ACIP**
  - How vaccine are typically recommended
  - The COVID-19 ACIP work group
  - ACIP recommendation for COVID-19 vaccines
- **Pfizer Study**
  - Methods
  - Primary outcome
  - Efficacy
  - Adverse events
Objectives

- Review traditional and accelerated vaccine development
- Discuss the role of Operation Warp Speed in COVID-19 vaccine development

Vaccine Hesitancy

- Prior to COVID-19 pandemic
  - Hesitancy among general population
  - Top 10 threat to Global Health
- COVID-19 vaccine
  - Political polarization
  - Concern of shortcuts in vaccine development.
  - Social Media disinformation

Watel et al. Lancet Infectious Disease 2020
COVID-19 Vaccine Timeline

Traditional Vaccine Development: Shingrix
Operation Warp Speed: COVID-19 vaccine development

- Produce and deliver 300 million doses of safe and effective vaccines available and deployed by mid-2021.
- Key goals
  - Ensure safety and effective of COVID-19 vaccines
  - Reduce morbidity and mortality of COVID-19 disease through effective and efficient distribution of COVID-19 vaccines
Three Entities with Distinct Roles in COVID-19 Response

- **Operation Warp Speed**
  - USG body responsible for strategic approach, coordination and resource allocation

- **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**
  - NIH established Public-private partnership for coordinating COVID-19 response

- **COVID-19 Prevention Network**
  - NIH Funded networks - Phase 3 trial execution

**OWS: Selected COVID-19 Vaccine Candidates**

- **Nucleic Acid vaccines**
  - Moderna
  - Biontech
  - Pfizer

- **Protein vaccines**
  - Novavax
  - GSK
  - Sanofi

- **Viral Vector Vaccines**
  - Johnson & Johnson
  - AstraZeneca
Harmonized Protocols for Clinical Trials

<table>
<thead>
<tr>
<th>Collaborating clinical trial networks (CoVPN)</th>
<th>Harmonized efficacy trials</th>
<th>Collaborating labs 1. Defining COVID infection from disease 2. Quantitative immune responses to spike and epitopes 3. T cell Responses</th>
<th>Correlates of protection analyses within and cross protocols in different trials</th>
<th>Common data safety monitoring board (DSMB)</th>
</tr>
</thead>
</table>

- NIH/COVID Network-supported infrastructure

Phase III efficacy trials in OWS

- Randomized, Placebo-Controlled Efficacy Trial
- Sample size: approximately 30,000 volunteers
- Study population: age > 18, targeting subset at high risk of severe disease, diverse populations
- Primary endpoint: Prevention of symptomatic COVID-19 disease (virologically confirmed) Harmonized OWS immunogenicity assays and correlates analysis
- Common DSMB (NIAID Managed)
FDA Requirements to approve an EUA for a COVID-19 Vaccine

- Nonclinical studies
- Clinical studies should be large (30,000 patients) double blind randomized clinical trials
  - Efficacy with a point estimate for placebo controlled efficacy trials of at least 50%
- Median of 2 months follow up following final vaccination series.
  - Most, but not all, serious adverse events occur within that time

CDC plans for safety monitoring
Recommendation COVID-19 Vaccine

- Make a strong recommendation for COVID-19 vaccination
- Providers recommendation for immunization is associated with high vaccine uptake

Thank you to the scientific community

- ACIP members and ACIP COVID-19 working group
- Scientist at NIH
- FDA Advisory
- Scientist at Vaccine and Related Biological Products Advisory Committee (VRBPAC)
- Members of OWS
- Clinical Trial Participants

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mRNA Vaccines for COVID

Mary S. Hayney, PharmD, MPH, FCCP, BCPS
Professor of Pharmacy
University of Wisconsin School of Pharmacy

Learning objectives

• Describe the mechanism of inducing an immune response to mRNA vaccines
• Compare the known safety and potential risks of mRNA vaccines to other vaccine platforms
• State the vaccine efficacy for the COVID-19 mRNA vaccines
• Gather information about expected adverse effects following COVID-19 mRNA vaccines
mRNA vaccines—not that new

- Studied for more than 10 years
- Targets researched
  - Influenza
  - Cytomegalovirus
  - Zika virus
  - Rabies
  - Cancer
- Early efforts plagued by mRNA instability

mRNA vaccine safety

- Non-infectious
- Non-integrating
- Degraded by cellular processes
  - Duration can be regulated by modification and delivery methods
- Immunity to the vector not a consideration
mRNA advantages

- Modify mRNA to increase translation in cytoplasm
- Potential for rapid, inexpensive and scalable production

mRNA vaccine compared to other vaccine platforms

- **Infection risk**
  - Live attenuated

- **Wide array of antigens**
  - Live attenuated
  - Inactivated

- **Low reactogenicity**
  - Recombinant, subunit

- **Antibody induction**
  - Live attenuated
  - Inactivated
  - Recombinant
  - mRNA

- **CMI induction**
  - Live attenuated
  - mRNA

- **Easy to produce**
  - mRNA

- **Long-lasting protection**
  - Live attenuated
Formulation of mRNA vaccine

- Naked mRNA rapidly degraded by extracellular processes
- Coated with lipid nanoparticles
  - Protects mRNA from degradation
  - Facilitate entry into cell

How mRNA Vaccines Work
mRNA vaccine mechanism of action

• mRNA encodes some of the coronavirus spike protein
• mRNA in lipid coat enters cell
• Translated into viral spike protein
  • mRNA quickly broken down by cellular enzymes
  • mRNA does not enter cell nucleus
• Immune system recognizes viral protein
  • This antigenic protein is presented to the immune system
  • Initiates B cell (antibody) and cytotoxic T cell response

mRNA vaccines for COVID-19

• Moderna
  • 2 dose series
  • 30,000 participants ages 18-64 years and >65 years without risk factors
• Pfizer BioNTech
  • 2 dose series
  • 30,000 participants ages 18-85 years
Immune responses—COVID-19 mRNA vaccines

<table>
<thead>
<tr>
<th>mRNA vaccine</th>
<th>Neutralizing antibody</th>
<th>CD4+ response</th>
<th>Th polarization</th>
<th>CD8+ response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna mRNA1273</td>
<td>Robust</td>
<td>✓</td>
<td>Th1</td>
<td>Low</td>
</tr>
<tr>
<td>Pfizer BNT162b2</td>
<td>Robust</td>
<td>✓</td>
<td>Th1</td>
<td>✓</td>
</tr>
</tbody>
</table>


mRNA vaccines in clinical trials

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dosing schedule</th>
<th>Number in clinical trial</th>
<th>Vaccine efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna mRNA1273</td>
<td>28 day interval</td>
<td>30,350 15,184 (vaccine)</td>
<td>94.5% (95% CI 86.5-97.8%)</td>
</tr>
<tr>
<td>Pfizer BNT162b2</td>
<td>21 day interval</td>
<td>37,796 18,904 (vaccine)</td>
<td>95.5% (95% CI 88.8-98.4%)</td>
</tr>
</tbody>
</table>
Vaccine storage

• Storage requirements of vaccines under development

mRNA vaccine safety in clinical trials

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Any adverse effect</th>
<th>Local reaction</th>
<th>Local reaction Grade 3</th>
<th>Systemic reaction</th>
<th>Systemic reaction Grade 3 or 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine</td>
<td>Placebo</td>
<td>Vaccine</td>
<td>Placebo</td>
<td>Vaccine</td>
</tr>
<tr>
<td>Moderna mRNA1273</td>
<td>94.5%</td>
<td>59.5%</td>
<td>92.0%</td>
<td>28.9%</td>
<td>9.1%</td>
</tr>
</tbody>
</table>

Grade 3 local reaction: requires narcotics for pain; significant discomfort at rest, redness or induration >10cm or prevents daily activity
Grade 3 systemic reaction: prevents daily activity (specific guidelines for organ system) or requires narcotic use
Grade 4 systemic reaction: requires ER visit or hospitalization
Other common adverse events

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Frequency</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna mRNA1273 Vaccine</td>
<td>63.0%</td>
<td>36.5%</td>
</tr>
<tr>
<td>Headache</td>
<td>59.6%</td>
<td>20.1%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>44.8%</td>
<td>17.2%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>14.8%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Fever</td>
<td>0.6%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

Moderna mRNA adverse effects

- Grade 3 local reactions more common after dose 2
  - 3.5% vs 7.0%
- Local AE onset day 1 and lasted 2 days after dose 1 and 3 days after dose 2
- Fever in 0.8% after dose 1 and 15.6% after dose 2
- Systemic reactions persisting beyond 7 days
  - Vaccine group 11.9%
  - Placebo group 9.5%
- Reactogenicity milder in individuals aged 65 years and older
Questions

• So many
• Endpoint of trials is prevention of disease
  • Questions remain regarding infection or transmission
• Public acceptance
• Research should continue after EUA or licensure

Resources

• CDC COVID-19 Vaccination
  https://www.cdc.gov/vaccines/covid-19/index.html
The Role of the
U.S. Advisory Committee on Immunization Practices
in COVID-19 Vaccines

Jonathan L. Temte, MD, PhD
Associate Dean for Public Health and Community Engagement
University of Wisconsin School of Medicine and Public Health

Objectives

• Gain an understanding of the typical process for vaccine recommendation

• Appreciate the role of the ACIP COVID-19 work group and its relationship to ACIP

• Recognize the current ACIP recommendations for COVID-19 vaccines
Events in vaccine development

Identification of Candidate Disease

Laboratory isolation of antigens

Vaccine Development

Application to FDA

Human Testing For Safety And Response

Animal Testing For Safety And Response

Phases of clinical trials

Preclinical
Phase 1
Phase 2
Phase 3
FDA Review
Phase 4

Clinical Trials

Drug Approved for Testing in Humans
Drug Submitted for FDA Approval
Drug Approved

20-80 Participants
100-300 Participants
1,000-3,000 Participants
1,000+ Participants

To Confirm Safety and Effectiveness
Phases of clinical trials

• **Phase 1**: clinical trials focus on safety
  - 20–100 healthy volunteers
  - Assesses how the size of the dose may be related to side effects
  - Serological effects

• **Phase 2**: clinical trials assess dosing
  - several hundred volunteers
  - additional information on common short-term side effects and how the size of the dose relates to immune response

• **Phase 3**: clinical trials assess efficacy and safety
  - Participation of hundreds or thousands of volunteers
  - Placebo-controlled RCTs

Safety assessments

- Initial safety assessment occurs > 63—70 days after the last participant in a trial receives the first dose
- **Per FDA Updated Guidelines**: minimum of 60 days after last dose received in 50% of participants
Efficacy Assessments

Per FDA Updated Guidelines: minimum of 50% estimated efficacy / lower confidence interval ≥ 30%

- Pfizer:
  - Primary efficacy analysis involved 170 cases
  - Efficacy against any COVID-19 disease; 28 days after 2nd dose was 95%
    - 162 observed in the placebo group versus 8 in the vaccine group
  - Efficacy was consistent across age, gender, race, and ethnicity demographics
    - Observed efficacy in adults over 65 years of age was over 94%

- Moderna:
  - Primary efficacy analysis involved 196 cases of COVID-19
  - Efficacy against any COVID-19 disease; 2 weeks after 2nd dose was 94.1%
    - 185 cases in the placebo group and 11 in the vaccine group
  - Efficacy against severe disease was 100%
    - 30 cases in the placebo group and 0 cases in the vaccine group

Events in vaccine development
Emergency Use Authorization

- Food and Drug Administration (FDA) can use the Emergency Use Authorization (EUA) authority to facilitate the availability and use of vaccine needed during this public health emergency.
  - Attention is still given to safety and efficacy
  - This can shorten the time between development of a vaccine and its deployment
Work Group

- ~50 members
- CDC subject matter experts
- Consultants
- Guests (industry)
- Not a Federal Advisory Committee
- Creates policy options

ACIP

- 15 voting members
- Ex officio members
- CDC secretariat
- Federal Advisory Committee
- Provides advice on recommendations

Recommendations

- The U.S. Centers for Disease Control and Prevention, (CDC) through its Advisory Committee on Immunization Practices (ACIP), reviews data on any authorized vaccine
- ACIP provides recommendation for appropriate use of any COVID-19 vaccine in the U.S. civilian population
- Recommendations detail dosing and interval, special populations, and precautions and contraindications
The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Kathleen Dooling, MD; Nancy McChesney, PhD; Mary Chamberland, MD, MSc; Mona Marin, MD; Megan Wallace, DrPH; Beth P. Bell, MD; Grace M. Lee, MD; H. Kripp Talbot, MD; José R. Romero, MD; Sara E. Oliver, MD

December 3, 2020


Sara E. Oliver, MD; Julia W. Gargano, PhD; Mona Marin, MD; Megan Wallace, DrPH; Kathryn G. Curran, PhD; Mary Chamberland, MD, MSc; Nancy McChesney, PhD; Doug Campos-Outcalt, MD; Rebecca L. Morgan, PhD; Sarah Musher, MD; José R. Romero, MD; H. Kripp Talbot, MD; Grace M. Lee, MD; Beth P. Bell, MD; Kathleen Dooling, MD

December 13, 2020

Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 in persons aged 16 years and older. The Pfizer-BioNTech COVID-19 vaccine is a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19).

These CDC clinical considerations are informed by data submitted to the Food and Drug Administration for Emergency Use Authorization (EUA) of the vaccine, other data sources, general best practice guidelines for immunization, and expert opinion. In addition to the following considerations, the EUA conditions of use (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html) should be referenced when using the Pfizer-BioNTech COVID-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html
Review of Pfizer and Moderna Covid-19 Vaccine Studies

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Division of Gastroenterology and Hepatology
Director, Inflammatory Bowel Disease Center
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Covid-19 Vaccine Studies

Covid-19 Vaccine Headlines

F.D.A. Clears Pfizer Vaccine, and Millions of Doses Will Be Shipped Right Away

Covid-19: F.D.A. Authorizes Moderna Vaccine for Emergency Use, Adding Millions of Doses to U.S. Arsenal

At Least 128,000 People in the U.S. Have Received the Covid-19 Vaccine
NY Times 12/19/2020

Covid-19 Vaccine Headlines

At Least 556,000 People in the U.S. Have Received the Covid-19 Vaccine
By The New York Times  Updated Dec. 21, 2020
Pfizer Vaccine Study Design

- mRNA vaccine
- 43,548 participants ≥ 16 were randomized 1:1 to vaccine or placebo by intramuscular injection at day 0 and 21
- Participants were followed for a median follow-up of 2 months
- Primary endpoints were safety and development of symptomatic Covid-19

Demographics

- M=F
- Age > 55 years old: 42.2%
- Performed in Argentina, Brazil, South Africa, US
- Median age at vaccination: 52 years old (16-91)
- Hispanic or Latinx: 28.0%
- African American: 9.3%
- Obese: 35.1%
Primary Outcome

- 162 symptomatic cases in the placebo arm and 8 in the vaccine arm
- Of the 10 severe COVID cases 9 were in the placebo arm and 1 in the vaccine arm
- Some early protection was demonstrated 12 days after the first dose
- Seven days after the second dose 95% efficacy was observed

Pfizer Vaccine Safety

- Vaccine recipient had local reactions (pain, erythema swelling) and systemic reactions (fever, headache, myalgias) at higher rates than placebo recipients with more reactions following the second dose
- Most were mild to moderate and resolved rapidly
- Systemic events were more common in younger recipients (<55) than in older recipients (>55)
- Most common reported systemic events were fatigue and headache (59% and 52% respectively)
- Severe systemic events were reported in less than 2% of vaccine recipients
Moderna Vaccine Study Design

- mRNA vaccine
- 30,400 participants in the US ≥ 18 were randomized to vaccine or placebo by IM injection at day 0 and 28
- More than 7,000 participants over age 65 and more than 5,000 participants < 65 with high risk co-morbidities such as diabetes, obesity and cardiac disease
- 11,000 participants from communities of color (37%) including Hispanic and African American
- Primary endpoint was prevention of symptomatic Covid-19 infection
- Secondary endpoints included prevention of severe Covid-19 disease and prevention of infection by SARS-Cov-2
- Participants were followed for a median of follow-up of 2 months

Modernase Vaccine Efficacy

- Efficacy data from the final scheduled analysis of the primary efficacy endpoint (data cutoff of 11/21/2020, with a median follow-up of >2 months post-dose 2)
- Vaccine efficacy of 94.1% (95% CI: 89.3%, 96.8%), with 11 COVID-19 cases in the vaccine group and 185 COVID-19 cases in the placebo group
- Efficacy demonstrated against severe COVID-19 with 30 cases in the placebo group and none in the vaccine arm
Modern vaccine efficacy

- Vaccine efficacy when stratified by age group was 95.6% (95% CI: 90.6%, 97.9%) for participants 18 to <65 of age and 86.4% (95% CI: 61.4%, 95.5%) for participants greater than 65 years of age.

- Consistent high efficacy (≥ 92%) was observed across age, sex, race and ethnicity and among persons with underlying medical conditions and participants with previous SARs-CoV-2 infection.

- Rate of asymptomatic disease as measured by development of COVID antibodies was not reported.

Modern vaccine safety data

- Safety data through 11/25/2020 with a median of 9 weeks of follow-up.

- Solicited local reactions were mild to moderate and present at higher rates in vaccine group with more reactions after the second dose which resolved rapidly.

- Severe adverse reactions occurred in 0.2% to 9.7% of participants, were more frequent after dose 2 than after dose 1, and were generally less frequent in participants ≥65 years of age as compared to younger participants.

- Systemic adverse reactions (grade ≥3, defined as interfering with daily activities) occurred in 0.8% of vaccine recipients and included fatigue (4.2%), headache (2.4%), myalgias (1.8%), chills (1.7%) and injection site pain (1.4%).
Modernah Vaccine Safety Data

- Serious adverse events occurred in 0.6% of vaccine recipients and 0.5% of placebo
- Three cases of Bells palsy in vaccine arm and 1 in the placebo arm
- There were no anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine

Pfizer vs. Moderna mRNA Vaccines

- Pfizer vaccine needs to be stored at about minus 75 degrees Celsius, about 50 degrees colder than any vaccine currently used in the US
- Pfizer vaccine can be put in the refrigerator for only five days before it expires
- Moderna vaccine can be kept at about minus 20 degrees Celsius (same as home freezer)
- Moderna vaccine can also be kept in a refrigerator for 30 days before it expires
What We Do Not Know

- What is the safety and efficacy of these vaccines after two months?
- What is the safety and efficacy in children, pregnant women and immunocompromised patients?
- Will the vaccine protect against asymptomatic infection and transmission to unvaccinated patients?
- What happens if the second dose of vaccine is missed?

CDC Recommendations

- Do not co-administer Covid vaccine with other vaccines
- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
- Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination
- Counsel patients about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html
CDC Recommendations: Pregnancy

• While the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in ICU admission, mechanical ventilation, or death as well as possible increased risk of adverse pregnancy outcomes, such as preterm birth
• If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated
• Consider the level of COVID-19 community transmission, the patient’s personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine and the lack of data about the vaccine during pregnancy

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html

CDC Recommendations: Pregnancy and Lactation

• Those who are trying to become pregnant do not need to avoid pregnancy after Pfizer-BioNTech COVID-19 vaccination
• There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion
• mRNA vaccines are not thought to be a risk to the breastfeeding infant
• A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html
Monitoring for Adverse Events Post Vaccination: V-safe

- Smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination
- You can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine
- Depending on your answers, someone from CDC may call to check on you and get more information
- V-safe will remind you to get your second COVID-19 vaccine dose if you need one


Triage of Persons Presenting for Pfizer Vaccination

<table>
<thead>
<tr>
<th>CONDITIONS</th>
<th>PRECAUTION TO VACCINATION</th>
<th>CONTRAINDICATIONS TO VACCINATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMUNE/IMPAIRING CONDITIONS</td>
<td>Moderately/severely acute illness</td>
<td>None</td>
</tr>
<tr>
<td>PREGNANCY</td>
<td>Risk assessment</td>
<td>NSA/A</td>
</tr>
<tr>
<td>ECONOMICAL</td>
<td>History of severe allergic reaction (e.g., anaphylaxis) to a previous dose including Pfizer-BioNTech vaccines</td>
<td>History of severe allergic reaction (e.g., anaphylaxis) to an injectable vaccine</td>
</tr>
<tr>
<td>AGE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACTIONS
- Risk assessment
- Potential deferral of vaccination
- 15 minute observation period if vaccinated

ACTIONS
- 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine | Do not vaccinate

ACTIONS
- 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause
- 15 minute observation period: Persons with allergic reaction, but not anaphylaxis

* See Special Populations section for information on patient counseling in these groups

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html
Advisory Committee on Immunization Practices
Considerations for Vaccine Prioritization

Update to ACIP recommendations from 12/20/2020 for vaccination in Phase 1a (health care personnel, and long-term care facility residents), if the COVID-19 vaccine supply is limited, the following groups should be offered vaccination:

- **Phase 1b**: persons aged 75 years and older and frontline essential workers
- **Phase 1c**: persons aged 65-74 years, persons aged 16-64 years with high-risk medical conditions, and other essential workers

Overcoming Vaccine Hesitancy will be a Major Challenge

- “COVID 19 is a first disease to have an anti vaccine movement before it had a vaccine” (Tom Frieden, MD, Former Director, CDC 2009-2017)
Influenza Season 2020-2021

• Mild influenza season so far likely due to social distancing
• As of 11/20, approximately 49% of US adults have been vaccinated, up slightly from 44% at the same time last year
• 35% of US adults do not plan to get the influenza vaccine
• Encourage patients to get their flu shot to avoid hospitalizations and use of ICU beds!


Virtual Grand Rounds

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COVID-19 Resource Center
Core COVID-19 Calculators
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