COVID-19 for Pediatric Populations

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Disclosures

• No financial disclosures
• What gets said here today may change based on new data and recommendations
  – Knowledge is shared more rapidly through ECHO
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- Project Firstline is a national collaborative led by the CDC to provide infection control training and education to frontline healthcare workers and public health personnel
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  - CDC is an agency within the Department of Health and Human Services (HHS)
- The contents of this program do not necessarily represent the policies of CDC or HHS and should not be considered an endorsement by the Federal Government
Agenda

• Demographics
  – Disease and vaccination rates in Illinois

• Infection control in the office in the time of vaccination

• COVID-19 vaccines
  – 12-15 year olds
Epidemiology
Chicago Cases
7 day Positivity rate 3%
(5/20/2021)

Illinois Cases
7 day Positivity rate 2.6%
(5/25/2021)

https://covidactnow.org/us/illinois-il?s=1330330
Infection Control
Is it Post-Masking for Those Vaccinated?

- Well, not quite
- CDC changed its guidance on masking
  - Those who are vaccinated
    - Still need to follow guidance at workplace/local businesses
    - If you travel, still take steps to protect yourself and others
    - Still be required to wear a mask on planes, buses, trains, and other forms of public transportation
      - Fully vaccinated international travelers arriving in the US are still required to get tested 3 days before travel by air into the US (or show documentation of recovery from COVID-19 in the past 3 months) and should still get tested 3-5 days after their trip
    - If symptoms of COVID-19, should get tested and stay home and away from others
    - People who have a condition or are taking medications that weaken the immune system, should talk to their healthcare provider to discuss their activities as they may need to keep taking all precautions to prevent COVID-19

Is it Post-Masking for Those Vaccinated?

• Those who are not vaccinated should wear a mask if
  – 2 years of age and older
  – Any time in a public setting
  – Any time traveling on a plane, bus, train, or other form of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations
  – When around people they don’t live, including inside their home or inside someone else’s home
  – If around someone with symptoms of COVID-19 or has tested positive for COVID-19

### Fully Vaccinated People

- Walk, run, wheelchair roll, or bike outdoors with members of your household
- Attend a small, outdoor gathering with fully vaccinated family and friends
- Attend a small, outdoor gathering with fully vaccinated and unvaccinated people
- Dine at an outdoor restaurant with friends from multiple households
- Attend a crowded outdoor event, like a live performance, parade, or sports event

### Unvaccinated People

- Visit a barber or hair salon
- Go to an uncrowded, indoor shopping center or museum
- Attend a small, indoor gathering of fully vaccinated and unvaccinated people from multiple households
- Go to an indoor movie theater
- Attend a full-capacity worship service
- Sing in an indoor chorus
- Eat at an indoor restaurant or bar
- Participate in an indoor, high-intensity exercise class

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Masks

- Clear masks or cloth masks with a clear plastic panel are an alternative
- If using this type of mask, make sure
  - You can breathe easily
  - Excess moisture does not collect on the inside of the mask
  - Do not sleep with this type of mask, since the plastic part could form a seal around the mouth and nose

FDA approved

https://buy.theclearmask.com/collections/consumer/products/clearmask-bulk

What About in the Office

- Healthcare facilities should continue to follow the infection prevention and control recommendations for unvaccinated individuals when caring for fully vaccinated individuals
  - Healthcare facility includes acute care facilities, long term acute care facilities, inpatient rehabilitation facilities, nursing homes/assisted living facilities, home healthcare, mobile clinics, and outpatient facilities
- Recommendations for use of source control or PPE remains unchanged
  - Source control refers to use of well-fitting cloth masks, facemasks, or respirators to cover a person’s mouth and nose and recommended for everyone in a healthcare facility, regardless of symptoms
  - Patients may remove their source control when in their rooms but should put it back on when around others or leaving the room
  - Cloth masks, facemasks and respirators should not be placed on children under age 2, anyone who cannot wear one safely, (i.e., anyone who is unconscious or incapacitated or has condition that prevents wearing it
- HCP should wear well-fitting source control at all times while they are in the healthcare facility, including in breakrooms or other spaces where they might encounter co-workers
  - HCP should try to wear the same respirator or well-fitting facemask throughout their entire work shift
  - HCP should remove their respirator or facemask, perform hand hygiene, and put on their community source control when leaving the facility at the end of their shift
- Encourage Physical Distancing

Why Not Get Rid of Masks in Healthcare Facilities?

• Not everyone who gets vaccinated is fully or partially protected
  – Risk of getting COVID is very low for those vaccinated, on the order of 0.01% and dropping given risk of exposure is decreasing
  – But, exceptions exist and are important to know about:
    • Limited data on vaccine protection in people who are immunocompromised
    • Who is immunocompromised
      – Not sure for this purpose but includes and may not be limited to:
        » Receiving chemotherapy for cancer, hematologic malignancies, being within one year from receiving a hematopoietic stem cell or solid organ transplant (although data suggests it could be years longer), untreated HIV infection with CD4 count < 200, combined primary immunodeficiency disorder, and taking immunosuppressive medications (e.g., drugs to suppress rejection of transplanted organs or to treat rheumatologic conditions such as mycophenolate and rituximab, receipt of prednisone >20mg/day for more than 14 days.)

Infection Control Includes Vaccination

• Facilities should continue to promote and provide vaccination for all HCP
• During patient visits, make the COVID-19 vaccine a new vital sign
  – Ask everyone, parents and child if they are vaccinated and offer to discuss the topic
COVID Youth Vaccination
# Demography for 12-15 and 16-25 year olds (Safety population)

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2</th>
<th>Placebo</th>
<th>BNT162b2</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12-15 Years (N=1131) n (%)</td>
<td>16-25 Years (N=1867) n (%)</td>
<td>12-15 Years (N=1129) n (%)</td>
<td>16-25 Years (N=1903) n (%)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>567 (50.1)</td>
<td>921 (49.3)</td>
<td>585 (51.8)</td>
<td>882 (46.3)</td>
</tr>
<tr>
<td>Female</td>
<td>564 (49.9)</td>
<td>946 (50.7)</td>
<td>544 (48.2)</td>
<td>1021 (53.7)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>971 (85.9)</td>
<td>1443 (77.3)</td>
<td>962 (85.2)</td>
<td>1510 (79.3)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>52 (4.6)</td>
<td>189 (10.1)</td>
<td>57 (5.0)</td>
<td>179 (9.4)</td>
</tr>
<tr>
<td>American Indian or Alaska native</td>
<td>4 (0.4)</td>
<td>32 (1.7)</td>
<td>3 (0.3)</td>
<td>18 (0.9)</td>
</tr>
<tr>
<td>Asian</td>
<td>72 (6.4)</td>
<td>108 (5.8)</td>
<td>71 (6.3)</td>
<td>108 (5.7)</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>3 (0.3)</td>
<td>10 (0.5)</td>
<td>0</td>
<td>3 (0.2)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>23 (2.0)</td>
<td>76 (4.1)</td>
<td>29 (2.6)</td>
<td>74 (3.9)</td>
</tr>
<tr>
<td>Not reported</td>
<td>6 (0.5)</td>
<td>9 (0.5)</td>
<td>7 (0.6)</td>
<td>11 (0.6)</td>
</tr>
<tr>
<td><strong>Racial desig.</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>132 (11.7)</td>
<td>604 (32.4)</td>
<td>130 (11.5)</td>
<td>575 (30.2)</td>
</tr>
<tr>
<td>Non-Hispanic/non-Latino</td>
<td>997 (88.2)</td>
<td>1259 (67.4)</td>
<td>996 (88.2)</td>
<td>1322 (69.5)</td>
</tr>
<tr>
<td>Not reported</td>
<td>2 (0.2)</td>
<td>4 (0.2)</td>
<td>3 (0.3)</td>
<td>6 (0.3)</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>1131 (100.0)</td>
<td>1333 (71.4)</td>
<td>1129 (100.0)</td>
<td>1364 (71.7)</td>
</tr>
<tr>
<td>Others*</td>
<td>0</td>
<td>534 (28.6)</td>
<td>0</td>
<td>539 (28.3)</td>
</tr>
</tbody>
</table>

*Argentina, Brazil, Germany, South Africa, Turkey

Note: All 12-15 year olds from the US; ~72% of 16-25 year olds from the US

Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 12-15 and 16-25 Year Olds

Redness and swelling severity definition: Mild = >2-5 cm, Moderate = >5-10 cm; Severe = >10 cm; Grade 4 = necrosis

Pain at injection site severity definition: Mild = no interference, Moderate = some interference; Severe = prevents daily activity; Grade 4 = ER visit or hospitalization

Dose 1: 12-15 yrs N = 2254; 16-25 yrs N = 1084. Dose 2: 12-15 yrs N = 2175; 16-25 yrs N = 984

<table>
<thead>
<tr>
<th>System Organ Class/PT</th>
<th>BNT162b2 (30 μg) (N=1131)</th>
<th>Placebo (N=1129)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>ANY EVENT</td>
<td>5</td>
<td>0.4%</td>
</tr>
<tr>
<td>GASTROINTESTINAL DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Abdominal pain</td>
<td>1</td>
<td>0.1%</td>
</tr>
<tr>
<td>*Constipation</td>
<td>1</td>
<td>0.1%</td>
</tr>
<tr>
<td>INFECTIONS AND INFESTATIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#Appendicitis</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>#Focal peritonitis</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>NERVOUS SYSTEM DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Neuralgia</td>
<td>1</td>
<td>0.1%</td>
</tr>
<tr>
<td>PSYCHIATRIC DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>4</td>
<td>0.4%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>3</td>
<td>0.3%</td>
</tr>
<tr>
<td>Suicidal ideation</td>
<td>1</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

*Abdominal pain, constipation and neuralgia were in the same participant

#Appendicitis and focal peritonitis were in the same participant
Lymphadenopathy in 12-15 Year Olds

- 9 cases (0.8%) in BNT162b2 and 2 cases placebo (0.2%)
  - 7 (0.6%) were related to vaccination; 1 (0.1%) in the placebo group
  - Primarily Left axillary or Left cervical
  - Onset within 2-10 days after vaccination
  - Duration 1-10 days where reported (others were ongoing at the time of the data cutoff date).
- In adults (16-55 years of age), 52 participants (0.4%) in the BNT162b2 group and 2 participants (0.0%) in the placebo group had lymphadenopathy events reported up to the unblinding date and assessed by the investigator as related to study intervention.
  - The majority of these events occurred in the arm and neck region, were reported within 2-4 days after vaccination (usually after Dose 2), and typically resolved within approximately 1 week.

Myocarditis

- VaST concluded that there are relatively few reports of myocarditis to date and that these cases seem to occur:
  - Predominantly in adolescents and young adults,
  - More often in males than females,
  - More often following dose 2 than dose 1, and
  - Typically within 4 days after vaccination
  - Most cases appear to be mild, and follow-up of cases is ongoing.
- Per CDC: the number of cases of myocarditis does not appear to be greater than would normally be seen in young people (about 10 to 20 of every 100,000 people each year develop myocarditis).
- Of over 5 million people who received the vaccine in Israel, around 62 cases of myocarditis were recorded in days after the vaccination
  - 56 of these cases arose on administering the second shot and most of the affected were men under 30.

https://www.cdc.gov/vaccines/acip/work-groups-vast/technical-report-2021-05-17.html
https://www.pharmaceutical-technology.com/news/israel-myocarditis-pfizer-vaccine/#:~:text=Of%20over%20five%20million%20people,affected%20were%20men%20under%2030
Efficacy Data

• Efficacy analyses based on cases reported from at least 7 days after Dose 2 through the data cutoff date, the observed VE
  – 100% (95% CI: 75.3%, 100%) for individuals without evidence of prior SARS-CoV-2 infection before and during vaccination regimen,
  – 100% (2-sided 95% CI: 78.1%, 100%) for those with or without evidence of prior SARS-CoV-2 infection

• No severe cases of COVID in any participant

Geometric Mean Ratio (GMR) Neutralization Titers in Randomized Subgroup

<table>
<thead>
<tr>
<th>Assay</th>
<th>Dosing/ Sampling Time Point</th>
<th>BNT162b2 (30 μg)</th>
<th>12-15 year</th>
<th>16-25 years</th>
<th>12-15/16-25 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 neutralization assay - NT50 (titer)</td>
<td>2 / 1 Month</td>
<td>n</td>
<td>GMT (95% CI)</td>
<td>n</td>
<td>GMT (95% CI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>190</td>
<td>1239.5 (1095.5, 1402.5)</td>
<td>170</td>
<td>705.1 (621.4, 800.2)</td>
</tr>
</tbody>
</table>

Limitations

Evidence type: 1=high; 2=moderate; 3=low; 4=very low; ND, no data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Importance</th>
<th>Design (# of studies)</th>
<th>Findings</th>
<th>Evidence type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic lab-confirmed COVID-19</td>
<td>Critical</td>
<td>RCT (1)</td>
<td>Pfizer-BioNTech COVID-19 vaccine is effective in preventing symptomatic COVID-19</td>
<td>1</td>
</tr>
<tr>
<td>Hospitalization due to COVID-19</td>
<td>Important</td>
<td>No studies</td>
<td>Data not available from any studies</td>
<td>ND</td>
</tr>
<tr>
<td>Multisystem inflammatory syndrome in children (MIS-C)</td>
<td>Important</td>
<td>No studies</td>
<td>Data not available from any studies</td>
<td>ND</td>
</tr>
<tr>
<td>SARS-CoV-2 seroconversion</td>
<td>Important</td>
<td>No studies</td>
<td>Data not available from any studies</td>
<td>ND</td>
</tr>
<tr>
<td>Asymptomatic SARS-CoV-2 infection</td>
<td>Important</td>
<td>No studies</td>
<td>Data not available from any studies</td>
<td>ND</td>
</tr>
<tr>
<td><strong>Harms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>Critical</td>
<td>RCT (1)</td>
<td>5 SAEs among vaccinated and 2 among unvaccinated; certainty in the estimate was very low. No SAEs were judged to be related to vaccination.</td>
<td>4</td>
</tr>
<tr>
<td>Reactogenicity</td>
<td>Important</td>
<td>RCT (1)</td>
<td>Severe reactions were more common in vaccinated; any grade ≥3 reaction was reported by 10.7% of vaccinated vs. 1.9% of placebo group</td>
<td>1</td>
</tr>
</tbody>
</table>

Summary

• It works like in adults and perhaps better
• Safety data is reassuring but numbers remain relatively small compared to adult trials
  – Pain at the injection site, fatigue, headaches, chills, joint pain and muscle pain were seen in about 1/3rd to 2/3rd of the recipients and about 20% had fever after dose 2
  – About 10% of recipients compared to 2% of placebo had >grade 3 reaction
  – Lymphadenopathy was identified as related to vaccination in about 1%
  – There were no related SAEs but there were 5 SAEs in the vaccinated group
  – Myocarditis?
  – No deaths were reported
  – No reason to believe any impact on puberty or fertility
• Overall, the data support Pfizer vaccine use in 12-15 year olds

Co-administration with Other Vaccines

- Data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA.
- Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.
- COVID-19 and other vaccines **may now be administered without regard to timing**
  - This includes simultaneous administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days.
- Particularly important change since adolescent vaccines as compared to 2019, are:
  - Tdap – down 18.9%
  - HPV – down 19.3%
  - Meningococcal conjugate vaccine – down 15.1%

Contraindications and Precautions

• MIS-C
  – Prior MIS-C may be an indications to delay vaccination for up to 90 days
  – No data currently in this population, probably safe but who knows
• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine is absolute contraindication
• Immediate allergic reaction of any severity to a previous dose is a precaution and should lead to discussion with allergist
  – Case reports of patients doing fine with next dose
• Known polysorbate allergy is no longer a contraindication to mRNA vaccination
Vaccine Hesitancy

In the United States overall...

8% are Watchful. They're waiting to see what happens next.

9% are Cost-Anxious. They want the vaccine but can't afford the time or cost.

4% are System Distrusters. They feel the health care system doesn't treat them fairly.

14% are Covid Skeptics. They don't believe the threat.

https://www.nytimes.com/interactive/2021/05/18/opinion/covid-19-vaccine-hesitancy.html
Vaccine Hesitancy

• COVID skeptics
  – Emphasize that vaccination is their own, personal choice — one that can help them protect friends and family members

• Cost anxious
  – Vaccination is totally free
  – See if getting time off is acceptable for this reason as some business will

• System disruptors
  – Making vaccinations of people they know as visible as possible
  – Tracking and illuminating efforts to ensure the vaccine rollout is equitable and sharing that with the community is key

• Watchful
  – Opt-in to vaccines when ready
  – Making vaccinations of people they know as visible as possible

https://www.nytimes.com/interactive/2021/05/18/opinion/covid-19-vaccine-hesitancy.html
Vaccine Hesitancy

• Some opening lines
  – The vaccines are highly effective in preventing illness -- even more effective than the annual flu vaccine
  – COVID vaccine will help protect you from getting sick
  – The quickest way for life to return to normal is for most people to get vaccinated
  – Nearly all providers who have been offered the vaccine have taken it
  – Millions of people have been vaccinated safely
  – The COVID vaccines have been held to the same rigorous standards as other vaccines; corners were not cut, red tape was eliminated to expedite the approval process
  – Have you talked to your child about the vaccine and how they feel about it
• Follow the conversation with an offer to direct them to how to get vaccinated
# Vaccine Hesitancy

**Addressing Mistrust About COVID-19 Vaccines Among Patients of Color**

Douglas J. Opel, MD; Bernard Lo, MD; and Monica E. Peek, MD, MPH, MS

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## Motivational Interviewing Techniques

<table>
<thead>
<tr>
<th>Technique</th>
<th>Rationale</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open-ended questions</td>
<td>Helps identify, explore, and understand patients’ COVID-19 vaccine concerns</td>
<td>“Can you tell me more about what is worrying you?”</td>
</tr>
<tr>
<td>Reflection statements</td>
<td>Encourages partnerships, deepens rapport, and broadens understanding of patient motivations</td>
<td>“I hear that you want to be sure that the COVID vaccine is safe for you.”</td>
</tr>
<tr>
<td>Affirmation statements</td>
<td>Helps patients feel supported, appreciated, and understood, which can improve their engagement in an open discussion</td>
<td>“You’re not alone. Several of my patients have similar concerns.”</td>
</tr>
<tr>
<td>Ask permission to share</td>
<td>Puts patients in a less defensive posture and improves receptivity to information being shared</td>
<td>“May I share my view with you?”</td>
</tr>
<tr>
<td>Statements that support patient autonomy</td>
<td>Enhances a patient’s sense of control and helps them feel more at ease with the conversation</td>
<td>“I want you to know that this is your decision to make.”</td>
</tr>
<tr>
<td>Rolling with resistance</td>
<td>Meeting patient resistance with curiosity (an opportunity to understand more about the patient’s perspective in a nonjudgmental, respectful way) rather than confrontation encourages continued patient engagement</td>
<td>“I am hearing that you don’t think you’ll get the COVID vaccine anytime soon. Tell me more about what is concerning you.”</td>
</tr>
</tbody>
</table>

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### Vaccine Hesitancy

<table>
<thead>
<tr>
<th>Concern</th>
<th>Example Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am really worried I'll get sick after the vaccine and won't be able to go to work.</td>
<td>&quot;You want to make sure that if you get vaccinated, it won't impact your ability to work. That makes sense.&quot; After listening and further exploring the patient's concerns, consider: &quot;It's true that some people will experience side effects. These side effects are similar to those from other vaccines—muscle aches, fever, and soreness at the injection site. You might want to get vaccinated before having a few days off.&quot;</td>
</tr>
<tr>
<td>Why should I trust the government since people like me have been guinea pigs for testing in the past?</td>
<td>&quot;I understand why you have a lot of mistrust. The government and research systems have not always treated your community fairly.&quot; After listening and further exploring the patient's concerns, consider: &quot;There are now people of color leading and working in research studies to make sure their communities are protected from harm, yet have equal access to the benefits of scientific discovery. Would it be OK if I shared my medical perspective on how COVID vaccines were tested?&quot;</td>
</tr>
<tr>
<td>I just hear a lot of talk about how the vaccine will give people COVID.</td>
<td>&quot;You are not the only one with those concerns. There is a lot of information out there on COVID and the vaccine, and it is hard to know what is true and what is false.&quot; After listening and further exploring the patient’s concerns, consider: &quot;This is one of those false pieces of information. You cannot get COVID from the vaccine. Can I tell you about how about the COVID vaccine works?&quot;</td>
</tr>
</tbody>
</table>

Getting a Vaccine at UCM

- Adolescents with their own MyChart accounts can schedule appointments through MyChart or by calling **773-834-8221**
- Any child or adult including those that haven’t receive medical care at UChicago Medicine can schedule appointments by calling **773-834-8221**
- Children who receive vaccinations must be accompanied to the vaccination clinic by a parent or guardian
Where Else?

• For a list of vaccine sites in Chicago for people 12 and up: https://www.chicago.gov/city/en/sites/covid19-vaccine/home/city-sites.html

• For those outside of Chicago, they can go to https://www.vaccines.gov/ and put in their zip code and then find a location for the Pfizer vaccine
  – They can also find sites for Moderna and J & J but those are only for people 18 and up
• Discussion