MINI GRAND ROUNDS

COVID-19: Vaccine Guidance and Q&A with Erie County Commissioner of Health Gale Burstein, MD, MPH

Other speakers include:

Sarah Hopseker, PharmD, Pharmacist, Erie County Department of Health

Joyce Zmuda, MD, President of Buffalo Pediatric Society, Pediatrician, Delaware Pediatrics

Sarah L. Berga, MD, President, UBMD Obstetrics and Gynecology, Medical Director, OBGYN & Women's Health Program Development, Oishei Children's Hospital, Kaleida Health (July 14 only)

Heather Link, MD, MPH, Maternal Fetal Medicine Specialist (July 21 only)

DATE

Wednesday, July 14, 2021 (Session 1)
Wednesday, July 21, 2021 (Session 2)

TIME

7:30-8 a.m.

SKYPE DETAILS

Click HERE to join Skype meeting

Trouble joining? Try Skype Web App

Audio participation only:
Dial: 1-716-859-7444
Enter Conference ID: 89356794
(Virtual seating capacity is 250 participants)

Great Lakes Health System of WNY

ACCREDITATION This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the University at Buffalo Jacobs School of Medicine and Biomedical Sciences and Optimum Physician Alliance, LLC. , a Great Lakes Health affiliate. The University at Buffalo Jacobs School of Medicine and Biomedical Sciences is accredited by the ACCME to provide continuing medical education for physicians.

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Great Lakes Health System of WNY

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Kaleida Health

Welcome to Today's Great Lakes Health Mini Grand Rounds

The presentation is being recorded. Please mute your audio line.

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Great Lakes Health System of WNY

COVID-19 Vaccine Update

GALE BURSTEIN, MD, MPH
ERIE COUNTY COMMISSIONER OF HEALTH
CLINICAL PROFESSOR OF PEDIATRICS, JACOBS SCHOOL OF MEDICINE

July 14, 2021: The information presented here is current as of today's date unless otherwise noted. All data are provisional. For the latest information, reference links within the presentation or visit www.erie.gov/covid19

Why vaccinate?

- COVID-19 can cause serious disease and death, including during pregnancy and for newborns.[1]
- COVID-19 vaccine is safe and effective, including during pregnancy. [2]
- COVID-19 vaccine works.
  - 96% of 183 Erie County COVID-19 related deaths reported in April – mid-July were NOT fully vaccinated.
- Primary care is the best setting to offer COVID-19 vaccine, just like flu or any other vaccine.
  - Those who have not yet been vaccinated will likely only agree if encouraged by their PCP. [3]

[1] https://jamanetwork.com/journals/jamapediatrics/fullarticle/2779182?resultClick=1
[2] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html
[3] https://www.nejm.org/doi/full/10.1056/NEJMp2106137

COVID-19 Pandemic among Unvaccinated

- Last week, number of reported COVID-19 cases ⬆156% compared to prior week
  - (68 cases ⟶ 174 cases)
- Many cases report recent travel to South where low vaccination rates
- Many cases were not fully vaccinated

What has changed with COVID-19 vaccine

- There is no minimum or maximum COVID-19 vaccine order requirement from ECDOH.
  - COVID-19 vaccine available from ECDOH to community providers Monday - Friday with 24 hours' notice.
- COVID-19 vaccine storage is compatible with community provider vaccine refrigerator storage systems.
  - Pfizer and Moderna vaccines may be stored in vaccine refrigerator (2-8°C/36-46°F) for up to 31 and 30 days, respectively.
  - Janssen vaccine, stored refrigerated, remains stable until its expiration date.

What has changed with COVID-19 vaccine

continued

- No minimum interval between COVID-19 vaccine and other vaccine administration.
  - May administer COVID-19 vaccines and other vaccines without regard to timing. (i.e., simultaneous administration of COVID-19 vaccines and other vaccines on same day or co-administration within 14 days)
- NYSDOH eliminated penalties for responsible wastage of COVID-19 vaccine if a provider cannot use all doses in a vial due to low demand.
  - While enrolled providers should follow best practices to use every dose possible, but not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

New York State COVID-19 Vaccination Demographics: Age Group

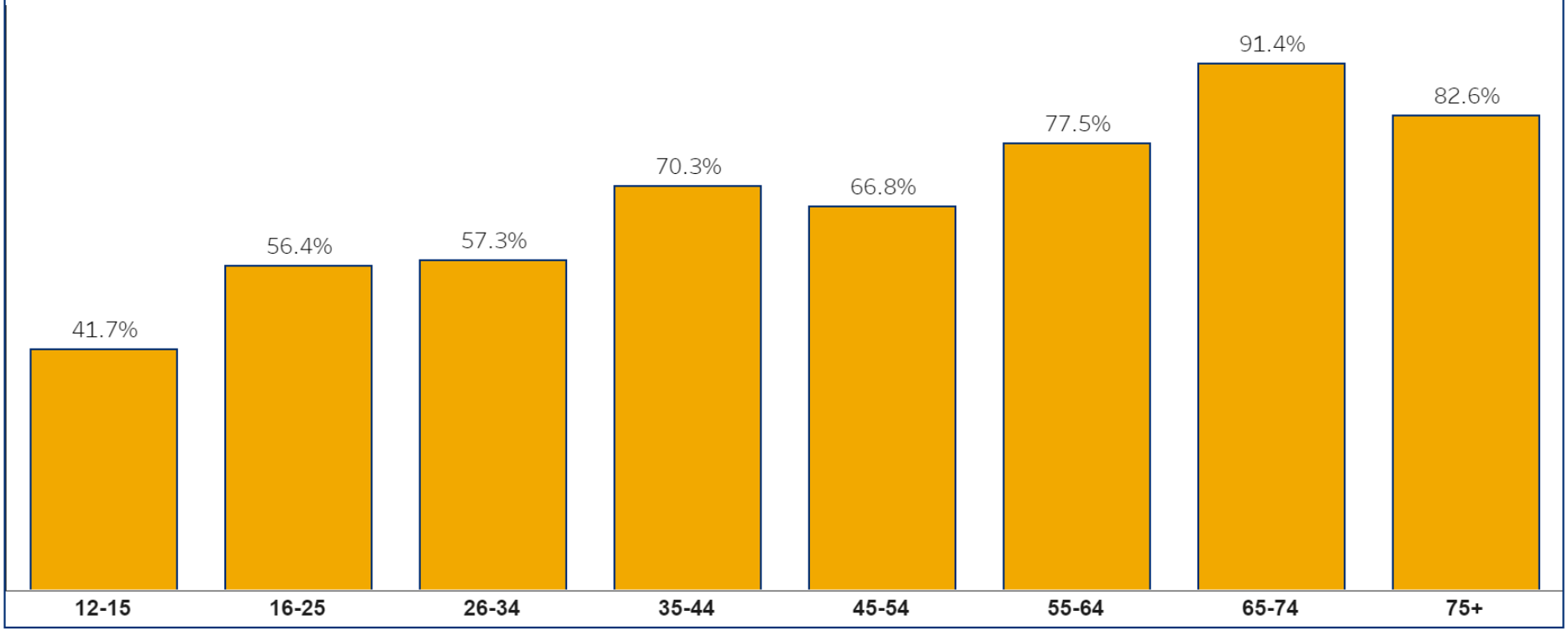
Data as of: 7/20/2021 10 AM

Region: Western New York

County: Erie

- (•) People with at least one Vaccine Dose
- ( ) People with completed Vaccine Series

% of Population Vaccinated by Age Group



https://covid19vaccine.health.ny.gov/vaccine-demographic-data

Erie County COVID-19 Vaccine: ZIP Codes

Zipcode	City	% of 0-19 population vaccinated (with at least one dose)	% of 20-34 population vaccinated (with at least 1 dose)	% of 35-64 population vaccinated (with at least 1 dose)	% of 65+ population vaccinated (with at least 1 dose)	% of 20+ Population Vaccinated
14112	North Evans	n/a	15.6%	n/a	46.7%	33.4%
14034	Collins	17.8%	22.4%	28.9%	79.3%	34.5%
14061	Farnham	1.1%	12.0%	40.5%	100.0%	36.7%
14070	Gowanda	11.4%	21.1%	36.5%	64.3%	37.9%
14035	Collins Center	0.0%	100.0%	30.2%	100.0%	44.4%
14030	Chaffee	9.6%	37.3%	41.7%	70.5%	47.5%
14211	Buffalo	12.5%	34.6%	54.4%	69.0%	50.8%
14208	Buffalo	10.6%	34.2%	61.7%	58.1%	51.1%
14170	West Falls	15.4%	51.2%	42.1%	100.0%	52.6%
14215	Buffalo	10.2%	32.9%	56.6%	88.7%	53.4%
14206	Buffalo	13.7%	40.6%	56.7%	65.4%	54.0%
14004	Alden	13.7%	38.8%	52.0%	73.1%	54.3%
14210	Buffalo	14.9%	38.5%	59.8%	72.1%	54.4%
14080	Holland	14.3%	40.7%	49.6%	83.7%	55.6%
14204	Buffalo	8.7%	41.8%	55.6%	75.2%	55.6%
14111	North Collins	14.7%	39.7%	50.9%	100.0%	55.8%
14025	Boston	16.0%	57.4%	53.8%	60.0%	56.1%
14212	Buffalo	12.8%	45.4%	61.7%	71.5%	58.7%
14055	East Concord	12.8%	46.6%	49.4%	100.0%	58.7%
14207	Buffalo	13.2%	38.9%	73.8%	75.2%	59.9%
14218	Lackawanna	11.7%	39.1%	63.3%	82.9%	60.6%

http://www.erie.gov/covidmap

COVID-19 Vaccine Redistribution

SARAH HOPSEKER, PHARMD

ERIE COUNTY DEPARTMENT OF HEALTH

Vaccine Request Form

- No minimum or maximum quantity requirements
  - Pfizer – 6 doses per vial
  - Moderna – Maximum 11 doses per vial (10 -11 doses per vial)
- Requests can be made at any frequency
  - Weekly/biweekly/monthly
- Completed forms may be submitted to **Sarah.Hopseker@erie.gov** and **Melissa.Calhoun@erie.gov**

Pick-Up Location

- **500 Commerce Dr. Amherst, NY 14228 Suite 1**
- Park in the front parking lot and call 716-406-7545
- A member of the vaccine distribution team will meet you at the front door
- Hours: Monday – Friday 8:30 AM – 4 PM

Cooler Requirements

- Acceptable coolers: Hard-sided coolers or polystyrene/Styrofoam coolers
  - Soft-sided coolers should not be used for transport
- Thermometer and temperature probe required
- Temperature Requirements:
  - Refrigerated transport: **2 – 8 °C / 36 – 46 °F**
  - Frozen transport:
    - **Moderna: -50 to -15 °C / -58 to 5 °F**
    - **Pfizer: -25 to -15 °C / -13 to 5 °F**

Beyond Use Dates

- Pfizer: Unpunctured vials must be used within 31 days after thawing begins
  - After the vial is punctured: Contents must be used within 6 hours
- Moderna: Unpunctured vials must be used within 30 days after thawing begins
  - After the vial is punctured: Contents must be used within 12 hours

Special Considerations

- Pfizer vaccine must be reconstituted
  - 1.8 mL of 0.9% NaCl
  - Diluent will be provided
- Moderna does NOT require reconstitution

Transport Form

Send completed form to Sarah.Hopseker@erie.gov

COVID-19 Vaccine Transport Tracking Sheet

Providers must email completed Vaccine Transport Tracking Sheet to covid19vaccine@health.ny.gov. Please include "transport tracking" in the subject line.

Date of transport: _____ Name of provider releasing vaccine: _____ PIN: _____

Name of contact person at releasing provider: _____ Phone number of contact person: _____

Temperature of *releasing* storage unit on day of transport: _____ ☐ °C ☐ °F Time placed in transport container: _____ ☐ AM ☐ PM

Vaccines will be transported *(Select one)*:

Refrigerated
2°C to 8°C (36°F to 46°F)

- **Moderna, Pfizer, and Janssen vaccines**
- Use portable refrigerator unit or qualified container and packout with DDL
- Keep vaccines out of direct sunlight
- Transport only full, unpunctured vials
- Minimize shocks and vibrations during transport
- Include hours used for transport when calculating the beyond use date (BUD) for Moderna and Pfizer vaccines
- **Never refreeze thawed vaccine**

Frozen
Varies by manufacturer (see below)

- **Moderna and Pfizer vaccine**
- Use a portable freezer unit or qualifiedcontainer and packout with DDL
- Never transport or store Moderna vaccineon dry ice or below -50° C (-58° F)
- **Moderna** frozen temperature range is -50° C to -15° C (-58° F to 5° F)
- Keep vaccine out of direct sunlight
- Pfizer frozen temperature range is -25° C to -15° C (-13° F to 5° F)
- Include hours of transport in 2-week limit for Pfizer frozen storage
- Pfizer vaccine transported frozen may be returned to ULT storage one time
- **Never refreeze thawed vaccine**

Ultra-frozen
-80°C to -60°C (-112°F to -76°F)

- **Pfizer vaccine only**
- Use original thermal shipping container with dry ice or a portableultra-cold freezer that can maintain a temperature of -80° C (-112° F)
- **Transport only full trays of Pfizer vaccine at ultra-frozen temperatures**
- Keep tray(s) in original packaging to protect vaccine from light
- Do not open trays or remove any vials until ready to thaw
- Place trays in ultra-cold storage within five minutes of unpacking
- **Once removed from ultra-cold storage, vaccine must be used within one month (31 days)**
- **Never refreeze thawed vaccine**

Vaccines included in this transport *(Attach additional sheets if needed)*:

Manufacturer	Lot #	Expiration Date	Beyond Use Date (BUD)[1]	# of Doses[2]	Cold Chain Maintained(Y/N)[3]	Comments

[1] *The BUD for Moderna vaccine will be 30 days after thawing begins. The BUD for Pfizer vaccine is 14 days in the freezer and 31 days after thawing begins.*
[2] *After 2/16/2021, count six doses per vial for Pfizer vaccine.*
[3] *If temperature goes out of range during transport, report immediately to vaccinetempexcursion@health.ny.gov*

Name of provider receiving vaccine (or alternate storage location): _____ PIN: _____

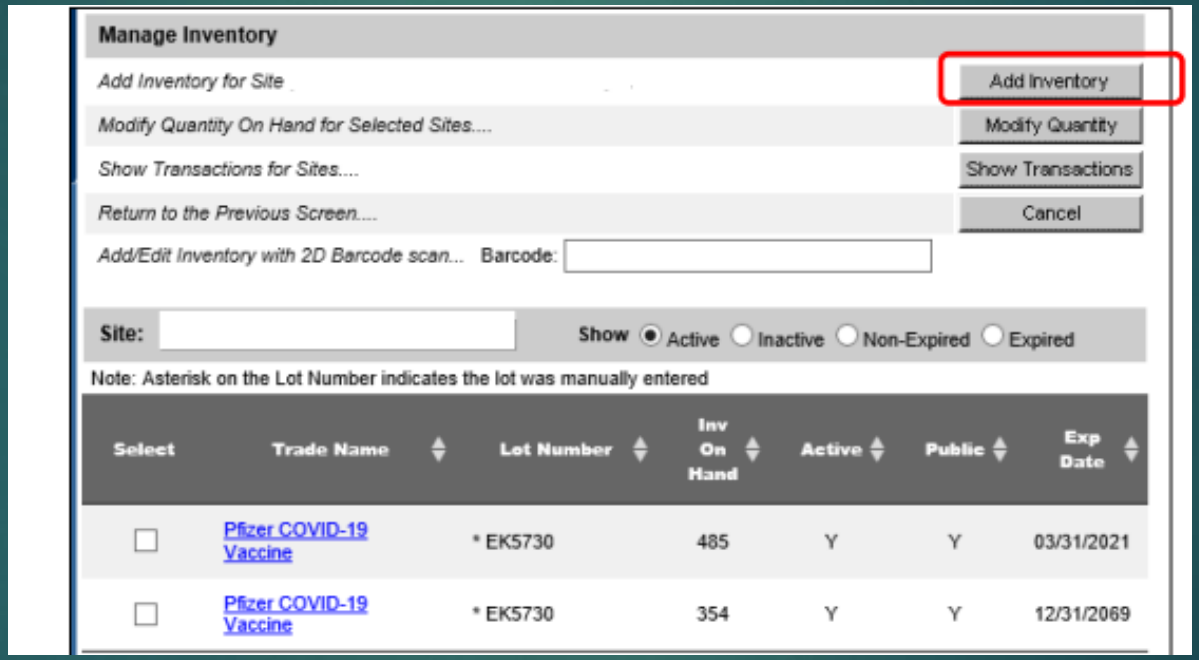
Name of contact person at *receiving* provider: _____ Phone number of contact person: _____

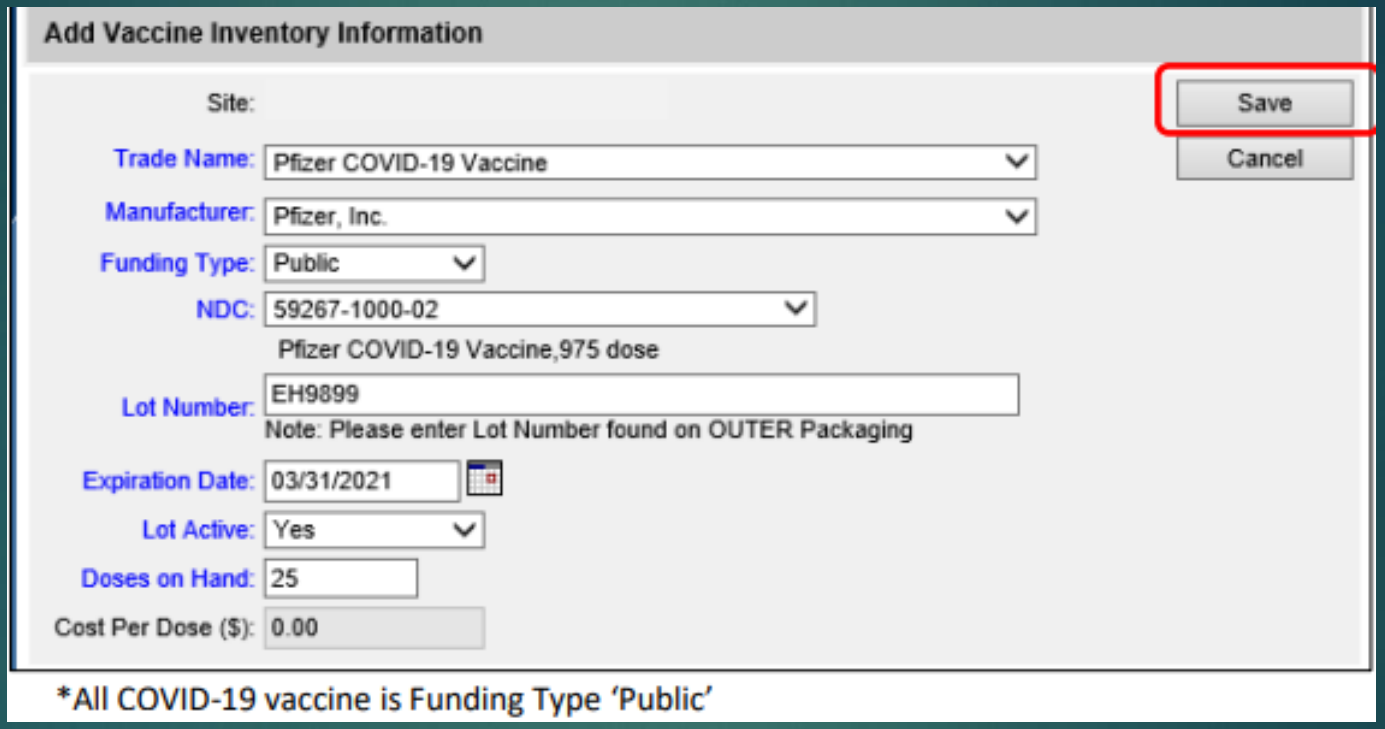
Time arrived at receiving location: _____ ☐ AM ☐ PM Temperature of transport container upon arrival: _____ ☐ °C ☐ °F

Temperature of *receiving* storage unit on day of transport: _____ ☐ °C ☐ °F Maximum temperature reached during transport: _____ ☐ °C ☐ °F

NYSIIS Inventory

- Manually add the vaccine information into NYSIIS inventory





*All COVID-19 vaccine is Funding Type 'Public'

Questions?

716-339-0238
Sarah.Hopseker@erie.gov

COVID-19 Vaccination and Pregnancy

Heather Link, MD, MPH
Clinical Assistant Professor
Jacobs School of Medicine and Biomedical Sciences | UB SUNY
Maternal Fetal Medicine Specialist
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Disclosures
Heather M. Link MD/MPH
January 2021

CONSULTING:

World Health Organization, Geneva Switzerland March 2020, *paid*

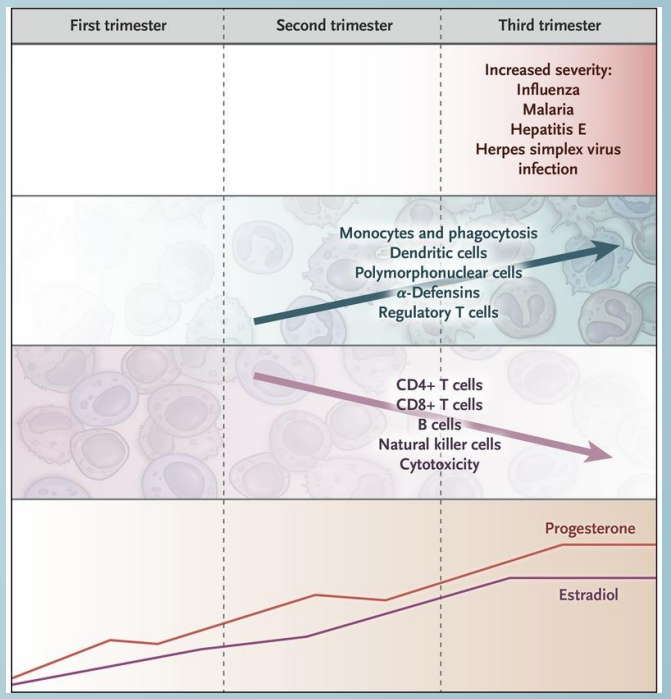
JOHN R. OISHEI Children's Hospital | Leading with CARE

COVID-19 Vaccination and Reproduction: Pregnancy, Lactation, and Fertility Quick Summary

- **Vaccination is safer for all aspects of reproductive function than COVID-19 infection**
- Women and men seeking to conceive or undergoing infertility care should get vaccinated
- Women who are currently pregnant should get vaccinated
- Women who are currently lactating should get vaccinated
- We need more research to determine the impact of COVID-19 and vaccination on gametogenesis, particularly for men and women undergoing fertility preservation, but vaccination is likely to be better for fertility than COVID-19 infection
- **Clinicians need clear sound bites to confidently convey the safety of COVID-19 vaccination**

Immunologic Changes of Pregnancy

- Adaption of the maternal inflammatory response
  - Changing TH1:TH2 cytokine profiles
  - Hormonal shifts mediate inflammatory pathways



Morbidity and Mortality Weekly Report

Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020

Laura D. Zambrano, PhD[1,*]; Sascha Ellington, PhD[1,*]; Penelope Strid, MPH[1]; Romeo R. Galang, MD[1]; Titilope Oduyebo, MD[1]; Van T. Tong, MPH[1]; Kate R. Woodworth, MD[1]; John F. Nahabedian III, MS[1]; Eduardo Azziz-Baumgartner, MD[1]; Suzanne M. Gilboa, PhD[1]; Dana Meaney-Delman, MD[1]; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team

TABLE 2. Intensive care unit (ICU) admissions, receipt of invasive ventilation, receipt of extracorporeal membrane oxygenation (ECMO), and deaths among symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 (N = 409,462), by pregnancy status, age, race/ethnicity, and underlying health conditions — United States, January 22–October 3, 2020

Outcome*/Characteristic	No. (per 1,000 cases) of symptomatic women: Pregnant (n = 23,434)	No. (per 1,000 cases) of symptomatic women: Nonpregnant (n = 386,028)	Risk ratio (95% CI): Crude†	Risk ratio (95% CI): Adjusted†,§
Invasive ventilation††				
All	67 (2.9)	412 (1.1)	2.7 (2.1–3.5)	2.9 (2.2–3.8)
ICU admission¶				
All	245 (10.5)	1,492 (3.9)	2.7 (2.4–3.1)	3.0 (2.6–3.4)
ECMO***				
All	17 (0.7)	120 (0.3)	2.3 (1.4–3.9)	2.4 (1.5–4.0)
Death§§§				
All	34 (1.5)	447 (1.2)	1.3 (0.9–1.8)	1.7 (1.2–2.4)

Vaccination in Pregnancy

- Vaccines currently available under the Emergency Use Authorization have not been tested in pregnant and lactating women
- Moderna + Pfizer Vaccines currently available in the US are mRNA vaccines
- Johnson & Johnson Vaccine is made utilizing deactivated adenovirus

ACOG Recommendations

Pregnant Individuals

ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups. While safety data on the use of COVID-19 vaccines in pregnancy are not currently available, there are also no data to indicate that the vaccines should be contraindicated, and no safety signals were generated from DART studies for the Pfizer-BioNtech and Moderna COVID-19 vaccines. Therefore, in the interest of allowing pregnant individuals who would otherwise be considered a priority population for vaccines approved for use under EUA to make their own decisions regarding their health, ACOG recommends that pregnant individuals should be free to make their own decision in conjunction with their clinical care team.

Society for Maternal-Fetal Medicine
High-risk pregnancy experts

For media interviews, contact:
Kerri Wade, MPA
kwade@smfm.org
+ 1 (202) 517-6121

Experts in High-Risk Pregnancy Respond to the FDA's Decision to Offer the Newly Approved COVID-19 Vaccine to Pregnant and Lactating People

Healthcare Workers Among the First Expected to Be Impacted

In general, SMFM strongly recommends that pregnant and lactating people have access to COVID-19 vaccines and that they engage in a discussion about potential benefits and unknown risks together their with healthcare providers regarding receipt of the vaccine. As stated previously, counseling should balance the lack of data on vaccine safety for the fetus, risks to pregnant people from COVID-19 infection, and a person's individual risk for infection and severe disease.

Vaccination Considerations for People who are Pregnant or Breastfeeding

Updated Dec. 28, 2020 Languages Print

COVID-19 Vaccination Considerations for People Who Are Pregnant

CDC and the independent Advisory Committee on Immunization Practices (ACIP) have provided information to assist pregnant people with their decision to receive the COVID-19 vaccine. At this time, ACIP recommends that certain groups (e.g., healthcare personnel, followed by other frontline essential workers) are offered vaccination during the first months of the COVID-19 vaccination program. People who are pregnant and part of a group recommended to receive the COVID-19 vaccine may choose to be vaccinated. If they have questions about getting vaccinated, a discussion with a healthcare provider might help them make an informed decision.

Vaccination in Lactating Women

- No vaccines have been tested in this population
- Physiology does not suggest increased risk

- Studies of donated breastmilk have found SARS-CoV-2 IgA + IgG antibodies in breastmilk for 2 weks after vaccination.
  - These antibodies have shown strong neutralizing effect suggesting possible protective effect against infection for infants

Resources

- https://www.who.int/teams/sexual-and-reproductive-health-and-research/areas-of-work/sexual-reproductive-health-and-rights-in-health-emergencies/covid-19
- file:///C:/Users/hmlink/Downloads/The_maternal_immune_system_during_pregnancy_and_it.pdf
- https://www.nejm.org/doi/full/10.1056/nejmra1213566
- https://cdn-links.lww.com/permalink/aog/b/aog_136_2_2020_06_02_tolcher_20-1208_sdc1.pdf
- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
- https://jamanetwork.com/journals/jama/fullarticle/2778766
- https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true
- https://pubmed.ncbi.nlm.nih.gov/33563823/

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http://medicine.buffalo.edu/cme/education/records_request/transcript_request.html.

The transcript will include all UB CME Certified activities that you have attended during the time period that you are requesting.

Thank you for your participation!

The recording of today's session and PDF of the slides, along with previous Mini Grand Rounds, can be found on all three sites:

https://www.kaleidahealth.org/kyi/news/?i=14428

https://www.kaleidahealth.org/coronavirus/#testing

https://opawny.com/for-physicians/mini-grand-round-series/