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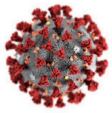

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Webinar Series

COVID-19: CALTCM Rounds

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- **Please mute your microphone when you are not speaking to keep background noise to a minimum.**
- During Q&A, you are invited to unmute your line to ask questions and participate in the discussion.
  - **Review your name** and make any necessary adjustments.
  - **Please do not talk over others.**
  - **Close all other windows and apps**, especially mail and messaging programs.

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Director, Postgraduate Residency Program, Jewish Home for the Aging; Associate Professor of Pharmacy Practice and Administration; Western University of Health Sciences

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Amanda Kamali, MD
Medical Officer
Epidemiology, Surveillance and Modeling Section, COVID-19 Response
Infectious Diseases Branch
California Department of Public Health

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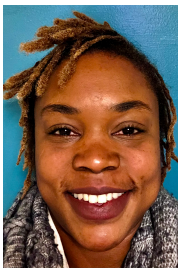

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Anne-Marie Louissaint, LNHA, RCFE, MHA
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Immediate Past-President and
Chair, Public Policy Committee
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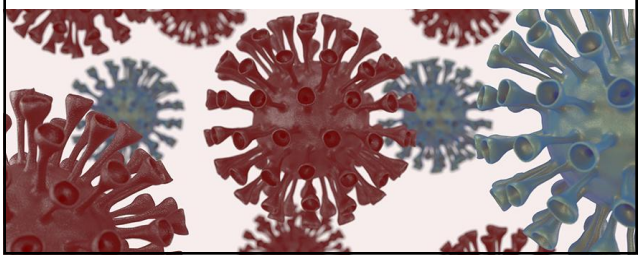
The "Three V's":
Variants, Vaccines, and Visitation



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Variants

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Vaccines

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ADRs of the mRNA Vaccine and How to Report

Janice Hoffman Simen, PharmD, EdD, APh, BCGP, FASCP
Associate Professor pf Pharmacy Practice and Administration
Western University of Health Sciences

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Definition of Adverse Drug Reaction (ADR)

- According to the World Health Organization (1972)
  - *"A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function."*[1]
- According to the FDA
  - Defines a serious adverse reaction as one in which "the patient outcome is death, life threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage."[2]

1.Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden, glossary, http://www.who-umc.org/graphics/8321.pdf, p. 1. (taken from Management Sciences for Health and World Health Organization. 2007. Drug and Therapeutics Committee Training Course. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.)
2. Kessler DA. Introducing MEDWatch. A new approach to reporting medication and device adverse effects and product problems. JAMA. 1993;269(21):2765-2768.

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Comparison of COVID-19 Mild ADRs

Reaction	Pfizer Vaccine		Moderna Vaccine	
Injection site Pain	Pain 83.1%		Pain 86%	
Swelling	1st dose 5.8%	2nd dose 6.3%	1st dose 6.7%	2nd dose 12.6%
Redness	1st dose 4.5%	2nd dose 5.9%	1st dose 0.2%	2nd dose 2.1%
Delayed injection site reactions (> 8 days redness, swelling, rash-like)	None reported		1st dose 0.8%	2nd dose 0.2%
Fever	1st 3.7%	2nd 15.8%	1st 0.9%	2nd 17.4%
Fatigue	1st 47.4%	2nd 59.4%	1st 38.4%	2nd 67.6%
Headache	1st 41.9%	2nd 51.7%	1st 35.3 %	2nd 62.8%
Chills	1st 14%	2nd 35.1%	1st 9.2%	2nd 48.6%
Muscle pain	1st 21.3%	2nd 37.3%	1st 23.7%	2nd 61.6%
Vomiting	1st 1.2%	2nd 1.9%	1st 9.4%	2nd 21.4%
Diarrhea	1st 11.1%	2nd 10.4%	None reported	

https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine
http://labeling.pfizer.com/ShowLabeling.aspx?id=14471
https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

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Interventions for ADRs of COVID-19 Vaccines

- Pain at site of injection
  - Apply a clean, cool, wet washcloth over the area.
  - Use or exercise your arm.
- Reduce discomfort from fever
  - Drink plenty of fluids.
  - Dress lightly.
- *NOTE: there have been no deaths from the vaccine yet*

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https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

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SERIOUS ADRs: Coronavirus Vaccine

Adverse Reaction	Pfizer Vaccine Rate of serious ADR 0.8% vaccine 0.6% placebo	Moderna Rate of serious ADR 1.0%, vs 1.0% placebo	Comments
Appendicitis	8 (vaccine) 4 placebo	None	
Bell's palsy (facial paralysis)	4 (vaccine) vs placebo	3 (vaccine) vs 1 placebo	
Lymphadenopathy	64 (vaccine) 6 (placebo)	1.1%	
Anaphylaxis	2 in UK; 2 in Alaska	None Allergic reaction: (injection site rash, itching) 1.5% vs 1.1% placebo	
Intractable Nausea/Vomiting	None	1 vaccine	Prior headache, N/V hospital
Serious facial swelling	None	2 vaccine	Both had dermatologic fillers

https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine
http://labeling.pfizer.com/ShowLabeling.aspx?id=14471

https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

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Reporting Vaccine Adverse Events to Pfizer

- Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS).
  - Toll-free number is 1-800-822-7967 or
  - Report online to https://vaers.hhs.gov/reportevent.html
    - Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.
- Direct to Pfizer :
  - www.pfizersafetyreporting.com
  - 1-866-635-8337 1-800-438-1985

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https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine
http://labeling.pfizer.com/ShowLabeling.aspx?id=14471

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Reporting Vaccine Adverse Events to Moderna

- Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS).
  - The VAERS toll-free number is 1-800-822-7967 or
  - Report online to https://vaers.hhs.gov/reportevent.html
- Direct reporting to ModernaTX, Inc
  - Provide a copy of the VAERS form to ModernaTX, Inc.
    - Email :ModernaPV@modernatx.com
    - Phone:1-866-MODERNA (1-866-663-3762)

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https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

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Reporting to VAERS
(Vaccination Adverse Event Reporting System)

- Healthcare providers are **required by law** to report to VAERS
  - Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Healthcare providers are strongly **encouraged** to report to VAERS:
  - Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
  - Vaccine administration errors
  - Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.
- **If you need further assistance with reporting to VAERS, please**
  - **email info@VAERS.org or**
  - **call 1-800-822-7967**

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https://vaers.hhs.gov/reportevent.html

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Checklist for Reporting to VAERS

- ☐ Information about the PATIENT who received the vaccine
  - ☐ Name, address, phone number and email address
  - ☐ Date of birth plus Age at vaccination
  - ☐ Sex (male or female)
  - ☐ Date and time of vaccination
- ☐ Date and time adverse event (ADR) started
- ☐ Whether the patient was pregnant at time of vaccination and the due date (for females only, if applicable)
- ☐ Prescriptions, OTC medications, dietary supplements, and herbal remedies being taken
- ☐ Allergies to medications, food, or other products
- ☐ Other illnesses at the time of vaccination (one month prior)
- ☐ Chronic or long-standing health conditions
- ☐ Information about the person completing or submitting the VAERS form Name, address, phone number and email address
  - ☐ Relation to the patient (For example: healthcare professional, parent, caregiver, etc.)
- ☐ Information about the healthcare professional
  - ☐ Name, phone number for best healthcare professional to contact to get more information about patient and ADR Information about the place where the vaccine was given
  - ☐ Facility/clinic name, fax number, address and phone number

https://vaers.hhs.gov/reportevent.html

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Checklist for Reporting to VAERS
(continued)

- ☐ Facility type: (Eg.: Clinic, office, hospital, pharmacy, workplace, etc.)
- ☐ Information about which vaccines were given and what happened
- ☐ Vaccine type and brand name, manufacturer, and lot number
- ☐ How the vaccine was given (route of administration, body site, dose number if part of a series)
- ☐ Description of ADR, including medical treatment and diagnosis
- ☐ Results of medical tests and laboratory tests
- ☐ Outcome of the ADR (Eg.: Office visit, ER visit, hospitalization, etc.)
- ☐ Whether patient has recovered from the adverse event
- ☐ Any other vaccines received by the patient within a month prior to the current vaccine(s) (include vaccine type and brand name, manufacturer, lot number, and how the vaccine was given)
- ☐ Adverse event(s) after previous vaccinations
- ☐ Patient's race and ethnicity

https://vaers.hhs.gov/reportevent.html

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FDA Adverse Events Reporting to *MedWatch*

- *MedWatch*, is the FDA's medical product safety reporting program for health professionals, patients and consumers.
  - **Prescription and over-the-counter medicines**
  - **Biologics** such as blood components, blood/plasma derivatives and gene therapies.
  - **Medical devices** such as hearing aids breast pumps, and pacemakers.
  - **Combination products** such as pre-filled drug syringe, metered-dose inhalers and nasal spray.
  - **Special nutritional products** such as dietary supplements, medical foods and infant formulas.
  - **Cosmetics** such as moisturizers, makeup, shampoos, hair dyes and tattoos.
  - **Food** such as beverages and ingredients added to foods.
- ***VACCINES NEED TO BE REPORTED TO VAERS***

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https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

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Reporting Using V-SAFE

- **V-safe** is a smartphone-based tool
- Uses text messaging and web surveys
- Provide personalized health check-ins after receiving a COVID-19 vaccine.
- V-safe allows quick communication to CDC if you have any side effects after getting the COVID-19 vaccine. Depending on answers, a call from CDC may occur to check on you to get more information.
- **V-safe** will also remind you to get your second COVID-19 vaccine dose if you need one.

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Visitation

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