Adverse Events Following Vaccines: An Overview for Clinicians

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Objectives

- Brief review of the approach to evaluating clinical adverse events following immunization.
- Review the Vaccine Adverse Event Reporting System (VAERS)
- Comparison of the different means to communicate COVID-19 vaccine side effects and adverse events following immunization (AEFI)

My Background in Vaccines

- In military healthcare, allergy “owns” immunizations and vaccine-related concerns.

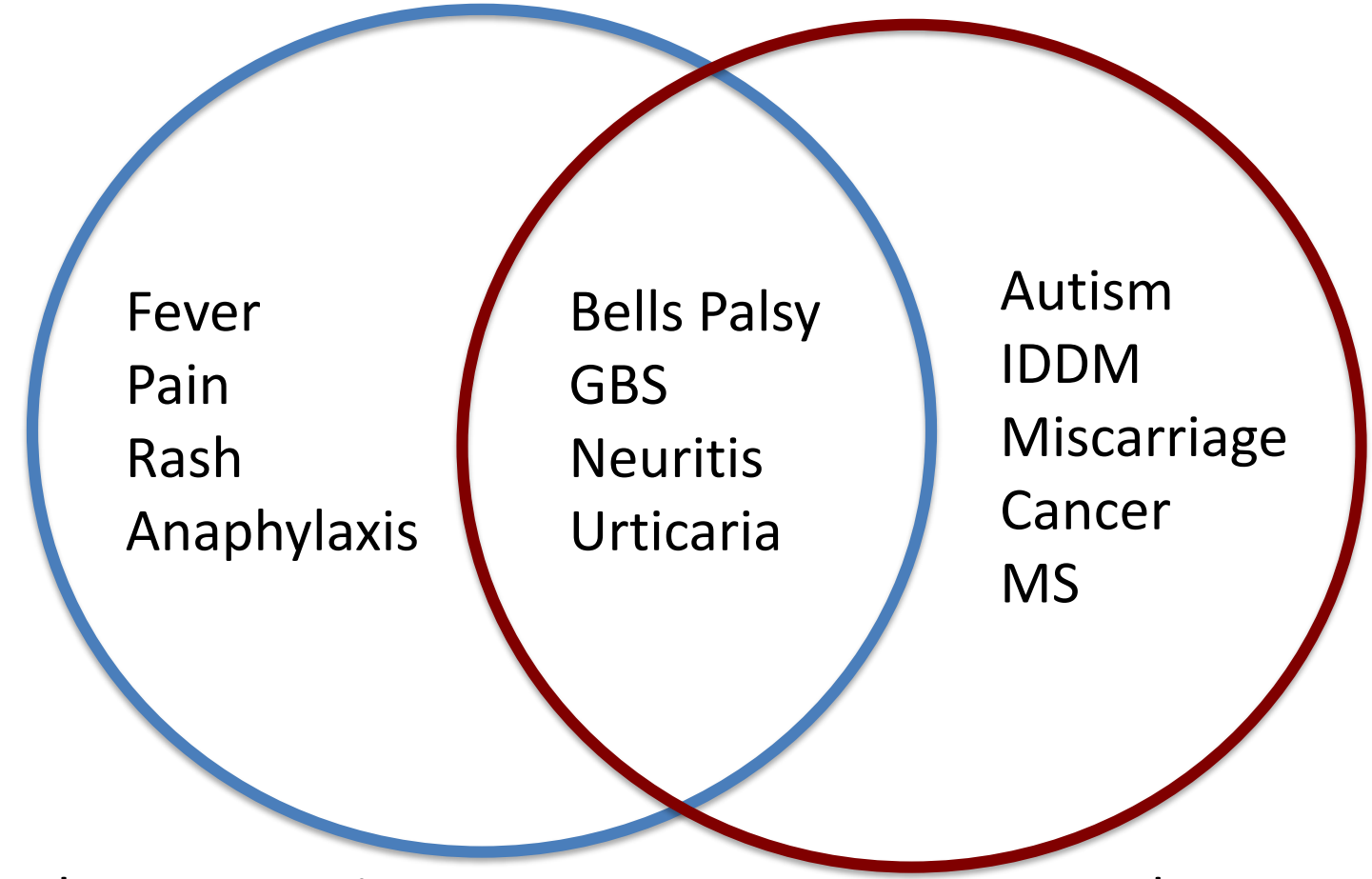
- A DoD agency for centralized review of AEFI (VAERS, HIPAA-compliant email, and global 24/7 telephone)
  - Also responsible for centralized education and training for immunizations

Terminology

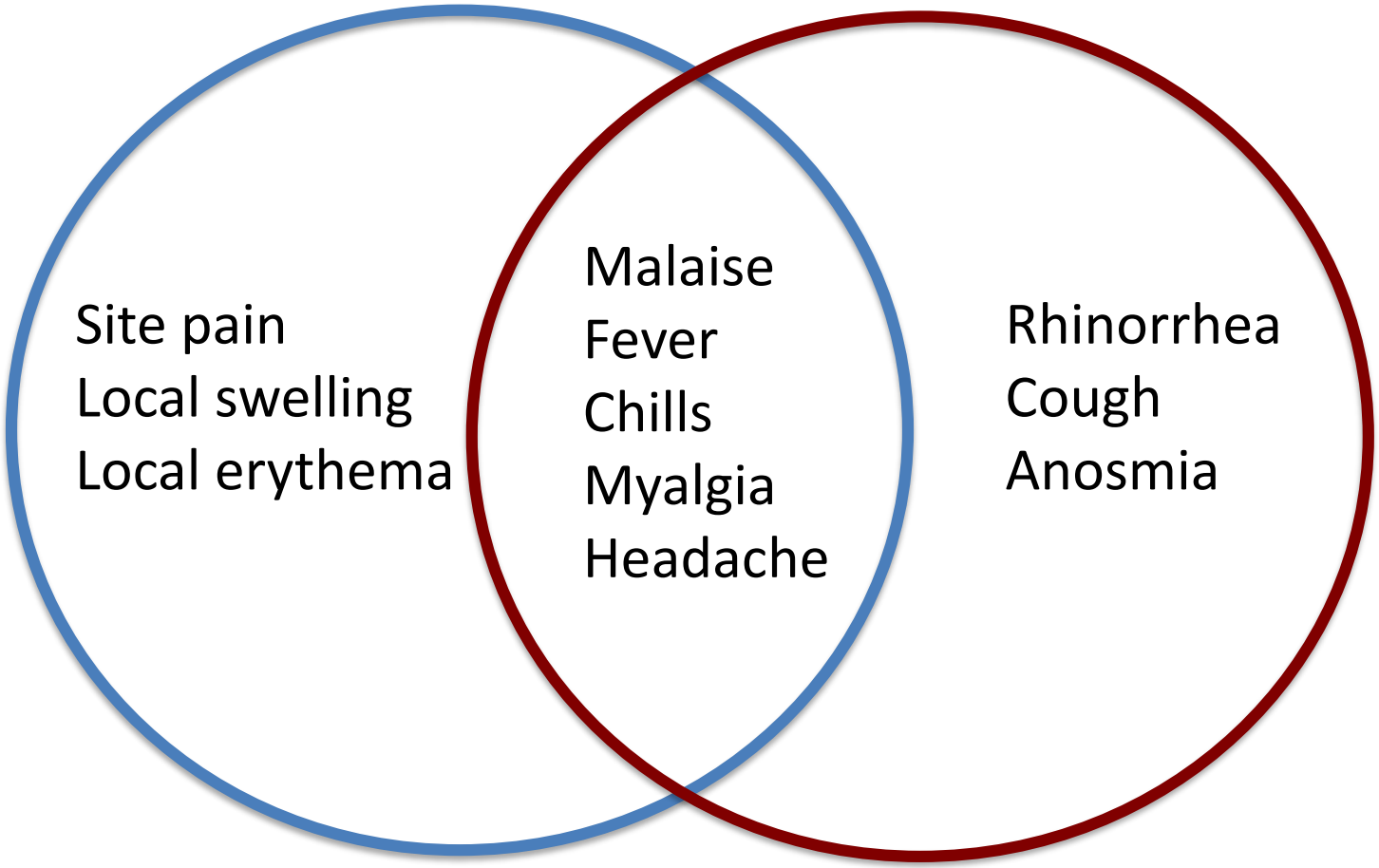
- Adverse Reaction/Effect
  - Side effects/reactions likely caused by the vaccine
  - Range from mild and common to severe and rare
  - Local reactions
  - Hypersensitivity reactions
  - Fever, malaise

- Adverse Event Following Immunization (AEFI)
  - ANY event following a vaccine within days to weeks after vaccination
  - May be a true adverse reaction due to vaccine
  - May be only coincidental

Adverse Reaction vs Adverse Event



COVID-19 Vaccine Side Effects vs COVID-19 Infection Symptoms



Common Clinical Pitfalls

- Treating a large local reaction or Arthus reaction as cellulitis
- Exempting a patient from future vaccination based on expected side effects (fever, malaise, arm pain, etc)
- Exempting a patient with a history of GBS from all future immunizations
- Assuming causality based on temporal relationship of event to vaccination (Anchoring Bias)

For Clinicians: A Way to Approach an AEFI

- Is there a temporal relationship?
- Is there biological plausibility?
- Are similar events/symptoms a known AEFI? Do they happen with other clinical conditions?
- Is there objective evidence to explain a different cause?
- What preceded the event: illness, travel, other medications?
- Patient history of similar symptoms unrelated to a vaccine? Or similar symptoms from other vaccinations?

For Clinicians: A Way to Approach an AEFI

- Patient stating the vaccine caused their symptoms does not make the diagnosis of causality.
  - If vaccine were not a part of the history, how would you evaluate and manage the clinical symptoms?

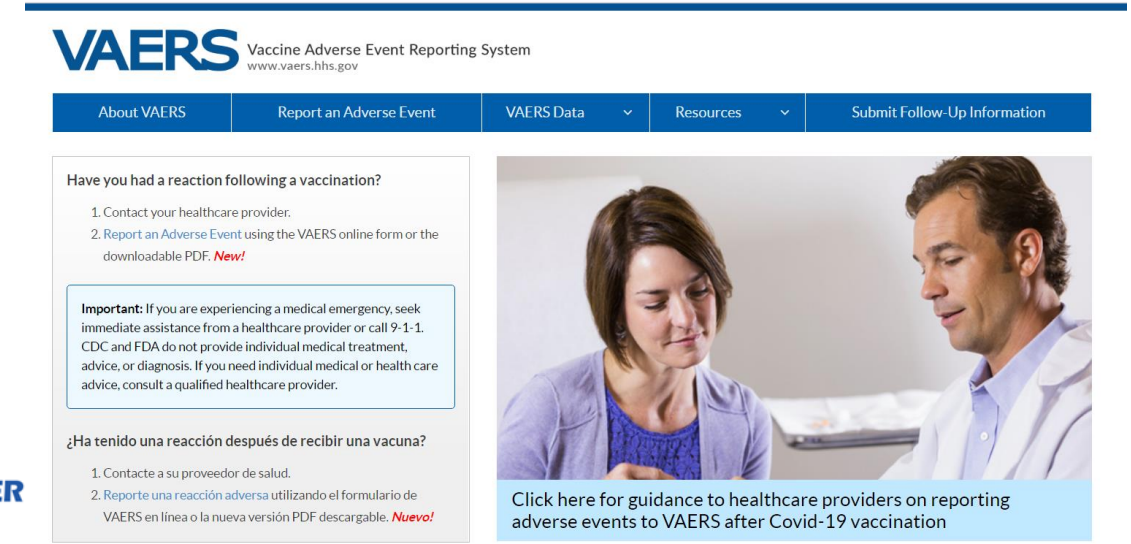
- Potential immediate allergic reactions (anaphylaxis and anaphylactoid):
  - If symptoms are mostly subjective or presentation is unclear, draw a serum tryptase (within 4 hours of symptom onset) to assist the allergist later

Vaccine Adverse Event Reporting System (VAERS)

vaers.hhs.gov

VAERS

- Established in 1990
  - Joint effort between the CDC and FDA
- Post-marketing passive surveillance program
  - An early warning system for potentially serious vaccine-caused adverse events
- ANYONE can file a VAERS report (patients, parent/guardian, clinician)
- VAERS reporting does not require “proof” of causality – submitting a report is reporting an event happened, not what caused the event
- No time limit for filing
- VAERS report ≠ vaccine injury compensation filing



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VAERS & Privacy

- All records received by VAERS are kept confidential as required by law.
- Can submit online via HIPAA-compliant interface or mail-in printed report.
- The patient's consent is not required to release medical records to VAERS.
  - Under HIPAA, VAERS is considered part of a public health activity
  - CDC and FDA are public health authorities collecting this data, thus individual authorization is not necessary before releasing information.

VAERS Reporting for Healthcare Providers

Required to Submit

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Strongly Encouraged to Submit

- Any adverse event that occurs after the administration of a vaccine
- Vaccine administration errors

Required VAERS Reporting and COVID-19 Vaccines

Under the EUA, there are additional details about reporting requirements for healthcare providers.

- Vaccine administration errors, whether or not associated with an adverse event (AE).
- Serious AEs regardless of causality:
  - Death
  - A life-threatening AE, including anaphylaxis of any severity
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
  - A congenital anomaly/birth defect
  - An important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 ***infection*** that result in hospitalization or death
- Vasovagal syncope

Strongly Encouraged VAERS Reporting

- Any clinically significant adverse events following vaccination, even if you are unsure if the vaccination caused the event.
- Moderate vaccination site redness, swelling, and/or pain.
- Mild to moderate constitutional symptoms that resulted in patient missing work due to symptoms.
- Clinicians can also provide patients with information on how to submit their own VAERS report.
  - Please provide them with name of manufacturer and lot # for vaccine the patient received

VAERS and COVID-19 Vaccines

- VAERS reports should include "Pfizer-BioNTech COVID-19 Vaccine EUA" or “Moderna COVID-19 Vaccine EUA” in the description section of the report (Box 18 on VAERS report)

- Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967.

- No deadlines for VAERS submission (timely reporting is encouraged)

- Additional data can be added to existing VAERS report, but you need the VAERS Report # to add documents to existing report.

Workflows for QMC AEFI

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Comparison of V-Safe, VAERS, and QMC Employee/COVID Hotline

QMC Hotlines

- For Patients
- Real-time communication & clinical advice
- Internal way to track calls, securely document, & set up clinical follow up

V-Safe

- For Patients (PUSH communication on smartphone at set time intervals)
- Near real-time data for CDC/FDA
- Queens cannot directly access data
- Severe reactions may get telephone follow-up
- V-Safe does not automatically push to VAERS

VAERS

- For Patients and Clinicians
- Inherent delay in capturing all reports at CDC/FDA
- Queens can access limited data
- Clinicians are have required reporting situations

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NOTE: None of these are for emergency medical management

Healthcare Workers Vaccinated at Queens

All vaccinated at Queens	**Immediate symptoms requiring medical attention**	Immediate clinical management, ER if indicated	Queens vaccination team submits VAERS
Queens Employee	-Severe symptoms requiring ER, +/-hospitalization -Moderate symptoms -Symptoms requiring sick leave	Employee Health Hotline 808-691-8720	-EH enters VAERS
Non-Employee HCW	-Moderate symptoms -Mild symptoms	-Community COVID Hotline 808-691-2619 -T-con or visit with PCM	-PCM enters VAERS report or provides VAERS info to patient to file
General Population	-Moderate symptoms -Mild symptoms	-Community COVID Hotline 808-691-2619 -T-con or visit with PCM	-PCM enters VAERS report or provides VAERS info to patient to file

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VAERS Reporting: Final Tips

- For all clinicians entering a VAERS report: include the VAERS report number in EHR for documentation and reference if additional data needs to be uploaded into VAERS.
- Best practice to inform patient if you file a VAERS report
- If symptoms or adverse event is not on the list of required reporting, can encourage patient to submit their own VAERS report
- Curious about VAERS reports? You can access HIPAA-compliant data submitted (can scope in to state-level but not facility level)

Mahalo

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