Mass Immunization Training

For personnel responsible for managing PODS



11 • 10 • 2020

Previous Topics

- Selecting a Site
- Staffing Your Clinic
- Vaccine Storage & Handling
- Screening for
 Contraindications
- Vaccine Administration
- Typical Reactions vs. Adverse Reactions
- Workflows (including drive-thru)

Register Today! MASS IMMUNIZATION TRAININGS

For personnel responsible for managing PODS (program directors and managers)

Session 1: September 29, 2020 9:00 – 10:30 AM Planning your POD: Vaccine Storage & Handling Procedures and How to Select & Staff Your Site

Session 2: October 22, 2020 9:00 – 10:30 AM Managing Day-Of Operations: Tools and Resources to Keep Patients and Staff Safe

Register: https://whyimmunize.org/ mass-immunization-trainings/ Are you helping your fire department or EMS program plan and execute a mass flu immunization clinic?

Are you starting to think about how your EMS program will distribute a COVID-19 vaccine to large groups of people?

If so - this training is for you!

PREWORK REQUIRED*

*PREWORK REQUIRED! You will be required to take a Community Clinic Module before Session 1. Look for the link to the module once you register.

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Preparing for Tough Conversations

Vaccine Safety

How the Immune System Works

COVID-19 Vaccine Development



We foster community wellness and advocate for good public policy and best immunization practices.

- Partners like you!
- Over 400 coalition members
- Working **together** can improve outcomes



Welcome

Machrina Leach, RN, BSN

Nurse Program Manager Maricopa County Department of Public Health Immunization Expert



Rebecca Nevedale

The Arizona Partnership for Immunization (TAPI) Facilitator

Will Humble

The Arizona Public Health Association Executive Director **Public Health Expert**

Ouestions?

- Selecting a Site
- Staffing your Clinic
- Vaccine Storage & Handling
- Screening for Contraindications
- Vaccine Administration
- Typical Reactions vs.
 Adverse Reactions
- Workflows (including drive-thru)





What to discuss

Physical considerations

Availability of volunteers

Marketing Assistance

Parking/ traffic control

POLL: Where are you most likely to host your next mass immunization clinic?





What NOT to do? At flu clinics At drive-thru clinics

POLL: What mistakes did you make in your mass immunization clinics?





Preparing for Tough Conversations



Your Staff

Immunizers



Preparing for Tough Conversations



POLL: Which statements do you AGREE with regarding the COVID-19 vaccine?



How does it work again?



How are they made?



How are they tested and monitored?

Nova Immunity and Vaccines Explained Video

https://www.youtube.com/watch?v=lXMc15dA-vw

Vaccines trick your immune system to do this



The Human Immune System Functions

- Detect
- Destroy
 - Takes time
 - Cough, inflammation, fever
- Remember

Vaccines trick the body into doing these things



Liveattenuated

Measles, mumps, rubella (MMR) Rotavirus Smallpox Chickenpox Yellow rever

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Inactivated Hepatitis A Flu (shot only) Polio Rabies

Types of Vaccines

Subunit, recombinant, polysaccharide and conjugate Hib Hepatitis **B** HPV Whooping cough Pneumococcal Meningococcal Shingles





Recombinant vector (platform-based)

Liveattenuated

Measles, mumps, rubella (MMR) Rotavirus Smallpox Chickenpox Yellow fever

- Attenuated (weakened) form of the "wild" virus or bacterium
- Must replicate to be effective
- Immune response similar to natural infection
- Usually produce immunity with one dose*

*except those administered orally



General Rule

 The more similar a vaccine is to the disease-causing form of the organism, the better the immune response to the vaccine



Hepatitis A Flu (shot only) Polio Rabies

Cannot replicate

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- Different immune response (humoral)
- Unaffected by antibody in the blood
- Generally require 3-5 doses
- Antibody titer diminishes with time
- Adverse events mostly local with or without fever



General Rule

- <u>Increasing</u> the interval between doses of a multidose vaccine does not diminish the effectiveness of the vaccine.
- <u>Decreasing</u> the interval between doses of a multidose vaccine may interfere with antibody response and protection.

Types of Vaccines

Subunit, recombinant. polysaccharide and conjugate Hib Hepatitis **B** HPV Whooping cough Pneumococcal Meningococcal Shingles

- Uses pieces of the germ
- Give strong immune response targeted to key parts of the germ
- Can be used on almost everyone
- Boosters often needed

Why do some vaccines require "boosters"?

- Use Toxin made by the germ that causes the disease
- Immune response to parts of germ that cause the disease (rather than the germ itself)
- Boosters often needed





- The body's own cells use genetic material to produce antigens
- Years of investigation and research to date
- Some veterinary vaccines



Recombinant vector (platform-based)

DNA



Why do I need to know this?

- Lots of different ways to create immunity – no one way is cleaner, safer or better
- Methods researched for many, many years:
 - How immune systems respond
 - Pros/ cons of different strategies
- Creating vaccines is NOT NEW



SARS-CoV-2

 Every possible strategy ever used to make a vaccine is being used









Phases of Clinical Trials



- Phase 1: clinical trials focus on <u>safety</u>
 - 20–100 healthy volunteers
 - Assesses how the size of the dose may be related to side effects
 - Determines whether vaccine creates immune response
- Phase 2: clinical trials assess dosing
 - Several hundred volunteers
 - Additional information on common short-term side effects/ safety and how the size of the dose relates to immune response
- Phase 3: clinical trials assess <u>efficacy</u> and safety
 - Participation of thousands of volunteers
 - Placebo-controlled RCTs

Other Information – Human Trials



Oversight

Constant progress reports Site visits throughout trial



Safety Standards

Drug trials VS Vaccine trials



What's Different

- Market Need
- Political Will
- Licensing

- Partnership & Collaboration
- Timeline





Pre-Clinical Phase

Collective Meaning-Making in "Real Time"

NIH, WHO, Government, Philanthropy, Biomedical, Academia from around the world







6 – 12 months



Information-Sharing, Collective Review Boards



COVID-19 Vaccine Safety Trials

Pfizer mRNA 32,000-44,000

Moderna mRNA 30,000

Vaccine Safety Trial Participants			
Vaccine	Year	Age vaccine indicated	Participants
Polio – IPOL	2000	2 months +	2,719
PCV7 – Prevnar	2000	2 – 24 months	41,723
Dtap – Daptacel	2002	2 months - 7 years	18,046
Tdap – Boostrix	2005	11 years +	6,192
Tdap – Adeacel	2005	11 years +	11,758
MCV4 – Menactra	2005	11 years +	10,942
RotaTeq	2006	2 – 8 months	67,469
HPV – Gardasil	2006	11 – 46 years	26,985
Shingles – Zostavax	2006	60 years +	41,943
Rotarix	2008	2 – 8 months	86,801
HPV – Cervarix	2009	11 – 26 years	48,989
MCV4 – Menveo	2010	11 years +	9,729
PCV13 - Prevnar 13	2010	2 – 24 months	50,774
			Mean 32,698
			Medium 26,985

Science Protected

Same # study volunteers (30K)
Unprecedented transparency



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How will we save time in the licensing phase? "Operation Warp Speed"







https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html#anchor 1593624850886

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• Takeaways

- Safety is central
- Using the same "tried and true"
 - Scientific technologies
 - Clinical trial protocols
- Unprecedented collaboration & transparency
- Increased staffing, funding
- Timesavers
 - Manufacturing alongside trials
 - Harmonized trials
 - Reducing beurocracies



What should we expect in launch?

And remember... this is still a new disease.

How a vaccine's safety continues to be monitored



FDA and CDC closely monitor vaccine safety after the public begins using the vaccine.

The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

Vaccine Adverse Event Reporting System (VAERS)

VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.

Vaccine Safety Datalink (VSD) and Post-Licensure Rapid Immunization Safety Monitoring (PRISM)



- Two networks of healthcare organizations across the U.S.
- VSD can analyze healthcare information from over 24 million people.
- PRISM can analyze healthcare information from over 190 million people.

Scientists use these systems to actively monitor vaccine safety.

Clinical Immunization Safety Assessment Project (CISA)

CISA is a collaboration between CDC and 7 medical research centers.

- Vaccine safety experts assist U.S. healthcare providers with complex vaccine safety questions about their patients.
- CISA conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).

FOR MORE INFORMATION, VISIT HTTPS://WWW.CDC.GOV/VACCINESAFETY

Ongoing Safety Monitoring

- Every batch is tested (potency, purity, sterility)
- FDA inspections of labs
- Additional testing and research (DoD, VA, NIH, OIDP)

Every new vaccine = Extra safety monitoring

Vaccine safety assessment for essential workers (V-SAFE)



 Text messages or email from CDC with follow-up – daily 1st week post-vaccination and weekly thereafter out to 6 weeks

2. Any clinically important event(s) reported by vaccinated person

Healthcare workers, essential workers, etc.

VAERS call center



3. Follow-up on clinically important event, complete a VAERS report if appropriate



RE-POLL

Which statements do you AGREE with regarding the COVID-19 vaccine?

YOU are a subject matter expert.

How do I have difficult conversations?

Chat in questions you expect to get now!

Be Confident

Use Your Resources

Be Honest



- CDC.gov
- TAPI.org
- Children's Hospital of Philadelphia Vaccine Education Center
- ADHS
- Your County Health Department
- Your Medical Director
- Your friends at TAPI <3



Be Confident

Use Your Resources

Be Honest



Overcoming Objections

- "This vaccine came out way too fast."
- "It's too new. I want to wait before getting one."
- "It gives me the flu."
- "But I've never gotten the shot before and have always been fine!"





Stay Tuned! More when COVID available

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Call to Action



Thank you.

FIREFIGHTER