Mass Immunization Training

For personnel responsible for managing PODS
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)
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
Questions?

• 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

Your Staff - Immunizers
Other Colleagues - Closed POD
Community - Patients & Families
POLL: Which statements do you AGREE with regarding the COVID-19 vaccine?
Nova Immunity and Vaccines Explained Video

https://www.youtube.com/watch?v=lXMc15dA-vw
The Human Immune System Functions

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

*Vaccines trick the body into doing these things*
Types of Vaccines

- Inactivated
- Subunit
- recombinant
- polysaccharide
- conjugate
- Toxoid
- DNA

Hepatitis A
Flu (shot only)
Polio
Rabies
Diphtheria
Tetanus
Hib
Hepatitis B
HPV
Whooping cough
Pneumococcal
Meningococcal
Shingles
Types of Vaccines

1. **Live-attenuated**
   - Measles, mumps, rubella (MMR)
   - Rotavirus
   - Smallpox
   - Chickenpox
   - Yellow fever

2. **Inactivated**
   - Hepatitis A
   - Flu (shot only)
   - Polio
   - Rabies

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

4. **Toxoid**
   - Diphtheria
   - Tetanus

5. **DNA**

6. **Recombinant vector (platform-based)**
Types of Vaccines

1. **Live-attenuated**
   - 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 1

- The more similar a vaccine is to the disease-causing form of the organism, the better the immune response to the vaccine
<table>
<thead>
<tr>
<th>Types of Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles, mumps, rubella (MMR)</td>
</tr>
<tr>
<td>Rotavirus</td>
</tr>
<tr>
<td>Smallpox</td>
</tr>
<tr>
<td>Chickenpox</td>
</tr>
<tr>
<td>Yellow fever</td>
</tr>
<tr>
<td>Inactivated</td>
</tr>
<tr>
<td>Hepatitis A</td>
</tr>
<tr>
<td>Flu (shot only)</td>
</tr>
<tr>
<td>Polio</td>
</tr>
<tr>
<td>Rabies</td>
</tr>
</tbody>
</table>

**Inactivated**

- Cannot replicate
- 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

- Increasing the interval between doses of a multidose vaccine does not diminish the effectiveness of the vaccine.
- Decreasing the interval between doses of a multidose vaccine may interfere with antibody response and protection.
Types of Vaccines

3

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”? 
Types of Vaccines

- 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

4

Toxoid

Diphtheria Tetanus
Types of Vaccines

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

Types of DNA Vaccines

- Recombinant vector (platform-based)
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
Identify Disease

Pre-Clinical Phase
- Isolation of antigens
- Vaccine Development

Animal Model Studies
- Prove the concept
- Examine immune response & **safety**

Phase I
- **Safety** & immune response
- Small # of healthy people

Phase II
- Dose-ranging, safety & immune response
- Thousands of people

Phase III
- Compare to placebo
- Tens of thousands of people

Licensure & Recommendation
- FDA Licensing
- CDC recommendation

Manufacturing Process

Launch/Phase 4
- Continual Monitoring
- Testing for immunocompromised
Identify Disease
- Pre-Clinical Phase
  - Isolation of antigens
  - Vaccine Development
- Animal Model Studies
  - Prove the concept
  - Examine immune response & safety

Phase I
- Safety & immune response
- Small # of healthy people

Phase II
- Dose-ranging, safety & immune response
- Thousands of people

Phase III
- Compare to placebo
- Tens of thousands of people

Licensure & Recommendation
- FDA Licensing
- CDC recommendation

Manufacturing Process

Launch/ Phase 4
- Continual Monitoring
- Testing for immunocompromised
Identify Disease

Pre-Clinical Phase
- Isolation of antigens
- Vaccine Development

Animal Model Studies
- Prove the concept
- Examine immune response & safety

Phase I
- Safety & immune response
- Small # of healthy people

Phase II
- Dose-ranging, safety & immune response
- Thousands of people

Phase III
- Compare to placebo
- Tens of thousands of people

Licensure & Recommendation
- FDA licensing
- CDC recommendation

Manufacturing Process

Launch/Phase 4
- Continual Monitoring
- Testing for immunocompromised
Identify Disease
- Pre-Clinical Phase
  - Isolation of antigens
  - Vaccine Development
  - Animal Model Studies
    - Prove the concept
    - Examine immune response & safety
  - Animal Model Studies
  - Examine immune response & safety

Phase I
- Safety & immune response
- Small # of healthy people
  - Phase II
    - Dose-ranging, safety & immune response
    - Thousands of people
  - Phase III
    - Compare to placebo
    - Tens of thousands of people
  - Licensure & Recommendation
    - FDA Licensing
    - CDC recommendation
  - Manufacturing Process
  - Launch/Phase 4
    - Continual Monitoring
    - Testing for immunocompromised
Phases of Clinical Trials

• **Phase 1:** clinical trials focus on safety
  • 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 efficacy 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
1. **Identify Disease**
   - Pre-Clinical Phase
     - Isolation of antigens
     - Vaccine Development
   - Animal Model Studies
     - Prove the concept
     - Examine immune response & **safety**

2. **Phase I**
   - Safety & immune response
   - Small # of healthy people
   - 12 – 36 months

3. **Phase II**
   - Dose-ranging, safety & immune response
   - Thousands of people
   - 6 – 24 months

4. **Phase III**
   - Compare to placebo
   - Tends of thousands of people
   - 6 – 24 months

5. **Licensure & Recommendation**
   - FDA Licensing
   - CDC recommendation
   - 3 – 18 months

6. **Manufacturing Process**
   - 6 – 36 months

7. **Launch/ Phase 4**
   - Continual Monitoring
   - Testing for immunocompromised
   - 6 – 36 months

---

**Timeline:**
- **Pre-Clinical Phase:** 6 – 36 months
- **Phase I:** 12 – 36 months
- **Phase II:** 6 – 24 months
- **Phase III:** 6 – 24 months
- **Licensure & Recommendation:** 3 – 18 months
- **Launch/ Phase 4:** 6 – 36 months
What’s Different

- Market Need
- Political Will
- Licensing

- Partnership & Collaboration
- Timeline
Identify Disease

Pre-Clinical Phase
- Isolation of antigens
- Vaccine Development

Animal Model Studies
- Prove the concept
- Examine immune response & safety

Phase I
- Safety & immune response
- Small # of healthy people
- 12 – 36 months

Phase II
- Dose-ranging, safety & immune response
- Thousands of people
- 6 – 24 months

Phase III
- Compare to placebo
- Tends of thousands of people
- 6 – 24 months

Licensure & Recommendation
- FDA Licensing
- CDC recommendation
- 3 – 18 months

Manufacturing Process

Launch/ Phase 4
- Continual Monitoring
- Testing for immunocompromised
Pre-Clinical Phase

Collective Meaning-Making in “Real Time”

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

Pre-Clinical Phase
- Isolation of antigens
- Vaccine Development

Animal Model Studies
- Prove the concept
- Examine immune response & safety

Phase I
- Safety & immune response
- Small # of healthy people

Phase II
- Dose-ranging, safety & immune response
- Thousands of people

Phase III
- Compare to placebo
- Tends of thousands of people

Licensure & Recommendation
- FDA Licensing
- CDC recommendation

Manufacturing Process

Launch/Phase 4
- Continual Monitoring
- Testing for immunocompromised

12 – 36 months
6 – 24 months
6 – 36 months
3 – 18 months
Funding
Ready for next phase as soon as science is there

Manufacturing
Scaled up effort – No gap between information in Phase III and availability

Harmonized Trials
Information-Sharing, Collective Review Boards

1–7 YEARS

6–12 months
<table>
<thead>
<tr>
<th>Vaccine Safety Trial Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
</tr>
<tr>
<td>Polio – IPOL</td>
</tr>
<tr>
<td>PCV7 – Prevnar</td>
</tr>
<tr>
<td>Dtap – Daptacel</td>
</tr>
<tr>
<td>Tdap – Boostrix</td>
</tr>
<tr>
<td>Tdap – Adeacel</td>
</tr>
<tr>
<td>MCV4 – Menactra</td>
</tr>
<tr>
<td>RotaTeq</td>
</tr>
<tr>
<td>HPV – Gardasil</td>
</tr>
<tr>
<td>Shingles – Zostavax</td>
</tr>
<tr>
<td>Rotarix</td>
</tr>
<tr>
<td>HPV – Cervarix</td>
</tr>
<tr>
<td>MCV4 – Menveo</td>
</tr>
<tr>
<td>PCV13 - Prevnar 13</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
</tr>
<tr>
<td><strong>Medium</strong></td>
</tr>
</tbody>
</table>
Science Protected

- Same # study volunteers (30K)
- Unprecedented transparency
Identify Disease

Pre-Clinical Phase
Isolation of antigens
Vaccine Development

Animal Model Studies
Prove the concept
Examine immune response & safety

Phase I
Safety & immune response
Small # of healthy people

Phase II
Dose-ranging, safety & immune response
Thousands of people

Phase III
Compare to placebo
Tends of thousands of people

Licensure & Recommendation
FDA Licensing
CDC recommendation

Manufacturing Process

Launch/ Phase 4
Continual Monitoring
Testing for immunocompromised
How will we save time in the licensing phase?

“Operation Warp Speed”

3 – 18 months
The Vaccine Life Cycle
safety at every phase

Safety is a Priority
During all phases of vaccine development, authorization or approval, and use

https://www.cdc.gov/vaccinesafety/ensuring_safety/history/index.html#anchor_1593624850886
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)

1. 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

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
More Resources

- 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
THE ODDS A CHILD WILL...

Be a pilot: 1 in 2,662

Get struck by lightning: 1 in 10,000

Make the US Olympic Team: 1 in 380,228

Get elected to US Congress: 1 in 577,094

Become a billionaire: 1 in 749,382

Have severe allergic reactions after the MMR and Hepatitis B vaccines: 1 in 1 million

Sources:

As you can see, odds are that your child won’t have an adverse reaction after being vaccinated. And in the rare event that it did happen, even a life-threatening allergic reaction could be brought under control at the doctor’s office.
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!”
1. Billing Support
   Contact Jennifert@tapi.org

2. Evaluation
   Help us improve!

3. Resource Page
   Continually Updated
   Send resources!

4. Stay Tuned!
   More when COVID available

Don’t Forget!
Call to Action

Push it!
- Recommend
- Remind
- Remind again

Patients
- Get them in the door
- Target
- Market

Population Health
- Check other records
- No missed opportunities
Thank you.