EVENYONE WANTS A SAFE AND EFFECTIVE COVID-19 VACCINE.

COVID-19 Vaccine Approval Process & Efforts to Ensure Equitable Distribution

Amy Pisani - Executive Director - Vaccinate Your Family
Sarah Despres – Chair, Vaccinate Your Family
Special Guest, Julie Tierney - Chief of Staff, CBER/FDA
Aren't vaccines just a way for pharmaceutical companies (Big Pharma) to make money?

If I'm breastfeeding my baby, why do I need to vaccinate him or her?

If some vaccines are grown in human fetal cells, is it against Christian religions to be vaccinated?

Who monitors the safety of vaccines in the United States?

How can I be confident that vaccines don’t cause autism?
VYF Releases an Annual *State of the ImmUnion* Report

**Insurance Coverage Should Not Dictate Access to Childhood Vaccines**

<table>
<thead>
<tr>
<th>Vaccination Rates for</th>
<th>Private Insurance</th>
<th>Medicaid</th>
<th>Uninsured</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP (≥4 doses)</td>
<td>87%</td>
<td>76%</td>
<td>60%</td>
</tr>
<tr>
<td>MMR (≥1 Dose)</td>
<td>94%</td>
<td>89%</td>
<td>73%</td>
</tr>
<tr>
<td>Flu (≥2 doses)</td>
<td>69%</td>
<td>48%</td>
<td>35%</td>
</tr>
<tr>
<td>Combined 7-Vaccine Series*</td>
<td>75%</td>
<td>64%</td>
<td>47%</td>
</tr>
<tr>
<td>No vaccines</td>
<td>0.8%</td>
<td>1.2%</td>
<td>7.4%</td>
</tr>
</tbody>
</table>

**DID YOU KNOW?**

Disparities in Adult Vaccination Rates

Adult vaccination rates for shingles, as seen in the following statistics from 2018, varied greatly among racial/ethnic groups.

<table>
<thead>
<tr>
<th>Race</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whites</td>
<td>38%</td>
</tr>
<tr>
<td>Blacks</td>
<td>16%</td>
</tr>
<tr>
<td>Hispanics &amp; Asians</td>
<td>22%</td>
</tr>
</tbody>
</table>

**EVERYONE IN THE U.S. SHOULD HAVE ACCESS TO VACCINES**

Despite progress made since the establishment of the vaccines for children program in 1994, children still lack access to vaccines depending on where they live, their families' socioeconomic status, and their insurance status. Adults face similar challenges with additional racial and ethnic disparities.
VYF developed the “State of the ImmUnion COVID Edition”

<table>
<thead>
<tr>
<th>Program</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengthen IIS Systems</td>
<td>$400M</td>
</tr>
<tr>
<td>CDC Immunization Program</td>
<td>$1B annual appropriation + $900M one-time infusion</td>
</tr>
<tr>
<td>Influenza vaccination in 2020 and 2021</td>
<td>$700M for flu vaccine purchase + $300M for infrastructure grants</td>
</tr>
</tbody>
</table>
We Also Need to Begin to Solve Access Issues Now

Ensure Medicare Part D Programs cover vaccines at no cost to the patient

Ensure all Medicare Part D Programs cover vaccines at no cost to the patient

Ensure all children on CHIP are VFC-eligible

Ensure all state Medicaid programs cover vaccines at no cost to the patient

Identify underserved communities in your state and begin to develop outreach and distribution plans

Identify underserved communities in your state and begin to develop outreach and distribution plans
Access our State of ImmUnion Reports @vaccinateyourfamily.org
As we await the vaccines...
Efforts to Ensure Equitable Distribution
“An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will develop an overarching framework for vaccine allocation to assist policymakers in the domestic and global health communities in planning for equitable allocation of vaccines against SARS-CoV-2. The expectation is that such a framework would inform the decisions by health authorities, including the Advisory Committee on Immunization Practices (ACIP), as they create and implement national and/or local guidelines for SARS-CoV-2 vaccine allocation.”

NAM - Info related to the committee’s work can be found on the project website here: https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus.

VYF comments on first draft are available here: https://www.vaccinateyourfamily.org/about-us/announcements/
• Selected published frameworks for early COVID-19 vaccine allocation
• World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE)
• Johns Hopkins Bloomberg School of Public Health
• The National Academies of Sciences, Engineering, and Medicine
# COVID-19 vaccine priority group comparison

<table>
<thead>
<tr>
<th>Group</th>
<th>Johns Hopkins</th>
<th>National Academies</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare personnel</td>
<td><strong>Tier 1</strong>: Frontline healthcare personnel including LTCF providers; EMS</td>
<td><strong>Phase 1a</strong>: Frontline healthcare personnel including LTCF providers; EMS</td>
<td>Priority groups unranked</td>
</tr>
<tr>
<td></td>
<td><strong>Tier 2</strong>: HCP &amp; staff with direct, non-COVID patient contact; pharmacy workers</td>
<td><strong>Phase 2</strong>: Other healthcare personnel</td>
<td></td>
</tr>
<tr>
<td>Other essential workers</td>
<td><strong>Tier 1</strong>: Public transport, food supply workers; teachers &amp; school workers. Workers necessary for pandemic support: (e.g. vaccine manufacturers; public health workers/support)</td>
<td><strong>Phase 1a</strong>: Police, fire</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Tier 2</strong>: Frontline infrastructure; warehouse/delivery/postal; deployed military; police &amp; fire; TSA and border security; high-density or high-contact jobs</td>
<td><strong>Phase 2</strong>: Critical infrastructure at risk of exposure; teachers and school staff incl childcare workers</td>
<td></td>
</tr>
<tr>
<td>Underlying medical conditions</td>
<td><strong>Tier 1</strong>: Those with elevated risk of serious disease; members of social groups experiencing disproportionately high fatality rates</td>
<td><strong>Phase 1b</strong>: Significantly higher risk (≥2 CDC designated conditions)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Phase 2</strong>: Moderately higher risk (1 CDC condition)</td>
<td></td>
</tr>
<tr>
<td>Adults ≥65 years of age</td>
<td><strong>Tier 1</strong>: Adults ≥65 years including those living with or providing care to them</td>
<td><strong>Phase 1b</strong>: Older adults in congregate settings</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Phase 2</strong>: All older adults not in Phase 1</td>
<td></td>
</tr>
</tbody>
</table>
**Possible groups for Phase 1 vaccination**

**August ACIP meeting**
- Phase 1a:
  - HCP
- Phase 1b:
  - Essential Workers
  - High Risk Med Conditions
  - Adults ≥ 65 years old

**September ACIP meeting**
- Explore groups for phase 1b
  - Risk for COVID-19
  - Overlap between groups
  - Racial and ethnic composition
  - Summary of Work Group considerations
Overlap: Essential Worker & High-Risk Medical Conditions

- COPD: ~3%
- CKD: ~2%
- Cancer: ~4%
- CVD: ~4%
- Diabetes: ~7%
- Obesity (BMI > 30): ~30%

Essential workers
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.

Presented by Tom Shimabukuro, CDC/NCIRD to the ACIP Sept. 2020
FDA’s Role in COVID-19 Vaccine Development

Julia Tierney, JD
Chief of Staff
Food and Drug Administration
Center for Biologics Evaluation and Research
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