

The Next Generation of Every Child By Two

2020

STATE OF THE MUNION

SPECIAL SUPPLEMENT: COVID-19 VACCINATION



⁴⁴ Vaccines don't save lives, vaccinations do. A vaccine dose that remains in the vial is 0% effective no matter what the results of the clinical trials showed."

Dr. Walter Orenstein, former director of the United States Immunization Program at CDC (1988–2004)

The 2020 State of the ImmUnion report was released by Vaccinate Your Family in February. Weeks later, our nation was in the midst of a pandemic caused by a virus that struck down the nation. Not since the great influenza pandemic of 1918 has a virus as deadly as SARS-CoV-2 (the type of coronavirus causing the current COVID-19 pandemic) swept across our country. While it is easy to feel helpless, we must remember that we have some advantages over that generation. In 1918, influenza viruses had not yet been discovered, and many had no idea how the illness was spreading. The science of developing vaccines was also still in its infancy, leaving no hope of discovering and quickly developing a vaccine to protect those at risk.

Today, we understand how viruses spread, and we have cutting-edge technologies to develop vaccines more quickly than ever before. But, as Dr. Walter Orenstein notes, a vaccine is only effective if a person receives it. We must lay the groundwork now to ensure the people who most need a COVID-19 vaccine are able and willing to receive it. Until a vaccine candidate, or candidates, moves further along the development and testing process, and the Advisory Committee for Immunization Practices (ACIP) has an opportunity to review the research data, we cannot know exactly who will be recommended for vaccination. We, therefore, need to be prepared to reach each and every individual in communities across our country. The COVID-19 pandemic has shown us what those in public health have suspected for many years: Chronic underfunding and neglect of our public health infrastructure has left us vulnerable to infectious diseases and their damaging effects. While no one can be completely prepared for a pandemic, there are certain technologies, personnel and resources that can be put in place in the coming months to lessen the impact of this pandemic and future disease outbreaks.

Lower childhood vaccination rates for routinely recommended immunizations amidst the pandemic are also a cause for concern. As people follow stay-at-home and social distancing orders, many families are not keeping scheduled well visits and therefore missing out on protection from dangerous diseases such as measles, pneumococcal disease and *Haemophilus Influenzae* Type b (Hib). Our country cannot afford to follow a pandemic with an increase in cases or large outbreaks of vaccinepreventable diseases.

In this special supplement, Vaccinate Your Family has laid out the steps Congress can take now to ensure our country emerges from this crisis with a better ability to face infectious disease threats and a greater appreciation for the science of vaccinations.

MAKING DISEASE PREVENTION A PRIORITY

Too often, preventing diseases in this country has taken a backseat to other priorities, despite the fact that immunizations save both money and lives. The COVID-19 pandemic has demonstrated just how important it is to maintain and expand a robust network of immunizers and vaccination locations; to strengthen existing vaccination data collection systems; and to ensure no one has to skip vaccines due to their inability to locate or pay for vaccinations.



Childhood Vaccines Save Lives and Money¹

The vaccination of children born between 1994 and 2018 will prevent:



419 MILLION ILLNESSES: More than the population of the U.S.



\$1.9 TRILLION IN TOTAL SOCIETAL COSTS: \$5,000 for each person in the U.S.

STEP 1

Strengthen Immunization Information Systems (IIS)

We cannot do much to prevent diseases and identify gaps in our communities' immunity if we do not have accurate vaccination data on people of all ages. Immunization information systems (IIS), also known as immunization registries, are confidential, population-based, computerized systems that record all vaccine doses administered by participating providers to people residing within a geographic area. Every state, and many large cities, operate their own IIS.

Each of the systems collects and shares vaccination data across multiple healthcare organizations, clinics, and pharmacies in a given area, creating a comprehensive consolidated immunization record for each individual. Many IIS also allow vaccine providers to automate their vaccine inventory; allow expeditious tracking of vaccines in case of shortages and during vaccine recalls; and automatically flag high-risk patients for timely vaccinations. At the population level, an IIS can provide aggregate data for immunization programs to use in vaccination and disease surveillance. targeted outreach, and other program

operations — all with the goals of improving vaccination rates and reducing cases of vaccinepreventable diseases.

To be optimally effective, IIS should:

- Encompass all vaccinations received during each person's lifetime
- Contain immunization histories from both children and adults
- Meet the standards recommended by the <u>American Immunization Registry</u> <u>Association</u>
- Include all vaccine providers in the state, including pharmacists, OB-GYNs, visiting nurses, and any other providers who may be enlisted to help with the administration of vaccines. Those who have authorized access to children's immunization records, such as school nurses and staff from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) should also be considered also be considered for "read-only" IIS access.
- Share data across state lines to ensure that people who move to another state can still access their consolidated immunization records and avoid receiving too many or too few vaccinations, saving time and money and improving patient care.



 Include opt-out provisions, as they allow individuals to elect to have their information not included if desired. Opt-in systems often vastly undercount the number of vaccinations given as many people are not aware that they should include their vaccination records.

IIS have been effective tools for immunization programs for several decades; however, modifications to IIS will be required to facilitate mass immunization efforts for a new COVID-19 vaccine, including the onboarding of additional vaccine providers and ensuring that each IIS aligns with standards to facilitate better data exchange with other electronic health systems. The immunization community estimates it will cost at least \$400 million to properly modernize states' immunization information systems.

STEP 2

Correct Deficiencies in Funding for the CDC's Immunization Program

The Centers for Disease Control and Prevention's (CDC's) Immunization Program, also known as Section 317 of the Public Health Service Act, has been chronically underfunded for at least ten years. In their most recent Professional Judgment report to Congress, the CDC asks for a little over \$1 billion to adequately support the vaccination of children, adolescents and adults. This includes funding for immunization programs across the country to purchase vaccines for uninsured adults and others during public health emergencies, staff vaccination clinics, conduct targeted outreach and communication campaigns, monitor and contain disease outbreaks, and much more. In addition to an annual appropriation of \$1 billion (an increase of \$350 million), the Immunization Program will require at least \$900 million to make necessary improvements, which have been stalled for the past decade.

However, this is just the bare minimum needed during an average year to help ensure people of all ages receive recommended



vaccinations. During this extraordinary time, additional funds are needed to prepare the country for the upcoming influenza season and for a possible dual influenza and COVID-19 vaccination and education campaign in the fall of 2021. An extra effort must be made to vaccinate as many people in the U.S. against flu each season — both to limit the strain that vaccine-preventable diseases can put on hospital resources and to ensure vaccination programs have sufficient resources to vaccinate as many people as possible. Therefore, in both 2020 and 2021, the U.S. needs \$700 million for the purchase of 50 to 60 million doses of influenza vaccine and \$300 million for infrastructure grants through existing state cooperative agreements under the Immunization Program.

STEP 3

Ensure those on Medicaid and Medicare have Access to Vaccines at No Cost

Congress recently ensured that any future COVID-19 vaccine would be available to seniors under Medicare Part B, thereby ensuring it would be available with no out-of-pocket costs to one of the populations most at risk of serious complications from the coronavirus. That does not, however, solve the problem that **some seniors still do not have first-dollar coverage for other recommended vaccines under Part D** most notably shingles and Tdap (tetanusdiphtheria-pertussis) vaccines. Nor does it ensure that the pregnant women and other adults on Medicaid have equitable access to vaccines.

Each state's Medicaid program is structured differently, making it difficult to understand how many people truly have access to free vaccinations with no copays. As an important first step to understanding gaps in vaccination access for all ages, **Congress should request a General Accounting Office (GAO) report on how each state approaches vaccination coverage for those on Medicaid**.

Congress must support healthcare payment measures that expand access and protect first-dollar coverage and needs to explore ways to incentivize healthcare providers to accept more Medicaid patients. Congress should direct the Center for Medicare & Medicaid Innovation (CMMI) to develop a model to encourage a streamlined payment for vaccination counseling, administration and patient follow-up.



Add All Children in State CHIP Programs to VFC

Children who live in rural areas, as well as those who are on Medicaid, are <u>less likely</u> <u>to be fully vaccinated by as much as 20%</u> <u>for some vaccines</u>. Uninsured children are also less likely to be protected than those who are privately insured. The difference is startling: <u>Over 7% of uninsured children</u> <u>receive no vaccines</u>, compared to less than 1% of privately insured children. This is particularly alarming because children on Medicaid and those who are uninsured are both eligible for free vaccines through the federal Vaccines for Children (VFC) program. Unfortunately, not all children enrolled in state CHIP programs are



eligible for vaccines through the VFC program. Ensuring all children on CHIP are eligible for the VFC program will allow many states to better protect children from deadly vaccine-preventable diseases.

Insurance Coverage Should Not Dictate Access to Childhood Vaccines²

VACCINATION RATES FOR	PRIVATE INSURANCE	MEDICAID	UNINSURED
DTaP (≥4 doses):	87%	76%	60%
MMR (≥ 1 Dose):	94%	89%	73%
Flu (≥2 doses):	69%	48%	35%
Combined 7-Vaccine Series*:	75%	64%	47%
No vaccines:	0.8%	1.2%	7.4%

Plan for COVID-19 Vaccine Distribution Now

While we may not know exactly how many doses of COVID-19 vaccines we will have or for whom those doses will be recommended, it is essential that vaccine distribution plans are developed now so that rapid deployment can occur when needed. The CDC uses a vaccine distributor for the Vaccines for Children program (VFC), who then ships doses from central distribution centers. These centers receive vaccines directly from manufacturers and then deliver those doses directly to healthcare providers or other vaccine providers as directed by state and local authorities. **This distribution system was successfully expanded during the 2009 H1N1 influenza pandemic and will be the most efficient way to distribute approved COVID-19 vaccines**. Regular communication between Congress and the CDC to understand the CDC's planning process and needs is crucial to ensure a smooth vaccine rollout and delivery.

Members of Congress can also encourage their states to start planning for local vaccine dissemination. A statewide taskforce that includes both officials and experts, such as your state's Immunization Program Manager, will help ensure your constituents are able to receive a vaccine as soon as possible. States can also use this coming flu season as a test run for implementing new vaccination locations and procedures. Higher influenza vaccination rates mean less people with serious flu complications, thus reducing a community's need to use up limited and costly medical resources such as hospital beds, ventilators, personal protective equipment, and more. As a result, communities will have more lifesaving resources available for those in need due to COVID-19 and other non vaccine-preventable diseases.



INCREASE APPRECIATION FOR, AND CONFIDENCE IN, VACCINES

An effective, safe and abundant supply of COVID-19 vaccine will do our country little good if people are hesitant to receive it. Recent polls have demonstrated that many people in the U.S. are willing to receive a COVID-19 vaccine. However, some of those who were reluctant to get the vaccine cited concerns about the speed with which the vaccine will be developed. Many medical and public health experts have also stated the need for key safety and efficacy checkpoints to be met.

Now is the time to begin discussing the rigorous process all vaccines — including candidates for a COVID-19 vaccine undergo before being approved by the FDA and how vaccines are continuously monitored for safety after being recommended by the ACIP. There is a tremendous amount of misinformation circulating about COVID-19 vaccine candidates and other vaccines. Congress can help set the record straight:



For regular updates on these and other vaccine issues, please email info@vaccinateyourfamily.org. **Talk to your constituents.** As leaders serving in office during an unprecedented time in our country's history, you can make sure your constituents are receiving accurate information about vaccines. Share fact-based information in your newsletters, during virtual town halls and in media interviews. Encourage the people in your districts and states to keep up with routine vaccinations and prepare them to follow CDC guidelines on receiving a COVID-19 vaccine. <u>Vaccinate Your Family's website</u> has up-to-date information to help you address common and new vaccine myths.

Support the VACCINES Act of 2019 (H.R. 2862), which authorizes the CDC to fund local responses in communities who are hesitant about vaccinating. Many of the measles outbreaks in 2019 happened in tight-knit communities that rely on each other for medical information rather than government agencies, healthcare systems or other "outside" organizations. African Americans are another group that may be less likely to seek out vaccination services due to mistrust of the government and healthcare system. Now, with disinformation about future COVID-19 vaccines on the rise, it is even more critical that states and local officials have the resources they need to identify communities with serious concerns about vaccines and create culturally-, ethnically, and racially-sensitive resources to address hesitations.



2

Stay up-to-date on COVID-19 vaccine developments. BIO has a comprehensive <u>tracker of all vaccines, antivirals and treatments</u> currently in development. The tracker is updated every week with the latest information on clinical development.

UNDERSTAND THE DIFFERENCE BETWEEN THE COVID-19 AND NORMAL VACCINE APPROVAL PROCESS



Standard Vaccine Development

10-20 years

DEVELOPMENT (UP TO 12 YEARS)

- Developing a vaccine takes years to ensure it is safe and effective, and will remain so over time
 - · Exploratory stage: Research and discovery
 - Pre-clinical stage: Test tube and animal studies
 - · Clinical trials: Ensuring safety and effectiveness in healthy human participants
 - 1. Phase 1: tens of volunteers
 - 2. Phase 2: hundreds of volunteers
 - 3. Phase 3: tens of thousands of volunteers

COVERAGE AND REIMBURSEMENT (6-12 MONTHS)

The U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends optimal timing and population for vaccination based on scientific evidence. Their recommendations impact how vaccines are covered by both commercial and government insurance programs

REGULATORY REVIEW AND APPROVAL [8 (PRIORITY) TO 12 MONTHS (STANDARD)]

A vaccine candidate must undergo regulatory review and be approved by the Food and Drug Administration (FDA) before it can be made available for broad distribution to patients

- · The FDA conducts in-depth evaluations of safety and effectiveness to make sure benefits outweigh potential risks
- · The Vaccine Adverse Event Reporting System (VAERS) and other safety systems continuously monitor safety to reveal any potential rare side effects

MANUFACTURING (6-36 MONTHS)

Vaccines may be manufactured at facilities around the country or world

- · Each vaccine batch is tested and re-tested to ensure quality and consistency between batches
- · Growing cells and viruses can take two days to three months · It can take years of research to safely inactivate a virus that
- causes disease but provides immunity · There are multiple phases of transportation and storage
- to ensure safe delivery

Emerging Pandemic Vaccine Development Goal of 12-18 months



DEVELOPMENT (UP TO 12 MONTHS) In accelerating vaccine development, scientists

- carefully balance speed and safety
- Pre-clinical stage
- Clinical trials: Ensuring safety and effectiveness in healthy human participants is done in parallel, while maintaining trial size, quality, approval of regulatory trials, and ability to scale up
- · Initial results can modify the existing trial as it moves forward

MANUFACTURING

In a global emergency, widespread manufacturing of a vaccine can be scaled up to commercial levels before clinical trials are complete. Each vaccine batch is still tested and re-tested to ensure quality and consistency between batches

*Emeraency Use Authorizations (EUA) are not the same as product approvals, and are only utilized when there are no adeauate approved and available alternatives. Manufacturers will continue to seek full regulatory approval for products that receive EUA.

As a matter of urgency, a robust global collaboration of scientists, and public and private partners are developing a safe vaccine that meets all vaccine development criteria

REGULATORY REVIEW AND APPROVAL (8-12 MONTHS)

- There is continuous and early collaboration with federal agencies (FDA, CDC, HHS) to ensure a rapid and appropriate approval process
- · If a vaccine candidate indicates a positive immune response, preliminary evidence of efficacy, and an adequate safety profile, approval could be considered early for emergency use, first in high-risk populations such as healthcare workers, the elderly and those with pre-existing conditions*
- · FDA, CDC and private partners comprehensively monitor safety after the public begins using the vaccine

COVERAGE AND REIMBURSEMENT (14 DAYS)

Coverage of vaccines will be available in both public and private markets. Vaccine distribution is unique during a pandemic, and federal response is done in coordination with state administered response





RESOURCES AND USEFUL LINKS



Commonly Requested Information for Constituents

- Vaccinate Your Family: The Next Generation of Every Child By Two is a leading source of evidence-based vaccine information. You can find information on common questions about vaccines, vaccine safety oversight, disease outbreaks and other topics on our website and social media pages. Learn more at:
- Vaccinate Your Family (Vaccinateyourfamily.org)
- <u>Shot of Prevention Blog (Shotofprevention.com)</u>
- Facebook (@VaccinateYourFamily)
- <u>Twitter (@Vaxyourfam)</u>
- Instagram (@VaccinateYourFamily)
- YouTube (@VaccinateYourFamily)

Policy Resources

- Trust for America's Health: COVID-19 Policy <u>Response Brief</u> examines the nation's ability to respond to public health emergencies, tracks progress and vulnerabilities, and includes a review of state and federal public health preparedness policies and a state-by-state map rating of preparedness.
- <u>317 Coalition</u> is solely focused on advocating for increased federal funding for the National Center

for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention, and as such will focus on implementing the policies of the Advisory Committee on Immunization Practices and other relevant policy-making bodies.

- Adult Vaccine Access Coalition is fostering an inclusive partnership of organizations to inform and engage federal policymakers in working towards common legislative and regulatory solutions that will strengthen and enhance access to and utilization of adult immunization services across the health care system.
- Association of Immunization Managers enables immunization program managers to work together to effectively prevent and control vaccine-preventable diseases and improve immunization coverage in the United States and its territories.
- Association of State and Territorial Health Officials is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, and the District of Columbia, and over 100,000 public health professionals these agencies employ.
- Immunization Coalitions Network of the Immunization Action Coalition offers a searchable database to locate state and local

immunization coalitions and a host of state policy resources.

- <u>National Association of County & City Health</u> <u>Officials</u> is comprised of over 2,800 Local Health Departments across the United States.
- <u>American Academy of Pediatrics</u> offers an overview of recent disease outbreaks and vaccination rates.
- The Centers for Disease Control and Prevention has created an infographic outlining the country's process for vaccine approval and ongoing oversight.

Annual Vaccination Rate Data

- Child Rates: <u>https://www.cdc.gov/vaccines/imz-managers/coverage/childvaxview/interactive-reports/index.html</u>
- School Rates: <u>https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/data-reports/index.html</u>
- Teen Rates: <u>https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/index.html</u>
- Adult Rates: <u>https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/index.html</u>
- Flu Rates: <u>https://www.cdc.gov/flu/fluvaxview/</u> index.html



VACCINATE YOUR FAMILY

The Next Generation of Every Child By Two

Vaccinate Your Family: The Next Generation of Every Child By Two

Our mission is to protect people of all ages from vaccine-preventable diseases by raising awareness of the critical need for timely immunizations, increasing the public's understanding of the benefits of vaccines, increasing confidence in the safety of vaccines, ensuring that all families have access to life-saving vaccines, and advocating for policies that support timely vaccination.

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