ACHI
INSPIRING HEALTHY ACTS

WHY IMMUNIZATIONS MATTER

December 2020

Introduction

Immunizations represent one of the most important achievements in public health, providing both individual and community-level protections against many diseases which once had devastating consequences. As the COVID-19 pandemic continues to impact the U.S., the race to develop an effective vaccine has been a key priority. With the development and emergency authorization of a new vaccine comes the need for heightened public outreach efforts in what may be the largest mass vaccination campaign in U.S. history. In this explainer, we discuss the importance of immunizations, standards used to determine vaccine safety and efficacy, immunization recommendations and vaccine coverage estimates, and additional context regarding the development and distribution of a COVID-19 vaccine.

Immunity

Immunity is "protection against a disease … as indicated by the presence of antibodies in the blood (and) can usually be determined with a laboratory test."[1] Immunization is "the process by which a person becomes protected from disease."[2] People may gain protection from infectious diseases through individual immunity or through the community.

INDIVIDUAL IMMUNITY

There are two ways to acquire individual immunity — actively or passively.[3]

- Active immunity — acquired by disease contraction or vaccination (usually permanent)
- Passive immunity — acquired from antibodies produced by another source, e.g., mother to child (limited protection)

TABLE 1: VACCINE EFFECTIVENESS FOR FOUR DISEASES BY NUMBER OF DOSES

Vaccine	Effectiveness	Dose(s)
Measles	97%	2
Mumps	88%	2
Inactivated Polio	99%	3
Varicella	85%	1

Most vaccines are an altered version or component of the bacterium or virus associated with the disease.[4] When the vaccine is injected, the body's immune system detects a dead or weakened

organism and reacts by producing antibodies against the organism.[5] Depending on the disease, one dose of a vaccine is enough to protect a person but in most cases, multiple doses boost antibody production; even with multiple doses, rates of effectiveness vary (see Table 1).[6,7,8]

In contrast, the first COVID-19 vaccine authorized for use in the U.S. (along with other leading vaccine candidates) utilizes a new approach to vaccines called messenger ribononucleic acid (mRNA). Instead of using a weakened or inactivated bacterium or virus to trigger an immune response, mRNA vaccines give instructions to cells to create a non-infectious piece of a spike protein. A spike protein is a type of protein found on the surface of some viruses, including the virus which causes COVID-19. When our cells create a piece of this protein, this triggers an immune response that produces antibodies that then protect us from becoming infected if we are exposed to the real virus.[9]

Dosing and intervals between doses for the leading COVID-19 vaccine candidates vary. For example, the U.S. Food and Drug Administration (FDA) granted emergency use authorization (EUA) for a COVID-19 vaccine developed by Pfizer-BioNTech on Dec. 11, 2020. This vaccine requires two separate doses given at least three weeks apart. Another leading candidate developed by Moderna also requires two doses, but the duration between doses is at least four weeks.[10] A two-dose regimen is common for many vaccines and allows for the production of more antibodies to provide protection against a virus. The first dose of these vaccines helps to create an initial immune response, and the second dose acts as a booster and helps to create additional antibodies and strengthen immune response. The duration between the doses is to ensure that the second shot is given when a person's immune response is highest and is determined by efficacy data obtained during the clinical trial process.[11]

The effectiveness of a vaccine reflects how well the vaccine performs under "real world" conditions, in contrast to published vaccine efficacy rates representing how well a vaccine performs under ideal conditions in a clinical trial.[12] While clinical trial data indicate that both the Pfizer-BioNTech vaccine and the Moderna vaccine have approximately 95% efficacy rates, their rate of effectiveness is expected to be lower once distributed in real-world settings. Because no vaccine is 100% effective in preventing initial disease, vaccines need to be tested regularly and updated to maximize effectiveness in preventing disease outbreaks.[13]

HERD IMMUNITY

Herd, or community, immunity occurs when enough people in a defined community are immune to an infectious disease (through vaccination and/or prior illness) to decrease the spread of a disease when it occurs.[14] For herd immunity to protect people who are not immune, a large

percentage of people in the community must be resistant to the disease in order to lower the likelihood that the disease will spread from person to person. This percentage is the herd immunity threshold. The threshold varies by the contagiousness of the disease, but most efforts target a goal of 90% protected.[15]

A case study of a measles outbreak in 1970 on the Texas-Arkansas border[16] highlights two issues: 1) the effectiveness of vaccinations, and 2) the importance of herd immunity in protecting all individuals (vaccinated or unvaccinated).[17,18,19]

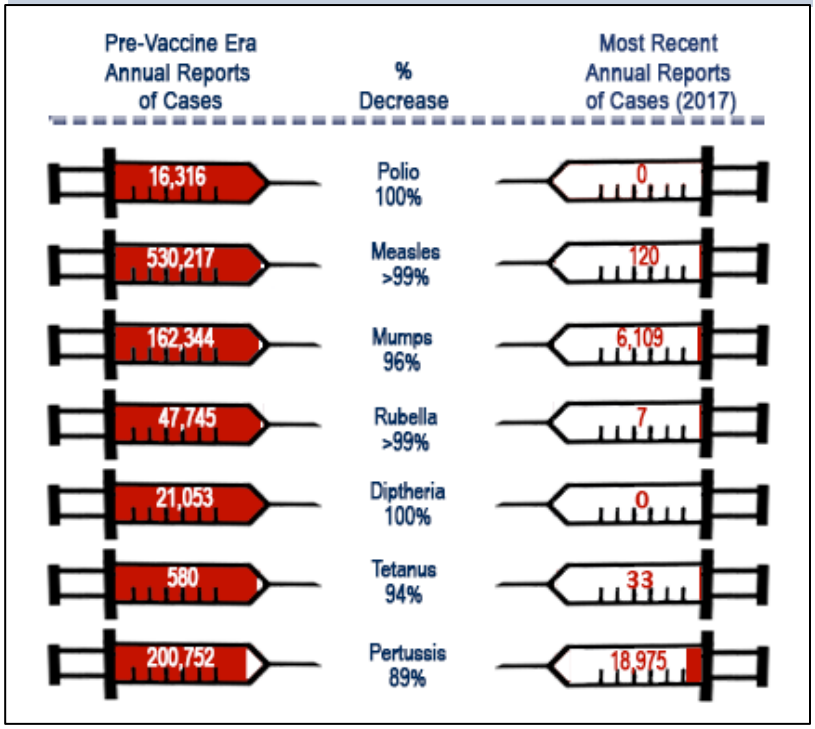
CASE STUDY: 1970 TEXAS–ARKANSAS BORDER MEASLES OUTBREAK[16]

- In 1970, there was a measles outbreak in Texarkana, TX, and Texarkana, AR.
- Of 606 reported cases, 95% occurred in Texarkana, TX.
- Measles immunization was required for children admitted into school in Arkansas, but not in Texas.
- In Arkansas, the vaccination rate was 95% for children ages 1–9, compared to 57% in Texas.

An increased level of individualized immunity leads to greater community immunity. Projections indicate that vaccinations of children born between 1994 and 2018 will prevent 419 million illnesses, help avoid 936,000 deaths, and save nearly $1.9 trillion in total societal costs, including $406 billion in direct costs.[20]

The combination of infections (and resulting antibody protections) from COVID-19 and large-scale vaccination efforts will both contribute to herd immunity from the virus. For COVID-19, most models show that 60% to 70% of a community will need to be immune to reach herd immunity.

Figure 1. Decrease in Reported Cases



Before the introduction of vaccinations at the beginning of the 20th century, infectious diseases exacted an enormous toll on the U.S. population.[21] For example, at its peak in 1952, there were more than 21,000 cases of paralytic polio.[22] During the 20th century, some of the diseases that had caused illness and significant numbers of deaths were eradicated or significantly reduced by advances in science.[23] Figure 1 shows pre-vaccine-era annual reported cases and the most recent reported cases for select diseases, as of 2017.[24] Incidence reductions have led not only to health protection but also tremendous cost-benefit savings.[25] These savings, highlighted in a 2007 report, noted a benefit of $4.76–$5.61 for each dollar spent on varicella vaccine and a benefit of $1.96 for each dollar spent on the hepatitis A vaccine.[26]

Safety & Effectiveness

Modern vaccines are safe and effective, but no vaccine is completely effective or completely safe for all recipients. Unfavorable or adverse events after immunization have been reported with all vaccines, ranging from frequent, minor, local reactions to extremely rare, severe, systemic illness, such as that associated with the yellow fever vaccine.[27] Despite anecdotal reports and considerable media attention regarding a connection between vaccines and autism spectrum disorder (ASD), no credible scientific proof has connected vaccines to ASD. This issue has been studied extensively in the U.S. and abroad, and no linkage between vaccines and ASD has been found.[28]

The process for developing a potential COVID-19 vaccine has been guided by the same safety and effectiveness standards applied to other approved vaccines. Investigational vaccine candidates must undergo clinical trials with thousands of study participants, culminating in data evaluated by the FDA to determine the vaccine's safety and effectiveness. Although the

development of a COVID-19 vaccine has been expedited compared to the typical timeframe for development, the FDA has emphasized that the same rigorous standards required under the traditional approval process have not been compromised. During a public health emergency such as the COVID-19 pandemic, the FDA can provide access to vaccines through the expedited emergency use authorization (EUA) mechanism. Granting an EUA for a vaccine does not equate to full approval by the FDA, which requires a more rigorous process. Manufacturers of COVID-19 vaccines authorized under EUAs are expected to continue clinical trials in order to obtain more safety and effectiveness data and pursue full approval (or licensure) of the vaccines.[29]

There are two independent advisory committees that review data on vaccine candidates and make recommendations to health agencies: the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the Advisory Committee on Immunization Practices (ACIP). VRBPAC is an FDA advisory committee charged with evaluating data regarding the safety, effectiveness, and appropriate use of vaccines. VRBPAC makes a recommendation to the FDA on whether an EUA should be granted for a vaccine candidate. ACIP reviews vaccine clinical trial data to develop recommendations on who should receive the vaccine. On Dec.1, 2020, ACIP voted to prioritize initial doses of an authorized vaccine for healthcare workers and residents of long-term care facilities. Ultimately, state health departments are responsible for determining how vaccines will be distributed, but recommendations from ACIP guide these decisions.

The FDA also requires a vaccine manufacturer to submit a plan in its EUA request for active safety monitoring for individuals who receive a COVID-19 vaccine under an EUA. Additionally, both the FDA and the Centers for Disease Control and Prevention (CDC) have shared responsibility in post-authorization vaccine safety monitoring. This includes maintaining and monitoring multiple reporting systems which capture adverse events associated with authorized vaccines reported by healthcare systems and vaccine recipients.[30]

Immunization Recommendations

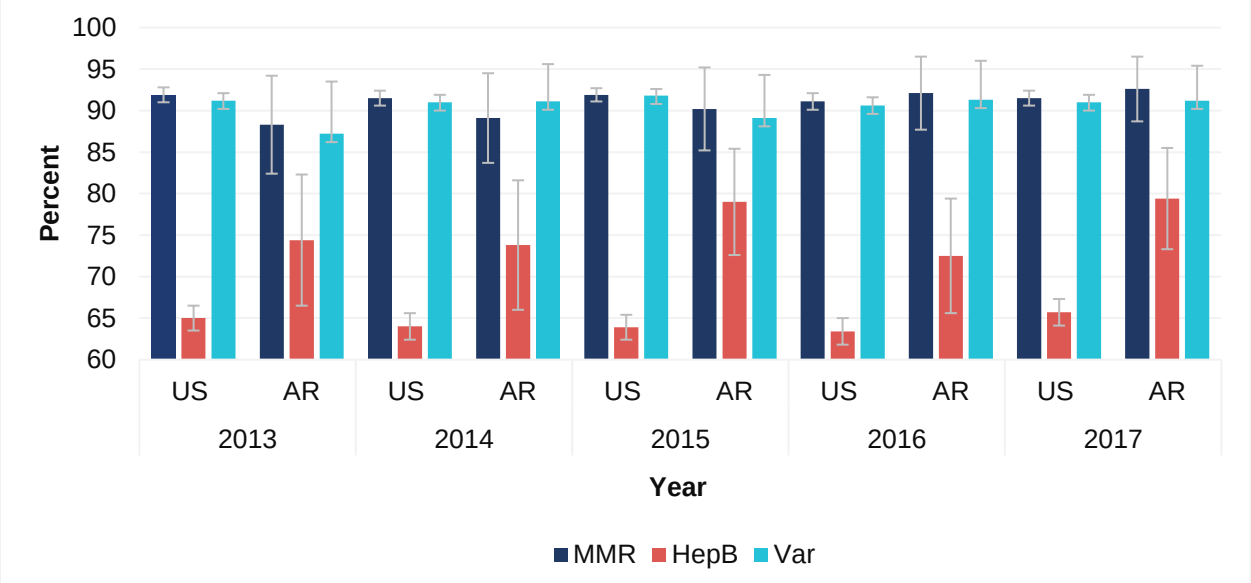
The CDC advises following vaccination recommendations and scheduling unless otherwise medically indicated.[31] For children entering kindergarten, the Arkansas Department of Health follows the CDC's recommendations requiring children to have the following six vaccinations: polio vaccine; measles / mumps / rubella vaccine (MMR); hepatitis B vaccine; hepatitis A vaccine; varicella (chickenpox) vaccine; and diphtheria / tetanus / acellular pertussis (DTaP), diphtheria / tetanus / pertussis (DTP), or diphtheria / tetanus (DT pediatric) vaccine.[32] However, Arkansas is one of 15 states, as of June 2020, that offer an exemption for philosophical reasons

to immunizations due to personal, moral or other beliefs.[33] Increased concentrations of individuals with exemptions may decrease overall herd immunity and contribute to an increase in vaccine-preventable disease outbreaks.[34]

Figure 2 depicts vaccination coverage among children ages 19–35 months in the U.S. and in Arkansas from 2013–2016.[35] Arkansas ranked among the worst states for overall vaccination rates during that period. In 2017, Arkansas ranked 35th among all states for the percentage of children age 19–35 who received the recommended doses of the following vaccines: DtaP, hepatitis b, haemophilus influenzae type b vaccine, MMR, and pneumococcal conjugate vaccine.[36]

Even with these vaccination gaps and variations in vaccination rates over time, there remains a level of consistency in vaccination rates nationally and locally that contributes to the relatively few outbreaks occurring in this era compared to the pre-vaccination era.[37]

FIGURE 2: VACCINATION COVERAGE AMONG CHILDREN AGES 19-35 MONTHS



Conclusion

Public health practitioners recognize that not all diseases can be prevented by vaccines and may require different approaches to protect Americans.[38] A more fully vaccinated population has less potential risk of disease than a less vaccinated population does, because vaccination helps limit the size, length, and spread of disease. Public health policy should aim for 100% coverage.[39]

The challenges presented by the COVID-19 pandemic have led to a groundbreaking vaccine development timeline. While there may be concerns among the general public regarding a new COVID-19 vaccine, the same scientific and regulatory standards have been applied to ensure its safety and effectiveness. Although early polling from September 2020 data indicated that only 63% of Americans would take a COVID-19 vaccine, data released in early December 2020 showed that the percentage had risen to 71%.[40] To bring the pandemic under control and work closer towards achieving herd immunity, every American will need to be ready to take the COVID-19 vaccine when the opportunity arises.

REFERENCES

For a full list of references, please visit www.achi.net/library/why-immunizations-matter

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