What Can the United States Do to Prevent Another Pandemic?

Commit to Modernizing Influenza Vaccines

By Madison Hayes

THE ISSUE

The Covid-19 pandemic has laid bare the acute vulnerabilities in the United States’ health security policies and capacities. While the Covid-19 crisis is far from over, we cannot afford to be complacent about what has long been understood to be a principal health security threat: influenza viruses.

The consequences of seasonal and pandemic influenza are well documented. In the 2017–18 influenza season, an estimated 45 million Americans fell ill with nearly 21 million seeking care from a health provider and 810,000 requiring hospitalization. Over 100 years ago, the 1918 influenza pandemic killed 675,000 Americans. Beyond the human cost, seasonal influenza costs the United States over $10.4 billion in direct medical costs and $87 billion in total economic burden every year.¹ The costs of pandemics and novel viruses are even more staggering. The U.S. gross domestic product (GDP) shrank 32.9 percent from April to June in the wake of Covid-19—the largest decline since 1945.²

To address this threat, there are concrete steps the United States should take to combat chronic challenges with influenza vaccines. The United States should strongly support universal influenza vaccine (UIV) development. Until UIV is achieved, the United States should take specific steps to embrace the modernization of seasonal influenza vaccine production, boost vaccine demand and confidence, and ensure close collaboration with partners in the global influenza system.

WHY SHOULD WE WORRY ABOUT INFLUENZA?

In the midst of a historic coronavirus pandemic, it may be difficult to believe that another virus could pose a threat to the public health and economic security of the American people. Yet, history has proven the reality of this threat with influenza pandemics in 1918, 1957–58, 1968, and 2009.³

Just because we are reeling from a coronavirus pandemic does not mean we are exempt from another influenza pandemic—now or in the future. The same conditions that propelled SARS-Cov-2—the coronavirus that causes Covid-19—around the globe in December 2019 persist today: population growth, urbanization, increasing animal-human interactions, rising global temperatures, and globalization.⁴

Of more immediate concern, experts warn that if Americans do not practice appropriate prevention measures such as seeking influenza vaccination, washing their hands, social distancing, and wearing a mask, circulating seasonal influenza and Covid-19 will exacerbate one another, adding further strain to an already overburdened health system. Dr. Redfield, Director of the Centers for Disease Control and Prevention (CDC), expressed this concern in August saying this could be the “worst fall” that “we’ve ever had.”⁵ In preparation, the CDC has purchased 9.3 million additional doses of influenza vaccines for uninsured adults as compared to last year’s 500,000.⁶
Several countries in the southern hemisphere—such as Australia, Chile, and South Africa—have experienced mild influenza seasons due to increased influenza vaccine uptake and other protective measures in place as a result of Covid-19. The CDC released a report in mid-September predicting that Covid-19 interventions and influenza vaccination could reduce influenza transmission in the 2020–2021 season. However, other experts fear that the United States will not experience the same decreases in influenza cases due to the inconsistent adoption of Covid-19 prevention measures and historically low influenza vaccine uptake. For example, only 49 percent of Americans got an influenza vaccination in 2018–2019.

For these reasons, it is critical that the United States strengthens its influenza vaccine infrastructure and encourages vaccine confidence and demand immediately—even as it grapples with another viral crisis.

### WHAT IS SEASONAL INFLUENZA?
Seasonal influenza is defined as predictable outbreaks of respiratory disease caused by various influenza viruses that spread from person to person. The 2017–2018 influenza season was the most severe in a decade, killing 61,000 Americans. The 2017–2018 influenza season demonstrated deep vulnerabilities within the U.S. health system and its capacity to prevent and treat outbreaks of infectious disease—a harbinger of the challenges the system would face in 2020 with the arrival of a novel coronavirus.

The onslaught of patients led several states, like Alabama, to declare a state of emergency, asserting they could not provide care in a “traditional, normal, and customary manner.” Hospitals across the nation proved unable to cope with the surge and resorted to such measures as erecting tents in parking lots and treating patients in hallways. These health system vulnerabilities have played out even more dramatically since the onset of Covid-19 and could worsen this fall. Supplies of personal protective equipment (PPE) are already depleted and the workforce that would traditionally be preparing for influenza is focused on Covid-19.

### WHAT IS PANDEMIC INFLUENZA?
Pandemic influenza refers to a global outbreak of a novel influenza virus. Pandemic influenza was ranked one of the top ten threats to global health in 2019, just before the novel coronavirus emerged in China. As the Covid-19 pandemic has painfully demonstrated, viruses never-before-seen in humans can wreak havoc on immune systems that are not as equipped to protect themselves. Experts have long considered pandemic influenza to be a major health security threat because influenza viruses are highly unstable and mutable, and they are known to jump from animal reservoirs to humans quite easily. The result could be a novel, pandemic influenza outbreak with a similar trajectory to the Covid-19 pandemic.

There is also historic precedent for a devastating influenza pandemic. 2018 commemorated 100 years since the deadly Spanish Flu infected 500 million people and left 50 million dead globally. Despite the name, the strain was believed to have originated in the U.S. Midwest, before spreading worldwide amid the disorder of World War I and hitching a ride on the increasingly robust global transportation system. As has become clear, the highly globalized and interconnected world of the 2020s is the ideal vehicle for a novel respiratory virus.
WHY ARE VACCINES OUR MOST IMPORTANT WEAPON TO COMBAT INFLUENZA?

Vaccines that protect humans against the most dangerous viral pathogens remain the most important weapon in our arsenal to counter both seasonal and pandemic influenza threats. The global race for a Covid-19 vaccine illustrates the importance of maintaining a robust influenza vaccine infrastructure that can be rapidly mobilized in case of a severe influenza season or influenza pandemic. The alternative is what the world faces today: hundreds of thousands of people die while the world attempts to construct an international vaccine manufacturing and distribution system in record time.

WHY DO WE NEED NEW INFLUENZA VACCINES EVERY YEAR?

It is well-known that the influenza virus is highly mutable. It evolves rapidly, constantly making genetic changes that result in a virus that is more infectious to humans and potentially avoids the protection afforded by that season’s vaccines—what scientists call either antigenic drift or shift. Small mutations, called antigenic drift, often result in similar viruses and therefore can still be protected against by an appropriately targeted influenza vaccine. However, small changes can accumulate over time and result in antigenically different viruses. In a more dangerous scenario, the virus undergoes antigenic shift and makes a dramatic change. For example, antigenic shift can confer the ability to jump from an animal to a human, or two viruses can infect the same host and swap genetic information—which is particularly worrisome as humans often have little or no immunity against the new strains. This is what happened with the novel influenza A (H1N1) virus in 2009, which possessed genetic information from pigs, humans and birds. H1N1 infected over 60 million Americans resulting in nearly 275,000 hospitalizations and 12,500 deaths.

Therefore, influenza production infrastructure has to be designed to adapt to these genetic changes and to the emergence of novel influenza strains. This makes influenza vaccine production more complicated than, for example, polio vaccines, where production remains relatively static.

SEASONAL INFLUENZA VACCINES

Influenza seasons generally follow predictable patterns—peaking in the northern and southern hemispheres at opposite times of the year and creating two influenza seasons. The international community has made a concerted effort to monitor the circulating viruses year-round with national influenza centers in over 100 countries through the Global Influenza Surveillance and Response System. The World Health Organization (WHO) appointed five Collaborating Centers for Reference and Research on Influenza housed in the United States, United Kingdom, Australia, Japan, and China. As many countries are reticent to share strain information bilaterally, this system serves as the best mechanism to collect the necessary data. Every six months, these centers make their best estimation of the three to four strains that will be prevalent in the upcoming season.

The CDC presents this consensus recommendation to a Food and Drug Administration (FDA) advisory panel which makes the final determination of which vaccines will be produced for the nation. Once communicated to private manufacturers, they require four to six months to produce and validate that season’s influenza vaccines. Unfortunately, this gap between prediction and utilization means that the viruses have the chance to mutate away from the anticipated strains while other strains can unexpectedly predominate. The production system simply is not agile enough to adjust course and increase effectiveness substantially mid-season.

As it stands, this system only produces influenza vaccines that are 10 to 60 percent effective on average. When the vaccine matches well, it saves lives. The CDC estimates that the seasonal influenza vaccine prevented over 40,000 deaths during a nine-year period from 2005 to 2014. Conversely, if the match is poor, lives are at risk—particularly among the most vulnerable.

Despite a deep reliance on these global mechanisms, the United States officially informed the UN Secretary General of its intent to terminate its membership in the WHO in the next year, which could complicate this collaboration. To date, it is not fully understood how the United States will continue to participate in the global influenza community once it is no longer a member of the WHO. Long-time experts have grave concerns over how the United States will be able to produce effective influenza vaccines for future influenza seasons without full participation in the WHO. Nancy Cox, former head of the CDC’s influenza division, said the United States would be “flying blind” on seasonal influenza vaccines without the WHO collaboration.
**PANDEMIC INFLUENZA VACCINES**

The United States’ decision to end its membership with the WHO has additional implications for pandemic preparedness. The United States could have limited access to information on emerging zoonotic threats that occur in other countries—shared via WHO’s Pandemic Influenza Preparedness Framework. Pharmaceutical companies and laboratories rely on the sharing of these samples to further viral research and development.

In the case of a novel pandemic influenza virus, it would take a minimum of six months to develop and validate a vaccine—with even more time to produce and distribute it. Even with an intensive, concerted effort to create a vaccine, hundreds of thousands could die in the waiting period. Today, the world is in the midst of an agonizing 12–18 month wait before a coronavirus vaccine becomes broadly available. A vaccine for the 2009 H1N1 influenza did not become widely available until after the peak of the pandemic—essentially rendering it useless.

Major changes to influenza vaccine infrastructure are necessary to avoid these costly delays. The improvement of influenza vaccine infrastructure and technologies should be a central pillar of U.S. efforts to build pandemic preparedness.

**HOW COULD UIV BE A SOLUTION?**

Is it possible to develop one vaccine that could protect against all possible variations of influenza for an extended period of time? Such a vaccine would take both seasonal and pandemic influenza off the table as health security threats. This simple idea is the driving force behind a global push for a universal influenza vaccine (UIV).

**WHAT IS UIV?**

In theory, a true UIV would protect against all strains for a lifetime, encompassing both seasonal and pandemic flu. In practice, this idea has proven to be highly complex, leading to varying definitions of UIV. The U.S. government has defined UIV as a vaccine with 75 percent effectiveness against a certain subgroups of influenza viruses with protection for at least one year for all age groups.\(^{21, 22}\)

**THE COMPLICATED SCIENCE**

Efforts to develop a universal influenza vaccine have been ongoing for many years, and experts estimate at least another ten will pass before we have one. While antigenic drift or shift is often cited as the core obstacles to influenza vaccines, another stark challenge is the phenomenon of imprinting. Essentially, the body shows the strongest immune response to the first viral encounter in life. If a baby is first exposed to a fairly common strain, it can offer some widespread immunity throughout their lifespan.

Evidence from both the 1918 and 2009 influenza pandemics demonstrated a decreased susceptibility of the elderly population due to cross protection from strains encountered in childhood.\(^{23}\) While the science behind development efforts is complicated, researchers are generally seeking to identify elements common to all or many influenza viruses. Influenza viruses are constructed with hundreds of haemagglutinin (H) proteins covering the surface, characterized by a bulky head attached to the virus by a stem. These proteins enable infection by binding the virus to the host cell. Traditional influenza vaccines single out the head due to its visibility and resulting strong immune response, but the heads’ tendency towards mutation accounts for the generally low efficacy rates of seasonal vaccines. One such approach to UIV targets the stem of H proteins—considerably more stable and consistent across viruses. Yet, stem-specific responses do not tend to show the same strength of antibody response, a problem complicated by imprinting.

Scientists are working on a multitude of approaches other than stem-specific responses; some candidates target proteins inside the virus while others hope to stimulate T cell response.
to infection.\(^2\) Despite the often-cited ten-year timeline, scientists lack a clear consensus on the most effective path to the development of UIV. It is still unclear whether these UIV candidates will truly protect against all strains. Because influenza viruses mutate so frequently and rapidly, they have an infinite ability to produce new strains. How can scientists protect against viruses that do not yet exist, but will inevitably occur?

Despite these challenges, there is a broad consensus that UIV would be a major step in strengthening pandemic preparedness globally. With as little as one year of broad protection, the current production system would become obsolete—no longer requiring influenza vaccines to be reformulated every six months. Increased effectiveness would likely increase confidence and could raise influenza vaccination rates. A recent study published by the National Academy of Sciences simulated a future in which Americans had access to a 75 percent efficacious UIV. If UIV replaced all seasonal vaccines, the study projects the prevention of 17 million cases, 251,000 hospitalizations, 19,500 deaths, and $3.5 billion in direct healthcare costs.\(^2\) The road to UIV remains long and complicated, but the United States should take sustained action to capitalize on the potential of a long-lasting, broad spectrum influenza vaccine.

**VACCINE PRODUCTION TECHNOLOGIES**

Despite the extensive efforts of the scientific community, UIV may be ten years or more from fruition. In the meantime, the United States needs influenza vaccine production technology that is faster, safer, and more scalable than our current system that relies on outdated processes. The status quo simply will not protect us in the case of severe seasonal influenza or a deadly pandemic.

**TRADITIONAL EGG-BASED PRODUCTION**

Influenza vaccine production utilizing chicken eggs has been the standard for 70 years. While inexpensive and time-tested, egg-based production is simply too slow to respond effectively to emergency pandemic threats or adjust to viral mutations mid-influenza season.\(^2\) It is for this reason that seasonal influenza predictions occur six months in advance and may poorly match circulating strains. Additionally, eggs have the potential to mutate the virus in the laboratory, resulting in vaccines that stimulate weaker or completely different immune responses than intended.

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*Experts predict that the full replacement of seasonal influenza vaccines with a universal influenza vaccine would prevent:*  

- **17 MILLION** Influenza cases  
- **251,000** Hospitalizations  
- **19,500** Deaths  
- **$3.5 BILLION** Direct healthcare costs  


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*Taiwan researchers sort through eggs used for the cultivation of swine flu vaccine in 2009.*

Photo By Patrick Lin/AFP via Getty Images
WHAT ARE THE ALTERNATIVES?

Former Biomedical Advanced Research and Development Authority (BARDA) Director Rick Bright emphasized the urgent need for a market shift to other alternatives when he said, “When I look at a need to produce 600 million doses of influenza vaccine in a very short timeline of a pandemic, it’s going to be really important that we have all horses in the race. So eggs and cells and recombinant.”

Other alternatives exist and are FDA approved for producing influenza vaccines. The first is cell-based vaccine production, which uses animal cells instead of eggs to host virus replication. This production method is preferable to egg-based production for several reasons. First, it allows the vaccine production to be completed much more quickly. Experts also believe that cell-based vaccine production could produce stronger immune responses more similar to what is seen with wild influenza viruses. Former FDA Commissioner Scott Gottlieb reported that the only cell-based vaccine on the market in 2018 was about 20 percent more effective than its egg-based counterparts. Additionally, cells can be frozen and banked in advance of an emergency, and therefore are less susceptible to supply chain disruptions.

A second FDA approved method of producing influenza vaccines is recombinant technology, the only 100 percent egg free approach on the market. This method isolates a certain gene found in the wild influenza virus and combines it with another virus. This virus grows effectively in insect cells where it is allowed to replicate before it is purified for vaccine production.

The industry has demonstrated a reluctance to move to cell and recombinant technologies, which many experts attribute to lack of financial incentives. Currently, manufacturers are rewarded for delivering vaccines in time for influenza season and not for speed of production or their efficacy. Implementing alternative technologies would require significant financial investment to rebuild production infrastructure.

ADJUVANTS: A NECESSARY BOOST

Adjuvants have the potential to boost the body’s immune response to existing vaccines. Utilized for over 70 years, adjuvants are substances added to vaccines to help the body recognize the vaccine’s antigens as foreign. This strengthens the body’s immune response, conferring longer and stronger protection from the virus. Modern adjuvants target specific components of the immune system. Adjuvants also have the potential to extend influenza supplies, as many countries demonstrated during the 2009 H1N1 pandemic. With the addition of these specific compounds, less vaccine can be used for each person.

WHAT U.S. POLICIES HAVE ALREADY BEEN PUT IN PLACE?

The Covid-19 outbreak has the potential to fundamentally change how the U.S. government approaches emerging infectious diseases and the national security threat they pose. Even before the pandemic, there were several promising policy developments related specifically to influenza.

NATIONAL STRATEGIC PLANS

Parts of the U.S. government have been working to improve influenza vaccine production technologies for over a decade. BARDA provides grants to manufacturers with the intention of moving a portion of the influenza vaccine market out of egg-based production and to alternative methods of production such as recombinant influenza vaccines.

One recent example is the six year, $226 million contract to increase capacity to produce recombinant vaccines and technologies with Sanofi Pasteur. The project includes action to retain domestic capacity by refitting a manufacturing facility in Swiftwater, Pennsylvania. Sanofi’s capacity to produce recombinant vaccines is expected to double, allowing Sanofi to provide nearly 100 million doses of recombinant vaccines in the event of an influenza pandemic. BARDA’s research funding has also resulted in the FDA approval of two non-egg influenza vaccines: Flubok and Flucelvax. Flubok production has proven to be significantly faster, a critical value in the event of a pandemic.

In early 2018, the National Institute of Allergy and Infectious Disease (NIAID), a part of the National Institute
of Health (NIH), unveiled a strategic plan for universal influenza vaccine research. The plan calls for heightened focus on three areas of research: improving understanding of how the influenza spreads and progresses in a population; characterizing what makes humans immune and; supporting rational design of a universal influenza vaccine. NIAID recently initiated the Collaborative Influenza Vaccine Innovation Centers (CIVICs) program with a $130 million grant over five years to create a network of research centers focused on designing novel vaccine candidates and delivery platforms.

CONGRESSIONAL ACTION
Building on this momentum, Senator Edward Markey (D-MA) and Representative Rosa DeLauro (D-CT) introduced the Flu Vaccine Act in 2018, aiming to facilitate investment in universal influenza vaccine research. When the bill was introduced, Markey noted, “increased federal investment in a vaccine will help predict the right strain for the next season, produce a more optimal vaccine, and protect all Americans against all strains of this virus.” Though the 2018 bill did not pass the House or Senate, it did catalyze appropriators to include a $140 million investment in NIAID’s strategic plan in fiscal year (FY) 2019. This is a substantial increase from the previous funding level of $60 million two years prior. Markey and DeLauro reintroduced the Flu Vaccine Act in February 2019 calling for an even greater investment of $1 billion dollars total or $200 million over five years. This funding was achieved for FY 2020 in the end of year spending package signed in December 2019—another $60 million increase from the previous fiscal year.

PRESIDENT TRUMP’S EXECUTIVE ORDER
In September 2019, President Donald Trump signed the “Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health.” The president’s action was a clear commitment at the highest levels of government to the improvement of influenza vaccine technologies to address a major health security threat.

The order calls for the establishment of a National Influenza Task Force co-chaired by the Secretaries of Defense and Health and Human Services (HHS). The Task Force had 120 days to submit a report with a five-year plan including recommendations to encourage non-profit, academic, and private sector innovation and to increase vaccination rates amongst key populations. In early October 2020, the Task Force began holding virtual listening sessions with stakeholders.

VACCINE PREPAREDNESS SAVES TIME, MONEY, AND LIVES
It must also be acknowledged that strides are being made in the herculean global effort to develop a Covid-19 vaccine. In the United States, the federal government has launched Operation Warp Speed, a $10 billion effort that aims to accelerate the Covid-19 vaccine development and manufacturing process. A partnership between the Department of Defense (DoD) and Health and Human Services, Operation Warp Speed seeks to develop 300 million doses of safe and effective vaccine for American citizens by January 2021. Thus far, the project has committed $6.5 billion for BARDA and $3.5 billion for NIH field trials—a massive investment in comparison to previous influenza vaccine investments.

With over 200 vaccines in development around the world, it is not yet clear how the Covid-19 vaccine race will impact influenza vaccine technologies or infrastructure as a whole. There are, however, lessons to be learned regarding the external factors and challenges that could potentially impact future efforts on influenza. First, it is too late and too costly to wait until a pandemic or large outbreak to begin investing in vaccine infrastructure and
technology. Second, once there is a vaccine, populations must be willing to take it.

Vaccine hesitancy and mistrust, which has been on the rise in the United States and globally, will play a key role in the success of the Covid-19 vaccine and future influenza vaccines. In testimony on Operation Warp speed in early July, the directors of NIH, CDC, and BARDA stated that it is “important that Americans have confidence in all vaccines.” Today, many people in the United States are unsure if they will accept a newly developed Covid-19 vaccine. A May 2020 poll found that only 50 percent of Americans plan to be vaccinated and 31 percent were not sure. This mistrust is particularly prevalent in marginalized communities who are also at higher risk for Covid-19. The Working Group on Readying Populations for Covid-19 Vaccine led by John Hopkins University and Texas State University explained, “If poorly designed and executed, a Covid-19 vaccination campaign in the United States could undermine the increasingly tenuous belief in vaccines and the public health authorities that recommend them.” Beyond vaccine confidence, the United States must also work to improve awareness and combat complacency around these vaccines.

WHAT DOES THE UNITED STATES NEED TO DO NOW TO ADVANCE INFLUENZA VACCINES?

The Covid-19 pandemic caught the United States—and the world—unprepared. It would be negligent to ignore the lessons of this pandemic and fail to strengthen the preparedness infrastructure for influenza threats. Understandably, much of the vaccine development community is focused on the rapid development and scale-up of a Covid-19 vaccine. This pandemic has shown a spotlight on the necessity of a versatile and efficient global vaccine development infrastructure.

As the United States reconsiders its health security capacities, the improvement of influenza vaccine technologies and infrastructure should be a central tenant of a new approach to both mitigating seasonal influenza outbreaks and preventing future influenza pandemics—both real and looming threats.

1. INVEST IN UNIVERSAL INFLUENZA VACCINE DEVELOPMENT

The U.S. government should ensure that the modernization of influenza vaccine technologies receives the necessary investment to prevent another potential pandemic. In fall 2019, the CSIS Commission on Strengthening America’s Health Security recommended $200 million annually over five years as an important step to further the critical UIV effort. While this level of funding was achieved for FY 2020, it is critical to ensure that this funding is sustained over the next four years, even as the Covid-19 response demands ample federal resources.

2. INVEST IN MODERNIZING VACCINE PRODUCTION TECHNOLOGY

Funding for later stage universal influenza vaccine research at BARDA should also be maintained, as its efforts are crucial for bringing universal influenza vaccines and alternatives to egg-based vaccines to the market. There should also be serious consideration given to expanding CDC’s complementary research on emerging and circulating influenza viruses, vaccine effectiveness, and the production of vaccine candidates for newer production platforms.
3. BOOST ANNUAL VACCINE DEMAND AND CONFIDENCE

These additional complementary research efforts should focus on combatting vaccine hesitancy and improving influenza vaccine uptake in the United States and globally.

4. REVERSE WITHDRAWAL FROM THE WHO

The United States should ensure that its role in the Global Influenza Surveillance and Response System is not disrupted by its withdrawal from the WHO. Deciding which influenza vaccines are available each fall is wholly dependent on a WHO-led collaboration to collect data from over 100 countries. To date, it is not fully understood how the United States will continue to participate in the global influenza community once it is no longer a member of WHO—which could make the United States vulnerable to developing less effective influenza vaccines.

CONCLUSION

Dr. Anthony Fauci, the Director of NIAID and the United States’ top infectious disease doctor, put it best: “The only thing predictable about influenza is that it’s unpredictable.” As it stands, the United States is woefully underprepared with suboptimal vaccines to protect against both seasonal and pandemic influenza. The devastation of Covid-19 has demonstrated that now, more than ever, we must be prepared for both seasonal influenza outbreaks and potential pandemics by carrying out these four key recommendations.

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ENDNOTES


22 The CDC describes four types of influenza viruses: A, B, C, and D. Human Influenza A and B viruses are responsible for the annual flu season, while Influenza A is the only known type to cause flu pandemics. Influenza C and D (https://www.cdc.gov/flu/about/flu/viruses/types.html).


27 In the case of Covid-19, the major vaccine candidates funded by the
United States are not using egg-based production. The concern is that this virus does not replicate properly in eggs and that production would be too slow for the needs of the pandemic.


35 Ibid.


39 Ibid.
