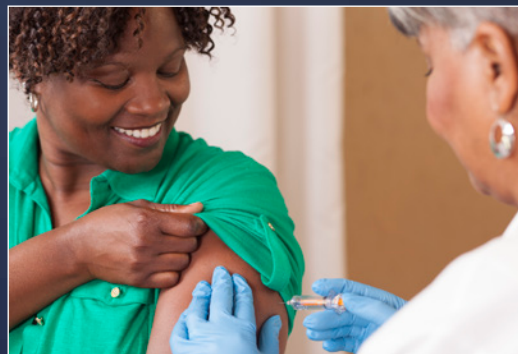
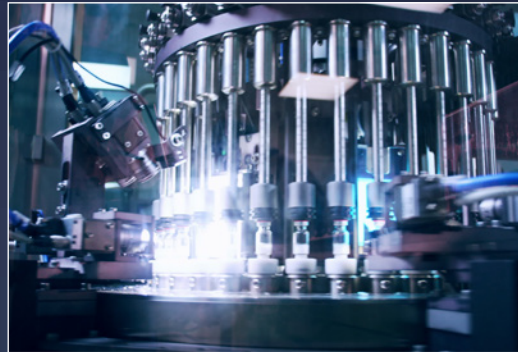


National Influenza Vaccine Modernization Strategy 2020-2030



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EXECUTIVE SUMMARY

Influenza poses a serious threat to national security and public health. Each year, seasonal influenza results in hundreds of thousands of hospitalizations and tens of thousands of deaths in the United States. Furthermore, influenza viruses have the potential to cause pandemics, which occur when a novel influenza virus – to which humans have little to no immunity – emerges, allowing the virus to spread easily from person-to-person. An influenza pandemic can occur at any time with little warning; any delay in detecting a novel influenza strain; sharing of influenza virus samples; and in developing, producing, distributing, or administering a therapeutic or vaccine could result in significant additional morbidity and mortality.

Vaccination is currently the most effective strategy for preventing influenza infection. While substantial progress has been made in national influenza preparedness and prevention, significant gaps remain: domestic influenza vaccine production is inefficient and insufficient, vaccine effectiveness is less than optimal, and vaccination rates across the United States are too low. To address these gaps, it is critical to modernize the United States' influenza vaccine enterprise. This requires leveraging a comprehensive and collaborative approach to increase the accessibility and utility of diagnostics, to improve therapeutics, to enhance manufacturing capacities, and to increase vaccination coverage. Most importantly, there is a critical need for vaccines that are more effective, efficiently-produced, and domestically-manufactured.

Accordingly, as directed by the Executive Order (EO) 13887 on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, this National Influenza Vaccine Modernization Strategy (NIVMS), 2020-2030, outlines a vision for the United States' influenza vaccine enterprise to be highly responsive, flexible, resilient, scalable, and more effective at reducing the impact of seasonal and pandemic influenza viruses. This vision is supported by three overarching strategic objectives:

1. Strengthen and diversify influenza vaccine development, manufacturing, and supply chain;
2. Promote innovative approaches and use of new technologies to detect, prevent, and respond to influenza; and
3. Increase influenza vaccine access and coverage across all populations.

These strategic objectives align with the four policy objectives outlined in the EO, which, together, culminate in a strategic approach with a vision to systematically transform the United States' influenza vaccine enterprise. To adequately prepare for, prevent, detect, and respond to both seasonal influenza epidemics and inevitable pandemics, it is imperative that we continue to invest in domestically-based seasonal and pandemic preparedness efforts by collaborating with domestic and international stakeholders across sectors. Execution of this strategic approach over the next ten years will require innovative partnerships, financial investments, and efficient utilization of resources.

INTRODUCTION

Influenza is a serious public health, economic, and national security threat. Every year, circulating seasonal influenza viruses infect tens of millions of people in the United States, leading to hundreds of thousands of hospitalizations and tens of thousands of deaths (Figure 1).¹ Widespread influenza infection can significantly compromise national security by diminishing the domestic workforce (including military personnel), weakening critical infrastructure, and impeding logistics networks. The September 2019 Council of Economic Advisors (CEA) Report estimates that seasonal influenza costs the United States approximately \$361 billion per year.² Moreover, influenza viruses have a potential to cause pandemics due to their high mutation rate and could result in millions of deaths worldwide. The CEA Report also indicates that such events are likely to cost between \$413 billion to \$3.79 trillion to the United States' economy, depending on their severity and scope.³



Source: Centers for Disease Control and Prevention

FIGURE 1: ESTIMATED RANGE OF ANNUAL INFLUENZA BURDEN IN THE UNITED STATES SINCE 2010*

*The top range of these burden estimates are from the 2017-2018 influenza season. These are preliminary and may change as data are finalized.

While currently available influenza vaccines are imperfect, they still represent the most effective strategy to prevent influenza infections, reduce the severity of illness, save lives, and respond to both seasonal influenza epidemics and potential pandemics. Currently, influenza vaccine manufacturers produce seasonal vaccines based on pre-season sales and on the predicted start of influenza seasons. This production and delivery process is not designed for maximum flexibility to respond to a newly emerging seasonal virus that is not matched to the forecasted vaccine composition; this process is neither optimized nor incentivized for the speed and scale expected to be needed during a pandemic. During a pandemic, any delay in detecting a novel strain; sharing of influenza virus samples; or developing, producing, distributing, or administering a vaccine could result in significant additional morbidity and mortality. While substantial progress in influenza preparedness and prevention has been made, significant gaps remain: domestic vaccine production is inefficient and insufficient, vaccine effectiveness is less than optimal, and vaccination rates across the United States are too low.

Coordinated partnerships – involving federal, state, local, tribal, and territorial (SLTT) governments; industry and private partners; non-governmental organizations; academia; professional associations; the

¹ Centers for Disease Control and Prevention. "Disease Burden of Influenza." Retrieved from [Disease Burden of Influenza](#)

² Council of Economic Advisors (CEA). (2019). "Mitigating the Impact of Pandemic Influenza through Vaccine Innovation." Retrieved from [Mitigating the Impact of Pandemic Influenza through Vaccine Innovation](#)

³ Ibid

World Health Organization and other international stakeholders; and consumers – are critical to address gaps in vaccine effectiveness, coverage, sustainable manufacturing, and diagnostic and treatment capabilities. The Executive Order (EO) 13887 on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health⁴ aims to address these gaps through four policy objectives:

- Reduce the United States’ reliance on egg-based influenza vaccine production;
- Expand domestic capacity of alternative methods that allow for more agile and rapid responses to emerging influenza viruses;
- Advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunity; and
- Support the promotion of increased influenza vaccine immunization across recommended populations.

While the EO requires a five-year approach, influenza vaccine development and licensure is a time consuming, complex, and expensive process requiring a combination of public and private involvement. Therefore, the NIVMS provides a 10-year strategic approach to systematically transform the United States’ influenza vaccine enterprise to be more robust, resilient, scalable, and nimble in the face of seasonal influenza epidemics and future influenza pandemics.

Vision and Strategic Objectives

The NIVMS provides a foundation on which the US Government (USG) and its partners can contribute to a common vision of a domestic influenza vaccine enterprise – one that is highly responsive, flexible, scalable, and more effective at reducing the impact of seasonal and pandemic influenza viruses.

The NIVMS seeks to inform governmental and non-governmental policies and programs; encourage coordinated planning and activities; and guide prioritization of investments of time, workforce, funds, and other resources.

Vision: A domestic influenza vaccine enterprise that is highly responsive, flexible, scalable, and more effective at reducing the impact of seasonal and pandemic influenza viruses

To achieve this vision and carry out the four EO policy objectives, the NIVMS 2020-2030 is focused on three overarching strategic objectives:

1. Strengthen and diversify influenza vaccine development, manufacturing, and supply chain;
2. Promote innovative approaches and use of new technologies to detect, prevent, and respond to influenza; and

⁴ White House. (2019). The Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health. Retrieved from [Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health](#)

3. Increase influenza vaccine access and coverage across all populations.

All USG activities are subject to the availability of appropriations and standard budget development processes.

Guiding Principles

The following set of principles guides decision-making that addresses both national security and public health needs in response to seasonal and pandemic influenza on a timely, cost-effective, reliable, and sustainable basis. These guiding principles describe the characteristics that aim to modernize domestic manufacturing capacities; spark innovative vaccine technology; foster rigorous research and development; and promote vaccine coverage across populations. Ultimately, the capacity and capabilities developed for influenza preparedness would enable the USG to respond more effectively to other emerging infectious diseases.

Expand Public-Private Partnerships

An inclusive approach will be used to expand public-private partnerships, including researchers, developers, SLTT governments, manufacturers, regulators, purchasers, policy makers, and international stakeholders to monitor the impact of influenza, bring new and improved vaccines and other medical countermeasures (MCMs) to market, and facilitate increased immunization.

Promote a Financially Sound Pathway

Public funding should leverage private investment to sustain the seasonal influenza vaccine market, which in turn will support pandemic response needs, precipitate innovation, and expand opportunities for all sectors.

Increase Public Education, Awareness, Engagement, and Access

Communicating vaccine effectiveness and encouraging annual influenza immunization using evidence-based and scientifically sound methodologies are essential to increase public trust in vaccines and influenza vaccination rates.

STRATEGIC OBJECTIVES

The overarching vision of the NIVMS is supported by three strategic objectives that align with the four policy objectives from the EO (see Annex A: NIVMS Strategic Objectives Crosswalk to EO 13887 for additional information). The associated objectives for each strategic objective will require dedicated and focused attention over the next ten years.

STRATEGIC OBJECTIVE 1: STRENGTHEN AND DIVERSIFY INFLUENZA VACCINE DEVELOPMENT, MANUFACTURING, AND SUPPLY CHAIN

Today, the majority of influenza vaccines are produced in chicken eggs — a process that takes up to nine months to develop and manufacture a vaccine — thus limiting the vaccine’s utility for early pandemic control. Moreover, growing the virus in eggs can inadvertently introduce mutations that may potentially render the final vaccine less effective. Nearly 50 percent of egg-based influenza vaccines are manufactured overseas; insufficient domestic production capacities introduces risks that could hamper our ability to address both seasonal and pandemic influenza.

Alternative manufacturing techniques, including those derived from cell-based, recombinant and other synthetic technologies, have a relatively shorter manufacturing time and do not rely on a supply chain of eggs. Therefore, they have the potential to accelerate the availability of both seasonal and pandemic influenza vaccines, and could also allow for vaccines that more closely match circulating influenza strains. However, currently these new technologies are significantly more costly than production in eggs,⁵ and the current domestic enterprise for manufacturing these types of vaccines is not sufficient for continuous, large-scale manufacturing.

It is a priority for the USG to reduce the time between declaration of an influenza pandemic and widespread distribution of vaccine sufficient to cover the United States' population. To this end, the USG is committed to delivering first doses of a finished vaccine within 12 weeks.⁶ Therefore, it is imperative for the USG to build and maintain national sources of raw materials to ensure a resilient supply chain. Fundamental to influenza preparedness is continuous surveillance and virus characterization to inform vaccine composition and development. For this reason, it is critical to expand global influenza surveillance capacity. Finally, investments in innovative antigen and adjuvant selection strategies could improve the effectiveness of both egg-based and novel vaccine technologies, ultimately enhancing the scale, quality, and efficiency of manufacturing processes.

Objectives

- Objective 1.1: Partner with manufacturers and other private sector stakeholders to promote the development and production of non-egg based influenza vaccines that are safe and effective in all populations.
- Objective 1.2: Develop and implement a sustainable investment strategy with the private sector that allows flexibility in financing for advanced development, licensure, and manufacturing of current and promising new vaccine candidates and vaccine production platforms.
- Objective 1.3: Sustain, leverage, and expand current domestic manufacturing capacities to transition to faster and more scalable vaccine production platforms.
- Objective 1.4: Increase and sustain domestic seasonal influenza vaccine production capacity using alternative technologies that can be leveraged for pandemic response to deliver first doses of a finished vaccine within 12 weeks of an influenza pandemic declaration.

STRATEGIC OBJECTIVE 2: PROMOTE INNOVATIVE APPROACHES AND USE OF NEW TECHNOLOGIES TO DETECT, PREVENT, AND RESPOND TO INFLUENZA

Current influenza vaccines are designed to protect against the three to four influenza virus strains most likely to spread and cause illness during a given influenza season. Since influenza viruses are constantly evolving, current influenza vaccine composition must be reviewed and updated each year. It is also critically important to identify and assess the pre-pandemic potential of viruses.

A “universal” influenza vaccine, one that provides robust, long lasting protection against multiple subtypes of influenza, would be the most effective MCM to reduce morbidity and mortality from

⁵ Council of Economic Advisers (CEA). (2019). “Mitigating the Impact of Pandemic Influenza through Vaccine Innovation.” Retrieved from [Mitigating the Impact of Pandemic Influenza through Vaccine Innovation](#)

⁶ U.S. Department of Health and Human Services. (2017). “Pandemic Influenza Plan: 2017 Update.” Retrieved from [Pandemic Influenza Plan: 2017 Update](#)

seasonal and pandemic influenza infections. Currently, there is a promising pipeline of cross-protective vaccine candidates entering into clinical trials, underpinned by research that builds on our understanding of immune protection against influenza viruses. Since a universal vaccine is likely years away, it is critical that the USG continues to support improvements to vaccines using existing technologies and support complementary MCMs such as antiviral drugs, other therapeutics, and diagnostic tests.

Targeted USG investments and incentives are needed to stimulate advances in science and discovery and to translate these advances into innovations. Therefore, the USG should support traditional and non-traditional partnerships to accelerate the development, licensure and domestic manufacturing capacity of transformative vaccine platforms; antigens, adjuvants, and other vaccine components; therapeutics; devices (e.g., respirators, ventilators); diagnostics; and other MCMs. As influenza MCMs are being developed, it is important to ensure coverage of children, older adults, and other at-risk individuals. Moreover, it is critical to enhance federal and state capabilities to collect, analyze, and share real-time data on pandemic and seasonal influenza threats. These data are critical for coordinated public health response, vaccine development, and effective use of all MCMs.

Objectives

- Objective 2.1: Promote innovative approaches to enhance domestic and global surveillance, characterize seasonal and pandemic influenza viruses, and monitor vaccine effectiveness and safety.
- Objective 2.2: Improve influenza vaccines, diagnostics, and therapeutics using an aligned and integrated research agenda across government agencies, the private sector, and academic institutions to facilitate the transition to alternative technologies.
- Objective 2.3: Apply the full range of regulatory authorities and expedited programs to promote the licensure of new influenza vaccine candidates and the approval of other relevant MCMs.
- Objective 2.4: Advance the development of a universal influenza vaccine that provides robust, long-lasting protection against multiple subtypes of influenza and is suitable for all populations.

STRATEGIC OBJECTIVE 3: INCREASE INFLUENZA VACCINE ACCESS AND COVERAGE ACROSS ALL POPULATIONS

The Centers for Disease Control and Prevention recommends annual influenza vaccination for everyone six months of age and older (with rare exception). Despite these recommendations, seasonal influenza vaccination rates in the United States are far from ideal – about 45 percent of adults and about 62 percent of children were vaccinated during the 2018-19 influenza season.⁷ There are a number of factors contributing to these low vaccination rates, including lack of public trust, vaccine misconceptions, and lack of access to vaccines. To address these contributing factors, it is imperative that the USG and its partners provide consistent and harmonized communications about the benefits of influenza immunization across all populations and promote increased access to influenza vaccination to improve immunization coverage.

⁷ Centers for Disease Control and Prevention. (2019). "Flu Vaccination Coverage, United States, 2018–19 Influenza Season." Retrieved from [Flu Vaccination Coverage, United States, 2018-19 Influenza Season](#)

Objectives

- Objective 3.1: Increase and expedite access to influenza vaccines across all recommended populations.
- Objective 3.2: Improve the public’s understanding of influenza risk, as well as confidence in vaccine safety and effectiveness, through evidence-based messaging.
- Objective 3.3: Promote influenza immunization across recommended populations.
- Objective 3.4: Improve existing methods and develop alternative methods for influenza vaccine administration.
- Objective 3.5: Improve capabilities and capacity for management and tracking of influenza vaccination.

IMPLEMENTATION APPROACH

The National Influenza Vaccine Modernization Task Force (Task Force) is co-chaired by the Department of Health and Human Services (HHS) and the Department of Defense (DoD). The HHS Assistant Secretary for Preparedness and Response and the DoD Assistant Secretary of Defense for Health Affairs have been designated by their respective Secretaries to coordinate implementation of the NIVMS, monitor progress, and make course corrections, as needed. The Task Force will bring together key interagency partners, including senior leadership from HHS, DoD, Department of Justice, U.S. Department of Agriculture, Department of Veterans Affairs, Department of Homeland Security, and other federal partners. The Task Force will also engage non-federal entities such as SLTT governments, health care stakeholders, academia, private industry, non-governmental organizations, and international stakeholders, as appropriate.

National Influenza Vaccine Modernization Task Force

- Department of Health and Human Services
 - Assistant Secretary for Preparedness and Response (ASPR) (Co-Chair)
 - Biomedical Advance Research and Development Authority (BARDA)
 - Center for Disease Control and Prevention (CDC)
 - Centers for Medicare and Medicaid Services (CMS)
 - Food and Drug Administration (FDA)
 - National Institutes of Health (NIH)
 - National Institute of Allergy and Infectious Diseases (NIAID)
 - Office of the Assistant Secretary for Health (OASH)
- Department of Defense (DoD)
 - Assistant Secretary of Defense for Health Affairs (Co-Chair)
 - Office of the Assistant Secretary of Defense for Homeland Defense and Global Security
 - Office of the Director of Defense Research and Engineering for Research and Technology
- Department of Agriculture (USDA)
- Department of Homeland Security (DHS)
- Department of Justice (DoJ)
- Department of Veterans Affairs (VA)
 - Veterans Health Administration (VHA)

The Task Force will develop an implementation plan to accomplish the strategic objectives in coordination with existing influenza vaccine related strategic plans. This implementation plan will identify activities and anticipated timelines, including activities that will be completed in the near-term

(i.e., within five years). On an annual basis, the Task Force will assess progress towards achieving the vision outlined in the NIVMS. The Task Force will also help coordinate interagency efforts to promote an integrated and modernized influenza vaccine enterprise.

CONCLUSION

Influenza vaccination is the most effective strategy to prevent influenza infections, reduce the severity of illness, and save lives during seasonal outbreaks and pandemics. While influenza is one of the greatest public health and national security challenges, other emerging infectious diseases can also have a devastating impact on human health and the economy. The capacity and capabilities developed for seasonal and pandemic influenza preparedness will enable the USG to respond more effectively to other emerging infectious diseases. Collaborative efforts across the federal government, academia, the private sector, and international stakeholders over the past decade have advanced influenza vaccine technologies. However, significant gaps remain in vaccine effectiveness, pace of vaccine production, sustainable manufacturing, and vaccine access and coverage across all populations. Therefore, the NIVMS positions the USG and its partners to respond more quickly and effectively to future influenza pandemics and, simultaneously, strengthen our response to seasonal influenza. Advancing the United States' vaccine enterprise is a formidable task and must be coordinated across federal and SLTT governments, private partners, non-governmental organizations, academia, professional associations, and international stakeholders.

ANNEX A: NIVMS STRATEGIC OBJECTIVES CROSSWALK TO EO13887

The EO on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health is organized around four policy objectives:

- Reduce the United States' reliance on egg-based influenza vaccine production;
- Expand domestic capacity of alternative methods that allow for more agile and rapid responses to emerging influenza viruses;
- Advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunity; and
- Support the promotion of increased influenza vaccine immunization across recommended populations.

These policy objectives drive the vision of a modernized domestic influenza vaccine enterprise that is highly responsive, flexible, scalable, and more effective at reducing the impact of seasonal and pandemic influenza viruses. To achieve this vision, the table below illustrates how the four policy objectives and key actions of the EO overlap with the strategic objectives in the NIVMS.

EO Policy Objective: Reduce the United States' reliance on egg-based influenza vaccine production

NIVMS Strategic Objectives	NIVMS Objectives	EO Key Actions
<p>Strategic Objective 1: Strengthen and Diversify Influenza Vaccine Development, Manufacturing, and Supply Chain</p>	<p>Objective 1.1: Partner with manufacturers and other private sector stakeholders to promote the development and production of non-egg-based influenza vaccines that are safe and effective in all populations.</p>	<p>Explore options to expand the production capacity of cell- and recombinant-based vaccine candidates used by industry (EO: 4(a)(iv)(B))</p>
	<p>Objective 1.2: Develop and implement a sustainable investment strategy with the private sector that allows flexibility in financing for advanced development, licensure, and manufacturing of current and promising new vaccine candidates and vaccine production platforms.</p>	<p>Estimate the cost of expanding and diversifying domestic vaccine-manufacturing capacity to use innovative, faster, and more scalable technologies, including cell-based and recombinant vaccine manufacturing, through cost-sharing agreements with the private sector, which shall include an agreed-upon pricing strategy during a pandemic (EO: 4(a)(i)(A))</p> <p>Estimate the cost of expanding domestic production capacity of adjuvants in order to combine such adjuvants with both seasonal and pandemic influenza vaccines (EO: 4(a)(i)(B))</p> <p>Estimate the cost of expanding domestic fill-and-finish capacity to rapidly fulfill antigen and adjuvant needs for pandemic response (EO: 4(a)(i)(C))</p> <p>Evaluate incentives for the development and production of vaccines by private manufacturers and public-private partnerships, including, in emergency situations, the transfer of technology to public-private partnerships — such as the HHS Centers for Innovation and Advanced Development and Manufacturing or other domestic manufacturing facilities — in advance of a pandemic, in order to be able to ensure adequate domestic pandemic manufacturing capacity and capability (EO: 4(a)(i)(E))</p>

EO Policy Objective: Reduce the United States' reliance on egg-based influenza vaccine production

NIVMS Strategic Objectives	NIVMS Objectives	EO Key Actions
		<p>Provide OMB with a cost estimate for transitioning DoD's annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, scalable, and more innovative technologies (EO: 4(b)(i))</p> <p>The Secretary of VA shall provide OMB with a cost estimate for transitioning its annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, scalable, and more innovative technologies (EO: 4(c))</p>
<p>Strategic Objective 2: Promote Innovative Approaches and Use of New Technologies to Detect, Prevent, and Respond to Influenza</p>	<p>Objective 2.2: Improve influenza vaccines, diagnostics, and therapeutics using an aligned and integrated research agenda across government agencies, the private sector, and academic institutions to facilitate the transition to alternative technologies.</p>	<p>Support, in coordination with the DOD, NIH, and VA, a suite of clinical studies featuring different adjuvants to support development of improved vaccines and further expand vaccine supply by reducing the dose of antigen required (EO: 4(a)(i)(F))</p> <p>Update, in coordination with other relevant public health agencies, the research agenda to dramatically improve the effectiveness, efficiency, and reliability of influenza vaccine production (EO: 4(a)(i)(G))</p> <p>Identify opportunities to use DoD's vaccine research and development enterprise, in collaboration with HHS, to include both early discovery and design of influenza vaccines, as well as later stage evaluation of candidate influenza vaccines (EO: 4(b)(iv))</p> <p>Direct, in coordination with the VA, CDC, and other components of HHS, the conduct of epidemiologic studies of vaccine effectiveness to improve knowledge of the clinical effect of the currently licensed influenza vaccines (EO: 4(b)(ii))</p>

EO Policy Objective: Reduce the United States' reliance on egg-based influenza vaccine production

NIVMS Strategic Objectives	NIVMS Objectives	EO Key Actions
		<p>Use DoD's network of clinical research sites to evaluate the effectiveness of licensed influenza vaccines, including methods of boosting their effectiveness (EO: 4(b)(iii))</p> <p>Accelerate, in collaboration with HHS, research regarding rapidly scalable prophylactic influenza antibody approaches to complement a universal vaccine initiative and address gaps in current vaccine coverage (EO: 4(b)(vii))</p> <p>Expand vaccine effectiveness studies to more rapidly evaluate the effectiveness of cell based and recombinant influenza vaccines relative to egg-based vaccines (EO 4(a)(iv)(A))</p> <p>Further support the conduct, in collaboration with the DoD, BARDA, CDC, of applied scientific research regarding developing cell lines and expression systems that markedly increase the yield of cell-based and recombinant influenza vaccine manufacturing processes (EO 4(a)(iii)(C))</p> <p>Investigate, in collaboration with HHS, alternative correlates of immune protection that could facilitate the development of next generation influenza vaccines (EO: 4(b)(v))</p>

**EO Policy Objective: Expand domestic capacity of alternative methods,
which allow more agile and rapid responses to emerging influenza viruses**

NIVMS Strategic Objectives	NIVMS Objectives	EO Key Actions
Strategic Objective 1: Strengthen and Diversify Influenza Development, Vaccine Manufacturing, and Supply Chain	Objective 1.3: Sustain, leverage, and expand current domestic manufacturing facilities to transition to faster and more scalable vaccine production platforms.	<p>Assess, in coordination with BARDA and relevant vaccine manufacturers, the use and potential effects of using advanced manufacturing platforms for influenza vaccines (EO: 4(a)(iii)(D))</p> <p>Direct the conduct of a study to assess the feasibility of using DoD’s advanced manufacturing facility for manufacturing cell-based or recombinant influenza vaccines during a pandemic (EO: 4(b)(vi))</p>
	Objective 1.4: Increase and sustain domestic seasonal influenza vaccine production capacity using alternative technologies that can be leveraged for pandemic response to deliver first doses of a finished vaccine within 12 weeks of an influenza pandemic declaration.	<p>Further implement vaccine production process improvements to reduce the time required for vaccine production (e.g., through the use of novel technologies for vaccine seed virus development and through implementation of improved potency and sterility assays) (EO: 4(a)(ii)(A))</p> <p>Develop, in conjunction with the CDC, proposed alternatives for the timing of vaccine virus selection to account for potentially shorter timeframes associated with non-egg-based manufacturing and to facilitate vaccines optimally matched to the circulating strains (EO: 4(a)(iii)(B))</p>
Strategic Objective 2: Promote Innovative Approaches and Use of New Technologies to Detect, Prevent, and Respond to Influenza	Objective 2.1: Promote innovative approaches to enhance domestic and global surveillance, characterize seasonal and pandemic influenza viruses, and monitor vaccine effectiveness.	Develop a plan to expand domestic capacity for whole genome characterization of influenza viruses (EO: 4(a)(iv)(C))

EO Policy Objective: Advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunities

NIVMS Strategic Objectives	NIVMS Objectives	EO Key Actions
Strategic Objective 2: Promote Innovative Approaches and Use of New Technologies to Detect, Prevent, and Respond to Influenza	Objective 2.3: Apply the full range of regulatory authorities and expedited programs to promote the licensure of new influenza vaccine candidates and the approval of other relevant MCMs.	
	Objective 2.4: Advance the development of a universal influenza vaccine that provides robust, long-lasting protection against multiple subtypes of influenza and is suitable for all populations.	Through the Director of NIH, provide to the Task Force estimated timelines for implementing NIH's strategic plan and research agenda for developing influenza vaccines that can protect individuals over many years against multiple types of influenza viruses (EO: 4(a)(ii))

EO Policy Objective: Supporting the promotion of increased influenza vaccine immunization across recommended populations.

NIVMS Strategic Objectives	NIVMS Objectives	EO Key Actions
Strategic Objective 3: Increase Influenza Access and Coverage Across All Populations	Objective 3.1: Increase and expedite access to influenza vaccines across all recommended populations.	Through the administrator of CMS, examine the current legal, regulatory, and policy framework surrounding payments for influenza vaccines, and assess adoption of domestically manufactured vaccines that have positive attributes for pandemic response (such as scalability and speed of manufacturing) (EO: 4(a)(v)) Increase influenza vaccine use through enhanced communication and by removing barriers to vaccination (EO: 4(a)(iv)(D))
	Objective 3.2: Improve the public’s understanding of influenza risk, as well as confidence in vaccine safety and effectiveness, through evidence-based messaging.	
	Objective 3.3: Promote influenza immunization across recommended populations.	Enhance communication to healthcare providers about the performance of influenza vaccines in order to assist them in promoting the most effective vaccines for their patient populations (EO: 4(a)(iv)(E))
	Objective 3.4: Improve existing methods and develop alternative methods for influenza vaccine administration.	Estimate the cost of developing, evaluating, and implementing delivery systems to augment limited supplies of needles and syringes and to enable the rapid and large-scale administration of pandemic influenza vaccines (EO: 4(a)(i)(D))
	Objective 3.5 Improve capabilities and capacity for management and tracking of influenza vaccination.	