**OFFICE OF THE UNDER SECRETARY OF DEFENSE**
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**PERSONNEL AND READINESS**

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

OCT - 3 2025

Dear Mr. Chairman:

The Department's response to House Report 118–529, pages 199-200, accompanying H.R. 8070, the Servicemember Quality of Life Improvement and National Defense Authorization Act for Fiscal Year 2025, "National Influenza Vaccine Modernization Strategy Implementation," is enclosed.

This report answers congressional requests to outline the Department of Defense's (DoD) progress in implementing the DoD-specific tasks within the National Influenza Vaccine Modernization Strategy (NIVMS), including its plan to maximize procurement of modernized influenza vaccines from domestic manufacturing sources. It also includes DoD's strategic considerations when procuring annual influenza vaccines, the insights on moving procurement to domestic manufactured non-egg-based vaccines, and current options for such vaccines on the market. Lastly, this report provides updates on DoD's full list of NIVMS activities, which aim to strengthen and diversify influenza vaccine development, manufacturing, and supply chains, and to promote innovative approaches to detection, prevention, and response.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and their families.

Sincerely,

[redacted]

Sean O'Keefe
Deputy Under Secretary of Defense for
Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

[redacted]

# Report to the Committee on Armed Services of the House of Representatives

# National Influenza Vaccine Modernization Strategy Implementation

## September 2025

The estimated cost of this report or study for the Department of Defense is approximately $17,000 in Fiscal Years 2024 - 2025. This includes $16,000 in expenses and $610 in DoD labor.
Generated on 2025Jan22 RefID: C-1A63E88

# TABLE OF CONTENTS

## EXECUTIVE SUMMARY

This report is in response to House Report 118–529, pages 199-200, accompanying H.R. 8070, the Servicemember Quality of Life Improvement and National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2025. The National Influenza Vaccine Modernization Strategy (NIVMS) aims to modernize the Nation's approach to influenza vaccine research, development, and manufacturing, and to increase vaccine uptake and access. Within the NIVMS Action Plan, the Department of Defense (DoD) is tasked with seven activities designed to leverage the Department's unique capabilities and resources to support the overall goals of the strategy.

This report provides a market survey of U.S.-manufactured influenza vaccines that align with NIVMS objectives, as well as the Department's procurement considerations and plan. The report also provides an update on DoD's list of NIVMS tasks, which aim to support the Nation's efforts to strengthen and diversify influenza vaccine development, manufacturing, and supply chains, and to promote innovative approaches to influenza detection, prevention, and response.

## PURPOSE

### NDAA Language

House Report 118–529 indicates the House Armed Services Committee is aware of DoD's intent to evaluate the transition of DoD's annual procurement of influenza vaccines to those that are domestically produced and not reliant on traditional egg-based manufacturing. Further, the committee requested the Secretary of Defense to provide a report including the following:

> (1) an update on the NIVMS implementation plan tasks agreed to by the Department and any obstacles to implementation;
> (2) a detailed timeline for when the Department expects to complete tasks agreed to by the Department in the NIVMS implementation plan;
> (3) a budgetary assessment to determine the costs of implementing tasks agreed to by the Department in the NIVMS implementation plan and the associated accounts that will be required to execute implementation; and
> (4) a market survey of domestically manufactured modernized influenza vaccines that meet the requirements set forth in NIVMS and a plan to maximize procurement of modernized influenza vaccines from domestic manufacturing sources.

### Requirements

A NIVMS update is due annually for 5 years and the final update was most recently provided on June 15, 2024. Importantly, this report is a DoD-specific supplement that is distinct from the annual requirement.

# BACKGROUND

## Executive Order

In September 2019, Executive Order (EO) 13887, "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health," directed Federal Agencies to develop a 5-year strategy to modernize the Nation's approach to influenza vaccine research, development, and manufacturing, and to increase vaccine uptake and access.

The National Influenza Vaccine Task Force — co-led by the Department of Health and Human Services (HHS), Administration for Strategic Preparedness and Response and DoD, Office of the Assistant Secretary of Defense for Health Affairs and with support from the Departments of Justice, Agriculture, Veterans Affairs, Homeland Security, State, as well as the White House — led the development of the NIVMS. The strategy was publicly released on June 8, 2020.

Since the release of the strategy, HHS and DoD have been coordinating interagency influenza vaccine activities across three strategic objectives.

1. Strengthening and Diversifying Influenza Vaccine Development, Manufacturing, and Supply Chain;
2. Promoting Innovative Approaches to Detection, Prevention, and Response; and
3. Increasing Vaccine Uptake and Access.

In addition to developing the strategy, the Task Force is required to submit an annual update on implementation to the White House during each of the 5 years following the publication of the strategy. The Task Force developed an iterative implementation plan establishing activities (including actions that support and expand on EO directives), leads and/or supporting departments/agencies, completion timeline, and progress updates.

## DoD Tasks in NIVMS

The NIVMS 2020-2030 tasks DoD as lead for the below seven activities:

- 1.2.5: Provide the Office of Management and Budget with a cost estimate for transitioning annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, scalable, and more innovative technologies.

- 1.3.4: Assess the utility of DoD's advanced manufacturing (ADM) facilities for development of cell-based or recombinant influenza vaccines during a pandemic.

- 2.2.4: Investigate alternative correlates of immune protection that could facilitate development of next-generation influenza vaccines.

- 2.2.5: Accelerate research regarding rapidly scalable prophylactic influenza antibody approaches to complement a universal vaccine initiative and address gaps in current vaccine coverage.

- 2.2.7: Conduct vaccine efficacy studies to enhance understanding of the clinical effect of existing licensed influenza vaccines.

- 2.2.8: Evaluate the effectiveness of licensed influenza vaccines, including methods of boosting their effectiveness.

- 2.2.9: Identify opportunities to use DoD's vaccine research and development enterprise for both early discovery and design of influenza vaccines and later-stage evaluation of candidate influenza vaccines.

**Goal of NIVMS – Addressing the Unique Risk of Influenza**

Influenza remains an ever-present threat to health security, due to its constant evolution, ability to evade our immune systems, unique genetic structure, and ability to reassort with other viruses.

The influenza virus's constant evolution makes annual vaccination essential to protect against the latest strains and prevent widespread illness. Mutations are a natural process, and the accumulation of some mutations over time may be advantageous to the virus, some may result in no differences, and still others result in a "dead end" where the virus does not propagate beyond the original host. Changes to proteins on the surface of the influenza virus due to the gradual accumulation of mutations, or "antigenic drift," may evade preexisting immunity, resulting in the need for an updated flu shot each year.

In addition to the annual threat of seasonal flu, the influenza virus poses a persistent pandemic risk due to its unique genetic structure and ability to reassort with other viruses, potentially giving rise to highly contagious and deadly new strains. The influenza A virus genome has eight discrete segments. Co-infection of one host cell with two different influenza A viruses can result in progeny viruses containing gene segments of both parental viruses (i.e. genetic reassortment). If the attributes of the progeny virus causes illness in those infected people to spread easily from person to person in a sustained way, an influenza pandemic may result. The most recent example of an influenza pandemic occurred in 2009 from a genetic reassortment of human, avian, and classical Eurasian influenza A viruses in swine to which there were no immediate vaccines and resulted in 280,000 global deaths. The role of circulating annual influenza is therefore a critical element of pandemic influenza risk and prevention.

By modernizing diagnostic, vaccine, and therapeutic technology as envisioned through the NIVMS, the U.S. Government is laying the foundation to mitigate and expeditiously respond to the risks from influenza. The national strategy directs efforts toward strengthening and diversifying influenza vaccine development, manufacturing, and supply chains; promoting innovative approaches and new technologies for detection, prevention, and response; and expanding vaccine access and coverage across populations. Non-egg-based influenza vaccines, as identified in NIVMS, have the potential to impact each of the points in the vaccine production

timeline and are therefore central to the nation's influenza modernization strategy. DoD supports NIVMS objectives and is moving to transition its annual influenza vaccine procurement to solutions that are non-egg-based vaccines meeting NIVMS criteria, as well as leveraging its research, development, and manufacturing assets and abilities to support national efforts to progress our understanding of the virus and possible medical countermeasures.

**Key Considerations for DoD Procurement of Influenza Vaccines**

- Approvals: In selecting vaccines for procurement, DoD makes preferential use of immunizations approved by the Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP). DoD is also committed to its responsibilities towards the NIVMS.

- Impact on Morbidity: DoD prioritizes vaccines that reduce serious illness, preserve operational stability, and reduce pressure on healthcare infrastructure. The Department seeks to account for variation in effectiveness in at risk populations across the range of Military Health System (MHS) beneficiaries, particularly children younger than 2 years, those with chronic conditions, and adults aged 65 and older.

- Overcoming Adaption: The process of repeated replication in chicken eggs during vaccine production can lead to adaptive mutations, resulting in a virus that is better suited to replicate in avian cells than human cells. This phenomenon, known as egg adaptation, can compromise the efficacy of traditional egg-based influenza vaccines. In contrast, cell-based and recombinant vaccine production methods avoid this issue, yielding vaccines that more closely resemble the native virus and are better suited to protect against human infection. This issue is particularly pronounced for the influenza A virus subtype H3N2, which tends to undergo more significant egg-adapted changes due to its poor growth in chicken eggs, leading to reduced immune protection against circulating H3N2 viruses. As a result, these alternative production methods have been shown to confer improved vaccine performance during H3N2 seasons.

- Production Agility and Speed: DoD emphasizes high-volume flexible production, accelerated manufacturing, and delivery capabilities that guarantee a sufficient, readily deployable supply. DoD, and the NIVMS, seek agility in an urgent production line and prioritize the technologies that enable shorter time to production for a potential emergent influenza production, by warm-basing those technologies through annual influenza production.

- Price: Consistent with the MHS formularies, DoD seeks cost-effective vaccine options. However, the Department may pay a premium for vaccines that: 1) offer enhanced protection in sub populations; or 2) enhance national security and economic security consistent with the goals of NIVMS.

- Resourcing: All procurement is subject to funding availability within the relevant appropriations. Specific to NIVMS, the Department may seek to use alternate funding lines or appropriations to cover the price difference of non-egg-based vaccines in cases where the justification for use is not specifically related to the health benefit but rather national security or economic security.

## PROGRESS, OBSTACLES, TIMELINES, AND BUDGETARY ASSESSMENTS FOR DOD NIVMS IMPLEMENTATION PLAN ACTIVITIES

This section addresses elements (1)-(3) of the congressional reporting requirement. Presented below is the list of the activities for which NIVMS 2020-2030 tasks DoD as lead, followed by a description of the relevant updates, timelines, and budgetary assessments.

### NIVMS Activity 1.2.5

In summary, DoD estimates that it would cost approximately an additional $20.5 million overall, to switch all of DoD procured influenza vaccines from traditional egg-based to domestically manufactured cell-based and recombinant vaccines. This estimate represents acquiring cell-based vaccines for all age groups under the age of 65 and acquiring recombinant vaccine for people 65 and older.

The cost estimates provided in this document are for informational purposes only and are not intended to serve as formal pricing or commitment of purchase. Cost estimates are based on publicly available information and are directional only. Actual costs are likely to vary. Costs do not account for potential cost increases if the circulating H5N1 impacts the current price point of egg-base influenza vaccines.

DoD has programmed funding for egg-based vaccine.

### NIVMS Activity 1.3.4

DoD has assessed the utility of its ADM facility in Alachua, Florida and found it to be a key enabler for pandemic response. Although initial plans to utilize the facility for the coronavirus disease 2019 (COVID-19) vaccine and therapeutic manufacturing were delayed, exercising these ADM capabilities during that period proved their value in responding to pandemics, including influenza. The facility demonstrated expanded capacity for manufacturing cell-based vaccines using advanced technologies.

Chemical and Biological Defense Program funding efforts at the Alachua facility ended in Calendar Year (CY) 2024 when National Resilience became the owner and operator in exchange for DoD retaining priority access at the facility through CY 2030. DoD is assessing first and second order impacts following National Resilience's June 2024 announcement that it will be closing the Alachua site as part of its facility restructuring.

Beyond DoD assets, DoD continues to work closely with Biomedical Advanced Research and Development Authority (BARDA) to further enhance its medical countermeasures capabilities.

**NIVMS Activity 2.2.4**

DoD has been actively investigating alternative correlates of immune protection to facilitate the development of next-generation influenza vaccines. Core lines of effort include advanced characterization and mapping of important epitopes on circulating influenza virus strains, exploration of alternative assays, and development of assays for clinical evaluation of vaccines. This research has focused on multiple aspects of influenza immunology, including host response, viral families, such as Hemagglutinin and Neuraminidase, and platform technologies, which are critical for developing effective influenza vaccines. In addition, DoD supports interagency collaborations, including supporting development of assays for clinical evaluation of vaccines through the National Institutes of Health Collaborative Influenza Vaccine Innovation Centers program.

These research efforts are ongoing and include the following specific studies:

- The Uniformed Services University of the Health Sciences (USUHS) Department of Pediatrics has developed analyses platforms for T cells and innate immune responses as correlates of protection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that can be utilized for influenza.

- The USUHS Department of Pediatrics also contributed to the understanding of immune responses through its support of the Epidemiology, Immunology, and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EPICC) study on SARS-CoV-2, which has implications for influenza research.

- USUHS' Infectious Disease Clinical Research Program (IDCRP), in collaboration with the Defense Health Agency (DHA), is also conducting a study called the Pragmatic Assessment of Influenza Vaccine Effectiveness in the Department of Defense (PAIVED), which examines comparative "real-world" clinical effectiveness, as well as immunological correlates of protection against influenza, including T cell immune markers. The immunological analyses from the PAIVED study are expected to be completed in 2026. In addition to effectiveness and correlates of immune protection, PAIVED is examining influenza- and respiratory infection-associated healthcare utilization and costs in the context of vaccine use. The budget for the study is currently funded through the IDCRP, and these funds are set to expire in FY 2026.

**NIVMS Activity 2.2.5**

DoD efforts to accelerate research regarding rapidly scalable prophylactic influenza antibody approaches were conducted through the Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Platform (P3) program. This program aimed to revolutionize

outbreak response capabilities to allow rapid discovery, characterization, production, and testing of medical countermeasures. Of note for influenza, the program included support for developing a pan-influenza antibody and bispecific antibodies against H1. Much of P3's work pivoted to address SARS-CoV-2 in early FY 2020.

The DARPA P3 program came to an end in 2023 and technologies were transitioned to the Generative Unconstrained Intelligent Drug Engineering (GUIDE) program at Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense and to BARDA, in addition to commercialization.

**NIVMS Activities 2.2.7 and 2.2.8**

DoD has been actively engaged in efforts to enhance understanding of the clinical effect of existing licensed influenza vaccines, evaluate their effectiveness, and methods of boosting their effectiveness. The Department's efforts across these two NIVMS tasks are closely linked and has spanned several clinical trials and studies:

- The USUHS/IDCRP/DHA PAIVED clinical study, mentioned above, aims to assess the efficacy of influenza vaccines. This clinical study has been conducting annual assessments of influenza vaccine effectiveness. The study is in its final analysis phase and primary analysis results are available at: https://clinicaltrials.gov/study/NCT03734237.

- DHA in collaboration with the Naval Medical Research Center have been conducting the Melatonin and Vaccine Response, Immunity, and Chronobiology Study (MAVRICS), investigates the relationship between melatonin and vaccine response. Outcomes from this clinical trial are available at: https://pubmed.ncbi.nlm.nih.gov/39539030/

- USUHS in collaboration with the IDCRP, are conducting an Acute Respiratory Infections at the Academy study, which characterizes influenza vaccine breakthrough infections, including congregate outbreaks, with epidemiological, clinical, and strain genotypic/phenotypic data. This work is ongoing and ongoing updates are available at: https://idcrp.usuhs.edu/research-areas/acute-respiratory-infections

- The USUHS Department of Pediatrics has been conducting research on the Army Liposome Formulation (ALF) and its variants, including Army Liposome Formulation containing QS21 saponin (ALFQ), in collaboration with the Walter Reed Army Institute of Research. ALF is a vaccine adjuvant that has shown excellent safety and potency in clinical trials, and its improvements, such as ALFQ, have exhibited strong immunostimulatory effects. The research team has published studies on ALFQ and has developed an in-vitro cell line modeling system for messenger ribonucleic acid (mRNA) vaccine platforms, which is pending publication. Additionally, they have submitted a grant application to the Military Infectious Diseases Research Program for further funding. This project is currently facing challenges due to funding uncertainty and bioinformatics hurdles.

**NIVMS Activity 2.2.9**

DoD has been working to leverage its vaccine research and development enterprise to support the development of influenza vaccines, building on lessons learned from COVID-19 vaccine development. Since the launch of NIVMS, DoD has taken the following actions:

- The Vaccine Acceleration by Modular Progression program, which is a vaccine development platform that facilitates rapid delivery of safe and effective vaccines, for 2 years, with year two progressing as expected.

- The GUIDE program, which is an advanced computational system and may be leveraged to support influenza efforts, has also been executed for 2 years, with year two progressing as expected.

- The DoD Global Emerging Infections Surveillance (GEIS) system continues its routine global respiratory surveillance through DoD labs, which may detect novel respiratory viruses or strains. GEIS does not conduct or fund research and development activities.

- The studies outlined in response to the other NIVMS tasks (e.g., PAIVED, EPICC, MAVRICS, etc.) are also expected to contribute valuable insights and contribute toward understanding of design and evaluation of influenza vaccines.

## MARKET SURVEY AND PLAN TO MAXIMIZE PROCUREMENT OF DOMESTICALLY MANUFACTURED MODERNIZED INFLUENZA VACCINES

This section addresses element (4) of the congressional reporting requirement. Presented below is a review of the current options for non-egg-based vaccines on the market and a plan to maximize procurement of modernized influenza vaccines from domestic manufacturing sources.

**Market Survey**

- Background on NIVMS Guidance: NIVMS does not provide a specific definition or set of requirements for modernized influenza vaccines. Rather, it outlines objectives toward a modernized U.S. influenza vaccine enterprise that is highly responsive, flexible, resilient, scalable, and more efficient at reducing the impact of seasonal and pandemic influenza viruses. The strategy encourages the adoption of non-egg-based vaccines because of potential improvements in speed, scale, efficacy, and resiliency. It makes note of promising manufacturing techniques derived from cell-based, recombinant, and other synthetic technologies, which have a relatively shorter manufacturing time, do not rely on a supply chain of eggs, and therefore 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. NIVMS also calls for expanded domestic manufacturing capacities,

with a goal of being able to deliver first doses of a finished vaccine within 12 weeks of an influenza pandemic declaration.

- Types of Non-Egg-Based Influenza Vaccine: There are two types of non-egg-based influenza vaccines currently licensed that meet NIVMS guidance: cell-based and recombinant. DoD is also monitoring next-generation seasonal influenza vaccines in development, such as mRNA, which is in research pipelines but is not commercially available.

**Cell-Based Vaccines**

- How it Works: Cell-based vaccines use mammalian cells (Madin-Darby Canine Kidney, or MDCK cells) as the growth medium for viral cultivation, instead of fertilized hens' eggs.

- Impact on Morbidity: Use of cell-based candidate vaccine viruses in vaccine production has the potential to offer better protection compared to traditional, egg-based flu vaccines. This is because the viruses used to make cell-based vaccines might be more similar to circulating "wild" flu viruses than the viruses grown in eggs and used to make egg-based vaccines.

- Policy Considerations: The process eliminates dependency on egg supply chain and allows for the "banking" of frozen cells, enabling a more rapid production scaling if egg supply is limited. The DoD has numerous strategic directives seeking to onshore manufacturing, and active pharmaceutical ingredient (API) development, to mitigate intentional and unintentional supply chain vulnerabilities. The DoD will seek vaccine production modalities that evaluate time to manufacture during annual and urgent development scenarios.

**2024-2025 respiratory season**

**Availability:** There is one cell-based influenza vaccine approved in the United States for the 2024-2025 respiratory season: Flucelvax Trivalent manufactured by Seqirus, Inc.

**Approval:** Cell-based vaccine is licensed for use in people 6 months and older.

**Domestic Manufacturing:** The cell-based seasonal influenza vaccine and associated APIs are fully manufactured in Holly Springs, NC.

**Cost:** On average across age groups and presentations, a cell-based vaccine would cost an estimated five dollars ($5.13) more when compared to average prices for currently licensed egg-based vaccines.

**Recombinant Vaccines**

- How it Works: Recombinant vaccines are manufactured through synthetic laboratory methods without egg-based cultivation. A gene is taken from the influenza virus, combined with a harmless virus, and used to instruct cells to produce a specific antigen, which is then collected, purified, and packaged as a vaccine.

- Impact on Morbidity: As with cell-based vaccines, use of recombinant production methods has the potential to offer better protection compared to traditional, egg-based flu vaccines. This is because the antigen produced through recombinant methods can be more similar to the antigen found on circulating "wild" flu viruses, which can lead to better protection compared to traditional, egg-based flu vaccines.

- Policy Considerations: As with cell-based vaccines, the recombinant vaccine production process removes dependencies on egg supply chains. This production process is the fastest because it bypasses the need for candidate vaccine viruses adapted for growth in eggs or the development of cell culture-based vaccine viruses. DoD has numerous strategic directives seeking to onshore manufacturing, and API development, to mitigate intentional and unintentional supply chain vulnerabilities. DoD will seek vaccine production modalities that evaluate time to manufacture during annual and urgent development scenarios.

**2024-2025 respiratory season**

**Availability:** There is one trivalent recombinant influenza vaccine approved in the U.S. for the 2024-2025 respiratory season: Flublok Trivalent manufactured by Sanofi Pasteur Inc.

**Approval:** Recombinant flu vaccine is licensed for use in persons 18 years of age and older. Recombinant flu vaccine is also one of the three vaccines that are preferentially recommended for people 65 years and older because a review of existing studies suggested that, in this age group, these vaccines are potentially more effective than standard dose unadjuvanted flu vaccines.

**Domestic Manufacturing:** The manufacturer has domestic manufacturing capabilities and U.S. country of origin for APIs.

**Cost:** On average across age groups, a recombinant vaccine would cost an estimated sixty-eight dollars ($68.25) more when compared to average prices for currently licensed egg-based vaccines, and sixty-nine dollars ($69.15) more when compared to the preferentially recommended egg-based flu vaccines for people 65 years and older.

**Table 1. Summary of Currently Available Influenza Vaccine Options**

| | Egg-Based | Cell-Based | Recombinant |
|---|---|---|---|
| **Commercially Available** | Yes | Yes | Yes |
| **Approved for** | People 6 months and older | People 6 months and older | People 18 years of age and older. |
| **Possible to manufacture domestically** | Yes | Yes | Yes |
| **Currently Manufacturing Domestically** | Yes | Yes | Yes |
| **Removes egg supply chain dependency** | No | Yes | Yes |
| **Manufacturing Attributes** | Relies on eggs to be grown impacting time to produce.<br><br>Egg adaption decreases effectiveness particularly in H3N2 dominant influenza.<br><br>Sequential development of strains — dependent on Government selection and approval. Risk is on manufacturer to produce in advance of approvals.<br><br>Ability to add adjuvants to enhance effectiveness with lower antigen levels. | Lack of cell-adaption increases effectiveness in H3N2 dominant influenza.<br><br>Sequential development of strains—dependent on government selection and approval. Risk is on manufacturer to produce in advance of approvals.<br><br>Ability to add adjuvants to enhance effectiveness with lower antigen levels. | Lack of cell-adaption increases effectiveness in H3N2 dominant influenza.<br><br>Sequential development of strains — dependent on Government selection and approval. Risk is on manufacturer to produce in advance of approvals.<br><br>Comparative increase in antigen per vaccine. |
| **Manufacturing Time During Annual Vaccine Production** | Can take up to 9 months due to need to grow eggs.<br><br>With planning it is similar production time to other production modes. | Faster than egg-based because of cell banking (does not require growing eggs)<br><br>Similar production time to other production modes. | Faster than egg-based because of lab based techniques<br><br>Similar production time to other production modes. |
| **Manufacturing Time During Emergency Production** | Can take up to 9 months due to need to grow eggs; unable to shorten timelines for development under urgent needs | Faster due to cell banking that allows rapid thawing and initiation of production when compared to egg-based | Faster due to lab-based techniques allowing rapid initial production when compared to egg-based |

| | | | |
|---|---|---|---|
| **Estimated additional cost to DoD** | Approx. $14/dose | Approx. +$5.13/dose | Approx. +$68.25/dose |
| **Meets NIVMS priorities** | No | Yes | Yes |

**Plan to Maximize Procurement**

The Department annually procures influenza vaccine to meet overseas, operational, and continental U.S. demand to reduce risk of severe disease, hospitalization, and death in its beneficiary population and those authorized to received influenza vaccine from DoD. DoD only procures FDA-approved vaccines that have been recommended by the CDC's ACIP.

DoD estimates that it would cost on average approximately $5.13 per dose more to purchase cell-based vaccines and $68.25 per dose more to purchase recombinant vaccines instead of egg-based vaccines.

DoD annual influenza vaccine procurement for delivery in the direct care system is estimated at 3.1 million doses for the 2024-2025 respiratory season. This represents doses acquired for beneficiaries who receive their flu vaccine at a military medical treatment facility (MTF); however, it is important to note that not all TRICARE beneficiaries are enrolled at an MTF or choose to receive their flu vaccine through the military healthcare system. Many beneficiaries (approximately 1MM) receive flu vaccines through convenience-based alternatives in the civilian sector, such as local pharmacies, and many receive cell or recombinant vaccines.

**Challenges to Procurement of Non-Egg-Based Influenza Vaccine**

- Funding Alignment: The estimated additional cost to switch DoD's procurement of influenza vaccines to entirely to domestically manufactured non-egg-based options is $20.5 million. Historically and currently, the Defense Health Program appropriation was used to purchase vaccines, for delivery in the direct care system, at the lowest available price point, assuming comparable efficacy and following CDC's ACIP recommendations. Currently CDC states no preferential recommendation for non-egg-based influenza vaccines specific to health benefits, although there are scientific studies that show the benefits in sub populations. At the same time, NIVMS and national security priorities encourage investing in vaccines that offer a range of enhanced benefits, including on morbidity. However, the primary justification was to warm-base public health production capacity in preparation for a potential pandemic influenza. The Department has not historically prioritized the additional funding (approximately $5 per dose) because it would cause a decrement in other healthcare delivery or readiness portfolios and has not asked requested the additional funding come from another appropriation or budget line.

**Table 2. Cost Estimate for Egg-Based and Egg-Free Flu Vaccines (2024–2025)**

| Age Groups and Presentations | Doses Required | Egg-Based | | Non-Egg-Based | |
|---|---|---|---|---|---|
| | | Cost / Dose | Total Cost ($M) | Additional Cost / Dose | Additional Cost Total ($M) |
| Multi-dose vial, 18y + | 322,090 | $14.14 | $4.56 | +$5.10 | +$1.64 |
| Prefilled Syringes, 18y + | 1,145,750 | $14.59 | $16.72 | +$5.17 | +$5.92 |
| Multi-dose vial, 36m + | 206,880 | $14.14 | $2.93 | +$5.10 | +$1.05 |
| Prefilled Syringes, 36m + | 1,187,180 | $15.52 | $18.43 | +$4.24 | +$5.03 |
| Prefilled Syringes Pediatric | 177,480 | $15.42 | $2.74 | +$6.06 | +$1.08 |
| Prefilled Syringes, 65y + | 83,100 | $14.34 | $1.19 | +$69.15 | +$5.75 |
| **TOTAL** | 3,122,480 | | **$46.55** | | **+$20.47** |

- Current Efforts: In fall of FY 2025 DoD, through the Defense Logistics Agency (DLA), solicited bids for its 2025-2026 seasonal influenza vaccines. As previously mentioned, DoD follows CDC and its ACIP recommendations and currently there is no preferential recommendation for non-egg-based influenza vaccines. However, the Department is conducting a pilot in alignment with NIVMS objectives, a portion of DoD's total 2025-2026 seasonal influenza vaccine was directed as a non-egg-based solicitation, while the majority of DoD's seasonal influenza vaccine solicitation remained open to either egg-based or non-egg-based manufacturers. Manufacturer engagement with this pilot and future resourcing will help dictate the pace to full transition.

- Cost Estimate Assumptions: The following provides sources of data and other assumptions made in the development of this estimate:

  - Doses Required: Quantities provided by DLA on doses acquired for beneficiaries who receive their flu vaccine at an MTF. These estimates consider that not all TRICARE beneficiaries are enrolled at an MTF or choose to receive their flu vaccine through the military healthcare system, with some opting for convenience-based alternatives in the civilian sector.

  - Egg-Based Costs: The costs of egg-based vaccines are based on the averages of currently licensed vaccines available per category, sourced from publicly available CDC-negotiated pricing information for 2024. The specific vaccines used for each category are:

    - Multi-dose vial, 18 years and older: Fluzone and Afluria.
    - Prefilled Syringes, 18 years and older: Fluzone, Fluarix, and Afluria.
    - Multi-dose vial, 36 months and older: Fluzone and Afluria.
    - Prefilled Syringes, 36 months and older: Afluria.
    - Prefilled Syringes Pediatric: Fluzone, Fluarix, and Afluria.
    - Prefilled Syringes, 65 years and older: Fluzone.

- Cell-Based Vaccine Costs: The costs of cell-based vaccines are based on publicly available CDC-negotiated pricing information for Flucelvax for 2024 and are used for non-egg-based cost estimates for all age groups below 65 years.

- Recombinant Vaccine Costs: The costs of recombinant vaccines are based on the maximum CMS payment allowance for Flublok for 2024 and are used for cost estimates for the age group 65 years and older.

**Note:** The cost estimates provided in this document are for informational purposes only and are not intended to serve as formal pricing or commitment of purchase. Cost estimates are based on publicly available information and are directional only. Actual costs are likely to vary. Costs do not account for potential cost increases if the circulating H5N1 impacts the current price point of egg-base influenza vaccines.

## ACRONYMS AND TERMS

| Acronym | Term |
|---|---|
| ACIP | Advisory Committee on Immunization Practices |
| ADM | advanced manufacturing |
| ALF | Army Liposome Formulation |
| ALFQ | Army Liposome Formulation containing QS21 saponin |
| API | active pharmaceutical ingredient |
| BARDA | Biomedical Advanced Research and Development Authority |
| CDC | Centers for Disease Control and Prevention |
| COVID-19 | coronavirus disease 2019 |
| CY | Calendar Year |
| DARPA | Defense Advanced Research Projects Agency |
| DHA | Defense Health Agency |
| DLA | Defense Logistics Agency |
| DoD | Department of Defense |
| EO | Executive Order |
| EPICC | Epidemiology, Immunology, and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential |
| FDA | Food and Drug Administration |
| FY | Fiscal Year |
| GEIS | Global Emerging Infections Surveillance |
| GUIDE | Generative Unconstrained Intelligent Drug Engineering |

| | |
|---|---|
| HHS | Department of Health and Human Services |
| IDCRP | Infectious Disease Clinical Research Program |
| MAVRICS | Melatonin and Vaccine Response, Immunity, and Chronobiology Study |
| MHS | Military Health System |
| mRNA | messenger ribonucleic acid |
| MTF | military medical treatment facility |
| NDAA | National Defense Authorization Act |
| NIVMS | National Influenza Vaccine Modernization Strategy |
| PAIVED | Pragmatic Assessment of Influenza Vaccine Effectiveness in the Department of Defense |
| P3 | Pandemic Prevention Platform |
| USUHS | Uniformed Services University of the Health Sciences |

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