



A Global Initiative for Advancing Pandemic and Seasonal Influenza Vaccine Preparedness and Response

Concept Note
December 2020

Harnessing Lessons from the Efforts Mitigating the COVID-19 Pandemic

BACKGROUND

While the world responds to the COVID-19 pandemic, novel influenza viruses continue to be a constant pandemic threat. These viruses, which could appear at any time, can lead to circumstances and ramifications similar to or worse than the current experiences resulting from the COVID-19 pandemic. Both domestic and global efforts, such as the U.S. National Influenza Vaccine Modernization Strategy 2020-2030 and the WHO Global Influenza Strategy 2019-2030, have called for the development of more effective influenza vaccines complemented by modern, adaptable manufacturing technologies that can scale production and meet demand during a pandemic.

The global response to COVID-19 has pushed the boundaries on what is possible for rapid pandemic response in several areas, including vaccine research, development, manufacturing, equitable distribution, allocation, and administration. These unprecedented actions could inform and advance future pandemic and seasonal influenza vaccine preparedness efforts. Furthermore, the global COVID-19 response has provided new data around the efficacy and best practices surrounding non-pharmaceutical interventions (NPIs), such as social distancing measures. NPIs have proved to be vital tools to mitigate the impact of pandemics before vaccines become available. Lastly, examining current issues from the pandemic influenza angle can inform ongoing conversations and appropriate links for the directions, scope, and resources for a global health security research and development ecosystem.



OBJECTIVE

The National Academy of Medicine (NAM) will establish an International Committee (IC) in coordination with the U.S. Health and Human Services Office of Global Affairs (OGA) to inform and facilitate its efforts to advance global influenza pandemic preparedness. This International Committee will provide the OGA an iterative, interactive, multi-disciplinary, expert-informed process for assessing the global impact that capabilities, technologies, processes, and policies developed for COVID-19 could have on pandemic and seasonal influenza global preparedness and response, especially regarding vaccine development.

The NAM International Committee will convene domestic and international experts from across sectors (e.g., government, academia, industry, civil society, international public health organizations) and a variety of disciplines (e.g., global public health; infectious disease prevention; influenza vaccine research, development, and manufacturing; pandemic preparedness and response; virology, and immunology).

The IC will take a comprehensive approach to explore the current state of the art and provide recommendations to improve the global design, composition, clinical trials, production, scale-up, regulatory approval, distribution of influenza vaccines, and post-approval surveillance for adverse events. These recommendations will be developed by four concurrent National Academies consensus study committees and released as four consensus reports.

THE PRESSING NEED FOR GLOBAL PANDEMIC PREPAREDNESS

To fulfill its task, the IC, in coordination with OGA, will:

- establish four workstreams to discuss the emerging evidence on research and development for COVID-19 relevant to advancing seasonal and pandemic influenza global preparedness and response related to:
 - **Vaccine research and development, including platforms in discovery and manufacturing;**
 - **Distribution and supply chain;**
 - **Public health interventions and countermeasures (NPIs, Diagnostics, and Treatment Strategies);**
 - **International coordination, innovative partnerships, and sustainable financing for Influenza preparedness and response;**
- develop statements of task for each workstream to initiate consensus studies that will be fulfilled individually by a NASEM consensus study committee;
- organize a public evidence-gathering National Academies workshop to discuss critical themes, gaps, and topics related to the initiative's four workstreams to inform the work of the consensus study committees;



- plan an international conference to discuss the finalized report recommendations and propose a path forward for the implementation of these recommendations;
- disseminate and monitor progress on the recommendations from the consensus study reports;
- provide a mechanism of coordination and collaboration among domestic and international stakeholders;
- advise the National Academies on discussions regarding future activities and ad-hoc studies on pandemic and influenza preparedness and response.

CONSIDERATIONS

Each consensus study committee will consider the following topics when developing its conclusions and recommendations:

- Successful and novel COVID-19 technology and platforms;
- Sustainable financing infrastructure (lessons learned from COVID);
- Seasonal and pandemic influenza vaccine global and US capacity, allocation, and distribution, including market share of traditional egg-based, cell- and recombinant-based vaccines;
- Domestic and global resource limitations and constraints in the supply chain experienced during COVID-19, particularly those impacting vaccine manufacturing capacity;
- Promising public-private business models to sustain advanced domestic manufacturing in the U.S. and other countries to ensure manufactures can meet local and global demand for influenza medical countermeasures, including opportunities to maintain large-scale pandemic vaccine capacity in the interim;
- Opportunities for strengthening national and global programs to acquire, equitably deliver and evaluate epidemic vaccines, taking advantage of seasonal influenza and COVID-19 vaccination experiences;
- Lessons learned for actions and global coordination to propose models for improved collaboration on clinical trials and vaccine confidence to improve uptake;
- Emerging best practices for implementation of NPIs, therapeutics, and rapid, point-of-care, or at-home diagnostics to mitigate pandemic effects;
- Strategies developed for currently available vaccines to optimize protection and account for disease burden and risk of COVID-19 in vulnerable populations; and
- Consider national pandemic influenza plans adapted for other respiratory pathogen pandemics.



TIMELINE October 2020 - September 2021

October - November 2020

- NAM International Standing Committee (IC) appointed
- IC establishes 4 workstreams (WS)

December 2020

- IC Meetings #1 and #2
- IC finalizes statements of task for 4 consensus studies

January 2021

- 4 consensus study committees appointed

February 2021

- Committees (WS1-4) Meeting #1
- Committees identify needs for commissioned papers and consultations

March 2021

- Committees (WS1-4) Meeting #2

April 2021

- IC convenes public evidence-gathering workshop discussing critical topics and themes
- Committees (WS1-4) Meeting #3

May 2021

- Committees (WS1-4) Meeting #4

June 2021

- Committees (WS1-4) Meeting #5 if needed

July 2021

- Report review process begins

September 2021

- Report release - NAM and IC convenes an international report launch conference
- Other dissemination events

For More Information

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