

# New U of M-led analysis finds urgent need for new influenza vaccines

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**MINNEAPOLIS/ST. PAUL (EMBARGOED until 10:00 a.m., October 15, 2012)** – According to a new report from the University of Minnesota’s [Center for Infectious Disease Research and Policy \(CIDRAP\)](#), current influenza vaccines offer less protection against seasonal influenza than previously reported. As a result, the misperception that current vaccines are highly effective in fighting influenza has become a barrier to creating new, more effective vaccines.

Innovative influenza vaccines currently in investigational research offer the potential of lasting, broad and potent protection against both seasonal and pandemic influenza, but substantial research and policy support is needed to further their development and evaluation.

In addition, the report finds that as part of an effort to reduce influenza illness and death, policy shifts toward a universal recommendation for influenza vaccination often were based on professional judgment and not on sound data.

The new report, *The Compelling Need for Game Changing Influenza Vaccines* from the CIDRAP Comprehensive Influenza Vaccine Initiative (CCIVI), follows a review of more than 12,000 peer-reviewed publications, documents, transcripts and notes dating back to 1936 and interviews and follow up with nearly 100 experts in influenza vaccine research, development, and use.

“We urge people to get their flu shot. The present vaccines are the best interventions available for seasonal influenza,” said [Michael T. Osterholm, Ph.D., M.P.H.](#), University of Minnesota infectious disease expert and the CCIVI report’s lead author. “However, these vaccines do not offer consistent, high-level protection – especially in individuals at risk of medical complications or those aged older than 65 years. Unfortunately, these are the populations where we need the vaccines to work the best. We need new influenza vaccines that work for everyone, most of the time.”

Researchers found that during some influenza seasons, current vaccines offer more protection for most of the population than being unvaccinated. However, compared to most routinely recommended vaccines, influenza vaccine protection is substantially lower.

“We can no longer accept the status quo with regard to influenza vaccine research and development,” added CCIVI expert advisory group chair, Alfred Sommer, Ph.D, Johns Hopkins Bloomberg School of Public Health, after reviewing the latest report. “Only with new game-changing vaccines can we ever really be prepared for the next influenza pandemic.”

## Suboptimal protection

According to CCIVI researchers, influenza vaccine efficacy in healthy adults has been frequently cited as 70% to 90% since efficacy and effectiveness studies began in the 1940's.

"The problem with those statistics," said Osterholm, "is that much of the data from which these percentages are derived come from studies with less than optimal methodology and poorly defined clinical outcomes." He said that studies using optimal methodology have not found the same level of protection often attributed to the current vaccines.

Furthermore, the researchers found that three decades ago, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) began expanding vaccine recommendations based on the concept of "indirect benefit," or, put another way, protecting people who would come in contact with higher-risk populations.

Then, from 1999 through 2010, ACIP incrementally added more subgroups to its recommendations, moving toward universal recommendations for vaccination on the basis of expert or organizational opinion without evidence of vaccine effectiveness.

After reviewing optimal influenza vaccine efficacy and effectiveness studies from 1967 to 2012, the CCIVI research team found that injectable **trivalent inactivated influenza vaccines (TIV)**:

- Protects healthy adults 18 to 64 years of age at a rate of approximately 59 percent
- Lacks consistent evidence of protection in children age 2 to 17 years of age
- Inconsistent evidence of protection in adults 65 years of age and older

A review of optimal influenza vaccine efficacy and effectiveness studies from 1967 to 2012 found that the nasals spray **live attenuated influenza vaccine (LAIV)**:

- Protects young children 6 months to 7 years of age at a rate of approximately 83 percent
- Lacks consistent evidence of protection in adults 60 years of age and older
- Lacks evidence of protection in individuals 8 to 59 years of age

According to CCIVI researchers, these figures are problematic because they demonstrate one of the primary barriers to new influenza vaccine development: perception that current influenza vaccines are already highly effective.

Compounding challenges, current U.S. government regulatory process for approving new influenza vaccines is primarily designed for incremental changes to existing vaccines, which isn't conducive to developing new, game-changing vaccines.

Additionally, contrary to current policy goals - which focus on increasing production capacity - CCIVI researchers say addressing key public health challenges related to the effectiveness of current vaccines needs to be a priority.

### **The next step**

The report determines that significant policy, investment, leadership and organization barriers must be overcome to develop the next generation of influenza vaccines that can protect those most at risk of serious illness and death and reduce the global impact of the next influenza pandemic.

The CCIVI team concludes by stressing the need for novel-antigen, game-changing seasonal and pandemic influenza vaccines that have superior efficacy and effectiveness compared to current vaccines. They also stress that scientifically sound estimates of influenza vaccine efficacy and effectiveness must become the cornerstone for policy recommendations regarding vaccine use and for driving efforts to develop new, more protective vaccines.

The authors conclude that present vaccines are the best interventions available for seasonal influenza but that consistent, high-level protection eludes the present generation of vaccines, especially in individuals at risk of medical complications or those aged older than 65 years.

### **About the study**

The Comprehensive Influenza Vaccine Initiative (CCIVI) study, led by Michael Osterholm, Ph.D., M.P.H., director of CIDRAP, and professor of Environmental Health Sciences in the University of Minnesota School of Public Health, was published today by CIDRAP and can be found on its website [here](#).

The primary objectives of CCIVI were to provide a comprehensive review of all aspects of 2009/10 pandemic A(H1N1)pdm09 influenza vaccine preparedness and response based on the events of the pandemic vaccine effort and to review the scientific and programmatic basis for the current seasonal influenza vaccine efforts. This review included all aspects of influenza vaccine research and development, financing, manufacturing, efficacy, safety, regulatory issues, procurement, distribution, vaccine usage, public education, consumer acceptance, and public policy.

A 13-member Expert Advisory Group (EAG) was established, comprised of internationally recognized experts in all aspects of vaccine research and development, manufacturing, safety, delivery, and financing. The EAG was chaired by Alfred Sommer, Ph.D., former dean of the Bloomberg School of Public Health at Johns Hopkins University.

The study's authors include Michael T. Osterholm, Ph.D., M.P.H., University of Minnesota; Nicholas S. Kelley, Ph.D., University of Minnesota; Jill M. Manske, Ph.D., M.P.H., University of Minnesota; Katie S. Ballering, Ph.D., University of Minnesota; Tabitha R. Leighton, M.P.H., University of Minnesota; Kristine A. Moore, M.D., M.P.H., University of Minnesota.

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