

Influenza Key Points

October 25, 2011

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CDC Key Points:

***The Lancet Infectious Diseases* publication entitled “Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis”**

Background

- A recently published article in *The Lancet Infectious Diseases* entitled “Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis,” provides a review of existing flu vaccine efficacy* and effectiveness* studies. These are studies that measure how well flu vaccines work in people. This article is available online through *The Lancet Infectious Disease* website: www.thelancet.com/journals/laninf/issue/current.
- The review screened 5,707 total articles of which 5,676 were excluded according to specific exclusion criteria. The remaining 31 articles were included in the analysis for this review.
- These 31 articles comprise 17 randomized controlled trials and 14 observational studies. They were published between Jan 1, 1967 and Feb 15, 2011 (a 44- year time period), and used highly accurate laboratory testing techniques – specifically RT-PCR (reverse transcription polymerase chain reaction) or culture – for confirmation of influenza illness.
 - The review reported that flu vaccines can provide moderate protection against confirmed flu illness, but that protection can be lower – sometimes substantially so – in some flu seasons.
- **Study findings included the following:**
 - The authors highlight the importance of the continued use of current flu vaccines.
 - Overall, the flu shot (i.e., trivalent influenza vaccine or TIV, for short) had 59% efficacy against flu in healthy adults. The nasal spray flu vaccine (i.e., live attenuated influenza vaccine or LAIV, for short) prevented flu in 83% of children 7 years of age or younger.
 - The 2009 H1N1 monovalent vaccine used during the 2009 H1N1 pandemic had a median effectiveness of 69% against medically attended 2009 H1N1 illness in people younger than 65 years of age.
 - The authors report that there is a general lack of evidence showing flu vaccines protect adults aged 65 and older in the 31 studies that met the criteria used to determine which studies would be used for this analysis.
 - The review recommends that new flu vaccines with improved clinical efficacy and effectiveness are needed to further reduce influenza-related morbidity and mortality.

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- * **Note:** For more information on flu vaccine study design, including descriptions of vaccine effectiveness vs. efficacy studies, please see CDC's online Q&A for health professionals at www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm.

CDC Perspective

- CDC considers the article entitled "Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis," published in *The Lancet Infectious Diseases* on October 25, a helpful review of selected, previously published studies.
- The findings from this review are generally consistent with work on vaccine effects that has been presented and published by CDC and others in the last few years.
- The study validates findings accepted by CDC and the Advisory Committee on Immunization Practices (ACIP) for some time now, including:
 - Influenza vaccines are generally effective in preventing influenza.
 - However, it is recognized that current influenza vaccines have limitations in terms of how well they work, including how well they work to protect different groups of people.
 - How well the flu vaccine works (i.e., its ability to prevent flu illness) can range widely from season to season and can also vary depending on the health and age of the person being vaccinated.
 - During years when the viruses in the vaccine and circulating viruses are very well matched, it's possible to measure substantial benefits from vaccination in terms of preventing flu illness.
 - However, during years when the viruses in the vaccine and circulating viruses are not well matched, it's possible that no benefit from vaccination may be observed.
 - CDC acknowledges from a scientific perspective that additional studies are needed to fully quantify the benefits of flu vaccination in the elderly and people at high risk for flu complications; however, the best studies (e.g., efficacy studies involving randomized, controlled trials) are difficult to conduct in these groups for ethical reasons.
 - For example, randomized, controlled studies in which some people get vaccine and others get placebo provide the strongest scientific evidence, but withholding vaccine from the elderly and people with high-risk chronic health conditions could place them at undue risk for serious illness, should they become sick with the flu.
 - Even so, well done observational studies have demonstrated the value of influenza vaccines in this population. Given this and the substantial disease burden in this group, CDC strongly supports annual vaccination in this group.

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- Scientists at CDC and elsewhere continue to work on developing better ways to design and evaluate studies for measuring the benefits of flu vaccine in the elderly and people with high risk conditions.
- Despite the need for more data, there are studies available that show the elderly and people with chronic high-risk medical conditions benefit from flu vaccination.
- The public health community, the federal government and industry are investing and supporting the development of new and improved influenza vaccines. (For more information on new vaccine research initiatives, see the National Institutes of Health (NIH) Flu Vaccine Research webpage www.niaid.nih.gov/topics/flu/research/vaccineresearch/pages/default.aspx or contact HHS BARDA (Biomedical Advanced Research and Development Authority): www.phe.gov/about/barda/Pages/default.aspx).
- For example, on February 23, 2010, the Food and Drug Administration (FDA) approved Fluzone High-Dose, an inactivated influenza virus vaccine for people aged 65 years and older to prevent disease caused by influenza A and B viruses.
 - This is the first U.S. licensed influenza vaccine that was designed to better protect the elderly against seasonal flu by using a higher dose to produce a stronger immune response. In clinical studies, Fluzone High-Dose demonstrated an enhanced immune response compared with Fluzone (standard dose flu vaccine) in people 65 and older. For more information on high dose flu vaccine, see www.cdc.gov/flu/protect/vaccine/qa_fluzone.htm.
- Also, new studies on adjuvants (substances that are added to vaccines to boost the immune response) show promise in improving protection in certain age groups.
 - For example, a recent study in the *New England Journal of Medicine* entitled "Oil-in-Water Emulsion Adjuvant with Influenza Vaccine in Young Children" by Vesikari et al, found that use of a specific adjuvant improved immune protection against flu in infants and young children. (Link: www.nejm.org/doi/full/10.1056/nejmoa1010331.)
- In addition, FDA licensure of the intradermal flu vaccine in the United States for the 2011-2012 flu season marks a technological improvement in the amount of antigen required to produce an effective immune response. This has potential vaccine dose sparing benefits. For more information on intradermal flu vaccine, see www.cdc.gov/flu/protect/vaccine/qa_intradermal-vaccine.htm.
- While CDC continues to encourage and acknowledge the need for better flu vaccines, CDC also recognizes that existing flu vaccines are the best tool currently available for people to protect themselves against the flu. This tool should be used more broadly to protect as many people as possible.

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- CDC has made available online information describing recent studies of flu vaccine effects as well as answers to common questions for both general and professional audiences.
 - For an updated CDC overview of flu vaccine effects studies, including a summary of recent study results and methodological considerations and limitations for conducting such studies, please see “Influenza Vaccine Effectiveness: Questions and Answers for Health Professionals”: www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm.
 - For answers to common questions about how well the flu vaccine works (directed towards a general audience), please see www.cdc.gov/flu/about/qa/vaccineeffect.htm.
- For more information on flu vaccines see www.cdc.gov/flu/protect/vaccine/ (general public) and www.cdc.gov/flu/professionals/vaccination/ (health professionals).
- Note: the CDC key points document issued to partners for the 2011-2012 season has extensive information related to how well influenza vaccines work.