ABOUT THE STUDIES PRESENTED AT IDWEEK 2024

The Impact of Low Influenza Immunization Rates on U.S. Hospital System Resources. A Dynamic Model Estimation[1]
Researchers used a dynamic age-stratified transmission model that incorporated data from two U.S. flu seasons with varying incidences (2011-2012 for low incidence and 2017-2018 for high incidence) to estimate the impact of low influenza vaccination rates on the disease burden and U.S. hospital system resources. The study evaluated eleven different flu vaccination rates: 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65% and 70%.

The model assumed the use of quadrivalent flu vaccines for all ages and the total number of acute hospital and intensive care unit (ICU) hospital beds available for influenza in the U.S. at 300,000 and 30,000, respectively. The assessment measured the number of symptomatic cases, general practitioner visits, hospitalizations, and ICU stays and deaths, estimating an average VE of 42% based on seasonal reports from the U.S. Centers for Disease Control and Prevention (CDC).

This study concluded that increasing vaccination rates to at least 45% is essential for managing health outcomes and easing hospital burdens, particularly in ICUs. Results indicated that the estimated 35% vaccination rate achieved during the 2023-24 season could result in significant healthcare stress, predicting 62 million infections, 28 million general practitioner visits, 861,000 hospitalizations, and approximately 127,000 deaths in a high-incidence season.

Relative Vaccine Effectiveness of Cell-Based Versus Egg-Based Quadrivalent Influenza Vaccines Against Test-Confirmed Influenza in the United States 2022-23 Influenza Season[2]
Researchers applied a retrospective test-negative design among individuals aged 6 months to 64 years vaccinated with either QIVc or QIVe in 2022-23 and who had an influenza test obtained in routine outpatient care within +/- 7 days of a documented acute respiratory or febrile illness. Exposure, outcome, and covariate data were obtained from outpatient electronic health records linked to pharmacy and medical claims.

rVE was calculated by comparing the odds of testing positive for influenza among QIVc recipients with the odds among QIVe recipients, using a doubly robust analysis that combined inverse probability of treatment weighting with multivariable adjustment. The study included 43,086 tested patients, of whom 18.6% received QIVc and 81.4% received QIVe.

QIVc was generally more effective than QIVe in preventing test-confirmed influenza in the outpatient care setting, with an estimated rVE of 7.7% (95% CI: 0.9% – 13.9%).

This study showed increased relative effectiveness of QIVc compared to QIVe in preventing outpatient test-confirmed influenza in the population aged 6 months to 64 years during the 2022-23 season in the United States. These findings add to the body of evidence supporting improved effectiveness of cell-based versus egg-based vaccines.

Relative Effectiveness of Cell-Based Influenza Vaccines versus Egg-Based Influenza Vaccines: A Review of Test-Confirmed and Clinical Diagnosis-Based Outcomes[3]
Researchers identified 10 studies reporting on the rVE of QIVc vs QIVe/TIVe among persons aged 4–64 years from a prior systematic literature review (PROSPERO CRD42020160851) that included studies published between 01-January-2016 and 25-February-2022. Additionally, a scoping review was conducted to identify additional studies published between 25-February-2022 and 01-March-2024. A DerSimonian and Laird random effects model was applied for the meta-analyses of these data.

Among persons aged 4–64 years, the pooled rVE demonstrated a consistent benefit of QIVc for both outcome types, with estimates of 11.9% (95% CI, 3.0%–20%; n studies=3) for 2017–2018, 11.8% (4.2%–19.4%; n=2) for 2018–2019, and 10.0% (2.7%–16.7%; n=1) for 2019–2020 in preventing test-confirmed influenza and 18.7% (8.7%–27.6%; n=2) for 2017–2018, 5.9% (4.3%–7.5%; n=2) for 2018–2019, and 10.1% (6.1%–14.0%; n=2) for 2019–2020 in preventing clinically diagnosed influenza.

Researchers found that for persons aged 4–64 years, QIVc showed increased effectiveness over QIVe/TIVe across the three influenza seasons for both test-confirmed influenza and clinically diagnosed influenza. The results do not suggest systematic over or underestimation of rVE for prevention of clinically diagnosed compared to test-confirmed influenza.

Estimated Additional Burden Averted for the 2022-2023 influenza season from Use of Cell-Based Influenza Vaccines Compared to Egg-Based Influenza Vaccines Among People 0-64 Years of Age in the United States[4]
Researchers analyzed overall burden averted due to influenza vaccination via a CDC modeling method extended to a relative VE (rVE) context. The model utilized 2022-2023 CDC data on influenza vaccine uptake, influenza incidence, influenza-related healthcare resource (HRU) use and deaths.

CDC estimates of the absolute VE (aVE) (any vaccine) were used as the aVE of IIV4. A rVE of 7.7%, estimated in a 2022-2023 retrospective test-negative design study, was applied.

Results suggested that the use of ccIIV4 instead of IIV4 during the 2022-2023 flu season in the U.S. could have averted an additional 622,826 symptomatic cases, 307,682 outpatient visits, 3,680 hospitalizations, 559 ICU admissions, and 127 deaths, indicating a significant potential reduction in influenza's impact.

A Clinical and Economic Comparison of Non-Egg Influenza Vaccines in Adults 18-64 Years in the U.S.[5]
Researchers used a compartmental dynamic transmission model among individuals aged 18–64 years, calibrated to match infection data from the U.S., to estimate the clinical and economic impact of QIVc compared to QIVr over one influenza season.

Epidemiological data and vaccination coverage rate were obtained from CDC official databases. Vaccine effectiveness data against outpatient visits and hospitalizations, were obtained from published U.S. observational studies including outpatient and hospital setting outcomes (2018-19 and 2019-20 seasons).

The study showed that QIVc compared to QIVr exhibited fewer outpatient visits (585,936) and emergency department visits (12,492), and a comparable number of hospitalizations (503). QIVc compared to QIVr resulted in a higher overall number of quality-adjusted life years (QALYs) gained (2,546) and a reduction in total associated costs by US$2.9B. Cost savings were driven mainly by the lower 2023-24 acquisition costs, for QIVc versus QIVr (≈-50%).

Study Limitations
The above studies featuring RWE were subject to the typical limitations associated with retrospective cohort analyses. Unmeasured and residual confounding remain a potential source of bias as in all observational research. The amount and quality of data available on individuals may vary and clinical and claims data do not include all data that could inform and adjust for health seeking behavior, such as individual or contextual socioeconomic data. Studies included outcomes which were obtained as part of routine care and not performed according to pre-set screening criteria, including test confirmed influenza in the retrospective test-negative designs. Vaccination in these observational studies was not randomly assigned.

As with all simulations, analyses based on models have several limitations based on a model's parameters and available data, as well as annually varying vaccine effectiveness. Modeling may underestimate the true number of cases averted for several reasons. Studies may not account for the indirect benefits of vaccination, such as herd immunity and reduction of transmission due to reduction in cases. Additionally, CDC disease burden estimates correspond to the overall population (including both vaccinated and unvaccinated people), which may cause an underestimation of averted cases in the unvaccinated. Additionally, modeling may not capture potential variability between sub-groups where groupings such as age-specific data were not present.

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FLUCELVAX® (Influenza Vaccine) IMPORTANT SAFETY INFORMATION

What is FLUCELVAX® (Influenza Vaccine)?
FLUCELVAX is a vaccine that helps protect people aged 6 months and older from the flu. Vaccination with FLUCELVAX may not protect all people who receive the vaccine.

Who should not receive FLUCELVAX?
You should not receive FLUCELVAX if you have a history of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine.

Before receiving FLUCELVAX, tell your healthcare provider about all medical conditions, including if you:

- have ever had Guillain-Barré syndrome (severe muscle weakness) within six weeks after getting a flu vaccine. The decision to give FLUCELVAX should be made by your healthcare provider, based on careful consideration of the potential benefits and risks.
- have problems with your immune system or are taking certain medications that suppress your immune system, as these may reduce your immune response to the vaccine
- have ever fainted when receiving a vaccine

What are the most common side effects of FLUCELVAX?

- pain and/or redness where the vaccine was given
- headache
- extreme tiredness
- muscle aches

Additional side effects seen in children include:

- tenderness, bruising and/or a raised hardened area where the vaccine was given
- sleepiness
- irritability
- diarrhea
- changes in eating habits
- feeling unwell (malaise)

These are not all of the possible side effects of FLUCELVAX.
You can ask your healthcare provider for more information and for advice about any side effects that concern you.

What do I do if I have side effects?
Report any severe or unusual side effects to your healthcare provider**.**

To report SUSPECTED ADVERSE REACTIONS, contact CSL Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

Before receiving this vaccine, please see the full US Prescribing Information for FLUCELVAX. You can ask your healthcare provider or pharmacist for information about FLUCELVAX that is written for healthcare professionals.

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[1] Mould-Quevedo, J. et al (2024). The impact of low influenza immunization rates on U.S. Hospital System Resources. A dynamic model estimation.
[2] Stein, A. et al (2024). Relative Vaccine Effectiveness of Cell-Based Versus Egg-Based Quadrivalent Influenza Vaccines Against Test-Confirmed Influenza in the United States 2022-23 Influenza Season.
[3] Imran, M. et al (2024). Relative Effectiveness of Cell-Based Influenza Vaccines versus Egg-Based Influenza Vaccines: A Review of Test-Confirmed and Clinical Diagnosis-Based Outcomes.
[4] Stein, A. et al (2024). Estimated Additional Burden Averted for the 2022-2023 influenza season from Use of Cell-Based Influenza Vaccines Compared to Egg-Based Influenza Vaccines Among People 0-64 Years of Age in the United States.
[5] Mould-Quevedo, J. et al (2024). A Clinical and Economic Comparison of Non-Egg Influenza Vaccines in Adults 18-64 Years in the U.S.