# GSK Flu 2018 Update

Luis Romano, MD
US Medical Affairs Director
Influenza Vaccines

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## Simplifying flu vaccination for providers

With the FDA approval of an expanded indication for FLUARIX QUADRIVALENT in January 2018, GSK can now offer two flu vaccines that enable providers to use the same 0.5-mL dose for all recommended individuals.

| Vaccine* | Presentation | Age Group (Indication) |
|---|---|---|
| Fluarix Quadrivalent Influenza Vaccine | 0.5-mL prefilled, single-dose syringe | ≥ 6 months |
| FluLaval Quadrivalent Influenza Vaccine | 0.5-mL prefilled, single-dose syringe<br>5-mL multidose vial (ten 0.5-mL doses) | ≥ 6 months |

*Fluarix and FluLaval are registered trademarks of the GSK group of companies.

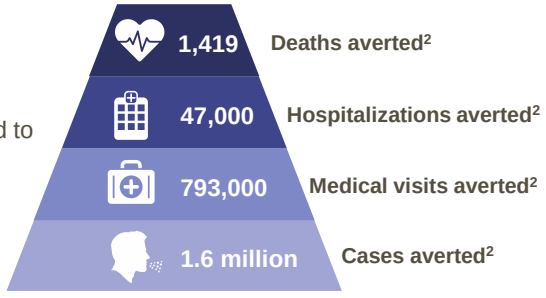
## Shifting the conversation from vaccine effectiveness to public health benefits




## Flu vaccination prevents millions of illnesses, medical visits, hospitalizations and deaths annually

Even during seasons when vaccine effectiveness (VE) is reduced, vaccination reduces the number of influenza cases and severe outcomes

Overall VE of **19%**[1] can still lead to




1. CDC. Seasonal Influenza Vaccine Effectiveness, 2005-2018. Available at: https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm. Accessed April 2018.
2. CDC. Estimated Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths Averted by Vaccination in the United States. https://www.cdc.gov/flu/about/disease/2015-16.htm. Accessed April 2018.

## Assessing vaccine efficacy against clinically significant aspects of influenza

D-QIV-004 study: Vaccine efficacy in children 6-35 months of age[1]

| | Moderate-to-severe influenza | Any severity influenza |
|---|---|---|
| **Fluarix QIV efficacy (97.5% CI)** | **63% (52-72)** | **50% (42-57)** |
| **Fluarix QIV (N = 5707)** | 1.6% (90 cases) | 4.3% (242 cases) |
| **Control (N = 5697)** | 6.0% (344 cases) | 11.6% (662 cases) |

**The "moderate-to-severe influenza" endpoint captures the more clinically significant outcomes of influenza[2]**

1. Claeys C, et al. *The Lancet Child Adol.* 2018;2(5):338–349. 2. Jain VK et al. *N Engl J Med.* 2013;369:2481–2491,



## GSK Flu: 2018-2019 season

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GSK expects to supply approximately 40-45 million doses across both seasonal flu vaccines for the US market in the 2018-19 season.**

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**Final quantities will be n demand & production capabilities

# Thank you!



## Important Safety Information for FLUARIX QUADRIVALENT and FLULAVAL QUADRIVALENT

- Do not administer FLULAVAL QUADRIVALENT or FLUARIX QUADRIVALENT to anyone with a history of severe allergic reactions (eg, anaphylaxis) to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLULAVAL QUADRIVALENT or FLUARIX QUADRIVALENT should be based on careful consideration of the potential benefits and risks
- Syncope (fainting) can occur in association with administration of injectable vaccines, including FLULAVAL QUADRIVALENT and FLUARIX QUADRIVALENT. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
- If FLULAVAL QUADRIVALENT or FLUARIX QUADRIVALENT is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons

## Important Safety Information for FLUARIX QUADRIVALENT and FLULAVAL QUADRIVALENT

- In clinical trials with FLULAVAL QUADRIVALENT in adults, the most common solicited local adverse reaction was pain and the most common solicited systemic adverse reactions were muscle aches, headache, fatigue, and arthralgia. In children 6 through 35 months of age, the most common solicited local adverse reaction was pain and the most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite. In children 3 through 17 years of age, the most common solicited local adverse reaction was pain. In children 3 through 4 years of age, the most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite. In children 5 through 17 years of age, the most common solicited systemic adverse reactions were muscle aches, fatigue, headache, arthralgia, and gastrointestinal symptoms. (See Adverse Reactions section of the Prescribing Information for FLULAVAL QUADRIVALENT for other potential adverse reactions and events)



## Important Safety Information for FLUARIX QUADRIVALENT and FLULAVAL QUADRIVALENT

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- Vaccination with FLULAVAL QUADRIVALENT or FLUARIX QUADRIVALENT may not result in protection in all vaccine recipients