

The Prudent Prescriber

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Flu Season 2016-2017

- * No FluMist this year!
- * Can you spell adjuvant, doctor?
- * The CDC vs the FDA: To Tamiflu or not to Tamiflu, that is the question.

The CDC again recommends that everyone over 6 months of age receive the flu vaccine. The vaccine antigens this year in the northern hemisphere are similar to those used in the 2016 vaccine in the southern hemisphere. Reports from down south suggest a "fair match" between the vaccine and the circulating viruses.

A/California/7/2009 (H1N1)
A/Hong Kong/4801/2014(H3N2)
B/Brisbane/60/2008
B/Phuket/3073/2013

Up to Date recommends the quadrivalent over trivalent flu vaccines; ACIP has made no statement.

FluMist

In June of this year, the Advisory Committee on Immunization Practices (ACIP) recommended: **"The live attenuated influenza vaccine (LAIV) nasal spray Flu Mist should not be used during the 2016-2017 flu season."** In May, 2016 data from the US Influenza Vaccine Effectiveness Network became available and showed that during the 2015-16 flu season the vaccine effectiveness (VE) of Flu Mist was 3% (CI -49% to 37%) for kids 2 through 17 years. In comparison, flu shots' VE was 63% (52% to 72%) for the same age group.

Pharm Reps \neq Rational Prescribing

(PR)



(RP)

Antibiotics do

NOT



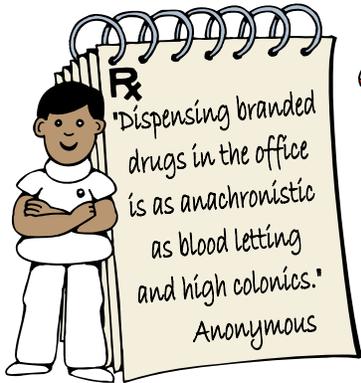
help

acute bronchitis

β -blockers in post-MI save lives



Pill splitters save BIG



R
"Dispensing branded drugs in the office is as anachronistic as blood letting and high colonics."
Anonymous



CHE?

Think:

Ace
Aldactone
B-blocker
Dig
Diuretic



Avoid these expensive "me-too" drugs:



Intermezzo
Vimovo
Livalo
Pristiq
Viibryd
Edarbi
Daliresp



Treat patients > 60 years to 150/90



NOW AVAILABLE
ON THE
GENERIC MARQUEE

Frova \rightarrow frovatriptan
Voltaren gel \rightarrow diclofenac Na 1% gel
Crestor \rightarrow rosuvastatin
Nuvigil \rightarrow armodafinil
Jalyn \rightarrow dutasteride/tamsulosin
Ortho Tri-Cyclen Lo \rightarrow Tri-Lo-Marzia,
Tri-Lo-Sprintec, & others

The data from 2015-2016 follows two previous seasons (2013-2014 and 2014-2015) showing poor and/or lower than expected vaccine effectiveness for the nasal vaccine.

Not without rebuttal, AstraZeneca, the makers of FluMist have resurrected their own older data that shows, on whole, that the FluMist vaccine has been comparable or modestly less effective than the inactivated influenza vaccine (IIV) over the last ten years. Astra Zeneca will continue to manufacture and market FluMist in other countries.

My Take: Pediatricians who routinely order 80% FluMist and 20% injectable flu vaccine will be scrambling to get their kids immunized.

Fluad

In November, 2015, the FDA approved Fluad (trivalent, 2 As and a B) for use in prevention of seasonal influenza in people 65 years of age and older. It is the first flu vaccine with an adjuvant.

Recall adjuvants are added to vaccines to enhance or direct the immune response of the vaccinated individual. The adjuvant in Fluad is M59, an oil in water emulsion of squalene oil, a naturally occurring substance found in humans, other animals and plants. It is uncertain how M59 affects the immune system.

There has been some feedback to the FDA that the fast track approval of Fluad is all about getting the adjuvant on the market to use in other vaccines and less about the flu vaccine itself.

The international studies that brought Fluad to market compared it with a standard non-adjuvant trivalent flu vaccine in 7,082 participants. Results: Fluad induced antibody levels were comparable to the levels induced by the non-adjuvant vaccine. There are no published clinical trials of efficacy in preventing the flu.

What is problematic with this study?

→ Of the 7,000+ participants, only 1000 were from the USA and over 2400 of the participants were from countries with a high percentage of Asian and Hispanic peoples. Responses to vaccines are significantly affected by genetic factors.

→ The trial exclusion criteria created a much healthier study group than the over 65 year population in the US, two thirds of whom have two or more chronic conditions.

→ Fluad recipients had more local reactions and more systemic reactions than those given the non- adjuvant vaccine.

→ There are no data to suggest that it is safe to give multiple doses of this new vaccine nor are there safety data regarding giving Fluad with other vaccines.

My Take: The ACIP has not made a recommendation on this vaccine, but I will. Don't go there! Too little data, too soon!

HD Fluzone

- ▶ Third season for this quadrivalent high dose (4 times as much antigen as standard flu vaccine) approved for patients over 65.
- ▶ Clinical studies show that 220 persons need to be immunized with HD vaccine vs standard flu vaccine to prevent one more case of influenza.
- ▶ HD vaccine is associated with significantly more local reactions than standard vaccine, but no more serious reactions. Up to Date recommends this vaccine for seniors. ACIP has made no statement.
- ▶ HD Fluzone cost is 1/3 greater than that of the standard influenza vaccine.

My Take: I'll stick with the standard vaccine this year. HD Fluzone is not cost effective compared to the lower priced standard vaccine.

Anti-virals for flu: Why the FDA and CDC do not agree

- ▶ CDC urges patients with influenza to take Tamiflu, claiming that the action *could* “save lives.” (Italics mine)
- ▶ The FDA claims that Tamiflu does not prevent hospitalizations or save lives.
- ▶ Lancet, (Dobson et al, May 2, 2015), 3 of 4 authors have financial relationships with Roche and Gilead, the manufacturer and patent holder of oseltamivir. NNT to prevent one hospitalization is 100. Shortening of illness by 24 hours. (This is the study that the CDC likes to quote.)
- ▶ BMJ (Jefferson et al, April 9, 2014), Tamiflu reduces duration of symptoms by 16 hours in adults and 29 hours in kids. Tamiflu had no effect on hospitalizations or complications, like pneumonia or death. (This is the FDA’s go to study.)
- ▶ Finally , a third meta-analysis Health Technol Assess May 2016 looking at many of the same studies concludes that neither Tamiflu (oseltamivir) nor Relenza (zanamivir) have any protective effect on mortality. The use of Tamiflu is associated with significant vomiting in both adults and children, NNH 22 and 19, respectively. Tamiflu reduced the time to first alleviation of symptoms by 16.8 hrs. Relenza, by 14 hours.
- ▶ Jeannie Lenzer, an associate editor of the BMJ (Feb 5, 2015) points out that the CDC Foundation was created by Congress “to connect the CDC to the private sector to advance public health.” The CDC has received financial contributions from Gilead, Genetech and Roche, part of which have been funneled directly to the public campaign to promote Tamiflu for influenza.
- ▶ In Grand Junction, Tamiflu costs a cash paying customer \$156-\$160 at multiple pharmacies for a 5 day supply of 10 capsules (GoodRX 9/15/16)

My Take: Money trumps science, again. Avoid prescribing Tamiflu.

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