Investigational 'Bird Flu' Vaccine Well Tolerated

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CHICAGO — The MF59-adjuvanted H5N1 influenza vaccine was as well tolerated as the widely used adjuvanted seasonal FLUAD influenza vaccine among adults in a large phase III multicenter study sponsored by Novartis Vaccines.

Local and systemic reactions occurred significantly less often with the MF59-adjuvanted H5N1 influenza vaccine than with FLUAD in adults; results were similar in the elderly.

No vaccine-related serious adverse events or deaths were reported among the 4,226 healthy participants in this study, the largest to date to assess the safety and tolerability of a prepandemic H5N1 vaccine.

"This is the first report of an antigen-sparing adjuvanted H5N1 vaccine that has an acceptable safety and reactogenicity profile in adults and the elderly, indicating that it can be used in a prepandemic setting," Dr. Angelika Banzhoff, of Novartis Vaccines, in Marburg, Germany, and her associates reported in a poster presentation at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

In adults, 66% who received the H5N1 vaccine reported any local or systemic reaction in the week after dose one, compared with 74% who received FLUAD.

Prepandemic vaccination has been proposed to prime the population and offer cross-protection against a range of heterovariant influenza virus strains. As of Oct. 12, 2007, 331 cases of laboratory-confirmed avian influenza have been reported to the World Health Organization, including 202 related deaths.

Participants in the study were randomized to receive two intramuscular doses, 3 weeks apart, of either the MF59-adjuvanted H5N1 influenza vaccine (7.5 mcg H5N1 influenza antigen/dose) or FLUAD (15 mcg each of A/H1N1, A/H3N2 and B antigens). Both vaccines were developed by Novartis Vaccines.

A total of 4,207 patients received dose one and were included in the safety analysis. Of these, 3,155 received the H5N1 vaccine (2,914 adults aged 60 years or younger and 241 elderly aged 61 or older) and 1,052 had FLUAD (971 adults and 81 elderly). A total of 4,143 patients also received dose two.

In all, 66% of adults who received the H5N1 vaccine reported any solicited local or systemic reaction in the week following dose one, compared with 74% who received FLUAD. Corresponding values for the week following dose two were 47% and 49%.

Most reactions were mild or moderate and short lived, with most patients reaction free by 1 week post dose, the investigators reported at the meeting sponsored by the American Society for Microbiology.

Significantly fewer patients in the H5N1 group than in the FLUAD group experienced induration (10 vs. 15), swelling (7 vs. 11), or pain (53 vs. 61) after dose one. And significantly fewer patients in the H5N1 group experienced chills (10 vs. 15), malaise (15 vs. 22), myalgia (17 vs. 25), headache (17 vs. 24), or fatigue (20 vs. 26) after dose one.

After dose two, the incidence of local and systemic reactions was similar between the two treatment groups.

Severe reactions were reported after dose one by 3% of patients in the H5N1 group versus 7% in the FLUAD group, and by 2% of patients in both groups after dose two. Thirteen adult patients reported 17 serious adverse events up to 3 weeks after dose two.

The proportion of elderly patients experiencing local or systemic reactions following dose one was generally lower than that for adult patients, and was largely similar between the two treatment groups after both doses one and two.

In all, 50% of elderly patients receiving H5N1 vaccine reported any solicited local or systemic reaction in the week following dose one, compared with 48% receiving FLUAD. Corresponding values for the week following dose two were 38% and 27%.

For both doses, most local and systemic reactions were short lived, with the exception of arthralgia, which persisted beyond 1 week in 3% of elderly patients in the H5N1 group following dose one.

Six elderly patients reported eight serious adverse events up to 3 weeks after dose two, the investigators reported. ■

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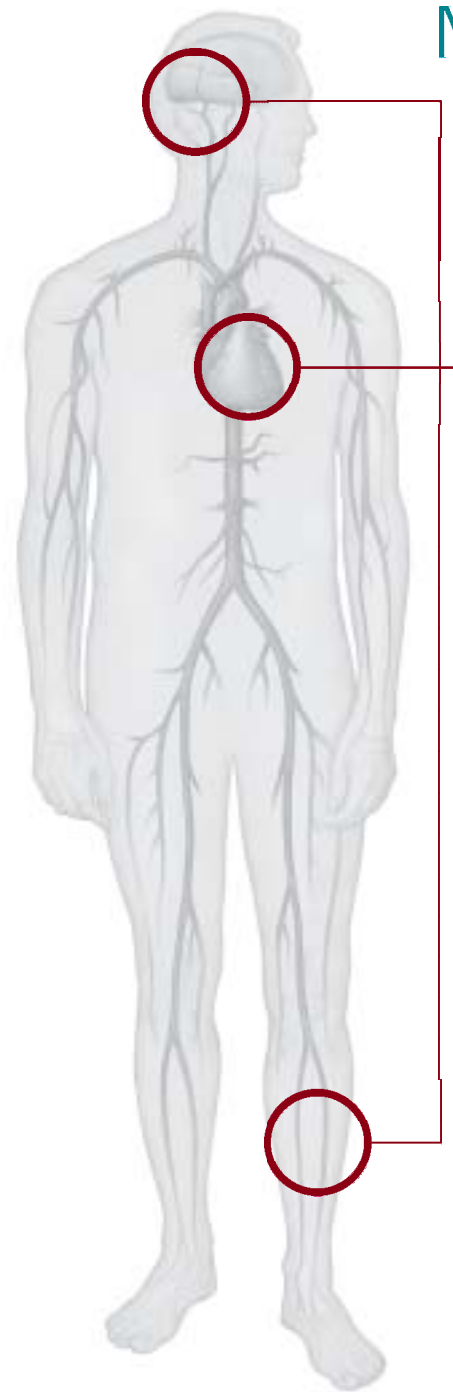
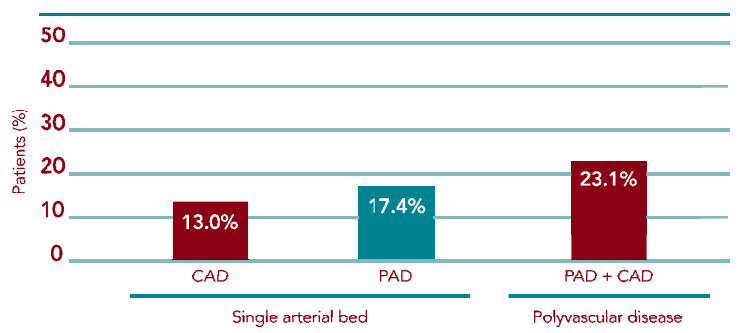


About 1 in 5 patients with established PAD had a major cardiovascular event within 1 year[1]

REACH Registry: 1-year Incidence of CV Death, MI, Stroke, or Hospitalization[1*]



The REACH (**RE**duction of **A**therothrombosis for **C**ontinued **H**ealth) Registry is the first outpatient registry to outline the real-world burden of atherothrombosis on a global basis. Baseline data have been collected from more than 68,000 patients in 44 countries. A total of 64,977 patients were included for the 1-year follow-up.

REACH is sponsored by sanofi aventis and Bristol-Myers Squibb.

*Causes for hospitalization included TIA, unstable angina, and other ischemic arterial events, including worsening of PAD.

The REACH Registry, which included more than **68,000 patients,** is one of the largest and most recent observational studies to outline the real-world burden of atherothrombosis.[1]