ABSTRACT
This letter to the editor brings to the attention of researchers an initiative to develop a baculovirus reference material repository. To be successful, this initiative needs the support of a broad panel of researchers working with baculovirus vectors for recombinant protein production and gene delivery for either therapy or vaccination. First there is a need to reach a consensus on the nature of the reference material, the production protocols and the baculovirus characterization methods. It will also be important to define repository and distribution procedures so that the reference material is available to any researcher for calibrating experimental data and to compare experiments performed in the various laboratories. As more and more baculovirus-based products are licensed or in the final stages of development, the development of a repository of baculovirus reference material is timely. This letter describes the requirements for the reference material and for the project as a whole to be successful and calls for a partnership that would involve academic, industrial laboratories and governmental organizations to support this international initiative.


Protective efficacy of a trivalent recombinant hemagglutinin protein vaccine (FluBlok®) against influenza in healthy adults: A randomized, placebo-controlled trial

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ABSTRACT
Background: Development of influenza vaccines that do not use embryonated eggs as the substrate for vaccine production is a high priority. We conducted this study to determine the protective efficacy a recombinant, baculovirus-expressed seasonal trivalent influenza virus hemagglutinin (rHA0) vaccine (FluBlok®).

Methods: Healthy adult subjects at 24 centers across the US were randomly assigned to receive a single injection of saline placebo (2304 subjects), or trivalent FluBlok containing 45 mcg of each rHA0 component (2344 subjects). Serum samples for assessment of immune responses by hemagglutination-inhibition (HAI) were taken from a subset of subjects before and 28 days after immunization. Subjects were followed during the 2007–2008 influenza season and combined nasal and throat swabs for virus isolation were obtained from subjects reporting influenza-like illness.

Results: Rates of local and systemic side effects were low, and the rates of systemic side effects were similar in the vaccine and placebo groups. HAI antibody responses were seen in 78%, 81%, and 52% of FluBlok recipients to the H1, H3, and B components, respectively. FluBlok was 44.6% (95% CI, 18.8%, 62.6%) effective in preventing culture-confirmed influenza meeting the CDC influenza-like illness case definition despite significant antigenic mismatch between the vaccine antigens and circulating viruses.

Conclusions: Trivalent rHA0 vaccine was safe, immunogenic and effective in the prevention of culture confirmed influenza illness, including protection against drift variants.