Comparative immunogenicity of recombinant influenza hemagglutinin (rHA) and trivalent inactivated vaccine (TIV) among persons ≥65 years old

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ABSTRACT
Alternative substrates for influenza vaccine production are needed to ensure adequate supplies. We evaluated the relative safety and immunogenicity of recombinant hemagglutinin (rHA) or trivalent inactivated vaccine (TIV) among 869 ≥65-year-old subjects in a randomized clinical trial. Virologic surveillance for influenza-like illness (ILI) was conducted during the 2006–2007 epidemic. Vaccines were well tolerated. Seroconversion rates vs. influenza A/H1N1 and H3N2 antigens were superior in the rHA group, but were inferior vs. influenza B; however, results for influenza B are confounded since the vaccine antigens were different. ILI frequencies were low and similar in both groups. Studies assessing relative immunogenicity of vaccines using identical B Ags are warranted.

Development of a simple and high-yielding fed-batch process for the production of influenza vaccines

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ABSTRACT
A robust and reliable GMP-compatible fed-batch process was successfully developed for the production of recombinant hemagglutinin (rHA) proteins by expresSF\textsuperscript{®} cells. The feeding solution, feeding strategy as well as the cell density at infection were optimized to maximize the final rHA production yields without affecting the existing rHA recovery protocol and downstream process. A simple and stable feeding solution was formulated and a rational feeding regimen designed to yield, depending on the rHA baculovirus used, between 2- and 3-fold enhancements in volumetric rHA production with increased specific productivity compared to the batch culture. Recombinant HA from fed-batch cultures could be simply recovered following cell lysis and purified through chromatographic steps. Overall, the increased rHA yield was maintained throughout the whole process. The performance, reproducibility and scalability of the fed-batch process was successfully demonstrated in 12 bioreactor runs of 2- and 10-L working volume using five different rHA encoding baculoviruses.