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Safety of MF29-adjuvanted influenza vaccination in the elderly : results of a comparative study of MF59-adjuvanted vaccine versus nonadjuvanted influenza vaccine in Northern Italy

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Abstrak

MF59-adjuvanted trivalent influenza vaccine (Novartis Vaccines and Diagnostics, Siena, Italy) has been shown to be more effective than nonadjuvanted vaccine in the elderly population. Here we present results from a large-scale, observational, noninterventional, prospective postlicensure study that evaluated the safety of MF59-adjuvanted vaccine in elderly subjects aged 65 years or more. The study was performed in 5 northern Italian health districts during the 2006-2007, 2007-2008, and 2008-2009 influenza seasons. The choice of vaccine-either adjuvanted vaccine or a nonadjuvanted influenza vaccine-was determined by individual providers on the basis of local influenza vaccination policy. Hospitalizations for potential adverse events of special interest (AESIs) were identified from hospital databases and then reviewed against recognized case definitions to identify confirmed cases of AESI. Cumulative incidences were calculated for AESIs in predefined biologically plausible time windows, as well as in a 6-month window following vaccination. During the 3-year study period, 170,988 vaccine doses were administered to a total of 107,661 persons. Despite the large study size, cases of AESI resulting in hospitalization were rare, and risks of AESI were similar in both the MF59-adjuvanted and nonadjuvanted vaccination groups. In conclusion, similar safety profiles were observed for both nonadjuvanted and MF59-adjuvanted seasonal influenza vaccines in elderly recipients.