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International collaboration to assess the risk of Guillain Barré Syndrome following Influenza A (H1N1) 2009 monovalent vaccines

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Collaborators (121, tra cui Addis A)

BACKGROUND

The global spread of the 2009 novel pandemic influenza A (H1N1) virus led to the accelerated production and distribution of monovalent 2009 Influenza A (H1N1) vaccines (pH1N1). This pandemic provided the opportunity to evaluate the risk of Guillain-Barré syndrome (GBS), which has been an influenza vaccine safety concern since the swine flu pandemic of 1976, using a common protocol among high and middle-income countries. The primary objective of this project was to demonstrate the feasibility and utility of global collaboration in the assessment of vaccine safety, including countries both with and without an established infrastructure for vaccine active safety surveillance. A second objective, included a priori, was to assess the risk of GBS following pH1N1 vaccination.

METHODS

The primary analysis used the self-controlled case series (SCCS) design to estimate the relative incidence (RI) of GBS in the 42 days following vaccination with pH1N1 vaccine in a pooled analysis across databases and in analysis using a meta-analytic approach.

RESULTS

We found a relative incidence of GBS of 2.42 (95% CI 1.58-3.72) in the 42 days following exposure to pH1N1 vaccine in analysis of pooled data and 2.09 (95% CI 1.28-3.42) using the meta-analytic approach.

CONCLUSIONS

This study demonstrates that international collaboration to evaluate serious outcomes using a common protocol is feasible. The significance and consistency of our findings support a conclusion of an association between 2009 H1N1 vaccination and GBS. Given the rarity of the event the relative incidence found does not provide evidence in contradiction to international recommendations for the continued use of influenza vaccines.