Spontaneous reporting of adverse events following immunisation against pandemic influenza in Denmark November 2009-March 2010.

https://arctichealth.org/en/permalink/ahliterature99811

Author: Maja Folkenberg
Torbjörn Callréus
Henrik Svanström
Palle Valentiner-Branth
Anders Hviid

Author Affiliation: Consumer Safety Division, Danish Medicines Agency, Copenhagen, Denmark.

Source: Vaccine. 2010 Dec 18;

Date: Dec-18-2010

Language: English

Publication Type: Article

Abstract: Our study reviews the spontaneous reports of adverse events following immunisation submitted to the Danish Medicines Agency during the 2009-2010 influenza A/H1N1v season. During the study period (4 November 2009-31 March 2010), 607 reports comprising 1885 adverse events were reported among 339,507 influenza A/H1N1v vaccinated individuals (reporting rate, 179 per 100,000 vaccinated). The majority of individual case safety reports (85%) were submitted by physicians and other health care professionals and concerned known and non-serious reactions occurring within 1 day of vaccination (82%). Events of special interest as defined by EMA prior to vaccination campaign start, comprised 1% of all events. In conclusion, we did not observe any strong signals of any unknown or serious adverse events associated with influenza A/H1N1v vaccination in Denmark. Our experience also demonstrates the well-known limitations of spontaneous reports with respect to evaluation of a casual relationship and highlights the importance for a timely availability of background events rates and the need for new approaches to study late adverse effects following immunisation.

PubMed ID: 21172382 View in PubMed