Reviewer's report

Title: Effectiveness of a MF-59TM-adjuvanted pandemic influenza vaccine to prevent 2009 influenza A/H1N1-related hospitalisation; a matched case-control study

Version: 1 Date: 9 March 2011

Reviewer: Marta Valenciano

Reviewer's report:

Discretionary revisions:

Interesting paper bringing information on pandemic vaccine effectiveness against hospitalisations.

Some recommendations:

1) Could you explain briefly (even if there is a reference) what were the criteria for hospitalised cases to be swabbed? What is the representativeness of swabbed patients? Who entered the data for hospitalized cases. As the data source for cases and controls was different, it would be important to clearly show the differences in data collection, variables definition (e.g. chronic diseases?), data validation.

2) What is the representativeness of the GPs included in the study compared to all GPs? Are they representative of the vaccine coverage of the population giving rise to the cases? Would it be possible to know the number of hospitalized cases among these GPs catchment population and in the rest of GPs? The difference in vaccine coverage?

3) Time was an important confounding factor during the pandemic in all studies published. In that sense:

I don´t understand very clearly the matching by time criteria. You mention “calendar date” but how was it exactly done?

Would it be possible to have estimates stratified by time or restricted to the influenza peak?

It would be interesting to see a graph with recruitment of cases and controls by time (index week?)

4) Exposure

You define a valid vaccination as > 7 days before the index date. Have you tried to stratify according to different delays (8-13, >14)?

For the missing data on vaccination, you can also try imputing data.

5) How was the matching on chronic diseases done? What was the distribution of chronic diseases among cases and controls?
6) Adjustment
- You have adjusted by age, sex, chronic condition and addressed in the restricted analysis frailty bias. Do you know if, even after matching, those variables had some residual confounding effect? Have you adjust for any other potential confounding factor? If data were not available, may be this can be mentioned in the discussion as limitation.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.