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Vaccination against pandemic influenza 2009

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In issue 5/2012 of this journal, Charlotte Haug claims that the Norwegian Institute of Public Health was aware that the vaccine Pandemrix had not been «clinically tested», and that «WHO's own vaccine safety committee had expressed concerns», and that the new influenza was «harmless to the vast majority of people» (1). Of these assertions, one is wrong, one is partly wrong and one is correct.

The vaccine *had been* clinically tested. First, Pandemrix had been tested on several thousand persons with another virus (the bird-flu virus H5N1). Second, several thousand persons had been administered Pandemrix with the A(H1N1) pdm09 virus in clinical studies, some of which were described in the assessment report of the European Medicines Agency, published 24 September 2009. (2). Third, in mid-October several countries that have good systems for monitoring side effects decided to start using Pandemrix.

To have the best possible information, we delayed the decision on whether to recommend giving the vaccine to everybody until 23 October 2009. On that date we had evidence that Pandemrix did not produce frequent, serious side effects. However, in the information leaflet we declared that this was being continuously monitored, since rare side effects might only be detected later.

In doing so, we followed the advice from the WHO vaccine-safety committee (3), which four months previously had recommended vigilance when the vaccine was brought into use, although the committee of course did not warn against such use. Monitoring systems were in place. A separate form for

reporting side effects had been published, and the full identities of those vaccinated were registered in the System for Vaccination Control, which allows us to correlate this information with data from the Norwegian Patient Registry.

Haug correctly asserts that we had a realistic impression of the pandemic. Already on 27 April 2009, we wrote that (4): «If a pandemic develops, we currently believe that it will be mild, with low lethality.» We subsequently monitored its development closely, and could give increasingly better descriptions of the disease (5) and predictions of its development. In a review, the Directorate for Civil Protection and Emergency Planning (6) concludes: «One of the key tasks of the NIPH in the context of the pandemic was to monitor the situation and assess risks and uncertainty associated with its further development» and that «the institute's analyses were largely confirmed by actual events.»

When we nevertheless chose to offer the vaccine to everybody, the decision was based on the fact that there were good reasons to fear that some serious influenza cases and deaths could also occur outside the traditional risk groups, but without anybody being able to predict in advance who would be afflicted. We wanted to provide everybody in Norway with an opportunity to reduce their risk.

LITERATURE

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