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What did they know, and when did they know it?

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Editor

At least 35 children have been diagnosed as having narcolepsy since being vaccinated against «swine flu» in autumn 2009. What were the grounds for recommending mass vaccination of the entire Norwegian population?

The American senator Howard Baker (born 1925) asked the damning question during the Watergate inquiries: «What did the president know, and when did he know it?» The judgement passed on the president's actions would have differed, depending on whether he had been aware of the break-in into the Democratic party headquarters in the Watergate building before it happened or whether he had only learned about it afterwards. That is often the way it is. When considering in retrospect whether an action or a decision was correct or not, we need to be precise about what information was available when the decision was made. Drawing on information that became known at a later date – irrespective of whether it puts the decision in a positive or a negative light – is not constructive. But looking at what was actually known, and making a new assessment can be both sensible and instructive.

At least 35 children have been diagnosed as having narcolepsy after being vaccinated against «swine flu» in autumn 2009, and the question of whether it was right to recommend mass vaccination of the entire Norwegian population has naturally arisen. Director-General Bjørn-Inge Larsen of the Directorate of Health has stated that he would not have recommended vaccinating children today, but he, the Director-General of the Norwegian Institute of Public Health and the Minister of Health all defend the decision to carry out mass vaccination, and maintain that it was correct at the time when it was made. Was it? What did the health authorities really know about how dangerous the new influenza was, how effective the vaccine was and what risk there was of side effects when the decision to vaccinate was made in October 2009?

We now have more insight into this, because the Institute of Public Health has made available 51 status reports and 50 other reports on the pandemic that they sent to the Directorate of Health and the Ministry of Health and Care

Services in the period 26 April 2009 – 7 January 2010 (1). We can follow developments in what was known about the pandemic almost from day to day, from the time it appeared in Mexico in April 2009 until the worst was over in Norway in January 2010.

Were we facing a potentially serious disease when the decision to perform mass vaccination was made on 23 October 2009? According to Director-General Geir Stene-Larsen of the Institute of Public Health, the answer is «Yes». In the Norwegian daily *Aftenposten* on 18 February 2012, he states: «A pandemic is regarded as a potentially serious disease. The Spanish flu took the lives of 30 to 40 million people.» And he continues: «In retrospect, we can see that this was a mild pandemic, and that it was not necessary to take measures as strong as those we did take. But we only learned that afterwards.» The fact that the director uses the term 'pandemic' incorrectly (again), I will not take issue with here. I will rather ask: «Is it true that it was only *after* October 2009 that it became clear that this was a mild pandemic?» The answer is no – according to the Institute of Public Health's own status reports to the Directorate of Health. The following conclusion is reached already in the fifth status report on the pandemic, dated 30 April 2009: «Risk assessment: The event is in the process of becoming a pandemic, but probably a mild pandemic of long duration and low lethality.» On 8 May 2009 it is reported that the new virus is less infectious than ordinary seasonal influenza. In the course of the summer, data come in from all over the world that confirm the estimates with increasing certainty. On 28 July 2009, for example, it becomes clear that the pandemic is less dangerous than ordinary seasonal influenza. «The lethality arrived at on the basis of confirmed cases will be an overestimate, as the denominator employed does not include all the undiagnosed cases. We estimate lethality at somewhere between 1/1 000 (0.1 %) and 1/10 000 (0.01 %). By way of comparison, the lethality of seasonal influenza is estimated to be around 2/1 000 (0.2 %).» And figures from the southern hemisphere, where the influenza season was already almost over, proved that fewer than initially feared fell ill.

In the late summer of 2009 it was quite clear, then, that we were facing neither the Spanish flu nor SARS – fortunately. And this was *before* the mass vaccination was launched. Yes, as early as at the end of May the Institute of Public Health was already sure enough that the pandemic was going to be mild that they were wondering if we shouldn't try to get out of the agreement that had been made concerning the purchase of pandemic vaccine – at a cost of many hundreds of millions of kroner. Quote (29 May 2009): «Since there is much to indicate that the disease is mild, are there grounds for considering the possibility of influencing or renegotiating with GlaxoSmithKline to buy less vaccine or none at all?»

And what about the vaccine? What did the health authorities know, and when? Is it true that they were unaware that the vaccine could cause serious side effects? The answer to this question, too, is no. The very real danger of serious side effects was discussed both here in Norway and by WHO. The Institute of Public Health's report of 8 May 2009 contained the following communication from WHO: «WHO reminded participants of severe side effects (Guillain-Barré syndrome) caused by the vaccine used during the H1N1 swine flu epidemic in 1976. Therefore, WHO commissioned an authoritative review for consideration

by the WHO Global Advisory Committee on Vaccine Safety (GACVS) at their meeting on 17 – 18 June 09.» At its June meeting, the committee discussed both the risk associated with Guillain-Barré syndrome and the importance of setting up active monitoring systems and clinical studies that could reveal rare, serious side effects and, in the event, also the underlying mechanism. There was also considerable concern about what the adjuvant in the influenza vaccine would imply, and the committee stressed that there were very limited data pertaining to safety, not least for children and pregnant women. The entire minutes of the meeting can be read on WHO's website (2).

The relationship between the seriousness of the disease and the safety of the vaccine was also discussed in the Institute of Public Health's report of 20 July 2009: «The European Medicines Agency, EMEA, (represented by their pharmaceuticals committee, CHMP) will decide this week what documentation they require in order to approve the vaccine. There are two alternatives: Theoretically, the vaccine could be approved on the basis of technical documentation only. In that case the approval could come by the beginning of October. We regard this as improbable, given the fairly mild nature of the disease, and that this is a vaccine with a new antigen and new adjuvant. The normal procedure will be for EMEA to wait for clinical testing and therefore not approve the vaccine before the beginning of December.» The vaccine was approved by EMEA on 25 September 2009, i.e. without clinical testing.

So, what did the health authorities know, and when did they know it? On 23 October 2009, when they took the decision to recommend mass vaccination of the entire Norwegian population, they knew that we were facing a mild influenza that was not dangerous to the great majority. The vaccine was not clinically tested, and WHO's own vaccination safety committee had expressed concern.

LITERATURE

1. Rapporter for helsemyndighetene og helsetjenesten under influensa A(H1N1)-pandemien. www.fhi.no/eway/default.aspx?pid=233&trg=MainArea_5661&MainArea_5661=5631:0:15,5099:1:0:0:::0:0 (27.2.2012).

2. Global Advisory Committee on Vaccine Safety, report of meeting held 17 – 18 June 2009. www.who.int/vaccine_safety/Jun_2009/en/index.html (27.2.2012).

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