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## Covid-19: Pfizer-BioNTech vaccine is “likely” responsible for deaths of some elderly patients, Norwegian review finds

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The Pfizer-BioNTech covid-19 vaccine is “likely” to have been responsible for at least 10 deaths of frail elderly people in nursing homes in Norway, an expert review commissioned by the Norwegian Medicines Agency has concluded.

The expert group was established at the end of February 2021 to look into the cause of the first 100 reported deaths of nursing home residents who had received the Pfizer-BioNTech vaccine. At the time, around 30 000 elderly nursing home residents had been vaccinated.

Although the mortality rate in nursing homes is generally very high and the deaths of some nursing home residents after vaccination was anticipated, the Norwegian Medicines Agency wanted to determine whether the vaccine had possibly hastened any deaths and to gain a clearer understanding of the risks and benefits of its use in frail elderly people.

The review reported on 19 May and concluded that a causal link between the Pfizer-BioNTech vaccine and death was considered “likely” in 10 of the 100 cases, “possible” in 26 cases, and “unlikely” in 59 cases. The remaining five were deemed “unclassifiable.”<sup>1</sup>

While emphasising considerable uncertainty around its conclusions, the expert group acknowledged a risk that adverse reactions to the vaccines among very frail patients could initiate a cascade of complications, which in the worst case scenario could lead to earlier death.

### Extremely frail patients

“Frail patients can benefit from vaccination because they are at great risk of serious illness and even death if they become infected with the covid-19 virus,” said Sigurd Hortemo, senior medical consultant at the Norwegian Medicines Agency. “Nevertheless, the expert group believes that, for some of these frail patients, common adverse reactions may have contributed to a more serious course of their disease.”

The group noted that more thorough assessment of the benefits and risks of vaccination could have been made for some very frail elderly people, particularly during the first few weeks of the vaccine’s use. People with a very short life expectancy have little to gain from being vaccinated, it said, noting a genuine risk that the time of death will be brought forward and that they will experience adverse reactions to the vaccine in the last days of their life.

The benefits of vaccination for very frail people with very short life expectancy should therefore be carefully assessed against the associated risks, and it may often be better not to vaccinate, the group recommended. However, the guidelines on risk assessment—issued by the Norwegian Institute of

Public Health shortly after the first reported deaths of frail elderly patients after vaccination—were adequate, it said. These advise that doctors should assess such patients individually to determine whether the benefits of vaccination outweigh the side effects. The guidelines recommend that, ahead of vaccination, doctors should consider the benefits and disadvantages of giving the vaccine to extremely frail patients (such as those whose frailty is ranked 8 or 9 on the Clinical Frailty Scale or equivalent) or terminally ill patients.

Preventive measures such as good hydration, medicine reviews, and optimised treatment of comorbid conditions may also reduce the risk of fatal consequences from adverse reactions to vaccines, the expert group added.

### Health authorities

As of 18 May 2021, 155 deaths had been reported in Norway after vaccination with the Pfizer-BioNTech vaccine, and most deaths involved elderly and very frail nursing home residents.<sup>2</sup>

Pfizer has said in a statement that all decisions on the rollout of vaccine programmes reside with health authorities and that the Norwegian health authorities had previously issued updated recommendations on vaccinating terminally ill and extremely frail patients.

“More than 300 million doses of the Pfizer-BioNTech covid-19 vaccine have been administered globally,” said Pfizer. “Serious adverse events unrelated to, but close in timing to vaccination, are expected to occur at a similar rate in vaccinated individuals as they would in the overall population.”

Only the BioNTech-Pfizer and Moderna vaccines are now part of the covid-19 vaccination programme in Norway. On 11 March officials suspended the use of the AstraZeneca vaccine because of concerns about blood clots, and in April the Norwegian Institute of Public Health recommended no further use of that vaccine.<sup>3</sup>

Geir Bukholm, director of the Division of Infection Control and Environmental Health at the Norwegian Institute of Public Health, said, “Since there are few people who die from covid-19 in Norway, the risk of dying after vaccination with the AstraZeneca vaccine would be higher than the risk of dying from the disease, particularly for younger people.” As of 25 May, Norway had recorded 782 deaths from covid-19.<sup>4</sup>

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- 2 Norwegian Medicines Agency. Reported suspected adverse reactions of covid-19 vaccines. 20 May 2021. <https://legemiddelverket.no/english/covid-19-and-medicines/vaccines-against-covid-19/reported-suspected-adverse-reactions-of-covid-19-vaccines>. <https://legemiddelverket.no/Documents/English/Covid-19/20210520%20Reported%20suspected%20adverse%20reactions%20coronavirus%20vaccines.pdf>.
- 3 Norwegian Institute of Public Health. Norwegian Institute of Public Health's recommendation about AstraZeneca vaccine. 15 Apr 2021. <https://www.fhi.no/en/news/2021/astrazeneca-vaccine-removed-from-coronavirus-immunisation-programme-in-norw/>.
- 4 Norwegian Institute of Public Health. Daily report and statistics about coronavirus and covid-19. Updated 25 May 2021. <https://www.fhi.no/en/id/infectious-diseases/coronavirus/daily-reports/daily-reports-COVID19/>.

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