



London, UK

Cite this as: *BMJ* 2021;372:n149

<http://dx.doi.org/10.1136/bmj.n149>

Published: 15 January 2021

Covid-19: Norway investigates 23 deaths in frail elderly patients after vaccination

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Doctors in Norway have been told to conduct more thorough evaluations of very frail elderly patients in line to receive the Pfizer BioNTec vaccine against covid-19, following the deaths of 23 patients shortly after receiving the vaccine.

“It may be a coincidence, but we aren’t sure,” Steinar Madsen, medical director of the Norwegian Medicines Agency (NOMA), told *The BMJ*. “There is no certain connection between these deaths and the vaccine.”

The agency has investigated 13 of the deaths so far and concluded that common adverse reactions of mRNA vaccines, such as fever, nausea, and diarrhoea, may have contributed to fatal outcomes in some of the frail patients.

“There is a possibility that these common adverse reactions, that are not dangerous in fitter, younger patients and are not unusual with vaccines, may aggravate underlying disease in the elderly,” Madsen said. “We are not alarmed or worried about this, because these are very rare occurrences and they occurred in very frail patients with very serious disease,” he emphasised. “We are now asking for doctors to continue with the vaccination, but to carry out extra evaluation of very sick people whose underlying condition might be aggravated by it.” This evaluation includes discussing the risks and benefits of vaccination with the patient and their families to decide whether or not vaccination is the best course.

More than 20 000 doses of the vaccine have been administered over the past few weeks in Norway and around 400 deaths normally occur among care home residents every week.

The Paul Ehrlich Institute in Germany is also investigating 10 deaths shortly after covid-19 vaccination.¹

Asked if any deaths had occurred in UK patients after vaccination, the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) said that details of all suspected reactions reported in association with approved covid-19 vaccines would be published along with its assessment of the data on a regular basis in the future. Based on the available published reports from the clinical trials, the MHRA said it did not currently anticipate any specific safety concerns.

In a statement, Pfizer said, “Pfizer and BioNTech are aware of reported deaths following administration of BNT162b2. We are working with NOMA to gather all the relevant information.

“Norwegian authorities have prioritised the immunisation of residents in nursing homes, most of whom are very elderly with underlying medical conditions and some of whom are terminally ill. NOMA confirm the number of incidents so far is not alarming, and in line with expectations. All reported deaths will be thoroughly evaluated by NOMA to determine if these incidents are related to the vaccine. The Norwegian government will also consider adjusting their vaccination instructions to take the patients’ health into more consideration.

“Our immediate thoughts are with the bereaved families.”

¹ Zusammenhang unwahrscheinlich: Institut prüft zehn Todesfälle nach Impfung [German]. NTV. 14 January 2021. www.n-tv.de/panorama/Institut-prueft-zehn-Todesfaelle-nach-Impfung-article22292066.html.