

Prognosis

# Norway Raises Concern Over Vaccine Jabs for the Elderly

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- ▶ Death count raised, age threshold lowered from initial report
  - ▶ Country suggests vaccines may be too risky for the elderly
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Norway expressed increasing concern about the safety of the [Pfizer Inc.](#) vaccine on elderly people with serious underlying health conditions after raising an estimate of the number who died after receiving inoculations to 29.

The latest figure adds six to the number of known fatalities in Norway, and lowers the age group thought to be affected to 75 from 80. While it's unclear exactly when the deaths occurred,

Norway has given at least one dose to about 42,000 people and focused on those considered most at risk if they contract the virus, including the elderly.

Until Friday, the vaccine produced by Pfizer and BioNTech SE was the only one available in Norway, and “all deaths are thus linked to this vaccine,” the Norwegian Medicines Agency said in a written response to Bloomberg on Saturday.

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“There are 13 deaths that have been assessed, and we are aware of another 16 deaths that are currently being assessed,” the agency said. All the reported deaths related to “elderly people with serious basic disorders,” it said. “Most people have experienced the expected side effects of the vaccine, such as nausea and vomiting, fever, local reactions at the injection site, and worsening of their underlying condition.”

Official reports of allergic reactions have been rare as governments rush to roll out vaccines to try to contain the global pandemic. U.S. authorities reported 21 cases of severe allergic reactions from Dec. 14-23 after administration of about 1.9 million initial doses of the Pfizer vaccine. The first Europe-wide safety report on the Pfizer-BioNTech vaccine is due to be published at the end of January.

## Australia’s Concern

Australia, which has an agreement for 10 million doses of the Pfizer vaccine, is seeking urgent information on the issue from the producer, health authorities and Norway’s government, Health Minister Greg Hunt told reporters in Melbourne on Sunday.

Australia's Therapeutic Goods Administration will seek "additional information, both from the company, but also from the Norwegian medical regulator," Hunt said. Australia's foreign ministry will also contact its counterpart in Norway on the issue.

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Norway's experience doesn't mean that younger, healthier people should avoid being vaccinated. But it's an early indication of what to watch as countries begin to issue safety monitoring reports on the vaccines. Emer Cooke, the new head of the European Medicines Agency, has said tracking the safety of Covid vaccines, especially those relying on novel technologies such as messenger RNA, would be one of the biggest challenges once shots are rolled out widely.

Though the two Covid-19 vaccines approved so far in Europe were tested in tens of thousands of people -- including volunteers in their late 80s and 90s -- the average trial participant was in his or her early 50s. The first people to be immunized in many places have been older than that as countries rush to inoculate nursing-home residents at high risk from the virus.

## Too Risky

The findings have prompted Norway to suggest that Covid-19 vaccines may be too risky for the very old and terminally ill, the most cautious statement yet from a European health authority.

The Norwegian Institute of Public Health judges that "for those with the most severe frailty, even relatively mild vaccine side effects can have serious consequences. For those who have a very short remaining life span anyway, the benefit of the vaccine may be marginal or irrelevant."

Pfizer and BioNTech are working with the Norwegian regulator to investigate the deaths in Norway, Pfizer said in an e-mailed statement. The agency found that "the number of incidents so far is not alarming, and in line with expectations," Pfizer said.

"We are aware that deaths have also been reported in other countries, but do not have full details of this yet," Norway's medicines agency said. "There are also differences between

countries in who is prioritized for vaccination, and this could also affect the reporting of side effects, including death.”

“The Norwegian Medicines Agency has communicated, prior to the vaccination, that when vaccinating the oldest and sickest, it is expected that deaths will occur in a time-related context with vaccination. This does not mean that there is a causal link between vaccination and death. We have also, in connection with the reported deaths, conveyed that it is possible that common and known side effects of the vaccines may have been a contributing factor to a serious course or fatal outcome,” the agency said.

– *With assistance by David Stringer*

*(Adds comment from Australian minister in sixth paragraph)*

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