COVID-19 vaccination: BioNTech/Pfizer

No. 2020/29, The Hague, December 24, 2020

Executive summary

Health Council of the Netherlands

The BNT162b2 vaccine against COVID-19, which was developed by BioNTech and Pfizer (brand name *Comirnaty*), has recently been assessed by the European Medicines Agency (EMA) and approved by the European Commission. This means that it can be used in the Netherlands to combat the COVID-19 pandemic. The Minister of Health, Welfare and Sport has asked the Health Council of the Netherlands to advise on the use of this vaccine in various target groups that are eligible for vaccination. The Committee on the Medical Aspects of COVID-19 has assessed the vaccine, based on the criteria used by the Health Council when advising on vaccinations.

COVID-19 involves a high burden of disease

When assessing the potential use of vaccination, the first criterion is that there must be a considerable burden of disease. That is clearly the case with COVID-19. By mid-December, the municipal health service (GGD) had confirmed 628,577 cases of disease and 10,168 deaths due to COVID-19. Advancing age and chronic disorders are factors that increase people's risk of severe morbidity. The average age of patients on the wards was 67. For those in the ICU it was 64. The vast majority of deaths have occurred among the elderly, many of whom lived in nursing homes.

The vaccine is effective in adults, the elderly, and in medical risk groups

Another criterion is that vaccination must be efficacious and effective. The vaccine is administered in two doses, approximately three weeks apart. The BNT162b2 vaccine's efficacy against COVID-19 was calculated for a group of over 36,000 people, half of whom received the vaccine and the other half a placebo. This revealed that vaccination provides effective protection for adults, as well as for the elderly and medical risk groups. Its efficacy was well in excess of 90% in all groups. As yet, nothing is known about the duration of protection, nor about the extent to which vaccination might prevent viral transmission.

Vaccine is sufficiently safe: any adverse effects are usually mild

Another important criterion is the safety of vaccination. The BNT162b2 vaccine is sufficiently safe and is well-tolerated. Vaccines, like all medicinal products, can have adverse effects. The purpose of vaccination is to induce a response from the immune system. This is often accompanied by associated transient symptoms. Most of those who are vaccinated with the BNT162b2 vaccine experience adverse effects after both the first and second dose. These mostly involve mild to moderate pain at the injection site, as well as fatigue, headache, and muscle pain. Such reactions were more

common in younger people, and they mostly occurred after the second dose. Most of these adverse effects resolved within a few days after vaccination.

Vaccination is acceptable: the benefits outweigh the drawbacks

In the Committee's view, the benefits of vaccination (health gains resulting from protection against COVID-19) outweigh the drawbacks (adverse effects that are usually mild and short-lived). Thus, the criterion of acceptability has also been met. Given the current lack of data concerning the cost-effectiveness of vaccination, this aspect cannot yet be assessed.

Recommendation: administer the vaccine primarily to elderly people aged 60 and above

Vaccination with the BNT162b2 vaccine is efficacious, sufficiently safe, and acceptable for adults, the elderly, and medical risk groups. Accordingly, the Committee recommends using the BNT162b2 vaccine in public vaccination programmes against COVID-19. The vaccine's efficacy in the elderly – the group with the greatest burden of disease from COVID-19 – exceeds all expectations. Thus, the Committee recommends that the BNT162b2 vaccine should be primarily used in elderly people aged 60 and above, starting with the oldest age group. This is in line with vaccination strategy 1, as formulated in the Health Council's recent advisory report on vaccination strategies. This strategy will deliver the greatest health benefits while also counteracting the influx of COVID-19 patients into hospitals, thereby easing the pressure on the healthcare system. According to the Committee, the BNT162b2 vaccine should only be used to a limited extent, to vaccinate those care-sector staff who provide long-term care. More specifically, this should only be done if the medical risk groups in their care cannot themselves be vaccinated. The vaccine could also be used very selectively in the area of curative care. This would help to maintain the provision of care in situations where a decline in care-worker availability is resulting in acute health impairment. According to the Committee, care workers in general could be vaccinated using the AstraZeneca vaccine. This is based on current projections, which show that as many as 4.5 million doses of this vaccine could be delivered by early 2021.

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).
The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.
Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity.
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Preferred citation:
Health Council of the Netherlands. COVID-19 vaccination: BioNTech/Pfizer.
The Hague: Health Council of the Netherlands, 2020; publication no. 2020/29.