衞生防護中心
Centre for Health Protection

Joint Scientific Committee on Emerging and Zoonotic Disease and Scientific Committee on Vaccine Preventable Diseases

Consensus on the Use of BNT162b2 among Frail Elderly in Hong Kong

(As of 8 February 2021)

Introduction

The Joint Scientific Committee on Emerging and Zoonotic Disease and Scientific Committee on Vaccine Preventable Diseases together with the Expert Advisory Panel to the Chief Executive (JSC-EAP) convened on 7 January 2021, in advance of the completion of the Advisory Panel on COVID-19 Vaccines (AP)'s review of the Emergency Use Approval applications, to provide interim recommendations to the Government on allocation of initial doses, and on COVID-19 vaccines for use in Hong Kong, subject to the approval of emergency use by the Government. The consensus interim recommendations reached subsequent to the joint meeting on 7 January 2021 had been published on the website.

2. The Advisory Panel on COVID-19 Vaccines (Advisory Panel), set up to advise the Secretary for Food and Health on the authorization of

COVID-19 vaccines for emergency use based on the available data concerning safety, efficacy, quality and scientific evidence, issued a report dated 22 January 2021 advising the Secretary for Food and Health (SFH) that under the current pandemic situation, the benefits of the COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection) outweighs its risk for use in Hong Kong for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. On 25 January 2021, the Secretary for Food and Health authorized the emergency use of the BNT162b2 in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K).

3. Currently, BNT162b2 has been used in COVID-19 vaccination programmes in over twenty countries, with varying vaccination policies, population groups prioritized in early phase of programme and immunization safety surveillance systems for adverse events following immunization (AEFI). While the Advisory Panel considered the emerging safety profile of BNT162b2 is presently favourable, it was noted that several death cases in very frail subjects associated with its use were reported in some European countries, such as Norway and Germany. The Advisory Panel suggested the Government to seek more information from the applicant and relevant health authorities to be provided to the Joint Scientific Committees for examination.

4. This consensus statement summarized the information obtained and the latest position of the JSC-EAP on the use of BNT162b2 among frail elderly in Hong Kong.

Background

Adverse events following immunization (AEFI)

5. Adverse events following immunization (AEFI) is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. There should be immunisation safety surveillance systems in place to ensure effective monitoring and prompt actions in response to AEFIs. The causality of each event will then be further evaluated systematically based on multiple criteria. Temporal association between vaccination and the occurrence of adverse events does not necessarily imply causality. Adverse events can simply happen due to coincidental events. Under circumstances where vaccine recipients have underlying comorbidities, it would be particularly difficult to differentiate any coincidental adverse event (including death) from true vaccine-product related reactions.

Reports from overseas jurisdictions on deaths among frail elderly after use of BNT162b2

6. The Department of Health obtained information from various sources, including media reports as well as from overseas health authorities. A summary of such reports and actions from highlighted overseas jurisdictions is provided in Annex 1.

Norway

7. Norway has prioritized residents in nursing homes, persons over 85 year-old, selected groups of healthcare professionals and employees in healthcare service to enroll in its vaccination program. A total of 30 deaths were recorded as of 21 January 2021 after vaccinating around 70,000 people. For some

of the reported cases, the reporting party states that there is no suspected causal relationship with the vaccination. For some other patients with severe frailty to begin with, there is a risk that mild adverse reactions might contribute to a more severe course of their underlying illness, which eventually lead to death. Norwegian Institute of Public Health's latest suggestions has concluded that the majority of frail elderly still benefit from the COVID-19 vaccine, with any side effects of the vaccine outweighed by a reduced risk of a severe COVID-19 disease course. As for people with severe frailty and those with a very short life expectancy, it is advised that the attending doctor should make a careful overall assessment in consultation with the patient and their relatives for a decision on whether to take the vaccine.

Germany

8. As of 17 January 2021, Germany has vaccinated over 1 million people and 21 cases of deaths were reported, including 9 cases having unknown causes of death. These 21 cases had a median age of 87 years, all had underlying diseases such as carcinoma, renal insufficiency, Alzheimer's type dementia, encephalopathy, etc. When compared with the background mortality rate, there is no significant increase in the observed number of deaths.

Switzerland

9. Five deaths were reported in Switzerland after vaccination of about 170,000 elderly as of 21 January 2021. These fatal cases were found to have severe underlying diseases which could explain the deaths. While Switzerland will keep the current vaccination strategy, the health authority stressed the importance of individual benefit-risk evaluation as the AEFIs (e.g. fever) could be harmful to the frail group or terminally ill patients.

Latest assessment by the World Health Organization on safety and efficacy for the use of BNT162b2

10. According to the draft background document prepared by the Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 vaccines published on 14 January 2021, current evidence supports a high level of confidence in older adults (>55 years old) and a moderate level of confidence in individuals with underlying conditions that BNT162b2 are efficacious in preventing COVID-19, with an overall estimated vaccine efficacy of 94.6% (CI: 89.9-97.3%)[1].

11. As for safety assessment for the use among older adults and individuals with comorbidities or health states that increase risk of COVID-19, SAGE considers that there is moderate and low level of confidence respectively that the risk of serious adverse events following one or two doses of BNT162b2 vaccine COVID-19 is low.

12. Subsequent to the reports of deaths among frail elderly following vaccination with BNT162b2, the Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 Vaccine Safety subcommittee met virtually on 19 January 2021 for a careful review of all available information, including overview provided by experts invited from the European Medicines Agency (EMA) and the Uppsala Monitoring Center (UMC) on deaths reported in Europe and in the WHO global database (VigiBase). The subcommittee came to the conclusion that current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2, and the available information does not

[1] World Health Organization. Background document on mRNA vaccine BNT162b2 (Pfizer-BioNTech) against COVID-19. Accessed on 28 January 2021. Available at: https://www.who.int/publications/i/item/background-document-on-mrna-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19

confirm a contributory role for the vaccine in the reported fatal events[2].

Conclusion and Recommendation

13. Based on the available information and recommendations from overseas jurisdictions and the World Health Organization as of January 2021, there is currently no evidence suggestive of any unexpected or untoward increase in mortality in frail elderly following the use of BNT162b2. There is also no clear evidence suggesting the reported deaths were due to the use of BNT162b2.

14. It is concluded by the JSC-EAP that for most frail elderly, the benefit of reducing the risk of a severe COVID-19 disease course outweighs the risk of receiving the vaccine.

15. **For elderlies with severe frailty** (e.g. bedridden elderly in RCHE) especially those at the most extreme age groups (such as those above 85 years old), any mild adverse event from pharmaceutical products including vaccines might worsen their original disease course or condition. **The benefits and risks of receiving BNT162b2 in these particular groups should be evaluated separately by attending clinicians and such clinical assessment should be exercised with greater caution.** As stated in the consensus interim recommendation published in January 2021, any individual who is experiencing acute febrile diseases should delay their vaccination and this recommendation applies to the use of BNT162b2 among frail elderly.

16. Currently, safety data on the use of BNT162b2 remains limited and long term data are lacking. As mass COVID-19 vaccination programs continue

[2] World Health Organization. GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2. Available at: https://www.who.int/news/item/22-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2

worldwide, information regarding rare adverse events and long term side effects will be emerging. Any latest reports and data regarding the safety and efficacy of BNT162b2 should be closely monitored and the benefit-risk balance should be re-evaluated for the safety of the population, including the subgroup of frail elderly.

Annex 1: Reports of deaths related to use on BNT162b2 in highlighted countries

Reporting country	Vaccine candidates used in programme	Vaccinated population	Number of death reported	Details of death cases	Number of AEFIs reported	Age distribution (year) of patient with AEFIs	Investigation/causality assessment	References
Germany (as of 17 Jan 2021)	Comirnaty Moderna	1,139,297 (99.8% Comirnaty)	21	14 female 7 male Age range: 56-99 yr Mean age: 83.5 yr Median age: 87 yr	647	< 60: 420 60-79: 74 80 +: 74 Unknown: 79	All death cases have underlying disease and there was no significant increase of mortality rate compared to baseline mortality rate	https://www.pei.de/DE/newsroom/dossier/coronavirus/coronavirus-inhalt.html;jsessionid=00BBE4BD57A1574364CC37B0CD08933F.intranet242?nn=169730&cms_pos=5
Norway (as of 21 Jan 2021)	Comirnaty Moderna	71,971 (Unknown % Comirnaty)	30	Not available	104	18-59: 20 60-79: 18 80 +: 62 Unknown: 4	Majority of frail elderly would benefit from the COVID-19 vaccines	https://legemiddelverket.no/nyheter/reported-suspected-adverse-reactions-to-covid-19-vaccines-as-of-21-january-2021

Reporting country	Vaccine candidates used in programme	Vaccinated population	Number of death reported	Details of death cases	Number of AEFIs reported	Age distribution (year) of patient with AEFIs	Investigation/causality assessment	References
								https://legemiddelverket.no/Documents/Engli sh/Covid- 19/Reported%20suspected%20adverse%20reactions%20to%20coronavirus%20vaccines%20as%20of%20January%2021%202021.pdf
Switzerland (as of 21 Jan 2021)	Comirnaty Moderna	About 170,000 (Mostly elderly) (Mostly Comirnaty)	5	Age range: 84-92 yr	42	Not available	No concrete evidence to suggest the vaccination was the cause of death	https://www.swissmedi c.ch/swissmedic/en/ho me/news/coronavirus-covid- 19/verdachtsmeldunge n-impfstoff-covid19.html