The Hong Kong College of Paediatricians and Hong Kong Society for Paediatric Immunology Allergy and Infectious Diseases

Joint Position Statement on BioNTech Vaccination in Adolescents with Allergic Diseases

Background

The COVID-19 pandemic has struck the world for 18 months now. Although COVID-19 mainly affects the elderly and those with chronic medical conditions, children can also suffer physically from this viral infection. Furthermore, children and adolescents are disproportionally affected by the adverse psychosocial effects of prolonged school closure, denial of play opportunities in playgrounds, social restriction, isolation in quarantine facilities and rising rates of domestic violence and child abuse.[1]

Meticulous infection control practice, social distancing and mass COVID-19 vaccination are the key strategies to contain the present pandemic and minimise its public health and societal impact. The first COVID-19 vaccines approved in Hong Kong include BioNTech BNT162B2 mRNA vaccine (Comirnaty) and inactivated virus vaccine (CoronaVac). As of 15 June 2021, Hong Kong has administered a total of 2,964,805 vaccine doses, including 1,203,222 (17.7%) with the second vaccine dose, out of its 7,510,000 population (as of 2019).[2, 3] This suboptimal vaccine uptake raises concerns about our inability to establish sufficient herd immunity in our community to halt or mitigate the COVID-19 pandemic. Our College has recently issued an appeal to adults in stable health to receive COVID-19 vaccines as an effective and safe method to protect themselves and their children from being infected.[4]

The FDA expanded the emergency use authorisation of the BioNTech vaccine to include adolescents aged 12-15 years on 10 May 2021, in addition to its existing licensure for subjects aged 16 years and older.[5] In Hong Kong, the Secretary for Food and Health announced on 3 June 2021 to lower the age limit for the BioNTech vaccination programme from 16 to 12 years. Despite the large numbers of adults and adolescents who have already received mRNA vaccines worldwide, adverse events have only rarely been reported. Nevertheless, there have been reports of severe allergic reactions to these vaccines which, in view of the high prevalence of allergic diseases in adolescents, have led to growing concerns amongst parents about whether youngsters with allergic diseases are fit to receive this vaccine.

This Position Statement encourages adolescents aged 12-17 years old to receive the BioNTech vaccine and includes a fact sheet on this vaccine and recommendations about when to consider referral to a College-accredited Paediatric Immunology, Allergy and Infectious Diseases (PIAID) Fellow for evaluation.

Fact sheet related to allergies and the BioNTech vaccine

- This vaccine is packaged in multi-dose vials and must be diluted before use. There are no added adjuvants or preservatives, while lipids, sucrose and salts are added as excipients to stabilise the active vaccine substance (mRNA encoding SARS-CoV-2 spike glycoprotein).
- This mRNA vaccine does not contain any live virus, so it can be safely given to patients with impaired immune response. However, it is possible that the vaccine immunogenicity and efficacy are lower in such patients.
- Most adverse events (e.g., injection site pain and redness, fatigue, headache, fever, chills, myalgia, arthralgia, regional lymphadenopathy) following immunization are a result of the vaccine stimulating a protective immune response instead of being allergic in nature.
- Allergic reactions after BioNTech vaccine have been reported to occur in 11.1 cases per one million doses, including anaphylaxis in 5 cases per one million doses.[6] Other allergic reactions include skin rash, urticaria and lip/face angioedema. Seventy-one percent of these allergic reactions occurred within 15 minutes of vaccination. To date, there has not been any confirmed anaphylactic death due to this vaccine.
- Anaphylaxis can happen to anyone, anywhere and anytime. There is no correlation with age, sex, asthma, atopic status or previous non-severe reactions.[7]
- Polyethylene glycol (PEG), also known as macrogol, is a polyether compound widely used as an additive in cosmetics, pharmaceutical products and foods. For this vaccine, a PEG with a molecular weight of 2,000 g/mol (PEG 2000) is used to improve the aqueous solubility of the lipid nanoparticle.[7]
- IgE-mediated allergic reactions and anaphylaxis to PEGs of different molecular weights have previously been reported.[8] However, PEG allergy and anaphylaxis following mRNA vaccination are rare.

Position statement on the relevance of allergies to BioNTech vaccination

The personal and societal benefits of BioNTech vaccination outweigh the risk of non-severe adverse vaccine reactions in adolescents. In particular, a very recent study showed that this vaccine was highly effective against COVID-19 and safe when administered to 12-to-15-year-old recipients.[9]

At this time, the BioNTech vaccination is ***contraindicated only*** under the following condition: individuals with a history of anaphylaxis[10] to this vaccine or its components (e.g., PEG) as confirmed by appropriate allergy testing (Appendix 1 – anaphylaxis defining criteria).

Subjects require ***referral and evaluation*** of their fitness to receive the BioNTech vaccine by one of the College-accredited PIAID Fellows if they have:

- History of *immediate* and *severe* allergic reactions to *drugs or vaccines containing PEG* (Appendix 2 – list of PEG-containing drugs);
- History of *immediate* allergic reaction to the first dose of BioNTech vaccine

"*Severe*" refers to occurrence of any non-cutaneous adverse reactions (e.g., respiratory, cardiovascular or severe gastrointestinal); "*immediate*" means within 4 hours.

Allergy to unrelated drugs, food, insect venoms or inhalant allergens (e.g., house dust mites, pollens, animal dander, moulds) as well as asthma, allergic rhinitis and eczema are ***not contraindications*** for BioNTech vaccination. Individuals with these allergic conditions can receive the BioNTech vaccine.

The above recommendations are supported by authorities and organizations including the US Food and Drug Administration and drug package insert, US Centers for Disease Control and Prevention, American Academy and College of Allergy, Asthma and Immunology, Australasian Society of Clinical Immunology and Allergy, Ministry of Health of Singapore and the Scientific Committee on Vaccine Preventable Diseases of the Centre for Health Protection, Department of Health, the Government of the HK Special Administrative Region.[5, 11-15]

COVID-19 vaccine recipients should be observed for at least 15 minutes after vaccination. Patients with a history of severe allergic reactions after foods, unrelated drugs or vaccines can proceed with BioNTech vaccination, but they are advised to be given a longer observation (30 minutes) after vaccination.[16]

Clinicians administering the BioNTech vaccine should be prepared to recognise symptoms of anaphylaxis as early as possible, promptly manage such severe allergic reactions, and activate further emergency medical services while continuing to care for the patient.[16] Patients who develop immediate allergic reaction after the first dose of BioNTech vaccination should be referred to a College-accredited PIAID Fellow for evaluation. *Unless such evaluation excludes BioNTech allergy, these patients should not receive the second dose of this vaccine.*

As COVID-19 vaccines are administered to millions of people globally in the upcoming months, more pharmacovigilance and post-marketing surveillance data will be available to assess the incidence of vaccine allergy and its risk factors as well as the occurrence of rare immune-related adverse events. In case of any change in the licensed age limit for an inactivated virus vaccine and availability of other marketed COVID-19 vaccines and newer generation of vaccines in the future, there will be additional vaccination options and allergy testing strategies.[17] Our College and Society will update this document in due course.

This document was endorsed by the Councils of both organisations on 15 June 2021.

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