

### Updates on adverse events following immunization with influenza vaccine

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October 24, 2020

With the rise in reported cases of serious adverse events following immunization with influenza vaccines, Vaccination Injury Investigation Group and Korea Expert Committee on Immunization Practices (KECIP) were convened on 23 and 24 of October, respectively, to review the results of epidemiological investigation and to discuss vaccination safety. The death cases reviewed so far have been assessed to have very low causality to vaccination. Continued vaccination is advised for influenza prevention. KDCA advised that the investigation results should be shared with relevant institutions and that people who receive vaccination should be fully informed of the safety measures.

#### Reports of adverse events following influenza vaccination

- A total of 1,154 cases of adverse events following influenza vaccination have been reported this year up to 23 October. Causality to vaccination has not been found.
  - Local reactions (177 cases)
  - Allergic reactions (245 cases)
  - Fever (204 cases)
  - Other (480 cases)
- Among them, 99 cases of adverse events following immunization have been reported related to vaccines subject to recall or collection related to vaccine distribution and white particles.
  - Local reactions (38 cases)
  - Allergic reactions (22 cases)
  - Headache / muscle pain (7 cases)
  - Stomachache / vomiting (4 cases)
  - Other (10 cases)

#### Deaths following influenza immunization

Total	Sex		Age group					
	Male	Female	Under 60	60-69	70-79	80 and above		
45(3)	25(1)	20(2)	5	2	22(1)	16(2)		

\* Number of reported deaths during the period 10.16.~10.24.13:00

\*\* The figures inside parentheses indicate deaths following report of severe reaction



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Total	City										
	Seoul	Busan	Daegu	Incheon	Gwangju	Daejeon	Ulsan	Sejong			
45 (3)	6	2	5	2	0 (1)	1 (1)	0	0			
Province											
Gyeonggi	Gangwon	Chung- buk	Chung- nam	Jeon- buk	Jeon- nam	Gyeong- buk	Gyeong- nam	Jeju			
3 (1)	2	0	3	5	5	4	6	1			

- \* The above figures include reported cases for which no causal relationship to vaccines or immunization has been found and should not be construed as indicating deaths caused by immunization.
- □ Korea Expert Committee on Immunization Practices (KECIP) held on 24 October were informed of the findings from investigation by the Vaccination Injury Investigation Group. Both the KECIP and the Investigation Group are of the view that the deaths reviewed so far have low causal link to the immunization.
  - Anaphylaxis was one of the most common serious adverse events following influenza immunization within 24 hours.
    - After reviewing the individual cases, the Injury Investigation Group concluded that all 26 cases of deaths reviewed have low causality between death and immunization based on temporal proximity, underlying medical conditions, and autopsy results.
  - Retesting or discontinuation of vaccines will be considered in the future if two or more severe adverse events (such as death) occur from the same lot number and the causality between the adverse event and immunization cannot be excluded.
  - According to the 20 interim autopsy results by National Police Agency and National Forensic Service, 13 cases were identified with cardiovascular diseases (8), cerebrovascular disease (2), or other (3) from the primary autopsy findings. (These are interim results and subject to change upon new findings)
  - Upon comprehensive review of the findings, the Expert Committee on Immunization Practices stressed the importance of the need for influenza vaccination to reduce the risk in light of the ongoing current COVID-19 pandemic.
    - The Committee recommended that the influenza immunization program should be continued as scheduled and recommended preliminary examination for the elderly before administrating vaccine and sufficient observation for any adverse events following the vaccine administration.
- □ KDCA Commissioner Dr. JEONG Eun Kyeong advised the public to take time to receive immunization on a day with good health condition as this season's influenza duration and scale is projected to likely be relatively small and delayed in comparison to previous years.



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- The commissioner also recommended the public to drink plenty of water while waiting to receive vaccination and to disclose any pain, chronic conditions, or history of allergic reactions to the healthcare provider prior to receiving vaccination and to stay in the clinic or hospital for 15-30 minutes after receiving the vaccine for observation for any possible adverse reactions and to take sufficient rest on the day of immunization.
- O Temporary minor reactions to vaccination such as topical pain on the vaccinated spot, reddish swelling, edema, muscle pain, fever, or nausea are common and will usually disappear within 1-2 days. However, in the event of shortness of breath, rashes, or severe dizziness following immunization, medical attention should be sought immediately.