

Fluzone® High-Dose Influenza Vaccine Question and Answer Document Updated - September 2017

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1. What is high dose inactivated influenza vaccine and how is it different from other influenza vaccines?

High dose trivalent inactivated influenza vaccine (HD TIIV) or Fluzone® High-Dose is an unadjuvanted vaccine that contains a higher antigen content per dose than standard dose (SD) TIIV formulations. HD TIIV contains 60 µg of hemagglutinin (HA) protein for each of the three vaccine strains (180 µg in total) compared to 15 µg of HA per strain (45 µg in total) in SD TIIV. Both HD and SD TIIV are delivered by intramuscular (IM) injection in a 0.5 mL volume per dose. HD TIIV comes in a 0.5 mL pre-filled syringe.

2. For whom is this vaccine indicated?

Fluzone® High-Dose is approved for use in Canada for adults 65 years of age and older.

3. What is the safety profile of high dose inactivated influenza vaccine?

In some studies, HD TIIV has been associated with a higher rate of injection site (e.g., pain, induration) and systemic reactions (e.g., malaise, myalgia, fever) in the 7 days following vaccination

than SD TIV, but these adverse events were typically mild and short-lived with most resolving within three days. Serious adverse events (SAEs) were rare, and similar in frequency to SD TIV. However, studies to date were likely under-powered to detect rare SAEs, such as Guillain-Barré Syndrome. Post-marketing surveillance of vaccine safety remains an important process to which all vaccine providers are expected to contribute.

4. What is the current National Advisory Committee on Immunization (NACI) recommendation for use of HD TIV?

The NACI Statement on Seasonal Influenza Vaccine for 2017-2018 indicates four types of influenza vaccines are available for use in elderly Canadians 65 years of age and older, without explicitly recommending the preferential use of one product over another.

The NACI statement also concludes that, based on the available evidence, HD TIV should provide superior protection compared with standard dose TIV for adults ≥ 65 years of age and that superior relative protection compared to standard dose TIV appears to increase with increasing age over 65 years. This may be interpreted by some as indicating a NACI preference for the use of HD TIV in elderly adults. Provincial and territorial immunization program committees have sought clarity from NACI on this issue and NACI has confirmed that a preferential use recommendation for HD TIV was not their intent. NACI has instead clarified that any influenza vaccine currently approved for use in Canada may be used to provide protection against seasonal influenza in seniors.

While there are preliminary indications that adults 65 years of age and older may be relatively better protected by HD TIV, additional studies are needed to confirm enhanced benefits that are consistent across seasons and vaccine strains, and especially among adults over 75 or 85 years of age who are most vulnerable to the severe complications of influenza. Furthermore, other considerations not taken into account by NACI, such as absolute impact and incremental cost-effectiveness, also apply in determining whether a particular vaccine product warrants preferential recommendation and public funding over other available options.

5. What is the current Advisory Committee on Immunization Practice (ACIP) recommendation for use of HD TIV in the United States?

The US Advisory Committee on Immunization Practices has also not recommended preferential use of any particular influenza vaccine for elderly adults 65 years of age and older. HD TIV has been approved for use in the US since 2009.

6. Why is HD TIV not publicly funded in BC?

In addition to approval by Health Canada and a recommendation for use based on available scientific evidence by NACI, other factors are also relevant for provinces to consider when deciding whether a vaccine product should be preferentially funded over other available options. This includes consideration not only of relative protection but also absolute reduction in disease burden,

the numbers needed to vaccinate to achieve that, the relative costs and incremental cost effectiveness, as well as feasibility and logistics of implementation.

The BC Communicable Disease Policy Advisory Committee has reviewed the information currently available on HD TIIV. The cost of high dose TIIV is more than 8 times that of standard dose TIIV. Although the NACI statement states that based on available evidence, high dose TIIV should provide superior protection compared to standard dose TIIV for adults 65 years of age and older, this is based on the limited information available to date. The Committee concluded that the strength of the evidence and anticipated incremental benefit of high dose TIIV relative to standard dose TIIV is not commensurate with the additional cost. A similar decision has been made in the other Canadian provinces and territories for the 2017-18 season with the exception of Manitoba where Fluzone® HD will be offered to residents of long term care facilities 65 years of age and older.

7. What is my professional responsibility to tell clients/patients that this product is an alternative to publicly funded influenza vaccine?

It is important to recommend influenza vaccine to your patients who are 65 years of age and older to protect them from the serious complications of influenza.

However, there are several influenza vaccines on the Canadian market in any given season, and not all are provided in every jurisdiction or through publicly funded programs.

Given the lack of an explicit recommendation for preferential use of high dose TIIV by NACI and/or endorsement of superiority by provincial advisory committees, providers are under no greater obligation to inform patients of the high dose TIIV option than any other TIIV product approved for seniors in Canada.

In contrast, providers are expected to inform their patients about availability of vaccines for which there is not a publicly funded option (e.g., zoster vaccine).

8. Where can I obtain more information on HD TIIV?

The following sources of information are available online:

- NACI [Statement on Seasonal Influenza Vaccine for 2017-2018](#)
- Sanofi Pasteur [product monograph](#)
- Sanofi Pasteur [Fluzone® High-Dose](#) page

9. Where can members of the public access high dose influenza vaccine?

HD TIIV will be available through many pharmacies throughout BC.