

Flu-vaccine concerns: Current information – Oct 30th, 2012

There is much public concern about the recent flu-vaccine recall from Novartis, and understandably so. Also, many news reports are presenting different information about what the impact of the recall and what it means.

The recall affects Agriflu® and Fludac®, both of which have been used in Saskatchewan; as such, the Saskatchewan vaccination program has been temporarily halted. All of Saskatchewan's supply is currently from Novartis. The vaccines have NOT been recalled, but distribution and administration has been halted until analysis is complete.

The following is a summary of Novartis' official statements regarding the recall, as well as information put out by local health authorities.

Novartis' Statements (1,2,3):

- Reason for recall:
 - One batch of Agriflu® and Fludac®, which was NOT distributed, was found to have visible protein aggregates
 - The protein aggregates have been identified as hemagglutinin and neuraminidase, which are the proteins found on the outside shell of a flu virus
 - The protein aggregation has not been seen in any other batches of vaccines produced in the facility
- Safety concerns:
 - Protein aggregates do not cause any harm
 - Protein aggregates naturally occur in vaccines commonly and dissolve when shaken up
 - It is standard vaccination procedure to visually verify the vaccine is free of particulate matter before administration
 - If particulate matter is found in the vaccine which does not dissolve after shaking, it is not administered
 - Of the 2 million doses administered so far, no adverse effects have been reported
 - A doctor visit is NOT necessary
- Efficacy concerns:
 - Protein aggregates do not affect the efficacy or potency of the vaccine
 - Testing has confirmed the potency of the vaccines
 - Re-vaccination is not necessary

Health Region's Statements:

- Safety concerns:
 - Protein aggregate could be a cause for an allergic reaction (4)
 - However, this would be an immediate reaction, so anyone who has already been vaccinated have no reason to worry
 - No other safety issues identified (5)
- Efficacy concerns:
 - Protein aggregates have been observed in vaccines in the past which have not caused a loss of efficacy (5)
 - However, one expert notes that too much protein aggregation can potentially reduce the immune response and also increase post-vaccine reactions (sore-arm, redness at injection site) (6)

Summary

The vaccine has been suspended for use as a precautionary measure. There are no safety issues identified, and likely no efficacy issues requiring re-vaccination.

References:

1. Novartis, *10 key facts at a glance – Novartis Influenza Vaccines*.
<http://www.novartis.com/downloads/newsroom/product-related-info-center/10-Key-Facts-at-a-Glance-en.pdf>
2. Novartis, *Q&As with Jeffry Stoddard, Head Global Medical Affairs*.
http://www.novartis.com/downloads/newsroom/product-related-info-center/QAs-with-Jeffrey-Stoddard-Head-Global-Medical-Affairs-Novartis_en.pdf
3. Novartis, *Information for Doctors and Patients*.
<http://www.novartis.com/newsroom/product-related-info-center/influenza-vaccines-information-center/information-for-doctors.shtml>
4. Interview with Dr. Paul Hasselback, Vancouver Island Health Authority:
<http://www2.canada.com/nanaimodailynews/news/story.html?id=070dfc1e-9e89-4591-ae71-272a1d0e5b69>
5. Health Canada notification, http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2012/2012_162-eng.php
6. Interview with Dr. Allison McGeer; Infectious Disease consultant Mount Sinai Hospital, Toronto:
<http://www.cbc.ca/player/News/Health/ID/2297503804/>

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