



Nebraska Department of Health and Human Services



HEALTH ALERT NETWORK

Update



TO: Nebraska Healthcare Providers and Public Health Partners

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RE: **Updated Guidance for the use of CSL's 2009 H1N1 Monovalent Vaccine**

DATE: December 1, 2009

CSL Biotherapies is an authorized manufacturer of both the 2009 trivalent seasonal flu vaccine and the 2009 H1N1 Monovalent Influenza Vaccine. Both of these vaccines are formulated as a multidose vial (10 doses/vial) and as a single-dose (0.5 cc) prefilled syringe. Until recently, these vaccines were approved only for persons aged 18 years and older.

The FDA expanded the approved use of these vaccines to include children aged 6 months and older. The immediate affect on the national H1N1 flu vaccination program is that CSL's pre-filled syringe and multi-dose vial formulations can now be used in substantially broader range of ages. CDC is making a programmatic recommendation and issuing clarifying guidance on use of CSL 2009 H1N1 monovalent vaccine that takes into account practical logistical considerations of allocation, ordering, and distribution of vaccine and ancillary supply kits.

Recommendation

Both the CSL H1N1 monovalent pre-filled syringe and multi-dose vial vaccine formulations should be reserved for individuals aged 3 years and older if alternative products are available.

Rationale

Pre-filled syringe presentation: Using the CSL H1N1 pre-filled syringe vaccine in children aged 6-35 months would result in wastage of one dose per syringe. Since children aged 6-35 months would only require a half dose of this vaccine, only half of the contents of the syringe could be used. Transfer of some or all of the contents of one syringe to another syringe is not permissible nor is using the same syringe to administer the remaining half dose to another individual. Therefore, the only option is to discard the remaining half

dose. With the current limited supply and availability of vaccine nationwide, CDC discourages using a half dose of CSL H1N1 pre-filled syringe vaccine on a child aged 6-35 months and discarding the remaining half dose.

Multi-dose vial presentation: While CSL's H1N1 multi-dose vial vaccine is now licensed for use in individuals aged 6 months and older, CDC is treating this formulation as being for use in individuals aged 3 years and older for the purpose of allocating and ordering vaccine and ancillary supply kits (the multi-dose vial kits used for all H1N1 vaccines contain supplies that are intended for use in children and adults aged 3 years and older). CSL H1N1 multi-dose vial vaccine formulation will continue to be ordered as a 100 dose (0.5mL per dose) minimum order size and CDC will allocate one multi-dose vial ancillary supply kit for each 100 doses of multi-dose vial vaccine. If providers choose to administer half doses of the multi-dose vial formulation to children aged 6-35 months, they will effectively be short half the number of needle/syringe units, alcohol pads, vaccination record cards and sharps containers. Providers will be required to use their own ancillary supplies to make up the difference and print out additional shot cards from the CDC website (http://www.cdc.gov/flu/freeresources/2009-10/pdf/influenza_record_card2009.pdf). This situation also applies to the Sanofi Pasteur multi-dose vial vaccine formulation that is licensed for individuals aged 6 months and older.

If you have any questions or need clarification on this guidance please contact the CDC Immunization Desk at eocimmunization@cdc.gov.

Information regarding the approval by the FDA may be found on the internet at the following address:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181975.htm>