

Poster Section: Vaccine Development and Production, Immunization

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Poster Title: Prospective Pilot Safety Study Administering 2 Doses of Inactivated Influenza Vaccine to Infants 10 to 22 Weeks of Age

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Background: Although infants younger than 6 months have the highest influenza hospitalization rates, trivalent inactivated influenza vaccine (TIV) is not licensed for use in this age group.

Objective: To assess the safety and immunogenicity of 2 doses of TIV administered to infants.

Method: Healthy infants (10 to 22 weeks of age) received two 0.25 ml doses of either the 2004-2005 or 2005-2006 TIV vaccine formulation separated by at least 28 days and separated from routine infant vaccinations by 14 days. Reactions were assessed by daily diary cards and telephone calls for 7 days after vaccination. Serum was collected prior to the first dose of vaccine and 1 month after the second dose for hemagglutination inhibition antibody (HAI) titers. During influenza season, weekly telephone surveillance was conducted, and infants with fever or respiratory symptoms had nasal washes performed for viral culture.

Results: In 2004-2005, 19 infants completed the study, and 23 infants completed the study in 2005-2006. The mean age at enrollment was 16 weeks. TIV was well tolerated, with no fever attributed to vaccination. Local injection-site symptoms included pain in 21.4%, redness in 19%, and swelling in 7%. HAI data are shown below. After dose 2 of TIV, seronegative infants (pre-titers <1:8) were significantly more likely to have a seroresponse (postvaccination titer of $\geq 1:8$) than seropositive infants for both H1N1 and H3N2 ($P < .01$). Immune responses to influenza B were uniformly poor. One child developed influenza B with a mild clinical course.

Conclusion: Two doses of TIV administered at 10 to 22 weeks of age appears to be safe. The presence of maternally derived antibody titers prior to administration with TIV is associated with a lower rate of seroresponse to H1N1 and H3N2 in the infants

Prevaccination titer	Seroresponse (4-fold increase)		
	Yes	No	Total
Influenza H1N1 Seronegative (< 1:8)	15	7	22
Seropositive ($\geq 1:8$)	4	14	18
<i>P</i> value=.005			
Influenza H3N2 Seronegative (< 8)	17	13	30
Seropositive (≥ 8)	1	9	10
<i>P</i> value=.013			
Influenza B Seronegative (< 8)	2	26	28
Seropositive (≥ 8)	2	10	12
<i>P</i> value=.570			