



DEFENSE HEALTH BOARD
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FALLS CHURCH, VA 22041-3206

MAY 5 2008

DHB

MEMORANDUM FOR: The Honorable S. Ward Casscells, Assistant Secretary of Defense for Health Affairs

SUBJECT: Off-Label Vaccine Use and Vaccination of Military Recruits During Summer Months

1. References:

- a. Presentation: Vaccine Use in Military Recruits to the Defense Health Board, 12 December 2007, by CAPT Neal A. Naito, Public Health Bureau of Medicine and Surgery, Department of the Navy.
2. At the request of the Navy Public Health Advisory Board, the Defense Health Board was asked to deliberate and make recommendations on the following questions:
 - a. Whether recruits younger than 18 years of age develop less immunity when receiving a mixed series of pediatric and adult doses of a particular vaccine as opposed to receiving only the adult dose.
 - b. If recruits at basic training should be vaccinated against influenza if vaccines were made available during the summer period.
3. The Navy brought the questions forward as a result of the issues experienced with Twinrix®. The Board received a presentation from the Public Health Bureau of Medicine and Surgery and reviewed minutes from the meeting held on 12 December 2007.

FINDINGS

4. Recruits under 18 years of age currently receive pediatric vaccination doses. For series vaccinations, recruits under 18 years receive the pediatric followed by the adult dose. The combination Hepatitis A and B vaccine (Twinrix®) is of particular interest, since there is a different dosing schedule for recipients less than 18 years of age, than for adults. Single dose vaccinations of Havrix® (Hepatitis A) and Energix® (Hepatitis B) are administered to military recruits under 18 years of age, and comprise half of the adult doses. The concern arises as to whether recruits who are younger than 18 years of age develop less immunity when receiving a mixed series of pediatric and adult doses of a vaccine.
5. The cutoff age of 18 years for Twinrix® is based on issues pertaining to current licensure of this product in the US for adults age 18 years and older. At present, no scientific evidence exists indicating Twinrix® would not be safe or effective in 17-year old recipients.

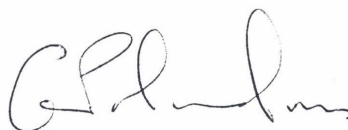
SUBJECT: Off-Label Vaccine Use and Vaccination of Military Recruits During Summer Months- DHB 2008-05

6. Currently, administration of influenza vaccine at military basic training sites is discontinued annually when the vaccine's expiration date is reached. Vaccinations are restarted when the next year's vaccine becomes available in the fall.
7. According to data from the Febrile Respiratory Illness Surveillance Network maintained by the Naval Health Research Center (NHRC), several cases of influenza A H3 occurred during July-August 2007 in basic training at Fort Benning, the Marine Corps Recruit Depot (MCRD) at San Diego, and within a fleet after port stops in the South Pacific. Therefore, influenza constitutes a risk to recruits and can adversely impact basic training during summer months.
8. At this time, no scientific data indicates the administration of influenza vaccine to military recruits during summer months would result in adverse immunologic effects.

CONCLUSIONS

9. **Based on the above findings, the Board provides the following recommendations to the Department:**
 - a. **Currently there is no biological evidence indicating that a difference in immunity, and thus vaccination efficacy, would result from the mixed use of pediatric and adult vaccine doses among recruits less than 18 years of age.**
 - b. **The adult dose age cut-off of 18 years is driven by administrative matters (such as age of consent) rather than biological data. The Board recognizes that with the exception of documented immunological differences between neonates and adults, there is no evidence defining a clear biological basis for an age cut-off for the administration of pediatric versus adult vaccine doses. Although this scientific question is not fully relevant to DoD, it is an area where further research is needed.**
 - c. **Giving last year's influenza vaccine to basic trainees should not preclude providing them with the current year's influenza vaccine when it becomes available. In many cases, the Service member will have completed training and arrived at his/her permanent duty station.**
10. The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:



Gregory A. Poland, M.D.
DHB, President

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Months- DHB 2008-05

cc:

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