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HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

28 OCT 1999

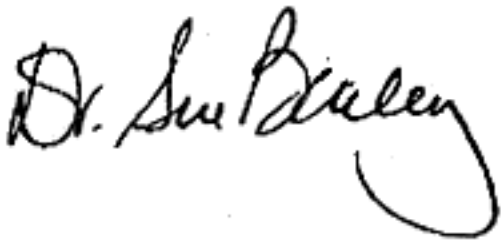
MEMORANDUM FOR: SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE
DEPUTY DIRECTOR FOR MEDICAL READINESS, J-4,
THE JOINT STAFF

SUBJECT: Policy for the Use of Lyme Disease Vaccine

The Department of Defense policy shall be to provide Lyme disease vaccine to beneficiaries of the Military Health System in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC). Persons requesting Lyme disease vaccine shall be informed of the available data on the safety and effectiveness of the vaccine, the continued importance of personal protective measures and avoidance of tick habitats in preventing infection, and the criteria used to assess individual risk. The decision to administer Lyme disease vaccine should be based on an assessment of individual risk, which depends on a person's likelihood of being bitten by *Borrelia burgdorferi* infected ticks. The attached information paper provides details of the ACIP recommendations.

Lyme disease vaccine is not recommended as a routine vaccine for military service members. The vaccine should be considered for occupational groups of military members and/or Department of Defense civilian employees whose duties result in frequent or prolonged exposure to tick-infested habitats in areas of high or moderate risk for Lyme disease. Lyme disease vaccine is not recommended for persons who have minimal or no exposure to tick-infested habitat. It is not recommended for persons who reside, work, or recreate in areas of low risk or no risk. The vaccine shall not be administered to children less than age 15 years.

This policy is effective immediately and shall be included in Service and Joint Staff plans and policies for immunization of military members and other health care beneficiaries. TRICARE regions and medical treatment facilities are encouraged to develop policies and procedures for responding to requests for Lyme disease vaccine. Local policies should be made in consultation with local civilian and military public health officials. Any requests for additional funding should be forwarded through Service channels along with an outline of the local policies that justify the unfunded requirement to provide the vaccine.



Dr. Sue Bailey

Attachment:
As stated

Additional Information on the Use of Lyme Disease Vaccine

The Centers for Disease Control and Prevention (CDC) published the "Recommendations for the Use of Lyme Disease Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" in *Morbidity and Mortality Weekly Report*, Vol. 48, No. RR-7, June 4, 1999. The complete ACIP recommendation report is available online at: ttp://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4807a1.htm.

The Food and Drug Administration licensed LYMErixä (Lyme Disease Vaccine, Recombinant OspA), SmithKline Beecham Pharmaceuticals, for use for persons 15-70 years in the United States. Three doses of LYMErixä are required for optimal protection. The first dose is followed one month later by a second dose; a third dose is administered 12 months after the first dose. Vaccine administration should be timed so that the second dose of the vaccine (year one) and the third dose (year two) are given several weeks before the beginning of the *B. burgdorferi* transmission season, which usually begins in April. In clinical studies, the vaccine efficacy in preventing Lyme disease in the first year (after 2 vaccine doses) was 49% and increased to 76% in the second year after the third dose. Although there are no formal recommendations for booster doses at this time, vaccine efficacy appears to decrease after two years and additional booster doses may be required in order to maintain acceptable levels of protective immunity.

In the randomized, controlled (phase III) clinical trial of LYMERix^{TM}, 5,469 subjects received at least one dose of vaccine and 5,467 subjects received at least one injection of placebo. Unsolicited reports of soreness at the injection site were received from 24.1% of vaccine recipients and 7.6% of placebo recipients. Myalgia, influenza-like illness, fever, and chills were more common among vaccine recipients than placebo recipients, but none of these symptoms were reported by more than 3.2% of subjects. Per the vaccine's package insert, when a subset of Lyme disease vaccine recipients were surveyed, 93% reported local soreness, 41% reported local redness, and 3.4% reported fever. The safety and efficacy data for licensure of the Lyme disease vaccine came from clinical trials involving 6,478 individuals who received a total of 18,047 doses of vaccine; most had follow-up for 20 months after receiving the first dose of the vaccine. There were no statistically significant differences in the incidence of adverse events more than 30 days after receiving a dose of vaccine between vaccine and placebo groups in the phase III trial.

The ACIP recommends that Lyme disease vaccination should be considered for persons aged 15-70 who

reside, work, or recreate in areas of high or moderate risk AND engage in activities (e.g., recreational, property maintenance, occupational, or leisure) that result in frequent or prolonged exposure to tick-infested habitat. Lyme disease vaccination may be considered for persons who are exposed to tick-infested habitat in high or moderate risk areas but whose exposure is neither frequent nor prolonged. At present, CDC identifies at least some counties in the following states as having areas of high risk for Lyme disease: Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Wisconsin. Some counties in the following states currently are identified as having areas of moderate risk for Lyme disease: California, Minnesota, Vermont, Illinois, and Indiana.

Travelers to areas of high or moderate risk are generally expected to be at lower risk for Lyme disease than those who permanently reside in endemic areas, but individual assessment of risk should consider the frequency and duration of exposure to tick-infested habitat.

Persons requesting Lyme disease vaccine need to be informed of the available data on the safety and effectiveness of the vaccine, the importance of continuing personal protective measures and avoidance of tick habitats to prevent infection, and the criteria used to assess individual risk. The decision to administer Lyme disease vaccine needs to be made based on an assessment of individual risk, which depends on a person's likelihood of being bitten by ticks infected with *B. burgdorferi*. Primary determinates of this risk are the density of vector ticks in the environment (which varies by place and by season), the prevalence of *B. burgdorferi* infection in the ticks, and the extent of person-tick contact, which is related to type, frequency, and duration of a person's activities in a tick-infested environment. Vaccine recipients should be counseled that even though immunized they need to continue personal protective measures and avoid tick habitats to minimize their risk of Lyme disease and other arthropod-borne illnesses.

The Lyme disease vaccine is not recommended as a routine vaccine for military service members. The Armed Forces Epidemiological Board (AFEB) reviewed the surveillance data on human disease and tick populations in military training areas located in areas endemic for Lyme disease. At present, the disease threat does not justify routine immunization of military personnel. Use of personal protection measures and avoidance of tick habitats remain the most effective tools to avoid infection. The vaccine may be indicated for selected occupational groups of military members or DoD civilian employees that are at high risk because their duties place them in environments where frequent and prolonged exposure to *B. burgdorferi* infected ticks is anticipated. Local conditions and risk information should be used to determine the added benefit of vaccine.

Lyme disease vaccine is not recommended for persons who have minimal or no exposure to tick-infested habitat. Vaccine is not recommended for persons who reside, work, or recreate in areas of low risk or no risk. Lyme disease vaccine is not licensed for use and should not be administered to children less than 15 years of age. The vaccine licensed for use in the United States has not been evaluated against *B. burgdorferi* strains that circulate in areas of Europe and Asia; the vaccine's ability to protect against infection with the Eurasian strains is uncertain.

Patients and health care providers need be alert for early signs of Lyme disease. Early detection and treatment of an infection can significantly reduce morbidity.

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Last update: 12/10/1999