Changing dosing, administration of anthrax vaccine reduces side effects

September 30 2008

Reducing the number of doses of an anthrax vaccine and changing its administration to intramuscular injection resulted in comparable measures of effectiveness but with fewer adverse events, according to a study in the October 1 issue of *JAMA*.

"Simpler and better tolerated regimens for vaccination with anthrax vaccine adsorbed (AVA) are needed," the authors write. The licensed AVA vaccination regimen is administered by injection below the skin (subcutaneously) at 0, 2, and 4 weeks and 6, 12 and 18 months, with annual boosters thereafter. Data supporting this regimen are limited.

The Centers for Disease Control and Prevention, Atlanta, in collaboration with several U.S. clinical study sites and the Anthrax Vaccine Research Program Working Group, conducted a randomized clinical trial, which included 1,005 enrollees, to assess safety and serological outcomes of alternative schedules and routes of administration of AVA. Participants received AVA by the subcutaneous (SQ) or intramuscular (IM) route at 0, 2 and 4 weeks and 6 months (4-SQ or 4-IM; n = 165-170 per group) or at a reduced 3-dose schedule (3-IM; n = 501). A control group (n = 169) received saline injections at the same time intervals.

The researchers found that at month 7, after completion of the priming series (1st four injections), all groups had serum antibody responses that were "noninferior to" (i.e., no less than) the licensed regimen. Most injection site adverse events (AEs), such as warmth, tenderness, itching,

abnormal redness of the skin and swelling, occurred at lower proportions in the 4-IM group compared with the 4-SQ group. The odds ratio for ordinal pain (response ranging from no pain to extreme pain) reported immediately after injection was reduced by 50 percent for the 4-IM vs. 4-SQ groups.

"Our data demonstrate that a 3-IM regimen (omission of the week 2 dose) elicits serum antibody responses at month 7 that are noninferior when compared with regimens containing 4 doses of AVA (SQ or IM). Intramuscular administration was associated with a significant reduction in injection site AEs. Changing the injection route from SQ to IM may increase vaccine acceptability. Reducing the number of doses in the AVA regimen would have the added benefit of increasing the number of doses available for prophylactic use," the authors conclude.

Source: JAMA and Archives Journals