

USAMMDA INFORMATION PAPER

PRODUCT: ENTEROTOXIGENIC ESCHERICHIA COLI VACCINE (WR/SW/NV)

DESCRIPTION: The enterotoxigenic *Escherichia coli* (ETEC) vaccine is an orally administered vaccine intended to prevent severe diarrhea and fever caused by toxic strains of the bacterium *E. coli*. The vaccine consists of killed, whole cells of the five most common strains of enterotoxin-producing *E. coli*, combined with a recombinantly produced beta subunit of the cholera toxin. The cholera toxin beta subunit is similar to the beta subunit found in the *E. coli* heat-labile (sensitive) toxin. The enterotoxins of the cholera organism and the ETEC organism cannot cause illness unless both alpha and beta subunits are present, but the beta subunits alone can induce strong immune responses. SBL Vaccin AB, Stockholm, Sweden, manufactures the vaccine. ETEC bacteria cause diarrheal disease that varies in severity from a mild one-day illness with abdominal cramps, vomiting, mild diarrhea and fever, to a severe diarrhea similar to cholera that causes severe dehydration and shock from fluid loss. ETEC causes more than 600 million cases of diarrhea per year and kills some 800,000 infants per year worldwide. ETEC causes most diarrhea in soldiers deployed to developing countries. ETEC diarrhea frequently interfered with the duties of U.S. troops during Operation Desert Shield/Storm (ODS). During ODS, 57 percent of troops experienced diarrhea, over 33% due to ETEC. Diarrheal illness from ETEC can limit significantly the mobility of U.S. Forces and decrease their efficiency and functional capability at critical times soon after deployment.

ISSUES/ ACTIONS:

- A Phase 2 clinical trial was completed assessing vaccine efficacy in 314 Egyptian infants and young children. The adjusted vaccine efficacy estimate was twenty percent in the trial. The principal investigator's conclusion was that "the ETEC/cCTB vaccine failed to elicit significant protection against non-severe ETEC diarrhea in this community-based pediatric setting."
- An In-Process Review was held during 2QFY04 to review this vaccine program. Their recommendation was to terminate the program because of the low efficacy shown in the Phase 2 trial.
- The Milestone Decision Authority concurred and signed an Acquisition Decision Memorandum on 4 Feb 2004 terminating this program.
- This is the last information paper for this ETEC vaccine. Efforts are on-going in Tech Base research to meet this requirement using other vaccine technologies.

BPL #: 306

DA PROJECT/TASK: Infectious Diseases

PE/PROJ 643807.849ND

MAMP RANK: 4/36

ARMY ORD: ETEC Vaccine; CARDS #1494 9 Aug 94

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