DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vaccine To Protect Children From Anthrax—Public Engagement Workshop

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Biodefense Science Board’s (NBSB) Anthrax Vaccine (AV) Working Group (WG) will hold a public engagement workshop on July 7, 2011, to discuss vaccine to protect children from anthrax. This meeting is open to the public and prior registration is required. The public may attend in-person or by teleconference.

DATES: The NBSB’s AV WG will hold a public engagement workshop on July 7, 2011, to discuss vaccine to protect children from anthrax. The meeting will be from 9 a.m. to 4 p.m. ET.


FOR FURTHER INFORMATION CONTACT: E-mail: nbsb@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d–7) and section 222 of the Public Health Service Act (42 U.S.C. 247a), the Department of Health and Human Services established the NBSB. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response. Background: In a letter dated 27 April 2011, the Assistant Secretary for Preparedness and Response (ASPR), Dr. Nicole Lurie asked the NBSB to consider issues related to the use of anthrax vaccine adsorbed (AVA), BioThrax®, for children. AVA is currently in the Strategic National Stockpile and licensed for use only by healthy persons 18 to 65 years of age for traditional pre-exposure vaccination. It may be used in a declared emergency under an Emergency Use Authorization (EUA) for this same population as post-exposure prophylaxis in combination with licensed antibiotics for prevention of anthrax disease. However, the pediatric population is not covered by the EUA due to lack of safety and immunological data related to the vaccine. If there was known exposure of a population of individuals to anthrax there would be subsequent decisions about, for example, deployment of medical countermeasures (MCMs), evacuation versus sheltering-in-place, and the airborne spread of anthrax outside the city.

Questions about the need for a vaccine program for populations that may continue to live in impacted areas may be raised. Because studies have been done to show safety and effectiveness of anthrax vaccine only for adults, if such an anthrax attack were to occur in the near future, the only way to use the existing vaccine to protect children would be to use an investigational new drug (IND) clinical protocol. These factors complicate operational response and public messaging.

The NBSB has previously identified the need to look at other MCMs for pediatric populations. This Public Engagement Workshop provides an opportunity to include the public in the discussion about vaccines to protect children from anthrax or treat children exposed to anthrax. The forum includes discussion of the types of data and types of studies that may be needed to show whether existing FDA-approved vaccines, could also be used for children. No decisions or recommendations will be made at the Workshop.

Availability of Materials: The meeting agenda and materials will be posted prior to the meeting on the Workshop’s July meeting Web page at http://www.phe.gov/PREPAREDNESS/LEGAL/BOARDS/NBSB/Pages/default.aspx.

PROCEDURES FOR PROVIDING PUBLIC INPUT: Any member of the public planning to attend in-person must register in advance by e-mailing nbsb@hhs.gov.
with “Vaccine to Protect Children from Anthrax—Public Engagement Workshop” as the subject line and provide name, address, and affiliation. If you need special assistance, such as sign language interpretation or other reasonable accommodations, please include that in your registration e-mail. A “listen-only” teleconference number will be provided on the Web site. Written comments and/or questions may be submitted in advance or during the Workshop and will be provided to the Workshop hosts. There will be two scheduled public comment periods during the Workshop. Public comments will be limited to 2 minutes per person.

Dated: June 8, 2011.

Nicole Lurie,
Assistant Secretary for Preparedness and Response.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–11–11HJ]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 or send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an e-mail to ombr@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Comparing the Effectiveness of Traditional Evidence-Based Tobacco Cessation Interventions to Newer and Innovative Interventions Used by Comprehensive Cancer Control Programs—New—Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Tobacco use remains the leading preventable cause of death in the United States, causing over 443,000 deaths each year and resulting in an annual cost of more than $96 billion in direct medical expenses. The only proven strategy for reducing the risk of tobacco-related morbidity and mortality is to never smoke, or to quit if tobacco use has been initiated. In 1999, CDC’s Office on Smoking and Health established the National Tobacco Control Program (NTCP) to encourage coordinated, national efforts to reduce tobacco-related morbidity and mortality. The NTCP provides funding and technical support to Tobacco Control Programs (TCPs) in all 50 states, the District of Columbia, eight Tribal support centers, eight U.S. territories or jurisdictions, and six national networks. TCPs offer evidence-based cessation interventions to increase successful quit attempts.

Tobacco control is also a top priority for Federally-funded Comprehensive Cancer Control (CCC) programs. Currently, 65 organizations are funded through CDC’s National Comprehensive Cancer Control Program (NCCCP): All 50 states, the District of Columbia, seven Tribes/Tribal organizations, and seven U.S. territories/Pacific Island Jurisdictions. CCCs work to establish coalitions, assess the burden of cancer, and implement state cancer plans that address interventions from primary prevention to treatment and survivorship. The NCCCP is managed by CDC’s Division of Cancer Prevention and Control (DCPC).

Evidence-based tobacco cessation interventions include counseling offered through telephone quitlines (QLs) as well as Web-based counseling services. Although all states currently provide a telephone QL, only 0.05% to 7.25% of adult smokers receive tobacco cessation services via a state QL each year. Mass media (e.g., television, radio, print) has been shown to be the most important and comprehensive driver of call volume to QLs in some localities, but is resource intensive. Two recent studies comparing the relative effectiveness of telephone versus Web-based interventions have begun to clarify the impact of each intervention but are limited in their generalizability to current TCP activities. To date there are no comprehensive studies that have examined TCP promotional strategies, the populations affected by these strategies, and their effect on QL and Web-based cessation program usage.

To address this gap in knowledge, CDC proposes to conduct a new study of state-based TCPs and their client populations. The study will consist of two components: (1) Quitline promotional activities, and (2) cessation intervention.

Quitline Promotional Activities. The overall goal of this study component is to characterize state-based TCP promotional activities in terms of type and level of advertising; impact in relation to QL call volume; and client characteristics. This study component is based on existing sources of information and entails minimal burden to respondents. Up to 50 state-based TCPs will be asked to participate over a 15-month period. Responding states will provide media purchasing information related to cessation promotional activities and permission to extract deidentified QL call volume data from the National Quitline Data Warehouse (NQDW, OMB No. 0920–0836, exp. 7/31/2012). CDC’s data collection contractor will also attempt to obtain Web traffic data using publicly available tools.

Cessation Intervention. The overall goal of this study component is to describe relationships among mode of cessation service delivery (telephone vs. Web); client demographics; and quit success in the last 30 days. A total of 8,000 respondents aged 18 years (4,000 clients who use QL services and 4,000 clients who use Web-based services) will be recruited to participate in the study on a voluntary basis. Regular access to cessation services will be provided to individuals who choose not to participate in this study. Respondents will be recruited from up to four states over a period of up to 12 months. The four participating states must be current NCCCP grantees, have existing relationships with their state TCP, have both telephone and Web-based tobacco cessation programs, and have a state-wide QL registry that conforms to the North American Quitline Consortium’s Minimal Data Set (MDS), which provides the framework for the NQDW data collection.

Information collection for the cessation study component will consist of an intake data using MDS-compliant