

*Matters to be Discussed:* The agenda includes a discussion of the public health assessment, updates from the Public Health Assessment, Health Needs Assessment, Agenda, and Outreach and Communications Workgroups. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* La Freta Dalton, Designated Federal Official, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E-54, Atlanta, Georgia 30333, telephone 1-888-42-ATSDR(28737), fax 404/498-1744.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 9, 2002.

**Alvin Hall,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

[Program Announcement 02074]

#### **Interventional Epidemiologic Research Studies to Reduce Mother-to-Child HIV-1 Transmission and Improve Infant Survival in Resource-Limited Countries of High HIV-1 Seroprevalence; Notice of Availability of Funds**

##### **A. Purpose**

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program to support interventional epidemiologic research studies to reduce the burden of HIV/AIDS by preventing mother-to-child HIV-1 transmission peripartum and during breastfeeding in international settings of high HIV-1 seroprevalence. This cooperative agreement will receive cofunding by the National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH) during FY 2003. This program addresses the goals of CDC's HIV Prevention Strategic Plan through 2005.

The purpose of this program is to conduct studies which include clinical trials in resource-limited countries that aim to reduce the risk of perinatal HIV-

1 transmission near the time of delivery and during the breastfeeding period among HIV-1 infected women who reside in resource-limited settings and who choose to breastfeed. Also, within the context of these trials, nested research studies will assess mechanisms of transmission during lactation and/or issues related to the effectiveness of, or successful implementation of these interventions.

##### **Background**

Worldwide over 600,000 infants each year become HIV-1 infected through mother-to-child transmission. Recent international perinatal trials demonstrated that short course antiretrovirals including zidovudine (AZT), zidovudine/lamivudine (AZT/3TC) and nevirapine (NVP) can reduce the risk of early HIV-1 transmission by about 40 percent in the first 6-14 weeks following delivery. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has recommended that each of these drug regimens can now be considered as possible options for reducing the risk of mother-to-child transmission in resource-limited settings.

However, the global health goal of maximally reducing mother-to-child HIV-1 transmission in resource-limited settings to the low rates (*i.e.*, 5 percent or less) achieved within the U.S. and Europe is yet to be accomplished. Ongoing breast milk transmission results in a near doubling of transmission by 24 months or about 9 percent absolute transmission attributed to breastfeeding between 2-24 months. Two recent studies, a randomized trial of breast milk versus formula in Nairobi and the South African Intrapartum Nevirapine Trial (SAINT) Trial in South Africa compared transmission rates between breastfed and non breastfed infants. Both studies suggest that the first 6-8 weeks may pose the highest risk period of breast milk transmission with about 5-6 percent higher transmission risk for breastfed compared to formula fed infants in the first two months of life. After these first 6-8 weeks, based on observational data from Malawi, ongoing transmission from exposure to breast milk is about 0.6 percent-0.7 percent per month in the first year; and about 0.2-0.3 percent per month in the second year of life.

Currently most HIV-1 infected women in resource-limited settings breastfeed, often into the second year of life. This decision may be related to a number of factors: lack of awareness of their HIV-1 status, cultural norms and strong social reinforcement of breastfeeding, fear or stigma, concerns

regarding optimal infant nutrition and also water safety, or cost of breast milk substitutes. Given the high rates of breastfeeding among HIV-1 infected women in resource-limited areas, prevention of HIV-1 transmission during lactation remains a pressing perinatal research challenge.

##### **Examples of Research Areas**

#### **I. Clinical Trials Addressing Prevention of HIV-1 Transmission During the Breastfeeding Period**

The primary aim of this Program Announcement is to support international clinical trials designed to reduce both peripartum and breastfeeding HIV-1 transmission in rural or urban settings in resource-limited countries.

Critical research areas in preventing mother-to-child HIV-1 transmission that applicants may address, include but are not limited to, clinical trials directed at one of the following areas:

Trials of short course combination antiretrovirals in the last several weeks before delivery designed to reduce viral load to a nondetectable level, followed by maternal or infant antiretroviral prophylaxis during the first several months of lactation;

Trials of short course antenatal or peripartum antiretrovirals paired with infant immune prophylaxis (*e.g.*, HIV-1 vaccine) aimed at protecting the infant throughout the breastfeeding period;

Trials assessing the efficacy of infant combination antiretroviral prophylaxis given to breastfed babies whose mothers were only identified as HIV-1 infected at labor and delivery; and/or

Combinations of above.

#### **II. Nested Research Studies Within Proposed Trials**

Investigators should also propose 1-2 nested research questions within the trials addressing mechanisms of transmission during lactation; and/or issues related to effectiveness of, or successful implementation of the intervention. Such studies might include but are not limited to: lab studies addressing mechanisms of transmission during lactation; lab studies assessing the development and waning of drug resistance for antiretrovirals used for perinatal HIV-1 prevention; strategies that enhance uptake of voluntary counseling and testing using rapid HIV testing to support enrollment into the proposed trial; strategies to enhance adherence to antiretrovirals or immune trial interventions antenatally and during lactation; assessment of factors affecting mode of feeding or weaning decisions;

evaluation of toxicity and other complications of antiretrovirals interventions among HIV-1 infected women during pregnancy and post partum, and their infants; and testing of simplified tools for monitoring drug toxicities in community-based health care facilities.

#### *B. Eligible Applicants*

Applications may be submitted by indigenous universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, operating in settings with high antenatal HIV-1 seroprevalence (*i.e.*, 5 percent or greater) in resource-limited countries. For the purposes of this announcement, HIV-1 seroprevalence rates, circa 2000, as compiled by the U.S. Census will be used to determine eligibility. These rates can be accessed at: <http://www.census.gov/ipc/www/hivtable.html>.

#### *C. Availability of Funds*

Approximately \$1,000,000 million is available in FY 2002 and an additional \$500,000 in FY 2003 to fund two awards to develop and carry out interventions aimed at maximally reducing perinatal HIV-1 transmission near the time of delivery and during the breastfeeding period; and within the context of these trials, nested studies to assess mechanisms of transmission during lactation; and/or issues related to effectiveness of, or successful implementation of the intervention.

It is expected that the average award will be \$750,000 a year. All awards will begin on or about September 30, 2002 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

All requests for funds, including the budget contained in the application, shall be stated in U.S. dollars. Once an award is made, the Department of Health and Human Services (DHHS) will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

#### *1. Use of Funds*

Applicants may contract with other organizations under this cooperative agreement; however, applicants must perform a substantial portion of the activities (including program management and operations) for which funds are requested.

The costs that are generally allowable in grants to domestic organizations are likewise allowable to foreign institutions and international organizations, with the following exception:

**Indirect Costs:** With the exception of the American University, Beirut, the Gorgas Memorial Institute, and the World Health Organization, indirect costs will not be paid (either directly or through a sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

#### *Needle Exchange*

No funds appropriated under this Act shall be used to carry out any program distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

#### *2. Funding Preference*

Preference will be given to achieve geographical diversity.

#### *D. Program Requirements*

In conducting activities to achieve the purpose of these programs, the recipient will be responsible for the activities listed under 1. (Recipient Activities), and CDC/NIH will be responsible for conducting activities listed under 2. (CDC/NIH Activities).

#### *1. Recipient Activities*

a. Develop research study protocols; and obtain local IRB approval.

b. Develop and manage standardized data collection forms.

c. Identify, recruit, obtain and carefully document informed consent; and enroll an adequate number of study participants as determined by the study protocol(s) and the program requirements described in the Program Announcement.

d. Follow up and assume appropriate clinical care of study participants during the trial as described by the study protocol.

e. Establish and monitor procedures to ensure the rights and confidentiality of all study participants.

f. Perform laboratory tests (when appropriate) and data analysis as determined in the study protocol.

g. Collaborate and share data and specimens (when appropriate) with other collaborators to answer specific cross cutting research questions.

h. Contribute blood specimens (at least every 6–12 months depending on the protocol requirements) for shipment and storage at a centralized repository system.

i. Conduct or help with coordination of data analysis; as well as present and publish research findings.

j. Facilitate the establishment of, or engage an existing Community Advisory Board (CAB) to give ongoing community input related to the proposed research from the study inception through completion and eventual dissemination of study results to the community.

k. Develop or enhance linkages and strong collaboration with CDC Global AIDS Program (GAP), ministries of health, nongovernmental organizations (NGO's) and other groups relevant to carrying out the research; and to implementing research findings following completion of the trial.

**Note:** Recipients addressing the same or similar research issue(s) should state their willingness to participate in collaborative studies with other CDC- or NIH-sponsored researchers, including using common data collection instruments, specimen collection protocols, and data management procedures, as determined in post-award planning conferences.

#### *2. CDC/NIH Activities*

a. Provide technical assistance in study design in order to facilitate the overall research project.

b. Facilitate and assist in the development of research protocols for IRB (institutional review board) review by the cooperating institutions participating in the research project.

The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Assist in designing a data management system.

d. Assist in performance of selected laboratory tests.

e. Work collaboratively with investigators to help coordinate research activities across sites involved in similar research projects such as nested laboratory studies.

f. Assist in the analyses of research information and the presentation and publication of research findings.

#### *E. Application Content*

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to address them in laying out the proposals for your application.

#### *F. Submission and Deadline*

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available in the application kit and at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>

Please obtain this program announcement and all attachments which are necessary for completing your application, at the Internet address referenced above. Program Announcements published on the **Federal Register** do not include attachments which are sometimes crucial to the development of your application.

On or before July 15, 2002, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if hard copies of the applications are either:

A. Received on or before the deadline date; or

B. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in A. and B. above will be returned to the applicant.

#### G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

##### 1. Demonstrated Access to Relevant Study Populations, and Demonstrated Capability To Recruit and Retain Study Participants Into a Clinical Trial (Total of 25 points)

a. Evidence of ability to successfully recruit and follow mothers and their infants in longitudinal research studies. Applicants should include relevant information from previous studies documenting annual recruitment and retention rates including loss to follow up in these studies.

b. For the proposal responding to research or program area, evidence of approximately 5 percent or greater HIV-1 seroprevalence among pregnant women in the catchment area described in the application; and/or ability to recruit and retain at least 500 HIV-1 infected pregnant women and their HIV-1 exposed infants annually in settings where many HIV-1 infected women breastfeed.

C. Demonstrated access to and laboratory capability to carry out HIV-1 serologic testing for mothers and PCR

testing of infants, monitor responses to antiretroviral therapy including possible toxicities (e.g. hematology, blood chemistries).

##### 2. Description and Justification of Research Plans (Total of 40 points)

a. Understanding of the research objectives as evidenced by the high quality and scientific rigor of the proposed plans for research and a study design appropriate to answer research questions.

b. Demonstration of a well designed innovative clinical trial which investigates and addresses:

Maximal reduction of mother-to-child HIV-1 transmission during both the peripartum period and during lactation using antiretrovirals and/or immune-based interventions; nested studies within these trials which assess related research questions related to the trials such as mechanisms of transmission during lactation; development and waning of antiretroviral resistance; and/or issues related to effectiveness of, or successful implementation of the intervention strategies; strategies to enhance adherence to antiretrovirals or immune trial interventions antenatally and during the breastfeeding period; evaluation of potential toxicities of interventions; and testings of simplified tools for monitoring drug toxicities in community-based health care facilities.

c. Originality and quality of the proposed clinical trial research, and direct relevance of the research to maximally reduce mother-to-child transmission in high prevalence resource-limited settings with particular emphasis on reducing viral load in the last trimester and assessing prophylaxis strategies during lactation. The extent to which the proposal builds on current knowledge, extends or creates new knowledge and does not replicate past or present research efforts.

d. Demonstrated willingness of the applicant to work with CDC/NIH staff on development of the research protocol and willingness to collaborate on related studies with other investigators funded under this Program Announcement.

e. Feasibility of plans to recruit, follow and retain study participants in a longitudinal research protocol within the framework of the project period. This includes demonstration of the experience of the investigator in following mothers and infants in either longitudinal epidemiologic studies and/or in clinical trials, and the comprehensiveness of the plan to protect the rights and confidentiality of all participants.

f. Adequacy of sample size to address research questions, and demonstration

of available statistical expertise to carry out subsequent analyses of trial results. Thoroughness of plans for data management, data analysis, and laboratory analysis; reasonableness of data collected; and statistical rigor.

g. Extent to which proposal demonstrates feasible plans for coordinating research activities of multiple local clinical sites, statement of potential willingness to work collaboratively with other grant recipients in other settings if similar or multi-site protocols were developed, and with CDC/NIH. Letters of support from cooperating organizations that demonstrate the nature and extent of such cooperation should be included, as well as GAP in-country directors and ministries of health.

h. Extent to which proposal delineates plans for setting up or engaging an existing Community Advisory Board to give ongoing community input into the research study from its inception, through completion and eventual dissemination of study results to the community.

i. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic and racial groups in the proposed research.

This includes:

(i) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation;

(ii) The proposed justification when representation is limited or absent;

(iii) A statement as to whether the design of the study is adequate to measure differences when warranted.

(iv) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

##### 3. Research and Intervention Capability (Total of 25 points)

a. Availability of qualified and experienced senior Principal Investigators (PI) and Co-PI's. Extent of familiarity and quality of Principal Investigator and other senior Co-Investigators' experience and expertise pertinent to proposed research or programmatic activities, including experience in perinatal and pediatric HIV-1 infection epidemiologic or clinical trial research; or other epidemiologic and clinical trial research. Evidence of sufficient time dedicated to the proposed project.

b. Applicant group's ability to carry out the proposed research as demonstrated by the training and

experience of the proposed research team and organizational setting, including demonstration of ability to collect, manage, and analyze accurate data in a timely manner.

c. Clarity of the described duties and responsibilities of project personnel.

d. Demonstrated research infrastructure as evidenced by presence of current funding for ongoing research, program implementation and training (examples of other funding for infrastructure might include funding from National Institutes of Health, Medical Research Council, Agence Nationale de Recherche sur le SIDA (ANRS), Emory AIDS International Training Research Program (AITRP), Fogarty International Center (FIC), Wellcome Trust, Elizabeth Glaser Pediatric AIDS Foundation, and other private foundations, etc.

e. Experience and evidence of ability to provide voluntary counseling and testing (VCT) in antenatal clinics, and to offer VCT at labor and delivery for women who are not tested antenatally.

f. Adequacy of plans for project oversight to assure quality of data and specimen collection.

(1) Evidence of ability to collect complete data including interviews of mothers in the immediate postpartum period, and to obtain blood samples from HIV-1 infected mothers enrolled around the time of delivery.

(2) Evidence of ability to collect complete and accurate data, and to obtain regular blood samples from HIV-1 exposed infants, with at least one blood sample during the first 48 hours after birth, and at follow up pediatric health maintenance visits.

(3) Ability to oversee specimen collection for the timely processing, storage, and retrieval of laboratory specimens as needed. This includes transfer of certain specimens to a central repository (e.g., at CDC) and transfer of other specimens to designated laboratories for specific laboratory studies.

g. Evidence of capability to address informed consent issues, enhance social support and foster adherence to the antiretroviral prophylaxis regimen, with special attention directed at adherence to the neonatal component of the regimen.

h. Documentation of appropriately constituted local IRB in place to review the protocol.

i. Adequacy of facilities, equipment, data management resources, and systems for ensuring data security and patient confidentiality.

j. Demonstration of working relationships with any proposed collaborators and extent to which

services to be provided by external experts or consultants are documented by memoranda of agreement.

k. Demonstration of research staff with epidemiologic, behavioral, clinical, administrative, laboratory, data management and statistical analysis expertise needed to conduct the proposed research.

l. Adequacy of time line for completion of project activities.

#### 4. Linkages and Planned Approaches to Translate Successful Research Findings Into Practice (10 points)

a. Demonstration of linkages to the following groups are required: CDC Global AIDS Program (GAP) staff in currently funded CDC GAP countries or to relevant CDC staff in non GAP countries working on HIV-1 related activities, Ministry of Public Health, Community Advocacy Groups; and linkages are strongly recommended with nongovernmental organizations (NGO's), international agencies such as UNICEF, UNAIDS, and WHO.

b. Demonstration of a plan of action to translate and transition research findings to appropriate responsible groups that would result in upscaling and implementation in local or national communities. Linkages with other area hospitals, local ministry of health and a local Community Advisory Board are strongly encouraged.

5. Demonstration of Sound Fiscal Policies, and Fiscal Oversight by the Institution Which Would Receive the Funding Under this Application.

#### 6. Budget (not scored)

The extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

#### 7. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

#### H. Other Requirements

##### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. annual progress report;
  2. financial status report, no more than 90 days after the end of the budget period; and
  3. final financial status and performance reports, no more than 90 days after the end of the project period.
4. Applicants are required to provide measures of effectiveness to evaluate the accomplishment of the various

identified objectives of the cooperative agreement. These measures must be objective and quantitative and must measure the intended outcome. The submission of these measures shall be a data element to be submitted with, or incorporated into the annual progress reports.

5. Awardee is required to obtain an annual audit of these CDC/NIH funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

6. A fiscal Recipient Capability Assessment may be required with the potential awardee, pre or post award, in order to review their business management and fiscal capabilities regarding the handling of U.S. Federal funds.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see attachment I of this announcement.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-4 HIV/AIDS Confidentiality Provisions
- AR-6 Patient Care
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-22 Research Integrity

#### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 307 of the Public Health Service Act (42 U.S.C. sections 241(a) and 242l). The Catalog of Federal Domestic Assistance number is 93.943.

#### J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements." NIH funding announcements can be found on the NIH home page internet address—<http://www.nih.gov> Click on "Grants" then "NIH Guide for Grants and Contracts".

To obtain business management technical assistance, contact: Dorimar Rosado, Grants Management Specialist, Grants Management

Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Colgate Building, Room 3000, 2920 Brandywine Road, Mailstop K-69, Atlanta, GA 30341, Telephone: (770) 488-2738, Email address: drosado@cdc.gov

For program technical assistance, contact:

Mary Glen Fowler, MD, Chief, Mother-Child Transmission & Pediatric and Adolescent Studies Section, Epidemiology Branch, Division of HIV/AIDS Prevention Surveillance & Epidemiology, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-45, Atlanta, Georgia 30333, Telephone: (404) 639-5190, E-mail: MFowler@cdc.gov

Dated: April 30, 2002.

**Sandra R. Manning,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 02-12254 Filed 5-15-02; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Healthcare Infection Control Practices Advisory Committee (HICPAC): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

*Name:* Healthcare Infection Control Practices Advisory Committee.

*Times and Dates:* 8:30 a.m.-5 p.m., June 17, 2002; 8:30 a.m.-4 p.m., June 18, 2002.

*Place:* Swissotel, 3391 Peachtree Road, NE, Atlanta, Georgia 30333.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare associated infections and healthcare-related conditions.

*Matters to be Discussed:* Agenda items will include a review of the Draft Guideline for

Preventing Transmission of Infectious Agents in Healthcare Settings (formerly Guideline for Isolation Precautions in Hospitals); the Draft Guideline for Disinfection and Sterilization in Healthcare Settings; the Draft Guideline for Prevention of Healthcare-associated Pneumonia; and updates on CDC activities of interest to the committee.

Agenda items are subject to change as priorities dictate.

#### *Contact Person for More Information:*

Michele L. Pearson, M.D., Executive Secretary, HICPAC, Division of Healthcare Quality Promotion, NCID, CDC, 1600 Clifton Road, NE, M/S A-07, Atlanta, Georgia 30333, telephone 404/498-1182.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 9, 2002.

**Alvin Hall,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee on Immunization Practices: Announcement of Meeting and Request for Comments on Formulating Recommendations for the Use of Vaccinia (Smallpox) Vaccine

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

*Name:* Advisory Committee on Immunization Practices (ACIP).

*Times and Dates:* 8:30 a.m.-5:30 p.m., June 19, 2002.

8 a.m.-3 p.m., June 20, 2002.

*Place:* Atlanta Marriott Century Center, 2000 Century Boulevard, NE., Atlanta, Georgia 30345-3377.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

*Matters To Be Discussed:* The Committee will discuss, among other items, the administration of vaccinia (smallpox) vaccine. Because of the considerable interest in the use of vaccinia (smallpox) vaccine, there will be a public comment period on the morning of June 19, not to exceed four hours, during which members of the public will be able to address the ACIP members on making recommendations for the use of vaccinia (smallpox) vaccine. Other topics to be discussed at the meeting include: a summary of the May 8-9 Smallpox Working Group meeting; update on CDC preparedness activities; public participation in formulating vaccine policy; update from the National Immunization Program, Food and Drug Administration, Vaccine Injury Compensation Program, National Institutes of Health, National Vaccine Program, and the National Center for Infectious Diseases; ACIP recommendations and influenza surveillance; Vaccines for Children vote on influenza vaccination of children 6-23 months; recommendations for mishandled vaccines; 2003 recommended childhood immunization schedule; recommended adult immunization schedule; update of vaccine supply; Institute of Medicine update on hepatitis B vaccine and neurological disorders; and combination DTap-HepB-IPV vaccine.

Agenda items are subject to change as priorities dictate.

Anyone wishing to make an oral presentation should submit their request in writing, to the contact person by close of business June 7, 2002. The request should include the name, address, and telephone number of the participant; the approximate time needed, and a copy of the presentation or a brief summary of the topic to be presented. Depending on the number of requests, up to 10 minutes will be allowed for each oral presentation. Anyone wishing to submit for consideration written comments regarding the use of vaccinia (smallpox) vaccine should submit the written comments to the contact person by June 14, 2002.

#### *Contact Person for More Information:*

Gloria A. Kovach, Program Analyst, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE, m/s E61, Atlanta, Georgia 30333. Telephone 404/639-8096.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 9, 2002.

**Alvin Hall,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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