IV. Content of Published Reports

The data reported will be used to provide a picture of the national rates of pregnancy and live birth achieved using ART as well as clinic-specific, live-birth rates. The annual report will have four components:

(A) A national component, which will provide a comprehensive picture of success rates given a variety of factors including age, reason for ART, type of ART procedure, number of embryos transferred etc. This is possible because the large number of cycles at the national level allow accurate statistical reporting of success rates that is not possible with the smaller number of cycles carried out in individual clinics.

(B) A clinic-specific component which will provide success rates for all ART cycles using fresh, non-donor embryos, success rates for ART cycles using thawed embryos, and success rates for ART cycles using donor oocytes or embryos.

Success rates will be reported by specific age groups. In addition, the clinic-specific component will provide other information that may be useful to the consumer such as types of services the clinic offers (*e.g.,* gestational surrogacy, single women), the number of cycles carried out, the percent distribution of types of ART, the types of infertility problems the clinic sees, the frequency of cancellations, the average number of embryos transferred per cycle and the percentage of multiple pregnancies and births (twins and triplets or greater).

Pregnancy and live birth success rates will be defined and characterized as described below.

For fresh, non-donor cycles, success rates will be defined as

1. The rate of *pregnancy* after completion of ART according to the number of:

a. All ovarian stimulation or monitoring procedures.

2. The rate of *live birth* after completion of ART according to the number of:

a. All ovarian stimulation or monitoring procedures.

b. Oocyte retrieval procedures.

c. Embryo (or zygote, or oocyte) transfer procedures.

For cycles using thawed embryos and cycles using donor oocytes or embryos success rates will be defined as

1.The rate of *live birth* after completion of ART according to the number of:

a. Embryo (or zygote, or oocyte) transfer procedures.

(C) An appendix containing a consumer-oriented explanation of all medical and statistical terms used in the report.

(D) An appendix containing a list of all reporting clinics and a list of all clinics that did not report data (See above, **Who Reports** section, for a full description of clinics that will be considered to not be in compliance with the federal reporting requirements of FCSRCA; such clinics will be listed as non-reporters in the published report.) This appendix will contain the names, addresses, and telephone numbers for all reporting and non-reporting clinics. It will also contain information on the laboratories used by reporting clinics.

The entire annual report will be available to the general public. As resources allow, additional information may also be published.

[FR Doc. 00–22425 Filed 8–31–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[PA #00130 et al.]

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: HIV/AIDS Prevention Program Development and Technical Assistance Collaboration With Countries Targeted by the Leadership and Investment in Fighting the Epidemic (LIFE) Initiative, et al.

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: HIV/AIDS Prevention Program Development and Technical Assistance Collaboration with Countries Targeted by the Leadership and Investment in Fighting the Epidemic (LIFE) Initiative, PA #00130; Prevention Program Development and Technical Assistance to Improve Blood Safety and Reduce the Impact of HIV/AIDS in Countries Targeted by the LIFE Initiative, PA #00133; LIFE—Global AIDS Activity, PA #00134; HIV/AIDS Prevention Program Development and Technical Assistance Collaboration for Faith Communities in Countries Targeted by the LIFE Initiative, PA #00137; Youth-Focused HIV/AIDS Prevention Program Development and Technical Assistance Collaboration with Countries Targeted by the LIFE Initiative, PA #00138; and HIV/AIDS Prevention Program Development and Technical Assistance Collaboration for Public Health Laboratory Science with Countries Targeted by the LIFE Initiative, PA #00139.

Times and Dates: 10:00 a.m.–Noon, September 13, 2000 (Open); Noon–4:30 p.m., September 13, 2000 (Closed); 8:30 a.m.–4:30 p.m., September 14, 2000 (Closed).

Place: Centers for Disease Control and Prevention, 12 Corporate Square Boulevard, Building 12, Conference Rooms 1203 and 1307, Atlanta, GA 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to P. L. 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcements 00130, 00133, 00134, 00137, 00138, 00139.

This notice is published less than 15 days prior to the meeting due to administrative delays.

Contact Person for More Information

Chad Martin, Special Assistant to the Director on Youth and HIV Prevention, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 8 Corporate Square Boulevard, M/S E35, Atlanta, Georgia 30329, telephone 404/639–5217, e-mail cmartin@cdc.gov.

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 the both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 29, 2000.

John C. Burckhardt,

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

[FR Doc. 00–22599 Filed 8–30–00; 12:58 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interim Hepatitis B Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: A hepatitis B vaccine has recently been approved for administration in a two dose schedule to adolescents 11 to 15 years of age as an alternative to the three dose schedule. This additional schedule necessitates a revision of the vaccine information statement entitled, ''Hepatitis B Vaccine: What You Need to Know'' (dated December 16, 1998), which was developed by the CDC as required by the National Childhood Vaccine Injury Act of 1986 (NCVIA). To ensure that up-to-date information is

available regarding this additional schedule, CDC is distributing the following interim hepatitis B vaccine information statement which may be used pending completion of the formal revision process.

DATES: Effective September 1, 2000. Any health care provider administering hepatitis B vaccine approved for administration in a two dose schedule may provide the interim hepatitis B vaccine information materials contained in this notice (which are dated August 9, 2000) to parents/legal representatives prior to immunization in lieu of providing the December 16, 1998 version of the hepatitis B vaccine information materials.

FOR FURTHER INFORMATION CONTACT: Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E–05, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, (404) 639–8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Public Law 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers, whether public or private, to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

Vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of the vaccine. Effective June 1, 1999, health care providers are also required to provide copies of vaccine information materials for the following vaccines that were added to the National Vaccine Injury Compensation Program: hepatitis B, Haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines.

The materials currently in use for Td tetanus diphtheria vaccine were published in a **Federal Register** notice on June 20, 1994 (59 FR 31888). The current materials for diphtheria, tetanus, and pertussis containing vaccines, other than Td vaccine, were published in a **Federal Register** notice on January 9, 1998 (63 FR 1730); those for hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), and measles, mumps, rubella vaccines on February 23, 1999 (64 FR 9042); and the current materials for polio vaccines, along with the current instructions for use of all of the vaccine information materials, were published in a **Federal Register** notice on December 17, 1999 (64 FR 70914).

Interim Hepatitis B Vaccine Information Materials

A hepatitis B vaccine has recently been approved for administration in a two dose schedule to adolescents 11 to 15 years of age as an alternative to the three dose schedule. This additional schedule necessitates a revision of the vaccine information statement entitled, ''Hepatitis B Vaccine: What You Need to Know'' (dated December 16, 1998). To ensure that up-to-date information is available regarding this schedule, CDC is distributing the following interim hepatitis B vaccine information statement, dated August 9, 2000, which may be used pending completion of the formal revision process.

Availability of Vaccine Information Materials (Vaccine Information Statements)

Copies of the interim hepatitis B vaccine information materials and the other CDC vaccine information materials, and instructions for their use, can be downloaded from the CDC website at: http://www.cdc.gov/nip/publications/VIS/. Single camera-ready copies of the vaccine information materials, and copies of the instructions for their use, are also available from State health department immunization programs.

Hepatitis B Vaccine: What You Need to Know

1. Why get Vaccinated?

Hepatitis B is a Serious Disease

The hepatitis B virus can cause short-term (acute) illness that leads to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

It can also cause long-term (chronic) illness that leads to:

- liver damage (cirrhosis)
- liver cancer
- death

About 1.25 million people in the U.S. have chronic hepatitis B virus infection.

Each year it is estimated that:

- 200,000 people, mostly young adults, get infected with hepatitis B virus
- More than 11,000 people have to stay in the hospital because of hepatitis B
- 4,000 to 5,000 people die from chronic hepatitis B

Hepatitis B vaccine can prevent hepatitis B. It is the first anti-cancer vaccine because it can prevent a form of liver cancer.

2. How is Hepatitis B Virus Spread?

Hepatitis B virus is spread through contact with the blood and body fluids of an infected person.

A person can get infected in several ways, such as:

- during birth when the virus passes from an infected mother to her baby
- by having sex with an infected person
- by injecting illegal drugs
- by being stuck with a used needle on the job
- by sharing personal items, such as a razor or toothbrush with an infected person

People can get hepatitis B infection without knowing how they got it. About ⅓ of hepatitis B cases in the United States have an unknown source.

3. Who Should Get Hepatitis B Vaccine and When?

(1) Everyone 18 years of age and younger

(2)Adults over 18 who are at risk

Adults at risk for hepatitis B infection include people who have more than one sex partner, men who have sex with other men, injection drug users, health care workers, and others who might be

exposed to infected blood or body fluids.

If you are not sure whether you are at risk, ask your doctor or nurse.

People should get 3 doses of hepatitis B vaccine according to the following schedule. If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

HEPATITIS B VACCINATION SCHEDULE

WHEN?	WHO?		
	Infant whose mother is infected with hepatitis B virus	Infant whose mother is not infected with hepatitis B virus	Older child, adolescent, or adult
First Dose	Within 12 hours of birth	Birth–2 months of age	Any time.
Second Dose	1–2 months of age	1–4 months of age; (At least 1 month after first dose).	1–2 months after first dose.
Third Dose	6 months of age	6–18 months of age	4–6 months after first dose.

—The second dose must be given at least 1 month after the first dose.
—The third dose must be given at least 2 months after the second dose and at least 4 months after the first.
—The third dose should not be given to infants younger than 6 months of age.

Adolescents 11 to 15 years of age may need only two doses of hepatitis B vaccine, separated by 4–6 months. Ask your health care provider for details.

Hepatitis B vaccine may be given at the same time as other vaccines.

4. Some People Should not get Hepatitis B Vaccine or Should Wait

People should not get hepatitis B vaccine if they have ever had a life-threatening allergic reaction to baker's yeast (the kind used for making bread) or to a previous dose of hepatitis B vaccine.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting hepatitis B vaccine.

Ask your doctor or nurse for more information.

5. What Are the Risks From Hepatitis B Vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Getting hepatitis B vaccine is much safer than getting hepatitis B disease.

Most people who get hepatitis B vaccine do not have any problems with it.

Mild Problems

• soreness where the shot was given, lasting a day or two (up to 1 out of 11 children and adolescents, and about 1 out of 4 adults)

• mild to moderate fever (up to 1 out of 14 children and adolescents and 1 out of 100 adults)

Severe Problems

• serious allergic reaction (very rare).

6. What if There is a Moderate or Severe Reaction?

What Should I Look for?

Any unusual condition, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If such a reaction were to occur, it would be within a few minutes to a few hours after the shot.

What Should I do?

• Call a doctor or get the person to a doctor right away.

• Tell your doctor what happened, the date and time it happened, and when the vaccination was given.

• Ask your doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1–800–822–7967.

7. The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1–800–338–2382 or visit the program's website at http://www.hrsa.gov/bhpr/vicp

8. How Can I Learn More?

• Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.

• Call your local or state health department's immunization program.

• Contact the Centers for Disease Control and Prevention (CDC):
—Call 1–800–232–2522 or 1–888–443–7232 (English)
—Call 1–800–232–0233 (Espanol)
—Visit the National Immunization Program's website at http://www.cdc.gov/nip or CDC's Hepatitis Branch website at http://www.cdc.gov/ncidod/diseases/hepatitis/

U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, National Immunization Program—Hepatitis B (8/9/2000) (Interim) Vaccine Information Statement
42 U.S.C. 300aa–26

Dated: August 28, 2000.

Candice Nowicki,

Acting Director, Executive Secretariat, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–22428 Filed 8–31–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Developmental Disabilities Council Program Performance Report.

OMB No. 0980–0172.

Description: A Development Disabilities Council Program Performance Report is required by federal statute. Each State Developmental Disabilities Council must submit an annual report for the preceding fiscal year of activities and accomplishments.

Information provided in the Program Performance Report will be used (1) in the preparation of the Annual Report to the President, the Congress, and the National Council on Disabilities and (2) to provide a national perspective on program accomplishments and