

member of the public who would like to participate in this session is encouraged to contact the Executive Secretary at his/her earliest convenience. It is requested that those who wish to have printed material distributed to the Committee provide thirty (30) copies of the document to be distributed to the Executive Secretary, ACBSA, prior to close of business April 27, 2009. If it is not possible to provide 30 copies of the material to be distributed, then individuals are requested to provide at a minimum one (1) copy of the document(s) to be distributed prior to the close of business April 27, 2009. It also is requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Executive Secretary prior to close of business April 27, 2009.

Dated: April 8, 2009.

**Jerry A. Holmberg,**

*Executive Secretary, Advisory Committee on Blood Safety and Availability.*

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BILLING CODE 4140-41-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Solicitation of Written Comments on Draft National Vaccine Advisory Committee Vaccine Safety Working Group Recommendations to the Immunization Safety Office

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

**ACTION:** Notice.

**SUMMARY:** The National Vaccine Program Office (NVPO) is soliciting public comment on the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group draft Recommendations to the Centers for Disease Control and Prevention's Immunization Safety Office (ISO).

**DATES:** Comments on the NVAC Vaccine Safety Working Group draft report should be received no later than 5 p.m. on May 13, 2009.

**ADDRESSES:** Electronic responses are preferred and may be addressed to [vaccinesafetyRFI@hhs.gov](mailto:vaccinesafetyRFI@hhs.gov). Written responses should be addressed to National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Room 715-H, Washington, DC 20201, Attention: Vaccine Safety RFI.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kirsten Vannice, National Vaccine Program Office, Department of Health and Human Services, Hubert H.

Humphrey Building, 200 Independence Avenue, SW., Room 443-H, Washington, DC 20201; telephone (202) 690-5566; fax 202-260-1165; e-mail [vaccinesafetyRFI@hhs.gov](mailto:vaccinesafetyRFI@hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Ensuring the optimal safety of vaccines and immunizations is important to everyone. The National Vaccine Program Office (NVPO) is located within the Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services (HHS), and has responsibility for coordinating and ensuring collaboration among the many Federal agencies involved in vaccine and immunization activities. NVPO also has responsibility for managing and providing support services for the National Vaccine Advisory Committee (NVAC). NVAC is a statutory Federal advisory committee that was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The Centers for Disease Control and Prevention's (CDC) Immunization Safety Office (ISO) has significant responsibility for monitoring and studying the safety of vaccines after they are licensed and used in the United States (<http://www.cdc.gov/vaccinesafety>). ISO has drafted a five-year scientific agenda that identifies vaccine safety issues to consider for scientific study, in addition to any new questions that may arise. The draft ISO Scientific Agenda can be found at: [http://www.cdc.gov/vaccinesafety/00\\_pdf/draft\\_agenda\\_recommendations\\_080404.pdf](http://www.cdc.gov/vaccinesafety/00_pdf/draft_agenda_recommendations_080404.pdf) and the addendum at [http://www.cdc.gov/vaccinesafety/00\\_pdf/draft\\_recommendations\\_add\\_080410.pdf](http://www.cdc.gov/vaccinesafety/00_pdf/draft_recommendations_add_080410.pdf).

Since not all questions and issues can be addressed at once, setting priorities is also important, and ISO has requested a review of the draft Scientific Agenda by the National Vaccine Advisory Committee (NVAC) for the purpose of identifying gaps and setting priorities. The NVAC Vaccine Safety Working Group has written a draft report of recommendations on the content and priorities of the draft ISO Scientific Agenda. The draft report may be found at <http://www.hhs.gov/nvpo/nvac/reports.html>.

Through this request for information (RFI) HHS is seeking comments from

everyone, including stakeholders and the broad public, on the NVAC Vaccine Safety Working Group draft report. Comments received will be available for public viewing on the NVAC Vaccine Safety Working Group Web site (<http://www.hhs.gov/nvpo/nvac/vaccinesafety.html>).

##### II. Information Request

NVPO, on behalf of the NVAC Vaccine Safety Working Group, requests input on the draft Working Group report (<http://www.hhs.gov/nvpo/nvac/reports.html>). In addition to general comments, NVPO is seeking input on any additional gaps not addressed in the ISO Scientific Agenda nor the NVAC Vaccine Safety Working Group draft report, and/or prioritization criteria and its application to the ISO Scientific Agenda.

Please limit comments to 6 pages.

##### III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in vaccines and vaccine safety. Some examples of these organizations include but are not limited to the following:

- General public;
- Advocacy groups and public interest organizations;
- State and local governments;
- State and local public health departments;
- Vaccine manufacturing industry, distributors and other businesses;
- Health care professional societies and organizations.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. All comments submitted will be made publicly available. Anonymous submissions will not have their comments posted and will not be considered.

The submission of written materials in response to the RFI should not exceed six pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses. Any information you submit will be made public. Consequently, do not send proprietary, confidential, financial, business confidential, trade secret, or personal information that you do not wish to be made public.

**Public Access:** Responses to this RFI will be available to the public on the NVAC Web site at <http://www.hhs.gov/nvpo/nvac/vaccinesafety.html>. You may access public comments received from this RFI by going to the above Web site.

Dated: March 31, 2009.

**Bruce G. Gellin,**

*Deputy Assistant Secretary for Health,  
Director, National Vaccine Program Office,  
U.S. Department of Health and Human  
Services.*

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Centers for Disease Control and  
Prevention**

[60Day-09-08AU]

**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 and send comments to Maryam Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta,

GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@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**

Assessing Problem Areas in Referrals for Chronic Hematologic Malignancies and Developing Interventions to Address Them—New—Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

One of the six aims of the Institute of Medicine's Crossing the Quality Chasm report is to improve the timeliness of care for patients. Data from Europe and

Canada, as well as single-site studies in the United States, allude to a problem of timely referral and diagnosis for patients with cancer. Despite the advent of new diagnostics and therapeutics for patients with chronic hematological malignancies, the size and scope of a potential problem regarding their referral from primary care providers to specialists is not well-defined in the current literature.

CDC proposes to conduct a one-time study to collect qualitative and quantitative information on optimal and sub-optimal referral patterns for patients with confirmed or suspected chronic hematologic malignancies. Information will be collected to identify specific factors related to delays in diagnosis and/or referral to appropriate medical specialists. Information will be collected through in-depth interviews with hematologic cancer patients, in-depth interviews and focus groups with primary care providers, interviews with specialists in hematology and oncology in Texas, and a one-time postal survey to a sample of primary care providers in Massachusetts.

The ultimate goal is to develop tools that will improve the awareness, diagnosis, and referral of persons with chronic hematological cancers by primary care providers.

There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hours)
Community Hematologists and Oncologists.	Hematologists and Oncologists Interview Phone Recruitment Script.	100	1	2/60	3
	Hematologists and Oncologists Interview Guide.	18	1	1.5	27
Patients .....	Patient Interview Phone Recruitment Script.	50	1	2/60	2
Primary Care Providers (PCP) .....	Patient Interview Guide .....	18	1	1.5	27
	PCP Survey Cover Letter .....	250	1	2/60	8
	PCP Survey .....	150	1	20/60	50
	PCP Opt-Out Card .....	100	1	2/60	3
	PCP Survey Reminder Letter .....	200	1	2/60	7
	PCP Interview Phone Recruitment Script.	100	1	3/60	5
	PCP Interview Guide .....	18	1	1.5	27
Total .....	PCP Focus Group Phone Recruitment Script.	50	1	3/60	3
	PCP Focus Group Guide .....	18	1	2	36
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