

**Attachment 2b**

**Summary of Public Comments and CDC Response**

**Assessing Problem Areas in Referrals for Chronic Hematologic Malignancies and  
Developing Interventions to Address Them**

**Federal Register Notice:** A 60-day Notice was published in the *Federal Register* on April 13, 2009, Vol. 74, No. 69, pp. 16873-16874.

**CDC received 2 public comments in response to the Federal Register Notice**

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**1. 4sightresearchpartners**

This morning, I read in the Federal Register (<http://www.federalregister.gov/inspection.aspx#special>) the proposal for Referrals for Chronic Hematologic Malignancies, 2009-08337.

How do I track the progress of this request? I'd like to see the results, and preferably, know when the results are posted. I'm a research analyst of life science companies, including hem/onc biotechs.

I track some Citizen Petitions through regulations.gov, but I don't believe that will work for this. I appreciate any help you can provide.

Regards,

Michael

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**CDC Response**

“Thank you for your inquiry regarding the Federal Register notice 09-0410 concerning CDC’s planned project on Referrals for Chronic Hematologic Malignancies. We are happy to send the results of this study to you directly when they are available.”

## **2. The American Society of Hematology**

The American Society of Hematology (ASH) requested additional information about the proposed project, including an outline of study methodology and draft information collection instruments, which were provided for ASH's review. The American Society of Hematology also submitted a letter of support for the project which included recommendations pertaining to study design (see letter, attached). CDC's reply to the letter is included below.

### CDC Response

CDC considered ASH's recommendations and provided the following reply:

"Thank you for your inquiry and follow-up related to Dr. Solberg's letter, on behalf of the American Society of Hematology, regarding CDC's planned study on Referrals for Chronic Hematologic Malignancies (Federal Register Vol. 74, No. 69, pp. 16873-16874). The letter recommends that the study be conducted in a broader geographic region than Texas and Massachusetts. We agree that more national representation is desirable. The funds for this formative research study, however, do not allow such an endeavor at this time. Our plan is to use the information we collect in this study to develop and test an intervention that shortens the time between diagnosis and seeing a specialist.

As the study progresses, we are most happy to share results with you and discuss potential areas of collaboration in future research. Again, thank you for your encouragement."



# AMERICAN SOCIETY OF HEMATOLOGY

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June 9, 2009

Maryam Daneshvar  
Acting Reports Clearance Officer  
Centers for Disease Control and Prevention (CDC)  
1600 Clifton Road, MS-D74  
Atlanta, GA 30333

Re: Assessing Problem Areas in Referrals for Chronic Hematologic Malignancies and Developing Interventions to Address Them (74 FR 16873)

Dear Ms. Daneshvar,

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to comment on the Center for Disease Control and Prevention's (CDC) proposed data collection project entitled: *Assessing Problem Areas in Referrals for Chronic Hematologic Malignancies and Developing Interventions to Address Them*. ASH represents over 11,000 hematologists in the United States who are committed to the treatment of blood and blood-related diseases. ASH members include hematologists and hematologist/oncologists who regularly render services to patients with hematologic malignancies including: leukemia, lymphoma, and multiple myeloma.

ASH applauds the CDC for initiating a study to collect qualitative and quantitative information on referral patterns for patients with confirmed or suspected chronic hematologic malignancies. ASH believes that timely referrals and treatment are critical to the quality of care for patients with hematologic malignancies and strongly believes the CDC project will provide the evidence to support this notion.

ASH believes that the proposed collection of information is necessary and will have practical utility. A delay in diagnosis can be harmful for any patient, including those with hematological malignancies. For example, such delay might allow a separate medical condition to progress and interfere with eventual optimum treatment; or delay might result in a worse prognosis due to multisystem organ dysfunction arising from uncontrolled malignancy. Delay in diagnosis of Polycythemia vera or essential thrombocythemia might result in a preventable catastrophic thrombotic event. Myelodysplasia might progress to leukemia and higher grade lymphomas be more difficult to cure if diagnosis is delayed and non-hematological organ dysfunction occurs.

Other specific examples of worsened outcomes expected from delay in diagnosis include malignant dysproteinemias (e.g., Waldenström's macroglobulinemia or multiple myeloma) which may progress to hyperviscosity syndrome, pathological fractures or renal failure if not diagnosed early after recognition of abnormal blood counts or routine serum chemistry tests.

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Delayed diagnosis due to misdiagnosis (*e.g.*, confusing mantle cell lymphoma with chronic lymphocytic leukemia (CLL)) should also be considered as an important factor as well as delays in referral back to the hematologist for suspected complications of treatment (*e.g.*, complications of radiation for Hodgkin's disease).

ASH believes that the proposed data collection on delay in diagnosis and timely referral to a hematologist will result in improved quality of care for all patients with hematologic malignancies. Diagnosis and treatment of these patients requires highly specialized care that only a hematologist or hematologist/oncologist is trained to provide. For example, all acute and chronic leukemias and lymphomas require assessment by a hematologist because treatments vary greatly based on tumor type and location and because the disease advances rapidly.

Although the proposed collection has a great potential of producing very descriptive information about the current state of hematology/oncology practice, ASH would like to express its concern that the data received will be too geographically narrow and reflect very limited sets of providers in the United States. Such a limited scope of collection sources may prevent the maximum data utility and generalization of the findings to the primary care and general hematology/oncology practitioner community. Although the Agency is aware of these limitations, ASH strongly urges CDC to consider enhancing the quality and utility of this data collection by expanding it to include more diverse practices all over the country. ASH will be happy to serve as a resource for the Agency to assist with the dissemination of information on this data collection and the final results of this study.

In order to minimize the burden of this data collection on respondents, ASH strongly recommends that the CDC should employ an on-line survey that participants can easily access. The most useful on-line survey would be set up to allow the respondents to individually log on from any computer with internet access, to progressively save the information being imputed so that the responders can go back to it later and edit, and, finally, sufficient time for response.

ASH also requests that the CDC share the findings of this project with the Society soon after the studies are complete. The Society believes the findings will help focus future educational initiatives and help result in better quality of care for our patients.

Again, thank you for the opportunity to submit these comments. ASH looks forward to working with the CDC as this project moves forward and would be pleased to provide you with any additional information on the issues raised in this letter. It is the Society's hope that we not only help with the collection of this information, but also once the data is collected, work with you to achieve the goals of this project. Please contact Stephanie Kart, ASH Government Relations Manager at (202) 776-0544 or [skart@hematology.org](mailto:skart@hematology.org) for further assistance.

Sincerely,



Lawrence A. Solberg Jr, MD, PhD  
Chair, Committee on Practice