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

Supporting Statement

Part A

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A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval by the Office of Management and Budget (OMB) for a new, one-year data collection request to conduct a formative research project that will inform the development of an intervention prototype for increasing referrals from primary health care providers to hematologic specialists. Qualitative and quantitative information will be collected using three different methods: in-depth interviews, focus groups and survey. The data collection for which approval is sought is in accordance with CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer, authorized by Section 301 of the Public Health Service Act [42 USC 241] (Attachment 1). The proposed project is central to the prevention research agenda of the Division of Cancer Prevention and Control, CDC.

The quality and timeliness of health care in the United States is critical to the health of the population. Numerous efforts to assess and improve the quality of health care are supported through the Insitute of Medicine (IOM) Health Care Quality Initiative (http://www.iom.edu/CMS/8089.aspx). One of the reports produced through the initiative, *Crossing the Chasm*,[1] described significant delays in all aspects of care delivery, including access to appointment, waits in offices and facilities, prolonged response to diagnostic findings and overdue implementation of therapeutic interventions. The IOM panel concluded that delays in diagnosis can result in emotional distress, physical harm, and lack of respect to patients, and thus identified improving timeliness of patient care as one of six aims. A separate report produced through the IOM initiative, *To Err is Human*, identified mistakes and delay in diagnosis as a key diagnostic error for quality improvement efforts.[2]

Research conducted in the United Kingdom provides additional insight into the issues. Analysis of National Health Service Data[3] revealed that delays in diagnosis and specialty referral are common and that patients who saw primary care providers were more likely to experience delays.[4] Several other patient characteristics were implicated in excess delay, including age, socioeconomic status, race/ethnicity, and marital status.[5] Additional data from Europe and Canada, as well as single-site studies in the United States, specifically 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.[6] The most salient papers come from the United Kingdom, where studies of lymphoma[7] and myeloma[8] patients identified female gender and heavier symptom burden as additional contributors to delay. For lymphoma alone, the calculation of delays ranges dramatically, from 103 days (UK, lymphoma)[3] to 240 days (UK, lymphoma chart review),[9] to 137 days (Canada, lymphoma).[7] To our knowledge, however, no study has specifically assessed primary care physicians' attitudes and practices regarding the screening and diagnosis of hematological malignancies in the United States.[6] The complex, time-sensitive nature of the health care system makes delays in any aspect of the care process problematic and difficult to remedy.

To address this gap in knowledge, the Centers for Disease Control and Prevention (CDC) requests OMB approval to conduct research that will elucidate current practice patterns for the referral of patients with chronic hematological malignancies. The principal information collection will engage primary care physicians (PCPs) since they are most often the first point of contact in the medical system for cancer patients, and as such, serve a critical role in facilitating cancer diagnosis and treatment. The PCP has long been expected to expedite the referral of patients with suspected malignancy to hematologists or oncologists. While clear guidelines exist for screening and detecting the more common malignancies such as breast, colon, and cervical cancer, the hematologic malignancies pose a special problem for the primary care physician because they often present with subtle signs and symptoms. This is especially true of the chronic hematologic malignancies such as chronic lymphocyte leukemia (CLL), (CML), myelodysplastic syndrome (MDS), multiple myeloma (MM) and certain indolent types of non-Hodgkin's lymphoma (NHL). Moreover, until the last decade, patients had few treatment options and primary care providers may not have felt that referrals to specialists would impact the long term outcome of the patient. Information will also be collected from patients and from community hematologists and oncologists.

The specific aims of the project are to (1) document the specific problem(s) with respect to early recognition of chronic hematologic malignancies and referral pathways of these cases; (2) identify factors that contribute to the problem(s); (3) using an intervention mapping approach,[10] develop a prototype of an intervention based on findings from Aims 1 and 2 to address the identified problem(s) and factors for full development at a later time; and (4) develop a protocol to evaluate the intervention in an efficacy trial.

Privacy Impact Assessment

As required for privacy impact assessment, the following items are described below: 1) an overview of the data collection system, 2) a delineation of the items of information to be collected and 3) an indication of whether the system hosts a website.

Overview of the Data Collection System

Three different collection methods will be used to collect data. In-depth interviews and focus groups will be conducted by University of Texas Houston (UTH) and MD Anderson Cancer Center (MDACC) in Texas. Dana Farber Cancer Institute (DCFI) will conduct the PCP survey in Massachusetts. The information collection from PCPs will involve a postal survey, in-person or telephone interviews and in-person focus group discussions. The information collection from oncologists and hematologists will involve in-depth interviews conducted by telephone. The information collection from patients will consist of in-depth interviews. Data will be kept for one year after publication.

Items of Information to be Collected

We propose administering a one-time postal survey to primary care providers (physicians) in Massachusetts with the purpose of understanding their knowledge of and ability to recognize hematologic conditions, and their patterns of referral for patients with suspected chronic hematological malignancies to hematologists, oncologists and other specialists. In addition, we propose conducting in-depth interviews with hematologists and hematologic cancer patients in Texas to identify the factors related to delays in referrals. Lastly, we propose focus groups of primary care providers in Texas to better understand their perceptions of factors that facilitate or inhibit timely referrals. Name and address from existing lists will be used only to

recurit participants. REspnses data are de-identified (see Section A.10 for further description of process for de-identifying data). The exploratory nature of this proposed work fits the budget and strengths of each site.Together, these qualitative and quantitative data will be used to develop an intervention protoype which aims to reduce the time between diagnosis and referral of hematologic malignancies. The intervention prototype will be piloted at a later time.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The proposed data collection does not involve the collection of information from websites or website content directed at children less than 13 years of age.

A2. Purpose and Use of the Information Collection

This is a one-time data collection for formative research on general practitioners' and hematologists' attitudes and practices regarding referral of patients for chronic hematological diseases. Since no existing database contains this information, not collecting it would thwart the efforts to develop a behavioral intervention relevant to improving providers' referral behaviors.

Findings of this study will be shared for inclusion in a curriculum being developed elsewhere which actively seeks to educate primary care physicians to improve the diagnosis and referral of hematologic cancer patients. Not sharing it will mean incurring cost twice to find the same information.

Privacy Impact Assessment Information

The purpose of the project is to gain insight into the patterns of referral of patients with chronic hematologic malignancies and to develop prototypes of interventions focusing on PCPs. The ultimate goal is to develop tools that will improve the awareness, diagnosis, and early referral of persons with chronic hematologic cancers by PCPs. Data collected in this formative phase will be interpreted as a collective to provide insights to how providers and patients become aware of need for referral to a hematologic specialist. Using the Intervention Mapping protocol with these insights,[10] an intervention prototype will be developed for piloting and an efficacy trial in future phases. Overall, the aim is to improve the timeliness of care for chronic hematologic disease.

Pre-existing records will be used to establish eligibility. Potential respondents will be identified from these pre-existing records and queried as to their interest in participating in the study. PCPs and community oncologists who agree to participate will provide information about professional practices and referral patterns. Patients who participate will provide information about their experiences as patients. Information from all perspectives (PCP, oncologist, patient) is necessary to identify system-wide strengths, weaknesses, and communication issues. The information is necessary to design an intervention that is responsive to the needs of both patients and health care providers, and facilitates improved care and referral for patients.

Information in identifiable form will be collected. A coded identifier will be assigned to each respondent and all questionnaires and opt-out cards will be identified with the coded identifier. The IIF will be collected by a contractor and maintained in linkable format for two years. After publications, the linkage information will be destroyed. We do not intend to share linkage information. It is maintained for quality assurance purposes only. The proposed data collection will have little or no impact on the respondent's privacy.

3. Use of Improved Information Technology and Burden Reduction

Interviews and focus groups by their nature are not amenable to electronic information collection techniques, and therefore, have no electronic data collection mechanisms. To further reduce response time, the provider survey provides an option for completion via a web-based survey tool as well as the traditional paper survey. The web-based option is estimated to be used 50% of the time. No other data collection components of the project involve the use of automated, electronic or mechanical collection methods.

4. Efforts to Identify Duplication and Use of Similar Information

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. To our knowledge, no study has specifically assessed primary care physicians' attitudes and practices regarding the screening and diagnosis of hematological malignancies in the United States.[6]

The CDC has established an integrated initiative focusing on hematologic cancers. Twelve projects are funded to raise awareness about hematologic cancers (leukemia, lymphoma, and myeloma), including symptoms and treatments, to improve survivors' quality of life. See Attachment 16 for a brief synopsis of each of the initiative. Although these projects do share a focus on hematologic cancers, these aims of these projects do not overlap with our proposed work. As mentioned earlier, no similar data were found in our search of the literature.

5. Impact on Small Businesses or Other Small Entities

Physicians in private offices could possibly be respondents. Since the questions are to identify individual physician feelings and behaviors, it is not feasible to create a short form for doctors employed in small businesses. Every effort has been made to keep the survey and interviews focused on the key issues identified in the data collection instruments. We will not exceed the burden estimate for each component of the project.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection for formative research on general practitioners' and hematologists' attitudes and practices regarding referral of patients for chronic hematological diseases. Since no existing database contains this information, not collecting it would thwart the efforts to develop a behavioral intervention relevant to improving providers' referral behaviors. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5CFR 1320.5

All guidelines are met and the request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Notice was published in the Federal Register on April 13, 2009, Vol. 74, No. 69, pp.16873-16874 (see Attachment 2a). The American Society of Hematology (ASH) requested and received additional information about the project, which included draft data collection instruments and an outline of study methodology. Based on the information provided, the

American Society of Hematology submitted a letter of support with further recommendations concerning study design. This letter is included as Attachment 2b.

B. Efforts to consult outside the agency.

Since the aim of this project is to increase referrals by primary care physicians, it necessitates expertise both in hematology and in changing provider behavior. Hematologic experts at MD Anderson Cancer Center (MDACC) and the Dana Farber Cancer Institute (DFCI) were consulted for study design, survey sampling, and survey development several times during 2007 and 2008. Experts in developing interventions to change provider behavior at the University of Texas, Houston (UTH) were also consulted during the same time period for study design, survey content, and formative research activities, which would inform the process of intervention development and included the focus groups and interviews. Their names and contact information are listed below.

DANA FARBER CANCER INSTITUTE

Craig Earle	617-632-5564	617-632-2270	Craig_Earle@dfci.harvard.edu	44 Binney Street/Smith 271 Boston, MA 02115-6084
Gregory Abel	617-632-2304	617-632-2270	Gregory_Abel@dfci.harvard.edu	
Christopher Friese	617-632-4939	617-344-0427	Christopher_Friese@dfci.harvard.edu	
Lysa Magazu	617-582-7935	617-632-2270	Lysa_Magazu@dfci.harvard.edu	

MD ANDERSON CANCER CENTER

Louis Foxhall	713-792-2202	713-745-2646	lfoxhall@mdanderson.org	Office of Physician Relations - Unit 220 1515 Holcombe Blvd Houston, TX 77030-4009
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UNIVERSITY OF TEXAS HOUSTON

Maria Fernandez	713-500-9626	713-500-9750	Maria.E.Fernandez@uth.tmc.edu	7000 Fannin, UCT Suite 2522 Houston Texas 77030
Pat Mullen	713-500-9658	713-500-9750	Patricia.D.Mullen@uth.tmc.edu	
Kay Bartholomew	713-500-9630	713-500-9750	Leona.K.Bartholomew@uth.tmc.edu	

We expect to share the findings with the project officer for the contract with the Institute of Continuing Medical Education (formerly Vox Medica) with the intention of including relevant findings in their curriculum for physician education.

9. Explanation of any Payment or Gift to Respondents

Primary care providers who participate in the survey will be offered an incentive of $100, PCPs in the interviews offered $50, and PCPs in the focus groups will be offered a light meal in advance to encourage participants to arrive on time. Hematologists participating in the interviews will receive $50. Patients participating in the interviews will be offered $30. The incentive for the survey was determined as part of the survey pilot test. The other incentives were based upon previous experiences in using these methods. Physicians are difficult to reach and there are many demands on their time. The incentives are needed to promote efficient recruitment of respondents into the study.

10. Assurance of Confidentiality Provided to Respondents

CDC's collaborators will have access to information in identifiable form (IIF) to facilitate screening for study eligibility as well as recruitment and scheduling. The consent processes advise prospective respondents that only study staff will have access to the information being collected, and describe the privacy safeguards that will be implemented. Respondents will be informed that data will be treated in a confidential manner and will not be disclosed unless otherwise required by law. Safeguards such as the separation of IIF from response data are described in more detail below. CDC will receive a de-identified data set.

Letters of approval for the project from the Institutional Review Boards of Dana Farber Cancer Institute, MD Anderson Cancer Center and the University of Texas at Houston are included in Attachment 15.

A. Privacy Act Determination. This submission has been reviewed by ICRO, who has determined that the Privacy Act does apply. The applicable System of Records Notice (SORN)

is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. After data has been collected, information is primarily retrieved by unique participant identifier codes, not by IIF. Access to the files that link IIF to coded identifiers is strictly limited. No IIF will be transmitted to CDC.

All respondents will be recruited from pre-existing record systems. The American Medical Association master file will be used to identify potential respondents for the PCP survey. The MDACC Involved Provider Database will be used to identify potential respondents for the interviews with PCPs and community oncologists/hematologists. The MDACC data warehouse will be used to identify potential respondents for the patient component of the study.

A minimum amount of demographic information will be collected for descriptive analysis of physician respondents.

Potential respondents for the patient component of the study will also be identified from a pre-existing record system at MDACC. The recruitment data file contacting IIF (contact information) will not contain information from the patient record. Information to be collected from patients during interviews will describe their personal experiences with diagnosis, referral, and treatment.

B. Safeguards. A coded identifier will be assigned to each respondent, and all questionnaires and opt-out cards will be identified with the coded identifier.

When the data are entered into the study response database, each record will be identified only by this coded identifier. A separate computer file that links the study identifier to the subject's name will be maintained for one year past publication of findings. The cover letter for this study will describe the procedures used to safeguard privacy (Attachment 7).

For the focus groups, a set of appropriate codes will be developed for use in the qualitative analysis of the data. Qualitative analysis will be conducted using Atlas.ti.

For the interviews, MDACC staff will audio record, de-identify, and transcribe tapes of interviews, and provide them to UTH for analysis. No personal identifiers will be included in transcripts. Tapes and transcripts will be kept in a locked file, only accessible by the Principal Investigator and Project Director. Tapes will be destroyed after they are transcribed. A set of appropriate codes will be developed for use in the qualitative analysis of the data. Qualitative analysis will be conducted using Atlas.ti.

For the PCP survey, DFCI study staff will enter the responses submitted on paper into a password-protected Microsoft Access or MySQL database designed for this study. Participants choosing to respond electronically will submit responses via a secure web survey using the Illume Survey design and management system. Paper copies of questionnaires and other study materials will be kept in a locked file cabinet to which only the study staff will have access and destroyed one year after manuscript publication.

For the focus groups, MDACC staff will audio record, de-indentify and transcribe tapes of focus groups, and provide them to UTH for analysis. No personal identifiers will be included in transcripts, and only the research team will have access to the transcripts. Tapes and transcripts will be kept in a locked file, only accessible by the Principal Investigator and Project Director. Tapes will be destroyed after they are transcribed.

C. Consent. The procedures for obtaining consent have been approved by the appropriate IRBs. The appropriate consent-related information for PCPs is included in the survey cover letter (Attachment 7). PCPs who do not wish to participate in the PCP survey have the option of returning an opt-out card (see Attachment 9) to the study coordinator. For other study components, informed consent will be obtained at the time of the interview or focus group (see consent information in Attachments 4A, 6A, 12A, and 14A).

D. Voluntary Nature of Participation. Participation in the study is voluntary for all respondents (PCPs, community oncologists/hematologists, patients). The cover letter for PCPs (see Attachment 7) informs them that participation is voluntary. The voluntary nature of participation is also described in the informed consent process.

11. Justification for Sensitive Questions

Questions that may be deemed to be sensitive may be those that pertain to knowledge that is relevant to professional competence. These questions are essential for the identification of behaviors that may need to be altered to improve referrals. Race/ethnicity questions may also be considered sensitive by a portion of respondents; however, these questions are necessary for the interpretation of results of the information collection. All data will be de-identified and shared only in aggregate so that the behavior of individual PCPs or other providers is not singled out.

12. Estimates of Annualized Burden Hours and Costs

A. Estimates of the hour burden are presented below in Table 12A. They were derived from pilot tests of the instruments with nine or fewer individuals for each instrument. Scripts for asking if interested in the study were timed with other staff members. The community oncologists and hematologists interview phone recruitment script can be found in Attachment 3 and the interview guide in Attachment 4. The patient interview phone recruitment script can be found in Attachment 5 and the interview guide in Attachment 6. The PCP survey cover letter can be found in Attachment 7, the PCP survey in Attachment 8, the PCP Opt-Out card in Attachment 9, and the PCP reminder letter in Attachment 10. The PCP interview phone recruitment script can be found in Attachment 11 and the interview guide in Attachment 12. The PCP focus group phone recruitment script can be found in Attachment 13 and the focus group guide in Attachment 14. Data will be collected over a one-year period. A total of 198 burden hours is estimated.

A.12A Estimated Annualized Burden to Respondents					
Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Community Hematologists /Oncologists	Community Hematologists and Oncologists Interview Phone Recruitment Script	100	1	2/60	3
	Community Hematologists and Oncologists Interview Guide	18	1	1.5	27
Patients	Patient Interview Phone Recruitment Script	50	1	2/60	2
	Patient Interview Guide	18	1	1.5	27
Primary Care Providers	Primary Care Provider Survey Cover Letter	250	1	2/60	8
	Primary Care Provider Survey	150	1	20/60	50
	Primary Care Provider Opt-Out Card	100	1	2/60	3
	PCP Survey Reminder Letter	200	1	2/60	7
	Primary Care Provider Interview Phone Recruitment Script	100	1	3/60	5
	Primary Care Providers Interview Guide	18	1	1.5	27
	Primary Care Provider Focus Group Phone	50	1	3/60	3

	Recruitment Script				
	Primary Care Providers Focus Group Guide	18	1	2	36
				Total	198

B. Annualized estimates of the costs to the respondents are presented below in Table A.12B. The source of wage-per-hour figures was the Department of Labor website (www.dol.gov). Specifically, the http://www.bls.gov/oes/current/oes_ma.htm website was accessed for Massachusetts provider wages and the website http://www.bls.gov/oes/current/oessrcst.htm was accessed for Texas provider and patient wage information. Both were accessed on August 12, 2008. The total estimated annualized cost to respondents is $13,827.

A.12B Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage Rate	Total Cost
Community Hematologists /Oncologists	Community Hematologists and Oncologists Interview Phone Recruitment Script	100	1	2/60	$82.57 (TX)	$275
	Community Hematologists and Oncologists Interview Guide	18	1	1.5	$82.57 (TX)	$2,229
Patients	Patient Interview Phone Recruitment Script	50	1	2/60	$18.21 (TX)	$30
	Patient Interview Guide	18	1	1.5	$18.21 (TX)	$492
Primary Care Providers	Primary Care Provider Survey Cover Letter	250	1	2/60	$92.40 (MA)	$770
	Primary Care Provider Survey	150	1	20/60	$92.40 (MA)	$4,620
	Primary Care Provider Opt-Out Card	100	1	2/60	$92.40 (MA)	$308
	PCP Survey Reminder Letter	200	1	2/60	$66.25 (TX)	$442

	Primary Care Provider Interview Phone Recruitment Script	100	1	3/60	$66.25 (TX)	$331
	Primary Care Providers Interview Guide	18	1	1.5	$66.25 (TX)	$1,789
	Primary Care Provider Focus Group Phone Recruitment Script	50	1	3/60	$66.25 (TX)	$166
	Primary Care Providers Focus Group Guide	18	1	2	$66.25 (TX)	$2,385
					Total	$13,837

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other record-keeping requirements associated with this information collection.

14. Annualized Cost to the Government

The annualized cost to the government of this one-year data collection is presented in Table A14 below. It includes the costs of the data collection contract and costs of CDC staff who oversee the project. Research Triangle Institute (RTI) of North Carolina is the primary contractor, and as such, receives the funds directly from the government. RTI distributes funds to the subcontractors (DFCI, MDACC, and UTH).

A. 14 Estimates of Annualized Cost to the Government	
Item	**Annualized Cost**
Lead Technical Monitor @ 2.5% FTE Oversees project and monitors scientific procedures and ethics of data collection.	$2,500
Contractor - RTI Issues subcontracts for data collection; provides guidance on procedures and documentation to establish subcontracts; coordinates and participates in conference calls among contractor, CDC and subcontractors; and provides guidance subcontractors to develop work plans and budgets.	$450,000 - $200,000 to Harvard/DCFI - $200,000 to UTH/MDACC - $50,000 to RTI
Total	**$452,500**

15. Explanation for Program Changes or Adjustments

This is a new, one-time data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The overall project plan with publications indicated can be found in Attachment 17.

Project schedules for the survey, interviews, and focus groups are presented below in Tables A.16-1, A.16-2, and A.16-3, respectively.

A.16-1 Survey Time Schedule – Harvard/DCFI	
Activity	**Time Schedule**
Introductory letters and surveys sent by FedEx to potential respondents	2 weeks after OMB approval
Follow-up post card sent to non-responders	4 weeks after OMB approval
FedEx 2nd copy of cover letter and questionnaire to non-responders	6 weeks after OMB approval
Telephone non-respondents	8 weeks after OMB approval
Data entry and cleaning	10-16 weeks after OMB approval
Data analysis	16–24 weeks after OMB approval
Publication	20-40 weeks after OMB approval
Final Report	42 weeks after OMB approval

A.16-2 Interview Time Schedule – UTH/MDACC	
Activity	**Time Schedule**
Generate list of potential respondents	1-2 weeks after OMB approval
Contact potential respondent by phone to invite to participate in study(includes multiple attempts)	2-4 weeks after OMB approval
Interview respondents	4-10 weeks after OMB approval
Data entry and coding	10-18 weeks after OMB approval
Data analysis	18–28 weeks after OMB approval
Publications	28-40 weeks after OMB approval
Final Report	42 weeks after OMB approval

A.16-3 Focus Group Time Schedule – UTH/MDACC	
Activity	**Time Schedule**
Generate list of potential respondents	1-2 weeks after OMB approval
Contact potential respondent by phone to invite to participate in study(includes multiple attempts)	2-4 weeks after OMB approval
Hold focus groups	4-8 weeks after OMB approval
Data entry and coding	8-14 weeks after OMB approval
Data analysis	14–24 weeks after OMB approval
Publication	28-36 weeks after OMB approval
Final Report	42 weeks after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date of OMB approval will be displayed. There is no requested exception.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification are requested.

References

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