



Educational Needs Assessment to Identify the Decision-making and Information-seeking Patterns of Clinicians Managing Patients with Hematologic Malignancies

CE Outcomes, LLC AND the University of Nebraska Medical Center
Provided to Pfizer Medical Education Group

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INTRODUCTION

Pfizer Medical Education Group (Pfizer) has requested a proposal to provide an analysis of the educational needs of oncologists, oncology nurses, and pathologists managing patients with hematologic malignancies (HM), including leukemia and non-Hodgkin's lymphoma. We are privileged to present this proposal, developed by a partnership between CE Outcomes, LLC (CE Outcomes) and the University of Nebraska (Nebraska) which describes our approach to independent identification, documentation, and analysis of physician needs in this area. Included in this proposal is an overview of project expectations, estimated budget, publication plan, and timeline to support this effort.



BACKGROUND

There have been exciting recent advances in the treatment of hematologic malignancies, benign hematologic disorders, and disorders of hemostasis and thrombosis. Discoveries related to the molecular pathogenesis of these disorders have led to the development of targeted agents that are revolutionizing treatment. These advances have the capability of improving survival and decreasing morbidity for large numbers of patients.

However, these advances require that diagnostic and treatment guidelines are revised relatively frequently and there is a large gray area at any point in time between what some experts consider the leading--- but unvalidated---edge of research and what others consider the new state of the art in clinical care. Recent articles have identified wide variations in the way physicians manage different types of leukemia. There is a lack of consensus and significant variation in the indications for allogeneic stem cell transplantation as well as the choice of conditioning regimens, choice of post-transplant immune suppression, and the way graft-versus-host disease is treated.^{1 2 3 4} Additionally, wide variation in the investigation and management of immune thrombocytopenia was noted at an international consensus conference⁵ and the National LymphoCare Study documented wide variations in the choice of initial therapy for follicular lymphoma.⁶ This report also found that certain groups of patients were often not treated according to NCCN guidelines. This is a significant problem since practice variations are associated with poorer outcomes. Survivorship issues for cancer survivors are an area of increasing interest for patients and physicians and are being mandated by the government. Unfortunately, recent studies have demonstrated a lack of knowledge regarding guidelines for follow-up and surveillance of adolescents treated for lymphoma.⁷

Additional evidence of practice gaps was demonstrated at the Maintenance of Certification and Lifelong Learning Workshops that are conducted at the American Society of Clinical Oncology (ASCO) Meetings for the American Board of Internal Medicine. Responses to an audience response system survey at the 2009 meeting revealed knowledge gaps regarding the molecular targets of various tyrosine kinase inhibitors, and similar errors in questions regarding the use of lenalidomide for relapsed multiple myeloma. A large proportion of physicians failed to correctly answer questions regarding the role of hydroxyurea for essential thrombocythemia. Incorrect answers at the 2010 session also identified significant knowledge gaps despite evidence from meta-analyses and randomized trials published in journals such as

¹ Lee SJ, Joffe S, Artz AS, et al. Individual physician practice variation in hematopoietic cell transplantation. *J Clin Oncol* 26:2162, 2008.

² Pidala J, Lee SJ, Quinn G, et al. Variation in management of immune suppression after allogeneic hematopoietic cell transplantation. *Biol Blood Marrow Transplant* 17:1528, 2011.

³ Astwood E, Vora A. Personal practice: how we manage the risk of bleeding and thrombosis in children and young adults with acute lymphoblastic leukemia. *Br J Haematol* 152:505, 2011.

⁴ Khaled SK, Thomas SH, Forman SJ. Allogeneic hematopoietic stem cell transplantation for acute lymphoblastic leukemia in adults. *Curr Opin Oncol* 24:182, 2012.

⁵ Provan D, Stasi R, Newland AC, et al. International consensus report on the investigation and management of primary immune thrombocytopenia. *Blood* 115:168, 2010.

⁶ Friedberg JW, Taylor MD, Cerhan JR, et al. Follicular lymphoma in the United States: First report of the National LymphoCare Study. *J Clin Oncol* 27:1202, 2009.

⁷ Henderson TO, Hlubocky FJ, Wroblewski KE, et al. Physician preferences and knowledge gaps regarding the care of childhood cancer survivors: a mailed survey of pediatric oncologists. *J Clin Oncol* 28:878, 2010.



Blood and Journal of Clinical Oncology. For example, 23% of physicians felt that maintenance rituximab was indicated for diffuse large B-cell lymphoma patients in complete remission after R-CHOP. In addition, only 62% of physicians knew the appropriate management of a patient with acute lymphoblastic leukemia, and only 14% correctly answered a question relating to prognosis for patients with acute myelogenous leukemia.

After the 2010 of the American Society of Hematology (ASH) meeting, attendees were surveyed regarding current clinical practices for T-cell lymphomas, B-cell lymphomas, multiple myeloma, and acute myelogenous leukemia. Approximately 2/3 of respondents were from the United States. These surveys demonstrated a high clinical impact from presentations regarding new drugs (romidepsin and pralatrexate) for T-cell lymphomas. A similar impact was noted regarding presentations about new management options for mantle cell lymphoma and other new agents including brentuximab vedotin, CAL-101, and panobinostat. The survey also indicated that more than 50% rated the plenary session abstract regarding treatment of asymptomatic follicular lymphoma as having a very high or high clinical importance.⁸ Presentations on lenalidomide maintenance for multiple myeloma as well as arsenic trioxide for acute promyelocytic leukemia were felt to be practice-changing.

These examples provide evidence for significant knowledge gaps and the need for specific areas of emphasis and training for physicians and other healthcare providers who manage patients with hematologic malignancies.

EVALUATION METHODOLOGY

Healthcare quality researchers have long recognized that “interventions to improve [clinician behavior] should be tailored to potential barriers. Ideally, possible barriers are analyzed before the quality improvement interventions are developed to influence both type and content of the intervention.” In a comprehensive review of barrier analysis studies, results suggest “there is often a mismatch between the level of identified barriers and the type of interventions selected for use.”⁹

In order to efficiently support the most relevant and effective education for clinicians managing patients with HM, there must be an understanding of the existing educational gaps. CE Outcomes and Nebraska propose to utilize a qualitative and quantitative approach to understand the educational needs of oncologists/hematologists, oncology nurses, and pathologists to accelerate the adoption of evidence-based innovations to optimally manage patients with HM. While the RFP specifically requested analysis of oncologists/hematologists, opening the assessment to a wider array of clinicians allows for an overall perspective and insight into the decision-making process of the team that manages patients with HM.

The information gathered through such an assessment will provide:

- Independent documentation of practice patterns and barriers faced by clinicians managing patients with HM;
- A strategic educational plan with supporting evidence to prioritize grant support in order to improve patient health outcomes;

⁸ Ardeshtna KM, Qian W, Smith P, et al. An intergroup randomized trial of rituximab versus a watch and wait strategy in patients with stage II, III, IV, asymptomatic, non-bulky follicular lymphoma (Grades 1, 2, and 3a). A preliminary analysis. *Blood* 116:5, 2010 (abstr 6).

⁹ Bosch M, et al. Tailoring quality improvement interventions to identified barriers: a multiple case analysis. *J Eval Clin Pract* 2007;13:161-168.



- Baseline data for examining trends and comparing effectiveness of supported educational programs over time and across programs.

The proposed assessment objectives and process are described below.

PROJECT SCOPE AND OBJECTIVES

Formative Phase: Literature Review and Nominal Group Technique (NGT) Sessions

CE Outcomes and Nebraska will conduct a review of current literature documenting the performance gaps in the US in the management of patients with HM published from 2006-2012. This review will provide information related to the existing gaps between established goals and evidence and actual clinical practice. The evidence in the literature will guide the development of assessment questions to further investigate current practice patterns, attitudes, and barriers for managing patients with HM. A summary of this review, with accompanying references and methodology, will be provided in the final report.

Additionally, CE Outcomes will conduct focus groups with a national panel of community and academic-based oncologists, oncology nurses, and pathologists to determine their perspectives on specific areas of concern in managing patients with HM that can be addressed by education. These focus groups, also known as Nominal Group Technique (NGT) sessions will be to identify system, practice, and patient-related barriers which impede the optimal management of patients with HM. These sessions systematically elicit and prioritize responses to specific questions (eg, which barriers can best be addressed through education).^{10,11,12,13} Three sessions will be conducted: one for oncologists, one for oncology nurses, and one for pathologists.

These approaches will allow a grounded information base to develop instruments to discern areas for further inquiry.

Practice Pattern and Gap Analysis

CE Outcomes and Nebraska propose to identify the unmet needs, practice patterns, barriers, and attitudes of medical and hematologic oncologists (at academic medical centers or community cancer centers/clinics), as well as oncology nurses and pathologists, utilizing a case vignette survey assessment tool. Case vignettes have gained considerable support for their value in predicting healthcare provider practice patterns globally. Results from recent research demonstrate that case vignettes (compared to chart review and standardized patients) are a valid and comprehensive

¹⁰ Kristofco R et al. (2005) Attributes of an ideal continuing medical education institution identified through nominal group technique. *J Contin Educ Health Prof* 25: 221-8..

¹¹ Colon-Emeric CS et al. (2004) Barriers to providing osteoporosis care in skilled nursing facilities: perceptions of medical directors and directors of nursing. *J Am Med Dir Assoc* 5: 361-6.

¹² Delbecq AL et al. (1975) Group techniques for program planning: a guide to nominal group and delphi processes. Glenview, IL: Scott Foresman.

¹³ Shewchuk, R et al. (2007) A standardized approach to assessing physician expectations and perceptions of continuing medical education. *J Contin Educ Health Prof* 27: 1-10.



method to measure a processes of care in actual clinical practice.^{14,15,16,17} Furthermore, case vignettes are more cost-effective and less invasive than other means of measurement.

Following each patient case description, a series of clinical questions will be posed to the clinicians to assess their practice choices. In addition to the cases and clinical questions, items will be developed to assess related issues including, what factors influenced the physicians decision, challenges to optimally managing patients, confidence in managing patients, perceptions and attitudes related to managing patients with HM, information-seeking patterns, and demographic characteristics.

Suggested domains for survey questions include the following:

Knowledge and Attitudes

- What are clinician attitudes toward the current evidence, trials, and guidelines for patients with HM?
- How confident are oncologists and oncology nurses in treating patients with HM?
- What do clinicians know about the mechanism of action of available therapies?
- What concerns do clinicians have related to the treatment of HM?
- What treatment expectations do they convey to their patients?
- How do they assist their patients with adherence to medications?

Practice Patterns

- How are patients referred to oncologists? Do patients with HM get referred back to their primary physician at any point?
- What agents do oncologists use through their progression of treatment?
- How do oncologists monitor patients on therapy (eg, cytogenetics, FISH, molecular studies, mutational analysis)?
- Do oncologists or pathologists make the key decisions regarding testing?
- What endpoints do they use to make therapeutic decisions?
- How do oncologists switch therapies?
- How do oncologists treat advanced stage disease?
- When, if at all, would an oncologist choose to refer a patient with HM to another specialist?
- What are the perceived barriers to effectively managing patients with HM?

Information-seeking Patterns

- What are the perceived barriers to adopting new information or treatment approaches for patients with HM?

¹⁴ Peabody JW, et al. (2000) Comparison of vignettes, standardized patients, and chart abstraction: A prospective validation study of 3 methods for measuring quality. *JAMA*. 283: 1715-22.

¹⁵ Peabody, JW, et al. (2004) Measuring the quality of physician practice by using clinical vignettes: a prospective validation study. *Ann Intern Med* 141:771-80.

¹⁶ Luck J, et al. (2006) An automated scoring algorithm for computerized clinical vignettes: evaluating physician performance against explicit quality criteria. *Int J Med Inform* 75:701-7.

¹⁷ Peabody JW, Liu A. (2007) A cross-national comparison of the quality of clinical care using vignettes. *Health Policy Planning* 22:294-302



- Where do clinicians go for information on HM?
- When advances are made in the field, how do clinicians first learn about them?
- Are there educational resources that would be useful for clinicians, but are unavailable or inaccessible?
- What resources do clinicians use when explaining rare diseases to patients? Is there more needed in this area?

Demographics and Practice Characteristics

- Years in practice
- Specialty, board certification
- Volume of patients seen per week, volume of patients seen per week with HM
- Practice setting (eg, academic, private solo, private group)

Instrument validation and IRB review

After the draft survey instruments have been developed, the survey instruments will be field tested for content and structure validation with members of the intended target audience. Additionally, CE Outcomes and Nebraska will submit the study protocol and instruments to the University of Nebraska Medical Center Institutional Review Board (UNMCIRB) for review and approval; IRB approval is a significant factor in ensuring appropriate methods are employed in a research project that has, as one of its aims, the dissemination of the findings within peer-reviewed publications.

Participant recruitment and distribution

Surveys will be distributed by CE Outcomes to clinicians who treat patients with HM. A sample size of 150 oncologists (75 community-based, 75 from academic centers), 75 oncology nurses, and 100 pathologists will be used. This number is sufficient for a statistically significant sample with the ability to conduct subanalyses by key demographic variables. Respondents will be provided with a \$50 gift card for completion of the survey. Attention will be made to ensure a national sample representing all US regions. CE Outcomes will be responsible for fulfilling payment of all incentives.

Analysis and Confirmation

Descriptive and inferential statistical tests will be conducted on all data. The descriptive analysis will provide the percentages, means, and proportions for each question. The inferential statistics will provide information regarding the influence of practice characteristics (eg, volume of patients seen, years in practice, practice environment) on practice patterns and decisions. Inferential analyses may include Chi-square, linear regression, and T-test when applicable. All data will be presented in aggregate form and will not reveal individual responses of the respondents.

Following the survey implementation and the subsequent analysis of the data collected, relationships among the variables assessed will have been identified. To validate and further describe the findings of the research, CE Outcomes and Nebraska will conduct 3 structured confirmatory interviews with practicing oncologists, 2 interviews with oncology nurses, and 2 with pathologists in order to better understand the implication of the results of the survey to practice and confirm identified resource needs and informational sources. Physicians will receive an honorarium of \$300 for their participation. CE Outcomes will be responsible for fulfilling payment of all incentives.



REPORTING

CE Outcomes and Nebraska will provide a final report to the Client in the form of a PDF document and PowerPoint presentation.

The final report will include

- an executive summary;
- an overview of the purpose of the assessment;
- complete methodology;
- final surveys and interview scripts for all groups;
- characteristics of the sample from the survey;
- results from the overall study, including summaries of interviews and focus groups;
- suggested recommendations that may help the Client support education in this area;
- the publication plan.

Publication

To distribute and publicize the findings from this study, CE Outcomes and Nebraska propose to: 1) develop a manuscript from the study findings for potential publication within a professionally appropriate peer-reviewed journal; and 2) develop an abstract for submission to a professional society conference.

Manuscript: CE Outcomes and Nebraska will author and submit the manuscript to appropriate journal(s) for review for publication, and respond to reviewer comments. The following journals for submission of the manuscript, based on the main themes and results evident in the data:

- The Oncologist
- Leukemia
- Leukemia Research
- Journal of Clinical Oncology

Presentation: CE Outcomes and Nebraska will author an abstract for submission to an appropriate professional society annual meeting and upon acceptance develop and present the poster. Where possible, the submissions will be developed with the consultation of an expert clinician in the appropriate area to help interpret and translate the data to each particular audience. Meetings that will be considered include:

- ASCO Annual Meeting
- ASH Annual Meeting
- Pan-Pacific Lymphoma Conference
- American Association of Cancer Educators (AACE) Annual Meeting
- NCCN Annual Conference

PROJECTED TIMELINE

The following timeline reflects a start date of December 12, 2012. If the project is not initiated by the client by this date, the project timeline is subject to change.



Project tasks and activities	Projected timeline
Initiation of project	Week 1
Literature review	Week 1-4
Focus group sessions	Week 2-4
Development of survey instruments	Week 3-6
Submission to WIRB	Week 7
Survey implementation	Week 13 – Week 16
Data analysis	Week 17
Physician summative interviews	Week 17-18
Development of final report, initiation of publication plan	Week 19 -21