Title

CML, ALL, or B-Cell Lymphomas: Understanding Professional Practice Gaps and Educational Needs Among Hematologist Oncologists in the United States, a collaboration by the *Annenberg Center for Health Sciences at Eisenhower, Clinical Care Options,* and *AXDEV Group Inc.*

Project Description

The Annenberg Center for Health Sciences at Eisenhower, Clinical Care Options (CCO), and AXDEV Group Inc. will strategically work together to perform 1) an in-depth exploratory *qualitative* assessment of attitudinal, motivational, interprofessional, and contextual issues and barriers to the optimal treatment and management of chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), and B-cell lymphomas, in academic and community cancer centers across the United States, including the Lucy Curci Cancer Center, and 2) an in-depth confirmatory *quantitative* assessment to validate and expand upon gaps/barriers identified in the qualitative assessment and to assess tumor/treatment/regimen specific gaps. This study will contribute to widen the understanding of the various factors that are affecting clinical reasoning among medical oncologists, beyond the evidence-based clinical processes, in order to better inform the design and deployment of future continuing medical education activities.

Study Rationale

Hematologic malignancies encompass a myriad of complex diseases and therapeutic regimens, which present constant challenges to treating clinicians. Physicians, particularly oncologists, face a multitude of barriers in overcoming the challenge of staying current in a rapidly changing field; this creates an ongoing educational/professional practice gap among the target audience.[1] These obstacles not only include cognitive-behavioral barriers (such as lack of knowledge and professional skill) but also attitudinal or rational emotive barriers as well as physician/healthcare professional–specific, patient-specific, resource, and systems/process barriers.[2] Both external and CCO survey data indicate that there are many educational needs and practice gaps among hematologists/oncologists illustrated by uncertainty as to the optimal management of CML, ALL, and B-cell lymphomas.[3,4,5,6,7,8,9] Interestingly, in support of the existence of barriers other than knowledge and skill, responses to activity outcomes questions for a CCO-developed interactive treatment decision tool for patients with

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1. John S, Niederhuber JE. Keeping pace. Oncologist. 2008;13:4-5.
2. Cochrane LJ, Olson CA, Murray S, Dupuis M, Tooman T, Hayes S. Gaps between knowing and doing: understanding and assessing the barriers to optimal health care. J Contin Educ Health Prof. 2007;27:94-102.
3. Jaffe ES, Pittaluga S. Aggressive B-cell lymphomas: a review of new and old entities in the WHO classification. American Society of Hematology Education Program Book. 2011. Available at: http://asheducationbook.hematologylibrary.org/content/2011/1/506.full. Accessed November 7, 2012.
4. Barrans S, Crouch S, Smith A, et al. Rearrangement of MYC is associated with poor prognosis in patients with diffuse large B-cell lymphoma treated in the era of rituximab. J Clin Oncol. 2010;28:3360-3365.
5. Pasquini R, Cortes JE, Kantarjian HM, et al. Survey of the frontline treatment and management of chronic myeloid leukemia (CML) in a real-world setting: the 3rd annual update of the Worldwide Observational Registry Collecting Longitudinal Data on Management of Chronic Myeloid Leukemia Patients (The WORLD CML Registry). Program and abstracts of the 53rd American Society of Hematology Annual Meeting and Exposition; December 10-13, 2011; San Diego, California. Abstract 1695.
6. Nachman JB, La MK, Hunger SP, et al. Young adults with acute lymphoblastic leukemia have an excellent outcome with chemotherapy alone and benefit from intensive postinduction treatment: a report from the children's oncology group. J Clin Oncol. 2009;27:5189-5194.
7. Data on file. Clinical Care Option's survey of US Oncology physicians. "Working Groups in Chronic Myelogenous Leukemia: Key Issues in Primary Treatment, Evaluation, and Second-line Therapy." 2011.
8. Friedberg JW. Relapsed/refractory diffuse large B-cell lymphoma. Available at: http://asheducationbook.hematologylibrary.org/ content/2011/1/498.full. Accessed November 7, 2012.
9. Khal B. Maintenance in (high-tumor-burden) FL: how I help patients decide. Available at: http://www.clinicaloptions.com/Oncology/Treatment%20Updates/ClinicalThought/Lymphoma1.aspx. Accessed November 7, 2012.

CML, 23% of participants indicated that expert recommendations did not affect their treatment plan, suggesting there are barriers beyond knowing the correct approach to changing or continuing treatment in CML.[10]

Educational Needs Assessment Methodology

Clinical reasoning denotes the cognitive process by which a physician evaluates and manages a patient's medical case and renders a treatment decision. Clinical reasoning has been presented by Pelaccia and colleagues as a dual process combining rational decision making *and* intuitive decision making, as represented in Figure 1 below.[11] This approach recognizes that the complex clinical decision making employed by hematologists/oncologists in the treatment and management of hematologic malignancies such as CML, ALL, and B-cell lymphomas is not *solely* subject to evidence, clinical guidelines, and standards of care. Critical individual factors—such as professional experience, illness heuristics, pattern recognition, and motivation—as well as interpersonal and contextual factors have a substantive impact on hematologists'/oncologists' clinical reasoning processes and treatment decisions.[12] It behoves educators to ensure an in-depth understanding of both the rational and intuitive decision factors in order to design optimal educational interventions.

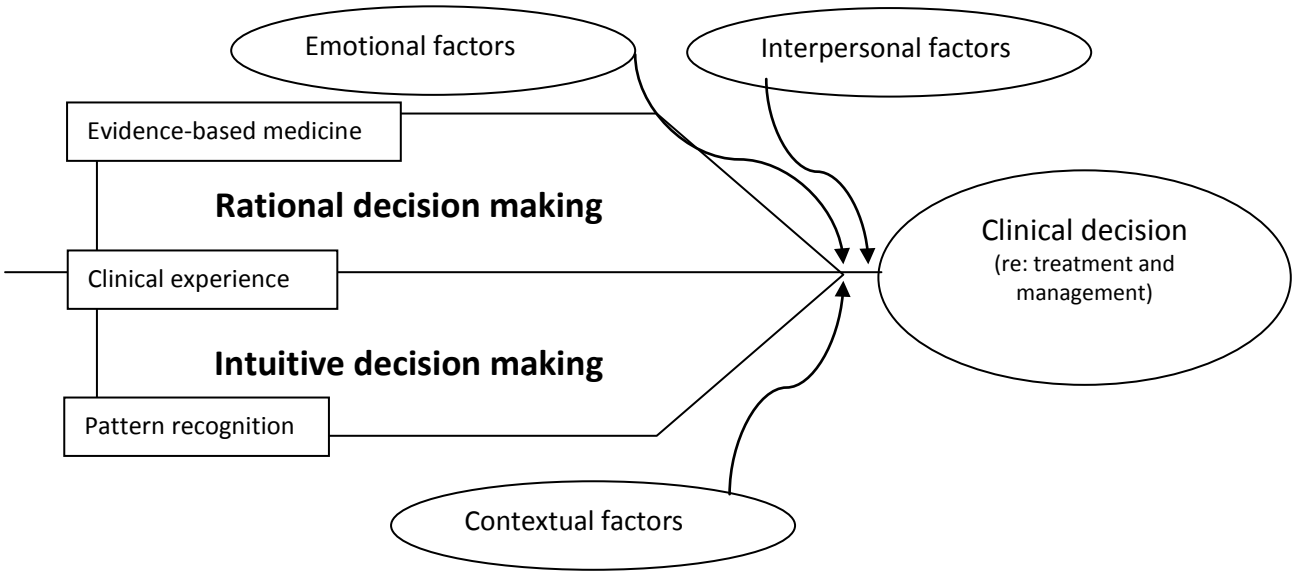

Figure 1. The multifactorial aspect of the clinical reasoning process.[11,12]

Drawing from the tenets of clinical reasoning and considering the various factors that affect clinical decision making, the collaborators will design the educational needs assessment of hematologic malignancies, specifically focused on CML, ALL, and B-cell lymphomas, to facilitate the understanding of those complex factors beyond the rational, evidence-based clinical processes. This educational needs assessment is designed to be an in-depth exploration of the various factors that affect clinical reasoning among hematologists/oncologists in community and academic cancer centers in the United States to inform future medical education and performance improvement programs.

A behavioral research approach including 2 phases (see Figure 2 below) will be deployed. The first phase will be qualitative to foster an exploration of the attitudinal, motivational, and contextual issues—the **intuitive decision-**

10. Data on file. 2012. Clinical Care Options learner data. CML chronic myeloid leukemia: expert guidance on monitoring response to first-line tyrosine kinase inhibitor therapy.
11. Pelaccia T, Tardif J, Tribyv E, Charlin B. An analysis of clinical reasoning through a recent and comprehensive approach: the dual-process theory. Med Educ Online. 2011;16:5890.
12. Charlin B, Lubarsky S, Millette B, et al. Clinical reasoning processes: unravelling complexity through graphical representation. Med Educ. 2012;46:454-463.

making factors as outlined by Pelaccia and colleagues—inherent to clinical reasoning in hematologic malignancies. This phase will help inform the design of the second phase, which would be quantitative and confirmatory in nature, with a particular focus on the **rational decision-making factors,** including tumor treatment, regimen, and management decision factors that influence clinical reasoning decisions in CML, ALL, and B-cell lymphomas.

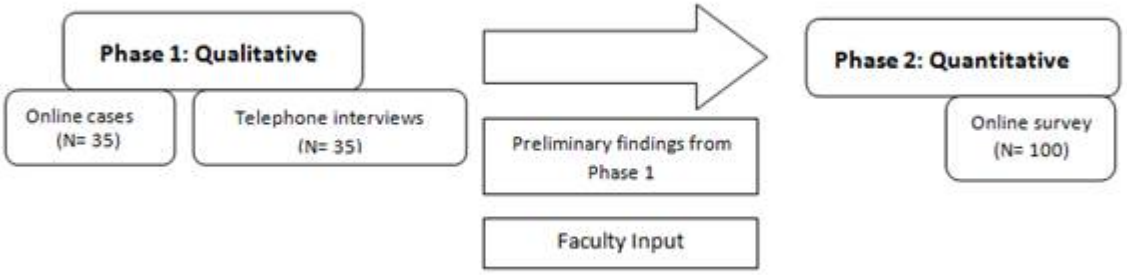

Fig 2. Two-phase educational needs assessment in CML, ALL, and B-cell lymphomas methodology design.

Phase 1: Qualitative
In Phase 1: Qualitative, iterative cases and semi-structured interviews that specifically trigger intuitive decision-making factors influencing clinical reasoning will be designed based on best practices in the assessment of the clinical reasoning factors in medical education.[13,14]

1. Cases: Iterative complex medical cases built to explicitly tap into the physicians' intuitive decision-making process will be designed with key faculty and educational assessment experts. Iterative complex medical cases will be built to explicitly tap into the different factors that come into play in the clinical reasoning process, including the rational decision making, the intuitive decision making, and other emotional and interpersonal factors. Each case will be completed online prior to the interview, by a subset of clinical hematologists/oncologists from the 10 participating community cancer centers (3-4 participants from participating cancer center; N = 35).

2. Semi-structured interviews: After completion of the case, participants will be invited to an in-depth 45-minute telephone interview. The interviewer will guide interviewees through each decision taken in the case and will probe for additional information in order to understand the different personal, contextual, affects, and behaviors that has influenced his/her clinical reasoning. Emphasis will be placed on understanding the underlying factors (emotional, interpersonal, and contextual) that affect the CML, ALL, and B-cell lymphomas treatment and management decision making process, above and beyond clinical guidelines, evidence, and/or standards of care. The last section of the interview will discuss the perceived needs of the healthcare providers in relation to continuing medical education, with a particular focus on what is practical and what is relevant for educational development.

13. Durning SJ, Artino AR Jr, Pangaro LS, van der Vleuten C, Schuwirth L. Perspective: redefining context in the clinical encounter: implications for research and training in medical education. Acad Med. 2010;85:894-901.
14. Durning SJ, Artino AR, Pangaro L, van der Vleuten CS, Schurwirth L. Context and clinical reasoning: understanding the perspective of the expert's voice. Med Educ. 2011;45:927-938.

Domains of exploration for the qualitative phase include, but are not limited to:

- Intrinsic motivation/professional fulfillment
- Level of comfort/confidence with current treatment options
- Balancing patients expectations with treatment outcomes
- Patient–provider clinical relationship
- Patient ownership/ accountability issues
- Value of quality of life vs. prolonging life
- Risk–benefit analyses
- Shared decision making and patient engagement strategies
- Multidisciplinary team roles and responsibilities

Phase 2: Quantitative

An in-depth confirmatory *quantitative* assessment will be conducted to validate and expand upon gaps/barriers identified in the qualitative assessment and to assess tumor/treatment/regimen specific gaps. Potential areas for investigation include new advances in care, sources of information consulted for best practices and/or education, gaps in competence (e.g., treatment duration, switching treatment options, adverse effects, monitoring response and addressing adherence), and barriers to adoption of new treatment options. Subject to faculty final approval, specific questions that may be addressed in the quantitative phase include:

Examples: Potential areas of investigation for survey questions

- In what contexts would you consider advising clinical trial enrollment for patients with CML, ALL, or B-cell lymphomas?
- How do you manage toxicities associated with traditional chemotherapy agents, tyrosine kinase inhibitors, and other available treatments?
- What tools do you use and what biomarkers do you test for when evaluating treatment response?
- What are the barriers to your use of biological therapies in your patients with hematologic malignancies?
- When considering treatment for your patients with CML, what factors do you consider the most important in selecting the appropriate agents or combination regimens?
- What would be the most important considerations in the decision to change therapy for CML?
- What criteria would you contemplate when selecting patients with ALL for transplantation? In treating a patient with relapsed ALL, what are your primary concerns with the currently available therapies?
- When treating patients with aggressive large B-cell non-Hodgkin's lymphomas (eg, diffuse large-B cell lymphoma) what would influence your decision to select traditional chemotherapy vs rituximab or other biological therapies as the most appropriate treatment? How do you stratify low-risk vs. high-risk patients with these diseases?

Quantitative Assessment
Participants will be invited via email from the CCO membership. Interested participants will be invited to consent to the study and to complete the 15- to 20-minute online survey.

The survey, using information gathered from the experts as well as information from the qualitative assessment, will be designed to capture baseline data on perceived and observed professional practice gaps using questions on practice challenges and case vignettes. The data collected from this survey will be compared with the results of the qualitative assessment and other important information relevant to finalization of the needs assessment and defining of the practice gaps to be published in the final report.

Faculty Recruitment/Engagement
The **2** faculty members responsible for providing expert insight into the surveys and evaluations in this program will be chosen jointly by the Annenberg Center and CCO's editorial team.

Dissemination Plan
The findings from this study will be made available in the public domains in the following sequence:

1. The reports of findings (qualitative and quantitative) will first be presented to Pfizer
2. Summary of findings will be presented to the cancer centers that participated in the study
3. A manuscript will be developed for submission in peer-reviewed journal
4. Abstracts will be developed for submission at key conferences for presentation of findings (quantitative and qualitative) (e.g., American Society of Clinical Oncology)
5. Summary of findings will be posted to the CCO Web site, as well as on key websites in the continuing education community (e.g., Alliance for Continuing Education in the Health Professions)

Note: The collaborators are aware that wide dissemination of the summary of findings to the cancer centers and continuing education community may impede chances of publications or presentation to conferences but has been prioritized to be sensitive to Pfizer request for rapid dissemination of findings. Timing of each sequence of the dissemination plan will need to be reconsidered accordingly.

Workplan Overview
The Qualitative Survey Phase: December 2012 - March 2013

Phase and Tasks	Roles and Responsibilities	Time
Review of literature and of existing data sources, standards of care evidence-based medicine Characterize types of community cancer centers for the qualitative assessment	• CCO (co/lead) • Annenberg (co/lead) • Expert faculty (consulted)	• December 2012
Development of assessment framework and logic for qualitative phase Design of qualitative assessment to assess critical reasoning skills, with particular focus on the contextual/systems/attitudinal barriers to best practices for these diseases in community and academic cancer centers (IRB optional)	• AXDEV (lead) • Optional: Expert faculty for 2 cases on critical decision making in each therapeutic area	• December 2012 - January 2013
Recruitment/enrollment of healthcare providers into qualitative assessment Recruitment of participants from cancer centers for qualitative assessment	• CCO (co/lead) • Annenberg (co/lead); Lucy Curci Cancer Center	• January - February 2013
Data collection through case and telephone interviews (N = 35) Conduct and deploy qualitative assessment in community and academic cancer centers	• AXDEV (lead)	• February - March 2013
Analysis and multidisciplinary interpretation of	• AXDEV (lead)	• March 2013

qualitative data from telephone interviews, and quantitative data from cases Analyze qualitative findings Interpret qualitative findings	• AXDEV (lead) • Expert faculty (consulted)	• March 2013

The Quantitative Survey Phase: April 2013 - June 2013

Phase and Tasks	Roles and Responsibility	Time
Development of assessment framework and logic for quantitative phase Design quantitative assessment to assess contextual/systems/attitudinal barriers, as well as tumor/treatment/regimen specific gaps	• CCO (lead) • Annenberg (consulted) • Expert faculty (consulted) • AXDEV (consulted)	• April 2013
Data collection through online survey (N = 100) Deploy quantitative assessment to CCO membership	• CCO (lead)	• May 2013
Analysis and multidisciplinary interpretation of quantitative data from survey (N = 100) Analyze of quantitative findings Collectively interpret quantitative findings	• AXDEV (lead) • CCO (consulted) • Annenberg (consulted) • Expert faculty (consulted)	• June 2013

The Publication Phase: July 2013 - Completion

Phase and Tasks	Roles and Responsibility	Time
Develop reports of findings (quantitative and qualitative) to present to Pfizer, cancer centers, and other Web sites (eg, CCO, Alliance)	• AXDEV (lead) • CCO (critical review) • Annenberg (critical review) • Expert faculty (critical review)	• July 2013
Submit reports to Pfizer, cancer centers, and other Web sites	• CCO (co-lead) • Annenberg (co-lead)	• July 2013
Develop manuscript of findings (quantitative and qualitative) for submission to peer-reviewed journal	• AXDEV (lead) • CCO (critical review) • Annenberg (critical review) • Expert faculty (critical review)	• August 2013
Submit manuscript to peer-reviewed journal (optional; acceptance cannot be guaranteed)	• AXDEV (lead)	• August 2013
Develop abstract for presentation of findings (quantitative and qualitative) to conferences (e.g., American Society of Clinical Oncology)	• CCO (lead) • Annenberg (critical review) • Expert faculty (critical review) • AXDEV (critical review)	• August 2013
Submit abstract to conference	• CCO (lead)	• As per society