Title

Renal Cell Carcinoma: Understanding Professional Practice Gaps and Educational Needs Among Medical Oncologists in the United States, a collaboration by *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 renal cell carcinoma (RCC) 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.

Rationale for Study

The management of advanced RCC is very complex, with several agents approved during the last few years and no defined optimal initial systemic treatment or evidence supporting optimal sequencing of the agents, resulting in a significant challenge for clinicians and potentially compromised outcomes for patients.[1] 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 oncologists illustrated by uncertainty as to the optimal management of RCC.[4-9] 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 advanced RCC, 20% of participants indicated that expert recommendations did not impact their treatment plan suggesting there are barriers beyond knowing the optimal treatment for this malignancy.[10]

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10. Data on file. 2012. Clinical Care Options Learner Data. CML Chronic Myeloid Leukemia: Expert Insight Into Optimal Treatment for Individuals With Advanced Renal Cell Cancer.

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 complex clinical decision making such as the one that occurs by oncologists in the treatment and management of RCC is not *only* 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 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.

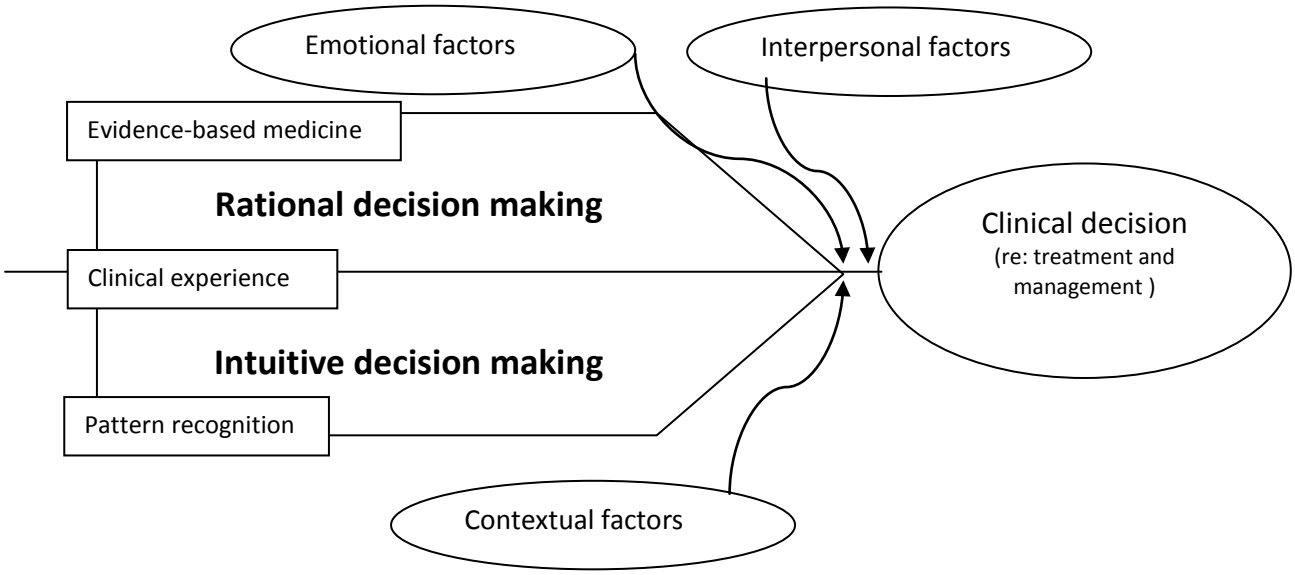

Figure 1. The multifactorial aspect of the clinical reasoning process.[11,12]

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 RCC 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 medical oncologists in community and academic cancer centers in the United States in order 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-making factors** as outlined by Pelaccia and colleagues—inherent to clinical reasoning in RCC. 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 RCC.

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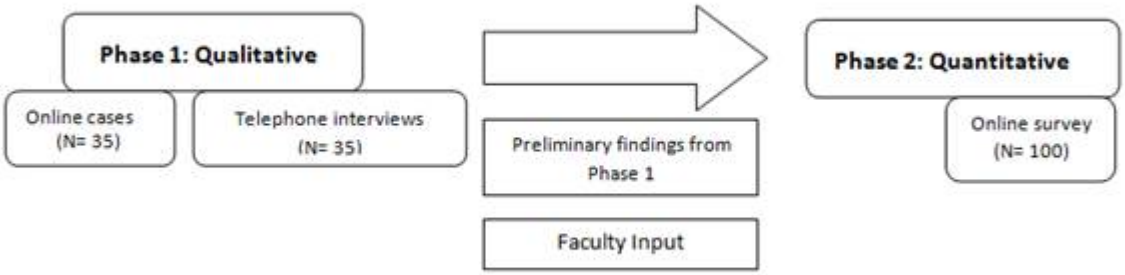

Fig 2. Two-phase educational needs assessment in RCC methodology design.

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.[5,6]

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 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-minutes 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 RCC 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.

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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
- Financial constraint/reimbursement

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 of RCC, 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, examples of questions that may be addressed in the quantitative phase include:

- Which patients with metastatic RCC may benefit from cytoreductive nephrectomy?
- How do you choose which specific therapeutic agent to use for individual patients with newly diagnosed metastatic RCC?
- How will recent data comparing pazopanib and sunitinib affect first-line therapy selection by clinicians and their patients?
- What constitutes a significant clinical benefit in RCC?
- When do you discontinue using one agent and switch to another in patients with metastatic RCC?
- Should treatment-related toxicities be managed with supportive care, dose reductions, treatment breaks, switching agents, or a combination of the above?
- How do you decide whether to continue using VEGF-targeted therapy or switch to an mTOR inhibitor in patients who progress on previous systemic VEGF-targeted therapy?
- Is there a “best” sequence of therapy to use for patients with metastatic RCC?
- What is the status of adjuvant therapy for patients with resected RCC?

Sample Recruitment Approach

Qualitative Assessment

Strong execution of the qualitative assessment phase of this project will rely on CCO's extensive experience in local and regional live education in a variety of oncology topics, including more than 200 live events between July 2009 and present. CCO has identified and maintains a database of nearly 700 community cancer centers, hospitals, and large oncology practices around the country that we have previously approached as potential targets for placement of oncology educational activities. The CCO database includes the appropriate educational coordinators for contact within each location that has previously indicated an interest in and willingness to accept placement of educational activities from outside parties. CCO staff (assisted by third-party contractors with expertise in recruitment) are responsible for contacting the education coordinators regarding interest by hematology oncology specialists at that institution for participation in telephone interviews about their practices in the treatment of patients with RCC.

The Luci Curci Cancer Center, a member of the Eisenhower Medical Center (EMC) to which Annenberg Center is affiliated, has been identified as one of the key centers to include in the qualitative assessment because it represents one of several community cancer center models. Luci Curci serves an elderly population that is often resident in the area only during the winter months. The care of these patients is often coordinated with major academic centers. Because of the relative affluence of this patient population, they often have higher performance status than the comparable age cohort in other communities and therefore receive more aggressive treatment. Centers serving similar "snow bird" populations are found in Arizona, Florida, the Carolinas, and other communities with mild climates.

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

The Quantitative Survey Phase: April 2013 - June 2013

Phase and Tasks	Roles and Responsibility	Time
Development of assessment framework & 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 (eg, 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 deadline