Renal Cell Carcinoma: Understanding Professional Practice Gaps and Educational Needs among Oncologists in the United States

A collaboration by

The Annenberg Center for Health Sciences at Eisenhower
Clinical Care Options
AXDEV Group Inc.

Final Report

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Executive Summary

This final report summarizes the findings from an integrated analysis of the data collected through a mixed-methods needs assessment in renal cell carcinoma (RCC). This needs assessment was designed and deployed through a collaboration among the Annenberg Center for Health Sciences at Eisenhower, Clinical Care Options, and AXDEV Group, Inc. It was designed to increase the understanding of the factors that affect the clinical reasoning of US medical oncologists in the care they provide to patients with this condition. Results will contribute to the body of knowledge in the field and provide evidence to support the design of clinical tools, educational programs and performance improvement interventions.

Data was collected through an online survey (142 respondents) and in-depth interviews (27 respondents). The following seven (7) practice performance gaps in the treatment and management of patients with RCC were identified through a mixed-method analysis of both qualitative interviews and quantitative survey:

1. Lack of knowledge on the important predictors of poor risk / short survival in RCC
2. Challenges with the selection of an optimal treatment option for patients with poor risk
3. Challenges in the clinical decision-making on the need for continuation/escalation of dose for current agent or switching to another agent based on patient response
4. Challenges in rapidly integrating newly FDA-approved agents in clinical practice
5. Challenges in properly recognizing non-radiologic progression and its importance in treatment decisions
6. Challenges in multi-disciplinary collaboration, specifically with surgeons and primary care physicians
7. Lack of knowledge of quality of life assessment tools and lack of skills to optimally consider quality of life in the formulation of a treatment plan, contributing to challenges optimizing the risk-benefit balance of a treatment plan

There are several causalities that may underlie the above gaps and barriers to optimal care in RCC, such as the low prevalence of RCC compared to other types of cancers. This would likely necessitate a certain prioritizing by medical oncologists in regards to keeping themselves up-to-date with the latest treatment options for cancer types they encounter with higher frequency in their practice. In addition, the extensive reliance of medical oncologists on clinical practice guidelines, which are often not updated with the most current data, may hinder their willingness to incorporate new agents and tools into optimal management strategies for their patients with RCC.

These seven (7) practice performance gaps have been found in significant proportion in the whole sample of respondents. Evidence from this study indicates key practice performance gaps that are addressable from an educational perspective, and clinically relevant by their impact on delivery of optimal care, clinical efficiencies, and patients' health outcomes. Specific recommendations for the development of targeted educational activities are provided within this report. Group-specific comparison of findings was performed to provide evidence-based data to better target and adapt nationwide educational programs. The development of a manuscript to be submitted to a peer-reviewed journal, and the dissemination of the findings from this needs assessment with external stakeholders through multiple channels, is deemed important to ensure the sharing of the key outcomes of this study with the oncology and medical education communities.

Introduction

The Annenberg Center for Health Sciences at Eisenhower, Clinical Care Options (CCO), and AXDEV Group have collaborated to develop and deploy a national needs assessment in renal cell carcinoma (RCC), financially supported by an unrestricted educational grant from Pfizer US.

This needs assessment aims to provide a broader understanding of the various factors that are affecting clinical reasoning among medical oncologists treating patients with RCC at academic medical centers and/or at community cancer centers and clinics in the United States. Findings from this needs assessment will help better inform the design and deployment of future interventions such as continuing medical education (CME) activities.

This needs assessment was conducted in two phases:

> 1) An in-depth exploratory *qualitativ*e assessment of attitudinal, motivational, interprofessional and contextual issues, and barriers to the optimal treatment and management of RCC; and
> 2) An in-depth confirmatory *quantitative* assessment designed to validate and expand upon gaps/barriers identified in the qualitative assessment and assess tumor/treatment/regimen specific gaps.

This final report to Pfizer includes the integrated analyses of the data from both phases of the study and highlights some clear practice performance gaps in the treatment and management of patients with RCC. Investigation of the causalities of those gaps, as well as group-specific analysis, as a function of clinical experience, clinical setting and RCC caseload, are also included.

Study Objectives

The objectives of this needs assessment are as follows:

1. Increase understanding of the factors that affect the clinical reasoning of medical oncologists in the care they provide to patients with renal cell carcinoma (RCC)
2. Identify practice performance gaps and critical educational needs in RCC among medical oncologists in the US to help guide the design of future educational interventions
3. Contribute to the body of knowledge on the practice performance gaps of medical oncologists as they provide care to patients with RCC

Methodology

Study Design

This needs assessment study was designed and deployed in two phases; one qualitative exploratory phase and one quantitative confirmatory phase (see Figure 1). Two distinct independent ethical approvals were obtained to ensure informed consent, protection and confidentiality of participants, ethically acceptable level of compensation (i.e., fair market value, but not enough to create coercion) and increase possibility of acceptance to peer-reviewed journals. The qualitative phase was approved by IRB Services on February 19, 2013, and the quantitative phase was approved by Eisenhower Medical Center Institutional Review Board on May 16, 2013.

This study was initiated by conducting a review of the literature to form hypotheses on gaps in the knowledge, skills and clinical confidence of US oncologists managing the care of patients with RCC. The generated hypotheses informed the design of the research tools to be used in both phases of the study. Phase 2 design was further supported by findings from Phase 1. A synthesis of the key findings from the literature review can be found in **Appendix A** of this report.

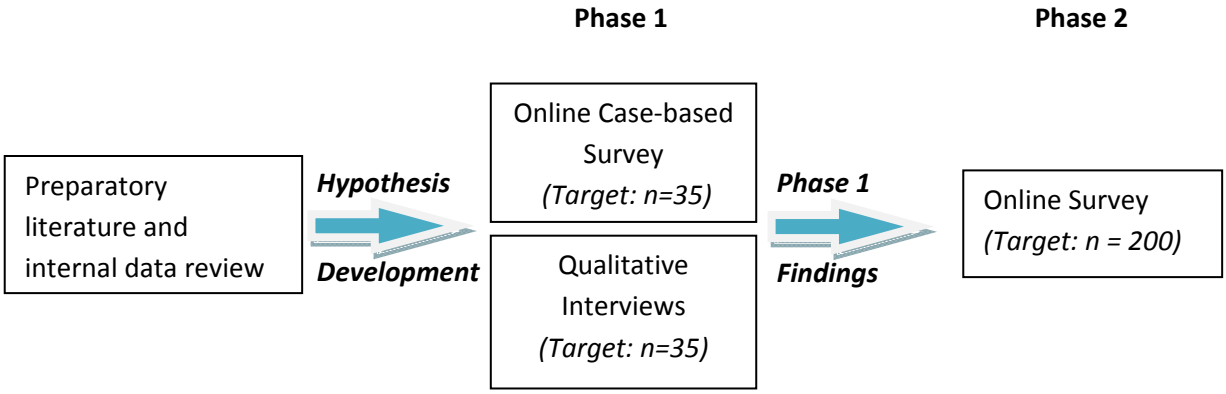


Figure 1. Two-phase design of the educational needs assessment in renal cell carcinoma.

In the qualitative phase of the study, medical oncologists were recruited to participate in a 45-minute qualitative telephone interview. The telephone interview was comprised of semi-structured questions based upon domains identified in the literature and internal data review process (see Table 1). The interview focused on the provider's own challenges experienced in the diagnosis, treatment and management of patients with RCC. The personal, contextual, and behavioral factors that influence a provider's clinical reasoning process, above and beyond clinical guidelines, evidence, and/or standards of care were also addressed.

The interviewer's semi-structured questions were also guided by the participant's answers to a short online questionnaire comprising of iterative complex medical cases that was completed by participants prior to the date of the interview. Those cases, designed by key faculty and educational experts, tapped into the physicians' intuitive decision-making process regarding topics such as treatment choices, monitoring of disease progression and management of different profiles of patients with RCC.

The two (2) key faculty involved in this project were: a director of a genitourinary oncology program and an associate professor of medicine, both specializing in RCC, each from a preeminent US medical/cancer center.

Findings from the qualitative phase, as well as information gathered from the literature and expert faculty were used to inform the design of a 15-20 minute quantitative survey deployed in phase 2 of the study. The survey consisted of a mix of multiple choice questions, rating scale questions and case vignettes.

Table 1. Domains used to formulate the semi-structured open-ended questions of the telephone interviews.

- Attitudinal and confidence issues that may impact:
  - Application of guidelines
  - Optimal individualized therapeutic strategies
  - Decision to switch or maintain therapy
- Collaboration skills, and their impact on:
  - Provision of multidisciplinary support/education
  - Referrals
  - Relation between oncologist and other specialists
- Communication skills
- Balancing patients' expectations with treatment outcomes
- Patient-related factors (preferences, previous experiences, psychosocial concerns)
- Factors influencing choice between quality of life vs. prolonging life

Recruitment, Eligibility, and Inclusion Criteria

Invitations to participate in both phases of the study were sent through email to a list of CCO members and contacts at cancer institutions. Clinical Care Options' Oncology membership includes more than 138,000 clinicians worldwide including more than 23,000 physicians in the United States. Invitation to the phase 1 qualitative interviews included a web link where interested participants could learn about the study, sign a consent form and answer pre-screening questions to determine their eligibility. To be eligible to participate in the qualitative phase of the study, the participants had to be actively practicing in oncology, and have a caseload of ≥ 5 patients with RCC per year. A purposive sampling method was used to ensure that collection of a diverse ensemble of perspectives, representative of the reality of RCC care, by including a sample with a mix of gender, years of practice and practice setting. Inclusion criteria for the quantitative phase of the study were the same as for the qualitative phase. However, the minimum RCC patient caseload was reduced from ≥ 5 to ≥ 1 per year to allow for identification of challenges in the group of practitioners most likely to be unfamiliar with those diseases.

Data Analysis

The semi-structured telephone interviews were audio-recorded, with the consent of the participants, to be transcribed and coded for analysis. The interviewers' notes of the participants' answers were also compiled along with the discussion notes from two debriefing sessions conducted among all interviewers and the research team. The qualitative data from the interviews were coded using NVivo qualitative data analysis software (QSR International Pty Ltd. Version 7, 2006) through a process called modified thematic analysis[i]. The approach included three steps: data familiarization (where the researcher immerses him/herself in the data), data coding (where the researcher codes and classifies data according to broad areas of interest), and theme identification (where the researcher identifies specific themes with substantial data emerging from the domains of exploration investigated). The data collected from the online cases in phase 1 and from the quantitative survey in phase 2 were analyzed using SPSS 12.0 software (SPSS, Chicago, IL). Respondents' answers to each of the questions in the quantitative survey in phase 2 have been compared with optimal or acceptable answers (as identified by treatment guidelines and faculty experts). This was done to determine the gap in practice in relation to the most up-to-date data or best practices. In the tables of results, Faculty's optimal choices have been highlighted in green, where as choices described as also acceptable have been highlighted in yellow. Triangulation of data was performed to confirm or validate the findings from the quantitative

phase with the findings from the qualitative interviews in order to allow for inference of potential causalities to the identified practice performance gaps.

This report includes key findings as they relate to the overall sample under study. In addition, sub-group differences (per years of practice, practice setting, and RCC caseload) are also reported when found to be both statistically and educationally significant. These sub-group differences were calculated using ANOVA for ordinal variables, for which means could be calculated (semantic differential rating scales, number of optimal answers) and Pearson's Chi-square test (hereafter referred to as Chi-square) for nominal variables (i.e., multiple choice questions), for which means are meaningless. Finally, potential causalities underlying the practice performance gaps are also investigated and presented.

Results

Description of Sample

For the qualitative phase 1 of the study, 27 medical oncologists were recruited, met the inclusion criteria, and were interviewed. For the quantitative phase of the study, a total of 207 participants agreed to the online consent form and started answering the online survey (Table 2). Of those, 19% of respondents did not complete the demographic questions. Although many of them answered a sufficient proportion of the survey to be considered in the analysis, their eligibility (i.e., them meeting our research inclusion criteria) could not be confirmed. To avoid any risk of bias, an initial analysis was performed separately on the group of respondents with missing demographic data. Upon a review of the data, this group of respondents was statistically more likely to select "unsure" as an answer to a question when that option was provided. This could have contributed to them not completing the survey, including the demographic questions. To ensure this group of participants did not bias the study results, the analyses were performed for the rest of the data by including the 142 respondents with completed demographic data and confirmed eligibility.

Table 2: Recruitment and eligibility of participants

	Recruited	Non-eligible	Missing demographic information	Analyzed sample
Qualitative	41	14 (34.1%)	---	27
Quantitative	207	25 (12.1%)	40 (19.3%)	142
Total - (qualitative and quantitative)	248	39 (15.7%)	40 (16.1%)	169

The demographic characteristics of the sample used for the analysis is presented in Table 3. Overall, the participants were experienced clinical practitioners, with 40% having more than 20 years of medical practice. The sample represents a variety of practice settings, with academic medical centers (36.6%) and group practices (29.6%) being the most predominant sub-groups. Although 2.1% of respondents (n=3) reported that 0% of their caseload was represented by patients with RCC, those respondents had a minimum of 1 patient with RCC per year, as per the inclusion criteria. When compared, the qualitative sample included a higher proportion of less experienced oncologists than the quantitative sample. More participants in the qualitative phase were seeing more than 20 RCC patients per year. The two samples were otherwise similar in their distribution of the demographic variables.

Table 3: Demographic characteristics of participants.

	Qualitative (n:27)		Quantitative (n:142)		Analyzed sample (n:169)	
Years of practice	**n**	**%**	**n**	**%**	**n**	**%**
10 years or less	18	66.7%	45	31.7%	63	37.3%
11 to 20 years	4	14.8%	40	28.2%	44	26.0%
More than 20 years	5	18.5%	57	40.1%	62	36.7%
Practice setting	**n**	**%**	**n**	**%**	**n**	**%**
Academic medical center	9	33.3%	52	36.6%	61	36.1%
Government hospital	1	3.7%	6	4.2%	7	4.1%
HMO/Managed care	0	0.0%	3	2.1%	3	1.8%
Hospital system	2	7.4%	15	10.6%	17	10.1%
Group practice	10	37.0%	42	29.6%	52	30.8%
Non-affiliated community /small private hospital	2	7.4%	6	4.2%	8	4.7%
Solo practice	2	7.4%	15	10.6%	17	10.1%
Other	0	0.0%	3	2.1%	3	1.8%
Did not answer	1	3.7%	0	0.0%	1	0.6%
Percentage of caseload being RCC	**n**	**%**	**n**	**%**	**n**	**%**
0%	0	0.0%	3	2.1%	3	1.8%
1-10%	19	70.4	130	91.5%	149	88.2%
More than 10%	8	29.6	8	5.6%	16	9.5%
Did not answer	0	0.0%	1	0.7%	1	0.6%
Number of RCC patients per year	**n**	**%**	**n**	**%**	**n**	**%**
1-4	0	0.0%	30	21.1%	30	17.8%
5-20	13	48.1%	88	62.0%	101	59.8%
More than 20	14	51.9%	24	16.9%	38	22.5%

Key Findings

The following seven (7) key practice performance gaps were identified from the mixed method analysis of the data:

1. Lack of knowledge on the important predictors of poor risk/short survival in RCC
2. Challenges with the selection of an optimal treatment option for patients with poor risk
3. Challenges in the clinical decision-making on the need for continuation/escalation of dose for current agent or switching to another agent based on patient response
4. Challenges in rapidly integrating newly FDA-approved agents in clinical practice
5. Challenges in properly recognizing non-radiologic progression and its importance in treatment decisions
6. Challenges in multi-disciplinary collaboration, specifically with surgeons and primary care physicians
7. Lack of knowledge of quality of life assessment tools and lack of skills in optimally considering quality of life in the formulation of a treatment plan, contributing to challenges optimizing the risk-benefit balance of a treatment plan

There are several causalities that may underlie the above gaps and barriers to optimal care in RCC, such as the low prevalence of RCC compared to other types of cancers. This would likely necessitate a certain

prioritization by medical oncologists in regards to keeping themselves up-to-date with the latest treatment options for cancer types they encounter with higher frequency in their practice.

Each of these educational gaps, and their respective causalities and clinical relevance, will be detailed in this section. Results from the survey responses, when available, will be presented, supported and explained by the responses to the qualitative phase. Direct quote excerpts from the interviews have been included to facilitate the interpretation and understanding of each finding.

Practice Performance Gap #1
Lack of knowledge on the important predictors of poor risk/short survival

When asked an open question about the criteria they most often use for risk stratification of patients with RCC, the most frequently reported was the Memorial Sloan Kettering Cancer Center (MSKCC) risk criteria. The use of MSKCC criteria is considered straightforward and not challenging by most participants. The specific factors most frequently mentioned by qualitative survey participants were levels of lactase dehydrogenase (LDH), hemoglobin, and corrected serum calcium:

> *"I use the MS, the Memorial Sloan-Kettering cancer criteria and it's really clear cut, there's five things, you just plug it in and depending on the number you can really easily determine where they lie."*

> *"Well I use* […] *Memorial because* […] *I have the most track record, but most of them are more or less the same. These are clinical factors* […] *for example hemoglobin level, LDH's, number of metastatic size, when the diagnosis was made, how many months,* […]*these are basically clinical factors and I want to put a factor that are easily obtained."*

As seen in Table 4, a majority of respondents to the quantitative phase 2 survey successfully identified the 5 important predictors of poor risk/short survival among the 8 factors that were presented to them. However, the 3 factors that were not identified as important predictors by expert faculty, albumin levels, renal function and cardiac function were incorrectly reported as important predictors by 66%, 55%, and 43% of participants respectively. 16% of respondents reported being unsure that cardiac function was a predictor of poor risk/short survival.

In looking at the number of right answers obtained, as displayed in Figures 2 and 3 (below), 54% of participants identified 4-5 factors properly. When considering the questions where the right answer was "yes, this is an important predictor of poor risk/short survival", 46% of respondents answered all of them correctly. For the questions where the correct response was "no, this is not a predictor of poor risk/short survival", 51% or respondents answered all of them incorrectly.

A significant difference was observed according to the experience of the respondents (ANOVA; p=0.003). Oncologists with 10 years of experience or less had a mean of 5.7 answers out of 8 aligned with the Faculty's answers and practice guideline recommendations, while their more experienced colleagues, with more than 10 years of experience had 4.8 correct answers. Another significant difference (ANOVA; p=0.030) was observed between respondents from academic medical centers (mean of 5.5) and their colleagues from non-academic hospitals, Group/solo practice (mean of 4.8). Finally, oncologists with higher RCC caseloads had more answers matching the Faculty's answers and practice guideline recommendations (ANOVA; p=0.001): respondents with 1-4, 5-20, and more than 20 cases of RCC per year had 4.2, 5.1, 5.9 correct answers, respectively.

Table 4: Answers to question 1 (Faculty/practice guideline-supported optimal answers in green)

	Which of the following factors are predictors of poor risk/short survival?							
	A. Lactate dehydrogenase level (n:140)		**B. Hemoglobin level** (n:138)		**C. Cardiac function** (n:129)		**D. Karnofsky performance score** (n:139)	
Response	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Yes	116	82.9%	127	92.0%	55	42.6%	130	93.5%
No	11	7.9%	4	2.9%	54	41.9%	6	4.3%
Unsure	13	9.3%	7	5.1%	20	15.5%	3	2.2%
	E. Renal function (n:135)		**F. Interval from diagnosis to start of systemic therapy** (n:135)		**G. Serum calcium level** (n:139)		**H. Albumin level** (n:135)	
Response	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Yes	74	54.8%	97	71.9%	115	82.7%	89	65.9%
No	47	34.8%	26	19.3%	15	10.8%	29	21.5%
Unsure	14	10.4%	12	8.9%	9	6.5%	17	12.6%

Figure 2: Number of right answers obtained by the respondents to the 8 questions related to predictors of poor risk/short survival (n:141)

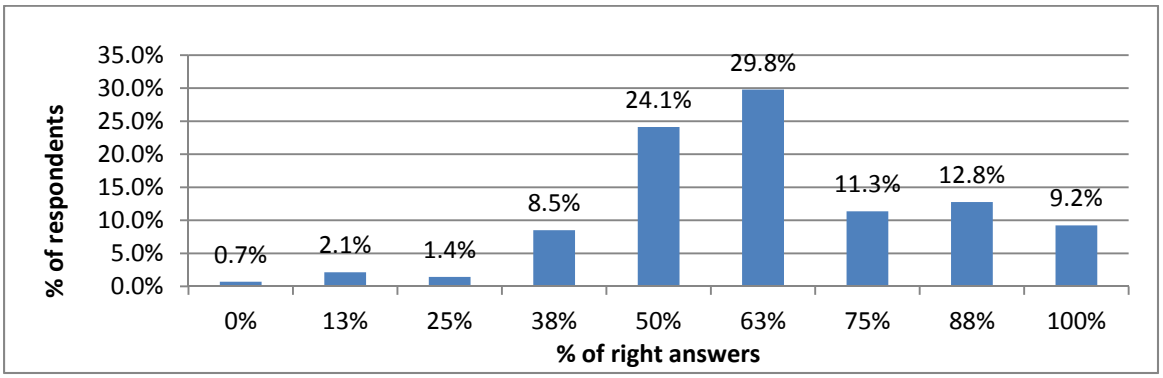
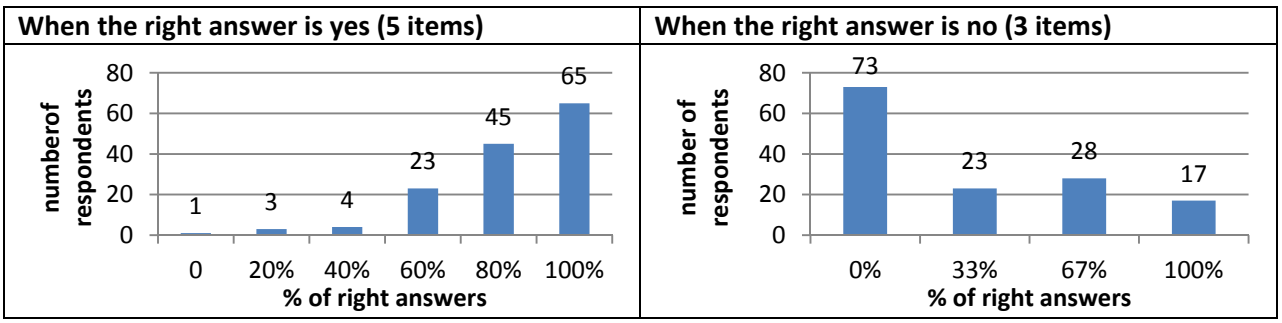


Figure 3: Number of right answers obtained by the respondents to the 8 questions related to predictors of poor risk/short survival, when the right answer is yes and when the right answer is no (n:141)



Relevance to Clinical Practice

Some medical oncologists had difficulty in identifying factors which are not important predictors of poor risk/short survival, as such. This could indicate that oncologists are using risk stratification tools without a full working knowledge of the exact factors included in the tool. That in turn would imply that they might not be on the look-out for those individual factors, between uses of the tool, and it could impact their proactivity. On the other hand, there is the possibility that some respondents may have been confused by the wording of the question, interpreting "short survival" in a broader sense than what was intended. For example, even though cardiac risk is not a predictor of poor risk in RCC *per se*, it can shorten survival on its own (i.e., cardiac risk-associated mortality). This could have incited respondents to answer "yes" to all items, whether they are poor risk predictors or not. Regardless of this possibility, the results do suggest a need to utilize education to reinforce best practices with regard to risk prediction as it relates to treatment selection in RCC.

Practice Performance Gap #2
Challenges with the selection of an optimal treatment option for patients with poor risk

Participants had a low level of agreement with faculty in terms of optimal treatment for patients with poor risk. Temsirolimus, the response which expert faculty selected, clinical practice guidelines recommend, and the treatment option most supported by current evidence in this setting, was chosen by 38% of respondents. Sunitinib and sorafenib were chosen by 11% and 12% of respondents respectively. The choice of treatment was unclear for 11% of respondents. Respondents with a higher yearly caseload (more than 20 patients per year) were significantly more likely to choose temsirolimus vs. respondents with smaller caseload (1 to 4 per year, or 5 to 20 per year), (58% optimal answer comparing to 21.4% and 36.9%, respectively) (Chi-square, p=0.049). Additionally, a higher percentage of oncologists with 10 or less years of experience responded in alignment with the faculty's/practice guideline-supported choice, compared to their more experienced colleagues (49% vs. 32%; Chi-square, p=0.034). No significant sub-group difference was observed according to the respondents' clinical setting.

The assessment of poor risk versus good risk using the MSKCC criteria is considered useful in selecting optimal treatment by a portion of respondents to the qualitative phase 1 survey:

> *"We use the Memorial Sloan-Kettering criteria to define the risk category of a patient with advanced RCC* [...] *So if they're in highest risk group, we often times recommend an IV drug which is called Temsirolimus which has a grade one—a category one—recommendation. If they have a good or intermediate risk group, we would recommend some of the other options* [...] *Often times, it helps us to define the treatment option for some of our patients based on how aggressive their disease is, based on that criteria."*

Some respondents indicated not currently selecting treatment based on assessment of MSKCC or other predictors of poor risk:

> "[The MSKCC criteria are] *easy to use, but they lack the clinical implication. It does not really change much for me. Except for performance status, I don't really go about other things.* [...] *risk factors help you sub-classify these patients into good risk or poor risk, but then what? You have metastatic disease, are you not going to offer treatment to the patient with good risk metastatic disease* […] *as opposed to poor risk."*

> *"So these risk factors were designed more when we had interferon as one of the only agents to treat, but now we have six or seven drugs* […] *basically, to* [use] *the risk factor in terms to select the drug* […] *you don't do it. I would say that the risk factors are valuable to determine prognosis.*

So when you're talking to the patient, and the patient has a high grade or intermediate grade risk factor, the patient has to understand that the survival and response rate of the treatment will be less than if the patient has a grade one or good risk factors. But I believe that the way that I see the risk factors is more to determine prognosis. Not necessarily to decide how to select drugs."

Relevance to Clinical Practice

For the case that was presented (Table 5), the guidelines recommend the use of temsirolimus (NCCN 2013). The fact that answers were more evenly distributed among the answer options indicates a considerable degree of variability in the clinical practice of medical oncologists. It is interesting to see that more experienced oncologists, with higher caseloads of patients with RCC, are more aligned with faculty-selected and guideline-indicated answer of temsirolimus. Nevertheless, the number of participants choosing answers other than temsirolimus remains non-negligible. In part, this finding may reflect a lack of awareness of key evidence in RCC vs. other tumor types: due to the lower prevalence of RCC compared to other types of cancers, some oncologists prioritize obtaining information and keeping themselves up-to-date for more frequent cancers first, thus creating a potential barrier to optimal care. Importantly, some clinicians emphasized their view of risk level as useful in helping to sub-classify patients with an eye toward determining prognosis, and not necessarily as a way to select treatment, as the direct quotations in this report suggest.

Table 5: Answers to question 5 (faculty's optimal answer in green and other acceptable choices in yellow)

Q5. In addition to enrollment in a clinical trial, which of the following agents do you recommend as first-line therapy to treat newly diagnosed patients with advanced/metastatic RCC who are classified as MSKCC/NCCN poor risk? (n:136)	n	%
A. Axitinib	2	1.5%
B. Bevacizumab/interferon	5	3.7%
C. Everolimus	13	9.6%
D. High-dose interleukin (IL)-2	7	5.1%
E. Pazopanib	11	8.1%
F. Sorafenib	17	12.5%
G. Sunitinib	15	11.0%
H. Temsirolimus	51	37.5%
I. Unsure	15	11.0%

Practice Performance Gap #3

Challenges in the clinical decision-making on the need for continuation/escalation of dose for current agent or switching to another agent based on patient response

An important clinical issue often faced by medical oncologists in their continuing management of patients with RCC is hypertension. When choosing a treatment choice for a patient with treatment-related hypertension which is unresponsive to single/initial anti-hypertensive therapy (Table 6), 67% of the respondents to the quantitative phase 2 survey selected at least one of the answers aligned with those of expert faculty (Maintaining the dose/schedule with initiation of a second anti-hypertensive (53%), maintain dose/schedule and refer to a cardiologist (14%)). 34% selected at least one of the non-aligned answers. Reducing the dose of the treatment, which was not selected by the expert faculty, was

the choice of 17% of participants. The distribution of answers was not significantly linked to experience, RCC caseload or primary clinical setting.

Table 6: Answers to question 6 (Faculty optimal answers in green)

Q6. How do you manage patients with advanced/metastatic RCC who develop treatment-related hypertension that does not resolve with a single/initial antihypertensive treatment? (n:137)	**n**	**%**
A. Maintain dose/schedule; refer to cardiologist for further management	19	13.9%
B. Maintain dose/schedule; initiate second antihypertension agent	72	52.6%
C. Reduce dose of treatment agent	23	16.8%
D. Stop treatment	4	2.9%
E. Switch to a new agent	8	5.8%
F. Adapt a "wait-and-see" approach	6	4.4%
G. Unsure	5	3.6%
Comparison of Q6 responses to Faculty's answers (n:137)	**n**	**%**
Selected one of the 2 optimal answers	91	66.4%
Selected one of the non-optimal choices	46	33.6%

Managing treatment related hypertension is reported by participating oncologists as something they are capable of themselves, although many prefer to refer to a specialist, as indicated by the following responses to the phase 1 qualitative survey:

> *"I think there's a lot of complexity when it comes to anti-hypertension medications, especially when you're trying to achieve a response and you may be utilizing the high blood pressure as a marker response* [...] *plus you have to take into consideration that the way some of these anti-hypertensives work, and that's to use the CYP3A4 pathway, that it also is a same way that a lot of these tyrosine kinase inhibitor therapies, like axitinib, sunitinib, work. So you have to be aware that there are drug interactions and you may have to adjust or change the anti-hypertensive medications."*

> *"I can tell you most medical oncologists don't like to take care of severe high blood pressure."*

> *"I don't think there have been a lot of new medications in terms of managing hypertension, not since I finished medical school, at least. So I think, initially, I would kind of try to do that* [manage hypertension myself]*, especially if we're using a beta blocker* [...] *If we start getting into ACE inhibitors with poor renal function, it might be different. I might avail myself of an expert."*

New evidence supporting dose escalation of certain agents for a patient who is responding well to treatment with a particular dose may seem counterintuitive to treating clinicians, as indicated by the following directly quoted response in the qualitative survey:

> *"If the disease is stable, and the patient is tolerating the treatment well and having a good performance status, it's about engaging their lives; then, I would be more inclined to continue the treatment if the patient wishes, rather than start changing the medication to try to achieve a cure, which has really very rarely been shown. So the response rates are very low, and most of our data*

is based on progression-free survival, so it's really hard to say, 'I'm going to cure you and extend your life indefinitely,' because there's no data showing that."

To that end, discrepancies were identified between respondent- and expert faculty-selected, evidence-based answers regarding the treatment of patients with "good-risk" RCC treated with axitinib for 4 weeks with no progression, elevated blood pressure and no adverse events (Table 7). The answer aligned with expert faculty recommendations and current evidence[ii], selected by 27% of the sample in the qualitative phase 2 survey, was the continuation of axitinib at an elevated dose. Respondents with a higher yearly caseload were significantly more likely to select this treatment option than respondents with smaller caseload (50% accurate answer in participants with caseload above 20 patients per year, compared to 20% and 23% for 1-4 and 5-20 patients respectively. Respondents' answers were not significantly correlated with years of clinical experience or practice setting. The answer chosen most frequently by the overall sample of respondents (61%) was to continue therapy at the current dose.

Table 7: Answers to question 7 (faculty's optimal answers in green)

Q7. For a patient with "good-risk" metastatic RCC who was treated with axitinib for 4 weeks and has no signs of progression, no increase in blood pressure, and no adverse events, what would you recommend in terms of these options? (n:141)	n	%
A. Continue treatment with axitinib at its current dose	86	61.0%
B. Continue treatment with axitinib, but escalate dose	38	27.0%
C. Discontinue treatment with axitinib and switch to another agent	4	2.8%
D. Pause treatment with axitinib; restart when progression is detected	4	2.8%
E. Unsure	9	6.4%

Relevance to Clinical Practice

Results indicate that oncologists are not utilizing the most optimal management strategies supported by current clinical trial results to determine when or if changing the treatment dosage would allow them to achieve optimal response with their patients with RCC. Either those recent trial results have not been communicated enough in the oncology community, or respondents do not feel the trial conditions reflect the reality of their practice. Underlying causes could also include attitudinal factors such as resistance to change, due to comfort using the drug they have experience with, or lack of motivation in keeping oneself updated with RCC, considering the relatively low prevalence of the tumor. A link can be made to gap #5, as oncologists might, just like they are for newly approved treatments, be waiting for guidelines to be adjusted, or for their local tumor boards to modify their decision algorithm.

Practice Performance Gap #4

Challenges in rapidly integrating newly FDA-approved agents in clinical practice

When quantitative phase 2 participants were asked to rate the importance of certain factors regarding the integration of newly approved therapies, the publication of phase III results in a peer-reviewed journal was the factor with the highest importance score (mean=1.98, SD=1.24; scale of 1=most important to 5 = least important). Other factors considered important included changes in guidelines (mean=2.21, SD=1.14); expert recommendation by consult (mean=2.36; SD=1.06), and tumor board decision (mean=2.37; SD=1.08). The factors with highest mean (and thus, lowest importance) rating was

formulary changes (mean=2.91, SD=1.03). Responses to the ten factors surveyed are presented in Table 8 (see next page).The integration of newly approved agents to practice becomes challenging for respondents as the number of drugs approved on the market increases:

> *"I think that the reason why it becomes difficult for me in metastatic renal cell is that there are now quite a few drugs approved."*

'Expert recommendation as part of CME activity' was reported as significantly less important (ANOVA; p=0.048) by respondents with higher caseload. Oncologists with more than 20 RCC cases per year ranked the item at a mean of 3.0, compared to means of 2.3 and 2.6 for those with 1-4 and 5-20 RCC cases per year respectively. 'Recommendation from respected colleague' was a higher ranked choice for oncologists with more than 10 years of clinical experience (mean of 2.3, compared to 2.7 for oncologists with 10 years of experience or less). No significant sub-group difference was observed by practice setting.

Not all practicing oncologists have the same access to clinical trials, where they can try newly or soon-to-be approved agents and learn about their efficacy:

> *"It is a challenge, because practicing in a community-based center, we don't have access to clinical trials, we don't know much about it, we don't hear about it, and even if we do, it's a challenge for the patient to give them an opportunity to* [participate in] *appropriate clinical trials. For various reasons, either you don't know about it, or you don't know much about it and* […] *may not be able to have the patient participate in it."*

Familiarity with drug also affects selection of treatment:

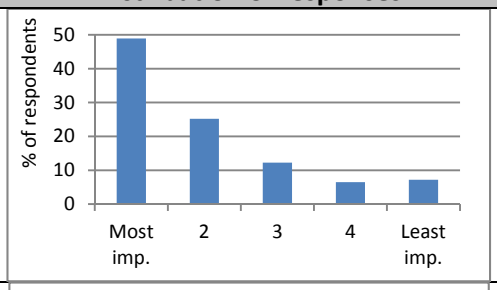
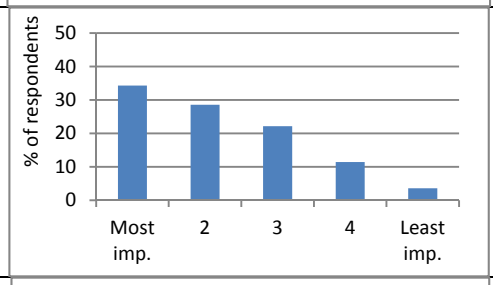
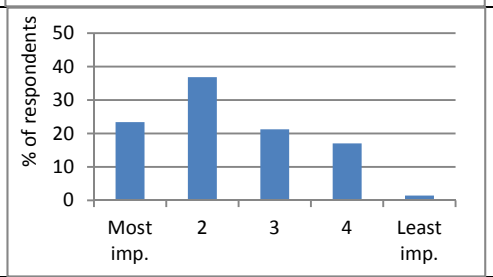
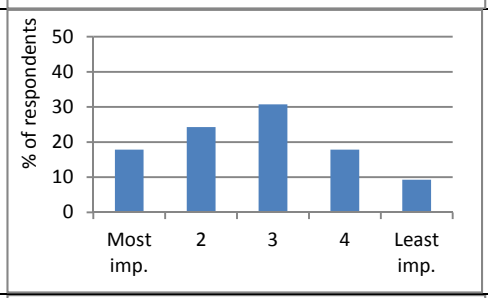
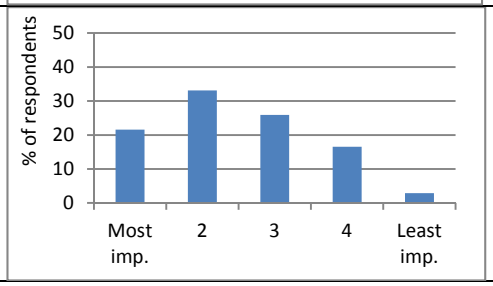
> *"So sometimes I might err on the side of using something I'm more familiar with, rather than using something novel because I may not be able to manage the side effects or recognize the side effect profile."*

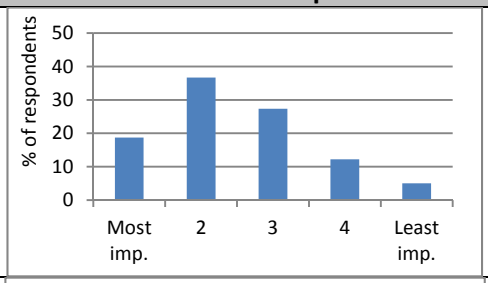
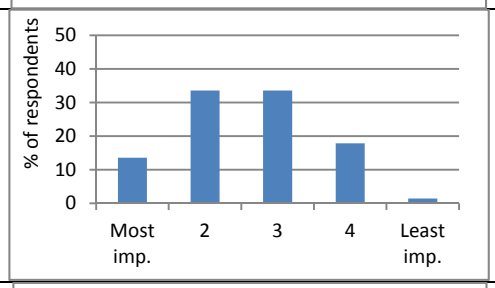
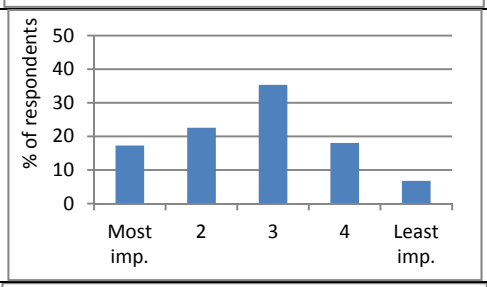
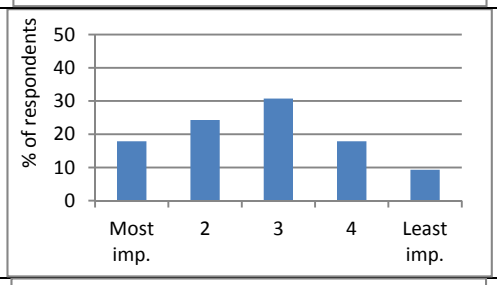
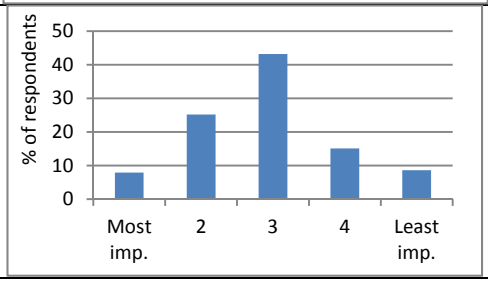
> *"I think there's more medications* [...] *I think pazopanib's just been approved, and sunitinib is also, but they haven't really been tested head to head. So I use what the guidelines* [state]*, and I use the data available. It's difficult to know if any of these medications would be better than sunitinib based on the fact they haven't really been compared head to head."*

Relevance to Clinical Practice

Guidelines play an important role in the willingness of US medical oncologists to integrate newly–approved agents into clinical practice. It could be that physicians feel more comfortable using a new agent once it is included in guidelines, or that their current practice protocols (and the drugs accessible/available in their practice setting) are guideline-based. However, as it can take more than several months for new guidelines to be updated after a new agent is made available, this may delay the use of evidence-based drugs that could benefit patients and improve disease outcomes. A somewhat unexpected finding was that 'tumor board decision', was rated as an important, but not the most important, factor by survey participants in integrating newly FDA-approved agents into clinical practice. The Tumor Board may not be relevant to all respondents enrolled in the study. However, when applicable, the tumor board of many institutions is responsible for deciding which drugs will be integrated into clinical practice in a given setting or patient population. Although reimbursement has been reported to be a limiting factor by many participants in this study, it does not score high as a factor of importance for incorporating new drugs into practice.

Table 8: Answers to question 14

Q14. What information/recommendation/experience do you require before integrating newly US Food and Drug Administration–approved agents into your clinical practice? Scale: 1 (most important) to 5 (least important) ***(Items presented from most important to least important based on means)***	**Mean**	**SD**	**Distribution of responses**
I. Publication of the phase III results in a peer-reviewed journal	1.98	1.24	
D. Guideline changes	2.21	1.14	
B. Expert recommendation by consult	2.36	1.06	
J. Tumor board decision	2.37	1.08	
E. Recommendation from respected colleague	2.46	1.10	

Q14. What information/recommendation/experience do you require before integrating newly US Food and Drug Administration–approved agents into your clinical practice? Scale: 1 (most important) to 5 (least important) *(Items presented from most important to least important based on means)*			
	Mean	**SD**	**Distribution of responses**
H. Expert recommendation at a live symposium or plenary presentation	2.48	1.09	
C. Expert recommendation as part of CME activity	2.60	0.98	
G. Reimbursement	2.74	1.15	
A. Personal experience from enrolling patients on clinical trials investigating the agent	2.76	1.21	
F. Formulary changes	2.91	1.03	

Practice Performance Gap #5
Challenges in properly recognizing non-radiologic progression and its importance in treatment decisions

When presented with two (2) cases related to treatment adjustments in the presence of non-radiologic progression (Table 8), there was misalignment between respondents' answers and expert faculty recommended answers. With regard to a case related to treatment with pazopanib in the presence of non-radiologic progression (Question 8), 40% of participants in the quantitative phase 2 survey selected answers aligned with faculty recommendations (which were either to switch to axitinib (18.6%), sunitinib (11.4%), everolimus (7.9%) or sorafenib (2.1%). The answer most frequently selected by respondents (22%) was to discontinue treatment. Continuing treatment with pazopanib until clear progression was selected by 10.7% of the respondents. Respondents with less years of experience (10 years or less) were significantly more likely to answer a recommended answer than respondents with more years of experience (10 years or more) (44.4% vs. 23.2%; Chi-square, p=0.030). There was no significant relationship found between the answers given and RCC caseload or practice setting.

For the second case (Question 9), respondents were asked about their choice of therapy for a progressing patient with chronic obstructive pulmonary disease, the respondents' answers were distributed almost equally among all of the alternative answers. The optimal answer was selected by 22% of respondents. Sunitinib and temsirolimus, not considered as recommended answers, were chosen by 20 % and 12.7 % of respondents, respectively. Answers to this case question were not significantly related to experience, practice setting, or caseload.

Oncologists reported that their choice was influenced by their previous experience with the available drugs:

> *"Most of us, ultimately, although there's a recommendation, we will use one of these three combinations based on our experience with patients. For example, with sunitinib in general, they're more experienced because this drug has been around for a longer time and, therefore, a lot of us feel pretty comfortable using it. And if you have treated this disease for a while and you have seen some patients really doing very well, you're kind of biased to use a drug that worked in the past with some of your patients."*

Relevance to Clinical Practice

When it comes to complex cases, there are often a variety of answers that could be considered reasonable. This study compares what has been identified as optimal or reasonable answer choices, as selected by expert-faculty and supported with current evidence and/or practice guidelines, with what the participating oncologists have answered. For the two cases on non-radiologic progression, the repartition of answers all across the possible choices, and more than half of the respondents in one case (Question 8), and 75% of the respondents in the other case (Question 9) did not select optimal treatment options. This demonstrates a lack of knowledge on non-radiologic progression and a lack of skill to adapt treatment decisions in light of non-radiologic progression. This may also be a consequence of a larger gap reported in this study, where defining disease progression in general appears challenging to practicing oncologists.

Results indicate that oncologists are not using the most recent clinical trials results to determine when escalating the dose would allow them to achieve optimal response with their patients with RCC. Either these new recent trial results have not been communicated sufficiently in the oncology community or respondents do not feel the trial conditions reflect the reality of their practice. Underlying causes could also include attitudinal factors such as resistance to change, due to comfort using the drug they have experience with, or lack of motivation in keeping oneself updated with RCC, considering the relatively

low prevalence of the tumor. A link can be made to gap #6, as oncologists might, just like they are for newly approved treatments, waiting for guidelines to be adjusted, or for their local tumor boards to modify their decision algorithm.

Table 9: Answers to questions 8 and 9 with comparison with Faculty acceptable (yellow) answers

Q8. A 65-year-old woman with clear-cell RCC is diagnosed with metastases to the liver by computed tomography scan, 2 years postnephrectomy. She is assessed as MSKCC good risk. After 2 months of treatment with pazopanib, her alanine aminotransferase and bilirubin concurrently increase to 4 and 3 times the upper limit of normal, respectively, but there is no clear sign of radiologic progression. What action do you take regarding her treatment? (n:140)		
	n	**%**
A. Continue pazopanib until clear progression	15	10.7%
B. Switch to axitinib	26	18.6%
C. Consider a clinical trial	8	5.7%
D. Switch to temsirolimus	12	8.6%
E. Switch to everolimus	11	7.9%
F. Switch to sorafenib	3	2.1%
G. Switch to sunitinib	16	11.4%
H. Offer palliative therapy only	2	1.4%
I. Stop treatment	31	22.1%
J. Unsure	16	11.4%
	n	**%**
Total of acceptable choices for Q8	56	40.0%

Q9. For a 70-year-old patient with metastatic RCC, hemoglobin level of 9.5 g/dL, and an ECOG performance status of 2 due to shortness of breath from chronic obstructive pulmonary disease resulting from a history of heavy smoking, what would be your choice of therapy at this stage? (n:142)		
	n	**%**
A. Axitinib	11	7.7%
B. Temsirolimus	18	12.7%
C. Everolimus	16	11.3%
D. Pazopanib	31	21.8%
E. Sorafenib	7	4.9%
F. Sunitinib	28	19.7%
G. Bevacizumab/interferon	5	3.5%
H. High-dose interleukin (IL)-2	2	1.4%
I. No treatment	8	5.6%
J. Unsure	16	11.3%

Practice Performance Gap #6
Challenges in multi-disciplinary collaboration, specifically with surgeons and primary care

Oncologists reported that their collaborative relationship with surgeons can sometimes be challenging. The main causality reported by the participants was that surgeons do not see the patients and their tumors from the same perspective. Although qualitative survey participants recognized that this different perspective can enrich their own, they mentioned that finding a common ground was not always easy. Another causality mentioned was that surgeons are more difficult to reach for consultations than oncologists, because they spend extended periods of time in the operating room,

> *"The surgical oncologists are a little bit different because they are trained completely differently.* […] *We don't always think about the patient in the same way that they do. So that becomes a little bit more of a challenge, plus the fact that they're usually in the OR the entire day and are more difficult to reach and have good communication with.* […] *we do have these bi-weekly tumor boards where a multidisciplinary team can meet to discuss specific patients, but* […] [for the] *majority of* [patients]*, the communication has to go by phone calls and emails."*

> *"The challenges, right now basically to make sure that everyone understands* […] *the treatment plan for the patients from all these different specialties. For example, the surgeon understands that – do you think this patient will need some other resection later or if they have metastasis, it can still be potentially resectable or if it is not resectable – or would chemo help and then re-evaluate later* […] *All the different specialties need to be involved with the whole treatment plan of the patient, so they know the comprehensive plan for the patient."*

Study participants also reported challenges in their relations with PCPs. They highlighted what they perceive as a negative attitude about oncology, in general, and management of metastatic disease, in particular, from some primary care physicians, which could impact patients' perception of their disease and treatment. According to oncologists, this negativity stems from a lack of knowledge on recent developments in the treatment of RCC that have resulted in prolonging the life of patients. The participants to this study did not spontaneously mention a role for oncologists to educate their primary care colleagues in order to facilitate the collaborative process. However, a separate survey conducted by CCO indicated that oncologists did feel they had a role in educating their colleagues from other specialties on cancer related topics[iii].

> *"Primary care physicians may say* [to the patient]*, 'the treatment's not going to do you any good anyway, so you're just going to get sick, and this is going to cost a lot of money; maybe you shouldn't even go to see the oncologist.'"*

> *"I think most of the time, primary care* [physicians] *think once the patient has metastatic cancer it's like a death sentence; they're less rigorous to control their other co-morbidities,* […] *With metastatic RCC, patients will live for several years. We really need to address* […] *their hypertension, diabetes, those kinds of control issues. We really need to make them realize this is not* […] *a death sentence. You need to try to control the other stuff; patients can live for a while, with relatively good quality of life."*

Study participants also reported difficulties in their collaborations with other specialties as it relates to the co-management of comorbid conditions that are affected by the RCC medications. Contrary to their collaboration with primary care, oncologists did report on the importance of establishing a two-way collaboration to inform other specialists on the potential side-effects of drugs primarily used in oncology, despite reporting that collaboration as sometimes challenging; for example:

"It's quite challenging for [cardiologists] *to keep up with the literature to know what drugs are now approved or for the oncologists standpoint, that their drugs will cause the hypertension to get worse* […]*So you need to basically have a two-way communications with the other cardiologists. This patient has hypertension, but now we put them on* [sunitinib], *so he may need an increase in their hypertension medication while he's on* [sunitinib], *so the cardiologists know that the increase in their blood pressure is not because of their medications not working, but the patient has side effects from the oncologic treatment".*

Relevance to Clinical Practice

An important caveat to this particular finding is that the scope of this study did not allow investigation of the perspective of primary care physicians and specialists on their collaboration with oncologists. Nonetheless, this finding has important implications for clinical practice, especially in the current context, where there is an important trend towards inter-disciplinary delivery of care. The possible interactions between a patient's co-morbid condition and the side-effects of medications are part of the risks associated with a RCC treatment plan and necessitate collaboration among oncologists, who understands the effects of the chemotherapeutic agents, and clinicians from other specialties who understands the co-morbid conditions. Oncologists could play a more prominent role in proactively informing their colleagues of oncology-specific treatment considerations that could impact other specialties' areas of expertise.

Practice Performance Gap #7

Lack of knowledge of quality of life assessment tools and lack of skills in optimally considering quality of life in the formulation of a treatment plan, contributing to challenges optimizing the risk-benefit balance of a treatment plan

A majority of the oncologists participating in the qualitative survey reported not using any particular tool to assess quality of life in their patients. Furthermore, the definition of quality of life varies greatly between respondents, from "pain and fatigue", to "keeping one's job", to "being able to pursue one's daily activities".

"I think basically for me it [the quality of life] *is pain and fatigue primarily.* […] *I think it's difficult, but I think it's subjective at the end of the day. So, by and large, I see these patients once every three to four weeks and it's just through questioning and I don't have any particular validated tool to assess these issues with patients, so that's somewhat difficult. It's literally me just asking them how they're doing."*

Oncologists also described quality of life as something very subjective, and therefore not easily and readily measurable. They reported that patients, just like physicians, may all have a different perception of what quality of life means for them. Consequently, communication about it can be challenging, as the different definitions can lead to confusion and/or misunderstanding.

"Patients are afraid sometimes that their quality of life will be significantly impaired with chemotherapy, so their perception is important. And quality of life is something that often times patients like to use or even physicians like to use, but it has a very subjective meaning to everyone and, therefore, there's a lot of misunderstanding. […] *So the perception that each of us has about quality of life and expectations is quite important and unique and it's very individualized in many ways."*

Data also indicate that this lack of clear definition and assessment strategies creates a challenge when trying to monitor changes in the quality of life, and when trying to adapt treatment decisions to the quality of life of the patient.

> *"When a patient says what about fatigue, whether he'll be able to keep his job* […]*That's also quite challenging, sometimes you have to address that with these patients and sometimes you have to switch treatments from* [sunitinib] *to do something like everolimus. So those are all considerations and sometimes you have to do dose reduction based on these side effects, so it's challenging and these patients need to be routinely monitored for it."*

> *"I start their treatment then I assess them for their functioning, how they're enjoying their life, so that they're able to enjoy and keep doing things that they enjoy doing* […] *how functional they feel they are, how they're able to enjoy spending time with their family and friends.* […] *I don't really have any strict hard and fast guidelines to say this is quality of life; their quality of life is variable as you know for each and every patient."*

Oncologists reported challenges in optimizing the risk-benefit balance of a treatment plan, as a result of the challenges described above and related to quality of life.

> *"it's challenging because if the patient had a good response to the treatment and then they develop side effects, we don't want to dose reduce or stop the treatment because they are responding well, but on the other hand, it's not acceptable as well to have the patients enduring all the side effects that may limit their quality of life. So it's a balance because we want the patients to continue on the medication that is effective for them, but still they do not have to suffer the side effects that make their quality of life worse."*

Findings indicate that the challenge in establishing the best possible risk-benefit balance in a treatment plan lies in the sum of factors that need to be taken into account. Among the factors most often mentioned were patient's quality of life, patient's comorbidities, age and general physical condition, MSKCC score, prognostic factors, potential side-effects, patient's preferences, and the physician's experience with the therapeutic agents.

> *"So balancing has to deal with getting to know the patient,* […]*with adjusting the dose that is needed, or giving them a longer break than what you usually do—even deciding if you're going to start treatment or not because sometimes you may need to wait. For some people who have an excellent lifestyle, they are not willing to sacrifice it all* [due to] *treatment related side effects. So I think balancing has to do with a lot of art, in a way, to adjust the dose, to have breaks, and to decide* [on] *wanting a treatment."*

> *"These treatments are for the long-term, so I always tell the patients it's like walking the marathon: you have to be able to have the endurance to handle therapy for a prolonged period. So I would say the biggest challenge is finding the right drug, for the right patient, that's going to work for the longest amount of time* [and] *reap the most benefits."*

> *"At the end of the day, the biggest thing for me is* [a] *patient's disease burden or symptoms, their risk, and their underlying co-morbidities and then I have to put that together to determine which therapy would basically give them the largest benefit with the least amount of risk."*

Relevance to Clinical Practice

Quality of life is a central element to consider in recommending a treatment plan to a patient. It is an essential part of evaluating the risk/benefit ratio of each available agent. Therefore, any challenge affecting the monitoring and assessment of quality of life will affect the clinical decision-making for treatment recommendations.

Findings suggest that patients with RCC, a complex disease for which many factors are weighed in clinical decision-making, may not receive the optimal treatment. Consequently, these patients may be subjected to unnecessary and avoidable medication side-effects, receive drugs that do not fit their preferences, or that are not optimally adjusted to their individual profiles.

Study Caveats

Given that the goals of this needs assessment were to identify gaps, challenges, and barriers, less attention was given to areas in which care is known to be excellent. Since the methodological approach is based on self-reporting, there is the possibility of bias due to erroneous self-assessment. However, triangulation was used to strengthen the trustworthiness of the findings and limit such bias. Self-selection bias is also a possibility, as participation in the study was voluntary, but the utilization of purposive sampling improves the probability of having a sample that is representative of the targeted population.

A sub-set of participants, from whom we did not have the complete demographic information, were removed from the analysis to obtain a more homogenous group. This analysis on a smaller sample has not limited our integrated analysis but may reduce the power to detect significant between group differences for the next phase of analysis of this study that will be included in the final report and subsequent manuscript to be submitted for publication.

Recommendations and Conclusions

Evidence from this study indicates seven (7) key practice performance gaps, addressable from an educational perspective. Each of these gaps underlines issues that can impact patients' access to optimal care, clinical efficiencies, and consequently, patients' quality of life and/or survival rates.

The challenges described in practice performance gap #1 (knowledge on the important predictors of poor risk/short survival) and practice performance gap #2 (with the selection of an optimal treatment option for patients with poor risk) could be combined together and be addressed simultaneously through a workshop on risk and treatment decisions. While practice performance gap #3 (clinical decision-making on dose modification based on patient response) could be addressed through a workshop on treatment selection in RCC based on disease- and treatment-related toxicities, comorbidities and response to therapy. A third recommended workshop could target practice performance gap #5 (Challenges in properly recognizing non-radiologic progression and its importance in treatment decisions).

Practice performance gaps #3 and #5 (Challenges in the clinical decision-making on the need for continuation/escalation of dose for current agent or switching to another agent based on patient response; challenges in properly recognizing non-radiologic progression and its importance in treatment decisions) also provide opportunities to provide oncologists with new tools designed to facilitate optimal practice performance, such as decision support tools or algorithms that could guide the practitioner in his/her clinical decision-making.

In all three cases, the ideal workshop should be interactive and case-based to ensure application of the knowledge acquired in the clinical decision process, and development of the decision-making skills needed to arrive at an informed decision, rather than through didactic sessions that would address solely the knowledge components of these gaps.

Practice performance gap #4, on the challenges in rapidly integrating newly FDA-approved agents in clinical practice, is more appropriate for knowledge-based continuing medical education interventions.

However, some of the oncologists who would most benefit from such an educational initiative could be the most resistant or least interest to attend, as they could prefer to wait for guidelines to be adapted, or for decisions from their local tumor board.

The challenges in multi-disciplinary collaboration highlighted by practice performance gap #6 could be used to inform the development of a multi-specialty educational session, where both parties could inform the other about their area of expertise. For example, such an initiative could have cardiologists and oncologists discuss together different RCC-related cardiac conditions, RCC therapeutic agents with cardiac side-effects, and how the two specialties could better collaborate to minimize the exacerbation of one by the other.

Interventions targeting practice performance gap #7 (Lack of knowledge of quality of life assessment tools and lack of skills in optimally considering quality of life in the formulation of a treatment plan, contributing to challenges optimizing the risk-benefit balance of a treatment plan) should be deployed in three phases. In the first phase, didactic methods would be used to inform oncologists on existing tools that could support them in their monitoring and assessment of quality of life. In the second phase, a more interactive and case-based approach would be used to develop oncologists' skills in applying the tools, and integrating quality of life into their RCC treatment plan. In the third phase of the program, other components of the risk-benefit balance in the formulation of a treatment plan would be addressed.

Although significant differences were found by setting, clinical experience or caseload within these practice performance gaps, these differences may not warrant development of different educational interventions. Nuances could be included in the development, such as using slightly different cases for different audiences, but most importantly, the deployment strategy should be adjusted in an effort to reach physician populations in which the gap is more important.

This final updated report presents a definitive assessment of the causalities for each performance practice gaps described in this report. In addition, group-specific analysis (e.g., years of practice, practice setting, caseload) are provided to inform adjustments and nuances of educational activities deployed nationally, based on the gaps described here.

In addition to its value for informing the design of educational programs, it will be valuable to disseminate the findings from this needs assessment with external stakeholders through multiple channels. The development of a manuscript to be submitted to a peer-reviewed journal has been planned and remains recommended in light of the findings presented in this report. It will allow sharing of key outcomes of this study with the oncology and medical education communities and will contribute to the demonstration that Pfizer is committed to excellence in educational research and design.

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Appendix A: Key highlights from the published literature

The high variety and complexity of patient presentations, combined with the large number of new agents being approved for use in this condition in recent years, make the treatment and management of RCC challenging to practicing oncologists. The ideal choice of a first agent to use, the optimal sequence of agents to use, and the optimal combined use of these agents with surgical interventions for RCC are not yet known[1,2,3], A cohort study of 269 patients with urological cancers, including 94 renal cancers, reported that consultation with a multidisciplinary team resulted in change of diagnosis for 17% and change of treatment for 36% of the renal cases, suggesting that clinicians are not sure which approaches are optimal and lack confidence in treatment selection.[4] CCO learner data indicate that important questions remain regarding management of adverse events, especially hematologic toxicities.[10] These data show that 65% of physicians would inappropriately choose dose reduction or therapy discontinuation over supportive care for a patient with metastatic RCC experiencing moderate treatment-related adverse effects,[5] in keeping with data from community-based studies. Recent evaluation of practice patterns in 18 US community oncology clinics indicated that community-based oncologists were more likely than oncologists in tertiary care centers to recommend treatment modification or discontinuation because of adverse events.[6]. Inappropriate dose reduction and discontinuation may negatively impact the clinical outcome of patients with metastatic RCC.

Uncertainties and controversies have also been observed in the field around what signifies progressive disease in RCC, what is appropriate prognostication and disease stratification (e.g., Memorial Sloan-Kettering Cancer Center or International Prognostic Score), and how to ascertain “poor risk” in advanced disease.[7]

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