Original Study

Identifying the Needs of Health Care Providers in Advanced First-Line Renal Cell Carcinoma: A Mixed-Methods Research

Patrice Lazure,[1] Matthew T. Campbell,[2] Monica Augustyniak,[1] Edgar A. Jaimes,[3] Mehmet A. Bilen,[4] Emily A. Lemke,[5] Eric P. Cohen,[6] Ginny Jacobs[7]

Abstract

This study identified challenges affecting medical oncologists, nephrologists, physician assistants, nurse practitioners, and registered nurses involved in the care of advanced (unresectable and metastatic) renal cell carcinoma. Challenges included staying current with emerging therapies, weighing in patient's preferences for treatment, promoting a collaborative approach to care, and sharing patient information. Insights can inform the development of educational interventions.

Introduction: Systemic treatments for metastatic or unresectable renal cell carcinoma (mRCC) are rapidly evolving. This study aimed at investigating challenges in the care of mRCC to inform future educational interventions for health care providers (HCPs). **Materials and Methods:** The sequential mixed-method design consisted of a qualitative phase (semistructured interviews) followed by a quantitative phase (online surveys). Participants included US-based medical oncologists, nephrologists, physician assistants, nurse practitioners, and registered nurses. Interview transcripts were thematically analyzed. Survey data was descriptively and inferentially analyzed. **Results:** Forty interviews and 265 surveys were completed. Analysis revealed four challenges in the care of mRCC patients. A challenge in staying current with emerging evidence and treatment recommendations was found with 33% of surveyed HCPs reporting suboptimal skills interpreting published evidence on the efficacy and safety of emerging agents. A challenge weighing patient health and preferences in treatment decisions was found, especially among HCPs with 3 to 10 years of practice (37%) who reported suboptimal skills in assessing patients' tolerance to side effects. Promoting a collaborative care approach to the management of immune-related adverse events was a challenge, specifically related to barriers involving nephrologists (eg, diverging treatment goals). Breakdowns in communication were reported (46% of HCPs), especially in the monitoring of side effects and treatment adherence. **Conclusion:** This study revealed key challenges faced by HCPs when treating and managing patients with mRCC across multiple providers. Future interventions (eg, community of practice) should aim to address the identified gaps and promote a team-based approach to care that strengthens the complementary competencies of HCPs involved.

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Introduction

Cancers of the kidney or renal pelvis were estimated to be diagnosed in 76,000 patients with approximately 14,000 deaths in the United States (US) alone in 2021.[1] The most common type of kidney cancer is renal cell carcinoma (RCC), with clear cell being the most common histology. Approximately 30% of patients with RCC are found to be metastatic at time of diagnosis.[2] For simplicity

Abbreviations: RCC, Renal Cell Carcinoma; mRCC, Advanced (Unresectable or Metastatic) Renal Cell Carcinoma; TKI, Tyrosine Kinase Inhibitor; NCCN, National Comprehensive Cancer Network; IMDC, International Metastatic RCC Database Consortium; HCP, Health Care Providers; ONC, Medical Oncologist; NEP, Nephrologist; PA, Physician assistant; NP, Nurse Practitioner; RN, Registered nurse; EMR, Electronic Medical Record.

All co-authors contributed to the interpretation of data and have contributed sufficiently to this article to be considered as authors, as per the ICMJE authorship requirements.

[1]AXDEV Group Inc., Brossard, QC, Canada
[2]The University of Texas MD Anderson Cancer Center, Houston, TX
[3]Memorial Sloan Kettering Cancer Center, New York, NY
[4]Winship Cancer Institute of Emory University, Atlanta, GA
[5]Medical College of Wisconsin, Wauwatosa, WI
[6]New York University School of Medicine, New York, NY
[7]AXDEV Global Inc., Virginia Beach, VA

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Address for correspondence: Patrice Lazure, M.Sc., AXDEV Group Inc., 210-8, Place du Commerce, Brossard, QC, J4W 3H2 Canada
E-mail contact: lazurep@axdevgroup.com

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we will refer to advanced (unresectable or metastatic) clear cell renal cell carcinoma as mRCC in this paper.

Systemic therapy has evolved rapidly for mRCC with the development of immune check point inhibitors and small molecule tyrosine kinase inhibitors (TKIs) directed at vascular endothelial growth factor receptors. These are new options for treatment of regionally extensive or mRCC.[3] In the selection of initial therapy, the National Comprehensive Cancer Network (NCCN) guidelines have recommendations based on a patient's International Metastatic RCC Database Consortium (IMDC) prognostic score.[4,5] At present, a patient with intermediate or poor risk disease has a NCNN category 1 recommendation (ie, high-level evidence / consensus that the intervention is appropriate) to receive nivolumab plus ipilimumab, pembrolizumab plus axitinib, nivolumab plus cabozantinib, or pembrolizumab plus lenvatinib.[6] Challenges to select appropriate treatment are emerging, which are potentially caused by the lack of head-to-head comparisons between different agents.[7]

There has been little real-world evidence published on the clinical use of recommended first-line therapy agents for mRCC since their introduction in the US. This challenges HCPs to know exactly what to expect in terms of adverse events, especially when these new drugs are used in patients who have comorbidities.[8] Further research is also needed to determine the optimal sequence of systemic therapy agents for mRCC.[3]

To better understand potential challenges that US-based HCPs face when caring for patients with first-line mRCC, and inform continuous professional development interventions, an educational needs assessment was deployed with the following objectives:

- Assess the knowledge, skill, confidence, and attitudes of HCPs in the treatment, management, and coordination of care of patients with mRCC across interprofessional team members.
- Assess contextual and systemic barriers preventing application of knowledge, and optimal care.

Materials and Methods

A mixed-methods sequential design was used,[9] consisting of a qualitative exploratory phase followed by a quantitative validation phase (Fig. 1). This type of design was leveraged to obtain a more complete picture of the studied phenomena, thanks to the complementary nature of both methods: Qualitative findings offering rich contextual insight into the root causes of the studied phenomena (ie, the what and why), and quantitative findings offering insight into the extent to which previously identified findings are present in a larger sample size.[10,11]

The qualitative exploration phase consisted of 45-minute semistructured interviews with open-ended questions. Findings from this phase were used to create a 15-minute online survey designed to quantify the preliminary findings.[12] The sample consisted of medical oncologists (ONCs), nephrologists (NEPs), physician assistants (PAs), nurse practitioners (NPs), and registered nurses (RNs). The size of the qualitative sample was determined based on estimated requirements to reach data saturation and maximum variation in our purposive sampling.[13] The size of the quantitative sample was determined in a way to assure a statistical power of 0.8 when conducting $\chi 2$ analysis with up to 4 degrees of freedom and $\alpha = 0.05$.[14] The study protocol was reviewed and approved by Veritas IRB (Montreal, QC, Canada), an international independent ethical review board.

Recruitment

Invitations to participate in the study were sent by email to potential participants from two separate and independent panels (one for the qualitative phase and another for the quantitative phase), consisting of members registered to provide their perspective on topics related to health care. Both panels operate in compliance with the International Chamber of Commerce (ICC) and the European Society for Opinion and Marketing Research (ESOMAR) code of conduct and ethical standards for research.[15] The invitations included a link to a secure website directing participants to a screening questionnaire and an informed consent form. Participants who successfully completed this screening step were asked to either share their availability for the interview or were redirected to the online survey.

Research Criteria

To be eligible, participants had to be actively practicing in the US for a minimum of 3 years as a ONC, NEP, PA, NP, or RN. They were also required to have a minimum monthly caseload of 8 patients with advanced RCC. PAs, NPs, and RNs had to be specialized in oncology or having practiced in an oncology setting for at least 3 years (in general medical oncology or genitourinary medical oncology). In addition, purposive sampling[16] was used to ensure a variety of practice settings (academic vs. community-based), years of practice (3-10 years, 11-20 years, 21 years or more), practice locations (rural, urban, suburban), and identified gender. Inclusion criteria and purposive sampling criteria applied to both study phases.

Data Collection

For the qualitative exploration phase, the interview questions were developed based on a preliminary review of the literature and a discussion with a panel of clinical experts (co-authors MTC, EAJ, MAB, EAL, EPC) to identify potential gaps and challenges in clinical practice. The semistructured format of the interview included open-ended questions and probes to enable the trained interviewers to elicit further elaboration from the participants. The interviews were conducted in English between August and October 2020. They were recorded with participants' consent and then transcribed for analysis.

The development of quantitative measures was informed by the findings of the qualitative phase, to help shed light on the extent to which previously identified trends occurred in a larger sample. [9-11] The quantitative validation phase used a 15-minute online survey (see Supplemental Material 1) to validate the qualitative findings with a larger sample across the various professions, practice settings, and years of practice. Participants rated their level of knowledge and skill considering professional expectations using a 5-point rating scale (1 = no, 2 = basic, 3 = intermediate, 4 = advanced, 5 = expert knowledge/skill). Attitude and beliefs of participants were assessed via a five-point Likert-type scale (1 = strongly disagree to 5 strongly agree). Participants were also asked to rate the frequency to which they performed clinical tasks

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(1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always) and the quality of various sources of information (1 = very poor, 2 = poor, 3 = fair, 4 = good, 5 = excellent). For each of the survey items, participants had the opportunity to select "not relevant to my current practice." The survey was fielded from February to March 2021.

Analysis

The interview transcripts were analyzed in NVivo software (QSR International Pty Ltd, Version 12, 2018, Burlington, MA) with an approach drawing from the principles of directed content analysis[17] and thematic analysis.[18] A coding tree was developed with themes based on the structure of the interview guide and the literature review. New themes were added during the coding process as they emerged from the transcripts and during interviewer debriefing sessions.

The survey data underwent a quantitative analysis with SPSS software (version 27.0, IBM Corporation, Armonk, NY) with cross-tabulations (Pearson's $\chi 2$ test) to assess differences in the distribution of responses by subgroups (eg, profession). Knowledge and skill ratings were grouped into 2 categories: "sub-optimal" (for 1 = none, 2 = basic, 3 = intermediate) and "optimal" (for 4 = advanced, 5 = expert). Agreement ratings were grouped in 3 categories: "disagree or strongly disagree," "neither agree nor disagree," and "agree or strongly agree." Frequency ratings were grouped into 2 categories: "never, rarely or sometimes," and "often or always." Quality of information ratings were grouped into 2 categories "very poor, poor or fair" and "good or excellent."

Data Integration and Trustworthiness

For the final analysis, qualitative and quantitative findings were combined through triangulation, a process that enhances the trustworthiness of final findings by overcoming the biases intrinsically associated with analyses based on a single method, source, and interpretation viewpoint.[19] Triangulation of sources was also employed to contrast the perspectives of the different professions and specialties, as well as triangulation of investigational perspectives through the multidisciplinary interpretation of findings between educational (co-authors PL, MA, GJ) and clinical experts (co-authors MTC, EAJ, MAB, EAL, EPC).

Results

A total of 1,690 invitations for interviews and approximately 6,500 invitations for surveys were sent out. Response rates were 7.9% and 18.6% for respective phases of the study. Of those who replied to the invitation, 305 participants met eligibility criteria and successfully completed the study (40 interviewed, 265 surveyed) (Table 1). Most participants in both phases practiced in community (ie, nonacademic affiliated) settings. In the qualitative phase, 33% of participants had 3 to 10 years of practice, 45% had 11 to 20 years, and 23% had 21 years or more. In the quantitative phase, percentages were 38% for 3 to 10 years of practice, 46% for 11 to 20 years, and 16% for had 21 years or more.

Triangulated findings underscored 4 key challenges in the care of patients with mRCC as convergent themes from the combined qualitative and quantitative data. Challenges related to treatment and management of mRCC included: 1) staying current with emerging evidence and recommendations, and 2) weighing in patient health and treatment preferences. Challenges related to the coordination of mRCC care included: 3) promoting a collaborative care approach, and 4) transferring patient information across multiple providers.

Treatment and Management

1) Challenges staying current with emerging evidence and recommendations

Surveyed ONCs (25%), PAs (36%), and NPs (49%) reported suboptimal knowledge levels of "TKIs currently indicated for the first-line treatment of mRCC." A statistically significant difference in the distribution of sub-optimal knowledge ratings was identified by profession ($P = .03$, Table 2, Row A). Similarly, 28% of surveyed ONCs, 33% of PAs, and 54% NPs reported suboptimal knowledge levels of "when it is appropriate to combine TKIs with immunotherapy for the treatment of mRCC" ($P = .02$, Table 2, Row B). Qualitative data revealed a feeling of being overwhelmed by the myriad of emerging therapeutic options and the challenge of using the IMDC risk stratification tool to decide which combination therapy is most appropriate for patients with mRCC:

> *"*[everolimus] *was out of the barn, and then* [sunitinib] *came to the market, and then came the mTOR inhibitors. And then it exploded. Now, we have so many TKIs, a bunch of inhibitors, I-O's* [immuno-oncology agents]. *It's actually become confusing now, there's so much."*
>
> – Medical Oncologist, Academic

> *"What is the best choice between the standards of care? Pembrolizumab, axitinib or I-O* [an immuno-oncology agent] *plus TKI versus ipilimumab/nivolumab combination, specifically for intermediate and poor-risk IMDC patients? That is really the key question here."*
>
> – Medical Oncologist, Community

According to survey results, only 42% of ONCs reported often or always considering the IMDC risk model in treatment recommendations. Surveyed ONCs (37%), PAs (23%), and NPs (30%) reported suboptimal knowledge of "current recommendations regarding the dosage of TKIs for mRCC," with no statistically significant difference in the distribution of suboptimal knowledge ratings by profession ($P = .25$, Table 2, Row C). Surveyed ONCs (43%), PAs (61%) and NPs (34%, $P = .01$) agreed or strongly agreed with the statement that: "National Comprehensive Cancer Network (NCCN) guidelines are extremely challenging to follow when it comes to the first-line treatment of advanced or metastatic RCC." In addition, surveyed ONCs (25%), NEPs (29%), PAs (37%), NPs (38%) and RNs (41%) reported suboptimal skill in "interpreting published evidence on the efficacy (eg, progression-free rate) and safety (eg, toxicity rate) of emerging agents in first-line mRCC", with no statistically significant difference in the distribution of suboptimal skill ratings by profession ($P = .37$, Table 3, Row A).

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Table 1 Description of Sample by Phase (Qualitative and Quantitative) and Specialty

Qualitative interviews	Medical Oncologists (n = 10)	Nephrologists (n = 8)	Physician Assistants (n = 8)	Nurse Practitioners (n = 8)	Registered Nurses (n = 6)	Total (n = 40)
Years of Practice						
3-10 y	4	0	5	4	0	13
11-20 y	3	7	3	2	3	18
21+ y	3	1	0	2	3	9
Setting						
Academic	5	3	2	3	2	15
Community	5	5	6	5	4	25
Location						
Rural	1	0	0	2	0	3
Suburban	4	3	3	3	4	17
Urban	5	5	5	3	2	20

Quantitative Survey	Medical Oncologists (n = 68)	Nephrologists (n = 54)	Physician Assistants (n = 49)	Nurse Practitioners (n = 47)	Registered Nurses (n = 47)	Total (n = 265)
Years of Practice						
3-10 y	26	17	28	14	15	100
11-20 y	30	30	17	22	23	122
21+ y	12	7	4	11	9	43
Setting						
Academic	34	12	7	13	18	84
Community	34	42	42	34	29	181
Location						
Rural	4	2	5	2	3	16
Suburban	27	23	11	26	18	105
Urban	37	29	33	19	26	144

Table 2 Percent of HCPs Who Self-Reported No, Basic or Intermediate Levels of Knowledge

Percent of …… who reported no, basic or intermediate knowledge of …		Profession			Total	Sig.[a]
		ONC	PA	NP		
A	"TKIs currently indicated for the first-line treatment of advanced or metastatic RCC"	25%	36%	49%	35%	$P = .03$
		(n = 17)	(n = 17)	(n = 23)	(n = 57)	
B	"when it is appropriate to combine TKIs with immunotherapy for the treatment of advanced or metastatic RCC"	28%	33%	54%	37%	$P = .02$
		(n = 19)	(n = 16)	(n = 25)	(n = 60)	
C	"current recommendations regarding the dosage of TKIs for advanced or metastatic RCC"	37%	23%	30%	31%	$P = .25$
		(n = 25)	(n = 11)	(n = 14)	(n = 50)	

Note: Nephrologists and registered nurses were not asked to rate their knowledge for these items.
Abbreviations: NP = Nurse practitioners; ONC = Medical oncologists, PA = Physician assistants
[a] Pearson's $\chi 2$ test indicating statistically significant difference in the distribution of suboptimal (no, basic or intermediate) vs. optimal (advanced or expert) knowledge ratings across professions at $P < .05$.

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Table 3 Percent of HCPs Who Self-Reported No, Basic or Intermediate Levels of Skills

Percent of ..... who reported no, basic or intermediate skills in ...		Profession					Total	Sig.[a]
		ONC	NEP	PA	NP	RN		
A	"interpreting published evidence on the efficacy (eg, progression-free rate) and safety (eg, toxicity rate) of emerging agents in first-line advanced or metastatic RCC"	25%	29%	37%	38%	41%	33%	$P = .37$
		(n = 17)	(n = 15)	(n = 18)	(n = 18)	(n = 18)	(n = 86)	
B	"assessing a patient's tolerance level to side effects when personalizing a first-line treatment for advanced or metastatic RCC"	32%	N/A[b]	29%	19%	35%	29%	$P = .38$
		(n = 21)		(n = 14)	(n = 9)	(n = 16)	(n = 210)	
C	"weighing the effectiveness of a targeted therapy for advanced or metastatic RCC against a potential toxicity"	21%	37%	35%	32%	39%	32%	$P = .22$
		(n = 14)	(n = 19)	(n = 17)	(n = 15)	(n = 17)	(n = 82)	

Abbreviations: ONC = Medical oncologists; NEP = Nephrologists; PA = Physician assistants; NP = Nurse practitioners; RN = Registered nurses.
[a] Pearson's χ2d test indicating statistically significant difference in the distribution of suboptimal (non, basic or intermediate) vs. optimal (advanced or expert) skill ratings across professions at $P < .05$.
[b] Item not asked to this specific profession group.

2) Challenges weighing in patient health and treatment preferences

About 34% of surveyed HCPs reported often or always encountering a "lack of information regarding patient's existing comorbidities prior to making a treatment decision." When asked to rate the quality of the sources of information, a statistically significantly higher proportion (38%) of HCPs with 3 to 10 years of practice rated as very poor, poor, or fair the quality of "medical history and clinical notes taken by other providers in relation to a patient's existing comorbidities," compared to 27% of those with 11 to 20 years and 19% of those with 21+ years ($P = .04$). Thirty-seven percent (37%) of surveyed HCPs provided low ratings for the quality of "documentation of patient's preferences, including desired quality of life" with no statistically significant difference in the distribution of low-quality ratings by years of practices ($P = .74$).

Suboptimal skills in "assessing a patient's tolerance level to side effects when personalizing a first-line treatment for mRCC" were found, especially among surveyed HCPs with 3 to 10 years of practice (37%), compared to 22% of those with 11 to 20 years and 23% of those with 21+ years ($P = .03$). Alongside, surveyed ONCs (21%), nephrologists (37%), PAs (35%), NPs (32%), and RNs (39%) reported in similar proportions suboptimal skills "weighing the effectiveness of a targeted therapy for mRCC against a potential toxicity" ($P = .22$, Table 3, Row C). Interviewed participants provided further insights on this challenge, expressing concerns on the severity of side effects associated with treatments for mRCC:

> *"We know the medication's working but it's causing them* [the patients] *such side effects that the quality of life that they're having is not worth it. In those cases, it's a difficult decision. Ultimately though, again, we let the patient make the decision."*
>
> – Nurse Practitioner, Academic
>
> *"If the treatment's potentially nephrotoxic, what's worse? Being on dialysis or not treating the cancer? And I don't think anybody knows that answer. I don't think there's any studies that have seen that."*
>
> – Nephrologist, Community

A smaller proportion of ONCs (57%) surveyed considered patient's preference in treatment recommendations, compared to those who considered patient's tolerance level to side effects (79%) and desired quality of life (85%).

Coordination of care

3) Challenge promoting a collaborative care approach

When asked to describe the key members of the multidisciplinary team in mRCC, interviewed participants named mostly oncologists, urologists, and internists. Nurses and advanced practice providers described their role in following up with a treatment, communicating with patients and supporting their education. Involvement of other specialties (eg, cardiologists, endocrinologists, rheumatologists, nephrologists) depended on the side effect that a patient with mRCC would experience and the need for additional care:

> *"It's a case-per-case basis. If a patient needs more help, or there's a complication, if there's something going on with the patient, then we're likely to communicate with the urologist and the oncologist more. I don't think there's a set rule. It depends on the patient, it depends on the severity of their disease, from a renal standpoint, and do the patients need the help or not?"*

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– Nephrologist, Community

Depending on the side effect, between 19% to 52% of surveyed NEPs reported never, rarely, or sometimes being involved by ONCs in the management of mRCC patients: Anemia (52%), electrolyte abnormalities (30%), uncontrolled hypertension (29%), nephritis (25%), proteinuria (25%), acute renal failure (24%) and chronic kidney disease (19%). But only few nephrologists (7-21%) indicated having sub-optimal knowledge of the signs and symptoms of renal complications and suboptimal skills to manage renal complications (Figure 2).

Suboptimal knowledge of therapeutic options and side effects, divergent treatment goals, and poor recognition of roles and responsibilities were among the most significant barriers to having nephrologists involved in the management of patients experiencing renal complications:

"You have to be extremely explicit in asking for their help. In general, other than having a confirmation that their kidney function is impaired, the nephrologist always blames the chemotherapy and then says to avoid nephrotoxic agents. It's not helpful."

- Medical Oncologist, Academic

"RCC is under-recognized by the nephrology community, such that its presence in curricula and research by this group is lacking."

–Registered Nurse, Community

4) Challenges transferring patient information across multiple providers

Survey results showed 34% of HCPs often or always experienced a loss of relevant patient documentation in the transfer of care across providers. Heavy workloads and a lack of communication pertaining to the prioritization of patient cases were described as barriers to optimal coordination of care by interviewed participants:

"… whether it is seen by the emergency room or discharged and/or the urologist or any other physicians, I would say instead of faxing over the records to the medical oncology office hoping that the patient records get to the right person […] *it is always good to communicate by the electronic method or by phone or some sort of electronic method to bring to light the urgency of the referral and expeditious taking care of the patient."*

– Medical Oncologist, Community

On average, 46% of surveyed HCPs reported experiencing breakdowns in communication between providers when caring for patients with mRCC. Of those, the majority reported having a breakdown in communication during the monitoring of side effects and patient compliance with treatment (61%), management of a patient's desired quality of life (58%), and treatment with targeted therapies (57%). Almost half (48%) experienced a breakdown during initial referral to ONCs. Few RNs (28%) reported having suboptimal skill levels in coordinating the care of patients with mRCC among providers.

Discussion

Results from this mixed methods study show persistent challenges faced by US-based HCPs involved in the care of patients with mRCC. As stated by Santoni et al[20], the absence of reliable predictive biomarkers can impede treatment selection for patients who could otherwise benefit from systemic therapies.[20] Investigations to find valid predictive biomarkers (eg, neutrophil-to-lymphocyte ratio) for mRCC are underway[21,22] but none are established at present. Consequently, HCPs are challenged to select an appropriate therapy. This study found that HCPs had suboptimal knowledge of when it is appropriate to combine TKIs with immunotherapy. Although multiple combinations have been investigated in recent years (eg, pembrolizumab/lenvatinib, nivolumab/cabozantinib, nivolumab/ipilimumab), there is no consensus in the medical oncology world as to what is the ideal first-line regimen.[23,24] A recent systematic review of phase III clinical trials comparing first-line immuno-oncology combinations with monotherapy (sunitinib) showed few combinations had improved overall survival and progression free survival for patients with mRCC, all having unique characteristics.[25] Different thought leaders have different opinions and contextualize clinical trial data differently.[24] Patient stratification by risk scores (IMDC and/or the Memorial Sloan Kettering Cancer Center models) can be used to decide which treatment is more accurate in first-line advanced or mRCC.[5,26] Pembrolizumab with axitinib combination is recommended for all risk groups, whereas nivolumab with ipilimumab combination is recommended only in intermediate/poor risk group.[27]

Unfortunately, this needs assessment found that providers, including ONCs, did not completely understand how to use the IMDC as a prognostic tool. This may explain why only 42% of ONCs considered the IMDC risk stratification score often or always in treatment recommendations for patients, despite it being an effective tool.[5] This finding underscores the need for knowledge-raising interventions informing ONCs of the IMDC risk stratification score (eg, online webinars and infographics) and engaging activities allowing targeted learners to assess their application of this tool in practice (eg, patient scenarios).

Participants in this study reported sub-optimal skills interpreting published evidence on the efficacy and safety of agents, as well as weighing the effectiveness of a targeted therapy for mRCC against a potential toxicity. These skill gaps could result in unnecessary risks for the patient since combining TKIs with immune checkpoint inhibitors, although a promising combination,[28] can often bring overlapping toxicities from both types of agents and should be managed differently.[29] It would be important to ensure greater representation of patients in clinical trials, ensuring they are referred not only from academic-affiliated institutions, but also community practices.

The information gathered in this study highlights the opportunity for HCPs to become better versed on treatments and combinations approved for mRCC and what to expect from them in terms of toxicities. Given that 28% of HCPs reported suboptimal skill assessing a patient's tolerance level to side effects when personalizing a first-line treatment for mRCC, future interventions may consider developing engaging educational content delivered in a manner that presents an efficient and collaborative exchange between an HCP and a patient. The exchange should consider the risks vs. benefits

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Figure 1 Mixed-methods research design.

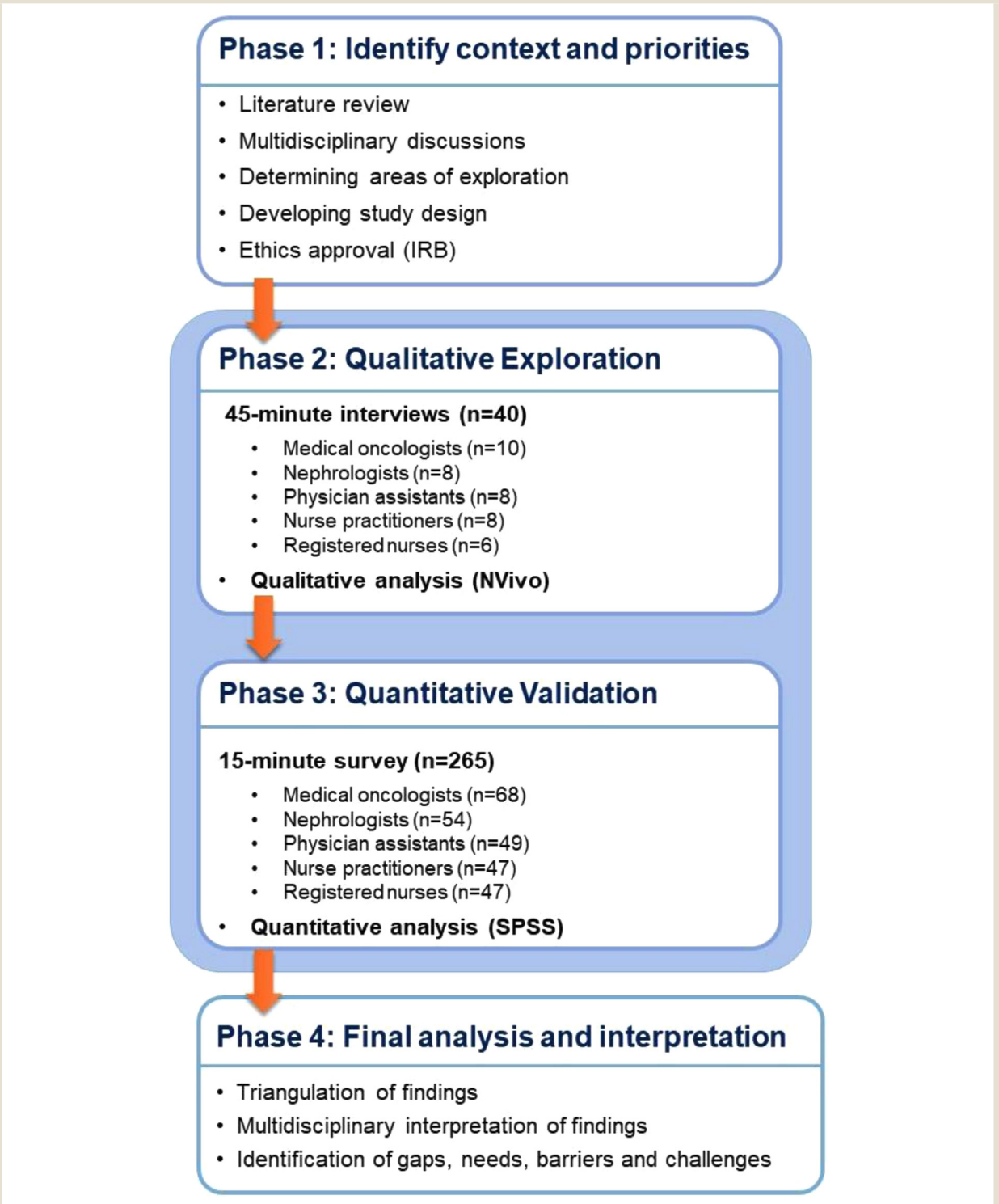

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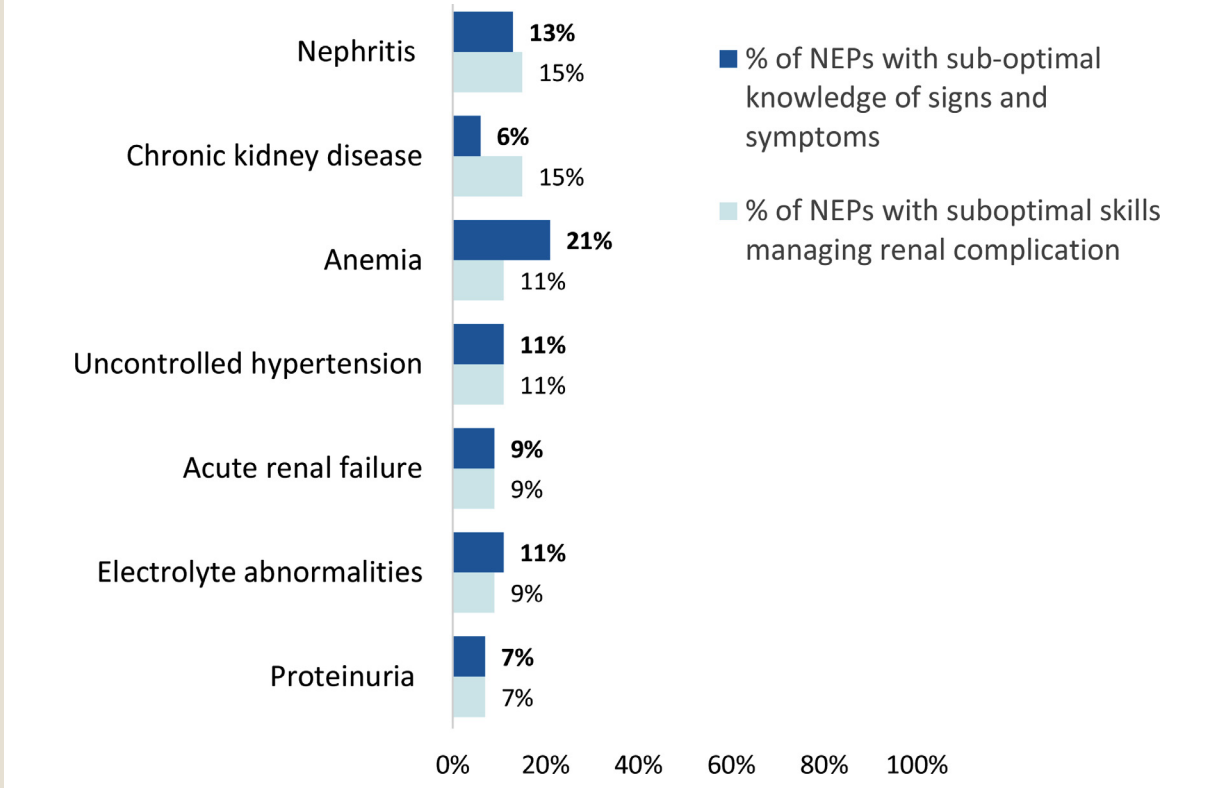
Figure 2 Percent of NEPs reporting suboptimal knowledge and skills in relation to renal complications.



of proceeding with a treatment for mRCC, as well as the tolerance level of the patient and their acceptance of side effects.

Of equal concern was the challenge of communicating critical patient information between HCPs regarding the urgency of care, existing comorbidities, and experienced treatment side effects to further personalize treatment. Participants in this study underscored the need for efficient electronic communications (eg, electronic medical records or EMRs) to share timely information between various specialists and health care professionals. The fact that a variety of electronic medical record (EMR) systems are used across practice settings and organizations within the US, and that those systems do not routinely facilitate efficient, comprehensive data handoffs may offer one explanation of why some patient information is lost in the transfer of care.[30,31] When different EMR systems are used, interorganizational communication and monitoring of external workups is more challenging. This is further complicated when patients require expedited care which puts their multidisciplinary team at a disadvantage when they are not employed within the same health system. In those cases, an exchange of critical information between health care providers should involve direct communication between parties and not be reliant upon access to a patient's electronic records. Effective multidisciplinary communication and collaboration is imperative to the optimal care of patients with mRCC, as treatments include various modalities, such as systemic therapy, surgery, and radiotherapy.[32] A focus on building stronger patient-centered teams with well-defined protocols would better align every member in terms of how to communicate with each other and with their patients, while more clearly outlining what to expect from colleagues.[32]

The greater involvement of nephrologists in the management of renal complications has been recently advocated for to optimize the care of mRCC patients, especially in the event of chronic kidney disease and acute renal failure, which significantly increase patients' mortality risk.[33] The present study indicates most nephrologists (79%) believe they have advanced or expert skills in managing renal complications. However, there are substantial barriers to involving them in the care of patients with mRCC. Included in those barriers is a perception among many oncology HCPs that nephrologists lack sufficient expertise in oncology, such as knowledge of the pathophysiology of mRCC, related treatments, and side effects of immuno-oncology agents. This gap could be remedied through targeted educational interventions for nephrologists aiming to acquire knowledge of the treatment landscape available in oncology and implications for the management of renal complications parallel with mRCC. Interventions could be interactive to support skill development in weighing the risks of cancer progression and potential renal complications.

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Another potential solution to remedy the communication gap highlighted here is to establish tumor boards and/or communities of practice on RCC care that would provide specialists, general practitioners, and advanced practice providers with the opportunity to discuss challenging cases either within their practice setting or with other experts in the country/world. Although tumor boards are common and may result in more accurate and complete diagnoses and treatments,[34] they are typically limited to including professions working within a same institution, and sharing the same patient cases, to help determine a consensus on the best course of action for the most challenging cases. In contrast, a community of practice, which originated in the business world, is defined as a group of people "bound together by shared expertise and passion for a joint enterprise" which may or may not work within the same institution, region or even country.[35] Such programs could provide oncology team members (eg, oncologists, nephrologists, nurse practitioners and others) with an opportunity to exchange knowledge and develop expertise in problem-solving with top leaders in the space of RCC practicing in different locations (eg, rural vs. urban locations).[36] We postulate that this type of peer-to-peer learning, drawn from actual clinical experience, could be especially beneficial as it pertains to the effective management of complex patient profiles within the context of recently-approved therapeutic combinations in the ever-evolving treatment landscape of mRCC.

Limitations

The findings presented here are based on data that was self-reported by participants rather than from objective observations. To minimize self-reporting biases,[37] triangulation[38] and purposive sampling[16] were used. Caution is warranted in terms of generalizing the findings to other HCPs involved in mRCC care, or to countries other than the US. Specific practice settings (eg, Veteran Affairs) may have characteristics (eg, a system-wide EHR) that could impact the presence or intensity of identified challenges. To ensure the benefits of developing precise activities for the targeted learners that meet the needs of the patient population, additional region-specific needs assessments should be conducted to inform locally tailored educational activities and offerings. Future studies could also include a broader range of specialties (eg, gastroenterologists, urologists, dermatologists) likely involved in the care of RCC patients, including the management of immune-related adverse events. Information available on members of the panels used to recruit participants only allowed for targeting potential candidates by profession and location. Thus, invitees not involved in RCC may have decided not to respond because they could anticipate from the email text that they would not have met the inclusion criteria. Nonetheless, the obtained response rates in this study are similar to those observed in other educational and behavioral needs assessments leveraging broad online panels of HCPs, and applying rigorous inclusion criteria to maximize sample representativeness to the targeted population under investigation.[39,40]

Conclusion

This study sheds light on the main challenges faced when treating and managing patients with mRCC across multiple providers. Numerous opportunities exist for educational activities to better equip providers in risk-stratifying patients, interpreting emerging evidence on available agents, and weighing the risks and benefits of treatments in collaboration with patients and other health care professionals. Greater involvement of nephrologists was underscored as an important solution to consider. As the treatment landscape changes and new agents which are currently under review in clinical trials receive approval, it would be prudent to revisit the implications that has on HCPs' ability to navigate the treatment options and effectively manage the care of patients with mRCC. We hope that the findings presented in this paper provide an opportunity for practicing clinicians to reflect on their own practice gaps and corresponding educational needs.

Clinical Practice Points

- The rapid development of systemic therapies for advanced RCC (especially if unresectable or metastatic, mRCC) has brought new challenges for the treatment and management of patients across providers, especially since there is still a lack of direct comparative evidence among the various therapeutic options.
- Current evidence suggests a lack of predictive biomarkers, difficulties predicting and managing side effects associated with new targeted therapies, and a need to validate optimal sequencing of treatment agents.
- The findings from this new study describe several other challenges faced by HCPs treating and managing patients with mRCC, including sub-optimal knowledge of dosage recommendations for targeted therapies and sub-optimal skills in interpreting scientific evidence pertaining to treatment agents.
- Challenges in the coordination of patients across multiple providers were also found, with evidence of communication breakdowns between providers during initial referral, treatment and management of patients, and sub-optimal involvement of nephrologists.
- HCPs involved in the management of patients with mRCC care can use insights derived from this study to reflect on their own competencies and seek appropriate educational solutions to address challenges experienced.
- Engaging in continuing medical education and continuing professional development interventions addressing the root of practice challenges is likely to optimize the treatment, and management of patients with mRCC.

CRediT authorship contribution statement

Patrice Lazure: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – review & editing. **Matthew T. Campbell:** Methodology, Validation, Writing – review & editing. **Monica Augustyniak:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft, Writing – review & editing. **Edgar A. Jaimes:** Methodology, Validation, Writing – review & editing. **Emily A. Lemke:** Methodology, Validation, Writing – review & editing. **Eric P. Cohen:** Methodology, Validation, Writing – review & editing. **Ginny Jacobs:** Conceptualization, Funding acquisi-

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tion, Investigation, Methodology, Project administration, Validation, Writing – review & editing.

Disclosure

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P. Lazure & M. Augustyniak are employees of AXDEV Group Inc. E. A. Jaimes owns stock in Goldilocks Therapeutics Inc. G. Jacobs is an employee of AXDEV Global Inc. M. T. Campbell, M. A. Bilen and E. A Lemke have nothing to disclose. E. P. Cohen discloses being supported in part by resources and the use of facilities at the Manhattan VAMC, New York City.

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Supplementary materials

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References

1. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. *CA Cancer J Clin*. 2021;71:7–33.
2. Kapoor A. First-line treatment options in metastatic renal cell cancer. *Can Urol Assoc J*. 2016;10:S236–s238.
3. Gulati S, Vaishampayan U. Current state of systemic therapies for advanced renal cell carcinoma. *Curr Oncol Rep*. 2020;22:26.
4. Motzer RJ, Jonasch E, Boyle S, et al. NCCN Guidelines Insights: Kidney Cancer, Version 1.2021: Featured Updates to the NCCN Guidelines. *J Natl Compr Canc Netw*. 2020;18:1160–1170.
5. Heng DY, Xie W, Regan MM, et al. External validation and comparison with other models of the International Metastatic Renal-Cell Carcinoma Database Consortium prognostic model: a population-based study. *Lancet Oncol*. 2013;14:141–148.
6. Motzer RJ, Jonasch E, Michaelson MD, et al. NCCN guidelines insights: kidney cancer, version 2.2020: featured updates to the NCCN guidelines. *J Natl Compr Canc Netw*. 2019;17:1278–1285.
7. Parmar A, Sander B, Bjarnason GA, Chan KKW. Systemic therapy in metastatic renal cell carcinoma: Emerging challenges in therapeutic choice. *Crit Rev Oncol Hematol*. 2020;152.
8. Pal S, Gong J, Mhatre SK, et al. Real-world treatment patterns and adverse events in metastatic renal cell carcinoma from a large US claims database. *BMC Cancer*. 2019;19:548.
9. Shorten A, Smith J. Mixed methods research: expanding the evidence base. *Evid Based Nurs*. 2017;20:74–75.
10. NIH Office of Behavioral and Social Sciences. *Best Practices for Mixed Methods Research in the Health Sciences*. 2nd ed. Bethesda: National Institutes of Health; 2018.
11. Regnault A, Willgoss T, Barbic S. Towards the use of mixed methods inquiry as best practice in health outcomes research. *J Patient Rep Outcomes*. 2017;2:19.
12. Schoonenboom J, Johnson RB. How to construct a mixed methods research design. *Kolner Z Soz Sozpsychol*. 2017;69:107–131.
13. Fusch PI, Ness LR. *Are We there yet? Data saturation in qualitative research*; 2015 *The Qualitative Report*;20:1408–1416.
14. Oyeyemi G, Adewara A, Adebola FB, SI S. On the Estimation of Power and Sample Size in Test of Independence. *Asian Journal of Mathematics & Statistics*. 2010:3.
15. ICC/ESOMAR. ICC/ESOMAR (International Chamber of Commerce/European Society for Opinion and Marketing Research) International Code on Market, Opinion and Social Research and Data Analytics: Accessed April 02, 2022. Available at: https://www.esomar.org/what-we-do/code-guidelines; 2016.
16. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. *Adm Policy Ment Health*. 2015;42:533–544.
17. Assarroudi A, Heshmati Nabavi F, Armat MR, Ebadi A, Vaismoradi M. Directed qualitative content analysis: the description and elaboration of its underpinning methods and data analysis process. *Journal of Research in Nursing*. 2018;23:42–55.
18. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A. Synthesising qualitative and quantitative evidence: a review of possible methods. *J Health Serv Res Policy*. 2005;10:45–53.
19. Turner SF, Cardinal LB, Burton RM. Research design for mixed methods: a triangulation-based framework & roadmap. *Organiz Res Methods*. 2017;20:243–267.
20. Santoni M, Cimadamore A, Cheng L, et al. Circulating tumor cells in renal cell carcinoma: recent findings and future challenges. *Front Oncol*. 2019;9:228.
21. Bratu O, Mischianu D, Marcu D, et al. Renal tumor biomarkers (Review). *Exp Ther Med*. 2021;22:1297.
22. Raimondi A, Sepe P, Zattarin E, et al. Predictive biomarkers of response to immunotherapy in metastatic renal cell cancer. *Front Oncol*. 2020;10:1644.
23. Rassy E, Flippot R, Albiges L. Tyrosine kinase inhibitors and immunotherapy combinations in renal cell carcinoma. *Ther Adv Med Oncol*. 2020;12.
24. Hahn AW, Klaassen Z, Agarwal N, et al. First-line treatment of metastatic renal cell carcinoma: a systematic review and network meta-analysis. *Eur Urol Oncol*. 2019;2:708–715.
25. Hahn AW, Shah AY, Campbell MT. First-line immune-oncology combinations for metastatic clear cell renal cell carcinoma (mRCC): a systematic review of phase III clinical trials. *Kidney Cancer*. 2021;5(4):1–11.
26. Motzer RJ, Bacik J, Schwartz LH, et al. Prognostic factors for survival in previously treated patients with metastatic renal cell carcinoma. *J Clin Oncol*. 2004;22:454–463.
27. Porta C, Cosmai L, Rizzo M. Individualizing renal cell carcinoma treatment through biomarkers discovery in the era of immune checkpoint inhibitors: where do we stand? *Curr Opin Urol*. 2021;31:236–241.
28. George DJ, Lee CH, Heng D. New approaches to first-line treatment of advanced renal cell carcinoma. *Ther Adv Med Oncol*. 2021;13.
29. Tran J, Ornstein MC. Clinical review on the management of metastatic renal cell carcinoma. *JCO Oncol Pract*. 2021;18(3):187–196.
30. Friedberg MW, Chen PG, Van Busum KR, et al. Factors affecting physician professional satisfaction and their implications for patient care, health systems, and health policy. *Rand Health Quart*. 2014;3:1.
31. Hassett MJ. Usability considerations in oncology electronic medical records. *J Oncol Pract*. 2017;13:539–541.
32. Yan M, Gregg R, Mahmud A. Outcomes of Multi-disciplinary Management of Metastatic Renal Cell Carcinoma. *Cureus*. 2019;11:e5901.
33. Perazella MA, Dreicer R, Rosner MH. Renal cell carcinoma for the nephrologist. *Kidney Int*. 2018;94:471–483.
34. Pillay B, Wootten AC, Crowe H, et al. The impact of multidisciplinary team meetings on patient assessment, management and outcomes in oncology settings: a systematic review of the literature. *Cancer Treat Rev*. 2016;42:56–72.
35. Cruess RL, Cruess SR, Steinert Y. Medicine as a community of practice: implications for medical education. *Acad Med*. 2018;93:185–191.
36. Fingrut W, Beck LA, Lo D. Oncology communities of practice: insights from a qualitative analysis. *Curr Oncol (Toronto, Ont.)*. 2018;25:378–383.
37. Althubaiti A. Information bias in health research: definition, pitfalls, and adjustment methods. *J Multidiscipl Healthc*. 2016;9:211–217.
38. Smith J, Noble H. Bias in research. *Evid Based Nurs*. 2014;17:100–101.
39. Heidbuchel H, Dagres N, Antz M, et al. Major knowledge gaps and system barriers to guideline implementation among European physicians treating patients with atrial fibrillation: a European Society of Cardiology international educational needs assessment. *EP Europace*. 2018;20:1919–1928.
40. Hayes SM, Sharief M, Ng P. Identification of clinician challenges in order to drive the development of competency-based education: results from an international needs assessment in multiple sclerosis. *J Eur CME*. 2015;4:27432.

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