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Changes, Challenges & Opportunities in Cancer Care During COVID-19 Era & Beyond

An Educational Service for Medical Oncologists, Hematologist-Oncologists, and Urologists

Changes, Challenges and Opportunities in Cancer Care During the COVID-19 Era and Beyond: Building on Lessons Learned From the Pandemic

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In this roundtable discussion, nation's leading cancer experts from across the country share their perspectives on current changes, challenges and opportunities for delivering cancer care during the COVID-19 era. The roundtable panel examines long-term implications of the pandemic on the management and treatment of cancer especially focusing on significant issues in patient safety, toxicities associated with the use of immunotherapy, COVID-19 vaccination, and clinical trial designs. In this discussion, experts also brainstorm a range of recommendations focusing especially on how the cancer community can capitalize on lessons learned from the pandemic to develop creative approaches that can be taken forward.

INTRODUCTION

The COVID-19 pandemic has caused unprecedented disruption across the spectrum of cancer care services, including cancer diagnosis, screening, clinical trials, and therapeutic management[1-7]. Since the COVID-19 outbreak, substantial decrease in launching new cancer trials or discontinuation of existing trials disrupted the pace of clinical research and new drug discovery with long-term negative consequences for cancer care[2-5]. At the outset of the ongoing COVID-19 crisis, the cancer community is adapting to the substantial challenges that the pandemic continues to pose[7,8]. The lessons learned by the cancer community in the wake of the COVID-19 pandemic offers an opportunity to reflect on the significant issues for delivering optimal cancer care and cancer treatment[9-11]. Interestingly, this outbreak has stimulated innovative approaches in cancer care in an unprecedented way[12]. Here, our distinguished panelists shared a year's worth of lessons that could be used to redesign the delivery of a high standard cancer care and the conduct of cancer clinical trials. The objective of this roundtable program is to gain insights into newly developed measures and recommendations for the cancer community to overcome the long-term impact of the outbreak.

Roundtable questions were distributed to panelists a week before the roundtable session, and the discussion was video recorded and transcribed. The following is a transcript of the roundtable edited for clarity.

Dr. Figlin: This is the Kidney Cancer Journey roundtable focusing on challenges and opportunities in the cancer clinical trials in the COVID-19 era. The purpose of today's roundtable is to gain your insights into how we are all thinking about delivering GU cancer care during the post COVID-19 pandemic world.

I am Robert A. Figlin, *Editor-in-Chief* of the *Kidney Cancer Journal* and the Spielberg family chair at Cedars Sinai Center in Los Angeles. I am really very happy to be joined by three distinguished kidney cancer and GU investigators from across the country. Joining me today are my colleagues Dr. Robert Motzer, the Jack and Dorothy Byrne Chair in Clinical Oncology at Memorial Sloan Kettering Cancer Center (MSKCC) and Professor of Medicine at Weill Cornell Medical College in New York, Head of the Genitourinary Oncology Service. Dr. Eric Jonasch, Professor, Department of Genitourinary Medical Oncology, Division of Cancer Medicine, Director, VHL Clinical Center, MD Anderson Cancer Center and Co-Chair, Renal Cancer Program, MD Anderson Cancer Center and Dr. Bradley McGregor, Clinical director for the Lank Center for Genitourinary Oncology at Dana Farber Cancer Institute, Professor of Medicine, Harvard Medical School.

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Gentlemen, thank you for taking time out of your busy schedules to join us today.

Bob, let me start out with you. Can you share your view on the role of delivering immunotherapy to kidney cancer patient population in the COVID-19 era?

Dr. Motzer: The COVID-19 pandemic really impacted our practice in many different ways. For one, this pandemic made it difficult for patients to access cancer care and to evaluate patients in our cancer center in Manhattan. This pandemic also made it difficult for healthcare providers to deliver timely cancer therapy to RCC patients. In terms of access to care, patients were screened coming into our clinic and patients were also concerned about coming into Manhattan with the COVID-19 and many times patients would postpone the standard follow-up tests or put them on hold. In return for that, we boosted our remote medical care using videos and so forth. Remote healthcare has been a real challenge. Because it is really new to us and for the most part we have all been practicing hands-on in-person visits. It really forced us to become familiar with these technical aspects.

It is also been a challenge in terms of managing people with metastatic kidney cancer who are on therapies. Because for the most part in the past, you gain so much from seeing somebody in the clinic and talking to them and getting their blood work done rather than speaking with them virtually and not having the comfort level of actually seeing them in person. It also influenced the very close doctor-patient relationship which is very important for a medical oncologist. This pandemic basically put a barrier on that relationship. It also made it difficult for clinical trials. I think that the number of patients going into clinical trials decreased during the pandemic. Patients did not want to come into centers to get into clinical trials as there was more of a concern about experimental medicines and their side effects and also about the impact of the COVID-19 infection. It also made it much more difficult to assess patients from a safety standpoint, because a lot of our safety assessments were compromised by the lack of ability for patients to come and get evaluated. I think it also impacted our treatment to a certain extent for many patients. With the uncertainty around the pandemic and the uncertainty around immunosuppression with the use of steroids, our decision was influenced in terms of when to start patients on systemic therapy or delay it. So it was really an extreme challenge to manage our population of patients with metastatic kidney cancer during the pandemic.

Dr. Figlin: *Bob, that is a great summary. The bigger question is to Eric at MD Anderson Cancer Center in Houston, should we as an organization establish some more coherent guidelines on how to think about our post-pandemic kidney cancer treatments? What are your thoughts about that?*

Dr. Jonasch: Yes, so a couple of things here Bob. First of all, the current guidelines that have been developed by ASCO and ESMO with regards to the general management of immunotherapies are excellent. We can certainly use them as guideposts on how to treat people with immunotherapy, and how to manage immunotherapy related side effects. Layering in then the specter of COVID-19, number one, what happens to an individual who is on immunotherapy who then gets the COVID-19 infection? How does that affect how we treat that individual? Unfortunately, a number of my patients have been infected with COVID-19 while they have been on active checkpoint antibody therapy. It is difficult to see on an individual or an anecdotal level whether or not they have suffered more. Some data suggests that COVID-19 outcomes in cancer patients are worse than people who are without cancer with COVID-19. So I think it is probably impacted them to some degree. As we then assess these individuals from a response perspective, the next question really would be – does the new lymphadenopathy we see on scans correlate with the recent COVID-19 infection or COVID-19? The answer is possibly yes. While you are looking at an individual who has COVID-19, who has pulmonary metastasis, who has inflammatory changes, you would do a RECIST assessment on that person. If patients are on a clinical trial, it certainly creates additional challenges, but not insurmountable ones. I think the last question really is, with the vaccines that are coming out, should we now not vaccinate individuals because of its potential risk? The data has been a little mixed. But there has been a recent paper that came out in the Lancet Oncology by Waissengrin et al, suggesting that the toxicities associated with IO therapy as a function of treatment after vaccination are not dramatically different. And so when my patients asked me, should they get vaccinated? I say, from a toxicity perspective, it is probably better to have a COVID-19 vaccine. From an efficacy perspective, I think it is still an unanswered question. If they get a COVID-19 vaccination, will this worsen the outcome of IO therapy? We still do not have answers.

Dr. Figlin: *That is a brilliant summary. So Brad in Boston, let's just turn our attention to designing clinical trials. how do we need to be thinking about clinical trial design and placing people who are recently COVID-19 vaccinated in the clinical trials post-pandemic?*

Dr. McGregor: I think that is a great question. I get the radiology reports for patients who are on the trials and they are concerned about increased lymphadenopathy correlated with the recent COVID-19 vaccine. So our radiologists are already putting this in the reports on a routine basis. But how do we interpret such data and put blinded, independent review in perspective? I think it is a difficult question to answer at this point of time. We have these different caveats especially once patients receive the recent COVID-19 vaccine. And we started looking at criteria and

interpreted that it may be related to the COVID-19 vaccine. Because from a clinical standpoint, our radiologists are doing this in trials all the time. So it remains to be seen how we incorporate such aspects into trial design.

Dr. Figlin: Yeah, but just to push you a little bit right now, I agree with that completely. Maybe Bob can weigh in as well. I see most of the trials that Bob, Eric and you have reported, are international trials. So patients are from all over the world where the population is highly heterogenous and patients may not have had the vaccine or have the same imaging evaluation as the Farber has, so how are we going to do these pivot international trials, post COVID-19.

Dr. McGregor: Yes, overall, it is challenging when dealing with international pivot trials. If you especially look at the COVID-19 vaccine-induced lymphadenopathy aspect, often these are not large enough to meet RECIST criteria as a new node. I think that is the fortunate thing. So if you are strictly going by RECIST criteria, you may not actually have 3 or 4 centimeter enlarged nodes from a COVID-19 vaccination in the international clinical trials.

Dr. Figlin: *So I want to stay on this topic just for a little bit. Bob, you have led some of the major international trials in kidney cancer, your thoughts about how the datasets will evolve over the next, six to 24 months, and then how we are going to be interpreting that data and how to navigate that. Any thoughts about that?*

Dr. Motzer: We do not really know what the impact of the pandemic will be on the clinical trial data. I think that has been somewhat industry sponsor-specific and the various sponsors have had their own plan in place to monitor follow-up and safety procedures during the COVID-19 pandemic. So, in terms of the studies that I am involved in, I am not aware that there has been a dramatic impact on safety for these trials. There was a study that I was involved with, where there was an issue in terms of getting imaging follow up on patients because of COVID. I think that is something we have to deal within the trial. But for the big phase-3 trials, we have not seen the data come back yet so we are not aware of the impact that you are speaking of. I have been also intrigued by the adenopathy associated with vaccination. So, what we have been doing is we have been timing the scans around vaccine, because I do not think it is a good idea to have a scan on a patient two days after they have a vaccine. But if you do scans two days before vaccination, it is It will be less of an issue and we have noticed that the adenopathy is really quick to resolve. Certainly, in blinded review, core imaging review, people would not know whether there was a vaccine that was responsible for the lymphadenopathy. So I think it is a difficult situation to resolve in trials.

Dr. Figlin: *It is a wonderful conversation, because I think just from the four of us, it may be that the timing of scan imaging and vaccination is important and should become part of data collection during trials, so that we are at least removing the variables from our evaluation of cancer therapy. So Eric, let me turn to you. We have had patients on immunomodulatory steroids and antibodies when they are getting immunotherapy. So how are you navigating through the conversation with your fellows and your patients about the appropriate role for managing the immune-related adverse events associated with immunotherapy?*

Dr. Jonasch: Yes, I guess the big question is - are we changing how we are doing this for individuals in the COVID era? The answer is no. We are clearly using immunomodulatory agents like steroids, IL-6 antibodies, and TNF antibodies, which can have an impact on immunosuppression. But I think it becomes a competing risk argument, which is more important? - managing the severe side effects from immunotherapy, or dealing with the potential increased risk of infectivity while they are on those treatments. I think you have to manage the toxicities from immunotherapy. You can also manage the risk of exposure by making sure that individuals follow safe practices. Recently CDC has announced that people do not need to wear a mask anymore if they are vaccinated. So, there are relaxations of guidelines at a national level. But I think that for our patients, especially for our vulnerable patients, we should probably continue to urge caution and take a conservative approach to the risk of COVID-19 exposure.

Dr. Figlin: *Brad, I want to change the conversation a little bit for all of us to talk about the impact of telemedicine. Bob made an absolutely critical point that the relationship between the medical oncologist and their patient inside that patient care room is a very intimate setting and that is not exactly captured by the Zoom call we are doing today. So, Brad, my question is how have you incorporated telemedicine, and do you think that there will be increased telemedicine going forward as the pandemic winds down or is that just going to dissipate?*

Dr. McGregor: Good question. I think telemedicine is here to stay. There are certain aspects that patients just really enjoy. We have been able to function with telemedicine to an extent and telemedicine will likely incorporate into medicine going forward. It is important to realize that telemedicine is a nice adjunct to in-person care. I do not think it is a replacement for in-person care if you intersperse it between in-person visits. Occasionally, I use telemedicine for the patients who got scared to come into the clinic but when significant cancer care is required or to make important decisions, I would also ask them to visit the hospital in-person to make sure how the patients are actually doing and get a better sense. So it comes out to a fine line where we need to use telemedicine in conjunction with in-person visits. I think that goes the same for clinical trials as well. As we look at the future of clinical trial designs, we can look to incorporate telemedicine as an adjunct wherever possible but not to the extent that it can completely replace in-person

visits.

Dr. Figlin: *What would be your recommendation for our community doctors who always prefer to have doctor-patient interaction but now have a hard job to deliver long-term VEGF TKI therapy without ever seeing the patient.*

Dr. McGregor: From my standpoint, I see out-front. When I start VEGF TKI and check labs for a patient probably every couple of weeks for the first month or so I feel comfortable doing maybe a telemedicine visit at two weeks. But after a month, I like seeing the patient in-person to assess and bring a blood pressure log. It does not put more onus on the patient, because anyway, the patient has to be in the clinic for other data collection that we would otherwise do in-person. I would be happy to see virtually at two weeks, but then I want to have more of a sense of what's actually going on with direct in-person interaction with patients. So it is actually beneficial for patients to come in. In the end, it just comes down to individual discussion with some patients.

Dr. Figlin: *And Bob, what's been your experience in Manhattan with your large patient population?*

Dr. Motzer: I think telemedicine is really a great tool that we need to incorporate into patient care. What I found is telemedicine is particularly useful for our patients who are getting routine follow up with scans and bloodwork and maybe are cancer free or do not require systemic therapy. For these patients, talking via zoom seems reasonable. But, for people who have significant medical problems, or who are on systemic therapy, physicians really need to be seeing those patients. In addition to just providing medications, another important component that really requires seeing the patients, is that physicians provide a tremendous amount of emotional support. It is much more effective to provide that emotional support and contact in person than doing only on a telephone or on a video screen. In the end, it is individual's preference in terms of the physician and the needs of the patient. Certainly, some would say safety visits for patients on chronic TKIs could be done by zoom. On the other hand, if people have symptoms or pain, or are having a very difficult time with regard to family situations, those patients are better off visiting their doctors in person.

Dr. Figlin: *Eric, so many of our patients who come to see us also see other health care providers, social workers, our dieticians and get supportive care, etc. what's been your experience with telemedicine at your center in Houston?*

Dr. Jonasch: Yes, it is clear that there are some advantages and disadvantages to telemedicine that Bob and Brad have outlined here. The access to other specialties in a timely manner as you pointed out is a downside in telemedicine. Another downside is the lack of access to labs that are done locally so patients may not have the reports in hand when speaking with the physicians. Also, the comprehensive care to some degree gets diminished. However, I would actually venture to say that from a social context perspective, patients still cannot bring their loved ones into the hospital with them. Being able to have a conversation with the patient, their spouse, and their children on Zoom without the need for wearing masks in their home environment is great. There are some advantages as patients find that it is more of a conversation with a friend on Zoom than it is a conversation with a doctor. We could improvise telemedicine approaches, for example, incorporate wearables to get vitals on the patient. Apple Watch 4.0 will be able to provide that information to us prior to us actually seeing the patient or while we are seeing the patient. Incorporating these elements into telemedicine and intercalating them with the in-person visits is the future. And I sincerely hope that medical authorities around the country will see that as being an advantage.

Dr. Figlin: *Brad, I would like to get a sense from the three of you whether you have seen patients presenting with a bit more advanced disease, because of maybe not seeing the physician early enough due to COVID-19. And we all get many of our referrals from our surgical colleagues or urologists. What are your thoughts about that? I mean, we do not necessarily need to speak about prostate cancer, where that is happening as well, or bladder cancer, but is there a clinical substantive delay in care that we are starting to experience and worry about in the kinds of patients that you are seeing?*

Dr. McGregor: That is a great question. I think from a GU cancer standpoint, it is more challenging because if you look at something like kidney cancer, bladder cancer, there's no screening in place. So patients often present with symptoms of disease, or we find kidney cancer because they have appendicitis incidentally. I have not seen patients in my clinic who have had hematuria that they have ignored for three months because of the pandemic. Generally, they still see their primary care doctor and get forwarded to the urologist with that workup. So far, I have not seen such a delay in screening but I think time will tell us how this changes with GU cancer people getting less PSA screening or less follow up due to COVID-19 related issues.

Dr. Figlin: *Bob, I know at Cedars during the height of the pandemic, we were having hundreds and hundreds of patients in the hospital with COVID-19, we had a postponement of elective and non-elective surgeries. What's been the experience at MSK?*

Dr. Motzer: that is exactly the same situation we had at MSKCC where during the worst part of the pandemic, a lot of the operating rooms were actually turned into ICU rooms with respirators for COVID patients and a lot of the surgeries that were considered non-emergent were not undertaken or postponed. It was a very difficult situation for patients who had a kidney tumor waiting for their nephrectomy. That is another

aspect in terms of how the pandemic has affected us. I agree with Brad's point. Now, I have not actually noticed in person that patients with kidney cancer presenting to me with a delayed diagnosis because of COVID-19. It certainly seems like a reasonable trend, but I have not observed that with people with GU cancer yet.

Dr. Figlin: *Over the last 15 years, the advancements that we have made in kidney cancer have been a direct result of aggressively placing patients on trials, asking important pivotal questions, and moving therapeutics to the system in a way that is unprecedented in our disease that we all manage. How do you think as a leader in this area that the future clinical trial, whether it is IITs or industry-sponsored research or novel immunotherapy should be designed?*

Dr. Jonasch: Yes, we clearly need to improve. Especially, we need to take lessons from the COVID-19 pandemic in terms of how we can make clinical trials more efficient and how we design our next generation of clinical trials. I am the head of the kidney cancer research consortium of DOD grant-funded mechanism that allows us to try to use informatics solutions to create efficiencies in clinical trial design and execution. I think broadly speaking as a field, we need to embrace such efficient strategies. It is challenging for patients to undergo treatment on a clinical trial with logistical issues. It is a sacrifice that patients are making on behalf of future cancer patients and we have to make that sacrifice as minimal as possible. We may want to add other strategies such as virtual visits, remote monitoring in design so that clinical trials can get less expensive, safer, quicker, and more efficient. So overall, it is going to be a win-win situation.

Dr. Figlin: *So Brad, let me ask you, What are your thoughts if you were to design a 1000 patient international clinical trial tomorrow in kidney cancer, will you be stratifying patients based on COVID-19 infection to ensure the arms are balanced and we are really evaluating the effects of treatment, not the comorbidities that the patients are undergoing?*

Dr. McGregor: It would be very challenging to do that going forward. The challenge is that how to find out if patients had COVID-19 or not in a certain area? And, it is difficult to assess if the side effect comes from the vaccine or from the cancer therapy? These important questions remain to be answered. So, for the clinical trial design, I would include the evaluation of the vaccine efficacy in patients who are on systemic therapy for cancer immunotherapy or chemotherapy. Also, I would be looking to see the antibody titers and how well the vaccines affect side effects overall. Until we really know how to assess COVID-19 and how it affects patients, it becomes very difficult to design a trial stratified by COVID-19 infection criteria.

Dr. Figlin: *I think we all do not want to see the COVID epidemic postpone or delay what we accomplished these years in the kidney cancer space? How are you thinking about that when you are meeting with either your junior investigators or your faculty that are under your guidance? How would you want us to be thinking about that going forward?*

Dr. Motzer: From one point, it is important to minimize the impact of COVID-19. So I recommend that patients who are not only in the US but also outside the United States get the vaccination. As Eric mentioned, the other point is to ensure patients who are treated in the clinical trials get adequate protection including wearing a mask to protect themselves as best as possible. We certainly do not want to see the COVID pandemic truncate our progress in kidney cancer. And so I think along those lines, it is important to discuss the impact of COVID in forums like this so that people are aware of COVID-19 and its potential impact on clinical trials so that we can conduct clinical trials in the setting of the pandemic. Conducting safety evaluations with telemedicine minimizes patients coming into centers and getting exposed. That is been very effective in United States, it would be a wonderful thing if it could be implemented outside of the the United States. We really have not seen a detrimental effect of either the vaccination or the impact of COVID-19 on immunotherapy response. It certainly has been a distraction but I do not think it is a reason to stop clinical trials. Such efforts should help us focus to continue our efforts in clinical trials in RCC.

Dr. Figlin: *Eric, in the Department of Defense and in the funding of clinical trials, are there special questions that we should be asking in the context of the post-pandemic?*

Dr. Jonasch: I think the two key questions we want to answer first are does treatment with immunotherapy worsen side effects from immunotherapy? The second question is, does having COVID or a vaccination alter the ability to respond to treatment? We have an opportunity probably with some of the trials that were winding down as the pandemic occurred. We have to do some retrospective analyses to see whether or not we can tease some of these important questions out. Moving forward, it is going to be a question of what is going to be the issue with COVID. Are we actually going to have this controlled at a national level? Will we have it controlled at an international level?

Dr. Figlin: Brad, as the clinical director of the Lank Center, a very important center nationally for GU studies at the Farber how are you taking the macro view as an institution to contribute to this effort?

Dr. McGregor: I think when COVID first happened in March of 2020, everything came to a screeching halt for about a month. But then, we quickly sort of started coming back and started taking samples as we started adapting to the system and tried to incorporate

those things. And overall, I would say like our clinical operations standpoint, therapies now are very close to where they were pre COVID with telemedicine as an adjunct. Even throughout the pandemic, we have seen clinical trials have been successful in accruing rapidly, Therefore, well designed smart trials can continue to thrive in this setting.

Dr. Figlin: Well, gentlemen, it is been a pleasure hearing your thoughts. It is always nice to see friends and colleagues. And I think our community will welcome as Bob mentioned, conversations like this and can start to inform both how we think about it as well as how we should think about it going forward, especially in the context of not losing the momentum, to address this difficult disease during COVID-19 era, and still wanting to accomplish all the things that we can still accomplish in this setting.

CONCLUDING REMARKS

As we move into the next stage of the pandemic, the biggest challenge is to rapidly adapt to much needed reforms and effectively translate emerging evidence into best practices in delivering a high standard cancer care and treatment. In this discussion, experts reinforced that although the current emphasis is on the management of oncology services, the cancer community should work towards bringing a fresh momentum to quality of care and clinical research in the era of COVID-19 and beyond.

Contributions

The roundtable panelists (authors) were invited to participate in this discussion by the journal. All authors listed in the manuscript contributed significantly to KCJ roundtable. All authors have read and approved the final version. The final content and article is the sole work of the authors.

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ONLINE CONTENT

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