

# Bladder Cancer and COVID-19 | Southeast Regional Update for Patients and Families.

This program was recorded on April 9, 2020

## BCAN | Stephanie Chisolm:

Hello, and welcome to Bladder Cancer and COVID-19 regional updates for patients. My name is Stephanie Chisolm, and I am the Director of Education and Research at BCAN. We do appreciate you joining us for this program as we do these programs around the country.

## BCAN | Stephanie Chisolm:

I'd like to have a few slides just so you can follow along with me. I first would like to welcome our presenters. We have urologist, <u>Dr. Scott Gilbert</u> from the Moffitt Cancer Center in Tampa, Florida, medical oncologist, <u>Dr. Matthew Milowsky</u> from the Lineberger Cancer Center in Chapel Hill, North Carolina, and radiation oncologist, <u>Dr. Connie Mantz</u> from 21st Century Urology in Florida, and community urologist, <u>Dr. Neal Shore</u>, who is a member of the BCAN Board of Directors and is part of Carolina Urologic Research Center in Myrtle Beach, South Carolina. Thank you so much doctors.

## BCAN | Stephanie Chisolm:

We really appreciate your sharing your time and expertise with us tonight. I'm going to go ahead and start talking a little bit about the concept of medical distancing. We're all very, very aware of social distancing. The medical distancing is something that seems to be happening in more and more communities around the country. I think it's really important to try to understand what that means as far as people are getting turned away from regular treatment or having <a href="mailto:surveillance">surveillance</a>, and there's a direct impact on patients. Patients are very nervous.

# BCAN | Stephanie Chisolm:

They're being asked to sit with their bladder cancer. I'd like to ask you, and we're going to start with Dr. Gilbert, to just talk a little bit about the medical distancing protocols that you are seeing implemented, and how does that really impact patient care in your institution? Again, you're speaking about your institution, but I think we can apply this to the general region as well. Dr. Gilbert, can you start off with that?

#### Dr. Gilbert:

Sure. Well, thank you for having me. It's a pleasure to be part of the call today. At Moffitt, we are screening patients as they come through. That's scaled over the past two weeks, so it was a symptom screen, and now we're starting to take temperatures for all patients coming through our doors. All patients are encouraged to wear masks, and all faculty, staff and nurses, and clinic staff are now wearing masks per CDC and in governmental recommendations. In terms of how we have triage who needs to be at the center and who doesn't, we've really scaled up our e-visits or electronic visits for return patients, established patients who just need a touch point conversation about results or scans or plans for future care.

#### Dr. Gilbert:

On the <u>surveillance side for cystoscopies</u>, which is very relevant for patients with non-muscle invasive bladder cancer, we've gone through our schedules and try to keep the highest risk patients on schedule for their routine cystoscopy. So patients who were diagnosed within the last year who are <u>finishing BCG treatments</u> or <u>other intravesical treatments</u>, and need a post interventional therapy evaluation, those patients are coming back in for surveillance, and any patients who develop new symptoms, so new ones at hematuria or blood through urine, or urinary symptoms that may be a result of their intravesical treatments.

#### Dr. Gilbert:

Those patients are being evaluated in clinic if they have symptoms that warrant a visit. In terms of patients who can be delayed, we do have to make some delays. So we use the EAU and <u>AUA</u> categorization of non-muscle invasive bladder cancer in terms of low risk, intermediate risk and high risk cases. So for patients who have completed all of their BCG treatments or several years without recurrence and have either a controlled high grade tumor that was treated years ago or have low grade disease, we're not seeing those patients for surveillance cystoscopy right now. We're trying to reschedule them and push their surveillance scopes out about three or four months.

#### Dr. Gilbert:

That causes some concern among patients, but we have to prevent community spread, and that includes our clinic spaces. We think that these are generally the cases that we can delay or see further down on the line. That's what's happening in our clinic, huge emphasis on electronic visits. I can pause here and talk about the operating room experience later on if you'd like or we can continue on that line.

#### BCAN | Stephanie Chisolm:

Well, let's hear from the others first, and then we'll come back to that. Dr. Milowsky, what's happening at UNC in the medical oncology space?

## Dr. Milowsky:

I think very similar to what Dr. Gilbert described. I mean, we're doing similar screening protocols. We're not having visitors in the hospital. We are ensuring that all have masks based on <u>CDC guidelines</u>. With regard to the prioritization of different procedures, priority urgent and emergent procedures and surgical cases are proceeding. I'm not a surgeon. That's the "level D" of our five levels. So we are still operating on patients with bladder cancer. Our urology colleagues is involved in those guidelines. In fact, one of our urologists is really at the top level in terms of working with administration toward refining those guidelines over time.

## Dr. Milowsky:

I think it's really important to acknowledge that all places are different. A lot of the issues stem from resource allocation needs based on number of cases and case fatality rates, et cetera, and so we may not be fortunately where other places are right now, such as certain spots in the Northeast and places like Louisiana. So we have perhaps more time to see how these things evolve before implementing some

of the additional perhaps stricter policies that are going on in other places, where the healthcare systems are becoming overwhelmed.

## Dr. Milowsky:

That lead time, I think, is going to be really helpful to those of us who are able to watch those other places ramp up their resources and understand how we allocate those resources when our case volume goes up.

## BCAN | Stephanie Chisolm:

Sure. I just want to point out, remember that *this recording is as of April 9th*. Two weeks from now, you don't know. We really don't know where this is going to go in the whole southeast region as well.

#### Dr. Gilbert:

That's exactly right.

## BCAN | Stephanie Chisolm:

Dr. Mantz, are you making any changes in some of the protocols that you're using for radiation oncology to treat bladder cancer?

#### Dr. Mantz:

Well, so far as bladder cancer is concerned, we'll see patients and cases that for the most part really merit immediate treatment, meaning that unlike in urology, where there's going to be a caseload of non-invasive bladder tumors for which there may be some deferment of a short period of time before further intervention is undertaken that for us, we're seeing patients with invasive bladder cancer, and almost always treated concurrently with chemotherapy. These are cases for which there's an urgency to treat, and so we do. How we manage those cases in terms of screening is similar as we have already heard from the other participants on the webinar that every patient is screened before they enter into the clinic for symptoms that are suggestive of COVID and may direct those patients to be assessed and tested.

#### Dr. Mantz:

We also have protocols in place for what to do for those COVID positive patients or those patients who are persons under investigation for COVID, who have an urgency for treatment and simply just need to come in and continue and resume their care. What we'll do is, and this is a line by the way with recommendations made by the CDC and also by my professional society, <u>ASTRO</u>, to segregate those cases toward the end of the workday, have the office free of any non-clinical staff, so the front desk people, the financial counselors, et cetera. We don't have any face to face direct patient care, be out of the office at the end of the day.

#### Dr. Mantz:

Then we minimize the number of therapists that are present and clinicians in order to render the services. There are special precautions that we'll take in the treatment room and other areas where the

patients wait and then are transported into the linear accelerator room for their treatment. There are deep clean procedures and PPE procedures that we follow that are unique for those cases. So we do. During the course of this, as we treat COVID positive patients, we also want to make sure that our staff that interacts with these patients remain healthy and safe.

## Dr. Mantz:

So they are always monitored for symptoms. Even if they feel completely well without fever or respiratory symptoms, we will query them twice a day, at the start of the day and at the end of the day, if they've developed any symptoms, take their temperatures, and make sure that we shunt them over for assessment and testing if they manifest even a single symptom. That's how we've managed. As with everyone else, we're obligated to the CDC guidelines. As those change from week to week, we look forward to hopefully in the near future that time when some of these restrictions may be lifted.

## BCAN | Stephanie Chisolm:

Thank you. Thanks very much. Dr. Shore, you're out there in the community urology practices. What is your perspective on all this from South Carolina? If you talk to any of your colleagues in other community practices, what are you sensing? What are you seeing there?

#### Dr. Shore:

Thanks, Stephanie. Thanks, I really think, to the BCAN leadership for having this program tonight. I think it's very important for the patients with bladder cancer or family members with bladder cancer who are listening in. I would echo everything that doctors Gilbert, Milowsky, and Mantz have said. I've had the opportunities part of my work through the large urology group practice association, we've had several programs now talking to community practices throughout the U.S., and recognizing that as was said earlier, depending upon the infectivity rate and your part of the country, and how it's impacting the resources of your particular institution or practice.

#### Dr. Shore:

So I think there's a theme that we're hearing. I don't want to repeat all the really important and well described and articulated comments that have already been said. It's a three-prong approach now regardless of academic or community settings, and that is first and foremost protecting patients from COVID, and cancer patients in particular who may be immunosuppressed or compromised are considered by some and appropriately so more vulnerable. So we have to protect patients and their caregivers. We have to protect secondly the staff as Connie mentioned. We have to make sure that we're protecting the physician and the clinician and the administrative staffs that have to offer care.

## Dr. Shore:

The care is multifaceted. It's prioritized based upon risk, so some of our patients with bladder cancer who have low risk disease versus those with high risk disease and those who are already advanced to receiving therapy, we have to do a good job of prioritizing their visits and their ongoing treatments, whether it's approved treatments or clinical trials treatments. That's the two-pronged approach to maintaining optimization of care and for our teams. The third thing that really coming into

consideration, and it's not just for bladder cancer patients, it's for all care, is the economic stability of our models.

#### Dr. Shore:

Oftentimes, depending again upon the infectivity rate currently or what may be coming down with different waves of ascendancy of these infectivity rates, we have to be cognizant of our economic models. No doubt is impacting large tertiary centers as well as community centers.

## BCAN | Stephanie Chisolm:

I just asked if anybody had any additional comments before we switch over to the next question. Nope? Okay. Let's talk a little bit about when is it okay to have delays in treatments or surveillance? You've mentioned it a little bit, but I think this is a big concern for most of our participants. They really are worried if they are told that they can't get treatment at their facility. Maybe there's a risk that's happening in their community. Should they travel? What should they do? Should they go outside to find the treatment someplace else?

## BCAN | Stephanie Chisolm:

What do you suggest, and when is it all right to push things back? Is there a time that it's okay in medical oncology if you're on chemo or immunotherapy? Same thing with radiation, is there a way that you could skip some visits? What is okay and what is not? We'll talk a little bit more about what constitutes urgent need for getting into care next, but when is it alright to delay the treatment or surveillance? Dr. Gilbert, do you want to start?

## Dr. Gilbert:

Sure. I want to emphasize that we spent, and I think this is similar across the country, physicians have spent hours and hours poring through schedules and trying to prioritize patients who need to stay on schedule. Like at UNC, at Moffitt, we are proceeding with the highest risk and most urgent cases. The listening audience may have read in the news that most hospitals and medical centers have wound down elective surgery. We don't consider bladder cancer an elective condition. We don't consider the procedures that are required for its treatment to be elective, but there are cases where there can be a shift or a delay in instituting those therapies.

#### Dr. Gilbert:

For the muscle invasive bladder cancer population, we're continuing to see them in our clinics, and refer patients to <u>neoadjuvant chemotherapy</u> or <u>chemo radiation therapy</u> where appropriate for patients who are undergoing or scheduled for <u>bladder removal or cystectomy</u>. Those cases are continuing in our operating rooms, but our operating rooms are about 50% of their total capacity right now. We're running at a slower clip because there are other types of cases that have been delayed and shifted. So any high risk cancer cases, and this includes upper tract urothelial carcinoma where patients need to have their kidneys and ureters removed.

#### Dr. Gilbert:

Those are staying on schedule and being done. For the endoscopic cases, for patients being evaluated, if they have a higher risk of non-muscle invasive tumor, a tumor in the bladder that needs to be treated and removed, if there's uncertainty whether or not they have muscle invasive disease versus non-muscle invasive disease and they need a resection to determine that information, those are also proceeding with treatment. There are cases of patients who need a surveillance cystoscopy and surveillance bladder biopsies.

#### Dr. Gilbert:

Those procedures are being pushed back. We start with a one-month delay, and we hope that we're through this at the end of the next month, but if we're not, then we'll have to push those cases back further. The audience should be aware that there's research and data behind looking at delays and optimal time points for surgery in particular, and most of the studies come down to a three-month window of there being a safety space of three months from an initial treatment or diagnosis to definitive treatment, where you don't really see a decrease in outcomes or worse outcomes.

#### Dr. Gilbert:

We have a little bit of a time buffer. We hope that we're through this in three months, and everyone's back and on course, and all of the surgeons who are working are expecting a busy summer, expecting weekend surgeries, expecting late night after hour surgeries. All of this is trying to be coordinated on the back end on the administrative side. There's a lot of scheduling, rescheduling and thinking going through who gets a phone call and is informed that their procedure won't be happening within the next 30 to 45 days.

#### BCAN | Stephanie Chisolm:

I imagine it's going to be quite a nightmare when things do die down, and everybody's expecting to get their treatment right away. What about at UNC, Dr. Milowsky?

## Dr. Milowsky:

I think, again, echoing a lot of what Dr. Gilbert is experiencing in terms of where his healthcare system is at, I think sounds fairly similar to where we are at with UNC. I think there's a couple of important points. One is really what is the data? The other is what is the state of the state? Again, I go back to what's happening in places like New York versus what's happening in other states. Obviously, there's a significant difference, and the ability to do things in one place, are going to be quite different than the ability to do things in another place that has a much lower caseload.

#### Dr. Milowsky:

If you look at the actual data for cancer patients, it's limited. There's data that's come out of Wuhan, which is pretty extraordinary that they've been able to generate data so quickly, and there is a suggestion that there is likely a higher case fatality rate in cancer patients as compared to those patients without cancer. One of the other data points that has come out more recently from a small 28 patients study is that patients with COVID who are treated with anti-cancer therapy within 14 days have a more severe situation and poor outcomes.

#### Dr. Milowsky:

What we don't really know is much about the issue of withholding immunotherapy or chemotherapy in patients. There's actually really no good data telling us exactly what to do under those circumstances. So, what we are doing is based on current conditions, we are proceeding with neoadjuvant chemotherapy in patients with muscle invasive disease. We are using both chemotherapy and immunotherapy in patients with more advanced disease, and so from a medical oncology standpoint, we're conducting a lot of virtual visits. We have APPs and providers that are limited, but in the cancer hospital that are caring for our patients.

## Dr. Milowsky:

There may be opportunities to increase the intervals between treatments. For example, certain immunotherapy drugs have approvals in Europe to give less frequently as compared to the States, and so depending upon what the circumstances are, again, in your region, there are opportunities potentially to hold off on giving therapies. This may help under circumstances where resources are constrained and the healthcare system is overwhelmed. Again, there's really the data and the state of the individual place where one's practicing. We really don't have a lot of that data quite yet.

## BCAN | Stephanie Chisolm:

We're just now starting to see some early studies that are coming out from the situation that started in Seattle, but it's not really showing the impact of what these delays are all about. I understand that you guys are really relying heavily on some of the data that might be broader on previous studies that might have shown some benefit or no risk by delaying some of these treatments. We really are trying to figure this out as we go along. I think, from that patient perspective, that makes it very scary because they know these are the protocols.

# BCAN | Stephanie Chisolm:

These are the guidelines. This is what my doctor is supposed to be following, so it does stress them out a whole lot. Dr. Mantz, what's going on with the radiation? Are you changing? Is it okay to skip a dose? If somebody's not feeling well, or they just don't want to come in for that particular round of radiation, what's going on? What are you seeing in that field?

#### Dr. Mantz:

No. If we have a patient who is currently under investigation or has been diagnosed with COVID, and if in our physician's judgment and after some consideration of balance of risks between continuing treatment and perhaps compromising that patient's ability to recover from COVID, or withholding treatment if the consideration instead is that the respiratory illness is more serious and merits priority over cancer treatment, that if it's the latter that let's say the patient has gone through several weeks of chemo radiotherapy for treatment of his bladder cancer, and has had a drop in blood counts in excess of what you might typically see and is under investigation or is indeed COVID positive, and ultimately, then there's a mutual decision between the radiation oncologist and the chemotherapy physician to withhold treatment until the patient converts into COVID negative, and symptoms recover, and then you can have the patient come back.

#### Dr. Mantz:

For the most part, patients will recover if positive within a very relatively short timeframe of a couple of weeks. That's not beyond the bounds of what's recoverable in terms of chemo radiotherapy if we've started a course of treatment for a patient. What we have in radiation oncology is a set of tools by which we can calculate what the last dose was with a gap in treatment, and make up that last dose on the back end of the treatment schedule. Meaning that in principle, once we commit a patient to radiation therapy, we want to start and finish as expediently as possible, and not to miss treatments.

#### Dr. Mantz:

In principle, again, there's a risk of having cancer cells repopulate in between missed treatments for those days. There are formulas that we can use in order to calculate what's the dose of radiation needed to fill in that gap. Then we apply that additional dose at the very end of the treatment course. We have that maneuver. It's one that's based, for the most part, on theory, but there is some science to support that for certain diseases that delays in treatment of a week or longer do compromise the chance of achieving local cure of the cancer in the bladder.

#### Dr. Mantz:

As I said, we'll apply these methods of calculation to make up for lost time. No, but again, and I think to echo what the other panelists have stated, this is really a case by case determination whether we're looking through our schedules and trying to determine who can be telehealth and who really should be coming in. We do the same for our patients on treatment may be symptomatic or at some risk for COVID, and make unique decisions on a per case basis about who should really continue and who should stop, and always in concert with our medical oncology colleagues.

## BCAN | Stephanie Chisolm:

Great. Thank you.

## Dr. Milowsky:

Stephanie, I would just make the point on the heels of what Dr. Mantz is saying that I do think that with the data and what we know about our oncology drugs, in patients who are COVID positive, there's a very, very strong rationale to discontinue anti-cancer therapy. I think that that's a really important point to make. There is again data that suggests that that is, in fact, what should be done. Again, a small study, but I think that we all feel as though that's probably something that's certainly ought to be done.

## BCAN | Stephanie Chisolm:

Thank you, thanks for sharing that. That's important information for people to have. Dr. Shore, what are your thoughts on when is it okay to delay for treatment and or for surveillance? When do you feel comfortable in general?

#### Dr. Shore:

I think the overarching theme that the audience should be hearing is that there are patients who clearly need treatment sooner rather than later. That would be our patients who have muscle invasive disease, our patients who have already chosen a treatment paradigm and certainly our patients with advanced or metastatic bladder cancer upper tract urothelial cancer. There is the concept or the possibility if that family has had a recent exposure, and it's not clear if they have COVID-19 or not, that even the potential to wait a couple of weeks through quarantining or if they're fortunate enough to be able to get testing, that's not an unreasonable possibility to delay at that point.

#### Dr. Shore:

We certainly don't want to delay of any kind of significant patients who have very aggressive advanced disease or who are pending surgical radiation or systemic therapies. Now, that's very different from patients who may have a low grade or intermediate grade papillary disease. They've had a resection. Maybe they've already had some intravesical BCG and or possibly had intravesical chemotherapy. I think that's a very different journey on the bladder cancer spectrum, and so those patients were basically saying, "Okay, is it not unreasonable at all to wait to come back in for intravesical therapies?"

#### Dr. Shore:

I think most of us would agree that it is reasonable to wait because we don't want to overburden, overtax the clinic system, whether it's in the community or at tertiary centers. We want to be respectful of our infectivity rates. We want to be respectful of the personal protective equipment that we have available to safeguard both patients, their families, and the healthcare staff. There is these two ends of the spectrum, and so I think the message that you're hearing or the audience should be hearing is that we are very aware of prioritizing these risk return ratios.

#### Dr. Shore:

With each week that passes from the time this became very front and center by CDC recommendations and what everybody's now glued to on the television and the updates in your state, your city and nationally, it's a very fluid process. I think the good news is we're starting to see some more optimistic estimations in the modeling, but we still have to be very aware, as was said at the beginning of the program, that there are hotbeds, and the communities that have hotbeds are really under tremendous, more stress, and so that's where the prioritization is appropriate.

## Dr. Shore:

I hope that the folks who are listening tonight don't get overly anxious. I understand that they could be, if they're sensing any delays. A few weeks in delay or even a couple of months of delay for someone with low grade bladder cancer to have a cystoscopy is probably very appropriate as opposed to a couple of months delay in someone receiving systemic therapy or interventional surgeries or radiation for more aggressive disease. That's the one-on-one discussion that a patient who has bladder or upper track urothelial cancer has with his providers.

## BCAN | Stephanie Chisolm:

Great. Thank you guys so much. This is great. As far as looking at these urgent needs for people to get into care, what would you say quantifies an urgent need for somebody to reach out to their provider? They may be thinking, "No, I don't want to go to my provider because I'm afraid of catching COVID or giving them COVID or whatever." What should be in people's mind as they might experience a side effect or adverse event or symptom? What are some of the key things you think, "Hey, we need to know about this, and we need to figure out how to get you in for care."

## BCAN | Stephanie Chisolm:

Dr. Gilbert, what do you think are urgent need that patients should be paying attention to?

## Dr. Gilbert:

For folks who are on the active treatment course of intravesical therapy, any change in symptoms that's out of proportion to what they were counseled were routine symptoms associated with treatments or what they'd experienced before with a routine infusion or installation would be a reason to at least have a conversation with the provider team, probably starting with a nurse phone call. As I alluded to earlier, most medical centers have scaled up and stood up telehealth visit capabilities amazingly quickly, and we're doing 50% of our visits in our clinic through telehealth visits.

## Dr. Gilbert:

You can always add people on to have a video conference about their symptoms, and provide symptom management remotely. For urgent conditions that require immediate medical attention, you call the doctor's line and they instruct you if you're having a medical emergency, call 911. You have to use your good judgment, and you may need to go to urgent care center or an emergency room. That may be a blocked catheter or inability to empty the bladder because of bleeding or blood clots, high fevers associated with the recent treatment, things of that sort.

## Dr. Gilbert:

There has to be some common sense that even though there's a risk to coming to an emergency room where there may be symptomatic and asymptomatic COVID patients, if you have symptoms or conditions that require medical management, you're going to need to come to the facility and get that attention.

## BCAN | Stephanie Chisolm:

Dr. Milowsky, are there key medical situations, these adverse events that people can get side effects from their treatments with chemo or immunotherapies maybe that really need to come to the attention of their providers?

## Dr. Milowsky:

I think, patients really ought to understand. I mean, we're here for them. I think Dr. Gilbert had mentioned this and others. We have really been scouring our schedules and ensuring that those patients who need to be seen are seeing those patients who need telephone or video virtual encounters have

those encounters done. I've actually been incredibly impressed with our ability to communicate with patients by both telephone and video encounters. I think we're going to learn a tremendous amount from this experience, and some of that will be good just in terms of the way that we interact with our patients and the access that our patients actually have to us through the electronic medical record, MyChart, et cetera.

## Dr. Milowsky:

I think, so for us, patients who are on chemotherapy or immunotherapy who have issues that's related to fever on chemotherapy that would otherwise need to be seen, those patients still need to be seen. Patients with immunotherapy who have the possibility of immune related side effects, significant diarrhea, or other symptoms or signs, those patients still need to be seen. Not all patients need to go to the emergency room. A lot of hospitals will have infusion centers where patients can be evaluated, particularly in medical oncology such that they don't have to go to the emergency room.

#### Dr. Milowsky:

There are providers in those infusion centers who are able to manage those patients. In the event that they need to be admitted, those patients are admitted. There will, of course, be patients always who need to go to the emergency room, but again, patients should contact your providers. That may be a nurse triage that will get a provider to make a determination about what the best course of action is, but we're here, and we're taking care of our patients in the way that we've always taken care of our patients in terms of their ability to contact us, but we're doing a lot of that virtually.

BCAN | Stephanie Chisolm:

Thanks. Dr. Mantz?

## Dr. Mantz:

I mean, I would agree with the same. I think just to carry a point forward, this telehealth experience has been new to many of us in medicine. The technology has been available for a number of years. For various reasons, physicians, practices and hospital systems really have not taken full advantage of it until needing to do so in a crisis like this. In the present, if either I have a sense that a patient is suffering a complication or a new problem that merits face to face visit for assessment, or if the patient has a concern that just can't be articulated well, and if there's any doubt open, I'd rather see that patient face to face.

#### Dr. Mantz:

Then our clinic and staff would follow all necessary precautions to limit the risk of exposure. I think looking forward and after this crisis finally abates, my bet is that medicine is going to take much fuller advantage of telehealth services in order to be able to glean the seriousness of the patient's complaint much more sharply and to better triage that patient, instead of, I think, what happens today. Either there's an over commitment to having every patient come in, whether there's truly a need or not for an immediate assessment of a complaint, or I think in some cases, if, as a result, clinics are overloaded, some patients that really could be coming in to have a complaint address do not.

#### Dr. Mantz:

I think, an electronic means of being able to very efficiently gain an insight to a patient, and hear them out and see them instead of just hear them by telephone gives us additional insight as to what might be really going on and will make us, I think, much smarter than we are today, and being able to triage patients accordingly. I'm encouraged by that. To me at least, it's an unintended positive consequence of this unfortunate event is that we'll be able to leverage electronic platforms like this much more effectively than we have historically.

## BCAN | Stephanie Chisolm:

Dr. Shore, any other thoughts?

#### Dr. Shore:

Yeah. I think one thing that we're going to start to see more of, the unique thing about bladder cancer patients or upper track cancer patients, is we always like to interrogate and evaluate urine, looking for red blood cells in the urine and urine biomarkers. There are several of the different commercial tests, and the companies are doing some very forward thinking and innovative approaches upon physician and clinician recommendations to send the tests to the actual patient homes. Again, it obviates the need for the patient to come to the clinic, avoids the risk of exposure and contamination to COVID potentially, but yet, the container will be sent to the home.

#### Dr. Shore:

The patients can urinate into the container, and then it can be sent for additional testing. The whole notion around urine biomarker testing and even urine culture testing for infection, this will be, I think, some of the silver lining that we'll see in addition to this incredible efficiency regarding telehealth and telemedicine. I do think that'll be another opportunity for optimization and efficiency of care.

## BCAN | Stephanie Chisolm:

I think you guys have done a really great job presenting all this information. You actually have answered a lot of these other questions. What do we think we're going to speak going forward? We're looking at this idea of having your urine shipped off to have it an analyzed without having to go into your doctor, and this concept of telehealth. Anything else you feel is important that patients should know before we open it up to questions from the audience?

## Dr. Milowsky:

I would just make the point, Stephanie, that the medical community is really working hard collaboratively together. I mean, I can tell you as an example that there's a medical oncologist working at a large academic medical center that is now pulling a lot of resources to potentially care for COVID patients, our community physicians that have really just been tremendous in supporting us and our patients, and being able to care for those patients really in an outstanding way in the community. So, we are really all trying to work together to provide the best care to our patients with bladder cancer.

#### Dr. Milowsky:

It's really a collaboration among many. In at least where I am, the community's been absolutely fantastic.

## BCAN | Stephanie Chisolm:

There's a question from one of our participants who has low grade non-muscle invasive disease. Their doctor, I think they're going in for a scope coming up in the next couple of weeks. The doctor said they can either come into the large medical facility for that cystoscopy or perhaps go to a different medical facility. Then they also have the choice of waiting. How does the patient make that choice if the doctor puts it on them to say, "Well, you could come in or you could go someplace else. See if you can get in, or you can just wait two months?" How do you advise them? Anybody can weigh in on that?

#### Dr. Gilbert:

A little bit has to do with the context of when their initial tumor was removed. I would want to have a cystoscopy appointment for someone who had a recent tumor removed within three or four months after their initial scraping of the tumor for their first surveillance cystoscopy. In the setting of low grade disease that falls into a lower risk category than, for example, someone who has multi, several high grade tumors that are invasive into the layer underneath the urothelium, and needs BCG. That initial surveillance cystoscopy might be pushed out a month or for six weeks or so until we're past this epidemic.

#### Dr. Gilbert:

If they're further out, then the European data and guidelines actually recommend a fairly spaced surveillance schedule, where fairly quickly, you can move people to annual cystoscopies once they've had a few initial negative cystoscopies their first year after tumor removal as long as their bladder is clear and there are no recurrences. It's contextual, and it depends on where you are in that spectrum of surveillance. I've been telling my patients who are disease free, as I said earlier, and they've had clear bladders for more than a year, many of them for more than two years, that their surveillance schedule for cystoscopy within the next one or two months is not the priority.

## Dr. Gilbert:

The priority is to reduce community spread and stay healthy, and keep our resources available at the hospitals in case a surge comes in Tampa or in other parts of Florida for where I practice.

## BCAN | Stephanie Chisolm:

Great. For patients who've had a diversion, and they might have another issue, perhaps a urinary tract infection, their symptoms are not critical enough to go to the hospital but they need to get in for care, is this something that you see telehealth helping them with? How do you prove that it's a urinary tract infection or not something more serious? What would you do for those kinds of patients? What's your recommendation?

#### Dr. Gilbert:

Well, we get calls frequently about urinary tract infections. The initial assessment is typically done with a nurse phone call, unless it's so severe that the symptoms warrant the patient going to the doctor's office or urgent care center. I think with telehealth, it's a prime opportunity to do that exchange, that visit remotely via conference and make a plan. As Dr. Shore mentioned, maybe sending a urinary tract culture kit to the home and processing it that way to get that information back. For minor symptoms and things that could be managed in an ambulatory setting, a lot of that can be managed over the phone or through telehealth channels, I think, effectively.

## BCAN | Stephanie Chisolm:

I've gotten some questions that are specific to different institutions. I think that your recommendation always is going to be to call into your facility and see if people are being seen in different institutions like Vanderbilt or some of the others or someplace in Atlanta. They should be checking to see what's going on locally by speaking directly with their physician's office. Correct? It's so hard to say we're doing a thing about the South East region. I know that each of your institutions are so unique as to what your experience is.It's hard to say we're speaking on behalf of everybody in the southeast region.

#### Dr. Gilbert:

We can't. We can't speak for people who live in other areas of the southeast region or who receive care at other facilities, because the number of cases and the region's response to the epidemic is so variable. At Moffitt and in Tampa Bay, we have a relatively low case volume, so we're trying to keep it as close to business as usual as possible, but it's also hard to predict when case counts will start rising. So we didn't talk a lot about that. It's been in the news a lot, but the social distancing measures are to prevent surges and growth in cases.

#### Dr. Gilbert:

If you have too many people coming through clinic and too many people in close contact, that's where you can have asymptomatic spread, and get into more of a problem area.

## Dr. Milowsky:

I would just add, Stephanie, that the risk benefit analysis that everyone is making within healthcare systems and providers is also at the level of the individual. It could be a patient with bladder cancer, but if one is in a hotspot, as Dr. Shore mentioned, and they also have coexisting medical problems that potentially could lead to a more serious COVID infection, then that really needs to be taken into consideration in making a decision about whether or not the risk benefit profile weighs in favor of seeing that patient at that time, or if it would be better to have a delay.

## Dr. Milowsky:

This is in a lot of ways a moving target, but that risk benefit analysis is important to understand is also at the individual level too. We think about that a lot as providers.

## BCAN | Stephanie Chisolm:

I imagine it's really stressful to have to make some of these decisions. I'm getting a note from one of our participants saying that they have high grade non-muscle invasive disease carcinoma in situ. They've had TURPs a couple of times in the fall. They finished BCG in February, and they were supposed to be going back in for cystoscopy with any potential for <u>TURBT</u> that might be needed, but now it's been postponed indefinitely, possibly June or July. I know if they can't get in to see their doctor, then there's nothing else that they can do, but they want to know how long would be too long to wait?

#### Dr. Gilbert:

We don't have great data around how long it's too long to wait in that situation. We do know that BCG continues to work after you've stopped getting it. So there's this latency period where your immune system is still stimulated, and they're still effect. We know that giving maintenance therapy at three and six month intervals increases the efficacy and decreases the recurrence rate. So there's a booster effect of the immune system receiving the BCG and the bladder, but I'll remind everyone that the science behind BCG is not perfect. The six weeks, for example, we don't know whether four weeks is right or six weeks is right.

#### Dr. Gilbert:

Six was chosen because the vials came in six vials. The packages came in six vials, so we chose six vials. Similarly with the surveillance cystoscopy schedules for three and four months for a few years, and then spacing out to six months, there's never been any well conducted randomized control trial, looking at high intensity surveillance versus low intensity surveillance, spacing those visits out. These are guidelines that are not necessarily evidence based, and so it's really hard to answer those questions, because we just don't have that data.

# BCAN | Stephanie Chisolm:

I expected we're going to have a lot more data when this is all over with as we begin to do an analysis of this situation. For cystoscopy, already, we've covered this, but CT scans, MRIs, those other additional follow up scans that people are being told that they needed to have, and now they're being told they can't get in there. Is there a concern about any of those and delaying some of those other scans?

## Dr. Shore:

I'll answer the question in terms of as Scott was saying, I completely agree. A lot of the protocol dogma for high risk, NMIBC, BCG unresponsive patients, and even our MUC or muscle invasive bladder cancer patients or our metastatic cancer patients is based upon an interval or of scanning or scoping that we've said, on average, it's a three-month interval. If you were to do it at two months or four months, it really can be predicated upon a particular risk benefit analysis for patients. That said, patients, I think, need to be aware that certain hospital systems depending upon their infectivity burden and their scaling down on personnel, have really limited resources to take care of the totality of their trauma patients, their COVID patients, and all the other cancer patients.

#### Dr. Shore:

I would try to reassure patients that waiting a couple of weeks to even a month to get an imaging is probably perfectly fine, especially if you have high risk or advanced disease. I think once you start pushing out past a couple of months, that could certainly become a cause for significant concern. Now, I'm talking about in just diagnostics and in imaging. In terms of treatment and therapeutics and or surgery, that's a little bit different. I only make the comment so that the listening audience says, "Okay, I understand." You should be not thinking that they're being marginalized in terms of the quality of their care.

## BCAN | Stephanie Chisolm:

I just wanted to remind people that BCAN does have a Frequently Asked Questions page. We are keeping that updated as we begin to know more and more, so I do encourage everybody to visit our website <a href="www.bcan.org/covid-19-faq">www.bcan.org/covid-19-faq</a> to find out more as we get more evidence. I know there have been a number of questions coming into our office, and I'm sure you're getting them as well. People are hearing about the potential for a BCG vaccine possibly being used to protect healthcare workers.

## BCAN | Stephanie Chisolm:

They're thinking, "Well, if I'm getting BCG, am I also protected?" I tried to explain that what they get from BCG for bladder cancer, it is more of an intravesical in their bladder treatment. Can any of you maybe just talk a little bit about that, about what we know about this BCG potential vaccine, just so we can cover that because I know there were a couple of questions that came in today? If we're not in the position to answer that, we can always push it back. Again, I will let people know more as we get more information.

#### Dr. Gilbert:

I think that there's a news feed that went out about the BCG immunizations potentially conferring immune benefit for other conditions other than tuberculosis. This has been actually researched by investigators in terms of diabetes, for example. There are some studies starting in Europe, I believe, where they want to look at patients who've been immunized for tuberculosis with BCG versus those who haven't and their risk for COVID. There may be a non-target benefit or carryover from the BCG immunizations, but to your point, for bladder cancer, we don't do immunizations internally.

#### Dr. Gilbert:

Sometimes, we do in the setting of a clinical trial, but the 99%, the lion's share is intravesical therapy, and so we don't know whether that carryover non-target effect if it does exist, would be the same mechanism compared to immunization patients. As you mentioned earlier, we're going to learn a lot. It's going to take a year or two to collect and filter through all the data, but there's definitely interest in the clinical trial space to examine that question and see if, in fact, that's an effective therapy for COVID.

## BCAN | Stephanie Chisolm:

Great. Thank you so much. Anything else any of you want to add and share with our community?

#### Dr. Shore:

Just one word about the BCG vaccine, a lot of folks have heard about the worries in the BCG shortage. If we were to use and enroll and initiate some of these BCG vaccines as a protective study to especially help people who are at risk as an immunoadjuvant, the use of one vial of BCG would potentially inoculate upwards of 50 patients in a study. So even though we're all aware of the BCG shortage and BCAN has been championing ways to get good information out there, we're aware of the importance of the optics around using a vial for vaccine purposes and study.

#### Dr. Shore:

There have been anecdotal suggestions and other folks as the use of the intradermal vaccine. It might actually be beneficial in preventing other forms of viral infection. That's why it's being looked at. I want to reassure the audience that we're aware and it is important to not think that this will compromise an already compromised BCG shortage within the country.

## BCAN | Stephanie Chisolm:

Yes. We have spoken to the folks at Merck, and they have confirmed their commitment to make sure that they are continuing their rapid production as much as they possibly can, and distribution specifically for bladder cancer use because they know it's so critical. This is all really good information. Any other last thoughts before I end the program? No? I'd like to thank everybody for joining our program on bladder cancer and COVID 19, the southeast regional update. I really hope that everyone will follow up and complete the survey that we'll be doing.

## BCAN | Stephanie Chisolm:

I'd like to thank Dr. Gilbert, Dr. Milowsky, Dr. Mantz, and Dr. Shore for giving up their time to come in and help share their knowledge and experience about what's going on locally so that our patients are feeling secure and have the right questions to ask their providers. Thank you again.

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