

Speakers:

Jayshree Shah, APN-C, RN, MSN, BSN, BS

Tracey Iraca

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Jayshree Shah: So, I think we have about a half an hour or so, 45 minutes probably, to kind of go over stuff in regards to MDS, anything related to your questions regarding MDS, caregivers advocacy, medication, symptoms, whatever you guys want to talk about. This is your forum, your floor. How was lunch?

Q1: Good.

Jayshree Shah: Don't fall asleep on me. I hope everybody ate a cookie or a brownie.

Do you guys have a need (inaudible 0:48) questions about anything related to what we discussed today or your thinking, you're digesting besides the lunch?

Q2: I just have one question about there's going to be something up about the thing that's going to be on the 24th at... in New Haven. Is that something that we would go to as well or is that something is mostly professional people?

Jayshree Shah: No. It's actually for you guys as well. I will be there myself along with another physician from New Haven, Connecticut and MDS Foundation is doing another patient forum similar to today and you will hear that doctor's perspective of MDS, what they have at their facility, clinical trials, what's available, how do they treat their patients with MDS and how they go about it and, again, I will be there doing the nurse's perspective and you'll be listening to my lecture again and, again, having the floor basically open to patients and caregivers to talk about MDS and what's happening to them and how they're living with MDS. Everybody's welcome. We have some patients that like to go to one to the other. Sometimes we hold forums in Long Island. So, New York City then patients come over there and vice versa. So, it varies depending on availability, how much you want to travel and the doctors sometimes. Patients love seeing and hearing different physicians' perspective on how they take care of patients with MDS. So, it's nice to hear different physicians share their knowledge in and about MDS. Yes, sir?

Q3: I don't remember if it was said or not, but what does Fox Chase Cancer Center have that other hospitals don't have for MDS?

Jayshree Shah: For MDS. So, I know Hackensack does not have the clinical trials that she just talked about. We don't have that. We have different trials for MDS and you would have to come to Hackensack for a consultation to learn about the different trials that we have and I think that's the beauty of you guys living in the East Coast. We were talking about that at lunch that East Coast is so awesome in that way because there's so many different cancer centers, academic cancer centers, that are keen on learning about MDS and doing research and it can go from literally from Massachusetts

all the way down to Maryland with John Hopkins area. So, you have a big span of different areas that focuses on MDS which is nice and you can shop around. Yes.

Q4: Then you probably should shop around if you want to move. I want to go overseas.

Jayshree Shah: To overseas to live or to vacation.

Q4: No, to vacation, but actually it's to Habitat for Humanity.

Jayshree Shah: Well, that's the beauty of MDS Foundation. We can link you to a Centers of Excellence meaning like this place, Fox Chase, that is specialized in knowing how to take care of MDS patients. So if and when you are ready to go travel overseas, beforehand reach out to MDS Foundation and they will provide you with the nearest Centers of Excellence, so your information, your healthcare information, you will have and your doctor will communicate with the doctor at the Centers of Excellence overseas and you can be shared.

Q4: Wow.

Jayshree Shah: That's the purpose. That's why you're here today. I'm so happy you came.

Q4: Thank you.

Jayshree Shah: Yes?

Q5: Maybe I missed it, but are the presentations available somewhere? Your presentation and the doctor's?

Jayshree Shah: They are. Tracey, the presentations that were done today, they're online or they're transcribed.

Deborah Murray: I can send them by E-mail.

Jayshree Shah: Okay. Deborah can send them by E-mail just make sure you share your E-mail with her.

Q6: If you were... I've been going to treatment when you had (inaudible 5:22) every month to get your inoculations or whatever and you wanted to go to a different state... Say you were going to go to Florida for the winter, could you... Can you get it done like two or three... It hasn't happened yet...

Jayshree Shah: Snowbird.

Q6: I was going to say no wives and that's even better that's going to go somewhere you got to go somewhere, but you were going to be gone for several months but you are undergoing these things

and you wouldn't have to go back to, say, here or Hackensack or whatever. Could it be possible to get your treatments...?

Jayshree Shah: Of course

Q6: ... with the doctor...

Jayshree Shah: Communicating. You need to set up, obviously, a treatment plan from your doctor here. Pretend this is your facility that you're getting treated with the facility in Hawaii. Pick a place in Maui that is open for business for cancer center specifically. If not cancer center, maybe a doctor that focuses on patients with MDS or iron deficiency anemia or something of that sort of in the blood disorders to communicate and they will have to reach out to each other and say I am accepting you as a patient for three months and I will keep you posted along the way. You as a patient will also make sure that you keep records, so when you go back your doctor here at Fox Chase has all this information what happened to you in three months.

Q6: Okay. Thank you.

Jayshree Shah: I always tell patients keep records of stuff. That's why you have the book with you today. Make copies if you need to so you can keep a record, so you can communicate. You can communicate to help us as healthcare providers there's papers always going back and forth, but you can be the intermediate party in helping to bridge it. Sometimes there's missing papers. So, we always need help. Yes.

Q7: We've talked about medical treatments and standards such as Vidaza and others and we've talked about clinical trials and all of us wish that there was a pill out there on the table that we could take and go home and it was all over with, but that's not the case. Has anyone ever looked at anything or written anything on how to go about looking at the notion of a clinical trial or the standard procedure and looked at the outcomes for people that got involved in clinical versus the ones that may have stayed on the standard drugs or is there anything out there to help someone think through with some clarity other than wishfulness about the clinical trials?

Jayshree Shah: Sure. So clinical trials, the purpose of it is, believe it or not, is to compare a standard therapy with a new compound - versus a new compound. So, the purpose is to find out if that new compound will over shine, be beneficial, for the purpose of finding out whether it's working or not for the patient. So, it does compare to the standard therapy. Now, if you're asking me just in general about explaining something about a clinical trial, there's different phases of different clinical trials.

Q7: I was really kind of curious about people who are betting on clinical trials. What's their track record?

Jayshree Shah: So, clinical...

Q7: It sounds great, but what are your odds if you're on a clinical trial that you'll receive a benefit as compared to (inaudible 9:12) that... for the standard therapies and is it a good game to get into?

Jayshree Shah: It's a patient decision, but I think it's important to be informed decision.

Q7: And that's the heart of my question. How do I do that?

Jayshree Shah: And I think for you as a patient you will need to know if I choose not to do the clinical trial, what are my options for standard. Do I only have one option for standard, two, three, how many options do I have remaining? That's number one avenue that you want to review. Sometimes with clinical trials there's criteria that you have to meet. Sometimes you have to do one standard therapy to fail at to be eligible for a clinical trial. Sometimes they may say I want a brand new MDS patient with no exposure to any chemicals, no treatments, no nothing as part of the clinical trial. So every clinical trial has criteria to meet. Sometimes you meet them, sometimes you don't. What I tell patients is standard therapy will always be there. It's not going anywhere. So if you decide not to do the clinical trial, standard therapy will always be there as an option available. The clinical trial is there as a means to get medications to see if they work and get them approved at a safe level, obviously. Without doing clinical trials on patients... for patients who have MDS on Vidaza, we wouldn't have gotten Vidaza approved. We wouldn't have gotten Dacogen approved. So, patients like yourself who think about wanting to do clinical trials, it's something for you to be very informed. Ask the questions and how do you do that? You go through the logistics of what the drug is, what are the side effects, what phase of clinical trial it is. Is it in the beginning phase with phase one where the drug is literally found to be effective on cancer cells, but they haven't tested it on humans. Phase two, do you want to see maybe 20 patients and find out what dose adjustment do we need to do for those 20 patients first. Then the next 20 patients with the higher dose, the next 20 patients with the little bit of a higher dose. Which dose is appropriate for that type of cancer and the dosing for it? Phase three is basically an entire room full of audience here filled with MDS patients and they're on a clinical trial. So, it's a larger population to find out symptoms and management, toxicity, all of those things come into play for phase three. So, that's why it's important to know trial that you want to consider enrolling. Being informed is huge. Phase four is pretty much a done deal. The trial is working. It's effective and we now are ready to put on a market and we're just waiting for FDA to say check. Yes?

Q8: This reminds me about SIG-110. Is it peculiar to Fox Chase? Do they have a patent on it or is it...

Jayshree Shah: Oh, I don't know.

Q8: ... is it in phase three or four?

Jayshree Shah: I don't know. It sounds like from what I heard today that I think they were doing phase two, but they're expanding their experiments or clinical trials to fitting different populations of patients with different levels of MDS as well as AML. So, they're doing different things. I can't

comment too much because I don't know. What you may want to do is, again, go onto that website that she mentioned and I would also mention to you is clinicaltrials.gov.

Q9: .gov?

Jayshree Shah: .gov, G-O-V because it's a federally run website.

Q10: National Institute?

Jayshree Shah: Yeah. Regular... just all the clinical trials have to be inputted into that system. Yeah?

Q11: I... There's a clinical trial that I was told about. It's two of them. One of them starts with an A and D together for a series of five days and then so many days off or a month off and then you do it again. It's a complete cycle. The other one is a double blind study which I had a feeling one of them would be that and I'm definitely not interested, you know, with the placebo and...

Jayshree Shah: Sure.

Q11: So, what do you think about that? What do you say about these double blind studies and how... what kind of information has been retrieved from that?

Jayshree Shah: There are many different types, again, of clinical trials. I think what you need to find out from the physician is what is their end product that they're looking for. What is their primary end product? What are they looking...? Are they looking for people to survive? Are they looking for a response? Are they looking for...? What are they looking for actually? And I think it's a personal choice. Nobody pressures patients to enroll in a clinical trial. It's a voluntary decision. At any point you decide to enroll and say five days later you're saying to yourself, "You know what? I don't feel comfortable. I want to not do this anymore," you tell your doctor you don't want to do this anymore and you want standard treatment. Fine.

Q11: What if you say that. Are you able to do another blind study? I mean...

Jayshree Shah: Of course.

Q11: I mean a clinical trial.

Jayshree Shah: Of course you are as long as you're eligible, you meet the criteria and it's applicable for your type of disease. Yes? Yes, miss?

Q12: I just wanted to clarify because I am actually in clinical research and a double blind study just means that it's blinded to both you and the physician. It doesn't mean there's a placebo control arm of it. So in oncology, very rarely see any kind of medication being compared to a placebo which means just like a sugar pill. So, it's usually standard of care versus what new medication they're

looking at and the questions you need to ask when you go into a clinical trial will be what kind of follow up am I receiving? How are they monitoring, how effective my treatment is being and you can always make a choice and always consult with your doctor to determine whether or not you should continue on the clinical trial or if you want to stop and you want to do a different therapy. So before you say no to a clinical trial, sit down and really talk to the nurse, talk to the doctor, find out what kind of standard of care you'll be getting in that trial and for those people who don't have insurance, it may be a great option because they are more conservative in your follow up, in your care, so you will get the same type of care that you're getting now. So, just keep your mind open, make sure you're asking the right questions, but no worries. An oncology study will not have a placebo arm. It's not... you're going to get some form of treatment and, again, you have to make a decision based on data. You can talk about the data based on what phase the study is. You can ask your physician, hey, is this the phase three study? They should have a lot of data on dosing, toxicities already because they're going to file for approval. So, you can ask those very... those questions and make an educated decision on how to move forward.

Q11: Is there a website that I can get these questions?

Q12: You can go to patient advocacy groups. You can go to the NCI, the National Cancer Institute. I'm sure they'll have information. If you Google thoughts about clinical trials, something should come up with questions that you might want to ask your physician and they'll give you a consent form. So, you have to read through the consent form. A lot of it is over your head, it's over my head and I develop them, but just sit down and just go through all the consents and in some of this stuff the side effects will scare you just like some of the medications that you get you'll see...

Q11: It's 73 pages one trial.

Q12: Yeah. It's ridiculous, unfortunately, but that's the way it is.

Jayshree Shah: Yeah, but that's, again, you have to understand when you're doing a clinical trial you want them to be at that detailed because you don't want just a one page clinical trial and be like, oh yeah, I just need your signature here and not go through all the things that possibly could happen and it's so important to make sure that we inform you of the things that could possibly happen and it's scary. It's scary. It's not easy. Tracey, quick question. With the research component, do we include that in the binder with adding on? Maybe we could and having patients understand about clinical trials?

Tracey Iraca: I'm actually not sure if it's in there or not, but definitely questions like you were saying.

Jayshree Shah: I think it would be a great idea to add it in or consider it maybe in the future for people to know that that... because we're always sending referring patients for clinical trials here and there because when you guys call and say, "Is there a trial available?"

Tracey Icara: Exactly. Actually, Audrey Hassan, our patient liaison, when she screens people just even by first contact she already is thinking of a trial that may be beneficial to you and she'll always... she's perfectly willing to talk for as long as it takes to talk through those trials. You'll find in our newsletter and in our handouts there are some flyers for different clinical trials. That doesn't mean they're the only ones that exist. They're just the ones that we're highlighting at this moment. So, there's multiple trials and Audrey can help you navigate clinicaltrials.gov and answer those questions.

Jayshree Shah: Good point. So yeah. We can work on something adding it into our binder on top of all the other stuff that we noted in understanding about MDS.

Q13: Are clinical trials routinely limited to only high risk people?

Jayshree Shah: No, not at all. It depends on the design, the way the physicians and the companies they want to design the trial. So, it could be specifically designed for, for example, patients who have MDS, deletion 5 and they're doing standard therapy with... or comparing two different compounds, the compound that they're studying and the standard therapy. So again, it's a specific type of need. So, trials are... it depends on the physician and what they're trying to achieve. They want to see whether this compound is going to have a response to deletion 5... 5Q like Dr. Raza. Yeah.

Q14: I don't know if you can answer this, but my doctor has mentioned Vidaza. I take Neupogen and Aranesp now. I get a shot of each once a week. Is there an advantage from the Vidaza to the two drugs that I get now?

Jayshree Shah: So, it depends on where you are for you with your disease and what level of disease that you have in your system meaning if and when... So, Neupogen what this gentleman is receiving is growth factors. He's receiving growth factors is to stimulate that garden that I talked about to tell the seed let's get churning, keep moving and it includes two different entities to help them specifically the white blood cells and the red blood cells for him. Again, it's an individualized treatment plan to the type of MDS that he has and it's at a level where the doctor thinks that using growth factors to stimulate that garden, the bone marrow, will help and revive the garden, the bone marrow. So, it's a special kind of like different fertilizer, not the weed killer, fertilizer like different... you know, what you use in the garden, different manures, little of the soil, calcium, all the different things. So in your aspect and your treatment plan, it's Neupogen growth factor, white blood cell stimulation and Aranesp the red blood cell. Vidaza is usually reserved for a next step if and when your fertilizers stop working.

Q14: My hemoglobin's gone down. I mean, it used to hover around 9.6. Now, it's down to 8.8. It's been that way for about a month now. So, that would be my next progression would be the Vidaza. Right?

Jayshree Shah: Correct.

Q14: Okay. I got you.

Jayshree Shah: So it all depends on what level of disease you have and that's why I tell patients know what type you have, how much you have, where you're at in the category. Is it a low, low risk? Is it a low risk? Intermediate 1, 2, high or higher risk, closer to AML? That's important so you understand where you are at in your treatment plan.

Q14: Well, I'm low risk. That makes sense.

Jayshree Shah: Yes.

Q14: Okay. You answered it. Thank you.

Jayshree Shah: No problem. So, who's going on vacation? I heard one vacationer going to... Where did she say she was going? (Attendee), where'd you go?

Q15: The Caribbean.

Jayshree Shah: Caribbean, East Caribbean. Yes. So, I'm excited for her. Hope you don't have any hurricane. Where are you going?

Q16: We're going to go hopefully in December we're going to go to Washington State.

Jayshree Shah: Washington State.

Q16: Seattle, Tacoma.

Jayshree Shah: In December.

Q16: Yeah. It's a nice time.

Jayshree Shah: That's cold.

Q16: No, it's not.

Jayshree Shah: Are you going to Vancouver? Are you going to take a trip to Vancouver?

Q16: It's (Attendee)'s son lives there with his wife and grandchildren.

Jayshree Shah: Oh, that must be nice.

Q17: My son lives there, but it's really the four grandchildren.

Jayshree Shah: Forget about the son. It's about the grandkids. I hear you. That must be nice. I went to Seattle in May and I hit, no lie, it was that one weekend I went there. It was a cheese festival. It

was the best. I got cheese farmers coming from north of... in Washington all the way down to California and they all came there at Pike Market to like sample and showcase their cheeses and they got barrels and barrels. On top of it, they had wine. You can't go and get better than that. It was the best weekend.

Q17: That's mild. I was stationed at Fort Lewis which is now Lewis-McChord and it was always mild temperate there.

Jayshree Shah: Nice. I love Seattle. A special place in my heart.

Q17: I like Mount Rainier. Mount Rainier is the best.

Jayshree Shah: I haven't been there. Next time. Any other vacations? We're just looking forward to the holidays. Right? Halloween, Thanksgiving, they all come roll around.

Well thank you, guys, again for coming and sharing and I hope to see you again if not here maybe somewhere else and only wish you guys a wealth of happiness and health and keep me posted if you guys need anything and you have MDS Foundation, both Tracey and Deb to reach out and Audrey to reach out to for any resources, questions that you may have. Thank you for having me come over. I appreciate it.

(Applause)