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Speakers:

Azra Raza, MD

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

Dr. Goldberg

**Tracey:** Hopefully you enjoyed your lunch. We're going to keep on moving now. This is Jayshree. I introduced her in the beginning, but she'll get started with our next presentation.

**Jayshree Shah:** Thanks, Tracey. Thank you all for coming out on I would say a chilly October, definitely October fall weather on a Saturday to spend this afternoon with us. Dr. Raza had a wonderful, wonderful presentation about MDS. My part of this presentation is simple and concise in regards to, again, modifying it in a simple manner that you as patients and caregivers can understand. We also have Dr. Goldberg in the back for reference in case I have forgotten a little bit of MDS from being a little bit out of touch. So, I'm a nurse practitioner at Hackensack. My role as a nurse practitioner is to take care of all different types of cancer patients and I've had the privilege of working with Dr. Goldberg for eight plus years in the setting of all different types of leukemias and that just does not have to be AML or ALL, but it was CML, MDS, anything with an abnormal blood value or an abnormal CBC that you guys know of as complete blood count we took care of. So, I've had the pleasure of working with him for many years and just recently a few years back shifted gears again in working in GI, gastro intestinal cancers, and lung cancer including immunotherapy and phase one clinical trials. So, I'm very privileged and honored to be here today to speak to you about MDS as far as *Building Blocks of Hope* which is what today's afternoon is about with patient and caregiver forum. So, this is your opportunity to ask questions and share. So, I'm going to leave pretty much most of my presentation to you, meaning the floor to share your knowledge, your questions and ideas because we learn not just through me doing a nice presentation which you're so patient and wanting to listen to what I have to say, but I actually want to learn and hear what you have to say and share with others. My presentation is quite short though just to let you know.

So, this is a list of all the different Nurse Leadership Board which does not just include Jersey. It includes around the world of all different nurses, nurse leadership boards, which is great because we're including nurses from different countries - Europe, Asian countries, to share their knowledge in what's happening in their vicinity and their practice so that we can learn from them. So, it's about sharing which is what today's goal is.

So, when to start treatment. Treatment triggers. We talked about when do we do treatments for MDS patients? It can vary. Some patients don't need treatment. Some patients do. Are some patients more transfusion dependent? Some patients are not. What risk are they? Are they low risk? Intermediate? High risk and Dr. Raza expanded on the whole topic about when is it time to treat? Is in the progression and the prognosis of MDS itself.



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Individualized treatment selection is a key. Patients who are here today, you, representing as having MDS represents that all of you probably all of you have different type of MDS and all of you share one commonality which is, again, cytopenias, but the subgroups is different which is makes it so individualized and the treatment plan for each of you is individualized.

So, key principles in therapy of MDS. Again, the only cure is an allogeneic bone marrow transplant. Yet, age alone should not exclude active therapies. All active therapies for MDS require time to work. It can vary from four to six months until the therapy start kicking in. So, patience is definitely a virtue when you have MDS. Having a good team to work with you to share with you about being patient, reviewing the lab results, going over what to expect from the beginning is really important.

Blood counts often get worse before they get better. As you know with different therapies, as you're basically taking care of the blasts in the bone marrow to clean it up if you want to call it and when you do clean it up it takes a while to clear up and make room for new stem cells for it to proliferate and create the regular blood cells and mature into regular cells that is supposed to function. Proactive management of side effects in early phases of treatment are key to obtaining the best response.

So, this is a nice slide because it explains why time is required. It's a slow process. Blood counts drop as MDS progresses and normal blood cells are crowded out by an abnormal stem cells in the bone marrow and blood which is this part right here and then as the treatment cleans the marrow, blood counts may drop further. Patients may experience hematologic toxicities such as low blood counts requiring possible blood transfusions to support you whether it be blood or platelets or both.

And the bone marrow begins to recover allowing it to make healthy blood cells. Again, you're cleaning out the bone marrow to make room for new healthy cells to grow into maturation. Patients can be weaned off from supportive care to robust response sets in and it takes a while and, again, it can vary from four to six months, sometimes a little bit longer depending on the type of therapy and different clinical trials that some of you are being part of.

Early toxicities may be difficult or discouraging for the patient because I think the expectations early on may be different from what's being told. Oh, yes, you'll have a response immediately. Well, it takes a while especially in MDS because it's liquid tumor. It's bone marrow involvement. It's not like in the lung cancer world which is what I work in where you give chemotherapy you see the result within three cycles which is anywhere from a month and a half to two months you'll see a radialatric (sp? 7:21) difference. This is different. Bone marrow takes a while when you're cleaning it up and when you're giving those therapies.

So, key principles of therapy for MDS. Time is definitely required and it for the best response anywhere from four to six months. Cytopenias often get worse as I talked and explained. There



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are strategies for getting through the initial cycles of therapy whether it be dose modifications, supportive care and definitely setting expectations early on to letting you know that it's a slow process and it's going to take time.

So, this is a nice slide because it's, I believe, this is Sandy's patient. Trilineage response following four cycles of Azacitidine which is Vidaza. Vidaza is a hypomethylating agent that's given to patients for treatment of MDS and... let me see if it has this over here. So, if you look over here the hemoglobin, again, referral evaluation and diagnosis and observation. This is the hemoglobin and as the patient is diagnosed with MDS going down to the hemoglobin of eight and then once you start giving the Vidaza, cycle one back in 2010, the hemoglobin slowly creeps up to in the cycle between one and two, but then it also bottoms out requiring possible low level of anywhere from 7.5 it looks like and then it goes back up and then it starts to start to work and do what it's supposed to do and the same thing in regards to the platelets. When it bottoms down and then the response starts kicking in in the bone marrow to clean up all the bad cells and the same thing with the white blood cells as well.

So, patient response over 10 years of Lenalidomide treatment which is Revlimid. Another of Sandy's patients. Sandy is a nurse practitioner in Arizona who actually developed the *Building Blocks of Hope* in conjunction with other nurses. Sustained moderate but asymptomatic cytopenias. This is a nice chart for people that enjoy looking at charts about response and monitoring. So, you're going over with the hemoglobin of nine and then when you start therapy a span of 10 years. Look how sustained the hemoglobin is and as maintained of patients who have a specific mutations. Sustained hemoglobin while you're on therapy and maintained. Again, patients who have a specific mutation we can use a target therapy specifically for deletion 5 patients with MDS this therapy is more appropriate and maintained. So, that's where we're shooting for with any type of cancer nowadays. We're looking for targeted therapies and new novel agents to try for specific mutations that MDS patients have.

So, what can I do to stay healthy and these are some things that have been shared by patients recommendations what to do and you guys probably concur having a great balanced diet. I have patients here today that tell me, "Jayshree, my wife monitors everything I eat," and I hear that quite frequently or vice versa and telling me that she wants to make sure that I eat a balanced diet to maintain proper nutrition, proper support whether it be vitamins, minerals which is important. So, what can you do? Having a balanced diet would be a definite start. Daily activities and exercise. I think that also goes hand in hand with the balanced diet. Keep active. Whether you need a nap here or there that's okay to do and modify, but staying active is very important and not to stay in bed. Have projects to work with. Have expectations to know you can start a project but know that you can finish it in four months versus two months. Avoid infection. Again, it's the flu season. All those things come into mind. Make sure you get your flu vaccines, pneumonia vaccine whatever you need to maintain, prevent infection. Avoid bleeding. If you have a low platelet count of in the 50s, less than 50s potentially or something like that make sure you're not working with a hacksaw. Hacking away the wood for the winter. Have somebody else do that.



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Continue to enjoy things you love. Live. It's all about you and how you want to modify your life to the disease now that you have and how to maintain, exercise, stay active. Get enough rest and that's also important in the package. We heal. As humans we heal when we sleep. So, it's so important to get proper rest. Take advantage of the available resources. That's why you're here today. Want to learn from each other and also the MDS Foundation is here as a great resource and support to intertwine with possibly starting a patient support group as a start. Ask for help when needed. Be an active participating in building hope because as humans, I think that's the first key find is having hope and maintaining it and sustaining it.

That's it for my presentation. I'm going to keep it really short. I'm leaving the floor now to you guys. So, anybody want to share any Halloween stories coming up? I'm going to shut that off, so you have a blank screen to look at. Anybody want to share anything regarding their story or what's happening what they're doing something different to maintain a balanced diet, activity. How do you live today with MDS? No brave soul? Alright! Go ahead.

**Q1:** I'm a gym rat.

**Jayshree Shah:** You're a gym rat. Okay. Do share. What kind of exercises do you do?

**Q1:** I do cardiac rehab.

**Jayshree Shah:** Cardiac rehab. Okay.

**Q1:** (inaudible 14:07)

**Jayshree Shah:** On the treadmill and elliptical?

**Q1:** Yeah. (Inaudible 14:10) but I want to ask you a question. Have there been any research or any (inaudible) is a... could be... I'm trying to think of the word, but can do...

**Jayshree Shah:** DNA damage in itself when you... Okay. So, the question is does hair coloring cause an effect in development of DNA damage potentially those stem cells that Dr. Raza spoke about that one abnormal stem cell that creates a whole slew of something else that we don't want. I don't know of any research associated with that. To me as a human and my patient, I always tell them if it makes you feel good go for it, but there are different kinds of rinses, different hair colors, different things that your hairdresser potentially can do to kind of lower the chemical effect. If that makes you feel better I would say go for it.

Yes?

**Q2:** (inaudible 15:18)



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**Jayshree Shah:** Sure. So, CART therapy is a new novel way of collecting cells. Dr. Goldberg, do you want to help me with this because ALL they use ALL, I believe, or that area.

**Dr. Goldberg:** So, there's a whole field of what's called immunotherapy that is being developed and the idea is that (inaudible 15:49) system as Dr. Raza had mentioned, the immune... we make all these mistakes all the time. Our body is generating bad cells and our immune system specifically something called the T cell which is one of the white cells, part of your immune system. The T cells will recognize things that are broken or... and will actually clear them out. So, that's the T cells their job is to be sort of like the spies. They'll look for things, look for enemies. So, if you get an infection it's the T cell that actually says this is a bad thing, but then the rest of the immune system goes in and does the work. Well, they're trying to see if they can stimulate those T cells to fight cancers. So in a CAR T cell, the T is... what they do is they actually take out the white cells from a person and in the laboratory infect those cells and juice up essentially the T cells to be specific against that person's cancer and then now putting in those reprogrammed T cells they will go back into the person and maybe in the beginning they, obviously, didn't recognize it because the person got the cancer, but now that we've juiced up those T cells and made them angry when you put them back in hopefully now they will see the bad thing and go after it. Most of the CAR T cell rash therapy has been actually done in ALL, acute lymphocytic leukemia, where it actually has been extremely dramatic when patients have failed multiple chemotherapies even bone marrow transplants we see the CAR T cells can actually get a lot of those patients back into remissions and the remissions may last forever because the immune system now has been reprogrammed. They're actually now starting to look at other diseases and AML and myeloid diseases like myelodysplasia are on the pathway of things that they're going to be looking at although there's a little more tricky to get the white cells, these lymphocytes to fight the white cells, the myeloid cells than it is for ALL. So, we've... it's not an easy therapy though. It's sort of like going through a mini bone marrow transplant because when those T cells go back in they (inaudible 17:53) be angry and they can not only attack the cancer, but they can actually attack the whole body, but it is certainly on something that's actually being developed. There are programs actually here both in New Jersey (inaudible 18:07) Institute of Health actually has a big program. Michigan has a big program. So, there's a lot of programs. This is something that is the wave of the future maybe five – 10 years away from being prime time, but probably in the next couple of years you'll hear a lot more about it.

**Jayshree Shah:** Thank you. I knew he would have the answer.

Yes?

**Q3:** Besides (inaudible 18:31) therapy, (inaudible)

**Jayshree Shah:** Sure. It's known that if you have had 20 plus blood transfusions in a certain amount of timeframe that make sure that your doctor's 1) are checking your ferritin level. Let's

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begin with that. It's a blood test. It's not a bone marrow. It's a blood test called ferritin and that's indicative of identifying what level of iron building up is in your system and when you have that number that number is going to be a key factor because 1) it can be a little bit skewed. So, don't get discouraged if you get a number of greater than 1,000 and it's just over 1,000 it could be an inflammatory process that it could be skewed. So, (inaudible 19:27) you have it as a baseline, but to follow it through, but if that number is greater than 1,000, I think that 1) is to have that discussion with your oncologist to identify if it's present, the iron ferritin level of greater than 1,000. The normal is, I believe, less than 200 or... yeah. So, what I would like to do is definitely 1) have that conversation with your oncologist about what level it is, how often you are having the blood transfusions. The types of treatment for iron chelations are we have a few different options: 1) is you can do subcutaneous injections, IV therapy of IV iron chelation. That's an option. We also have pill form of two different types of pill form that you can use to iron chelate and that conversation really should be done with your oncologist and it's important to have that versus saying I want this therapy and then you have different side effect profiles or side effects from it. Making sure the therapy that's chosen for you you review the side effect profile and it's a commitment. It's a commitment for possibly a lifetime because if you're committee to receiving transfusion that's our ongoing process it's a commitment to monitor that ferritin level as a lifetime process and potentially to be on an iron chelation therapy for a lifetime and what are the side effects for iron chelation or iron buildup? Different things. It can be anything from head to toe I say and I start off with the pituitary gland, start off with also the heart buildup, the iron buildup on the heart what can effect and develop potentially different cardiac problems like CHF. This is not to scare you the information I'm sharing with you. This is to provide you that when you give something to your system which is a closed system which is your body and you're injecting blood transfusion which is an outside force, you're increasing the hemoglobin because you're feeling fatigued and you're symptom managing. So, you're inducing something into your closed system. The levels of your ferritin level may potentially build up as a marker. It's a marker to let you know that the iron has built up and it doesn't know where to go. Extra iron comes about each unit of blood transfusion is about 200 milligrams of extra iron that's floating in your body and you're like where does it land? It lands in your different organs and it stays there and it causes cellular damage at a very slow process, slow process over time. Not talking about immediate oh, God. The iron has landed in my system and now it's doing major damage. It just takes time and that's why we monitor the ferritin level. So, that's important having that conversation, talking about the different options, making sure you're monitoring the side effect profile, monitoring the lab values also which effect from taking those therapies whether it be pill form or IV form depending on the oncologists that they choose to as far as option-wise and I think Dr. Goldberg is going to be speaking on different iron overload after today's presentation. So, feel free to join him and ask him more specific questions if you like. What would be appropriate potentially for yourself or whoever else that has a development of iron overload because it is a side effect from getting multiple transfusions over time?

Yes?

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**Q4:** (inaudible 23:24)

**Jayshree Shah:** Anything you can do about fatigue. So, 1) identify what MDS you have, what subtype you have. That's important. The other things I tell patients with fatigue is have you had a thyroid checked? Vitamin B12 check, folate, vitamin D3. There's certain lab testing as a clinician that you can do to kind of dig a little bit more. We're like little private investigators. That's what I call myself because I need to dig a little bit more to find out what could be going on besides your MDS. So, if your hemoglobin is 10 and you're feeling extremely fatigued, could it be something else. So, identifying that something else is looking into trying to figure out digging a little bit more. Are you potentially nutritionally deficient in vitamin B6? I don't know, but would it help if you went to a nutritionist. What does your diet entail? Are you getting enough protein or are you just eating simple carbs? Something as simple as that could be an answer. So, having a thorough history of what you're doing on a day to day basis keeping a diary potentially that may be of help and I think that's discussed also in like *Buildings of Hope* and talking about what you do on a daily basis to prevent fatigue. Staying active, I think, it's number one. Gym rat definite. I think gym is a great thing because you want to maintain strength, muscle and cardio all together if it's possible. If you can get a prescription from your physician for a physical therapist go for it. I tell my patients all the time if you can't do something and you need a prescription, ask for it. Maybe your insurance company will cover it. There's all kinds of different programs and stuff that you can probably find in your community to be part of or even an academic center that they're offering that you can be part of and learn about and how to get involved with. Does that help?

Anybody else want to share their story of their MDS and what they're doing? Are you guys all doing standard treatment, Vidaza, Dacogen? Is anybody in a clinical trial? Yes?

**Q5:** (inaudible 25:57)

**Jayshree Shah:** You've been on several clinical trials with Dr. Raza. Okay. That's very nice. Are you all currently on a clinical trial?

**Q5:** (inaudible 26:09)

**Jayshree Shah:** Very nice. Can you speak into the mic if you don't mind?

**Q6:** Yes, I'm on a new clinical trial called Tipifarnib. I've been on the Rigosertib that she mentioned was very effective. The only problem with that with my body was that it developed cystitis in the bladder which was difficult to live with. So, the quality of life wasn't there. So, we decided to stop taking it, but it was very effective in keeping the hemoglobin high enough that I didn't need transfusions.

(inaudible 26:49)



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**Q6:** About four months apart which was great.

**Jayshree Shah:** How often were you receiving transfusions prior to being part of the trial?

**Q6:** Probably every three to four weeks.

**Jayshree Shah:** Wow.

**Q6:** Yeah. So, I cut it in half which was a small miracle, but the body just couldn't handle it. So, the quality of life wasn't there.

**Jayshree Shah:** Well, I'm sure she'll probably enroll you into a different trial now.

**Q6:** I'm going to right now... right now it's kind of positive, hasn't really helped the hemoglobin too much, but I'm looking forward. I've only been on it for two cycles and starting the third cycle this coming Wednesday.

**Jayshree Shah:** I hope it kicks in.

**Q6:** I hope so.

**Jayshree Shah:** Good. Very good.

**Q6:** As far as the ferritin level, I had my ferritin level checked every month and that'll vary for some reason. It'll go 1,200 and then it'll go up to 1,900 the next month and I'm on a chelation drug called Jadenu. I had my partner who reminds me of things. That has brought it down at one occasion to around 600.

**Jayshree Shah:** Very good.

**Q6:** Which is good.

**Jayshree Shah:** Yeah. That's really good.

**Q6:** So, a little sharing.

**Jayshree Shah:** Thank you. Thank you for sharing.

Yes, sir?



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**Q7:** This is sort of a not exactly a home remedy because it was suggested to me five years ago by Dr. Raza, but every day I juice. I have a Revel juicer and I juice with (inaudible 28:34) celery, kale, beets, apple or pear or pineapple (inaudible) important ginger root and fresh turmeric root.

**Q8:** It's all organic.

**Q7:** And this is all organic vegetables and I do that every day (inaudible 28:55) probably about 10 to 12 ounces.

**Jayshree Shah:** On a daily basis.

**Q7:** Every day. Yeah.

**Jayshree Shah:** How many people juice here? I got one, two, three, three people. That's great. So, again, that's another modality that you as patients and caregivers can choose in relation to adding the nutritional component of fresh vitamins coming from the fruits and vegetables to help you maintain and, again, it's all about personal individualized therapy. Think about it. For him that's what works for him and makes him feel good. What works for you? What works for you?

**Q9:** (inaudible 29:41)

**Jayshree Shah:** Yeah. Share.

**Q9:** I do yoga.

**Jayshree Shah:** You do yoga. Okay.

**Q9:** Seventy-four years old and I'm still doing yoga. So, that keeps me flexible and happy and I really watch my diet. I do a food log every day. I try not to exceed 1,200 calories because when you get older your body slows down, your metabolism slows down. So, it's a real balancing act to get the things I need and I supplement that with a lot of vitamins, just digress a little bit. I come from a family where three generations all had breast cancer – grandmother, mother and children. I'm the only female in my family that didn't get breast cancer, but I got MDS. So, go figure. We'll find out about that later in this thing we're in, but I do a lot of research. I love to read the research papers and I was so happy to hear Dr. Raza because for a couple of years now I've wanted to know the cutting edge therapies and what kind of clinical trials were going on, a lot of things, and it was almost like I felt like she personalized that for me.

**Jayshree Shah:** Very nice.

**Q9:** And so I found out if you keep busy, if you stay happy. This is my caretaker. We laugh and do a lot of fun things together and try to really look at things on the positive side. You get

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through it and it's fun. Life is good. I read a little thing that said happiness is now and I really agree with that.

**Jayshree Shah:** Happiness is what?

**Q9:** Now.

**Jayshree Shah:** Now. There you go. Happiness is now. We keep moving. I was speaking with (Attendee) earlier. He's a patient and he was sharing his story with me prior to lunch and it was an awesome story because he came... wanted to be a pharmacist and spent three years going into schooling for that and then decided to switch gears into through his... going for schooling for pharmacy and then went into totally different area of administrative, healthcare administrative, and he spent this career working at Monte, Montefiore Hospital, for what? Twenty-five years plus? Thirty?

**Q10:** It was several hospitals. Monte was nine years and then there was LIJ in New York Eye and Ear Infirmary which was the first and that's how I met my wife. So, I never really left the first hospital.

**Jayshree Shah:** Yeah. Sharing his story and he was telling me it's been an awesome ride, an awesome journey. It's devastating for the diagnosis component, but to learn and be part of something innovative and he's part of a clinical trial at Monte and I didn't know, I myself, didn't know that Monte had clinical trials specifically dedicated for MDS patients which is great. It's not just about Columbia, it's not about just Hackensack. It's about different places and it's just about finding out who has what applicable for your individualized MDS.

**Q10:** Truly I'm seeing Dr. Verme, Hameed Verme. He happens to be a professor of MDS. He's in the forefront and through the trial down and it's ACE-536 which is being developed here in New Jersey and it's under the management of Dr. Frederick Herman over in Munich, Germany who actually has an institute and he's known to be the best of the best in all of Europe. It was actually educated at Yale University and whatnot and went to school with Dr. Verme. It's been quite a journey. Actually, it's been quite joyful probably because I've been in healthcare, so I know what to expect. I studied pharmacy for a number of years before I went into finance and all and it's just been a fantastic journey. It's kind of ironic people hear cancer and they feel sorry for you, but it's been wonderful, but in addition to taking the drugs I'm also on vitamin A and D and C and E and (inaudible 33:49) Q10 and I have this regiment that I take in addition because it's all part of the immune system and we learned many years ago that it's basically a breakdown in immune system. Everybody wants to know why it's me. Chances are it's our everything both aging as well as chemistry as well all the toxins that's in the air and everything that we do today and eat and whatnot. So, we're basically (inaudible 34:14) immune system and one way, of course, is staying happy and staying joyful and staying positive and that's not an easy task for many people, but you can really look at your life and this is the journey I've taken is you look at



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your life from the beginning to today and just look at all the plusses that have happened along the way and, of course, we've all had the negatives as well and you'll see this... at least for me anyways, I saw this perfect picture that came together. I wouldn't have even had a contact with Montefiore if a particular doctor didn't hire me and he was going to take me into one of his health centers and he said, "You know, (Attendee)? You don't fit into this, but I'm the chairman of this new company called the Bronx Health Plan under Montefiore and we're going to start an HMO for it for the Medicaid recipients and the uninsured." He said, "I think you'd work better there," and if it wasn't for him I would have never been at Monte today and what was interesting is a few years ago I looked him up to see how he was doing and it turned out that he actually passed away on my birthday which talk about a rollback. It was quite good. So, I just suggest that everybody just take a look at your life and what has worked out in your life and look at the blessings whether it's your children, your grandchildren and all of that and put it all into perspective and it really helps on a daily basis. You'll never have a bad... for me anyways I never have a bad day which is good.

**Jayshree Shah:** Great attitude. Great attitude. Think positive. It's really important.

Yes?

**Q11:** In your own words can you explain what Dr. Raza (inaudible 35:53) the ICUS standard (inaudible 35:58)?

**Jayshree Shah:** Sure. To me that is actually a stratification of the IPSS. In my mind it's more of identifying is there an abnormal CBC you're working with and then how is that abnormal CBC progressing into potential leukemia. Is it and it's a process from grade one, two, three or four. You can put it in a simple form as grade one being not really significant. It's something abnormal. Something is there, not sure what it is. Number two grade is there is one part that's abnormal. Grade three is two parts are abnormal and grade four is three parts are abnormal and we need to fix it before it turns into leukemia. That's how I simply graded it. It's just those terms that she used is her way of identifying the abnormal CBC or abnormal cytopenias.

**Q11:** So, IPSS (inaudible 37:05)

**Jayshree Shah:** In my mind that's how I break it up. What do you think, Dr. Goldberg? What are your thoughts?

**Dr. Goldberg:** I think of it... I mean, from a formal standpoint in other words in order to get a diagnosis of MDS, of myelodysplasia put that legally on your chart and bill insurance carriers for that and to stamp it. The pathologist has to under the microscope see the abnormality, see dysplasia, see change (inaudible 37:35) it requires that the bone marrow look abnormal, but many patients who are sent to us they have... the doctor, the family doctor will see that the blood counts aren't normal and certainly blood counts are lower and (inaudible 37:52) when we do the

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bone marrow we don't see that change and the question is is that the early, early, early beginnings of MDS or is it the early beginnings of something else and what Dr. Raza showed you about half the time it is the early, early, early beginnings of MDS and over time the bone marrow will start to look uglier and then the pathologist can make that diagnosis and sometime that's an early, early change of something else. So, when we don't know what it is that's the idiopathic cytopenias of uncertain significant and that uncertain is because we don't really know what it's going to be and that's ICUS, I-C-U-S. So, that's the first step because just the blood counts look bad, but the bone marrow doesn't look bad and we don't know what that's really going to turn into MDS or not. A little bit farther down the road then you start to see CHIP. Where now they can say well, there really is something wrong with the bone marrow. We can see by a genetic test or by something else (inaudible 38:53) there is a carbon copy. One mother cell is giving up to daughters and that's not a normal cell, but we still don't have the ugly looking bone marrow yet. So, we still can't call it MDS. So, it's a little bit farther down the road, but it doesn't yet meet that diagnosis and that would be the CHIP. Then you get into now all of a sudden...

**Q11:** (inaudible 39:16)

**Dr. Goldberg:** Low risk.

**Jayshree Shah:** Low risk.

**Dr. Goldberg:** Low risk. Low risk. So then you've gone from a blood count that's a little bit bad, but the bone marrow doesn't look so bad. So, maybe it's MDS, maybe it's not to CHIP where the bone marrow doesn't look bad, but now we have some real feelings that this is going to be something because we have a gene or something else that (inaudible 39:40) MDS itself where the pathologist can actually now see it and everybody agrees it's MDS. We can see the abnormalities, but it's not affecting the bone marrow that bad. Your blood counts aren't that bad. Your chromosomes aren't that bad. That's low risk and then if the bone marrow continues to disintegrate which it doesn't always have to do. Sometimes it can just stay at low risk, but if now all of a sudden the bone marrow completely deteriorates it moves into the higher risk MDS and then in about 20 percent of time it can move all the way to leukemia, but 80 percent of the time it doesn't go through the whole thing. It may just stop at ICUS and people... I have had patients who (inaudible 40:21) abnormal blood counts and keep bone marrowing them every couple of years and I never see in it and that's (inaudible 40:27) and I have had people who've moved from beginning all the way to the end in a rapid succession and that's part of the uniqueness of each patient.

**Q11:** (inaudible 40:39)

**Dr. Goldberg:** (inaudible 40:50) so there are some... once the pathologist looks under the microscope and sees it being abnormal then we ask the pathologist to tell us what do you see

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that's abnormal? So, we're call it MDS because you see some abnormality, but give me a name of what you're seeing and so there can be refractory cytopenia... refractory cytopenia unilineage dysplasia which is RCUD which is where they're seeing (inaudible 41:19) the lineage. I mean, there's the red factory looks bad or the white factory looks bad or the platelet factory looks bad. One, that's one type of it. Then there's refractory cytopenias multilineage dysplasia, RCMD where the pathologist is saying I see multiple factories looking bad and/or the pathologist can say I have refractory anemia with excess blasts where I see the bone marrow looks ugly, but the thing I really want tell you, point your attention to is you have the beginnings of leukemia cells. All of those have a second component that can have the ring sideroblasts. They can have the iron problem in the bone marrow or not. The technicals of what the pathologist is seeing under the microscope and that would be on the pathology report.

**Q11:** (inaudible 42:08)

**Dr. Goldberg:** (inaudible 42:13) the iron overload from transfusions. That is a problem as Dr. Raza showed you that picture with those little iron granules in the bone marrow where the factories themselves can't use iron and that's why the blood factories are pulling apart. It's this big thing with the disease and that we now know that over 90 percent of those people will have a specific gene, SBF(inaudible 42:33).

**Q11:** (inaudible 42:36)

**Dr. Goldberg:** (inaudible 42:40) blasts are under the microscope. They're seeing little iron granules stuck in the red cell factories and the factory just don't know how to use them, but once again that's just a technical of the pathologist. So, MDS means the pathologist can say I look under the microscope and I see an ugly looking bone marrow. It's myelodysplasia and then all the other things I told you just now are we ask the pathologist tell me what did you see that made you say that and they're just the subtype names and some of them have prognostic importance. If you have a lot leukemia blasts, the RAEB, the refractory anemia (inaudible 43:17) actually are moving more towards leukemia. So, that extra information is extremely important to the (inaudible 43:24).

**Jayshree Shah:** Can I ask a question to all of you? Can I get a raise of hand of how many people take vitamins aside from prescribed medications that your physicians or practitioners have given you? Okay. So, it looks like about oh, my God, 90 plus people... percentage-wise. Okay. The reason I'm asking is I think it would be great to identify what types of vitamins you guys are taking and sharing that info...

**Q12:** The multivitamin (inaudible 43:55)

**Jayshree Shah:** He's taking a vitamin, too. Lea, one of the coordinators for the MDS Foundation she and I were just discussing in regards to adding a complementary component to



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already treatment modalities and I'm talking about complementary like yoga. I'm talking about acupuncture. I'm talking about vitamins as another modality. What types of vitamins can stimulate the immune system as (Attendee) said would benefit a patient, a person, to do what patients do on a daily basis. I don't know if that would be a great project to consider or think about. If there's an opportunity if you guys have the time can you share with us in the bottom of the questionnaire today of what vitamins you take? That's something that is of interest to me because I like to know what's the commonality vitamin that you all are taking and identify what makes you feel you're nutritionally supplementing that you think would be of benefit and if it's a list of 10 to 15 you can just say multivitamin if you don't want to list them all, but it would be helpful to identify. That would be something interesting to look into to consider in maybe a future project to even maybe complement a research paper in the future as a nursing leadership project. I don't know. Just thinking about it from my conversation with Lea and (Attendee).

Yes, sir?

**Q13:** Find out what's is the percentage of people getting this illness that worked in rail yards and gasoline stations? They say that it's a benzene preleukemia.

**Jayshree Shah:** Sure.

**Q13:** I want to know how many people get this disease from working in gasoline stations.

**Jayshree Shah:** Sure.

**Q13:** Is there a percentage?

**Jayshree Shah:** Sure. I don't know the percentage offhand, but that's one of the questionnaires that when I was working with Dr. Goldberg I would always ask as a new consoled patient that would come through have you been exposed to benzene in your lifetime so far? And there is definite research known that if you have been exposed for a long periods of time how long, I don't know. For somebody's immune system to develop the DNA mutation to occur in the development MDS maybe he can, Dr. Goldberg, can comment on percentage-wise, but there is a direct link. There's also Agent Orange. All different agents out there there's noted. Also pre-exposure to radiation, different areas. That's also directly correlated to development of MDS or even prior cancers and then you got chemotherapy and then you developed MDS like Robin Roberts. You guys know Robin Roberts? Breast cancer treatment, a few years later fast forwarding developed MDS. And then she got treated and then she got transplant from her sister as being a donor. So, she's on TV on "Good Morning America" speaking on a daily basis. So, I use her as a reference because TV spokespeople like herself everybody can relate to as far as having this type of cancer in regards to her having it, but she doesn't speak too much about it. I think she speaks more about the process of transplant itself and being a bone marrow registered donor, but she did have it. She did develop it a few years later after developing breast cancer.

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Yes?

**Q14:** You're mentioning possible environmental factors. Is there any discussion or research into possible either ethnic group or (inaudible 48:09) backgrounds that are disproportionately affected?

**Jayshree Shah:** Sorry, I missed that word.

**Q14:** Any national groups or ethnic groups that are disproportionately affected?

**Jayshree Shah:** Okay. Okay. So, the question is environmental factors with national ethnic groups.

**Q14:** No. I'm saying other than... forgetting environmental factors. You've addressed that.

**Jayshree Shah:** Oh, sure. So, different ethnic groups with certain ethnic groups are being high risk of development of MDS. Again, I don't think so that I know of, but I don't know, Dr. Goldberg can comment on that. Thank God we have him here, too.

**Dr. Goldberg:** So, MDS clearly has an out (inaudible 48:50) exposure. I mean, there's no question about that. Patients... and it's usually not like a one-time exposure. I mean, (inaudible 48:54) gasoline station for one summer and now I'm at risk. It's usually low levels of a poison for a long period of time and it can be things like (inaudible 49:04) where you use the cleaning... the fluids. Here in New Jersey (inaudible 49:11) we see a lot of the gasoline industry because of the refineries. In the Midwest people work with pesticides for long periods of time. So, it's not like one time exposure. (Inaudible 49:23) who have immune diseases. So, if you have something where your immune system is not (inaudible 49:30) those are patients who also have a higher incidence and that gets a little bit into the genetics because we can see there's a specific HLA type, a specific (inaudible 49:39) to be following called HLA-DR15 and some people... and about 10 percent of the population is born with, I think it's 10 percent, is born with that particular gene. It's just part of what you are and that just... but those patients have a much higher incidence of developing myelodysplasia. There's something unique about (inaudible 40:02) then get exposed to something. They can't fix that problem and that gene (inaudible 50:11) different rates. So, actually we will check for HLA-DR15 occasionally in patients. It's actually part of the MDS (inaudible 50:21) of follow this disease especially if somebody has what's called a hypocellular MDS. So, if the (inaudible 50:28) have Dr. Raza showed up that you have too many cells in the bone marrow because those mother cells are giving a lot of birth to (inaudible 50:41) reproducing but then the cells die off and that's why they become MDS. About 10 to 15 (inaudible 50:47) of an empty bone marrow, no factories at all. So, you stick a needle (inaudible 50:53) you find out that there's no factories there. Well, no factories makes no blood. Those patients actually often will have the so-called HLA-DR15 and you check that (inaudible 51:04)



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that then actually you don't use chemotherapies. You use immune therapies. So, horse serum which is an old treatment developed by the National Institute of Health to try to bring (inaudible 51:14). The MDS Foundation has actually done some research and actually has sponsored trials specifically looking at the immune (inaudible 51:20) with the MDS because it's a rare type of MDS and that's, obviously, one of the things that the MDS Foundation wants to do is to get research in areas where maybe their patients are being underserved.

**Jayshree Shah:** Somebody else raised their hand over here. Yes?

**Q15:** I (inaudible 51:42)

**Jayshree Shah:** It goes on and off.

**Q15:** I'm wondering if this... the question (inaudible 51:50) I'm told that personally I don't have cancer and yet I'm listening to... but I have MDS. (inaudible 52:00) that line where there's a dividing line or how to evaluate what I'm learning today.

**Jayshree Shah:** So, I believe I'm making sure I'm understanding your question. Is there a fine line between calling MDS a cancer. Yes. More or less. Okay. So, MDS as Dr. Raza said as of 2002 it...

**Q15:** (inaudible 52:22) explanation.

**Jayshree Shah:** Scientifically. Yes. And it is a malignant clone that is a stem cell that has developed into the cytopenias that play out. Play out meaning it shows up on your CBC, on your lab tests to indicate that there is a bone marrow problem. Dr. Goldberg has taught me this about MDS. I'd like to say it really simple. So, we have a garden. I like to use it as an analogy to explain about MDS and I carry this analogy with me as a simple modified version of what MDS is about. The garden represents your bone marrow and you have stem cells. Those are the seeds and you have different types of seeds. You have red blood cells seeds. You have platelet seeds and you have white blood cell seeds. They're supposed to be perfect seeds that you're planting in your garden, but what happens is sometimes they get chipped and they're abnormal seeds that turn into blast cells. Hence, they don't grow into the fruits and vegetables that you have planted or you wanted to plant. Hence, those weeds also come through. Those are the fibrosis that happens within your garden and you try to use the weed killer and the weed killer can be Vidaza, it can be Dacogen, it can be Revlimid, something to kind of hold it in check to clean out those weeds and to hopefully have those regular stem cells meaning those seeds, the proper seeds without any kind of misformed seeds be planted. So, that's really important to know that your bone marrow is the function and to me when there is an abnormal seed present that's an indicative or an indication that it's a malignant clone being present that could potentially turn into cancer.



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Yup? Yes?

**Q16:** Getting back to my (inaudible 54:32)

**Jayshree Shah:** The question is...

**Q16:** The person is under treatment. They should not take vitamins and wait maybe a week or two later to go on because the vitamin coats the blood cell. Have you heard that?

**Jayshree Shah:** Coats the blood cell.

**Q16:** Yeah.

**Jayshree Shah:** Okay. So, I've not heard that part. What I do ask my patients is to let me know besides the prescribed medications to let me know their herbs and vitamins that they're taking whether it be from this country or another country and I have a lot of patients from Central America, South America, all different countries that come in with their own vitamins because now they're scared and they're using that thinking that would help their cancer in addition to the chemotherapy or whatever treatment they're receiving. So, for 1) make sure you that you let your physicians, your oncologists, your practitioners know what you're taking. Don't hide it. Let them be aware of it. Have them research it. If they don't know it have the nutritionist research it. MSK, Memorial Sloan, has a great website for herbs.com I believe that's what it's called. You can look up the interaction or to learn about the herbs and to find out if it interacts with what you're taking as far as treatment. Now, if you're in a clinical trial that becomes even more important for the research nurse to be aware that you're taking something so that you get a proper outcome that they're shooting for versus hiding it or not letting them know what you're taking thinking it's not going to impact when it does and I haven't heard that term from you like meaning a coating of the cell.

**Q16:** I'm not speaking of something from another country. I'm talking about known. I'm talking about B12 injections, folic acid, such as that.

**Jayshree Shah:** Sure.

**Q16:** It was puzzling when I heard it. So, I didn't know if this is something that's being practiced or that I was just told.

**Jayshree Shah:** I don't know that part, but I think it's definitely deems a means of opening a conversation to find out more not just from the oncologist, but maybe from a nutritionist expert in identifying the relationship of how those vitamins coat the cell and how it impacts.

Anybody else? Yes.



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**Q17:** I've (inaudible 57:12) like immune prior to the MDS and/or (inaudible) my husband has but as far as like (inaudible) sometimes don't come out (inaudible) different doctors and they don't do... testing doesn't (inaudible) which just this it's just that. For (inaudible) immune or...

**Jayshree Shah:** Is that what happened to your husband and because you went to a few physicians?

**Q17:** My husband had (inaudible 58:01) listening to prior to (inaudible) had (inaudible)

**Jayshree Shah:** Kind of flare up or present itself.

**Q17:** (inaudible 58:16) Right. What type of doctor (inaudible) per se would do other testing to just make sure that you're saying it's ABC, but maybe it could be something else (inaudible).

**Jayshree Shah:** So, what you're saying is okay, so the person meaning somebody can present with an autoimmune presentation and then the MDS is found.

**Q17:** Right. (Inaudible 58:52) well it's this. It's fine. It's the thyroid. It's the (inaudible) kind of thing (inaudible) go into...

**Jayshree Shah:** Detail. So, I think 1) is getting a blood check and having an internist or somebody that knows that there is something abnormal and to kind of follow through why is it abnormal.

**Q17:** (inaudible 59:19) blood test that (inaudible) a particular (inaudible) the blood test.

**Jayshree Shah:** There is. There's a whole slew of panel of testing for specifically for MDS and that's actually found in your book, *The Building Blocks of Hope* in looking through what's involved in the testing in addition to a bone marrow. Now, if a person presents with an autoimmune component and it can vary. There's many diseases with autoimmune. Sometimes it takes...

**Q17:** (inaudible 59:51) went in, too. So, I'm just curious...

**Jayshree Shah:** People can present, again, with MDS not as the initial presentation of saying it's MDS. It can be an autoimmune component in the beginning, but it may flare up eventually where it may present itself to be an MDS which is the presentation on a CBC as being abnormal and they got to dig a little, but why has his hemoglobin dropped from 10 to all the way down to eight in a span of a year or two when they're not bleeding, they've had a recent colonoscopy and it's negative. So, those kinds of things need to be worked out to figure out the underlying causation



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which is what medicine is about and making sure that doctor or practitioner knows how to dig, be the investigator to find out why this person has what they do and not miss it.

**Q17:** (inaudible 1:00:57) and unfortunately it takes time (inaudible)

**Jayshree Shah:** To present itself. Right. It's true.

**Q17:** Now, you're (inaudible 1:01:08)

**Jayshree Shah:** There's a lot of stuff on *Building Blocks of Hope* for your reference. That's available on the website. So, feel free to download a certain part or all of it and use that as a great resource. I think MDS Foundation is a great avenue for different clinical trials, other patient forums to attend to learn from. So, it's a great resource, I think, overall.

Yes?

**Q18:** How does one get on a clinical trial? Do you have to send letters to doctors around the country to see if they're interested in your or is it something that your local doctor says oh, you're due for that now?

**Jayshree Shah:** So, if you're failing at therapy or processing of a therapy that you're currently on and you're interested in a clinical trial. Clinicaltrials.gov is a starting point, but I would say use MDS Foundation as your middle point to help you find what other clinical trials are available in additional to clinicaltrials.gov and you already heard Dr. Raza mention a whole bunch of stuff that she's doing and there's stuff happening at Monte. Different places, different avenues. So, I think it's all about you guys attending these forums to learn that there is other places that are doing different stuff and that's important because you always want to have what's plan B if plan is not working or it's not going to work or whatever the case.

Yeah?

**Q19:** It's so important what you're diagnosed with MDS to go to an MDS Foundation Center of Excellence because the physicians there have the experience and know exactly what treatments are available for you and you can find that in this book. If you live in New Jersey, unfortunately, there's only one place and that's Hackensack Medical Center. If you live in New York, there's many places you can go to.

**Jayshree Shah:** But you could also go to New York for a second opinion or third opinion if need be.

Yes, sir?

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**Q20:** How subjective is the process of identifying blasts? Specifically I've had two bone marrow biopsies. The first identified as RAEB1, five percent blasts. Two months later I had a follow up bone marrow biopsy (inaudible 1:04:04) second opinion and I was advised that the blast level was less than five percent. So, how subjective is it from pathologist to pathologist in making a determination (inaudible 1:04:20) percentage of blasts?

**Jayshree Shah:** It's not really the pathologist. It's actually the oncologist who collects the sample from you and you have to have a good practitioner and we have NPs, nurse practitioners, at our facility that do bone marrows as well in addition to the oncologist that collect the sample. Now, it's may be skewed a tad bit by one to two percent potentially overall, but it's in the realm of what was the initial diagnosis. So, just slightly above...

**Q20:** Well, yeah, because my initial diagnosis with my hematologist, she seemed to waver a little bit because it was exactly five percent and then when I had a follow up procedure it was less than five percent. Now, I must admit I had one round of Vidaza between those two subsequently (inaudible 1:05:26) Vidaza and I'm the wait and watch method. I'm just curious was to how subjective the call is as to the percentage of blasts.

**Jayshree Shah:** So, you receiving one dose of Vidaza may have affected a tad bit of something potentially. So, that may be the result of what the second biopsy resulted. I think another important part would be identifying were there any other mutations initially collected to follow through because that may change also in the future in collection whether it be blood sampling or bone marrow sampling. That may be something you could collectively look at, too.

**Q20:** Yeah. Initially in the initial (inaudible 1:06:15) bone marrow biopsy and aspirate and then on the second opinion there was (inaudible) a couple mutations, but it still... I went from Intermediate 1 from the first to low risk even with the mutations.

**Dr. Goldberg:** I will say since I spend a lot of time in front a microscope there is a lot of subjectivity. I mean, if you think about a garden with a couple weeds in it, five percent weeds, if you happen to scoop one end and that's where the weeds are you may think that there a lot more and if you scoop on the other end you may miss the weeds and so there's going to be some variability depending on the size of the biopsy. If they had a real big biopsy and they could look at a whole big piece of bone marrow then they may get a better sense of what how many weeds are in the garden (inaudible 1:07:14) and you may under or overestimate. So, it's very possible that you can be off by a couple percentage. I mean, you shouldn't be off by 10 percent or things like that, but a percentage here or there and you're exactly the problem person in that it's right when you're right on the edge, when you're right on the edge that five percent gets you one number because the RAEB1 versus the RAEB2 we have to as... have to write some rules down and so you say is less than five percent is in this category and more than five percent is in that category and if you're right on the edge it can really move that needle on the IPSS scoring systems, but it's very... there is a lot of subjectivity. It's not a... I wouldn't say it's not an exact

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science because you are looking at it, but there... the interpretation when you're looking at a piece of bone marrow and it's often difficult when it's right on the edge just to push you one way or the other and that's when you try to bring the whole piece or as they did with you wait a little bit of time, repeat the bone marrow and go back and make it... if it's going to make a huge decision point sometimes repeating and if it's going to be a difference between (inaudible 1:08:23).

**Q20:** In my particular case, I was advised to stop the Vidaza treatment because it wasn't necessary (inaudible 1:08:35) level of less than five and that was done at Columbia.

**Jayshree Shah:** That was the end product.

**Q20:** And...

**Jayshree Shah:** Yes, ma'am?

**Q21:** Is there a difference between iron infusions and transfusions?

**Jayshree Shah:** Sure. So iron infusions are actually the patients that are depleted of ferritin where their levels are like five or six or 10. My colon cancer patients, they're the ones who usually come in or gastric cancer patients potentially come in with low levels of iron because their body can't hold onto it. Potential a bleeding or the cancer being present. The red blood cell transfusion is already filled with iron from somebody else's collection and you're getting an extra 200 milligrams of free iron. So, that's the difference. Yeah. It comes with the package. If it came alone it would be like oh, wait. That's why I don't feel high or not high, but you know what I mean? Not short of breath or energized. Yes. Exactly. Fueled up. Whichever way you want to say it.

Yes?

**Q22:** Does blood type have any bearing on what we're discussing?

**Jayshree Shah:** Blood type. Not that I know of. No. He's saying no. Yeah. There's isn't Good question though. It's a good question. Good thought process. I feel like I'm getting a lot of scientific questions from you guys. It's great. Anybody else? Did you have a nice session today?

(Applause)

**Jayshree Shah:** Yeah. I think so, too. I think Dr. Raza did a fabulous job, but she couldn't have done it without you guys being here and being present and sharing your stories and your life and your journey. So, I say keep hoping. I know we're going to find a cure. It's near the future, really



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near in the future and you will probably see me again along with the MDS Foundation. Dr. Goldberg is speaking next, I believe in the next room.

Go ahead.

**Tracey:** This is officially the end of our MDS Foundation program. So, thank you all so much for coming. It was wonderful meeting you. If there's anything you need you know how to find us. There is another educational opportunity immediately following this specific to transfusions. Dr. Goldberg will be speaking. We decided to stay in this room just for the ease of not having to re-transport you. So, let's just take maybe two or three minute while we get Dr. Goldberg set up and if you need to stretch, otherwise we'll be right in here. Thank you so much for coming today. Thank you and also the evaluation. Debra passed or evaluation forms. I'll come along and collect them if you're staying your seat.

**Jayshree Shah:** Thank you all very much.

**Tracey:** Thank you.