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Defining Meaningful Response in Hidradenitis Suppurativa

Announcer:
You're listening to *On the Frontlines of Hidradenitis Suppurativa* on ReachMD. Your host today is Dr. Alexandria May.

Dr. May:
This is *On the Frontlines of Hidradenitis Suppurativa* on ReachMD. I'm Dr. Alexandria May, and today I'm joined by Dr. Chris Sayed to talk about what meaningful response looks like in hidradenitis suppurativa, or HS. Dr. Sayed is a Professor in the Department of Dermatology at the University of North Carolina School of Medicine. Dr. Sayed, welcome to the program.

Dr. Sayed:
Glad to be here. Thank you so much for having me.

Dr. May:
Well, let's jump right in, Dr. Sayed. We know that the term "meaningful response" can mean many things. So, before we get into the details, could you give us an overview of what it means to you when you're treating patients with HS?

Dr. Sayed:
The most important thing to me is that a patient feels happy with where they are. There are lots of ways we can try to grade disease and talk about how active things are at any given point.

For some patients, they're going to be super happy—if they've had really tough disease for a long time—to be 75 percent better by some of the measures that we use. But very often, to really feel like they're in a good place, they need to be at 90 percent or even 100 percent better, because if somebody starts with 10 abscess and they go down to two, they're going to feel like they still have an abscess almost all the time. And that's pretty hard to live with.

So, most of the time, we're shooting for very high response rates or very high levels of response to make sure that patients feel like they can live a relatively normal life hopefully. I tell patients all the time, "If I can get you to a day where you don't have to wear any bandages, you can come in, and you can say that nothing's hurting or draining right now," that's an ideal state and an ideal place to get them to.

Dr. May:
Now, we do have tools that can help quantify response in HS, including the Hidradenitis Suppurativa Clinical Response, which is an outcomes measure, and the International Hidradenitis Suppurativa Severity Score System. How do we use these measures in clinical trials or everyday practice, and are there any ways in which they fall short?

Dr. Sayed:
I think people consider those clinical trial measures. It requires counting every lesion in each body site, adding up total numbers, and trying to figure out what the high score response, whether that's a 50 percent or 75 percent reduction from one time point to the other. So it's really a response measure.

And the IHS4 just adds up the number of abscesses, nodules, and tunnels and gives each of them a certain score to give you a total score. So there, you could see that your score is this one day and this the next, and hopefully it's decreased, if we're adequately controlling these for patients.

In my clinic, which is a specialty clinic, I do count up lesions for patients, because I just want to know how they were doing when they

came in and how they're doing when they came back. And if all I said was, there are nodules and tunnels in the underarms, I really have no idea what was there before. So I'm relatively meticulous about that, because I'm tracking more carefully.

I think, for most people, they're going to rely much more on patient-reported outcomes, and not even specific ones, like a Dermatology Life Quality Index. I ask those too for patients, because I want to be aware of it. But for most people, it's going to be, "Okay, how are you doing today? Are you struggling right now? Are you able to do the things that you want to do? Is your disease interfering with school or work or your ability to take care of your kids?" I think it's much more nebulous in some ways, but it also is more in tune with what the patient is feeling, and we're responding to their needs more than some specific score that's better used in clinical trials, ultimately.

Dr. May:
So, outside of the scores, what patient-specific factors do you consider when determining what a realistic treatment goal might look like?

Dr. Sayed:
A lot of that depends on their starting point. If somebody just has occasional nodules when they first come in, their goal is probably going to be to have many fewer episodes of that happening and more clear days than they have days that something is somewhat active. If somebody comes in, and they have advanced disease with lots of tunneling and scarring, it's going to be hard to get them back to completely normal skin, or maybe quite as good as a patient that I'm intervening on earlier. And that's a big push recently: trying to make sure we jump in before a lot of that scarring and tunneling develops, which may not respond quite as well or as quickly to medications.

So for the patients who have more advanced disease, I'm going to say, look, our initial goals are going to be less pain, less drainage, and better physical functions, so that you can do the things that you need to do in life. It's probably a multi-step process of surgery and other things down the line to get you to the best you can be. This might be a path that we go down for the next two to three—or even five—years, depending on what your starting point is. On the other hand, again, if I catch a patient early, hopefully I can do most of what I need to do with medications and have a relatively simple path for them to follow so that they can feel good relatively quickly. So a lot of it's based on the starting point and what they're most likely to need over time.

Dr. May:
And when you're talking about treatment with a patient, how do you set expectations up front with them in terms of what certain therapies can or can't do for their HS?

Dr. Sayed:
Yeah, that can definitely be tricky. For a lot of the conditions we treat in terms of what patients are expecting, they think, "All right, I'm going to hopefully get a medicine, everything will clear up, and my skin can be as normal as possible." I think most of them are pretty realistic, that if they have a lot of scars and tunnels, there's probably not one single magic bullet that's going to fix them. And so, again, a lot of it depends on the starting point, and I try to set that expectation the best that I can.

If it's earlier on, I let them know, hopefully we're going to be able to avoid surgery for you, but that means staying on top of things with medications. I want fewer flares. I want them to not last as long and to not affect you as much. It's hard to get to completely zero because, just like any inflammatory condition, it has lots of ups and downs. But for the most part, we can hopefully get things pretty calm and into a place where the balance of medication, potential side effects, and all those benefits outweigh the drawbacks of them.

For somebody with more advanced disease, I lay out the path I was talking about earlier. And that took me a while to learn. When I first started, I hadn't seen patients with really advanced disease get to the point where they could be really happy over time. Having been in practice for 10 years now and having seen patients that had disastrous disease to start with, I've watched them, over the course of years, gradually get to the place where they are in pretty good shape, actually.

I can help lay that out and lay out the expectation for them early that we're going to start with medications first. We're going to calm things down. We have to put the fire out. We're probably going to have to think about multiple steps of surgery to get you to the best you can be, and that can be over a year if you want to be aggressive about that. You've got the ability to take time to heal and go through those procedures, or we can do it over the next five years if it's too disruptive to think about one major surgery one after the other. We'll spread it out at the pace that fits you best. And making it fit into the patient's life is one of the most important things. If it's considered only one drastic step, where everything has to be done at once, it feels overwhelming. But for a lot of patients, if they can take it at their pace, they see gradual improvement, and there's some light at the end of the tunnel, that's much more reassuring than just watching things get worse over time.

So expectation setting is really important. I don't want them to think I'm going to start your medicine, and that's the end of the discussion. This is the first step. Once we have you in a better, calmer place, we're going to start that long-term effort to get you the best you can be.

Dr. May:
For those just tuning in, you're listening to *On the Frontlines of Hidradenitis Suppurativa* on ReachMD. I'm Dr. Alexandria May, and I'm speaking with Dr. Chris Sayed about measuring response in HS.

So, Dr. Sayed, once a patient gets started on treatment, how long do you wait before deciding if it's working or not working? And does that timeline change depending on what kind of therapy you use?

Dr. Sayed:
HS has a lot of ups and downs. So somebody can have a good month by chance—or they could have a bad month by chance—right after they start a medication, and they think it's working well enough.

Most of the clinical trials are looking at week 12 or week 16 endpoints. And I think that is the minimum time it usually takes to see momentum move the right way. A lot of patients can be better even in that first month or within that second month. They feel like things are moving in the right direction, and that usually is reflected in pain reduction. As the inflammation decreases, they notice these early changes. Seeing which way it's going—and if that initial momentum keeps up—usually takes a good 12 to 16 weeks, like we see in trials.

Things can be better as more time passes. Especially if you look at some of the IL-17 and other data that comes out, if things are better at three or four months, there's a good chance they're going to be even better at six months, 12 months, or two years. So, if things are well controlled, there can be stable, continued healing that happens for them over time.

That being said, they can get to that 12 or 16-week time point and there is no improvement in the right direction. There's not even momentum starting. If they're better at six months, it's not because they had zero improvement through four months and then all of the sudden it spiked, and they got better at six months. There's typically gradual improvement as time goes on. So, if we come to a 12 or 16-week time point and they say, "Look, nothing is happening. Nothing is different," and I see them back, and I can tell from the previous lesion counts that I did that things are pretty much completely stagnant, I am probably going to move on at that point.

So if there's momentum three to four months in, sometimes I'll wait until that six-month time point. But if really nothing is happening, they're really unsatisfied, and I don't see any positive change, I'm going to change course pretty quickly, because the longer you wait to do that, the more that irreversible damage stacks up—just like if they're not getting any treatment. So it's time to act at that time point.

Dr. May:
Now, let's say a patient's lesion counts look better on exam, but they still report significant pain, drainage, or flares. How do you reconcile that difference, and what are your next steps in terms of adjusting their care?

Dr. Sayed:
That's why I like having more specific counts, because if all the information that's in the chart is kind of nebulous, it's hard to tell if things are changing or not. One abscess can be extremely painful and miserable, so if I just went by how much they're hurting in that one day, sure, it may look like they're not that much better. They're still struggling. They need something to change.

But if lesion counts are clearly quite a bit better than where they started from, I might try to put some things into context for the patient and let them know, "Look, I think things are moving the right direction for you. If we look at where you were before versus now, it seems like things are moving the right direction.

Let's focus on getting this flare under control and see if things normalize over the next four to six weeks." Sometimes, I will nudge somebody to hang in there a little bit longer.

But without that extra little bit of lesion count data or ways to get a sense of it, it's hard to redirect, and I would probably go with what the patient says, if I don't have anything better to go on.

Dr. May:
Lastly, what do you think is the most important thing for clinicians to remember when assessing treatment response in HS patients?

Dr. Sayed:
The most important thing is probably to try to assess disease stability and understand if areas like tunnels are getting worse and spreading to new areas over time. Are things advancing, and is more irreversible damage being done? One of the most important things to achieve is making sure they are at least stabilized and not getting worse, because a lot of what is resistant to further improvement are areas where there's tunnels and scarring that just can't remodel over a short period of time.

If there are no new lesions coming up over time and things seem very stable, often the next step has to be surgery to get people better and to get past that roadblock. If there's been so much physical change to the skin structure, there needs to be a physical solution of

some kind. That usually means thinking about how to mix surgery in. So, if you just give up on a medication early on, then you can miss that window to get people even better. Changing the medication may not, by itself, be enough to move the needle, but medication stabilization and then surgery gets people the best they can be a lot of times.

So recognizing those areas that are most resistant and recurrent and when it's time to jump in with surgery—rather than just continuing a cycle of one medicine after the other—becomes really important.

Dr. May:
That's a great comment for us to think on as we come to the end of today's program. I want to thank my guest, Dr. Chris Sayed, for joining me to discuss how we measure treatment response in HS. Dr. Sayed, it was great having you on the program.

Dr. Sayed:
Wonderful to be here and to have a chance to talk about HS. Thank you for having me.

Announcer:
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