Speaker 1: [00:00:30] The HD Insights Podcast is brought to you by the Huntington Study Group. The Huntington Study Group is a nonprofit research organization dedicated to conducting clinical research in HD and providing critical training on HD to healthcare professionals.

Speaker 1: Funding for this podcast is made possible through the generous support of listeners like you and sponsorship grants from organizations like Genentech, Teva Pharmaceuticals, Neurocrine Biosciences, Vaccinex and WAVE Life Sciences.

Kevin Gregory: [00:01:00] Hello and welcome again to the HD Insights Podcast. This is our sixth episode, and today we're going to be talking with Carolyn Gray. Now Carolyn is a clinical research nurse at the University of Kansas Medical Center.

Kevin Gregory: We were privileged, we had her in town here at the HSG headquarters a few weeks ago. We were able to sit down and talk with her on a subject that I think is going to be fairly unique so far for this podcast series, where we actually talk about the [00:01:30] efforts associated with coordinating a clinical trial from the perspective of a trial coordinator.

Kevin Gregory: I think a lot of you that have participated in clinical trials have most prominently worked with clinical coordinators. There's some interesting facets to that role on a trial that I think will be of interest to you and to people who maybe are considering participating in a clinical trial, or who have been associated with a clinical trial.

[00:02:00]

Kevin Gregory: Now I will preface this by saying this was a live in person interview. We had to work quickly to get it set up. We were in a space that wasn't super conducive to good quality audio recording, but we did the best we could.

Kevin Gregory: Again, I apologize in advance. I hate to take away anything from this great interview with Carolyn. It was just such a fantastic conversation that I did my best with the [00:02:30] audio levels and hopefully that works out. Again, episode six of the HD Insights Podcast with Carolyn Gray.

Kevin Gregory: Carolyn, thank you for joining us on the HD Insights Podcast. This will be the first time that we've had a chance to talk with a study coordinator on clinical trials. Before we get into that, and I know there's a lot of interesting topics to go down that people may not be aware of, whether they're participants, patients, families, [00:03:00] or even other researchers, first tell us a little bit about yourself.

Kevin Gregory: How did you get into Huntington's disease? How did you get involved and get to the position where you are now?

Carolyn Gray: Well, I've been in my current position for 30 years at the University of Kansas Medical Center. Prior to that, my background was in emergency medicine and critical care. I was just ready for a change and applied for a position in the [00:03:30] neurology department that was part clinical and part research.

Carolyn Gray: There was a new neurologist starting, Richard Dubinsky. We both started at the same time, and we've worked together for the past 30 years. I started out in the movement disorders clinic. We had just a handful of individuals and families with Huntington's disease.

[00:04:00]
Carolyn Gray: I just found them so interesting and so underserved. It seemed like the visits were just not adequate. We couldn't cover a fraction of what we needed to for a new patient, 30 minutes for a return patient, 15 minutes. It just wasn't time to get into all the issues.

Carolyn Gray: I approached Dr. Dubinsky that I would like to start a separate clinic for Huntington's disease. I had met a wonderful nurse by the name of Carol Moscowitz. Any of you who've been around with Huntington's disease or the HSG
[00:04:30] for a period of time would know who Carol is.

Carolyn Gray: She was such a mentor to so many of us. I said I would start a clinic and also a genetic testing program, but I wanted to travel to an established clinic and see how they did things. I went out to visit with Carol and learned a great deal.

Carolyn Gray: I also spent a few days at Johns Hopkins and came back to KU and started a clinic.
[00:05:00] We thought it would meet once a month, and it very quickly became a weekly clinic and has been since 25 years.

Kevin Gregory: Okay, I often ask the guests on the podcast about who their mentor is and you've led with that. What is it, just out of curiosity, about Carol that really put her as a mentor for you getting into this role?

[00:05:30]
Carolyn Gray: Well, she's just an inspiration I think to so many people. She had such a love of what she did as a nurse. She was just always so enthusiastic, willing to go the extra mile. Not only for her patients and their families, but for her peers.

Carolyn Gray: She was always so willing to share what she knew. I just always found her to be one
[00:06:00] of the biggest influences on those early days I had with Huntington's disease.

Kevin Gregory: Going back to when you first got into ... When you applied for a position on the neurology side and you've expressed the feeling about working with families with Huntington's disease, is there a story that stands out for you that was really the inspiration for you or something that you recall too now when people ask?

[00:06:30]
Kevin Gregory: What is the thing that you remember or that really touched you about somebody or a family dealing with the disease?

Carolyn Gray: Oh gosh, that's a really hard question thinking back, because there have been so

[00:07:00] many really profound stories. I think I was just so struck by the generational aspect of it. Seeing adult children with early symptoms, bringing their parent in with advanced symptoms.

Carolyn Gray: Having children that they knew were at risk. Just the nature, just the scope of the symptoms. It wasn't just looking at problems with movement. It wasn't just looking at problems with memory or psychiatric problems.

Carolyn Gray: [00:07:30] It was the combination of them all, and just how dramatically it affects every aspect of their life and their family's life. Then as time went by, seeing it go from one generation to the next as patients. Now we're seeing some of the third generation of the families we originally started working with.

Carolyn Gray: [00:08:00] I think actually maybe one of the things I was most drawn to was the strength of the families. What they were dealing with, and just how courageous they were in dealing with it. What for most of us would be absolutely overwhelming, and just the resilience of their spirit.

Kevin Gregory: [00:08:30] What are some of the things that you've seen in working with families over generations, where oftentimes it's a family member that becomes the caregiver and sometimes even that may be a child in the family? What are some of the things that you've seen families do to cope, or that has helped them really help each other through the ordeal?

Carolyn Gray: [00:09:00] That varies so much from family to family. I can think of families where certainly it's individuals at risk we're providing the care who go on to become symptomatic. Every day that they're providing that care, they know that they may be looking at the same future.

Carolyn Gray: If they've been tested and are gene positive, know with certainty that they'll be looking at that same future. On the flip side of the coin, I can think of a family, the wife of our patient, a gentleman was affected. His wife was his caregiver.

[00:09:30]
Carolyn Gray: Their child had onset in her early teens. She became her caregiver. She died in her early twenties. She's now raising her granddaughter. She's just provided ongoing care, and no one knows at this point if she will be providing another generation of care for HD or not.

Carolyn Gray: [00:10:00] Some families, they have an incredible support system. I was recently at a support group, and we were talking and a woman was talking about how her family managed the care of her mother who has advanced disease and they keep her in their home.

Carolyn Gray: They have multiple family members stepping in to provide day to day care. Another person in the support group came quite tearful and she said, "I have never heard anything like that. It makes me so sad. I wish my mother could have had help like

that." In that family there was no one to help.

[00:10:30]
Kevin Gregory: Yeah, with regards to your institution, and like you said, when you first started it was an underserved population trying to make sure that they had the time. Tell us a little bit about the evolution of that since then. What population were you handling then compared to now? How has the visits evolved in that time as well for patients?

[00:11:00]
Carolyn Gray: That's an interesting question I guess I'd never really thought about in that way. I think in the beginning it was such a learning curve. I mean, especially for me, I was learning about it with them in a way, and seeing what they needed and then trying to target the visits towards that.

Carolyn Gray: [00:11:30] I think to some degree it's still the same. If you've seen one person with Huntington's disease, you have seen one person with Huntington's disease. Everybody is so different, and I don't think you can really preplan a visit.

Carolyn Gray: I mean, we certainly have ... We know we're going to do the UHDRS. We know we're going to do certain things, but I just try to be really flexible in the visits. I think sometimes the most important thing they come away from at the visit is just having a chance to talk with somebody.

Carolyn Gray: [00:12:00] I'm a nurse by profession, but I think I spend a lot of my time almost as a social worker and listening to what people have to say and trying to problem solve with them. I think one of the most important things is it's a safe place for them to come and talk and feel like somebody really understands what they're trying to deal with.

Kevin Gregory: [00:12:30] Now your role on clinical trials and research projects as a site coordinator or a study coordinator, it's different from that of a principal investigator and what the primary researcher may do in that regard. Can you describe for the audience, what is the primary role of the coordinator when it comes to a clinical trial?

Carolyn Gray: [00:13:00] Well, I'm in a unique position, because a lot of people are strictly researchers, strictly clinical, they don't overlap. I am still fortunate enough to see patients clinically. That's really my favorite thing, just seeing people over time in the clinic and getting to know them so well.

Carolyn Gray: I often say that's both the best part and the worst part of my job. I have the privilege of getting to know them so well, but it's a very sad thing to see the decline, or to see it move into the next generation. I really still do both clinical and research.

[00:13:30]
Carolyn Gray: It's a good combination, because as coordinator you have a lot of different roles that you fill. One of the things is recruitment, and so when you're a part of a clinic it

makes recruitment much easier. You have a relationship with the families and the individuals with Huntington's disease.

Carolyn Gray: [00:14:00] It certainly helps me in that regard. As far as what the coordinator does for studies, really it starts at the very beginning with all the regulatory work and getting everything through your internal review board or your human subjects committee and ready to start, get all the forms in order and everything approved that you need in order to start the screening process.

Carolyn Gray: [00:14:30] Then it goes into patient selection, who meets criteria, talking with them about who's interested in this study. It's really a lot of scheduling and coordinating, bringing people in. Then once the study starts, there are specific rules that fall to the coordinator and specific roles that fall to the investigator.

Carolyn Gray: [00:15:00] Those vary greatly from study to study. There may be activities or scales that I've done for many, many years in a new study. I'll come about where that activity has suddenly delegated to the investigator. We each have specific roles, but most of the day-to-day study activity, I think it'd be fair to say is with the the coordinator. By far the most patient or study participant interaction is with the coordinator.

Speaker 1: [00:15:30] We'll return to the interview on the HD Insights Podcast in a moment. We hope that you're enjoying this episode. As a nonprofit organization, the Huntington Study Group relies on the generous support from the community and listeners like you to continue bringing you in depth content on HD, like this podcast series.

Speaker 1: If you like what you're hearing and are interested in supporting HD Insights through a grant or donation, please contact us through our email address, info@hsglimited.org, or by calling toll free at 1-800-487-7671. We greatly appreciate your support. Now back to our episode.

[00:16:00]
Kevin Gregory: From a patient perspective or a potential participant in a clinical trial, what are some things that you've experienced over the years that potential participants may not be aware of? There are a lot of buzz about trials and getting involved in clinical trials.

[00:16:30]
Kevin Gregory: Certainly we want participants to get into trials, because that's how we make new treatments available. Are there things that a person that wants to get into a trial that you've seen they weren't aware of or they didn't account for and it has become a challenge maybe to get them enrolled?

Kevin Gregory: Something that you would convey to the potential participant population to say, "Here's what you can expect if you're interested in getting involved in a trial."

[00:17:00]
Carolyn Gray: Well, I think certainly clinically we have a pretty good idea of what our population

is and who would qualify for a specific study criteria. Part of what we do at each clinic visit is just give an overview, and most especially with new patients, let them know the current state of research.

[00:17:30]
Carolyn Gray: How hopeful things are, what all the studies going on are. We just do a research overview at each visit, so patients can be kept up to date. Although with things like this podcast or websites, frequently patients come in asking about specific trials that they've heard about.

Carolyn Gray: One thing that they don't always understand is the whole process of inclusion, exclusion criteria. That if they want to participate in a study, why they might not
[00:18:00] meet that criteria. They tend to often look at it as, "Well you don't understand, I am willing to take any risk. It doesn't matter. I'll be ..."

Carolyn Gray: The word they'll use is a Guinea pig, because they're so desperate for a treatment. I think we have a real responsibility to make people understand the difference between a research study and a treatment. What the different arms of the study are.

[00:18:30]
Carolyn Gray: They may be assigned to placebo. You really want to assess their commitment when you're doing that, because what you don't want is somebody going into trial thinking they're going to have a vast improvement. When they don't see that, dropping out to go to the next study.

Carolyn Gray: I think a lot of it is about education. I'm not sure if that answered your question.

Kevin Gregory: No, I think the inclusion, exclusion criteria actually is very valuable. There definitely
[00:19:00] is that push to want to be involved in a trial because of the desperation and wanting to potentially be on the trial that something becomes the treatment or the cure. That's not really the intent of the trial, correct?

Carolyn Gray: Right, and you get into a lot of other issues. Some studies may require a caregiver not only involved on a daily basis or a certain number of days per week, but to attend visits. The sad truth is not everybody has a caregiver.

[00:19:30]
Carolyn Gray: Some people are pretty much on their own. Sometimes that can be difficult and they don't understand why that would preclude them from participation. Another issue is cancer. We've had a couple of people that have gone through treatment for cancer.

[00:20:00]
Carolyn Gray: Once they get the all clear and finish chemo or surgical intervention, don't understand why that would prevent them from going to a study when they're really not in it ... They don't have the medical clearance to do that.

Carolyn Gray: They really don't see the bigger picture, but only see their overwhelming desire to have access to any treatment that they think would be beneficial.

Kevin Gregory: [00:20:30] There are a number of other elements to a clinical trial that the coordinator has to deal with and that participants may not be aware of. It's not just interaction with the patients, it's not just the rating scales.

Kevin Gregory: [00:21:00] There's all aspects of documentation. Adhering to the study protocol obviously is very crucial, ultimately because these are endeavors that can be audited by the FDA. I know you've been through that experience and you're helping out the HSG by presenting a topic on FDA audit readiness for site coordinators and investigators.

Kevin Gregory: Describe that process. When do audits typically occur? How can they occur? What's involve?. What does that mean for a clinical trial typically?

Carolyn Gray: [00:21:30] Well, audits can occur for different reasons. You may have an audit because you're a very high enrolling site and the drug is being submitted for FDA approval. They'll come out and look at all of your records. In that case, you're notified ahead of time and have a chance to get everything in order.

Carolyn Gray: Audits can also be for what's called for cause, meaning a problem has been identified. In those cases, the FDA and auditor just appears at your facility without notice and the audit begins then. When you're audited, they just go through all the documents.

[00:22:00]
Carolyn Gray: They're looking for compliance, making sure you have met all the guidelines that were in the study protocol, looking carefully at how subjects were consented. Did they understand what they were participating in? Did they participate of their own free will?

Carolyn Gray: [00:22:30] That there was no coercion from anyone, whether it be family or site. They're really just looking to make sure that everything was done correctly to assure the safety of the subjects and people that would be taking the drug in the future, should it receive approval.

Kevin Gregory: [00:23:00] In terms of the amount of time that you ... Let's say a patient comes in for a trial visit. What percentage of the time would you say is spent with a patient, versus time required for all the administrative tasks associated with the trial? What's that mix?

Carolyn Gray: Well, that is a really, really good question. That's something that I think as coordinators we need to be really proactive about. When our time is being considered, you don't just look at times spent face to face with the subject.

Carolyn Gray: [00:23:30] I think that's probably one of the most overlooked things when you're budgeting your time. There's a lot of preparation ahead of time. Typically we'll receive all of the case report forms through a study portal and we'll go in and print them out.

Carolyn Gray: Well that takes time to print all those forms. Then there are headers that have to be filled out. There are laboratory kits. There's a lot of preparation that goes into the visit. Then you will see the study participant.

[00:24:00]
Carolyn Gray: There may be labs. In some cases you may have research personnel assisting you with preparation and shipping of the samples, but in a lot of cases you'll be doing it yourself. That can take well over an hour after a visit to get all those specimens ready to be shipped, especially if you need dry ice or special shipping instructions.

Carolyn Gray: [00:24:30] Then after you've finished all of that, you go back. You still have to do drug accountability, making sure that they're taking it as they're supposed to be, that there's adequate compliance. You'll finish filling out your forms, scoring any testing that you've done.

Carolyn Gray: [00:25:00] Then you have to sit down and do all the data entry. Most studies now are electronic, so you'll enter everything from your original source documents then into the electronic database. As you're entering it, usually the ideal is to have it entered within 24 hours.

Carolyn Gray: [00:25:30] Visits can be 50 or 60 pages easily forms. Then I try ... Every time I sit down to do data entry, I always try to log in and look for queries. Any questions that are coming back to me. These two sources don't match. You say they're on a medication for high blood pressure, but in their medical history or comorbid conditions, high blood pressure's not mentioned, which is correct?

Carolyn Gray: You need to look for those queries from the sponsor, address those in a timely fashion as well. I think it's about half and half, half time with the patient, half time completing the visit.

Kevin Gregory: [00:26:00] Carolyn, one of the big topics and certainly an important topic in a clinical trial is the notion of retention, participant retention, keeping participants that have enrolled in a trial engaged and seeing them through to the end of the trial.

Kevin Gregory: [00:26:30] Tell us a little bit, because you are interacting with patients so much, what are some of the strategies that you've used when you've had patients that are considering dropping out, or maybe looking at other trials and wanting to leave one for the other, how have you handled that? What are some of the techniques or tactics?

Carolyn Gray: I think one of the biggest advantages you can have is to have a relationship with the subjects and your families. It really allows you to talk more openly and to get a feel for what their thoughts are going into the study and what their level of

dedication to the study is.

Carolyn Gray: [00:27:00] I'm real open with individuals prior to enrollment about the length of the study, what it means to commit to a study, and an understanding of course that at any point they can drop out. That is completely their choice without any discrimination and future treatment.

Carolyn Gray: [00:27:30] At the same time, I want them to understand that while they have that right, they are making a commitment once they enter a study. That there are limited research dollars, and to have an individual go into a study just to wait until a better one comes along, or what they perceive as a better study comes along, they can really jeopardize multiple studies.

Carolyn Gray: Those individuals can't always be replaced. We really try to discuss that aspect. Now if somebody has a reason that they just have to drop out, the ideal would be to have them remain in the study without taking the study drug, but still coming for the visits we intend to treat.

[00:28:00]

Carolyn Gray: That's the next best option if they do have to drop out. I think the most important thing is just that early on education of what it means to be in a drug trial, what our commitment to them is, and what their commitment to us in return is.

Kevin Gregory: [00:28:30] Before we wrap up, and I do appreciate your time sitting down with us for the interview, I want to ask you in terms of your work, or your professional career, or just anything, what is it that you consider to be your proudest accomplishment?

Carolyn Gray: [00:29:00] I think that's a pretty easy one. It's just actually starting the clinic. I hope at the end of the day it will have made a real difference in people's lives. That they felt like there was a place to come where they could speak openly and people did understand what they were going through.

Carolyn Gray: I so frequently will have families or patients call me or write to me and say, "Thank you for everything that you do. We couldn't have done it without you." My response is, "I don't feel like I did very much. I wish I could have done more."

Carolyn Gray: [00:29:30] That they said, "No, you were there, you were always there and we knew we could call you." I think just starting the clinic and watching it grow has been something that I'm very, very proud of. Throughout that time, I was just young as I transitioned over to this job.

Carolyn Gray: [00:30:00] I've said it before, I grew up with the HSG. Much of what I learned, I learned from the HSG. I could never have had better teachers. There were so many, and [inaudible 00:30:06] was just such an amazing leader. I was always so incredibly impressed how inclusive he was of everyone on the research team.

Carolyn Gray: Just the fact that there were coordinators on the executive board that we were

[00:30:30] included into that, I just feel like I learned how to do research from the HSG.

Kevin Gregory: Well we appreciate having you as part of the group, and it's been very inspirational talking with you for the podcast. Carolyn, thank you so much for joining us.

Carolyn Gray: Oh, thank you for having me. I really enjoyed it.

Kevin Gregory: [00:31:00] Well that concludes our interview with Carolyn Gray from the University of Kansas Medical Center. Again, a longtime HSG member. She's served on numerous observational and clinical drug trials in movement disorders.

Kevin Gregory: We were thrilled to have her in person to sit down and chat with us about her role and her experience as a clinical coordinator. We have some fantastic guests lined up for some upcoming episodes of the HD Insights Podcast. We were able to speak with some folks as part of the HSG annual meeting in Sacramento, California. [00:31:30] Thanks again for tuning in, and we'll talk to you soon.

Speaker 1: We hope you enjoyed this edition of the HD Insights Podcast. Remember to subscribe to this podcast to make sure you automatically get the latest episodes to your device. Please rate and review this podcast with your feedback, so we can continue providing the best possible content.

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