Question and Answer

What about transportation cost? If somebody were very interested, say in doing a clinical trial that was in the city and they live in the suburbs is there some element built into a clinical trial that will help them get down there if they don't have transportation?

Katie Glavin:

Yes. Almost always. There's only been a handful of times I've seen where reimbursement is not an option. Again, this is when it's really important to look at that informed consent. It will talk about different payment. Typically it's on mileage. I know probably the most standard is if you're over 50 miles from the institution we will pay mileage. That's typically about a 50 cent mileage.

We also reimburse things for lunch if you have to travel, for example three hours. I'm in the middle of the Midwest so three hours isn't that far, but you can travel long distances. If we're driving three hours we can reimburse for food and that gas to and from. Another really good option is lodging.

We have different things called, in Kansas City it's the Hope Lodge. If you have a cancer diagnosis it is free. They have a community kitchen. You can bring your own food and there's usually a twin bed or two in different rooms and so you can stay there when you need to get your treatment. If it's a long drive and your treatment is at 8:00 AM you can actually have that approved to stay there so that you don't have to leave the house at 4:00 in the morning to get to your treatment.

There's many different options. It's always great to again ask. Often times we're giving you so much information. You've been diagnosed. You've had all this imaging. By the time you see the doctor and the research team you're probably worn out at that visit. Often times we're giving a lot of information.

Sometimes that's probably one of the biggest things I see is not really discussed. That's again when it's really, really important for us to ask those questions. Usually if you ask, it's usually never a no, but every once in a while on those really low funded trials they might say no. But usually we have other grants within our institution that can help pay for those additional costs as well.

Do you think most other big teaching hospitals have similar programs in place for their patients that might be interested in a clinical trial?

Katie Glavin: Yes. Typically the reimbursement is by the pharmaceutical company. If that clinical trial is opened at every state in the United States. We'll say they're at all 50 states. All 50 states, and all the patients participating in that specific clinical trial no matter where you're located in the country will have that mileage reimbursement. The lodging would be a little bit different. I think that there are so many different advocacy groups and not for profits that support our cancer patients that there are so many options that are just hidden. Always ask. If there's any kind of financial burden there's so many things we can do to help.

A few examples even that I've worked on are we can work with the pharma companies to get a drug at a reduced cost. Sometimes what people often overlook is that if you actually buy your medications at an institution or a large hospital we get bulk pricing so typically drugs are a bit cheaper purchased within the institution.

Most patients see a financial counselor to really just go over what is this going to cost me? Because a lot of times people think cancer is so expensive, and it really can be sometimes depending on your insurance coverage or what kind of treatments you're receiving. We always have our financial counselors really go over information on just what to expect so that we don't have that extra anxiety driven, "What kind of bill am I going to get?"

Then the other option too is we have what's called an endowment office. That's really all our donations and different things that people contribute to help our patients and our institution. I've even helped patients apply for those grants to help pay for their medication. The other thing we can even do is we can actually, if for instance you can't pay your rent because you're paying your medical bills we actually have grants and other things to actually help cover things like mortgage, and car payments, and food cost because your insurance and all your extra money is going to pay for that cancer care.

There's so many different angles where that financial burden can really be put at ease. You just really have to probably be the one driving that conversation. Like most of the time we're seeing so many patients in a day, sometimes that's not what we're focused on is the financials. And so it's always a big topic. We try to do our best to discuss it with patients at every visit. This is really great for patients, and their families, and caregivers to really ask these questions at these visits.

It seems as though there's a scarcity of trials in some locations and in others there are a lot more of them. But why is it that there seem to be pockets of places where there's a lot of trials, and then in some geographic areas even where there are large teaching hospitals there may not be a whole lot of trials?

Katie Glavin: Yeah. There's many angles to that that play a factor. One huge aspect is infrastructure. At KU we have about a team of 500 researchers to do all these clinical trials. When we see different institutions, especially private, it's a financial issue to staff this many people, to be able to bring all these trials on. Often times the institutions, like KU Cancer Center, don't make money off clinical trials. You have to find other financial support to really make sure that you can cover those costs because you're basically just always eating that cost.

Another aspect is the institutional support. Do you have the right teams in place? We have an IRB, so you have what's called a local and a central IRB. These are those review committees for patient safety. KU has its own review board. We have our own radiation safety review board. We have our Protocol Review Committee. If you have to outsource this it's very expensive.

Another aspect that's very expensive to clinical trials is to be able to maintain our databases, and space. Where can people that are conducting a clinical trial see patients? KU has a whole facility where we have designed it specifically to be 100% research patients and those visits.

When you're trying to squeeze into a patient's visit with their doctor and ask them all these questions it can bog down our standard of care clinics. Then that causes patients to wait longer. There's multiple different angles here that are important to know that infrastructure, those teams and those different levels of expertise.

The counter opposite side is you have to go through what's called a "site selection". There's two phases of being selected for a clinical trial. For example, if I really want this new drug and we want to bring it to KU. I actually have to have a conference where I bring that pharmaceutical company on site. They literally walk around the building with me and look at our laboratory.

That's to make sure that I'm not just telling them, "Hey, I have a lab. I can draw blood." They want to physically see it to make sure. They look at my CT imaging scan machines. They'll look at where our blood is processed. They will look at what rooms we see patients in. Where do we store our supplies? Where's the paper store? And if for some reason you don't meet all those requirements in order to conduct that study you will actually not be allowed to have that drug at your site.

There's different aspects that are required for us to have in order to bring that trial to our institution. This is where KU is a bench to bedside facility, and not every institution is. KU only became a full bench to bedside model probably about 10 years ago. We got a Phase 1 facility and that was the big piece of branching to that NCI dedicated cancer center.

What that means is we're allowed to monitor patients overnight to see really how those drugs metabolize through their blood. All these different aspects are so financially draining for institutions

sometimes they're just not interested in having research. My department is very huge on research so it's a big priority for us, but another department might not be as interested in it. It's kind of, part of it is you seeking out those clinical trials and you're also being selected to conduct them.

One aspect they look at that's very important is they actually get all of our resumes including our physicians, even the chair of my department, will send in his resume. It'll show what types of trials they've done, what kind of publications. What's their experience? What do they see as routine clinical care? Do they even have this patient population? Are they an expert or are they brand new in the field? All of these different things have different requirements in order for us to even onboard a clinical trial. I would say for a phase one to a phase three clinical trial it could take anywhere from the point of idea conception for us to actually open, anywhere from three months to a year. Once we hear about the trial we probably won't see it until the following year to actually be open in our clinic for us to give that drug to patients.

It's a very daunting process, and it's very timely and a lot of paperwork. Again this I hope makes people feel more comfortable that in order for us to even open a clinical trial it had to go through so many channels and safety boards to just even be opened. We get very excited when we get to accomplish and get that trial opened to be able to give our patients that extra treatment.

If an investigational drug is producing a benefit for a patient would they be able to continue to get the drug when the trial ends?

Katie Glavin: Most of the time yes. We call that compassionate care use. Let's say there is 10 people in this trial and it worked really well for 2 of them, but maybe it's not going to even make it to the next phase of that clinical trial. Those two people can still go through the channels to get that drug because it's working for them through that Compassionate Care Use protocol, and that takes a lot of work from your physician and you to fill all that information out to get those approvals.

At that point it becomes a different avenue because it's not on the market so getting insurance coverage to continue that drug off label is a different piece. We don't know what it should cost because it's not on the market yet, but at some point I don't know if that pharmaceutical company would gift it to them for free since they're not going to be able to go forward with it or if they would make someone pay for it.

The other kind of aspect you can do is let's say there's treatments such as the chemotherapies. They might only be four cycles for routine care. If it's really working for you and maybe you're not a surgical candidate you can keep getting those with what's called off label, meaning as long as the doctor feels comfortable treating you with those systemic chemos, or even immunotherapies they can keep giving you additional treatments as long as it's benefiting you.

If at any point those little lesions in there grow at all that treatment really is deemed no longer working. They won't want to continue that treatment should it not be beneficial for you anymore.

This is all about the results of a trial. Do patients ever get any feedback on what happened as a result of their participation or the overall results of the drug?

Katie Glavin: Yes. You should all receive that information. I actually sent these out the other day. When the trial is done the hard part is a lot of the treatment trials are really long trials. We might do long-term follow-up for 15 years. It might take us 15 years before you get a letter in the mail. If you move between that time and we lose your address sometimes it's really hard to get that information to you but when we finish the results we type up the letter and we include the publication link inside, or provide the publication itself in there to let you know what happened.

Usually by the time your treatment is done we know if it worked well or not for you even if we don't know whether it was that placebo or the standard of care, or the standard of care plus another drug. When we look at that, that data we really show... You'll hear three phases, that it was superior drug, equivalent, or less than equivalent. Really no matter what happens we want to share those results.

A lot of times people might ask, do you not publish bad results? We will publish all results good or bad because it's beneficial to the next person that might look at something very similar. That data should always be compiled and sent out in a letter to all patients who participated. I would say that's one thing that's often missed just because of the duration of these trials. Sometimes we just can't get it out to people. But if you even just throw the clinical trial information into Google it usually will pull up any results that we have as well.