SPEAKER 1: One of the issues that I'm going to be talking about today is how we decide who's a good candidate, and, you know, the reality is, is that although many dialysis patients can benefit from transplant, not necessarily everyone is a good candidate for transplant. And we wanted to kind of give you an idea of what goes into our decision making about that.

So what I'm going to be doing, in terms of the overview of the talk, is really talk about some of the high-level principles we use, in terms of making decisions about this, go through some of the steps and just make some points. You've heard some of this information along the way, particularly Trish, this morning, talked about the referral process and some of the evaluation process. So I'll go over some of those things and just kind of point out some issues that are, I think, are-- you know, just to highlight. And then I'll finish up just with some examples of the kinds of patients that might make good candidates and the types of patients that may not make good candidates, just to give you a flavor for the kind of range that we look at and give you some ideas as you're, you know, kind of taking care of the dialysis patients, which kinds of patients are, you know, potentially candidates and who may not necessarily be the best candidate.

So three main things that I'll expand on, in terms of the principles. First and foremost, you know, we're looking out for the patient's best interest. And I'll talk a little bit more about what I mean about that, but, obviously, we want to be doing right by the patient by doing a transplant, meaning that their quality of life is going to be better, hopefully, their health is going to be better, and they're not going to be harmed by the transplant. And so a lot of that, as you'll see, does depend on various factors, both medical and non-medical, and we'll talk about some of those.

The other thing that we do need to also think about, as a transplant center and as part of the transplant community, is the allocation of a precious resource. And I'll-- you know, Dr. Song earlier talked about some of the statistics in Michigan. I'm just going to give you a few examples kind of at national level statistics, but, unfortunately, we have a limited resource.

This is something that, you know, is different in many ways than other parts of medicine. I mean, typically, you know, if there's a particular drug treatment or something, you just have to decide, OK, does this make sense for the patient or not? But here's a situation where not everybody is going to have that treatment necessarily available because that treatment is a scarce resource, which is kidneys, essentially. So that is something that we need to think about, and from a kind of a transplant community perspective, we also need to think about how are we best utilizing the organs that we've got?

And then a final point, that I won't necessarily come back to, but I think it's really important to say, is that, we don't, as part of the decision-making process, what doesn't make it into is any kind of moral judgments. Everybody deserves an equal shot. What we decide, you know, based on is how they're going to do from the transplant, a lot of factors can play into that aspect.

So I'm going to take the, kind of, the precious resource side first. So what this graph shows is what's happening with the wait list.

Let's me see if this is a-- is that a-- yes, that's a pointer. OK.

So don't worry about these two curves. They're just patients who are active or inactive, and that's not that important to think about. It's just this total wait list, and this is the number of patients in the United States waiting for a kidney transplant. And it's an easy number to remember. It's 100,000 people in this country are waiting for a kidney transplant.

And you can see it's been going up. Interestingly, this is like, for the first time, over the last year, it's plateaued a little bit, but it's sitting at 100,000. Now, if we go to how many transplants are we doing, this is overall. The blue curve is deceased donor transplants. So those are people coming-- you know, essentially, organs available through the wait list, and this is living donation. And what you see, it's about one-third are living donors and two-thirds are deceased donors, and the total is essentially, about 16,000, 17,000.

So we've got 100,000 people waiting, and we're doing about 1/6 of that per year. And if you just look at the deceased donor, that's about 12,000. So about, you know, one in eight. So bottom line is that this is a very scarce resource. So the current need far exceeds the availability, six to one. So we have to carefully consider how the organs are getting used. We want to make sure that we're getting the best out of the organs, in terms of how they're utilized.

The other thing is, I want to make a point about living donor kidneys, because, you know, in a lot of situations, if a patient has a living, a potential living donor, you could argue, well, they're essentially bringing, you know, the kidney that would be used. So what about in that circumstance?

Well, the reality is, we still need to consider how they're likely to do with the transplant, both, again, from their perspective but also, from the perspective of this resource. Living donor kidneys, even when you have one available, is precious from the perspective of the fact that what we're asking from that living donor is for them to take on risk. They're an otherwise completely healthy person, and they're having to take on risk.

Fortunately, that risk is very small, but, nevertheless, in a completely healthy person, that's really a big deal to do. And so there's a certain obligation to that living donor to ensure that it makes sense to do this, that's it's going to be successful. There's a good chance that it's going to be a successful transplant.

So part of, you know, how do we decide how this is done? A lot of this is done kind of at a national level through policy. And some of this, Dr. Song talked about, is there are allocation policies. A lot of this is kind of out of our individual transplant center hands, but the other way in which, to some extent, this is regulated is, again, expectations around, you know, how will transplant patients do, their overall long-term survival and these kinds of things?

So transplant centers are held to those standards, and, to some extent, what determines how patients do is how transplant centers go about selecting patients. And so there's kind of a-- obviously, we want to do the best for the patient in front of us, but we also need to think about the, kind of, the bigger picture at the same time, and it can be a very difficult kind of tension to resolve sometimes.

So what makes a good transplant candidate? So we can kind of really simply, you know, they have to be healthy, willing, and able. So healthy, and I'll talk a little bit about this, is kind of based on them having a certain reasonable life expectancy, number one. Kind of with or without the transplant, how long are they likely to live? And then, we, obviously, want to be sure that we're not going to actually harm them by doing the transplant, and I'm going to say a few more words about this issue shortly.

The other thing, obviously, they need to be willing. A successful transplant requires a commitment. Obviously, dialysis requires a major commitment but so does transplant, and that's really important. Something that we try to emphasize when we talk to patients is that, you know, it's still not a cure, as such. It's still a chronic condition. They have, you know, potentially a tremendously improved quality of life and flexibility in what they're able to do day-to-day, travel, these kinds of things. But in order for the transplant to be successful, you know, they need to take their medications consistently. They need to get their blood work consistently. They need to show up to visits.

And then the other thing is, they need to be able to have the necessary support systems in place to be able to be successful, again. So, you know, having somebody who can potentially get them to those visits or helping, in some cases, you know, helping them with their medications or remembering to take their medications. And they need to have, you know, the finances are also important, because they need to be able to get the medications and pay for the medications, because if they're not going to be able to do that, then the transplant's just not going to be successful. We can provide from our end a lot of resources and support towards these ends, but, you know, ultimately, we need to be sure that, you know, between them and us, we're going to be able to get to a place where we can have a successful transplant.

So just a word about survival benefit. And I hesitated to put this figure on, because it's fairly nuanced. It's actually from really a landmark study that gets referenced all the time. I'm proud to say that this research was done at the University of Michigan, now, you know, almost 20 years ago. But then I remembered, you know, when-- sorry-- when thinking about this, is that I teach this to the medical students, and if they can get it, then this audience is going to have no problem with it.

So this is what this shows. This is, essentially, you know, we're doing a comparison to patients who are on the wait list here, because that's a more reasonable comparison. So the question is, you know, we can't do kind of a clinical trial, an experiment where we, you know, half the patients get a transplant and half the patients stay on dialysis, that wouldn't be ethical. So we want to see, well, you know, we want to try to get at, well, how would they do compared to just staying on dialysis?

Well, it's unfair to just compare it to all dialysis patients, because obviously, there's a selection process. So what these authors did was made a comparison to patients who were selected for the wait list but hadn't yet been transplanted. And so what they're doing is they're comparing the risk, you know, of death with getting a transplant versus staying on the wait list and plotted that over since the time of transplant. And this is the line of equality. So this is the same as the wait list.

So what you see is that early on, there's a blip. So there's actually a higher risk of death with the transplant early on. So what that is is because of the stress of the surgery, there is deaths relating to that. So that's what happens here. And then, you know, but as you go out, the benefit starts accruing, but it takes a while. So this is when things even out, but because there were some extra deaths here, it takes a while, almost up to about most of the way through the year before it's a net positive. And then, following that, it's all net positive.

So what this does is it gives us some principles. So we need to try to minimize this blip. So we want to make sure that patients that we're doing are going to be able to survive the surgery. The other thing is that it doesn't really make sense to do the transplant in people who have a fairly limited life expectancy no matter what, because they're not really going to see a benefit from the transplant, or they're going to see a small benefit from the transplant.

So we use these kinds of principles, in terms of deciding what kinds of patients we think would make good candidate for transplant. So this gets at some of the principles. It's like, we want to identify and exclude patients who are at high risk of peri- or post-operative mortality. We want to identify or exclude patients that have conditions that irreversibly limit life expectancy. And obviously, we want to identify or potentially exclude patients that have conditions that may be actually made worse by the immunosuppression that is associated with the transplant, so, in fact, of infections, cancers. Again, these are not necessarily irreversible but they need to be taken care of before we would proceed with the transplant.

So what about the steps? So we've talked a little bit about the referral process. There's the triage process that performs that initial intake. And one of the things I want to emphasize is that, you know, if in doubt, refer, and we'll perform that initial medical review. So we can-- you know, we're not going to necessarily waste the patient's time and bring them in for the full evaluation. If you're unsure, you can always send in refer. We can take a look and make that initial judgment.

The other thing is that you might see us trying to get records from you. Trish described that, and a lot of times, I just want to emphasize that it really does help us to get as much information beforehand as possible, because we can put it in context at the time we're actually seeing the patient, rather than kind of piece-mealing it, where we see the patient, then we get the records. I think it makes for better decision making to have all the information there. So if we're kind of bugging you about getting records or things like-- that's why.

So on the evaluation day, again, it's a multidisciplinary evaluation, and a big part of it is the education and counseling that happens formally in the education class, but it certainly happens individually with every member that they see that day, the social worker, the financial coordinator, the nephrologist, surgeon. As Trish mentioned, sometimes we'll make a decision. It will become obvious that they're not a good candidate, potentially at this time, and we may actually not go through with the full evaluation just so we're not wasting their time. And then, as we already mentioned, actually we don't do a lot-- although we get as many records as possible, we don't necessarily do a lot of testing in advance.

So after they're seen at that evaluation day, there's essentially a multidisciplinary committee meeting, and this happens fairly soon after. It's typically the Monday after the week of the evaluation, unless there's a holiday or something or unless it's been such a busy week that we end up having to defer patients to the following week. So usually within a couple weeks, there's going to be this multidisciplinary committee meeting. And again, that includes the full, kind of, complement and range of people that are part of our transplant team, so most of the-- the nephrologist, the surgeon, social worker, dietician, financial coordinator, psychologist, everyone's there. And we present the cases, even if we're fairly confident about where we think the decision should go, and we discuss it to allow everyone's input.

So one of the things is, we recognize that this is, many cases, it's a judgment call, and it's not always a situation where everyone agrees. So we use, kind of, the collective wisdom of the committee. You know, there is a concept, wisdom of the crowd, and I think, you know, a lot of the decision-making there is, where there are some uncertainties, where the science isn't kind of hard and clear-cut, we use the collective experience of everyone there in the room. Different perspectives-- it's a diverse panel of people, and it's people with a lot of experience, particularly in aggregate.

So there's three main categories of decisions that come out of that, one is closing the case, one is we need more information, time, or testing, and one is to actually list them. So closings-- so these are essentially people who are not currently deemed a candidate. And the term really sounds permanent, like case closed, but it's important to recognize, and I often will try to, you know, prepare patients for that kind of terminology, which they may hear, but it's not necessarily a permanent state of affairs. Essentially, we close the case, if we think that-- even if we think there are issues that can be resolved, if we think it's going to take much longer than six months.

So what we'll do is, we'll provide them with the information or potentially their providers with what they need to do in order to, kind of, come back. So it's not always a permanent kind of closure. Sometimes it is, and we try to make that clear if that's the case, if it's a condition that we don't think is ever, kind of, going to get better.

Very frequently, they fall into this kind of middle category, where we think they're potentially candidates but that we need more information, so more testing prior to making that final decision. Often, that's cardiac stress testing, or pelvic CAT scans. Often, we'll build in a particular of time to assess, say, their medical adherence, you know, to see if they can lose weight, improve they're kind of functional status, which is really important, resolve any kind of, if there are any psychiatric issues. And this also may involve, you know, requesting of additional records to clarify certain conditions or consultations with other specialists.

And then, there's the listings, and that sometimes happens right out of the gate. And these are, essentially, patients who we think are currently or, will in short order, be deemed candidates for transplantation. We will often list patients on hold. What that basically means is that they go on the list. So they start accumulating time, but they're on hold, meaning they won't be called for a transplant, for those patients where we think they're imminently going to be ready but still have a few more things to do. And we do that particularly for patients who are not yet on dialysis, because as Dr. Song had mentioned actually, it's been true in Michigan for a long time, once they're on dialysis, you know, their wait time dates back to the start of dialysis, regardless of when they're listed. So they're not losing anything there. But if they're not yet on dialysis, then there is an advantage to being listed.

The final point I'd make is that listing is a process. It feels black-and-white. It's like, OK, I'm listed, done. But it's a process. So we continue to evaluate patients for suitability on an ongoing basis. In fact, we see them back regularly, and their status can change. We also examine our own policies about who make-- you know, who will be good candidates for transplant and sometimes, we re-evaluate things, which can, again, change somebody's status.

So let me go through some examples. So these are examples of patients who are likely not to be candidates. So, again, metastatic incurable cancer, so cancers that are not really treatable, it's mostly palliative. Patients who have got coronary artery disease that's bad. They're still having chest pain. It's very severe, and there's nothing much that can be done about it. So if it's somebody who, you know, you can do a heart bypass and fix it, not a problem. But if they've already had that, and they're still having problems, that's the kind of thing.

And then patients with severe emphysema, for example, on home oxygen, where there's not likely to be any kind of reversibility. Patients with a history of non-adherence to their medical regimen-- again, this doesn't necessarily have to be permanent, but we would require them to have a period where they're able to demonstrate that they can be adherent to their medical regimens. Typically, we will look to see how they they do with dialysis, for example.

Other things are potentially severe obesity, although, again, we don't have necessarily a specific cut-off, and it depends highly on the fat distribution, which is why we like-- in those cases, many times, we want them to be seen particularly by the surgeons to evaluate technically whether it's possible. And someone had earlier asked about age, and, yeah, we don't have a specific age cut-off. Although, you know, typically 80 is-- once you hit 80 and above, it's much less likely, although not entirely impossible. And then patients with poor functional status, so they're not able to, kind of, get up and be active and physical. Sorry. Yeah.

So these are patients who may be a candidate. So I've tried to include things where you may think, oh, they wouldn't be a candidate or something like that. But so patients who've had amputations, again, if they can ambulate well with a prosthesis, that's not necessarily a contraindication. Patients who have hepatitis C, who don't have severe liver damage are potentially candidates. Patients with HIV are candidates, as long as they're on treatment and have undetectable viral loads. And as has also been mentioned, patients with a history of cancer may be candidates. They often require a waiting period, but if they've been treated and are believed to be in remission, they can be a candidate. And patients who may have, you know, depressed ejection fraction. so impaired cardiac function, but who are otherwise, doing very well physically, may be candidates. And then, again, obesity, it really depends on their fat distribution and other factors.

History of substance abuse-- again, if they've tackled it and fixed the problems, then they may be a candidate. And then, finally, patients who've got significant cognitive impairment-- I've put on there non-progressive. So typically, patients with, you know, progressive dementias are not likely to be a candidate, because they're likely to steadily get worse. But patients who have a stable significant cognitive impairment, so either congenitally or because of a traumatic brain injury or stroke, as long as they've got the support system, so a strong family system, somebody that can make sure that they're able to, kind of, adhere to the transplant regimen, they may, again, potentially be candidates.

So the take-away points are that, you know, decisions about transplant candidacy can be difficult. We try to kind of go back to a team approach to try to tackle those tough problems, because a lot of these do come down to best judgments, and we're trying to balance, you know, doing the best for the patient, trying to make sure we're making a good use of a very precious and scarce resource. And the bottom take-away point, I think, is that there are many nuances to transplant candidacy, and so if in doubt, refer. We'll take a look. Thank you.

[APPLAUSE]

Questions? Yes?

SPEAKER 2: I have a patient who is-- just got married. She's 27 and interested in getting pregnant. She'd been made active at another clinic and they've kind of had a negative reaction to that idea. How would you, then, [INAUDIBLE]

SPEAKER 1: So I mean, many times-- I mean, in terms of a successful pregnancy, someone who's transplanted is likely to do a lot better with that than somebody who's on dialysis. Typically, we would recommend that they usually wait for some period after the transplant to ensure stability, say, you know, a year or so. But it's definitely possible, and, although, a number of the medications are, you know, officially contraindicated for pregnancy, there's a lot of history, a track record of successful and safe use. Then we may make some switches in their regimen, but it's absolutely doable, and they're much more likely to have a successful pregnancy outcome with a functioning kidney.

Any other questions? Yes?

SPEAKER 3: Is there a specific year span for certain types of cancer?

SPEAKER 1: Yes. So the wait periods for various cancers is-- it can vary and it does vary, and for some, it's not even entirely clear what it should be. But the bottom line is that it is highly variable based on the cancer. There are some scenarios-- and also, the stage of the cancer, so both the type and the stage of the cancer. So some we can-- actually, does not require any wait period, and some may require five years or more, and some may require, say, two years. Now, that's our typical kind of thing, and it all just kind of depends on the particular cancer. So there's a lot of nuance to it. So it's hard to know.