American Diagnosis Podcast
Season 4 Episode 10: Stewardship Over Biodata Rebuilds Trust
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TRANSCRIPT

Céline Gounder: Back in 2020, when covid first showed up in his part of Washington state, Dr. Dakotah Lane wasn't worried.

Dakotah Lane: I'm Dakotah Lane. My Indian name given to me by my grandparents is Me-Musia. I'm a physician out at the Lummi Tribal Health Clinic, and I'm the executive medical director of this clinic.

Céline Gounder: Dakotah is also a member of the Lummi Nation. He had seen viruses like the H1N1 flu flare up and then fizzle out.

Dakotah Lane: And then all of a sudden it showed up in Seattle. And it went from this kind of joke — you know, "coronavirus, haha"; you know, "why don't we get a Corona beer?" type of thing — to all of a sudden like, "Oh my gosh, this is a pretty big deal."

[Light, bouncing, instrumental music plays softly.]

Céline Gounder: By March, the Lummi Nation had its first reported case of covid. The pandemic had reached the tribe.

Dakotah Lane: Even if you think about yourself and America in general, like we were really scared. We wanted something to protect us.

Céline Gounder: Soon after, Dakotah's team got a call. It was the University of Washington. They were running a covid vaccine trial. The university wanted to bring in groups, like Indigenous people, who aren't usually included in clinical research.

When the Lummi Nation's public health director, Dr. Cristina Toledo, found out, she told Dakotah what she thought.

Dakotah Lane: I went to school with Cristina. We're very good friends, and she's like, "Dakotah, you have to do this because if you don't do it, the first argument people are going to say is these vaccine trials only benefit white people."

Céline Gounder: Roughly 80% of the participants in the Pfizer and Moderna covid vaccine trials were white. White people make up about 70% of the U.S. population. Meanwhile, Indigenous people, who make up less than 1% of the U.S. population, were disproportionately affected by covid. A CDC [Centers for Disease Control and Prevention] report found that American Indians and Alaska Natives were 3½ times [as] likely to get covid [as] non-Hispanic whites.

A lack of diversity in clinical trials can lead to less effective treatments and reduced trust. Dakotah knew there was a chance that this trial could help his people.

Dakotah Lane: If we're looking for a solution, we need to be at the table and part of the solution.

Céline Gounder: But getting the tribal leadership and the community's buy-in wouldn't be easy.

Dakotah Lane: The Lummi community itself has some level of trauma with being the ends of research, and they are just suspicious of any outside researchers.

['American Diagnosis' theme begins.]

Céline Gounder: Indigenous people are often underrepresented in clinical trials. Part of the reason for that has to do with how research has been done in the past. Dakotah says, for a long time, many researchers did not explain their findings to the community. Or the work framed Indigenous people in ways that did not represent their values, and there were often broken promises about the supposed benefits of participating in research. Some tribes have opted out of participating in any outside research. Others have banished researchers from their land, but some tribes have taken another path.

In this episode, we'll learn why many tribes are wary of participating in outside scientific research …

Krystal Tsosie: They were called the "vampire projects" because Indigenous peoples felt like researchers were coming to them like vampire bats or vampires.

Céline Gounder: What could be at stake if they're not included in medical research …

Krystal Tsosie: We could actually be causing medical harm to Indigenous peoples because we don't have their information or the inclusion of their data in data sets.

Céline Gounder: And how some tribes are finding ways to make sure when they do participate in research, it benefits their community.

Dakotah Lane: When you have tribes take control of their destiny, we can do great things.

Céline Gounder: I'm Dr. Céline Gounder. This is “American Diagnosis.”

[‘American Diagnosis’ theme fades.]

Céline Gounder: Dakotah decided at a young age that he wanted to dedicate himself to helping his tribe.

Dakotah Lane: I just didn't know how to do it. So I actually started off … I went to electrical engineering school and I did that for a while. Working for, like, AT&T and IBM, but I discovered quickly I was stuck in a cube and it wasn't really getting me to where I wanted to be able to serve Lummi.

Céline Gounder: After a few years in the Peace Corps, he decided to become a doctor. He graduated medical school and returned to Washington state, where he started working at the tribe's clinic.

But being a doctor — the field of medicine — brings up unsettling memories and connotations for some of the Lummi.

Dakotah Lane: So this woman came out and she took some pictures, asked some questions of families of suspected children with fetal alcohol [syndrome], and then left. Nothing was ever heard of it.

Céline Gounder: She published a study in 1991 based in part on her research at Lummi. She started to build a reputation as an expert in the topic.

Dakotah Lane: Lo and behold, in one of her presentations and workshops, she had a picture of a kid who had fetal alcohol syndrome, and the picture comes up, and an angry elder stands up and says, “That's my grandson! I did not know that this person had fetal alcohol syndrome.”

Céline Gounder: Those stories were passed down.

Dakotah Lane: I grew up hearing the story. I mean, even as a kid, I was like, “Oh man, that sounds bad.”

Céline Gounder: Dakotah says some of the Lummi told him that they felt that the researcher used the tribe to advance her professional career without any benefit to the community.

Dakotah Lane: You know, fast-forward to the pandemic and there's still that same level and same skepticism of research because we just are suspicious of other outside researchers coming in almost for professional gain at the expense of the community.

Krystal Tsosie: There's such a history of extractive research in Indigenous communities such that “research” and “science” are sometimes dirty words.

Céline Gounder: This is Krystal Tsosie.

Krystal Tsosie: *Yá’át’ééh. Shí éí Kinłichii’nii nishłi doo Naakaai diné’e bashichiin. Tó’dichii’nii dashicheii doo Tłizi’łaní dashinalí. Shí éí Krystal Tsosie yinishyé.*

Hello, welcome. My name is Krystal Tsosie. I just introduced to you in Diné bizaad, or the Navajo language, my name and all of my clans. I am a citizen member of the Navajo Nation and also I'm co-founder and ethics and policy director for the Native BioData Consortium.

Céline Gounder: Like Dakotah, Krystal was driven from a young age to serve her tribe. At first, she thought she wanted to study cancer. But then she started to wonder if it was the right fit.

Krystal Tsosie: If a drug that, you know, I spend my entire life as a scientist investigating even makes it to the marketplace, who is it going to benefit first? And, unfortunately, I had the realization that it would probably benefit people of affluence who had, you know, the best “Cadillac” health insurance plans. It probably wouldn't trickle down to benefit economically disadvantaged communities like my own.

Céline Gounder: Krystal decided that she needed to pivot. She decided to get a master's in bioethics instead.

Krystal Tsosie: I actually came back to Arizona State University, which was my alma mater, my undergraduate alma mater. And they were mired in the aftermath of this really seminal lawsuit, the *Havasupai Tribe v. the Arizona Board of Regents*.

Céline Gounder: It's since become one of the most prominent cases of tribal research gone wrong. The case sent shockwaves through research and academic circles. And the outrage came with a demand for restitution.

Here's what happened: The Havasupai live near the Grand Canyon in Arizona. In 1989, a member of the tribe asked a researcher from Arizona State to study if the high rates of diabetes among the tribe were because of their genetics.

Krystal Tsosie: Which is something that ravaged the community as many Southwestern communities are affected by diabetes.

Céline Gounder: Consent forms were signed and blood samples were collected from the tribe. But the research did not find a connection between diabetes and Havasupai genetics.

Krystal Tsosie: But then the community was shocked to realize that their samples were being used to study other things with some stigma attached to it, like, for instance, schizophrenia. The word "inbreeding"￼ had been used in publications.

Céline Gounder: The Havasupai blood samples were also used in genetic studies that tracked the movement of people over generations. Some results from those studies challenged the tribe's origin narrative.

The Havasupai banished all Arizona State University professors and employees from their land after they found out. In 2004, the tribe sued Arizona State for $50 million in damages. The New York Times reported that the Arizona State geneticist says she obtained the right permissions. The lawsuit was settled in 2010, and the samples were returned to the tribe.

[Soft music fades.]

Céline Gounder: Cases like the Havasupai are an example of why some tribes don't want to participate in research. But Krystal says for those who do, there is real potential benefit. Knowing more could lead to better care.

Krystal Tsosie: Just to give you an example of, like, warfarin dosages, right?

Céline Gounder: Warfarin is a common blood-thinning drug. It's prescribed to prevent blood clots, which can reduce the risk of stroke or heart attack.

Krystal Tsosie: But for many years, we didn't have enough information from Indigenous peoples. And what we learned a few years ago is that warfarin dosages should be lower for people who are Native American. So we've actually been overdosing these individuals and perhaps giving them negative health outcomes. But that's not to say that the answer is to just recruit more Native American peoples.

Céline Gounder: Krystal says one of the assumptions that keeps coming up is that Indigenous people are interchangeable.

Krystal Tsosie: And just in the U.S. alone, there are over 574-plus federally recognized tribes. 574! That doesn't include the state-recognized tribes or people that have been displaced from outside of the U.S. into the U.S. So there's a huge amount of diversity of Indigenous peoples that people don't understand exists.

Céline Gounder: So Krystal wants to see different kinds of research. Not just genetics but environmental and social factors, too. She says the research must be done in a way that doesn't leave Indigenous people feeling exploited.

There are systems set up at research universities that are supposed to do just that. They're called institutional review boards or IRBs. Here's Dakotah Lane again, the executive director of the Lummi Tribal Health Clinic.

Dakotah Lane: There's no way, as a clinic, I could rely on the IRBs that are relied upon by academic centers. It just doesn't have that level of trust from the community.

Céline Gounder: But the Lummi Nation has its own review board: a tribal one, run by the Northwest Indian College.

Dakotah Lane: And the difference between tribal IRBs and academic IRBs: Academic IRBs only look at the patient. They look at the harms done to patients individually. Academic IRBs do a terrible job of looking at the harms done to communities.

Céline Gounder: When the covid vaccine research team came to Dakotah inviting the Lummi to participate, he knew they’d need the blessing of the tribal review board.

Dakotah Lane: And so, here we are, we just went through this extensive review process, from scientific review from the Northwest Indian College to the community review with our health commission, which is staffed with a lot of our elders, to the ultimate authority of the tribal council. And a week later, all of this sensational data comes out *[Dakotah laughs]*, and so then it was, like, “Ah, crap.”

Céline Gounder: When we come back, we'll hear what happened in Dakotah's vaccine trial, and how it has shaped the Lummi Nation's relationships with outside researchers. That's after the break.

[Intriguing piano plays in the background, then fades to silence.]

Céline Gounder: Pfizer, Moderna, Johnson & Johnson, and AstraZeneca all had vaccines racing to market in the fall of 2020. Dr. Dakotah Lane, the Lummi executive medical director, was working with the University of Washington to host a covid vaccine trial. It was set to start that September.

Dakotah Lane: And ultimately we ended up getting assigned the AstraZeneca vaccine.

Céline Gounder: Dakotah worked with colleagues at the University of Washington, the tribal college's review board, AstraZeneca, the Lummi Tribal Council, and another tribe nearby who would also participate, the Nooksack. Finally, the trial was approved.

Dakotah Lane: However, I kid you not, the week after we approved it, all of these sensational data came out that was published in the media, particularly around transverse myelitis.

Céline Gounder: Transverse myelitis is a rare neurological condition where the spinal cord becomes inflamed. Dakotah says the community was also wary about the safety of the vaccine. A town hall meeting was held over Zoom to answer questions.

Dakotah Lane: You know, all these comments would be, “How much did they pay council for this? I don't want to be guinea pigs.” And probably the most hurtful or harmful to me was comments from a few of my relatives, you know, [a] nephew, “Why are you doing this to us?”

Céline Gounder: Dakotah says poor communication with AstraZeneca complicated matters. He says he reached out to the study leaders and asked for more information.

Dakotah Lane: And we were like, “What's the actual data on this? Tell us.” You know, like, “Is it one in a million is a one in a thousand, you know, what are you seeing?” And they just, they just were silent.

Céline Gounder: KHN reached out to AstraZeneca. A spokesperson for the company declined to comment.

In the end, the Lummi Nation decided to pull out of the trial. No one from the tribe received the AstraZeneca vaccine. Dakotah says he was fine with the decision.

Dakotah Lane: You know, Lummis and American Indians were always last to the table. We're always last in line to get these fancy new drugs and, you know, I saw this as bringing this opportunity to the community and giving them a decision. And in this case, they said, "No." Which is just as powerful as saying yes.

[Music stops.]

Céline Gounder: Diné geneticist Krystal Tsosie is working to find other ways tribes can take control of the research process.

Krystal Tsosie: Tribes should have ownership and stewardship over their own data first and it should be researchers that should be requesting access to that data. Not the other way around.

Céline Gounder: The solution Krystal and a group of other Indigenous scientists and leaders came up with is the Native BioData Consortium. It's controlled by a tribal government and operated on tribal land by the Cheyenne River Sioux Tribe. It's a nonprofit.

Krystal Tsosie: There's no bio-prospecting or bio-commercialization or cooptation of data. The benefits are directly rolled back into the people and their communities.

Céline Gounder: When the biobank opened, Krystal says, there was a lot of interest from pharmaceutical companies.

Krystal Tsosie: And really their questions were, "What type of data do you have and what can we get access to?"

Céline Gounder: Krystal says the companies wanted access to their data sets to study common diseases in the United States. But the Native biobank wanted assurances that if the data were coming from Indigenous people the companies would prioritize Indigenous health needs.

Krystal Tsosie: And the answer was always the same from pharmaceutical companies. "Oh, well that wouldn't be commercially viable. That wouldn't be profitable" because [of] the fact that Indigenous peoples in the U.S. constitute 1%-3% of the population. It's not a huge market share.

Céline Gounder: So the Native BioData Consortium said "No" to those offers. Instead, Krystal says, the biobank only works with researchers who are willing to study the things the tribe wants.

Krystal Tsosie: It's been something that is great because now we have community members being active participants in the research process. And they're actually able to see not only transparency in the research process and demystifying the whole ordeal, but also, you know, feeling like they have more buy-in into the research product. So that they can actually understand that, yes, this is — the benefits of this are being rolled back into the community.

[Soft upbeat music begins.]

Céline Gounder: The Lummi Nation's experience with the covid vaccine trials did not end with AstraZeneca. The tribe participated in another trial — this time with the company Novavax.

Dakotah Lane: Ultimately this was a huge success. We ended up enrolling 64 patients, but it was quite effective. And so that was really amazing in my mind.

Céline Gounder: Dakotah says transparency and open communication with Novavax made the trials much easier.

Dakotah Lane: We received all this information from Novavax. They had nice little media handouts and how it works. We could give it to the community members. We could answer questions and we can answer them with accuracy and with data.

Céline Gounder: That might sound like a low bar when it comes to expectations for medical researchers — but it made a difference.

Dakotah Lane: It's almost like reassuring the community.

Céline Gounder: Do you feel like this experience with Novavax, a more positive experience, helped repair some of the past wounds with unethical research and show that there's a, quote, “right way” to do this?

Dakotah Lane: Oh, definitely. I can say with 100%. Having that as our win — that really cemented the trust that we can do this in a right way.

Céline Gounder: Dakotah says the tribe is planning on participating in a long-covid study with the National Institutes of Health, and a pilot project to treat methamphetamine addiction without prescription drugs, among others.

Dakotah Lane: When you have tribes take control of their destiny, we can do great things. When tribes are in control of their health and research, when they're in control of public policy, we can demonstrate that public health works.

[Music fades and ‘American Diagnosis’ theme begins.]

Céline Gounder: This season of "American Diagnosis" is a co-production of Kaiser Health News and Just Human Productions. Additional support provided by the Burroughs Wellcome Fund and Open Society Foundations.

This episode of "American Diagnosis" was produced by Zach Dyer and me. It was engineered by Zach Dyer. Special thanks to Bonnie Duran.

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I'm Dr. Céline Gounder. Thanks for listening to "American Diagnosis."

['American Diagnosis' theme fades to silence.]