The Breakthrough Freeze-Dried Vaccine That Transforms Accessibility

Announcer:

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Rebecca Griffin - Host:

Associate Professor Danielle Stanisic, welcome to HealthTech Talks.

A/Prof Danielle Stanisic - Guest:

Hi, Rebecca. Thank you for having me. It's great to be here.

Rebecca Griffin - Host:

Danielle, you're a principal research fellow at the Institute for Glycomics here on the Gold Coast. You are an immuno parasitologist and the co-lead researcher for the Malaria Vaccine Project at the institute. It's really wonderful to have this opportunity to chat with you, and I can't wait to hear more about what you do.

A/Prof Danielle Stanisic - Guest:

Thank you, Rebecca.

Rebecca Griffin - Host:

As we just mentioned, you're the co-lead researcher in Malaria Vaccine Project. For those of us who might not know, what is malaria and how common is it in Queensland and I guess the whole of Australia?

A/Prof Danielle Stanisic - Guest:

Malaria is a disease spread by mosquitoes and it's caused by parasites of the genus Plasmodium. It typically starts out with symptoms similar to the flu, so fever, headache, chills, cough, but in people who don't have immunity like your eye or young children who live in these areas with lots of malaria, it can rapidly progress to severe disease and even death. Many people don't actually realize that malaria is still a major global public health issue. There are over a quarter of a billion cases of malaria each year and over 600,000 deaths. Most of these deaths are in young children under the age of five.

There are actually eight different malaria parasites that can infect humans. People may have heard of Plasmodium falciparum. This is the most deadly malaria parasite, and it can cause severe malaria syndromes like cerebral malaria or acute respiratory distress or multiorgan failure. Plasmodium vivax is another parasite people may have heard of and not realize. This one has the ability to hide and lie dormant in your liver, and it can make you sick months or even years later after the initial infection. That's what happened to me.

I contracted malaria with this particular parasite up in Papua New Guinea and wasn't sick until six months after I left Papua New Guinea and was living in New York and ended up spending a week in

hospital in New York. I was obviously very lucky to have access to great healthcare over there, which unfortunately a lot of people who live in malaria endemic countries don't have access to. There are also a couple of malaria parasites that we call zoonotic malaria parasites because they primarily infect monkeys, but in recent years have also been shown to infect humans in parts of Southeast Asia and South America.

Rebecca Griffin - Host:

When you got sick with malaria, is that before your research started?

A/Prof Danielle Stanisic - Guest:

That was during my research, and embarrassingly, I thought I actually had the flu. Because as I mentioned earlier, initially it starts with flu-like symptoms and there was a lot of flu going around in New York at that time. It was people that I was working with and my boss who were basically like, "Danielle, I think you've got malaria. We should take you down to the hospital." By that point, I think that I wasn't particularly thinking straight. At night, I was having chills and fevers that were so bad that my bed would shake.

I actually am very lucky that I worked with people who work on malaria, so they were able to recognize it for what it was. As I mentioned, I was taken to the local hospital. Despite my travel history, they wouldn't recognize that I had malaria initially, tested me for things like meningitis. Eventually they gave me anti-malarial drugs, and it wasn't until two months later that I actually got an official diagnosis from the New York Public Health Unit.

Rebecca Griffin - Host:

You have firsthand experience with this?

A/Prof Danielle Stanisic - Guest:

Yes.

Rebecca Griffin - Host:

Is it more common in Northern Queensland or where is it most common here?

A/Prof Danielle Stanisic - Guest:

We don't actually have local malaria transmission in Australia. We were declared malaria free in 1981, but we do have the right mosquitoes up in the northern parts of Australia that are capable of spreading the malaria parasite. With climate change, for example, we might expect the distribution of those mosquitoes to increase. I mentioned we don't have local transmission, so all of the malaria we do see in Australia is imported. There are about five or 600 cases of malaria every year in Australia, mainly in people who've become infected overseas and then bring it back into Australia.

Now, if they were to live in a region with the right mosquitoes, this could actually result in a localized outbreak. I think it's important to mention that even though we don't have this local transmission, I don't think we can actually afford to be complacent in Australia because many of us travel for work or

go on holidays. Many of our neighboring countries like Papua New Guinea to the north have a lot of malaria. And in the end, we are all part of a global community and I think we have a responsibility to assist these countries impacted by this dreadful disease in whatever way we can.

Rebecca Griffin - Host:

If someone comes home from overseas and they have malaria, they can't give it to another person. It's just that if the mosquito was to bite them and get it. Is that how...

A/Prof Danielle Stanisic - Guest:

Yes. If they were bitten by the right mosquito, and I should stress, there are many different types of mosquitoes in Australia. Not all of them can spread the malaria parasite. If they were bitten by the right mosquito up in the northern part of Australia and the mosquito were to take up parasites in the blood that they take from the human host, yes, they could transmit malaria to somebody else.

The other concern would be if somebody were to come back with malaria and then donate blood. But having said that, Australian Red Cross Lifeblood have very strict protocols and very strict questionnaires around travel history to make sure that that sort of thing doesn't happen.

Rebecca Griffin - Host:

Your research project, what is that all about?

A/Prof Danielle Stanisic - Guest:

The research program that I co-lead is focused on developing a highly effective malaria vaccine. In the human body, the malaria parasite exists in different forms and in different organs. Our vaccine targets a parasite form that's in the blood inside the red blood cells. This is a form that makes people sick and ultimately can result in death if the person isn't immune and isn't treated promptly with drugs. There is already a malaria vaccine called Mosquirix that has been licensed in some African countries and it targets a parasite form in the liver.

Although it's been recommended for use in children in Africa who are at high risk, it only has a moderate effectiveness of less than 40% and the protection wanes pretty quickly. For that vaccine, yearly boosters would be required. Our vaccine approach is very different to Mosquirix and most of the other vaccines currently in development. Most of the vaccines are what we call subunit vaccines. They generally have one or two proteins, so just very small parts of the parasite.

These vaccines haven't worked very well when tested in the field for a number of reasons. The main reason is that the malaria parasite proteins included in the vaccine don't always match very well with the parasite strains that people are exposed to out in the field. Basically these vaccines don't protect well against these mismatched parasites and that's why they're not very effective. Our vaccine is very different as it actually contains the whole malaria parasite in the vaccine.

All parasite proteins are in the vaccine. Some of those will be found in all parasite strains. The main advantage to our vaccine approach is that it will, we hope, induce a very broad immunity against all the different parasite strains, and our preclinical study so far have supported this.

Rebecca Griffin - Host:

What stage is the trial at?

A/Prof Danielle Stanisic - Guest:

We have completed a pilot clinical study for our whole parasite vaccine here on the Gold Coast at the Griffith University Clinical Trial Unit. We're so lucky we can actually make our vaccine and evaluate it onsite here on the Gold Coast. In this study, we vaccinated volunteers who had never been exposed to malaria, and then we infected them with malaria parasites to see if the vaccine stimulated an immune response that could stop the parasites growing in their blood. Just under half of the volunteers were completely protected, which was really exciting.

To our knowledge, that's the first time that a vaccine targeting the blood form of the parasite has completely protected. Unfortunately, that form of the vaccine has to be made fresh on the day it's administered, so that's not really suitable for malaria endemic areas. We have now remade or reformulated our vaccine so it can be frozen or freeze-dried into a powder. That's way more suitable for deployment in countries and regions with malaria. We hope to start our phase one trial for this field deployable form of the vaccine at the end of this year.

Rebecca Griffin - Host:

As we said, you're the co-lead researcher. What does that actually mean, Danielle?

A/Prof Danielle Stanisic - Guest:

I co-lead the Malaria Vaccine Program with Professor Michael Good. Overall, this role involves a lot of decision-making in relation to the direction of the research and to how we execute it. For example, deciding what vaccine candidate should progress through from preclinical studies into clinical trials, deciding when's the right time to take it into clinical trials, and is further optimization of the vaccine required before moving to the next step.

Then as the malaria lab team leader, I also oversee the lab and the lab work, and I'm responsible for making the malaria vaccine for our clinical trial work and measuring the immune response and volunteers. Stepping away from the lab for a little bit, I need to make sure that all of the necessary paperwork and approvals, like the ethics approvals and regulatory approvals, are in place for us to conduct our research and for clinical research and vaccine manufacture.

That's actually quite a large part of the workload. Sourcing funding continues to be a big part of my job and we've been very lucky so far to receive funding from the Australian government, from Griffith University, and philanthropists for our research program. In particular, we've been supported by Rotary, who formed a partnership with Griffith University to help raise funds for the upcoming phase one trial. It keeps me very busy and new challenges are always popping up, so it's never boring.

One aspect that I particularly enjoy is the opportunity to establish new collaborations for our research program. As well as the Malaria Vaccine Program, I'm expanding our research scope by applying those vaccine platforms that we developed for the malaria parasite to other parasites of veterinary medical importance. At the moment, this involves working with a closely related parasite called the Babesia parasite. This parasite infects humans, cattle, and dogs.

In Australia, it's a major issue for the cattle industry. We've been very lucky to be awarded a small ARC grant to undertake a cattle trial in collaboration with researchers at the University of Queensland. That will enable us to test a vaccine targeting the Babesia parasite, and that vaccine is very similar to the one we've actually developed for malaria.

Announcer:

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Rebecca Griffin - Host:

Danielle, why have you chosen to research malaria?

A/Prof Danielle Stanisic - Guest:

I discovered parasites during my undergraduate degree and basically fell in love. They are just so incredibly interesting and clever. It was during my third year, we were given a lecture on malaria parasites by a professor who worked at the Queensland Institute of Medical Research. I was immediately fascinated and knew that this was the parasite I wanted to work on. This parasite has infected humans since ancient times. Molecular methods have detected parasite DNA in Egyptian mummies.

No matter what we throw at it in terms of anti-malarial drugs or even our immune response, it finds a way to survive. I ended up approaching this professor about undertaking a third year project in his lab on malaria, and then eventually stayed on and did an honors degree and PhD. Afterwards, I was incredibly privileged to have postdoctoral positions at New York University, WEHI, and the Papua New Guinea Institute of Medical Research all still working on malaria.

It was during my time in Papua New Guinea that my decision to focus my research career on the malaria parasite was really clarified. I mean, up until then, like many people, I had read and quoted the horrific statistics associated with malaria. The reality didn't really hit home until I was working and living in Papua New Guinea where malaria is an issue every day, and I saw the dreadful impact this disease has on young children, pregnant women and their families and communities.

It was then that I knew I wanted to help develop a vaccine that would prevent and hopefully contribute to the eradication of this parasite and a vaccine that would save lives. And now 20 years on after my PhD, I'm actually back developing a malaria vaccine with that very same professor, Michael Good, who delivered that lecture to me back in my undergraduate degree.

Rebecca Griffin - Host:

Oh, what a great story. And also, I'm not sure I've ever heard anybody say that they are in love with parasites. Now, going on from that, you're an immuno parasitologist and I don't imagine this is a very common job. I've certainly not heard of that before. What led you into this specialty?

A/Prof Danielle Stanisic - Guest:

It may not sound common, but I think there are actually many people working on parasites that can call themselves an immuno parasitologist. Because broadly speaking, an immuno parasitologist studies the immunological interactions between the host and the parasite. For me, that basically means trying to understand the human immune response to the malaria parasite and then thinking about how that can help us design a vaccine and how it can inform its development.

My fascination with the malaria parasite is what led me into this field. It, like many parasites, can actually change itself to escape the human immune response. For example, when a malaria parasite invades a red blood cell, it inserts some of its proteins into the red cell membrane, and these proteins help it stick to blood vessels and the body, for example, different organs like the brain and the kidney and the lungs. And if you're pregnant, even the placenta.

That stops it from being eliminated by the spleen and helps it to survive. If a human develops antibodies against these parasite proteins on the surface of the red cell, it can stop it binding. But the malaria parasite is clever. It can actually switch its genes so that a different parasite protein is shown instead. If you've got antibodies, it switches its gene, changes the proteins. You may not have antibodies to these new proteins, and so it allows it to escape the immune response.

The malaria parasite can also stop our immune system from functioning properly. It can stop some of the immune cells from being able to kill the parasite. Recently it's also been shown that the malaria parasite can also affect our immune response in terms of how well we respond to vaccines. In many ways, we're only just starting to understand some of these mechanisms of immune escape and immune suppression, and it really is a very interesting time to be an immuno parasitologist.

Rebecca Griffin - Host:

Yeah, it really is. Did you study science?

A/Prof Danielle Stanisic - Guest:

Yes. I actually had a very traditional career path. I did an undergraduate bachelor of science, and I did my third year project on malaria, and then I did an honors degree, and then a PhD. And all of that was through the University of Queensland.

Rebecca Griffin - Host:

Was your initial intention in terms of doing that degree? What did you think you would do at the end of it? I

A/Prof Danielle Stanisic - Guest:

I actually always wanted to study medicine, and it was actually during grade 12 that I was selected to attend something called the National Youth Science Forum. And that involved going down to Canberra and visiting research labs. I visited the John Curtin School of Medical Research and saw scientists and all the experiments that they did, and I thought, hey, actually that's something I might like to do. Science is I guess in my background as well. My father is a scientist. He studies snails.

Rebecca Griffin - Host:

Snails?

A/Prof Danielle Stanisic - Guest:

Snails. I've always been around labs. I definitely made the right decision. I love my research career and I love science. I'm always fascinated and trying to find out new things.

Rebecca Griffin - Host:

Interestingly, the work you're doing is all around the human body, which is that link to medicine. It's really an interesting career. Your project is at the Institute for Glycomics here on the Gold Coast. How does malaria fit into the work of the institute, Danielle?

A/Prof Danielle Stanisic - Guest:

The overall research program at the Institute for Glycomics is focused on discovering and developing next generation drugs, vaccines, and diagnostics to fight diseases of global impact. I think our research program certainly fits within that scope as we're developing a vaccine against a disease that continues to have a devastating global impact. Unfortunately, over the last few years we are seeing that the number of malaria cases and deaths are increasing rather than decreasing.

There's certainly this urgent need to develop additional tools like vaccines to regain control of this parasite and ultimately eradicate it. The institute and university do provide a very supportive research environment. It is a multidisciplinary institute, which has its advantages. We've been able to draw on expertise from outside our lab. For example, working with some of the chemists in the institute to assist our research.

Rebecca Griffin - Host:

Danielle, the institute is based at Griffith Uni, which is co-located here in the Gold Coast Health and Knowledge Precinct, which is where we're doing our interview from this morning. What collaborations and partnerships for the project have come from within the precinct?

A/Prof Danielle Stanisic - Guest:

We've been very lucky to collaborate with the Gold Coast University Hospital over the last decade. Our clinicians from the Immunology and Infectious Diseases Department, including Dr. John Gerrard, who's now the CHO. Kylie Alcorn and Jim Fink and others have collaborated as investigators on all of our malaria clinical studies.

They're the ones that have had the responsibility for the clinical management of all of our participants. To be honest, without their involvement, we would not be where we are today with our research, and we are very grateful for their time and commitment.

Rebecca Griffin - Host:

Danielle, what other kinds of organizations would you like to collaborate with and why?

A/Prof Danielle Stanisic - Guest:

Ultimately, we would like to link in with organizations who have experience in vaccine manufacturing and/or who have manufacturing capability for scaled up vaccine production. Producing vaccines at scale for large clinical trials is very different to the small scale production we've been able to successfully undertake so far at Griffith University. Our vaccine manufacturing process involves growing the malaria parasite in human red cells and adding human plasma to the growth medium, and that provides nutrients to feed the malaria parasite.

It would be great to collaborate with a company like CSL or the Australian Red Cross Lifeblood who've got a particular interest in blood and plasma products. I mentioned before that we hope to start our phase one trial at the end of the year. And in that trial, we will demonstrate safety and hopefully that the vaccine stimulates an immune response. After that, we would hope to partner with an organization, potentially pharma, to take our vaccine forward into clinical trials in malaria endemic countries.

Rebecca Griffin - Host:

Lumina is the commercial cluster for Gold Coast Health and Knowledge Precinct. How can it support your work and advancement in life sciences industry?

A/Prof Danielle Stanisic - Guest:

I think Lumina could provide unique opportunities for collaborations and partnerships to progress our vaccine development program. This could be, for example, related to expertise in the vaccine manufacturing or clinical trial space or even investment to progress our vaccine to the next phase. I think it's very important to recognize that very rarely is research a linear path.

There are always a lot of challenges and diversions along the way, many of which we haven't even thought of yet. Innovative research often requires novel out of the box solutions. I think the expertise and the contacts within this community here at the Gold Coast Health and Knowledge Precinct are an invaluable resource for any research program.

Rebecca Griffin - Host:

Danielle, your research is fascinating and I can't wait to hear the outcome. Thank you so much for your time today.

A/Prof Danielle Stanisic - Guest:

Thank you very much, Rebecca.

Announcer:

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