# Episode 17 – New Era of Medicine: The Future of Vaccines

## With Dr. Lisa Morici

Diane (00:00):

What's in store for vaccines in the future? Well, leave it Vax Matters to answer the question.

Diane (00:13):

Hello there. Thank you again for joining us today. I'm Diane Deaton. So this Vax Matters episode covers a really intriguing topic, the future of vaccines. Now obviously, I can't tell you what the future holds for vaccines, but our guest today, Dr. Lisa Morici, certainly can. Dr. Morici is a professor at the Tulane University School of Medicine, focusing on vaccine mediated immunity against difficult infections, as well as vaccine discovery and development. Dr. Morici, thank you so much for taking the time to join us on this special episode.

Dr. Morici (00:53):

It's my pleasure. Thank you for having me.

Diane (00:55):

Indeed. So with the COVID-19, we saw the first widespread use of M, or messenger, RNA vaccines. Dr. Morici, are there any other new types of vaccines now being researched and developed?

Dr. Morici (01:12):

Yes, this is a really exciting time for the field of vaccinology. The COVID-19 pandemic was a, a, you know, a really great opportunity to show the world the power of the messenger RNA vaccines, but there are certainly other platforms that have been in development as long as that messenger RNA vaccines. It's taken us 30 years to get these vaccines to the point where they were ready for use in the human population. And so we have other vaccine technologies that are similar to the messenger RNA vaccines and we refer to these as plug and play vaccines. And what we mean by that is that once you have your platform or your technology like the messenger RNA, you can quickly adapt that technology to a different disease.

Dr. Morici (01:58):

So for example, the messenger RNA vaccine is the genetic instructions for making the spike protein from the SARS-coV-2 coronavirus. And it turns out that targeting the spike protein with our immune system is a great way to protect us from that virus. If another virus were to emerge and we knew which proteins to target on that virus, we can simply take the instructions for that protein and plug it into the messenger RNA technology and then we would have a vaccine that would hopefully be a f- highly effective against that new virus.

Dr. Morici (02:34):

There are other technologies out there like the messenger RNA vaccines. We have DNA based vaccines that are very similar. Those are nucleic acid-based vaccines as well. We have what are known as viral vectored vaccines. Those were the types of, uh, vaccines that you saw with the

Johnson and Johnson COVID vaccine, as well as the AstraZeneca vaccine. And we also have live recombinant vaccines that we're exploring for use against other diseases.

Diane (03:01):

Are there any certain vaccines that are more common? I don't know if that's the right question or not, or maybe more, used more. I, I, I love what you're talking about, your plug and play. I don't think I've ever heard of that terminology before. But could you talk just a little bit more about, uh, the DNA vaccines and the live recombinant? I'm not sure if I even repeated that or said that correctly from what you said, I repeated that correctly. But what, can you go into a little bit more detail on those if you don't mind?

Dr. Morici (03:31):

Sure. Sure, I'd be happy to. So with the advent of molecular biology and our ability to manipulate genetic material in the laboratories, this really opened up a whole new avenue of research for vaccine design. So typically, if you think about a traditional vaccine like the flu vaccine, that required us to grow a large amounts of a flu virus, inactivate that virus, and then purify it, put in the vials and then distribute it for use. And so when individuals would get vaccinated with the flu vaccine, we're actually injecting the inactivated flu virus into your arm. And we know, we've used these for decades and we know they are highly safe vaccines.

Dr. Morici (04:12):

But the problem with that manufacturing, uh, is that we, we, we have to anticipate which flu virus is going to circulate each year. And so it's sort of a race between our manufacturing abilities and the virus. We, we need to grow up the material, make the vaccine before the virus, you know, gets to the United States and then we have to get that vaccine into, into the arms of recipients.

Dr. Morici (04:36):

With these new plug and play technologies, all we simply have to do is plug in the genetic sequence for the proteins of the virus. And so we can make these a lot faster. And so I think the mRNA vaccine, for example, really showed us the utility of these plug and play vaccines which again, DNA vaccines, messenger RNA vaccines, viral vectored vaccines, they all fit inin- into this plug and play group. They really are useful in responding very quickly to a threat. Um, it may be that these technologies don't necessarily work against all infectious diseases. But they're, they've certainly shown their utility in combating, uh, viruses that have quickly emerged in the human population and, and are posing a threat globally.

Diane (05:23):

Doctor, a few minutes ago we were taking about, you were talking about the different phases of the trials of the vaccine, phase 1, phase 2, phase 3. And a- wu- could you explain a little bit what you're looking at in each of the phases before it's actually, uh, introduced to the public? That's fascinating how this is so very, very particular that is has three different phases before it reaches the public.

Dr. Morici (05:49):

Yes, absolutely. I'm, I'm happy to talk about clinical trials because I think it's really important that people understand how seriously we take, uh, safety, uh, you know, and how, how seriously we put safety first for any vaccine that might be authorized for use in the human population.

Dr. Morici (06:05):

And so obviously clinical trials are done before it's made available, um, t- to the general public. And so the clinical trials are typically done in phases where you have, uh, an early phase known as phase 1, followed by phase 2 and then followed by phase 3. And in phase 1, you enroll typically a few dozen individuals. Usually no more than a hundred. And what you're looking at is safety of the vaccine in the, in the, in the folks that have volunteered to participate in the trial and you're looking for, um, immunogenicity. And what we mean by immunogenicity is does the vaccine induce the desired immune response that you think is associated or needed for protection.

Dr. Morici (06:49):

So for example, if we use the COVID vaccine clinical trials as, as an example, in the phase 1, uh, clinical trials, we were first making sure that those messenger RNA vaccines were safe, that they didn't induce any severe side effects in the majority of individuals or even in, eh, in, in a few individuals. And then we were also looking at, at dosage.

Dr. Morici (07:12):

So any time we introduce a new platform, like a vaccine, we, we don't necessarily know what target dose is needed to induce an antibody response or a T-cell response. And so in phase 1, this often gives you an opportunity to look at, okay, I'm gonna pick three different doses, let's say 50, 100, and 200 mcg for example, of messenger RNA and I'm going to study how much each of those induces an antibody response and what the side effects are to each of those doses. And then you can make sure that you're using the least amount of material to cause the least amount of side effects, that that gives you the most important n- and robust immune response.

Dr. Morici (07:57):

So it may be that the lowest dose isn't immunogenic enough, but the highest dose could be, you know, the side effects are unacceptable. And so you might go with the middle dose and heh-

Diane (08:07):

Mm-hmm.

Dr. Morici (08:07):

... and sort of say "This is giving us a decent immune response and the side effects are acceptable. And when we talk about accep- acceptable side effects, we're talking about things like, you know, I don't feel good. I have some redness in my arm. I might have a little bit of a fever. Um, that's, that's what we expect from most vaccines. And that's simply your body responding to the vaccine in a appropriate manner.

Diane (08:30):

Yes.

Dr. Morici (08:30):

Because-

Diane (08:31):

Yeah.

Dr. Morici (08:31):
... all vaccines are designed to induce an immune response.

Diane (08:34):
Mm-hmm.

Dr. Morici (08:34):
And an immune response is an inflammatory response. And any time you have inflammation, you're gonna not feel great. But it's an acceptable and appropriate immune response to the vaccine.

Dr. Morici (08:45):
Um, if we're seeing people passing out, that would be an unacceptable-

Diane (08:49):
(laughs)

Dr. Morici (08:49):
... immune response and that dose would be considered-

Diane (08:51):
Yeah.

Dr. Morici (08:51):
... too high and taken off, um, from further clinical trials. And so-

Diane (08:55):
Need to be adjusted.

Dr. Morici (08:56):
... the phase 1-

Diane (08:56):
Yes. Yeah.

Dr. Morici (08:57):
... yeah, the phase 1 is sort of a, you know, a, a, a, a trial period in a-

Diane (09:01):
Okay.

Dr. Morici (09:01):
... few individuals and those individuals are carefully monitored, um, to make sure that they're getting all of the I'm- you know, all of the, uh, all of the checks and balances are there. Those people are,

are offered, you know, um, great, great medical follow-up, uh, when they participate in a clinical trial. Once the phase 1 clinical trials, the data looks good, then you can proceed to a phase 2.

Dr. Morici (09:22):

A phase 2 is where you greatly expand the number of people that you enroll in the trial. So now you're talking about a few hundred to a few thousand volunteers. And in this situation, you've probably decided on the dose that you're gonna use and you're doing more extensive testing for safety and immunogenicity. So making sure the majority of people who are vaccinated are not showing any unacceptable side effects and that they're inducing the immune response that you anticipate the vaccine will, will create.

Dr. Morici (09:53):

And then finally, you move on to phase 3. Now, phase 3 is often where a lot of vaccines, um, fail. And-

Diane (09:59):

Oh.

Dr. Morici (09:59):

... and what people probably don't appreciate is they, it's not necessarily that they fail b- because of safety. They wouldn't have made it to phase 3 if they're not safe.

Diane (10:07):

Right, right.

Dr. Morici (10:08):

They typically fail in phase 3 because they don't protect. And so this is where you-

Diane (10:12):

Oh.

Dr. Morici (10:13):

... this is where efficacy comes into play. This is where you're looking at how well does the vaccine protect you from the disease that it is intended to prote- provide protection for. And so this is where, for the COVID vaccines, we heard the FDA w- wa- was telling the vaccine manufacturers "We expect 50% efficacy or greater in order to authorize this for use in the population. If it's less than that, we, we may not, you know, we may not authorize it." And this is where we were super excited because the messenger RNA vaccines gave us 94 and 95% efficacy.

Diane (10:47):

Wow.

Dr. Morici (10:48):

It was just, it was just amazing how well they worked.

Dr. Morici (10:51):

Um, and so those are the, those are your typical ways that a vaccine proceeds through clinical trials before the FDA will even consider it for emergency use authorization and ultimately approval for licensure. And even after those clinical trials, all vaccines are carefully monitored through numerous mechanisms for safety and any adverse events that they might cause in extremely rare circumstances like one in a million or one in 10 million that the clinical trials simply don't have enough people in them to, to, to detect those rare events.

Diane (11:27):

A- and you know what was so interesting to me when you're talking about the different phases, I would just be a member of the public and getting my information from my, from my doctor and from experts such as yourself, you would think that once a vaccine got to phase 3 that it would be just almost a no brainer that it would be approved and go on. But as you said, it was the efficacy. And that, I have to tell you, you know doctor, that was a new word for a lot of us when we were talking about COVID-19. Everything was about the efficacy of the COVID-19. Will it work w- long term? What are we talking about all these people? So you, I, uh, I appreciate you explaining and taking the time, you know, today to explain that on our podcast what that means.

Diane (12:12):

Now, another question that I have relating to, uh, the different clinical trials and the phases, what, what is the length of time? Eh, the, kinda the turn around? Does it, does, does it depend on the vaccine? On the disease you're looking for? What, how, what is an appropriate amount of time? Is, uh, is it different with each, with each disease or each vaccine?

Dr. Morici (12:36):

That is a great, great question. And typically, from the time a new vaccine is discovered or invented till the time it is authorized for use in humans, the average period for most vaccines is a minimum, uh, of 10 years.

Diane (12:52):

10 years.

Dr. Morici (12:53):

10 years.

Diane (12:54):

Oh my goodness.

Dr. Morici (12:57):

And-

Diane (12:57):

I did not know-

Dr. Morici (12:57):

... and-

Diane (12:57):
... that.

Dr. Morici (12:57):
... and, and there is a huge financial investment by the, by the pharmaceutical companies to get that vaccine into licensure and we, and we've already s- talked about how most vaccines, despite the length of time and the amount of money that goes into backing those vaccines, most vaccines will end up failing. And so there's a lot of financial risk on the part of the manufacturers and the pharmaceutical companies who are, who are developing vaccines.

Dr. Morici (13:22):
And so if we think about the COVID pandemic-

Diane (13:25):
Mm-hmm.

Dr. Morici (13:25):
... a-

Diane (13:26):
Mm-hmm.

Dr. Morici (13:26):
... lot of individuals were very frightened by the rapid production of these vaccines, and they thought "Well, you know, these things have just magically appeared and now they're being, you know, they're telling us to put these vaccines in our bodies. I don't trust this for a second because, you know, Lisa just told us that, you know, vaccines typically take 10 years from discovery to, to licensure. How is this possible?"

Dr. Morici (13:51):
And so what's, you know, what's important to realize is that there are a number of var- of variables that go into vaccine development and eventual use in humans. The first is, is money. It always comes down to money. Who-

Diane (14:03):
Doesn't it always. Yeah.

Dr. Morici (14:04):
... who is, it always does-

Diane (14:06):
Yeah.

Dr. Morici (14:06):

... right? So who is backing the financial risk? And, and for the development of this vaccine? And so in, in a typical scenario, that's the pharmaceutical company. That's whoever owns the rights to the vaccine. They're putting all of that money into that, in the, into that vaccine. And so they're gonna do it slowly. They're gonna take their time with their phase 1. Make sure it works before they even start on phase 2. And they're not, and, and when you think about each of these phases like we talked about, as you move through the phases, the number of people enrolled in those phases increases. So the number of vaccine vials that you have to manufacture increases. So your cost increases. And so you can imagine in a typical situation the manufacturer is going to proceed slowly. They're going to take their time. They're gonna make sure that as they proceed through these clinical trials that, that they're getting positive results before they even start to scale up manufacturing so that they can reduce millions of vials.

Dr. Morici (15:06):

Um, the other thing is that you need volunteers for these clinical trials. So are pil- are people willing to enroll in your vaccine clinical trial? For COVID, people were willing. People wanted to help. We were desperate for vaccines to save lives. And so we had terrific people step up and say, "I wanna be, I wanna play in this, you know, I wanna, I wanna be a part-

Diane (15:27):

Mm-hmm.

Dr. Morici (15:28):

... and play my role. I wanna, I wanna get vaccinated." And so we had volunteers lining up immediately for the clinical trials for the COVID vaccines. That may not necessarily occur as quickly with a vaccine for another disease.

Dr. Morici (15:41):

And then, um, finally, to, to assess efficacy in phase 3 clinical trials, you need disease. You need circulating disease to tell you if the vaccine is working. So if you think about COVID, there was a lot of disease circulating around the globe, so we were very quickly able to determine efficacy in clinical, in phase 3 trials because the minute people were getting vaccinated, people were either getting infected or not getting infected with the virus. So we knew very quickly that it was working. As opposed to something like Zika. We have, you know, vaccines n- and clinical trials for Zika virus, but it's very hard to assess vaccine efficacy because Zika basically disappeared. And so we're not seeing Zika cases like we saw with COVID. And so it takes much more time to gather the data in phase 3.

Dr. Morici (16:33):

And so while the COVID-19 pandemic demonstrated our ability to rapidly and quickly, um, get a vaccine into, in, you know, f- into the public, uh, population for protection against a disease, it, it certainly showed what we're caple- of, ca- capable of doing. There was also, sort of, the perfect situation where the financial risk was mitigated by the government. Um, people were willing to line up, you know, for, for clinical trials, and the case rates of disease were so high that we were able to assess efficacy very fast.

Diane (17:07):

And-

Dr. Morici (17:07):

And so for all of those reasons, um, we were able to, you know, to move the vaccine much, much faster than we would in, in other scenarios.

Diane (17:16):

And the virus was so plentiful. (laughs) It was everywhere. So with all of those that you were saying that was pretty much coming together in a short period of time, a perfect storm so to speak.

Dr. Morici (17:29):

That's absolutely right. That's absolutely right.

Diane (17:32):

Well that's, it was interesting too when you were talking about, you know, the vaccines and the developments and 10 years, but with this, with the COVID it was much faster. Do you think in the future, maybe, I don't know if it's already happening or maybe in a perfect world, can we start seeing vaccines being developed faster than in the past? Or is it always going to develop on how plentiful the virus is or what we're, we're trying to, t- stay healthy from?

Dr. Morici (18:01):

Yeah. So I think, you know, the plug and play technologies have certainly shown their, um, utility in rapidly responding to, to something that might emerge that we're not expecting or a closely related, uh, virus like another coronavirus or, a, a, and influenza virus that we, you know, that we've never seen before. Um, and so I think, you know, these, these technologies, um, by their nature are more amenable to going fast as opposed to having to isolate the virus, coronavirus in lar- in large batches. But again, it, it will come down to, um, you know, who- who's going to finance the, the manufacturing, who's going to conduct the clinical trials, finance the clinical trials. Are we going to get people to volunteer in those clinical trials? And is there enough of the virus or the bacteria circulating in the population that we can very quickly determine the efficacy.

Dr. Morici (18:58):

Um, you know, in some circumstances that may be the case. And in others it won't be. Um, but it certainly, you know, the COVID pandemic shows us that when we put our minds to it and we come together, um, we can do things, you know, very, very well and, and very fast.

Diane (19:14):

Absolutely.

Dr. Morici (19:14):

Um, but unfortunately for other diseases, it, that hasn't been the case.

Diane (19:18):

You mentioned, uh, you touched on a, just a, a few minutes ago about, uh, the possibility of some promising cancer vaccines that we may be seeing in the near future. Could you elaborate on that a little bit more, doctor?

Dr. Morici (19:32):

Yeah, sure. I can talk about a few. Um, I, I, I primarily focus on vaccines against infectious diseases. But when you think about cancer vaccines, you can think of them in two different categories. So we have preventive vaccines against cancer. And then therapeutic vaccines. So what do we me- mean by that?

Dr. Morici (19:49):

Preventive vaccines would be you vaccinate someone to protect them from ever developing cancer. And we actually have vaccines already that do that. So the HPV vaccine, the human papillomavirus vaccine which we, um, you know, uh, recommend for, uh, young adults, um, and in young, you know, young, basically young adults that the, this vaccine is, is remarkable because it can prevent cervical cancer from developing in individuals. Another example of a preventive vaccine for cancer is the hepatitis B vaccine. Because we know hepatitis B virus can ultimately cause liver cancer in an individual. So just simply by getting these vaccines, you can protect yourself from ever developing s- certain cancers.

Dr. Morici (20:37):

Um, in terms of therapeutic cancer vaccines, uh, we actually use the vaccine that is, um, u- utilized globally for the prevention of, uh, childhood tuberculosis which is known as the BCG vaccine. This is a vaccine that is used to treat bladder cancer here in the United States which has-

Diane (20:57):

Really? I hadn't heard of that. Wow.

Dr. Morici (20:59):

It sure does. Yeah. It has great, what we call, immunomodulatory effects. It means it helps provoke, promote healing in the bladder as well as prevention of, of tumor recurrence. And so we utilize that B- that BCG vaccine for something that it was never even intended to be used for. And it just shows you sometimes the power of, um, o- of vaccines.

Diane (21:23):

Incredible.

Dr. Morici (21:24):

And then we also have a vaccine for prostate cancer which is one of, um, our newer technologies that we think about. We, we term these precision, uh, vaccines or more personalized vaccines. So these are vaccines that actually use the cells from a specific individual. We take those cells out of the, out of their body, we manipulate them in the lab and then put them back in their body so that they can cau- can promote their immune system to fight the cancer in their body. And so this prostate, um, you know, therapeutic vaccine is one of the examples of, um, how immunology and our understanding of the immune system is helping us now, uh, fight tumors and other cancers, eh, ih- in the body. So I think we're gonna see a lot more in the future, um, in terms of not only vaccines, but, but tools like, uh, CRISPR gene editing where we can actually go in and, and treat diseases either by removing or adding, um, segments of genes, um, that are either causing disease or absent and, a- and cause disease.

Diane (22:31):

What an incredibly exciting time. When you're talking about all the research, what we have learned from the past, how we're taking that going forward to make it, you know wr- the children, our children's generation, our grandchildren's generation. This is gonna be a whole different ball game, doctor.

Dr. Morici (22:50):

Yeah. I'm excited to see what the, what the future holds. Um, you know the, I think the, the, the newer generation, you know, has grown up in a society where they've, you know, with the exception of the COVID pandemic, um, where they were really sort of protected from infectious diseases. And if you talk to the older generations, you know, they remember things like polio and diphtheria and how-

Diane (23:12):

Indeed.

Dr. Morici (23:12):

... awful-

Diane (23:13):

Yeah.

Dr. Morici (23:13):

... those diseases were. And, you know vaccines have really saved us from some of the most horrific infectious diseases. And so applying these to, you know, newly emerging viruses or cancers, um, and, and possibly even things like fentanyl. Um, we have-

Diane (23:28):

Mmm.

Dr. Morici (23:28):

... vaccines that can actually prevent, um, overdose in-

Diane (23:32):

Heck yes.

Dr. Morici (23:32):

... animal models.

Diane (23:33):

Yeah.

Dr. Morici (23:33):

And so we might even be able to use vaccines to prevent, um, uh, you know, drug overdose which would be amazing.

Diane (23:39):

That would be truly amazing. A lot of people I know that I know that you've heard this, when we were talking about the vaccines for COVID, etc., and just, just your vaccine regimen that we have to have children and as adults, some people say, uh, "But I'm terrified of, of needles. I have a horrible fear of needles. I can't do this. I can't take a vaccine." So doctor, are there different types of vaccine delivery that's now being studied possibly?

Dr. Morici (24:09):

Yes. We do have other routes of delivery for vaccine administration. So we have, here, currently oral vaccines. So, uh, vaccines against cholera for example. Oral polio virus. Some of you guys might remember taking the, uh, oral polio virus-

Diane (24:25):

Mm-hmm.

Dr. Morici (24:26):

... uh, vaccine. We don't, uh, use that vaccine here in the United States anymore. We use the inactivated polio virus vaccine in a, in our pediatric population because we've eliminated polio from the western hemisphere until-

Diane (24:38):

Thank goodness.

Dr. Morici (24:38):

... quite recently-

Diane (24:39):

Oh my gosh.

Dr. Morici (24:39):

... where we've seen it circulating-

Diane (24:41):

Mm-hmm.

Dr. Morici (24:41):

... in major cities. Um, but, uh yeah. So there's oral vaccines. We've seen intranasal vaccines before. So we've had intranasal vaccines for flu virus. Um, but it turned out that, you know, that vaccine did not work necessarily any better than the inactivated flu vaccine that we get injected by needle into our muscle. We've heard a lot of talk about the development of either oral or intranasal vaccines for COVID to better promote, um, immune responses in our upper respiratory tract, like our nasal tract. Um, that would be an advantage because vaccines that are delivered mucosally, perhaps intranasally, for example, can prevent respiratory viruses from even, even colonizing in our nasal tract. And that would be really important, for example, to cut through, cut down on breakthrough infections-

Diane (25:31):

Mm-hmm.

Dr. Morici (25:32):

... and continued transmission of respiratory viruses. So I think we're gonna see a lot more in the future, um, with intranasal vaccines. Um, again, we do have oral vaccines. Sometimes delivering a vaccine orally is difficult because getting things through the stomach without them degrading is tricky, right? So stomach acids can chew up vaccines.

Diane (25:54):

True, yes. Yeah.

Dr. Morici (25:56):

Um, but there's a lot of interest in intradermal vaccines. So things like patches that you can put on the skin that contain the vaccine ingredients in the patch and you simply wear the patch and you don't feel anything and the, and the vaccine is getting delivered intradermally. Those are, those are in development as we speak. And, um, I think those hold great promise as well. And so for people who don't like needles or, or places in the world where it's difficult to get people, um, you know, to, to, uh, you know, to get syringes and needles, uh, out to rural villages, it might be, you know, much more easier to distribute patches and then just pass them out and people can self-apply them.

Diane (26:39):

Well that-

Dr. Morici (26:39):

So I think we're gonna see a lot.

Diane (26:41):

... you know, and that leads me perfectly into the next topic or the next question about, eh, uh, there are a lot of vaccine preventable diseases. They're rare here in the US, but that's not the case as you just mentioned overseas and in other countries. And so let's just, eh, if you don't mind, about the technologies and vaccine delivery techniques, one being the patch, uh, being studied to help improve the vaccine rates possibly in developing countries, are there others? And I gotta tell you when you think about that patch it's so easy to think this has helped just millions of people stop smoking. That patch is incredible. So why not would that not be used? That, that's a, an amazing, uh, relevance now of what we're looking at with the, the vaccines.

Dr. Morici (27:25):

Yes, exactly. And I think, you know, there are, there are other issues with distribution to developing countries.

Diane (27:32):

Mm-hmm.

Dr. Morici (27:32):

Parts of the world that don't have refrigeration or deep freezers like we talked about with the COVID vaccines and the messenger RNA vaccines. Early the in pandemic those were you know, um, uh, really, uh, available to the developed world because they required minus 80 freezers. So [inaudible 00:27:51]-

Diane (27:50):

Oh gosh.

Dr. Morici (27:51):

... freezers in order to keep the messenger RNA from degrading. And so they had to keep the, we had to keep them very cold. And so obviously getting something like that to sub-Saharan Africa, for example, or India is, is much more difficult when you're trying to reach, um, much more rural populations that don't have these types of facilities for storage.

Dr. Morici (28:12):

And so they're, you know, they're doing a lot of work now, for example, with the messenger RNA vaccines to make them in a way that they are stable at s- you know, standard refrigeration or even room temperature. Um, some vaccine platforms are amenable to freeze drying, so you can lyophilize them. M- m- it's a term meaning you just create a powder out of them and then you can reconstitute them with some type of liquid later and then administer those into the arms of individuals. So it depends on the vaccine whether an- any ingredients in the vaccine, whether or not it needs to be kept at room temperature or refrigeration or minus 80 freezers. And, and that certainly impacts who you can give it to and where it can go in the world.

Diane (29:00):

A- and again, eh, the, some of the developing countries, it's really, ih- uh, a doctor is hard to come by in some spots. So some of this it sounds like, uh, it wouldn't necessarily require a trained medical professional to administer.

Dr. Morici (29:16):

That's right. That's right. Um, and so you know, I think certainly your oral, uh, vaccines, um, and patch-based vaccines are, are, you know, if, ih- if we can get those technologies to work against some, you know, some of the diseases that we, that we still are hoping to eradicate-

Diane (29:35):

Mm-hmm.

Dr. Morici (29:35):

... that would be terrific.

Diane (29:36):

Wow.

Dr. Morici (29:36):

So things like tuberculosis and malaria, you know, in those circumstances, oral vaccines probably wouldn't work well. Oral vaccines are going to stimulate great immunity in your gut. But getting that

type of immunity, for example, to the, to the lungs where tuberculosis resides might be difficult. Um, and so looking at perhaps intradermal delivery for tuberculosis, we, we, we, we've done a lot of work in that regard. Um, and, y- and, and that certainly seems to be a great route for vaccination.

Diane (30:08):
Mm-hmm.

Dr. Morici (30:08):
Also patches would be amenable to that. Um, yeah. We're gonna see, we're gonna see a lot of new-

Diane (30:13):
Gosh.

Dr. Morici (30:13):
... technologies I think in the future that, that can overcome some of these barriers.

Diane (30:18):
And again, that shi- that's fabulous. You know, as we're starting kind of a wrap up or wind down our, our podcast today doctor, uh, the new improved vaccines, new improved. Do we have, are there many that are in clinical trials now? Um, how, how do you discern what's, what's out there right now in a clinical trial and possibly an estimated time frame that we're gonna see some new, new items come up on the, on the medical scope?

Dr. Morici (30:49):
Yeah, sure. O- you know, there's, uh, there are s- uh, several vaccines in, in, in phase 3 clinical trials.

Diane (30:56):
Oh, okay.

Dr. Morici (30:57):
Eh, and we talked, we talked a little bit about phase 3 being sort of that critical period and then, you know, shortly thereafter if the results were great, that we could see authorization of, of the vaccines. And so one of those is, is a vaccine for Lyme disease.

Diane (31:11):
Oh.

Dr. Morici (31:12):
Um, and so that phase 3 trial is anticipating completion in 2024. Um, and that would be, you know, if the results were good, then hopefully we would have a, a l- uh, a vaccine to prevent Lyme disease. I think recent estimates from the CDC suggest that nearly half a million people each year in the United States are diagnosed and treated for Lyme disease.

Diane (31:35):

Oh, I had no idea.

Dr. Morici (31:35):
So that would be-

Diane (31:35):
Oh my gosh.

Dr. Morici (31:38):
Yeah. We're, we're, we're down here in, you know, Louisiana so we don't see as much Lyme disease.

Diane (31:43):
Mm-mm.

Dr. Morici (31:43):
But the northeast and other parts of the world like Europe, you know, Lyme disease is a real problem. And so a vaccine for Lyme disease, um, you know, may not be offered to everyone or necessarily recommended to everyone, especially if you're in a state with very low cases of Lyme disease. But it would be a welcome vaccine in areas where Lyme disease is endemic, meaning present in high amounts.

Diane (32:05):
Mm-hmm. And that's in 2024.

Dr. Morici (32:07):
[inaudible 00:32:07] also there's-

Diane (32:07):
Is that what you said? Excuse me.

Dr. Morici (32:07):
2024 would-

Diane (32:09):
Wow.

Dr. Morici (32:09):
... be the, the estimated completion date for the phase 3-

Diane (32:12):
Okay.

Dr. Morici (32:12):

... um, if, if it goes as, as anticipated. So perhaps by 2025 we would have a, have a vaccine if, if it, if it looked good. Um, there's also a vaccine clinical trials for, for RSV, um, respiratory syncytial virus which we talked about earlier. That one is also anticipating completion in 2024. Um, it's being tested in adults right now. Um, but that would be something that could reduce, um, you know, severe disease in, in many individuals, um, on, on an annual basis. And, um, you know I think if there is a disease, uh, out there that, that there's a need for vaccination, you can bet that in pre-clinical studies, um, it's being pursued.

Dr. Morici (32:56):

And so what we s- when we talk about pre-clinical studies, we're talking about, um, either pharmaceutical companies or academic institutions, um, like we do here at Tulane. Uh, these are, uh, studies that we're conducting in, n- in, in the laboratory in animal models before they're ever advanced to phase 1 clinical trials-

Diane (33:14):

Mm-hmm.

Dr. Morici (33:15):

... um, ih- in humans. And so things like, um, multi-drug resistant bacterial pathogens. Uh, the World Health Organization has classified multi-drug resistance as, uh, as a significant threat to the human population. In fact, some models predict that by the year 2050, mo- di- eh, uh, di- deaths due to multi-drug resistant infections from bacteria will fer- will surpass cancer, um, in-

Diane (33:44):

Hm.

Dr. Morici (33:44):

... terms of, of, of the, the, the deaths that they cause. And so there's a great amount of interest right now in developing vaccines against drug resistant bacteria like Pseudomonas aeruginosa, uh, Klebsiella pneumoniae and even some of our sexually transmitted diseases like chlamydia and gonorrhea that we're now seeing drug resistant strains emerge. So imagine having a, a, a you know, a, a s- a sexually transmitted disease, you've been infected with chlamydia and antibo- antibiotics are no longer effective at clearing the infection. So we have to invest in vaccines now, um, and other strategies to prevent those diseases.

Diane (34:23):

And I am a little curious living here in south Louisiana as we do, uh, we have mosquitoes down here sometimes the size of small puppies. I mean they're, they're gigantic. What about West Nile? Is there any update on the West Nile virus?

Dr. Morici (34:41):

You know, I, I have learned to never take anything for granted with viruses.

Diane (34:46):

Yeah.

Dr. Morici (34:48):

And so they are, um, you know, viruses are very, uh, good at adapting to, to their reservoir and to the human population. And so I, I don't like to think of viruses as, um, you know, as completely eliminated unless we have, uh, you know, conducted a massive immunization campaign and declared it, you know, eliminated from the world-

Diane (35:11):

Right.

Dr. Morici (35:11):

... like we did with, um, polio, at least for the western hemisphere. And smallpox, you know, that we eradicated it from the world. Eh, as long as viruses continue to circulate in their, in their reservoirs, so birds or rodents, um, they, they can always make the jump at some point, uh, you know, through a vector as you mentioned, whether that's a mosquito, a tick or, or some other type of insect vector, they can always make the jump into the human population. And we're still trying to understand when and how they do that. Um, and what are the factors that cause that to happen.

Diane (35:47):

Dr. Morici, you have been just incredible, an incredible guest on our podcast today about the future of vaccines. Is there anything that we didn't touch on that you would like to leave our listeners with today? Is there anything at all that, uh, you would like to make sure that folks understand?

Dr. Morici (36:07):

Well, I would just really love to encourage your listeners that any time a new vaccine is introduced, to please, please rely on reliable sources like the CDC, the Department of Public Health, your clinician, someone with a, a scientific or medical background that is relying on, you know, science and, and, and, and data to inform you about the vaccine. There has been so much vaccine hesitancy-

Diane (36:36):

Mm-hmm.

Dr. Morici (36:36):

... and misinformation in recent years that is being spread on social media by conspiracy theorists and others. And it's doing great, great harm to our society. All of these myths that were s- were spread about the COVID-19 vaccine were wrong. They were incorrect. They were not based on fact. And vaccines have really been one of the most powerful public health tools we've had to prevent deaths in the human population. So please, please put your confidence in vaccines and get your vaccine.

Diane (37:11):

Well said. Thank you, Dr. Morici. Very well said and that's why we have this podcast that goes across all vectors, all people. You know, it's, it's so important that folks know what their options are. How they're can help themselves. And they are getting the truth. They're getting the facts from professionals such as yourself. And again, thank you for your time today. We so appreciate all your expertise and all your, your just incredible knowledge.

Diane (37:39):

So what a fabulous episode we had today. Thank you all for taking this journey along with us on Vax Matters.