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Preventing Seasonal Influenza: Making the Case for Cell Based Vaccines

Announcer:
Welcome to ReachMD. This medical industry feature, titled “Preventing Seasonal Influenza: Making the Case for Cell-Based Vaccines” is sponsored by Seqirus.

Here’s your host, Dr. Jennifer Caudle.

Dr. Caudle:
Egg-based manufacturing methods for influenza vaccines are well-established and have been a mainstay of production for more than 60 years, but the emergence of a cell-based manufacturing method has changed our production approach. What will this paradigm shift look like? And are there new opportunities and challenges to address along the way? These questions and more ahead on today's program.

This is ReachMD. And I'm your host, Dr. Jennifer Caudle. And joining me to review cell-based methods for manufacturing influenza vaccines is Dr. Lauren Angelo, associate dean of academic affairs and an associate professor of pharmacy practice at Rosalind Franklin University of Medicine and Science College of Pharmacy. Dr. Angelo, welcome to the program.

Dr. Angelo:
Thank you, Dr. Caudle. It's my pleasure to join you today to discuss this important topic.

Dr. Caudle:
Before we dive into the manufacturing process, Dr. Angelo, let's first do some level setting for our audience. Um, it's safe to say that most are generally aware of influenza's heavy toll on healthcare systems, both nationally and globally. But what are the current stats on this infectious disease?

Dr. Angelo:
That's a great place to start because the numbers are pretty astonishing. When we look at across the world, about 5 to 10 percent of adults each year are infected with the influenza virus. And this could result up to 5 million severe illnesses and 650,000 deaths. But what makes preparing for the flu season challenging is not being able to predict the severity of a flu season from one year to the next. So you'll see when the CDC monitors its activity, that they do so throughout the influenza season. And we can see from a week-to-week basis really what's happening. And so one of the ways they look at this is – is something called influenza-like illness, or ILI, and what we can see is the percentage of visits for ILI charted across the weeks throughout the influenza season. And when we look at these charts, it – it's variable from one season to the next in terms of severity. But even within a season where the peaks occur, uh, can - can obviously differ from one year to the next. And so we never really know going into a flu season whether it's going to be mild or severe.

When we look at this year in particular, across the globe, the numbers in cases are just shockingly low. And that's due to the – the COVID-19 pandemic we're in. It's just interesting to see how everybody's taking all of these precautions, they’re wearing masks, they’re - they're staying away from large crowds, and that's really impacted the transmission of the influenza virus.

But when we look at years past, obviously that's not been the case. Even last year was a really bad flu season. And we look at the 2017-2018 season, that burden was really high. In fact, it was the highest we've seen since the 2009 H1N1 pandemic.

So that just serves as a reminder of how severe some of these diseases can be. When you look at the CDC data around that particular year and some of their estimates that they've come out with, approximately 45 million people were infected with the influenza virus. Over

800,000 people were hospitalized. And there are approximately 61,000 death during just that year alone.

Dr. Caudle:
Now, it's widely understood that vaccines remain the best defense against influenza. But given how variable this pathogen is, there's a corresponding need to create new vaccines every year. So can you give us an overview of how this is accomplished from a manufacturing standpoint?

Dr. Angelo:
Sure, that manufacturing process actually starts well in advance of the influenza season, so scientists are – are looking at that activity both in the northern hemisphere and the southern hemisphere as a means to select what the vaccine strain will be for the upcoming flu season. And so with egg-based vaccines, once that strain is selected and the virus strains that we know, uh, that will be in the vaccine, uh, those then are injected into eggs, which are incubated. And in the case of the cell-based method, the strains are introduced into cell culture and the virus replication occurs in host cells. Once that viral fluid is harvested from the eggs or from the cell culture, it's tested for potency and safety. Then the strains are purified and they're mixed together to formulate those vaccines, which are put into our vials, our prefilled syringes, our nasal sprayers in the correct dosages. Each vaccine then undergoes quality control tests, and this includes sterility testing. And those results are submitted to the FDA. The FDA reviews those results. Assuming everything checks out okay, then the lot numbers – or the lots are released. And those go back to the manufacturers who can then begin shipping the vaccines out to our pharmacies, our clinics, um, our health systems, our health departments for use in the public.

Dr. Caudle:
And what are some of the challenges associated with the traditional egg-based manufacturing process?

Dr. Angelo:
Well, before we explore those challenges, I think we do need to acknowledge that the egg-based manufacturing method has made a tremendous contribution to public health. As you mentioned in the beginning, this has been the primary means for influenza vaccine production for decades. So although this process is well established, it's well understood, the process itself for manufacturing is rather complex and it involves, uh, numerous steps.

It actually takes about one to two eggs just to manufacture one vaccine. So we need millions of chicken eggs to - to be acquired before production can even begin. And as you might expect, there are certainly some inherent challenges in this process.

And one of those challenges is just the sheer length of time that's needed to acquire all those eggs. If there are unexpected strain changes, then that production response time is further hindered. The same holds true for the ability to increase vaccine production if a new strain emerges, as we might see in a pandemic.

Because this production method relies on the avian supply chain and avian influenza outbreak could compromise that supply.

And we know that not all influenza strains grow well in eggs in this can create unexpected delays in the vaccine production process.

There's also the potential for mutations to occur in the hemagglutinin protein during that egg adaptation process. So this occurs when the influenza viruses pass through the egg, which can lead to an antigenic mismatch between the vaccines and the circulating viruses. If this were to occur, it may result in reduced vaccine effectiveness.

So all these challenges, whether separately or various combinations from one season to the next, can complicate that egg-based manufacturing process.

Dr. Caudle:
So, Dr. Angelo, let's turn our focus to the cell-based method as a different option to the traditional egg-based method. What benefits does it offer?

Dr. Angelo:
With the cell-based method, there's no need to secure or rely on millions of eggs for vaccine production. This alone bypasses several logistical challenges that we spoke about with the egg-based manufacturing process. The cell-based method uses a proprietary mammalian cell line so it can grow a wide variety of influenza strains, and it provides an effective filter against most contaminant avian and human viruses.

Since this is a continuous cell line grown in suspension, it's free of animal-derived culture components, it can support high viral yields, and perhaps most importantly, it's well suited for rapid scale-up. It's possible for synthetic working cell candidate vaccine virus to be created within about five days. And then as early as 10 days, a viable vaccine could be made available. This ability to rapidly scale up is especially crucial in the event of a pandemic similar to where we are now.

And when we look at COVID-19, and - and the need to get COVID-19 vaccines produced, we're talking about mass production. And mass production for any vaccine relies in part on the speed at which large quantities a vaccine can be made available.

And I think with cell-cultured vaccines, it's important to point out that extensive quality control measures and genetic sequencing during the manufacturing process ensure that the cell-based influenza vaccine maintains high fidelity to the World Health Organization selected vaccine strains.

Dr. Caudle:
It's definitely an important take-home message, Dr. Angelo. You know, looking ahead, then, what kind of impact do you see this cell-based method making towards the influenza burden we face year after year?

Dr. Angelo:
Well, from my vantage point, I think the cell-based method is - plays an important role in decreasing the influenza of burden. The best way to decrease the illnesses, the hospitalizations, and deaths due to influenza is to vaccinate. And the cell-based vaccine and technology used offer an alternative method to the egg-based manufacturing process. It provides an option that does not rely on an adequate supply of eggs. It does not undergo egg-adaptive changes which can sometimes lead to an antigenic mismatch. And it's suitable for rapid scalability that would be crucial during times of a pandemic.

Now is the time to verify that all of our patients who can receive the influenza vaccine, have been vaccinated. The last thing we want are cases of influenza in addition to coronavirus. As immunization providers. It's important to know what influenza vaccines are available for our patients and the benefits inherent with each. The more knowledgeable and enthusiastic we are about influenza vaccines, the more likely our patients will get vaccinated.

Dr. Caudle:
That's certainly true. And considering just how much of an impact influenza continues to have on our patients and our healthcare systems as a whole, I think you've given us a lot to think about and maybe more than a little hope on the horizon.

I'd like to thank my guest, Dr. Lauren Angelo, for helping us better understand various methods of vaccine production platforms for seasonal influenza. Dr. Angelo, it was great speaking with you today.

Dr. Angelo:
Thank you. It was great to be here. I appreciate the opportunity.

Announcer:
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