**PRESS RELEASE**

**Panel discussion addresses questions about pregnancy**

**and breastfeeding in relation to COVID-19 infection and vaccines**

**Suva, Fiji.** The Fiji National University’s (FNU) College of Medicine, Nursing and Health Sciences (CMNHS) continues to enlighten Fijians on COVID-19, its impact and the role of vaccination, through a series of virtual panel discussions.

Organized and moderated by CMNHS Associate Dean Research and Director of the Fiji Institute of Pacific Health Research (FIPHR), Dr Donald Wilson, the recent panelists consisted of Professor Michelle Giles, an Infectious Disease Physician and Professor of Obstetrics and Gynaecology at Monash University, Melbourne; Professor Caroline Homer, Co-Program Director, Maternal, Child and Adolescent Health at the Burnet Institute in Melbourne and Honorary Emeritus Professor of Midwifery in the Faculty of Health at the University of Technology Sydney; and Fiji’s National Advisor for Family Health and national coordinator for the current COVID-19 vaccination programme, Dr Rachel Devi.

The panel discussion on Tuesday, 13 July 2021 was conducted via Zoom and live-streamed on the FNU and CMNHS Facebook pages.

Discussions highlighted the concerns about pregnancy and breastfeeding, in relation to the COVID-19 infection and vaccines.

Below are highlights of key issues discussed;

**Can a vaccine (Fiji uses AstraZeneca currently, or any other vaccine), affect an unborn child?**

Professor Giles said that there is no evidence that the COVID vaccines negatively affect or have any harmful effects on an unborn child.

“A lot of women are probably thinking, is this vaccine safe for my baby or is it harmful? The additional question is, is COVID-19 harmful for my baby? Because we have no evidence that the vaccine is harmful to the baby but we actually have a lot of evidence that if you get COVID-19, that can be quite harmful to both you as a mom and for your baby,” she said.“We can talk about the risk to you as a mum, which is an increased chance of being admitted to hospital and an increased chance of being admitted in an intensive care unit, and increased chance of being on a ventilator. But I know lots of women, including myself, when you're pregnant you don't think too much about your own health and you really worry a lot more about your baby. But we also have evidence that if you get COVID infection, there's an increased chance maybe of having an early or preterm birth which can have significant impacts on the baby.”

“I get asked this question a lot – is the vaccine harmful to the baby and my answer is at this stage we have no evidence if it’s harmful to the baby, but we have a lot of evidence that getting COVID itself in pregnancy can be harmful to the baby. So I think they're important questions to consider together.”

**Roughly, what are the statistics on the effects or the risk?**

“So probably there's a meta-analysis which has been published in the British Medical Journal, that's probably one of the best scientific references to look at in terms of outcomes for mothers and babies and that shows about a **two to three-fold risk**. It depends on which study you look at, of having serious illness hospitalization, admission to intensive care and it's not quite as high as that. I can't get the number exactly off the top of my head, but it's about a twofold increased risk,” said Professor Giles.

Professor Homer explained that the risk of being sick if a pregnant woman gets COVID is much higher than if a non pregnant woman gets COVID.

“That's a really important message to take away and the preterm birth rate is about one and half times more likely, probably up to two times in some studies but you're more likely to have a baby early and that means that your baby is going to have to need care in a nursery, or in some sort of facility, sometimes being separated from you and your family.”

“We also know that the pregnant women get more sick (so severe COVID infection or COVID disease), women who are older (so being more than 35 years is a risk), women who are larger (so having a BMI which is the way we work out whether people are large, obese or overweight – if the BMI is over 30 then that puts you more at risk), if you have high blood pressure (we know high blood pressure across the Pacific is a very common problem in people so high blood pressure in pregnancy puts you more at risk of getting severe COVID infection), and also having diabetes (and again across the Pacific diabetes is a big problem), one of the non-communicable diseases that is really common, and again, women who have diabetes and get COVID, are more likely to get very sick.”

Dr Devi highlighted there were a significant number of COVID positive pregnant women in Fiji.

“We know that they were initially isolated and kept at the Makoi birthing unit and we know there were times when it was full. We know that we had quite a bit, more than 15 to 20 for sure so we know the numbers were high and we still continue to see them as well. I will not be able to tell about the complications probably faced by some of them but I did hear of some miscarriages happening in pregnancy,” she added.

**In terms of pregnancy, when is the ideal time for women to get vaccinated?**

Professor Giles said this was an area where they were accumulating information over time.

“The AstraZeneca vaccine, which for maximum protection, is ideally given three months apart - two doses, and the two doses is actually very important in terms of high levels of protection against the circulating delta strain of the virus.”

“We don't actually have information from clinical studies at this stage to advise about what’s the optimal time to be vaccinated. What it really comes down to is the risk of exposure, and allowing adequate time to get protection. What I mean by that is if you get vaccinated today, with the AstraZeneca vaccine, it takes a couple of weeks to get those antibodies and as I said, a second dose to really boost your protection up to 80% mark against the chance of hospitalization.”

“If you only get your first dose quite late in pregnancy you will have some protection so it's important that at any time you should think about getting the vaccine when you have access to it, but if you leave it too late you actually may not get the optimal protection at the time you're most at risk. So we're trying to balance that in pregnant women, and it appears from that data that pregnant women who get sickest are usually in their second or third trimester.”

“So when I’m talking to a pregnant woman about the time, you know the vaccination, it would be ideal to get both doses in before the third trimester so that the woman has best protection that she possibly can get when she’s at the greatest risk of severe disease.”

“My message would be, don't leave it to too late because the whole point of vaccine during pregnancy is to have the best protection we can when you're most likely to get sick. But when I give that advice, I'm very clear that we actually don't have (if you ask me to show you) the clinical evidence, where it shows when pregnant women should be ideally vaccinated.”

“The other question that comes up a lot is what about vaccinations in first trimester of pregnancy, because a lot of women worry about having any medical intervention actually in first trimester of pregnancy. We know that the rates of miscarriages (this has got nothing to do with vaccination, this is just background rates of miscarriage), are higher in the first 12 weeks. So some women (when I talk to them about vaccination), are more comfortable to not get vaccinated in the first trimester of pregnancy. Now, it's important to say that that isn't because we have any data at this stage that says it's dangerous or harmful to get vaccinated in the first trimester, but it is something that I know having talked to lots of pregnant women about that, they often defer any treatment or any intervention.”

“Many international guidelines don't specify a time during pregnancy to get the vaccination and it really depends on your local epidemiology. If you're at higher risk of being exposed, you should get vaccinated as soon as you are able to. If you are lower risk, (so we had certain scenarios locally in our city where there was low circulating virus, so if you're a pregnant woman and there's low circulating virus), you may elect to get your first dose after the first trimester.”

“I would be worried about you getting infected in the second trimester and getting really sick and having no protection. So it's really weighing up all of those factors in the absence of clear evidence about the optimal gestation for vaccination in pregnancy at this stage with the COVID vaccine” Professor Giles explained.

**Fiji’s stance on the above question.**

Dr Devi stated “when we started vaccination there weren't many cases in the country but as we've progressed, we've escalated.”

“We have widespread community transmission here, and especially within the Suva-Nausori corridor. We know Lautoka, Nadi – the Western Division is springing up slowly. Now, there's quite a lot of changes we've made in terms of this context.”

“We are getting the Moderna vaccine while we have the AstraZeneca vaccine. We are encouraging and we're getting all pregnant women vaccinated as we speak. Now that we are getting the Moderna vaccine, pregnant women are one of our first priorities.”

“We know we can give them either Moderna or AstraZeneca, or any of the COVID-19 vaccines that has gone through the processes but we are encouraging a lot more of the Moderna for obvious reasons, for the 28-day period where we can get the second dose administered as well. So that's one of the important reasons and like you rightfully mentioned, that the second and third trimesters is where the risk is high,so the earlier the protection and vaccination, the better the prevention of any severe illness. So these are the moves of the country right now as we progress,” said Devi.

Professor Giles emphasized that pregnant women should not worry about getting the Moderna vaccine as there is a lot of safety data available on the Moderna vaccine.

“We actually have much more safety data in pregnancy for the mRNA vaccine - that's the Pfizer vaccine or Moderna vaccine than we do for the AstraZeneca.”

“There have been many, many thousands of pregnant women who've received the Moderna vaccine, particularly in the United States and there's a good publication that summarizes their experience using Moderna vaccine in pregnant women.”

“What we know is that pregnant women are not more likely to have side effects to the vaccine. So let me make that really clear - they're not more likely to, and they’ve also looked at pregnancy outcomes. They've followed these women right to birth and there is not any of the things that you would normally worry about, such as abnormalities in the baby or stillbirth or preterm birth. There's actually no increased rate of any of those either reported with the Moderna or the Pfizer vaccine. So again, I completely support, based on what you've described, that women should get vaccinated with either vaccine, as soon as they can. But if there are women who have particular concerns about one vaccine, we have a lot of accumulating safety data for the Moderna vaccine, which is also very reassuring,” said Professor Giles.

**So the transmission of infection from mother to baby, or that infection, where would you say is the highest risk of that happening? What part of the pregnancy particularly, or is it at the delivery stage?**

Professor Homer explained there's been a number of studies working out whether vertical transmission is possible, where the infection is transmitted from the mother to the baby during pregnancy.

“You all know from other viruses that this is a concern, but we haven't seen evidence of this with COVID-19 in the studies that have been undertaken. Therefore, we don't think there is this vertical transmission through pregnancy.”

“It is possible that the baby can become infected once the baby's born and that’s mostly airborne, touching – when the mother picks up the baby and the baby's close while breastfeeding. We are recommending in Australia that women keep mother and baby together, because we know the benefits of keeping the mother and baby together are really important, particularly for the baby's health, but that women do very careful hand washing, and wear a mask when they're breastfeeding their baby.”

“We're not advocating that the baby goes into a nursery and they are keep them apart, because that has other risks. Breastfeeding is really important. Even if the woman has COVID infection, obviously, if she's very sick, and can't care for her baby, that's a different story. But for women who have the virus, but are not sick, keeping the mother and baby together, doing all the careful hand washing, wearing a mask, is really important and continuing to breastfeed the baby, right from the beginning is very important.”

“We haven't seen newborn babies getting very sick from COVID in the literature. They don't seem to get very sick very quickly, even if they do get the infection,” said Professor Homer.

Professor Giles added that they have witnessed mild COVID infections in babies.

“Some young infants who get infected may not have symptoms at all. Actually, it's detected by the investigations that we do such as a swab for COVID virus. The message is, the younger you are, the milder the disease is, is really what we see. Having said that, there are exceptions, and we do see some very sick children or some very sick babies, but it is definitely the exception and it's quite rare.”

“This brings up another interesting consideration that I just might mention, because it ties in nicely with the benefits of vaccine in pregnancy. We also know that women who get the COVID vaccine in pregnancy, the purpose of it is of course for them to make antibodies that protect them from getting infected and severe disease, we’ve also looked at whether those antibodies are found in breast milk or whether they cross the placenta and we actually know that both of those things happen.”

“One of the potential benefits and I say “potential” because our focus is really on the mom who can get really sick from COVID - that's what we're trying to stop. But one of the other things that can happen is that if you are a pregnant woman and you get vaccinated, you may also provide some protection to your baby by those antibodies that are expressed in breast milk and that cross the placenta. That's how some other vaccines protect babies when moms get vaccinated in pregnancy.”

“It's not the main aim of the vaccine programme, but it's just another important benefit to be aware of, that they can also get antibodies that may protect them if they're exposed,” professor Giles explained.

Professor Homer added that breastfeeding was recommended regardless of infection, and regardless of vaccination.

“We have no evidence that there's a problem with breastfeeding and being vaccinated at the same time, not necessarily exactly the same time, of course, but you don't need to stop breastfeeding to have your vaccine, and you don't need to wait days or weeks afterwards. You can breastfeed straight away,” said Professor Homer.

Confirming Fiji’s stance on this, Dr Devi said “we’ve definitely stood by that as well, where we vaccinated our mothers, even when they were lactating from the very beginning.”

“I'm glad a lot did come through while some were reluctant but gradually they did come around. We're hoping to see a lot of that happen because of that layer of protection, of course for both. So that's of essence.”

“In terms of the severe illness and disease for babies, we know in Fiji we have had a number of these when doing contact tracing of primary contacts. We did have toddlers who were positive and they were almost asymptomatic, or they did very well throughout it. The vaccination is obviously the layer of protection in this context.”

**Will our women get to choose between AstraZeneca and Moderna? And how will you decide on who gets what if that’s the case?**

Dr Devi said pregnant women can choose between the AstraZeneca and the Moderna vaccines.

“There are the two vaccines in Fiji right now - AstraZeneca and Moderna, and while we are offering that, the faster immunity aspect with Moderna the mRNA vaccine (2nd dose within 28 days), if individuals choose to get vaccinated with the AstraZeneca, obviously, they can go ahead with it.”

“That option is theirs of course, but having said that, we are encouraging pregnant women to get Moderna for obvious reasons, that’s the 28 days gap between dose one and dose two, and early protection, just in light of all the cases that we have around Fiji, and the community transmission that is flaring up rather quickly.”

**Explain about the safety of the vaccines for preexisting conditions, and there's a specific mention about rheumatic heart disease and also deep vein thrombosis or a bleeding problem, and the use of aspirin.**

Professor Giles stated “there is actually no specific medical condition that is a contraindication to getting these vaccines and in fact, generally speaking, the more medical conditions you have, the more important it is to be vaccinated because actually you're at higher risk of severe disease from COVID.”

“Specifically with the mRNA vaccines and you mentioned one heart condition, which is myocarditis and pericarditis. It has been seen outside of the clinical trial, when we monitor once we roll out bigger numbers of these vaccines, and in younger ages, we've seen that there is a rare side effect of myocarditis, that's been noted often with the second dose of mRNA vaccine and it is higher in Moderna than Pfizer.”

“It's very rare but it is more common in males, and in younger age groups. So that may be where the question has come from about another heart condition. At the moment the data that we have on that rare side effect is that it is mild, and it occurs, and it often self-resolves with the normal treatment of myocarditis within a week or so. It's not severe and most of those cases haven't had prolonged hospitalization, but we don't know about long term impacts of that, that's being followed up now.”

“At the moment all the international guidance that I'm aware of are stating that there are no preexisting conditions that t would exclude you from getting those vaccines - so even if you have a preexisting cardiac conditions such as rheumatic fever or any other heart disease, you should still get the vaccine. And that's probably really, really important because if you have a preexisting cardiac condition, you're at increased risk of severe disease from COVID. That's the information on myocarditis and pericarditis related to the mRNA vaccines.”

“The clotting issue, we've looked at that a lot with the AstraZeneca vaccine. We call it TTS or thrombosis with thrombocytopenia syndrome, which is a particular recognized side effect to the AstraZeneca vaccine in all around the world where the data that has been looked at. The past history, for example of a DVT is not a contraindication, to getting the AstraZeneca vaccine. A family history of blood clots is not a contraindication to getting the AstraZeneca vaccine. There is an inherited thrombophilia. And there's some other rare conditions that we know about that are not contraindications to getting the AstraZeneca vaccines.”

“For your population, for the majority of the people, it's very safe to get the AstraZeneca vaccine. But having said that, there is this rare complication that is recognized, it's not usually predictable and it's not preventable in the sense of there's no evidence that you should take aspirin to prevent getting this rare side effect.”

“What’s important, I think, is just people knowing about this condition and the typical time that you can get this rare clotting, quite serious side effect is around 10 to 14 days after the AstraZeneca, and it's usually after the first dose. So very, very rare after the second dose. The reason it's important for people to be aware of it, I think, is that if they had symptoms, like severe abdominal pain or headache, at they recognize it, at about 10 days or so after they got the vaccine, it's essential that they would go and see their doctor about that.”

“Most of the common things like a past history of a clot is not usually a contraindication to getting the AstraZeneca vaccine. Some countries have introduced precautions. So for example, in my setting, if you have a past history of some rare blood clots, and we call them CVST, cerebral venous sinus thrombosis, or another one in the certain circulation, if you have clots in those unusual sites, before, as a precautionary measure, we use an alternative vaccine such as such an mRNA vaccine in that population, but by far for the majority of people that don't have those rare contraindications.”

“The key message is that the benefits of the vaccine far outweigh the very rare side effects that have been reported with the vaccines. When you're weighing up risk and benefit, you're much more likely, if you get COVID, to get sick, end up in hospital and possibly die from COVID, than of having one of these very rare side effects,” Professor Giles explained.

Dr Devi stated that Fiji has vaccinated almost 363,000 individuals and they haven't found any of these rare blood clot issues or anything as such.

“We have investigated two but they were both cleared. That in itself is to say that the risks from not getting the vaccine is obviously high, in terms of severe disease. We have seen that the deaths in Fiji while we've crossed that 15 number recently, we know majority or almost 80% or close to 90% were not vaccinated. And some of them were vaccinated but they just had their one dose and that was like just a week or two away. So that would not have been able to protect them from severe disease at all. And unfortunately, they succumbed to COVID but it's evident already in Fiji on how the vaccine is working.”

**After a pregnant woman tests COVID positive with either mild, moderate or severe disease, how should a patient's obstetric care look like after that?**

Professor Homer explained that for the most part the decisions around the obstetric care or the maternity care, are based on the wellness of the woman.

“So for most women, there will be no change, particularly for mild or moderate disease. It also depends on what stage of the pregnancy they're in, but the treatment is to manage the disease going forward and keep the woman as well as possible.”

She highlighted that there was no need to do an emergency cesarean section or induction of labour or to do anything specific that's related to the pregnancy.

“The important thing is that managing the woman’s care as much as possible to keep her well, and to keep her safe. So there are some treatments that we can use in pregnancy. The most common one you will know of is dexamethasone, which we use anyway for women who are at risk of preterm birth, so it's quite a safe drug to use and we can use it in this population.”

“In terms of thinking, do you need to do anything different for her obstetric care in terms of cesarean or induction or separation of mothers and babies – the answer is “no”. It's really dependent on keeping the mother as well as possible and managing her symptoms, her respiratory condition, her breathing problems.”

**So immediately after the period of let's say, isolation, when do you take them back in to join the normal antenatal care?**

“Once the 14 days are over, have no symptoms, (I'm not sure what you're doing in Fiji about testing until people become negative), but essentially, say a woman got COVID in early or mid-pregnancy, she recovered, then she should be put back into the system when she's not infectious, in whichever way that your system is deciding that. But these women should go on to have normal care, provided obviously that they have recovered well from the COVID infections,” Professor Homer highlighted.

Providing further explanation on this, Professor Giles stated “I don't know if you've noticed this with the pregnant women that you've cared for in Fiji but one thing that we did notice in our setting is that pregnant women can deteriorate very quickly from an oxygenation perspective.”

“They might be okay, in terms of their oxygen saturation and their symptoms, but actually, within a very short period of time, 24 or 48 hours, they can deteriorate significantly. The only thing I would add is that it's important to appreciate that because a woman might be well and be able to be managed at home, but actually needs very close monitoring, and some of that has to do with many of the physiological changes of pregnancy, that might mean that her respiratory state is compromised earlier more quickly than we would anticipate. So I would just say be aware of that potential for rapid deterioration in a pregnant woman.”

“There is no reason to induce labour for the majority of women or to perform a cesarean section but earlier on in the epidemic that was done quite a lot. Some of that was because we were really learning very quickly about how severe the disease was and that some women who are very sick on ventilators like in pregnancy, I've certainly been involved in a few cases where decisions have been made to perform a cesarean section, because it was really thought that that will potentially help with ventilator support. That’s really supporting the woman's respiratory status, but that is you know, the sickest pregnant woman in ICU - that's the scenario we're talking about where you may consider an earlier delivery. And that's really just to try and facilitate supporting her cardio respiratory status but that would be the exception.”

Professor Giles emphasised that as a general rule, a woman should have her standard antenatal care, it should not be compromised because she has COVID.

“Most of that doesn't have to be done face to face, but she can still have the ongoing care and monitoring while she's infectious. But the majority of women after 10 to 14 days, there's no reason for them not to have their ongoing antenatal care, especially face to face if that is required, or the model of care. So I would encourage that they don't stay away from hospitals or healthcare settings beyond that 14 days, for fear of infecting other people because that's not what's likely to happen.”

**What would you say to women who are probably thinking about Moderna vaccine?**

Dr Devi emphasised that the message from this session was pretty clear – encouraging all the women to get the vaccine even if you are pregnant and the earlier the better.

“Just encouraging all Fijian women have conceived or are in any trimester or are in any time of the pregnancy to go ahead and get the jab.”

Dr Devi also highlighted that they will not be cross-vaccinating anyone.

“If anyone out there has already gotten their AstraZeneca during their pregnancy, they will get the AstraZeneca. For those who have not gotten vaccinated will be offered the Moderna but they can either choose AstraZeneca or Moderna.”

**If you had your first shot and then tested positive, what happens to the second shot?**

Professor Giles explained that if you get COVID after your first does, you are really getting a natural second dose and so you actually get a really good boost in antibodies and immune response.

“We would be recommending differing the second dose and the timeframe is a little bit variable. You may not actually need a second dose at all and we are still waiting on clarification for that with more data on that or it might be worth waiting even longer for people who have had COVID, we are recommending waiting six months before they get their vaccine because you have a natural high protective level of antibodies that will weigh in overtime. This is something that we want more information on. There is certainly no urgency to rush out and get a second dose,” Professor Giles added.

**Ends.**

**ABOUT THE PANELISTS**

**Professor Michelle Giles**

Professor Giles is an Infectious Diseases Physician and Professor in the Department of Obstetrics and Gynecology at Monash University. She works clinically as an infectious diseases specialist with an interest in infections in pregnancy and maternal immunisation and is Director of the Infections in Pregnancy service at Monash Health. Her research centres on maternal immunisation including safety, implementation and impacts on birth outcomes. She is also a member of the Australian Technical Advisory Group on Immunisation.

**Professor Caroline Homer**

Professor Homer is Co-Program Director, Maternal, Child and Adolescent Health at the Burnet Institute in Melbourne and Honorary Emeritus Professor of Midwifery in the Faculty of Health at the University of Technology Sydney. She has more than 30 years of experience in midwifery practice, education and international work especially in the Asia Pacific region with UNFPA. She has conducted a number of studies on the indirect impact of COVID-19 of mothers and babies and on COVID-19 vaccination intentions in pregnancy.

**Dr Rachel Devi**

Dr Devi is a public health physician who is currently Fiji’s National Advisor for Family Health, and the national co-ordinator for the current COVID-19 vaccination programme. She is passionate to see the vaccination programme succeed, and hopes to address the common questions around the vaccination programme in Fiji.

**About the Moderator**

**Dr Donald Wilson**

Dr Wilson is an epidemiologist and a public health physician by background. He is currently the Associate Dean Research and Director of the Fiji Institute of Pacific Health Research (FIPHR) for the College of Medicine, Nursing and Health Sciences (CMNHS) at FNU.