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Questions Answered About the HPV Vaccine

You are listening to ReachMD, The Channel for Medical Professionals. Your host is Dr. Lisa Mazzullo, Assistant Professor of Obstetrics and Gynecology at Northwestern University Medical School, The Feinberg School of Medicine.

Genital human papilloma virus or HPV is the most common sexually-transmitted disease in the United States with almost 6.2 million new cases of HPV infection diagnosed annually. Gardasil, the HPV vaccine available in the United States since June of 2006, and 18 million doses have been given yearly.

Today we are joined by Dr. Sharmila Makhija who is the Director and Associate Professor of Gynecological Oncology at Emory University in Atlanta, Georgia, to discuss some of the effectiveness, safety, and expanded scenarios that are challenging us now as we face HPV vaccination.

DR. LISA MAZZULLO:

Welcome Dr. Makhija.

DR. SHARMILA MAKHIJA:

Thank you so much.

DR. LISA MAZZULLO:

I know you have talked before with us so expertly about some of the HPV information, but just to briefly review why do you think the population of HPV prevalence is so high in the 20 to 24-year-old woman?

DR. SHARMILA MAKHIJA:

Well, we see that that's probably the peak of their sexual debut and so we see that they have a higher incidents of HPV, but having said that we are finding that the earlier you can vaccinate a young woman meaning before they even get exposed to HPV, the more effective this vaccine can be.

DR. LISA MAZZULLO:

You know, I think that it's always interesting as a person who is in general Ob-Gyn practice when we think about **(01:30)** encouraging folks to have their 9 to 13-year-old vaccinated. I mean how do you tell a parent please let's give your child a vaccine for an STD?

DR. SHARMILA MAKHIJA:

Absolutely. I mean, it's a very difficult situation to even bring up to discuss with a family member and you know one of the first instincts that a parent will have is that oh my child doesn't do this, which is true, you know we like to believe that a 9-year-old is not doing this. However, what we try to do is to approach is that it's in effect going to protect her from in the event she does get exposed to it later on, even if she is with one person she marries young doesn't mean that she is going to be very sexually active before she gets married, but even if its that one person she marries and if he has been exposed to it, then he is exposing her. So in essence we are trying to protect her from any type of exposure later on, but having said that we still continue to have the routine Pap smear screening tests.

DR. LISA MAZZULLO:

Do you think some of the challenge in this vaccination discussion with the young woman is the fact that we don't know how long it really lasts?

DR. SHARMILA MAKHIJA:

Well so it's interesting because some of the new indications from the FDA recently is that it appears to at least have an anamnestic response so it goes along with the immune memory and we see that. If a patient has had the vaccine, there are current studies ongoing that are at the 7-year mark and we will probably have more of that data in 3 years, but it does appear that if a patient has received a vaccine **(03:00)** and then gets challenged or exposed to it, they are able to mount a large immune response or what we call an immune memory. So that actually has been proven in a phase II study, so that's more reassuring and that was at the 4-year mark. So we will have more data as it goes along and with any type of vaccine. I mean, that's all was the concern. You need a booster and things like that, but I think that that's already being examined by the company and it is something that will need to be brought out into light if it's not effective for that long, then we need to talk about a booster. For right now, it appears to be effective at the 4-year mark.

DR. LISA MAZZULLO:

I'd also like to talk a little bit about the challenge of giving the patient this medication in general, I find I have a lot of our college age women who receive, who will get the first or second dose when they are here, go to school and are supposed to get the third dose there and aren't able to. Do you have any thoughts about the effectiveness of the vaccine if it's not given in the protocol which currently exists?

DR. SHARMILA MAKHIJA:

Sure, so you know the beauty of this study that you know was done was that it was an international study so you had a large number of patients and you had realized scenarios where patients would even get one dose and not come back because of whatever reason; they move or they forget or they just didn't like getting the vaccination, and when they did come back, there was a small subset that we found that it was still about 80% effective. Now, it's not something we want to advocate that okay, you can just get one and be fine, but we did see in a small subset. **(04:30)** Of course, that wasn't powered for that, but that it did appear to be about roughly 80% effective after one dose, but it is important that even if they come back late and it has past the scheduled interval, you can still continue and pick up from where you left off.

DR. LISA MAZZULLO:

You were talking about Pap smear screening as well and you know certainly this vaccine does not obviate the need for Pap smear screening, but what happens if in the midst of the protocol you find someone has an abnormal Pap smear why you are in the process of giving them a vaccine or even before they have given it?

DR. SHARMILA MAKHIJA:

Well, that's an excellent question and that's you know again we are coming back to real life scenarios, you know in an ideal world we would give them 3 vaccines, they have had normal Pap smear during that time and they won't develop an abnormal Pap smear, but what happens is, and you know, we have these situations many times, you have a 20-year-old which you've been seeing in your office since she was a young girl and she gets the first dose of the vaccine and even though her Pap smear is normal, and then she comes in with some other problem bleeding, you know whatever issue she has and then you find she has an abnormal Pap smear. Even if she had an abnormal Pap smear to begin with, you still need to work that up, but you can still get the vaccine and what we try to emphasize is that you know this vaccine is protective against 4 strains of the HPV virus, two of which are associated with about 70% of cervical cancers, two with the genital wart, but that in essence she is very unlikely to have been exposed **(06:00)** to all 4, so even if she has an abnormal Pap smear, more likely that's due to one of the strains if any of the strains. So she is still going to benefit from receiving the vaccine because she is still in essence going to be protected from the other three types if she has one of them already.

DR. LISA MAZZULLO:

Do you think there is any role for HPV testing or typing before the vaccination is given?

DR. SHARMILA MAKHIJA:

And that's another great question. That's what we get asked so many times. I think that that technology is still under development and it is actually getting quite more sophisticated. I tend to not do that because I think it adds a lot of cost without a lot of information primarily based on what I just said that you know more than likely she is only going to be exposed to one type of the strain, so typing her for all these other ones will not really be of any benefit, especially when we don't know if some of them even cause any issues. So I tend to not do that. Now, it's interesting when I was in Korea at a meeting there, most of the physicians there do type, so you know it's a regional issue, it's what you are comfortable with. I don't think there is anything wrong with it, but I certainly don't think you need that before you administer the vaccine.

DR. LISA MAZZULLO:

And in developing countries where there are so few pathologists and cervical cancer is still the primary cause of female death, I think a lot of them are returning to HPV typing because it's easier for them to process.

DR. SHARMILA MAKHIJA:

Absolutely, or at least get some type of support to help offset the cost, but then again I feel very strongly you know we work in India quite a bit and I feel like that money is best used **(07:30)** by giving the vaccine instead of trying to do all those other typing, you know at

least use it to prevent her to getting the HPV subtypes and developing a cervical lesion or cancer.

DR. LISA MAZZULLO:

Just because we are talking about it, which patients do you HPV type in your patient population?

DR. SHARMILA MAKHIJA:

I don't type any, but the physicians that refer to me do type actually at a young age, or interestingly enough, in the older or what we call them mid-adult or the adult women groups, so those that are over the age of 40, they tend to do that and that's something that I was going to bring up even when you brought up before about the high rate of HPV in the 20 to 23-year-old, we also see that in the adult women groups, those that are over 40, there is a lot of question about well as those women are already exposed why you need to vaccinate those women. Well, it's not FDA approved for that older group of women, but we are finding that that population of women are either getting divorced or you know remarrying so they are more susceptible to acquiring the HPV infection, so you know there are a lot of interesting issues that are developing and really it came about because we had quite a few patients who are bringing their daughters and say can I have that too, so that has been studied in the older group of women and it's still under review right now by the FDA.

If you are just tuning in, you are listening to ReachMD, The Channel for Medical Professionals. I am Dr. Lisa Mazzullo and we are speaking with Dr. Sharmila Makhija (09:00) about the clinical challenges of HPV vaccination that are facing physicians today.

DR. LISA MAZZULLO:

Dr. Makhija, I am wondering now if you are giving someone the vaccine, we are talking about scenarios where if they had an abnormal Pap and that would be okay, what if someone gets pregnant in the midst of the vaccination plan or timing.

DR. SHARMILA MAKHIJA:

It's not approved for vaccinating during pregnancy, however, as it was a international study, we found that the population in Brazil were actually getting pregnant constantly during the vaccination series so obviously if you have a patient that comes in and you have to do a pregnancy test beforehand, and if it's negative, they can get the vaccine. Now let's say you have given one dose and they come in for their next or their second dose and you found that they are pregnant, well you do have to counsel them that you know even before that about the effects on pregnancy which it is actually considered to be safe, but it's not FDA approved during pregnancy, you cannot give them the additional doses of the vaccine until they have delivered and even if they are breastfeeding, they can still receive the vaccine, but until they complete their pregnancies, you have to hold their dose and then you pick up wherever you had left off. That's an excellent question because we found that those women in Brazil that did get pregnant in the midst of the vaccination series do not have a higher rate of any congenital malformations in the babies that were born from those women compared to the general population. **(10:30)**

DR. LISA MAZZULLO:

Thank you so much to Dr. Makhija who has been our guest and we have been discussing the clinical challenges of HPV vaccinations. Thank you for listening.

For more details on the interviews and conversations in this week's show or to download this segment, please go to www.reachmd.com/womenshealth.

You are listening to ReachMD, The Channel for Medical Professionals. Welcome to Patient Safety News provided by the Food and Drug Administration, the FDA, Protecting and Promoting the Public Health. Today's highlight is hosted by Mark Barnett and Anita Reiner.

ANITA REINER:

The Institute for Safe Medication Practices is warning again about the possibility of mixup between ephedrine and epinephrine. Not only do the names of these drugs look and sound similar, but since they are both used as vasopressors and vasoconstrictors, they are often stored next to each other.

MARK BARNETT:

ISMP cites a recent case in which a 57-year-old patient was admitted for excision of a neuroma on her foot. An anesthesiologist gave a verbal order for ephedrine, but the nurse taking the order heard epinephrine and that's what the patient was mistakenly given.

ANITA REINER:

ISMP makes several recommendations for reducing the chance of these mixups. First avoid storing epinephrine and ephedrine side by side. **(12:00)** Use tallman letters on computer inventory listings, shelf labels, and other places where the drug names appear. Use screen alerts on automated dispensing cabinets, keep large vials of epinephrine out of clinical areas to reduce the chances of preparing large amounts of a drug. To ensure an independent double-check, have the pharmacy prepare infusions and bolus doses for these drugs, except in emergencies and finally when conveying orders verbally use the read back technique. Read back means that the person receiving the order transcribes it directly onto the patient's record or prescription as it's being given. Pending order is read back to the prescriber rather than repeating it back for memory.

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Welcome to Doctor's Digest, a feature of ReachMD Radio on XM160. Doctor's Digest, bridging the gap between the business of medicine and the practice of medicine.

How can patients be compensated when something goes wrong without destroying the physicians who treat them. The medical liability situation has been on the minds of physicians on and off for the past 30 years. In the year 2000, medical liability insurance premiums

began to sky rocket pushing the subject on to the radar screens for patients and politicians as well.

The topic of medical liability reform has inspired prolonged and heated debates (13:30). Some argue that the present court system fosters an environment of fear that leads many young doctors to avoid high-risk specialties and they think twice about setting up a practice in a rural area or in a state without tour reforms. Another issue is whether doctors are feeling pressure to order expensive an unnecessary tests and procedures simply to reduce the risk of being found liable later on.

Various states have experimented with a number of plans including placing a cap on damage claims and imposing a statute of limitations with mixed success. The AMA and other physician groups advocate placing a limit on noneconomic damages such as pain and suffering. In California, for example, there is a cap of 250,000 dollars for noneconomic damages, but the impact of such caps is not entirely clear. Some say that a low cap can be harmful to severely injured patients and although some argue that caps will reduce the cost of healthcare, others point out that there is no evidence of reduced costs in those states that have imposed caps.

Recently there has been discussion about ways to compensate injured patients without trying to place blame on providers, some state legislatures have introduced bills to establish demonstration projects such as health courts that will be alternative to the tort system. There is growing support (14:30) for federal legislation to help states finance such measures. Many believe that health courts offer a promising, if partial solution, to the overall problem.

You've been listening to Doctor's Digest, a feature of ReachMD Radio on XM160.

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