NWX-HRSA OPR REG9 (US)

Moderator: Nidhi Jain
January 19, 2021
4:20 pm CT

Jane Segebrecht: All right, good afternoon and thank you so much for joining us for today's seminar – New Cervical Cancer Guidelines for Screening and Management During COVID-19 and Beyond. My name is Jane Segebrecht and I lead Strategic Initiatives for the Health Resources and Services Administration Office of Women's Health. And it is my pleasure to kick off our inaugural event in our HRSA Office of Women's Health Leadership Series.

So I'm going to scoot back one slide, great. So whether you come to cervical health from a clinical, programmatic or policy perspective, HRSA, OWH and our partnering host the HRSA Office of Regional Operations hoped that today's webinar will leave you with new ideas, innovations and practical approaches to bring to your work in women's health leadership.

So we have a very full agenda today. And we will start with an overview of Cervical Health Awareness Month. That's the health observance which coincides with today's event. Then we'll share some context for today's federal host. Next we'll shift to the heart of today's talk. First you'll hear from Dr. Rebecca Perkins on her work addressing cervical cancer throughout the lifespan. And next you'll hear from Dr. (Sue) Ghosh on her experiences strengthening cervical HPV testing and cytology during COVID-19 in a HRSA-supported health center – the East Boston Neighborhood Health Center. And we will close with your questions. So please add them to the chat box throughout today's event and we'll be gathering those to answer. We will also open up phone lines at the end of today's talk for your questions.

In the meantime please also feel free to introduce yourself, your organization and your location in the chat. We look forward to seeing where folks are joining us from today.

And then if you would like to revisit any of the information that we share, please see the materials including our slides in the lower left-hand corner to download. And we already know that we may run a bit long today. So if you have to step away know that there will be a full archived recording provided about a week after today's event.

So we will get started. So January is Cervical Health Awareness Month and cervical health includes many aspects. And today we'll be focusing just on cervical cancer and also HPV. And within that we'll be focusing on cervical cancer screening, management and also cervical cancer prevention. Cervical cancer is pervasive. It's the fourth most common cause of cancer for women. And it's a sentinel malignancy of health disparity. We know that women with routine access to accurate screening which can identify and remove precancerous lesions rarely develop the cancer and even less frequently die from it.

Women with fewer resources are less frequently vaccinated, screened and treated particularly at the precancerous stage. And we know that cervical cancer does not discriminate. So during today's presentation we want to emphasize the need for inclusive language and management guidelines also to be inclusive for this health topic. So anyone with a cervix is at risk for cervical cancer and cervical health warrants sensitive prevention screening and treatment for all patients including sexual and gender minority populations.

So cervical cancer carcinogenesis follows a universal flow from infection with human papillomavirus or HPV, persistence and progression to precancer and then cervical cancer. And public health prevention through HPV vaccination prevents several cancer-causing types of HPV especially HPV Type 16. And in addition to cervical cancer HPV is a risk factor for five additional types of cancers. So some types of head and neck cancers particularly oropharyngeal cancer, penile, anal and vaginal cancers.

And vaccination is a critical public health intervention. But we know that cervical cancer can still arise among women with HPV before the vaccine era. So control efforts based solely on vaccination of adolescents are estimated to take about another 40 years. In response our office -- the HRSA Office of Women's Health -- is working with our partners at the National Institutes of Health and National Cancer Institute and the HRSA Office of Regional Operations to improve screening and diagnosis. And new risk-based management consensus guidelines published by the ASCCP which is formerly known as the American Society of Colposcopy and Cervical Pathology can accelerate cancer controlled by decades.

The guidelines were developed through a large consensus effort involving several clinical organizations, federal agencies and patient representatives and several NIH National Cancer Institute Scientists performed extensive risk assessment and systematic literature reviews to support the development of the guidelines. And you'll get a deep dive on these guidelines later on in the talk.

So before we dig further into cervical cancer just a bit about HRSA. HRSA supports more than 90 programs providing healthcare to people who are geographically isolated, economically or medically challenged. And the agency does this through grants and cooperative agreements to more than 3,000 awardees.

This includes community and state-based organizations, colleges and universities, hospitals, states, local and tribal governments. And every year HRSA programs serve tens of millions of people including people living with HIV/AIDS, pregnant women, mothers and their families and those unable to access quality healthcare.

Examples of our key programs include the Ryan White HIV/AIDS Program, the Maternal and Child Health Block Grant, the Maternal Infant and Early Childhood Home Visiting Program, National Health Service Corps and Nurse Corps and then also the Health Center Program.

The Health Center Program is a key collaborating program in addressing cervical health. It includes 1,400 HRSA funded health centers which operate roughly 12,000 service delivery sites across every U.S. state and territory. And health centers serve more than 28 million people. That's 1 in 12 nationwide who rely on a HRSA-funded health center for affordable and accessible healthcare. That's 1 in 9 kids, 1 in 5 rural residents, 1 in 3 living in poverty and more than 385,000 veterans.

And every year health centers report on several clinical quality measures and related Healthy People 2020 Goals including their rates on cervical cancer screening. However we know that all health centers right now have a shift in their focus to respond to COVID-19.

So during the COVID-19 pandemic health services worldwide are going through important adaptations. And HRSA fully recognizes the extraordinary ways in which a public health crisis is disrupting normal health center workflows and care delivery.

In addition to the provider relief fund HRSA has awarded over $2 billion to the health center program to help health centers respond to the COVID-19 pandemic. And through several rounds of funding HRSA's investments include supporting health centers to expand screening and testing needs, acquire medical supplies, boost telehealth capacity and maintain or increase health capacity and staffing levels to address this public health emergency.

On the prevention front we recognize and are still learning the ways cervical cancer screening strategies have shifted during COVID-19 and we understand that there will likely be a surge for need of screening following the pandemic.

So my office -- the HRSA Office of Women's Health -- leads women's health-related activities across HRSA programs that provide healthcare to women and girls who are geographically isolated or economically vulnerable. And according to the U.S. Department of Labor women make approximately 80% of the healthcare decisions for their family.

So our work to support the health, wellness and safety of women across the lifespan helps women served by HRSA programs, their families and the communities in which they live. And we conduct our work by integrating evidence-based women's health programming across HRSA's bureaus and offices and by leading collaborations with other federal and non-federal partners.

So today we are pleased to announce our new Office of Women's Health Leadership Series. And we will host bi-monthly events with proactive approaches to promote women's health. We plan to cover a broad range of innovative topics in maternal health, care coordination for women experiencing substance use disorder, telehealth, violence prevention and cardiovascular health. And we are so glad that you're here today for our first

event. And we hope you can join us for future installments. Please look out for announcements and also contact us if you would like to receive updates as well.

So lastly a word on our work to address cervical health. As part of the cancer moonshot HRSA Office of Women's Health is partnering with several federal partners to co-sponsor a cervical cancer roundtable to support the goal of accelerated cervical cancer control and prevention.

And our partners include the HRSA Office of Regional Operations, several different parts of the National Cancer Institute, the NIH Office of Women's Health Research and the HHS Office of Population Affairs. And this roundtable series which will be held in the coming year will focus on bi-directional sharing of new guidelines, scientific innovation such as self-sampling for HPV, provider technical assistance and opportunities to strengthen our federal coordination to increase access to cervical health services within community health centers and other safety net settings of care.

So I will now pass it over to (Nettie James).

(Nettie James): Good afternoon everybody. My name is (Nettie James). I work in the HRSA Office of Regional Operations. Just a little bit about ORO. We are a national network of 10 regional offices. And we are very excited to be working with the Office of Women's Health. ORO's mission is to provide on the ground research - outreach to increase the reach, impact and awareness of HRSA programs. ORO can extend the reach of HRSA programs by using our knowledge of the regional landscape proximity and networks of local contacts and states and territories. We conduct outreach to expand knowledge about HRSA's programs. We engage partners of various levels and we broker our

relationship to advance HRSA's priorities and provide strategic action. And there is a link on this slide if you want more information.

Today I would like to introduce our speakers. First we have Dr. Rebecca Perkins and she is an Associate Professor of the Obstetrics and Gynecology of Boston University School of Medicine. And she practices gynecology at Boston Medical Center and East Boston Neighborhood Health Center. She is very dedicated to reducing health disparities in cervical cancer. And her current research is focused on improving utilization of HPV vaccination and cervical cancer screening guidelines.

Dr. Perkins Co-Chairs the National HPV Vaccination Roundtable and the President's Cancer Panel on the Cervical Cancer Subcommittee. We also have Dr. (Sue) Ghosh and she is a gynecologist/oncologist practicing at East Boston Neighborhood Health Center. She is currently working on quality improvement projects and cervical cancer screening and pre-natal care. Prior to this position Dr. Ghosh was a community GYN/oncologist in San Diego in Riverside County. So we will move onto our first speaker Dr. Perkins.

Oh and this is some information sorry about how you can reach us. And this is HRSA. And we will move onto our main speaker, thank you.

Dr. Rebecca Perkins: Great, thank you so much. Can you guys hear me okay?

(Nettie James): Yes.
Dr. Rebecca Perkins: Excellent.

Jane Segebrecht: You sound great.

Dr. Rebecca Perkins: Great, all right. So I have three giant objectives today which I will try to cover in a very short amount of time. The first is to describe how HPV infections cause cancer, how HPV vaccination works to disrupt the natural history of HPV infection to prevent cancer. And then for those who weren't able to be vaccinated before they were exposed to HPV how we can still prevent cervical cancer through screening and management of abnormal results.

So the bottom line is for young adolescents and young women specifically talking about cervical cancer. We want to vaccinate between the ages of 9 and 12. And you can get vaccination up through the age of 26. Cervical cancer screening doesn't begin until the age of 21 or 25 if you're following the American Cancer Society guidelines. And then beyond the age of 26 – so 27 to 65, screening is really going to be your best way of preventing cervical cancer. HPV vaccination can be offered through the age of 45 but it really is not considered a population level intervention to prevent cancer at that point because 80% of people will already have the HPV infection that will go onto cause cancer.

This is one of my favorite graphs of all time and you will see it multiple times throughout this presentation because it describes how HPV infections turn into cervical cancer. Most people about 80% of people will acquire an HPV infection shortly after sexual debut. And for most people that infection will be controlled by the body. We don't really say cleared anymore because we know it can reactivate decades later. But it can be controlled by the body and become undetectable and at that point wouldn't be doing any harm.
That happens for most people. But for people who see infection is persistent meaning you can detect it every time you do an HPV test, usually within about 5 to 10 years those individuals will go on to develop a precancer of the cervix.

If a precancer remains and is not treated and I'm talking about CIN3 or cervical epithelial place or grade 3 which is the highest grade of precancer, that can go on anywhere from, you know, 3 to 30 years later to become an invasive cervical cancer. But the good news is we understand the timeline very well. And so there's multiple points to interrupt it so cancer doesn't have to develop.

This slide illustrates the typical course of an HPV infection in a population of women. So this is the population of women where everyone has HPV and a detectable HPV infection at time zero. And if you march out through time by about three years almost everybody's HPV infection is undetectable. That doesn't mean it's gone forever but it does mean that it's not doing them any harm.

For those individuals who still have HPV detectable by vaginal cervical screening you can see that the top pink line is getting bigger which means they are starting to develop precancer at an appreciable rate. And by the time you get out to seven years with a persistently detectable HPV infection, about half of the people will have a precancer by then.

When you follow people with a precancer which was done only once then should never be repeated, they do go on to develop invasive cancer. So we never do that anymore. We would never follow a precancer we have to treat it with the exception if the woman is pregnant you can treat it when she delivers. So HPV cancer prevention has two phases. The first is vaccination. Vaccination is primary prevention. We vaccinate adolescents and prevent infections that can lead to cancer.

The second phase is secondary prevention. This is screening adults to detect and treat precancer before cancer develops. The current recommendations for HPV vaccination is to vaccinate everybody males and females between the ages of 9 and 26. On time vaccination is ages 9 to 12 and catchup vaccination is ages 13 to 26.

If a child starts their HPV vaccinations before the age of 15 they only need two doses given 6 to 12 months apart and if they're rather late starting on their 15th birthday or later then they will need three doses at 0, 2 and 6 months. For the midlife adults the 27 to 45-year-olds not middle age which of course is much older. They can be offered HPV vaccination but it's not routinely recommended due to low population level benefits. So the CDC does not recommend discussing this with all patients.

Back to my favorite graph. I told you you'd see this multiple times. This really explains why HPV vaccination works. So we are vaccinating people ideally at the age of 9 to 12. And you can see that is well before the onset of that big green peak of HPV infection. You can vaccinate all the way to the age of 26. But studies show that once you're 18 and older the vaccine effectiveness drops off dramatically because a lot of people have already seen at least one HPV by then and sometimes more.

So vaccinating early adolescents basically the person has antibodies before they ever see the virus and so they can't get the infection. What we want to see is that they don't get the infection. If they don't have the infection they don't get precancer and if they don't get precancer they can't get cancer. So what's very exciting is that that theory has actually been borne out with real world data in the decade plus that we've had HPV vaccination available. So this first slide shows that the amount of vaccine type infections has dropped off dramatically in young women. Between the pre-vaccine era of

2003 to 2006 and the late vaccine era of 2011 to 2014 we see a 71% decline in HPV 16 and 18 in our 14 to 19-year-olds and a slightly smaller decline in our 20 to 24-year-olds. And among girls who are vaccinated we've seen 89% decline with a 34% protection for unvaccinated girls indicating some herd immunity.

So the next thing. So now we've seen that HPV vaccination is decreasing infections with oncogenic HPV. The next thing you want to see is that precancers are reduced. And we see this as well. We see a dramatic reduction in precancers in women ages 18 to 24 but actually increasing precancers in older ages. So that is we hope due to vaccination although there have been some changes in our screening and management protocols as well in those very young women.

But the real answer is cancer. People want to know that cancer is being eliminated or reduced by HPV vaccination and now just this year one small bright spot of news in the deluge or terrible news of 2020 was this article in the New England Journal of Medicine which showed that when girls were vaccinated before the age of 17 they were 88% less likely to develop cervical cancer by the age of 30. And this is actually in a population of undergoing routine screenings. So this shows the impact of vaccination even on top of a routine screening program.

And so you can see here at the orange line that sort of shoots up starting at the age of 23 when they start screening is the unvaccinated girls. The dashed blue line is those with vaccines late at 18 and over so it's lower but there's still an appreciable amount of cancer. And then that green line on the bottom which is completely flat and almost zero shows the basically lack of cancer in those who were vaccinated before the age of 17. So this is an extremely exciting article.

And people do continue to worry whether HPV vaccination is safe and the answer is a resounding yes. They have looked for basically any possible side effect you could come up with and have found nothing. So that people can be very, very confident that there are no serious side effects.

Unfortunately HPV vaccination does lag behind other adolescent vaccinations. We have about 80 to 90% coverage with our tetanus booster and meningitis vaccines in early adolescents and we're lower with HPV vaccination. Now it is going up. Well it was going up. At least as of 2019 71.5% of our adolescents had initiated the series. And over half had completed it.

So we are doing pretty well. The lines are going up. But what we really want to see is the lines for HPV vaccination are right on top of the lines for the tetanus and meningitis vaccine. And that the teens are completely protected with their two doses. So we definitely still have work to do and unfortunately a lot of catchup work to do after 2020 when we know a lot of vaccinations didn't happen and believe we have an accumulative deficit of a million doses which is now probably even more than the last time I checked.

So HPV vaccination is going to be critical to protect our young people against cervical cancer as well as vaginal, vulvar, oral anal and oropharyngeal cancers. But what about preventing cervical cancer in adults? As I mentioned when someone is a fully fledged adult is probably too late to vaccinate them and have it prevent cancer.

And unfortunately we still have quite a bit of cervical cancer in the United States. We see almost 14,000 cases. We saw almost 14,000 cases in 2020 with over 4,000 deaths. And unfortunately that number is higher than the last

time I had pulled it so we're not actually – that number's moving in the wrong direction.

When we talk about screening we're not back again to my favorite graph. You're screening here really between the ages of 25 and 65. And that makes sense because the purpose of screening is to detect HPV infections that have gone on to cause precancer so you can prevent cancer. And you can see that the peak of precancer is really between the age of 25 and 35. So that's a really crucial time to be screening. And you want to be screening with your most effective test which is an HPV test.

The first fundamental concept of screening is that the longer an HPV infection has been present the higher the risk of precancer and cancer. It matters how long the infection's been there. It matters what type it is with HPV 16 being the most dangerous. And really that's what matters. Those patient factors aren't as important if you know they're screening an HPV infection history.

Another crucial concept is the HPV testing is better than Pap testing alone for detecting precancer. Pap testing detects only to 50 to 70% of precancers that are actually there versus HPV testing that detects more than 90%. And that's why you have to repeat Pap testing very frequently. And it doesn't confer long-term protection against the development of precancer the way a negative HPV test does.

So this graph shows a woman's risk of precancer following either a negative Pap test alone which is that blue line that sort of goes straight up towards the top of the screen compared to her risk if she had a negative HPV test alone which is the dashed red line or a past HPV co-test which is the green line. And you can see there's really very little difference between the HPV test by itself or the past HPV co-test. And both of them are dramatically superior to a

negative Pap alone in reassuring someone that they not only don't have a precancer but that they won't develop one over the next few years.

The current recommendations for screening are between the ages of 21 and 24 to do just a Pap every three years. And obviously to catch up HPV vaccinations that are not already vaccinated. Between the ages of 25 and 29 you can do either a Pap or HPV testing. And between the ages of 30 and 65 you can do either HPV testing every 5 years, Pap, HPV co-testing every 5 years or Pap testing alone every 3 years.

Over the age of 65 you can discontinue screening but only if women meet extremely strong criteria. They have to have had no history of precancer in the past 25 years. They cannot be immunosuppressed. They cannot be HIV positive. They must have had at least 10 years of documented normal screening which means you're looking at the results and seeing that they were normal and no abnormalities in that time. Most women will not actually meet those criteria and you have to keep screening them until they do.

Not everybody also is eligible for a five-year or routine screening interval. So it used to be that everybody got a Pap test every year which was essentially managing everybody as if they had just been treated for precancer which was over screening. But the flipside of that is now you have to figure out who needs to be screened more often and who can actually qualify for that five-year interval or three years if you're talking about Pap alone.

You have to make sure someone does not have abnormal uterine or vaginal bleeding because if they do you need to work that out and a Pap and HPV test is part of that. You want to make sure they didn't have a hysterectomy that removed the cervix. If they don't have a cervix they do not need cervical cancer screening unless the cervix is removed for precancer.

You need to make sure they're not HIV positive or immunosuppressed because they are at higher risk of cervical cancer and need to be screened more often. You need to make sure they didn't have an abnormal test within the past 10 years or treatment for precancer within the past 25 years. If they had any of those then they're still at higher risk and they need to be seen more often.

If they answer no to all those questions only then does your patient qualify for routine screening. This means in your general population of patients about 80% will qualify for routine screening and 20% will not. So you will need to make sure that you are figuring out if someone can go to five years and not just saying oh yes I see that there was a co-test three years ago. You definitely don't need another test right now because they might especially if you don't check the results and make sure it was negative.

New guidelines were released in April of 2020 to improve management of abnormal cervical cancer screening tests so HPV and Pap tests. And the goal is to increase the accuracy and reduce the complexity for providers and patients.

The good news about these guidelines is they are designed to be enduring. Prior guidelines require major updates every 5 to 10 years. And we are hoping that we have adequately designed these guidelines that they should ride out everyone's career. We want them to be good for a minimum of 10 years, ideally for 20. And that all of the new technologies can be adapted within the framework I'm about to describe. So while it's a little bit of a heavy lift upfront because it's a big change, we're hoping that it will be a worthwhile change and will make things easier and better for patients in the long run.

The sentimental concept underlying management is that the management is based on a patient's risk of having precancer not just on the result of their test. So a recommendation to do a colposcopy or do a treatment procedure or to bring them back sooner than a routine screening interval is going to be based on a patient's risk of precancer or CIN3 which is determined by a combination of their results today and what has happened to them in the past.

This means that the same test result might yield a different management recommendation depending on what came before. What am I talking about? So past history influences current risk. One of the most common abnormal screening test results you see is an HPV positive ASCUS result. So this is a Pap smear that's a little bit abnormal and the patient has HPV.

Now the patient's risk of precancer with the same result can be very, very different depending on what happened before. So if this is a patient who has been, you know, on time with screening, never had an abnormal and her most recent result was a negative co-test or HPV test, her risk of having precancer with this slightly abnormal result is very low. It's only 2%. So she actually doesn't need a colposcopy this year. She just needs to come back in a year.

If you don't know what her prior results were or if it was only a Pap test and not an HPV test, then her risk doubles. Now it's 4 1/2% and she does need a colposcopy to make sure she does not have precancer right now. If you know that her most recent result was a positive HPV test with a normal Pap, her risk is 5 1/2% and she needs a colposcopy right now. And if you have very, very limited colposcopy spots in your clinic and you're trying to figure out who needs to come back first, it's your patient with the same result -- the HPV positive ASCUS -- who was just treated for a cervical precancer because her

risk is double that of the other patients. It's now 10%. And so she needs to come back first.

So you can see here that with the same result today the patient's risk of precancer is very, very different depending on what came before. So the idea of these new guidelines is the recommendations are more tailored, they're more personalized and this can improve management. We can expedite diagnosis and treatment for high-risk patients while at the same time performing fewer invasive procedures on low-risk patients. The risk stratification allows that prioritization when we're addressing COVID related practice changes.

It's really a paradigm shift. The older guidelines were sort of like a map. Most of the time you kind of had them memorized. You knew what you were supposed to do. And occasionally if you had an odd case and you couldn't remember you would consult the paper algorithms and it would be, like a map and you would say oh yes I'm supposed to go down this line over here and do this with this patient.

The new guidelines function more like a GPS. We have many, many of our combinations really beyond the scope of simple human memorizing. Believe me I have tried to memorize all of them. I can't and it's not worth it because I spend way too long. So you really to facilitate you could do guidelines we're working on various different clinical support tools that can help tell you where your patient falls within the framework.

These are currently available through ASCCP. There's a phone application you can buy and then a free web app which is downloadable in the same place. It's sometimes a little tough to find but it is free.

The guiding principle for the guidelines is equal management of equal risks. So it's a little busy but I'm going to walk through it. So if you go from the bottom to the top it goes from the lowest risk up to the highest risk. So the lowest risk is someone who is HPV negative and with a NILM or negative normal Pap. This is about 90% of your patients. And their risk of having a precancer is somewhere in the neighborhood - of having precancer today is somewhere in the neighborhood of 1 in 10,000 you can ignore them. They're very, very low risk and we don't have to worry about them right now.

Moving up to the next bracket. These are patients with HPV positive results but normal Pap result or the extremely rare HPV negative (ELSO) result. And those patients have a risk of about 1 to 2% of needing colposcopy – I'm sorry of having precancer right now. And so their recommendation is to just come back in a year.

It is important to note that coming back in a year is no longer a normal thing. People used to oh the annual Pap you've been fine. I just come to the doctor every year. No, no, no. Now the normal interval that someone would come in for routine screening is five years. So if you're telling someone to come back in one year that actually means they're really quite high risk and you need to be tracked. And the patient needs to know that we didn't say one year and meant three years. We didn't say one year and mean you're fine you come back in five years. We meant one year because we are watching you for precancer.

The next bracket is the HPV positive ASCUS or low grade. Those have a risk of about 4% and they meet the colposcopy threshold. And then you have your high-grade Pap results – your H cells and ASC H. And those have risks between 25 and 50%. And their risks are so high that they can actually be considered for what's called expedited treatment which means they just go

straight to getting a LEEP or a treatment procedure and in some cases you can actually just skip right by the colposcopy.

So this is the entire framework which we hope will survive for decades. So for every patient we look at what is their risk of having precancer right now. If it is 4% or higher they need to have something done to them right now. Either a colposcopy if their risk is 4 to 24% or an option of having a LEEP procedure or diagnostic treatment procedure right now skipping the colposcopy if their risk is 25 to 60% or 25% or higher really.

If their risk of having a precancer right now is less than 4% you don't need to do anything to them this year. They can come back in one year, three years or even five years depending on what that result is and what their history is. So when you translate this into managing actual patients we're going to manage our high-risk patients more aggressively meaning we can skip the colposcopy and go straight to a LEEP. We manage our medium risk patients the same. So the ones who most patients who went to colposcopy before will continue to go now. And we can manage low-risk patients less aggressively.

Specifically these are patients who've been screened routinely. It's always been negative and they've been screened with HPV testing or co-testing. They can - if they have a new HPV test we know it hasn't been there for very long so we don't need to take them to colposcopy right away.

So who actually meets threshold for an expedited treatment? There are two conditions where patients it's actually preferred that they skip the colposcopy and go straight to the treatment. One is HPV 16 positive H cells. So if you have HPV typing available and you find HPV 16 which is the HPV super villain and the Pap is high grade, that patient has a 64% chance of having the highest grade of precancer and about an 80% chance of having at least a CIN2

or a sort of moderate precancer. So if you do a colposcopy and you don't find anything you probably missed it. So that patient should just go straight to LEEP.

Similarly if you have an HPV positive patient with a high-grade Pap result who hasn't been screened in five years or more, she also can go straight to LEEP and skip the colposcopy. The benefit of this is not having your patient get lost to follow up.

A sample way to talk about this with patients is the following. The results of your screening tests indicate that you probably have a precancer. They do not indicate cancer which is excellent but I recommend we do a treatment procedure. This will give us both the information of a biopsy making sure you don't have cancer and we'll also treat your precancer at the same time. Then obviously you should explain the LEEP procedure and if your patient really prefers to have a colposcopy first that's okay.

The patients who are medium risk should have a colposcopy. So this is anybody who is HPV positive twice in a row; anyone who is HPV 16 or 18 positive even if the Pap results are normal which the HPV 16 and 18 are very aggressive; any high-grade Pap result because that indicates something going wrong even if the HPV results are negative which they rarely are but occasionally they are and low-grade Pap results that are HPV positive unless they've recently had a negative screening HPV test.
So who are the low-risk people we can manage less aggressively? Basically they are people who have had regular screening with HPV testing or co-testing and it's been negative. If they all of a sudden have a new positive HPV test with a low-grade abnormal Pap, that's probably just a new infection. And we know from the earlier slides that if an HPV infection hasn't been there for very long they're very unlikely to have a precancer.

Having a negative screening co-test reduces their risk of having a precancer right now from 4% to 2% so basically cuts it in half and they don't meet the colposcopy threshold anymore. They need to come back in a year.

So an example of this would be a 38-year-old who presents for screening. She has had negative screening at regular intervals. Her most recent results were negative. HPV and Pap co-test at the age of 33 and this year her screening results are ASCUS HPV positive. What do we do? Well she had a negative co-test. Then she was ASCUS HPV positive. Her prior negative co-test reduces her risk of having precancer. So she gets to skip coming in for a colpo during the pandemic. She gets to come back next year.

What we can say to her is since you just tested negative for HPV means this infection hasn't been active in your cervix for very long. The new positive test could mean a new infection or it could mean an old exposure that you had sometime in the past has become active again. The good news is that your risk of developing precancer of the cervix is very low in either case so we don't need to do a biopsy this year. You still need to come back next year for another test. And if that test is positive you need a biopsy at that time. If she comes back again her HPV is positive again and now she has had HPV positive twice in a row so now it's considered persistent and she needs a colposcopy.

The last thing I want to cover before I turn it over to Dr. Ghosh is surveillance. So this is bringing people back in one year, three years or five years. I'm sorry. The five-year – if someone's going to come back in five years we think they should have a precancer risk equivalent to the general population with one negative HPV test or co-test. And it's pretty difficult to achieve that within 10 years of normal result. So the shortcut here is that if

someone has had an abnormal result of any kind in the past 10 years they should probably be coming back at either one year or three years.

The three-year return is an equivalent risk to the general population with a negative Pap test. And a one-year return is anybody who doesn't quite meet the threshold for three years but also doesn't meet the threshold for a colposcopy. And that's why this is a very high-risk category because someone could have just missed the colposcopy threshold. And so you don't want them to get lost and not come back in three years or five years.

So the third fundamental concept is that after an abnormal result patients enter a surveillance period of close follow up. All abnormalities require an initial period of surveillance at one-year intervals followed by a longer period of surveillance at three-year intervals.

If they just had a low-grade abnormality then they just require one negative HPV test or co-test before they get to extend that to three years. But if they've had precancer or CIN 2/3 they need three in a row. So they need an HPV test or co-test that's negative at 6 months, 18 months and 30 months before they get to extend out to three-year intervals.

And then once they've done the three-year intervals they need to continue to be screened for at least 25 years even if they undergo a hysterectomy, even if they, you know, turn over the age of 65 during that time period. And we don't really have an end time for when that risk goes down because as long as the data keep accruing this sixfold increase in the risk of invasive cervical cancer tends to appear to continue, so it's perfectly reasonable to continue screening your patient past the age of 65 if they remain in good health and would prefer to keep screening.

So in summary when you're talking about young girls and adolescents ages 9 to 20 what you want to do to prevent cervical cancer is vaccinate them. Between the ages of 21 and 26 you will often need screening and catchup vaccination if they haven't gotten the vaccine. And between the ages of 27 and 65 it's important to make sure all of our patients get screening especially between the ages of 45 and 65 when people tend to forget that they need to keep screening but their cancer rates are going up. And the risk in this age group is determined by their past HPV screening history.

And so I would like to say thank you very much. And I will turn it over to Dr. Ghosh.

Dr. (Sue) Ghosh: Thank you Dr. Perkins. Good afternoon everybody. Can people hear me?

Jane Segebrecht: You sound good (Sue), thank you.

Dr. (Sue) Ghosh: Okay I just want to confirm. So I'm really glad to be here this afternoon to share some insights regarding cervical cancer screening from a community healthcare perspective. I do not have any disclosures. So what I would like to cover with my time is specifically I work at East Boston Community Health Clinic in East Boston, Massachusetts. And I'd like to just give a perspective regarding HPV and cervical cytology screening and what we're doing at our health center. I'd like to talk about who is the East Boston patient. How we have adapted to the cervical cancer screening update that Dr. Perkins just reviewed. What are we doing to track abnormal cervical and cytology and HPV tests at East Boston and what are our biggest issues regarding routine cervical cytology and HPV testing.

So East Boston Clinic is in as I said East Boston. It is basically close to Boston Logan International Airport and close to downtown Boston,

Cambridge, Bunker Hill. It's really a – it's a great neighborhood. It's a great community. And our clinic in 2020 celebrated the 50-year anniversary which was awesome.

I'm proud to mention that East Boston has been a six-time awardee of top places to work in our city. And in 2020 we were also named as a best in state employer by Forbes Magazine. And I just think 2020 was just a year unlike any other and, you know, we as a community health center we were so thrilled that the work that we do together to maintain a respective, diverse and high-performing culture was being acknowledged in these ways.

This slide actually – the people that are in that slide that's actually part of our women's health OB/GYN staff. And the South End community clinic in Boston has now come under the East Boston umbrella. So we are happy to have them join with their patients as well as their staff and providers.

East Boston – the departments that East Boston has include adult medicine, family medicine, women's health services with obstetrics and gynecology, pediatrics and pedi dental, an emergency department and vision health.

The demographics for our patient population include that 70% of our patients are Latin X, approximately 17% of our patients are considered white, 5% of our patients are considered black, 5% of our patients are considered Asian. And the remaining approximate 3% are included in the unreported more than run race and specific Islander Native American.

And the insurance payers for our East Boston patients a little over 40% of our patients have private payers – HMO, PPO, et cetera. A little over 30% of our patients are uninsured. Twenty percent of our patients have Medicaid and a little over 5% of our patients are straight Medicare patients.

Looking specifically at the impact of COVID-19 on cervical cancer screening at East Boston, the first thing I want to mention is that cervical cancer screening is done by three departments at East Boston neighborhood health clinic - the OB/GYN Women's Health Department, Family Medicine and Adult Medicine.

And in looking at the number of total cervical cancer screens done annually comparing 2019 to 2020 we're seeing a considerable drop in looking at pre-pandemic versus during pandemic. And those screening guidelines that we're using are based on the U.S. preventative service taskforce guidelines. So half testing between the ages of 21 and 29 and half in HPV co-testing between the ages of 30 and 65.

So the first – the second objective I wanted to touch upon is at East Boston what are we doing with the update that Dr. Perkins just went over regarding looking at co-testing or cervical cytology screening as a risk-based endeavor and not a straight algorithm. And going from the map to the GPS and what are we doing as a clinic in order to update our syncing on how did we implement this.

So I mean we're lucky. We have Dr. Perkins on staff and with us and we're incredibly lucky to have her. So she actually has given departmental presentations more in depth than the one that was given specifically regarding the update to our departments that perform cervical cancer screening. And the gynecologic M.D.s that are on staff including me and Dr. Perkins we're always available for questions. So any staff member who has a Pap smear, a co-test result that is abnormal this year and they want to know what needs to happen based on previous results, et cetera, we're always available to answer those questions and help with guidance.

The third aspect of making sure that the update that has been described by Dr. Perkins that we're monitoring, that we're doing it appropriately is that East Boston does have a workflow where all abnormal cervical cancer screenings are reviewed by one GYN M.D. and that happens to be me for East Boston. I review all of the abnormal Pap smears and HPV testing. And I do that about every four to six weeks for the entire clinic. So not just for GYN patients but for all three departments that are performing cervical cytology and HPV testing.

And just to describe what's happened most recently in reviewing Pap smears and HPV tests that needed to be corrected based on these new guidelines, between September and November our clinic had 100 abnormal screening results. And 10 of those I needed to correct. And between November and December that percentage decreased to 8%. And in January I just did that screening and it actually is less. It's 6%. So people are becoming used to the risk-based strategies regarding these abnormal results and they're getting the hang of the update.

How do we at East Boston track abnormal cervical cytology and/or HPV testing? So to follow these abnormal screens we do have a tracking system that we have as part of our electronic medical record and we use Epic. And essentially all abnormal Pap smears and HPV results and any abnormal colposcopy or LEEP biopsy results are entered into a tracking system. And I'm just going to use CECT as an abbreviation for other slides in this presentation.

And depending on the department is how the results are entered or who enters the results. So for family medicine and gynecology the ordering provider is the one that enters the results into this tracking system, enters the appropriate

follow up into the tracking system and also any referrals that need to be done if a patient needs a colposcopy or a recall within the system to have a Pap smear done within one year.

For our adult medicine department it's a little bit different. Our adult medicine department has 30 physicians and 27 nurse practitioners. And this department has decided to have one Pap smear champion. So they have one physician's assistant who actually is responsible for entering the results and follow up into the system and setting up appropriate follow up.

So every four to six weeks the same GYN M.D. I essentially review every single abnormal cervical cytology and HPV result for East Boston. And I check for two things. One, has that result been placed in the tracking system and number two has the appropriate follow up of these results been setup and placed into the tracking system.

So for me if those 10 patients – excuse me the previous slide stating that I needed to change the follow up for some of these abnormal results. For family medicine and gynecology I informed the ordering provider and for adult medicine I informed the one Pap champion to be able to let them know that the follow up that they set forth is not based on our newest guidelines or that something – an abnormal result has not been placed into the tracking system.

Some pros that I've noticed regarding having a Pap champion within a department is that there is definitely more streamlined communication in having one provider being able to obtain that information and do any appropriate changes. But there are also cons which include that, you know, if this P.A. is actually on vacation, et cetera, you know, there could be a little bit of a delay of getting Pap smears tracked and followed appropriately.

I wanted to share what I mean by our Pap tracking system. And I know sometimes with slides it's difficult to see. But this is actually from – these are screenshots from Epic and I wish I had a pointer but I'm going to describe this hopefully so that people understand it.

So the left half of the screen is an actual abnormal Pap smear. The patient had an atypical squamous cell result. And if I was live and actually scrolling through the abnormal results, at the bottom of the results we would come to the right aspect of this slide which shows a cervical cancer screening history results and follow up. So this is our tracker.

So October of 2020 this patient had the atypical squamous cell result. And normally what we do we actually click on this blue thin prep Pap result for the date. And that allows us to get to a smart form to enter results of the Pap smear into the tracker as well as follow up.

So for the 2020 Pap results the follow up states colposcopy. And the actual result shows the atypical squamous cell Pap. And when we initially look at this part of the Pap tracker, initially this information is not present - the atypical squamous cell and the colposcopic follow up. After clicking on the result we get to a smart form.

And that smart form allows us to capture cervical cancer screening results as well as colposcopic results - week results and specifically if we wanted to follow the sampling endocervically or an endocervical curettage we can actually follow those results. In looking at the different possibilities of Pap smear results those are all present. Combinations of HPV results are present, colposcopic results and results of the LEEP excision and also the follow up and who will be following the abnormal results.

Well actually I want to go back and do one more thing. So in having this tracking system why is that important? Why do we have it? We have the ability to have cytology and pathology in one page. So for us to be able to look up a patient's results we can look up their Pap smears that have been tracked and basically at the end of the Pap result everything that has been placed into that Pap tracker appropriately -- so Pap smears, colpos, LEEPs -- that information allows you to have a one place to be able to see cytologic and pathologic results and follow up.

And it also allows us having this system allows us to create reports through Epic based on patients that have been entered into the cervical cytology tracker which from a quality improvement perspective allows us to create reports for meaningful outreach for those patients that are higher risk.

So for example if we have a patient that needs a colposcopy in six months and we want to check all of the patients in our clinic that have been placed in the tracker who moved this type of follow up, we will be able to create a list of those patients and subsequently confirm that these things have been scheduled and an appropriate outreach has been done.

Lastly I wanted to touch base on routine cervical cytology and HPV testing at East Boston. In running our report and I'm sorry my little ellipsis is off. It's driving me crazy. In running our report for East Boston using our health maintenance feature within Epic we are able to see all of the patients who are overdue for cervical cancer screening. And when I created these slides in December – the beginning of December we had approximately 7,500 patients that are overdue and that's an issue. And that's something that we are actively trying to remedy. And it's definitely going to take time.

And the two aspects that we are actively trying to figure out answers to are the following. The first is accurate data. So this report of 7,500 patients it's not accurate. And we are trying to figure out the most efficient and financially responsible way to create an accurate list.

There are times that our health maintenance has been set incorrectly. Say a patient several years ago needed a Pap smear done and then needed to be repeated in one year. And that change was never placed back to a routine schedule. So it's possible that that patient does not need a Pap smear this year. She needs it in two more years. Or if a patient had a hysterectomy and it hasn't been captured and the hysterectomy not for precancer. You know there are several different reasons why that list can be incorrect.

So we are currently trying to figure out and to get departmental volunteers including physicians, PAs, NPEs to all take a part of this list and to confirm that the patient actually does need screening. And I do mention, you know, we are an FQHC who is part of the American Cancer Society, NFL Cancer Catchup Grant. So we are – I think we just hired somebody. But we were actually trying to make sure that we are hiring a cancer navigator to aid in the effort for cancer screening – all cancer screening for East Boston. But some of that effort will definitely be going to cervical cytology and HPV for outreach.

The second part is outreach. So for us we are currently in the process of creating what we think are going to be Saturday morning clinics. So a session, a clinic, with all female providers, nurse practitioners, medical assistants, front desk staff in appropriate, you know, communicating with patients in a language specific outreach and media campaigns when necessary. And we're trying to figure out again a fiscally responsible way to set this up so that we can decrease that huge change in Pap smears that were done, you

know, previously in 2019 versus 2020 and that gap of overdue Pap smears that has definitely grown in this past year that honestly is going to take some time to get back to any meaningful baseline.

What is possible in the future and I think actually Jane mentioned this in her introduction but patient's self - HPV self-sampling. And it is something – it's an innovation for cervical cancer screening which will be invaluable. And especially in how we've had to stop or lessen, you know, routine cervical cancer screening this would be a great way eventually to help us catch up on this. So it's something to definitely look forward to in the future.

And in looking at general resources we have some links again for the ASCCP as Dr. Perkins mentioned regarding its new app with the update or the Web based feature to be able to understand when your patient based on their cervical cytology and HPV history will need their next screening, et cetera.

The National Cervical Cancer Coalition which is a great site regarding education for HPV and cervical issues and it does have materials and tools regarding prevention, detection and screening awareness. And always the American College of Obstetrics and Gynecology which does have consensus statements and practice updates regarding cervical health.

So I'd like to thank everybody for participating. And maybe I think that's all I have to say.

Woman 1: Okay well great. So now we have some questions that we can address. I'm looking at the chat box but operator do we want people to call in too or just do the chat box or…

Coordinator: It's up to you guys. I can give the (unintelligible) if they'd like to ask a question over the phone as well.

Woman 1: Okay let me go through the chat box first and we'll see if we have time.

Coordinator: Okay great.

Woman 1: Okay. So there's one question about if a patient has ASCUS and an HPV test – positive HPV test with a previous unknown and is there any age consideration when doing the risk-based certification and Dr….

Dr. Rebecca Perkins: Sure. Yes, so ASCUS HPV positive in anyone 25 and older is managed the same. And the 21-to 24-year-old is managed more conservatively where you wouldn't have a colposcopy right away. But in anyone 25 and older if they're ASCUS HPV positive with an unknown they would get a colposcopy.

Woman 1: Okay. And then also there was a question about which test do you need with the co-test Pap and HPV? Okay let me see if I can…

Dr. Rebecca Perkins: So the management guidelines tried to accommodate all of the various screening options. So we need in order to do risk-based management you need to have an HPV test. Cytology alone is definitely not preferred by the American Cancer Society for screening and is not preferred for the management because you need the HPV test to really do good detection of precancer and discrimination between your risk of precancer. But whether you use an HPV test by itself -- a primary HPV test or a Pap HPV co-test -- it doesn't matter. You can screen with either one.

I didn't have time to get into this but if you're doing primary HPV screening any positive HPV test the lab will reflex to get a cytology. So if you're doing

primary HPV screening your negative HPV test would be, you know, the final result of the negative screening your patient, you know, is done and can go home and, you know, come back for her next screen. But if the HPV test result is positive, the lab would run a cytology and so you would get both those results back at the same time to be able to manage your patient.

Woman 1: Okay. And then there's a question about how do we balance these new guidelines with current UDS requirements?

Dr. Rebecca Perkins: So that's a good question. So the use UDS really focuses on screening. And it should follow USPSGS guidelines which allow for screening with Pap alone, with co-testing or with primary HPV testing. So whatever your clinic is doing for screening should be in line with those guidelines and which are also in line with the American Cancer Society guidelines and will qualify under UDS. UDS doesn't have specific quality metrics for follow up after an abnormal result. So it wouldn't apply to the follow up. It's just applying to screen.

Woman 1: Okay. And there's a question about any data showing a change to other HPV strains that are causing dysplasia.

Dr. Rebecca Perkins: That's an excellent question. Yes there was concern in the beginning that if we vaccinated against certain HPV types other HPV types might come in and cause cervical dysplasia or precancer. That hasn't happened. We're just getting rid of the bad ones and the cervical precancer or dysplasia rates are going down. There hasn't been any evidence of type replacement with other (unintelligible) types.

Woman 1: Okay. And then there's a question about what about other follow up recommendations based on clinical assessment such as CD screening, contraception?

Dr. Rebecca Perkins: Right. So cervical cancer – so HPV testing is not – shouldn't be part of your routine STI screening. So if your patient goes oh, you know, I had it with a partner I had an exposure you would do, you know, your gonorrhea, your chlamydia your trichomonas, your syphilis, your HIV depending on these exposures maybe hepatitis. HPV wouldn't be part of that unless you happen to also notice that the patient was due for cervical cancer screening.

So it's not considered an STI screen it's a cervical cancer screen. And, you now, your patient in terms of, like, checking their contraception or, you know, changing their (LARF) or something, like, that you would just do that at whatever interval that was indicated. But anytime you do that it's an opportunity to see if the patient is due for cervical cancer screening.

And, you know, if you notice that you're changing a Nexplanon in somebody or changing an IUD and it's been, you know, 4 1/2 years since their last cervical cancer screening test and they don't come in very often, you know, take that opportunity to get that routine screen at that time because we don't see patients – we often don't see patients every single year. So every time they come in for whatever – their yeast infection and whatever it is they think they're coming in for it's always important to see if they're due for a screening especially because patients, you know, will come in for the yeast infection. You'll do a speculum exam and then they'll think they had a cervical cancer screening because they had a speculum exam. So patients often don't realize that they're not up to date. So it's really important to check at every opportunity.

Woman 1: Okay we only have time for a couple more so I'm just going to look through the chat. And there's a couple questions to (Sue) about the East Boston – the Epic, the tool. Is that a homegrown tool or is that available to all Epic users?

Dr. (Sue) Ghosh: So that is something that is available to Epic users. But it is something that your I.T. department has to be involved obviously in having that as part of your Pap smear result and putting that sort of, like, turning it on. But it isn't something that was solely created for East Boston. It is something that can be done for all Epic users.

Woman 1: And last is there a way to make a report or a dashboard in Epic to group those with abnormal screenings so care coordination management can occur?

Dr. Rebecca Perkins: Yes. So that's the thing about the tracker is so we have a Epic report that is basically we can run it and it's every single patient that has a result or follow up that is in the tracker system. And then to be able to use that report. That report is connected to Outreach. So if you're going to have, you know, a cancer care navigator, et cetera be responsible for Outreach in certain groups of high risk patients, et cetera, that is possible. So yes the tracking system does lead to a report which has connections to Outreach within the Epic system, yes.

Woman 1: Okay well great. It's probably time. Jane what do you think? Do we…

Jane Segebrecht: Yes I think, you know, we're just about 20 minutes after the hour and I know that there are additional questions and we're so appreciative for everybody's interest today and for the folks who hung on. We will follow up by email if we've not responded to your question. So look out for an email and either Dr. Perkins or Dr. Ghosh will be in touch with feedback or the HRSA Office of Regional Operations or HRSA Office of Women's Health team. And we just

really want to thank everyone for your work and your leadership in this space and wish everyone well.

So I think we'll go ahead and wrap today and there will be a recording available. And we will send that out about a week after today's presentation. So thank you all very, very much for your time today. Have a great week ahead.

END