

[MUSIC PLAYING]

**DAVID A. NACE, MD, MPH, CMD:** So I'm going to talk about the topic of vaccines in older adults. The United States has a pretty robust childhood vaccination program that I think everybody is aware of. But when it comes to adults and older adults, it really is an area that has been really underdeveloped. And over the last 10 years, what we've been doing from a public health standpoint working with the CDC, the National Adult Immunization Summit and others, has been trying to bring the attention back to what vaccines do older adults need and what's the body of knowledge that practitioners need to have.

And as a result, what we've done is we've started to incorporate stuff into the maintenance of certification training. And we've also started to include this information into the recertification exams that we take in internal medicine and family practice. So having taken two of these fund exams over the course of the last five years, it's always an enjoyable experience to take that re-cert exam, I can tell you that vaccinations are covered. And so it is an area that you'll need to be aware of.

So I have no pertinent disclosures relevant to this presentation. Look, I'm the father of three daughters. I have plenty of conflicts. I just don't have conflicts of interest. You know, is that my sweater? Were you in my room? Do you really listen to Nickelback? And dad, were you born in the 1900s. All of those are conflicts but they don't relate to this.

The objectives that I'm going to do are basically go through vaccine-preventable diseases and convince you that it's important to vaccinate and talk a little bit about the vaccines from a practical standpoint. So we're going to go through these cases, a couple of cases throughout. And all the cases the names have been changed to protect the guilty.

Catherine is an 83-year-old female. She has a history of hypertension, a-fib, osteoarthritis, and diabetes. And she comes to your office in October to establish primary care. She's a non-smoker. She doesn't drink any alcohol. She's widowed and lives in the country. And she's an active gardener, which is an understatement. She's actually pretty much a farmer.

She's in a lot that is large next to a very wooded area. She last received the flu shot in February. She's had the pneumococcal polysaccharide 23 vaccine when she was diagnosed with diabetes at the age of 67. She's not had a shingles vaccine and her last tetanus shot was two years ago. So the question is, what vaccines do you recommend for Catherine? Influenza, the 23 valent pneumococcal vaccine, the 13 valent pneumococcal vaccine, the shingles vaccine, and TDAP? Influenza, the 13-valent pneumococcal vaccine, shingles, and hepatitis B and TDAP? Or the influenza, the 23-valent, the 13-valent, shingles, the Lyme disease vaccine, and TDAP?

The 23-valent, the 13-valent, shingles, and Lymes disease? Or the 23-valent and 13-valent and shingles? If you said the second one, you would be correct. So the influenza, the 13-valent, the shingles vaccine, the hepatitis B vaccine, and the TDAP. So I'm just taking a look over here. Some of the-- it looks like some of the wording is coming up kind of strange on the-- and I apologize-- on the slides. Not sure why that is doing that.

So if you voted for the Lyme-- how many of you thought about the Lyme vaccine? Anyone? So there is an approved Lyme vaccine. It's approved for dogs. And this actually would be my aunt and if you called her a dog, I think she would be highly offended. So she doesn't get the Lyme vaccine in this one. So the ones that we're going to talk about through the presentation today is the vaccines that are listed here. And we're going to go through these relatively quickly because there are a lot of slides in here.

I've included the information I think is going to be pertinent to the mock exam, to your practice, to recertification. We may not get through TDAP or the ones at the end because we're shifting our frames around a little bit during the presentation here. So I will go a little bit fast through some of these areas. This comes from the CDC website. It's really helpful if you want to look age-based vaccines, what is recommended for each of those ages. And I won't go through this in detail but it is there as a reference material for you.

We'll start with the flu vaccine. We know that everybody who is over 65 needs a flu vaccine. We know that everybody over six months of age needs a flu vaccine. And we know every health care worker needs it and everybody here should have had their flu vaccine. If you haven't seen your flu-- gotten your flu vaccine, see me at the end. I have one with me.

Flu is a geriatric disease. 90% of the people that die from flu are over the age of 65. The older you are, the more likely you are to be hospitalized, 16-fold higher among those 85 and older compared to younger individuals over 65. The number of cases of hospitalization and flu and deaths are increasing as the population ages. And this is particularly important for those individuals who live in congregate living settings, such as nursing homes, assisted or independent living facilities.

You can have attack rates up to 60% and case fatality rates of 55%. Part of my job is to respond to outbreaks. And over the last 20 years, I've managed well over 150 outbreaks across the country. And I can tell you I've seen attack rates that have been at least in the 20% range. So it's not unheard of. And it has quite an impact. So this just shows you the aging of the US population. You can see that over the next 20 years or 30 years we're going to have about 5% of the US population 85 and older. And I think everybody is probably pretty much aware of that.

So how are we doing with vaccinations in Pennsylvania? In terms of older adults, about 72% of folks right now are receiving the flu vaccine. And that's pretty good, actually. That's the fourth highest in the country. So Pennsylvania ranks pretty well. The rest of the country, the average is about 65%. However, when you think 72%, that means over 25%, over one out of four people, who are supposed to get the vaccine are still not getting the vaccine.

So what questions about influenza vaccine can we have? This case, I think, describes one very nicely. Judy is an 85-year-old female. She has heart failure with preserved ejection fraction, hypertension, obesity, and major depression. She comes to the office in October for her annual flu shot. Which flu vaccine is recommended by the ACIP for Judy? So the standard regular dose quadrivalent vaccine, the high dose trivalent vaccine, the adjuvanted trivalent vaccine, the recombinant quadrivalent vaccine, the live attenuated vaccine, or I have no bloody idea.

The first four. So the live attenuated vaccine is not recommended for older adults. It's recommended, I believe, up to age 49. I have to look it up every time because I don't use it in this particular population. So all of the other ones are equally recommended by the ACIP and CDC. And there's no preference for one of those vaccines over the other. This table I've included in your handout and it lists all the different vaccines.

I've put the brand names in there. Again, I don't have any conflicts of interest. I put it in there because you'll hear the brand names and you're not sure which one fits into which category, you have it there. There are the abbreviations. You may see these as you read through any of the stuff that comes out of the CDC on influenza. The abbreviations I find to be terribly unhelpful because they make absolutely no sense.

And then you have the dosage and the technology there. You can see that most rumors are still egg-based although we do have cell and recombinant technology. And we'll talk about that in just a moment. So all of these are approved vaccines for older adults. So if they're all approved, is that really the best recommendation? And the ACIP has still not made that preferential recommendation, in part, for some reasons we'll talk about in a minute.

But we start looking at some of these newer vaccines, is there any evidence that they are actually any better than the standard dose vaccine? And this is the first study that we'll talk about. This was done in community dwelling older adults. Diaz Granados did a study looking at 32,000 patients across the US and Canada over a two year period. It looked at high dose versus standard dose trivalent vaccine. Followed the individuals over the entire flu season. And they looked at clinical outcomes as well as immunogenicity.

And what they essentially found was that there was a 24% reduction in clinical disease, proven clinical by PCR or by cell culture. And so that's a meaningful outcome. That's actually clinical disease. If you look at the titers, you can see the titers there. The titers for the standard dose vaccine for each one were 270 versus 481. So the titers are roughly twice as high for the high dose vaccine versus a standard dose vaccine. And that seems to transmit into reduced clinical burden.

Does that mean anything? Well, we don't know. This is community dwelling. What we did was our group actually did a study looking at nursing home patients. This was the first study to be done in the nursing home population, again, over the same two year period. We looked at 205 subjects, high dose versus trivalent, and we looked at only immunogenicity. It was single blinded but that was the-- the patients were blinded to it. Actually the people running the laboratory tests and the principal investigator, myself, were blinded. Only the study coordinator actually knew.

We looked at titers all the way up to six months out. And it's a frail population, which is different than that community-based study. The mean gait speed here was 0.7. So these were individuals, many of whom had walkers in order to get around. And they were getting around very slowly. And what you see is that, again, the titers were twice as high for the high dose vaccine.

What you'll notice is, if you looked at that prior slide, the titers were 270 and 480. Here they're 27 and 78. So there's about a 10 to 15-fold difference in some of these numbers compared to the titers found elsewhere. Now, you can't compare titers lab to lab. There is up to a fourfold difference. But there's not up to a 10 to 15 fold difference. And what we see is a frailer population responding less well to a vaccine.

Still, the high dose seemed to perform a little bit better. Stefan Gravenstein did a study here that looked at, again, the nursing home population. This was a cluster randomized trial. So they actually took the facility and randomized facilities rather than patients. And what they found over 800 nursing homes and 92,000 patients was that there was a reduction in those homes in which high dose was used in hospitalizations for a number of causes, for respiratory illness, for pneumonia, and then of course for all cause hospitalizations.

Some of those numbers are really tight, the 0.9 adjusted relative risk for all hospitalizations all cause. You say, well, that's not much of a difference. But when you think that there are, you know, 25% of the US population-- and the US population's about 330 million-- this comes out to a lot of patients, money, and hospitalization. So even that small difference actually has a big bearing on the health care system.

So for high dose vaccine, there seems to be data that is better than the standard dose. What about the recombinant vaccine? And we have data from a few studies. There is one that was looking at 9,000 patients over the age of 50. And again, clinical disease, PCR-confirmed disease, a 30% reduction compared to standard dose vaccine. The adjuvanted vaccine, same thing, reduced hospitalizations for influenza pneumonia, reduced hospitalizations for cardiovascular events, and reduced influenza-like illness for those residents of long term care facilities.

So why don't we recommend one of those vaccines over the standard dose? It's because we're afraid to be gutsy here. We know it works better. All these vaccines seem to work better than standard dose vaccine. We haven't compared any of those vaccines against each other, the newer vaccines. And so ACIP has been reluctant to come forward and pick one of those against the other.

Are there other considerations that we should think about in picking a vaccine? And it's this, our technology for growing vaccines, for manufacturing, has been based on egg technology. We grow them in eggs. So we go out to Malaysia or wherever the new strain is. We identify it. We immediately put it into eggs. We start to propagate it. And then we send it off to reference laboratories and also to pharmaceutical companies.

And what happens is when you take that virus and you put it inside the egg, the virus is sneaky. It actually starts to change a little bit and it directs itself to attack the avian antigens. So it's targeting and changing in response to the chicken. And so what ends up happening is there's a little bit of a drift. And we think that's why the vaccine sometimes is not as effective, even though it's the right strain, there's a slight genetic difference between what's circulating and what is actually in the vaccine.

So that seems to play a significant role. The cell vaccines, the recombinant vaccines, don't have that problem. And so the thought is that might be why the recombinant vaccine looked like it had 30% effectiveness at a lower antigen dose than the high dose vaccine did, which came in around 24%. So in summary, what you need to know for the boards is that one vaccine is not recommended over the other for older adults. They're all considered equal.

However, high dose, recombinant, and adjuvant all looked like they work a little bit better. Again, no head to head trials. What we've done at UPMC, back in 2014, we went to the high dose vaccine. So we have about four years of experience with this now. We still continue to have some outbreaks of influenza within our facilities, although I have to say the size and scope of those outbreaks have gone down dramatically.

An outbreak now is one to two cases for us in long term care in most circumstances, where it used to be 20, 30 cases. Part of that is also we went to mandatory vaccination. That's something that I was helping to push for for about 10 years. And that certainly makes a difference in terms of transmission and mortality. So when health care workers get their vaccine, there is a 40% reduction in mortality among the patients.

And then this year what we decided to do is we decided to get rid of the egg-based vaccines. Unless you're less than four, there's only one vaccine that's approved there. So between the ages of four and 18, the Flucelvax, the cell cultured. And then 18 above is the recombinant. We chose those because we're trying to compare how the company that manufactures flu cell vax works.

We have a lot of experience with the company that makes Flu Block. But we just need to be-- we don't want to put our all our eggs in one basket, if you would. So other questions on flu. One of the ones that comes up pretty regularly is, do I give it now or do I wait? Should I stay or should I go? And this is actually a debate.

People have very strong opinions on this and they're all wrong. So it doesn't matter which one you have. So there are some folks that will say, I'm not going to vaccinate until the end of October or November or December or some made up date because I want the immunity to last all season. There are others that say you should do it in August the minute the vaccine comes out.

There are folks that have told me that the ACIP is now recommending to hold the vaccine and give it in October. I read that recommendation statement every year and it doesn't say that. It hedges the bets, actually. So the data is all observational. So there's not a lot of-- there are no randomized trials looking at this.

And what we found is that some studies there seems to be a waning of immunity and a waning of clinical protection. And other studies it's not there. And our study that we did in the nursing home population, there was very minimal difference at six months. There's less than a log difference in the titers. And it certainly wouldn't have made a difference in terms of clinical protection.

So what we do know is that if you wait, you will miss patients. So they will not come back. Something will happen. They'll take a trip to Hawaii or someplace fun while you're working. And you just won't get them back in time. So the CDC does point out that 3/4, 75%, of all peak flu seasons happen in January or later.

And that's the rationale that some people will point out. I like to always look at things as the glass half full. And that means that 25%, one in four of those outbreaks, are happening in December, November, October, or September. So if you wait, you're going to miss those flu seasons. And we've seen that happen pretty significantly. And that's where we've had a significant number of our outbreaks.

So I personally don't believe in waiting. I think you should give the vaccine as soon as you can. And no formal frame has been observed. It's not wrong to give it early. It's not wrong to technically give it late but you're playing that game of time. So the other thing I'll point out just before we leave flu is that Amelia Earhart did not get her flu vaccine before she left. I'm just saying, it's not causation, necessarily, but I'm just pointing that out. You don't want the same thing to happen.

All right, pneumococcal disease. I hopefully don't need to convince anybody this is the most common cause of community-acquired pneumonia. 900,000 cases occurring annually in the United States. And of those hospitalized, 5% to 7%, roughly, will die of the disease. If you look at invasive pneumococcal disease, again, a disease of the elderly, 90% of those cases are in older adults and yet four out of 10 older adults are not vaccinated.

So there are two types of vaccines that are available. The third one, the one at the bottom, the PCV7, forget about it. It's only licensed for kids. So you have the polyconjugate vaccine 13, which is the newer recommended vaccine. And the pneumococcal polysaccharide 23, which is the older vaccine we used to call pneumovax. So it's relatively straightforward. After the age of 65, you get both of them.

The question is, which one comes first? How many of you-- how many of you think that the 13 should come first? How many think the 23 should come first? Depends on the immunization status, yeah. Yeah, so if you're naive to this, you should get the 13 vaccine first, followed by the 23 vaccine at least a year later. And the easiest way to remember that is the numbers go up in order, so 13 comes before 23. It's easiest way to remember that.

For those who have gotten a previous dose of the 23 vaccine, after the age of 65, you just need to give the 13-valent vaccine. For those who were vaccinated with the 23-valent before the age of 65, when you turn 65, start at 13. And then wait a year and go to the 23. As long as it's five years out after that last 23-valent. So that the recommendations from the CDC. It is really hard to remember this, though. And you will have patients that will come in with all kinds of combinations. Three or four the most common scenarios you're going to have here, 75-year-old comes in once to establish primary care.

She never had a pneumonia shot, which one do you give? 13, good. Same patient comes in, established from primary care. She's got one in the past, she doesn't remember. Actually, she doesn't remember if she's gotten one in the past. She can't remember that far back. Her prior internist was shot. What's the most appropriate course?

13 followed by the 23, right. Right, you give the entire series. OK, Jane comes in, established primary care. She knows she's been vaccinated before and it was prior to 2014 and it was after the age of 65. She has no idea what vaccine. And her internist office was located near the Zambelli fireworks, which burnt down. Which vaccine? 13, yes. If it's unknown, go with the 13.

And the key here is you might say, well, it could have been the 13 she received before. The date of 2014 is the date. After 2014, the new vaccine was recommended. Prior to that it was rare to receive the 13-valent. And then you have an 89-year-old lady. She's in a long term care facility. She's got multiple comorbidities. When she was 67 she had the 23-valent. She had a booster of the 23-valent at 72. And then she had the 13-valent one year ago.

Should she get another booster? OK, good. There are no boosters. So one of the things we see in long term care quite frequently are-- is this concept that you need to give the vaccine every five years. You don't need to give the vaccine every five years. There are no boosters. So we still continue to see that quite regularly. So there are many other scenarios that are out there. This is from the Society for Post-Acute and Long Term Care Medicine.

What we have done is put together a toolkit for you. There's some clinical vignettes on there. I've gone through every possible scenario that you can imagine. You know, the person comes from Russia, was immigrated through the Aleutian Islands and walked down in person. And she has this vaccine and she doesn't know which one it is. And it comes with valerian root because they're all from Russia. Whatever the clinical scenario is, we have it there and you can look at it.

And it's not just for long term care residents. It's for all older adults. We also have an assessment template note on there that you can use too. All right, hepatitis B. So how many of you routinely give hepatitis B within the office practice? Anyone? A few folks. Surprised, maybe 50%. So hepatitis B is actually recommended for older adults with diabetes, or for adults with diabetes in general.

And what we know is that individuals that have diabetes have a higher risk for hepatitis B. And this came out of actually work in the long term care facilities. And that's how I got pulled in and got put on the ACIP workgroup for hepatitis B because they asked my opinion and I gave it to them in four pages. And next thing you know, I was in trouble. And I was on the committee.

What they found was that there were a number of outbreaks. And I think you can see here, this is a subsequent data. There was some original data that they had used. But this is essentially a six year period and there were 23 outbreaks of hepatitis B that occurred, 175 cases. And you say, well, that's not too much. There are 330 million people in the US. But it was 11,000 people that had to be screened as contacts. And you can imagine the time that it takes to do that.

The worst part was, 3/4 of them are in long term care facilities. So the good news is that when the first portion of this study was done a decade ago most of them were in nursing homes. Most of them are now in assisted living facilities. So we're making some progress here within the nursing facilities. Assisted living still needs to catch up. What's the risk? Anybody know what the risk is? Glucomers. Glucomers.

If you're a diabetic, you're having your glucose checked on a regular basis. It is profoundly difficult for use of glucomers and other point of care testing devices. This also applies to meters for INRs. When you think about it, when you check somebody's blood sugar, you have to, when you're done, take your gloves off, wash your hands. Put new gloves on. Open up the packet of the cleaning solution. Clean the meter off. Take your gloves off. Wash your hands.

You also have to make sure that the solution that you use for your meter is approved by the meter device manufacturer. Some of that cases it's water is what they recommend. And the last I checked is hepatitis is not killed by water. So this is a big, big challenge. The glucose meters are notorious. And it just takes a microscopic--you can't even see the blood and it transmits the hepatitis B virus. And some of these outbreaks have been quite lethal and had 90% mortality rates among them.

So it's a significant issue. It's gotten the attention of the FDA. The FDA has issued this warning. If you're using a meter in your office, make sure, by all means, you have a process to clean it after every single use. It's really important. In the nursing home, I guarantee you it will result not just in a lawsuit but criminal activity. So you'll be charged under the murder statutes, actually, if somebody dies as a result of this. CMS has also issued warnings with regards to it.

So it is a very, very serious issue. What we did, when we looked at this, the question came up-- originally, they wanted to make sure that everybody with hepatitis B-- or with diabetes-- in a nursing home was vaccinated for hepatitis B. The problem is, the average age of my patients is 88. And when you think about that, if you have somebody who is 90 and on hospice with diabetes, are you going to give them a three shot series over six months? It makes absolutely no sense.

Not only that, the response rate is 11% after the age of 80. So the chance of it working is not very good. And originally, they said well, we would just repeat the series. You know, if the person is still alive, you could think about that. But if they're not alive, it really doesn't tend to work. So what we did was we looked at the quality adjusted life years. At the age of 60, it was about 5 million if you vaccinated older adults.

So we did a permissive. So between the ages of 19 and 59, it's recommended that you get the hepatitis B vaccine if you have diabetes. And you should get it as soon as possible after the diagnosis because at some point you're going to use that glucometer. Above the age of 60, it depends on the person, how healthy you are, what's your life expectancy, is their frailty involved, et cetera.

It's again, a three shot series, zero, one, and six month intervals. There is no recommendation for tighter testing for patients at this point in time. For health care workers, there is, not for the patients. All right, this is a painful one to look at, herpes zoster. There we go. So you have this patient named Ned. And he comes in. He's 85. Routine follow up, hypertension. And he has COPD, for which he has had several intermittent courses of steroid taper over the last 10 years.

He had shingles seven years ago. He's also had the Zostavax live attenuated shingles vaccine two years ago. And he asks about this new thing he heard on the news called the new shingles vaccine. Which of the following would you recommend? He's already vaccinated with the Zostavax. No vaccination at this time, but the recombinant in five years. Vaccinate with one dose of the recombinant now. Vaccinate with two doses of recombinant now and in six months. Phone a friend.

So this person would be a candidate to get the new vaccine and it's two doses. So even though they've had the shingles vaccine as recently as two years ago with the older vaccine. So one of the things that we've been wondering is we're vaccinating children against chicken pox on a regular basis. Does the varicella vaccine actually reduce the incidence of herpes zoster and the answer is no.

You can see here that the incidence has been increasing among all older adults. And the older you are, the more likely you are to get this. You can actually get shingles from the chickenpox vaccine. So it can be latent in the area of the injection. And it can actually reactivate. So there have been cases of that that have occurred as well. So the zoster vaccination is still important despite our efforts at childhood vaccination.

Two vaccines, the live attenuated, which is the older vaccine, and then the new, inactivated, recombinant vaccine. The new vaccine is two doses. They're given between two months and six months apart. So first dose two months later or six months later, and then the second dose. It's also recommended for 50 and older. The older one was recommended for 60 and older.

So there is a little bit of a difference on the age. Why don't we do the older vaccine? Well, this was the data that they published showing about a 50% effectiveness against zoster. And you can see when you got became 70, it went down a little bit but it was still close to 40%. And you think, well, that's not too bad. This next slide is why I don't get funding from Merck. This is what they showed to the FDA.

And the older you got, the worse it got in terms of your vaccine effectiveness. The numbers that at 90 or above were so small that it's hard to be-- it's not significant at that age. But you can see that with each five year increment, the effectiveness declined. This is the effectiveness of the new recombinant vaccine. It's running about 90% regardless of whether you're above 50 or above 60-- excuse me, above 70. So highly effective.

This graph you say, well, you know, that last group there, 70 and above doesn't look as effective. But remember, this is a scaling issue. So it's 96% effective for those 50 and over and it's 91% on this far right hand. So 91%, 96%, that's not much of a difference and I'll take it. So it's highly effective for the prevention of post hepatic neuralgia, as well as for the zoster.

So what are the recommendations? These get a little bit confusing. The recombinant vaccine, the new vaccine, is recommended now preferentially. So anybody moving forward should get two doses of that, aged 50 and above. It's recommended for everyone that's got the prior vaccine. Again, age 50 and above. It's recommended over the old vaccine. Do we ever recommend the old vaccine?

Sometimes you can, actually. So it's for immunocompetent adults 60 and over who are allergic to the new vaccine or got the first dose and didn't like it and they don't want to get the second dose. So in those circumstances, you might be able to make an argument for it. So in general, you're not going to use the old vaccine.

So the new vaccine is the one that's preferred. How many of you have heard there's a shortage of this? Yep, OK. How many of you have tried to get it-- well, I won't ask that because then you have to tell me your age. Don't tell me, no. What do you do when you're trying to figure out-- there's a shortage and trying to triage.

The CDC doesn't have any recommendations at this point in time in terms of triaging people for this vaccine. What I tend to think is that it's probably best to use some common sense. So if you know of an individual who's at risk for immunosuppression, they go through bouts of steroid use periodically for some autoimmune disease or for COPD or something else, that person is at higher risk for shingles and post-hepatic neuralgia. And that would be a person at high priority.

Somebody who is in their 80s and borderline living independently, a case of shingles could put that person in the nursing home or could kill them. So that's the type of person who is frail that I would think would benefit. If you're 65 and you're playing golf, and you're lifting weights, you probably don't need the vaccine right now.

So at some point, once the vaccine shortage clears up, you might be advised to get it. But right now, you could hold off. So yeah-- I'm going by the-- yep. And then a couple of things to think about is also to the folks that need the second vaccine, so they've had the first dose. Those should be prioritized. I know the VA is proceeding with that classification as well.

So that is, I think, the end of the slides. I did put this in. This is on the Medicare learning network. It is information about payment for vaccines. It is very difficult. How many of you give the shingles vaccine in your office? A surprising number do. So OK, we're actually not giving it in our offices. We've run into too many barriers within our office to get it and we're actually referring it out because it is covered under part D. It's not covered under part B.

And the question is, will that change? I've actually had discussions with the auditor general, you know, and for CMS. We've had discussions about this particular policy. We've also had discussions with the OIG and a few other groups. But it is not going to change anytime soon. So for the foreseeable future, part D for that one. And I'll leave out the TDAP. You can read about that information. Tdap, one dose is required for all adults 18 and over.