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Expert Interviews

National HIV Curriculum Podcast

Switching ART Regimens: A Discussion

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The three National HIV Curriculum Podcast editors discuss the multiple factors they consider before switching to another oral ART option or to injectable cabotegravir/rilpivirine, including adherence, patient preference, weight gain, NRTI resistance, HBV status, and dosing schedules.

Topics:

- NRTI
- HBV
- CAB-RIL
- genotypes
- weight gain

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Transcript

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introduction**[00:00] Introduction**

Hello, everyone. I'm Dr. Brian Wood from the University of Washington in Seattle. Welcome to the National HIV Curriculum Podcast. This podcast is intended for health care professionals who are interested in learning more about the diagnosis, management, and prevention of HIV.

Dr. Jehan Budak is assistant professor of medicine at the University of Washington in the Division of Allergy and Infectious Diseases. She serves as assistant medical director for the Madison Clinic, which is our Ryan White-funded HIV primary care clinic at Harborview Medical Center in Seattle. She also serves as director of the HIV Pathway through the Internal Medicine Residency and as an associate editor for the National HIV Curriculum. Jehan, welcome.

Dr. Budak

Thank you. Hi.

Dr. Wood

Dr. Aley Kalapila is associate professor of medicine at Emory University in Atlanta. She's a clinical provider at Ponce de Leon Center, an outpatient HIV clinic there, also Ryan White-funded, and she attends on the Inpatient Infectious Disease Consult service at Grady Memorial Hospital. She also serves as an associate editor for the National HIV Curriculum. Welcome, Aley.

Dr. Kalapila

Thanks for having me.

Dr. Wood

I'm honored we get to talk again. In the last episode, we talked together about starting ART [antiretroviral therapy] and all the different considerations that come up. Here, we're really going to focus on optimizing and switching ART.

why-switch-oral-art**[01:22] Why Switch Oral ART?**

Dr. Wood

So, let's just start with a general question. Aley, I'm wondering if you can share examples from your clinical practice in which a patient who's, let's say, taking their meds and their viral load is suppressed but might benefit from a switch of their oral ART. When does that come up for you and what kinds of scenarios can you think of?

Dr. Kalapila

And so just to clarify, Brian, you're talking about switching from oral to oral, right, not oral to injectable?

Dr. Wood

Yeah, thanks for clarifying. We'll come back to injectable at the end. Let's focus on switching an oral regimen to a different, or newer, or simpler, or anything else that might come up in terms of a switch.

Dr. Kalapila

So, I think typically for patients who are virally suppressed, and my main reasons for wanting to switch, or I would obviously ask the patient, would be related to if they're having side effects or adverse effects from the treatment, right? So, if they have increased weight gain. I've had a couple of patients develop pretty bad diabetes on integrase inhibitor anchored regimens. And so, in those cases, I would definitely consider trying to switch and using a different anchor drug. Also, another time that I would consider switching is I've started someone on medications, and then they are diagnosed with a concomitant medical condition, be it an OI [opportunistic infection] or something else that could cause drug interactions, because the goal is really is to try to minimize the pill burden for the patient because it's no fun having to take 15 pills. And so those are probably the biggest reasons for why I would consider switching a patient. But again, I would do this in conjunction with having a full discussion with the patient, letting them know that this is what I'm thinking, and giving them the option of switching and saying, “I'm doing this in an effort to minimize drug interactions, but also to minimize, say, your pill burden or pill dosing frequency.” And I leave it to them to decide whether or not that is something that they want to do.

Dr. Wood

And Jehan, are there other scenarios you can think of that come up for you in clinic?

Dr. Budak

No, I think Aley covered them all. I think whenever I'm thinking about a switch, is it a switch because of an adverse effect? Is it because some other comorbidity, and we're going to run into issues due to tolerability, or again, those adverse effects, and/or are we just simplifying to improve pill burden or switching for drug-drug interactions, which is I think those are the categories that I see.

Dr. Wood

Aley?

Dr. Kalapila

The other times I have switched, and I think this is probably one where different people would have done things differently. I've certainly had one or two patients who, in the past, have been on elvitegravir-cobicistat-tenofovir alafenamide [EVG-COBI-TAF] or TDF-FTC [tenofovir DF-emtricitabine]. And when they come talk to me, it's very clear that they are missing doses. And in those cases, also, I get very nervous. I insist really to switch to something that's a little bit more potent. So, BIC-TAF-FTC [bictegravir-tenofovir alafenamide-emtricitabine] would be my go-to in those circumstances as well. So, I think probably that's another time when I would switch when I'm concerned that someone is on a not very potent regimen even though they're suppressed, and they're telling me that they're not taking their pills consistently.

Dr. Budak

I was just also saying, now that Aley's talking, I was like, oh, there's this other scenario and this other scenario, but just so many scenarios. But I'm wondering if you two have dealt with this, where—and this goes back to that whole patient preference thing—where a patient comes in, they're like, “my partner's on this med, can I get onto this med?” It's interesting how some people are really wedded to their regimen, and makes it hard to switch, or simplify, or intensify. And then, also, too, when somebody else sees somebody else on a medication and wants to switch because of that, and sometimes it's fine, and sometimes it's not. And so, I just think that that's interesting, especially with some of the direct-to-consumer marketing we see on television these days.

Dr. Wood

Absolutely. I think that's a great point, Jehan, and coming back to something I've heard you say before, really focusing on patient's priorities and their goals, what's most important to them. And in our last episode we talked about insurance coverage. That's certainly a consideration as well. Aley, I heard you bring up a lot of important considerations, such as pill burden, side effects, drug-drug interactions in the setting of missed pills, potentially choosing something that has a higher barrier to resistance. There's a lot of considerations there.

weight-gain**[05:31] Weight Gain**

Dr. Wood

Interesting to me, you brought up the weight gain issue. There's certainly an association between integrase inhibitors and TAF and more weight gain than other agents, other classes. I've had that come up for me in my clinic, I've had a couple scenarios where it really seemed like it might correlate with the ART, and we switched the ART, and the person didn't necessarily lose weight. So, it feels to me like a switch in that scenario does not guarantee weight loss, by any means. But I'm curious to ask both of your clinical experience, have you switched ART and seen it lead to weight loss or resolution of hyperglycemia or diabetes? I think it's an area in which everyone is still sort of figuring out what to do. Aley, what's your experience been?

Dr. Kalapila

I mentioned the weight gain mostly because we read about it a lot. Personally, I've had that less as an issue, but my challenge has been both for, like Jehan was saying, sort of the weight, trying to keep someone weight-neutral and then also the diabetes issue with integrase inhibitors is that again, certainly in my practice, my biggest concern is adherence. And I really don't have a ton of patients who are not either on a dolutegravir- or bictegravir-anchored regimen. And if they're not on that, they're on a protease inhibitor (PI)-anchored regimen precisely because of adherence issues. And, of course, as we know, PIs also are not the best for people who have metabolic syndrome and have diabetes and things like that. So, I'm stuck between a rock and a hard place. And my patients oftentimes would much rather be on something that would have fewer metabolic side effects, but quite frankly, putting them, for instance, on rilpivirine, TAF-FTC-rilpivirine or TAF-

FTC-etravirine, I would be a little bit more nervous about, again, because in those cases adherence is the biggest issue that I'm contending with.

Dr. Wood

Jehan, what has your clinical experience been?

Dr. Budak

Yeah, back to your question about the whole weight gain thing, I find that if I have a patient who has experienced weight gain on a regimen that I have recommended, we're switching usually to something that's more weight-neutral. I have not seen a big change in the weight as a result of that, but it is, I think it's something that's really important. Even if I am not sure that the medication was the cause of the weight gain, I do want to switch because I want them to trust in their medication and feel happy with their medication. And I think if anything in the back of their mind that maybe this is leading to weight gain, I think that's going to impact adherence. And so, I really want someone to be on board with the meds that they're taking. I think there's something interesting about this decade that we're in with regards to weight gain because people don't seem to care when I talk to them about their kidneys or their bone density, but they care when it's weight, and that is something that we can all see and is deeply personal. So, I just think that it's something that I am a lot more attuned to because people really care.

Dr. Wood

Absolutely, people care. And there's a lot of cardiovascular events, and we see that in our clinic and I don't know about you, but I have had people in my clinic who have passed from cardiovascular events. I think we should do everything we can to help people prevent that. I appreciate the points you both made and differences in perspective, and this is an evolving area and honestly, I hadn't even planned to ask you that question. So, thank you both for hearing me and sharing your clinical experience around that one. It's certainly a hot topic.

updating-art-regimens**[08:46] Updating ART Regimens**

Dr. Wood

Jehan, I'm going to switch gears a bit and put another question to you. We talked last episode about the recommended regimens for most people with HIV as starting regimens. We talked about bictegravir-TAF-FTC, we talked about dolutegravir with TAF-FTC or TDF-FTC. What if you see someone in your clinic who is taking a regimen that is not on that list, but they're taking it, their viral load is suppressed. What does your assessment and your conversation look like, and in what situations do you continue the option they're taking versus recommend a switch?

Dr. Budak

I think this is hard. I think all of us have talked about this whole concept of if it's not broken, don't fix it, but sometimes it will then break. And so, we do need to fix it in the future. I think that a scenario in which I think this is probably easiest to talk about would be somebody who's on an abacavir-containing regimen. And in fact, just the other week in clinic, I had success in getting somebody off abacavir-lamivudine-dolutegravir [ABC-3TC-DOL], when in prior years I hadn't, even though I'd discussed with him his metabolic profile, hypertension, diabetes, hyperlipidemia. And I kept being like, "I'm worried about the abacavir because there's an association." And he was always a little bit on the fence. And then now there was a change in the ART guidelines, I was able to say, "This is no longer recommended." And that really went a long distance and we were able to get him on to just dolutegravir-lamivudine, just lobbing the abacavir off. And so, I think that I have found that it's been useful to reference the guidelines, especially when there's a change. And there are some other people for whom it's just every visit you just start bringing it up and start chatting and saying,

hey, like that one patient that took me years to get off nevirapine, embarrassingly, because he really liked it. And so yeah, it's all over the map.

Dr. Wood

Thanks, Jehan. I'll just add that switch from dolutegravir-abacavir-lamivudine to dolutegravir-lamivudine, just dropping the abacavir is one I've been encouraging in my clinic as well for the reasons you mentioned. I don't see much benefit from the abacavir, and as we've discussed, it may raise cardiovascular risk.

Aley, what if someone's taking a regimen that is not on the recommended list? Which ones would you really encourage someone change or update? And which ones would you be okay with a person continuing, assuming their viral load is suppressed and they're feeling well and that is their preference?

Dr. Kalapila

So, I think same as you both for the abacavir, been trying to get people off of it, but in general, I don't have a ton of patients now on it anymore. Most of those patients who were previously on 3TC-ABC-dolutegravir now, at least for me anecdotally, I think have wanted to switch to injectable. So that's been pretty easy switch, actually. But otherwise, probably those times that I would consider switching, again, almost overwhelmingly for me personally, has been in situations where there is concern for adherence, and it's a low barrier regimen. And so oftentimes, it's a rilpivirine-anchored regimens more often than not is usually the case because I inherited a couple of patients who were on TAF-FTC-rilpivirine or TDF-FTC-rilpivirine. And then also I have a handful of patients that had been on elvitegravir-COBI-TAF-FTC, and again, told me that they were missing doses. Or I could even tell that they weren't filling their meds consistently, like it was stretching. They would come back and fill it every six weeks so every month, they were missing meds or stretching it enough that they were not filling their meds on a monthly basis. And I've had bad experiences with patients stretching their elvitegravir-anchored regimens and then coming in with integrase inhibitor resistance, and then you're stuck because then injectable is off the table and stuff. And so really, the times when I have considered primarily switching, if it isn't because of an adverse effect and it isn't because of a drug interaction with something that they're taking, then it is almost certainly because they're not on something that is potent and they're taking it not regularly. So, and I think that's kind of led me to switch.

Dr. Budak

To Aley's point, the residents and fellows know this about me. My two least favorite ART are elvitegravir and rilpivirine. PSA [public service announcement] for everybody listening, as Aley said, if someone's having adherence issues, please don't continue them on a COBI-elvitegravir-containing regimen or a rilpivirine-containing regimen because if there are issues long-term, there are serious consequences with regards to resistance and that really ruins the potential of CAB-rilpivirine [cabotegravir-rilpivirine] in the future for them. And so, I think I'm really glad you brought that up, Aley. And then the only other time that I'm thinking too is if I'm seeing somebody with housing insecurity and likely food insecurity, I talk about rilpivirine as well and sort of want to get them off of a rilpivirine-containing regimen, given the need for such a high-calorie meal with rilpivirine.

Dr. Wood

Thank you both. So, the take-home point I'm hearing, which is really important for listeners, especially if you're newer to the field, is remember that options like boosted elvitegravir, raltegravir, rilpivirine, efavirenz, those options have a much lower barrier to resistance than bictegravir or dolutegravir or then boosted darunavir. So, if someone is taking one of those, always important to assess how often they're taking their pills, if they're missing doses, assess for side effects. And I would say, I'd like you both to tell me if you agree or disagree, I would say it's not necessary to change one of those. If someone's taking it, their viral load is suppressed, they're feeling well, and that's their preference? But I always have a conversation with a person taking one of those options about how well they're taking it, about their side effects, about newer options.

And I always, at least, make sure they're informed about newer options and try to help them make a decision that's best for them in terms of making a switch or not.

nrti-resistance**[14:39] NRTI Resistance**

Dr. Wood

Let me switch gears a little bit and talk about an individual who has some NRTI [nucleoside reverse transcriptase inhibitors] resistance because that is a common scenario in clinical practice. So, Aley, I'd like to ask you if an individual has an M184V or an M184I; these are NRTI resistance mutations we see quite a bit. What do you see as the optimal ART options? And let's presume for this scenario, this is a person who takes their meds as prescribed and tends to maintain suppressed viral loads.

Dr. Kalapila

So, in that case, in general, I often prefer to use an anchor drug that is potent enough and also has a high barrier to resistance. And so, in those cases, I would probably use a TAF-FTC or tenofovir-FTC backbone and then combine that with either dolutegravir or bictegravir or a boosted protease inhibitor like boosted darunavir typically is what I usually go to. You can get TAF-FTC-darunavir-cobicistat coformulated into one pill. So that's typically my go-to choices when I know that someone has an M184V, M184I mutation, and I'm trying to pick a regimen for them.

Dr. Wood

Thanks, Aley.

two-drug-oral-art**[15:53] Two-Drug Oral ART**

Dr. Wood

For the sake of time, I'm actually going to move us to another question because, Jehan, I'm curious about this. In your clinical practice, if someone is taking a regimen and they're viral load is suppressed, when are you recommending a switch to a two-drug maintenance oral ART option, such as the FDA-approved options, dolutegravir-rilpivirine or dolutegravir-lamivudine? Or when you're reaching for other two-drug options?

Dr. Budak

I think it's interesting, of those two options, and I think a lot of the times I'm thinking about two-drug options are actually in the low-barrier clinics in which I work, in which the combination of dolutegravir and boosted darunavir is what I am actually using more so than the other two, just because of the nature of potential resistance mutations, adherence issues, et cetera, in some of the patients in whom are in the low-barrier clinic. So, I think that's actually the two-drug regimen I use the most. Then, the next most often one I use is dolutegravir-lamivudine because, as we've discussed, it's easy, especially if somebody's on an abacavir-3TC-dolutegravir-containing regimen to remove the abacavir and just do dolutegravir-3TC. And then, least commonly, I'm using dolutegravir-rilpivirine, and that's because when I talk about rilpivirine, at least to the residents and the fellows, I refer to rilpivirine as the princess and the pea in that, and maybe I'm using the story wrong, but basically there's a lot of stipulations, whether it be the food, the need for an acidic environment, the initial viral load, which I know we're talking about switch, so hopefully everyone's viral load is less than 100,000. And then also a CD4 count being greater than 200 based on the ECHO and THRIVE study. So, I don't love that combination as much, as much as the dolutegravir-3TC. And usually, why I'm making that change is probably comorbidities and wanting to do a TAF-bearing regimen or, actually just adverse effects, renal issues, and then drug-drug interactions.

Dr. Wood

Aley?

Dr. Kalapila

I agree with everything that Jehan said. I think you may have mentioned it, or I might've missed it, but I think probably the biggest thing for me was also to make sure that they don't have hepatitis B. And this is always a big thing and I see a fair amount of it in Atlanta. And so, I'm always a little bit apprehensive. And we also don't have Heplisav in our clinics in terms of vaccines. And the response rate to Recombivax, which we have, is a little bit low, so these are sort of and other reasons for why the hep B status for me is extremely important before I switch to two-drug regimen. But again, all the reasons provided, they meet all these caveats that Jehan just stipulated, then I think I would be okay to switch them.

Dr. Wood

Aley, do you have a preferred two-drug switch option?

Dr. Kalapila

So, I usually will end up doing 3TC-dolutegravir. But quite frankly, I don't use it a whole lot, mostly because most of my patients who would qualify to be on that are doing just fine on BIC-TAF-FTC, so I don't necessarily always see the need. I haven't had a lot of issues where we've had to switch too much. But yeah, that would probably be the one that I would go to the first.

hbv-status**[19:00] HBV Status**

Dr. Wood

And Aley, for listeners who are newer to choosing ART and thinking about this, will you go a little deeper into the hep B status issue and why hep B is an important consideration before switching?

Dr. Kalapila

So, the [HHS] HIV and also the AASLD (or the American Association for the Study of Liver Diseases, I think it is) the guidelines that state that if someone has HIV and hepatitis B (HBV, hep B) co-infection, you have to have a fully active antiretroviral regimen that also has dually active antiviral agents against hepatitis B. So, the drugs that are active against hep B, that also have activity against HIV are tenofovir, lamivudine (or 3TC), emtricitabine (or FTC). So, it becomes extremely convenient when you put patients on TAF-FTC-bictegravir or tenofovir-FTC-dolutegravir because the tenofovir-FTC combination gives you your dual activity against hepatitis B.

But you cannot put them on 3TC-dolutegravir alone or 3TC or dolutegravir-rilpivirine because in 3TC-DOL case, you only have one agent that's active against hep B. And, of course, lamivudine has a low barrier to resistance for hepatitis B. And for dolutegravir-rilpivirine or, for that matter, injectable cabotegravir-rilpivirine, neither of those drugs have any hepatitis B activity. And if someone has hepatitis B and you're putting them on those regimens, you can have a hep B flare. So, those are the big reasons as to why you want to make sure that you know your patients hep B status before switching them to a two-drug regimen.

Dr. Wood

Thank you, Aley, for emphasizing that, and glad you mentioned injectable.

injectable-cab-ril**[20:41] Injectable CAB-RIL**

Dr. Wood

Let me put the question back to both of you in terms of the switch to long-acting injectable, two-drug therapy, cabotegravir-rilpivirine (CAB-RIL). In your clinic, who are you prioritizing for that switch? What are all the factors you are considering, and how does the counseling conversation go about the potential for that switch? Jehan, will you take that first?

Dr. Budak

Sure, I'm happy to. I think the rollout of injectable CAB-RIL has been difficult at many institutions, including our own, and including our own clinic. And so, I think really when I'm thinking about it, is the person virally suppressed, or is the person not virally suppressed? And I know initially we were just doing people who are virally suppressed, and now, in light of LATITUDE data, we are, and other people's data too, that we are doing more virally unsuppressed individuals. So, at the moment, given that there's such a long wait list in our clinic, I am prioritizing people who are not virally suppressed—at the moment, in our low-barrier clinics—because for those individuals, I really want to get them suppressed.

I think for those people who are already suppressed, things that we take into account are, what is their most recent viral load? What is their most recent CD4? What is the trajectory of their CD4 and viral loads? And for that, I'm interested because, like, do we have a genotype at baseline? Do we have a genotype that we believe that sort of shows any potential mutation as opposed to something that's archived and not present? What is their HIV subtype? What is their BMI? Where do they live? How can they get in to get transportation to come to clinic once every month or every two months? What's their cell phone number so we can get a hold of them? And those are just some of the examples of the things that we're considering.

Dr. Wood

That's great. Thanks, Jehan. And before I ask Aley the same question, Jehan, you mentioned resistance. If you don't have access to past resistance results and you are considering injectable cabotegravir-rilpivirine, and let's say, considering it for an individual who's taken multiple regimens in the past and for whom you don't have full records, are you ordering an archive also called DNA or proviral or PBMC [peripheral blood mononuclear cell] genotype?

Dr. Budak

Yes, and I say that somewhat embarrassingly. I think before starting to do a lot of CAB-RIL in the clinic, I was never getting an archived genotype, given that if we see something there, great, but if we don't see something there, it may not really signify anything. And so, I used to never get them. And then now, I do. But I only will get an archived genotype if somebody has come primarily from a different country and we have zero genotypic data, and we have no way to get genotypic data, and we don't even know what subtype they are. And typically, I will see if someone has two or more risk factors for virologic failure with CAB-RIL and that might be the determining factor if I'm going to get an archived genotype. Now, we will be looking at this data because I know that a lot of places don't do archived genotypes. And what we found was that the ‘juice was not worth the squeeze’ and this is because we didn't really know. And so, we sent a fair amount of archived genotypes, and it didn't actually change what we do in a lot of scenarios. So, we're actually meeting later this week to talk about potentially writing that up so that people learn from the fact that this is what we tried in this data-free zone, and I don't think that it's super worthwhile. What we will be doing, though, is if we don't have a subtype of HIV, the lab will be able to run that for us without doing a whole archived genotype, which is very nice because I would like to know if somebody has an A6 subtype, for example, as we know now that that is one of the potential risk factors for virologic failure.

Dr. Wood

Super interesting, Jehan. Thank you. Aley, I'd love to hear from you on the same questions. Who are you prioritizing for a switch to injectable cabotegravir-rilpivirine, and in what scenarios are you doing archive resistance testing?

Dr. Kalapila

Pretty much echoing the same things that Jehan said. So, as far as the prioritizing switching to injectable ART, I'm not in charge of the injectable program at the clinic, so it's easy for me because I can just place a referral, and then it takes a couple of months as it works its way through all the paperwork processing, insurance approval, blah, blah, blah. But, certainly, there are situations where I have someone who is really struggling with oral medications. I have concerns for developing drug resistance. I have messaged the injectable team and the leadership to say, “I would much rather you prioritize this patient than my patient who's on BIC-TAF-FTC and doing really well and wants to switch to injectable because they just don't want to take a pill but have been stable on this regimen for the last five years.”

So, that's kind of my approach to triaging or trying to prioritize which patients I would like to be seeing getting on injectable first. And I definitely have had some great successes on patients who I have cared for probably seven or eight years, who have really struggled with oral ART adherence and have at different points in time have gone off meds due to so many social or mental health related issues and are now doing amazingly well now that we've switched them onto injectable. In fact, I just saw someone today and it's amazing, just the transformation. So, I really have been trying to prioritize those patients that have struggled with it. In terms of the archive, so this is an interesting question. So, Jehan, I will totally agree with you that I think even when I first moved here, I had a couple of patients that I was trying to switch to other things, and I was getting this archive, and I realized 100% the ‘juice is not worth the squeeze.’ And certainly, talking to people that have way more experience than me, that has been their clinical experience as well. And so, I have not actually been getting a ton, and I haven't fortunately had to get a ton yet on my patients. We have been somehow able to get resistance profiles even from people that have moved to Atlanta from other states, we've been able to get some information. The struggle is definitely with patients who have traveled internationally. But again, in those cases, strangely enough, in my experience, at least with my patients, I have miraculously gotten genotypes from very resource-limited settings, actually. Not a lot, but enough, you know.

Dr. Budak

So you're saying I just need to look harder?

Dr. Kalapila

No, no, but I literally am seeing someone tomorrow who, actually he may not have had a genotype, but he came from a West African country, and he had CKD [chronic kidney disease], and so his GFR [glomerular filtration rate] was less than 30, so he just could not be put onto to TDF. So, he came to me on dolutegravir and boosted PI already. And I knew that his diagnosis, when he acquired it, it was recent, like it wasn't something that someone had historically been on some very, very old regimen and then was now trying to switch. So, I just fortunately have not had to deal with it. And thinking back to my previous years of practice, the one or two times I have gotten it, it has not given me a ton of valuable information, but I do think that it is a consideration every single time, especially for patients who are heavily NNRTI [non-NRTI] experienced.

And so, this ends up sort of being a discussion with the injectable team to decide if it's worthwhile getting it. The other problem for us, quite frankly, but it is an outside lab for us. So, the other issue I've run into is in the times that I've thought about getting it, I've either ordered it wrong or I have ordered it right, and then for some reason, the lab throws out the specimen, which has also happened.

Dr. Wood

I have also had challenges. So helpful to hear both of your clinical experiences. I do want to make a note for listeners that the HHS guidelines were very recently updated, and they do now have a statement that on a case-by-case basis, injectable cabotegravir-rilpivirine can be considered for individuals with detectable viral loads, but it really is a case-by-case basis. And again, this is an area where data is evolving, and things have

really shifted. I think when this option first came out, the majority of us considered a detectable viral load to be a contraindication to cabotegravir-rilpivirine.

And then data from the UCSF group and others, I think, just really, really encouraged us to keep more of an open mind about helping people to choose the best ART option for them and if this was the best option for them, even with a detectable viral load, as Aley was describing, it can lead to a lot of success and really can save people's lives. So, I think this really has evolved and shifted, and I just want listeners to know that in the guidelines now, there is this statement that it can be considered on a case-by-case basis, and we will have more discussions about it in the future.

patient-interest-injectable-art**[29:20] Patient Interest in Injectable ART**

Dr. Kalapila

I do have one comment and then actually maybe also a question for you guys. So, for my patients who are not struggling with adherence , who are doing very well on BIC-TAF-FTC, I can tell you that there's probably a distinct age gap in the patients who want to be on injectable versus not. And the reason is that for my younger patients, who only ever take one pill once a day, they're perfectly happy to switch over to injectable, because then it's no longer oral medications. Almost uniformly, my patients who are over the age of 40, who are on a statin or any other medications, who are *very* stable, and only see me twice a year, they're like, "Why do we want to come back to clinic to get an injection?" And so, the majority of those patients have basically said, "No, we have no interest in coming here more than twice a year. Obviously, we'll come to see you if we feel like we need to see you. But otherwise, we are very happy on this regimen because, you know, we have to take multiple other pills anyway." I'm just curious what you guys have in your practice. Has that been the case, or something different?

Dr. Budak

Yeah, I think great point, Aley, because I agree that if somebody has polypharmacy, then removing one of their 23 medications is maybe not super helpful and perhaps even more annoying if they have to come in and get the shot. My hypothesis is that that in older individuals, actually coming to clinic might be harder than continuing to take one pill when they're especially taking many other pills. And recently, I had a younger patient who had struggled with adherence in the past and is also on tacrolimus, mycophenolate, and prednisone for transplant and many other meds who said, "Thanks for bringing this up, but no, thank you. I'm still going to have to take so many other pills, so I'm okay just staying on my single-tablet regimen."

Dr. Wood

I find it to be quite variable. I think people hear about an injection for HIV treatment and get excited. And I find when I sit and talk to people about what that entails and the visits to clinic every one to two months and the injections, which can be quite painful, I do find that a lot of people say, "You know, actually, taking my simple oral ART regimen at home is totally fine. I'd rather not go through all that. I'd rather not come to the clinic that often." But I have other people who still is important for them to try to get the injectables because of the shame and the reminder from the oral pills every day, I think that is still reality and a major issue for people. So, I sit with folks who are interested or who may benefit, talk about what it involves, what's required, what the experience of getting the injections might be like. And I find some are still very enthusiastic for it, and others opt to “no,” just stick with their oral regimen. So, I think there is a lot to consider. Again, we’ll come back in the future for more discussion about considerations for people with detectable viral loads because that's an area where we've learned a lot, and I think it's really important.

counseling-injectable-timing**[32:13] Counseling for Injectable Timing**

For now, I think we've covered a lot of ground, and I'll just wrap up by asking you each one last question on that topic of counseling about the injections. How are you counseling individuals and choosing between every

one- versus every two-month injections? Jehan, will you start that?

Dr. Budak

Yeah, that's complex and it changes even in our clinic's protocol as we get more and more data. So, for the time being, if somebody is not virally suppressed and we are proceeding with CAB-rilpivirine, such as was done in LATITUDE, we are going to do once a month until we get data that in people who have difficulties with adherence that we can do Q [every] 2 months. So, at the moment, we're doing Q1 month for people who are not virally suppressed and have had difficulties with adherence. And then for the vast majority of people who are suppressed, we're doing Q2 months, but there are some individuals in whom may have one or two risk factors for virologic failure that we're just a little nervous about in whom we are sort of discussing Q month versus Q2 month and doing, and again, recognizing that we are privileged in this country to be able to choose between Q month and Q2 months as I know many other countries cannot choose between those two.

And then last, we have our own clinic's protocol regarding people who have BMIs that are greater than 30, that if they do not want to do an oral lead-in, we are doing Q month for the first couple of months and then transitioning into Q2 months. But if they do the oral lead-in, then doing Q2 months right away. And that's based on an amalgamation of data regarding people with BMIs that are greater than 30, recognizing this is a moving target and we are making adjustments to our protocols on a weekly basis.

Dr. Wood

Absolutely. That's a great point. Aley, can you speak to your clinic's protocols or how your counseling to patients goes about every one versus every two months?

Dr. Kalapila

Yeah, so I don't have too much more to add to what Jehan said because I'm also not on the team and so I do feel like they are adapting their protocol again based on data. But in general, the approach has been that if someone is not virologically suppressed, they'll remain on Q month for at least the first couple of months. And then once they're virologically suppressed and doing well, and they've demonstrated a commitment to coming for the visits, then they switch them to every eight weeks. And then for the patients who are already very stable on oral ART, and this is just a one-to-one switch, they go directly to Q eight weeks, at the moment. But beyond that, I am not super familiar, at the moment at least, with our protocol, but I do know that this is definitely an evolving target as we get more information.

closing**[35:00] Closing**

Dr. Wood

Absolutely. Well, we have covered a lot of ground. I want you both to know how much I appreciate you sharing your clinical experience, your expertise with myself and with listeners today. Thank you both so much for your time.

Dr. Kalapila

Thanks.

Dr. Budak

Thank you.

Dr. Kalapila

Looking forward to the next one.

credits**[35:15] Credits**

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