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Expert Interviews

National HIV Curriculum Podcast

Integrating Injectable ART into Clinical Practice

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Long-acting injectable ART (LAI) was not initially considered to be a treatment option for individuals with substantial barriers to taking oral ART. However, our understanding has evolved due to the experience of several clinics around the country, including the team at University of Mississippi Medical Center. In this episode, Dr. James "Ben" Brock, Associate Professor of Medicine, discusses practical aspects of implementing LAI into clinical practice, such as staffing models, patient counseling, adherence support, and payer considerations, plus explores its potential life-saving role for certain people with detectable viral loads, with National HIV Curriculum Podcast Lead Editor Dr. Brian Wood.

Topics:

- ART
- Injectibles
- LAI
- cabotegravir
- lenacapavir

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Transcript

Read along with the audio or jump to a particular chapter.

In this episode:

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intro--background**[00:00] Intro & Background**

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.

As background, use of long-acting ART [antiretroviral therapy], including injectable cabotegravir and rilpivirine, and also injectable lenacapavir, has evolved a lot since the original registrational trials and since FDA [Food and Drug Administration] approval of the drugs. In particular, clinical experience and data have grown for prescribing the long-acting injectable agents for individuals with detectable viral loads who have a history of barriers to taking oral ART every day.

In addition, clinics have been forced to navigate numerous obstacles to obtaining long-acting ART for patients who may benefit. This has led to great variability in adoption of the long-acting ART medications. Dr. Ben Brock and his colleagues at University of Mississippi (UMC) have been leaders in this area. They have published their experience with long-acting ART, including for individuals with detectable viral loads and including for some individuals with a history of NNRTI [non-nucleoside reverse transcriptase inhibitor] or INSTI [integrase strand transfer inhibitor] resistance. Today I get the honor of talking about this experience and lessons learned with Dr. Brock.

Dr. Brock is associate professor of medicine at the University of Mississippi Medical Center in Jackson, Mississippi. He trained in internal medicine and infectious diseases at the University of Mississippi and now serves as medical director for the university's Ryan White-funded HIV clinic. He is an accomplished clinician, researcher, and educator and has been involved in a number of observational studies and clinical trials. These have been studies of HIV treatment, including long-acting ART, and he has led publications of his clinic's experience with long-acting injectable antiretroviral therapy, and presented at the IDWeek 2024 conference on their experience prescribing long-acting cabotegravir/rilpivirine plus lenacapavir for individuals with detectable viral loads and a history of cabotegravir or rilpivirine resistance mutations. I'm very much looking forward to our conversation today and I welcome you, Ben.

Dr. Brock

Hey, thanks so much. I actually did Med-Peds [internal medicine/pediatrics], which I thought was a different perspective when I went into infectious disease. That pediatric background with such a focus on wellness when I came into HIV care really emphasized a lot of prevention and to making sure that everybody got their cancer screenings and vaccines and that sort of thing. That was a big part of my push when I took over the clinic.

Dr. Wood

That's great to know. Thanks, Ben, for adding that. I can see the benefit of that whole person focus on wellness.

Dr. Brock

And really, I feel like that's where HIV care has gone with integrase inhibitor era. We've gotten almost everybody in the clinic virally suppressed, and now it's talking about how do we keep them well from a holistic standpoint.

Dr. Wood

Absolutely. It's amazing the direction that has gone, and that makes me want to ask you a million other questions about that, and we'll have to plan a follow-up conversation about that focus on wellness and prevention.

Dr. Brock

Sounds good.

initial-phase-injectables**[03:28] Initial Phase of Injectables**

Dr. Wood

Today, let's talk about your experience with long-acting injectables (LAI) because I'd really like to hear, as a clinician, your practical experience, and how this has gone for you, and how it's evolved for you over time since these drugs were approved. So, let's start with the approval of long-acting cabotegravir/rilpivirine and thinking about individuals who, let's say, fit the description of those who are in the registrational clinical trial. So those who have a history of taking their oral ART every day and maintaining suppressed viral loads. So, how did it look for you when the long-acting cabotegravir/rilpivirine was initially approved, and we got that registrational trial data? How did you first integrate that into your clinical practice?

Dr. Brock

So, we were psyched for the customized trial before the FDA approval came through. That was a hybrid phase 3-4 implementation science study conducted by ViiV, and we had about 15 patients who were in the trial, and when the trial ended, they instructed us to transition patients over to commercially available cabotegravir/rilpivirine when it was available to us. And, we took that directive to heart and actually moved our patients over earlier than most of the other sites, and it was a great learning experience because it sort of forced us to help payers, including ADAP [AIDS Drug Assistance Program], figure out what we were going to do with this new formulation. First in class, right? So, usually, there's a big lag after FDA approval with payers adding things to their formularies and figuring out whether or not they're going to make it preferred, and we sort of forced them to work with us early on. There were a lot of peer-to-peers that our specialty pharmacy had with Blue Cross, Humana, and ADAP to figure out what we were going to do with that. And so, we had 15 patients just to bat as soon as soon as FDA approval came through that we had to transition over to commercially available and get our processes in place very early on.

Our program transitioned over time. It started out with specialty pharmacy really taking the lead in getting approvals through payers and tracking people's follow-up appointments. They got overwhelmed with that fairly quickly. And so, the next iteration with our clinic was moving over to our case managers. We have a cohort of Ryan White case managers who parsed out the patients across their different assignments. And so, each case manager had a handful of patients on injectable, and as the program grew, they also had difficulty making sure that their patients were hitting their appointments. And the third phase of our program moved to

a single case manager who is just over injectable ART. So now, for patients who are on injectable ART, we have an exclusive case manager who just oversees a nurse who oversees those patients now.

When we first moved those 15 patients over from the customized trial, we put a moratorium on new patients for a little while we sort of figured out our processes. And it's been sort of been boluses of patients where we open it up, and then 50 or so patients got enrolled, and then we had to put the brakes on it again to figure out how we're going to manage these patients, and close new enrollees for a while and then open it back up once we felt comfortable with our processes with the next phase. I think that that's a testament to the size of your clinic and what your clinic can accommodate. For large clinics that have a huge number of patients on injectable, their model will look different than a smaller clinic that only has a handful of patients. Because if you only have 10 patients or so on injectable, you don't need a full-time staff who just does that.

Dr. Wood

Absolutely. I think that's common, too, to do it in boluses and then reassess your processes if staff becomes overwhelmed and if you need to hire additional staff or create a new workflow before trying to get the injectables for a new cohort of individuals. And I think what you described there, Ben, about the evolution of different phases of staff support is super interesting and valuable, and I want to come back to that later for listeners.

patient-counseling**[08:00] Patient Counseling**

Dr. Wood

Let’s just stay for a moment on the individuals you and your clinic have prescribed injectables to who had suppressed viral loads, a history of being pretty good at taking their oral ART. Can you just tell me more about what the clinical evaluation looks like and how you assess readiness and eligibility for the injectables?

Dr. Brock

I'll say about 10% of our patients now are on injectables. So, direct-to-consumer marketing caused a ton of suppressed patients to seek out this therapy. They knew it was coming.

Dr. Wood

Ten percent is quite a lot. Let me just interject before you respond to my prior question: Was most of that, do you feel, patients seeking it out or providers recommending it? It sounds like it was the former.

Dr. Brock

I don't think we have any providers who are actively trying to transition patients who are doing well on oral ART to injectable. It was almost entirely patients asking.

Dr. Wood

Interesting. So, tell me a bit more what that conversation looks like when someone asks and assessing whether this might be the right therapy for that specific individual.

Dr. Brock

Yeah, it's been kind of an existential question we've had, with do we tell patients “no” when they’re doing fine on oral ART. You’re in an exam room with somebody who brings it up and says, "I'm interested in switching." And different patients have different reasons for why they want to switch, but they're all valid. And so, it's hard to, from a paternalism standpoint say, "Well, you're doing well on oral ART. I don't think that your

reason's good enough," just because you don't want to have to worry about having to take a pill every day or the pill stigma or whatever your reason is.

Dr. Wood

Absolutely.

Dr. Brock

So, we as a group, our identity, outside the era of paternalism of shared decision making, it's hard not to honor that request outside of, do we have the bandwidth to take on these additional patients? But that has been the first question I always ask before we entertain doing a benefits investigation is, I first reach out to our staff, the pharmacy, and our case managers, "Do you have the bandwidth to take on another patient?" Because there have been some times where they would say, “Uncle! We can't take on any more right now. I'm spread as thin as I can be.” And, from a patient safety standpoint, the stakes are so high with injectables. They really can't miss an injection visit. If NNRTI and pan-INSTI resistance develop, that's a catastrophic outcome. So, the stakes are really high with those injections, and I wouldn't want to overload those case managers who are making sure that everybody's making their injections on time.

Dr. Wood

But that's interesting to hear that that is really priority one question is: does the support team have the bandwidth to take this on?

Dr. Brock

The benefits piece is much easier. You know, that's almost always we can get them the medicines from that end.

Dr. Wood

And we'll come back to that.

contraindications**[11:01] Contraindications**

Dr. Wood

Clinically, what are you looking at, and what do you see now with all that we've learned as the contraindications or the reasons you would say, "I'm sorry, but this is just not the right therapy for you?"

Dr. Brock

I think the biggest one besides genotypic data, that's a person-level thing, that's more of a clinical thing, is whether or not they're going to come to injection visits. And I have used completed scheduled appointments with me and the rest of their visits as a surrogate marker for whether or not they're going to make it to their LAI injection visits.

Strangely, we try to make these prediction models, but we're very bad at guessing clinical outcomes. Prognosticating, that's one of the worst things that doctors do. And so, adherence to injection visits is really good, and part of it might be because we're self-selecting patients who are going to make it to visits, but we actually have picked patients who have difficulty taking oral medications.

So, I think that patients who get their injections maybe are more willing to come to those visits because they recognize how important that is, versus coming to rap with me about how things are going at the routine HIV

follow-up when they know they're taking their meds and they're doing well, and either can't or don't feel like coming to my visit, they know that they can reschedule that.

Dr. Wood

Absolutely.

adherence-support**[12:28] Adherence Support**

Dr. Wood

Tell me a bit more about what the adherence support and outreach looks like for you and your team and your patients. What does it look like trying to do reminders and help people to get to their injection appointments?

Dr. Brock

So we, again, have three full-time nurse case managers now who oversee this patient cohort, and they each have their own paper calendars outside of Epic. I asked this, they maintain all three. So, each of them have them at their desk and it's like, "Well, do you just keep your 80 patients? Each of you has about that many patients?" And she said, no, that they all record all 250 patients on the calendar separately and they cross-reference. So, I guess for convenience they keep them there.

They also use an Epic reminder list. And the Epic reminder list is kind of like a shared patient list, but it's a to-do task-based thing, and they update that with every patient on it. So, if a patient cancels an appointment in Epic, they fall off your schedule, and you may not notice, but in the reminder list, they don't fall off, the task becomes overdue. And, the Epic reminder list is oriented by date, so they use the next scheduled injection visit as the date for the next to-do list. So, they keep updating people when they get their injection. They'll update their next injection due on that reminder list so they can see by date on a list of who's due for their next visit.

We do multiple different reminder strategies. There's automated reminders that go via text and phone call and email to patients. And then our nurse case managers call to confirm their appointment beforehand and if they are late for it, they contact them same day. So, there's a lot of proactive stuff that day. I'm told by our case managers that they primarily use phone call and text. Of course, many patients will have not enough minutes to accept a phone call, but can still do text message. So, we have work cell phones that use text message to communicate as well and that's successful for many patients for whom we can't reach via phone call.

archive-resistance-testing**[14:42] Archive Resistance Testing?**

Dr. Wood

And Ben, coming back to clinical factors you consider. We haven't talked about viral load yet. We'll get there. You mentioned resistance testing. Hepatitis B status is something I think is important to look at and I just want to remind listeners about that. On the resistance piece, a question that has been raised a lot is whether for someone who has taken multiple regimens in the past may have had very large failure in the past, whether we should be looking at archive or DNA genotype resistance assays, and there's controversy around that. They're not perfectly sensitive or specific. I'm just wondering what your practice has been.

Dr. Brock

We have not been utilizing the archive resistance testing, and it's been a question that I've been raising for years. Obviously, we know post-hoc in clinical trials that patients who did fail were more likely to have those resistance at baseline testing, but they didn't use those baselines testing as exclusion criteria. And so, the

ethical question that we have is will we be boxing out patients who may potentially do well on this regimen because of an abnormal result? And that's not necessarily clinically significant. It's a really tough question.

Dr. Wood

I think tough but important question. I have struggled with that as well. And I have a lot of skepticism about that assay and the utility because of that question. Absolutely. So, I'm glad you said that.

baseline-viral-load**[16:12] Baseline Viral Load?**

Dr. Wood

So, let's talk about viral load. There was a lot of question in the initial approval of long-acting cabotegravir/rilpivirine about the potential efficacy and downsides of prescribing it for someone who has challenges to taking oral ART every day or someone who has a detectable viral load. Your clinic, I think, has been one of the leaders in this field, both offering this therapy and sharing your experience so others can learn from it. I'd love to hear the thought process and considerations that went into this for you and lessons you learned. Can you tell us a little bit about what that initial process went like for you?

Dr. Brock

Well, I think anyone in HIV care would recognize that long-acting ART would greatly benefit people with adherence issues. I remember hearing about the LATTE [Long-Acting Antiretroviral Treatment Enabling] studies over 10 years ago and thinking this would be fantastic for my patients who were not suppressed. I'm sure everybody was waiting for that. For whatever reason, drugs get studied either as a switch strategy or in treatment naïve. It's usually one of those two with ART clinical trials. And this drug was studied for switch only in virally suppressed patients and excluded the very group of patients who had the most potential to benefit.

The question then is, is the trial coming, or are we going to have to use ART off-label? And HIV medicine includes a lot of off-label use. Not everybody fits nicely into the antiretroviral naïve and no prior resistance category. And so, we piece together combinations all the time for patients who are more complex, who are treatment experienced, and we do the best we can. And that's kind of the ethical conclusion that I came to. It sounds like a lot of other people did as well, is the trial's not coming, we've got people who need this therapy, and their outcomes are going to be certainly poor if they can't get suppressed. And so, the ends justify the means.

So, we took a very conservative approach. I didn't want to offer it broadly without any real experience or data to support its use. And so, we gave it to one or two patients who had low CD4 counts who we had tried everything possible to get them suppressed, all the support with social determinants of health, optimizing the regimen, few pills as possible, pill reminders, et cetera. So we had done everything we had tried possible to get them suppressed on oral and it wasn't working and they were getting sick, so we offered one or two patients to switch and see how it went.

We tried them out for several months. It went well. We opened up to a few more patients. That went well too. And so, then we opened up more broadly, and we've put about 30 patients on who are viremic. And some of those were patients who were intermittently adherent, and we gave the injection when their viral load was in the low 1000s [cells/mm3]. We have one patient who a social worker was going to their house every day and administering oral ART, directly observed therapy to get them suppressed to switch them. And then some people whose viral loads were 600,000, and we just did the best we could.

And remarkably, everybody got down to suppressed. Some people took a little while longer, so not everybody got to less than 20 in a month, which makes you uneasy. But if you have a 600,000 viral load and you get an injection of a long-acting agent, a couple of them took like three months to get less than 200, but the alternative was switching back to oral ART and that wasn't really acceptable.

They've all done really well, and we have all of them out at this point in the initial report. We published that in CID [*Clinical Infectious Diseases*] as a brief report, and we have data past 18 months at this point for everybody. Some people are a few years out on this regimen, and we've had four people who've had rebound viremia among nearly 250 patients. So, really good success rate, better than trial data, remarkably. And, the reason is because of the case managers having really great rapport with the patients and holding their hands.

But what's odd is that baseline viral load at initiation was not predictive of whether or not you were one who failed. And so, it's the same things as previous, people either had some minor NNRTI mutations that we didn't recognize or obesity kind of the other reasons, but once you get to suppressed, you're like everybody else on injectable ART, and everybody who was viremic got down and didn't rebound with resistant mutation. So, really exciting!

Dr. Wood

Real exciting, really incredible to hear, really lifesaving for people.

patient-feedback**[21:27] Patient Feedback**

Dr. Wood

I wonder what kind of feedback you've heard from the individuals themselves who have transitioned to long-acting ART, especially those who had so many struggles with oral ART over the years.

Dr. Brock

What's weird is the persistence of satisfaction with your regimen. If you're on oral and you're doing well, and you're not interested in switching to injectable, you're usually very happy with your regimen and fine with it. And, likewise, for people who decide to switch, they're usually very happy with it and don't want to switch back, and it's fantastic.

There's a bit of self-selection there, so for people who wanted to switch to injectable, they usually had a reason underlying with their oral ART. I think some of that may be perception of increased efficacy with injectable medications. We have that same issue with antimicrobial stewardship and IV antibiotics that injections are better medicines than oral. But a lot of those reasons are pill stigma or the anecdote of having to remember to take a medicine every day. With hypertension medicines, diabetes medicines, if you miss a dose, the stakes aren't that high, but patients recognize that the stakes are really, really high with missed doses with oral ART. And we've had patients report that a weight has been lifted off of them from not having to remember to take that medicine every day. So, apparently, there's a lot of anxiety around missed doses, even from people who do take their medicines every day. Not to mention the pill stigma. The psychological well-being of our patients on injectable is really the biggest anecdote that we've heard that patients are just doing much better from an emotional space.

Dr. Wood

And that is a huge, incredibly important thing.

Dr. Brock

It's non-tangible. It's hard to really quantify that.

if-when-to-switch**[23:24] If and When to Switch**

Dr. Wood

Given what you said that all the support staff and resources can quickly become overwhelmed, who are you and your clinical team prioritizing for the injectable therapy? Is it the individuals taking oral ART with suppressed viral loads? Is it those missing doses, detectable viral loads? Does it depend? Who are you now prioritizing?

Dr. Brock

In my own practice, it's my own style, I have prioritized patients who were viremic the whole time. And they may be persistently or intermittently viremic, but that has been my cohort of patients, that has been the group that I've always prioritized. And I actually don't have very many patients who were suppressed and switched. And I've had the real discussion around efficacy with this therapy versus oral with patients. So, it's an extensive discussion that I have with a suppressed patient who wants to switch. Because I don't think that it's better than oral ART. There are a lot of drawbacks for patients who are suppressed. If they stop it, it's out of their system, and treatment-emergent resistance is very uncommon with modern oral ART regimens. And then the headache of having to come to an injection visit every two months for two large injections.

So, my personal patients that are on injectable, I think all of them were viremic and switched. Our other providers have a different style, and so, the vast majority of the patients in our group practice were suppressed and switched.

Dr. Wood

I think it's just so fascinating how this has evolved. There are so many important lessons here about how lifesaving this therapy can be for individuals who struggle with daily oral ART and who have detectable viral loads, and detectable viral load should not be a contraindication. And I think what you're getting at is a lot of the considerations when a clinician sits with a patient about the pros and cons. I don't know about you, but some people I sit with in clinic who ask about injectables, especially people who've taken their daily oral ART well for years, when I talk about the every one- or two-month injection visits and I talk about the potential injection-site pain, sometimes they say, "No, no, no, look, I'd rather take my oral ART at home every day and come in every six months." But others, like you said, it is for a variety of reasons really important to switch to the injectables, and I think it's important we hear that, understand why, and engage them in that discussion, and move towards that goal if it is really important to them, and there is no major, major contraindication.

So, it was helpful coming back to what you said before, to hear what you see as the big, big contraindications. Major drug resistance I heard you mention, staff just feeling totally overwhelmed and not having the bandwidth at that moment to take it on might mean there may need to be a delay. Are there other things that lead you and your team to say, "look, right now may not be the right moment?" You mentioned you can usually get it through insurance and benefits and you got it on the ADAP formulary.

payer-considerations**[26:39] Payer Considerations**

Dr. Wood

Are there other things that might lead you to say, "Look, we need some more time. Now may not be the right moment?"

Dr. Brock

Payer considerations with viremic patients is a challenge, and I know we're going to talk about getting that approved.

Dr. Wood

Let's go there. What has that process been like for you? And I also haven't had the right moment yet to ask

you about adding lenacapavir to the mix. So, that's something you also have written about, which I've learned a lot from you and others about clinical situations in which that can be useful. So, insights into when you add lenacapavir and insights into approval for the long-acting agents, including lenacapavir, would be really, really great to hear.

Dr. Brock

Sure. Mississippi Medicaid has listed cabotegravir/rilpivirine as a preferred agent, so that has been our easiest one and there really are no questions asked if it's on the PDL (preferred drug list) as preferred. And so, when we prescribe that, whether it's viremic or not, it's been fairly straightforward for Medicaid beneficiaries.

Other payers, whether commercial or ADAP, do usually want viral load data and getting our viremic patients have almost all been Medicaid beneficiaries. The strategy we've taken with some patients who had intermittent adherence is to use the viral suppression and switch option as a carrot to say “If you can just stick with it for a few weeks, come back in for a viral load so we can get that lab and show viral suppression, then we can send it on to your payer, whether ADAP or commercial, and then we can get you the approval.” That's worked in multiple patients where they're able to take the medicines and willing to for a few weeks, just not long-term.

One thing as far as clinical stuff, too, that we'll talk about I guess with lenacapavir, is mutations. Do all mutations exclude you from it? There are mutations that are NNRTI-associated but maybe have no effect on rilpivirine. You know, the K103N mutation's the obvious one. But there are other mutations that NNRTI that maybe don't affect rilpivirine. What if they are minor rilpivirine mutations? They're there but they're minor mutations that do almost nothing to the agent. Is that an exclusion? There are several INSTI mutations that have the same issue with second-generation INSTIs and either little to no effect on that drug. In combination, they have an effect, or they have no effect at all. Does that mean we can't use it?

Dr. Wood

So, tell me more then, about how this process went for you, especially initially considering long-acting agents for individuals with some history of virologic failure, some degree of rilpivirine or cabotegravir resistance, or both. What was it like considering the addition of other agents like lenacapavir, trying to get that approved, and prescribing it for especially those first couple of cases?

Dr. Brock

Well, for starts, I guess in the approval process, even for people who are virally suppressed, no single person makes that decision. We have more than one pair of clinical eyes looking at a case before we decide to move forward. And so, our injection nurses, the case managers, actually, do a genotype survey, they try to find historical data, they go to other locations and try to get any genotype possible, and they've actually caught some mutations that our clinicians missed. So, I think having almost like a panel of people clinically reviewing the case; if we had somebody who's more questionable, they've got some mutations, usually more than one person will weigh in before we decide as a group whether or not this would be appropriate. At this point, for somebody who has an INSTI or NNRTI mutation that has no effect on the agent, we will usually try the injectable cabotegravir/rilpivirine by itself without the lenacapavir, and I have tried to limit lenacapavir's addition to people with rilpivirine mutations and ideally fully active integrase.

So, I think there's some evidence now, there is some evidence at least in phase 2, that lenacapavir and integrase inhibitors as a two-drug regimen works. And so, we're waiting on phase 3 data for some accommodations for that, but that's at least encouraging that we have these other agents clinically that we could use.

And so, it sort of evolved out of that. We had these viremic patients who had adherence issues for years. Some of them were quite sick, and they got put on injectable ART, and they did fantastic. And then you've got

a cohort of treatment-experienced patients who especially knocked out NNRTIs, and they also were sick. And what do you do as a clinician when you have a therapeutic option out there that might work, and you're putting together these random combinations of protease inhibitors and NNRTIs? For some patients, you're entertaining like maraviroc and enfuvirtide, but you have a long-acting agent out there. So, it was the same thing. We tried it on a couple of patients, and it worked great, and so we opened up to more, and now we've got nearly 15 patients who have successfully been suppressed on lenacapavir and injectable cabotegravir and rilpivirine.

And, oddly, no one in that group has failed. The viral kinetics of this combination are very encouraging, and most of them are less than 200 and stay that way. Sometimes, you've got patients who are getting their injections on time with cabotegravir and rilpivirine, and we'll have blips here and there for no clear reason. I have not seen that with lenacapavir and cab/rilpivirine strangely.

Dr. Wood

Were there major barriers to approval of that combination when you added the lenacapavir?

Dr. Brock

The first couple of peer-to-peers were challenging. These have been also mainly Medicaid beneficiaries. That was early on when lenacapavir was first coming to market. But, at this point, we've not had as many challenges with that. But then again, it's been predominantly limited to Medicaid.

managing-injection-site-reactions**[33:12] Managing Injection-Site Reactions**

Dr. Wood

And how about any pearls in your experience about helping individuals with injection-site reactions and tolerability?

Dr. Brock

I just had a session with my injection nurse about this to get her feedback because this is mainly her wheelhouse. She said that she does a lot of education, and so she feels like that's the biggest thing with injection-site reactions. I was thinking shots hurt; how does knowledge prevent pain? But she gives them coaching, including physically instructing them how to do gluteal stretches. So, she found that gluteal stretching exercises help, also gluteal massage but not right over the injection site, but in and around the glutes she feels helps. Certainly, cold packs, and then making sure that it's administered appropriately and the right needle size and that sort of thing, not hitting the periosteum, but she feels like these different exercises helps a ton and that injection-site pain is improved with it.

Dr. Wood

Those are great words of wisdom. Please thank her.

Dr. Brock

She also said topical menthol. So apparently, green isopropyl alcohol, she said, has menthol in it, and patients will administer to that area, and that menthol helps. So, whether it's Icy Hotâor some other menthol containing topical stuff to the glutes at the injection site.

Dr. Wood

These are great. I hear from my patients they can be quite painful. So, I think these tips are appreciated.

team-based-care**[34:40] Team-based Care**

Dr. Wood

So, Ben, one thing you've written about and talked about here and hinted at here a couple of times is just the close collaboration needed and teamwork needed with nursing staff, pharmacy, case management. I was wondering if you could talk a little bit more about your lessons learned, and why that's so important, and what you would recommend for other clinical teams looking to ramp up long-acting injectable therapy in terms of the team-based care.

Dr. Brock

So, our specialty pharmacy is on site. The UMC pharmacy is our specialty pharmacy, and they have pharmacists in the clinic, so the dialogue is real-time. I'm not sure how individuals would dialogue if they had a contract pharmacy that wasn't on site. There's shipping issues and storage issues. So, intersecting with ADAP, I guess, is our outside pharmacy that we have to interact with and make sure we have close communication with.

When a new patient is being considered for injections is the time when a lot of the dialogue is occurring on the front end. If I have a patient who I'm considering for this, I include their regular case manager, the injection nurses, the pharmacy in a big group discussion to review the case, make sure everybody checks off on it. So, every single party has to review it and make sure that it's appropriate. They've got the payer, they don't have any genotypic issues, there are no psychosocial issues that they feel like are a major barrier that are insurmountable. So, everybody signs off on it. The injection nurses, of course, dialogue with the pharmacy predominantly.

What's weird is that medical visits are almost on autopilot with these injection nurses. We have standing orders, so they can verbal viral loads, and often, by the time they get to me for my regular visit, they've had a recent lab that shows viral suppression, and their regular appointments with them are scheduled by them. So, I feel almost superfluous in this process once they're on it and doing well. I guess that gives an opportunity to focus on their other issues like hypertension and vaccinations and that sort of thing.

Dr. Wood

General wellness and preventative care, as you brought up at the beginning, which is incredibly important too.

lessons-learned**[37:01] Lessons Learned**

Dr. Wood

So, Ben, before we wrap up, I thought it was very interesting to hear at the beginning the evolution of how your adherence support has gone at your clinic, and you talked about different stages and, currently, you have dedicated staff, dedicated case managers really focusing on outreach and supporting adherence to injection visits. And I wonder if you could just talk a bit more about lessons learned and any advice on supporting injection visits for other clinics looking to ramp this up. What would you say have been your most important lessons learned?

Dr. Brock

I'm going to have to lean on my other staff for this question. Because I don't do a lot of this. But, assistance with transportation is a huge one. Making any appointment. I think once we started offering medical transportation assistance, that was the single biggest thing that improved my uptake in appointment adherence. Automated reminders, having people doing proactive outreach if they miss an appointment, and

it's same day, trying to get them back in within the week because their window is closing before they have to do the re-induction. And then just having a team, having alternate communication methods to text, not just phone call.

Dr. Wood

Yeah, absolutely. Maybe frame things a little differently. We recently talked with [Dr.] Aadia Rana about the big paradigm shift in terms of who should be included in clinical trials. And I think one thing that's so fascinating about long-acting ART is the paradigm shift about who is a candidate and the potential value of offering long-acting ART to people who have struggled to take oral meds to people who have detectable viral loads. And I think your clinical experience has contributed to that paradigm shift. And [Dr.] Monica Gandhi and the UCSF [University of California, San Francisco] team and others have talked about how patients aren't hard to reach, that they're hardly reached by our system and our system needs to shift. And I think that is another really important, just, framework and paradigm shift. So maybe before we close, I can just ask on your reflections on that perspective based on your experience.

Dr. Brock

The standard medical clinic is the thing that I think we're hoping to get out of with mobile services. They're mobile screening clinics that lends itself obviously very nicely to mobile clinics to screening, but having a mobile clinic that can do phlebotomy, have a social worker that's addressing the social determinants of health, and then have an injection nurse who's administering injectable cabotegravir/rilpivirine. That's our hope for next steps, kind of our next iteration. And, I'd really like to see how that is adaptable to the rural health issue.

Obviously, with the Ending the HIV Epidemic initiative, rural Mississippi was tapped as one of the priority states because of a high endemicity in rural areas, and that could be a great solution for people who live outside of our metro area and have transportation issues. And batching injections that way, to go out to one area and administer 10 injections, and draw the viral loads while they're there. I think is our next big step is sort of thinking about how the system can reach people who don't do as well with a standard clinic hub model.

Dr. Wood

Absolutely. Ben, I have a million other questions I could ask you. I definitely want to have you back at some point to talk about whole person wellness, preventative care, and so many other topics. But for now, thank you for sharing your time and expertise with us today.

Dr. Brock

Hey, it was a pleasure. Thanks so much, Brian.

Dr. Wood

Thank you.

credits**[40:57] Credits**

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