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Rapid Start ART — A New Model for HIV Care

Announcer:
Welcome to CME on ReachMD. This activity entitled *Rapid Start ART: A New Model for HIV Care*, is jointly provided by Global Education Group and Integritas Communications, and is supported by an independent educational grant from Gilead Sciences, Inc. Prior to beginning the activity, please be sure to review the faculty and the commercial support disclosure statements, as well as the learning objectives.

Dr. Flash:
We are fortunate that modern medicine and current anti-retroviral regimens have rendered HIV a manageable chronic illness, and not the death sentence it was in the early years of the AIDS epidemic. Today, people living with HIV who adhere to their ART regimen can achieve undetectable levels of the virus, which importantly means that they can't transmit the virus; however, many of the new cases we see every year are the result of transmission from people who have a diagnosis of HIV, but either have not started ART or have not stayed on ART. Listen as Dr. Isolde Butler and Dr. Charlene Flash, who specialize in HIV care and prevention examine one approach that may help get more patients undetectable faster. Rapid start ART or same-day start.

Hello, and welcome to the CME program in which we will discuss best practices in the use of Rapid Start antiretroviral therapy for HIV. I'm Dr. Charlene Flash, Associate Chief Medical Officer at Legacy Community Health, and Clinical Assistant Professor at Baylor College of Medicine in Houston, Texas. I'm joined today by Dr. Isolde Butler, an Infectious Disease and Internal Medicine Physician at Crescent Care in New Orleans, Louisiana. Hello.

Dr. Butler:
Hello.

Dr. Flash:
Dr. Butler, please start us off by reviewing the role of treatment as prevention as a key strategy in ending the HIV epidemic in the United States.

Dr. Butler:
So, I'd like to frame this in the context of the U.N. AIDS 90/90/90 goal. What that goal states is that we hope to have 90% of people living with HIV be diagnosed and aware of their diagnosis. Of those people who know they have HIV, we'd like to see 90% of them have access to effective antiretroviral therapy. And of those who have access to therapy and start treatment, we'd like to 90% reach viral suppression. What makes the 90/90/90 goal so powerful is that we know those people who take HIV medication and are able to achieve viral suppression cannot transmit the virus to other people. This is an incredibly powerful tool we sometimes refer to as treatment as prevention, and so – or TasP. So the first step to achieving that goal is to have an HIV test, because you can't achieve viral suppression if you don't know your diagnosis.

Dr. Flash:
That's true. Now, as we set the stage for our audience and briefly review the state of antiretrovirals today, can you talk about the safety and effectiveness of our current antiretroviral regimen?

Dr. Butler:
Absolutely. The last several years we've come a long way in terms of particularly tolerability and safety of our antiretroviral therapies. With the introduction of some of the newer INSTI class integrase inhibitors, we've seen a reduction in pill burden and reduction in side effects in many of our first-line regimens. The DHHS and IAS guidelines would corroborate what we now know today that regimens are simpler than ever, they're more well tolerated by patients than ever. Some of the research that I and some of my colleagues conducted demonstrated that the benefits of having once-daily dosing, whether it's with a single tablet or multiple tablets allows people to be more likely to be adherent and to be more likely to drive down their viral loads. And so you'll see that all of our first-line regimens are with incredibly tolerable medications, mostly in the integrase inhibitor class, and most of them are either one tablet once a day or two tablets once a day to allow for efficient use and high adherence among patients. So, Dr. Flash, can you talk a little bit about the concept of rapid ART and what that means?

Dr. Flash:
So, the concept of rapid ART or rapid start, is the concept that once someone is HIV tested and gets their diagnosis, that we efficiently initiate them on antiretroviral therapy. Now to fulfill this, linkage to care is essential. It requires thoughtful referral, it requires thoughtful conversation with patients so they understand their diagnosis and what indeed you're telling them about initiating therapy. You don't just want to get that first pill into them and then not actually link the care. So those are all core elements for a successful rapid start program. When you think about rapid initiation in primary care, I would say that one of the most important elements is to test for HIV. Most patients don't walk in with a sign that says they're HIV positive, and you know, even if they come in with something that says that they're HIV positive, I generally confirm the test. At sites where primary care providers might not have the benefit of point-of-care or rapid testing, which allows you to do a fingerstick to identify someone who is HIV positive within 15 or 20 minutes of the test, it's important for us to be aware of our local colleagues and partners. It's important to know your resources so you can get people efficiently into care. So, as we think about this efficient initiation in care, it's important to consider what lab tests are needed prior to initiating rapid ART. Can you tell us a little bit about that, Dr. Butler?

Dr. Butler:
Well, we find now with rapid ART, although we still order the same battery of tests that we traditionally have when initiating ART. We don't need to wait for the results to come back. And that has really been a game changer with the ART phenomenon. One study, the DIAMOND study, was a study taking a look at a PI-based regimen for rapid start. And what they found was no patients needed to be stopped because of genotype abnormalities and they only had 5 out of 109 who were stopped for any sort of lab abnormality. And three of those were actually restarted by the study investigators after taking a closer look. So, in general, the labs that we normally order wouldn't preclude people from starting on a rapid ART regimen. Particularly, the INSTIs, we have good data showing genotypes are not really necessary prior to starting an INSTI. Their thresholds for resistance are quite good, and transmitted resistance just doesn't seem to be a big issue right now with the integrase inhibitor class. When we think about how to start antiretroviral therapy efficiently, the DHHS recommendations as of 2018 show that we should make sure that we're utilizing drugs that have a high barrier to resistance. And that would mean avoiding things that would have a low barrier to resistance, such as the NNRTIs or the non-nucleoside reverse transcriptase inhibitors. The recommended regimens then would be things that are integrase based such as bictegravir, dolutegravir, or PI-based, such as darunavir-based regimens. As we work towards rapid initiation of antiretroviral therapy, that could include same-day initiation if indeed feasible. There are times when that's not feasible, and that could still be considered rapid start if it's not the same day, but you really want to make the efficient initiation of therapy your goal. As we think about the nuts and bolts of how to actually get this done, Dr. Butler, would you share some of your experiences with linkage and antiretroviral therapy initiation within 72 hours?

Dr. Butler:
So, the clinic where I work is a federally-qualified clinic in New Orleans, Louisiana, and we've published some results on our experience with the rapid start program. My colleague, Jason Halperin, was very instrumental in getting this off the ground for us. And what we found in our rollout, which started at the end of 2016, is it's very doable in a primary care setting. It does require a few things. You want to make sure that your providers have buy-in and are engaged and interested in the process, and that they have some flexibility in their schedule to see an urgent patient at the drop of a hat. So if somebody comes in with a new HIV diagnosis, you want to make sure that they're able to be seen that same day or within 72 hours. So scheduling flexibility becomes an important point. In our first year, we had 77 patients with a new HIV diagnosis come through our door. Of those, 71, so about 92%, were immediately started on ART within the first 72 hours. And we've had great success over that year with retaining them in care. The vast majority of them achieved viral suppression by 30 days, and maintained that viral suppression for the remainder of the year. We did some transmitted resistance; however, in no cases did we have to switch regimens because of that. My point from all of this is that rapid ART is something that's feasible in a primary care setting. It does take a little bit of coordination, and we had great support from our local state officials and

Ryan White officials, but it is something that can be very doable within the context of an HIV practice. The benefits go beyond just viral suppression to retention. And I think also giving patients a sense of empowerment and taking control of the illness from the very moment that they find out their diagnosis. And so we also found our clinic provides PreP to a large number of patients, as well. And we found that this was a nice dovetail to our already existing PreP program. So if somebody came in looking for PreP and unfortunately found out that they have an HIV diagnosis, we were able to treat them that same day and turn this into a rapid-start visit rather than a PreP visit. Really what we're finding is that this treatment as prevention is an important tool in our toolkit moving forward for HIV prevention. So the research tells us that rapid ART is a safe and effective treatment for HIV. Can you talk a little bit about some of the systemic and structural barriers that we – that need to be overcome at the clinic level.

Dr. Flash:
At some agencies and clinics, HIV testing and diagnosis occurs off site. And so in those cases, the primary barrier is actually getting the person from the site of testing to the site of potential treatment. Another barrier is that sometimes when you get to that potential place of treatment, there are complex eligibility criteria that require a certain CD4 count before you can initiate therapy. Another core barrier that exists is another structural barrier in terms of the limitations and access to medications without an identified payer source. Some patients come in and they are diagnosed with HIV and they didn't come in knowing that they were going to have that positive diagnosis, and they may not be insured. They may not have an identified payer source. Or they may be underinsured, and so the cost associated with their care is exorbitant, even though they have insurance. The other thing that can be complicated for agencies and clinics is having the flexibility and provider scheduling so that when you have a person you diagnosed and you want to get them started on medication, is there someone who indeed can get them onto their schedule and see them? Now, some spaces have had creative solutions where they utilize nurse practitioners as opposed to MD or DO clinicians, or utilize standing delegated orders to initiate some of those first steps. So there are creative solutions, but that schedule really can be a barrier. The other potential barriers are outside of these structural issues and can reside in people's beliefs. Whether it's provider beliefs or staff beliefs, some people still feel as though you need to have those, not just the lab tests but the lab results before you can initiate therapy. Now, lab draws are important. I'm not saying that you should not draw those screening labs on patients, but you don't necessarily have to wait for the results before you initiate therapy. A regimen can be adjusted later if necessary. Although you described a very powerful example of rapid initiation in an underserved setting in a safety net clinic, which is a federally-qualified health center, some might wonder what if the patient does have resistance? Or what if they do have abnormal kidney function? Or what if, what if, what if? Well, with close follow-up, those regimens can be adjusted if necessary. And you can still adhere to those patient's needs. And what we've noted, if you initiate someone on therapy rapidly, you're actually more likely to have them come to their follow-up visit. So despite the many benefits of rapid start or rapid ART initiation, we also want to make sure that, as we get excited about this new way of starting therapy for our patients, that we don't get so excited that we coerce the patient. We still need to create a system where the rapid start option is available to patients, and patients understand that you can start today but you don't have to. We need to emphasize educating patients so that we elevate their health literacy and their understanding of their diagnosis, especially for people where the concept of HIV is something that's completely new and foreign, and not push away patients who may need more time to contemplate a start and say, you know, 'It's alright, doc, I'd rather start in a couple of days to get a moment to digest.' In those cases, it's still important to rapidly engage that patient. So rapid start doesn't always mean that if you don't put the pill into the person's mouth, then you're doing a bad job. You want to rapidly engage that patient and let them know that this doesn't have to be a death sentence, and we will as efficiently as possible initiate you antiviral therapy. So, as we reflect on the pros and cons of rapid start and some of the barriers and pitfalls, what would you say are your two primary takeaways for this activity?

Dr. Butler:
I think rapid start is something that can be very effective, but like you said, you have to make sure you lay the groundwork within your clinical setting. My second takeaway for primary care providers would be again test, test, test. Test patients, be aware of HIV as a diagnosis that's out there, do the sexual history-taking, and assess your patient. And then know who your referral sources are. Make sure that you're aware of who in your community is offering this kind of treatment.

Dr. Flash:
You know, if I had to reflect on what I think additional takeaways might be, it's understanding that treatment as prevention and indeed the mode of initiating treatment efficiently or rapid start is part of our continuum of care for patients. A lot of primary care sites, community sites have become very excited about PreP or pre-exposure prophylaxis. That excitement doesn't have to stop there. Taking those steps to efficiently link people to care and get them initiated on therapy is part of that continuum that will allow us to achieve our ultimate goal of ending the HIV epidemic. Eventually we'll want to put each other out of business.

Dr. Butler:
Absolutely.

Dr. Flash:
And so, when I think about what's needed, I recognize that new drugs are nice, but we have wonderful drugs. Simpler regimens are nice, but we have simple regimens. What's really needed is the implementation science, the activities around the structural barriers, and the institutional efficiencies that have to be constructed to allow people to get started efficiently on medications. And I think if we're able to do that, we'll get ahead of this thing.

Dr. Butler:
Absolutely.

Dr. Flash:
So, thank you, Dr. Butler for this very informative discussion, and for joining us for this CME program.

Dr. Butler:
Thank you so much for having me.

Dr. Flash:
And thank you for joining us for this CME program. Please remember to complete the CME posttest and the evaluation.

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