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# ANTIRETROVIRAL THERAPY UPDATES WITH PROTOCOL FOR RAPID INITIATION

Asa Radix, MD

10/20/2021

**Antiretroviral Therapy Updates with Protocol for Rapid Initiation**

**[video transcript]**

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Dr. Asa Radix is the Senior Director of Research and Education at the Collin law Community Health Center in New York and a clinical associate professor of medicine at NYU. Asa is certified in internal medicine and infectious disease, and completed postgraduate training in public health and epidemiology. Asa research focuses on LGBT health, STI slash HIV risk and HIV prevention. Asa alongside Dr. Noga Shaliv are the main authors of the New York State Department of Health AIDS Institute clinical guideline, one to initiate art with protocol for rapid initiation. Thank you so much, Dr. Radix, for collaborating with CEI to create this new course and presenting today. And now I'll let you take it away.

00:55
Hey, thanks. Thank you so much, Tara for the introduction. And I'm really pleased that so many of you have joined today to talk about rapid initiation of AR T. I have no financial disclosures. And today, we have a few different learning objectives. And the first is to discuss the evidence that supports Rapid Start of antiretroviral treatment to people with HIV. We're also going to look at some of the data that support HIV treatment as prevention and u equals u, you've probably heard undetectable, is an transmissible statement. We're going to identify safe and efficacious rapid AR T regimens based on known patient characteristics, as well as regimens to avoid and we're going to think about some of the patient level and institutional barriers that come along with rapid initiation and think about some of the best practices for implementation. Now, hopefully, we'll have a robust discussion at the end of this tool. So I'm going to go ahead and start with a case that this is ml. She's 28 years old. She's a transgender woman who presents her routine physical exam and she's asymptomatic. Her past medical history, she has hypertension, she takes hydrochloric biocide, as well as gender affirming hormone therapy. She's a nonsmoker. There's no history of substance use. She has sex with cisgender men, and was last screened for HIV three years ago. And that test was negative. So she's talking to point of care rapid HIV test. And the test is reactive. There is no history of renal or hepatic concerns. So I have a question for you. The first question is, which of the following best describes the recommendations for starting antiretroviral therapy and people with HIV, so a AR T is recommended and all persons with HIV, B, AR T is recommended only when the CD for count is less than 500. C AR T is recommended when the HIV RNA is over 50,000 copies. And D AR T is recommended only when the CD for count is less than 50. Excellent and looks like the majority 92% agree that AR T is recommended for all persons with HIV. Perfect. Second question, when would you recommend starting antiretroviral treatment A is today, B when the confirmatory results are available, and that will be around two to three days when the CD four and viral load results are available. So five to seven days, and D When HIV genotype is available, and that will be around in most cases four weeks. Excellent. So we have about 71% say today, but there are about a quarter who would delay a treatment between two days and four weeks. So and, you know, the correct answers today, you know, treatment should be offered today. And we will review the evidence for that during this tour. So I wanted to

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to recognize that, you know, there have been managed shifting guidelines over the years and when to start HRT, you know, what's debated for quite some time. And, you know, for those of us who started doing, you know, providing HIV care a long time ago, to me it was in the 80s. You know, the benefits of AR T in those days was really offset by, you know, toxicity of the medications that we had as well as the truth that medications weren't fully effective in those early years. But you know, starting in the mid 90s When we started having combination AR t, you know, protease inhibitors were introduced, and we started using three active medications. This, you know, resulted in a dramatic reduction in deaths, there was still a question about when, when should we start. So, you know, when I talked about shifting guidelines it went from, we start when the sequel count is less than 200, I remember when the guidelines change to, you know, less than 350. And then it was less than 500. But, you know, between 2012 and 2015, as a result of several studies, and all the international guidelines and the US guidelines. So, you know, HHS and the New York, state department of health and PE DSUSA, all shifted to saying that we should be studying AR T at any city to count clinical stage. And, you know, we knew that, at that point, you know, on the basis of studies, such as HP Channel Five, two and a start that if you delayed treatment, it resulted in increased mortality, diminished CD for recovery, avoidable hospitalizations, as well as the higher rates of opportunistic infections and the cost of treatment, as well as increased rates of HIV transmission. So we shifted to, again, starting at all stages and see the full camp. And just to talk a little bit about the START study, this was an international multi site, open label randomized control trial to decide determine whether early AR T was better over delayed air T. And the results showed that serious AIDS related events like tuberculosis, and cactuses are common. Also, non AIDS related events were far less likely neon got treated early. So the immediate AR t. So again, since 2012, the guidelines in the US have recommended the AR t get started without delay in people who are newly diagnosed with HIV. You know, despite I'll say, despite these changes in the guidelines, and again, this, you know, era of universal treatment, people often wait up to three to four weeks before AR T is actually started. And that's because of delays that happen at every step. So someone has a reactive screen, you know, they used to wait for a confirmatory test, they'd wait for a visit, that often, you know, have to wait to resistance testing. So that could be anywhere from three to four weeks. And, you know, then getting the prescription and how do you pay for the prescription. So, you know, there was a opt in again, quite a long way. So people started treatment. Now at the same time, we were starting to look and we still do look at the HIV care continuum that looks at the states from you know, people getting diagnosed until when they are virally suppressed. And we see in the United States, the less than 60% of people living with HIV virally suppressed. So you know, the key thing is, how do we shorten this time from having a reactive screen to initiate the HRT and hopefully, as a result of that, we can shorten the time for people to become virally suppressed, and a greater number of people who are virally suppressed? So here's another question. Rapid initiation of AR T has been shown to a increased uptake of era t be improved viral suppression at 12 months, see, improve retention in cat at 12, months, and D all of the above? Okay, and we have about 86% have chosen the correct answer, which is all of the above.

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So I did want to talk a little bit about the evidence that supports rapid initiation of HRT. And we know you know, over the years, several studies really have investigated studying AR T on the

same day, or at least within seven days of initial HIV reactive screen. And I should say that the studies have been done around the world so and even in settings that have fewer resources than the United States. And think about that, you know, for those of you who are in community health centers and complain about limited resources that, you know, the evidence supporting rapid initiation, you know, again, has been done throughout the world. And we've had, you know, observational studies as well as in a randomized controlled trials. And this you know, on this slide, we're seeing the results of a Cochrane review that really revealed that rapid HRT initiation was associated with improved Linkage to Care, improved uptake of HRT, better viral suppression and improve retention at 12 months. So definitely, there's evidence supporting rapid initiation. And so, you know, currently, if you look at the New York State Department of Health ace Institute recommendations, but also the HHS guidelines, they do recommend clinicians offering rapid initiation of HRT, and preferably on the same day to all individuals who are candidates. And we'll be talking a little bit more about eligibility for this. Now, the other thing I wanted to talk about was u equals u. And, you know, really, the other term for this is treatment as prevention and understanding that effective treatment prevents sexual HIV transmission. So what is the evidence for u equals u. And I'll say that first we had the HPT N Oh, five two study which randomized myths mixed HIV status, heterosexual couples to early or delayed arg initiation. And it showed that when people were, the person living with HIV was virally suppressed, the HIV transmission just did not occur. And there were also some observational studies we have called one of the two and opposites attract that provided even more data from around the world and even more diverse populations. Looking at mixed HIV status couples that included cisgender, MSM, and again, very diverse populations over 14 countries, showing that when the person living with HIV had full suppression of their viral load that there were no we say followed genetically linked transmission. So the person living with HIV was just not transmitting HIV to their partner, again, if they were virally suppressed. So you know, we were using this now in public health campaigns, you'll see you know, undetectable is and transmissible. And I think a few key things that this is sexual transmission. So we do not apply this, for example, for folks who are using injection drugs, it also is important to understand that we people need to be virally suppressed for six months. And after studying AR t for the first six months, we do recommend that another method of protection is use either condoms or that the partner is receiving, you know, pre exposure prophylaxis or PrEP. And also the barrel suppression is less than 200 copies. And, you know, I think that there are so many key points besides the fact that, you know, there's no transmission, there are definite benefits to the individual, which includes that it reduces the stigma associated with HIV. It can incentivize PRT initiation and adherence for the person living with HIV, and of course, their community benefits. So reduction in community viral load, which we definitely seen in New York City and in San Francisco, and reduces transmission risk, and engenders more support for the, for the person with HIV. So really, those are the data and the reason why, why this is a huge part of, you know, the public health campaign and ending the epidemic. So the key point here is that clinicians should recommend, same day era t for all people who are newly diagnosed with HIV.

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You know, and as we say that, and I can see, you know, some of you who perhaps haven't started rolling this out in your own institutions, you're already thinking of the massive barriers, potential barriers to initiating AR T on the same day. So, you know, thinking about it, that, you

know, someone who's just had this reactive test, you know, you know, what are their feelings about it, they have, you know, beliefs and attitudes. So, are they even going to accept that diagnosis, you know, and that's often linked to their trust in their provider, you know, they might have concerns about confidentiality, again, they may have concerns about stigma and concerns that they can even take a pill every day. Now often, the patients that we see have very significant psychosocial issues, you know, they can have unstable housing, food insecurity, they may have substance use history or mental health conditions that can all impact on their ability to to take a daily pill, and of course, the big issue who's going to pay for this so you know, considering cost concerns, the providers, you know, as providers because we also have our own concerns, you know, we've always done it a certain way, how are we going to switch? You know, do I really feel comfortable starting someone with medication? What on medication when I don't have any test results available, including resistance tests, including knowing their renal or hepatic function? And, of course, there are the many structural and systemic issues that play a role here. So, and, again, cost is one of the biggest, but there are also issues around how do we schedule people in to see a provider when their providers are already seeing, you know, the, that so many patients in a very limited time. So, you know, we'll talk about some of these issues as we go forward. But, you know, I will say that, if you access city or state guidelines, you'll see that there's a very valuable tool. So they created a, you know, a protocol that shows the different steps for rapid HRT initiation that you can actually use as a foundation for, you know, your individualized clinic protocols, and also allows you to think about the key steps that you would need to cover. So that would include how do you identify people who are eligible for rapid initiation? How are you going to integrate counseling and education? And what are the topics that you need to cover? If you identify people who have psychosocial issues? How are you then going to, you know, assess and refer them? What baseline tests are needed? Are they different? Or are they the same. And as you start initiating AR, T, thinking about the regimens you might need to have on hand and available, and also, the big issue is payment assistance and follow up with clients who've initiated AMT and of course, the, we'll be talking today, you know, we'll be you know, we start people on specific regimens, but there's also the ability to modify those. So, here we have another case. This is a 32 year old cisgender man who presents with four days of fever, swollen glands, rash, fatigue, and a sore throat with mouth sores, he has sex with cisgender men, he uses condoms, almost always, he has no history of using crap or PEP, and unexamined has a you know, a maculopapular rash on upper chest, non oxidative pharyngitis, cervical and axillary lymphadenopathy, and you suspect acute HIV infection, a point of care HIV test is negative, as you would expect for acute HIV infection. So, is he a candidate rapid air t? So the answers are a yes, you can initiate era T before the viral load result is available, and B now you need confirmation of viral load before starting. So we have a bit of a split here. So 65%, say yes, is the candidate. And if 35% saying no? And the answer is yes, you can initiate AR T before the viral load result is available. Now if we go back to the rapid AR T guidelines from the AIDS Institute, you know, to determine whether a patient is a candidate for rapid AR T, the clinician should confirm that the individual has one of the following or reactive point of care HIV test result or confirmed HIV diagnosis or in this case, suspected acute HIV infection.

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So it is important to recognize that there are, you know, a host of people who would be available who would be eligible for treatment. And we'll be talking about some of the caveats, for example, no medical conditions or otherwise that require deferral of rapid arity as we continue with cases. So, you know, one of the things that you're, you're probably thinking about is, you know, how am I going to counsel somebody, you know, you know, when our visits are very short, we've just got a reactive result. How are we going to talk to a person who's probably extremely overwhelmed by the, you know, by their result, I'll say that it, it really is necessary to provide the usual level of education, about HIV to someone when you're when you're initiating, you know, rapid initiation of HRT. So, thinking about you know, what is HIV, what is CD for cells, what is a viral load, what is persistence and you still need to present people with the available treatment options and discuss risks and benefits of treatment. You need to discuss the importance of adherence to avoid the development of drug resistance. And you also need to discuss, you know, HIV transmission and use of safe sex practices and avoidance of needles sharing activity, you know, in this conversation, so there it is, it's a lot to discuss, but I'm assuming that all everyone on this call, you already have pamphlets and information and mechanisms of having these conversations with clients. The New York State also emphasize that, you know, during this discussion of AR t as a personal benefit to reduce, you know, kind of long term complications related to HIV that you do have a discussion of u equals u and reduction of HIV transmission risk after starting effective HRT. So, again, this is an additional component that you do need to incorporate, I mean, you will need to discuss patient readiness, again, discussing cycles and identifying psychosocial barriers that can interfere with adherence as well. And, of course, once you identify the barriers, you know, you should, you will need to be in a position to offer patients necessary ferals, you know, including things like housing assistance or behavioral health. And, you know, the multitude of assessing and addressing the multitude of issues that might come up in these conversations. The other point is that up to having the discussion, you may still have clients who decline AR T immediate AR T. And in that case, it's important to schedule a follow up so that you can have these compensations again, I will say, though, that in you know, one of the first centers in the United States that started this was in San Francisco, and the San Francisco General Hospital. And in their situation they looked at, you know, they made an offer to everyone, and over 96% of their patients chose to start HRT immediately or on the next day. So I think you if you haven't done this already, and you have concerns, definitely very few people declined to initiate. So there is a medical history checklist. And this might look familiar, because this is the these are the data that we collect on everyone who's newly diagnosed data results of the last HIV test in a serostatus of sex partners, and their AR T regiments of, you know, previous use of antiretroviral medications, including PrEP or PEP. And you'll see why this is important when we start talking about regimens, whether or not they have underlying medical conditions, specifically renal or liver disease, and what medications they take over the counter medications. And this is to ensure that you're, you can advise them about drug drug interactions, whether they have allergies, history of substance use symptoms. So we'll be talking about this but you want to assess for signs of symptoms that could be consistent with meningitis, their psychiatric history, and again, whether they are pregnant or are planning to be pregnant. This slide shows the baseline laboratory tests that are recommended for people who are initiating and are tmes up and again, you'll see these look very familiar. So

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HIV antigen antibody assay, viral load, baseline, HIV genotype, baseline city for count, screening for viral Hepatitis, a metabolic comprehensive metabolic panel, STI screening, your analysis and pregnancy tests for those who might who have the capacity for pregnancy. So, again, as I said, these are very familiar, you really do need to get these baseline tests that the key point is that you do not need to wait for these test results before initiating a RT. Again, this good practice statement is from the AIDS Institute guideline. So again, for patients with a reactive HIV antibody screen that is pending confirmation, you should ensure that the person understands the benefits of rapid HRT we discussed this before. And to mention you know, these following items of the screening test results are not diagnostic. It is rare, but a false positive test is possible. So you will be doing a follow up. For example, by Are load. And if the confirmatory tests are negative, you will be discontinuing AR T. And it's really important to emphasize the benefit of starting AR T early, definitely outweighs negligible risk of taking arity for a few days, and then stopping it, if confirmed HIV negative. And I'll also say that for many clients, you know that there is, you know, ongoing HIV risk. So this would be a definite time to discuss options such as PrEP. It's also important to know provide these results, as soon as they're available, again, discontinue arity, if the if the result is negative, and again, reinforcing appearance, and next steps, if it is positive, if the person declines rapid AR t, you can discuss options for deferred initiation now, at a later time, ensure the person is linked to HIV primary care and continue with next steps. So, you know, sometimes we're asked about, well, you know, should we repeat the test, and definitely, if, if you want to minimize the possibility of a false positive, you can go ahead and do a second HIV screen, it's even recommended if you have an opportunity in your clinic that you have a second type of point of care test, for example, in a second manufacturer, you can go ahead and use that. So, you know, key points here, the rapid AR T initiation is the standard of care now in New York State. And it's efficacious, safe and highly acceptable, with very few people declining the offer of immediate AR t, you know, there are potential barriers that, you know, can be addressed through appropriate counsel, counseling and linkage to support services. So, here we have another question. You know, Mo is interested in studying AR T today, so, which regimen would be the best regimen? To start, we have big tiger there, tapping into sitting in favour ins TDF emtricitabine, saw your Tiger via back in the movie then saw your Tiger there, and the movie then recovering, tap, and emtricitabine. So about 73% chose a and second was C, which was the die, you take a bit of acronym if you didn't regimen and, and D was also chosen to regiment or you take a beer and the nicotine. Actually, everyone chose, you know, it was quite a spread here. So let's look at what the correct answer was. It was option a

28:06
tiger they're tough interested in. So let's think about choosing a rapid AR T regiment. So before you initiate AR T AR T, remember, you're going to be thinking about whether or not the person's had any prior use of air views, including PrEP workout, which can increase the risk for baseline resistance, you're going to be assessing for other medical conditions, comorbidities, and other medications also over the counter. And that can affect the choice of a regimen. You know, you're going to be getting the, you know, resistance testing the genotype, you don't have them right now, but you're going to be sending that out that may cause you to modify a regimen later on. And you're also asking people about the chance of pregnancy. But what I want to do first is

to look at that this is not the these aren't the regimens for rapid initiation. These This is a list of regimens from HHS recommended initial regimens for most people with HIV, and we're going to look at them and decide whether or not these would be possible when you don't have test results. So the first regimen is the Tegra. Vir tap into Citavi. So could you use that, you know, you can't use it if you're granted interest is less than 30 or severe liver impairment but, you know, especially if you've had a patient you've been following for awhile, you'll probably know those results or someone has a history of renal issues they can probably tell you so that regimen is probably safe to initiate you're going to have your metabolic studies back tomorrow. Yeah, probably you can use that. The second regimen here is dial your Tiger via a backwardness etc. Can you start that today? The man issue is that you cannot start it without knowing the HLA B 5701. results because you don't want to run the risk of someone being positive. And, you know, obviously having severe outcomes, so this is not something that you would want to use. What about this regimen? Don't you Tiger there, and Tanaka, Vir and FTC? Can you use that? Again, you're going to have kidney results within 24 hours, that's probably a regimen that you can use. How about the last one? So you tagger via TTC nice regimen. But of course, there are requirements that you need to know the person's viral load because you can't use it in someone with a with a high viral load, you need to know whether or not someone has chronic Hepatitis B. And it's really important that you want your date you know, whether or not there are important mutations, so we're not going to have the genotype back. So, this is also not a regimen that we would be able to use for rapid initiation. So if you look at the AIDS Institute, preferred rapid arg ratchet as you can see, it really follows this kind of thought process. So yes, you can use McTaggart there, tap an FTC are interested to be in it's a single tablet formulations taken once a day. So you can use the W Tegra. Vir tap FTC. And there's another regimen that's been actually studied for rapid initiation, which is darunavir

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based regimens boosted darunavir Cobicistat tap MTC and this is a single tablet regimen, you do have to pay attention to drug drug interactions because of the boosting with Cobicistat. So you know, you really have three regimens to choose from. And, you know, think about making this you know, part of your rapid arity protocol. And again, you know, a few regimens that you need to avoid. You know, we've talked about this, but you shouldn't be thinking of the back of their mess, you don't know that hmap 57, or one status, you can't use recovering because you don't have the C four or viral load. The fabricants has is not as well tolerated because the height we've seen that side effects and higher rated resistance, and you can't use the two drug regimen, di tech or the a three etc. Because you again you don't know the viral load the hep B status or know if there's NRTI resistance so you know again choosing the regimen is important. He regimens used for rapid initiation of HRT are similar to usual recommended regimens, but they have been modified for reasons of efficacy, safety and tolerability in the absence of lab results. And you should also be aware of regimens that are not recommended for rapid stuff. And we've covered those already today. You know, if you strongly suspect resistance, for example, someone has recently been on PrEP or PEP, then you can use a regimen which includes both the darunavir based regimen plus DI e checker, and it's unlikely that you would you would need to use this but know that this this is an option. So MLS has a question. Isn't there a shot now? So what would you tell her about initiating long acting injectable AR t. So as you're probably aware, long acting injectable Capra Tegra Vir recovering was approved earlier

this year in the US, I believe it was January, on the basis of clinical trials that showed efficacy and non inferiority to standard regiments. And we had two studies the player and patterns, and then the class study. And this was a randomized phase three open label multicenter study. And you can see here 809 individuals, so AR T naive, would given die, Tiger bear, back of year and three, etc for 20 weeks. And then if they were undetectable, they were randomized to either continue this or to receive an oral D then with cabotegravir and rilpivirine. And then to continue to injectable in the Atlas study 705 individuals who are already receiving HRT for at least six months and you had an undetectable viral load. were randomized to either continue this or We're begin an oral lead in with Kevin Segovia, every two four weeks, and then continue to the intramuscular injection. And then of course we have I'll show you here, you know, 48 data, but really showing that in both cases I am cat attacker very recovering was non inferior. And so, you know, a wonderful, you know, new agent. But I think the key point here is that, and this is from the HHS guidelines that individuals without prior air these who wish to use long acting injectable in a cabinet tagger in February should first achieve viral suppression on another regimen. Before switching, they have to switch to the oral and then injectable cabinet Tegrity and recovery. So in her case, even though you know she is interested in she's heard about this, you know, injectable form, it would not be appropriate for a rapid start. We have another case this is PK PK is 45 years old and comes in with two weeks of cough, fever, mild shortness of breath and a three killer weightless. He was diagnosed with HIV

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one year ago, has a CD for

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350, an HIV RNA of 53,000. Again, this is 12 months time of diagnosis. He never returned for treatment, and he's on no medication respirations of 24 minute 202 saturations were 92%. And when they're on exam, he has oral thrush, his lungs were clear. A diagnosis was made presumptive of PCP and it was started on trimethoprim sulfamethoxazole. So my question is, in which of the following conditions or rapid initiation that same day started AR t not the appropriate? So a PCP v er cryptococcal meningitis C, pulmonary tuberculosis and D? Kappa C sarcoma. Okay, so looks like 48%, just under heart chose B cryptococcal meningitis, but there are a fair number who also chose pulmonary TB as well as PCP and just a few with ks. So, the correct answer was cryptococcal, meningitis, c. So, just to think about this, and, you know, we know that studying AR t, in the setting of many allies, you know, improves immune function and improves recovery. You know, in PCP, starting AR T early is better than deferring HRT until the infection is treated. And generally, we suggest the PRT is started within two weeks of a diagnosis of an opportunistic infection, except in two key cases, you know, if there's a diagnosis of meningitis due to TB of Cryptococcus, and there was actually a Cochrane review that looked at this looked at, I think, four or five studies, and they found that when people were initiating HRT early, before treatment was initiated. So before four weeks, that the people had cryptococcal meningitis or TB meningitis actually did far worse, and mortality was higher. So these are the cases where you would not want to do it. You do want to, in all situations, close monitoring for immune reconstitution inflammatory sin Dremo, Iris, and certainly, if you're not familiar with, with treating people, this would definitely be a situation where you'd want to refer to an HIV specialist or an infectious disease specialist. So when is rapid initiation not

appropriate? First, as we discussed, the business isn't ready, or the clients start a party, in which case she would follow them closely and offer a party's subsequent appointments. And then again, TB or cryptococcal meningitis and these are extremely rare in outpatient settings. So and again, these folks would require treatment ahead of time. So how do we monitor people who are started, you know, immediately on here T. Generally, we do suggest and again this from the guideline that people have followed up within 24 or 48 hours by telephone, or even an appointment just to see if how they're tolerating medication if they've been able to pick up the medication, their adherence, and so on. And then if possible, schedule an in person visit for seven days after PRT initiation. At the point that you get the resistance tests back and you know, HLA seven or one status, you can then modify regiments. Obviously, if someone turns out not to have HIV, you're going to discontinue HRT. But, you know, it's really important that you do follow up with people once you have these results. And one of the biggest issues is, you know, how are we paying for this? How is this going to be covered, it's very important. Many credits that use a rapid step protocol will provide patients with a starter pack. But you know, there's still the issue of what happens after that. You can, of course, direct enrollment and Medicaid for people who are eligible, you can use copay cards for people with commercial insurance, you can sign people up for aid app. You can access other options. They're also foundations. You know, some states, and I'll say, specifically, New York has streamlined application process to make treatment available immediately for uninsured patients. So we have

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you know, the New York State Department of Health, uninsured care programs. And but you obviously need to think about how you're going to roll this out and have you know, you'll definitely need a process for filling out forms and etc. So, you know, if you can just final consideration, so we can then go to questions. You know, when we think about same day air team, we've seen that it's, you know, effective and safe. But it's also extremely resource intensive. And as you look at the protocol that's been developed by the AIDS Institute, you need to think about all the steps. Now, who's going to determine that this person is eligible for same day AR T? Who's going to provide the counseling, the case management, the insurance, navigation, fill out paperwork? You know, how are you going to have a process for ensuring that the correct laboratory work gets done, especially things like the genotype, because you don't want to get into a situation where the person's now already started medication? And you're, you you've forgotten to go to certain tests? Who's going to do the assessment for opportunistic infections? And how are you going to choose the AR t, you know, I've shown you three potentially four regiments that you can use, how are you going to provide air to you're going to do start to pack we're going to provide people with, you know, you're going to provide a week, you're going to provide a month's worth of medication, and who's going to be responsible for scheduling appointments, and also the telephone check ins that are really so important to ensuring that people remain engaged in care.

**Tara** 43:17
Next slide. And this is just before the opening of the q&a. So we have a few questions in our q&a. So we have our first question. If a patient who got rapid art is virally suppressed within the first two months, would you still recommend extra protection for partners through six months? In front of these condoms? PrEP?

43:42
Right. So at that is actually a really great question, especially with the regimens that we have now. You know, they are so effective, especially, you know, the insti based regimens that we see people reaching viral suppression very, very early. You know, I will say that the, you know, the party line is six months, I mean, I think as an individual provider, I mean, I would say that that the important thing is reaching viral suppression. So, you know, I think it's, you know, would be important to discuss the data, and that, again, that the recommendation is six months, but the important thing is that they're virally suppressed, which is an answer not answer. The and I would also say, you know, in the studies, for example, Partner ONE, partner two and so forth, and, you know, because you did talk about PrEP, you know, there were you know, there were situations where the partner, Sarah converted, these were not, as we say, phylogenetically linked, so the partner was actually acquiring HIV from someone other than their primary partner. So I think discussions of PrEP are always, always important.

**Tara** 45:15
Great, thanks so much. Our second question we have here with rapid RT in setting up suspected acute HIV, could you potentially make the HIV diagnosis more difficult? If there is a delay in antibody response from very rapid viral load suppression, ie if the patient refuses labs that day?

45:35
Yeah, I mean, it is really important that you get baseline test results. I mean, this is, you know, in the HHS guidance guidelines, they're very clear to say that you absolutely need to get these tests done. You know, generally when someone is, you know, symptomatic, that's usually associated with a high viral load. So I mean, but, you know, you really have to get these baseline test results done. And even if you got them the next day, it'll be, again, unlikely the person would be, you know, virally suppressed in less than 24 hours, but it really would be extremely important to do that. And I'll say that, you know, I don't believe there have been any situations where someone has agreed to starting, you know, hair t get declined to us, I don't think that you're going to encounter that in, in real settings.

**Tara** 46:41
Great, thanks for that answer. And we have one more question here. How do you explain the differences between test and treat and rapid initiation?

46:51
Yeah, I mean, you know, test, you know, the test, and three is really, you know, testing three, treatments prevention. And this was a term that was used previously, the rapid initiation, though, is really talking about starting as soon as possible. So we're not talking about starting within a month, we're talking about, you know, same day starts, or at least, you know, within a day or two, so that, you know, 96 hours when, and then when you're talking about tested treat, you know, this was a term that was used when they were modeling, modeling, HIV, and reduction in community rates by saying, you know, basically, everyone who test positive gets treated, it doesn't really include that same day component. Only three, only three questions. Maybe I have

**Tara** 47:55
one more question. Okay. There's one in the chat. And this is good that we have you here as one of the authors of the guideline. So someone asks, Are the New York state guidelines the same used by New York City in their jumpstart program? Or John, start with the AR T? In capital, cats, so jump? Are,

48:16
right. So they're, they're on separate guidelines. So they're still following the protocols for rapid initiation? As far as I'm aware, and I will double check that to ensure that I'm not making a mistake. And I believe they're using the same guidelines. I should also say that HHS has also included a section on rapid initiation as being something that should be offered to clients. And you can also look at the HHS guidance. Okay, great. So my, my question was, so we have about just under 60 people on the call, and I'm just wondering, how many of you have started doing rapid initiation in your clinic? And maybe you can just put that in the chat when maybe if there are any, any concerns that have arisen that I have not discussed today?

**Tara** 49:25
Yeah, and if anyone wants to verbally discuss as well, you could raise your hand as a raise hand function. I'm here and we can unmute you. So you could ask your question. Okay, I don't see any leads coming in. Okay, well, if anyone does have any additional questions okay, we have a comment. Trillium has been doing rapid art since 2017 experience deftly It really helps. Yeah. Great. Okay, we have another comment. We try our best, but thankfully have only had a few PEP patients convert, we don't do other routine testing on other patients that receive positive results from the institution and are in baskets. So try our best to respond to those and get those patients in as quickly as possible as possible. Yeah. Thanks for those comments. Do you have any, I guess, responses, Dr. radix, as a clinician,

50:36
and so, you know, I work at calanoid. And, you know, we started doing rapid start quite some time ago. And one of the things that we did was keep a log, so it was really our nursing department catalogers you know, people starting time to achieving viral load of people who, whether people accept it or not, and it was really helpful for providers to see how rapid, you know, the how rapidly people achieve viral suppression compared to, you know, for example, the year before, and I think that really helped motivate, you know, providers to, to start thinking about this as really a valid option important option to offer people. So folks who were, you know, your clinics haven't started yet. I mean, hopefully, this presentation will, will help a little in moving that promote.

**Tara** 51:44
Great, thanks. And we have another comment. I apply the rapid initiation equals test in treat if the patient is prepared to start the same day or within two days. Okay, great. Thank you for that comment. Great. Thank you, Dr. Radix. for presenting today.

[End Transcript]