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# LONG-ACTING INJECTABLES IMPLEMENTATION – LESSONS LEARNED

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## **Long-Acting Injectables Implementation – Lessons Learned** **[video transcript]**

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Carlotta Starks is a nurse leader and bilingual advocate with a passion for creating inclusive work cultures and improving access to care for patients impacted by racism and other intersecting forms of oppression. With over 13 years of experience as a nurse, her Carlotta experience and workforce engagement and change management has made her a valuable asset as clinical program manager at Mount Sinai Institute for Advanced medicine. She studied at Northeastern University and the London School of Hygiene and Tropical Medicine. Thank you, Carlota, for joining us today, and I'll now turn it over to you.

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Hi, good afternoon, everyone. Thank you for joining this afternoon. And before we get into the presentation, I just wanted to share that I have no financial disclosures. And I also want to share a little bit more about the learning objectives, the lofty ones that I have created. So I'm going to describe a little bit of some of the lessons learnt that we've learned when it comes to engaging team members at the institute events medicine where I work. I'm also going to review quickly procurement of long acting injectables, including some points on navigating coverage and cost this in and of itself, as could be its own presentation. So I'm going to be going through it quickly. But also offer myself as a resource if anyone has any questions later on as well. Because I think this can be really the most challenging part of working with long acting injectables. And for the third learning objective, I'm going to describe some of the lessons learned when it comes to prescribing and administering the long acting injectables in our clinics. I really believe that all of us are shaped by a lot of our experiences and a lot of our background. And so I wanted to share two stories from two really formative roles that I've had in my career. And so my first nursing job was in Washington DC in a pediatric intensive care unit, where my first really sick patient was a baby who had to perinatal transmission of HIV. And it was shared during the nursing report, like when you get a report from the change of shift or the change of shift that the mother had been told by a friend to stop taking her antiretrovirals during her pregnancy. And this really like has always stood out to me. And in many ways, like changed my career, because a few things that automatically I thought it was like this could have been prevented. And that like lack of healthcare access, lack of health care information really do have devastating consequences to the patients that we serve. And thirdly, it also emphasized like how systemic and structural racism really are at the root of so much of the injustice is in our healthcare system, and so many of the heart of so much of the harm caused by healthcare systems. This patient in particular was from South East Anacostia, which in 2010, in the US was known to have some of the highest HIV rates in the country. And so it's just really left always left its mark on me. The second role that I wanted to highlight is Project Health moves. So I worked on a mobile healthcare van for about five years in Boston, in Boston and around the Boston area, where we primarily did STI HIV testing and harm reduction education for injection drug users, but also we did it at nightclubs, queer nightclubs, LGBTQ night clubs, kink nights. And for me, this really underscored that there are no hard to reach patients that if we are coming up, we're able to come up with innovative solutions, we're never going to be able to reach what stereotypically we

consider hard to reach patients in our healthcare system. And so me, I've just always really applied a lot of the lessons learned in Project Health moves, where it's like, there's enough, I think there's enough brilliant, compassionate and dedicated folks in the healthcare system to come up with innovative solutions to the problems that we're facing in the healthcare system right now. So a little bit about the Institute for Advanced medicine. We provide LGBTQ affirming and trans affirming care. And we have five different sites across Manhattan. I'll go into those sites in the next slide. But these are the longest day injectables that we're currently providing in our clinics. So for HIV treatment, we're doing injectable cabotegravir and rilpivirine, also known as Kevin Nuva, where we did our first one a cap revere a few two weeks ago. And then for HIV prevention, we're we're providing injectable carbotech revere or icab. And so for simplicity reasons, I'll be interchangeably using the brand names Kevin Nuvera aptitude, or also icab or icab, recovering. And so this is just a quick snapshot of the Institute for Advanced medicine. Obviously, I have my own bias, but I think we provide really exceptional care to the patients that we serve. We have five clinics throughout Manhattan. And so we have the Peter Kruger clinic, Samuels clinic Morningside clinic, Jack Martin foam clinic and the Comprehensive Health Program. And then this is just the numbers in these boxes represent The number of cabinet EBA patients that we see at each of these clinics, and then just to write it provide a bit of background, we did start Kevin Nuba in the fall of 2001. Want to just give a brief summary of long acting cab rotogravure recovering, I'm sure many folks are familiar as well. So it's an insti, as well as an NRTI that replicates NRTI. It's given as two separate injections in two separate sites. So we recommend that it's given in the ventral gluteal site. But from what we've seen at our sites, most of the patients and most of it a lot of nurses and a lot of patients prefer the dorsal gluteal route. But we do really recommend the ventral gluteal site. And it's given either once every month or once every other month. And then for long acting, capital Tegra, Vir, it's a PrEP medication. It's also given via either via the ventral gluteal dorsal gluteal site. And we just started as of last week getting to patients. I think, this week, we're going to have our our third so we're very much so in like our infancy stage of aptitude and learning what some of the working out some of the kinks that that do come up with long acting injectables. And I'm sure many folks who have started working in lung diseases are aware that there's lots of lots of kinks that have come up while we're building this plant as we're as we're flying it. On average, just a quick bit of information on that it's a capsid inhibitor. It's for folks with multidrug resistant HIV, that and it's also for folks who are not able to get viral suppression on their current antiretroviral therapy. Just to get us grounded a little bit. In the presentation, I wanted to share that I'm building off a lot of really important a lot of hard work that's been done before me, I joined the Institute for Advanced medicine in January 2022. But there was a lot of work groundwork done before me by the nursing leadership by medical leadership. And so I'm really, you know, just really building off of that. There's other references that you can refer to as well. So, in I believe it was March, there was an HIV eco with Jack Jackson, J crystal, as well as Judy Gora, some of our nursing and pharmacy leadership, that you can refer to it well as well, that describes getting your clinic ready for long acting injectables. And that like I wouldn't be all the information I'm sharing here is really a combination of a lot of collaborative work between leadership, medical leadership, nursing leadership, pharmacists and benefit specialists at the Institute for Advanced medicine. And so I just always want to give folks their flowers and really appreciate all the work that's been done for long acting injectables. Another resource that I just want to shout out and just like say Special thanks to we are one of the eight sites in the US that were selected for this grant, a

special project of national significance or spins grant. That's focusing on how we can implement long acting injectables with underserved populations. And so there's a few different community partners here that have been listed. So Columbia University, the Department of Health, sitting in New York, and the SE AIDS Training Education Center, and they're that big collaboration is making up ally up. But they've been really invaluable and provided a lot of resources for us getting scaling up and our long acting injectable program. And more resource resources are to come from them as well. So be on the lookout. And hopefully we can announce and share a lot of the resources that have come up after, after if some of the bar groups and our convenience. So the outline for the presentation I'm going to before I get started, I wanted to share a bit about our long acting injectable workflow and what has been working for us. And things that are not have been working for us share a little bit on best practices for engaging team members, procurement of long ID injectables, prescribing, administering monitoring, and again, additional acknowledgement acknowledgments. So this here is our most recent clinical workflow for long acting injectables. And so the first step is that the provider will identify a candidate suitable for long acting injectables, whether it's Kevin Nova, or aptitude. And we ask them to document that they meet the eligibility criteria in the electronic medical record. And then from there, we do what we're calling a case conference with the PCP nursing leadership and medical leadership, where we'll review different if the patient's a candidate, and I'll go into that a little, a little bit more a little later. Our nursing touch point is something that came out of a few different things but the nursing touch point is really just a educational phone call where the nurse goes through some additional points of the patient before starting lighting injectables and reviews. Expected you know expected wait times when it comes to benefits the length of appoint visits that it could take, as well as like the number of visits that could be that are on average every year. And so once the finishing touch point is completed, the patient's cleared. And from there, the provider will send the farm the prescription to the pharmacy, and will trigger the benefits investigation pathway. And that's a quick screenshot of what our workflow looks like. That was created in Visio. I wanted to go into detail on the long acting injectable LGA criteria, because I think this is a piece that I'm very proud of. But I think it's also been like really helpful for us. So it's a smart phrase and epic. And it's really as you can just keep see like a checklist that providers can check off when they do a quick chart review.

10:43

If the patient is meeting the criteria, and then addition, when the nurse goes in later does like a chart audit, they'll review that and see if anything's missing or see if there's anything that comes to our attention that they want to bring up. So I've included here are what is our eligibility criteria, and I wanted to highlight to two spots in particular two points. The provider has reviewed the dorsal gluteal and ventral gluteal site confirms it's an optional injection site, and that there's no silicone injections. Since silicone filler sort of injections can migrate. Anyone with silicone injections in their gluteal muscle is not a candidate for long acting injectables for us. And what we've also more recently done is had like a provider and a nurse huddle. And oftentimes, like if a patient is being seen by provider, have that quick nursing provider huddle and do a quick review of the injection site just to make sure that we're we think that there's optimal muscle mass, and then also wanted to review this point about chronic Hepatitis B, or Risberg, Hepatitis B infection, and then I'll go into one second. So this here is our Mount Sinai protocol, when it comes to switching patients on antiretrovirals. And it's a bit of a busy slide, but the next slide will

go into like a little bit more detail. But if any patient does have surface antigen body is surface antibody positive, they do have chronic Hepatitis B infection, and so we don't want them to continue on the antiretrovirals of their own, or make sure to start Hepatitis B treatment as well or an anti retroviral treatment that will cover Hepatitis B. And then we have this table here on the right, as well. That shows a little bit more okay, like what if, if the lab results what are the lab results coming back in and here to like we, with all of our patients starting acting injectables? We this is a huge part of the nursing chart review as well, is we're checking to make sure that our Hepatitis B Serologies have been done within the last six months, so that we have Hepatitis B surface antigen done the Hepatitis B core antibody and the surface antibody as well. And then just really quick here. So if a surface antigen is positive, the patient is not a candidate for long acting injectables. And so we want to start them on treatment for that. But I want to just like highlight this one piece, and this will be a quick question. So a patient is on icab RPV waitlist and has just updated has just had updated hep B Serologies. that patients have B surface antigen returns positive, which of the statements is the most accurate, the patient is a long acting injectable candidate, we can send the scripts over to the pharmacy patient is not a long acting injectable candidate. Patient is not a long acting injectable candidate until after they finished the hep B immunization series or patient is not an LI candidate. And oops, sorry, the pop up and they should start a hip be active. Eric T.

13:58

And so you can pull like a B, C or D. There is more than one correct answer. But just wanted to test folks to see which one is

14:09

the most accurate.

14:12

Okay, yes, correct. Most folks answer D. This patient is not a lot an LI a candidate and needs to start in territorial retrovirals that cover their heavy as well. This here is the the icab eligibility criteria. And again, I just bolded the no evidence of chronic Hepatitis B is so it's very important. A few other things that we include in our in our eligibility criteria, which I think is really helpful is we put at the bottom just additional notes that providers can look at to and use for education purposes for their patient but also that way it's just built into the into the smart set into the smart phrase excuse me, so I cap is not recommended for anyone under the under 35 kilos When it comes to lactation or chest feeding, really a conversation is needed with the patients because we were not we do we are aware that could be residual concentrations of abrogating the system for up to 12 months or longer. And then we also have this included our smartphones as well. So just a few notes on like for patients who are, who have childbearing potential. So if they do have any pregnancy plans, we want to offer birth control if desired. We also want to review quickly the risks and benefits regarding use of aptitude in pregnancy, including the lack of pharmacokinetic data. And really think it just having a conversation with the patient, if they are, of childbearing potential is, is key. A little bit, I wanted to speak a little bit to our case conference. So as much as possible, we like to have shared decision making when it comes to long injectables at the Institute for Advanced medicine. And so we involve a multidisciplinary team when it comes to this case conference. And you can see at the bottom, so our benefit specialist is involved. I'm

involved as the clinical program manager, nursing leadership from that clinic or that site, medical leadership. And that makes up the majority of the long acting injectable work group at that clinic, oftentimes to our pharmacist has also been like a very invaluable resource. But what we'll do is we'll review collaboratively if we think the patient is a good candidate, or if anything is outstanding that needs to be done. For example, like if we need if we need to draw the headpiece or allergies or if we do need to start in the hippie series for immunization. Another important part that I wanted to highlight for our protocol that we thought worked for us is that we do want these patients to come see the provider every four months. And so we what we decided is to alternate when the patient will see a nurse for injection and when they'll see the provider to check in about longer to injectables. And so obviously, when they see the provider, they'll still get the injection from the nurse. But we wanted to have this sort of alternating schedule every two months, starting on month four, to really just make sure also that the patient's checking in with their provider. And that we're like assessing on multiple fronts, how the long acting injectable treatments going. So when it comes to engaging team members, that there's always room for improvement. Personally, and I know this is one part that I've tried to be really intentional about. But I've also seen where like there's a lot more room for for us to grow, and how we get engaged and collaborate with our team. So what we've realized it's really important to have clear communication pathways where everyone understands what's the good communication pathways, there's a lot of folks that are involved in, like I said, shared decision making. So we want to make sure that folks know, okay, email, epic message, what's working best protocols and workflows have been establishing those have been key to sort of getting folks on the same page. And regular meetings as well has also been something that we've we've been doing. Every two weeks, we have a long acting injectable workgroup meeting to just address issues. And I think that's been really helpful just to advance and get things off off the ground. But we've also realized, like we need more than just these meetings, because oftentimes nurses and providers are not able to attend workgroup meetings. So many education sessions is something that we've more recently started and our first one was last month, and it was around heavy, the heavy Serologies and the importance of why we the rationale why you need to check them. And then we're going to have another one as well, that's just on the HIV tests, and when to do them for, for icab or opportune. Some of the key lessons learned is that like different forms of communication are needed for different teams. I am has five clinics across Manhattan. And there's a variety of like what works best for each team. But oftentimes epic messaging is sort of like the the best way because it keeps everything in the chart, but that we have also, in addition, been using emails as well, but trying to find the best form of communication that works for you and your team. I touched upon this a little bit, but meetings are a start. But we have seen that they're not really enough to communicate all the information and updates that are coming up with long acting injectables and also the changes to our workflows. So we we've made after realizing this, we've made some quick reference guides for nurses. They're just like a quick one pager of like nursing workflow for cabin Nova nursing workflow for aptitude. And I think that's been really helpful. We do have the nurse provider huddles as I mentioned, like we successfully had a provider and a nurse huddle the other day just to assess if the patient had a good injection site. They had a this patient had a BBL and so we they just wanted to examine together and they both were able to find a good injection site. When it comes to many education sessions to like I think this is something the first one was like really successful and I think we got a lot of really good engagement from our team members.

And so we want to keep continue to doing that like every month, because there's so many pieces of the long acting injectable workflow. And we want to be able to like discuss the rationale behind some of the decisions that we're making or the rationale behind some of these. Some of these protocolized points cruminate long acting injectables, lessons learned, I mentioned that this could be like a whole presentation in and of itself. But what's been really key for us is having a dedicated Benefits Specialist just for long acting injectables to help us navigate issues with coverage issues, if there's any denials. And that's key. Utilizing vive Kinect, I really recommend everyone signs up for Vive, connect initially with the Institute for Advanced medicine, we were not using the Kinect and now that we realize we there's so many others, we need it for some our folks are under insured or not insured. We're setting up trainings for our staff to do but I do wish that we had done that a little earlier in the in our process. With long acting injectables, site level reimbursement I'm not going to go into detail about because again, I think that could be a whole separate teeny training. And finance would be more qualified to speak to that. Delivery and storage. So how you get the medication really depends on on the patient's insurance and coverage. So if you get it from the farm, you can get it from a specialty pharmacy or hospital or hospital pharmacy. But if you when it comes to Kevin Ooba really just want to make sure that that's refrigerated and follow up call change, call chain management for that. I'm going to speak a little bit about the difference between medical benefit, which we affectionately call by and bill as well. Or oftentimes they're interchangeable. But so when a patient's insurance, it prefers medical benefit or covers these long acting injectables under medic benefit benefit. What it does is it triggers off triggers us from an ordering these medications from our internal hospital pharmacy from that Mount Sinai for pharmacy. So it's supplied from and paid for by the hospital. And then later, we're reimbursed by the patient's insurance. And this can take a few months, as we're seeing. We did our first buy and Bill, I believe it was in April, and we still haven't been reimbursed by patients insurance for that. Yeah. And then when it comes to billing, what we're going to do, we include the cost of the medication and the administration into the patient's bill. And then there's two different types of pharmacy benefit. And so the first one, the medication can be ordered and supplied by a hospital or clinic based Specialty Pharmacy. So we're very lucky that we have our co located pharmacies on site, specifically our comprehensive health clinic as well as Samuels and Morningside. And so what we've done is had, you know, we have really strong partnerships with them, and the medication is paid for by the patient's insurance before it's delivered to us. When this happens, the hospital or your clinic will only bill for the injection, administration visits and labs. And then there's also a pharmacy benefit where we work with specialty pharmacies such as a credo optimum and CVS specialty. And similarly the medications paid by the patient's concerns before delivery. And we only bill for the injection and administration and any lab visits.

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Some other lessons learned is definitely utilize the resources available to you. So the Vive Connect portal is is a really strong resource that many folks are using. We're utilizing long acting injectables, a benefit specialist is really I think most folks will say who are working longer skills necessary when it comes to maintaining your program. And so I think they're going to be key for a lot of folks, when it comes to upscaling your program because they having someone to navigate the prior authorizations navigate, okay, pharmacy benefit was denied, we need to start now to medical benefit is really key. And there's a lot of administration that goes behind the

scenes even before we get the medication on site. And so having someone dedicated into that role, like I cannot underscore how important that is. I know not everyone's going to be able to do that. But I think even just splitting parts of this parts of benefits navigate navigation among different staff has proven really quite quite difficult. It's it's been specimen much more streamlined now that we have one dedicated individual. And then our pharmacists have been really an invaluable resource. This is just a screenshot of the Vive Connect portal. It's an online based platform web based platform that you can get a training on. And then a few other lessons learned is that while you're when you're beginning the benefits investigation process, make sure to clearly communicate with the patient that it can take some time. Usually it's within like a week or two that we hear back from insurance, if it's approved or not or anything like that, then we need a prior authorization. But there have been other insurances that are taking two to three weeks. Also clear documentation of medical or pharmacy benefit. And EMR is something that we learned in the last few weeks where if someone from your finance team is trying to go through and just double check how this medication was covered, and under what part of the insurance, having super clear documentation like this is just medical Bennett, this was procured through MediCal benefit, this was covered by pharmacy benefit is necessary. And also having a really close relationship to your finance team. So letting them know if there are any new patients that are going to be on MediCal benefit. Because I think what's really key here too, is just making sure that we're able to track the reimbursement. And this is a piece where, you know, we've learned after the fact but okay, any new medical benefit, let's just give a heads up to our finance team so that they're aware, and they can keep close tabs on it when it comes to the reimbursement. So for prescribing and administering, I included some screenshots of our epic smart sets. These, since we don't have an ambulatory Mar, unfortunately, we had to build some smart set some from scratch. And so this took over about a year and it was a huge labor of love. And many folks in the long I think just over workgroup, we're working on it. And so I just shared a little bit more here in particular to Cabo Tegra Veer, long acting and turbo Tegra. Vir. So we had our smart splits for the loading doses be covering for month one and two, the loading doses needs to be given at month one, and then again at month two, before switching to the q2 months. And then the maintenance dose is starting at month four and then every two months thereafter. And I wanted to show also another epic smart set that we created just to really help streamline and make it easier to audit for ordering all the labs that are needed for starting icab. And so you can see here and I'll go on to the next slide. So when it comes to opportunity, there's two tests that we need seven days before the first injection, and oftentimes some insurance companies are asking for these results as well. So we do the antigen antibody, HIV lab based test, also sometimes just called a lab based fourth generation, and then as well, we want to do a viral load. And then these are the other baseline labs that we also want as well. So Hepatitis B serology, Hep C, syphilis, comprehensive metabolic panel, if someone has the capacity become pregnant with pregnancy test and or an HCG serum. And then at every visit, we're offering folks, triple site STI testing. And so these are baseline, but they're also annual, so I just wanted to like, share that as well. With this, we've decided as a as a workgroup that we wanted to have these before someone starts aptitude but also annually thereafter. This is a little more on our workflow with aptitude before someone gets the injection. So before each injection, we're doing a rapid point of care test, which RS is Abbott, which is a fourth generation test. And then we're also doing the PCR or the viral load. From there, we're also asking nurses to screen for any acute HIV symptoms that the patient might have had. And then administering the

aptitude. And I just wanted to highlight bring us up in a later point as well, anyone with a BMI over 30 utilize a two inch needle, and those are not provided in the cabinet kits that you'll get. This is just some like additional guidance. But like, like I mentioned before, really want to try to have the lab based antigen antibody testing the viral load done seven days before giving the aptitude and if you know like this is the one exception but like if the lab based antigen antibody test and the viral load are done within that seven day window for that first injection, we don't need to do a viral load for rapid. Some lessons learned when it comes to administration of these long acting injectables, pharmacists input is always key, I think, working with them to make sure when the medication was delivered, and if we if we have it before the appointment has really been essential. Making sure to do additional teaching with your nurses on the importance of using a two inch needle with a BMI over 30. So asking nurses even in their nursing audit or before they give the injection, check quickly the BMI just to make sure to use the correct needle. We've had to do some teaching and follow up teaching on the ventral gluteal site that's been preferred. And I think it's like been really helpful because we want to make sure that our nurses feel as comfortable as possible using that preferred site. And then Z truck method I think a little review on direct method has been helpful for folks. I know including for myself, because about our patients do are a bit more lean. And so it's been helpful to like, learn in practice, how to do the track. When it comes to monitoring, long acting injectable patients, I think this is one of the also main sticking points when it comes to expanding and upscaling programs. So find a system that I think works for you. Some of our, as I mentioned, we have five different clinics. And so what works at different clinics doesn't work at all, all of our sites. But there's two clinics in particular that prefer to use a shared drive document where we have listed out when the last injection was when the upcoming injections do. And what we've been told from nursing is like the less information on there, the better that way, they can just see what's necessary. For example, like when, when the PA is going to expire. One of our other clinics uses really successfully just a calendar, like so a handwritten calendar will go right in the next upcoming date for the patient. And then that way they can check okay, at they check the calendar every every day. Okay, who's next? Who do we need to order medication for make sure that medications for and then more recently, as of I think Monday, we've created a binder was Monday or Friday, or mounts at Mount Sinai Morningside clinic made a binder that has a lot of information in it, including a calendar when people are due. And I'll show a screenshot of what that looks like as well. But find a method that works best for you and your team. And as much as possible, involve your nursing staff as well. So what I'd recommend just to see what, what's going to work best for them. And what's going to be the easiest way for for tracking. This is just a quick photo of the Mount Sinai Morningside binder created by Judy and Eva. So I just wanted to say thank you. But we've included in there are our nursing guides, our quick one page reference guides, as well as our protocols. And then we have on the first page is just a list of every patient's every patient that's on cabin Nova. And then we've also included a perpetual calendar, which I'm going to show in the next slide. This was created by Jessica silk. And so it's something similar to the Depo Provera calendar, where like you can see let's just say, Okay, if the patient was given an injection on March on May 1, the target window is going to be from June 19 to July 3, and that's just for the one at the one month, I'm sorry, another team that every eight weeks. Another resource that I found, while creating this presentation to is vive has like a treatment, a treatment planner that I think is really helpful. So if you go to the cabinet of a healthcare provider website, and you click on the Resources for healthcare conditions, you can

click on this every two months treatment planner, and put the date that the patient received the injection and it'll print out I think, for the next year, or the next due dates and includes the window period. And so I think that's something that you could utilize if you if you find it helpful, could and provide to the patient as well or it's just like, okay, it'll list out all upcoming dates, and including the beginning and end of the window. For monitoring, just really want to encourage building in and thinking ahead of time how you want to do QA Qi

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I know for us there has been, we even with the best intentions, QA Qi can be one of the last things that you do. So checking when patients aren't, you know, are overdue. For example, for example, sometimes our patients are overdue for labs or for seeing a provider. So building in some sort of method that works for you. More what we're doing in our clinic is scheduling certain times where me and meet our Benefit Specialist are meeting just to review and do QA Qi and checking really when the prior authorizations and for those medical benefits. And the reason why I just bring that up too, because we did have a recent instance where we were ordering a Medicaid ordering Kevin Nova from our pharmacy, but the prior authorization for medical benefit wasn't done and we were we're not aware. And so really important to check those expiration dates and I think just buildings a certain time every month every week to make sure those prior authorizations are up to date. These are some valuable resources that I wanted to share with folks that that I've that I've used when it comes to like creating our protocols and workflows. So the word 86 long acting injectable anti-retroviral enteroviral guideline guidelines has been very helpful as a resource and those are public. With the San Francisco clinic, the American Academy of HIV medicine has a long acting injectable page that has a lot of resources as well. We're always looking at clinical info.hiv.gov. And then the New York State Department of Health AIDS Institute also has some really beneficial resources when it comes to long acting injectables. And as I mentioned ally up what part of the goal of the Elliot project is is to create best practices for long acting injectables for implementing them in your clinics, and particularly like when it comes to serving underserved populations. And so once we I believe after we have our second convening in October, we're going to start sharing some of those resources more widely. So be on the lookout for those I don't know, I don't know when those are coming. But I'll be very much. So promoting all those resources when they come out. This I also found helpful so this is from the American Academy of HIV medicine. And this was helpful to us creating art workflow. Yeah, and I went quite fast. So we're almost near the end. So I just, as I mentioned before, I really believe in giving folks their flowers. And so we wouldn't be here without a lot of the work and collaboration that's been done at the Institute for events medicine. And so our medical leadership has been key to creating our protocols creating, putting some systems in place that work for our staff, but also for our patients. nursing leadership has also been like really incredible when it comes to like, figuring out what's working, what we can improve upon. Our Benefit Specialist has really been keeping the program together. And then there's three pharmacists, Paulina, Jake, and Isha that have been really helpful to when it came to creating our epic smart sets. And then just making sure that we are on on top of all of our patients that are on long acting injectables. And so they've been, I think, one of our strongest resources. So if you have a pharmacist, definitely develop a close relationship with them. And then I wanted to shout out the communities of practice and the LA app team, as well as say thank you to Carrie,

Katherine Siri and Elizabeth who move in like really leading a lot of the charge when it comes to that the alley up initiative. providing some resources.

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And Phoebe, do you want to speak to this a little bit? Thank you so much for your presentation. We can open it up for some questions, and then I can speak to the all CDI line. So we have a few questions in the q&a. And in the chat, thank you for sending those in, keep them coming. So the first one is what types of topics are considered for eligibility criteria? Yeah, sure, I'm

37:34

gonna go back to that slide, because I went quickly through it. And then I think it'd be helpful. So the one, the first thing I think it's important to include is like the weight that we need to have folks weigh over 35 kilos. And then in addition to that, we just put some of the other contraindications when it comes to the eligibility criteria. So making sure that patients don't have a history of hypersensitivity to capital, Tegra Vir, this is particularly for aptitude. That there's no current symptoms of acute HIV, as well as that they agree and are open to or amenable to more frequent visits. What we're seeing with long acting just injectables is that it's a change of culture for our patients, who sometimes came in two to three times a year to see the provider. And we're taking Darrell daily oral antiretrovirals. But it's also a change of culture for our nursing staff, our providers as well, because patients are going to be coming a lot more frequently in to get injections. So we speak to patients a little bit about that. There's a few anticonvulsants, and also, medications that you can take if you're going to be starting aptitude.

38:49

And those are really the the main,

38:51

the main things, I think the hep B is something like I've tried to underscore a few times, but it's quite important. And then I'm just gonna go the in the cabin nuga eligibility criteria is also quite similar. Just want to make sure there's there's no drug to drug interactions, no treatment failure, and have been on stable and tech for us, we've decided that we want folks to be biologically suppressed for at least six months, and then also to be on a stable antiretroviral regimen for the last six months.

39:23

And that also answers another question we had in the chat about eligibility, eligibility criteria. And then we have another one, what is in place for undocumented persons who are uninsured to access your clinic benefits? Um, so I think it'd be

39:41

I think I'm gonna answer this because there are folks that would access. It's different for accessing our clinic but also, there's different resources available for folks who are trying to access these medications. And so we have a prevention team that will can work with folks to sign up for our assistance programs, as well. In New York State, but when it comes to insurance as well, the VA does have within that portal, we have assistance programs that we could that

can be utilized to access the medications as well. We haven't had any patients utilize these these benefits through Vive, which is why we're like making sure folks are trained on the beef portal. But other I know of other clinics who have had some success with the beef assistance programs.

40:26

Great opportunity. If we don't have a point of care testing in our office, does the patient have to wait for negative or negative tests before receiving the injection?

40:39

Tony, do you want to take that one? I believe Dr. Urbina mentioned he was going to be on the call.

40:50

We might be able to promote him to panelist if he's here. So let's hold on that for a second. Because we do have another question. What are the oral ARV regimens that achieve non detectable viral load that cannot be replaced by injectables?

41:09

Could you say it again, sorry, I was looking for him on that as a panelist,

41:11

actually, Dr. Pineda was just promoted to panelist. So let's go back to that first question that's in the chat here. And I'll repeat it for aptitude. If we don't have point of care testing in our office, does the patient have to wait for a negative test before receiving the injection? And your unmute doctor?

41:38

Okay, great. Yeah. So the quick answer is yes, you do have to wait for a negative test if you don't have that rapid point of care. So what the FDA kind of requires is that you have one diagnostic test that has been resulted and is negative prior to this subsequent injections. So that can be a fourth generation lab based test. The viral load needs to be drawn prior to each visit, but that one can be pending. So as long as you have the fourth gen resulted as negative and you have that result, the viral load can be pending prior to the injection.

42:30

Thank you. And then what are the oral ARV regimens that achieve non detectable viral load that cannot be replaced by injectables?

42:46

I can answer that one no. So there really isn't any kind of previous AR T regimen. It can be any as long as they're suppressed. And I think what's more important, so it can be any of the combination therapies. It's just if they have a previous history of resistance to primarily real pivoting, or to kappa Tegra veer or to drugs in those classes, where they may not be suitable

candidates for the injectables. But any AR T regimen that they're currently on, as long as they they don't have those previous potential for resistance would be fine. Prior to switch.

43:36

And we have another question here. What are your thoughts on giving incentives to patients to adhere to appointments? For example, patients who may be active drug users and on house,

43:52

I would support it. I think whatever incentives that we could provide, or that maybe a clinic has the resources to provide, I think would be helpful, I think with the ward 86 protocol, and especially with what we've been seeing, like that study that most recently came out from Dr. Gawande and others at UCSF, like, I think it's important for us to try to reach this population. And I think, as I mentioned previously, like I think, for me, there are no hard to reach patients. So whatever is innovative ways and edible, innovative solutions that we can come up with to reach folks that are unhoused. And for free to folks who are actively using drugs we should try to implement. I think a lot of clinics too, like might not a lot of like smaller clinics or might not have those resources. And I think even some hospital clinics might not have those resources. But maybe that's something I think there's more research that shows that that's been quite effective of getting folks to maintain their appointments we should try to push for on a broader level across HIV clinics and across the country. Do you want to add anything?

45:03

No, I just yeah, I, I am totally agree 100% with what you said. So I think anything we can do to incentivize patients, or just I, you know, I think would be great. I think just as like you mentioned, just part of the eligibility criteria just to kind of assess the patient's commitment to like coming to the clinic every two months, and kind of what's that like, and just kind of managing their expectations in terms of how much time is going to take for them to kind of go through the whole process of like, you know, bringing the rope hovering to room temperature, and then, you know, giving them the injection. So I think, yeah, just managing their expectations upfront, but anything that we can incentivize them with, I'm definitely support.

45:46

Great. And I think for me, this is like, part of the key of like, why I'm so excited about long acting injectable is because if we can reach folks who don't have viral load suppression right now, like we're going to be able to make a huge, huge difference. And so targeting folks that have traditionally been traditionally been what we call, like, difficult to reach. As I mentioned, I feel a little even weird saying that because I think it's a bit patronizing. But I think whatever we can do to center patients that do have HIV and don't have, and like have an uncontrolled viral load, we should be doing like I think, however, we can center, those folks in our care is going to be key because centering folks that have been the most marginalized or the most affected by systemic and structural racism is really going to be what's going to help us advance and improve HIV in our country, but also across the world. And so whatever we could do, I think we need to, we need to think of ways to implement them.

46:42

Thank you so much. And I want to note some services that CEI provides. They offer private webinars for your workplace, just like this one, is CEI line, where you can call with patient inquiries pertaining to HIV, hep, PrEP, HCV, Drug User Health STIs. And we offer clinical tools, which include HIV testing, PEP, and PrEP, clinical cards, and gender pronoun buttons. And I will send a link with that information in the email later, which will also include the slides. And we can take one more minute to see Oh, and yes, we have more another question coming in. And then appreciation in the q&a. Thanks, Michelle. From your experience, have there been any patients that a provider thought would be a good candidate with the collaborative team leader decided should not move forward with LA? What was the reason?

47:41

I'm Carlota? I give one. Okay. And then yeah, so we, um, had a provider that had this patient, and he wanted to start this patient and met all of the eligibility criteria. However, the patient did have silicone injections, which were basically picked up by our, you know, multidisciplinary team. And in this case, we actually did do an ultrasound of that region, and there were areas where, like, the silicone was definitely present. So again, you know, we brought that back to the provider. And then, you know, we we felt because of the risk of migration, because of the lack of data that this was not an appropriate patient to move forward with. So that that was one and then Carlota. I don't know if we have another but I know that there was one also where another provider had really wanted to start this patient and was very enthusiastic. And then I think upon just kind of case, conferencing, I think nursing has brought up that the patient had a lot of missed appointments that they kind of no showed. And, in fact, when the patient was kind of scheduled to start the whole process, they kind of no show that. So I think at that point, a decision was made maybe to hold back, not entirely, but that possibly from the input in terms of like commitment to, you know, coming to clinic every two months. And you know, that input maybe made the team decide that maybe at this point, this this is not the best candidate to move forward. So those are the two that I can kind of recall, I don't know Carlota. Were there any others are

49:20

on that second one, too. And other thing I just wanted to include is that like having someone with like no shows, someone with a high no show rate. We're not trying to say that these are not the best candidates. Like we're also trying to use showing up to your appointments as a way to encourage incentivize people to getting on long acting injectables. And so I believe there was like one or two cases where someone had, I think it was only really like two to no shows. And so in the case conference, what we decided was like if the patient was able to make their next follow up appointment with their provider, that we would begin having that discussion about long acting injectable, so not starting until we first could see Have a conversation with a provider and see if they were going to be able to attend their next appointment. The only other case that I think came up was there was one patient. And actually our pharmacist, Jake pick this up. There was one patient who had switched anti retrovirals, I think, multiple times in the last year. And so he had requested by his provider to switch to long acting to cabin Nuba. And then Jake really brought up like, listen, I think this patient is someone who might not be a good candidate, because they've switched so many different times. And they might not be someone who would tolerate some other side like some of the injection site reactions. And then I think it was

interesting, like I think within a few weeks or like within a week or two, the patient was like, actually, I don't want to do long acting injectables. And so we just really paused on that one, and had more time to focus on a case conference and to hear Jake's or pharmacist point of view on what that person was doing. wasn't a good candidate and it resolved itself because the patient was like just did dispose actually, I don't think I want to be on these meds I want to stay on my current regimen. And so sometimes the case conference has really been like helpful to to just put a pause on things and reassess and just reflect on certain items in the patient's chart.

51:14

Thank you to everybody for joining. Thank you Carlota and Dr. Urbina.

[End Transcript]