HUMAN SERVICES DEPARTMENT
COMMUNITY PARTNERSHIPS DIVISION
115 S Andrews Avenue, Room A360 • Fort Lauderdale, Florida 33301
954-357-8647 • FAX 954-357-8204

MEDICAL PROVIDER NETWORK MEETING

Date: April 1st, 2021 at 2:30 PM – 3:45 PM.
Location: WebEx Virtual Conference Room

Facilitator: Clinical Quality Management Staff
quality@brhpc.org
(954) 561-9681 ext. 1343

AGENDA

I. Call to Order

II. Welcome & Introductions

Clinical Quality Management Coordinator

Name: Vanessa Oratien
Phone: 954-561-9681 x 1343
Email: voratien@brhpc.org

III. Long-acting ARV Presentation

- Marylee Worley, PharmD.
  Nova Southeastern University
  AETC Program
- Registration Link

IV. Medical Provider Network Meeting Evaluation Results

V. Discussion: COVID-19 Vaccine

VI. Announcements

VII. Adjournment

Next Meeting Date: July 1, 2021

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MEDICAL PROVIDER NETWORK MEETING
Thursday, January 21, 2021
WebEx Virtual Conference Room

MINUTES

PROVIDERS PRESENT
Tara Griffin, APRN Memorial
Amy DiMauro, Pharm.D., AHF NorthPoint
Zack Henry, DO., AHF
Alicia Lee-Clarke, RN, MPA., Care Resource
Doug Steele MSN, RN, Care Resource
Sean Ellis, BSN RN, Care Resource
Michael Sension, M.D., CAN Community Health / Broward House
Gabby Britto, CAN Community / Broward House
Marvil Castro Santiago, NP, NBHD
Claudette Grant, NBHD
Nonglin Mel, M.D., NBHD

CLINICAL QUALITY MANAGEMENT (CQM) SUPPORT STAFF
Nicolette Duong
Whitney Saint-Fleur
Debbie Cestaro-Seifer

PART A RECIPIENT STAFF
Timothy Thompson
Kelsey Giglioli
Neil Walker

GUESTS
Angie Madhurie Mahraj, PharmD, AAHIVP, BCACP, BC-ADM., Broward Health

I. Call to Order

- This meeting was called to order at 2:32 p.m.

II. Welcome & Introductions

- CQM Support Staff welcomed everyone, made a statement of the goal for the meeting, and individual introductions were made.

III. Ryan White Formulary Review

- Review submitted change request forms. The Recipient facilitated this portion of the meeting and asked for feedback from participants regarding each of the medications that were recommended to be placed on the Part A Formulary. Some discussion surrounded the differences between the ADAP and Part A Formulary. The recipient reminded Medical Network members that future requests for medications to add to the Part A Formulary can be submitted on a rolling basis

throughout the grant year. Requests to add formulary medications must be received in writing by Recipient Staff. Once an application (see attachment) to add a medication to the Formulary is received and documented the request will be placed on the agenda of a quarterly Medical Network meeting.

- During this meeting, a total of six medications were reviewed and discussed by the Network members in attendance. The discussions were helpful to the Recipient who will conduct a cost analysis, look at affordable options, and use justifications provided by the Network members to present to the PSRA Committee.

The following is a summary of the discussion that took place among the Medical Network members regarding the six medications for which applications were received:

Dapagliflozin SGLT2 inhibitor

- Formulary Addition Requested
    I. Application request date: 1/8/21. The request was submitted by Broward Health (Anna Hayden, DO). Dr. Mahraj spoke as the representative. 40% of current RW Part A patients receiving HIV treatment and care at Broward Health who also have diabetes would be eligible to receive this medication if available. The brand name for this medication is Farxiga.
- Question/Comments
    I. Do other agencies anticipate a 40% utilization rate of this medication? CAN Community Health does not have this rate. CAN Community Health and Memorial defer to endocrinologists for managing their Part A patients with diabetes.
    II. Can you explain where the 40% utilization rate stems from? 40% of clients are diabetic. Not all of the patients with diabetes would require this medication; however approximately 20% of those individuals with diabetes would be prescribed this medication as recommended by the most recent ADA guidelines. Refer to the ADA guidelines below for more information about the recommendations/indicators for using this medication in patients who are diabetics.
        a) https://clinical.diabetesjournals.org/content/diaclin/38/1/10/F4.large.jpg .
    III. Can you clarify between ADAP and Formulary? Ryan White Part A clients often need assistance with medications during the interim period during which they are awaiting their ADAP eligibility to be completed/approved. This medication may only be needed for the first 30 days before a client has obtained ADAP eligibility. This medication, however, in not on the ADAP Formulary.

a) CQN Community Health believes this medication should be added to the ADAP Formulary for clients who require ongoing treatment with the medication.

IV. Will this medication be a Tier 1 medication?

a) Yes, this medication will be on Tier 1.

- Justification

I. ADA Guidelines: The medication is part of the 2021 ADA Guidelines (refer to Question 2). Dr. Maharaj has her diabetes certification and she and Dr. Hayden want to be sure the RW Part A Formulary includes this third line medication to Metformin. It is used together with diet and exercise.

Health Benefits: While sulfonylureas, metformin, and thiazolidinediones (TZDs) are on the ADAP Formulary, DPP-4 inhibitors such as Jenivia (currently on the ADAP formulary) do not reduce A1C. The SGLT2 inhibitor pharmaceutical class inhibits reabsorption of glucose in the kidney and thereby lowers blood sugar. SGLT2 inhibitors are used in the treatment of type II diabetes mellitus (T2DM). In addition to blood sugar control, this class of medications has shown to provide cardiovascular benefits in T2DM. This medication enhances blood sugar control as well as reduces body weight and systolic and diastolic blood pressure.

II. Costs: See below for pricing options.

GLP 1 agonists:
Ozempic Inj – 0.25mg/1.5ml $157.12 2mg/1.5ml $314.25
Rybelsus tabs – 3mg, 7mg, 14mg $355.74
Bydureon – 2mg ct $42.49
Bcise - $239.13
Victoza- 2 pens $0.05 3 pens $0.8 pens
Trulicity – 1.5mg - $233.44 0.75mg - $233.48 3mg + 4.5mg - $472.38

SGLT2 inhibitors:
Farxiga – 5mg, 10mg $0.27
Jardiance – 10mg, 25mg $0.27
Invokana – 100mg, 300mg $0.27

Semaglutide

- Medication Information

I. Application request date: 1/8/21. The request is for this medication to be added to the Formulary and was submitted by Broward Health (Dr. Anna Hayden). Dr. Mahraj spoke as the representative. 40% of the patients in the Ryan Part A program have T2DM and 20% would be

expected to utilize this medication. The brand name for the medication is Ozempic.

- Question/Comments
    I. The medication has similar justification that was discussed earlier (See previous discussion regarding Dapagliflozin, a SGLT2 inhibitor).
- Justification
    I. Costs: See above for pricing options. Drug has 340B pricing and it is affordable. .25mg Ozempic costs $157.12; 2mg costs $314 (less expensive alternative provided).

Liraglutide

- Medication Information
    I. Application request date: 1/8/21. The request is for this medication to be added to the Formulary and was submitted by Broward Health (Dr. Anna Hayden). Dr. Mahraj spoke as the representative. 40% of the Ryan Part A patients at Broward Health have T2DM and 15-20% would be expected to utilize this medication. The brand name for the medication is Victoza.
- Question/Comments
    I. The medication has similar justification that was discussed earlier (See previous discussion regarding Dapagliflozin, a SGLT2 inhibitor).
- Justification
    I. Costs: See above for pricing options. Drug has 340B pricing and it is affordable. 2 pens cost $ 0.05 and 3 pens cost $0.08.

Chlorthalidone

- Medication Information
    I. Application request date: 1/8/21. The request is for this medication to be added to the Formulary and was submitted by Memorial (Tara Griffin, APRN). 15% of the RW Part A patients receiving medical care at Memorial would be expected to utilize this medication.
- Question/Comments
    I. The Recipient will look at the Formulary alternatives and consider justification and cost and implications.
- Justification
    I. Health Benefits. The medication works better than the alternative which is hydrochlorothiazide. The medication is more potent and works better.
    II. Costs: The Recipient confirmed the pricing is inexpensive.

Ciclopirox

- Medication Information
    I. Application request date: 1/8/21. The request is for this medication to be added to the Formulary and was submitted by Memorial (Tara Griffin, APRN). 8% of the current RW Part A patients in the practice would be expected to utilize this medication.
- Question/Comments
    I. Memorial believes Ciclopirox, a topical medication, is a better alternative than the oral medication, Terbinafine (fungal medication), which is currently on the RW Part A Formulary. Ciclopirox is less toxic to the liver.
    II. CAN Community Health and NBHD clinicians do not prescribe Ciclopirox medication because treatment requires daily dosing and it can take over a year before results are seen.
- Justification
    I. Health Benefits: The medication is used to treat nail fungus. The only alternative is oral, and it is not as safe as the topical. The rationale for adding this medication to the Formulary is that patients could try it as a "first line" treatment option as opposed to starting the oral treatment regimen that does have potential liver toxicity.

Melatonin

- Medication Information
    I. Application request date: 1/8/21. The request is for this medication to be added to the Formulary and was submitted by Memorial (Tara Griffin, APRN). 10% of the RW Part A patients at the Memorial practice would be expected to utilize this medication.
- Question/Comments
    I. Tridentine is on the Ryan White Part A Formulary, but it is not on the ADAP Formulary.
- Justification
    I. Health Benefits: The medication is used as needed for insomnia. Melatonin is a very good first line therapy for patients with insomnia and although the medication is over the counter, many patients are unable to pay the co-pay. Ms. Santiago suggests increasing the dosage (1 mg is recommended youth) or providing a dosage range that would include youth and adults.

Additional Discussion

I. Network Members should contact the Recipient via email for medications that are not currently on the Formulary providing cost, and justification. See attached Application for RW Part A Formulary addition requests.

IV. COVID-19 Prevention

- COVID-19 Vaccine Administration Outlook
    1. The CQM Support staff gave a brief presentation on the recent COVID 19 Vaccine Survey information received from two provider agencies.
    2. Agencies look forward to receiving the Moderna vaccine, which has an easier to store profile as it relates to temperature compared with the Pfizer vaccine. It was reported that the Moderna vaccine will also be more readily available and can easily be stored in provider clinics and office settings. Overall, ~60% of clients continue to display hesitancy to receive the vaccine. CAN Community Health commented that vaccine hesitation has always been a challenge with their clients.
        I. CAN Community Health has patients who have requested the vaccine, but they are unable to access the online and phone scheduling process. The result is patient frustration. The agency recommends that their patients obtain the vaccine through the community and Florida Department of Health vaccine sites as more and more sites become available.
        II. NBHD looks forward to vaccine rollout that will accompany the vaccine initiatives established/organized by the new federal administration.
- Executive Order Suspending ADAP's CD4 and Viral Load Labs for Eligibility
    1. Recipient states the Executive Order will change later on February 26th, 2021. When queried about patients obtaining their laboratory tests during the pandemic SBHD and other agencies reported that patients in care were adherent in getting their labs drawn and keeping their appointments.
    2. Network members reported no challenges in patient adherence to medical appointment and labs.

V. Announcements

- All Medical Network providers are asked to complete the FY 20-21 Medical Network Meeting Evaluation Survey. The Survey takes 3 minutes to complete. The CQM Support Staff is working to obtain a 100% completion rate with all Medical Network members participating. Thank you in advance for completing the Survey. The link for the Survey is: https://survey.alchemer.com/s3/6121288/Network-Evaluation-Medical-Provider

- Agencies
    1. No announcements.
- Recipient
    1. DOH-Broward will open vaccination sites with a new scheduling system. CQM Support Staff will forward the press release to the networks. Contact 866-201-6313 to schedule vaccine administration for clients 65 and older and frontline healthcare workers.
    2. Link: http://broward.floridahealth.gov

VI. Adjournment

- The meeting was adjourned at 3:43 p.m.

Next Meeting Date: April 1, 2021

Medical Provider Network Meeting

April 1st, 2021

Housekeeping Rules

Mute Microphone

Participants will be automatically muted to limit background noise

Identify Yourself

State your name and agency when speaking

Use the Chat Box

Type in the chat box to identify yourself and agency, ask questions, and request additional clarification

Raise Your Hand

The “raise hand” option will notify the presenter of any questions that may arise

Ask Questions

Please save questions until the end of each slide

Welcome & Introductions

AETC AIDS Education & Training Center Program Southeast

HIV and long-acting ARVs: Focus on Cabenuva

MARYLEE WORLEY, PHARMD, BCIDP

FACULTY, SOUTH FLORIDA- SOUTHEAST AIDS EDUCATION &TRAINING CENTER

ASSISTANT PROFESSOR, PHARMACY PRACTICE

NOVA SOUTHEASTERN UNIVERSITY, COLLEGE OF PHARMACY

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Disclosures

The activity planners and speakers do not have any financial relationships with commercial entities to disclose.

The speakers will not discuss any off-label use or investigational product during the program.

This slide set has been peer-reviewed to ensure that there are no conflicts of interest represented in the presentation

Outline

Introduce injectable ARV (2-3 minutes)

Briefly describe efficacy and safety data of injectable cabotegravir/rilpivirine (3-5 minutes)

Describe how to start a patient on CABENUVA (cabotegravir/rilpivirine) (10-15 minutes)

Injectable ARV

FDA Approved: Cabenuva® (cabotegravir and rilpivirine, injectable formulation) and Vocabria® (cabotegravir, tablet formulation) on January 21, 2021

First Long-Acting ART approved

Other Long Acting ARVs in Research

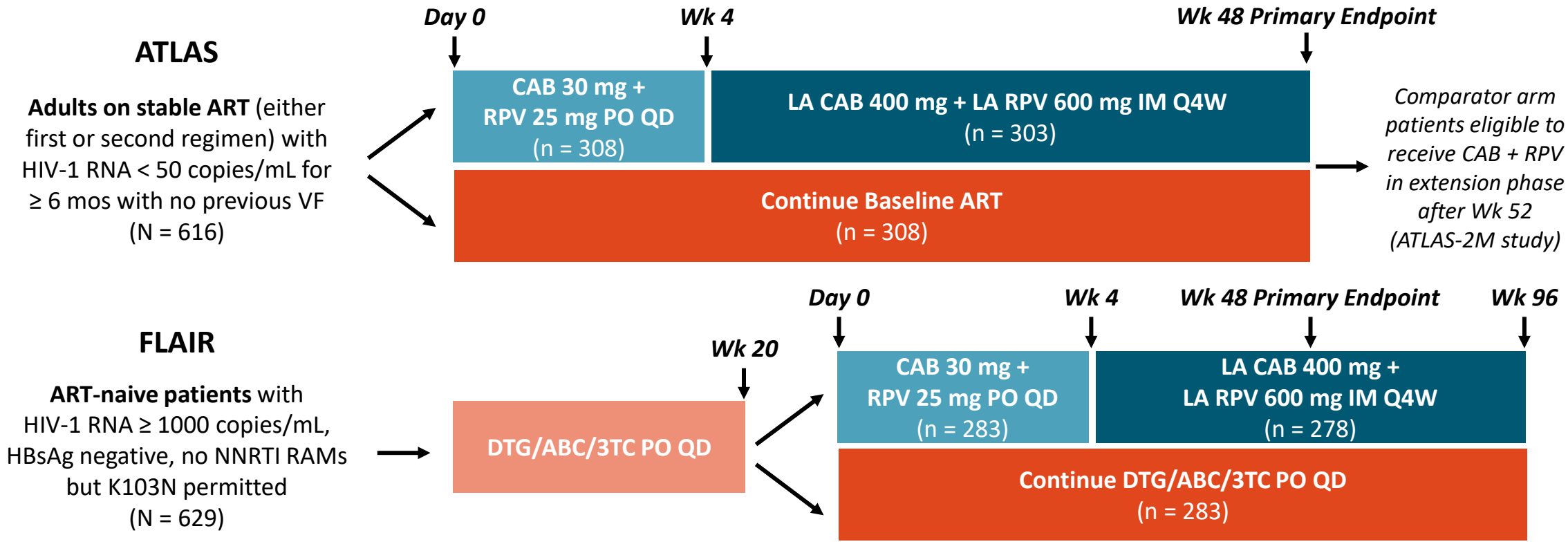
Drug Class	Drug	Formulation	Clinical Trial Stage
First nucleoside reverse transcriptase translocation inhibitor	Islatravir aka EFdA or MK-8591	Long-acting oral (weekly? Treatment, monthly? PrEP)	Phase II, Phase III trials: IMPOWER 22 and IMPOWER 24 (PrEP)
		Implant (subcutaneous polyethylene vinyl acetate membrane) – possibly yearly PrEP?	Phase II
NNRTI	MK-8507	Long-acting oral (weekly?)	Phase II
NRTI	GS-9131	Injectable? (oral trial terminated)	Terminated

ATLAS-2M data presented at CROI 2021, demonstrated efficacy/safety data for the use of Cabenuva (CAB LA 600 mg + RPV LA 900 mg IM) every 8 weeks (less frequent) [2,3]

1. Singh K. et al. Pharmaceuticals 2019, 12, 62; doi:10.3390/ph12020062, 2. Overton. CROI 2020. Abstr 34. 3. Jaeger. CROI 2021. Abstr 401.

ATLAS and FLAIR: Long-Acting Intramuscular CAB + RPV After Initial Virologic Suppression With Oral Therapy

- Multicenter, randomized, open-label phase III noninferiority trials

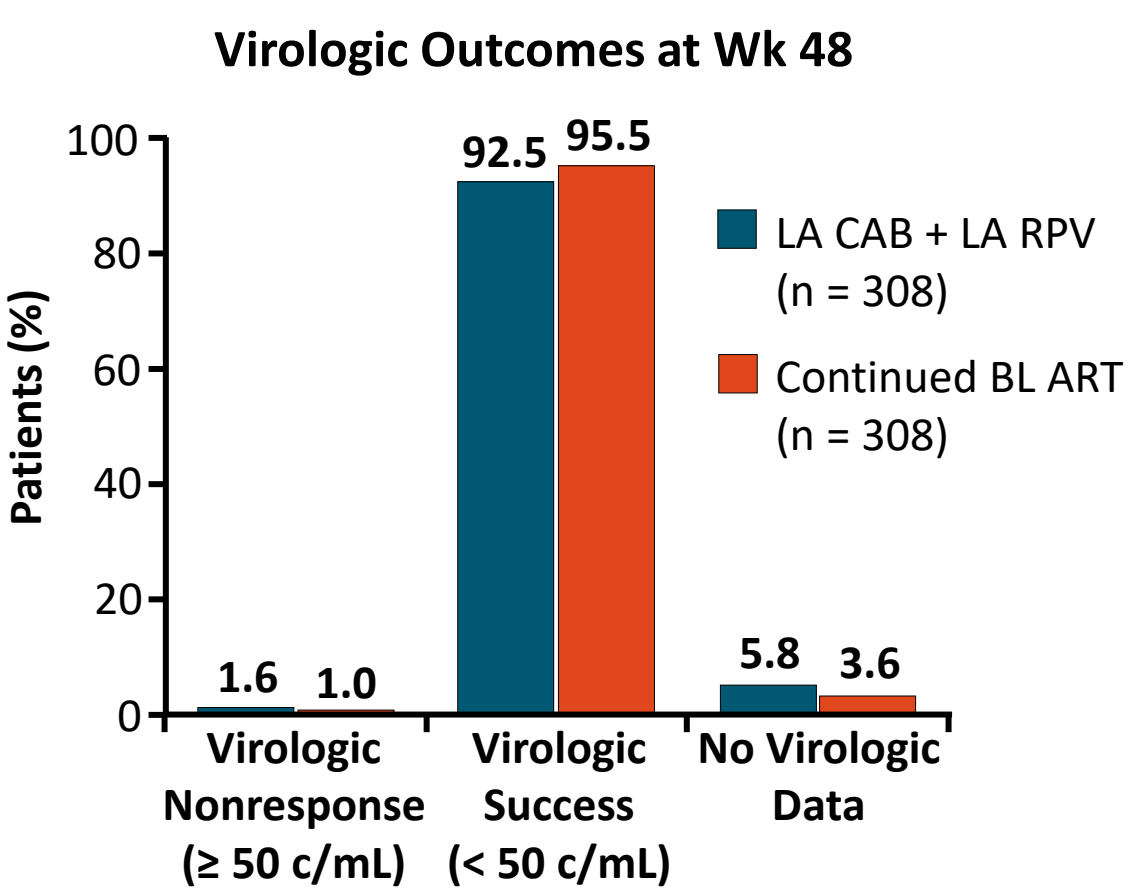


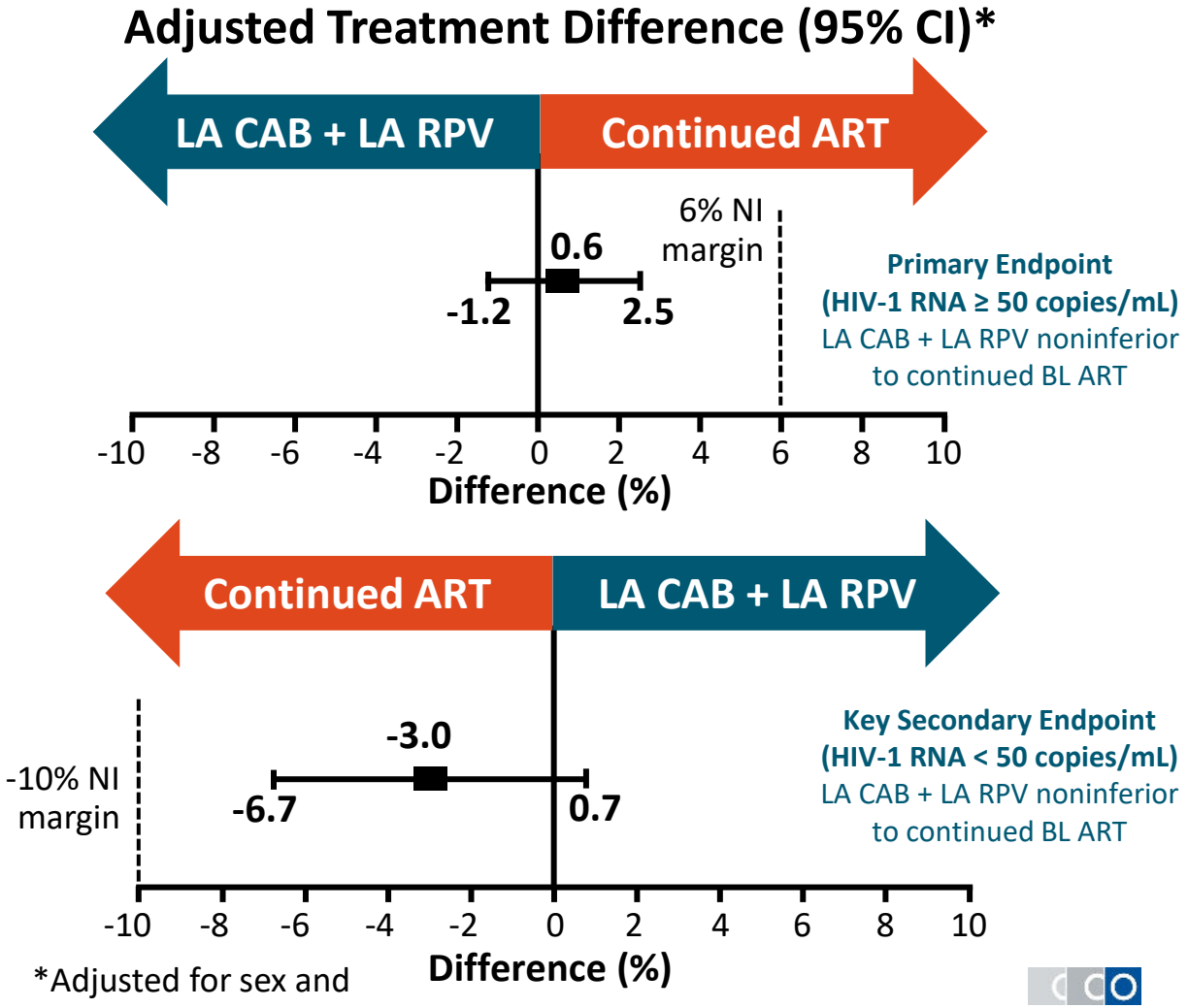
- Primary endpoint for both trials: HIV-1 RNA ≥ 50 copies/mL at Wk 48 by FDA Snapshot in ITT-E

1. Swindells. NEJM. 2020;382:1112. 2. Orkin. NEJM. 2020;382:1124.

Slide credit: clinicaloptions.com

ATLAS: Switch to Long-Acting CAB + RPV vs Continued 3-Drug ART in Virologically Suppressed Adults



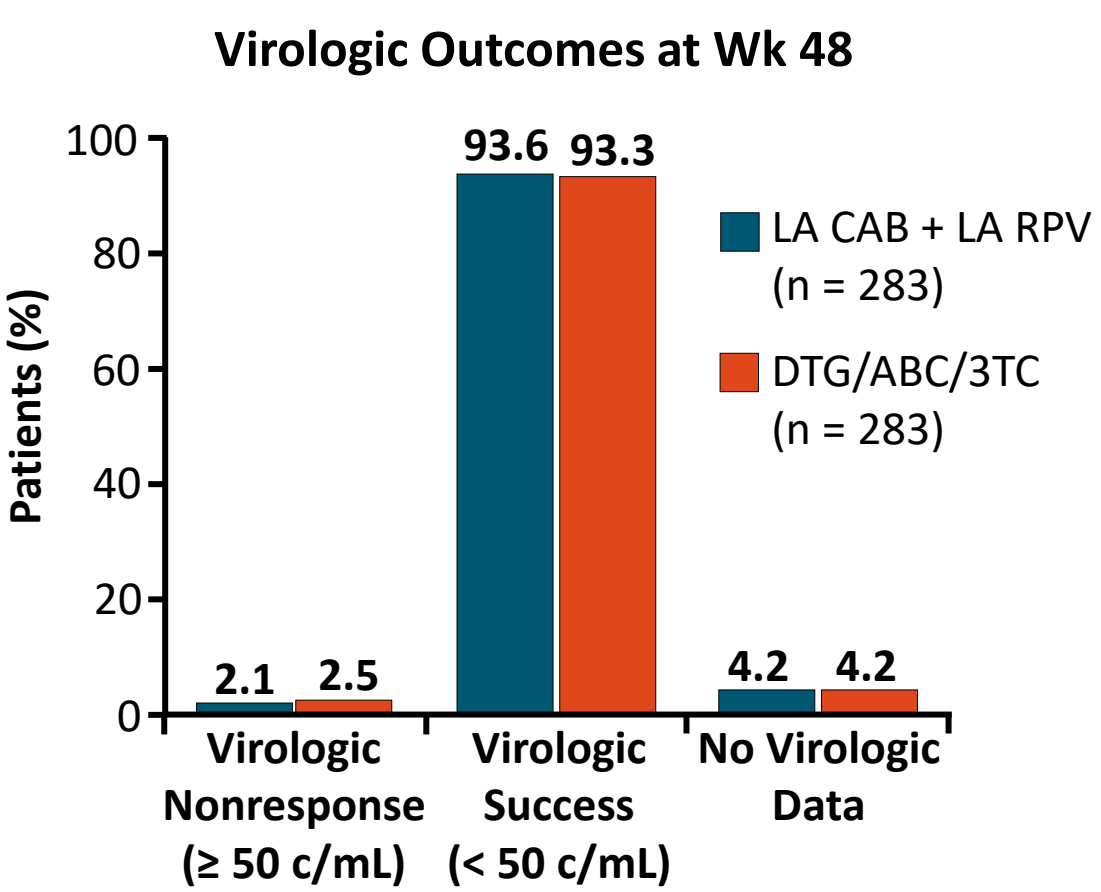


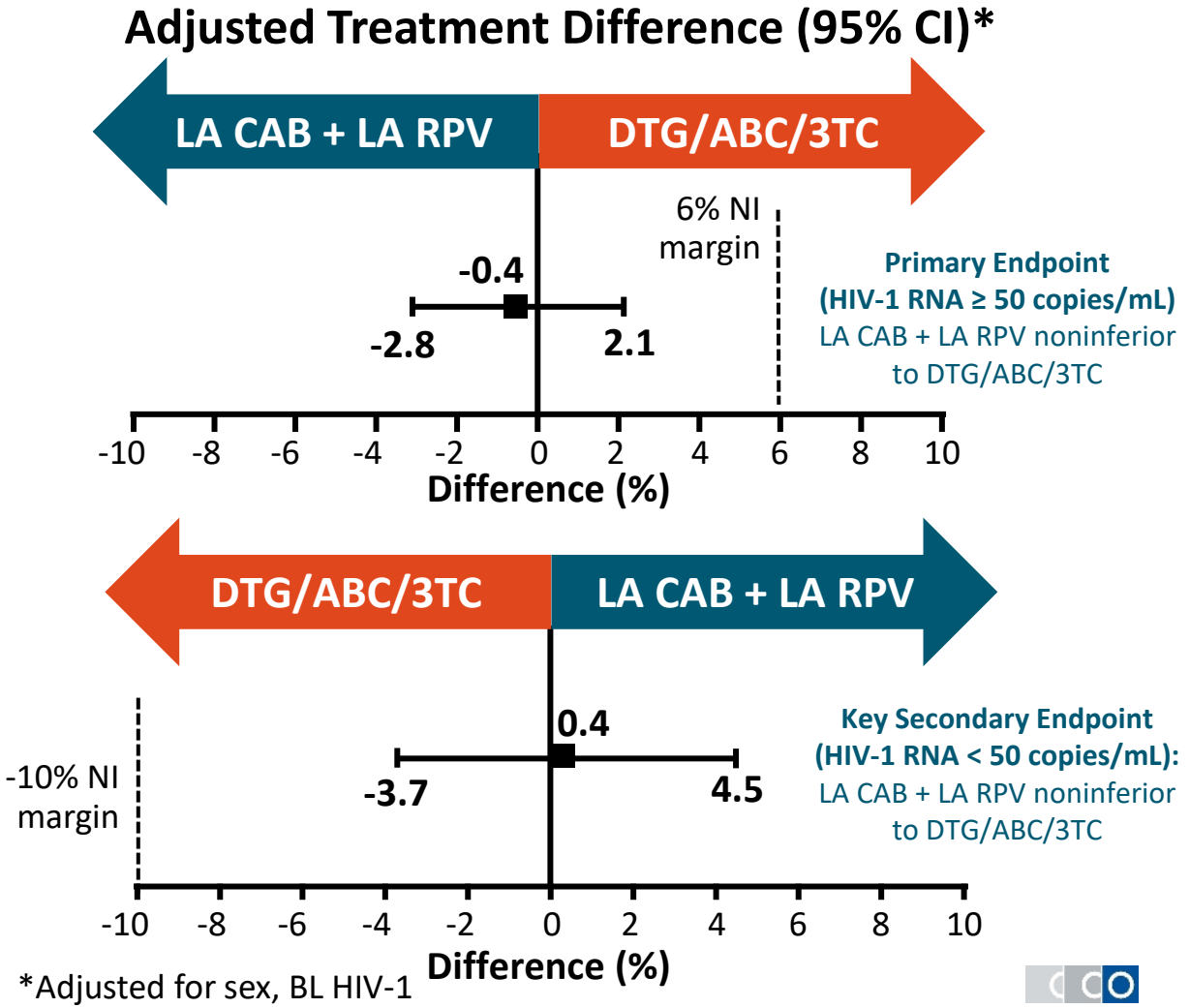
*Adjusted for sex and BL third agent class.

Swindells. NEJM. 2020;382:1112.

Slide credit: clinicaloptions.com

FLAIR: Long-Acting CAB + RPV Maintenance After Oral DTG/ABC/3TC Induction





- Noninferiority also observed at Wk 96
- No additional CVF during Wk 48 to 96 in CAB+RPV arm

*Adjusted for sex, BL HIV-1 RNA (< vs ≥ 100,000 c/mL).

Orkin. NEJM. 2020;382:1124. Orkin. CROI 2020. Abstr 482LB.

Slide credit: clinicaloptions.com

ATLAS and FLAIR: Treatment-Emergent Resistance With Long-Acting CAB + RPV

Study	Sex	Country	HIV-1 Subtype	Wk of Failure	NNRTI RAMs		INSTI RAMs*	
					Baseline	Failure	Baseline	Failure
ATLAS[1]	F	Russia	A/A1	8	E138E/A	E138A	L74I	L74I
	F	France	AG	12	V108V/I, E138K	V108I, E138K	None	None
	M	Russia	A/A1	20	None	E138E/K	L74I	L74I, N155H
FLAIR[2]	F	Russia	A1	20	None	E138E/A/K/T	L74I	L74I, Q148R
	M	Russia	A1	28	None	K101E	L74I	L74I, G140R
	F	Russia	A1	48	None	E138K	L74I	L74I, Q148R

*L74I not considered an INSTI RAM by IAS-USA guidance; not expected to affect CAB sensitivity.

- 101/483 patients had BL L74I in FLAIR: n = 64 from Russia, n = 60 with subtype A[3]
  - Presence of this polymorphism did not negatively affect proportion achieving HIV-1 RNA < 50 copies/mL at Wk 48
  - At Wk 96, no additional cases of treatment-emergent resistance

1. Swindells. CROI 2019. Abstr 139. 2. Orkin. CROI 2019. Abstr 140LB. 3. Overton. IAS 2019. Abstr MOPEB257. Orkin. CROI 2020. Abstr 482LB.

ATLAS and FLAIR: Patient-Reported Preference for Drug Delivery in Patients Receiving Long-Acting CAB + RPV

Study	Population	Preferred Regimen,* % (n/N)	
		Long-Acting IM	Daily PO
ATLAS[1,2]	▪ ITT-E	86 (266/308)	2 (7/308)
	▪ Responding participants	97 (266/273)	--
FLAIR[3.4]	▪ ITT-E	91 (257/283)	1 (2/283)
	▪ Responding participants	99 (257/259)	--

*Per single question in Wk 48 participant survey.

1. Swindells. CROI 2019. Abstr 139. 2. Swindells. NEJM. 2020;382:1112. 3. Orkin. CROI 2019. Abstr 140LB. 4. Orkin. NEJM. 2020;382:1124.

ATLAS-2M Wk 96 Results: FDA Snapshot Outcomes at Wk 96 in ITT-E

Wk 96 Snapshot Outcome (ITT-E), n (%)	CAB LA + RPV LA Q8W* (n = 522)	CAB LA + RPV LA Q4W* (n = 523)
HIV-1 RNA < 50 copies/mL	475 (91.0)	472 (90.2)
Adjusted difference† (95% CI)	0.8 (-2.8 to 4.3)	
HIV-1 RNA ≥ 50 copies/mL	11 (2.1)	6 (1.1)
▪ Data in window not < 50 copies/mL	2 (0.4)	2 (0.4)
▪ D/c for lack of efficacy	8 (1.5)	3 (0.6)
▪ D/c for other reasons while not < 50 copies/mL	1 (0.2)	1 (0.2)
Adjusted difference† (95% CI)	1.0 (-0.6 to 2.5)	
No virologic data	36 (6.9)	45 (8.6)
▪ D/c for AE or death‡	17 (3.3)	17 (3.3)
▪ D/c for other reasons	16 (3.1)	27 (5.2)
▪ On study but missing data in window	3 (0.6)	1 (0.2)

*No d/c due to COVID-19 but missing data for 4 study participants considered COVID-19 related.

†Based on CMH stratified analysis adjusting for following BL factors: prior CAB + RPV exposure (0 wks, 1-24 wks, > 24 wks).

‡2 deaths in maintenance phase: sepsis reported in Wk 48 analysis (Q8W arm) and suicide reported after Wk 48 analysis (Q4W arm).

Jaeger. CROI 2021. Abstr 401.

Slide credit: clinicaloptions.com

ATLAS-2M Week 96 Results: Confirmed Virologic Failures

- 1 additional participant in Q8W arm met CVF criteria between Wks 48 and 96 (Wk 88)*
  - K103N and Y181C NNRTI RAMs detected at virologic failure and retrospectively at BL
  - No INSTI RAM detected at BL or virologic failure (IN substitution L74L/I present at BL)
- 10/11 participants with CVF resuppressed on other regimens
- Phenotypic susceptibility to DTG retained in all CVFs

CVFs Through Wk 96	n	CVFs (%)	CVFs With RPV RAMs	RPV RAMs Observed at Failure	CVFs With IN RAMs†	Integrase RAMs at Failure
Q8W	522	9 (1.7)	7/9	K101E, E138E/K, E138A, Y188L, Y181C	5/9	Q148R,‡ N155H‡
Q4W	523	2 (0.4)	1/2	K101E, M230L	2/2	E138E/K, Q148R, N155N/H

*Male patient from US, BMI < 30 kg/m^2, subtype B HIV-1, VL = 1916 copies/mL at SVF visit and 9063 at confirmatory visit.

†7/7 Q8W and 1/1 Q4W CVFs had RPV resistance (fold-change > 2) and 3/5 Q8W and ½ Q4W CVFs had CAB resistance (fold-change > 2.5).

‡Or mixture.

Jaeger. CROI 2021. Abstr 401.

Slide credit: clinicaloptions.com

ATLAS-2M Wk 96 Results: Safety

- AE profile consistent from Wk 48 to Wk 96

AEs, n (%) [delta*]	CAB LA + RPV LA Q8W (n = 522)	CAB LA + RPV LA Q4W (n = 523)
Any AE	488 (96) [+15]	499 (95) [+17]
Drug-related AEs	415 (80) [+15]	413 (79) [+14]
▪ Excluding ISRs	122 (23) [+13]	146 (28) [+21]
Any grade ≥ 3	57 (11) [+16]	65 (12) [+16]
▪ Drug-related excluding ISRs[†]	8 (2) [+4]	10 (2) [+5]
Leading to withdrawal	18 (3) [+6]	19 (4) [+6]
▪ Drug-related excluding ISRs	8 (2) [+3[‡]]	12 (2) [+4[§]]
Any serious AE	33 (6) [+6]	28 (5) [+9]
▪ Drug-related excluding ISRs	3 (< 1) [+1[‖]]	3 (< 1) [+2[¶]]

*Represents new participants with AEs since Wk 48. [†]1 in each arm grade 4; none grade 5.
[‡]1 each: malaise and hyperhidrosis, headache, osteonecrosis. [§]1 each: Disturbance in attention and sleep disorder, nausea and vertigo, drug hypersensitivity, myocardial infarction. [‖]Osteonecrosis. [¶]1 each: drug hypersensitivity, myocardial infarction.

Jaeger. CROI 2021. Abstr 401.

Slide credit: clinicaloptions.com

ATLAS-2M Wk 96 Results: Injection-Site Reactions

- **Most (99%) ISRs were grade 1/2 in severity and resolved in median of 3 days (IQR: 2-5)**
- Number of patients experiencing ISRs decreased over study duration
- Only 1 patient withdrew due to ISR between Wks 48 and 96

Injection-Site Reactions, n (%)	CAB LA + RPV LA Q8W (n = 522)	CAB LA + RPV LA Q4W (n = 523)
Injections given	12,832	23,855
ISR events	3400	4157
▪ Pain	2662 (21)	3295 (14)
▪ Nodule	188 (1)	297 (1)
▪ Discomfort	134 (1)	148 (< 1)
▪ Grade 3*	54	50
Withdrawals due to ISR	7 (1)	11 (2)
Patients experiencing ISRs, % (n/N)		
▪ Week 48	23 (115/493)	20 (100/488)
▪ Week 96	16 (74/473)	12 (54/468)

*No grade 4 or 5 ISRs.

Jaeger. CROI 2021. Abstr 401.

Slide credit: clinicaloptions.com

Clinician Reference Guide

https://www.seaetc.com/sample-cabenuva-protocol-and-clinician-reference-guide/

Dr. Elizabeth Sherman, faculty for AETC, created this wonderful guide and example clinic protocol for clinicians interested in starting Cabenuva with their patients

Patient Selection

FDA indication:

- Complete regimen for HIV-1 infection treatment switch in adults who are virologically suppressed on a stable ART regimen
- No history of treatment failure and no known or suspected resistance to either CAB or RPV

Women of childbearing potential should utilize effective contraception and not plan to become pregnant.

History of good adherence and engagement in care with an understanding of the commitment needed to be adherent to monthly healthcare provider administered IM (gluteal) with two injections

- Currently only approved for **Q4w (monthly)** intervals
- 8-week interval dosing recently approved in Canada

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdf.

Before Cabenuva injection:

Criteria prior to initiating Cabenuva:

- Patient must be ≥ 18 years of age.
- Patient must have a confirmed diagnosis of human immunodeficiency virus type -1 (HIV-1).
- Patient was previously on a stable antiviral regimen
- Prior to initiating treatment with Cabenuva, patient has documented oral lead-in dosing for at least 28 days with Vocabria (cabotegravir) and Edurant (rilpivirine).

For patients taking acid-reducing medications

Oral rilpivirine is contraindicated with proton pump inhibitors (PPIs)

- PPIs should be stopped before the oral lead-in period and should remain stopped during the entire duration of the oral lead-in

Injectable rilpivirine does not interact with PPIs, PPI use can resume once monthly injections start

Oral rilpivirine requires dose separation from H2-receptor antagonists and antacids. Oral cabotegravir requires dose separation from antacids.

- Administer H2-receptor antagonist at least 12 hrs before or at least 4 hrs after oral rilpivirine
- Antacids (e.g. aluminum or magnesium hydroxide, calcium carbonate): Administer antacid at least 2 hrs before or at least 4 hrs after oral rilpivirine and oral cabotegravir

Medications contraindicated with Cabenuva®

Anticonvulsants	Antimycobacterials	Glucocorticoids (systemic)	Herbal product
• Carbamazepine • Oxcarbazepine • Phenobarbital • Phenytoin	• Rifabutin • Rifampin • Rifapentine	• Dexamethasone (more than a single-dose treatment)	• St. John’s wort

Oral Lead-In Period

Prior to starting monthly injections, patient initiates oral lead-in therapy:

- 30 mg Vocabria® (cabotegravir, tablet formulation) and 25 mg Edurant® (rilpivirine, tablet formulation) taken once daily with a meal of at least 500 calories for at least 28 days
- Oral lead-in therapy is ONLY available through TheraCom Pharmacy

An initial 30-day supply of oral cabotegravir (Vocabria®) and oral rilpivirine (Edurant®) in separate bottles will be provided for FREE, regardless of insurance, from TheraCom Pharmacy

- The free oral lead-in can be mailed to the patient or to the clinic

Purpose of oral lead-in period is to assess for the emergence of hypersensitivity reactions before starting the long-acting injections

- Common ADRs during oral-lead in period: headache, nausea, abnormal dreams, anxiety and insomnia

Monthly Injections

- Each injection appointment will need to factor in an extra 25 minutes for
  1) Vials need **15 mins** to come to room temp before drawing them into the syringe for injection
  2) Patient should be observed after injection for **10 mins** to ensure no adverse reactions

Initial monthly injection doses (loading dose):
• Single dose 600 mg cabotegravir (3 mL) AND • Single dose 900 mg rilpivirine (3 mL) • Given on the last day of oral lead-in therapy

Maintenance monthly injection doses:
• Single dose 400 mg cabotegravir (2 mL) AND • Single dose 600 mg rilpivirine (2 mL) • Every month after the initial injection doses

For intramuscular (IM) gluteal injection only

Cabenuva® injections are delivered into the gluteus muscle

- Each injection needs to be delivered as two separate injections in separate ventrogluteal sites (on opposite sides or 2 cm apart) during the same visit
- Opposite sides is to reduce injection site pain due to the large volume being injected
- Dorsogluteal site is another injection site option, however, the ventrogluteal site is recommended
- Patients with gluteal fillers were excluded from the clinical trials

Common adverse events

- Injection site reactions (pain is most common)
- Other AEs: fever, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash

CABENUVA: Co-packaged for intramuscular use

Pack contains both medications, also contains injection supplies and injection instructions

Prepare the injection site.

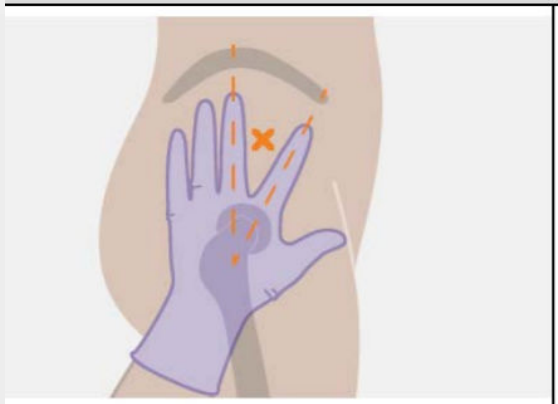


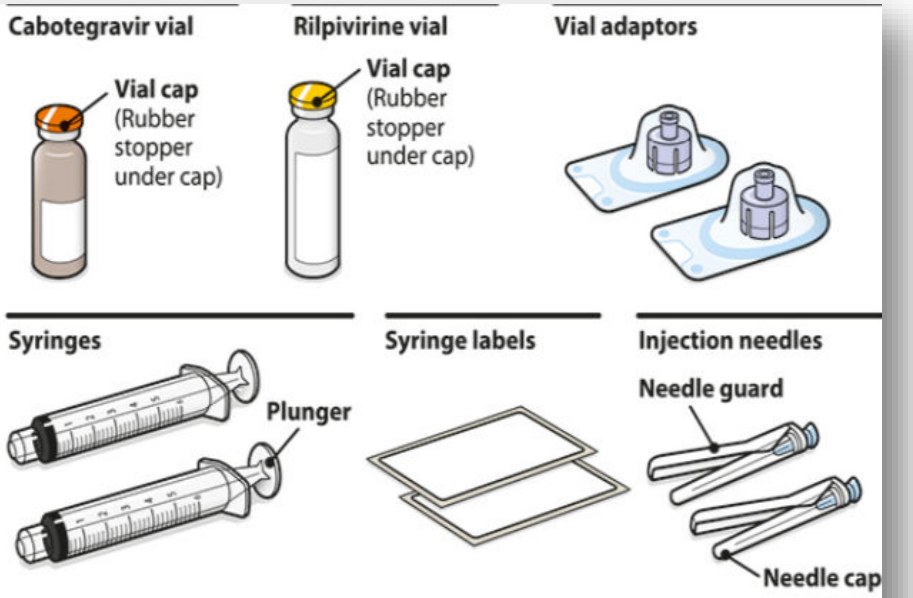
Figure L

Injections must be administered to the gluteal sites.
See Figure L.

Select from the following areas for the injection:

- Ventrogluteal, as shown (recommended)
- Dorsogluteal (upper outer quadrant)

Note: For gluteal intramuscular use only.
Do not inject intravenously.



Your pack contains:

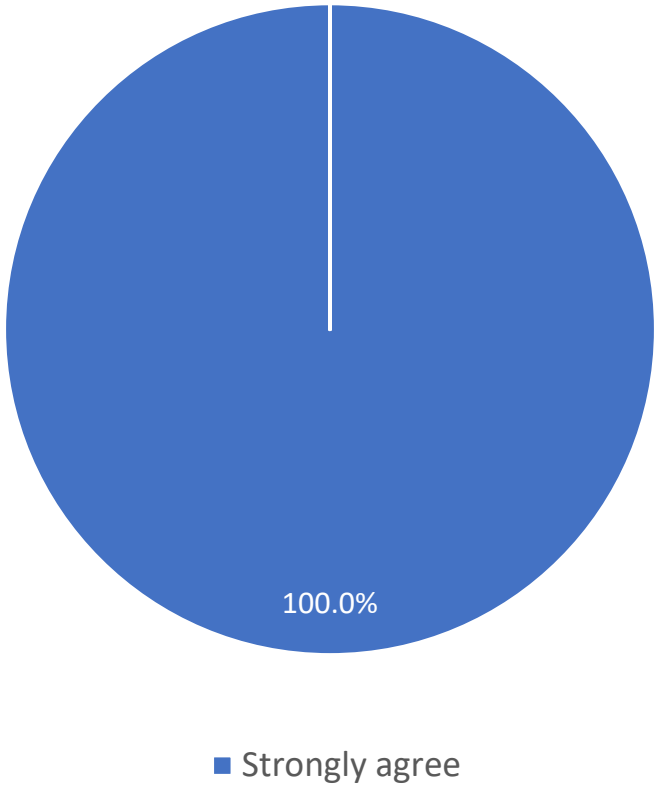
- 1 vial of Cabotegravir
- 1 vial of Rilpivirine
- 2 vial adaptors
- 2 syringes
- 2 syringe labels
- 2 injection needles (23 gauge, 1½ inch)

Questions

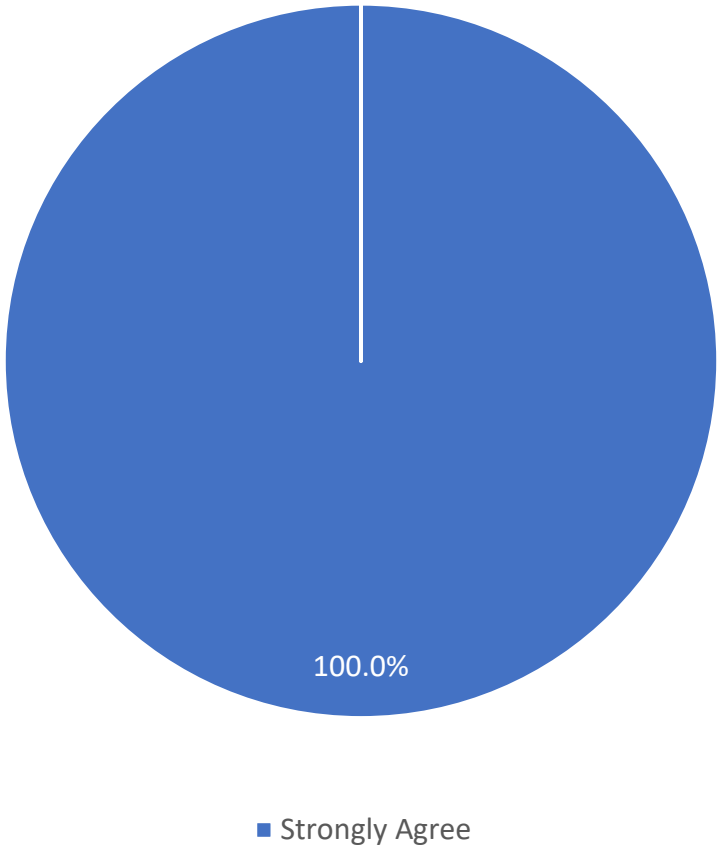
AETC AIDS Education & Training Center Program Southeast

Network Meeting Evaluation Results

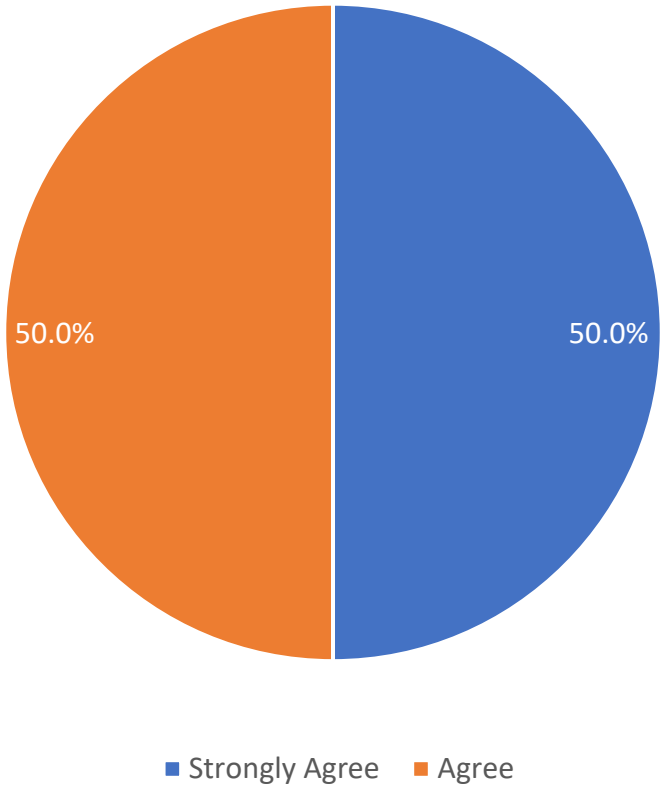
1. The meeting agenda consisted of topics that were informational, constructive, and beneficial to deliver Ryan White Part A services.



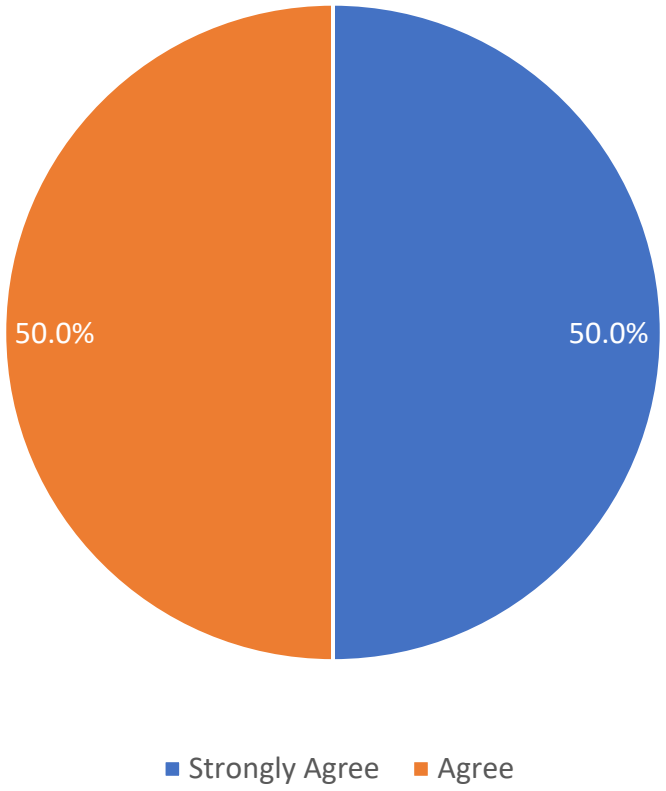
2. The meeting discussions were on-topic, constructive, and valuable.



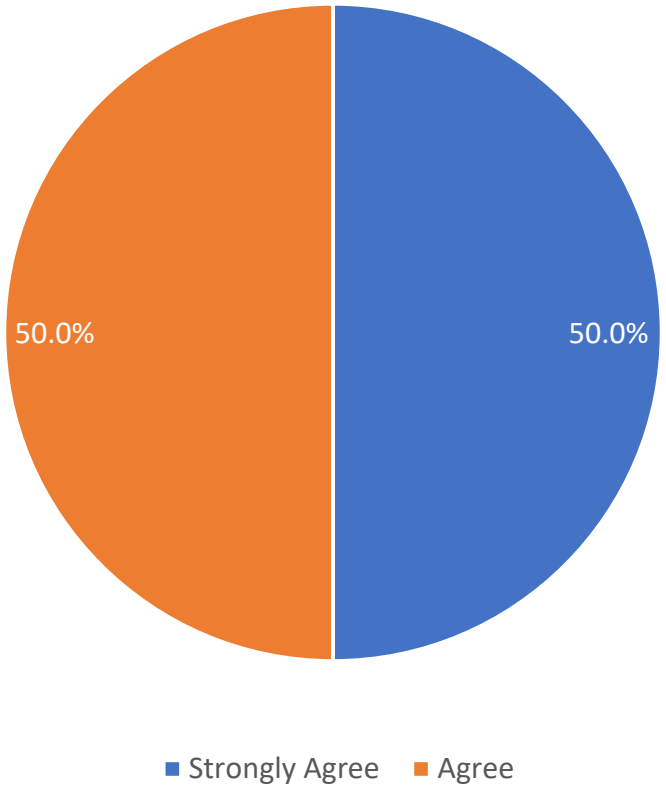
3. The meeting materials were well organized, visually appealing, and easy to follow.



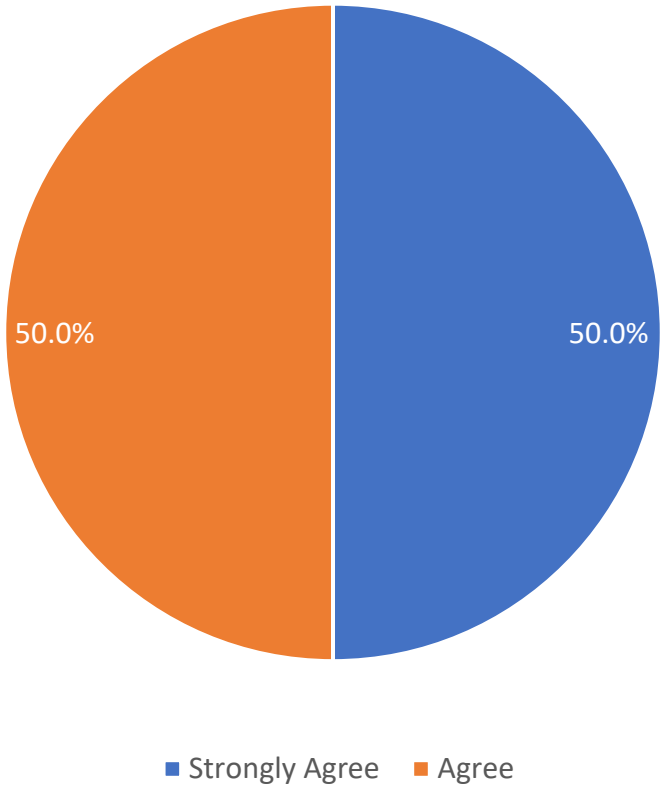
4. I was able to utilize WebEx meeting platform to effectively participate in this meeting.



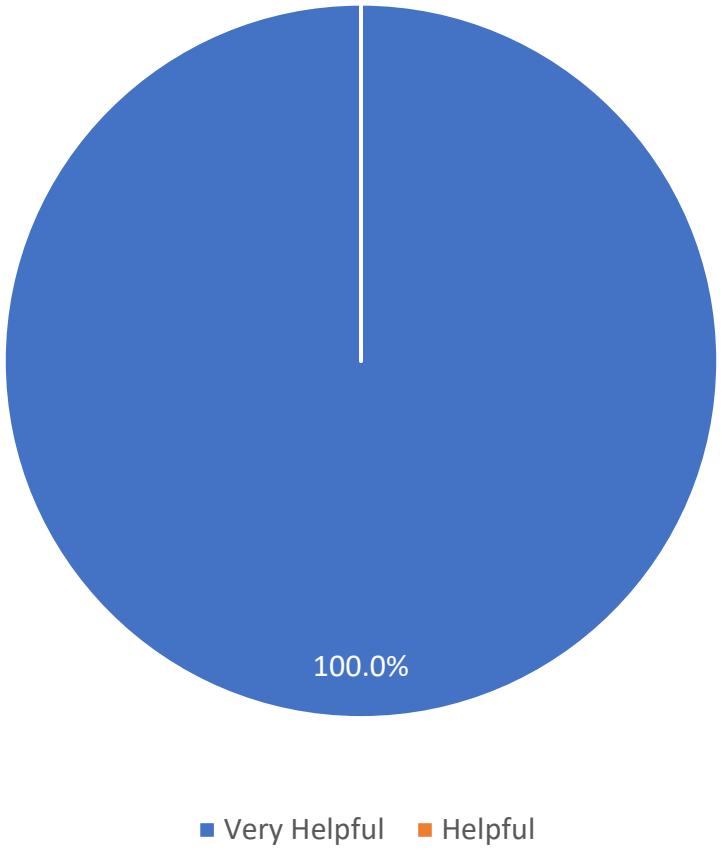
5. This meeting made progress towards improving the quality of care received by Ryan White Part A clients in the Broward EMA.



6. The meeting promoted an environment that encourage networking among participants.



7. Overall, I consider this meeting to be:



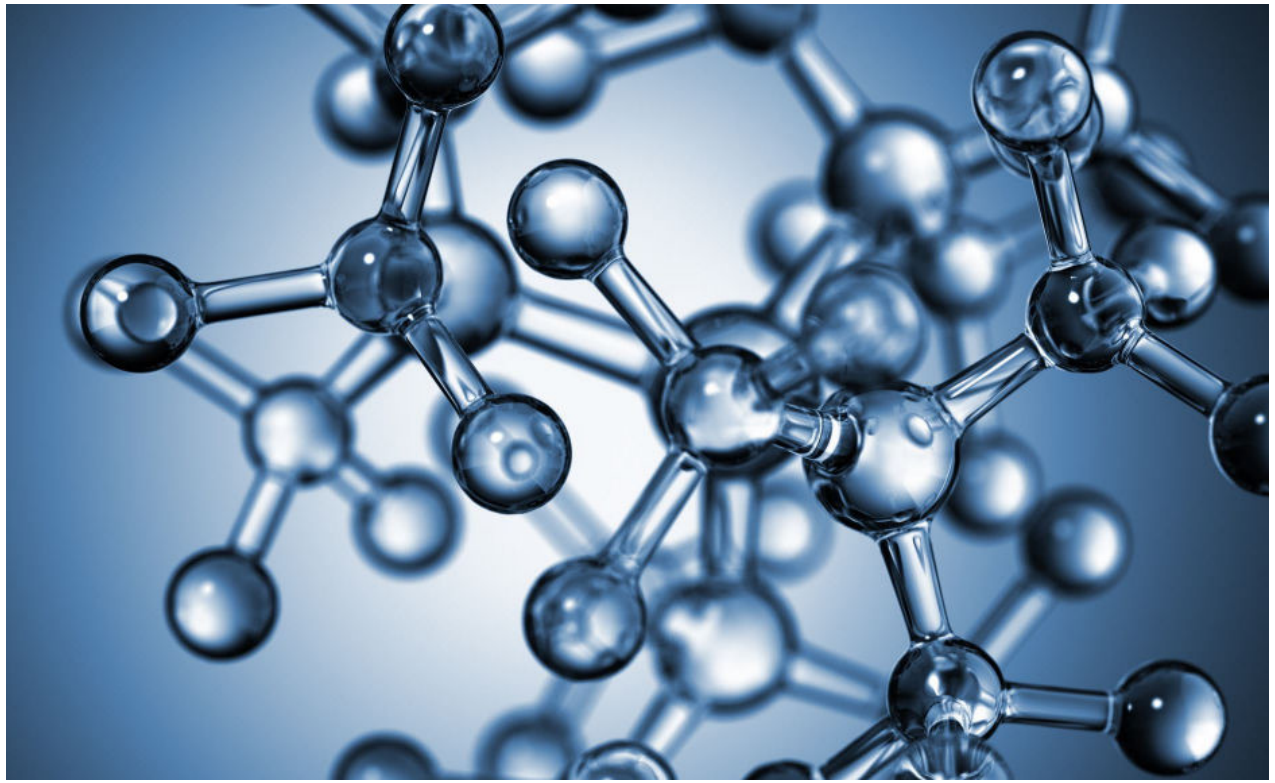
8. Please list a minimum of two discussion or training topics for future network meetings:

"Giving a review of the purpose of the meeting for new attendees will be helpful."

"Review latest recertification processes for both ADAP and Ryan White and any progress on merging the two. Discuss need for ongoing CD4 monitoring as per DHHS guidelines."

Additional Recommendations?

Discussion: COVID-19 Vaccine



Confidence

Hesitancy

Challenges

Announcements

Next Meeting Date:

July 1st, 2021