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Overview of LAI-ARV for Vulnerable patients living with HIV (“MyCab”) Program

This protocol is for educational purposes only and does not replace professional and clinical judgement.

Background/Current Standards:

In London, Ontario, most patients living with HIV (PLWH) typically receive treatment for their HIV from Healthcare providers affiliated with St. Joseph's Health Centre (SJHC) and/or London Intercommunity Health Centre (LIHC). Some patients with HIV take daily oral HIV medication (antiretroviral medication - ARV), and some receive injectable monthly or every two monthly HIV medication. Vulnerable patients including unhoused patients and/or patients living with addictions are supported by outreach workers and nurses to attend appointment at St. Joseph's Health Centre and/or LIHC. Many also receive the support of Middlesex London Health Unit's Outreach program workers to attend appointments.

As it stands with our current model of care, vulnerable patients still have difficulty:

- 1) Attending appointments to have HIV bloodwork drawn and/or see a physician
- 2) Taking daily oral antiretroviral medication, which can lead to poor control of their HIV

Aim of “MyCab” Program:

To evolve a more robust program of care for vulnerable patients to more safely and easily receive monthly injections of ARV therapy ("MyCab program"). The project engages a team of diverse health care providers including Physicians, RN, Outreach Workers, Pharmacy, Hospital Administration, and Public Health, who are already engaged in patient care.

Goals

1. Safe
2. Consistent
3. Supportive
4. Patient Centred

Aim of Quality Improvement / Monitoring:

The goal of this Quality Improvement project is to assess interest/feasibility, monitor and improve outcomes of HIV care for vulnerable PLWH. This intervention aims to provide a more robust care supports and infrastructure around injectable HIV medications to vulnerable populations. Cabotegravir/Rilpivirine has proven to be effective and safe in other settings. As it stands, some

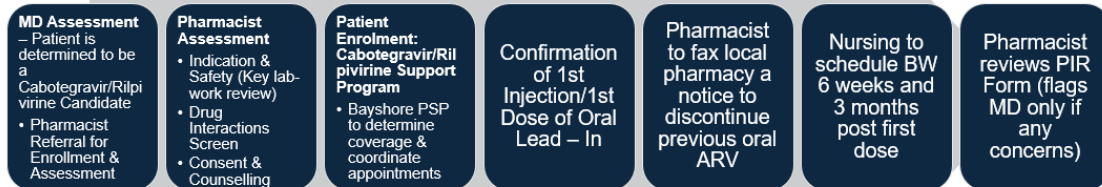
MyCab Protocol, Draft: Oct 2026

Written by: Dr. Megan Devlin (ID physician), Janhavi Bhalla (IDCP Pharmacist)

vulnerable patients are already receiving injectable ARV. This program aims to provide more structure and careful monitoring to serve this patient population.

Patient Flow Chart through MLHU Outreach and MyCare (Community Clinic) based Models

Original Cabotegravir/Rilpivirine Protocol



Outreach-based “MLHU Outreach” model



Key Stakeholders:

HIV/Infectious Diseases specialists
HIV Pharmacist
Health Unit Medical Officer of Health
Health Unit Outreach Team Coordinator
4 Health Unit Outreach Workers
Private Infusion Clinic/Pharmacy
Private Lab-work Company



Outreach Worker accompanies patient to private clinic



Taxi



Private Infusion Clinic / Lab-work Site

Community clinic-based, RN-supported “MyCare” model



Key Stakeholders:

HIV/Infectious Diseases specialists
HIV Pharmacist
2 HIV specialist RNs employed by Community Clinic serving vulnerable patients
Local Pharmacy to provide LAI-ARV (accessed by RN team)



HIV-RN engages with patient

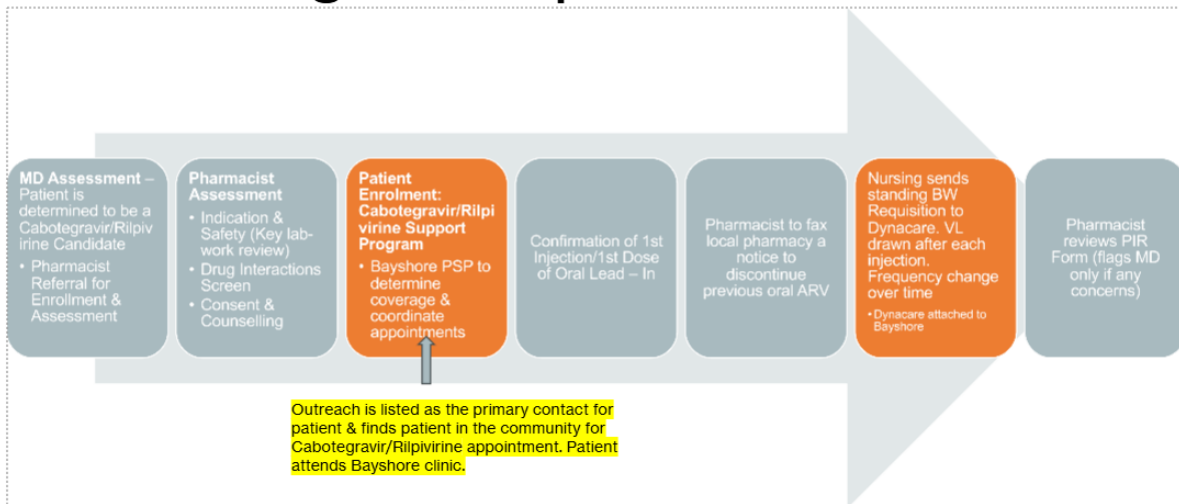


Community Clinic Serving Vulnerable patients



HIV-RN administers dose in community clinic

MLHU Outreach Cabotegravir/Rilpivirine Protocol



MyCare Cabotegravir/Rilpivirine Protocol



My-Care Patients receive injections
Q4weeks/Q8weeks (+/- 7 days)
Usually - all scheduled same day of the week
(improves access to trained staff and adherence)

Part 1: Patient Evaluation

- 1) Patient deemed appropriate to receive CAB/RPV by HIV care provider and Allied Health Care team (May include Outreach, RN, Pharmacy, Social Work)
- 2) Considerations:
 - a. **Patient Consent:**
 - i. Patient understanding and accepting of risks/benefits of q monthly injectable medication
 1. Risk of Virologic Failure (~1.5% in real world experience if virologically suppressed, 3.5% in real world experience if not virologically suppressed at time of initiation)
 2. Hepatotoxicity Risk
 3. Local Reactions
 4. Plan if unable to locate patient for injections
 - ii. Patient able to come to q 4 weekly appointments
 - b. **Medical Review:**
 - i. **Hepatitis B Status:** Hepatitis B Core Ab Negative, Surface Ag Negative
 1. Case by case discussion can be undertaken between patient and Health care provider if patient is Core Ab positive
 - ii. **Review for Resistance Mutations:** Review available genotype records and ARV history, No history of NNRTI or Integrase Mutations
 1. Reverse transcriptase mutations (NNRTI mutations which confer rilpivirine resistance): L100I; K101E; V106I and A; V108I; E138K and A, G, Q, R; V179F and I; Y181C and I; V189I; G190E; H221Y and H/L; F227C; and M230I and L; K103N+K238T, K103N+E138G+K238T; Y188L
 2. ▪ Integrase strand transferase inhibitor mutations (INSTI mutations which confer cabotegravir resistance): Q146L; S153Y; I162M; T124A; Q148H, K; C56S; V72I; L74M; V75A; T122N; E138K; G140S; G149A; M154I; N155H
 - iii. **Medication and Substances Review:** carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, dexamethasone, St John's wort (Hypericum perforatum), Cocaine. This is not an all-inclusive list.
 - iv. HIV Subtype A1/6
 - v. **Of note:** No known interaction with Methamphetamine, Hydromorphone, Fentanyl
 - c. **Social Factors:**
 - i. Outreach able to locate patient to help support patient to attend qmonthly injections and bloodwork appointments
 - ii. Method to contact patient identified

Part 2: Patient Logistics, Informed Consent and Counselling

- a) For MLHU Outreach team patients – HCP to ensure MLHU Outreach familiar with patient and believes is an appropriate patient for CAB/RPV
- b) For MyCare patient - HCP to complete **MyCab Intake form for MyCare Patients (See Appendix A)**
 - a. Includes important Information
 - Re: Logistics, Troubleshooting Plan, Injection Location/Blood-draw location, Pharmacy, Support Worker Contact Information etc
- c) Counselling by Physician/RN
 - a. Patient is willing, agreeable and able to **attend regularly scheduled appointments** (at their local site every four weeks)
 - b. Patient **willing and able to receive 2 injections** (1 per side) in the buttocks area on a monthly basis which may result in local pain/discomfort as well as have **bloodwork** (HIV viral load) drawn every 4 weeks initially
 - c. Patient can provide **multiple methods of contact** for the team to engage with them (ie a friend/family member If other modes of contact aren't accessible)
 - d. Patient understands that **missing doses can result in virologic failure and development of resistant virus**, which may mean their prior ARV regimen may be ineffective and they may be required to use an alternative oral and/or injectable regimen
 - e. Patient understands that there is a **1-3 % risk of virologic failure** even if they are attending regular injection appointments
- d) Patient added to CAB/RPV working list – Excel documents
 - a. Maintained by MyCare Team/Infectious Disease Team

Part 3: Prescriptions Created

- a. Provider creates prescription for Cabenuva (600/900mg x 1 then 400/600mg monthly – Pharmacist to check) and gives to Pharmacist

Drug Initiation Injection Dosing (Q 4-Weeks Initiation Dosing)

Initiation DOSE - **Cabotegravir 600 mg (3 mL) – Rilpivirine 900 mg (3 mL)**

Maintenance Injection DOSE - **Cabotegravir 400 mg (2 mL) - Rilpivirine 600mg (2mL)**

If BMI >30, Recommend nursing to exercise caution and consider larger needles on a case-by-case basis

- b. Prescription is faxed to Pharmacy (based on patient intake form)
- c. IDCP Pharmacist performs double check of required labs
 - BMI
 - Serum Cr
 - Hepatitis B Status
 - Medication Review
- d. **Requisition for HIV viral load, CBC, Cr, Liver Enzymes q 4 weekly** also kept at location
- e. LIHC/MyCare Specific:
 - i. Chapmans fills Cabenuva injection
 - MyCare RN picks up medication, stored at LIHC for the week
 - MyCare RN engages with patient to bring them to LIHC for injection
- f. MLHU Outreach Specific
 - Rx sent to Bayshore PSP
 - Outreach team supports patients to appointments at Bayshore

Part 4: Initial Injection Date & Administration

- a. Start date selected for a **Tuesday** (so Tuesday → Monday is available to find patient)
- b. Ideally Baseline Labs drawn day of injection and at each dose:
 1. CBC, Cr, Liver enzymes
 2. HIV Viral Load
 3. Requisitions available under prescribing physician name
- c. For MyCare Patients:
 - a. Dose Administered by MyCare RN after picking up Rx from Chapman's Pharmacy
- d. For Outreach Patients:
 - a.
- e. Dose Administered:
 - iii. **Patient Injection Reporting Form** (See Appendix B) Completed by Administering RN
 - iv. Faxed to SJHC –
 1. Reviewed by IDCP Team
 2. Filed in Chart (if no concerns)
 3. MD reviews if concerns/adverse events noted

Part 5: Missed Dose Protocol

- a) Missed Doses are managed on a Case by Case basis based on knowledge of the patient by the ID Physician, Outreach/MyCare Team, Pharmacist
 - a. This is an opportunity to reassess whether patient is an appropriate candidate

Historical Missed Dose Protocol (*taken/adapted from Ward 86 – we do not follow this protocol in our clinic, sharing for reference only*)

- b) Mycare RN/MLHU Outreach/(ACT) Keeping track of their local CAB/RPV list
 - a. Encouraging patient to attend appointment with reminder contact Friday before, and/or Monday before.
 - b. *Notes if patient has missed Tuesday Target date* (My Care only)
- c) **MyCare Early Missed Dose Protocol** (Tuesday (Day 0) -Thursday (Day 2))
 - a. **LIHC Activated to Find Patient**
 - b. **If no patient contact by end of day Thursday (Day 2)** – LIHC email IDCP Pharmacist/IDCP RN
 - i. Include in email –
 1. Patient Initials / J Number / DOB – Target Date
 2. Method for contacting/locating patient
 - c. IDCP Team sends Rx for Back Up Oral Regimen
 - i. Prezcoibix/Truvada Rx faxed to pharmacy to start **Day 10 (following Friday)** if patient has not received Cabenuva by that date

- d. **If patient found between Day 8-9 After scheduled Date** –
 - i. Administer Q 4-Weeks Maintenance CAB/RPV LA dose (400mg/600mg) IM
 - ii. Draw Viral Load
- e. **If patient found - 10-14 days after scheduled injection**
 - i. Administer Q 4-Weeks Maintenance CAB/RPV LA dose (400mg/600mg) IM
 - ii. Draw viral load –
 - iii. Start Prezcofix/Truvada while awaiting genotype and viral load
- d) **15-30 days or longer after scheduled injection**
 - a. **Administer Q 4-Weeks Initial (Induction) CAB/RPV LA dose (600mg/900mg) IM**
 - i. **Note dose: 600/900mg**
 - ii. • Obtain HIV VL and HIV genotype
 - b. • Schedule patient to return to clinic/practice next day

In general when Patient is found:

- a) Draw HIV Viral load and Genotype
- b) Discussion with patient re: staying on oral vs re-trying IM
- c) Of note: If Lenacapavir required – Compassionate Access will need to be completed.

Part 6: Ongoing Injections

- a. Continue q4weekly (or q 8weekly) injections
- b. Continue to fax **Patient Injection Reporting Form**
- c. If patient doing well with monthly injection x 4, can graduate to q8 weekly dose

Part 7: Continuous Quality Improvement

- a) **Excel Database/ spreadsheet** (See Appendix C) to be kept /tracked by IDCP Pharmacist and MyCare
- b) Encourage Local Sites to maintain their own **Excel Database Spreadsheet**

Part 8: Trouble Shooting

a) Virologic Failure Despite Receiving Dosing

- a. Based on Ward 86 data, this happened most commonly in the first 4-6 months of treatment
- b. Viral load 200-1000
 - i. IF this occurs:
 - 1. Send HIV Viral load and genotype
 - 2. Continue CAB/RPV while awaiting genotype
 - 3. Decision to start oral regimen made by MyCab MRP
 - 4. Repeat VL q 4 week

b) What if my patient is admitted to hospital (LHSC)

- a. Admission noted by local team or IDCP (MyCare, Outreach, ACT)
- b. Contact IDCP Outreach RN and IDCP Pharmacist via email
- c. If date of injection falls during hospital stay – IDCP team will reach out to HIV MRP and Medicine MRP who will Medicine (or other service) MRP/Admitting Pharmacist to order/administer dose in hospital
- d. * May need support/clarification with Hospital/Ward RN
- e. Complete communication is maintained between clinic and inpatient team to ensure safe transition back into community once discharged

c) What If my patient incarcerated at EMDC

- a. Incarceration noted by local team or IDCP (MyCare, Outreach)
- b. Email notification sent to IDCP Pharmacist
 - i. IDCP Team works with EMDC and MyCare/Bayshore/Outreach to share information on CAB/RPV logistics (last dose, frequency, target date, etc.)
- c. IDCP Team contacts EMDC Pharmacist for coordination of care.
- d. Complete communication is maintained between clinic and EMDC to ensure safe transition back into community once discharged

References:

- 1) Ward 86 Protocol: <https://gettingtozerosf.org/wp-content/uploads/2022/06/Ward-86-LAI-ART-Protocol-5-31-22-FINAL.pdf>
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- 4) Berend J van Welzen, Steven F L Van Lelyveld, Gerjanne Ter Beest, Jet H Gisolf, Suzanne E Geerlings, Jan M Prins, Gitte Van Twillert, Cees Van Nieuwkoop, Marc Van der Valk, David Burger, Annemarie M J Wensing, Virological failure after switch to long-acting cabotegravir and rilpivirine injectable therapy: an in-depth analysis, *Clinical Infectious Diseases*, 2024;, ciae016, <https://doi.org/10.1093/cid/ciae016>
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- 6) Cabenuva Prescribing Information: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF
- 7) Cabenuva Dosing Schedule: <https://cabenuvahcp.com/dosing/every-2-month/>
- 8) Liverpool Drug Interaction Screen. Accessed Sept. 10, 2023.
- 9) Gandhi, M et al. CROI. 2023

Appendix A: MyCab Intake Form (used by MyCare Team)

MUST BE COMPLETED AND DOCUMENTED IN POWERCHART ON ALL PATIENTS ENROLLING IN MYCAB PROGRAM

MyCab Program Intake Form

Date Form Completed:

Demographics:

- Patient Name: [data]
- Patient ID (J Number): [data]
- Patient DOB: [data]

Support MyCab Care Team: Recommend updating this section annually or as needed.

- Patient Support Team:
 - (Eg My Care / MLHU Outreach / ACT Team / Other)
- Patient Support Worker Main Contact Name (RN or Outreach worker): [data]
- Patient Support Main Contact Phone Number: [data]
- Alternative Support Contact: [data]

Pharmacy Information: Recommend updating this section annually or as needed.

- Cabotegravir/Rilpivirine Prescribing Pharmacy: [data]
- CAB/RPV Pharmacy Fax Number: [data]
- Back up Prescription Planned: [Prezcobix/Truvada]

Planned Injection Location & RN to Administer: [data] & [data]

Planned Bloodwork Draw Location & Individual (ideally same site): [data] & [data]

Patient Contact Methods: Patient to provide advice to team around troubleshooting/problem solving. Recommend updating this section annually or as needed.

- Best way to contact patient: [data]
- Back up way to contact patient: [data]
- Patient would like reminder contact ____ days in advance
- What should we do if we can not find /locate you: [data]
- Do you have a friend/partner who we could contact? [data]

Patient Consent (verbal review with patient):

- *Patient understands and accepts that there is a ~1-3% risk of this medication not working (virologic failure), and therefore may need new HIV oral or injectable regimen: Yes/No*
- *Patient understands and accepts that missed doses can result in development of HIV viral resistance, and therefore may need to use a new HIV oral or injectable regimen: Yes/No*
- *Patient understands and accepts possible side effects, include local site reactions: Yes/No*
- *Patient understands and accepts the injection is initially every 4 weeks, with bloodwork done at each injection: Yes/No*

Planned Start Dose Date: (Tuesday) [data]

MEDICAL Review:

- *Prior Genotypes Reviewed (Include Dates of Genotypes): [data]*
 - *(?Documented NNRTI or INSTI mutations?)*
- *HIV Subtype: (?A6/A1) [data]*
- *Hepatitis B Status: [data]*
- *Medication Review: [data]*
- *Substance Use Review: [data]*

Appendix B: Patient Injection Reporting Form

Cabotegravir and Rilpivirine

Patient Injection Reporting Form

Patient Information:

Last Name:	First Name:	Date of Birth:	J-Number
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Target Treatment Date:

Day:	☐ Every month ☐ Every 2 months
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Prescriber:

Name:	268 Grosvenor St. London, ON. N6A4V2	Tel: 519 646 6207 Fax: 519 646 6040
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Injection:

Date:	Time:	Location:
Cabotegravir (Intramuscular): Concentration ☐ 400mg/2mL ☐ 600mg/3mL Site: ☐ _____ Needle Length: ☐ 23-Gauge, 1.5inch ☐ Other: _____		Rilpivirine: (Intramuscular): Concentration ☐ 600mg/2mL ☐ 900mg/3mL Site: ☐ _____ Needle Length: ☐ 23-Gauge, 1.5inch ☐ Other: _____
Adverse Events/Additional Notes to Prescriber:		
Date of Next Appointment:		

Nurse Name:	Signature:	Date:
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Appendix C: Example of Excel Spreadsheet

Please contact Megan Devlin/Janhavi Bhalla if needed

Appendix D: San Francisco/Ward 86 Missed Dose Protocol (we do not follow this protocol in our clinic, sharing for reference only)



Late Injections

Before starting injections, we try to make sure our patients have a full month of oral ARV regimen on hand in case they can't make it in for an injection. (Not necessarily possible in our unstably housed folks.)

If someone re-engages after 30 or more days past injection visit day these are the actions we have taken:

- If we feel patient can take oral ART, at least short-term
 - Immediately draw HIV VL and GT. Start patient on DRV/c/FTC/TAF (Symtuza).
 - If HIV VL returns UD and we feel patient will re-engage for injections or if we think that they won't take Symtuza restart CAB/RPV
 - If HIV VL returns detectable
 - If patient is willing, continue Symtuza until GT results
 - If patient not able to adhere to oral ART, restart CAB/RPV and add LEN (with 2-day oral lead-in)
 - Once GT results, can decide appropriate regimen
-
- If we know patient won't or can't take oral ART
 - Immediately draw HIV VL and GT
 - Restart CAB/RPV and add LEN (with 2-day oral lead-in)
 - If HIV VL returns UD, continue CAB/RPV and can stop LEN
 - If HIV VL returns detectable, continue all 3 meds until GT results
 - Once GT results, can decide appropriate regimen

Dot phrase for late q4wk injection:

Patient last received CAB/RPV 400/600mg on *** and missed scheduled injection visit date of ***.
Treatment window (-/+7 days) ended on ***.

Based on W86 LAI-ART CAB/RPV protocol:

If patient receives injection ***

(8-9 days after scheduled injection)

- This is still within 7 days of 30 day injection cycle window & not considered late injection
- But patient has had a difficult time of making it to clinic every 4 weeks.
- Will switch him to 600/900mg dose every 8 week & schedule q6wk.

If patient receives injection ***

(10-14 days after scheduled injection)

- Obtain HIV VL (rapid resulting preferred) and HIV genotype
- Set reminder message to order labs? Yes
- Schedule patient to return to clinic/practice next day or be available by phone
- If HIV VL is detectable, start patient on DRV/c/FTC/TAF until genotype results become available

If patient receives injection ***

(15-30 days after scheduled injection)

- Administer Initiation CAB/RPV LA dose (600mg/900mg) IM and schedule again in 4 weeks. Then switch to q8wk
- Obtain HIV VL (rapid resulting preferred) and HIV genotype
- Set reminder message CAB/RPV LA 600/900mg q4kw x 2 doses then switch to every 8 week? Yes
- Schedule patient to return to clinic/practice next day or to be available by phone
- If HIV VL is detectable, start patient on DRV/c/FTC/TAF until genotype results become available

Dot phrase for late q8wk injection:

Patient last received CAB/RPV 600/900mg on *** and missed scheduled injection visit date of ***.
Treatment window (-/+7 days) ended on ***.

Based on W86 LAI-ART CAB/RPV protocol:

If patient receives injection ***

(8-9 days after scheduled injection)

- This is still within 7 days of "same date every 2 mth" injection cycle window & not considered late injection
- Administer Q 8-Weeks Dose of CAB/RPV LA dose (600mg/900mg) IM & continue with every 8 week dosing schedule

If patient receives injection ***

(10-14 days after scheduled injection)

- Administer Q 8-Weeks Dose of CAB/RPV LA dose (600mg/900mg) IM & continue with every 8 week dosing schedule
- Obtain HIV VL (rapid resulting preferred) and HIV genotype
- Has a reminder been placed to order labs? Yes
- Schedule patient to return to clinic/practice next day or be available by phone
- If HIV VL is detectable, start patient on DRV/c/FTC/TAF until genotype results become available

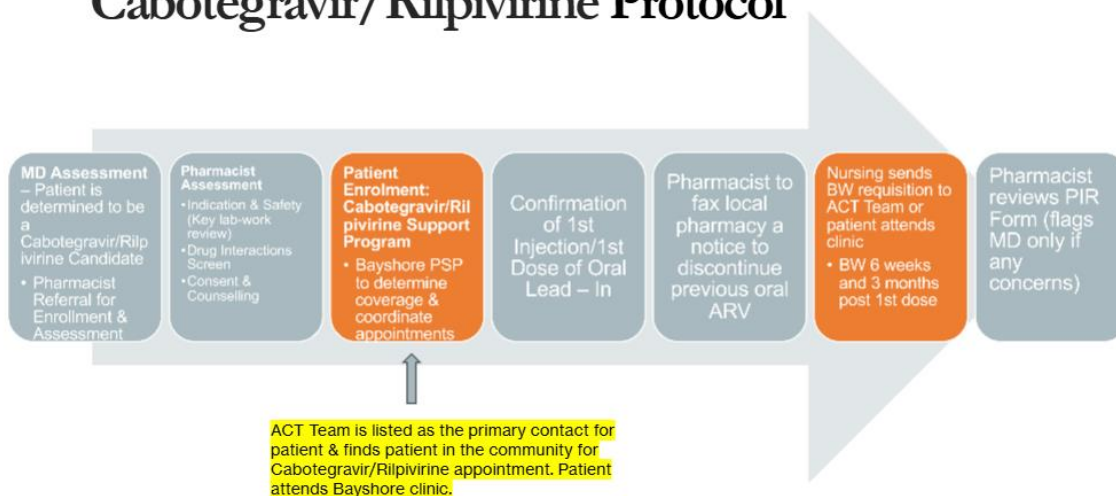
If patient receives injection***

(15-30 days after scheduled injection)

- Administer CAB/RPV LA dose (600mg/900mg) IM with plan to re-initiate injections 4 weeks apart for 2 consecutive months. Continue every 8 week dosing schedule thereafter
- Obtain HIV VL (rapid resulting preferred) and HIV genotype
- Has a reminder been placed to order 2nd q4wk dose? Yes
- Schedule patient to return to clinic/practice next day or to be available by phone
- If HIV VL is detectable, start patient on DRV/c/FTC/TAF until genotype results become available

Appendix E: Flowchart for ACT Team and EMDC (Elgin Middlesex Detention Centre)

ACT (Assertive Community Treatment) Cabotegravir/Rilpivirine Protocol



EMDC (Elgin Middlesex Detention Centre) Cabotegravir/Rilpivirine Protocol

