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## BACKGROUND

- Long-acting cabotegravir (CAB-LA) is highly effective as HIV PrEP and superior to daily oral F/TDF in sexually active adults
- Despite its superior efficacy, PrEP failures associated with CAB-LA have been described in clinical trials
- We report a 28-year-old gender diverse patient assigned male at birth whose HIV-1 infection was detected 91 days after transitioning from F/TAF to CAB-LA despite on-time dosing

## METHODS

- Electronic medical records were reviewed to assess patient history and CAB-LA administration
- Plasma 4th generation HIV-1/2 Ag/Ab combination immunoassay and HIV-1 RNA quantitative PCR were performed at each injection visit
- Plasma CAB concentration was performed by a research laboratory

## CASE DESCRIPTION

- Patient on daily F/TAF for PrEP 10 months prior, reporting one missed dose per week
- History of controlled hypothyroidism and self-reported hypogonadism with illicit use of IM testosterone and significantly elevated total testosterone levels
- Sexually active with cisgender men
  - condomless oral and anal sex
  - primary partner & 20-30 unique partners monthly
  - recently engaging in anal fisting intercourse
  - diagnosed with syphilis and mpox in past 6 months
- Primary partner was living with HIV resistant to NRTIs (65R, 118I) and INSTIs (92G) with undetectable HIV-1 RNA for over 24 months on DRV/c + DTG
- Uncomplicated administration of 600mg of CAB-LA into left gluteal medius on day 0, 27, and 91
- Flu-like illness with + SARS-COV-2 PCR on day 76; completed course of nirmatrelvir-ritonavir (NMV/r)

## RESULTS

- HIV 1/2 Ag/Ab non-reactive and HIV-1 RNA PCR not detected on Day 0 and 27 injections
- At 3rd injection on Day 91
  - HIV 1/2 Ag/Ab non-reactive
  - HIV-1 RNA PCR test detected at 1.48 log<sub>10</sub> c/mL
- Repeat testing on day 100
  - HIV 1/2 Ag/Ab reactive
  - HIV-1 Ab detected on differentiation assay
  - HIV-1 RNA PCR detected at 1.30 log<sub>10</sub> c/mL
  - unable to perform standard HIV-1 sequencing
- HIV-1 DNA qualitative PCR below LLOQ and HIV-1 proviral DNA resistance unable to be performed
- Plasma CAB concentration on Day 128 (Day 37 from most recent injection) 1180 ng/mL
- Fully suppressive ART regimen (DRV/c + DTG) chosen based on primary partner's regimen and historical genotypes

## CONCLUSIONS

- Patient's history and testing suggests HIV infection despite on-time and appropriate CAB-LA injections and detectable CAB concentration
- To our knowledge, this is the first case of CAB-LA PrEP failure outside the setting of a clinical trial
- Highlights diagnostic and management challenges that may occur with CAB-LA PrEP failures
- Reinforces need to better understand HIV-1 reservoirs in such breakthrough infections (ACTG A5321)

## ACKNOWLEDGMENTS

- Ebony Warren, MA; Howard Brown Health
- Mark Marzinke, PhD; Johns Hopkins University
- Raphael Landovitz, MD, MSc; UCLA Health
- Toyin Nwafor, MD, Heidi Swygard, MD, MPH, Sonia Patel, PharmD; ViiV Healthcare

