

IDWeek 2023 Recap

Focus on HIV prevention

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Center

A Project of the Division of STD Prevention
Massachusetts Department of Public Health
Funded by the CDC

HIV Post-Exposure Prophylaxis-in-pocket (PEP-in-pocket) “PIP”

Presenting Author(s)



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Rationale for PEP-in-pocket (PIP)

- Aim to address gaps in HIV preventive care
- PrEP is great, for people with semi-frequent exposures
- PEP works well, if you can get it
- Maybe PIP can bridge the gap

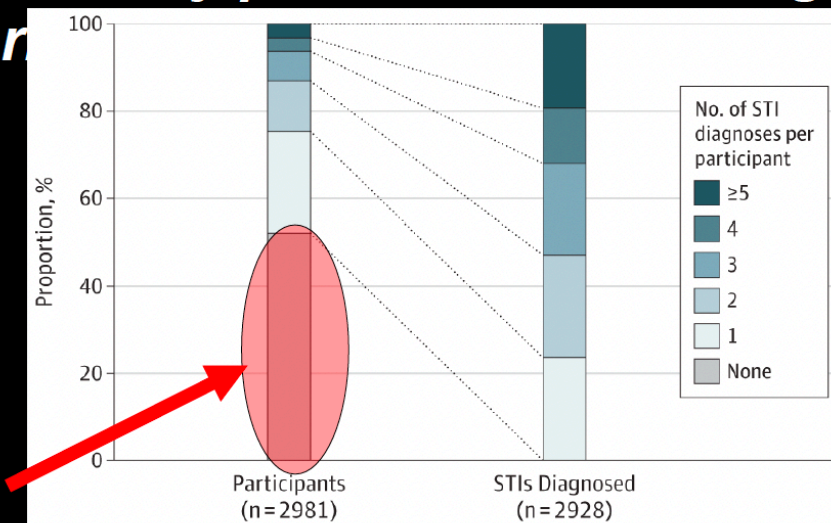


Zero-to-few exposures



Many exposures

“But my patients are all at high



JAMA, 2019

**Over 50% of patients on daily PrEP have 0 STIs in 1 year
Do they really need to be on PrEP? Some, but not all.**

PIP Basics

- How it works
 - Proactive prescription for 28 days of guideline endorsed PEP. Patients self-initiate PEP following an exposure.
 - Patients attend clinic on a non-urgent basis following initiation
 - Patients can transition between PrEP and PEP as indicated

Who Is Using PIP?

- Self-report 0 - 4 high risk HIV exposures per year
- May include individuals who:
 - Almost always use condoms, but infrequently don't (or can't)
 - Have had a condom break
 - Have decided to stop using PrEP, and want a back-up plan
 - Infrequently share injection drug equipment
 - Have difficulty accessing PEP in emergency situations
 - Rural/remote locations, lack of transportation, etc.



Medicine
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Retrospective cohort data

- 2 large HIV-prevention clinics in Toronto
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69 PIP courses initiated, 0 HIV infections

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- 5 PIP discontinuations— 4 by providers after risk assessment, 1 by patient due to side effects

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Transition between HIV prevention modalities

- 34 (31%) PIP → PrEP
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Cost-effectiveness

- PIP is 43% less costly per year (medication costs, clinic costs, other HIV/STI/health system costs)

PIP Summary

Benefits of PIP

- ✓ Protection for those with low frequency, higher- risk (often unanticipated) exposures
- ✓ Lowered barriers: Immediate access to HIV prevention, no need for ED or urgent care
- ✓ Decreased cost vs. daily PrEP
- ✓ Autonomy and agency over one's care
- ✓ More granular approach (more options)

Take home points:

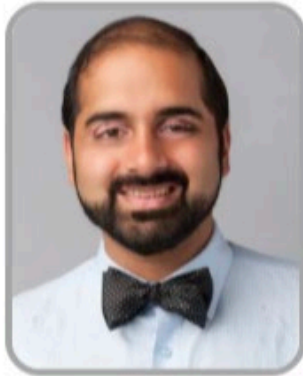
- PEP-in-Pocket (PIP) should be considered as one of several biomedical HIV prevention options
- People have dynamic HIV risk & we can match that with an appropriate HIV prevention modality
- **Next Steps:**
 - Prospective study
 - Community outreach
 - Patient education materials
 - Cost Effectiveness

Thoughts on PEP in pocket (PIP)?

- What is your initial reaction to PIP?
- Do you think PIP has a place in HIV prevention?
- Do you have any concerns about PIP?
- Would you consider implementing a similar program?

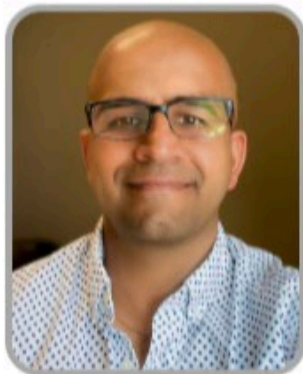
Squabbles among friends: Is it necessary to check HIV viral loads in PrEP clinic?

Faculty(s)



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University of Chicago
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Clinician / Associate Medical Research Director
Fenway Health / The Fenway Institute
Boston, MA, United States

The Future Is Here: HIV Screening in PrEP Clinics Needs a Facelift

Aniruddha (Anu) Hazra, MD



@AnuHazraMD



@UChicagoID



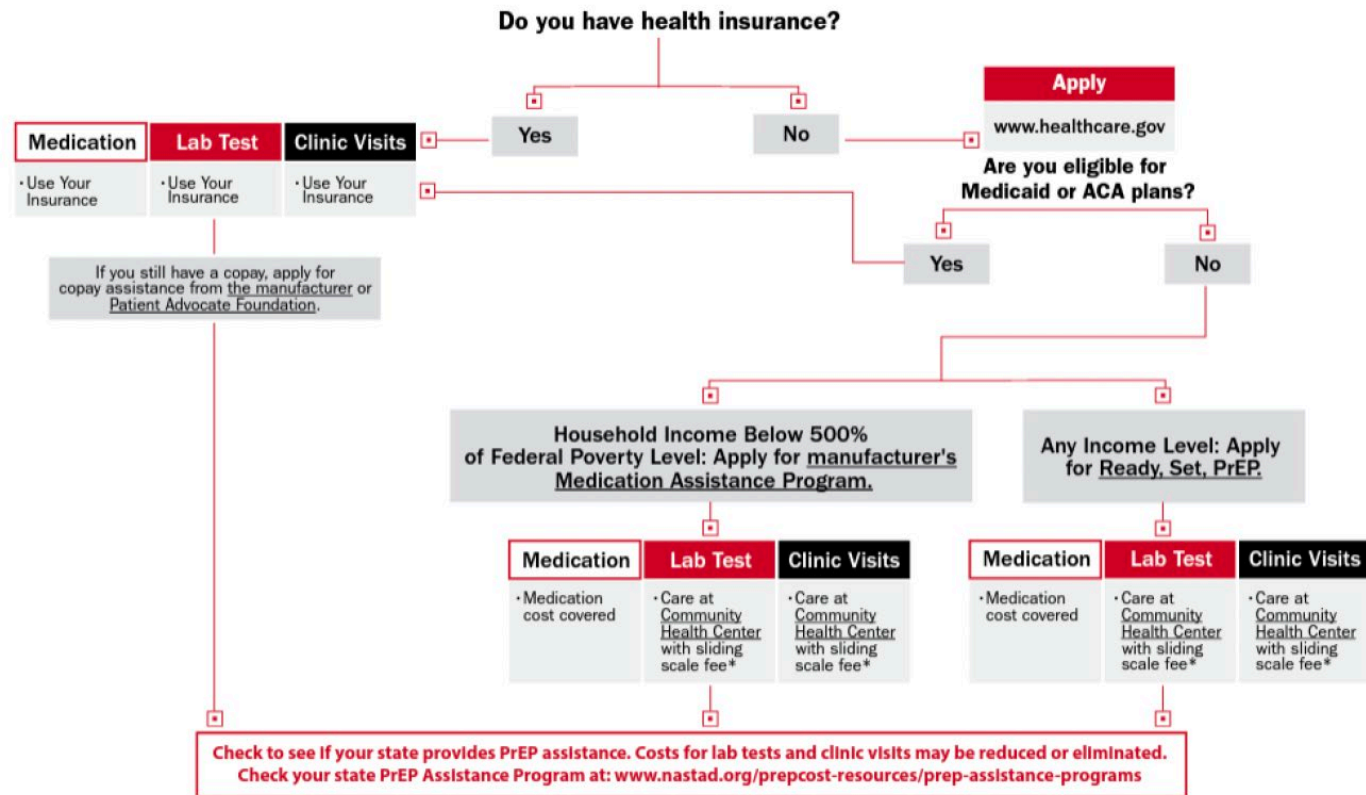
#StopHIVTogether

- Improved detection of acute HIV infection
- Fewer false positive results than ag/ab screening
- Clear benefit in detecting new HIV infections with long-acting PrEP agents
- Main concern is cost, but it's unclear what the cost is across health systems
- Future of HIV diagnostics is moving towards molecular assays
- We need POC/rapid HIV molecular diagnostics

The Case Against Mandatory HIV Viral Load Testing for PrEP Visits

- **Exacerbates Existing Inequities:** Mandatory HIV VL testing disproportionately impacts marginalized communities and those without insurance, widening healthcare disparities.
- **Resource Misallocation:** Using VL tests as a gatekeeping tool for PrEP diverts these crucial tests from their essential function—monitoring and managing the health of HIV-positive patients.
- **Introduces Individual Opportunity Costs:** Adding mandatory VL tests increases time and psychological burdens on individuals, potentially deterring them from seeking critical preventive care.
- **Complicates an Already Complex System:** States already have heterogeneous policies on PrEP and lab test assistance. Mandatory VL testing would add another layer of complexity, making the system more difficult to navigate and less accessible.

How do I Pay for Pre-Exposure Prophylaxis (PrEP)?



* To find a Community Health Center: findahealthcenter.hrsa.gov



Ending
the
HIV
Epidemic

Thoughts on HIV viral load testing in PrEP

- Do you side with or against routine HIV viral load testing for people on PrEP?
- What are the biggest challenges with viral load testing in your clinic?
- Has your site discussed the role of viral load testing for PrEP?

Diagnosing HIV in people on PrEP

Speaker(s)



Meredith E. Clement, MD (she/her/hers)

Associate Professor

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Orleans

New Orleans, LA, United States

Disclosure(s):

Meredith E. Clement, MD: Gilead Sciences: Grant/Research Support (Ongoing); Viiv Healthcare: Advisor/Consultant (Ongoing), Grant/Research Support (Ongoing)

Background

- PrEP can suppress early viral replication
- PrEP can delay antibody development and detection
- Continuing PrEP in a person who has acquired HIV has the potential to cause ART resistance.

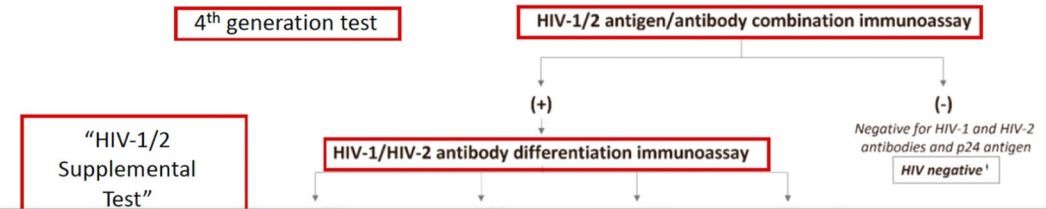
Overview

- Review diagnostic algorithms
- Describe breakthrough cases from real world and clinical trial data, focusing on CAB-LA
- Consider importance of HIV RNA testing to add to our diagnostic yield

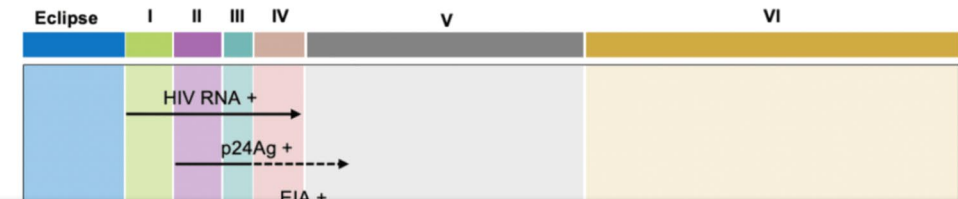
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Recommended HIV Diagnostic Algorithm



Fiebig Laboratory Stages of Early HIV-1 Infection



WHAT IS THE WINDOW PERIOD FOR THE HIV TEST I TOOK?

Nucleic Acid Test (NAT)*
window period

10-33 days



Antigen/Antibody Lab Test†
window period

18-45 days

Rapid Antigen/Antibody Test‡
window period

18-90 days



Antibody Test‡
window period

23-90 days



* Performed by a lab on blood from a vein.
† Done with blood from a finger stick.
‡ Most rapid tests and self-tests are antibody tests.

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Extended Analysis of HIV Infection in Cisgender Men and Transgender Women Who Have Sex with Men Receiving Injectable Cabotegravir for HIV Prevention: HPTN 083

Mark A. Marzinko,^{ab} Jessica M. Fogel,^a Zhe Wang,^c Estelle Piwowar-Manning,^a Ryan Kofron,^d Amber Moser,^a Pradip Bhandari,^a Ryann Gollings,^a Lane R. Bushman,^a Lei Weng,^e Elias K. Halvas,^f John Mellors,^g Peter L. Anderson,^h Deborah Persaud,^a Craig W. Hendrix,^b Marybeth McCauley,ⁱ Alex R. Rinehart,^j Marty St Clair,^j Susan L. Ford,^k James F. Rooney,^j Adeola Adeyeye,^m Suwat Chariyalertsak,ⁿ Kenneth Mayer,^{no} Roberto C. Arduino,ⁿ Myron S. Cohen,^o Beatriz Grinsztejn,^p Brett Hanscom,^q Raphael J. Landovitz,^r Susan H. Eshleman^a

TABLE 2 Key laboratory results (CAB arm, group 1)^a

Case ID	Subtype	No. of injections	No. of late injections	Time since last injection (days)	VL (copies/mL) at 1st positive visit	[CAB] (µg/mL) at 1st positive visit	DX delay	Time to site detection (days)	Drug administration after infection	Ag/Ab lab test result at 1st positive visit	Confirmatory Ab test result at 1st positive visit	Major INSTI RAM at 1st positive visit	Major INSTI RAM at any visit ^b	TDF-FTC administration	[TFV] (ng/mL) at 1st positive visit
A1	B	0	0	NA	4,010	BLQ	Yes	28	Yes	NR	NA	No	No	No	
A2	C	1	0	NA	50,080	BLQ	Yes	60	Yes	NR	NA	No	No	No	
A3	B	2	0	NA	1,360	BLQ	Yes	72	Yes	NR	NA	No	No	No	
A4	B	2	0	NA	44,180	BLQ	Yes	63	Yes	R	NEG	No	No	No	
C1	B	2	0	NA	120	6,301	Yes	47	Yes	NR	NA	No	Yes	No	
C2	BF	0	0	NA	494	BLQ	Yes	185	No	NR	NA	No	No	No	
C3	B	1	0	NA	SCA, 15.3	10,690	Yes	35	Yes	NR	NA	No	Yes	No	
D1	Likely B	10	1 ^c	56	130	1,613	Yes	112	Yes	NR	NA	Yes	Yes	No	
D2	Likely B	6	0	14	SCA, 6.1	1,405	Yes	98	Yes	NR	NA	Failed testing	Yes	No	
D3	BF	5	0	56	860	1,504	Yes	117	Yes	NR	NA	Failed testing	Yes	No	
D4	C	4	0	13	<40	2,017	Yes	45	Yes	NR	NA	Failed testing	Yes	No	
D															
D															
D															
D															
B															
B															

LEVI Syndrome

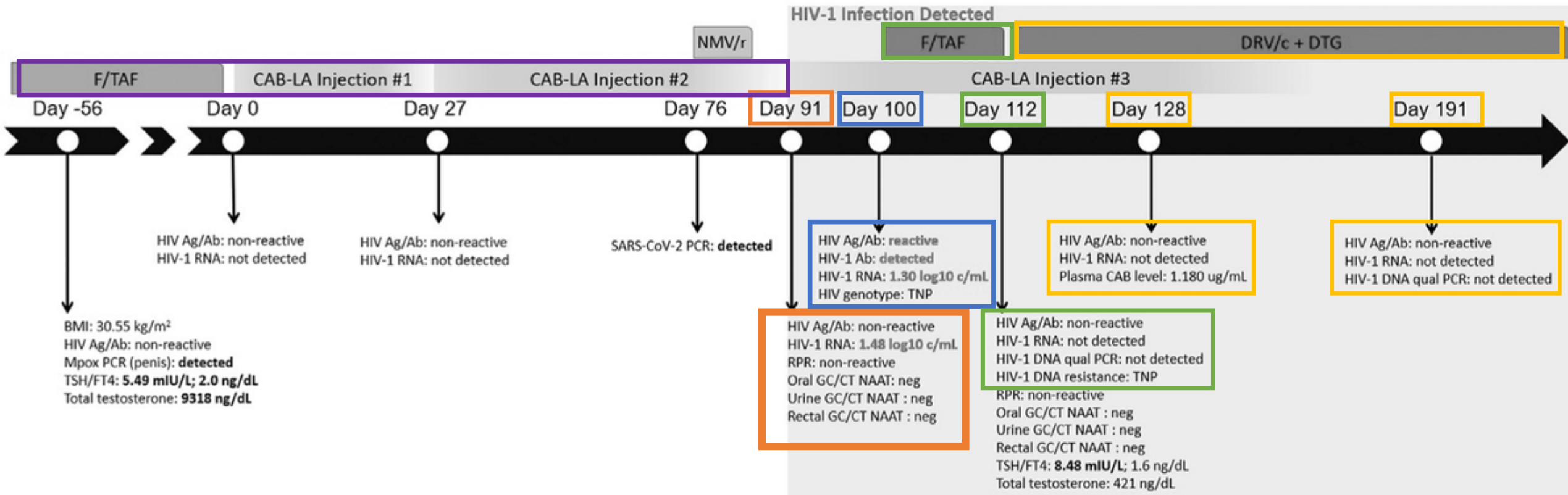
- Comparison of acute HIV infection (AHI) to infections that occur in the setting of long-acting early viral inhibition (LEVI)

	AHI	LEVI
Cause	Phase of natural HIV infection	Long-acting anti-viral PrEP agent (prototype: CAB-LA)
Onset	New infection	Infection during PrEP Initiation of PrEP agent during acute/early infection
Viral replication	Explosive	Smoldering
Symptoms	Fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen glands	Minimal, variable, often no symptoms reported
Detection	Ag/Ab assay, RNA assays (including less sensitive POC and pooled tests), DNA assays, total nucleic acid assays	Ultrasensitive RNA assay (often low or undetectable RNA, low/undetectable DNA, diminished/delayed Ab production)
Assay reversion	Rare	Common for many test types
Duration	1-2 weeks (until Ab detection)	Months (until viral breakthrough, drug clearance, or ART start); can persist months after the anti-viral agent is discontinued
Transmission	Very likely	Unlikely (except possibly through blood transfusion)
Drug resistance	No (unless transmitted)	Yes (can emerge early when viral load is low)

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Case of HIV in a patient with on time CAB-LA



Conclusions

- PREP is incredibly effective for HIV prevention. Breakthrough cases are extremely rare.
- Detecting HIV on PrEP is challenging, especially with long-acting formulations.
- If there is concern for new HIV infection, retest quickly with Ag/Ab test and the most sensitive HIV-RNA assay available.

Thoughts on diagnosing HIV in people on PrEP

- What's your reaction to hearing about breakthrough cases of HIV in people on PrEP, especially long acting cabotegravir?
- Have you heard of LEVI syndrome before this?
- What questions or concerns do you have about identifying these patients?