



Home Infusion Pharmacy:

The "HIP" Solution to Receive Long-acting PrEP

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 - Research disclosure: Funding from ViiV Healthcare
- Austin Ewing
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- Kristen LaGrotta
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Learning objectives

- Describe the challenges involved with administering long-acting cabotegravir (CAB-LA) for PrEP.
- Describe home infusion pharmacy (HIP) administration as a potential solution to these challenges.

Poll question #1

Which statement best describes you or your organization and long-acting cabotegravir for PrEP?

- A. We offer CAB-LA widely.
- B. We offer CAB-LA in special situations.
- C. We are developing a program to offer CAB-LA.
- D. We will not be offering CAB-LA.
- E. We are thinking about offering CAB-LA.
- F. My organization doesn't provide clinical services.

Poll question #2

If you work with clients, how often do they ask about long-acting cabotegravir (CAB-LA) for PrEP?

- A. Daily
- B. Weekly
- C. Monthly
- D. Less than monthly
- E. Never

Chat cascade response

If you or your organization do not offer long-acting cabotegravir, what are the major barriers?

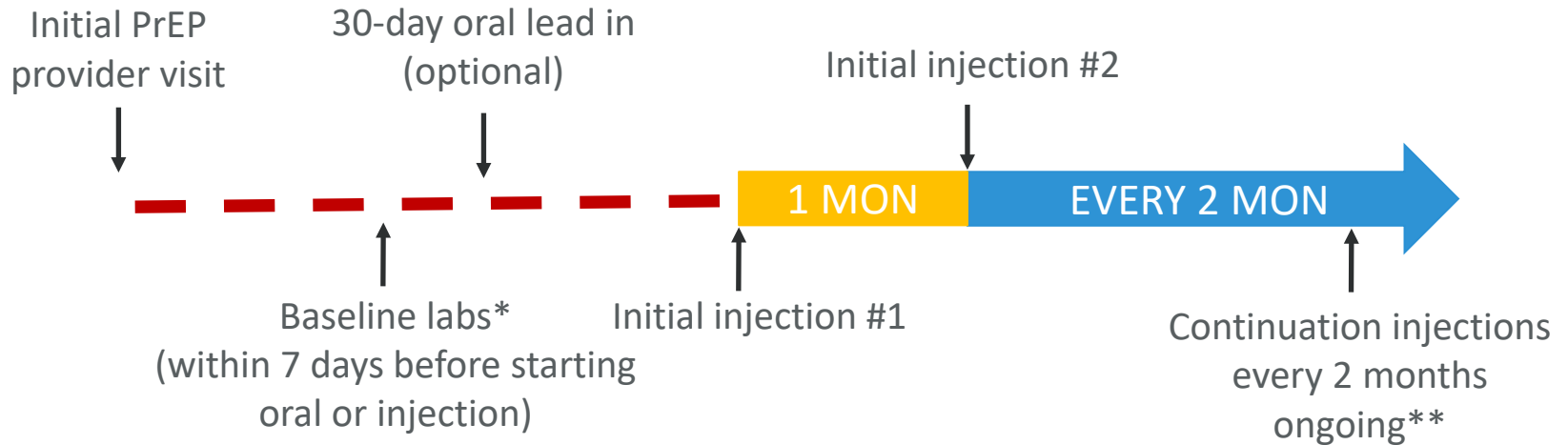
Part 1

CAB-LA PrEP: Benefits, Challenges & a Potential Solution

What is long-acting cabotegravir?

- First long-acting PrEP option approved by FDA (12/2021)
- Injectable integrase inhibitor
- Brand name: Apretude®
- Indicated for all at-risk adults & adolescents weighing ≥ 35 kg (77 lb)
- Sexual risk exposures only
- Requires healthcare provider administration

How is CAB-LA administered?



*HIV Ab/Ag and HIV RNA PCR at minimum. STI and viral hepatitis evaluation highly recommended.

**There is a monthly target injection date with an injection window of +/- 7 days from the target date.

Benefits of CAB-LA compared to oral PrEP



Challenges...

Opinion

VIEWPOINT

Long-Acting Cabotegravir for HIV Prevention Issues of Access, Cost, and Equity

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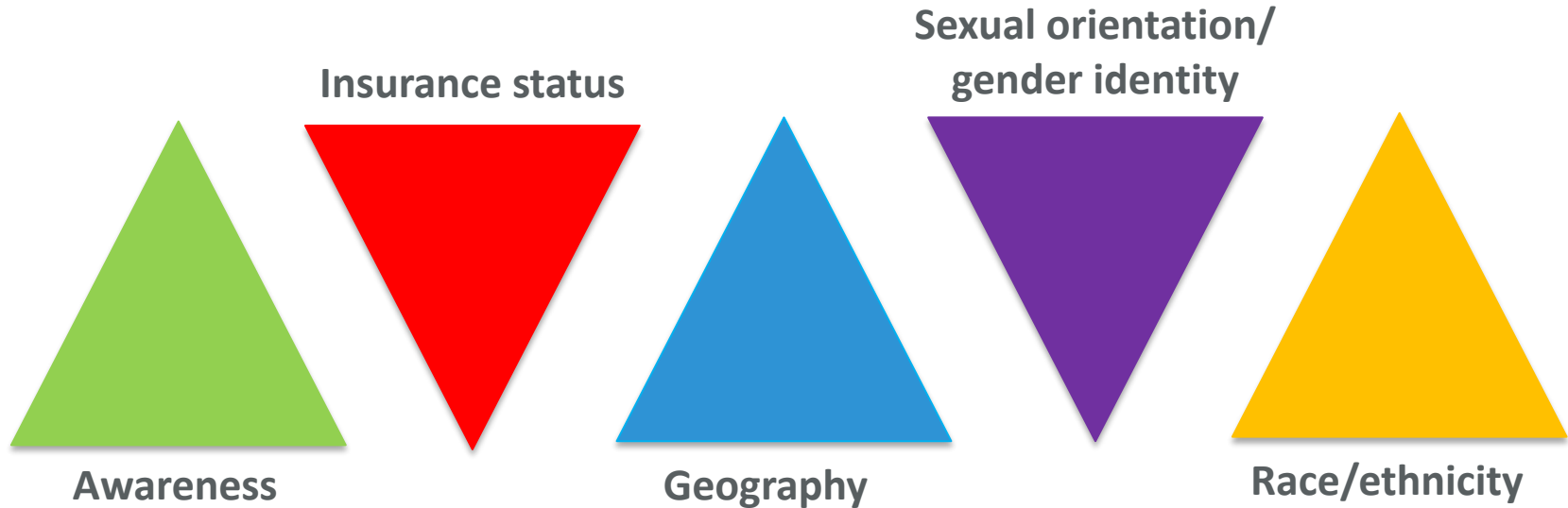
On December 20, 2021, the US Food and Drug Administration (FDA) approved long-acting cabotegravir, the first injectable medication to prevent HIV. Two randomized clinical trials that together included 7790 study participants demonstrated that long-acting cabotegravir was more likely to prevent HIV acquisition than daily oral medication for people at risk of sexually acquiring HIV, including men who have sex with men, heterosexual women, and transwomen.¹ The advantage of the medication medication. Disparities in PrEP access and use based on age, race and ethnicity, geography, sex, and gender identity are substantial. For example, in 2019, 63% of 300 650 White individuals for whom PrEP was indicated received a prescription compared with 14.0% of 312 820 Hispanic individuals and 8.2% of 468 540 Black individuals.⁴ More than two-thirds of the estimated 34 000 new HIV infections in the US per year occur among Black and Hispanic individuals.⁵



Challenges with CAB-LA

- Access
- Administration logistics
- Cost
- Indications
- HIV stigma

Access to CAB-LA



Administrative logistics with CAB-LA



Does the system support CAB-LA?



How will the medication be supplied?



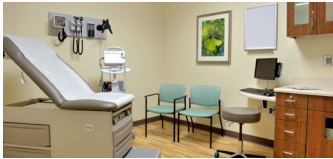
Who is going to administer the medication?



Are there supplies?



Ordering & tracking (panel management)?



Where will administration happen?



How will they be trained?



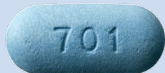


Who's paying?
How will billing happen?



Lab collection?

High cost of CAB-LA

Regimen	Route of Admin	Cost Per Dose	Annual Cost
CAB-LA		\$4,440 every 2 months	\$26,640 (administration fees not included)
F/TAF		\$2,032.26 monthly	\$24,387.12
F/TDF		\$30.19 monthly (generic)	\$362.28

Fees for labs and office visits not included.

F/TAF: Tenofovir alafenamide/emtricitabine (Descovy®)

F/TDF: Tenofovir disoproxil fumarate/emtricitabine (generic Truvada®)

CAB-LA: PositivelyAware.com, 5/29/2023

Oral PrEP: GoodRx.com, Safeway Pharmacy, 8/7/2022

Indications for CAB-LA



FDA-approved for all
genders and sexual
risk categories



Not approved for
people who inject
drugs as only risk
category*



Pregnancy and
breastfeeding?

HIV stigma

- Legal challenge to PrEP coverage under the Affordable Care Act
- Challenge based on religious freedom of businesses providing health insurance to employees
- *Braidwood Management v. Becerra*
- Currently a “stay pending appeal”

We need to decrease barriers.

Is home infusion pharmacy a
solution?

Oregon PrEP@Home Study



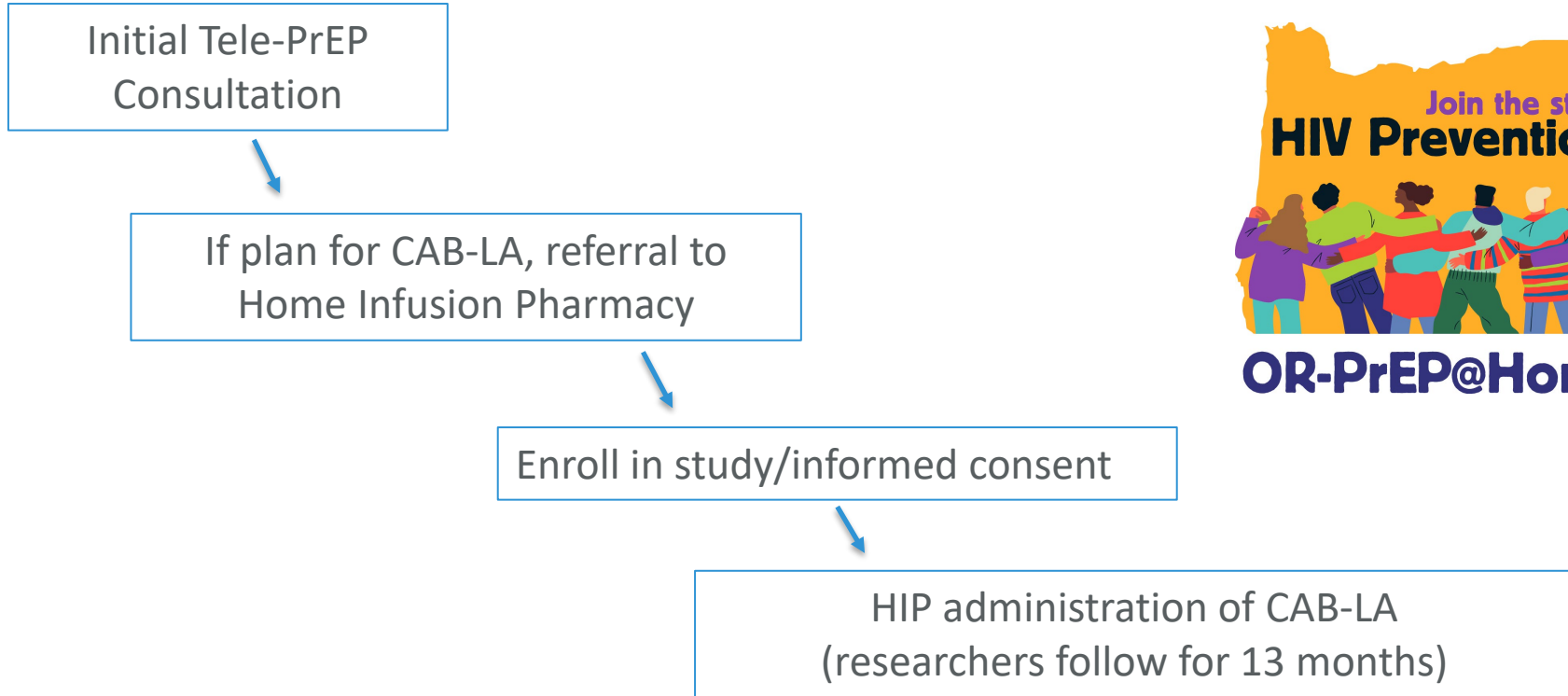
Demonstration project aiming to evaluate CAB-LA administration and participant satisfaction through a partnership between the OHSU Tele-PrEP Program and the OHSU Home Infusion Pharmacy

Oregon PrEP@Home Study



- Standard of care
- Launches summer 2023, 2-year study
- Independently sponsored OHSU research project with funding from ViiV Healthcare
- Particularly hoping to enroll urban and rural participants

Oregon PrEP@Home Study Pathway



OR-PrEP@Home inclusion criteria

- Age \geq 18 years
- Residence in Oregon
- English or Spanish spoken and written language ability
- Clinical eligibility for PrEP with CAB-LA including HIV-negative serostatus
- Access to stable Internet
- Access to a clean, safe location that is appropriate for home administration



OR-PrEP@Home exclusion criteria

- Clinical ineligibility for PrEP with CAB-LA
- Uninsured
- Lack of qualifying health insurance for HIP services
- Pregnancy*
- Residence outside of the home infusion program's catchment area
- Incarceration
- Decisional impairment



*Pregnancy is not a contraindication for CAB-LA. However, there is a lack of safety & efficacy data, which makes the inclusion of pregnant people in this study unfeasible. Nonpregnant people of childbearing potential are not excluded.

Part 2

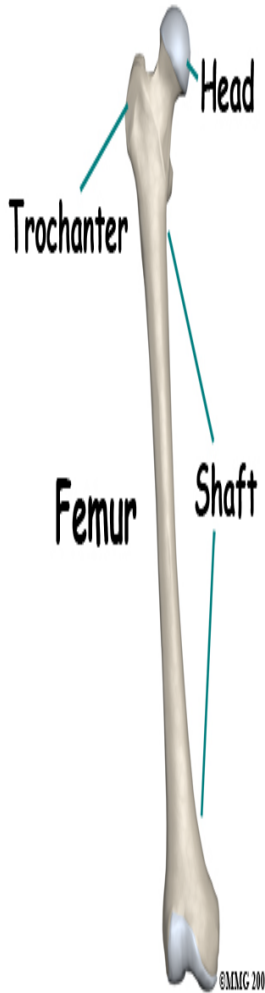
HIP Solutions to CAB-LA PrEP Challenges

Agenda



- OHSU Home Infusion Pharmacy “HIP” therapies
- What *is* HIP?
- What *isn't* HIP?
- HIP roles explored
- Hypothetical patient scenario
- Review patient touchpoints during referral process
- Hypothetical patient scenario care plan
- Referral information

HIP Therapies



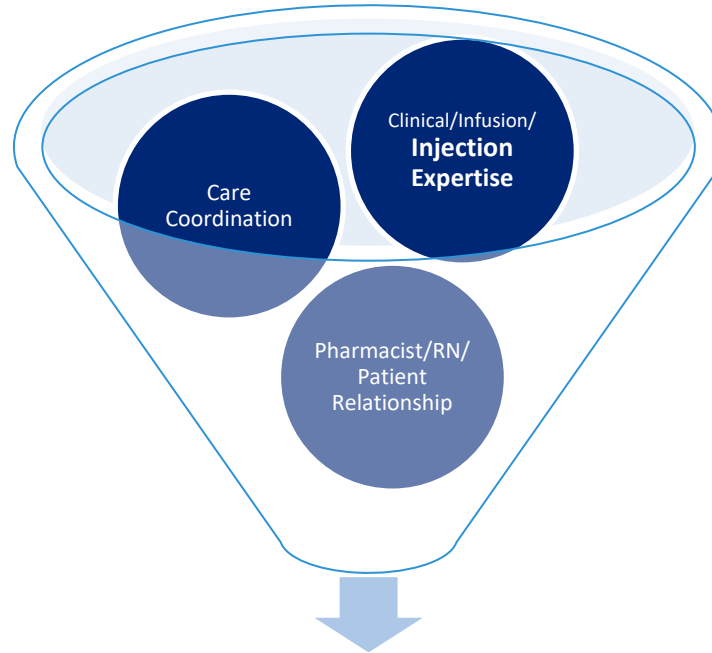
Core Therapies

- Antibiotics
- Hydration/Electrolytes
- Anti-emetics
- TPN

Specialty Therapies

- **LA-cabotegravir**
- LA- cabotegravir/rilpivirine
- Iron infusions
- IVIG/SCIG
- Monoclonal Antibodies (Infliximab, ocrelizumab)
- Enzyme Replacement Therapy

What *is* HIP?



“HIP” Patient Care in the Comfort of their Own Home



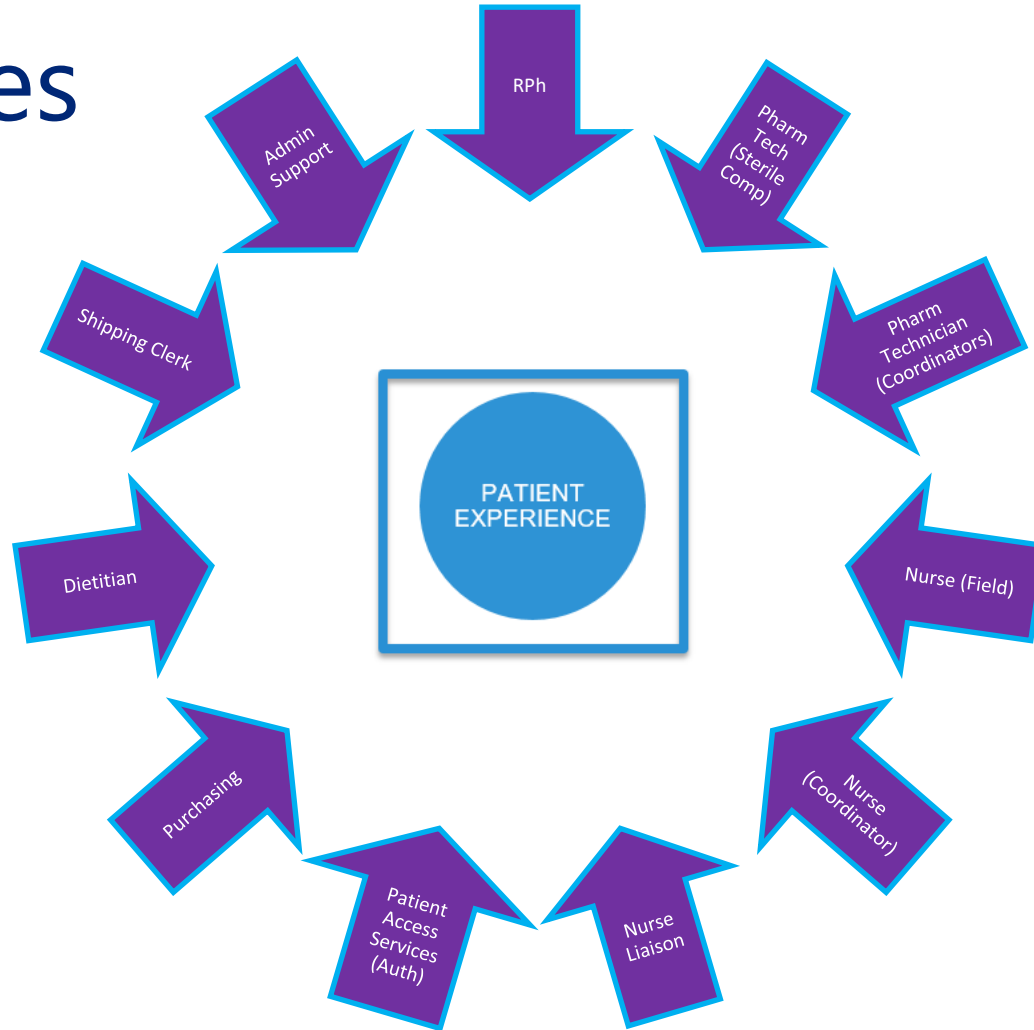
What *isn't* HIP?

~~Home Health~~

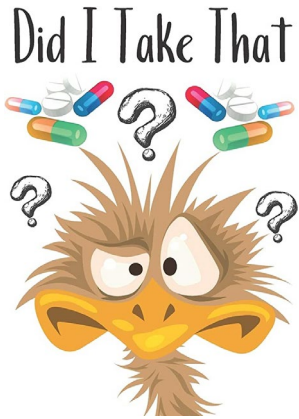
~~Ambulatory
Infusion Clinic~~

~~ER or
Urgent Care
Clinic~~

HIP Roles

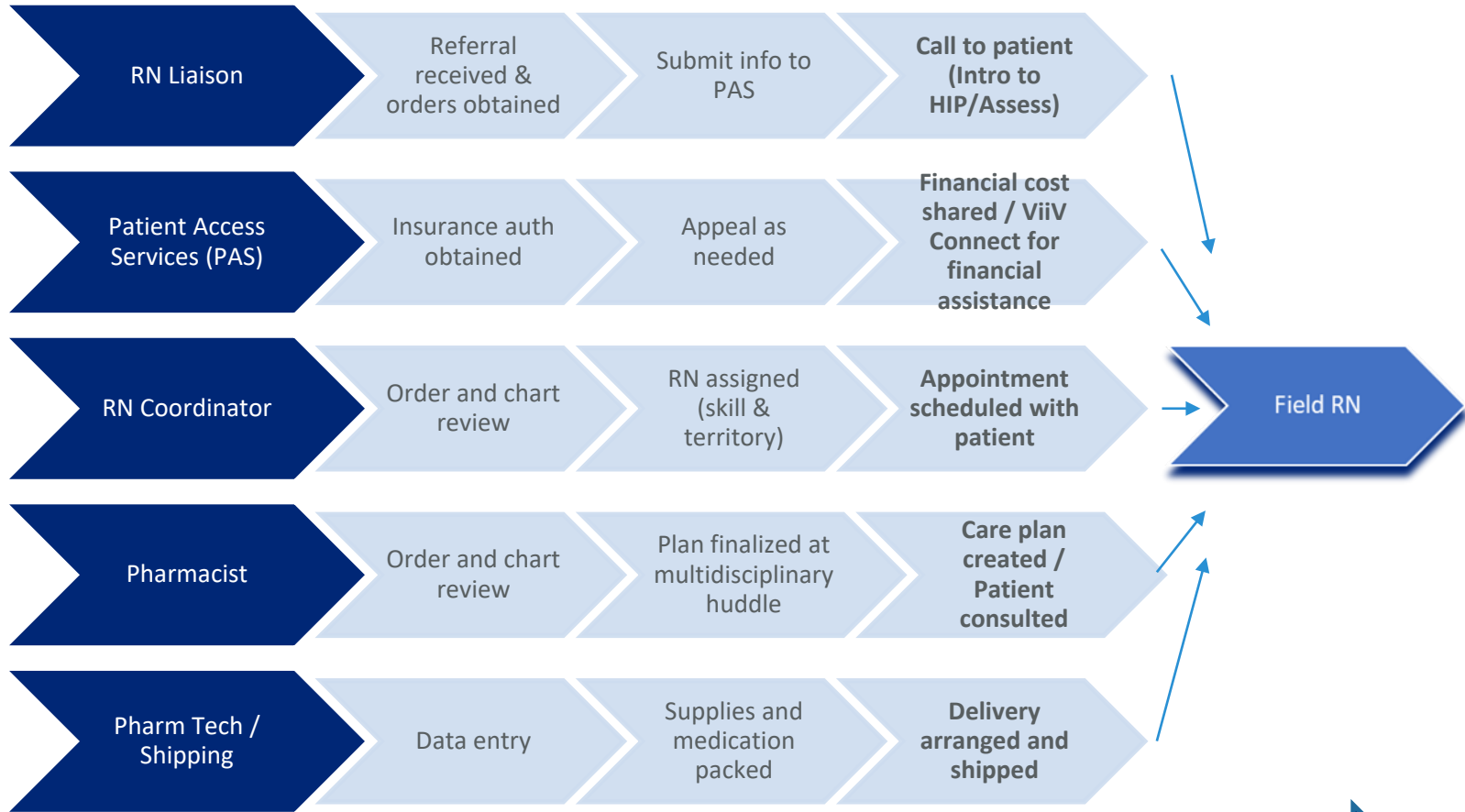


Patient Scenario*



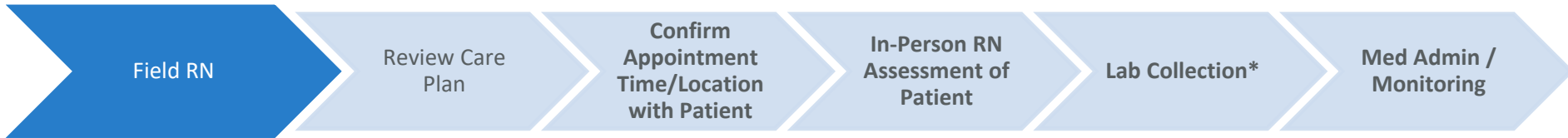
- Lincoln is a 30 year old transgender male from Salem, OR and is currently taking oral PrEP
- Currently misses up to 10 doses per month
- Has sex without barriers in a non-monogamous relationship
- History of STI's
- Interested in long-acting cabotegravir
- Primary provider referred to OHSU Tele-PrEP clinic →enrolled in study→ ultimately referred to HIP
- Concerns about cost and privacy

From Referral to Injection: **Patient Touchpoints**



One day to several weeks (Patient Care is main factor)...

From Referral to Injection: **Patient Touchpoints**



*As ordered by provider.

Mandatory: HIV ab/ag; HIV RNA PCR

Optional: syphilis, gonorrhea/chlamydia, hepatitis panel, CMP, other labs

Note: RN collects all blood tests. Patient self-collects urine and rectal, pharyngeal, vaginal swabs.



Lincoln*: HIP Care Plan Addresses Patient's Needs

Problem	Care Plan Resolution
Oral non-adherence	<ul style="list-style-type: none">✓ Target Treatment Date✓ Proactive refill calls
History of STI's	<ul style="list-style-type: none">✓ Labs reviewed after each visit✓ Provider manages positive results
Concern about cost	<ul style="list-style-type: none">✓ Manufacturer savings program✓ Proactive insurance re-auth✓ Use insurance preferred lab
Concern about privacy	<ul style="list-style-type: none">✓ Discreet shipping and storage options✓ Alternate site of care options
Cultural sensitivity	<ul style="list-style-type: none">✓ Field RNs trained in SOGI issues✓ Use of affirmed pronouns, avoiding stigma, etc

Study referral

- Toll-free: 1-833-770-1400
- E-mail: prepstudy@ohsu.edu
- Fax: 1-503-418-5505
- Web: www.ohsu.edu/school-of-medicine/general-internal-medicine/tele-prep



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Discussion?

