UNMC HIV ECHO Session 10

Welcome!

The University of Nebraska Medical Center's Specialty Care Center welcomes you to our 10th HIV ECHO session – **Your PrEP Roadmap**

Today's subject matter experts are:

Dr. Shawna Sunagawa, PharmD at Specialty Care Center

Gaye Gwion, MPH – HIV Prevention Coordinator at NDHHS

Andy Dillehay – HIV & Viral Hepatitis Program Manager at NDHHS

HIV ECHO Facilitator: Heather Saarela, BSPH

Sessions are held the first Thursday of every month

Disclosures

- Our HIV ECHO Project is made possible through our grant funding from ViiV Healthcare and is a sub-project of our IM-CAPABLE project.

UNMC HIV ECHO Session 10 Agenda

- Dr. Sunagawa will be presenting first on some clinical pearls on how to implement PrEP in clinical settings – AKA, a PrEP roadmap!
- Andy and Gaye from the NDHHS will present after Dr. Sunagawa to talk about the HIV team at the NDHHS. Who the folks are on the team, how to connect and partner with NDHHS, highlighting the work that they do for folks in Nebraska, as well as provide us with some info on their same day PrEP program!
- Announcements to be shared at the end.

ECHO After Hours!

As scheduling and time allows for our experts, we will offer ECHO After Hours after our sessions for any extra questions!

Andy and Gaye

Housekeeping Reminders:

We love discussion!

Please stay muted unless you are speaking.

We love to see your face!

Sessions will be recorded with links available later.

End of session surveys will be available.

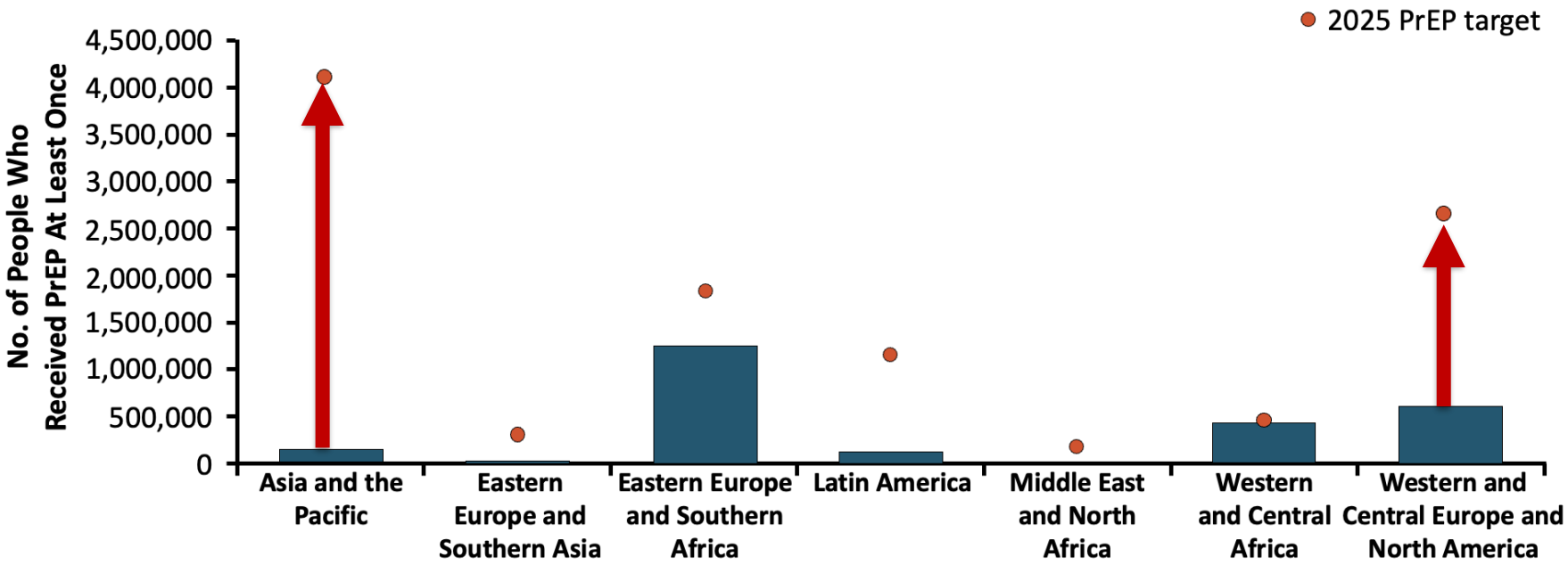
Your PrEP Roadmap: Clinical Pearls for Establishing a HIV PrEP Program

Shawna Sunagawa, Josh Havens

UNMC HIV ECHO Program – October 2025

University of Nebraska Medical Center

Full Potential of PrEP is Not Being Realized Globally



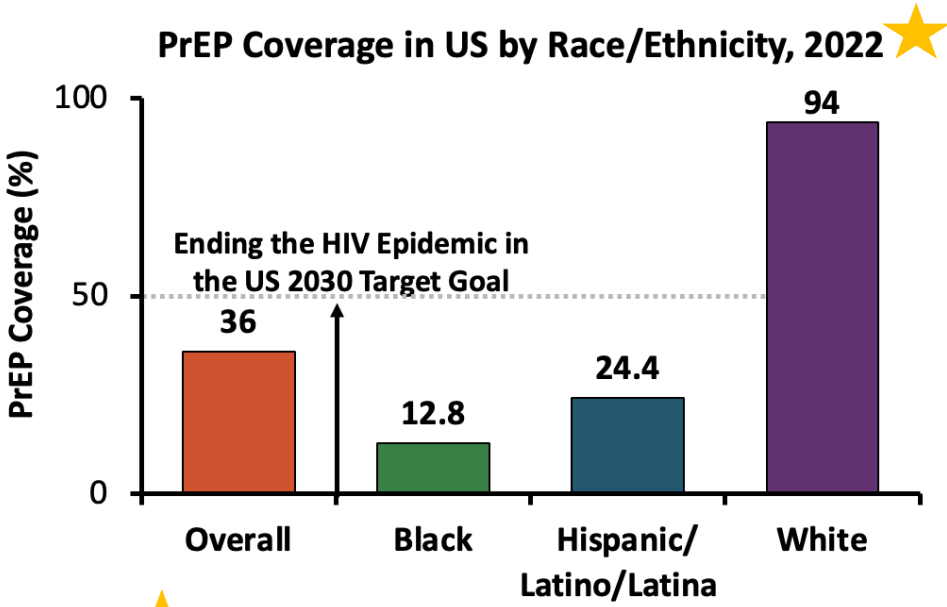
unaids.org/en/resources/documents/2023/global-aids-update-2023

PrEP Gap in the United States

1.2 million people likely to benefit from PrEP

In 2022, of those who could benefit, **few were prescribed** PrEP

41% of males	15% of females



CDC has paused PrEP (pre-exposure prophylaxis) coverage reporting to determine the best methodology for calculating PrEP coverage, and to update PrEP coverage estimates using updated methods and sources. Due to a formula error that affects a subset of race and ethnicity data, all race and ethnicity data have been removed from this site. CDC plans to resume PrEP coverage reporting in the next HIV Monitoring Report for all demographic groups, currently scheduled for publication in June 2025. Until updated PrEP coverage estimates are published, CDC advises against citing specific PrEP coverage data points, as historical estimates will be updated.

cdc.gov/hiv/library/reports/surveillance-data-tables/vol-4-no-3/index.html

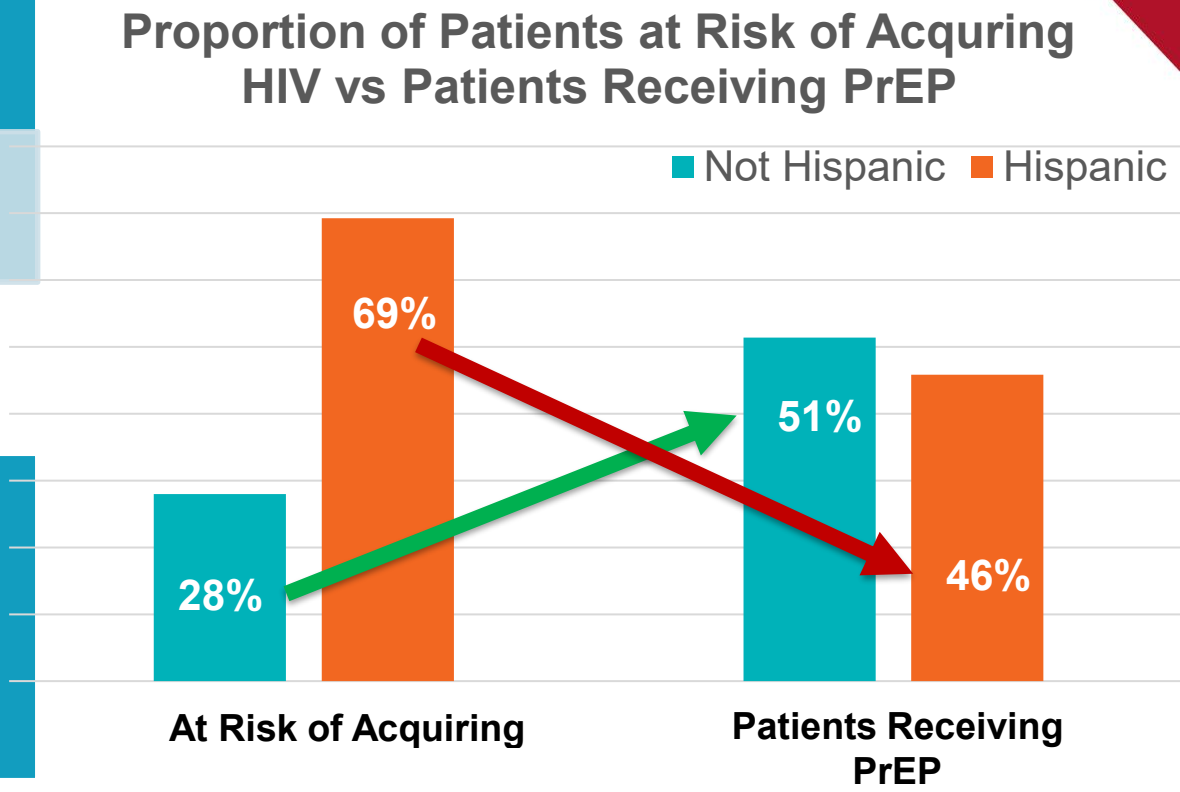
PrEP Gap Locally (Omaha, NE)

OneWorld

(Jan 1-June 30, 2024)

Evaluate missed opportunities for PrEP

"At Risk" cohort – patients screened for or with a positive STI, IVDU, receiving nPEP, or new HIV diagnosis



Witt, et al. In Progress. 2025.

UNMC SCC PrEP Demographics

Demographics	%
Age (years)	
< 27 years	13%
27 – 54 years	68%
> 54 years	19%
Race	
White	85%
Black	12%
Asian	3%
Ethnicity	
Non-Hispanic	87%
Hispanic	13%
Substance Use Disorder*	7%

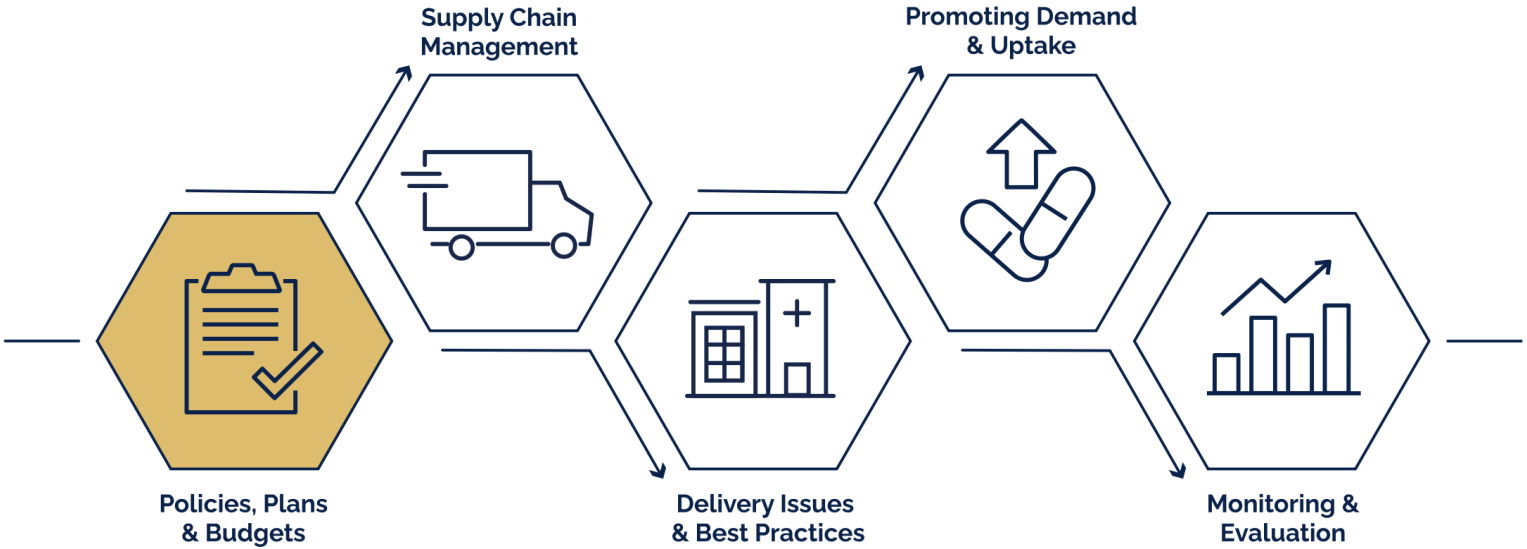
Demographics	%
Insurance	
Commercial	82%
Medicaid	11%
Medicare	3%
Veteran's Affairs	2%
Uninsured	2%
PrEP Agent	
F/TDF	87%
Daily	83%
On-Demand	17%
F/TAF	11%
IM CAB	2%

*All patients with substance use disorder endorsed regular methamphetamine use

Potential Approaches to Removing Barriers to PrEP

Key Barriers	Potential Approaches to Removing Barriers
Awareness of PrEP	• Patient and provider education • Improved communication between providers
Perceived risk for HIV acquisition	• Patient and provider education
Stigma	• Improved cultural humility via education and advocacy • Improved communication and understanding between patient and provider
Provider bias, distrust of healthcare system	• Patient and provider education • Addressing systemic biases via education, advocacy, etc.
Access to medical care	• Extending access to PrEP (e.g., pharmacies, mobile clinics, emergency rooms, substance use clinics, correctional facilities, etc.) • Leveraging technology to improve access (e.g., telemedicine) • Addressing competing priorities (e.g., food, shelter, safety, other healthcare, childcare, etc.)
Access to financial assistance	• Help navigating financial aid options
Adverse events	• Patient and provider education

Roadmap to PrEP Success



Policies, Plans, and Budget

Regulatory Requirements

- Any medical provider can prescribe PrEP
- Determine need for Collaborative Practice Agreement

Budgeting

- Start-up costs, operational expenses, and funding sources
  - Potential Funding Sources
    - Rural Health Clinics - ruralhealthinfo.org/topics/rural-health-clinics/funding
    - Federal Grant Funding NACHC - nachc.org/policy-advocacy/health-center-funding/federal-grant-funding
    - Gilead, ViiV, etc. - check their advocacy sections on their website for potential grant funding opportunities

UNMC SCC PrEP Collaborative Practice Agreement

2015
- CPA established

2016
- PharmD led PrEP
- 3 PrEP patients

2023
- 2 PharmDs
- ~150 PrEP patients

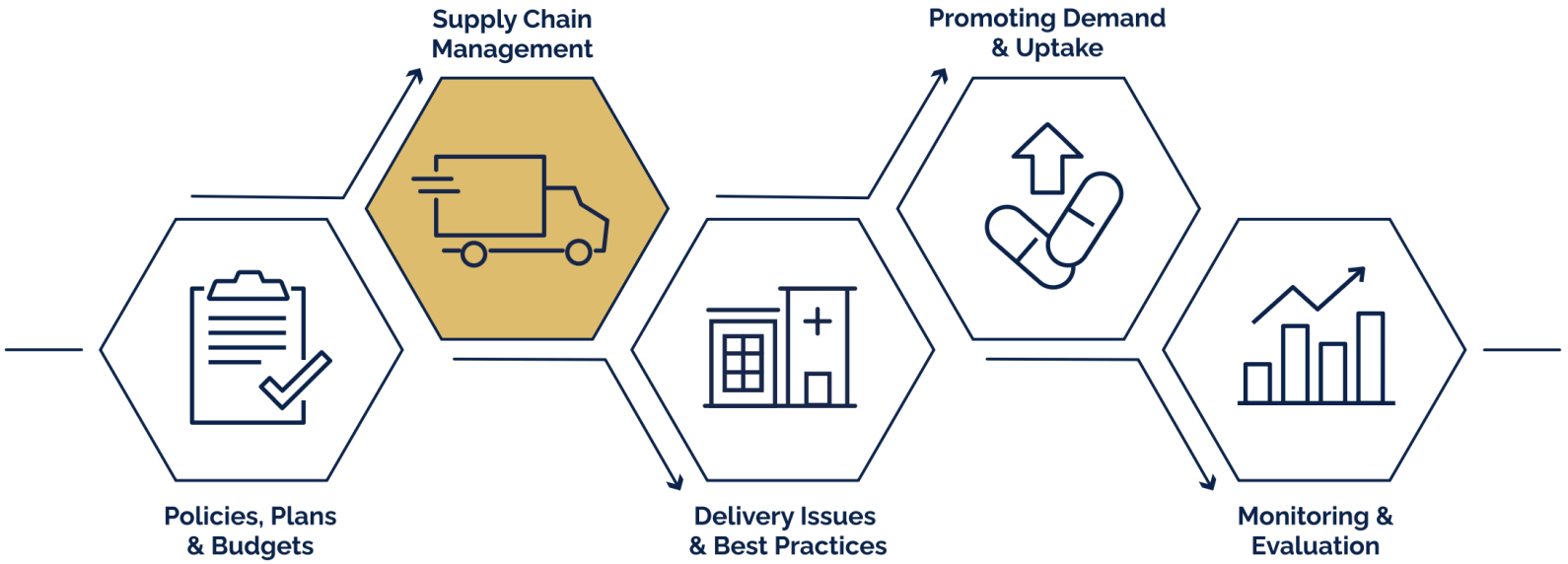
PrEP

- Direct patient appointments
- Provider referrals
  - Internal (UNMC)
  - External institutions
- Community outreach

PEP

- Provider referrals
  - Emergency Department
- Direct patient appointments

Roadmap to PrEP Success



Medication Acquisition Costs

Formulation (LA)	Cost/Unit	Cost/Year
Cabotegravir		
Oral (CAB – TheraCom)	Free	Free
Injection (every 2 months)	$3,700	$22,200
Administration Fee	$225	$1,350
Lenacapavir		
Oral (LEN – pharmacy Rx)	$705*	$2820*
Injection (every 6 months)	$11,290	$22,580
Administration Fee	$225	$450
Formulation (Oral)		
F/TDF (generic)	$69/month	$828
F/TAF	$1,446/month	$17,592

All prices are reported as WAC (wholesale acquisition cost)

*Only used for PO lead-in or possible bridging therapy

Laboratory Associated Costs

Lab	Frequency	Cost/Lab	PrEP Annual Cost
POC HIV Test	Baseline & Q2-6 Months	$25	$50-$150
HIV RNA*	Baseline & Q2-6 Months	$450	$900-$2700
CMP	Baseline, 3 Months, then QYear	$200	$600
HBV serologies	Baseline, Annually (IDU, if applicable)	$250	$250
HCV Ab	Baseline, Annually (IDU, MSM)	$125	$125
Syphilis Ab/RPV	Baseline, Q3-6 Months	$75	$150-$300
CT/GC Screening	Baseline, Q3-6 Months	$300/site	$2,700
Total Annual PrEP Lab Cost (Gross)			$3,925

*We don't routinely do RNAs with oral PrEP; Q2 months for CAB; Q3-6 months for LEN

PrEP Cost for Your Patients

Total Annual PrEP Costs (Gross)				
	CAB LA	LEN	F/TDF	F/TAF
Annual Lab Costs	$6,275	$4,775	$3,925	$3,925
~~Annual Drug Costs~~	~~$23,500~~	~~$25,850~~	~~$828~~	~~$17,592~~
~~Annual PrEP Costs~~	~~$29,825~~	~~$30,625~~	~~$4,753~~	~~$21,517~~

- Most drug costs can be fully mitigated by secondary cost-sharing options
- Cost burden is from labs and administration fees +/- provider/visit fees
- Costs typically apply to deductible and max out-of-pocket

Cost Sharing Support Options

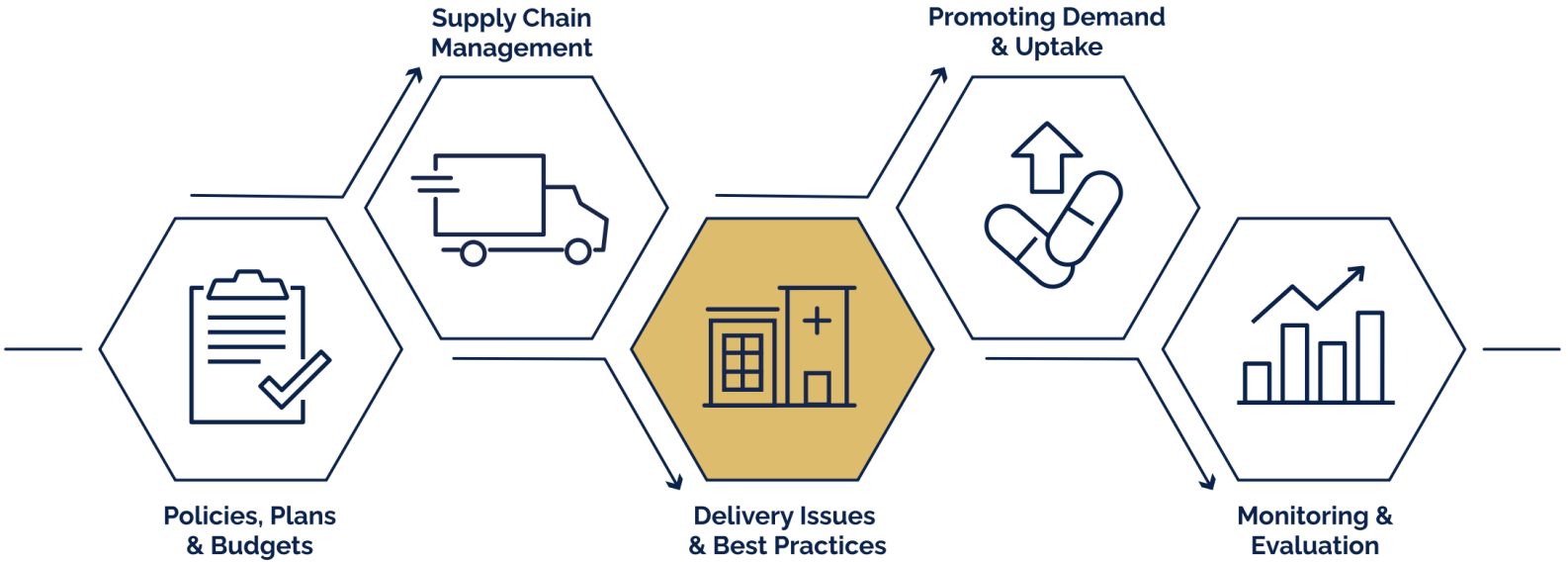
Cost-Sharing For Commercial Insurance (ex-Federal coverage; Medicare, Medicaid, VA/Gov)

Drug	Cost-Sharing Support	Program Access	Benefit Amount	Administration Support	Financial Requirements
CAB	Savings Program (https://www.viivconnect.com/for-providers/financial-support/)	Pharmacy or Medical	$13,000/yr	$100/injection	None
			$7,850/yr	$50/injection Up to $350/yr	
LEN	Advancing Access Program (https://www.gileadadvancingaccess.com/)	Pharmacy or Medical	$8,000/yr	$100/injection	
F/TDF F/TAF		Pharmacy	$7,200/yr	N/A	

Alternative Cost-Sharing For Commercial, Medicare, or VA/Gov Insurance (Grants)

Program*	Benefit	Eligibility	Coverage Types	Notes
Good Days	$10,000/yr	FPL ≤500%	Medicare, VA/Gov	www.mygooddays.org
Patient Advocate Foundation	$7,500/yr	FPL ≤400%	Any Insurance	copays.org
PAN Foundation	$3,600/yr	FPL ≤500%	Medicare	www.panfoundation.org

Roadmap to PrEP Success



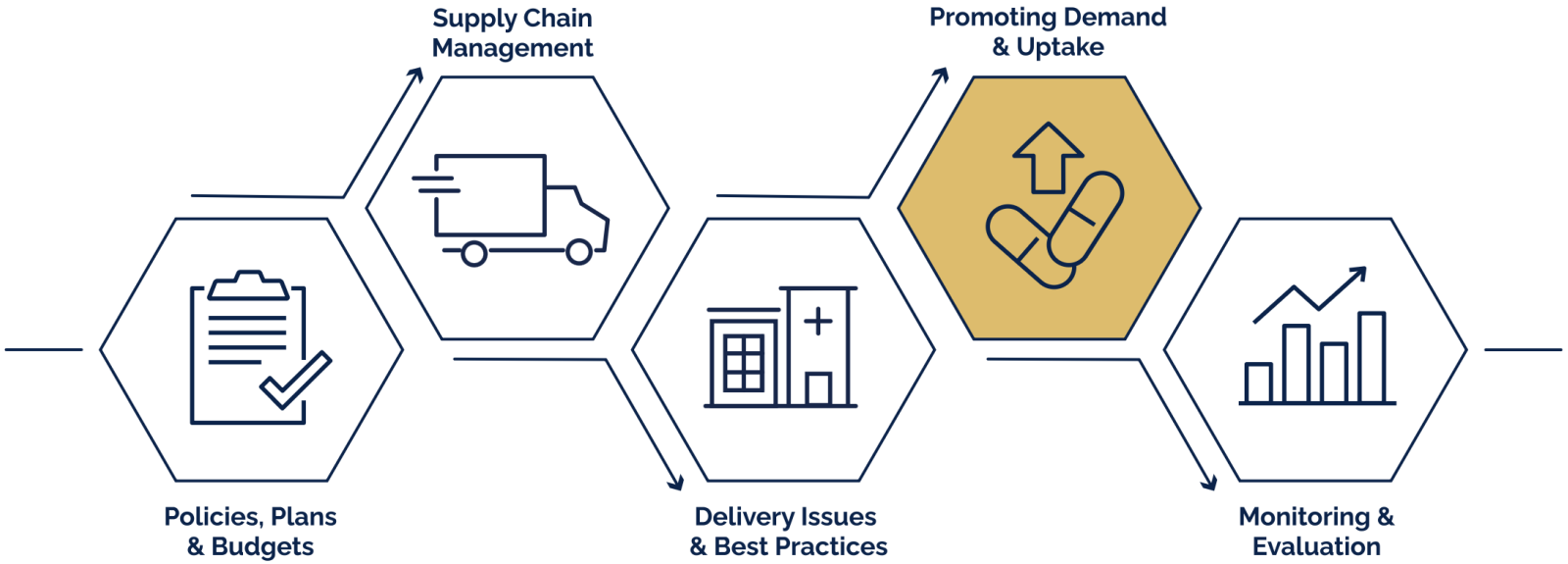
Best Practices – Programmatic

1. **Establish standard operating procedures and process flowcharts**
   - Help to ensure process consistency between staff and/or staff transition/training
2. **Establish billing support staff and processes**
   - Who will perform coverage determination?
   - Who will track reimbursement (third party and patient cost-sharing)
3. **Ensure drug access channels are open**
   - Institutional formulary approval
   - Distributor access
4. **Take an interdisciplinary approach to care**
   - Clinical
   - Pharmacy
   - Billing
   - Case Management – insurance coverage, transportation support, etc.
5. **Engage EHR technical support early**
   - Treatment plan builds
   - Patient tracking builds
   - Reminder system capacity
6. **Fiscal monitoring**
   - Track treatment financial metrics – profit/loss
   - Leverage 340B status if applicable

Best Practices – Patient Care

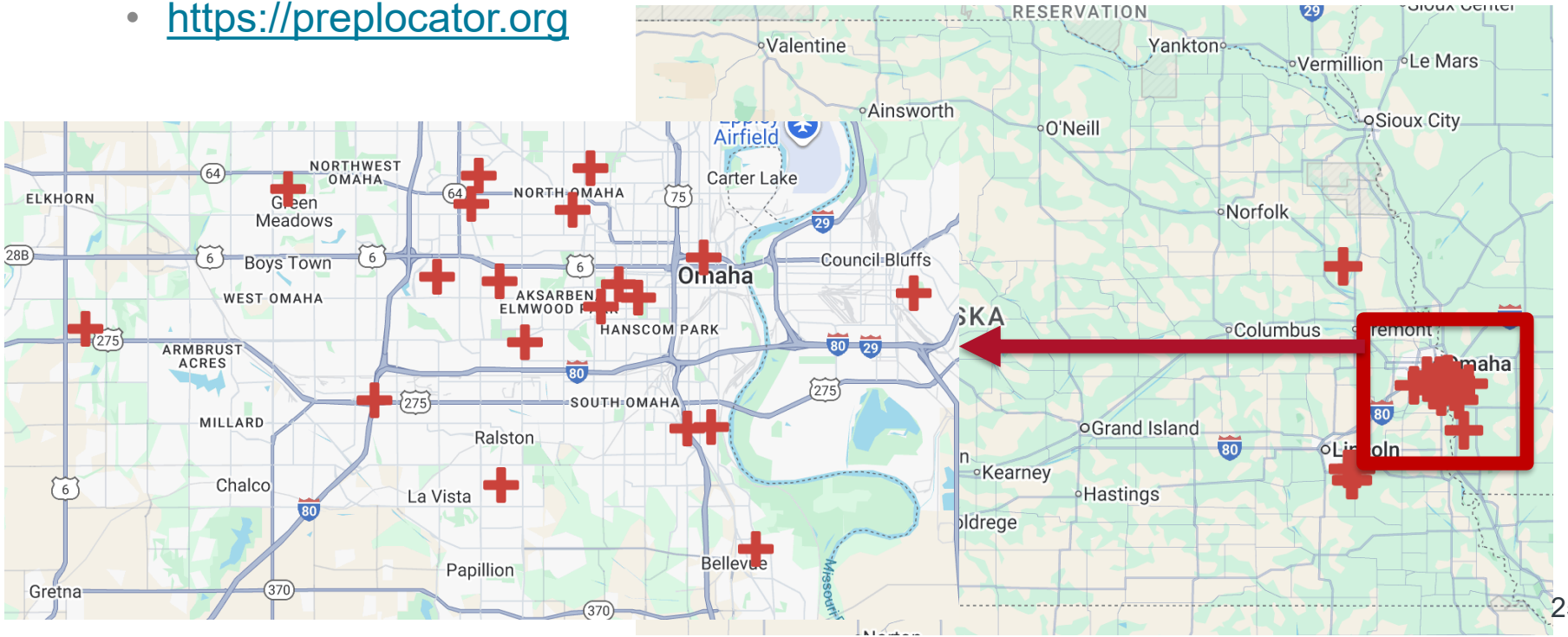
1. **Implement medical protocols**
   - PrEP administration: cdc.gov/hivnexus/hcp/prep/index.html
   - Laboratory testing
     - How will you obtain timely results? In house vs send out phlebotomy?
   - Emergency situations – adverse events, need for nPEP, etc.
2. **Ensure comprehensive patient education and support**
   - Implement prescribing and monitoring protocols
     - See PrEP ECHO session from Dr. Jenn Davis
   - Educational materials for both patients and providers
     - CDC PrEP Brochure: cdc.gov/hiv/media/pdfs/2024/04/cdc-hiv-stsh-prep-brochure-English.pdf
   - Potential to utilize PrEP Navigators/Champions
     - Assist patients with financial questions, coordination with patients and promoting retention in care (e.g. scheduling visits, follow-ups after missed appointments, etc)
3. **Consider if you'll offer any additional services**
   - Non-occupational post-exposure prophylaxis
   - Doxycycline post-exposure prophylaxis (doxy PEP)

Roadmap to PrEP Success

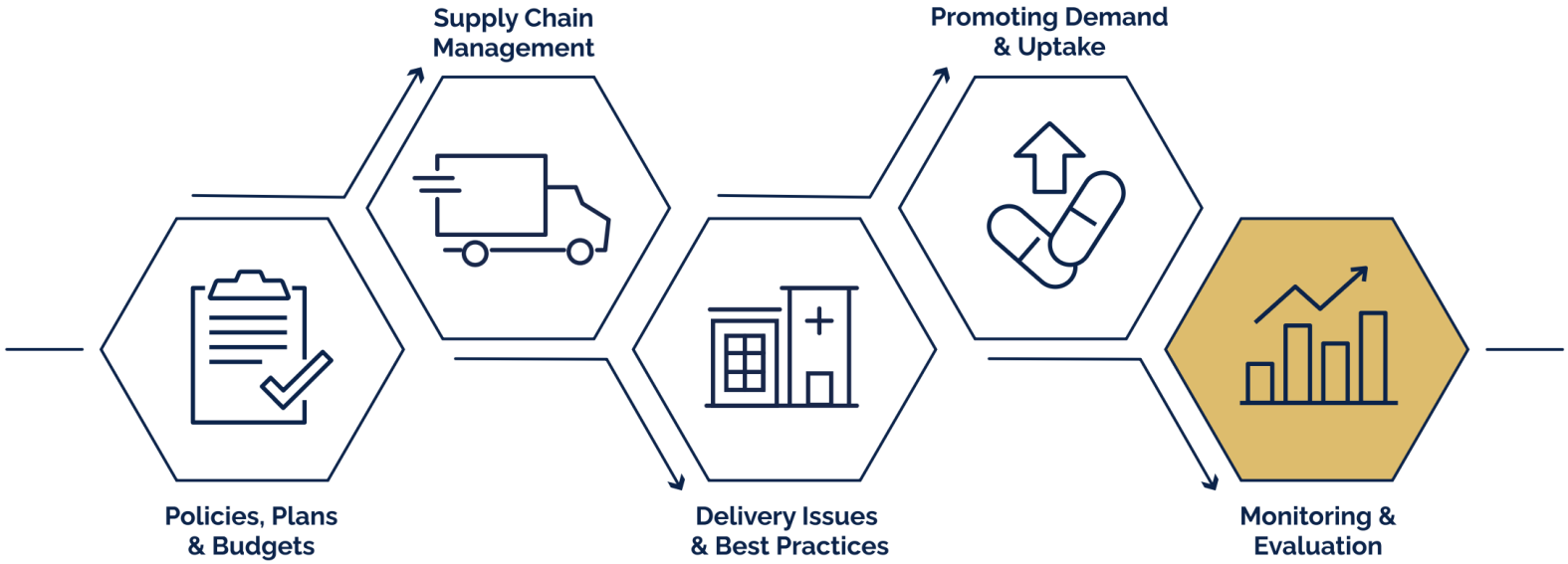


PrEP Locator

- If you're establishing a PrEP clinic, would recommend adding your clinic to this resource
  - https://preplocator.org



Roadmap to PrEP Success



Potential Metrics to Monitor

- Proportion of patients who fill their first PrEP Rx
- Number of missed PrEP appointments
- HIV PrEP persistence or retention in care
- Financial metrics*
- Scalability and staff effort requirements*

Data will be presented at IDWeek 2025 in a few weeks!

*Havens, et al. – focus on LAI program for treatment, but similar metrics could be tracked for PrEP

**O'Neill, et al. – effort required to scale up a LAI treatment program, need for dedicated staff

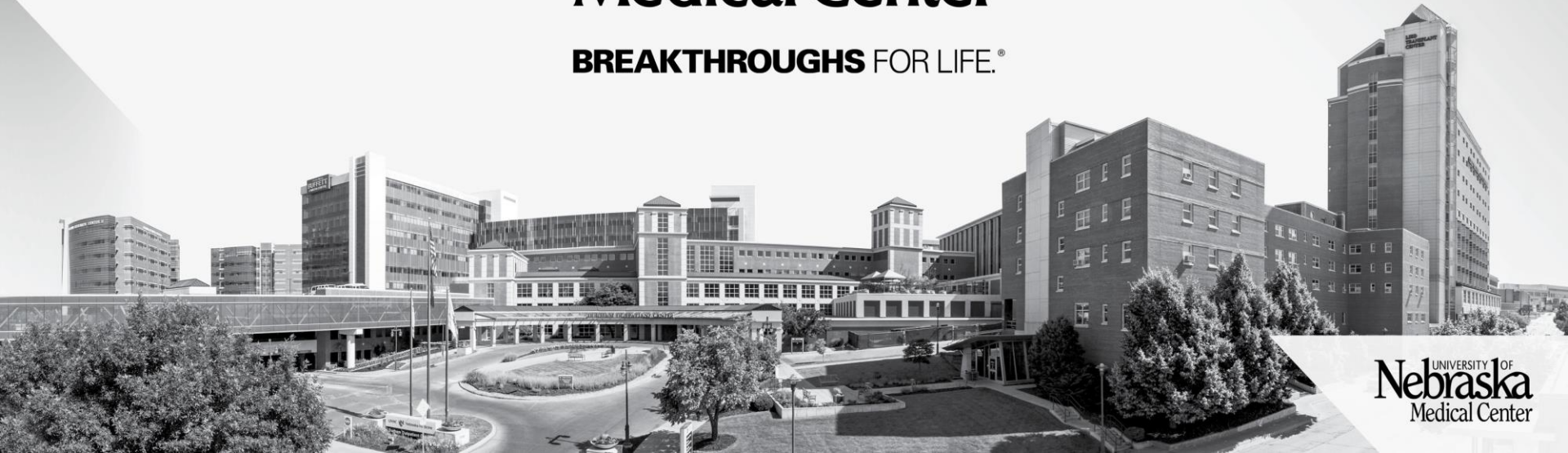
Questions | Discussion

Shawna: shsunagawa@unmc.edu

Josh: jhavens@unmc.edu

University of Nebraska Medical Center℠

BREAKTHROUGHS FOR LIFE.®



University of Nebraska Medical Center