INTEGRATING PHARMACIST-LED HIV PEP SERVICES THROUGH COLLABORATIVE CARE

Daniya S. Mathew, PharmD, AAHIVP
Clinical Pharmacy Specialist – Ambulatory Pharmacy Support Services

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Northwell Health

DISCLOSURE

I have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

ABBREVIATIONS

Medication Abbreviations	Additional Abbreviations	
• BTG: Bictegravir • TDF: Tenofovir Disoproxil Fumarate • TAF: Tenofovir Alafenamide Fumarate • DTG: Dolutegravir • RAL: Raltegravir • FTC: Emtricitabine • DRV: Darunavir • COBI: Cobicistat • 3TC: Lamivudine	• PrEP: Pre-exposure prophylaxis • PEP: Post-exposure prophylaxis • HIV: Human immunodeficiency virus • ARV: Antiretroviral • OSHA: Occupational Safety and Health Administration	• ALT: Alanine transaminases • AST: Aspartate aminotransferase • INSTI: Integrase strand transfer inhibitor • NRTI: Nucleoside reverse transcriptase inhibitor • CrCl: Creatinine clearance • JV: Joint Ventures • ASC: Ambulatory surgery center

PHARMACIST OBJECTIVES

- Explain the New York State Board of Regents standing order and protocol for pharmacist-initiated HIV post-exposure prophylaxis (PEP), including scope of practice, legal considerations, and documentation requirements
- Demonstrate effective pharmacist collaboration with providers, health-system pharmacies, and patients to initiate PEP and ensure continuity of care
- Analyze clinical and operational challenges pharmacists may encounter when initiating PEP and coordinating care

PHARMACY TECHNICIAN OBJECTIVES

- Explain the role of PEP in HIV prevention and the importance of timely access to therapy

- Demonstrate effective pharmacist collaboration with health-system pharmacies and patients to initiate PEP and ensure continuity of care

POST-EXPOSURE PROPHYLAXIS

BACKGROUND

- HIV is a virus that attacks CD4 T-cells, weakening the immune system and increasing one's risk of other infections
- It is a lifelong, non-curable disease, but is manageable with ARV
- HIV establishes infection within 24 – 36 hours after exposure
- PEP prevents HIV when started within 72 hours of potential exposure

CDC. *HIV Diagnoses, Deaths, and Prevalence*. 2025

BACKGROUND CONTINUED

- The first iteration of the U.S. Public Health Service (USPHS) recommendations advocating for the use of HIV occupational postexposure prophylaxis (PEP) dates to 1996
- HIV occupational PEP guidelines were updated multiple times with the most recent of these published as the 2025 HIV Occupational PEP Guidelines
- All health care facilities and clinics should have policies and procedures in place to ensure that appropriate mechanisms are available for timely management
- Occupational exposures, particularly those known to involve risk for HIV transmission, are urgent medical matters, and clinicians should be familiar with updated HIV occupational PEP guidelines

CDC. *HIV Diagnoses, Deaths, and Prevalence*. 2025

PEP CATEGORIES

PEP is for emergency situations, started within 72 hours (ideally 24 hours) of potential HIV exposure and continued for 28 days

Nonoccupational PEP (nPEP): exposure to nonintact skin or mucous membranes that presents risk for HIV transmission (source has HIV without viral suppression or viral suppression information is unknown)

Unprotected sexual intercourse, shared needles, syringes or injection devices, sexual assault

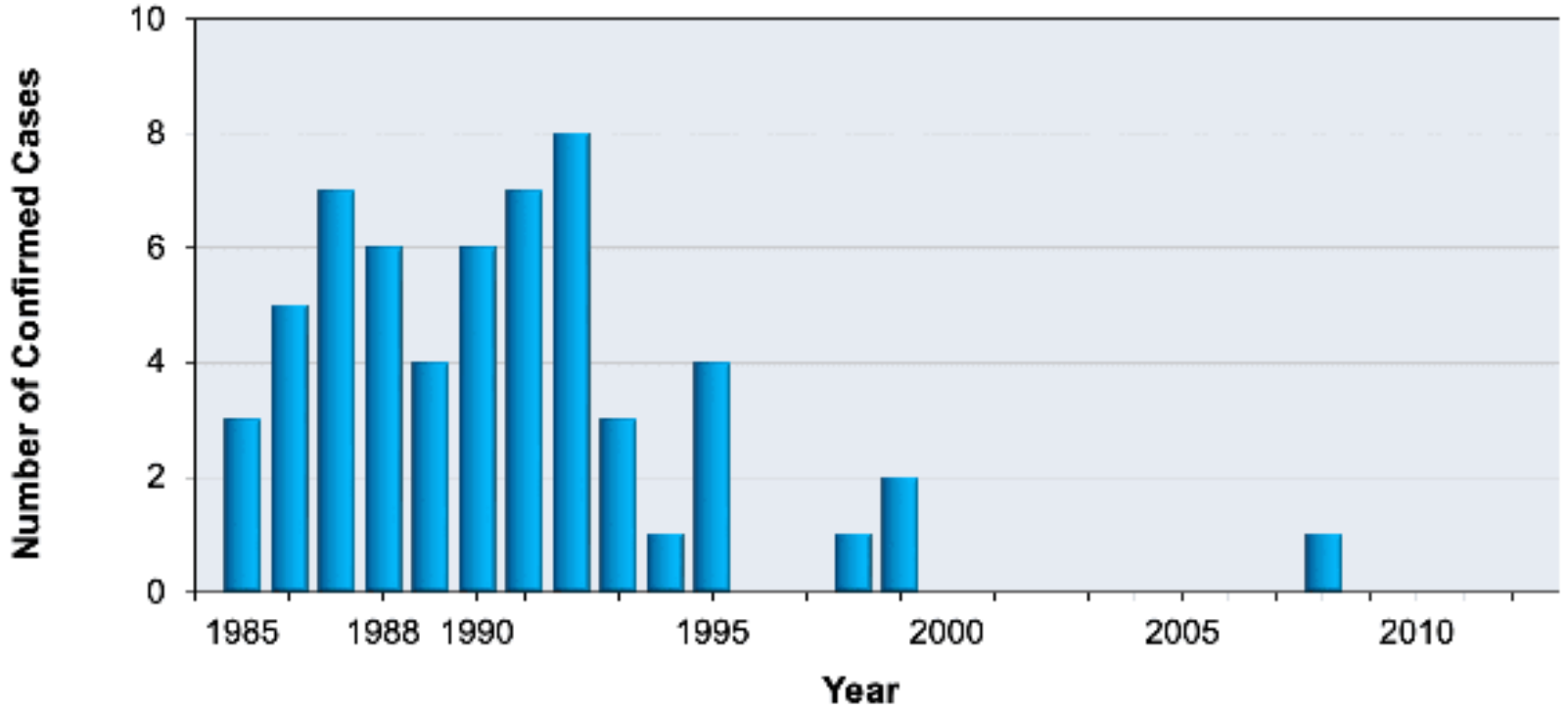
Occupational PEP (oPEP): All paid and unpaid people working in healthcare settings exposed to infectious body substances or contaminated equipment/surfaces

Needlestick, cut, contact of broken skin or mucous membrane with infectious tissue (blood, semen, vaginal fluid, etc.)

Kofman AD et al. *Infect Control Hosp Epidemiol.* 2025

Tanner MR et al. *MMWR Recomm Rep*. 2025

HISTORY OF OCCUPATIONAL HIV TRANSMISSION IN THE UNITED STATES



Joyce MP, Kuhar D, Brooks JT. MMWR Morb Mortal Wkly Rep. 2015;63:1245-6.

RISK FACTORS FOR HIV SEROCONVERSION IN HEALTH CARE WORKERS

Risk Factor	Adjusted Odds Ratio
Deep Injury	15.0
Visible Blood on Device	6.2
Needle in Source Vein/Artery	4.3
Postexposure Prophylaxis with Zidovudine	0.19

Cardo DM, Culver DH, Ciesielski CA, et al. N Engl J Med. 1997;337:1485-90

RATIONALE FOR HIV OCCUPATIONAL PEP

- A landmark study published in 1997 provided the first convincing evidence that HIV occupational PEP significantly decreased the risk of occupational HIV acquisition following a needlestick injury.

- In this report, investigators performed a case-control study of needlestick injuries involving health care workers and demonstrated that zidovudine PEP, which was typically taken for at least 4 weeks, reduced the risk of HIV seroconversion by 81% if implemented within 4 hours of the exposure.

- This study, along with CDC recommendations, led to the widespread use of antiretroviral therapy for HIV occupational PEP in the late 1990s.

Cardo DM, Culver DH, Ciesielski CA, et al. N Engl J Med. 1997;337:1485-90

RISK ASSESSMENT OF OCCUPATIONAL EXPOSURE EVENT

1. HIV status of the source patient
2. Type of body fluid involved in the exposure
3. Nature of the exposure (percutaneous, mucous membrane, or contact with nonintact skin)
4. Timing of when the exposure occurred

If the exposure is deemed an occupational exposure toa source patient known to have HIV, additional information should be obtained, such as

- Source patient's most recent plasma HIV RNA level
- Current ARV treatment (if any)
- History of HIV drug resistance
- Transmission of hepatitis B or hepatitis C virus

RELATIVE RISK OF FLUIDS IN OCCUPATIONAL EXPOSURE TO HIV

Relative Risk of Fluids in Occupational Exposure to HIV	
Category of Infectivity	**Fluid**
Infectious Fluids	Blood
	Visible bloody body fluids
Potentially Infectious Body Fluids	Semen and vaginal secretions
	Cerebrospinal fluid
	Synovial fluid
	Pleural fluid
	Peritoneal fluid
	Pericardial fluid
	Amniotic fluid
Not considered infectious	Nasal secretions
	Saliva
	Sputum
	Vomitus
	Feces
	Urine
	Sweat and tears
*Note: although semen and vaginal secretions are known to be infectious for HIV in sexual exposures, they have not been implicated in transmissions in the occupational setting.	

TIMING FOR INITIATION OF ARV THERAPY

- Health care workers with an indication for HIV PEP should receive their first dose of antiretroviral medications as soon as possible after the exposure event, and it may be administered up to 72 hours after the exposure.

- Animal studies have shown that HIV PEP is most effective when started as early as possible after exposure. In some situations, significant delays occur, usually because the health care worker failed to initially consider the exposure event significant enough to seek evaluation.

- If the delay extends past 72 hours, HIV PEP is likely to be less effective, and expert consultation should be obtained

PEP REGIMENS

Duration of therapy: 28 days

Preference and Regimen	Generic	Branded Combinations
Preferred: INSTI+2 NRTIs	BIC/FTC/TAF	Biktarvy®
	DTG + [FTC **or** 3TC] + [TAF **or** TDF]	Tivicay® + Descovy® Tivicay® + Truvada® Tivicay® + Cimduo®
Alternative: Boosted protease inhibitor + 2 NRSTIs	[DRV and COBI or DRV and RTV] + [FTC or 3TC] + [TAF or TDF]	Symtuza® (DRV/COBI/FTC/TAF) Prezcobix® (DRV/COBI) + (Descovy® **or** Truvada® **or** Cimduo®)

Tanner MR et al. *MMWR Recomm Rep*. 2025

PEP REGIMEN CONSIDERATIONS

PEP Regimen	Considerations/Adverse Effects
Biktarvy (BIC/FTC/TAF)	• Avoid if CrCl <30 mL/min • One pill once daily – convenient • **INSTIs adverse effects: Headache, insomnia, diarrhea, weight gain**

Tivicay (DTG) + **Descovy** (FTC/TAF)	• **DTG (INSTI):** No renal dose adjustments required
	• **Descovy:** Avoid if CrCl < 30 mL/min
	  • TAF: Greater metabolic adverse effects (long-term)
	• **Truvada:** Avoid if eGFR < 60 $\mathrm{mL/min/1.73^2}$
	  • TDF: proximal renal tubulopathy (long-term)
	• **Cimduo:** avoid if CrCl < 50 mL/min

Tivicay (DTG) + **Truvada** (FTC/TDF)	
Tivicay (DTG) + **Cimduo** (3TC/TDF)	

Tanner MR et al. *MMWR Recomm Rep*. 2025

PEP REGIMEN CONSIDERATIONS CONTINUED

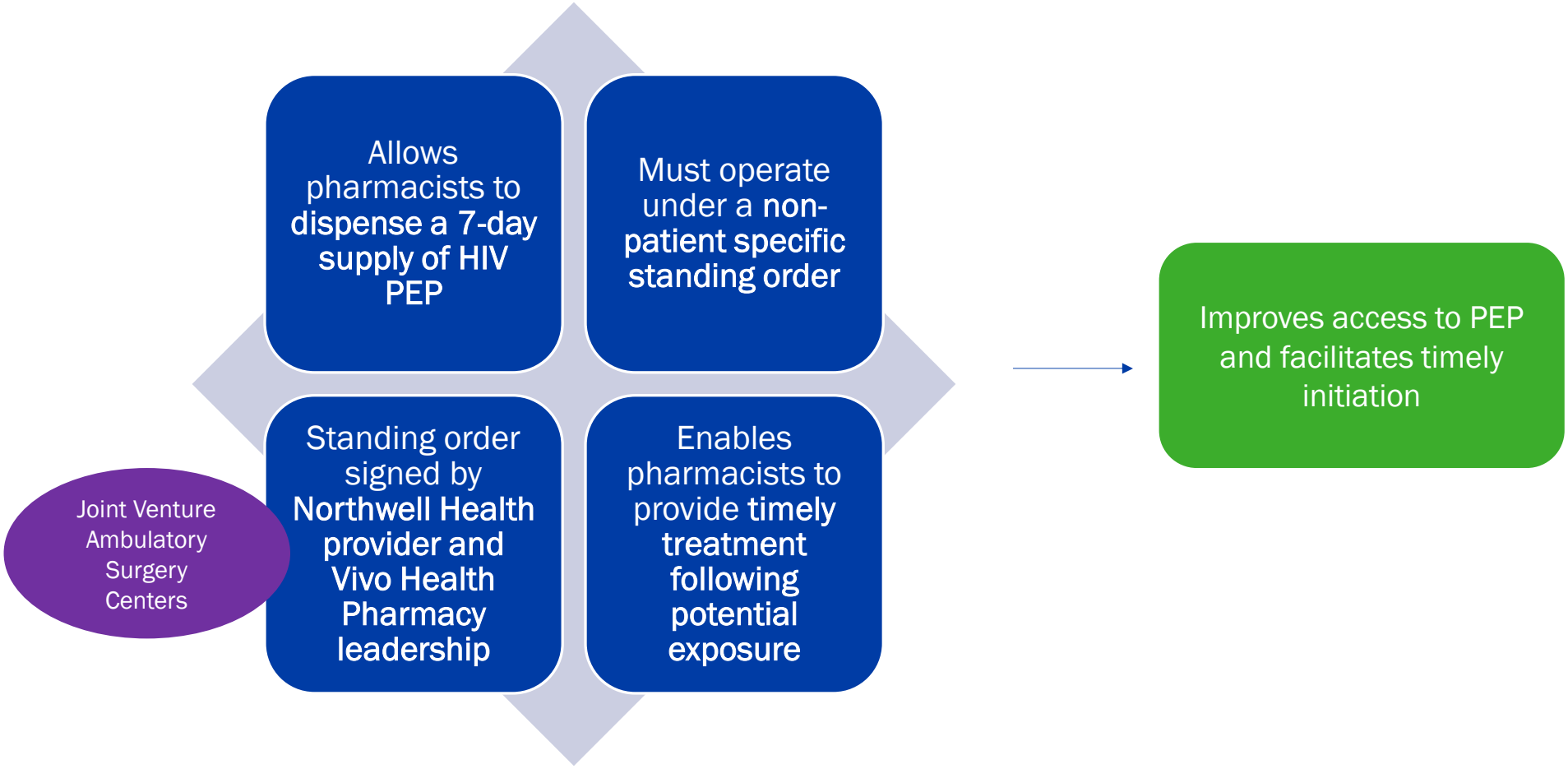
PEP Regimen	Considerations/Adverse Effects
Symtuza (DRV/COBI/FTC/TAF) **Prezcobix** (DRV/COBI) **+** **(Descovy or Truvada or Cimduo)**	• **DRV:** Drug-drug interactions (major CYP3A4 substrate and inhibitor) • Caution with sulfa allergy and DRV • **Protease inhibitor adverse effects: angioedema, hepatic dysfunction, metabolic abnormalities** • **Symtuza:** Avoid if CrCl < 30 mL/min

Tanner MR et al. *MMWR Recomm Rep*. 2025

PEP REGIMEN CONSIDERATIONS CONTINUED

Comorbid conditions (renal, hepatic function, HBV co-infection)	Pregnancy	Drug interactions	Previous exposure to ARV regimens
Source's history (drug resistance)	Pill burden and dosing frequency	Side effects	Cost and access

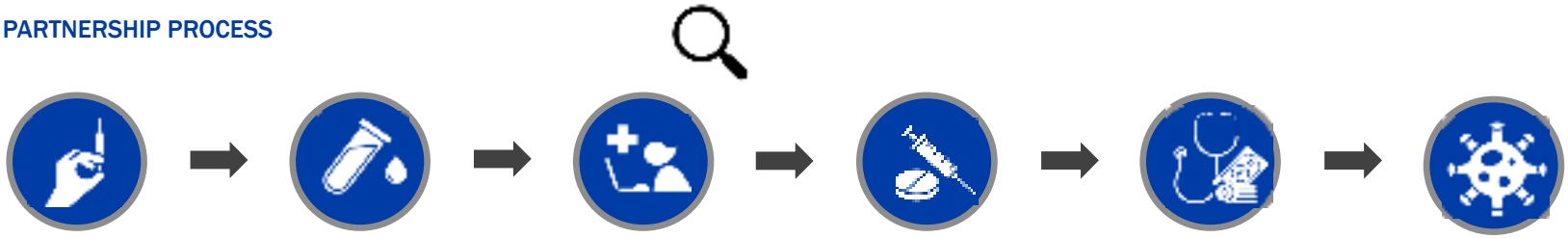
POLICY OVERVIEW: NEW YORK STATE STANDING ORDER FOR PHARMACIST-INITIATED PEP



JOINT VENTURE AMBULATORY SURGERY CENTERS

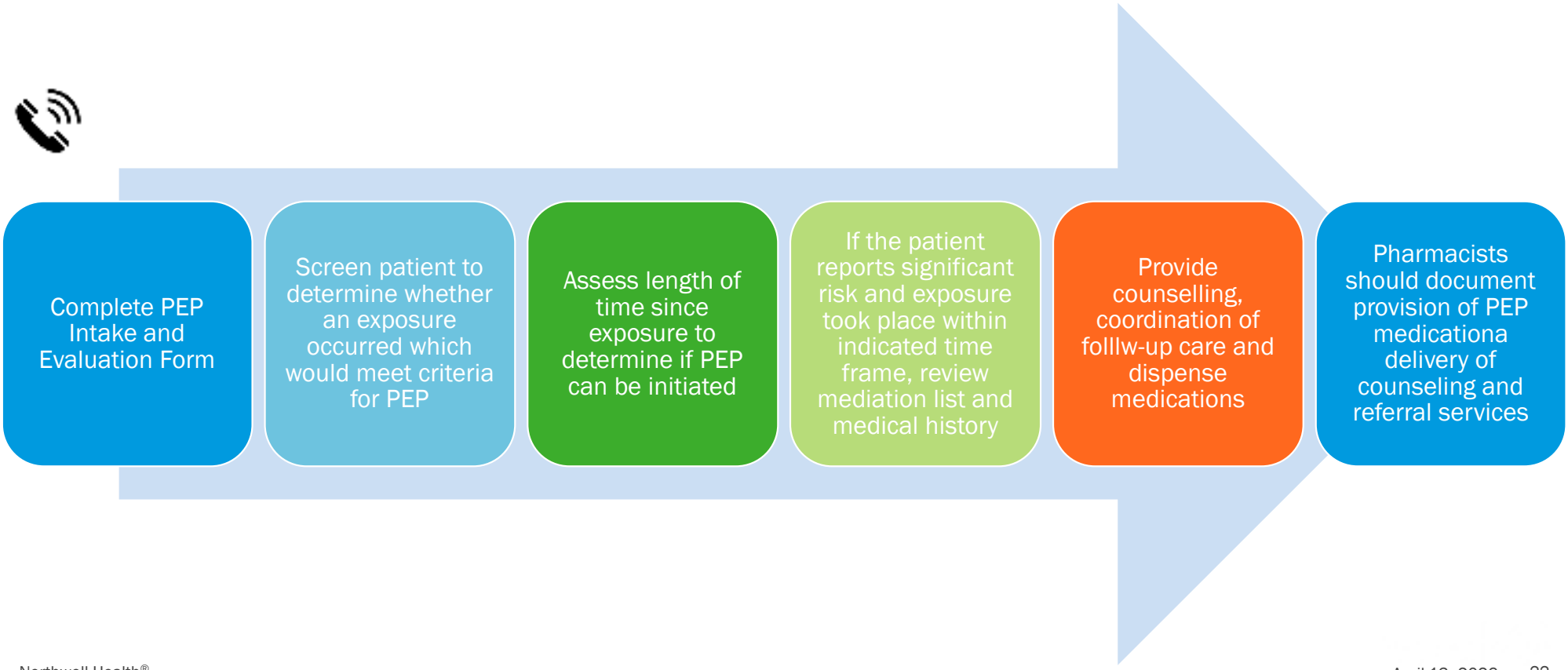
OCCUPATIONAL EXPOSURE PARTNERSHIP WITH VIVO HEALTH PHARMACY & DIVISION OF INFECTIOUS DISEASE

PARTNERSHIP PROCESS



1. Occupational hazard occurs at a JV ASC
2. Lab draw completed for patient & employee – results determine if drug should be continued or stopped
3. JV ASC employee joins VIVO telehealth pharmacy consult
4. VIVO prescribes & dispenses Post-Exposure Prophylaxis for JV ASC employee
5. VIVO bills ASC/ employer for the drug
6. Partner with Division of Infectious Disease to ensure continuity of care

VIVO HEALTH PHARMACIST TELEHEALTH CONSULT



PEP MEDICATIONS TO BE DISPENSED
ADULTS 18 YEAR OF AGE OR OLDER

Preferred: INSTI+2 NRTIs	BIC/FTC/TAF	Biktarvy®
	DTG + [FTC] + [TAF **or** TDF]	Tivicay® + Descovy® Tivicay® + Truvada®

PEP MEDICATIONS TO BE DISPENSED
ADULTS 12 YEARS OF AGE OR OLDER

Preferred: INSTI+2 NRTIs	RAL + [FTC] + [TAF **or** TDF]	Isentress® + Descovy® Isentress® + Truvada®

CLINICAL CHALLENGES IN PHARMACIST-INITIATED PEP

- Accurate exposure assessment
- Time-sensitive initiation
- Medication safety considerations (drug-drug interactions, allergies, comorbid conditions)

OPERATIONAL CHALLENGES IN PHARMACIST-INITIATED PEP

- Coordinate follow-up care
- Communication across collaborating teams
- Documentation requirements (patient evaluation, dispensing, referrals)
- Workflow integration into health system pharmacy operations
- Patient access barriers (delivery of medication within 72 hours of exposure)
- After hours occupational exposure
  - Ideally, ASC will direct employees with after-hours exposure to an ED or urgent care
  - If the employee refuses, ASC will contact telehealth pharmacy team to schedule a visit the next morning
  - Late prescriptions sent after STAT delivery window for same day
    - Patient can pickup medication from Vivo Pharmacy or STAT delivery scheduled for the following morning

JOINT VENTURE AMBULATORY SURGERY CENTERS

OCCUPATIONAL EXPOSURE PARTNERSHIP WITH VIVO HEALTH PHARMACY & DIVISION OF INFECTIOUS DISEASE

PARTNERSHIP BENEFITS

Improved staff satisfaction as they can be treated virtually, faster, & with improved drug efficacy

Cases on average per ASC no longer interrupted / rescheduled due to an occupational exposure

Improved patient satisfaction by no longer needing to reschedule cases if an occupational exposure occurs

Preventative treatment is expeditiously coordinated and effectively initiated in accordance with guidelines

Improved employee confidentiality & connection for longitudinal care with an Infectious Disease provider

PHARMACIST-LED HIV PEP SERVICES

- Building the interdepartmental collaboration between VIVO Health Pharmacy, the HIV Service Line Program of the Division of Infectious Diseases and the Northwell JV Operations ASCs around occupational exposure protocol has resulted in improved efficiencies, employee satisfaction, and patient satisfaction.

- With the newly developed process with VIVO's telehealth pharmacy consulting, the employees no longer need to leave the center immediately for treatment.

- Additionally, the time to medication administration has decreased, improving treatment efficacy. This has allowed the ASCs to continue operations with minimal interruptions.

- Through the standing order protocol, pharmacists serve as the first point of access for timely PEP initiation, while partnering with physicians and nurse practitioners to ensure follow-up care, testing, and long-term risk-reduction strategies

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Vivo Health Pharmacy

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- U.S. Department of Health & Human Services, Center for Disease Control and Prevention Post Exposure Prophylaxis Guideline https://www.cdc.gov/hiv/basics/pep.html
- HIV Clinical Education Initiative PEP Hotline 866-637-2342. Training programs for pharmacist with continuing education credits are available at www.ceitraining.org
- Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States. Center for Disease Control and Prevention. https://stacks.cdc.gov/view/cdc/38856