

HIV Non-Occupational Post-Exposure Prophylaxis (nPEP) and Processes of Patient Care

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Last Updated: August 27, 2020

Disclosures

No conflicts of interest or relationships to disclose

Overview

- nPEP Guidelines
- Medication regimens
- In-practice barriers to nPEP
- Obtaining and payment for nPEP medication
- Possible process solutions
- nPEP resources

nPEP DHHS Guidelines-April 2016

PEP STEPS

Moderate to high risk exposure → start nPEP

Start nPEP ≤ 72hs after exposure for greatest benefit

HIV Ag/Ab or Ab rapid test

Screening for other STIs, HepC, HepB, pregnancy

Determine regimen (all contain 3 drugs and taken 28 days total)

Follow up to determine tolerability, adherence, necessity, labs

See Dr. Harrington's ECHO PEP Presentation (May 2016) on MWAETC ECHO YouTube page at <https://youtu.be/Aj2PwEMpnQI>

Estimated Per-Act Risk for Acquiring HIV From an Infected Source, by Exposure Act

Exposure Type	Rate for HIV acquisition per 10,000 exposures
Blood transfusion	9,250
Receptive anal intercourse	138
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Insertive anal intercourse	11
Receptive penile-vaginal intercourse	8
Insertive penile-vaginal intercourse	4
Receptive or insertive oral intercourse	Low
Biting, spitting, throwing fluids, sharing sex toys	Negligible (technically possible, but unlikely and not well documented)

nPEP 28-day Regimens

Patient Group	Preferred/alternative	Regimen
Adults and adolescents ≥ 13yrs, including pregnant women, CrCl > 60	Preferred	TDF/FTC + RAL or DTG*
	Alternative	TDF/FTC + r/DRV
Adults and adolescents ≥ 13yrs, including pregnant women, CrCl ≤ 59	Preferred	AZT/3TC + RAL or DTG*
	Alternative	AZT/3TC + r/DRV
Children 2-12yr	Preferred	TDF/FTC + RAL
Children 4wk-2yr	Preferred	AZT/3TC + RAL or r/LPV
Children birth-4wk	Call pediatric specialist	

*DHHS Adult and Adolescent GL (Dec 2019): DTG as *Alternative* (instead of *Not Recommended*) for initial therapy in women of childbearing age.

DHHS Perinatal GL (Dec 2019): DTG as *Preferred* in *all* pregnant women, regardless of gestational age and *Alternative* in women trying to conceive.

Patient Case: Alice

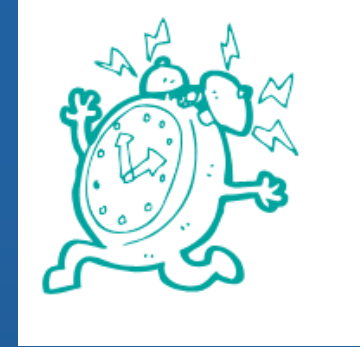
- 24yr old female presents to the ED 73hrs after several high-risk sexual encounters at a party, and does not use contraception because she “wouldn’t mind getting pregnant”. She does not like taking medication. It is Friday night.
- Interactive Q: What would you give her for nPEP?
 - A. Nothing, it’s past 72hrs
 - B. TDF/FTC + RAL
 - C. TDF/FTC + DTG
 - D. Phone a friend (expert to expert consultation)



Patient Case: Alice Continued

Friday

- Alice and provider decide on **TDF/FTC + DTG**
- Gets **1st dose from ED pharmacy AND 3-day nPEP take-home pack**
- 2 prescriptions are written for **30 days**



Monday

- PrEP/PEP coordinator** calls Alice (ED RN had Alice fill out ROI and left message for coordinator)
- PrEP/PEP coordinator and Alice fill out **PAP applications** online & by phone
- Monday afternoon **PAP apps approved**, and funds sent to pharmacy for filling
- Pharmacy must **order medications** for *next day* fill

Tuesday

- Alice picks up medication and takes **5th dose**

nPEP in Practice: Barriers Follow-Up of Patient

- Adherence to taking full PEP regimen= 40-57%
 - Lowest= adolescents, sexual assault, female
- Less likely to follow up at clinic:
 - Older age
 - Out of pocket payment (no insurance)
 - Sexual assault
- Starter packs vs full 28-day regimen dispensed:
 - Outcomes better when offered full 28-day course at presentation (fewer refusals, higher completion rates)
- Patient's mental health prevents follow up

nPEP in Practice: Barriers

Providers are not consistently prescribing nPEP

- Protocol and procedures not available
- Concern of drug side effects and viral resistance
 - nPEP guidelines not used
- Appropriate level of exposure risk not determined
 - Assuming HIV is not a problem

nPEP in Practice: Barriers

MWAETC nPEP Survey in Oregon

- Aim: determine nPEP barriers to access across urban and rural emergency departments and urgent care facilities
- 42 Emergency Departments, 63 Urgent Care managers and charge nurses surveyed across Oregon 6/2019 to 1/2020

Conclusions:

- ✓ Lack of nPEP practices, policies, and procedures, for high-risk exposure outside of sexual assault
- ✓ Poor communication within facilities, across health systems, and to external partners
- ✓ Low familiarity with nPEP community resources
- ✓ Prescribing that did not align with CDC guidelines

There is a significant need for training and education within Oregon Emergency Departments and Urgent Care Facilities

nPEP in Practice: Obtaining Medication

- Most Emergency Departments will have usual nPEP meds as 3-day take-home pack
- Pharmacies have HIV medications that are contracted with state ADAP
- Call patient's pharmacy ahead of time
 - Is medication in stock already?
 - Do you have to order medication and when will it be available?
 - Support staff will need to call pharmacy before patient visits



Where To Find the nPEP Meds: AIDS Drug Assistance Programs (ADAPs)

State	ADAP	Website
Alaska	Alaska ADAP	https://www.alaskanaiids.org/client-services/aids-drug-assistance-program-adap
Idaho	Idaho AIDS Drug Assistance Program (IDAGAP)	https://healthandwelfare.idaho.gov/Health/HIV,STD,Hepatitis/Section/HIVCare/tabid/391/Default.aspx
Montana	Montana Department of Public Health and Human Services ADAP	https://dphhs.mt.gov/Portals/85/publichealth/documents/HIV/STD/ADAPExtendedPharmacyDirectory.pdf
Oregon	CAREAssist	http://www.ramsellcorp.com/individuals/or.aspx
Washington	Early Intervention Program (EIP)	http://www.ramsellcorp.com/individuals/wa.aspx

Search for city under pharmacy locators on each ADAP website or call ADAP phone number to obtain pharmacy list

Pharmacist Prescribing nPEP in Oregon

- Oregon Board of Pharmacy approved pharmacist prescribing of nPEP with conditions (Aug 2020):
 - Continuing education (nPEP and trauma informed care)
 - State approved protocol use required
 - Geared toward retail pharmacists
- Improved access to evaluation, medication and follow up
- PrEP pharmacist prescribing may happen the near future



Payment for nPEP

- Each nPEP regimen ~\$4000.00 for one-month supply (without insurance)
- Private Insurance
 - Expect expensive cost-sharing
 - Consider deductibles, co-pays, prior authorizations, formulary restrictions
- Patient Assistance Programs (PAPs)
 - Manufacturer and non-manufacturer PAPs



Most patients will need assistance figuring out payment and filling out PAP applications

Manufacturer Patient Assistance Programs

Drug	Manufacturer	Contact	Website	Comments
Truvada (emtricitabine/TDF)	Gilead "Advancing Access"	Ph:800-226-2056 Fax:800-216-6857 M-F 9am-8pm EST	https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf	1. Fax enrollment form 2. Call 30min after faxing 3. Patient screened over phone 4.Approval voucher number given for pharmacy to fill
Tivicay (Dolutegravir)	Viiv Connect	Ph:844-588-3288 M-F 8am-11pm EST	https://www.viivconnect.com/portal/	1.Call or enroll online (24hr) 2.Receive voucher number and give to pharmacy *cannot have Medicare part D coverage
Isentress (Raltegravir)	Merck "Merck's Support"	Ph:800-727-5400 Fax: 800-528-2551 M-F 8am-8pm EST	https://www.merckhelps.com/docs/MPAP_Enrollment_Form_English.pdf	1. Provider and patient complete app together 2. Fax app with "Urgent" or "PEP" written on top -if form submitted by 2:30pm EST, med will be delivered to patient's home by 1:30pm EST next day

This information subject to change. Contact each program directly to verify current process. Updated Oct 2019

AETC nPEP Toolkit

https://aidsetc.org/sites/default/files/CCC_PEP_patient_assist_postcard_508.pdf



Setting nPEP Providers and Patients Up for Success

- Write nPEP procedures and protocols
- Provide ongoing education of ED, UC and clinic staff regarding nPEP use, availability
- Encourage use of nPEP guidelines
- Ensure warm hand-off to follow-up provider (someone to call patient)
- Connect with community resources and find PrEP/PEP coordinator
- Provide full 28-day regimen at presentation
- Write nPEP prescriptions for 30-day supply (or pharmacy may not fill)
- Offer prescriptions for supportive medications (nausea, insomnia)
- Find PAP application champion (PrEP/PEP coordinator, SARN, social work, MA, pharmacist)

Conclusions: PEP Talk

Set up providers, care-team, and patients up for success:

- ✓ nPEP protocols need to be written, communicated and followed
- ✓ Find the unique barriers each system
- ✓ Determine community partners and collaborate with them
- ✓ Assist patients on how to access and fund their medication



HIV providers (HIV ECHO attendees) will help detect and remove barriers so patients may have improved access to nPEP

nPEP Resources

- AETC nPEP Toolkit at <https://aidsetc.org/resource/non-occupational-post-exposure-prophylaxis-npep-toolkit>
- National HIV Curriculum (Nonoccupational HIV Post-Exposure Prophylaxis) at <https://www.hiv.uw.edu/custom/prevention/nonoccupational-postexposure-prophylaxis/summary>
- National Clinician Consultation Center PEPLine
 - 888-448-4911 (M-F 9am-8pm, SS & holidays 11am-8pm)
 - <https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/>

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Acknowledgment

The Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$2,911,844 with 0% financed with non-governmental sources.

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