

Non-Occupational Post-Exposure HIV Prophylaxis nPEP

Why?
When?
Who?
How?

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Objectives - at the end of the session participants will be able to:

- ▶ Review efficacy & safety data regarding nPEP
- ▶ Apply national and state guidelines for nPEP
- ▶ Understand evaluation and monitoring required for prescribing nPEP
- ▶ List the challenges of applying these guidelines in the real world of a community health center and consider solutions





CalLEN LORDE
COMMUNITY HEALTH CENTER

FQHC, Article 31

**2013: 14,875 patients, 77,500 encounters,
36% uninsured, 1,200 Transgender, 3,700 PLWHA**

Primary Care

HIV

Women's Health

Sexual Health

Anal Screening

**Transgender
care**

**Health
Education**

HOTT

Mobile Health

Dentistry

Mental Health

Pharmacy

Lab Services

Training

Research

Education

Agenda nPEP

nPEP and PrEP: Controlling the epidemic?

nPEP guidelines

Cascade of PEP provision data

Applying nPEP guidelines

CL nPEP delivery model

Evidence for PEP:

ANIMAL TRANSMISSION MODELS

PERINATAL CLINICAL TRIALS

OCCUPATIONAL PEP

OBSERVATIONAL STUDIES

What Possible Negative Consequences of nPEP?

????????

Considered Possible Negative Consequences of nPEP

Impact on Risk Reduction

Side effects

Selection of resistant virus

Cost

- Cost effectiveness

- Access

Considered Possible Negative Consequences of nPEP

Impact on Risk Reduction

Side effects

Selection of resistant virus

Cost

- Cost effectiveness

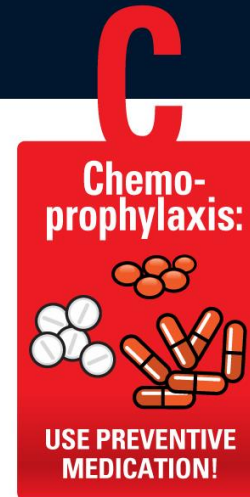
- Access

40,000 new HIV infections annually in US

Strategy for epidemic control: Patient Care & Public Health - nPEP and PrEP

Preventing malaria Mind before Madness

**YOUR
ABCD
AGAINST
MALARIA**



www.dietsmann.com/preventingmalaria

Dietsmann
Maintaining Energy

SOURCE: DIETSMANN

([HTTP://WWW.DIETSMANN.COM/PREVENTINGMALARIA](http://www.dietsmann.com/preventingmalaria))

Dietsmann
Maintaining Energy

PEPline 1-866-637-2342

nPEP Evaluation

Clinical Assessment and Plan

Substantial risk?

Timing?

Patient acceptance, adherence, follow-up?

Administrative Assessment and Plan

Insurance?

Ability to pay?

Immigration status?

24/7 PEPline 1-866-637-2342



Timing is critical

Blood transfusion

*Receptive penile-vaginal
intercourse*

Receptive anal intercourse

What's the risk?

Estimated per-act risk for acquisition of HIV, by exposure

Exposure Route	Risk per 10,000 exposures to an infected source	Reference
Blood Transfusion	9,000	74
Needle-sharing injection-drug use	67	75
Receptive anal intercourse	50	76, 77
Percutaneous needle stick	30	78
Receptive penile-vaginal intercourse	10	76, 77, 79
Insertive anal intercourse	6.5	76, 77
Insertive penile-vaginal intercourse	5	76, 77
Receptive oral intercourse	1	77 [†]
Insertive oral intercourse	0.5	77 [†]

*Estimates of risk for transmission from sexual exposures assume no condom use.

[†]Source refers to oral intercourse performed on a man.

SOURCE: CENTERS FOR DISEASE CONTROL AND PREVENTION
 (HTTP://WWW.CDC.GOV/MMWR/PREVIEW/MMWRHTML/RR5402A1.HTM)



Table 1: Consideration of nPEP According to the Type of Risk Exposure^a

**nPEP
recommended**

penile-anal sex
penile-vaginal sex
needle sharing

**nPEP
considered**

oral-vaginal sex
oral-anal sex
penile-oral sex

factors that increase risk should be considered

**nPEP not
recommended**

oral-oral contact
human bites

NYSDOH AIDS Institute

nPEP

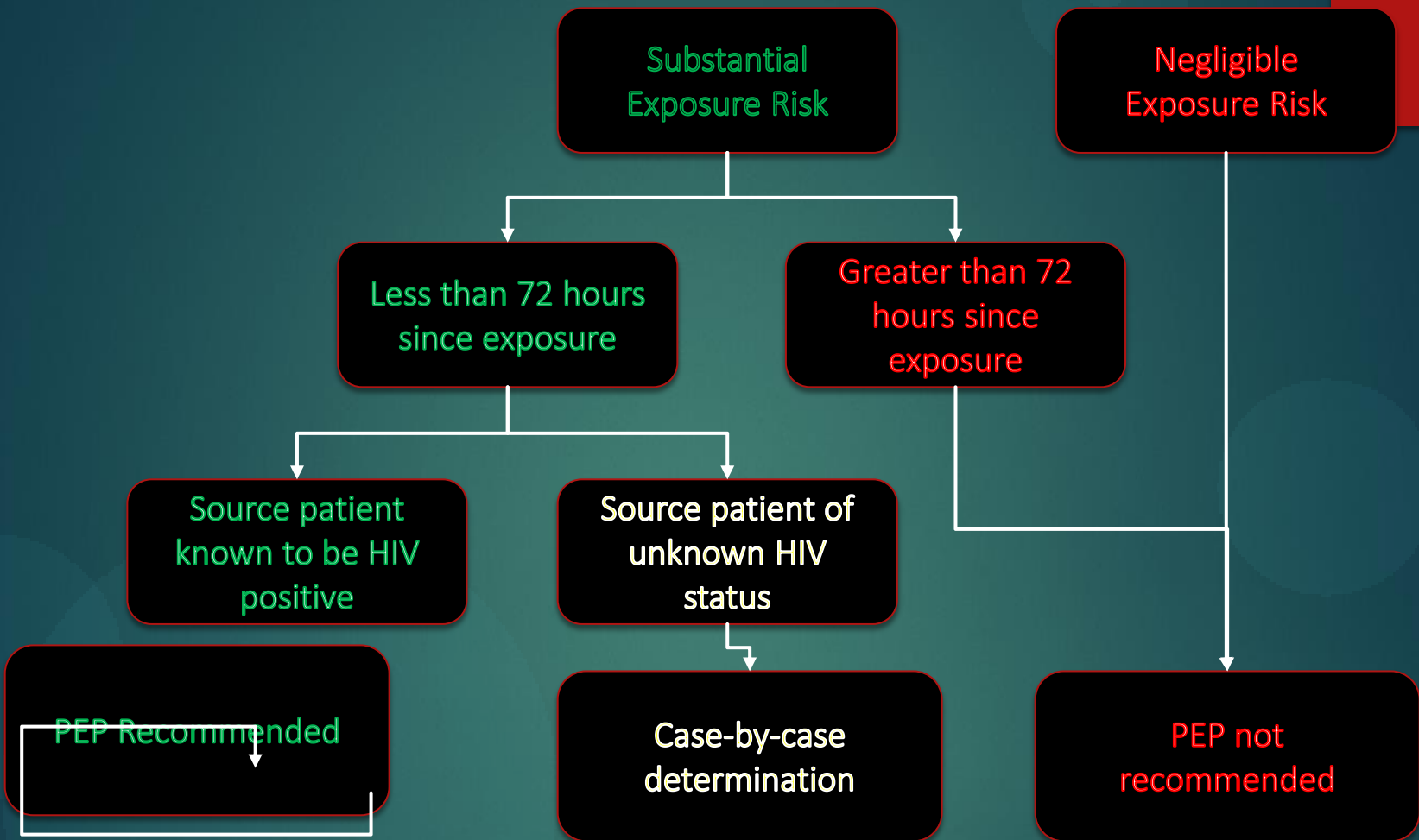
July 2013 Updates

www.hivguidelines.org

- ▶ Consider HIV VL test in source patient
- ▶ Baseline STI Screening
- ▶ Post exposure HIV test at 4 & 12 weeks
- ▶ Consideration for PrEP
- ▶ Choice of nPEP Rx



Figure. Algorithm for evaluation and treatment of possible HIV exposures. [DHHS 2005; USPHS 2013]



- Substantial Risk for HIV Exposure**
- Exposure of... vagina, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact
 - With... blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
 - When... source is known to be HIV-infected

- Negligible Risk for HIV Exposure**
- Exposure of... vagina, rectum, eye, mouth, or other mucous membrane, intact or non-intact skin, or percutaneous contact
 - With... urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood
 - Regardless... of the known or suspected HIV status of the source

33 YEAR WOMAN

WORRIED SHE'S BEEN EXPOSED TO HIV

IT IS NOW SUNDAY 3:00 PM



33 YEAR WOMAN

WORRIED SHE'S BEEN EXPOSED TO HIV

IT IS NOW SUNDAY 3:00 PM

WHEN? WEDNESDAY 11:00 PM

HOW?

CONTEXT?

Scenario 1

33 YEAR WOMAN

WORRIED SHE'S BEEN EXPOSED TO HIV

IT IS NOW SUNDAY 3:00 PM

WHEN? WEDNESDAY 11:00 PM

HOW?

CONTEXT?

**ARRANGE FOR COMPREHENSIVE STD
SCREENING, CONTRACEPTIVE COUNSELING,
PRIMARY CARE & CONSIDERATION OF PREP**

Scenario 1

33 YEAR WOMAN

WORRIED SHE'S BEEN EXPOSED TO HIV

IT IS NOW SUNDAY 3:00 PM

WHEN?

SUNDAY 8:00 AM

HOW?

RECEPTIVE ORAL SEX

CONTEXT?

Scenario 2

33 YEAR WOMAN

WORRIED SHE'S BEEN EXPOSED TO HIV

IT IS NOW SUNDAY 3:00 PM

WHEN?

SUNDAY 8:00 AM

HOW?

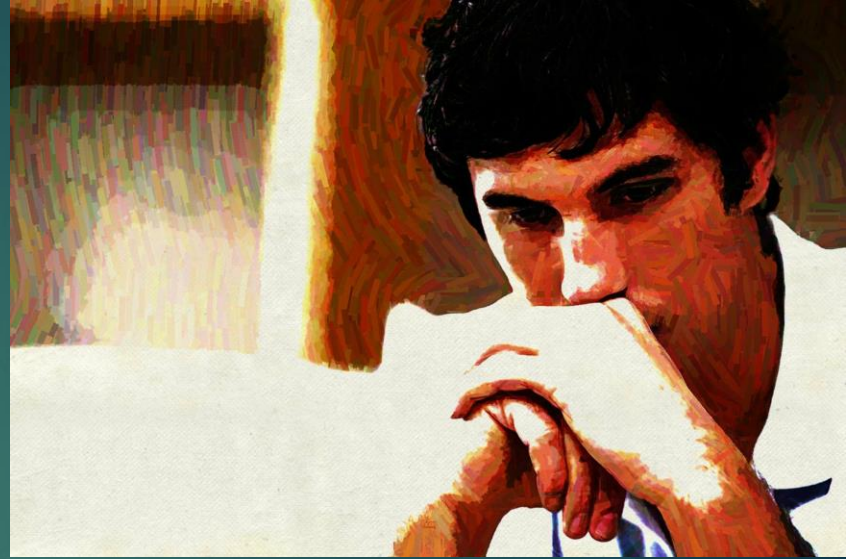
RECEPTIVE ORAL SEX

CONTEXT?

**ARRANGE FOR COMPREHENSIVE STD
SCREENING, CONTRACEPTIVE COUNSELING (IF
WARRANTED), PRIMARY CARE**

Scenario 2

**25 YEAR OLD MAN
WORRIED HE'S BEEN EXPOSED
TO HIV
IT IS SUNDAY 3:00 PM**



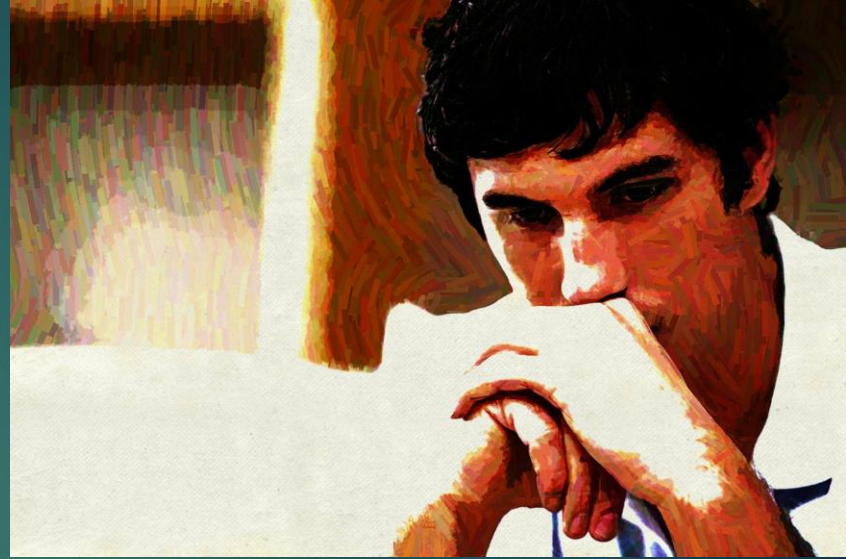
WHEN? SUNDAY 8:00 AM

HOW? RECEPTIVE ANAL SEX WITHOUT
CONDOM, WITH EJACULATION,
UNKNOWN STATUS OF PARTNER

CONTEXT? USUALLY HAS ORAL SEX OR ANAL
SEX WITH CONDOM

Scenario 3

**25 YEAR OLD MAN
WORRIED HE'S BEEN EXPOSED
TO HIV
IT IS SUNDAY 3:00 PM**



WHEN? SUNDAY 8:00 AM

HOW? RECEPTIVE ANAL SEX WITHOUT
CONDOM, WITH EJACULATION,
UNKNOWN STATUS OF PARTNER

CONTEXT? USUALLY HAS ORAL SEX OR ANAL
SEX WITH CONDOM

**NEEDS URGENT NPEP (COMPREHENSIVE STD
SCREENING, PRIMARY CARE & CONSIDERATION OF
PREP)**

Scenario 3

What tests to do & when?



Monitoring Recommendations After Initiation of PEP Regimens Following Non-occupational Exposures

Week	Baseline	1	2	3	4	12
Clinic Visit	X	X (or by phone)	X (or by phone)	X (or by phone)		
Pregnancy Test	X					
Serum liver enzymes, BUN, creatinine, CBC	X					
HIV test - Recommended even if PEP is declined	X				X	X
STI Screening - Recommended even if PEP is declined	X		X			
Hepatitis B and C						

See separate document

SOURCE: HIV CLINICAL RESOURCE

([HTTP://WWW.HIVGUIDELINES.ORG/CLINICAL-GUIDELINES/POST-EXPOSURE-PROPHYLAXIS/HIV-PROPHYLAXIS-FOLLOWING-NON-OCCUPATIONAL-EXPOSURE/](http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/))

HIV Clinical Resource

Office of the Medical Director, New York State Department of Health AIDS Institute
in collaboration with the Johns Hopkins University Division of Infectious Diseases

Remember to consider
Hep C



nPEP Evaluation

Clinical Assessment and Plan

Substantial risk?

Timing?

Patient acceptance, adherence, follow-up?

Administrative Assessment and Plan

Insurance?

Ability to pay?

Immigration status?



nPEP Flow sheet(s)

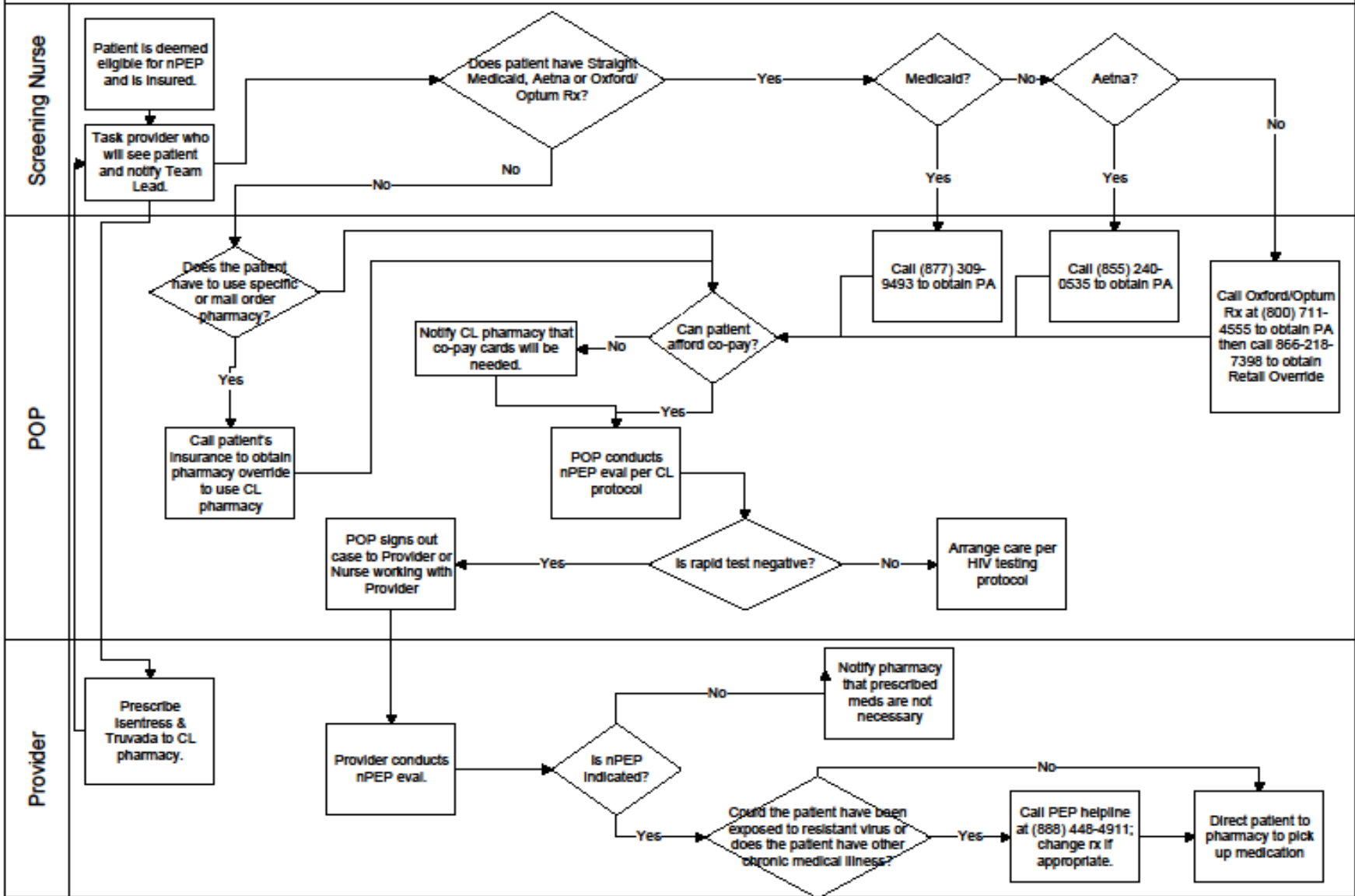
PPEP (private insurance)

PAP-PEP (pharmacy assistance program)

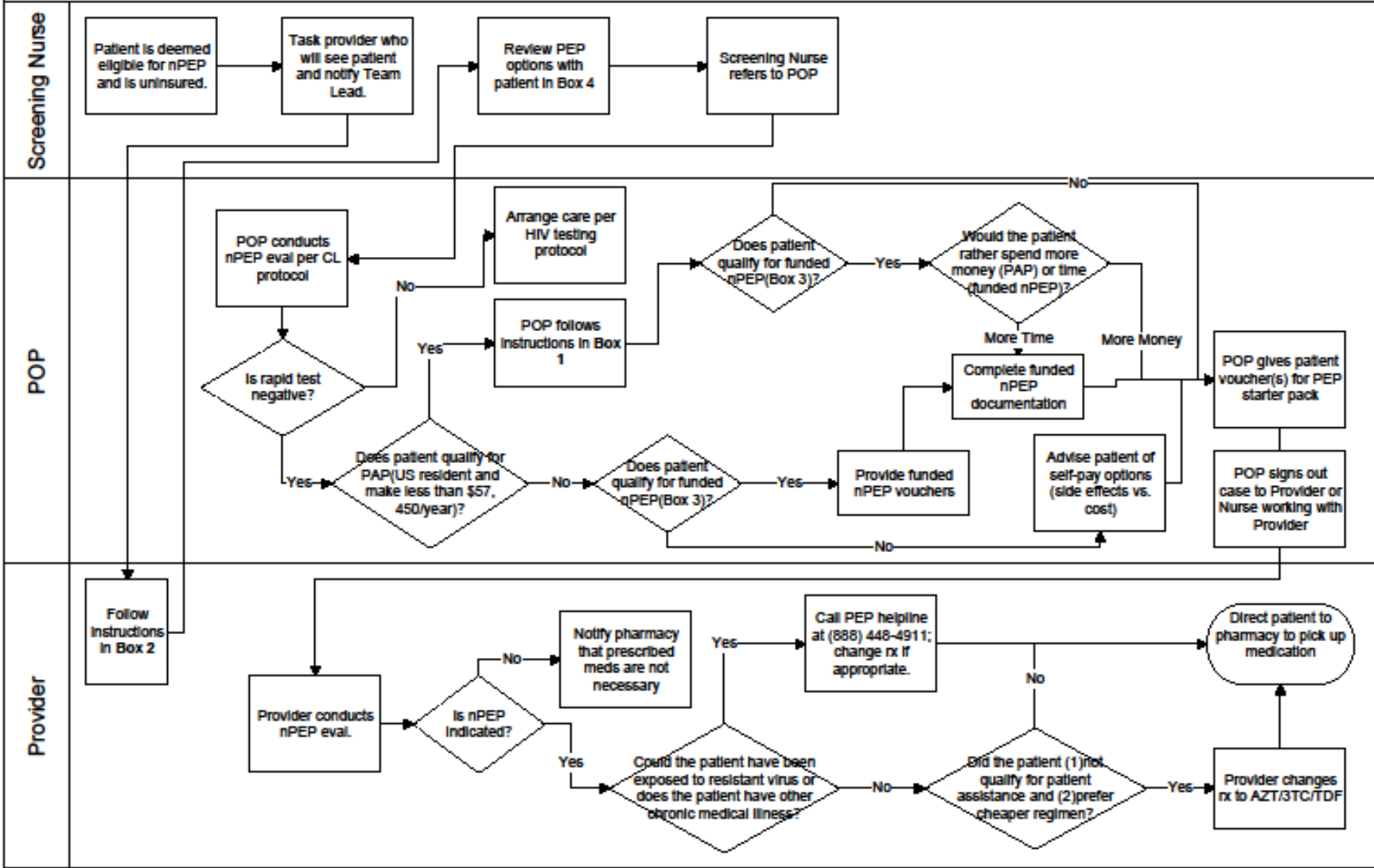
SPEP (self pay)

FPEP (funded PEP)

nPEP – Insured Patient



nPEP – Uninsured or Underinsured Patient



Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (nPEP)

Sexual Assault

Chapter 39 of the Laws of 2012 amending Section 2805-i of Public Health Law requires hospitals to provide the first seven days of medication to victims of sexual assault. Prescriptions must be given for the remaining 21 days.

Medicaid	PEP is covered.
Private Insurance	PEP coverage is based on plan. Large co-pay may be a consideration. NYS Office of Victim Services (OVS) may reimburse co-pays of a victim who submits an eligible application with the agency. Co-payment cards are available from the manufacturers. Gilead - 1-877-505-6986 Merck - 1-855-834-3467 or www.isentress.com
Insured, but does not use insurance	A victim may decline to provide insurance information if he/she believes provision of that information would substantially interfere with his or her personal privacy or safety. A victim may ask the provider to directly bill the OVS for the Forensic Rape Exam (FRE), including the first seven days of medication.
No Insurance	OVS may be directly billed as above and the victim may apply to OVS for expenses beyond the FRE, including a prescription for the remaining 21 days.
NYS Office of Victim Services (formerly the Crime Victims Board)	OVS has an Emergency Award Procedure designed to pay the pharmacy in 1-4 days. It is important that the forms be filled out correctly and submitted with the supporting information requested. Emergency awards are available for up to \$2,500. It is best to work with Victim Advocates in your community to pursue this process; they know the community connections and the procedure to expedite this process. Call 1-800-247-8035 or go to www.ovs.ny.gov for more information.

SOURCE: NEW YORK STATE DEPARTMENT OF HEALTH

([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))



Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (nPEP)

For All Other Non-Occupational Exposures in any Health Care Setting

Medicaid	PEP is covered.
Private Insurance	PEP coverage is based on plan. Co-payment cards are available from the manufacturers. Gilead - 1-877-505-6986 Merck -1-855-834-3467 or www.isentress.com
Insured, but does not use insurance	<ul style="list-style-type: none">• Treating institution provides immediate access to drugs.• Begin application process for Medicaid, if appropriate. (Coverage is not guaranteed).• Explore the Patient Assistance Programs from pharmaceutical companies.• Contact your human service/social work department for special funds.
Patient Assistance Programs	Common Patient Assistance Program Application (HIV) http://hab.hrsa.gov/patientassistance/index.html HIV meds are listed by company with instructions on how to submit the application. You may need to apply to more than one company depending on regimen chosen. <i>Please see specific application process on next page for Gilead and Merck.</i>

SOURCE: NEW YORK STATE DEPARTMENT OF HEALTH

([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))



Patient Assistance Programs

Gilead Patient Assistance

1. Fax a letter of medical necessity to 1-800-226-2056.

Include:

- Patient's name
 - Therapy needed
 - Date of exposure
 - Provider's signature
2. Call 1-800-226-2056 and notify them you have a patient who needs PEP.
- Tell them you faxed in a letter of medical necessity.
 - Give them time of fax
 - Number of pages
 - Your fax number
 - Have this information available:
 - Name
 - Address
 - Phone number
 - Date of birth
 - Social security number
 - Number of people claimed as dependents
 - Household income
 - Any insurance coverage
 - Provider name
 - Provider address
 - Provider phone number
 - Will take 5-10 minutes
 - Hours: Monday - Friday 9am-8pm EST
3. They will give you a voucher number to place on the prescription. The patient may go to the pharmacy to have the prescription filled with no out-of-pocket expenses.
4. **Co-payment Assistance:** Call 1-877-505-6986. Hours: Monday - Friday 8am- 8pm EST. Patient is given an authorization number to present with the prescription and other insurance at the pharmacy.

SOURCE: NEW YORK STATE DEPARTMENT OF HEALTH

([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))



Patient Assistance Programs

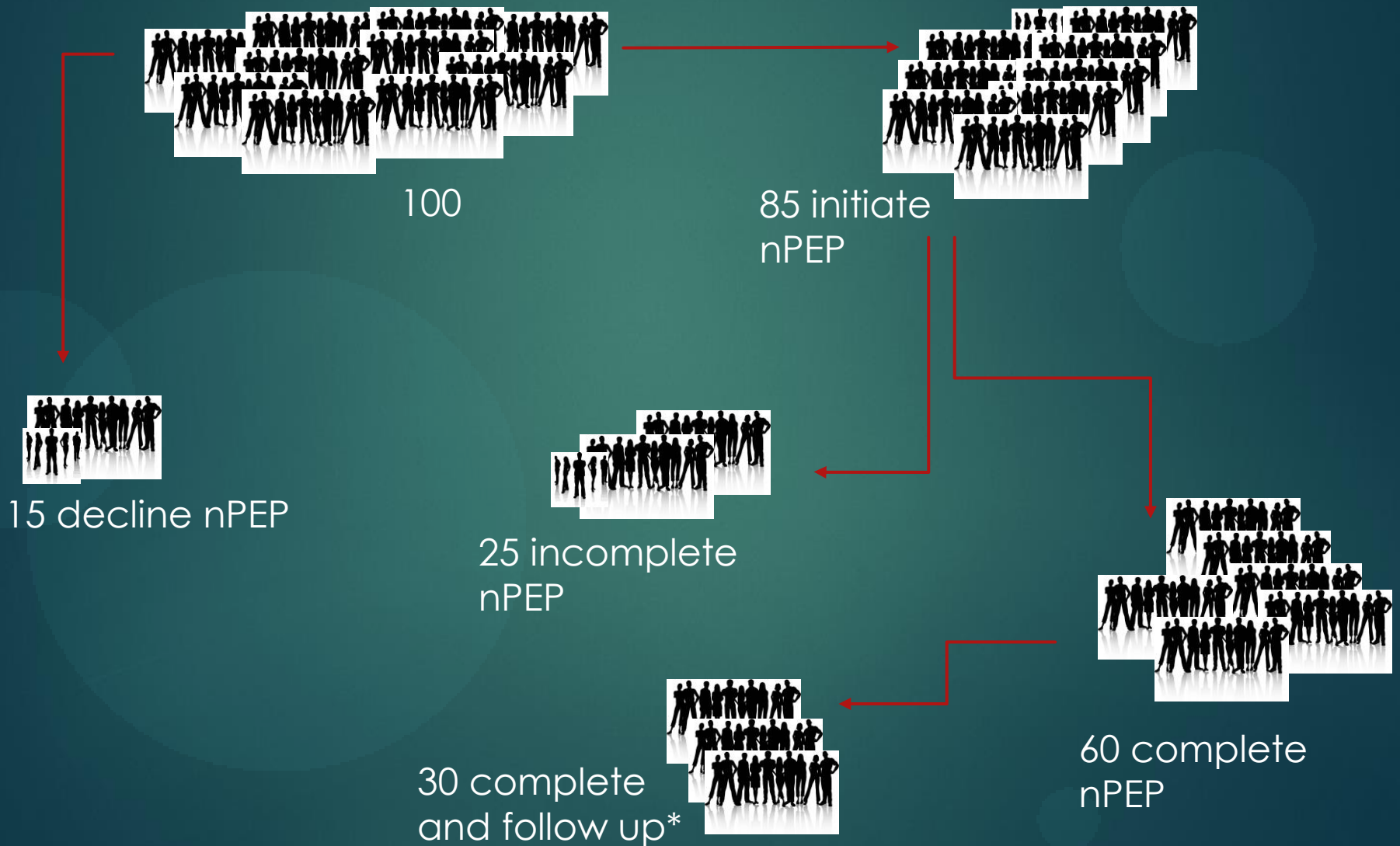
- 1. Merck Patient Assistance Program**
2. Locate form at www.needymeds.org
 - Under A-Z, look for Isentress (Raltegravir). (www.needymeds.org/papforms/isentr1196.pdf)
 - Support enrollment form
 - Print and fill out
 - **Indicate prescribing PEP**- this will expedite processing.
 - Fax to 1-866-410-1913. You may send fax any time. Hours of operation: 6am - 3pm PST Monday - Friday.
3. Call 1-800-850-3430 1-2 hours after sending fax.
4. Will send medications to provider or patient as indicated on form
 - If received by 12:30 PST, will have overnight delivery. (about 24 hours)
 - If received after 12:30 PST, will have next day delivery. (about 48 hours)
5. **Co-payment Assistance:** Call 1-855-834-3467 or www.isentress.com
 - For online application and coupon redemption
 - For presentation with the prescription and insurance coverage at the pharmacy.

SOURCE: NEW YORK STATE DEPARTMENT OF HEALTH

([HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENT_OPTIONS_NPEP.PDF](https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf))



PEP Cascade



PEPline 1-866-637-2342