Welcome to the IAFN, SAFE-TA, and MATEC Webinar:

PEP for Prevention of HIV: When, Why & How

• IAFN requests that you e-mail the names of any non-registered attendees who may be sharing this webinar experience with you so we can track attendance. Please send additional attendee names to INFO@IAFN.ORG today.

Thank you in advance for your help and cooperation!

This webinar was supported by Grant No. 2011-TA-AX-K021 awarded by the Office on Violence Against Women, U.S. Department of Justice. The opinions, findings, conclusions, and recommendations expressed in this presentation are those of the authors and do not necessarily reflect the views of the Department of Justice, Office on Violence Against Women.

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Joint Position on Universal Access to Anti-HIV Medication

The Association of Nurses in AIDS Care (ANAC), International Association of Forensic Nurses (IAFN), National Alliance to End Sexual Violence (NAESV), and National Sexual Violence Resource Center (NSVRC) recommend that systems be established to ensure that survivors of sexual assault have universal access to medications to prevent HIV following rape. In too many communities, access to these medications is lacking or inconsistent.

Joint Position (Continued)

In summary the above mentioned organizations recommend that:
- Health care providers treating sexual assault patients include HIV risk assessment and potential prophylaxis as a standard component of the medical-forensic examination.
- Anti-HIV medications be available where and when patients present after sexual assault.
- People who have been sexually assaulted not be expected to carry the financial burden for HIV nPEP.
- People who have been sexually assaulted have access to advocacy and supportive services before, during and after HIV testing and nPEP provision.

Learning Objectives

At the conclusion of this program, participants will be able to:
- Identify patients of sexual assault patients who are appropriate patients to receive antivirals post-assault.
- Select appropriate antivirals for patients who have been sexually assaulted.
- Identify resources in their respective practice settings to assist post sexual assault patients with acquiring antivirals.
Should be OBJECTIVES Not Agenda
Define HIV nPEP
Implement HIV nPEP
Resources for care
Kim Day, 9/5/2013
Non-occupational Postexposure Prophylaxis (nPEP) for HIV

Diane M. Janowicz, MD
Assistant Professor of Medicine
Indiana University School of Medicine
MATEC Indiana - Clinical Faculty

Global Summary of the AIDS Epidemic: 2011

<table>
<thead>
<tr>
<th>Number of people living with HIV</th>
<th>Total</th>
<th>34.8 million [31.4–35.9 million]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adults</td>
<td>30.7 million [28.2–32.3 million]</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>18.7 million [15.6–17.8 million]</td>
</tr>
<tr>
<td></td>
<td>Children (&lt;15 years)</td>
<td>3.3 million [3.1–3.8 million]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>People newly infected with HIV in 2011</th>
<th>Total</th>
<th>2.5 million [2.2–2.8 million]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adults</td>
<td>2.2 million [1.9–2.4 million]</td>
</tr>
<tr>
<td></td>
<td>Children (&lt;15 years)</td>
<td>330,000 [300,000–360,000]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AIDS deaths in 2011</th>
<th>Total</th>
<th>1.7 million [1.5–1.9 million]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adults</td>
<td>1.5 million [1.3–1.7 million]</td>
</tr>
<tr>
<td></td>
<td>Children (&lt;15 years)</td>
<td>230,000 [200,000–270,000]</td>
</tr>
</tbody>
</table>

WHO-HIV Department, November 12, 2013. WHO/UNAIDS/UNICEF

US HIV Epidemiology

- ~1.2 million persons living with HIV
- 21% of infected persons unaware of status!
- ~ 50,000 new infections/year
- stable for two decades
- $19 billion/year for prevention, care, & research

What is nPEP?

- antiretroviral (HIV) medications prescribed within 72 hrs to patients with a known or suspected exposure to prevent active HIV infection

- nPEP regimen similar to those used to treat HIV infection, but for 28 days
Estimated Per-Act Risk for Acquisition of HIV by Exposure Route

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Risk %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion (1 unit)</td>
<td>90-100%</td>
</tr>
<tr>
<td>Needle-sharing injection drug use</td>
<td>0.67%</td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>0.1-3.0%</td>
</tr>
<tr>
<td>Percutaneous needle stick</td>
<td>0.3%</td>
</tr>
<tr>
<td>Receptive vaginal intercourse</td>
<td>0.1-0.2%</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>0.06%</td>
</tr>
<tr>
<td>Insertive vaginal intercourse</td>
<td>0.03-0.09%</td>
</tr>
<tr>
<td>Receptive oral intercourse</td>
<td>0-0.04%</td>
</tr>
<tr>
<td>Mucosal Membrane Exposure</td>
<td>0.09%</td>
</tr>
</tbody>
</table>


Evidence for nPEP

- Animal models demonstrate variable results
- Macaque Model (SIV)
  - 4 animals, start 12 hrs after exp – x 28 d (0/4 SIV)
  - 4 animals, start 36 hrs after exp – x 28 d (0/4 SIV)
  - 4 animals, start 72 hrs after exp – x 28 d (1/4 SIV)
- Small window period during which ART may interrupt the initial infection of cervicovaginal mucosa or the dissemination of local infection

Evidence for nPEP

- Post-natal prophylaxis reduces HIV transmission at 14-16 w
  - Mother receives nevirapine during labor, baby within 72 h (25% transmission rate to 13.1%)
- Occupational PEP
  - 33 cases, 655 controls
  - AZT PEP reduced acquisition (OR: 0.19 CI: 0.06-0.52)

Observational Studies

- South Africa study of rape survivors
  - 480 women followed for 6 weeks
  - zidovudine + lamivudine (AZT + 3TC)
    - 1 acquired HIV (started 96 hrs after assault)
    - 1 woman who sought treatment 12 days after the assault acquired HIV (seroconverted at 6 wks)

- Brazilian study of sexually assaulted women
  - (AZT + 3TC)+/- indinavir if < 72 hrs
    - 0 of 180 PEP acquired HIV
  - no treatment if > 72 hrs, HIV- assailant, or condom used and no mucosal trauma
    - 4 of 145 untreated women acquired HIV

Evaluating a Patient following Non-occupational Exposure to HIV

- **Rapid**
  - Detect Antibodies to HIV
  - 20 minutes for results
  - Oral or finger stick
  - Results must be confirmed

- **Traditional**
  - Detect Antibodies to HIV
  - Hours or Days for results
  - Blood draw
  - Results must be confirmed

Step 1: Order an HIV Test
Step 2: Review Results

- **Reactive** HIV Screening Test:
  - Do **NOT** offer nPEP.
  - This patient **MAY** have HIV infection.
  - Confirm HIV infection with a Western Blot.
  - Refer patient to an HIV Expert.

- **Non-reactive** HIV Screening Test:
  - Your patient was not previously infected.
    - Window period of up to 3 months before Ab to HIV are produced after an exposure; during this period, HIV screening tests may be non-reactive! Discuss with your patients.
  - Your patient may be a candidate for nPEP.

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Step 3: Assess Risk

**Substantial Exposure Risk**
- 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 the source is known to be HIV infected

**Negligible Exposure Risk**
- Exposure of vagina, rectum, eye, mouth, or other mucous membrane, 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

DHHS. MMWR. 2005

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Step 4: Follow the nPEP Algorithm

- **Negligible exposure risk**
  - Source patient of unknown HIV status
  - nPEP not recommended
  - Case-by-case determination

- **Substantial exposure risk**
  - <72 hours since exposure
  - nPEP recommended

DHHS. MMWR. 2005
Step 5: Make an nPEP Recommendation

- The situation you described puts you at low risk for exposure to HIV. In this situation, we do not routinely recommend the HIV exposure medications. If you feel strongly that you want to be given these medications we will provide them for you.

- The situation you have described to me is a high risk situation because ____. We recommend the following medications because they have been shown to minimize the possibility of a patient becoming HIV positive. Your HIV screening was negative today, so we can start you on the medications.

Step 6: Prescribe nPEP

- Initiate within 2 hrs, up to 72 hrs
- Discuss and document:
  - Potential benefit, unproven efficacy & potential toxicity of PEP
  - Importance of adherence
  - Risk reduction & prevention behaviors
  - Signs & symptoms of primary HIV infection
  - Necessary clinical & lab monitoring follow-up
- Every patient prescribed nPEP should leave with a Starter Pack (enough meds for 3-7 days)

Labs Needed for nPEP

<table>
<thead>
<tr>
<th>Test</th>
<th>Baseline</th>
<th>4-6 Weeks Post</th>
<th>3 Months Post</th>
<th>6 Months Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV antibody</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum Liver Enzymes</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>BUN/ SCr</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>STD Screen</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B Serology</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Hep C Serology</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Pregnancy Test</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
### Common nPEP Regimens

**28 Days**

- **2 NRTI**
  - *Emtricitabine + Tenofovir (Truvada®)*
  - Lamivudine + Zidovudine (Combivir®)

- **II (Integrase Inhibitors)**
  - Raltegravir (Isentress) 400 mg twice daily
  - Dolutegravir (Tivicay) 50 mg daily

- **PI (Protease Inhibitors)**
  - Lopinavir 200 mg/Ritonavir 50 mg (Kaletra) 2 tablets twice daily
  - Atazanavir (Reyataz) 300 mg & Ritonavir (Norvir) 100 mg daily

(Nucleoside Reverse Transcriptase Inhibitors)

### Common Side Effects

- Diarrhea
- Nausea
- Fatigue
- Headache
- Dizziness
- Depression
- Insomnia
- Abnormal dreams
- Rash
- Icterus/jaundice
- Kidney stones

### Medications Contraindicated with Ritonavir

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Drug(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimycobacterial</td>
<td>Rifampin</td>
</tr>
<tr>
<td>Ergot Derivatives</td>
<td>Dihydroergotamine, ergonovine, ergotamine, methylergonovine</td>
</tr>
<tr>
<td>GI Motility Agents</td>
<td>Cisapride</td>
</tr>
<tr>
<td>Herbal Products</td>
<td>St. John’s Wort</td>
</tr>
<tr>
<td>HMG-CoA Reductase Inhibitors</td>
<td>Lovastatin, simvastatin</td>
</tr>
<tr>
<td>Typical Antipsychotic</td>
<td>Pimozide</td>
</tr>
<tr>
<td>Sedative/Hypnotics</td>
<td>Midazolam, triazolam</td>
</tr>
</tbody>
</table>
**nPEP + Contraception**

- Kaletra decreases the efficacy of OCPs.
  - additional forms of protection [should be using condoms anyway] to prevent pregnancy for up to 2 months after completing nPEP.

- Kaletra interacts with Plan B.
  - In situations where the patient has a high-risk exposure (assailant known HIV+), raltegravir could be considered over other drugs.

**Hepatitis B**

- If victim has evidence of full HBV vaccine series, no screening or prophylaxis is necessary.

- If victim is non-immune, risk for acquiring Hepatitis B if assailant was HBsAg+ (chronic hepatitis B or carrier state).
  - incidence of HBsAg+ in USA: 0.2%.

- Truvada has activity against Hep B and may be helpful in preventing acquisition

- Guidelines exist for giving HBIG for known positive Hep B assailants

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**Information All Patients Should Receive:**

- Written instructions on:
  - Importance of taking HIV medications as prescribed and until gone
  - How to protect themselves and others from HIV
  - Must use condoms for 3 months
  - Who to call if they have questions or concerns
National Post-Exposure Prophylaxis Hotline
1-888-448-4911
(24 hours per day and 7 days per week)

Implementation of HIV nPEP

Lee Wilbur, MD, FAAEM
Professor of Clinical Emergency Medicine
Vice Chairman; Department of Emergency Medicine
Director of Interprofessional Education
University of Arkansas for Medical Sciences

Why me?
- 2004 – 2013
- Medical Director Wishard Hospital Center of Hope.
- Medical Director Wishard Emergency Department HIV Team
- What is the Center of Hope?
- What is the Emergency Department HIV Team?
Topics to Discuss

- Rationale for nPEP
- Overcoming barriers from the Medical Director perspective
- The nPEP protocol at Wishard
- Liability concerns...how we feel protected.

Rationale

- IAFN: Joint Position on Universal Access to Anti-HIV Medication
- HIGHLY vulnerable population
- LOW rate of follow up historically

Barriers

- **Cost:** Who pays for the HIV test? Who pays for the Starter Packs? Who pays of the remainder of the nPEP
- **Follow-up:** Does everyone on nPEP need Infectious Disease Follow-up? What if the patient has side effects?
- **Staff:** Who are they? Their nPEP training?
- **Program Oversight:** Who? How?
Overcoming Barriers: Themes

- Putting together a strong team
- Collaborative relationships:
  Medicine, Nursing, Pharmacy, Administration, Law Enforcement, and the Community
- Removed barriers FROM THE PATIENT’S!
  - Eliminated need to f/u with Inf. Dz.
  - 5 day starter packs provided free
  - Remaining 23 days provided free **
  - No longer require blood draw prior to nPEP

Your Team

- Administrative Champion
- Pharmacy Advocate
- SANEs Trained on HIV nPEP
- Physicians (including Residents!)
- Social Work
- Community Pharmacy
- MATEC

Wishard Protocol: Sep 2013

When the HIV status of the assailant is **UNKNOWN**, then the preferred regimen is:

- **Truvada (tenofovir/emtricitabine)** - 1 tablet once a day
  - **If** Truvada is contraindicated, then
  - **Combivir (zidovudine/lamivudine)** - 1 tablet twice a day
Wishard Protocol: Amended

To be completed when protocol UPDATED and APPROVED. Moving to a 3 drug regimen.

Truvada Alone

Has few side effects and does not require monitoring; thus the entire 28 days can be dispensed – eliminating the need for routine I.D. Clinic follow-up and the reduction in follow-through that this may induce.

Wishard Protocol

For patients who are assaulted by someone KNOWN to be HIV-infected with unavailable or unknown medication and resistance history, the patient will be given the 5-day “starter pack” of medications:

- **Truvada (emtricitabine/tenofovir)** – 1 tablet daily
- **Reyataz (atazanavir)** 300 mg – 1 tablet daily
- **Norvir (ritonavir)** 100 mg – 1 tablet daily

This is a once-daily regimen which may be taken at any time of day. This can ONLY be used if patient is not taking and agrees not to take antacids of any kind, including proton pump inhibitors, H2 blockers, or TUMS.
Alternate Regimen

If the patient must be on acid suppression is:

**Truvada (emtricitabine/tenofovir)** – 1 tablet daily

**Kaletra (lopinavir/ritonavir)** – 2 tablets twice a day

Contraindications to the regimens above include an allergy to any of its components or a concurrent medication which significantly interacts with RITONAVIR. The list of interactions is long, and all medications must be cross-checked with the package insert or the Pharmacy. Some merely require close monitoring, others require dose modification, while others are contraindicated. Truvada should be adjusted for renal insufficiency which would necessitate a call to Infectious Disease.

Follow-up at Wishard (1)

**One** of the following two options below for follow-up will be offered based on the case complexity:

**Option A:**
A visit scheduled at the Special Medicine Clinic **within 5 days** The Special Medicine Clinic will provide a prescription for the remaining medications to complete a 28-day course of treatment, and consultation as needed for the patient. **This would be the preferred method of follow-up for complicated cases and those on 3 drug PEP regimens exposed to known HIV positive assailants.**

Follow-up at Wishard (2)

**Option B:**
A visit will be scheduled with the Center of Hope **within 5 days** to check on adherence and tolerance of medications. Center of Hope will email Infectious Disease, who will attempt to be available at the time of this appointment as needed, to either consult over the phone with the practitioner or to see the patient briefly in the Center of Hope setting if needed. **In particular for those individuals receiving Truvada alone, this second option may be better to avoid the trauma of being seen in the I.D. Clinic.**
Follow-up at Wishard (3)

A visit will be scheduled with the Center of hope at 2 weeks for follow-up CBC and LFTs for those patients on the Truvada-Reyataz-Norvir, Truvada-Kaletra, Truvada-Lexiva, and Combivir regimens (i.e., not needed for the Truvada alone regimen). If they are abnormal, the nurse will communicate these results with the Special Medicine Clinic at 630-6643.

Follow-up at Wishard (4)

- A visit will be scheduled with the Center of hope at 2 weeks for follow-up CBC and LFTs for those patients on the Truvada-Reyataz-Norvir, Truvada-Kaletra, Truvada-Lexiva, and Combivir regimens (i.e., not needed for the Truvada alone regimen). If they are abnormal, the COH will communicate these results with Infectious Disease.

- A visit will be scheduled at the Center of Hope or elsewhere at 6 weeks, 3 months and 6 months for follow-up HIV testing.

Nuts and Bolts

- Who writes the scripts?
- Who pays for the scripts?
A Note on Liability

- Collaborative Practice Agreements:
  - Medical Director signs for all SANE's
  - Provide scope of practice for Center of Hope

- Hospital approved protocols:
  - HIV Screening during SANE exam
  - SANEs operate within hospital protocol
  - Infectious Disease consultation
  - Pharmacy agreement

Summary

- **Rationale:** to serve a vulnerable population
- **Barriers:** Overcome through collaboration and communication
- **Protocol:** In consultation with Infectious Disease. Make an institutional policy.
- **Liability:** Minimal

Resources for Providing HIV nPEP to Uninsured & Underinsured

Lynn Young, LSW
Forensic Specialist,
Indiana University Health Methodist Hospital
Indianapolis, Indiana
Paying for the Medications

- All patients who are prescribed nPEP should leave with a starter pack of medications. This helps to fill the gaps if a patient has trouble getting the prescription filled.

- Insured Patients
  Should use their insurance (private or Medicaid). If they do not pay – then move to patient assistance. Co Pay Assistance programs are available also through Drug Companies.

- Non-Insured Patients
  The makers of Exposure Medications have great Patient Assistance Programs and will provide FREE drugs.

Importance of Starter Packs

- All patients (insured or not insured) who are prescribed nPEP should leave with a starter pack of medications.

- This helps to fill the gaps if a patient has trouble getting the prescription filled.

- Most Emergency Departments provide 4-7 days of treatment in their starter packs.

Truvada Patient Assistance

Advancing Access™ Program

Provides immediate access to Truvada® (emtricitabine and tenofovir disoproxil fumarate) for U.S. patients who cannot obtain reimbursement or afford to pay for all or part of the cost of Truvada. The program enables patients who meet program criteria to access Truvada on the same day they receive a prescription from their healthcare provider. Advancing Access also helps patients find insurance coverage and provides Truvada until other support covering the cost becomes available, if ongoing medication is needed beyond the emergent 28 days.
Accessing the Truvada Advancing Access™ Program

For more information about Advancing Access, physicians and patients may call:

1-800-226-2056 between 9:00 a.m. and 8:00 p.m. Eastern Time.

Immediate vouchers for medication assistance can be obtained with a statement of emergent need from an NP or MD faxed to 800-216-6857.

Kaletra and Norvir Patient Assistance

The AbbVie Patient Assistance Foundation

Provides AbbVie medicines at no cost to qualified patients who are experiencing financial difficulties and who generally do not have coverage available for these products through private insurance or government funded programs.

AbbVie Mission:
To enhance patient lives by providing AbbVie products to financially disadvantaged individuals who cannot access needed treatment through meaningful coverage.

Accessing AbbVie Patient Assistance Foundation

AbbVie Patient Assistance Foundation

For more information, physicians and patients may call:

1-800-222-6885
8:00 a.m. - 5:00 p.m. Central Time.

Company will provide priority fax line for urgent exposure referrals. Medications are shipped within 24-48 hours.
Combivir

VIIV Patient Assistance Program
Emergency Medication Voucher can be obtained same day by calling 877-784-4842.

Statement of emergent need by NP/MD can be faxed 877-784-4004.

Isentress
Support Program

Merck Patient Assistance
For information and application for assistance call 800-850-3430.

Applications marked “Urgent Exposure” can be faxed to 866-410-1913. Shipping of medication will occur in 24-48 hours.

REYATAZ
Bristol-Myer Squibb
Patient Assistance Program

For information and application call 888-281-8981. Applications for assistance marked “Post Exposure” can be faxed to 888-281-8985. Medication will be shipped within 24-48 hours.
Barriers to Patient Assistance

Patient assistance programs are not available on weekends.

Patients with health savings accounts/plans, or high deductibles may need to complete an appeal process for assistance if their need exceeds companies co-pay assistance programs.

Medicare D, Medicaid spendowns, and veterans may be excluded from co-pay assistance programs.

rxassist.org

A resource that is available to explore medication patient assistance and discounted programs for other medication needs your patient may express.