Introduction to non-occupational post-exposure prophylaxis (PEP) from sexual assault - Pediatrics

▪ **HIV PEP should be initiated < 72 hours after exposure. Ideally HIV PEP should be given as soon as possible after exposure, preferably within 2 hours. For high risk exposures, over 72 hours, consult Pediatric Infectious Diseases for patients <21 years old.**

▪ **The recommendation for PEP should be communicated simply and clearly to the patient, considering his/her emotional state and ability to comprehend the nature of antiretroviral treatment.**

▪ **If a sexual assault victim is too distraught to engage in a discussion about PEP or make a decision about whether to initiate prophylaxis at the initial assessment; the clinician should offer a starter pack of medication and make arrangements for a follow-up appointment within 24 hours to further discuss the indications for PEP.**

▪ **If the source person is known to be HIV-infected and information is immediately available regarding past and present antiretroviral therapy (ART) experience, current level of viral suppression, or resistance profile, the treating clinician, in consultation with a clinician experienced in managing PEP, should individualize the PEP regimen to maximize potential effectiveness against the exposed HIV strain. Initiation of the first dose and continuation of PEP should never be delayed while awaiting this information. If indicated, the regimen can be changed when more information becomes available.**

▪ **If a sexual assault victim decides to initiate treatment, a follow-up visit should be scheduled within 24 hours to review the decision, evaluate initial drug tolerability, reinforce the need for adherence to the regimen, and arrange for follow-up care.**

▪ **Discussions regarding initiation of PEP should include the following:**

◦**Potential benefit, unproven efficacy, and potential toxicity of PEP**

◦**Duration of PEP regimen (28 days)**

◦**Importance of adherence to the treatment regimen to prevent PEP failure or the development of drug resistance should infection occur.**

◦**Need to reduce risk and prevent exposure to others: during the 12-week follow-up period HIV-exposed individuals should be advised to: use condoms to prevent potential sexual transmission, avoid pregnancy and breastfeeding, avoid needle-sharing, refrain from donating blood.**

◦**Clinical and laboratory monitoring and follow-up schedule:**

- **Lab monitoring: After baseline HIV testing is performed at the time of initial encounter, sequential confidential HIV testing should be obtained at week 4, and week 12 post-exposure. If the post-exposure evaluation determined that PEP was indicated, but the exposed person declines PEP, serial testing should still be obtained.**
- **Clinical evaluation weekly while receiving PEP to assess treatment adherence, side effects of treatment, interval physical complaints, and emotional status.**

◦**Signs and symptoms of acute HIV infection (fever, rash, swollen glands, sore throat).**

PEP for sexually transmitted infections (STIs) other than HIV

- **For sexual assault victims, clinicians should offer prophylactic medication to prevent gonococcal and chlamydial infections. Routine baseline testing for STIs (gonorrhea, chlamydia, syphilis) is not recommended in cases of sexual assault because results of that testing may detect a STI present prior to or one transmitted at the time of the assault. This information can be used to bias a jury against a victim in court. If the patient refuses STI prophylaxis then GC/Chlamydia and trichomonas specimens should be sent to the Lab.**

Pregnancy Testing

- **Clinicians should obtain baseline pregnancy testing for sexual assault victims who are of childbearing age.**

Emergency Contraception

- **Emergency contraception should be discussed and offered to individuals who could become pregnant as a result of the assault.**

<u>Baseline labs:</u>

CBC
CMP
HIV testing (rapid antibody or 4th generation Ag/Ab combo).
    -PEP should be initiated without waiting for the results of the HIV test.
    -Refusal to undergo baseline testing should not preclude initiation of PEP.
Hepatitis B surface Antigen and Hepatitis B surface Antibody
Hepatitis C antibody
Pregnancy test

<u>HIV PEP regimen</u>: 28 day supply

≥12 years old and ≥35kg: tenofovir disoproxil/emtricitabine + raltegravir

≥2- <12 years old or ≤35kg or can't swallow pills: tenofovir disoproxil+ emtricitabine + raltegravir

<2 years old: zidovudine+ lamivudine + raltegravir

Patients should be sent home from the ER with a 7 day starter pack with follow up at:

- Jack Martin Clinic (212-241-7968) has sessions Monday and Thursday

- PEP hotline: 844-PEPNYC or 844-373-7692

<u>Hepatitis B Post Exposure Prophylaxis:</u>

▪ **When indicated, Hepatitis B immune globulin (HBIG) and hepatitis B vaccine should be administered as soon as possible after exposure preferably within 24 hours. Hepatitis B vaccine may be administered simultaneously with HBIG in a separate injection site.**

Source positive

If source known to be positive, patient not vaccinated or incompletely vaccinated: give HBIG + Hep B vaccine

If source known to be positive, patient fully vaccinated (written documentation preferred), response to vaccine unknown: give Hep B vaccine

Source unknown

If source is unknown and patient is unvaccinated or incompletely vaccinated: Vaccine

If source is unknown, patient is completely vaccinated, response to vaccine known
anti-HBs10 mIU/mL or higher: no need to vaccinate , do not give either HBIG or Hep B vaccine

If source is unknown, patient is completely vaccinated, response to vaccine unknown: no immediate prophylaxis, provider will check Hep B surface antibody result at follow up clinic visit and if deemed a nonresponder will initiate revaccination series

Source negative:

Does not need to be vaccinated for Hep B, can vaccinate anyone who is unvaccinated, incompletely vaccinated or a known nonresponder

STI prophylaxis

Gonorrhea: <45kg = Ceftriaxone 25-50 mg/kg IM x 1 (maximum dose of 125mg IM)

>45kg = Ceftriaxone 250 mg IM x1

Chlamydia: <45kg = Azithromycin 20 mg/kg PO x1

>45 kg = Azithromycin 1gram PO x1 or alternative (doxycycline 100mg PO twice daily x7 days)

Trichomoniasis: <45kg = Metronidazole 45 mg/kg/day PO divided into 3 doses x7 days

>45kg =Metronidazole 2 grams PO x1

HPV vaccine: females 9-26 years old and males 9-21 years old

References

New York State Department of Health and Aids Institute Clinical Guidelines

Aidsinfo.gov: Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016 from the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

http://www.hivguidelines.org/pep-for-hiv-prevention/after-sexual-assault/#tab_4

<table>
<tr><th>Drug</th><th>Formulation</th><th>Dose</th></tr>
<tr><td>Emtricitabine (Emtriva®)
(FTC)</td><td>200 mg capsule
10 mg/mL oral solution</td><td>Aged 0 to < 3 months: 3 mg/kg once daily (maximum dose 240 mg once daily)

Aged 3 months – 17 years, per body weight

<table>
<tr><td>Body weight (kg)</td><td>Dose</td></tr>
<tr><td>≤ 33 kg</td><td>6 mg/kg once daily (oral solution)
(maximum dose: 240 mg once daily)</td></tr>
<tr><td>> 33 kg</td><td>200 mg once daily (tablet)</td></tr>
</table>
</td></tr>
<tr><td>Lamivudine (Epivir®)
(3TC)</td><td>100 mg tablet
150 mg scored-tablet
300 mg tablet
10 mg/mL oral solution</td><td>Aged birth to < 4 weeks (≥ 32 weeks gestation at birth): 2 mg/kg twice daily
Aged ≥ 4 weeks to < 3 months: 4 mg/kg twice daily
Aged ≥ 3 months to < 3 years: 5 mg/kg twice daily (maximum dose 150 mg)
Aged ≥ 3 years: 5 mg/kg twice daily (maximum dose 150 mg) or 10 mg/kg once daily (maximum dose 300 mg)

< 14 kg – use oral solution

Aged ≥ 3 years and ≥ 14 kg – use 150 mg scored-tablet
<table>
<tr><td></td><td colspan="2">Dosage regimen using scored 150 mg tablet</td><td></td></tr>
<tr><td>Body weight (kg)</td><td>Morning dose</td><td>Evening dose</td><td>Total daily dose</td></tr>
<tr><td>14 – <20</td><td>75 mg</td><td>75 mg</td><td>150 mg</td></tr>
<tr><td>20 - <25</td><td>75 mg</td><td>150 mg</td><td>225 mg</td></tr>
<tr><td>≥ 25</td><td>150 mg</td><td>150 mg</td><td>300 mg</td></tr>
</table>
</td></tr>
</table>

<table>
<tr>
<td>Zidovudine (Retrovir®)
(ZDV; AZT)</td>
<td>100 mg capsule
300 mg tablet
10 mg/mL syrup</td>
<td>
Aged birth to 4 weeks (≥ 35 weeks gestation): 4 mg/kg twice daily OR weight-band dosing
<table>
<tr><th>Weight band (kg)</th><th>Oral syrup (10 mg/mL) twice daily</th></tr>
<tr><td>2 - < 3</td><td>1 mL</td></tr>
<tr><td>3 - < 4</td><td>1.5 mL</td></tr>
<tr><td>4 - < 5</td><td>2 mL</td></tr>
</table>
Aged ≥ 4 weeks (≥ 35 weeks gestation) and ≥ 4 kg:
<table>
<tr><th>Body weight (kg)</th><th>Twice-daily dosing</th></tr>
<tr><td>4 - < 9</td><td>12 mg/kg</td></tr>
<tr><td>9 - < 30</td><td>9 mg/kg</td></tr>
<tr><td>≥ 30</td><td>300 mg</td></tr>
</table>
(maximum dose: 300 mg twice daily)
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</tr>
<tr>
<td>Raltegravir (Isentress®)
(RAL)</td>
<td>25 mg chewable tablet
100 mg chewable tablet
400 mg tablet
10 mg/mL oral suspension</td>
<td>
Aged birth to 1 week (≥ 37 weeks of gestation): Approximately 1.5 mg/kg/dose once daily
<table>
<tr><th>Body Weight (kg)</th><th>Dose</th></tr>
<tr><td>2 - < 3</td><td>4 mg (0.4 mL) once daily</td></tr>
<tr><td>3 - < 4</td><td>5 mg (0.5 mL) once daily</td></tr>
<tr><td>4 - < 5</td><td>7 mg (0.7 mL) once daily</td></tr>
</table>
Aged 1 to 4 weeks: Approximately 3 mg/kg/dose once daily
<table>
<tr><th>Body Weight (kg)</th><th>Dose</th></tr>
<tr><td>2 - < 3</td><td>8 mg (0.8 mL) twice daily</td></tr>
<tr><td>3 - < 4</td><td>10 mg (1 mL) twice daily</td></tr>
<tr><td>4 - < 5</td><td>15 mg (1.5 mL) twice daily</td></tr>
</table>
Aged ≥ 4 weeks and weighing ≥ 3 kg to < 20 kg: Approximately 6 mg/kg twice daily
(maximum dose: 100 mg (10 mL)) twice daily
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</table>

<table>
<tr>
<td></td>
<td></td>
<td>
<table>
<tr><th>Body Weight (kg)</th><th>Dose</th></tr>
<tr><td>3 - < 4</td><td>25 mg (2.5 mL) twice daily</td></tr>
<tr><td>4 - < 6</td><td>30 mg (3 mL) twice daily</td></tr>
<tr><td>6 - < 8</td><td>40 mg (4 mL) twice daily</td></tr>
<tr><td>8 - < 11</td><td>60 mg (6 mL) twice daily</td></tr>
<tr><td>11 – < 14</td><td>80 mg (8 mL) twice daily</td></tr>
<tr><td>14 - < 20</td><td>100 mg (10 mL) twice daily</td></tr>
</table>
Weighing ≥ 11 kg: Use chewable tablets*
Approximately 6 mg/kg/dose twice daily (maximum dose 300 mg twice daily)
<table>
<tr><th>Body Weight (kg)</th><th>Dose</th><th>Number of chewable tablets</th></tr>
<tr><td>11 - <14</td><td>75 mg twice daily</td><td>3 x 25 mg twice daily</td></tr>
<tr><td>14 - <20</td><td>100 mg twice daily</td><td>1 x 100 mg twice daily</td></tr>
<tr><td>20 - <28</td><td>150 mg twice daily</td><td>1.5 x 100 mg twice daily</td></tr>
<tr><td>28 - <40</td><td>200 mg twice daily</td><td>2 x 100 mg twice daily</td></tr>
<tr><td>≥ 40</td><td>300 mg twice daily</td><td>3 x 100 mg twice daily</td></tr>
</table>
*Note: Chewable tablets are NOT interchangeable with film-coated 400mg tablets
</td>
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<tr>
<td>Tenofovir DF (Viread®)
(TDF)</td>
<td>150 mg tablet
200 mg tablet
250 mg tablet
300 mg tablet
40 mg/g powder</td>
<td>
Aged ≥ 2 to < 12: 8 mg/kg/dose once daily

< 17 kg or not tolerating tablets – use oral powder
<table>
<tr><th>Body weight (kg)</th><th>Oral powder once daily</th></tr>
<tr><td>10 - <12</td><td>2 scoops (80 mg)</td></tr>
<tr><td>12 - <14</td><td>2.5 scoops (100 mg)</td></tr>
<tr><td>14 - <17</td><td>3 scoops (120 mg)</td></tr>
<tr><td>17 - <19</td><td>3.5 scoops (140 mg)</td></tr>
<tr><td>19 - <22</td><td>4 scoops (160 mg)</td></tr>
<tr><td>22 - <24</td><td>4.5 scoops (180 mg)</td></tr>
<tr><td>24 - <27</td><td>5 scoops (200 mg)</td></tr>
<tr><td>27 - <29</td><td>5.5 scoops (220 mg)</td></tr>
<tr><td>29 - <32</td><td>6 scoops (240 mg)</td></tr>
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<table>
<tr><td>32 - <34</td><td>6.5 scoops (260 mg)</td></tr>
<tr><td>34 - <35</td><td>7 scoops (280 mg)</td></tr>
<tr><td>≥ 35</td><td>7.5 scoops (300 mg)</td></tr>
</table>
≥ 17 kg – use tablets
<table>
<tr><th>Body weight (kg)</th><th>Tablets once daily</th></tr>
<tr><td>17 - <22</td><td>150 mg</td></tr>
<tr><td>22 - <28</td><td>200 mg</td></tr>
<tr><td>28 - <35</td><td>250 mg</td></tr>
<tr><td>≥ 35</td><td>300 mg</td></tr>
</table>
</td>
</tr>
<tr>
<td>Emtricitabine/tenofovir DF (Truvada®) – FTC/TDF</td>
<td>FTC 100 mg/TDF 150 mg tablet
FTC 133 mg/TDF 200 mg tablet
FTC 167 mg/TDF 250 mg tablet
FTC 200 mg/TDF 300 mg tablet</td>
<td>Aged ≥ 12 years and ≥ 35 kg – One tablet (FTC/TDF 200mg/300 mg) daily</td>
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