

Additional Health Concerns - Treatment and Testing

Each patient must be assessed and treated as a unique individual. Allergies, current medications, and current health conditions must all be considered in determining the best plan of care. When treatment or prophylaxis is initiated, the patient should be counseled and given written information about the common side effects of the medication. The patient must also understand that the ingestion of antibiotic treatment may make a prescription oral contraceptive less effective.

Pregnancy

For female patients of child-bearing age, there is a risk of unplanned pregnancy as a result of rape. Also, the patient may present with a pre-existing pregnancy. Such patients should be tested immediately to determine if there is a pre-existing pregnancy. Results of this test may affect immediate decisions, such as administration of HIV prophylaxis. If the patient is pregnant and HIV infected, treatment protocols may vary depending on the stage of pregnancy, and an HIV specialist or obstetrician should be consulted.

Prophylaxis Against Pregnancy (Emergency Contraception) Resulting from Sexual Assault

Examiners are expected to adhere to and fully document services provided, consistent with the following standards of professional practice and Section 2805-p of the Public Health Law:

- Counsel female patients about options for prophylaxis against pregnancy resulting from sexual assault (also known as emergency contraception or "morning after" pill) and the importance of timely action. Prophylaxis should be taken as soon as possible after unprotected intercourse and should be taken within 72 hours to be effective, unless medically contraindicated. Optimally, the treatment should be initiated within 12 hours after the assault.
- Ensure that female patients are properly informed of the effectiveness rates, risks, and benefits associated with the provision of emergency contraception to prevent pregnancy resulting from sexual assault.
- Provide female patients with written information prepared or approved by the Department of Health relating to emergency contraception.
- Provide female patients with appropriate information to make an informed choice regarding emergency contraception to prevent pregnancy resulting from sexual assault, and ensure that such services are provided upon request to the patient without delay, unless medically contraindicated.
- No hospital shall be required to provide emergency contraception to a rape survivor who is pregnant.

Any undue delay in making this service available to a patient who elects to receive such treatment would not be consistent with the current standards of care for female victims of rape and sexual assault. As such, hospitals not complying in a timely fashion would not be considered in compliance with department requirements.

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The treatments listed on the following page are intended to prevent pregnancy. The requirements related to administration of prophylaxis against pregnancy (emergency contraception) resulting from sexual assault are consistent with the requirements of 10 NYCRR 405.9(b)(10) which states that:

"No hospital shall be required to admit any patient for the purpose of performing an induced termination of pregnancy, nor shall any hospital be liable for its failure or refusal to participate in such an act, provided that the hospital shall inform the patient of its decision not to participate in such act or acts. The hospital in such an event shall inform the patient of appropriate resources for services or information."

The post-coital methods that are currently recommended for prophylaxis against pregnancy following sexual assault are:

- Progestin-only pills (most effective oral alternative, fewest side effects)
- Combination contraceptive pills.

For emergency contraceptive pills, the treatment schedule is one dose within 72 hours of unprotected intercourse and a second dose 12 hours later. The number of pills per dose varies by brand - see table on page 43. At least 30 minutes before the first dose, administer an anti-emetic - for example, Prochlorperazine (Compazine) 10 mg sustained release capsule PO or 25 mg PR. Repeat dosage every 12 hours as needed.

For further information about prophylaxis against pregnancy, particularly options for women for whom hormonal methods may be problematic, please call 1-888-668-2528, or visit Princeton University's Office of Population Research at <http://ec.princeton.edu/>.

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Contraceptives Packaged Specifically for Emergency Use in the United States

<i>Brand</i>	<i>Manufacture</i>	<i>Pills per Dose</i>	<i>Ethinyl Estradiol per Dose (µg)</i>	<i>Levonorgestrel per Dose (mg)</i>
Plan B	Barr	1 white pill*	0	0.75

Standard Oral Contraceptives – Also Effective For Emergency Use

<i>Brand</i>	<i>Manufacture</i>	<i>Pills per Dose</i>	<i>Ethinyl Estradiol per Dose (µg)</i>	<i>Levonorgestrel per Dose (mg)</i>
Alesse	Wyeth-Ayerst	5 pink pills	100	0.50-
Aviane	Barr	5 orange pills	100	0.50
Cryselle	Barr	4 white pills	120	0.60
Enpresse	Barr	4 orange pills	120	0.50
Lessina	Barr	5 pink pills	100	0.50
Levlen	Berlex	4 light-orange pills	120	0.60
Levlite	Berlex	5 pink pills	100	0.50
Levora	Watson	4 white pills	120	0.60
Lo-Ogestrel	Watson	4 white pills	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white pills	120	0.60
Nordette	Wyeth-Ayerst	4 light orange pills	120	0.60
Ogestrel	Watson	2 white pills	100	0.50
Ovrette	Wyeth-Ayerst	20 yellow pills	0	0.75
Ovral	Wyeth-Ayerst	2 white pills	100	0.50
Portia	Barr	4 pink pills	120	0.60
Seasonale	Barr	4 pink pills	120	0.60
Triphasil	Wyeth-Ayerst	4 yellow pills	120	0.50
Tri-Levlen	Berlex	4 yellow pills	120	0.50
Trivora	Watson	4 pink pills	120	0.50

*Note: Recent studies indicate that both doses of Plan B can be taken at once, rather than needing to wait 12 hours for the second dose.

Source: Trussel J., Koenig J., Ellerston C., Stewart F. (1997). Preventing unintended pregnancy: the cost-effectiveness of three methods of emergency contraception. American Journal of Public Health 87(6), 932-937.

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The effectiveness of prophylaxis against pregnancy declines as the interval between intercourse and the start of treatment increases. Therefore, treatment should not be delayed. Optimally, treatment should be initiated within 12 hours of the assault. In cases where there has been significant delay in obtaining services, prophylaxis against pregnancy (emergency contraception) could be administered up to five days post-assault, but there is a significant drop in efficacy between 12 and 120 hours post-assault and emergency contraception should be taken within 72 hours if at all possible. All health care providers providing sexual assault examinations must be well-versed in prophylaxis against pregnancy resulting from sexual assault.

Patients should be advised to have a follow-up pregnancy test three weeks after the assault. Patients who have taken prophylaxis against pregnancy resulting from sexual assault must be advised that there is still a 1-2 percent chance of pregnancy despite correct use, or significantly greater, if not able to administer prophylaxis within 72 hours.

HIV and Other Viruses

Exposure to blood and/or body fluids of a carrier can result in HIV, hepatitis B, and hepatitis C in the patient, which can have serious life-threatening consequences. The patient must be offered testing for HIV, hepatitis B, and hepatitis C at the time of the health care and evidentiary exam.

HIV

The HIV testing and prophylaxis recommendations below are current as of July 2004. To check for updated recommendations or other HIV-related guidelines, visit the New York State Department of Health HIV guidelines website (www.hivguidelines.org).

Written, informed consent for HIV testing must be obtained. All patients to be tested for HIV antibodies should be provided with pre- and post-test counseling in compliance with New York State HIV Confidentiality Law (Article 27-F). The examiner should recommend HIV post-exposure prophylaxis (PEP) to patients reporting sexual assault when significant exposure may have occurred, as defined by direct contact of the vagina, anus, or mouth with the semen or blood of the perpetrator, with or without physical injury, tissue damage, or presence of blood at the site of the assault. PEP should be recommended based on the nature of the exposure, and not the likelihood of HIV infection in the assailant or local prevalence of HIV. If the patient is pregnant, treatment protocols may vary depending on the stage of pregnancy, and an HIV specialist should be consulted. If an HIV specialist is not available, consult the HIV Clinical Education Initiatives (CEIs) listed in Appendix T for information on how to reach an HIV specialist. Appendix T contains telephone numbers of specialists who are available for consultation 24 hours a day.

PEP should be offered as soon as possible following exposure, ideally within 1 hour and not more than 36 hours after exposure. Because of the need for early

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administration of HIV prophylaxis, in some instances medication may be administered before the evidence collection process is completed. Blood for baseline HIV serologic testing should be obtained before initiating PEP. The patient may be offered rapid HIV testing, using Oraquick or another rapid test. However, initiation of PEP should not be delayed until results are available. Refusal to undergo baseline testing should not preclude initiation of therapy. PEP should be offered even if the patient refuses baseline testing.

Treatment should be given for 28 days, according to the following regimen:

Zidovudine (ZDV) 300 mg PO bid *plus* Lamivudine (3TC) 150 mg PO bid
(or Combivir 1 tablet bid)
plus
Tenofovir 300 mg PO qd

Note: Recommended HIV regimens are frequently updated. For the most up-to-date regimen, consult the web site at www.hivguidelines.org.

Note: When the source is known to be HIV-infected, past and current antiretroviral therapy experience, viral load data, and genotypic or phenotypic resistance data (if available) may require the use of an alternate PEP regimen. [Consult an HIV Specialist for specific recommendations](#). Some anti-retroviral drugs are *not* routinely recommended for post-exposure prophylaxis: for example nevirapine, because it poses a risk of potentially fatal side-effects. Further information about PEP is available from the:

NYS DOH HIV Guidelines Website (www.hivguidelines.org), under: Clinical Guidelines, HIV Post Exposure Prophylaxis Guidelines

The HIV Clinical Education Initiative (CEI) provides 24-hour access to HIV specialists (see Appendix T for a list of HIV Clinical Education Center sites and contact information).

It is important to emphasize the need for sensitivity of a clinician when sharing a positive HIV test with an individual who has just experienced sexual trauma. A follow-up visit with a primary care physician, HIV clinic, or infectious disease specialist should be scheduled within 24 hours to review decisions, reinforce the need for regimen adherence, and to arrange for follow-up care if the patient has initiated treatment. If HIV PEP is initiated, the patient should be given the name and telephone number of a hospital clinician or service where the patient or her private physician can call for consultation on the management of PEP, including information about drug side effects and alternatives in case of drug toxicity. This information should be recorded on the patient's discharge plan. HIV serologic testing should be repeated at 4 weeks, 12 weeks, and 6 months following the assault.

For additional information about HIV and HIV Post-Exposure Prophylaxis, call the New York State AIDS Institute at (212) 268-6142.

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Hepatitis B and Hepatitis C

The hepatitis B surface antigen (HBsAg) test indicates exposure as early as 1-2 weeks after infection, but may not be detectable until as late as 12 weeks after infection; the hepatitis C antibody is not detected until 8-9 weeks after infection, however an early diagnosis of hepatitis C can be made using PCR (polymerase chain reaction) testing two to four weeks after exposure. As a result, the patient will not know immediately if she has been infected with these viruses during the assault.

If the patient has been previously vaccinated against hepatitis B and has a known response, generally no treatment is indicated. If the patient has not been previously vaccinated or has not completed the series, then the hepatitis vaccination series should be initiated. To assess whether the patient is already Hep-B immune (either from successful vaccination or previous infection), check Hepatitis B surface antibody (Anti-HBs) titre.

Management of the exposed person depends on the HBsAg status of the source, and the vaccination and anti-HBs response status of the exposed person. Recommended postexposure prophylaxis is described on the table below.

Recommended Postexposure Prophylaxis for Exposure to Hepatitis B Virus

Vaccination and antibody status of exposed person*		Treatment		
		Source HBsAg** Positive	Source HBsAg** Negative	Source Unknown or not available for testing
Unvaccinated		HBIG ^o X 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously Vaccinated	Known Responder ¹	No treatment	No treatment	No treatment
	Known Nonresponder ²	HBIG X 1 and initiate revaccination or HBIG X 2 ³	No treatment	Treat as if source were HBsAg positive (HBIG X 1 and initiate revaccination or HBIG X 2 ³)
	Antibody response unknown	Test exposed person for anti-HBs ^a - If adequate ¹ , no treatment is necessary - If inadequate ² , administer HBIG X 1 and vaccine booster	No treatment	Test exposed person for anti-HBs - If adequate ¹ , no treatment is necessary - If inadequate ² , administer HBIG X 1 and vaccine booster and re-check titer in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfections and do not require post exposure prophylaxis

** Hepatitis B surface antigen

^o Hepatitis B immune globulin, dose is 0.06 mL/kg and administered intramuscularly

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- ¹ A responder is a person with adequate levels of serum antibody to HBsAg (i.e. anti HBs \geq 10mIU/mL)
 - ² A nonresponder is a person with inadequate response to vaccination (i.e. serum anti HBs $<$ 10mIU/mL)
 - ³ The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.
- ^a Antibody to HBsAg.

Source: Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 8th ed. Washington DC: Public Health Foundation, 2004.

If the patient has begun the vaccination series and the baseline hepatitis B test shows pre-existing hepatitis B disease or evidence of previous vaccination, the vaccination series should be discontinued. Patients receiving the hepatitis vaccination series should have post-vaccination testing done 1-2 months after their vaccine series is completed.

The patient should also have baseline hepatitis C serology and serum ALT (alanine aminotransferase) obtained at the time of exam for sexual assault and repeated at four to six months post-exposure. Limited data indicates the treatment of hepatitis C might be most beneficial when started early in the course of hepatitis C infection. When hepatitis C infection is identified early, the individual should be referred for medical management to a specialist knowledgeable in this disease. There is currently no effective prophylaxis for hepatitis C. Immunoglobulin and antiviral agents are not recommended at this time for hepatitis C PEP.

The patient must be advised that until blood-borne disease acquisition is ruled out, condoms should be used when engaging in sexual contact, in order to decrease the possibility of exposing a sexual partner.

The most up to date guidelines may be accessed through the Centers for Disease Control and Prevention web site at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5106a.htm>.

Sexually Transmissible Infections (STIs)

The risk of contracting a sexually transmissible infection as a consequence of a sexual assault is unknown, but many STIs are preventable by prophylactic use of antibiotics. Chlamydia and gonorrhea are the two most common STIs, and because they can cause sterility and (rarely) life-threatening complications, all patients are given medication to prevent infection by these organisms. Trichomonas and bacterial vaginosis can be diagnosed or ruled out by a wet prep done in the emergency department, and treatment provided if positive. If a microscope is not available in the emergency department, the patient should be treated empirically. Because compliance failure may cause treatment failure, one-dose regimens are preferable.

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The standard protocol for antibiotic prophylaxis following sexual assault is:

- Ceftriaxone 125 mg IM* in a single dose; plus
- Azithromycin 1 g orally in a single dose, or Doxycycline 100 mg orally twice a day for 7 days; plus
- Metronidazole 2 g orally in a single dose (if indicated).

*Alternatives to Ceftriaxone 125 mg IM, approved by the CDC for treatment of uncomplicated gonorrhea infections are:

- Cefixime 400 mg orally in a single dose, or
- Ciprofloxacin 500 mg orally in a single dose, or
- Ofloxacin 400 mg orally in a single dose.

With the increase in resistant strains, it may be wise to avoid quinolones (ciprofloxacin and ofloxacin) for use in these individuals. In addition, while the risk from a one-time dose is low, quinolones should not be used in a person less than 17 years old due to a potential risk for damage to cartilage. The same is true for pregnant women or breast-feeding women due to similar potential effects of quinolones on cartilage in the developing fetus and infant.

Finally, in areas with high rates of syphilis, clinicians may wish to use a ceftriaxone single dose of 250 mg IM rather than the 125 mg as the higher dose combined with azithromycin is more effective against incubating syphilis.

Syphilis prophylaxis is not necessary at the initial exam. Testing should be done at a follow-up appointment, and treatment given if positive.

For an example of standing orders for a patient reporting sexual assault, see Appendix U.

Discussion/Rationale

Routine testing for gonorrhea, Chlamydia, and syphilis is not recommended for the following reasons. Testing for sexually transmissible infections at the time of initial exam usually ascertains whether a patient had an STD before the assault. Prior exposure to a sexually transmissible infection can be used to bias a jury against a patient in court. All patients are offered medication, as if infected, so testing a patient does not change the course of treatment. If the patient has symptoms of a sexually transmissible infection or clinical findings are questionable, testing is advised.

Examiners must inform patients of the possible risks of contracting a sexually transmissible infection, and provide them the information with which to make informed decisions regarding testing and treatment; antibiotic prophylaxis is standard care. Even when antibiotic prophylaxis is given, the patient should be counseled about the symptoms of STIs, and advised that if she develops symptoms, she should seek prompt follow-up care from her primary care provider, gynecologist, or local STD clinic. The patient must be counseled that until STD prophylaxis is completed,

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abstinence is advised, as sexual contact can lead to transmitting infection to a sexual partner. If sexual contact has occurred after the assault and before treatment, the patient must be advised that her partner should seek health care for STD evaluation.