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Issues - Prevention - Post Exposure-Prophylaxis (PEP)

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Twenty Top Questions and Answers About PEP

1. What is postexposure prevention (PEP)?
   PEP is counseling and education, HIV testing and medication that will be offered to people within 72 hours of exposure to HIV to help them to prevent becoming infected with HIV from that exposure and in the future.

2. Who is running this project and how is it funded?
   The San Francisco PEP project is a UCSF/SFGH/Department of Public Health collaborative project. The Principal Investigator of the project is Thomas Coates, PhD, Director of the Center for AIDS Prevention Studies and Professor of Medicine at UCSF. The Co-Principal Investigator is Mitchell Katz, MD, Interim Director of the SF Health Department. The Medical Director is James O. Kahn, MD, Associate Professor of Medicine, UCSF. Co-investigators include Julie Gerberding, MD, MPH; Joshua Bamberger, MD, MPH; Michelle Roland, MD; Sally Blower, PhD, Margaret Chesney, PhD and Jeff Martin, MD, MPH. The funding comes from the City of San Francisco, a National Institutes of Health Grant and from private donations.

3. Why is sexual and needle sharing PEP being developed now?
   PEP for sexual and injection drug use developed because of a number of advances in our understanding of HIV in recent years. First of all, medications to treat HIV became more effective with the advent of new reverse transcriptase inhibitors and protease inhibitors so we began to feel more confident about the possibility of using medications to prevent infection. Secondly, data from a study of HIV infected pregnant women showed a significant decrease in transmission of HIV from mother to newborn with pre and post delivery treatment with AZT. Thirdly, data from a study of health care workers showed that 28 days of treatment with AZT reduced the risk of infection by 79% after a needle stick exposure from an HIV infected patient. This pivotal study *did not* prove the effectiveness of AZT in preventing infection. In fact, this data is controversial and some people believe that a further study with more control over confounders is essential to determine the effectiveness of this treatment. In June of 1996, the CDC recommended PEP after a significant exposure to HIV in the occupational setting. Since that time we have been debating the value of and setting up the infrastructure for non-occupational PEP.

4. Do you think PEP medication will work?
   It is difficult to know for sure. It is biologically sensible and makes us think that it will. The data from the study of health care workers is not very convincing but the science behind PEP is a compelling reason to offer treatment after a potentially life threatening exposure.

5. What harm can come from PEP?
   The biggest concern is that people will see PEP as an alternative to practicing safe sex and using clean needles because they think they can take medications to prevent infection. PEP is not a replacement strategy for avoiding HIV exposure. Even if PEP is effective for virtually all significant exposures, an increase in risk behavior across the community could be bad. Another concern is that there will be some significant side effects from taking the medication. We do not believe that there are any long term effects of taking 28 days of anti-HIV medication. We have over 10 years of experience with AZT in both HIV infected and not infected individuals but less experience with some of the newer drugs. So far, we have not seen any long lasting side effects from taking 28 days of anti-HIV medication.

6. Will there be more resistance to anti-HIV medications because of PEP.
   We do not think so. Resistance gets develops when HIV is exposed to sub-optimal levels of anti-HIV medication for a prolonged period of time. Since HIV mutates relatively rapidly, a mutation that protects the virus from anti-HIV medication will allow a resistant virus to survive. We do not believe that resistance will develop in only 4 weeks when we use at least two anti-HIV medications. We will be testing all "breakthrough" infections for resistance to medications. We will also test the virus in the person that exposed the index case. We believe that if a virus that takes hold in the index person is resistant to medications it will be because the virus that individual was exposed to was resistant upon exposure. Most importantly, if the exposed person clears the infection as will happen in an estimated at

least 995 persons out of 1000, there is no chance of increasing the environmental prevalence of resistant virus.

7. What is the recommended medical regimen?
For most people we will offer AZT (retrovir, zidovudine) (300mg) and 3TC (Epivir) (150mg) twice a day. We will be offering these medications in a combination pill so the participant will be taking one pill twice a day. If an individual prefers not to take AZT, they will have the choice to take DDI and d4T also twice a day. We anticipate that most people will select the AZT/3TC option. If the patient knows the medication history of their partner and if the partner is suspected to have a resistant virus, we will offer a regimen that will best combat a potentially resistant virus including the addition of the protease inhibitor, nelfinavir.

8. Why do you recommend two drugs for most people instead of three?
We believe that postexposure prophylactic treatment is quite different than treatment after an established infection. One reason for this difference is the small number of viral particles that are present immediately after exposure compared to the large number of copies after infection. To help the body eradicate this small amount of virus, one or two medications should be adequate to reduce the number of copies effectively. For people with existing HIV infection, there are billions of viral copies. This large number of copies increases the chance of a resistant virus being present making it necessary to have medications that work at a variety of different sites in the viral replication cycle and thus requires three drugs to suppress the virus. Therefore, if someone is exposed to HIV that is already resistant to certain reverse transcriptase inhibitors we feel it is important to offer three medications instead of two. Finally, individuals must take the medications to get any benefit from the treatment. If the side effects are too unpleasant or the regimen is too complicated, people will not complete the treatment or take the medications correctly. We chose the combination pill so that individuals can take just one pill twice a day thereby increasing the likelihood that they will comply with the treatment and complete the full 28 days of medication.

9. Must everyone who is included in the study take medications?
No. As people come into the prevention sites, we will discuss with them at length their risk of becoming infected after their particular exposure. In addition, the patient will be counseled as to the theoretic value of taking medications as well as the side effects of medications. If the patient chooses not to take the medications, they can still be part of the study and get free antibody and viral load testing as well as intensive counseling to help them develop the skills necessary to avoid being exposed again in the future.

10. Who should be offered PEP?
PEP medication and counseling should be offered to any individual who has had a "significant" exposure to HIV. Starting medications as soon as possible after an exposure is beneficial. 72 hours after an exposure, HIV has become hidden within the cells of a person so that taking medications will be less likely to be effective. A significant sexual exposure is when a person has receptive or penetrative anal intercourse , receptive or penetrative vaginal or receptive oral intercourse with ejaculation. Significant sexual exposures are always without a condom (or when the condom breaks) and with someone who is HIV infected. Since it is not always possible to know if the person you are having sex with is HIV infected, PEP should be offered to anyone who has had a significant sexual exposure with a "high risk" partner. High risk partners are men who have had sex with men, anyone with a history of injection drug use, sex workers and anonymous partners. Anyone who shares contaminated needles should also be offered PEP participation

11. What are some of the side effects expected from taking medication?
Some people will get some nausea from most of the medications. Some people also report some fatigue. Rarely people develop anemia from the AZT and some of the other medications can produce diarrhea and rarely liver or pancreas inflammation.

12. When and where will PEP medication and counseling be available?
Starting October 1, 1997, we will begin a pilot phase of offering PEP. We will be offering this

treatment at two sites initially, Ward 4C at SFGH and City Clinic on 7th Street between Harrison and Folsom. We hope to open a third site on Polk Street soon. The SFGH site will be open 7 days a week for at least 4 hours a day. The 4C clinic will be open M-F from 9-5 and Saturday and Sunday 9-1230. City Clinic will be open M,W, F from 830-330 and Tuesday from 1-330pm and Thursday from 1-330pm. Appointments are not necessary and people should just walk in to these sites. We have a 24 hour hotline for people to call for more information. The 24 hour number is 502-5PEP.

13. What is the counseling part of PEP all about?
We think that taking medication after exposure to HIV will help prevent infection but we cannot be sure. However, helping people to develop skills to avoid exposure in the first place has been shown to be an effective strategy to reduce HIV infection. Counseling will be individualized to help people develop the life skills to avoid exposure and to cope with the fear of becoming infected as well as developing strategies to successfully take the medications during the 28 day treatment period. Also, the counseling will help people access other care such as medical, psychiatric, substance use and housing so that individuals who come to our prevention sites can be assisted in accessing their most needed services.

14. Will counselors be able to speak the language of the person seeking care?
We are committed to having Spanish and English speaking counselors. We will have translator services available for most other languages.

15. Do patients have to give their real name or can they stay anonymous?
We encourage people to give us their real name and we will do everything possible to keep the information they give us confidential including keeping all data under lock and key. However, if an individual chooses to give us a false name we will accept whatever name they offer. We will need them to give us the same name each time they come in for care.

16. How often does someone have to come in to be part of the study?
We want people to show up for counseling, medication refills and laboratory testing nine times throughout the year with five visits in the first six weeks. We will strongly encourage all people to keep all their appointments and will work hard to arrange our schedule to match the schedule of the subjects. We do offer a small financial compensation for the inconvenience of returning to the PEP site.

17. What laboratory tests will be done?
We will take blood for HIV antibody and HIV viral load upon entry to the study, again at 4 weeks and again at half a year and a year. We will also do some lab tests to make sure that the subject does not have any medical conditions that will make taking the medication dangerous. We will monitor these tests again at 4 weeks to be sure that the medications did not cause any harm. We will also be doing a pregnancy test at 2 weeks. We will evaluate the subject for other sexually transmitted diseases.

18. How much will the treatment cost?
No charge. As this is a research project, we do not expect the subject to pay for the counseling, testing or medications.

19. What is the difference between PEP and Early Intervention Treatment (Options Project)?
The idea behind PEP is to provide people who have had a known exposure to HIV but have not seroconverted, medication and counseling to prevent the individual from becoming infected (seroconversion). Early intervention, through the Options Project (call 502-8100) provides early diagnosis and treatment to people who are thought to be infected either because of acute retroviral syndrome, a positive viral load test or a known new infection within the past year. PEP hopes to prevent infection following exposure. Early Intervention hopes to delay illness from those already infected indefinitely.

20. Will individual who take PEP medication be ineligible for other research projects?
Some research projects demand that individuals enter the project having never taken anti-HIV medications. If an individual is already HIV positive before taking medications or becomes HIV positive after taking the medications, they may have some difficulty being enrolled in studies that

demand the subject to be anti-retroviral "naive." However, we believe that exemptions can be made for these few people who want access to these research studies.

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