HIV Postexposure Prophylaxis for Special Forces Soldiers

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Abstract

Exposure to human immunodeficiency virus (HIV) is a recognized occupational hazard to healthcare personnel. The virus also presents an operational hazard to deployed Special Operations Forces (SOF) personnel. Management guidelines for work related exposure to HIV mainly deal with healthcare workers in a first world hospital environment. Formal guidelines for postexposure prophylaxis (PEP) regarding potential HIV exposure in third world environments have not been established. SOF personnel deploy to regions such as sub-Saharan Africa with a reported HIV prevalence of 35% or higher. This article examines the case of a SOF servicemember exposed to HIV in a confrontation with host nation personnel, the problems with trying to utilize current CDC guidelines and host-nation healthcare capabilities, and a proposed solution devised to ensure appropriate PEP in future cases.

Introduction

Human immunodeficiency virus (HIV) is a known occupational hazard to personnel who work in a medical setting.[1,2,3,4,5,6,7] The United States Centers for Disease Control (CDC) has published guidelines for the management of worker exposures to HIV and recommendations for postexposure prophylaxis (PEP).[8] These guidelines are designed for the management of healthcare worker exposures to HIV that occur in the U.S. The guidelines are designed for use in the hospital setting where the source patient is often known and easily available for assessment. In these cases treatment providers have a known source, the medical history is available, and the patient can easily be assessed for HIV risk factors, testing, and follow-up.

Members of U.S. Military Special Operations Forces, particularly the U.S. Army Special Forces, are often involved in training exercises and other operations in third world countries where medical care is substantially below U.S. standards. Many of these countries, specifically those in sub-Saharan Africa, have a high prevalence of HIV in the population.[9,10,11] Currently the CDC guidelines provide a starting point for planning the medical response for Soldiers who sustain a significant exposure to blood and/or body fluids while working in these areas of endemic HIV disease.

Case

A 35 year-old U.S. Army Special Forces Soldier sustained a deep human bite in an altercation with a criminal in a sub-Saharan African country. The injured Soldier was traveling in a car with two other Special Forces Soldiers when they were stopped by armed criminals, who demanded the Soldiers' money and passports. The Soldiers were involved in a physical altercation during which the injured Soldier was able to disarm the criminal. However, in the process he was bitten deeply on his left forearm. At the time of the bite the criminal had blood on his face and in his mouth from wounds he had sustained during the fight. The bitten Soldier detained the criminals until the police arrived. Subsequently (approximately two hours after the bite) he went to the U.S. Embassy and had his wound cleaned by the embassy nurse. The Soldier contacted his unit medical officer (UMO) for recommendations. The UMO then consulted with his Group Surgeon. Due to the unknown nature of the source patient, HIV post-exposure prophylaxis was recommended. The U.S. Embassy had a supply of Combivir (300mg zidovudine and 150mg lamivudine) available. He was started on Combivir approximately eight hours post-exposure and then evacuated to the U.S. Upon his return he was started on a six-week treatment course of Indinavir in addition to the Combivir. He also received a baseline

HIV test (negative) and hepatitis panel. Prior to deployment, the patient had been immunized for hepatitis B and upon return tested negative for hepatitis C. Host-nation officials subsequently reported that the criminal who bit the U.S. Soldier was HIV positive. The Soldier has completed his course of HIV post-exposure prophylaxis and has remained sero-negative on follow-up testing.

TABLE 1. Recommended HIV postexposure prophylaxis (PEP) for percutaneous injuries

Exposure type	Infection status of source: HIV-positive, class 1*	HIV-positive, class 2*	Source of unknown HIV status†	Unknown source§	HIV-negative
Less severe¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted
More severe§§	Recommend expanded 3-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.
† For example, deceased source person with no samples available for HIV testing.
§ For example, a needle from a sharps disposal container.
¶ For example, solid needle or superficial injury.
** The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.
†† If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.
§§ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.

TABLE 2. Recommended HIV postexposure prophylaxis (PEP) for mucous membrane exposures and nonintact skin* exposures

Exposure type	Infection status of source: HIV-positive, class 1†	HIV-positive, class 2†	Source of unknown HIV status§	Unknown source¶	HIV-negative
Small volume**	Consider basic 2-drug PEP††	Recommend basic 2-drug PEP	Generally, no PEP warranted§§	Generally, no PEP warranted	No PEP warranted
Large volume¶¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP†† for source with HIV risk factors§§	Generally, no PEP warranted; however, consider basic 2-drug PEP†† in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).
† HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.
§ For example, deceased source person with no samples available for HIV testing.
¶ For example, splash from inappropriately disposed blood.
** For example, a few drops.
†† The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.
§§ If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.
¶¶ For example, a major blood splash.

The CDC Guidelines

In the Morbidity and Mortality Weekly Report, September 30, 2005 (Vol. 54, No. RR-9), the CDC published "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis." The guidelines are based on available literature, which shows that postexposure prophylaxis (PEP) can prevent infection after a significant exposure to HIV infected blood or body fluids.

The reported risk for HIV transmission after percutaneous exposure to HIV positive blood is 0.3% (95% confidence interval = 0.2% - 0.5%). The reported risk after a mucous membrane exposure is 0.09% (95% confidence interval 0.006% - 0.5%). There are three factors associated with an increased risk for infection, and all are related to the volume of blood or body fluid from the source. First, a device (such as a needle) visibly contaminated with the source blood is associated with an increased risk. Second, a procedure that involved a needle being placed directly in a vein or artery is associated with an increased risk. Finally, a "deep" injury (no definition of how deep was reported) was associated with increased risk.[12]

The guidelines are represented in the form of two tables that divide exposure types into "Less Severe" and "More Severe" categories for percutaneous injuries, and "Small Volume" and "Large Volume" exposures for mucous membranes and non-intact skin. These categories are then cross-referenced against the status of the source – "HIV Positive Class 1" (asymptomatic or low viral load), "HIV Positive Class 2" (symptomatic HIV or known high viral load), or "Source of unknown HIV status."[13] (See Tables 1 and 2.)

By plugging in the variables mentioned above, the tables can be used to generate a postexposure prophylaxis recommendation. There are four categories: "No PEP warranted," "Consider basic 2 drug PEP," "Recommend basic 2 drug PEP," and "Recommend expanded > /= 3 drug PEP." The CDC recommends four weeks of therapy for HIV PEP.

The Problem

In many third world countries the medical system lacks the capability to easily determine whether the source patient is class 1, class 2, or HIV negative. Source patients may be unavailable for testing and risk-assessment or may have no knowledge of an existing infection. The logistics of arranging for a host nation hospital HIV test

for the source are often problematic, or the test may be unavailable. In addition, the source may be reluctant to consent for testing because of the social stigma surrounding the diagnosis. In certain sub-Saharan African nations the HIV prevalence is reported to be up to 35%, with some sub-groups of the population have reported rates of up to 68%.[14] Based on the high prevalence rates one should assume when in sub-Saharan Africa that the HIV status of the source patient is positive if testing is unavailable. In other areas of the world, the unit medical officer must know the HIV rates and decide whether or not to assume source personnel are at increased risk for HIV disease.

Incorporating these circumstances into the guidelines, several types of exposure should be considered for HIV PEP with the basic or expanded regimen. These exposures include blood or body fluids on mucous membranes or non-intact skin, percutaneous exposure with a solid or large bore hollow needle with visible source patient blood on it, or percutaneous exposure to a needle used in the source patient's artery or vein. Another potential exposure that could be faced by Special Forces Soldiers in a third world setting is the receipt of blood or blood products for medical purposes.[15] A review of the Armed Forces Medical Intelligence Center "Medical Environmental Disease Intelligence and Countermeasures" CD-ROM demonstrates that no sub-Saharan African countries have safe blood supplies. However, a severely ill or injured Soldier may have to rely on local blood or blood products to survive. There are no studies done on the efficacy of HIV PEP in this situation, but it is not unreasonable to offer it to the patient.

Over the last several years the FDA has approved several rapid, easy to perform, and inexpensive HIV tests that can be done on whole blood (the Uni-Gold Recombigen HIV Test, the Clearview HIV 1/2 Stat-Pak, and the Clearview Complete HIV 1/2 Test) or whole blood and oral fluid (the OraQuick Advance Rapid HIV 1/2 Anitbody Test). If available to the medical personnel treating the exposed patient, the use of one of these tests can provide more information that can aid in the decision making process. See http://www.cdc.gov/hiv/topics/testing/rapid/rt-comparison.htm for a complete list of their complexity and costs.

A Solution

Many units conduct training and operations in Africa and other geographic areas that have high rates of HIV infection. Due to the close associations between Special Forces Soldiers and the host-nation military and civilian populations of many countries, there is concern for potential occupational exposures to HIV infected blood or body fluids. Occupational exposures can occur in many different scenarios. While doing host nation medical training, the unit Medic could be exposed by an inadvertent needle stick. Both medical and non-medical Soldiers could be exposed while caring for injured civilians or host nation soldiers. The potential for exposure to blood or body fluids is high while conducting humanitarian demining missions or explosives training due to the nature of blast injuries. The case presented was the result of an altercation during a robbery attempt.

The United States Special Operations Command has published Tactical Medical Emergency Protocols (TMEPs) for use by Special Operations Advanced Tactical Practitioners (ATPs). One of the TMEPs specifically addresses HIV post exposure prophylaxis. This is a good starting point when no other guidance is available, however, it fails to address the availability of a rapid HIV test and the recommendations for therapy while appropriate, are dated.[16] Currently, the TMEP for HIV post exposure prophylaxis is under revision in order to provide more treatment options. For units training and conducting operations in high risk areas, an expanded discussion is presented below.

One solution to mitigate the risk of exposures occurring in the deployed environment is a program in which each Medic deployed to a high risk area carries a supply of an expanded three-drug post-exposure prophylaxis. Anywhere from a five to fifteen day supply for one patient, dependent upon the ease of evacuation or repatriation, should be considered. As the number of drugs for the treatment of HIV has expanded, so have the recommendations for different drug combinations for post-exposure prophylaxis. The simplest is Atripla (emtricitibine/ tenofovir/efavirenz), which contains three drugs in one pill that is administered once a day. This combination has a high (52%) incidence of CNS side-effects, so even though it is the only 3-in-1 drug combination, consider it cautiously. Other potential three drug combinations include Combivir (AZT + lamivudine) one tablet PO bid + tenofovir 300mg PO qd or Truvada (emtricitabine/tenofovir) one tablet PO qd + AZT 300mg PO bid.[16] The unit medical officer planning on implementing an HIV post-exposure prophylaxis protocol should carefully look at the drugs available and their side-effect profiles (which are considerable). In addition, because new anti-retrovirals are regularly introduced, it is highly recommended that an infectious disease specialist be consulted during the development of a protocol. The Medics should be instructed verbally and in writing (on a reference sheet issued with the medications) on the indications, dosage, and side-effects of the PEP medications. Once a drug regimen is selected, if the side-effect profile

includes nausea, vomiting, or diarrhea, a supply of antiemetics or anti-diarrheals should be offered to control the side-effects of the HIV PEP medications. The protocol for the Medic should be to start HIV PEP within one hour of (or as soon as possible after) a significant exposure and to initiate the evacuation of the patient to the United States for four weeks of continued therapy. Evacuation of the patient back to the United States is recommended because the considerable side-effect profiles of these medications will likely make the patient non-mission capable. In addition, compliance with the regimen will likely be better if the patient is in a more supportive environment (home vs. deployed). If the source patient can be identified and tested using a rapid HIV test, the results can be used to determine whether or not to initiate therapy. Once the test sample is taken, the test itself only takes 20 – 40 minutes to produce a result. The initiation of HIV PEP for a significant exposure should not be delayed in the event it takes longer than one hour to locate and test the source patient. The Medic "reference sheet" should also direct universal precautions when providing medical care and should encourage immediate scrubbing and irrigation of wounds with soap and water.

DISCUSSION

While implementation of an HIV PEP program is important in maintaining the health of our Soldiers, it should be done in a deliberate fashion. In the case of U.S. Army Special Forces Soldiers, the HIV PEP medications are likely to be administered by a Special Forces Medical Sergeant. Special Forces Medical Sergeants (MOS 18D), Civil Affairs Medics (MOS 68WW1), Special Operations Aviation Regiment Medics (MOS 68WW1), and Ranger Regiment Medics (MOS 68WW1) are currently trained to Advanced Tactical Provider (ATP) standards at a minimum. This is the United States Special Operations Command equivalent to a NREMT-P; however, their training goes above and beyond that of an EMT-P. A Medic should have the ability to start the treatment under a strict protocol, and often in the absence of a physician. The unit protocol should be designed to ensure that there are adequate controls on the issue of the medications and that the medics, battalion surgeons, and battalion physician assistants are fully educated on their indications, contraindications, and side-effects.

There are several issues that need to be addressed when developing a protocol. The first is to ensure that the medications are used only for indicated significant exposures. This involves training the providers on the definition of what constitutes a significant exposure. Casual contact with HIV positive individuals and exposure to animal blood or body fluids do not pose a risk for HIV transmission. While unprotected sexual contact with host nationals is a risk for HIV transmission, it can be mitigated by education and condom distribution. This does not constitute an occupational exposure. The second issue is the side-effect profile of the medications. Patients frequently discontinue HIV PEP due to the gastrointestinal side-effects that include nausea, abdominal pain, cramping, and diarrhea. Medical providers need to be made aware of these side-effects and available treatment options. They should also be prepared to counsel their patient on the expected symptoms and methods of treatment to ameliorate the side-effects. Efforts should also be made to educate the patient's co-workers to reinforce the fact that though potentially exposed, the patient is not a transmission risk via casual contact. The third issue to be considered is the use of HIV PEP in the situation where the exposure is to blood/body fluids from a suicide bomber or bomb victim. In this situation, the prevalence of HIV disease in this population, as well as the availability of remains that could be used as a source for a rapid HIV test, should be considered when making the decision to initiate HIV PEP. Decisions will have to be made on a case by case basis, but in general, the CDC assessment of risk in this situation is that it is very low.

Issues to be Addressed in the Development of a Standard Operating Procedure:

- The level at which the HIV PEP medications and the Oraquick Rapid HIV Test Kit will be maintained. Team Medic, company Medic, or battalion Medic/PA/sSurgeon should each be considered based on the pre-mission planning.
- Identification of those exposures that will initiate an assessment of the need for HIV PEP.
- Development of a risk assessment that includes exposure type and status of the source. Include the availability of the rapid HIV test kit, but also must address those situations where the source patient is unavailable or refuses to be tested.
- Identification of the drugs to be used to initiate HIV PEP. At the least a three drug regimen should be considered and an infectious disease specialist with experience in treating HIV disease should be consulted to help select the drugs. Once the drugs are selected, consideration should be made for including drugs that will help treat the side-effect profiles of the HIV PEP regimen selected.
- The SOP should also include a plan for evacuation or repatriation of the exposed patient, and a plan for follow-up testing.

FDA-Approved Rapid HIV Antibody Screening Tests

February 4, 2008

	FDA Approval Received	Specimen Type	CLIA Category*	Sensitivity** (95% CI)	Specificity** (95% CI)	Manufacturer	Approved for HIV-2 Detection?	List Price Per Device^	External Controls
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	Nov 2002	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. www.orasure.com	Yes	$17.50	Sold Separately ($25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
Uni-Gold Recombigen HIV	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech www.unigoldhiv.com	No	$15.75 *$8.00•*	Sold Separately ($26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
Reveal G-3 Rapid HIV-1 Antibody Test	Apr 2003	Serum	Moderate Complexity	99.8% (99.2-100)	99.1% (98.8-99.4)	MedMira, Inc. www.medmira.com	No	$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.0-100)	98.6% (98.4-98.8)				

•*"Public health" price for public health programs that are recipients of CDC funds for expanded HIV testing*

* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

** Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

^ Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.

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CDC

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MultiSpot HIV-1/HIV-2 Rapid Test	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories www.biorad.com	Yes – differentiates HIV-1 from HIV-2	$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				
Clearview HIV 1/2 STAT-PAK	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.9% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Yes	$17.50 *$8.00•*	Sold Separately ($50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				
Clearview COMPLETE HIV 1/2	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.90% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Yes	$18.50 *$9.00•*	Sold Separately ($50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				

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Conclusion

The issue of HIV postexposure prophylaxis is important in the civilian management of occupational exposures to contaminated blood and body fluids.[2,7,8] The guidelines published by the CDC are intended for healthcare workers in the U.S. who have the resources of a highly developed medical system to draw upon. In contrast, U.S. Special Forces Soldiers operate in third world countries with rudimentary medical systems and high HIV prevalence. The potential for occupational exposure (even to non-medical personnel) is high. Medial officers in units that deploy to high-risk areas should strongly consider developing a protocol or standard operating procedure (SOP) that ensures that their medics are aware of and have access to the latest recommendations involving HIV PEP. By doing so, we will continue to "conserve the fighting strength" of our nation's most highly trained Soldiers.

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