Straightening out a bloody mess!

A Novel Bloodborne Pathogen Exposure Procedure

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  • Medical Director, Cincinnati Fire Department
  • Medical Director, Colerain Township Fire and EMS
Conflict of Interest

- none
- No pay
- No stock
- No endorsement
- Company provided testing units
Scope of the problem: Exposure Stats

• The National Study to Prevent Blood Exposure in Paramedics
  • **Survey study** – 6,500 paramedics sampled
  • 2,664 paramedics responded
  • 538 individuals experienced 895 exposures within the previous 12 months.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Route of exposure</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Needlestick/ lancet</td>
<td>Cut from</td>
<td>Mucous</td>
<td>Non-intact skin</td>
<td>Bite</td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N  Rate (95% CI)</td>
<td>sharp object</td>
<td>membrane</td>
<td></td>
<td>Rate (95% CI)</td>
<td></td>
<td>Rate (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>95 99 (28–171)</td>
<td>68 44 (3–86)</td>
<td>111 80 (51–110)</td>
<td>436 261 (135–387)</td>
<td>19 10 (4–17)</td>
<td>729 496 (298–694)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>37 102 (83–120)</td>
<td>14 24 (10–39)</td>
<td>36 101 (36–167)</td>
<td>72 106 (69–143)</td>
<td>6 b</td>
<td>165 345 (244–446)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### Other Studies of EMS Exposure Rates

**Table 3** Exposure incidence rates among emergency medical services providers and firefighters

<table>
<thead>
<tr>
<th>Study location</th>
<th>Study author</th>
<th>Exposure time period</th>
<th>Occupation</th>
<th>Needlestick injuries per 1,000 employee-years</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Louis, MO</td>
<td>Hochreiter and Barton (1988)</td>
<td>1982–1985</td>
<td>All EMS</td>
<td>145</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Paramedics</td>
<td>181</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Basic EMTs</td>
<td>87</td>
</tr>
<tr>
<td>Florida</td>
<td>Klontz et al. (1991)</td>
<td>1987</td>
<td>Paramedics</td>
<td>367(^a)</td>
</tr>
<tr>
<td>Portland, OR</td>
<td>Reed et al. (1993)</td>
<td>1988–1989</td>
<td>All firefighter-EMS</td>
<td>11(^a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Firefighter-paramedics</td>
<td>91(^a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Firefighter-EMTs</td>
<td>3(^a)</td>
</tr>
<tr>
<td>New York City, NY; Chicago, IL; Baltimore, MD</td>
<td>Marcus et al. (1995)</td>
<td>1989</td>
<td>EMS</td>
<td>200(^a)</td>
</tr>
<tr>
<td>Atlanta, GA</td>
<td>Woodruff et al. (1993)</td>
<td>1991</td>
<td>EMS</td>
<td>95(^a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Firefighters (non-EMS)</td>
<td>0(^b)</td>
</tr>
<tr>
<td>Baltimore, MD</td>
<td>Gershon et al. (1995)</td>
<td>1992</td>
<td>EMS</td>
<td>56(^a)</td>
</tr>
<tr>
<td>Fulton County, GA</td>
<td>Averhoff et al. (2002)</td>
<td>1992–1993</td>
<td>Firefighters (non-EMS)</td>
<td>11(^a)</td>
</tr>
<tr>
<td>Dade County, FL</td>
<td>Carrillo et al. (1996)</td>
<td>1993–1994</td>
<td>Paramedics</td>
<td>180(^a)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EMTs</td>
<td>30(^a)</td>
</tr>
<tr>
<td>United States (present study)</td>
<td>Boal et al.</td>
<td>2002–2003</td>
<td>Paramedics</td>
<td>100(^c)</td>
</tr>
<tr>
<td>California (present study)</td>
<td></td>
<td></td>
<td></td>
<td>26(^c)</td>
</tr>
</tbody>
</table>

EMS emergency medical services, EMTs emergency medical technicians

\(^a\) Calculated from data presented in original paper

\(^b\) No needlestick injuries among 611 firefighters over a 6 month period

\(^c\) Needlestick and lancet injuries
HIV Risk for Exposed Providers:

- needle stick/cut exposure
  - 0.3% (1 in 300) or ...
  - 99.7% of exposures do not lead to provider infection.
- eye, nose, or mouth (mucous membrane)
  - estimated to be 0.09% (1 in 1,000).
- non-intact skin
  - estimated to be less than 0.09%.
Other Factors Increasing risk for HIV infection

• Percutaneous exposure to a larger quantity of blood from the source person as indicated by:
  • a device (e.g., a needle) visibly contaminated with the patient's blood
  • a procedure that involved a needle being placed directly in a vein or artery
  • a deep injury.

• The risk also was increased for exposure to blood from source persons with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course (AIDS)
OSHA: 29CFR1910.1030

• .....in order to determine HBV and HIV infectivity.
  • source individual's blood shall be tested as soon as feasible after consent is obtained
• If consent is not obtained, the employer shall establish why that consent cannot be obtained.
• If the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.
• Results of the source individual's testing shall be made available to the exposed employee
**Question:** Is it a violation of 29 CFR 1910.1030 for a medical facility subject to OSHA authority not to perform "rapid HIV antibody testing" on a source individual after an exposure incident?

**Reply:** As you may know, the bloodborne pathogens standard provides that "the source individual's blood shall be tested as soon as feasible" after an exposure incident and after consent is obtained [29 CFR 1910.1030(f)(3)(ii)(A)]. At the current time there are at least four FDA-approved tests available for "rapid HIV antibody testing," which usually can confirm negative HIV status in less than an hour after blood is drawn from a source individual. They are widely available, easy to use, and inexpensive. Standard enzyme immunoassay (EIA) testing can take a much longer time, especially if facilities to perform the tests are not available locally. Therefore, an employer’s failure to use rapid HIV antibody testing when testing as required by paragraph 1910.1030(f)(3)(ii)(A) would usually be considered a violation of that provision. The use of rapid HIV antibody testing is supported by the current CDC recommendations for HIV post-exposure prophylaxis (PEP) in the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*, published on September 30, 2005. The CDC states on page 7 that having a "rapid HIV test could result in decreased use of PEP and spare personnel both undue anxiety and adverse effects of antiretroviral PEP." The document goes on to note on page 8 that "rapid HIV testing of source patients can facilitate making timely decisions regarding use of HIV PEP after occupational exposures to sources of unknown HIV status." Current guidance on the management of HBV and HCV exposure and PEP, as well as guidance for evaluation of the exposure source, is also contained in the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Postexposure Prophylaxis* (June 29, 2001),
Post Exposure Prophylaxis (PEP)

• PEP has been demonstrated to reduce seroconversion in both animal and human studies (50-84%)

• Current treatment “standard”
  • Start of PEP within 4 hours
    ▪ Based on animal models
  • What is the best timeline?
    ▪ Hours/not days
<table>
<thead>
<tr>
<th>Class and agent</th>
<th>Side effect and toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nucleoside reverse transcriptase inhibitors (NRTIs)</strong></td>
<td><strong>Class warning:</strong> all NRTIs have the potential to cause lactic acidosis with hepatic steatosis</td>
</tr>
<tr>
<td>Zidovudine (Retrovir®, ZDV, AZT)</td>
<td>Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness</td>
</tr>
<tr>
<td>Lamivudine (Epivir®, 3TC)</td>
<td>Abdominal pain, nausea, diarrhea, rash, and pancreatitis</td>
</tr>
<tr>
<td>Stavudine (Zerit™; d4T)</td>
<td>Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver function tests (LFTs), anemia, and neutropenia</td>
</tr>
<tr>
<td>Didanosine (Videx®, ddI)</td>
<td>Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity</td>
</tr>
<tr>
<td>Emtricitabine (Emtriva, FTC)</td>
<td>Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity</td>
</tr>
<tr>
<td><strong>Nucleotide analogue reverse transcriptase inhibitor (NtRTI)</strong></td>
<td></td>
</tr>
<tr>
<td>Tenofovir (Viread®; TDF)</td>
<td>Nausea, diarrhea, vomiting, flatulence, and headache</td>
</tr>
<tr>
<td><strong>Nonnucleoside reverse transcriptase inhibitors (NNRTIs)</strong></td>
<td></td>
</tr>
<tr>
<td>Efavirenz (Sustiva®, EFV)</td>
<td>Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity</td>
</tr>
<tr>
<td><strong>Protease inhibitor</strong></td>
<td></td>
</tr>
<tr>
<td>Indinavir (Crixivan®, IDV)</td>
<td>Nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia</td>
</tr>
<tr>
<td>Nelfinavir (Viracept®, NFV)</td>
<td>Diarrhea, nausea, abdominal pain, weakness, and rash</td>
</tr>
<tr>
<td>Ritonavir (Norvir®, RTV)</td>
<td>Weakness, diaphoresis, myalgia, circumscribed paresthesias, taste alteration, and elevated cholesterol and triglycerides</td>
</tr>
<tr>
<td>Saquinavir (Invirase®, SQV)</td>
<td>Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs</td>
</tr>
<tr>
<td>Fosamprenavir (Lexiva®, FOSAPV)</td>
<td>Nausea, diarrhea, rash, abdominal pain, weakness, and depression</td>
</tr>
<tr>
<td>Atazanavir (Reyataz®, ATV)</td>
<td>Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia</td>
</tr>
<tr>
<td>Lopinavir/ritonavir (Kaltra®, LPV/RTV)</td>
<td>Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides</td>
</tr>
<tr>
<td><strong>Fusion Inhibitor</strong></td>
<td></td>
</tr>
<tr>
<td>Enfuvirtide (Fuzeon®, T-20)</td>
<td>Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy, and cough</td>
</tr>
</tbody>
</table>

Summary

This report updates U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain human immunodeficiency virus (HIV). Although the principles of exposure management remain unchanged, recommended HIV postexposure prophylaxis (PEP) regimens have been changed. This report emphasizes adherence to HIV PEP when it is indicated for an exposure, expert consultation in management of exposures, follow-up of exposed workers to improve adherence to PEP, and monitoring for adverse events, including seroconversion. To ensure timely postexposure management and administration of HIV PEP, clinicians should consider occupational exposures as urgent medical concerns.
Cincinnati Program

• Exposed fire fighter goes to ED for evaluation
  • Blood drawn: Hepatitis, HIV
• Sample Source patient
  • if at hospital have blood tested.
  • If not, try to get blood
  • appropriate HIV testing by the hospital
• Result of source patient HIV test used as a factor in decision to start PEP
Problems: Old System

• Consent
• Actual Testing
  ▪ Who/How?
    ◦ RN
  ▪ How quickly was it done?
  ▪ Where is the patient
• ED MD issue
Consenting your patient.
Eagles Survey: Consent Issue

If your department tests the source patient (for HIV) after an exposure:

- Are you required to consent the source patient? [10 Yes, 10 No]
- If they refuse consent does your department have any other options? [11 Yes, 7 No]
Emergency Medical Services Personnel Exposure Law

(Emergency Medical Services Agency Version)

- EMS agencies must petition the court to obtain an order for testing a source individual if there is no blood available from the source individual and the source individual refuses to have blood drawn/tested. Such petitions submitted by EMS agencies must contain affidavits documenting that:
  - the hospital followed the protocol (below) and attempted to obtain bloodborne pathogen test results;
  - a significant exposure occurred; and
  - a physician with specialty training in infectious diseases, including HIV, has documented that the exposed person has provided a blood sample and consented to testing for bloodborne pathogens and that bloodborne pathogen test results on the source individual are needed to determine medical treatment for the exposed person.
Ohio Revised Code

• 3701.242 Informed consent to HIV test required.
  • Exemption:
    ▪ If the health authority determines that a health care provider, emergency medical services worker, or peace officer, while rendering health or emergency care to an individual, has sustained a significant exposure to the body fluids of that individual, and the individual has refused to give consent for testing.
Source Patient Testing Issues

- Nursing/phlebotomy issues
  - Testing of the exposed FF
    - Baseline HIV
    - Hepatitis panel
  - Testing of the source patient
    - Rapid HIV
    - Hepatitis panel
- Laboratory issues
  - Blood tube labelling
  - Reporting Test results
  - Who gets charged?
Where is the source patient?

- Jail / police custody
- Coroners Office
- Different ED
- Gone
Emergency Department Mishandling

• PHS guidelines for the management of occupational exposures to HIV were first published in 1985
• Updated in 2001.
• Focus groups conducted among ED physicians in 2002 indicated:
  • > 95% had not read the 2001 guidelines
• All physicians participating in the focus groups had recently managed occupational exposures to blood or body fluids.
Take control
A New Program friendly to EMS

Exposure Event → Complete Patient Care

Initiate Exposure protocol
Call "IC officer"

Process Exposed Provider

Draw Baseline Blood levels: HIV & Hepatitis

Collect source patient blood

Lab performance of HIV test

Sample source patient

Results reported

Decision to start PEP

Exposure Event → Complete Patient Care

Initiate Exposure protocol
Call "IC officer"

Sample source patient

Process Exposed Provider

Draw Baseline Blood levels: HIV & Hepatitis

Performance of HIV test

Results reported

Decision to start PEP
A Rapid Review of Rapid HIV Antibody Tests

<table>
<thead>
<tr>
<th>Test Kit Name</th>
<th>Manufacturer</th>
<th>Specimen Type</th>
<th>CLIA Category</th>
<th>Shelf Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick Advance Rapid HIV-1/2 Antibody Test</td>
<td>Orasure Technologies Inc</td>
<td>Whole Blood, Oral Fluid</td>
<td>Waived</td>
<td>8 months</td>
</tr>
<tr>
<td>Reveal G3 Rapid HIV-1 Antibody Test</td>
<td>MedMira, Inc.</td>
<td>Plasma</td>
<td>Moderate Complexity</td>
<td>1 year</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Test</td>
<td>Trinity BioTech</td>
<td>Whole Blood</td>
<td>Waived</td>
<td>1 year</td>
</tr>
<tr>
<td>Multispot HIV-1/HIV-2 RapidTest</td>
<td>Bio-Rad Laboratories</td>
<td>Serum, Plasma</td>
<td>Moderate Complexity</td>
<td>1 year</td>
</tr>
<tr>
<td>Clearview HIV 1/2 Stat Pak</td>
<td>Inverness Medical</td>
<td>Whole Blood</td>
<td>Waived</td>
<td>2 years</td>
</tr>
<tr>
<td>Clearview Complete HIV 1/2</td>
<td>Inverness Medical</td>
<td>Serum, Plasma</td>
<td>Moderate Complexity</td>
<td>2 years</td>
</tr>
</tbody>
</table>

Greenwald, *Current Infectious Disease Reports* 2006, 8:125–131
A Rapid Review of Rapid HIV Antibody Tests

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>OraQuick Advance Rapid HIV-1/2 Antibody Test</td>
<td><a href="#">OrasureTechnologies, Inc</a></td>
<td>Whole Blood, Oral Fluid, Plasma</td>
<td>Waived</td>
<td>6 months</td>
</tr>
<tr>
<td>Reveal G3 Rapid HIV-1 Antibody Test</td>
<td><a href="#">MedMira, Inc</a></td>
<td>Serum, Plasma</td>
<td>Moderate Complexity</td>
<td>1 year</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Test</td>
<td><a href="#">Trinity BioTech</a></td>
<td>Whole Blood</td>
<td>Waived</td>
<td>1 year</td>
</tr>
<tr>
<td>Multispot HIV-1/HIV-2 RapidTest</td>
<td><a href="#">Bio-Rad Laboratories</a></td>
<td>Serum, Plasma</td>
<td>Moderate Complexity</td>
<td>1 year</td>
</tr>
<tr>
<td>Clearview HIV 1/2 Stat Pak</td>
<td><a href="#">Inverness Medical Professional Diagnostics</a></td>
<td>Whole Blood, Serum, Plasma</td>
<td>Waived</td>
<td>2 years</td>
</tr>
<tr>
<td>Clearview Complete HIV 1/2</td>
<td><a href="#">Inverness Medical Professional Diagnostics</a></td>
<td>Whole Blood, Serum, Plasma</td>
<td>Waived</td>
<td>2 years</td>
</tr>
</tbody>
</table>

Greenwald, *Current Infectious Disease Reports* 2006, 8:125–131
# Accuracy of Rapid HIV Tests

<table>
<thead>
<tr>
<th>Rapid HIV test*</th>
<th>Specimen type</th>
<th>Sensitivity†</th>
<th>Specificity†</th>
<th>CLIA category</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick® Advance Rapid HIV-1/2 Antibody test</td>
<td>Oral fluid</td>
<td>99.3% (98.4–99.7)</td>
<td>99.8% (99.6–99.9)</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>99.6% (98.5–99.9)</td>
<td>100% (99.7–100)</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>99.6% (98.9–99.8)</td>
<td>99.9% (99.6–99.9)</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td>Reveal™ G-2 Rapid HIV-1 Antibody test</td>
<td>Serum</td>
<td>99.8% (99.5–100)</td>
<td>99.1% (98.8–99.4)</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>99.8% (99.5–100)</td>
<td>98.6% (98.4–98.8)</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td>Uni-Gold Recombigen® HIV test</td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>100% (99.5–100)</td>
<td>99.7% (99.0–100)</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>Serum and plasma</td>
<td>100% (99.5–100)</td>
<td>99.8% (99.3–100)</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td>Multispot HIV-1/HIV-2 Rapid test</td>
<td>Serum</td>
<td>100% (99.94–100)</td>
<td>99.93% (99.79–100)</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>100% (99.94–100)</td>
<td>99.91% (99.77–100)</td>
<td>Moderate complexity</td>
</tr>
</tbody>
</table>

*Trade names are for identification purposes only and do not imply endorsement by the US Department of Health and Human Services or the Centers for Disease Control and Prevention.
†95% CI
CLIA—the Clinical Laboratory Improvement Amendments of 1998.


Greenwald, *Current Infectious Disease Reports* 2006, 8:125–131
Rapid Test Steps

Oral Fluid
Swab lower and upper gum once. DO NOT swab the roof of the mouth, cheeks or tongue.

Fingerstick Whole Blood
Cleanse finger. Air dry. Puncture with lancet.
Wipe away first drop of blood. Fill the Collection Loop.
Rapid Test Steps

Oral Fluid
Swab lower and upper gum once.
DO NOT swab the roof of the mouth, cheeks or tongue.

Fingerstick Whole Blood
Cleanse finger. Air dry. Puncture with lancet.
Wipe away first drop of blood. Fill the Collection Loop.

20 minutes
Rapid Testing Issues

• Clinical Laboratory Improvement Amendment (CLIA) licensing:
  • Some tests are CLIA waived
  • Still requires laboratory affiliation
  • Recently infected source patients.
    • Patients infected within the previous 2-3 months may not be antibody positive = false negative
    • Additional risk behavior screening
  • For reactive (+) test results
    • Follow up confirmatory testing (Western blot)
    • Referral for HIV counseling
New program: Steps

1. Exposure
2. Infection Control Officer (ICO) notified
3. Complete care of the patient
4. ICO goes to the source patient to sample
5. Exposed FF goes to ED
6. ICO brings results of source patient HIV test to the ED
7. Physician discussion with exposed FF regarding PEP
Final Algorithm

- Offers EMS control over most of the process

1. Exposure Event
2. Complete Patient Care
3. Initiate Exposure protocol
4. Call “IC officer”
5. Process Exposed Provider
6. Draw Baseline Blood levels: HIV & Hepatitis
7. Collect source patient blood
8. Performance of HIV test
9. Results reported
10. Decision to start PEP
11. Sample source patient
Benefits of this program

• Rapid information that can be used for decisions regarding PEP

• Psychological benefit of knowing early results
Questions?

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