Straightening out a bloody mess!

A Novel Bloodborne Pathogen Exposure Procedure

- Donald A. Locasto, MD
  - Medical Director, Cincinnati Fire Department
  - Medical Director, Colerain Township Fire and EMS

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Conflict of Interest

- none
- No pay
- No stock
- No endorsement

- Company provided testing units

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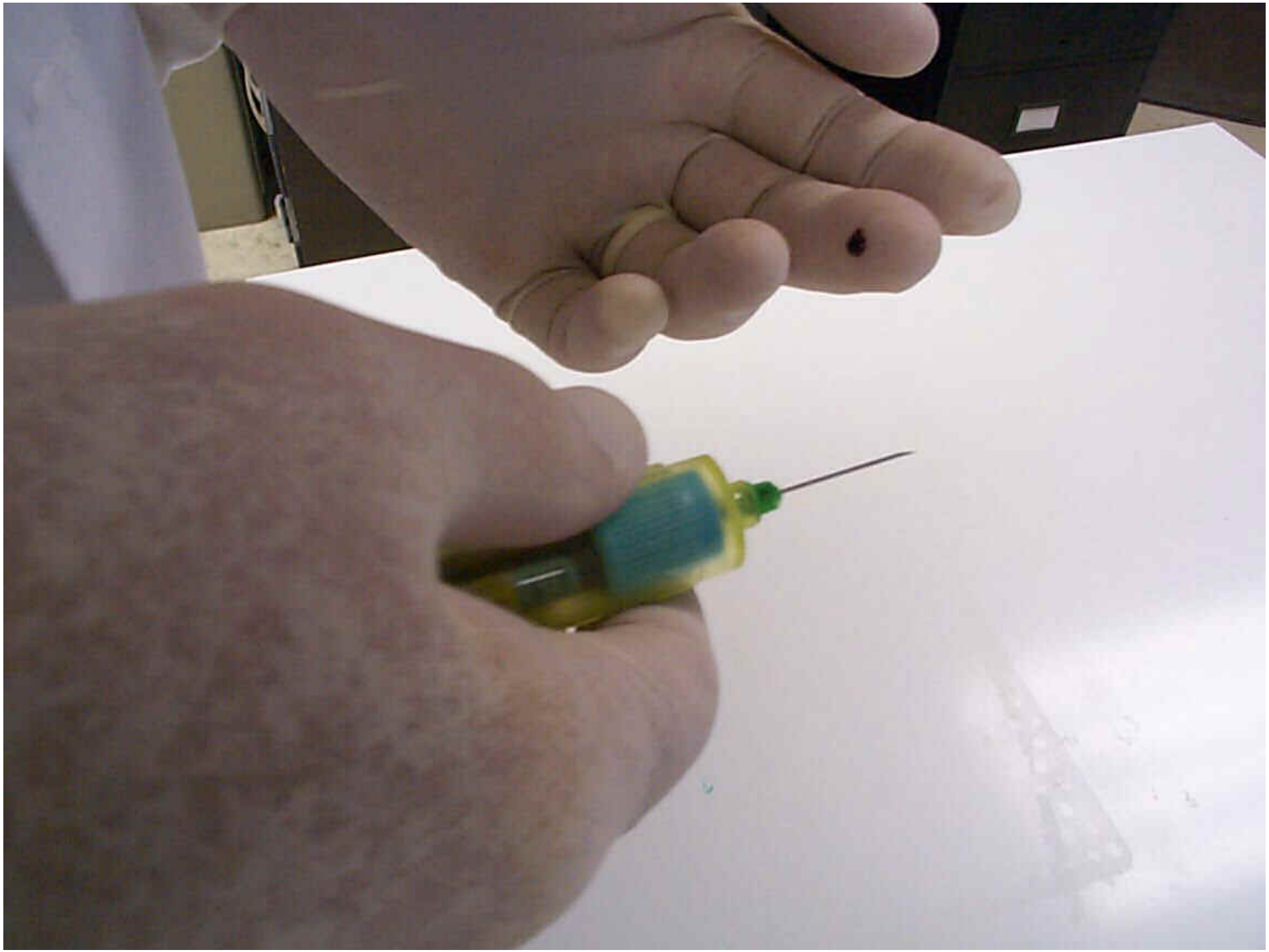

Scope of the problem: Exposure Stats

- 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 1 Incidence rates for exposure to blood by personal characteristics and route of exposure

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

Int Arch Occup Environ Health (2010) 83:191–199

Other Studies of EMS Exposure Rates

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

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

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

Int Arch Occup Environ Health (2010) 83:191–199

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%.

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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)

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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

OSHA Standards Interpretation

January 2007

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 indecreased 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

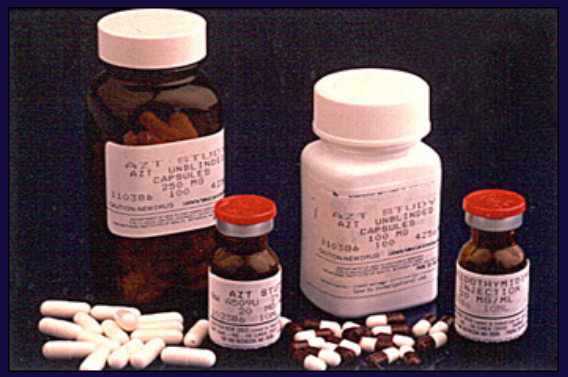

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TABLE 3. Primary side effects and toxicities associated with antiretroviral agents used for HIV postexposure prophylaxis, by class and agent

Class and agent	Side effect and toxicity
Nucleoside reverse transcriptase inhibitors (NRTI)	**Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis**
Zidovudine (Retrovir®; ZDV, AZT)	Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (Epivir®, 3TC)	Abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit™; d4T)	Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx®; ddI)	Pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Emtricitabine (Emtriva, FTC)	Headache, nausea, vomiting, diarrhea, and rash. Skin discoloration (mild hyperpigmentation on palms and soles), primarily among nonwhites
Nucleotide analogue reverse transcriptase inhibitor (NtRTI)	**Class warning: All NtRTIs have the potential to cause lactic acidosis with hepatic steatosis**
Tenofovir (Viread®; TDF)	Nausea, diarrhea, vomiting, flatulence, and headache
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
Efavirenz (Sustiva®; EFV)	Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity
Protease inhibitor	
Indinavir (Crixivan®; IDV)	Nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia
Nelfinavir (Viracept®; NFV)	Diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir®; RTV)	Weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and elevated cholesterol and triglycerides
Saquinavir (Invirase®; SQV)	Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs
Fosamprenavir (Lexiva®, FOSAPV)	Nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Atazanavir (Reyataz®; ATV)	Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia
Lopinavir/ritonavir (Kaletra®; LPV/RTV)	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides
Fusion inhibitor	
Enfuvirtide (Fuzeon®; T-20)	Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy, and cough

Sources: Package inserts; Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents—April 7, 2005. Washington, DC: National Institutes of Health; 2005. Available at http://aidsinfo.nih.gov/guidelines/default_db2.asp?id=50.

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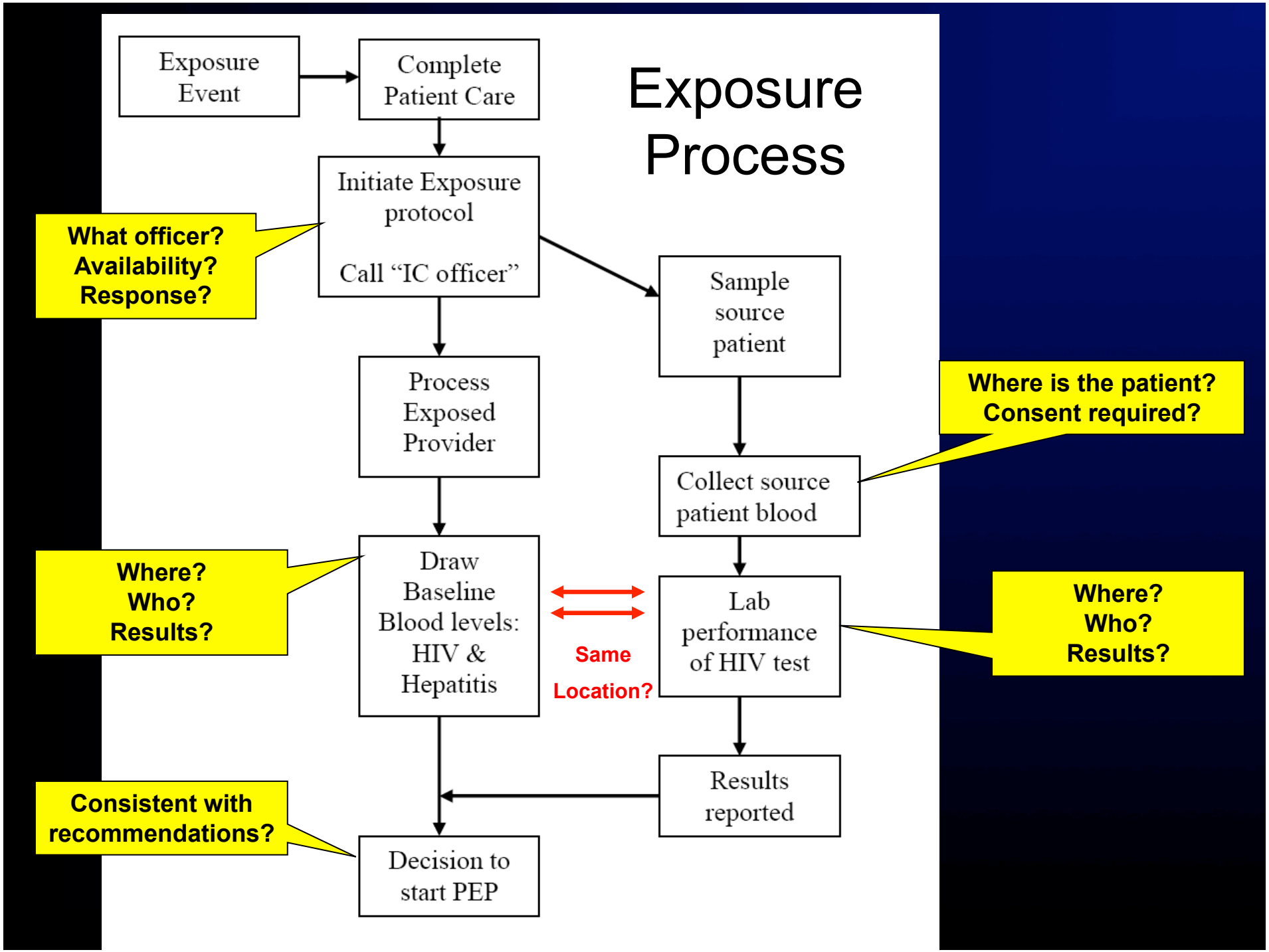
September 30, 2005 / 54(RR09);1-17

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

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.

Exposure Process



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

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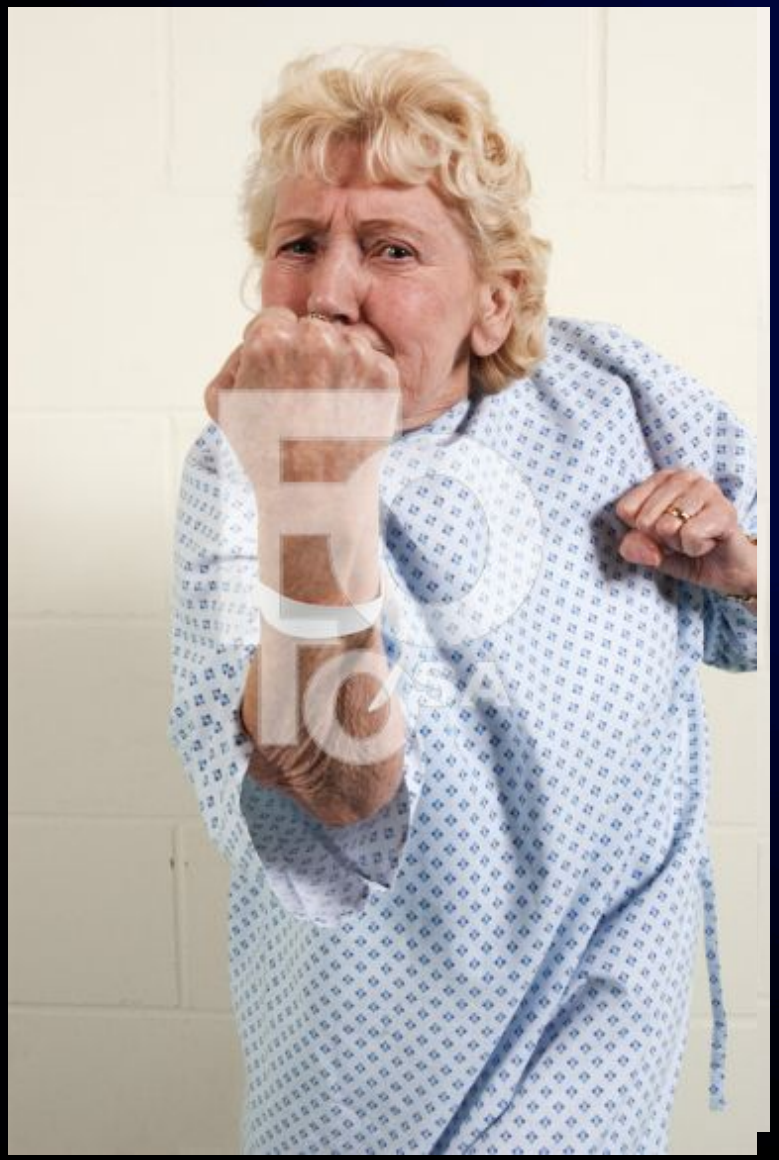
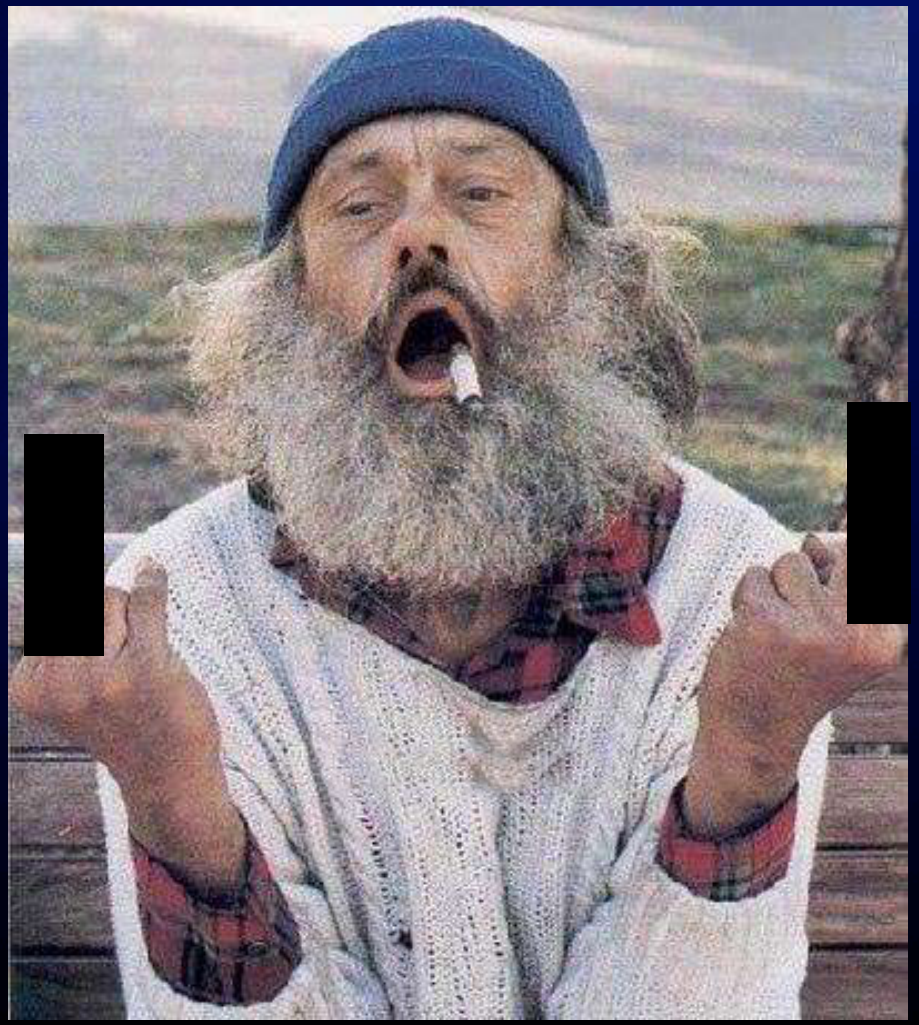
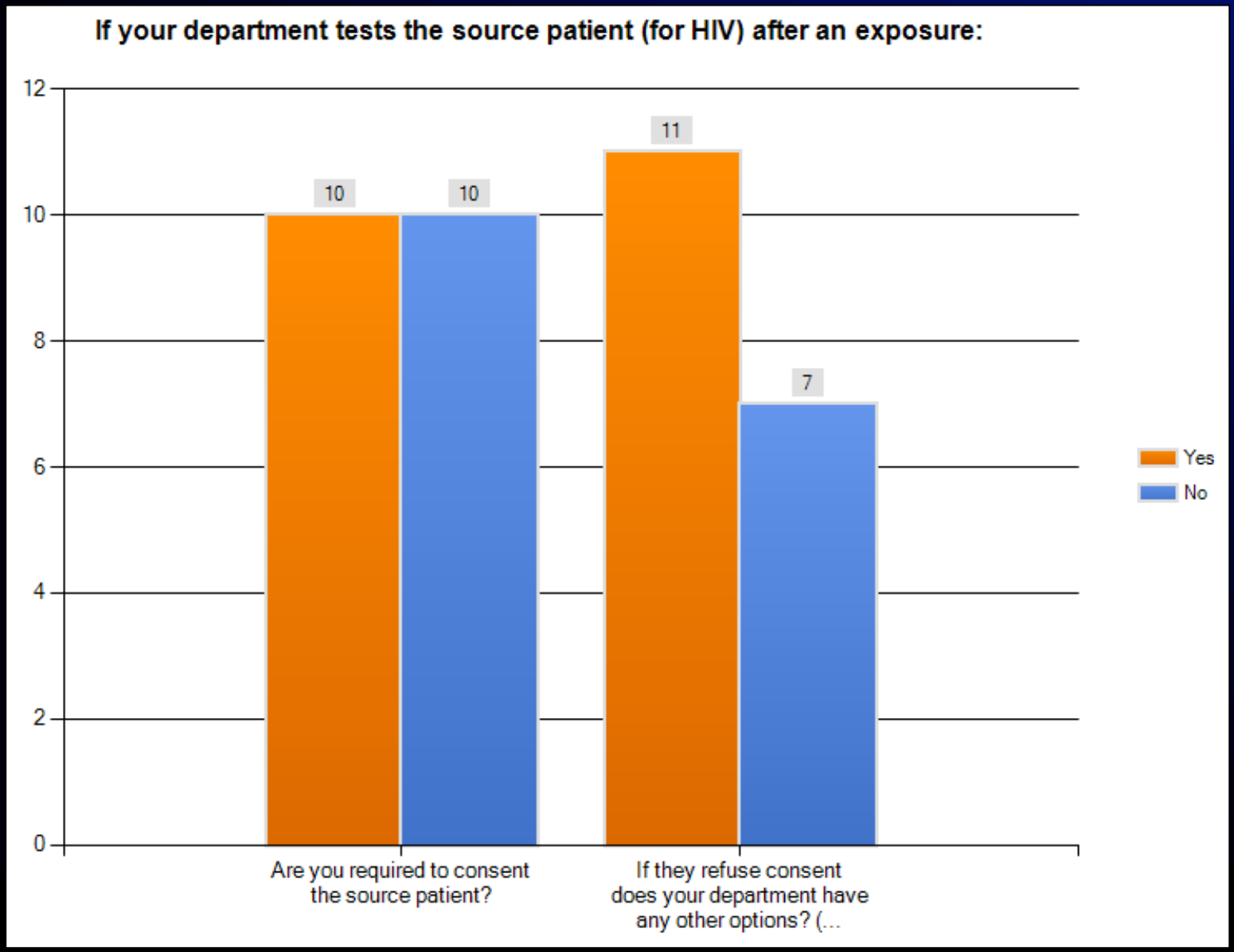
Consenting your patient.





Eagles Survey: Consent Issue



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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?

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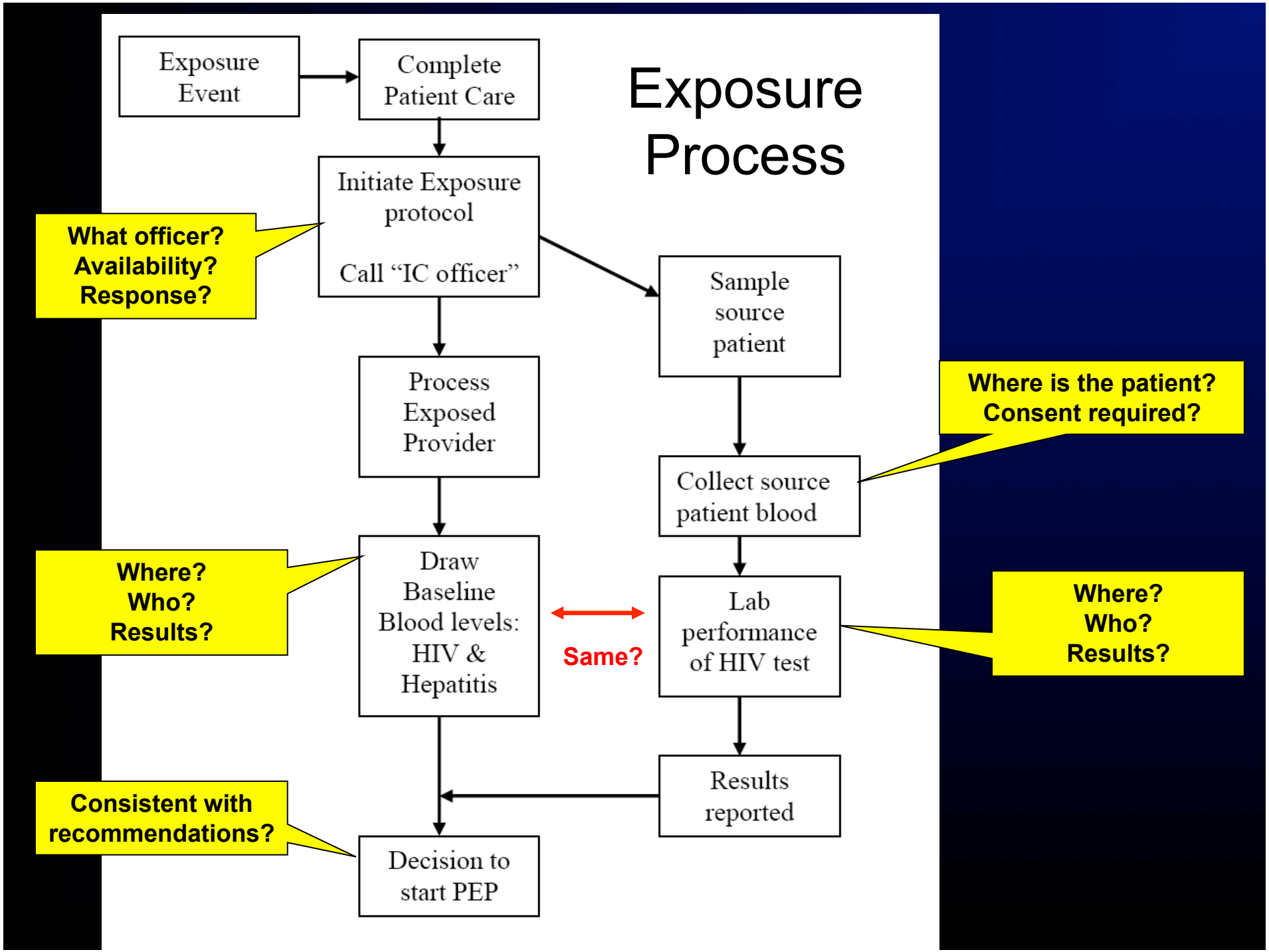
Where is the source patient?

- Jail / police custody
- Coroners Office
- Different ED
- Gone

Emergency Department Mishandling

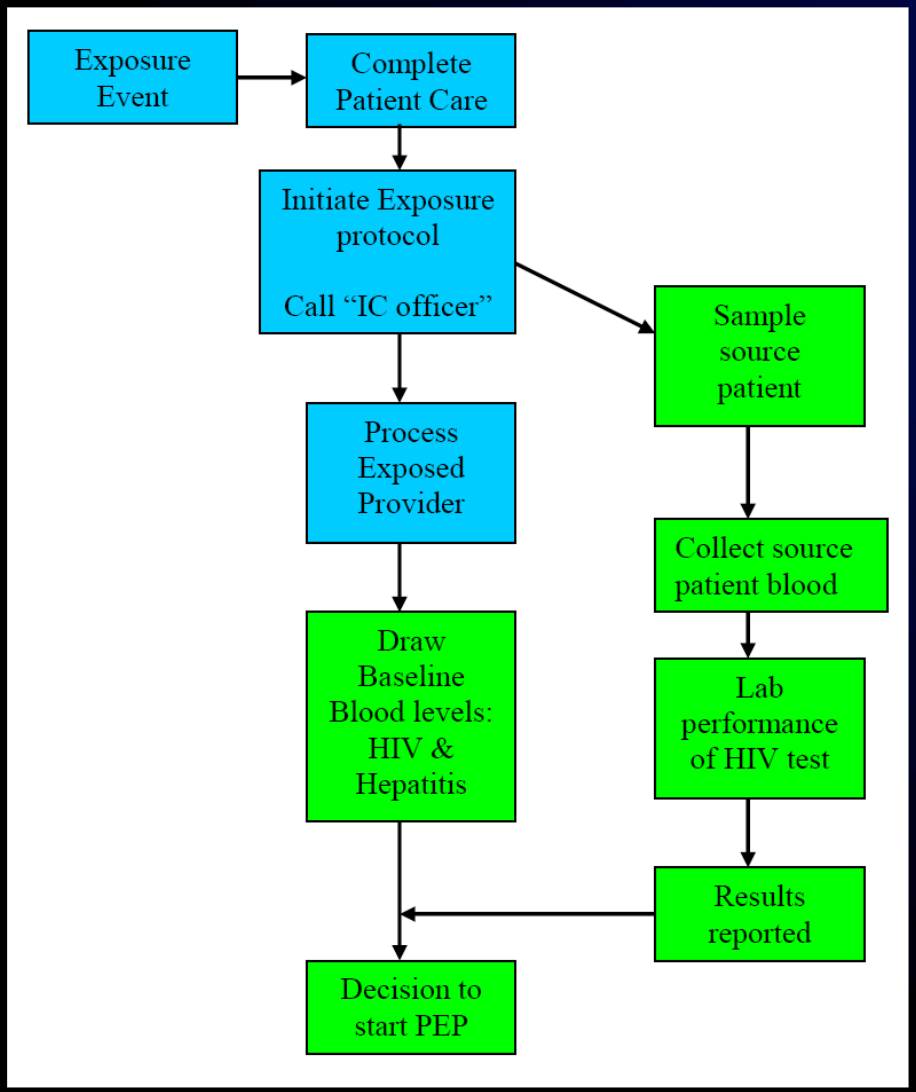
- PHS guidelines for the management of occupational exposures to HIV were first published in 1985
- Updated in 2001.
- Focus groups conducted among ED physicians in 2002 indicated:
  - > 95% had not read the 2001 guidelines
- All physicians participating in the focus groups had recently managed occupational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

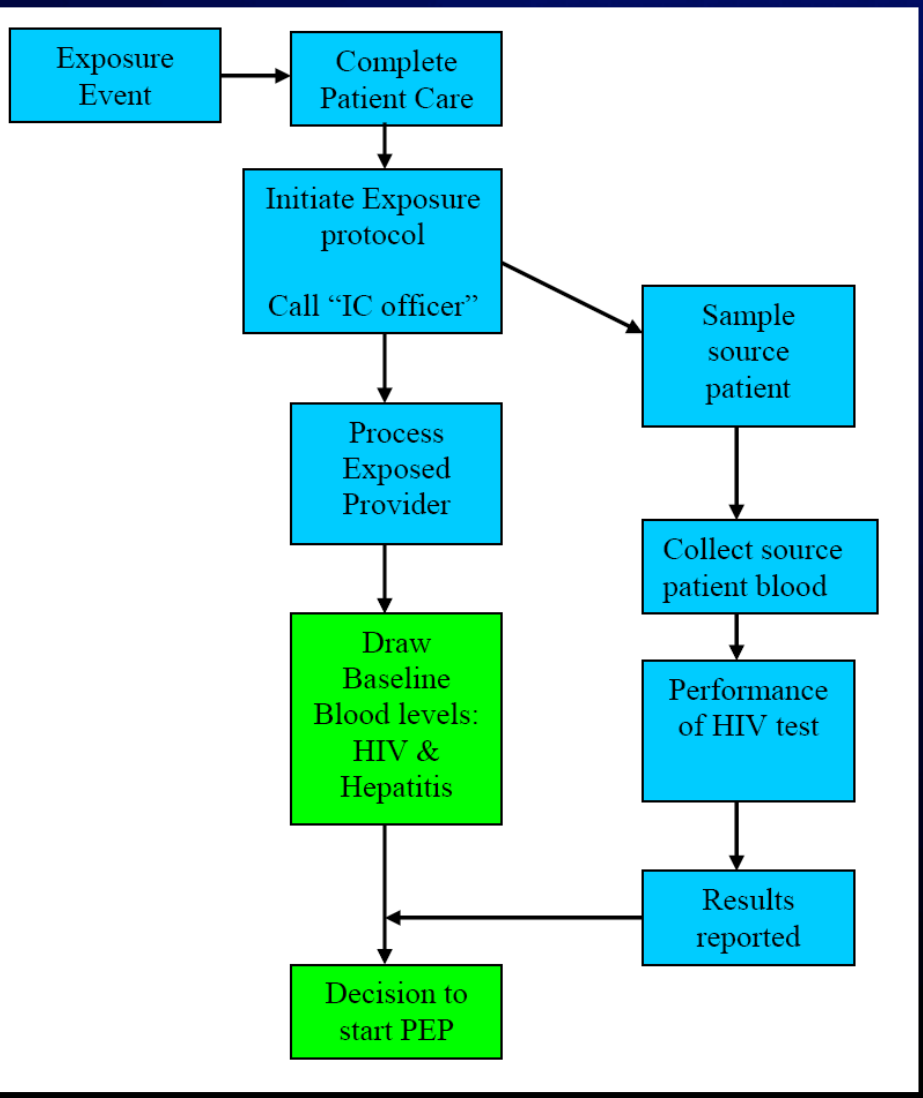
Exposure Process



Take control

A New Program friendly to EMS





A Rapid Review of Rapid HIV Antibody Tests

Test Kit Name	Manufacturer	Specimen Type	CLIA Category	Shelf Life
OraQuick Advance Rapid HIV-1/2 Antibody Test	OrasureTechnologies, Inc	Whole Blood, Oral Fluid	Waived	6 months
		Plasma	Moderate Complexity	
Reveal G3 Rapid HIV-1 Antibody Test	MedMira, Inc.	Serum, Plasma	Moderate Complexity	1 year
Uni-Gold Recombigen HIV Test	Trinity BioTech	Whole Blood	Waived	1 year
		Serum, Plasma	Moderate Complexity	
Multispot HIV-1/HIV-2 RapidTest	Bio-Rad Laboratories	Serum, Plasma	Moderate Complexity	1 year
Clearview HIV 1/2 Stat Pak	Inverness Medical Professional Diagnostics	Whole Blood	Waived	2 years
		Serum, Plasma	Moderate Complexity	
Clearview Complete HIV 1/2	Inverness Medical Professional Diagnostics	Whole Blood	Waived	2 years
		Serum, Plasma	Moderate Complexity	

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

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Reveal G3 Rapid HIV-1 Antibody Test	MedMira, Inc.	Serum, Plasma	Moderate Complexity	1 year
Uni-Gold Recombigen HIV Test	Trinity BioTech	Whole Blood	Waived	1 year
		Serum, Plasma	Moderate Complexity	
Multispot HIV-1/HIV-2 RapidTest	Bio-Rad Laboratories	Serum, Plasma	Moderate Complexity	1 year
Clearview HIV 1/2 Stat Pak	Inverness Medical Professional Diagnostics	Whole Blood	Waived	2 years
		Serum, Plasma	Moderate Complexity	
Clearview Complete HIV 1/2	Inverness Medical Professional Diagnostics	Whole Blood	Waived	2 years
		Serum, Plasma	Moderate Complexity	

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

Accuracy of Rapid HIV Tests

Table 1. US Food and Drug Administration–approved rapid HIV antibody tests for HIV-1 detection

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

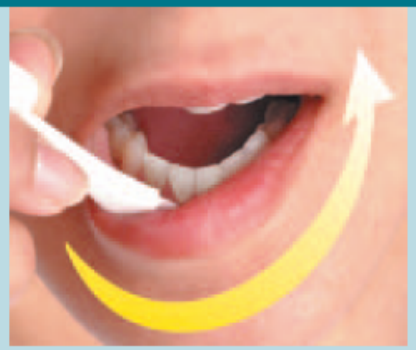
*Trade names are for identification purposes only and do not imply endorsement by the US Department of Health and Human Services or the Centers for Disease Control and Prevention.
†95% CI
CLIA—the Clinical Laboratory Improvement Amendments of 1998.
Modified from Health Research and Education Trust available at http://www.hret.org/hret/programs/hivtransmrpd.html.

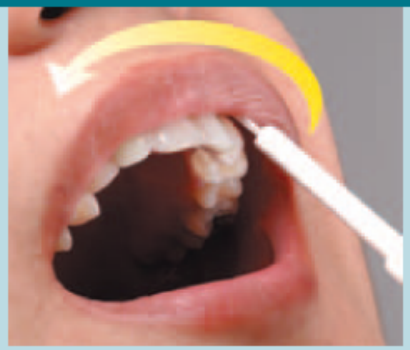
Greenwald, ***Current Infectious Disease Reports*** *2006,* ***8:****125–131*

Rapid Test Steps

Oral Fluid

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

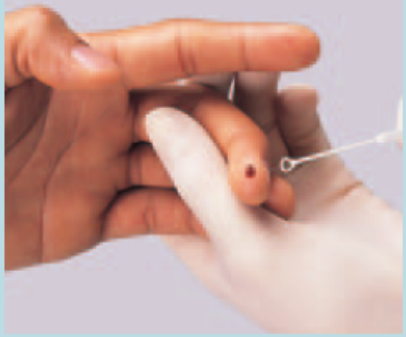


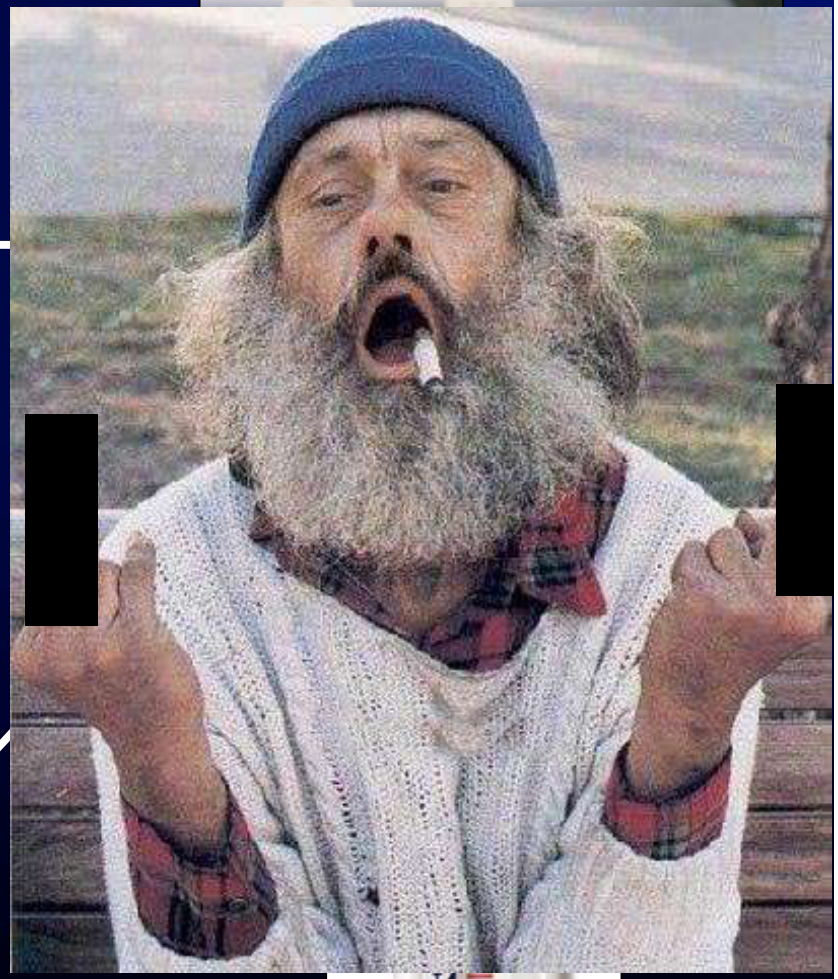


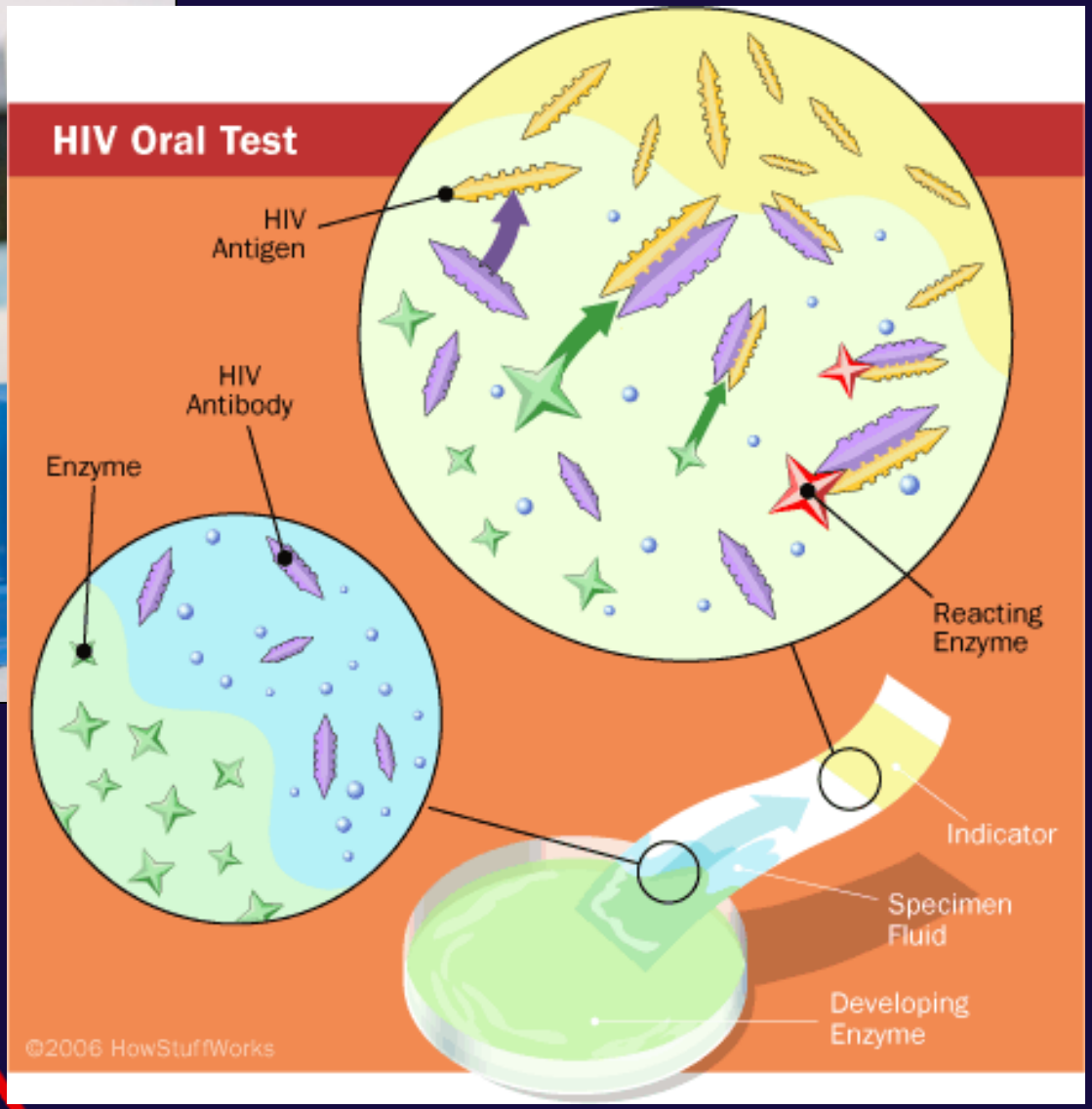
Fingerstick Whole Blood

Cleanse finger. Air dry.
Puncture with lancet.

Wipe away first drop of blood.
Fill the Collection Loop.







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PREGNANCY TEST
UNMISTAKABLE RESULTS!
Not Pregnant
Pregnant
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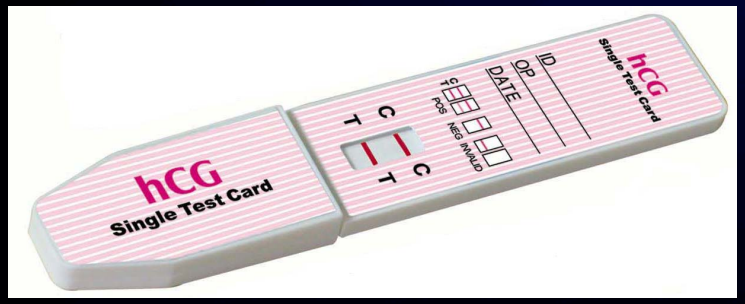
2 Tests
*99% Accurate at detecting typical pregnancy hormone levels. Note that hormone levels vary. See leaflet.


USE AS EARLY AS 4 DAYS BEFORE YOUR PERIOD IS DUE
NEW EASY READ
NO OTHER TEST TELLS YOU SOONER*
FIRST RESPONSE
Early Result Pregnancy Test
Over 99% accurate**
2 TEST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Pregnant
Not Pregnant

Rapid Test Steps

Oral Fluid

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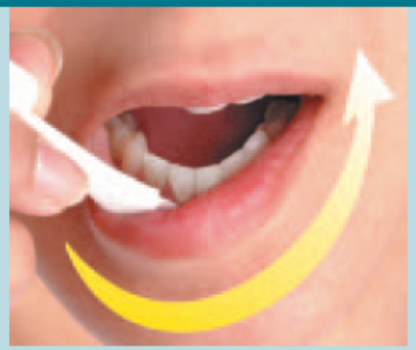

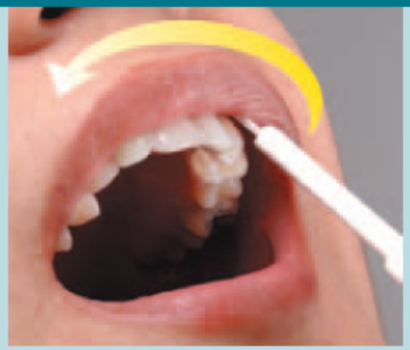

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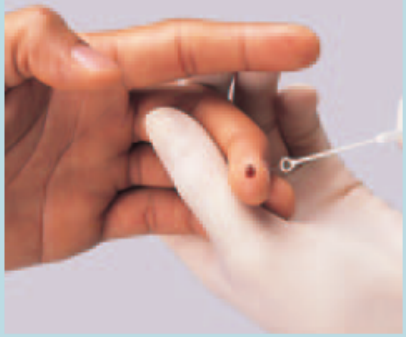

20 minutes

Rapid Testing Issues

- Clinical Laboratory Improvement Amendment (CLIA) licensing:
  - Some tests are CLIA waivered
  - 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

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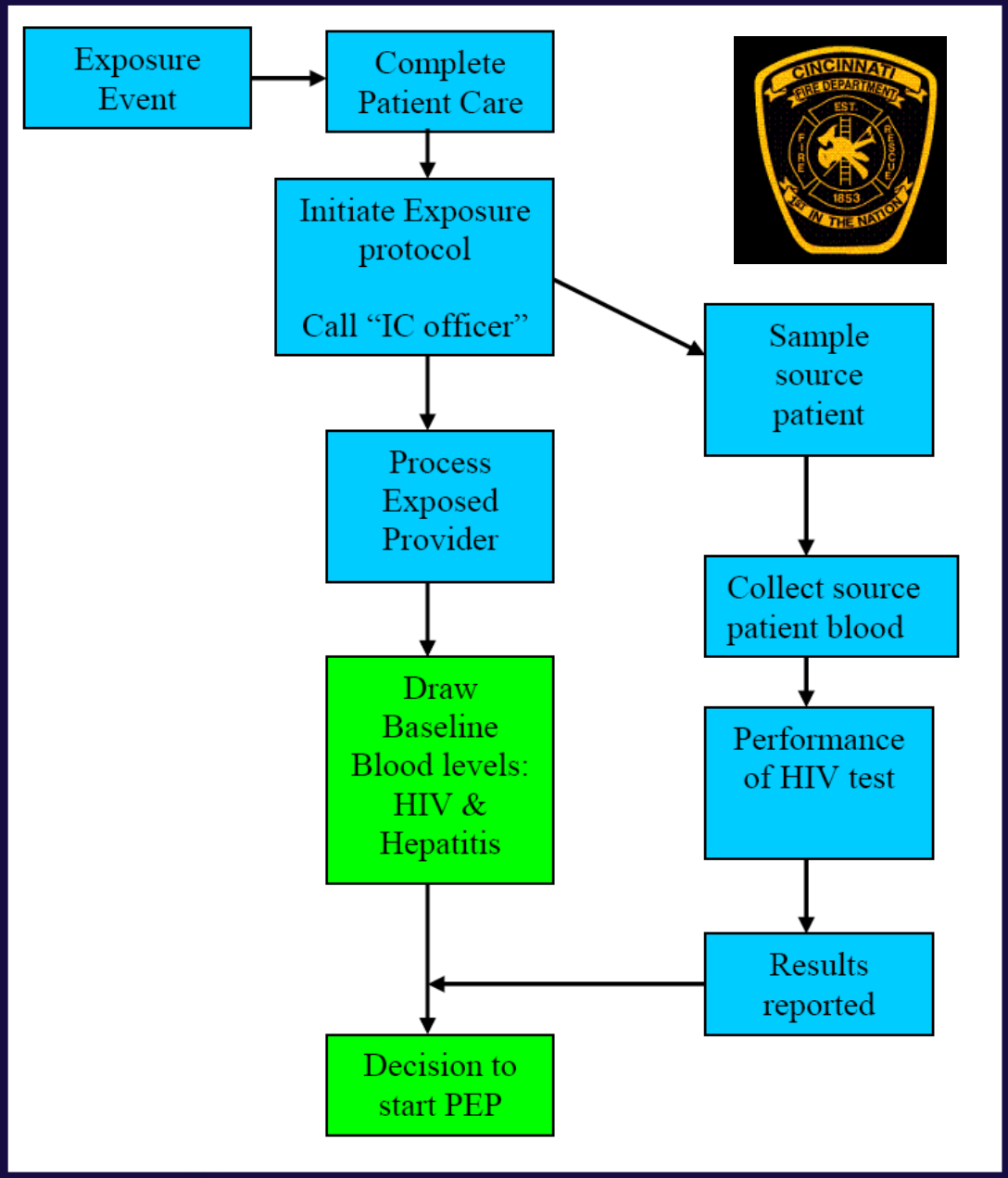
Final Algorithm

- Offers EMS control over most of the process



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Benefits of this program

- Rapid information that can be used for decisions regarding PEP
- Psychological benefit of knowing early results

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Questions?

Donald.locasto@uc.edu

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