Protocol For The Management of Health Care Workers (HCV) Exposed to Blood or Body Fluids Known or Possibly Contaminated with HIV (December 5, 1996)

BACKGROUND

The subsequent recommendations are based on the following currently available information:

a) Risk to Health Care Worker

The average risk for HIV infection from all types of reported percutaneous exposures to HIV infected blood is 0. 3 %. Factors associated with increased risk of transmission include:

1. Deep (intramuscular) injury
2. Visible blood on sharp device
3. Needle used to enter a blood vessel
4. Source patient with terminal AIDS

Average risks after mucus membrane and skin exposures to HIV infected blood are 0. 1 % and < 0. 1 %, respectively. Conversely, > 99 % of exposed health care workers will not become infected,

b) Efficacy of Post-Exposure Prophylaxis

Zidovudine (AZT) taken soon after exposure has been associated with a 79% reduction in the odds of HIV transmission. Failures using AZT have been reported. There is an increasing prevalence of AZT resistance among source patients, and thus AZT in combination with other agents is recommended. However, no data are available to determine the efficacy of combination therapy in this setting.

c) Prevalence of HIV Antibody Among Admissions to Mount Sinai

Based on a study conducted at Mount Sinai in 1990 (see Reference 4), the prevalence of HIV antibodies among admissions to this facility is approximately 0.6%. Therefore, the estimated risk of acquiring HIV from a needlestick injury from an unknown source at this facility would be 1.8 per 100,000 (i.e. 0.6% x 0.3%).

RECOMMENDATIONS

Combination therapy for 4 weeks should be offered or recommended to exposed health care workers (based on the table attached) using the following 3 drugs:

1. Zidovudine (AZT) 200 mg p.o. t.i.d.
2. Lamivudine (3TC) 150 mg p.o. b.i.d.
3. Indinavir 800 mg p.o. t.i.d.

Therapy should be instituted immediately within 1 to 2 hours of exposure but may be started as long as 72 hours after exposure.

SIDE EFFECTS/TOXICITY OF ANTIRETROVIRALS

1. Zidovudine (AZT) - nausea, fatigue, headache, and gastrointestinal distress: all resolve when therapy is stopped.

2. Lamivudine (3TC) - similar to AZT: does not increase the incidence of side effects of AZT; TERATOGENIC - avoid in pregnancy.

3. Indinavir - kidney stones (2 % - 3 %), prevent by increasing fluid intake; nausea, g.i. upset, headache, dizziness, fatigue, dry skin;

The following medications should **NOT** be taken while the patient is receiving indinavir: triazolam (Halcion), astemizole (Hismanol), cisapride (Prepulsid), terfenadine (Selddne), midazolam (Versed), and rifampin.

The long term side effects/toxicities of these agents are not known.

All individuals involved in the management and counselling of exposed health care workers must be familiar with the above information in order to enable them to provide knowledgeable and practical information.

POLICY FOR MANAGEMENT OF A HEALTH CARE WORKER EXPOSED TO BLOODIBODY FLUIDS KNOWN OR POTENTIALLY CONTAMINATED WITH HIV

1. All health care workers should report their injury immediately to:

   a) Occupatioaal Health (8: 00 a. m. to 4: 00 p. m. Mon. to Fri.)
   b) Emergency Department (After Hours, Weekends, Holidays)

   Strict confidentiality should be maintained.

2. Because the maximum benefit of antiretroviral therapy is achieved the sooner it is initiated (preferably within I to 2 hours following exposure), health care workers should be triaged for immediate assessment.

3. **If the source patient is known or** suspected to be HIV positive, then antiretroviral therapy should be offered or recommended as outlined in Table 1. If the source patient is unknown or the HIV status of the source patient is unknown, then the risks will be discussed with the health care worker based on the prevalence of HIV in the relevant population. The medication can be started as the discussions are in progress.

4. Every effort will be made to have the source patient tested for relevant blood borne pathogens, including HIV (see Appendix 3 for protocol for assessing source patients). However, prophylactic antiretroviral therapy should not be withheld pending the results of this testing since maximum benefit is achieved when therapy is initiated early. Therapy can always be discontinued if testing is negative.

5. Baseline bloodwork should be drawn on all health care workers for Hepatitis B surface antibody (HBsAb), Hepatitis C antibody (HCV), HIV and ALT. If the health care worker is a female of child bearing age and is not currently using an appropriate method of contraception, then a pregnancy test should be obtained before initiating therapy with 3TC. The health care worker should be instructed on the use of an appropriate method of contraception.

6. Follow-up monitoring of health care workers who choose to receive anti retroviral therapy will be done by an Infectious Disease Consultant (see Appendix 2 for list of available consultants). The Infectious Disease Consultant will be chosen based on initial consultation with the health care worker, the preference, if any, of the health care worker and the availability of the consultant.

7. The Emergency Drug Package will contain all drugs, written instructions and

potential adverse effects of the medication. Each package will contain sufficient drug for 3 days. Subsequent drug will be provided via Occupational Health/Pharmacy. A one week supply will be dispensed at a time.

8. Appropriate assessment and management with respect to Hepatitis B and Hepatitis C should. be done during the initial assessment of the health care worker. Appropriate guidelines and recommendations should be followed as outlined in the policies of the Occupational Health Department.

9. Follow up bloodwork should be done as follows:

   i) HIV 1/2 Antibody at 6 weeks, 12 weeks and 6 months

   ii) LFTs and CBC at 2 and 4 weeks post-injury (for those who choose to take drug therapy)

REFERENCES

1) Gerberding, J.L. 1996. Prohylaxis for occupational exposure to HIV. Ann Intern Med. 125:497-501.

2) Glatt, A.E. 1996. Proposed antiretroviral therapy guidelines for prophylaxis of ccupationally related HIV seroconversion: a practical approach. Infect Control Hosp Epid. 17:672-674.

3) MMWR. 1996. Update: Provisional Public Health Service Recommendations For Chemoprophylaxis After Occupational Exposure to HIV. 45 (22): 468-472.

4) Louie M., D. Low, S. Feinman, et al. Prevalence of Hepatitis B surface antigen, HIV-1 antibody and Hepatitis C antibody among admissions to a Canadian hospital. American Society for Microbiology, Dallas, Texas, U.S.A., May 5-9, 1991.

Appendix I

Table 1, Therapy Based on HIV-infected Source Patient

	Early	Symptomatic	Late AIDS
Percutaneous			
Minor	O[a]	R	SR
Major	R	SR	SR
Mucosal contact			
Minor	O	O	O
Major	R	R	R
Skin contact			
Minor	O	O	O
major	O	R	R

O=offer; R=recommend; SR=strongly recommend a Each episode must be assessed independently and risks/benefits should be discussed with the health care worker.

Appendix 2

Infectious Disease Consultants Available For Consultation and Follow-up of HIV-Exposed Health Care Workers

Mt. Sinai Hospital:

Dr. Allison McGeer	586-3118
Dr. Kelly MacDonald	586-8879
Dr. Tony Mazzulli	586-4695
Dr. Hillar Vellend	586-8474

The Toronto Hospital:

Dr. Irv Salit	340-3697
Dr. Sharon Walmsley	340-5871
Dr. John Conly	340-5047

Appendix 3

Assessment of Source Patient For HIV and Other Blood-Borne Pathogens

If the status of the source patient with respect to HIV and other blood-borne pathogens is not known, then the following procedures should be followed:

1) The individual who first assesses the health care worker should immediately contact the source patient's physician to notify him/her of the situation and to obtain any relevant information regarding the source patient. The source patient's physician should be asked to approach the patient and obtain consent for serologic testing for HIV, HBV, and HCV.

2) If the source patient's physician is unable or unwilling to approach the patient, or there will be a significant delay in his/her assessment of the source patient, then it is the responsibility of the source patient's physician to identify a member of his/her team who is familiar with the patient and can provide the relevant information. They must also approach the patient for consent for serologic testing as noted in point #1 above.

3) If neither the source patient's physician or designate is available, the Infectious Disease Fellow should be contacted. He/she will then review the source patient's history and approach the patient for consent for serologic testing for HIV, HBV, and HCV.

4) All relevant information regarding the source patient should be conveyed to the occupational health nurse', emergency room physician and/or Infectious Disease Consultant managing the health care worker. All information should be kept strictly confidential.

Appendix 4

Risk Factors for HIV Infection*

- Male homosexual
- Male bisexual
- Intravenous drug user (IVDU)
- Recipient of blood / blood products prior to Nov. 1985
- Sexual partner of known HIV-infected individual
- In the absence of other immunocompromising condition, a patient being treated for:
    - *Pneumocystis carinii* pneumonia (PCP)
    - Disseminated cryptococcosis
    - Mucus membrane or esophageal candidiasis
    - Disseminated CMV infection (eg. retinitis, pneumonia, g.i. tract)
- Sex worker

* This list is a guide and is not meant to be all inclusive. Each case will have to be assessed individually. The absence of any of these risk factors does NOT rule out HIV infection in the source patient.

HIV POST-EXPOSURE PROPHYLAXIS
COST INFORMATION

DRUG	DOSE	SUPPLIED	COST PER 72 hr SUPPLY	COST PER 30d Tx	COMMMENTS
ZIDOVUDINE (Retrovir®) – Glaxo Wellcome)	200mg po q8h	**100mg capsules** $95.43 per 50 caps $ 1.91 per capsule	$34.35	$343.55	
LAMIVUDINE (3TC® – Glaxo Wellcome BioChem)	150mg po bid	**150mg tablets** $264.00 per 60 tabs $ 4.40 per tab	$26.40	$264.00	• ensure patient is not pregnant prior to and during medication use
INDINAVIR (Crixivan® – Merck Frosst)	800mg po q8h	**200mg capsules** $ 497.70 per 360 caps $ 1.37 per capsule **400mg capsules** $ 494.70 per 180 caps $ 2.75 per capsule	$49.47	$494.70	• indinavir is moisture sensitive; company advises to keep in original container with desicants. • Once opened, drug is stable for 6 months • Unused drug (including opened bottles) can be returned to company for reimbursement
RETONAVIR (Norvir® - Abbott)	600mg po bid	**200mg capsules** $ 448.00 per 169 caps $ 2.67 per capsule	$48.00	$480.00	• packaged in 2 week supply • requires refrigeration • unused drug (unopened) can be returned to company for reimbursement
TOTAL COSTS			**$110.22* $108.75****	**$1102.25* $1087.50****	

***for indinivir combination; ** for retonavir combination**

References: 1. MSH drugstore; 2. MetroDIS bulletin, January 1996; 3. MetroDIS bulletin, October 1996