

## Lentiviral Vector or Retroviral Vector Postexposure Protocol

### INTRODUCTION

This policy applies to all employees at Western University.

Lentiviral vectors (LVVs) and retroviral vectors (RVVs) are increasingly being used in research labs to transfer genetic material (transgenes) into cells. LVVs are primarily derived from human immunodeficiency virus 1 (HIV-1), and RVVs are primarily derived from murine leukemia virus (MLV). When exposed to other dividing and non-dividing cells, LVVs can integrate their genetic material into the genome of the recipient cell. RVVs can only integrate their transgenes into dividing cells. Depending on the location of insertion into the recipient genome, it could increase the risk of the recipient cells developing into cancer (usually leukemia or lymphoma). In fact, prescribed gene therapy products with integrating lentiviral or retroviral vectors contain a Health Canada class warning that lists the potential risk of developing secondary malignancies.

Accidental occupational exposure to lentiviral vectors or retroviral vectors in a laboratory setting may put employees at risk for developing future cancers. Occupational exposures to LVVs and RVVs should warrant consideration for postexposure prophylaxis (PEP) to block the reverse transcription and integration of a transgene into an exposed individual's genome.

Careful adherence to proper workplace and laboratory protocols and wearing appropriate personal protective equipment when handling LVV and RVV specimens are the primary ways to prevent accidental exposures in the workplace.

There is no vaccine to prevent the integration of transgenes in the event of LVV or RVV exposure. However, there are antiviral medications that can be used for PEP following accidental exposure. Like HIV PEP, these medications prevent viral replication, thus preventing integration of LVV or RVV genes into affected cells.

All accidental exposures to LVVs or RVVs should be reported to Workplace Health immediately after first aid measures have been completed. If the exposure occurs outside of business hours, and the Workplace Health office is closed, the employee should go immediately to the emergency department at London Health Sciences Centre, University Hospital to receive medical care. A risk assessment will be completed during the initial medical assessment, and a recommendation regarding PEP will be given.

There are several different factors that inform the risk assessment in the context of an accidental exposure. These include the type of exposure (ie. percutaneous, mucous membrane, intact skin, nonintact skin), the extent of the injury (ie. splash, superficial scrape/abrasion, deep puncture), the type of device involved in the exposure (ie. hollow bore needle, solid needle), whether immediate wound care/first aid has been done, and the replication potential of the viral vector (ie. replication-competent, replication-deficient).

### **OBJECTIVES**

To provide an immediate and efficient response to individuals who have sustained accidental exposures to LVVs and RVVs

To provide up-to-date education on the risks and management of LVV and RVV exposure in the workplace

To provide prompt clinical assessment of individuals and to initiate immediate postexposure prophylaxis, where applicable

To provide information about the risks and benefits of postexposure prophylaxis for the purpose of obtaining informed consent regarding the PEP regimen

To provide clinical follow-up for individuals undergoing postexposure prophylaxis by monitoring for possible complications

### **PROCEDURE**

**IMMEDIATE FIRST AID:** Wash the wound site immediately with soap and running water for a full 15 minutes. For mucous membrane exposures, flush with water only, no soap, for 15 minutes.

**IMMEDIATE COMMUNICATION WITH HEALTH SERVICES:** Employee should contact Workplace Health (SSB 4159) at 519-661-2111 ext. 85472 immediately after first aid is complete. This will ensure an efficient and rapid response to the exposure. If the exposure occurs outside of business hours, report to the emergency department at London Health Sciences Centre, University Hospital (339 Windermere Rd.), bringing the After-Hours Care paperwork with them to inform the treating practitioner.

The Occupational Health Nurse will take a detailed history of the incident and inquire about first aid measures taken. An updated medical history and medication list will be obtained. In consultation with the Occupational Health Physician, a medical management plan will be outlined.

### **MEDICAL MANAGEMENT**

The exposed individual will be counseled about the risks and benefits of PEP medication. Consent for PEP will be obtained.

If PEP is being prescribed, draw blood for baseline HIV, CBC, ALT, Creatinine, and eGFR.

### **FOLLOW-UP**

If PEP treatment is given:

- provide education & counseling re: side effects
- repeat CBC, ALT, Creatinine, and eGFR at 2 weeks (and 4 weeks, if PEP treatment course is 28 days) if there were any abnormalities in these values at baseline

The employee's supervisor should submit an [Accident/Illness/Incident Report](#) (AIIR) to [uwoaiir@uwo.ca](mailto:uwoaiir@uwo.ca) within 24 hours of the incident.

### **AFTER-HOURS SERVICE**

Workplace Health is available to respond to LVV and RVV exposure emergencies during business hours, Monday-Friday, 8:30am-4:00pm. Outside of business hours, individuals with an occupational exposure must attend the nearest Emergency Department (London Health Sciences Centre, University Hospital), for assessment and treatment. It is important for the injured employee to bring the After-Hours Care paperwork with them to hospital; this will inform the treating practitioner about the risks of LVV and RVV exposure. All after-hours exposures should be reported to Workplace Health on the next business day to arrange timely follow-up care.

### **SITUATIONS WHERE EXPERT CONSULTATION IS ADVISED**

- Delayed reporting of incident (>72 hours since the exposure occurred)
- Known/suspected pregnancy or breastfeeding
- Toxicity to PEP medication

### LVV and RVV PEP REGIMENS

\*PEP should be started as soon as possible after exposure and no more than 72 hours after exposure

\*PEP regimen can be modified after starting, if needed

#### FOR REPLICATION-DEFICIENT VECTORS:

tenofovir disoproxil fumarate 300mg PO daily for **7 days**

**PLUS**

dolutegravir 50mg PO daily for **7 days**

#### FOR REPLICATION-COMPETENT VECTORS:

tenofovir disoproxil fumarate 300mg PO daily for **28 days**

**PLUS**

dolutegravir 50mg PO daily for **28 days**

### DURATION OF PEP TREATMENT

If the LVV or RVV is replication-deficient, the duration of PEP treatment is 7 days.

If the LVV or RVV is replication-competent, the duration of PEP treatment is 28 days.

### CONTACT LIST

#### PHARMACIES

Western University Campus Pharmacy

UCC Basement

Phone: 519-661-4058

Fax: 519-661-4092

Shoppers Drug Mart (8am-midnight, 7 days/week)

Adelaide at Huron  
1118 Adelaide St. North, London, ON  
Phone: 519-432-1809  
Fax: 519-645-8816

St. Joseph's Health Care Centre Prescription Shop  
Room A1-013  
268 Grosvenor St. London, ON  
Phone: 519-646-6100 ext. 66194  
Fax: 519-646-6202

### **INFECTIOUS DISEASE CONSULTANTS**

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### **REFERENCES**

Fujimoto GR, Wooley DP, Byers KB, Yang OO, Behrman AJ, Winters TH, Hudson TW. Update on Managing the Risks of Exposure to Lentiviral and Retroviral Vectors. J Occup Environ Med. 2024 Oct 1;66(10):818-825. doi: 10.1097/JOM.0000000000003166. Epub 2024 Jun 11. PMID: 38913827.  
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