Print-And-Go Sheets: Lentiviral Vector Post-Exposure Guidance



This information sheet identifies immediate first aid actions that should be taken following a lentiviral vector exposure.

Seek medical assistance immediately after a lentivirus exposure, and take this document to the medical staff providing treatment. Be sure also to display your Weill Cornell Medicine employee ID card when visiting the medical provider.

Note: This guidance document provides information that medical personnel can reference but does not give individualized medical care or treatment protocols.

How to Seek Medical Assistance

- For exposures Monday to Friday, 8:00 am 4:00 pm:
 - WCM Upper East Side Employees: Go to the Payson House basement Workforce Health and Safety (WHS) Clinic at 1315 York Avenue or call 212-746-4370.
 - Lower Manhattan Employees: Go to the NewYork-Presbyterian (NYP) Lower Manhattan WHS Clinic at 170 William Street, Rooms G73A and G73B or call 212-312-5249.
 - Students: Go to Student Health Services (SHS) at 230 E. 69th Street, Suite 2BB (between 2nd and 3rd Avenue) or call 646-962-6942.
- For exposures after business hours:
 - WCM Upper East Side Employees and Students: Go to the NYP Emergency Room at 525 East 68th Street or call 212-472-2222.
 - Lower Manhattan Employees: Go to the NYP Lower Manhattan Hospital Emergency Room at 170 William Street or call 212-312-5070.

Give this sheet to the physician so they understand that you may have been exposed to a lentiviral vector, and that this is a medical emergency.

You can contact the NYP ER at 212-472-2222 or by dialing 2-2222 from any campus phone.

Hazard Summary

Lentivirus vectors are retroviruses, such as HIV, modified for research and therapeutic applications that allow for their use as a carrier vehicle for genetic material. These are modified to broaden the cell types that can be targeted for introducing genetic material and modes of transmission of the vectors beyond percutaneous and mucocutaneous.

Exposure is a concern for individuals who have experienced direct parenteral inoculation, contact with mucous membranes or non-intact skin, or direct contact with droplets at a close range from an aerosol-generating procedure. Hazards of a lentiviral vector are referred to as insertional risk and include the effects of the expressed transgene or toxin introduced into the vector's target cell genome. This can introduce potential long-term problems, particularly when introduced in a genetically sensitive area.

Post-Exposure Evaluation and Treatment

1. VERIFY THAT FIRST AID WAS PERFORMED

- Wash skin thoroughly with soap and water for at least 5 minutes, and wash mucus membranes or eyes with plain water for at least 10 minutes.
- Do not squeeze the area of injury or use chemicals like bleach, as they are not known to be beneficial and may break down the skin's barrier function.

2. DOCUMENT AND UNDERSTAND THE EXPOSURE

- Confirm the type of lentiviral vector (e.g., HIV backbone) and its generation, replication incompetent or competent, transgenes
 of concern (e.g. oncogenes), knockdown or knockout of tumor-suppressor genes, or toxins carried by the vector.
- Verify what type of animal, cells, or tissues are being manipulated, as these may present additional hazards, including bloodborne pathogens (for human cells or tissues), zoonoses, chemicals, or drugs. Note that not all cells and tissues are screened for bloodborne pathogens prior to use in research, and that macaque cells and tissues may harbor macacine herpes virus 1 (herpes B virus).





- Determine if the exposure was mucocutaneous, percutaneous, or droplet; how large the exposure was, when it occurred, and what viral vector titer was involved.
- Determine the nature of the research (e.g., direct contact with vector, exposure to transfected cells/animals).
- If needed, contact the principal investigator (PI) with the exposed individuals' permission to understand the potential hazards.

MEDICATION

- Replication incompetent lentiviral vector exposures: There are no studies or national public guidelines on the benefits or risks of post-exposure prophylaxis for insertional risks. The WCM IBC recommends evaluation as soon as possible, within two hours or less. Timing is critical, and the sooner the treatment is applied, the better. The medical provider and exposed individual should discuss the nature of the exposure and consider post-exposure prophylaxis (PEP), along with the risks and benefits of antiretroviral therapy. Post-exposure prophylaxis should be administered within 12-24 hours to prevent insertional risks, particularly with a lentiviral vector carrying hazardous transgenes. After 72 hours, PEP benefits may not exist.
 - Recommended regimen: Raltegravir (Isentress) 400 mg BID with or without Tenofovir (Viread) 300 mg, once daily for 7 days for exposure to a transgene of concern. Isentress and Emtricitabine once daily for 7 days may be used as alternative drugs. However, this is an off-label use. Protease inhibitors, such as Kaletra, have no effect on transduction or integration of the lentiviral vector and therefore should not be used for insertional hazards.
- Replication competent lentiviral vector exposures: These should be treated similarly to a wild-type HIV BBP exposure. For this, follow the normal HIV exposure protocol for 28 days.

Note: Be sure to know the drug side effect profiles and any drug-drug interactions.

4. TESTING AND FOLLOW-UP

Testing for lentiviral vector exposure is generally not helpful. HIV testing may be useful if someone has undiagnosed HIV, as the PEP regimen could produce HIV resistance, and some potential risk for wild HIV recombination with the lentiviral vector does exist. Documentation of the exposure is critical to assess future related issues.

Baseline and follow-up lab tests are indicated for those prescribed PEP medications and typically include CBC with differential, BUN and creatinine, AST, and ALT testing.

Next Steps for Exposed Individual

- If evaluated at the ER, follow up with your respective campus provider (WHS or Student Health) the following business day and complete an accident report there.
- Notify your supervisor of the incident.
- Notify Environmental Health and Safety so the appropriate reports can be submitted to the Institutional Biosafety Committee and National Institutes of Health Office of Science Policy (NIH-OSP). This is required by law for all accidents that result in overt exposure to materials containing recombinant or synthetic nucleic acid molecules. EHS will handle subsequent reporting.

Contact Information

- EHS: 646-962-7233, ehs@med.cornell.edu
- NYP-ER: 212-472-2222
- Security: 212-746-0911
- Workforce Health and Safety: 212-746-4370 (NYP-Weill Cornell), 212-312-5249 (NYP Lower Manhattan)
- Student Health Services: 646-962-6942

References

- "Risks Associated with Lentiviral Vector Exposures and Prevention Strategies", R. Schlimgen et al 2016 Dec; 58(12): 1159– 1166. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5152689/.
- "Lentiviral Vector post-exposure prophylaxis" Columbia University Environmental Health and Safety. https://research.columbia.edu/sites/default/files/content/EHS/Homepage/LentivirusPostExposureProphylaxisPrintAndGo.pdf