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APPENDIX A

Instructions for Medical Care of Lentivirus/Retrovirus Vector (LVV/RVV) Exposures

To: Hospital ER Staff (*Preferred provider is St. David's Medical Center ER or St. David's affiliated ERs*)

From: University of Texas *HealthPoint* Occupational Health Program, **512-471-4647**

This employee works with lentiviruses and/or retroviruses and has experienced an exposure incident.

The University of Texas' consulting physician is the Director of St. David's Occupational Health Services (OHS) and may be contacted for questions regarding the treatment of this university employee.

St. David's Occupational Health Services Medical Director:

Office: 512-544-8195

After hours: 512-699-7022

External Emergency Room/Clinic Treatment Guidance:

- 1) **Lentivirus/retrovirus contact to intact skin:** Verify the area was washed with soap and water immediately after the exposure; no additional post-exposure follow-up care is indicated.
- 2) **Exposure to the eye, mucous membrane, non-intact skin, or parenteral exposure**
 - a. **Non-intact skin:** area of exposure(s) washed with soap and water for 15 minutes.
 - b. **Eye (contacts removed first) or mucous membrane exposure:** rinsed with copious amounts of water for 15 minutes using an eyewash or sink.
 - c. **Ingestion:** rinsed mouth; vomiting not induced.
- 3) **Document and understand the exposure:** Type of lentiviral/retroviral vector (e.g., HIV backbone) and its generation, replication deficient or competent, transgenes of concern, knockdown or knockout of tumor-suppressor genes, or toxins carried by the vector. Confirm 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 drug exposures. ****Macaque cells/tissues may harbor macacine herpes B virus.**
- 4) **Post-Exposure Prophylaxis:**
 - a. **Replication-deficient lentiviral/retroviral vector exposures:** There is no direct data to support using these medications (**making this an off-label use of FDA approved medications**).

Treating providers should consider offering PEP consisting of:

1. **dolutegravir 50 mg taken once a day for 7 days and**
2. **tenofovir disoproxil fumarate 300 mg taken once a day for 7 days.**

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Begin treatment as soon as possible; preferably within a few hours of exposure, but not greater than 72 hours since the primary goal of therapy is to prevent LVV/RVV vector integration and oncogenic risks. Taking with food increases peak concentration times. Protease inhibitors that **block maturation of the virus** would be ineffective against any of these replication-incompetent vectors because they never reach the maturation step. Exposure to cells or animal tissues that have been transduced with a lentiviral vector presents minimal risk and there is not likely benefit to post exposure prophylaxis, especially if the transduction occurred more than 72 hours prior.

Expert consultation can be made by calling the National Clinicians' Post-Exposure Prophylaxis Hotline (PEpline) at **888-448-4911**.

**** Those started on postexposure medications will need to be re-evaluated within 72 hours to monitor for any signs of drug toxicity and for any new information regarding the exposure.**

- b. **Replication competent lentiviral vector exposures:** These would require 28 days of treatment as with HIV.
1. **dolutegravir 50 mg taken once a day** and
 2. **tenofovir disoproxil fumarate 300 mg taken once a day.** As noted above, this is off-label use of FDA approved medications.

5) Post Exposure Baseline and Follow-up Lab Testing

Baseline testing should be done at the time treatment is initiated.

Baseline testing should include **(and will need to be repeated in 1 week):**

- **CBC with differential**
- **Comprehensive metabolic panel, including electrolytes, BUN, creatinine, AST, ALT, bilirubin, and ALP to assess liver and renal function.**
- **Fourth or fifth generation HIV p24 antigen/antibody test and hepatitis B surface antigen test** (to determine preexisting infection[s]) should be performed when PEP is initiated. HIV tests at baseline are important since some HIV PCR tests become positive with LVV exposures, as well as the fact that preexisting HIV infections can potentially mobilize transgenes to become replication competent. Hepatitis B infections can be asymptomatic and, if present, can lead to reactivation and severe liver damage if antiviral agents are withdrawn at the end of 7 days of treatment; therefore, treatment must be continued long-term in these individuals.
- **Repeat HIV test in 6 weeks.**