
STANDARD OPERATING PROCEDURE (SOP)

Seasonal Influenza Viruses

1. SCOPE and RISK ASSESSMENT

Influenza is a contagious respiratory illness caused by type A and type B influenza viruses. Type A influenza viruses can cause infection in humans as well as other mammals (horses, pigs, etc) and avian species (waterfowl, turkeys, chickens, etc). Type B influenza viruses can cause widespread infection in humans only. There are many subtypes of influenza A and B viruses, and the virus genotypes can change at any time due to antigenic drift and shift mechanisms. Therefore multiple varied strains of influenza viruses may circulate from year to year. These strains cause epidemic mild to moderate illness in humans every year and are commonly referred to as “seasonal” influenza viruses.

Person-to-person transmission occurs via the spread of nasal droplets from coughing and sneezing. Influenza infection may cause mild to serious disease and may be fatal in some persons. Symptoms of influenza infection are usually felt rapidly after infection and may include fever, headache, fatigue, sore throat, cough, nasal congestion and draining, and muscle aches. Recovery can occur within a few days or take up to 2 weeks. Complications such as pneumonia and sinus infections are possible in persons age 65 years and older, persons with chronic medical conditions like asthma, diabetes, or heart disease, and young children.

Laboratory-acquired infections have occurred. The primary lab hazard is inhalation of aerosols generated by laboratory procedures. Additionally, droplets may be transmitted by infected ferrets, and ferret-to-human and human-to-ferret flu transmission is recognized.

The Centers for Disease Control and Prevention (CDC) recommend annual influenza vaccination for almost all persons (infants under 6 months of age are excepted). Influenza vaccines are available in either a trivalent inactivated injectable vaccine (TIV) containing killed virus or in a nasal spray vaccine containing live but weakened or attenuated virus (LAIV). Each vaccine contains three influenza viruses (one A (H3N2) virus, one A (H1N1) virus, and one B virus) and is changed annually based upon surveillance and estimates of anticipated circulating seasonal influenza viruses. TIV is recommended for all persons greater than 6 months of age, including both healthy persons and higher-risk persons such as pregnant women, breastfeeding women, and HIV-positive persons. LAIV is recommended for healthy persons aged 5 to 49 years.

Safety and efficacy data are available. TIV has prevented influenza among up to 90% of healthy adults in randomized controlled trials and has reduced influenza-related hospitalization of immunized healthy adults by 90%. The primary adverse event reported is muscle pain at the injection site lasting a few days. Some persons report flu-like symptoms or increased severity of preexisting asthma symptoms; a recent study cited by CDC reported that flu-like symptoms or increasingly severe asthma symptoms occurred equally often in persons receiving the influenza vaccine and in persons receiving a placebo. LAIV has prevented influenza among up to 92% of children in randomized controlled trials. A randomized controlled trial involving adults occurred in a year in which the vaccine strains were not well-matched with circulating strains, and although the efficacy against influenza was only confirmed at 49%, vaccine recipients had significantly fewer (19%) severe influenza illnesses than placebo recipients. Persons vaccinated with LAIV can shed vaccine viruses; CDC reports that serious influenza illnesses have not been reported among unvaccinated persons who became infected with shed vaccine viruses. Both vaccines are contraindicated for persons known to have anaphylactic hypersensitivity to eggs.

This SOP was designed to establish a system of information and safeguards that should be followed at the University of Pittsburgh when working with seasonal influenza viruses or when working in shared laboratories or animal research areas in which influenza viruses or infected animals are manipulated.

2. PROCEDURE

2.1 Agents- Seasonal influenza viruses, type A or B viruses.

2.2 Employees at risk- Cultures of influenza viruses, experimentally infected laboratory animals, or experimentally infected materials of animal origin, such as poultry eggs, are a potential source of infection to exposed laboratory personnel. Additionally, personnel who are not manipulating influenza viruses or infected animals, but who are working in shared laboratories or animal rooms where viruses or infected animals are manipulated, are at potential risk for exposure.

2.3 Laboratory hazards -Ingestion, parenteral inoculation, and droplet or aerosol exposure of mucous membranes or broken skin with infectious fluids or tissues, are the primary hazards to laboratory personnel. There is a potential for infection resulting from work with infected animals, mainly through droplet transmission resulting from the coughing or sneezing of infected animals.

2.4 Required Procedures

2.4.1 All Principal Investigators (PIs) using recombinant influenza viruses must complete an application for work with recombinant DNA through the Institutional Biosafety/rDNA Committee (rDNA@pitt.edu and www.rcco.pitt.edu/rDNA/.)

2.4.2 All PIs using seasonal influenza viruses must also complete an EH&S registration workbook for the project. Registration workbook may be obtained from the web site www.ehs.pitt.edu or by calling EH&S at 624-9505.

2.4.3 Biosafety Level 2 practices and facilities are required for manipulating seasonal influenza viruses in a lab. Animal biosafety level 2 practices and facilities are required for work with influenza-infected animals. The key practice to reduce the potential for exposure to influenza virus is to conduct all manipulations of influenza virus with potential for aerosol formation within a certified biological safety cabinet.

2.4.4 All personnel working with seasonal influenza viruses or influenza-infected animals shall be offered and strongly recommended to receive the seasonal influenza vaccination semiannually (every six months) through Employee Health Services. Personnel who refuse vaccination and personnel who are medically contraindicated to receive the vaccine may be restricted from working with influenza viruses or influenza-infected animals.

2.4.5 Laboratory personnel not directly handling or manipulating influenza virus or animals exposed to influenza virus, but working in the same lab or animal room where influenza virus is utilized shall be offered and strongly recommended to receive the seasonal influenza vaccine semiannually (every six months) through Employee Health Services. It shall be the responsibility of the employee's supervisor or PI to assure that individuals in labs or animal rooms in which influenza viruses are utilized are offered the vaccine.

2.5 References

2.5.1 Centers for Disease Control and Prevention, Seasonal Flu website,
<http://www.cdc.gov/flu/basics.htm>.

2.5.2 Biosafety in Microbiological and Biomedical Laboratories, 5th ed., Centers for Disease Control and Prevention and National Institutes of Health. 2007. Washington, D.C.: U.S. Department of Health and Human Services.

2.5.3 Prevention & Control of Influenza - Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007 Jul 13; 56(RR06):1-54.

3. APPROVAL

The University of Pittsburgh's Biohazards Committee and EH&S have reviewed and approved this SOP as attested by the signatures of the Committee Chairperson and the Biosafety Officer.

Lee Harrison, M.D.
Committee Chairperson

April 15, 2008
Date

Stephen Rohrer, Ph.D.
University Biosafety Officer

April 15, 2008
Date