

2009 H1N1 Flu Virus

Information about Newly Emerging 2009 H1N1 Influenza (Swine Flu) Virus and Blood Safety

I. Background

The ongoing outbreak of new emerging 2009 H1N1 Influenza Virus (H1N1 flu) infections in the United States has raised questions about whether this virus can be transmitted through blood transfusion. No case of transfusion transmitted seasonal influenza has ever been reported in the United States or elsewhere, and, to date, no cases of transfusion transmitted H1N1 flu have been reported. FDA is continuing to work with the Centers for Disease Control and Prevention (CDC) and is in close contact with the AABB Interorganizational Task Force on Pandemic Influenza and the Blood Supply to monitor this outbreak and its impact on blood safety and availability.

At this time, it is important to remember that, when clinically indicated, the benefits of a transfusion far outweigh the risks, including any theoretical risk of H1N1 flu transmission through blood or blood products.

II. Blood Safety Provisions

Donor Deferral

Under FDA regulations, individuals who are not in good health are not suitable to donate blood and blood establishments must defer these potential donors. (See FDA regulations at 21 CFR 640.3.) Blood donor screening procedures currently in place at blood establishments should identify persons with symptoms of H1N1 flu infection. The symptoms of H1N1 flu in people are similar to the symptoms of regular human influenza and include fever, cough, sore throat, body aches, headache, chills and fatigue. Some people have reported diarrhea and vomiting associated with H1N1 flu. Severe illness and deaths have been reported among infected individuals in Mexico and in the U.S.

The donor screening procedures in place today are important measures in reducing the theoretical risk of transfusion transmitted H1N1 flu, particularly in areas where human cases are occurring. In addition, the continued standard practice of blood establishments in maintaining good hygiene and infection control practices will help to minimize possible spread of H1N1 flu in blood establishments. Staff member hand washing between contacts with different donors is especially important.

Additional information on illness with H1N1 flu and general control strategies can be obtained at the Centers for Disease Control and Prevention (CDC) website at <http://www.cdc.gov/swineflu/index.htm>.

Potential Component Quarantine and Retrieval

Consistent with FDA's October 2006 Guidance on Biologic Product Deviation Reporting for Blood and Plasma Establishments (see <http://www.fda.gov/cber/gdlns/devbld.htm>) Medical Directors of blood establishments should consider whether a post donation report of a flu-like illness in a donor indicates that the previously collected products are unsuitable and that the donor's suitability for future donations should be assessed (e.g. deferral until well.) In addition to routine reporting of identified cases of H1N1 flu to state and local health departments, medical directors with any case raising concerns regarding potential transfusion transmission of

influenza, may contact us at the Therapeutics and Blood Safety Branch of the CBER Office of Biostatistics and Epidemiology at 301-827-3974, as well as the CDC via state and local health departments, as appropriate.

Safety of Plasma Derivatives

The newly emerging 2009 H1N1 Influenza Virus is a large lipid-enveloped virus. Validation studies performed by the product manufacturers have shown that viruses with similar characteristics to this agent are effectively inactivated and/or removed by the manufacturing processes in place for these products.