

Date: December 7, 2009  
Reference: FDAA09016

**VIA EMAIL & USPS**

Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30333  
Email:cdcinfo@cdc.gov

**SUBJECT: Interim Infection Control Guidance on 2009 H1N1 Influenza for Personnel at Blood and Plasma Collection Facilities**

Dear Sir or Madame:

The Plasma Protein Therapeutics Association (PPTA) would like to submit comments on the “Interim Infection Control Guidance on 2009 H1N1 Influenza for Personnel at Blood and Plasma Collection Facilities”, [hereinafter, Interim Guidance]. PPTA is the international trade association and standards-setting organization for the world’s major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world’s needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat complex diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.

PPTA understands the importance of being prepared during a pandemic. PPTA members continue to evaluate and adjust accordingly to this fluid situation. PPTA would like the CDC to consider the following recommendations to the Interim Guidance. These recommendations are made in an effort to improve the ability of Source Plasma establishments to follow the CDC Interim Guidance and reasonable control the spread of H1N1.

**Specific Comments**

A. Infection control and environmental management practices

**Interim Guideline:** Phlebotomy staff should wash their hands with soap and water between contacts with different blood donors, and when gloves are used they should change gloves and cleanse their hands between contacts with different blood donors. Good hand hygiene will help prevent person-to-person spread of 2009 H1N1 influenza and other influenza viruses. Staff and volunteers should also wash hands at other

appropriate times, including when hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids. An alcohol-based hand sanitizer may be used as an interim measure when soap and water are not available and hands are not visibly soiled. (See also: CDC. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002; 51(RR16):1-45); <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>.) With regard to staff safety, the wearing of gloves and hand cleansing are governed by OSHA requirements pertaining to bloodborne pathogens in 29 CFR 1910.1030(c) (3) (ix) and 29 CFR 1910.1030 (d) (iii)–(vi) respectively.

**Recommendation:** PPTA recommends that the following be deleted “phlebotomy staff should wash their hands with soap and water between contacts with different donors, and when gloves are used they should change gloves and cleanse their hands between contacts with different blood donors.” PPTA proposes the following recommendation: “Phlebotomy staff should practice proper hand hygiene practices in accordance with Occupational Safety & Health Administration (OSHA) requirements, which should be designated clearly within the companies’ Standard Operating Procedure (SOPs).”

PPTA members understand the importance of proper hand hygiene practices in centers. Proper hand hygiene practices should be used at all times. These practices assist in assuring both center employee and donor health. PPTA members delineate hand-washing and glove changing practices in their SOPs. Practices delineated by PPTA members in SOPs must be compliant with OSHA regulations for bloodborne pathogens. These federal regulations define when gloves should be worn and changed. 29 CFR § 1910.1030 *et seq.* According to § 1910.1030(d) (3) of the Code of Federal Regulations, “gloves shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when, their ability to function as a barrier is compromised.” 29 CFR § 1910.1030(d) (3) (x). Federal regulation does not require employees to change gloves on each donor.

An essential step in the donation process is Donor Screening. This process occurs at each and every time a donor comes to donate. The primary purpose of this step is to evaluate if the donor is healthy enough to donate. Any donor that fails to meet these strict criteria is deferred. Only donors that are determined to be well and healthy through the screening process may proceed to the donor floor. Employees are also instructed not to come to work if feeling ill. These measures are already in place and assure a healthy environment for both the employees and donors. Glove- changing that includes hand-washing is unnecessary in this type of environment.

**Recommendation:** PPTA recommends references to the “*CDC: Guideline for Hand Hygiene in Healthcare Settings*” be deleted from the Interim Guidance. The recommendations made in this document are not applicable to Source Plasma centers. These recommendations are specifically directed to personnel in healthcare settings

that treat patients. The data and information used to formulate the recommendations are based on studies that occurred in hospitals or other healthcare facilities that take care of individuals who are sick, i.e. patients. These patients seek treatment for an illness or medical advice from healthcare workers. Source Plasma centers are not healthcare facilities and donors are not patients. Collection facilities do not provide treatment or medical advice to individuals who donate. As discussed above, to become a donor, a person must pass a vigorous screening process to establish that they are healthy enough to donate. Therefore, only well and healthy people are allowed on the donor floor. As stated above, hand-washing and glove-changing recommendations that are specific to healthcare settings that have patients are not appropriate for Source Plasma centers and do not recognize the purpose and uniqueness of a Source plasma establishment.

Moreover, a requirement for phlebotomist to wash hands in between each donor may pose a greater risk to the donor. At a Source Plasma center a phlebotomist is generally charged with tending to 6 donors within their designated area, sinks are not readily available in the designated area. A phlebotomist would have to leave the designated area to wash hands, causing a donor to be unattended during the plasmapheresis process. A phlebotomist must be available to their donors during the donation process to assess the donor for any possible adverse reactions that may occur.

B. Planning for Implementation of Additional Public Health Measures, if 2009 H1N1 becomes more widespread and/or More Clinically Severe than in Spring/Summer 2009

**Interim Guideline:** If 2009 H1N1 becomes more widespread and/or more severe than during spring/summer 2009, public health authorities may ask collection facility personnel to institute social distancing measures to help prevent disease spread. These may include:

- Conducting active evaluation of staff, volunteers, and prospective donors for influenza-like symptoms as they enter the collection site. Individuals with influenza-like symptoms should be asked to leave the site to reduce the risk of viral transmission.
- In addition, staff or volunteers should continue to assess themselves for influenza-like symptoms each day before leaving for work and should stay home if they are ill.

To be prepared:

- Collection facility personnel should plan and test ways to institute these social distancing measures during blood collection operations.

**Recommendation:**

PPTA recommends the following be deleted from the above section:

- Adjusting the physical configuration of collection sites and donor appointment schedules to reduce unnecessary physical contact between donors and between donors and staff.
- Collection facility personnel should plan and test ways to institute these social distancing measures during blood collection operations.

PPTA proposes the following recommendations:

- Collection sites should evaluate ways to reduce the proximity of donors in certain areas. These measures should assist in reducing unnecessary physical contact between donors and between staff and donors.
- Collection sites should develop plans that implement these measures. These measures should be adaptable and recognize that decisions may need to be made on a case by case basis. Decisions should take into consideration local health department recommendations.

Preparedness is vital to maintaining business continuity for Source Plasma establishments. This is true for any emergency situation. Social distancing is an important way to limit the spread of pandemic influenza and may be recommended at times from the local health department. PPTA members work closely with their respective local health departments to follow appropriate recommendations. PPTA believes it would be more appropriate to remove references to physical changes to a collection site and focus on the need to develop plans. It is also important to recognize that during local emergency situations decisions often need to be made quickly and plans need to be adjusted accordingly.

Should you have questions regarding these comments or would like to discuss these issues further, please contact me at the Association. Thank you for your consideration.

Sincerely,



Mary Gustafson  
Vice President, Global Regulatory Policy  
Plasma Protein Therapeutics Association