Advancing Transfusion and Cellular Therapies Worldwide

Association Bulletin #13-03

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To: AABB Members

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Re: Updated Criteria for Donor Deferral and Blood Component Retrieval in Known or Suspected Common Source Outbreaks of Hepatitis A Virus Infection

Summary

The AABB Board of Directors has approved recommendations of the AABB Transfusion Transmitted Diseases Committee regarding hepatitis A common source outbreaks or situations where an infected food handler has been identified and postexposure prophylaxis (PEP) has been recommended for persons exposed to potentially contaminated food. These recommendations update previous criteria for donor deferral and blood component retrieval. Association Bulletin #04-08 titled "Criteria for Donor Deferral in Known or Suspected Common Source Outbreaks of Hepatitis A Virus Infection" was released in 2004 following an outbreak in Pennsylvania that involved over 600 people. More recently another hepatitis A virus (HAV) outbreak has been documented which is described below. Within this newly released bulletin, HAV incidence rates are updated with references to the Centers for Disease Control and Prevention website (including associated links), changes to the preferred method of HAV PEP from immune globulin (IG) to HAV vaccine are described, and blood center actions in response to localized HAV outbreaks are reformatted into a numeric list. The recommended deferral period, conditions for deferral and product recall are unchanged; actions to be taken when recipient notifications resulting from donors who may have been exposed during an HAV outbreak occur have been added. Also included is the recommendation that prospective donors who may have been exposed to HAV during the outbreak should be deferred regardless of reported HAV vaccination status.

Association Bulletins, which are approved for distribution by the AABB Board of Directors, may include announcements of standards or requirements for accreditation, recommendations on emerging trends or best practice, and/or pertinent information. This Association Bulletin supersedes Association Bulletin #04-08 titled "Criteria for Donor Deferral in Known or

Suspected Common Source Outbreaks of Hepatitis A Virus Infection." It is intended to provide information to blood collection facilities for management of donors and blood components associated with known or suspected common source outbreaks of HAV infection.

Background

Hepatitis A incidence rates in the United States have fallen by more than an order of magnitude since the 1970s in association with immunization in high-risk communities.[1-3] The 2010 national incidence rate of 0.5 per 100,000 population was the lowest yet recorded.[1] The percentage of cases attributed to a common source outbreak (ie, water-borne or food-borne transmission via contaminated food or from an infected food handler) has remained low and was reported as 10% in 2010.[1] The annual incidence in each state can vary from year to year, depending on localized outbreaks. For example, HAV incidence was 8.2 per 100,000 in Pennsylvania as a result of a single outbreak in 2003 that involved over 600 people, but since has remained at a baseline rate of about 0.5 per 100,000[1,3,4] (http://www.cdc.gov/hepatitis/Statistics/2010Surveillance/Table2.1.htm.)

As this bulletin is released, an ongoing investigation of an outbreak linked to a frozen berry and pomegranate product has identified acute HAV infection in at least 150 people in eight states (http://www.cdc.gov/hepatitis/Outbreaks/2013/A1b-03-31/index.html.)

HAV transmission by blood products is rare but well documented.[5-7] Current questions on the donor history questionnaire are designed to elicit information from prospective donors who may have been recently vaccinated or exposed to hepatitis in other settings. Blood collection facilities should have procedures to address the small risk posed by common source HAV outbreaks.

The incubation period for hepatitis A ranges from 10 to 50 days, with an interval of approximately one month from exposure to symptoms, regardless of the route of infection.[2] Higher doses of virus lead to a shorter incubation period.[1] The presence of HAV nucleic acid in plasma ("RNAemia") without accompanying anti-HAV IgM can be detected over a similar period. Although HAV RNAemia in the presence of anti-HAV IgM may persist for a longer time, there is no evidence that persons with this testing profile are infectious.[8] A typical HAV profile shows peak infectivity during the two-week period that precedes the onset of jaundice and declining infectivity during the week after onset.[2]

Hepatitis A vaccine has replaced IG as the preferred means of PEP to protect people between the ages of 1 and 40 years after they have been exposed to HAV (http://www.cdc.gov/hepatitis/HAV/HAVfaq.htm#D1).[9] Vaccination must be given within two weeks of exposure. The single-antigen hepatitis A vaccine provides long-term protection and ease of administration as well as equivalent efficacy to IG in this age group. IG is indicated for persons at increased risk of severe or fatal hepatitis A infection, which includes adults older than 40 years of age (particularly adults 75 years and older), persons with chronic liver disease (e.g., cirrhosis), those who are immunocompromised, children under 12 months of age, and individuals who are allergic to the vaccine or a vaccine component. For persons 40 years and older, vaccine can be used if IG cannot be obtained.[9]

When evaluating the risk of food-borne transmission from an infected food handler, public health officials may use published algorithms to help guide decisions about whether to provide PEP to persons who ate food prepared by the infected food handler within two weeks of exposure. However, often this decision is based largely on subjective information obtained during interviews, on the judgment and experience of public health officials, and on practical considerations such as whether HAV vaccine or IG can be delivered to potentially exposed persons within two weeks of the exposure.[1] In many cases, evaluation of the situation does *not* lead to a recommendation for PEP. Collection facilities in communities with common source HAV outbreaks should coordinate their responses with the recommendations of local public health agencies.

Blood collection facilities become aware of hepatitis A common source outbreaks through media reports, communication from public health officials, or interviews with (and postdonation reports from) blood donors. The Food and Drug Administration currently has no published policy for management of donors who have been exposed to a potentially contaminated food/beverage/water source.

The recommendations in this bulletin address precautions for donor management and component retrievals related to possible exposure to hepatitis A during common source outbreaks. For information related to donor eligibility criteria for nonexposed vaccinated individuals or those potentially exposed to HAV in other settings, the current edition of AABB *Standards for Blood Banks and Transfusion Services* should be consulted.

Blood centers should also have policies to manage components and notify consignees when postdonation information regarding hepatitis A diagnosis is received or when a donor's sample, associated with plasma intended for further manufacture, tests positive for HAV RNA.

Recommendations

Identification of a Common Source Outbreak and Donor Deferral

1. Blood collection facilities should have standard operating procedures to manage hepatitis A outbreaks. The procedures should define the approach to both donor and product management.

2. Blood collection facilities should follow the determination of their local health departments regarding potential for exposure to HAV during the outbreak and the need for PEP. The blood center's medical director or another designated staff person should communicate with the local health department or public health authority, especially early in the course of an investigation, to understand the potential for exposure, the number of people involved, the affected geographic area, and dates of possible exposure.

3. The blood center should activate its process when the public health authority publicly announces either of the following circumstances:

    - A common source outbreak has occurred and PEP is recommended for groups of individuals.

    - The potential for an outbreak exists due to the discovery of an infected food handler or other common source and PEP is recommended for groups of individuals.

    In contrast, when the local health department notification does *not* include advice for specific individuals or groups to be evaluated for PEP, in most cases, the blood collection facility does *not* need to take action. Blood collection facilities will need to consult with the local health department when specific incidents arise and there is uncertainty about the potential of exposure in a community.

4. When the above criteria are met, blood collection facilities should take measures to identify donors who may have been exposed to HAV during a common source outbreak. This information may be elicited from donors using one or more mechanisms such as the following:

    - Providing written information to all presenting blood donors in the affected geographic area about the name of the involved establishment or food outbreak and the dates of possible exposure.

    - Asking an additional question during the health history interview in the affected geographic area about possible exposure to the hepatitis A outbreak.

    These measures should remain in place for at least 120 days after the date of the last possible exposure.

5. The deferral from blood donation should be for a period of 120 days from the date of last potential exposure; this represents more than two maximal incubation periods and is the observed period to clear RNAemia. Prospective donors who may have been exposed to HAV during the outbreak should be deferred regardless of reported HAV vaccination status.

Postdonation Information and Blood Component Retrieval

There are many scenarios in which blood has been collected from individuals in a community that may have experienced a common source exposure to HAV. Actions regarding component retrieval in each such scenario should be determined by the medical director at the blood collection facility.

If a donor was potentially exposed to HAV (ie, the donor would have been deferred had the information been known at the time of donation, as outlined above), the blood collection facility should discard any in-house components and retrieve any distributed product(s) that were collected during the period from the date of the donor's first potential exposure through 120 days after the date of the donor's last potential exposure.

The transfusion facility or transfusing physician should be notified according to the blood collection facility's policy. In the event that components have been distributed from a donor who may have been exposed during a common source outbreak and/or diagnosed with hepatitis A, the recipients should be tested by anti-HAV IgM; the use of HAV RNA is optional. If hepatitis A is suspected, the recipient should also be tested for elevated liver enzymes. If the recipient is found to be anti-HAV IgM and/or HAV RNA positive, then patient management consistent with hepatitis A infection should occur along with the activation of standard hospital infection control procedures.

The blood collection facility should not distribute plasma for further manufacture if it was collected from a donor who was potentially exposed to HAV. The collection facility should notify the plasma manufacturer if such distribution occurred.

References

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