Advancing Transfusion and Cellular Therapies Worldwide

Association Bulletin #16-04

Date: March 1, 2016
To: AABB Members
From: Donna M. Regan, MT(ASCP)SBB – President
Miriam A. Markowitz – Chief Executive Officer
Re: Zika, Dengue, and Chikungunya Viruses

Summary
This bulletin provides an update to the ongoing outbreaks of Zika virus in Mexico, the Caribbean, and Central and South America, as well as countries in other regions of the world. It was developed by the AABB Transfusion-Transmitted Diseases (TTD) Committee subsequent to the release of the February 16, 2016 Food and Drug Administration (FDA) Guidance document titled "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus" and incorporates information that is congruent with recommendations in the FDA Guidance. The FDA Guidance recommends implementation by March 15 in collection areas that do not have active Zika virus transmissions and implementation by March 1 for those blood centers collecting in areas with active Zika virus transmissions. This bulletin is intended to assist AABB members whose collection activities are **NOT** in locations currently listed on the Zika-Affected Areas web page maintained by the Centers for Disease Control and Prevention (CDC), http://www.cdc.gov/zika/geo/index.html. To obtain the most current information, members can subscribe to e-mail updates of CDC Travel Notices, including Zika, at http://wwwnc.cdc.gov/travel/page/zika-information. The focus of this bulletin is Zika virus, but the measures described should also be effective for chikungunya and dengue viruses.

This Association Bulletin supersedes #16-03, which addressed self-deferral criteria and described postdonation information (PDI) and actions for Zika, chikungunya, and dengue viruses. Included herein are:

- Information about the potential for transfusion-transmitted Zika virus infections.
- A recommendation to alter the donor history questionnaire (DHQ) to obtain recent travel and residency history relevant to Zika virus exposure and to defer donors with such exposure for 4 weeks after they leave an active Zika virus transmission area.
- Recommendations to facilitate a 4-week self-deferral of donors who meet specific criteria for possible exposure to Zika virus (see Attachments 1a and 1b).

- PDI materials and recommendations for use by blood collection organizations relevant to Zika, dengue, and chikungunya viruses (see Attachments 2a and 2b).
- Recommendations for collection facilities and transfusion services in response to PDI reports.

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 practices, and/or other pertinent information. This bulletin contains recommendations.

Background

Zika, a flavivirus, is transmitted by *Aedes* mosquitoes, most commonly by *A. aegypti*. This same vector, in addition to *A. albopictus*, transmits dengue (another flavivirus) and chikungunya (an alphavirus). Other modes of Zika virus transmission include intrauterine, perinatal, and sexual routes. The contribution of sexual transmission to the overall Zika virus risk is unknown at this time. There have been no cases of female-to-male sexual transmission.

Zika virus was first described in Africa and subsequently in Asia; it spread further to cause epidemics in the Pacific starting in 2007 on Yap Island, with subsequent spread in 2013 to French Polynesia and beyond. In 2015, Zika was recognized in Brazil and local (autochthonous) transmission has subsequently been reported in numerous countries and territories in the Western Hemisphere including Mexico, the Caribbean, and Central and South America. In addition, active transmission has been reported in tropical areas including several island countries in the Pacific and Cape Verde in the Atlantic. Further expansion is to be expected.

Travel-associated cases have been reported to CDC for several years, but the only vectorial transmissions in the United States have been in the Commonwealth of Puerto Rico, the US Virgin Islands, and American Samoa. During the period of 2015 to February 17, 2016, 82 travel-associated cases were reported in the continental United States.

When symptomatic, Zika virus infection typically causes a mild dengue-like illness with fever, rash, joint and muscle pain, conjunctivitis (red eyes), and headache that is characteristic of most recognized cases in the current pandemic. Asymptomatic infection occurs in approximately 80 percent of Zika-infected individuals. In contrast, the majority of individuals infected with chikungunya and the majority of adults infected with dengue exhibit symptoms. Relevant information on the signs and symptoms of Zika virus infection can be found on CDC's web page at: http://www.cdc.gov/zika/symptoms/index.html.

- Over 1.7 million chikungunya clinical cases occurred in the Americas, as reported by the Pan-American Health Organization during the 2013-15 outbreak.
- Over 2.3 million dengue clinical cases occurred in the Americas during calendar year 2015.
- To date, the exact number of Zika infections is unknown but the number of clinically recognized cases is estimated to exceed hundreds of thousands. Of great concern is the apparent epidemic of microcephaly, a devastating neurodevelopmental abnormality, co-

located in space and time with the ongoing Zika epidemic in Brazil. There is concern that this may be a consequence of maternal infection and transmission to the developing fetus, an association that is unique for a flavivirus. Zika infection has been confirmed by detection of Zika RNA in the fetal brain, amniotic fluid, or placenta in a small number of these cases. CDC has issued a travel advisory recommending that pregnant women avoid travel to areas experiencing a Zika virus outbreak. In addition, during the French Polynesian outbreak, there was a 20-fold increase in the number of reported Guillain-Barré syndrome cases.

The risk posed by Zika virus to the blood supply is unclear, but the potential for transfusion transmission of Zika virus was suggested when 2.8 percent of asymptomatic blood donors tested positive for Zika viral RNA during the French Polynesian outbreak. The maximum duration of viremia is unknown but believed to be 1-2 weeks. Although rigorous proof of transfusion transmission is lacking, there are two credible cases undergoing evaluation in Brazil. The high volume of travel between the United States or Canada and Mexico, the Caribbean, or Central or South America will place many US and Canadian travelers at risk for Zika virus infection as this situation evolves. This raises the possibility that asymptomatic infected donors—following their travel—or their sexual partners will present to donor centers and viremic donations will be collected, processed, distributed, and transfused.

In addition, incompletely characterized risks from transfusion persist for chikungunya and dengue viruses as well as other pathogens causing outbreaks outside of the United States and Canada. Several transfusion-transmission clusters associated with dengue viruses have been documented.

Table 1 provides data from two nationwide surveys (generated by the AABB TTD Committee and administered by America's Blood Centers and the American Red Cross) of more than 50,000 donors in the summer of 2014 (August-September) and winter of 2015 (February), estimating the amount of donor travel to various regions. The results of the survey administered in the winter indicated that 2.25 percent of otherwise fully qualified donors had traveled in the Western Hemisphere outside of the United States and Canada in the 28 days (4 weeks) before their donation. The survey showed some regional variation and it is to be anticipated that higher rates of travel might occur in specific locations, especially along the US-Mexican border.

Table 1. Percent of Presenting, Otherwise Acceptable, Donors Who Would Be Deferred for Travel in Mexico, the Caribbean, or Central or South America

	Travel within 14 Days		Travel within 28 Days	
	Summer Results	Winter Results	Summer Results	Winter Results
Mexico	0.19%	0.40%	0.52%	0.92%
Caribbean	0.16	0.48	0.48	1.18
C. America	0.02	0.13	0.06	0.26
S. America	0.03	0.07	0.07	0.20
Any of above	0.39	0.97	1.17	2.25

Spencer BR, Stramer SL, Dodd RY, et al. Survey to estimate donor loss to 14- or 28-day travel deferral for mitigation of CHIKV, DENV, and other acute infections (abstract). Transfusion 2015; 55(Suppl):3A.

Options to Reduce the Potential Risk of Transfusion Transmission

Current donor history and deferral criteria for travel to countries and areas where malaria is endemic will identify some of the regions affected by Zika virus outbreaks. However, because malaria is not endemic in many of the outbreak sites, malaria deferrals alone are not sufficient to address this potential risk. Use of the current DHQ will identify and disqualify symptomatic donors for any of the three arboviruses addressed in this Association Bulletin.

FDA recommends that information concerning travel to (or residence in) a location with active Zika virus transmission in the prior 4 weeks be obtained as part of the donor interview. To this end, the AABB Donor History Task Force has developed a question that establishments can include in the Additional Questions section of their donor history questionnaire—where local questions are added—along with the corresponding flowchart (http://www.aabb.org/tm/questionnaires/Pages/Additional-Questions-to-Evaluate-Donors-for-Risk-of-Zika-Virus-Infection.aspx). When such travel is documented, donor deferral is recommended for 4 weeks after the departure date from the area. Because the majority of the countries on the CDC Zika-Affected Areas list are in the Western Hemisphere (Mexico, the Caribbean, or Central or South America), the results of the AABB travel surveys indicate that the temporary donor loss from this new deferral criterion is expected to be approximately 2.25 percent of otherwise acceptable donors during the winter months when such travel is more common than in the summer months.

As described in this bulletin, the use of donor education information sheets to enhance postdonation symptom reporting to blood centers will help facilitate quarantine and recall of potentially infectious components from ill donors with exposure in Zika (or other arboviral) epidemic settings throughout the Americas and the tropics.

There are no licensed blood donor screening tests in the United States to identify Zika, chikungunya, or dengue RNA. FDA-approved pathogen reduction technologies have been shown to be effective for reducing arboviral loads and infectivity in platelets (West Nile, dengue, and chikungunya viruses) and plasma (West Nile, dengue, chikungunya, and Zika viruses).

Information Materials for Donors and Blood Centers

The attached materials were developed by the AABB TTD Committee and are recommended as an addition to donor educational materials already in use. Collection facilities may elect to use

these materials to alert donors to the need for self-deferral after travel to Mexico, the Caribbean, Central or South America, or other locations (Attachments 1a and 1b) and to educate blood donors about the major symptoms consistent with acute tropical infections, including those from Zika virus infection (Attachments 2a and 2b) in case they experience these symptoms following donation.

Recommendations:
At this time, AABB recommends the following actions:

- On or before March 15, 2016, blood collection facilities should implement deferral for donors who, during the prior 4 weeks, have traveled to (or resided in) locations with active Zika virus transmission as determined by information available on the CDC Zika-Affected Areas web page, http://www.cdc.gov/zika/geo/index.html. Facilities are encouraged to consult this resource on a daily basis as the spread of the virus has been very rapid. Deferral should be for 4 weeks after the date of departure from an active Zika virus transmission area; any time spent in an active transmission area is cause for deferral due to the aggressive daytime biting activity of the mosquito vectors. FDA recommends that this travel history be elicited as a part of the donor interview process.
    - Blood collection facilities are recommended to continue to supply donors with educational predonation material indicating that they should self-defer for 4 weeks if they have traveled to (or resided in) Mexico, the Caribbean, Central or South America, or other areas as specified on the CDC web page as those with active transmission.

- Donors should also be supplied with predonation educational materials indicating that they should self-defer if:
    - They have been diagnosed as infected with Zika virus in the past 4 weeks. In this case they should self-defer until 4 weeks have elapsed from the resolution of their symptoms.
    - They have experienced two or more symptoms compatible with Zika virus infection from the symptom list in Attachments 1b and 2b, provided these symptoms occurred within 2 weeks of departure from an area with active Zika virus transmission. These donors should self-defer for 4 weeks after resolution of their symptoms.
    - They have had sexual contact with a man who in the 3 months prior to the sexual contact has been diagnosed with Zika virus infection or traveled to or resided in an area with active Zika virus transmission. These donors should self-defer for 4 weeks after the last such sexual contact.

- Donors should be informed to call the blood collection facility if they subsequently realize that they should have self-deferred for one of these possible Zika virus exposures. This applies to donors who traveled to (or resided in) a location with active Zika virus transmission independent of whether they developed symptoms. In addition, donors are specifically asked to call the blood center if they engaged in such travel or residency and developed two or more of the listed symptoms in the 2 weeks following donation and/or they were diagnosed with Zika virus infection. Lastly, donors should also call the blood collection facility if they realize that they had sexual contact with a man who traveled to

or resided in an area with active Zika virus transmission in the prior 3 months. In the event that a donor calls back and supplies such information, the blood establishment should take the following actions:

- If you collected blood or blood components from a donor who should have self-deferred, who has been deferred, or who has provided postdonation information as noted above, undistributed in-date blood or blood components collected from that donor should be quarantined. All products from these donors should be destroyed or appropriately labeled for research. The collection facility should evaluate all in-date current, prior, or subsequent donations from donors who should have self-deferred or who were deferred to determine whether the donation was collected within the time interval that placed the donor at risk of Zika exposure. If so, the quarantine policy should apply.
- The collection facility should defer the donor for 4 weeks following: departure from a Zika-affected area; resolution of postdonation symptoms; sexual exposure as described above; and recovery from a diagnosis of Zika, dengue, or chikungunya virus infection.
- If blood components have been distributed and later determined that they should be quarantined, the collection facility should recall the components from the facility that received them.
- If blood components collected from a donor with a history (diagnosis) of Zika, dengue, or chikungunya virus infection in the past 4 weeks or from a donor who reports two or more of the listed postdonation symptoms within 2 weeks following donation have been transfused, the transfusion service should be notified with the intent of informing the transfusion recipient's physician of record about the need to monitor the recipient for Zika or other arboviral infection.

Suggested Reading

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Attachment 1a

What is the purpose of the Donor Self-Deferral Information Sheet to Reduce the Risk of Transfusion-Transmitted Zika?

The level of risk for transfusion-transmitted Zika virus infection is not known, but the following considerations are notable:

- There may be severe consequences of Zika virus infection for fetuses.
- Zika RNA has been detected in otherwise qualified donors.
- Two plausible cases of transfusion transmission of Zika virus have been reported in Brazil.
- There is a risk that an infectious unit could be transfused to a woman during a recognized or unrecognized pregnancy, to a fetus via intrauterine transfusion, or to recipients otherwise susceptible to severe morbidity.
- Zika virus is spreading rapidly in the Western Hemisphere outside the continental United States and Canada. Some tropical areas elsewhere in the world also show active Zika virus transmission.
- There are reported cases of sexual transmission of Zika virus; the duration of persistence of Zika virus in semen remains unknown but preliminary data indicate this period is longer than the persistence of virus in blood.

FDA has recommended that a travel question be added to the donor history questionnaire; this question will elicit information about travel to (or residence in) areas with active Zika virus transmissions in the past 4 weeks and reference the current list of Zika-Affected Areas from the CDC web page at http://www.cdc.gov/zika/geo/index.html. In addition to asking this question, AABB recommends that blood establishments continue to ask donors to self-defer for such travel or residency.

Further, the FDA has recommended that donors self-defer for 4 weeks as a way to reduce the risk of transfusion transmission of Zika virus under the following circumstances:

- After resolution of symptoms from a diagnosed Zika virus infection.
- After resolution of symptoms indicative of Zika virus infection (two or more from the CDC list (http://www.cdc.gov/zika/symptoms/index.html): fever, rash, joint pain, muscle pain, conjunctivitis (red eyes), or headache that occurred within 2 weeks of leaving an area that has active Zika virus transmissions. This symptom list should also detect donors at risk for chikungunya or dengue virus infection.
- After last sexual contact with a man who in the 3 months prior to the sexual contact had a Zika virus infection or has traveled to or resided in an area with active Zika virus transmissions.

If your organization chooses, you should provide Attachment 1b and the listing of areas determined to have active Zika virus transmission to all donors. Because the CDC listing changes on a regular basis as areas of active local transmission are added, it is important that blood establishments supply the updated list.

Attachment 1b

Donor Self-Deferral Information Sheet to Reduce the Risk of Transfusion-Transmitted Zika

Thank you for coming in to donate today: We will provide you a list of self-assessments and ask you not to donate today if any of these Zika risk exposures apply to you. Please return to donate when at least 4 weeks have passed since your departure from an area where Zika virus is found or your last risk exposure. We are doing this for the following reasons:

- Zika virus infection is spreading rapidly in the Western Hemisphere outside the continental United States and Canada as well as in other locations.
- Zika virus infection is mild in most people, but there is concern that Zika virus infection is causing serious brain injury to infants whose mothers have been infected during pregnancy and an increase in cases of Guillain-Barré syndrome, a temporary but serious disorder causing paralysis.
- Zika virus can be present in the blood of an infected person who has no symptoms of illness.
- There is concern that Zika virus can be transmitted by blood.
- There are reported cases of sexual transmission of Zika virus; the length of time that infectious Zika virus is present in semen remains unknown.

Self-assessments:
If any of these apply to you we are asking you NOT TO DONATE TODAY, but to consider donating again after you complete your 4-week self-deferral.

- Within the last 4 weeks, if you have traveled to or resided in any of the areas on the list provided to you (this list is prepared and updated by the US CDC and is available at http://www.cdc.gov/zika/geo/index.html), we ask you to return to make a blood donation more than 4 weeks after your departure from the identified area(s).
- If you have had a Zika virus infection, we ask you to return to make a blood donation more than 4 weeks after your symptoms resolve.
- If you have had two or more of the symptoms listed here within 2 weeks of leaving an area that has active Zika virus transmissions, we ask you to return to make a blood donation more than 4 weeks after your symptoms resolve. The symptoms are:
    - Fever
    - Rash
    - Joint pain/muscle pain
    - Conjunctivitis (red eyes)
    - Headache

  Further information about the symptoms associated with Zika virus disease can be found at http://www.cdc.gov/zika/symptoms/index.html.
- If you had sex with a man who, in the 3 months prior to your sexual contact, has had a Zika virus infection or has traveled to or resided in an area with active Zika virus transmissions (the same list that you were provided), return for your donation more than 4 weeks after the last sexual contact.

For further information speak with staff in the donor room or call xxx-xxx-xxxx.

Attachment 2a

What is the purpose of the Postdonation Information Sheet?

The Postdonation Information Sheet was developed in light of current Zika, dengue, and chikungunya virus outbreaks worldwide and the possibility that donors who travel to or reside in those areas may become infected. This Postdonation Information Sheet is designed to inform 1) any donor who has been in areas with active Zika virus transmission in the last 4 weeks, or following such travel, who develops symptoms consistent with these acute viral infections within 2 weeks after donation, or 2) any donor who has had sexual contact with a male at risk of Zika virus infection (diagnosed, or travel exposure) in the 3 months prior to such sexual contact to call back to the blood center.

If your organization chooses to use this Postdonation Information Sheet (Attachment 2b), it should be provided to the donor with your standard postdonation information materials. You should also provide a current listing of areas determined to have active Zika virus transmission to all donors. Note that the CDC listing changes on a regular basis as areas of active local transmission are added. You can obtain the most current information by checking daily at http://www.cdc.gov/zika/geo/index.html and/or by subscribing to e-mail updates at http://wwwnc.cdc.gov/travel/page/zika-information. You may choose to ask your donors to call the blood center with questions related to areas of risk.

Attachment 2b

Postdonation Information Sheet

Thank you for your donation today. Travel puts you at risk of getting infections not found in the United States and Canada. Of most concern at this time are tropical diseases caused by Zika, dengue, and chikungunya viruses, which are transmitted to humans by infected mosquitoes. Zika virus can also be transmitted sexually.

You were asked not to give blood if in the last 4 weeks you have traveled to (or resided in) areas where there is active Zika virus transmission. You may have traveled to (or resided in) one of those areas, or an area not yet recognized by the CDC as having active Zika transmission, and donated today. You might have been infected, but remained well. If you have any of the risk factors listed below, PLEASE notify us as soon as possible.

- If you traveled to (or resided in) any of the areas on this list (http://www.cdc.gov/zika/geo/index.html) in the last 4 weeks before you donated today. If you traveled outside the continental United States and Canada in the 4 weeks prior to your donation please check this website during the next 2 weeks as the CDC may identify new Zika-affected areas.

- If you traveled to (or resided in) these areas and you develop two or more of the symptoms listed below during the next 2 weeks:
    - Fever
    - Rash
    - Joint pain/muscle pain
    - Conjunctivitis (red eyes)
    - Headache

- If you were diagnosed with Zika virus infection any time within the last 4 weeks or you receive such a diagnosis during the next 2 weeks following your donation.

- If in the last 4 weeks you had sexual contact with a man, who in the 3 months prior to your sexual contact, was at risk for Zika virus infection (including a man with a Zika virus diagnosis, or a man who has traveled to or resided in an active Zika virus transmission area).

If you are diagnosed with a dengue or chikungunya virus infection, please also notify us as soon as possible.

By notifying us, you may prevent the blood that you donated today from being used and potentially infecting a patient receiving a transfusion.

(XXX) XXX-XXXX
Blood Center Name