AABB HOT TOPIC: Reducing the Risk of Transfusion-Transmitted Zika Virus in the US/Canada
February 17, 2016

Questions:

1. Is it ok to store umbilical cord blood stem cells as collected?

2. When will information be available regarding the Zika virus in regards to HCT/P donors?

3. What is the status for a blood donor screening test for use within the US (antibody and/or NAT)? Investigational or approved? There was NAT used in French Polynesia in 2013-14 outbreak.

4. Are there any plans to study the disease in animals? Is CBER going to make Zika virus positive samples available so we can evaluate clinical Zika PCR kits or in-house developed assays?

5. Is CBER going to publish guidelines for nucleic acid tests for Zika virus (i.e. limit of detection, etc.)

6. Are there any plans to study the disease in animals?

7. Comment of value or lack of value of sequence data to characterize donor recipient pairs in TTIs.

8. Would the FDA expedite review of the DHQ so centers may change forms once?

9. Why did FDA decide on deferral after sexual contact when so few cases have been described?

10. Should blood establishments be asking donors specific questions re sexual contact with someone who traveled to Zika risk area or only list this for donors to self-defer?

   I believe that there is still confusion regarding what additional questions are needed for the DHQ. How is one to know that a deferral is needed for sexual contact, if a question is not asked?

   In areas without active transmissions, FDA's guidance requires deferral of donors with a history of ZIKA or relevant sexual contact, but there is no requirement for DHQ questions to elicit this information. Can someone comment?

11. Page 6, 2c, sexual contact deferral: Why are female donors deferred for 3 months, but male donors only deferred for 28 days?

12. Donor Deferral recommendation c: Does this apply to a man who had EVER been diagnosed with Zika?

13. Will a question algorithm be provided?

14. Since the FDA has recommended screening for risk in the donor questionnaire, is it still necessary to have the self-deferral info on travel? We will be adding several other pieces of info we want them to read and too much info is discouraging....

15. Is it acceptable to use 2 of the symptoms plus travel history for FDA PDI recommendation?

16. Do you think we will see an increase in autologous units?

17. Is recovered plasma for further manufacture exempt from lookback/destruction?

18. FDA - Do you expect to change recommendation of import blood to PR for mandatory importing blood?

19. On page 4 of the Guidance, an active transmission area is defined as an area included on the CDC website listing of countries and US states and territories with local vector-borne (i.e., mosquito-
acquired) transmission of Zika. What happens when multiple US states have local vector-borne transmission? The options in the Guidance include obtaining blood from areas (states) w/o active transmission, use of PI (not universally available) or testing (also not available). Ultimately, even if a few states have local transmission, a large percentage of the US blood supply may not be available.

20. On page 4 of the Guidance, III.A.1.a.ii.b., it is recommended that a donor who exhibits signs and symptoms of Zika...should self-defer. How many signs and symptoms must the donor exhibit to self-defer? The AABB Bulletin recommends if a donor exhibits two or more, then the donor should self-defer.

21. On page 5 of the Guidance, III. A.1.b.ii. (areas w/o active transmission), it is recommended that the DHQ assess prospective donors for a history of residence in or travel to an area with active transmission of ZIKV in the past 4 weeks. Is this the only question that we are required to ask?

22. On page 6 of the Guidance, III.A.2 (areas w/o active transmission), it is recommended that we defer donors with a diagnosis or symptoms of Zika or a history of sexual contact in the past 4 weeks with a man who has been dx with or had symptoms suggestive of ZIKV in 3 months prior to that instance of sexual contact. Are these intended to be documented deferrals?

23. On page 8 of the Guidance, III.B.3.b (areas w/ active transmission), it is recommended that the DHQ assess prospective donors for a history of ZIKV infection or symptoms suggestive of ZIKV in the past 4 weeks, and a history of sexual contact in the past 4 weeks with a man who has been diagnosed with or had symptoms suggestive of ZIKV in 3 months prior to that instance of sexual contact. Why would this be required if products are pathogen reduced (apheresis platelets or plasma) or tested for ZIKV RNA universally? No additional questions are being asked about mosquito transmission which represents the greatest risk? If we are confident that testing or PI can mitigate the risk from mosquito transmission, why not the other modes of transmission? We are not required to ask such questions of donors related to WNV.

24. On page 9 of the Guidance, III.C.3 (all areas), it is recommended that if blood collected from a donor with a history of ZIKV in the past 4 weeks has been transfused, that the transfusion recipient’s physician of record is informed. Please clarify the 4 week period. Does the guidance mean that someone who is diagnosed with ZIKV within the 4 weeks after donating? What if someone was diagnosed with ZIKV three or six weeks before donating and the blood establishment learns this after the donation via PDI?

25. On page 11 of the Guidance, IV.B (areas w/ active transmission), it is recommended that the guidance for collections intended for intrauterine transfusion, transfusion in pregnant women, or transfusion in other at-risk recipients be implemented immediately. Since blood establishments do not know the intended recipients for the products they ship, presumably it will be the responsibility of the hospitals to select the appropriate product. Most hospitals will not have products from the continental U.S. or pathogen-reduced products immediately. How are they expected to comply?

26. GENERAL: As blood establishments work to implement the guidance, there will likely be additional questions. Should these questions be addressed to the assigned CSO and will FDA establish a mechanism by which these questions and answers will be posted to promote consistency in understanding and implementation?

27. GENERAL: Since blood establishments will need to take action to implement this guidance very quickly, including making necessary computer changes, will the FDA consider a delay in the implementation date of the Final Rule?
28. Has CDC defined what circumstances must be met to justify the designation "active transmission"? How many cases?

29. Can someone comment on the possibility of US becoming an active transmission location between now and 4 weeks?

30. Can you clarify the definition of the "area" of active transmission? I am particularly interested in the definition as it might apply to the continental US.

   Will country wide designation be implemented in the US if spreading occurs from Mexico across the Texas border?

   For the purposes of defining a local transmission area within the continental US, why are you defining by state rather than by zip code or county, given the large geographical area of certain states?

31. How does a location come off the list of areas with active transmission?

32. Do you foresee an epidemic similar to WNV in the spring and summer seasons in the Southern US states where we would need to screen our donors for travel to epidemic areas within the US? Especially if a test is not available?

33. Comment on quality of surveillance outside the US in the Americas, and CDCs listing of risk areas only at the country level. Can you be more granular with any confidence for example about Mexico?

34. Are there any plans to expand mosquito control, specifically in the countries where the epidemic exists, as well as the United States?

35. Can the CDC send blast e-mails when adding or removing countries from Zika endemic areas as they do for malaria?

36. Is there a way to visually identify the 2 species of mosquito that carry the Zika virus? Or do they look the same as other species?