

From the Ask the FDA and CMS/CLIA Session

2018 AABB ANNUAL MEETING, BOSTON

We asked about:

Ebola - Countries with Widespread Transmission

Background: We hear about Ebola outbreaks in the news. As blood establishments review SOPs to stay prepared for an Ebola outbreak, there is some confusion about where to find the necessary information from CDC.

In the January 2017 Guidance, “[Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus](#)”, Section III. states:

The recommendations in section III.A.2. and III.B. should be implemented when the CDC has classified one or more countries as having widespread transmission of Ebola virus. We recommend that you continue to follow the recommendations for 4 weeks after the date CDC classifies the last affected country as a country with former widespread transmission...

Example: Throughout the guidance, FDA refers to a CDC webpage that now has the title of “[2014-2016 Ebola Outbreak Distribution in West Africa](#)” yet the webpage contains no recent information. In addition, the webpage “[Current Outbreaks](#)” provides more recent information but nothing on widespread transmission. Our quality approach drives us to try to verify the absence of wide-spread transmission.

Questions:

8) Did CDC change the webpage content or titles?

9) In the absence of a change, what is the best way to confirm that CDC still has not identified widespread transmission of Ebola?

FDA confirmed the following:

- FDA worked closely with CDC to develop the Ebola Guidance and the recommendations should be implemented when the CDC has classified one or countries with widespread transmission of Ebola virus.
- CDC provided that specific link to FDA for use in the guidance.
- [FDA confirmed with CDC that CDC intends to post the information on that webpage](#) if there is widespread transmission.
- Currently there are Ebola cases in the Democratic Republic of the Congo (DRC), but this is not considered widespread transmission, so no information has posted.
- IF CDC determines there is widespread transmission of Ebola, FDA will work with CDC to ensure that information is posted on that webpage.

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**AABB COMMENTS:** FDA’s guidance provides the [correct link to the webpage designated by CDC](#) for this purpose. In support of their mission, CDC posts information for use by a very broad range people. For this reason – you will find many resources organized on a number of webpages. Rely on the link above provided in [FDA’s Guidance Jan 2017 Guidance](#).

Contact Regulatory Affairs at [regulatory@aabb.org](mailto:regulatory@aabb.org) if you have questions.