



Association for the
Advancement of
Blood & Biotherapies

Ebola Toolkit to Assist with the Evaluation of Donor Eligibility, Deferral, Product Management and Risk of Ebola Disease

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Note: Content has not changed from
the previous toolkit. Broken links have
been updated.

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I. Introduction

This Ebola Toolkit is intended to supplement your understanding of the recommendations in the FDA’s [January 2017 Guidance, Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus](#). These tools support a smooth transition and implementation of FDA recommendations in the event CDC classifies one or more countries with “widespread transmission of Ebola virus or cases in urban areas with uncertain control measures”. The checklist is included as a “quick reference,” and the flowchart maps a clear path for implementation of donor screening, deferral, and inventory management. These tools contain relevant hyperlinks to support compliance efforts as you ensure policies and procedures consistently meet FDA’s specific expectations for additional safety during the period of risk identified by CDC. A link to the final guidance itself appears in the title of the checklist.

[Checklist begins on the next page]

AABB Checklist for FDA's [Jan 2017 Ebola Recommendations](#)

USE WITH RECOMMENDATIONS IN SECTIONS III.A, B & C, PAGES 3-7 OF THE GUIDANCE

<p>III.A Donor Educational Material and Donor History Questionnaire</p> <p>IN THE ABSENCE OF WIDESPREAD TRANSMISSION - Implement by April 2017</p> <p>Implement Recommendation [III.A.1, page 4]: “...self-deferral of donors with a history of Ebola virus infection or disease should provide sufficient protection”</p> <p>___ Review AABB Blood Donor Education Material</p> <p>___ Update donor educational material to include self-deferral for Ebola virus infection or disease.</p>
<p>WITH WIDESPREAD TRANSMISSION CLASSIFIED BY CDC: Within 4 weeks you must:</p> <p>___ Modify your DHQ and aDHQ [III.A.2, pages 4-5]:</p> <p>Refer to AABB Ebola DHQ modified to assess individuals for Ebola risk.</p> <p>___ Modify your Ebola Education Material [III.A.2, page 5] to assist donors in answering the additional questions for Ebola risk.</p> <p>Refer to AABB Ebola Education Material; CDC: Ebola Disease Basics page which includes “Signs and Symptoms” information.</p>
<p>III.B. Donor Deferral</p> <p>Defer a donor for Ebola risk [III.B, pages 5 & 6]. Ebola is a transfusion-transmitted infection under 21 CFR 630.10(e)(2) and (h):</p> <p>___ Update SOPs for eligibility and deferral requirements.</p> <p>Refer to AABB Ebola flowcharts for donor eligibility and deferral criteria.</p>
<p>III.C. Product Retrieval, Quarantine, and Notification</p> <p>Blood and Blood Components Collected from Donors at Risk for Ebola Virus Infection or Disease Because of Risk Factors Related to Residency, Travel or Close Contact [III.C.1 page 6]:</p> <p>___ Quarantine/destroy all undistributed in-date products from such a donor.</p> <p>___ Notify consignees to retrieve/quarantine/destroy blood products from such a donor, if distributed for transfusion or for further manufacture*</p> <p>*For plasma pooled for further manufacturing, refer to recommendation III.C.1.b, pages 6 & 7.</p>
<p>Blood and Blood Components Collected from Donors Later Determined to Have Ebola Virus Infection or Disease [III.C.2 page 7]:</p> <p>___ As soon as possible, contact FDA upon learning of the donor’s EVD risk based on donation in the 8 weeks prior to disease onset or any time after disease onset.</p> <p>___ Notify state and local public health authorities, as applicable.</p> <p>___ Promptly retrieve/quarantine the blood products collected in the 8 weeks prior to disease onset, if collected from a donor who should have been deferred for Ebola risk.</p> <p>___ If transfused, transfusion services should notify the transfusion recipient’s physician of record regarding the need for notification and monitoring of the recipient for possible EVD.</p> <p>___ Manufacturers should contact the appropriate FDA review division to discuss the adequacy of their risk analysis if plasma collected from such a donor has been pooled for further manufacturing or manufactured into a finished product.</p>

Flowchart for Implementation of FDA's January 2017 Ebola Recommendations

By April 2017: Add [AABB Ebola Educational Material](#) for use during periods without widespread transmission. [VI, page 9, and III.A.]

Trigger additional Ebola recommendations:

AABB, FDA and/or CDC announce that CDC has classified one or more countries with "[widespread transmission of Ebola virus disease \(EVD\) or with cases in urban areas with uncertain control measures.](#)"

Within 4 weeks of the date of widespread transmission, you must implement:

1. Updated Ebola Education Material to assist donors with the Ebola questions. Refer to AABB Ebola Education Material. [VI, page 9 and III.A2. page 4]
2. Updated DHQ to assess donors for Ebola risk. Refer to [AABB Ebola DHQ and flowcharts](#) to add 5 questions to the end of the AABB DHQ. [III.A.2. pages 4 & 5]

III.A.2. Donor Risk Assessment and III.B Donor Deferral

Consistent with AABB model DHQs, assess individuals for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus (as required by 21 CFR 630.10(e)(2), as follows:

- a. A history of Ebola virus infection or disease. Defer indefinitely. [III.B.1, page 5]
Does not apply to convalescent plasma collection for treatment of EVD [as described in section V, page 8.]
- b. A history of residence in or travel to a [country with widespread transmission of EVD or cases in urban areas with uncertain control measures.](#) Defer for 8 weeks from date of departure [III.B.2, page 5].

In addition, further assess prospective donors for risk in the past 8 weeks based on:

- A history of close contact with a person confirmed to have EVD or a person under investigation (PUI) for EVD in whom diagnosis is pending. Defer for 8 weeks from date of last exposure [III.B.1 page 6].
Close contact; "that could have resulted in direct exposure to body fluids such as blood, urine, stool, saliva, semen, vaginal fluids or vomit, such as healthcare workers and other persons who care for, have lived with, or have otherwise been in contact with a PUI or a person confirmed to have Ebola virus infection or disease."
- A history of sexual contact with a person known to have recovered from EVD prior to that instance of sexual contact, regardless of the time since the person's recovery. Defer for 8 weeks from date of last contact [III.B.1, page 6].
- A history of notification by a public health authority that he or she may have been exposed to a person with EVD. Defer for 8 weeks from date of last contact [III.B2, page 6].

Continue until **4 weeks AFTER** the CDC determines no countries have widespread transmission. [III. Page 3]

III.C Perform Product Retrieval, Quarantine, and Notification

1. Quarantine/destroy all undistributed in-date products from a donor who should have been deferred for EVD risk. [III.C.1. page 6]
 - a. Notify consignees to retrieve/quarantine/destroy blood products, if you distributed products for transfusion or for further manufacture from a donor who should have been deferred. [III.C.1.a page 6]
 - b. For plasma pooled for further manufacturing refer to recommendation [III.C.1.b, pages 6 & 7].
2. Products collected from a donor later determined to have Ebola:

As soon as possible, contact FDA upon learning of the donor's EVD risk based on donation in the 8 weeks prior to disease onset or any time after disease onset. Notify state and local public health authorities, as applicable. [III.C.2. page 7]

 - a. Promptly retrieve/quarantine the blood products collected in the eight weeks prior to disease onset, if collected from a donor who should have been deferred [III.C.2.a, page 7].
 - If transfused, transfusion services should notify the transfusion recipient's physician of record regarding the need for notification and monitoring of the recipient for possible EVD.
 - b. Manufacturers should contact the appropriate FDA review division to discuss their conduct of adequate risk analysis if plasma collected from such a donor has been pooled for further manufacturing or manufactured into a finished product. [III.C.2.b, page 7]