

## DHQ v2.1 Crosswalk to DHQ v4.0

- This Crosswalk has been developed as a resource to assist with compliance efforts. It should not replace the full review of DHQ v4.0 and Accompanying Materials, which comprise the system of documents formally recognized by FDA.

DHQ v2.1 renumbered as --->	DHQ v4.0	Question and Flowchart Revisions	Basis for the Revision in DHQ v4.0
n/a	n/a	<ul style="list-style-type: none"> <li>Throughout the DHQ questions have been reordered to:               <ul style="list-style-type: none"> <li>focus attention on new content.</li> <li>group similar questions</li> </ul> </li> </ul>	
n/a	n/a	<ul style="list-style-type: none"> <li>Throughout the DHQ v4.0 Flowcharts, references have been added to the CFR, FDA guidance and AABB Standards.</li> </ul>	
n/a	n/a	<ul style="list-style-type: none"> <li>DHQ v4.0 Flowcharts: “Accept Donor” boxes have been removed.</li> </ul>	Donors are not “accepted” until they have completed the entire donor screening process. Therefore, the “Accept Donor” boxes in the Flowcharts have been removed.
1. Are you feeling healthy and well today?	1. Are you feeling healthy and well today?	<ul style="list-style-type: none"> <li>No revision</li> </ul>	n/a
2. Are you currently taking an antibiotic?	2. Are you currently taking an antibiotic?	<ul style="list-style-type: none"> <li>No revision</li> </ul>	n/a
3. Are you currently taking any other medication for an infection?	3. Are you currently taking any other medication for an infection?	<ul style="list-style-type: none"> <li>No revision</li> </ul>	n/a
<b>Refer to DHQ v2.1 Q33</b>	4. Are you pregnant now?	<ul style="list-style-type: none"> <li>The compound DHQ v2.1 question Q33, “Female donors: Have you ever been pregnant or are you pregnant now?” was broken into 2 questions.</li> <li>Note: DHQ v4.0 Q35 “Have you ever been pregnant?” assesses an individual who has been pregnant in the past 6 weeks but is no longer pregnant.</li> </ul>	<ul style="list-style-type: none"> <li>Member feedback described poor donor attention to the compound DHQ v2.1 question.</li> <li>Member feedback – Posing this question to all donors supports an individual donor assessment approach.</li> </ul>

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		<ul style="list-style-type: none"> <li>Q35 also assesses TRALI risk.</li> </ul>	
<p><b>4.</b> Have you taken any medications on the Medication Deferral List in the time frames indicated? (Review the Medication Deferral List.)</p>	<p><b>5.</b> Have you taken any medications on the Medication Deferral List in the time frames indicated? (Review the Medication Deferral List.)</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Information from page 2 of the Medication Deferral List has been removed and relocated to Flowchart Q5.</li> </ul>	<ul style="list-style-type: none"> <li>This information is intended to assist the donor historian when providing additional information to the donor about their deferral.</li> <li>It is more appropriately located with the flowchart.</li> <li>Additional information for PrEP/PEP/ART has been added following issue of the <a href="#">FDA's 2023 HIV Guidance</a></li> </ul>
<p><b>5.</b> Have you read the educational materials today?</p>	<p><b>6.</b> Have you read the <b>blood donor</b> educational materials today?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Clarification</li> </ul>	<ul style="list-style-type: none"> <li>The words "blood donor" were added to clearly identify the FDA required blood donor educational material which must be presented to the donor prior to donation.</li> </ul>
<p><b>6.</b> In the past <b>48 hours</b>, have you taken aspirin or anything that has aspirin in it?</p>	<p><b>7.</b> In the past <b>48 hours</b>, have you taken aspirin or anything that has aspirin in it?</p>	<ul style="list-style-type: none"> <li>Number change.</li> </ul>	
<p><b>7.</b> In the past <b>8 weeks</b>, have you donated blood, platelets or plasma?</p>	<p><b>8.</b> In the past <b>8 weeks</b>, have you donated blood, platelets, or plasma?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Comma added after platelets.</li> </ul>	<ul style="list-style-type: none"> <li>Donor eligibility statement was modified to include the assessment of a "single unit red blood cell donor"</li> </ul>
<p><b>8.</b> In the past <b>8 weeks</b>, have you had any vaccinations or other shots?</p>	<p><b>9.</b> In the past <b>8 weeks</b>, have you had any vaccinations or other shots?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Information on Jynneos vaccine was added to the flowchart.</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">AABB's Updated Information on Donation of CCP, Blood Components and HCT/Ps During the COVID-19 Pandemic</a></li> </ul>
<p><b>9.</b> In the past <b>8 weeks</b>, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?</p>	<p><b>10.</b> In the past <b>8 weeks</b>, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Information on Jynneos vaccine was added to the flowchart.</li> </ul>	
<p><b>DHQ v2.1 Area for Additional Questions</b></p>	<p><b>11.</b> In the past <b>3 months</b>, have you taken any medication by mouth (oral) to prevent an HIV infection? (i.e., PrEP or PEP)</p>	<ul style="list-style-type: none"> <li>New question added (moved from the area for additional questions).</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA's 2023 HIV Guidance</a></li> <li>AABB <a href="#">Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable</a></li> </ul>

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			<i>PrEP and the Impact on Blood Safety</i>
<p><del>18. Male Donors: In the past 3 months, have you had sexual contact with another male?</del></p>	<p><b>12.</b> In the past <b>3 months</b>, have you had sexual contact with a new partner? (refer to the examples of “new partner” in the Blood Donor Educational Material)</p>	<ul style="list-style-type: none"> <li>• New individual donor assessment question.</li> <li>• Examples of “sex with a new partner” have been included in the Note section.</li> <li>• Examples of “sex with a new partner” have been added to the Blood Donor Educational Material and the Flowchart.</li> </ul>	<p><a href="#">FDA’s 2023 HIV Guidance</a></p>
<p><del>19. Female donors: In the past 3 months, have you had sexual contact with a male who had sexual contact with another male in the past 3 months?</del></p>	<p><b>13.</b> In the past 3 months, have you had sexual contact with more than one partner?</p>	<ul style="list-style-type: none"> <li>• New individual donor assessment question.</li> </ul>	<p><a href="#">FDA’s 2023 HIV Guidance</a></p>
<p><b>15.</b> In the past <b>3 months</b>, have you had sexual contact with anyone who has ever <del>had HIV/AIDS or has ever</del> had a positive test for <del>the HIV/AIDS virus</del>?</p>	<p><b>14.</b> In the past <b>3 months</b>, have you had sexual contact with anyone who has ever had a positive test for HIV <b>infection</b>?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Revised to align with the language of the guidance</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA’s 2023 HIV Guidance</a></li> </ul>
<p><b>24.</b> In the past <b>3 months</b>, have you received money, drugs, or other payment for sex?</p>	<p><b>15.</b> In the past <b>3 months</b>, have you received money, drugs, or other payment for sex?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA’s 2023 HIV Guidance</a></li> </ul>
<p><b>16.</b> In the past <b>3 months</b>, have you had sexual contact with <del>a prostitute or</del> anyone <del>else</del> who has <del>ever taken</del> money or drugs or other payment for sex?</p>	<p><b>16.</b> In the past <b>3 months</b>, have you had sexual contact with anyone who has, <b>in the past 3 months, received</b> money, drugs, or other payment for sex?</p>	<ul style="list-style-type: none"> <li>• Revised to align with the language of the guidance</li> <li>• Revised <b>from</b> sexual contact with anyone who has “ever” <b>to</b> “in the past 3 months”</li> <li>• Flowchart includes a deferral recommendation for donors who have uncertainty about when their sexual partner</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA’s 2023 HIV Guidance</a></li> <li>• Donor satisfaction – objection to use of the word “prostitute” in the question</li> <li>• FDA guidance now includes eligibility assessment for donors who are unsure of when their sexual partner exchanged sex for money or drugs.</li> </ul>

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		<p>exchanged sex for money or drugs.</p> <ul style="list-style-type: none"> <li>Removed the word "prostitute".</li> </ul>	
<p><b>23.</b> In the past <b>3 months</b>, have you used needles to <b>take</b> drugs, steroids, or anything <u>not</u> prescribed by your doctor?</p>	<p><b>17.</b> In the past <b>3 months</b>, have you used needles to <b>inject</b> drugs, steroids, or anything not prescribed by your doctor?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Revised to align with the language in the guidance.</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA's 2023 HIV Guidance</a></li> </ul>
<p><b>17.</b> In the past <b>3 months</b>, have you had sexual contact with anyone who has <b>ever</b> used needles to <b>take</b> drugs or steroids, or anything not prescribed by their doctor?</p>	<p><b>18.</b> In the past <b>3 months</b>, have you had sexual contact with anyone who has used needles <b>in the past 3 months</b> to <b>inject</b> drugs, steroids, or anything not prescribed by their doctor?</p>	<ul style="list-style-type: none"> <li>Revised to align with the language in the guidance</li> <li>Revised <b>from</b> sexual contact with anyone who has "ever" <b>to</b> "in the past 3 months"</li> <li>Flowchart includes a deferral recommendation for donors who have uncertainty about when their sexual partner engaged in non-prescription injection drug use.</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA's 2023 HIV Guidance</a></li> <li>FDA guidance now includes eligibility assessment for donors who are unsure of when their sexual partner engaged in non-prescription drug use.</li> </ul>
<p><b>22.</b> In the past <b>3 months</b>, have you had or been treated for syphilis or gonorrhea?</p>	<p><b>19.</b> In the past <b>3 months</b>, have you had <b>syphilis or gonorrhea</b> or been treated for syphilis or gonorrhea?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Revised to align with the language in the guidance</li> </ul>	
<p><b>26.</b> In the past <b>12 months</b>, have you had sexual contact with a person who has hepatitis?</p>	<p><b>20.</b> In the past <b>3 months</b>, have you had sexual contact with a person who has hepatitis?</p>	<ul style="list-style-type: none"> <li>Number change.</li> <li>Timeframe for sexual contact was changed <b>from 12 months to 3 months</b>.</li> <li>Flowchart was modified to include follow-up questions to the donor based on the recommendations of</li> </ul>	<ul style="list-style-type: none"> <li>Follow up questions in the flowchart, assess donors for a history of sexual contact with a person who has hepatitis B or C.</li> <li>A donor who has had sexual contact with a person who has had other types of viral hepatitis such as CMV and mononucleosis is not deferred.</li> </ul>

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<p>27. In the past <b>12 months</b>, have you lived with a person who has hepatitis?</p>	<p>21. In the past <b>3 months</b>, have you lived with a person who has hepatitis?</p>	<p>the <a href="#">FDA's Sept 2017 Hepatitis Guidance</a>.</p> <ul style="list-style-type: none"> <li>• Number change.</li> <li>• Timeframe for having lived with a person who has hepatitis was changed <b>from</b> 12 months <b>to</b> 3 months.</li> <li>• Flowchart was modified to include follow-up questions to the donor based on the recommendations of the <a href="#">FDA's Sept 2017 Hepatitis Guidance</a>.</li> </ul>	<ul style="list-style-type: none"> <li>• Follow up questions in the flowchart, assess donors for a history of having lived with a person who has hepatitis B or C.</li> <li>• A donor who has lived with a person who has had other types of viral hepatitis such as CMV and mononucleosis are not deferred.</li> </ul>
<p>14. In the past <b>3 months</b>, have you had an accidental needle-stick?</p>	<p>22. In the past <b>3 months</b>, have you had an accidental needle-stick?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> </ul>	
<p>13. In the past <b>3 months</b>, have you come into contact with someone else's blood?</p>	<p>23. In the past <b>3 months</b>, have you come into contact with someone else's blood?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Flowchart was revised to differentiate types of contact.</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA's 2023 HIV Guidance</a></li> </ul>
<p>20. In the past <b>3 months</b>, have you had a tattoo?</p>	<p>24. In the past <b>3 months</b>, have you had a tattoo?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Information on permanent makeup was added as a Note.</li> </ul>	
<p>21. In the past <b>3 months</b>, have you had ear or body piercing?</p>	<p>25. In the past <b>3 months</b>, have you had ear or body piercing?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Donor eligibility statement includes a clarification from FDA.</li> </ul>	
<p>10. In the past <b>3 months</b>, have you had a blood transfusion?</p>	<p>26. In the past <b>3 months</b>, have you had a blood transfusion?</p>	<ul style="list-style-type: none"> <li>• Number change</li> <li>• Definition of allogeneic and autologous added to the flowchart eligibility statement.</li> </ul>	
<p>11. In the past <b>3 months</b>, have you had a transplant such as organ, tissue, or bone marrow?</p>	<p>27. In the past <b>3 months</b>, have you had a transplant such as organ, tissue, or bone marrow?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Definition of allogeneic and autologous added to the flowchart eligibility statement.</li> </ul>	

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12. In the past <b>3 months</b> , have you had a graft such as bone or skin?	28. In the past <b>3 months</b> , have you had a graft such as bone or skin?	<ul style="list-style-type: none"> <li>Number change.</li> <li>Definition of allogeneic and autologous added to the flowchart eligibility statement.</li> </ul>	
25. In the past <b>16 weeks</b> , have you donated a double unit of red cells using an apheresis machine?	29. In the past <b>16 weeks</b> , have you donated a double unit of red <b>blood</b> cells using an apheresis machine?	<ul style="list-style-type: none"> <li>Number change.</li> <li>The word “blood” was added for clarity.</li> </ul>	
28. In the past <b>12 months</b> , have you been in juvenile detention, lockup, jail, or prison for 72 hours or more consecutively?	30. In the past <b>12 months</b> , have you been in juvenile detention, lockup, jail, or prison for 72 hours or more consecutively?	<ul style="list-style-type: none"> <li>Number change.</li> <li>Flowchart updated to clarify deferral is “from date release from incarceration”</li> </ul>	
<b>New Question added</b>	31. In the past <b>2 years</b> , have you received any medication by injection to prevent HIV infection? (i.e., long-acting antiviral PrEP or PEP)	<ul style="list-style-type: none"> <li>Question added (moved from the area for additional questions).</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA’s 2023 HIV Guidance</a></li> <li>AABB <a href="#">Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety</a></li> </ul>
29. In the past <b>3 years</b> , have you been outside the United States or Canada?	32. In the past <b>3 years</b> , have you been outside the United States or Canada?	<ul style="list-style-type: none"> <li>Number change.</li> </ul>	<ul style="list-style-type: none"> <li>Updated guidance added, <a href="#">FDA’s December 2022 Malaria Guidance</a></li> </ul>
30. <del>From 1980 through 1996, did you spend time that adds up to 3 months or more in the United Kingdom countries of England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands?</del>	<b>REMOVED</b>	<ul style="list-style-type: none"> <li>This donor eligibility assessment is no longer required.</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA’s May 2022 CJD/vCJD Guidance</a></li> </ul>
31. <del>From 1980 through 2001, did you spend time that adds up to 5 years or more in France or Ireland? Time spent in Ireland does not include time spent in Northern Ireland which is part of the United Kingdom.</del>	<b>REMOVED</b>	<ul style="list-style-type: none"> <li>This donor eligibility assessment is no longer required.</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA’s May 2022 CJD/vCJD Guidance</a></li> </ul>
32. <del>From 1980 to the present, did you receive a blood transfusion in France, Ireland, England, Northern Ireland,</del>	<b>REMOVED</b>	<ul style="list-style-type: none"> <li>This donor eligibility assessment is no longer required.</li> </ul>	<ul style="list-style-type: none"> <li><a href="#">FDA’s May 2022 CJD/vCJD Guidance</a></li> </ul>

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<del>Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands?</del>			
34. Have you <b>EVER</b> had a positive test for <del>the</del> HIV/AIDS virus?	33. Have you <b>EVER</b> had a positive test for HIV infection?	<ul style="list-style-type: none"> <li>• Number change</li> <li>• Language changed to align with the guidance</li> <li>• Information added from the guidance on “reentry.”</li> <li>• Changed from an indefinite deferral to permanent deferral for individuals with a confirmed positive test result.</li> <li>• Added a reference to AABB Toolkit</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA’s 2023 HIV Guidance</a></li> <li>• AABB’s <a href="#">HIV Testing, Lookback and Reentry Toolkit</a></li> </ul>
DHQ v2.1 Area for Additional questions	34. Have you <b>EVER</b> taken any medication to treat HIV infection?	<ul style="list-style-type: none"> <li>• New question added (moved from the area for additional questions) Deferral was changed from indefinite to a permanent deferral for taking medication to treat an HIV infection.</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA’s 2023 HIV Guidance</a> AABB’s <a href="#">Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety</a></li> </ul>
33. Female donors: Have you <b>EVER</b> been pregnant <del>or are you pregnant now?</del>	35. Have you <b>EVER</b> been pregnant?	<ul style="list-style-type: none"> <li>• Two questions replace the DHQ v2.1 compound question Q33.</li> </ul>	<ul style="list-style-type: none"> <li>• Member feedback - Poor donor attention to this DHQ v2.1 compound question.</li> <li>• Member feedback – This individual donor assessment approach assesses TRALI risk for all donors regardless of gender.</li> </ul>
35. Have you <b>EVER</b> had malaria?	36. Have you <b>EVER</b> had malaria?	<ul style="list-style-type: none"> <li>• Number change.</li> </ul>	<ul style="list-style-type: none"> <li>• Updated guidance added, <a href="#">FDA’s December 2022 Malaria Guidance</a></li> </ul>



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<p><b>36.</b> Have you <b>EVER</b> received a dura mater (or brain covering) graft or xenotransplantation product?</p>	<p><b>37.</b> Have you <b>EVER</b> received a dura mater (or brain covering) graft or xenotransplantation product?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• The flowchart was revised to break out dura mater and xenotransplantation to reflect their different deferrals. (xenotransplant is an indefinite deferral and dura mater is a permanent deferral)</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA's May 2022 CJD/vCJD Guidance</a></li> </ul>
<p><b>37.</b> Have you <b>EVER</b> had any type of cancer, including leukemia?</p>	<p><b>38.</b> Have you <b>EVER</b> had any type of cancer, including leukemia?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Donor eligibility statement directs each establishment to define a deferral policy.</li> <li>• Reference to <i>AABB's BBTS Standards and Technical Manual</i> added</li> </ul>	
<p><b>38.</b> Have you <b>EVER</b> had any problems with your heart or lungs?</p>	<p><b>39.</b> Have you <b>ever</b> had any problems with your heart or lungs?</p>	<ul style="list-style-type: none"> <li>• Number change.</li> <li>• Donor eligibility statement directs each establishment to define a deferral policy.</li> <li>• Reference to <i>AABB's BBTS Standards and Technical Manual</i> added</li> </ul>	
<p><b>39.</b> Have you <b>ever</b> had a bleeding condition or a blood disease?</p>	<p><b>40.</b> Have you <b>ever</b> had a bleeding condition or a blood disease?</p>	<ul style="list-style-type: none"> <li>• Number change</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">FDA's 2023 HIV Guidance</a></li> </ul>
<p><b>40.</b> Have you <b>EVER</b> had a positive test result for <i>Babesia</i>?</p>	<p><b>41.</b> Have you <b>EVER</b> had a positive test result for <i>Babesia</i>?</p>	<ul style="list-style-type: none"> <li>• Reference to <i>AABB's Babesia Toolkit</i> added</li> </ul>	