

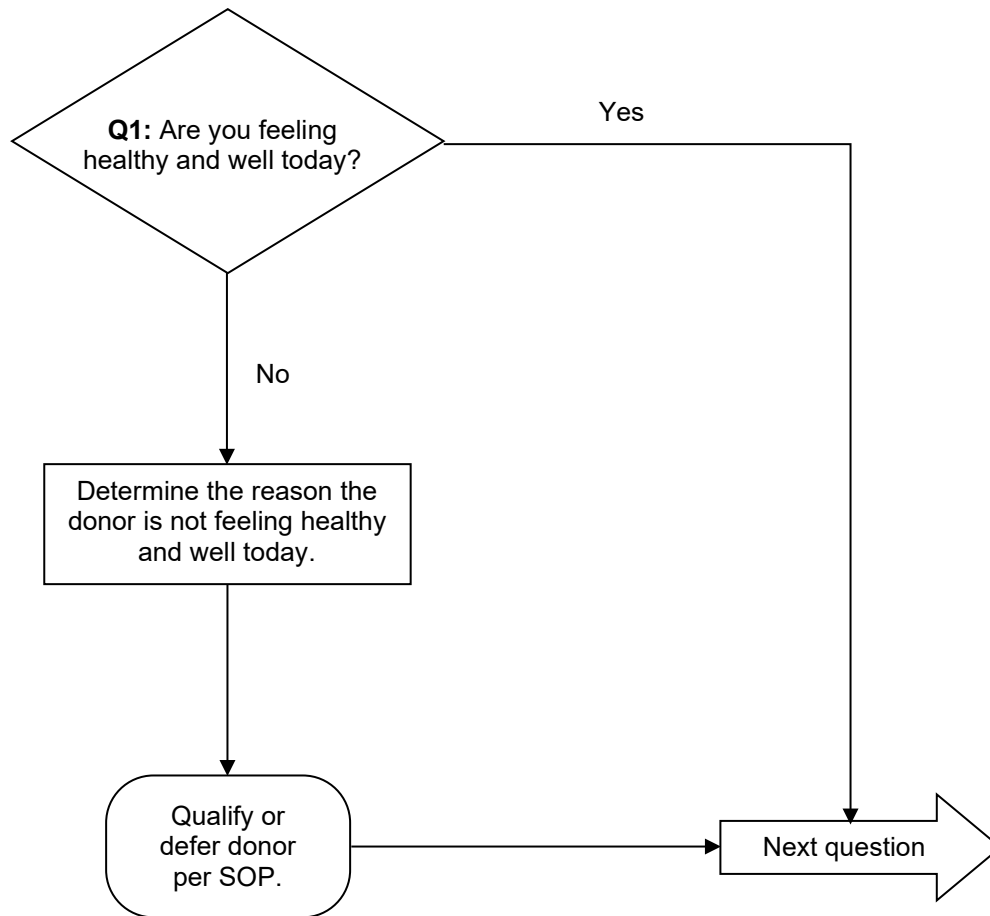
BLOOD DHQ v4.0 FLOWCHARTS

Question 1: Are you feeling healthy and well today?

Donor Eligibility: A person should be free of infectious diseases, including colds, on the day of donation. A person who is not in good health should not donate until it is determined that the underlying condition is not a cause for deferral.

Each blood establishment should follow established policies and procedures for determining donor eligibility.

[\[21 CFR 630.10\(a\), \(c\) and \(e\)\]](#)

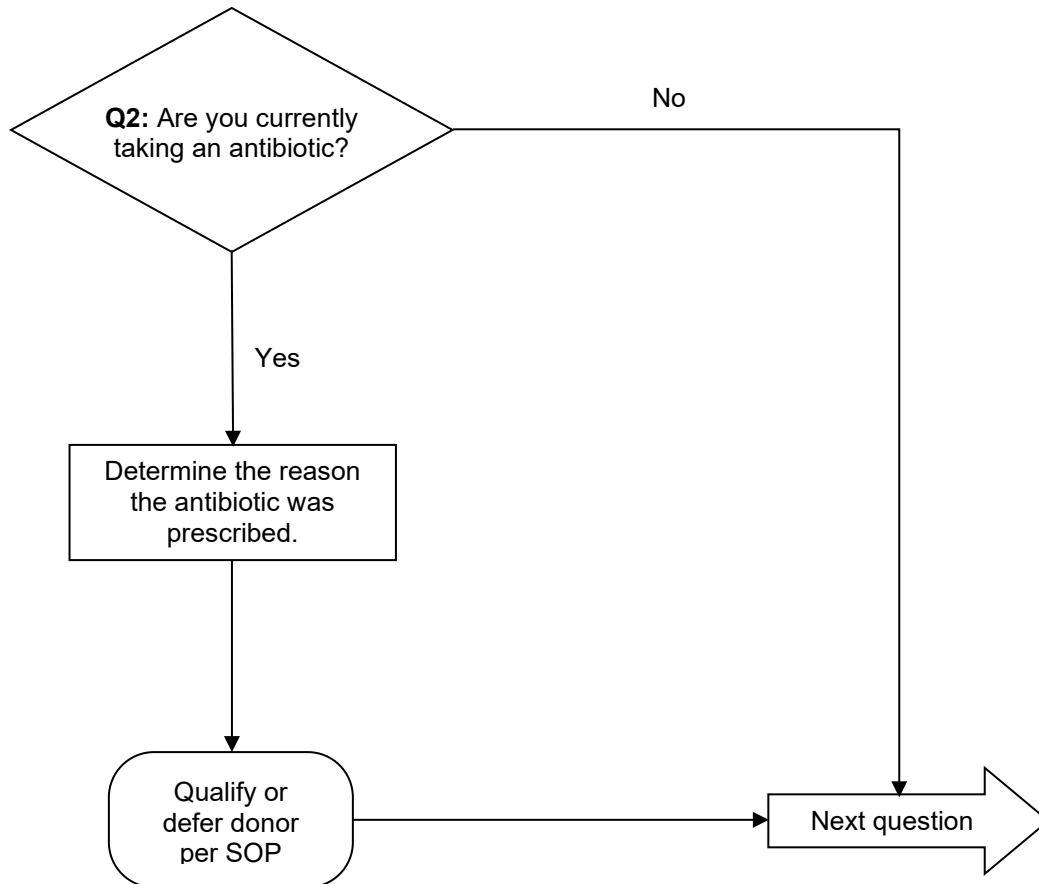


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Question 2: Are you currently taking an antibiotic?

Donor Eligibility: The reason the antibiotic was prescribed must be evaluated to determine if the person has a bacterial infection that could be transmissible by blood. A person with an infection should not donate.

[\[21 CFR 630.10\(e\)\(2\)\(ii\)\]](#)

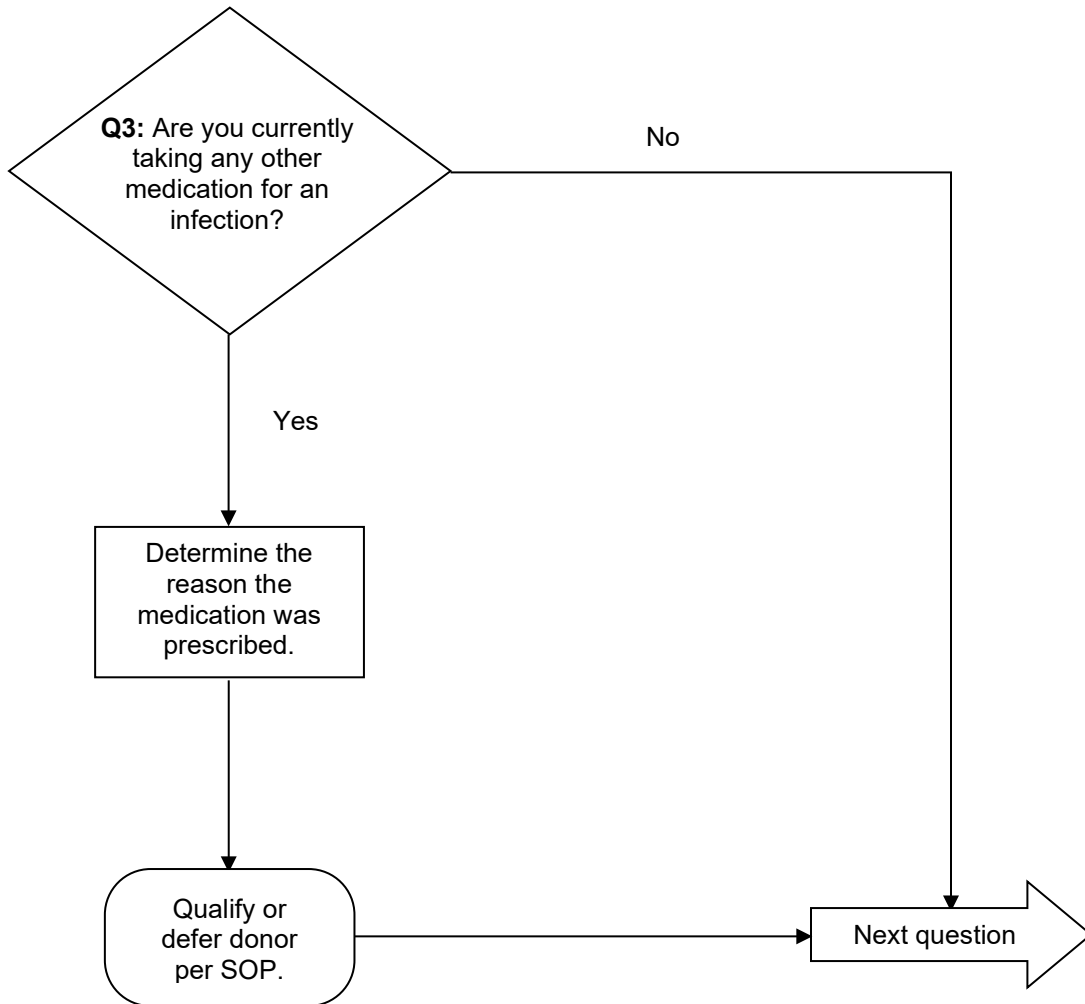


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Question 3: Are you currently taking any other medication for an infection?

Donor Eligibility: The reason for use of any medication to treat an infection must be evaluated to determine if the person has a viral, fungal, parasitic or other infection transmissible by blood. A person with an infection should not donate blood.

[\[21 CFR 630.10\(e\)\(2\)\(ii\)\]](#)



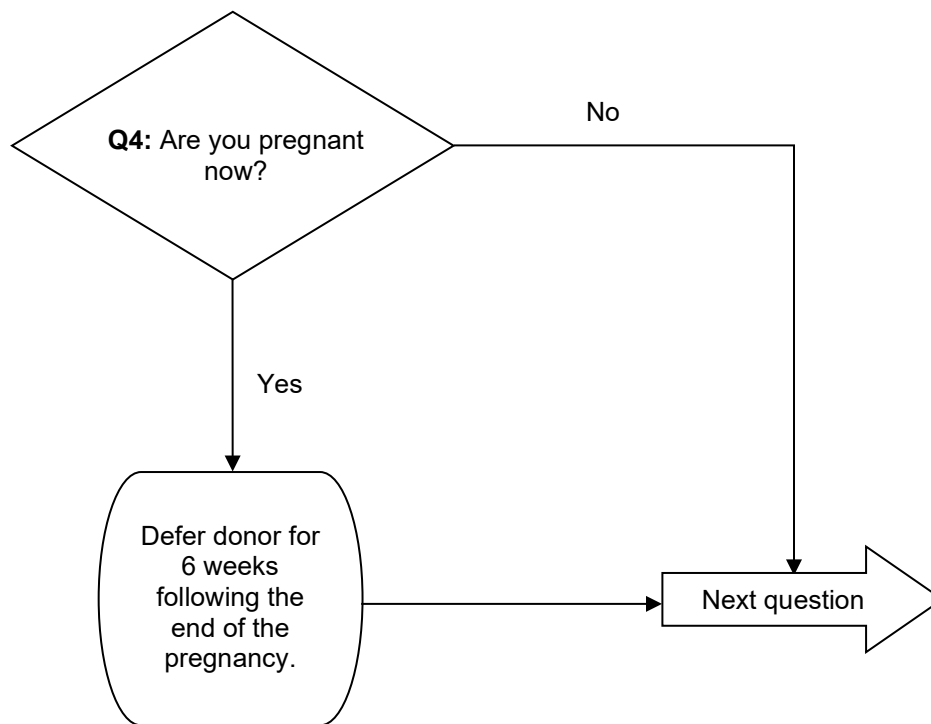
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Question 4: Are you pregnant now?

Donor Eligibility: For the safety of the donor, a donor who is currently pregnant is deferred for 6 weeks following the end of the pregnancy.

Note: Previous pregnancy, including pregnancy within the last 6 weeks, is assessed by Question 35.

[\[21 CFR 630.10\(e\)\(2\)\(v\)\]](#)

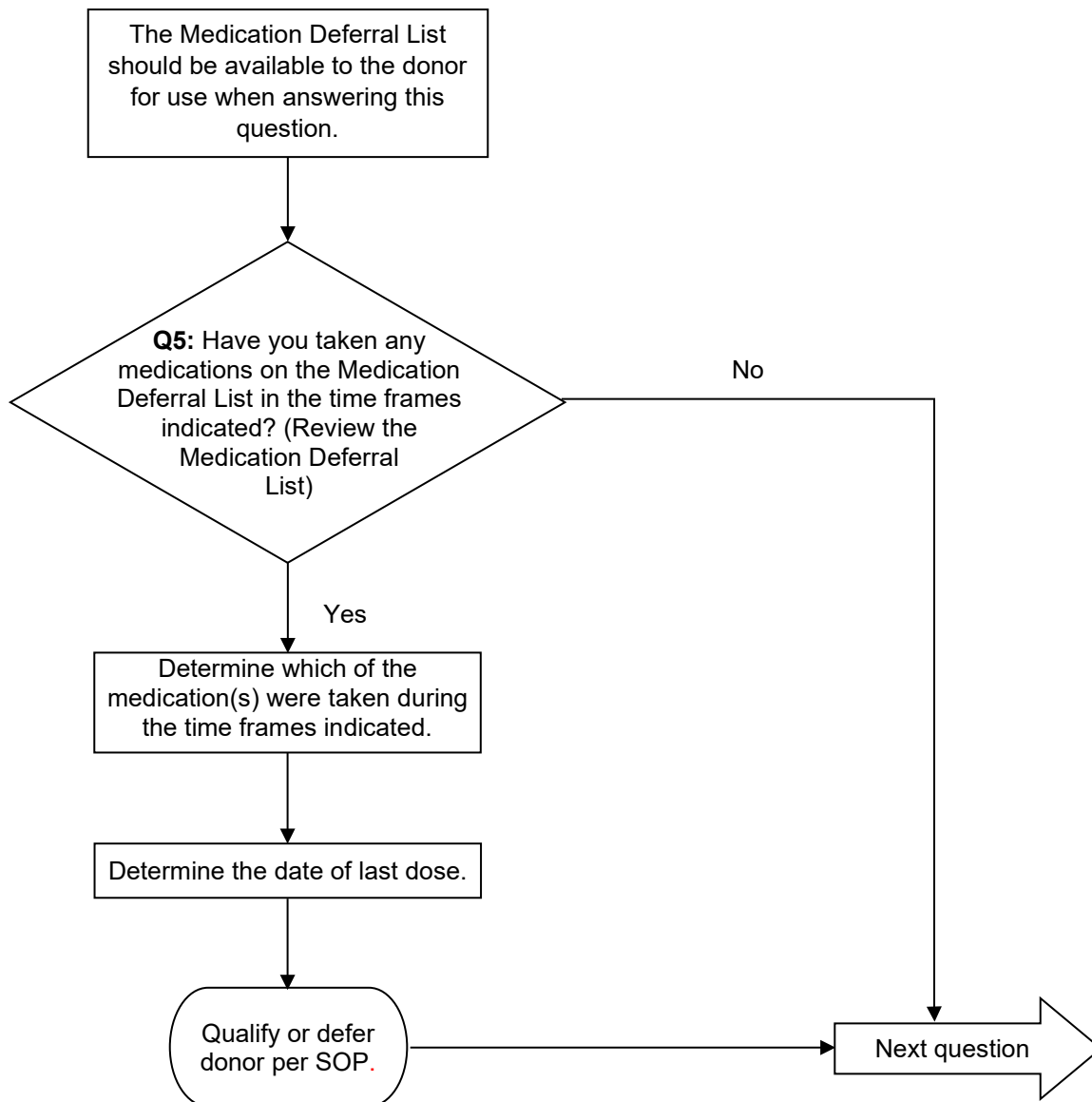


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Question 5: Have you taken any medications on the Medication Deferral List in the time frames indicated? (Review the Medication Deferral List.)

Donor Eligibility: Certain medications have been identified as having the potential to compromise the safety of the transfusion recipient or the donor. Therefore, a person taking medications listed on the Medication Deferral List in the timeframes indicated should be deferred for the appropriate period of time.

[[21 CFR 630.10\(e\)\(2\)\(ii\)](#), [21 CFR640.21\(b\)](#), FDA's May 2023 HIV Guidance, [Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products](#), III.B.2, 3, 4, FDA's December 2007 Guidance, [Collection of Platelets by Automated Methods](#), III.A, page 5 and AABB's 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](#)]



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The following information is included to assist the donor historian when providing additional information to the donor concerning their deferral:

Some medications may affect donor eligibility for the following reasons:

Antiplatelet agents affect platelet function, so people taking these drugs should not donate platelets for the indicated time. You may still be able to donate whole blood or red blood cells by apheresis.

Anticoagulants or "blood thinners" are used to treat or prevent blood clots in the legs, lungs, or other parts of the body, and to prevent strokes. These medications affect the blood's ability to clot, which might cause excessive bruising or bleeding when you donate. You may still be able to donate whole blood or red blood cells by apheresis.

Isotretinoin, finasteride, dutasteride, acitretin, and etretinate can cause birth defects. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman.

Thalomid (thalidomide), Revlimid (lenalidomide), Erivedge (vismodegib), Odomzo (sonidegib), Aubagio (teriflunomide), and Rinvoq (upadacitinib) may cause birth defects or the death of an unborn baby if transfused to a pregnant woman.

Cellcept (mycophenolate mofetil) and Arava (leflunomide) are immunosuppressants that may cause birth defects or the death of an unborn baby if transfused to a pregnant woman.

PrEP or pre-exposure prophylaxis involves taking a specific combination of oral medicines (i.e., short-acting antiviral PrEP) or injections (i.e., long-acting antiviral PrEP) as a prevention method for people who are HIV negative and at high risk of HIV infection. FDA has determined that the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals. Although "Undetectable = Untransmittable" for sexual transmission, this **does not apply to transfusion transmission**.

PEP or post-exposure prophylaxis is a short-acting treatment started as soon as possible after a high-risk exposure to HIV to reduce the risk of infection. FDA has determined that the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals. Although "Undetectable = Untransmittable" for sexual transmission, this **does not apply to transfusion transmission**.

ART or antiretroviral therapy is the use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection. HIV infection requires a permanent deferral despite treatment with ART. Antiretroviral drugs do not fully eliminate the virus from the body, and donated blood from individuals infected with HIV taking ART can potentially still transmit HIV to a transfusion recipient. Although "Undetectable = Untransmittable" for sexual transmission, this **does not apply to transfusion transmission**.

Hepatitis B Immune Globulin (HBIG) is an injected material used to prevent hepatitis B infection following a possible or known exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case; therefore, persons who have received HBIG must wait to donate blood.

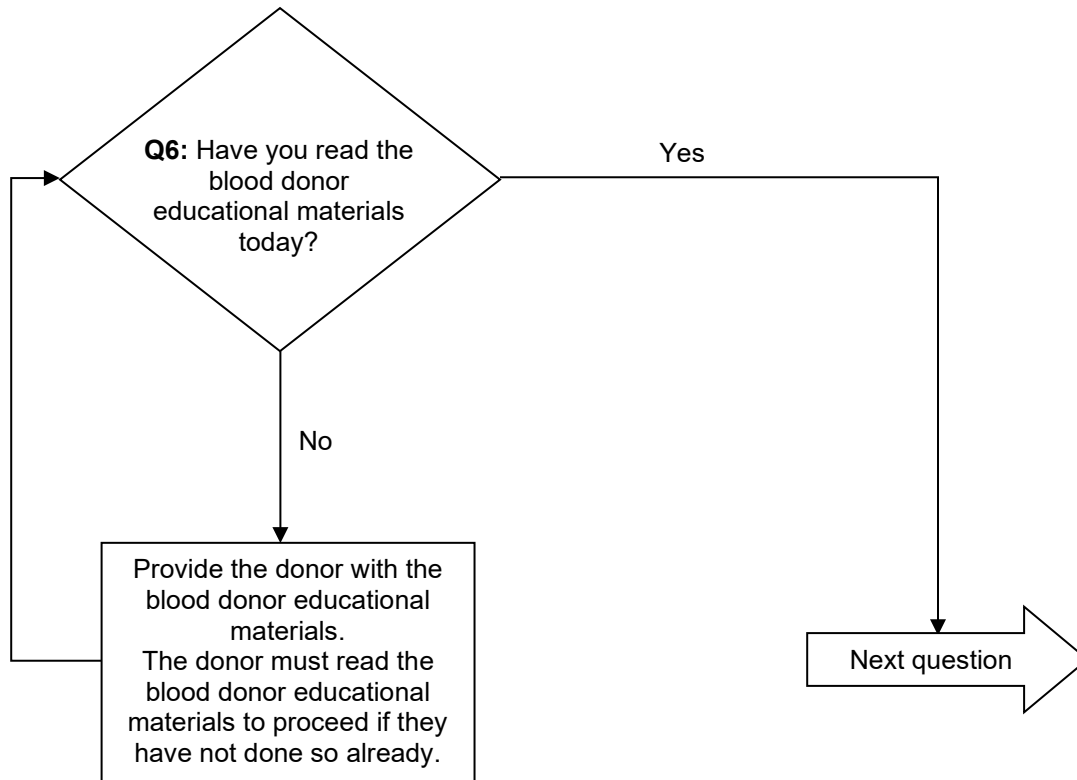
Experimental medications are usually associated with a research study, and their effect on the safety of transfused blood is unknown.

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Question 6: Have you read the blood donor educational materials today?

Donor Eligibility: Donors must read the blood donor educational materials prior to donating.

[21 CFR 630.10(b), (c) and (g)(2)(ii)(A) and [FDA's 2023 HIV Guidance](#), III.A.1 and 2]

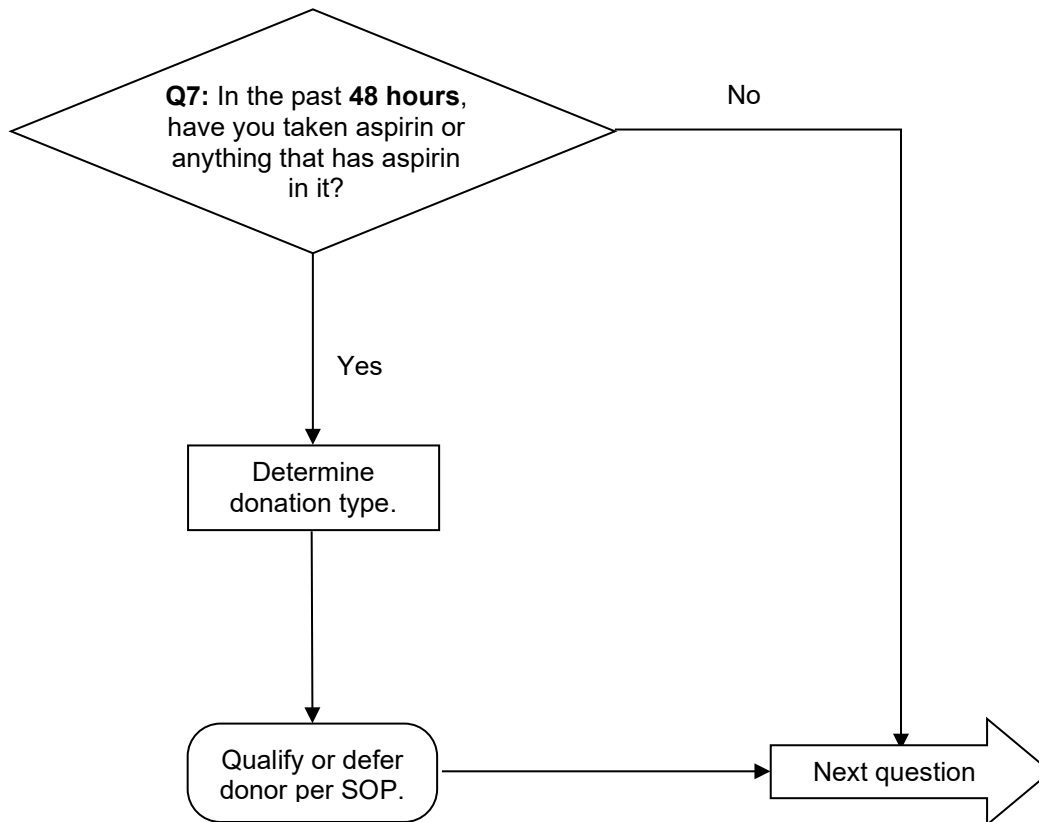


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Question 7: In the past **48 hours**, have you taken aspirin or anything that has aspirin in it?

Donor Eligibility: Aspirin irreversibly inactivates platelet function. A person taking aspirin or any medication containing aspirin should not be the sole source of platelets.

[21 CFR 640.21(b) and (c) and [FDA's December 2007 Platelet Guidance](#), III.A]

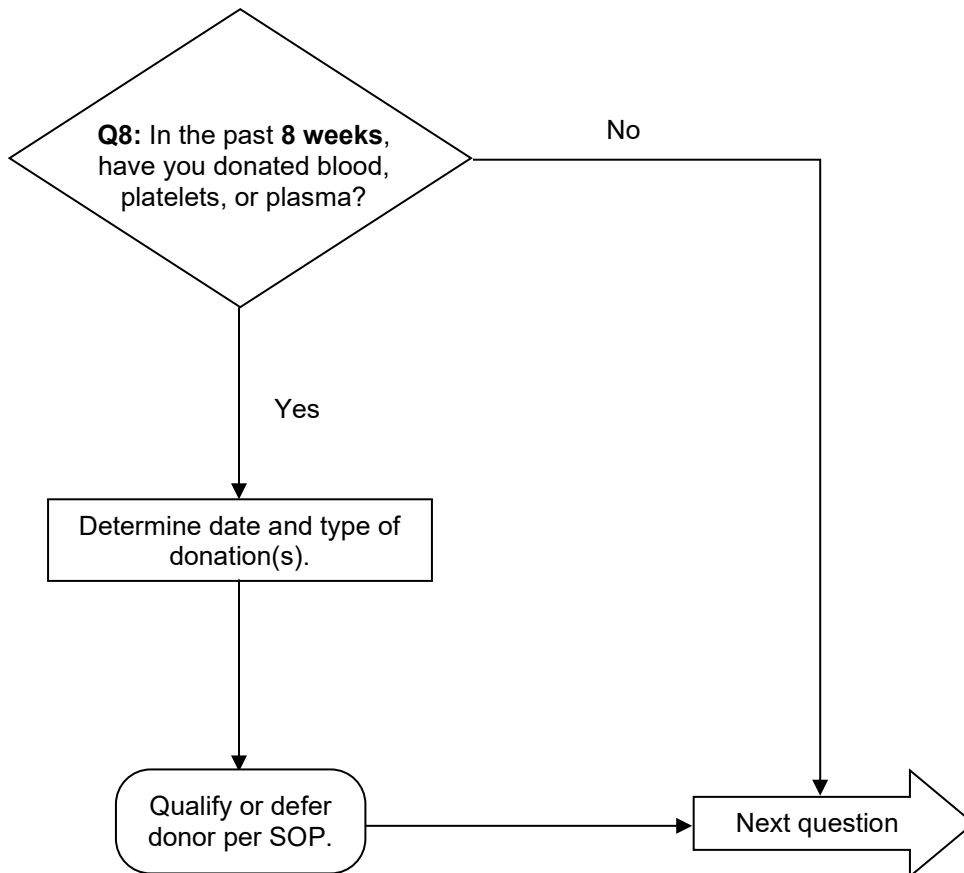


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Question 8: In the past **8 weeks**, have you donated blood, platelets, or plasma?

Donor Eligibility: A whole blood donor or a single unit apheresis red blood cell donor may donate a red blood cell containing product no more frequently than every 8 weeks. Donors of plasma, platelets or granulocytes by apheresis may donate no more frequently than every 2 days.

[21 CFR 630.10(d)(2), 21 CFR 630.15(a)(1)(i), 21 CFR 640.21(e) and *FDA's December 2007 Platelet Guidance*, III.B.3]



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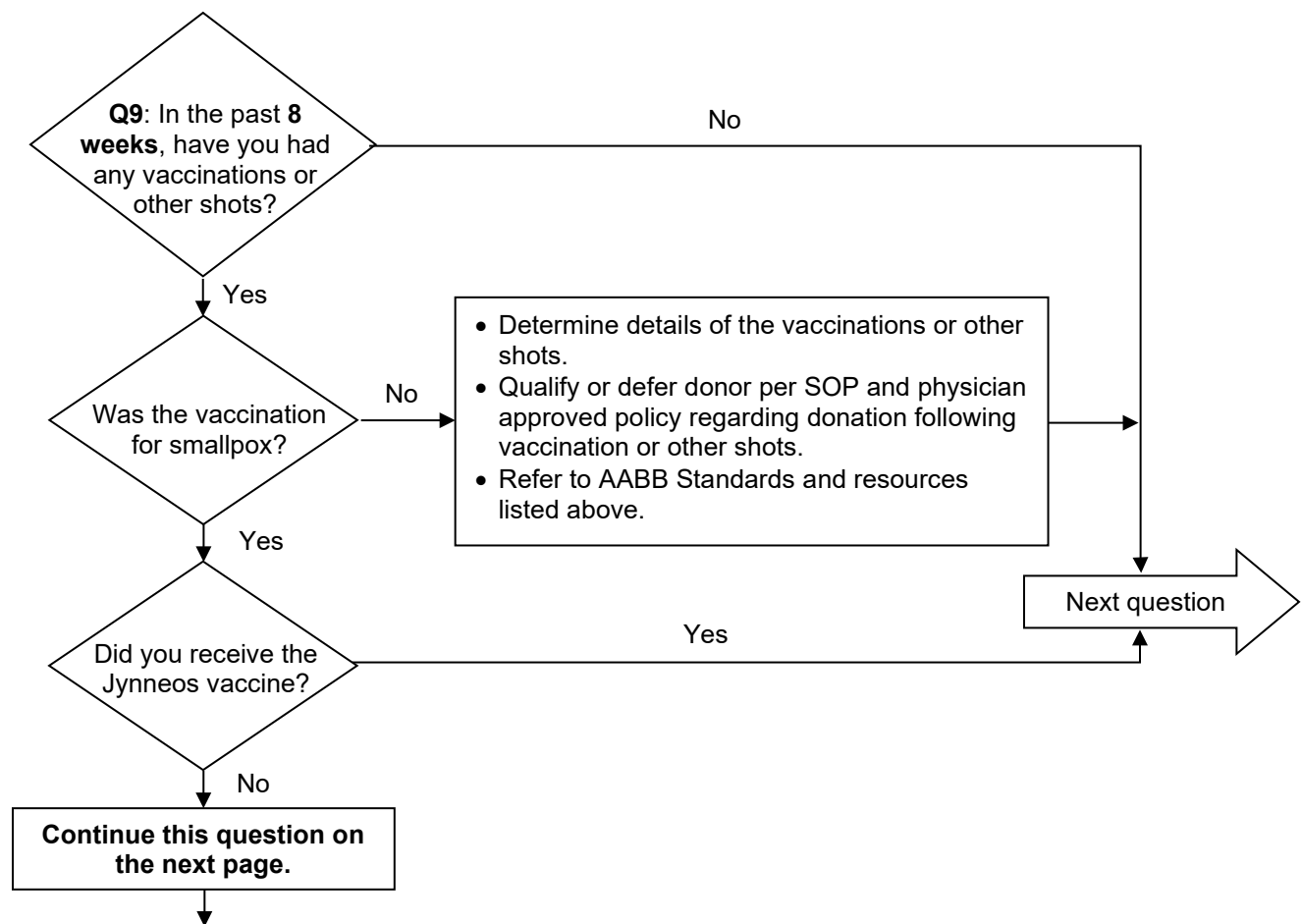
Question 9: In the past **8 weeks**, have you had any vaccinations or other shots?

Donor Eligibility: FDA recommends deferral for replication-competent smallpox vaccines as stated in FDA's December 2002 Guidance, [Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine \(Vaccinia Virus\) and Certain Contacts of Smallpox Vaccine Recipients Smallpox Vaccine](#) and consistent with the flowchart below. Donors are not automatically deferred following other vaccinations and the vaccine deferral policy is determined by the responsible physician. When developing a deferral policy, the physician may consider the following:

When developing a deferral policy and SOPs, the physician may consider the following:

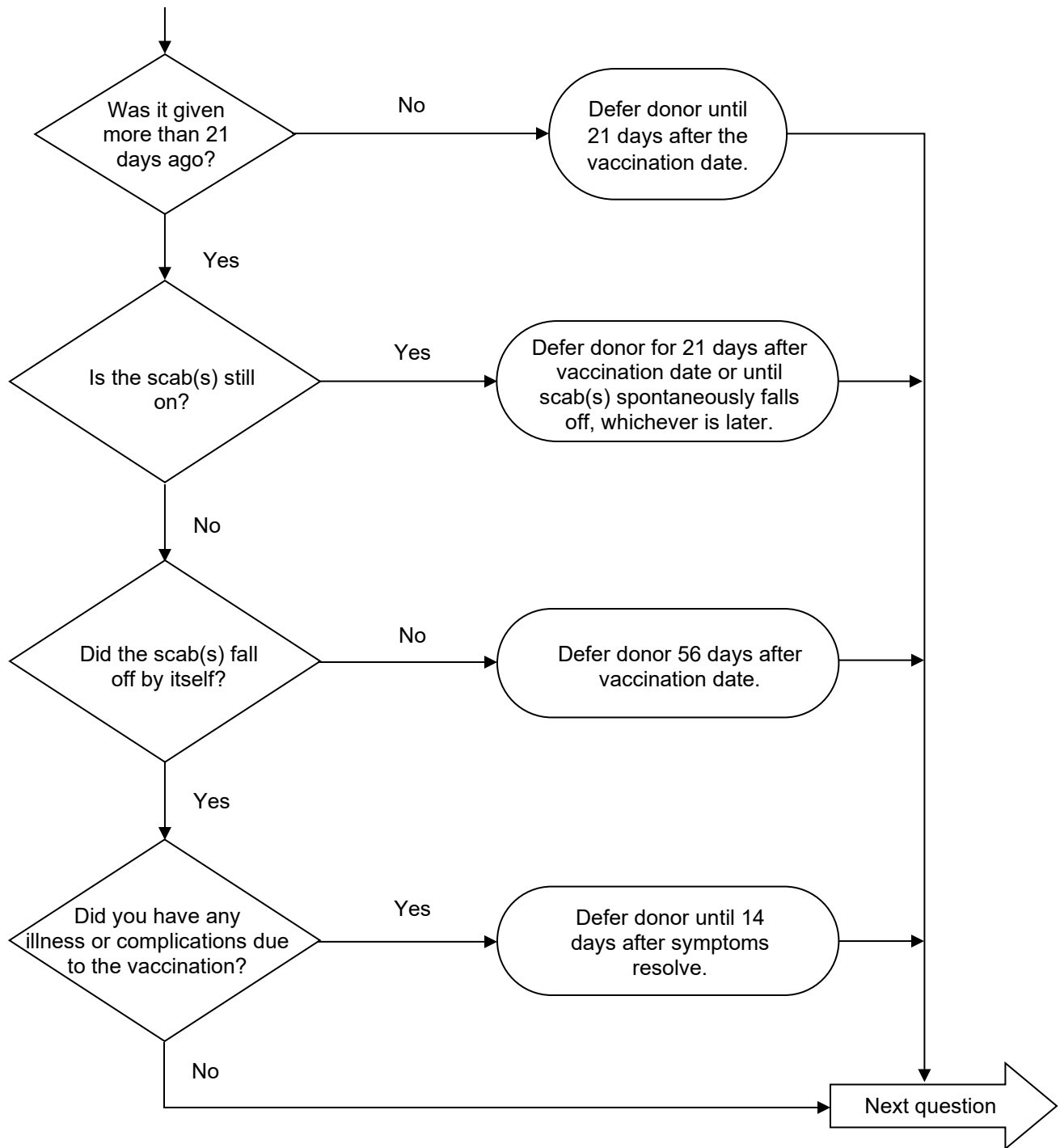
- **AABB ACCREDITED FACILITIES:** Refer to the current edition of the Standards for Blood Banks and Transfusion Services Reference Standard 5.4.1A for immunization and vaccination deferral requirements and [AABB's Updated Information on Donation of CCP, Blood Components and HCT/Ps During the COVID-19 Pandemic](#).

Note on 9alt Flowchart: The **9alt Flowchart** provides a simpler but more restrictive deferral scheme in which all donors who received the smallpox vaccination are deferred for a minimum of 56 days, regardless of when the scab fell off. Blood centers using these criteria should use **9alt Flowchart**.



BLOOD DHQ v4.0 FLOWCHARTS

Flowchart Question 9 continued:



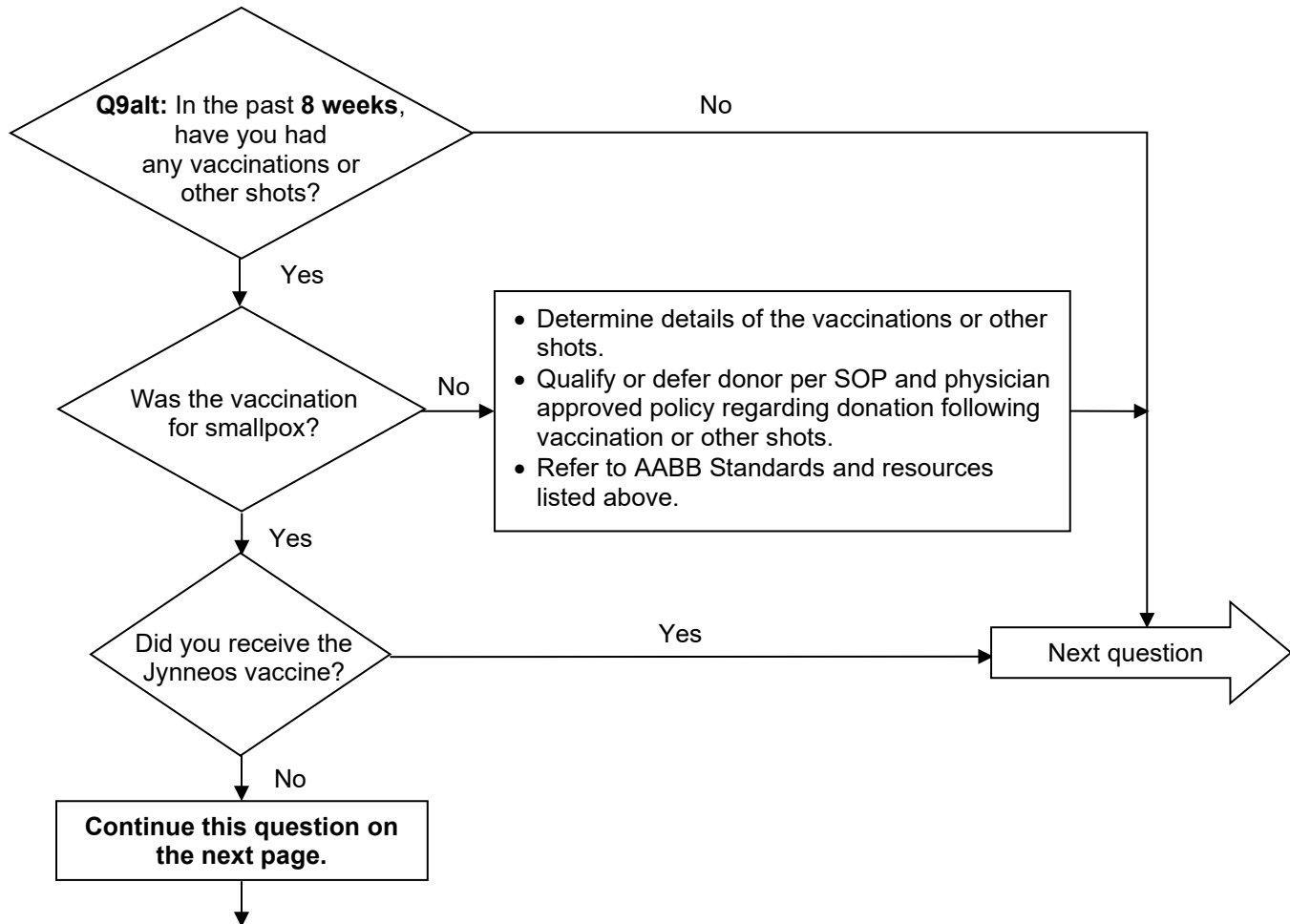
BLOOD DHQ v4.0 FLOWCHARTS

Question 9alt: In the past 8 weeks, have you had any vaccinations or other shots?

Donor Eligibility: FDA recommends deferral for replication-competent smallpox vaccines as stated in [Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine \(Vaccinia Virus\) and Certain Contacts of Smallpox Vaccine Recipients Smallpox Vaccine](#) and consistent with the flowchart below. Donors are not automatically deferred following other vaccinations and the vaccine deferral policy is determined by the responsible physician. When developing a deferral policy, the physician may consider the following:

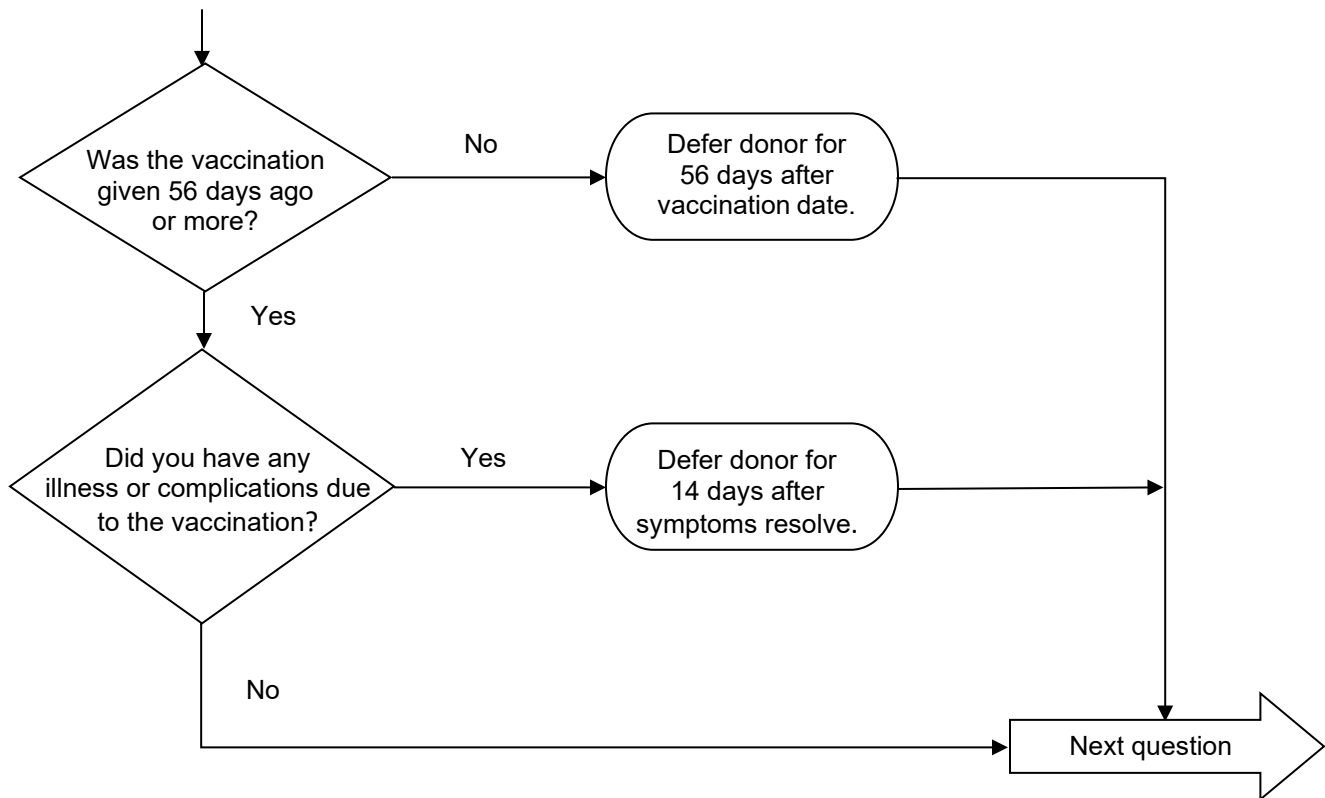
When developing a deferral policy and SOPs, the physician may consider the following:

- **AABB ACCREDITED FACILITIES:** Refer to the current edition of the Standards for Blood Banks and Transfusion Services Reference Standard 5.4.1A for immunization and vaccination deferral requirements and [AABB's Updated Information on Donation of CCP, Blood Components and HCT/Ps During the COVID-19 Pandemic](#).



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Flowchart Question 9alt continued:

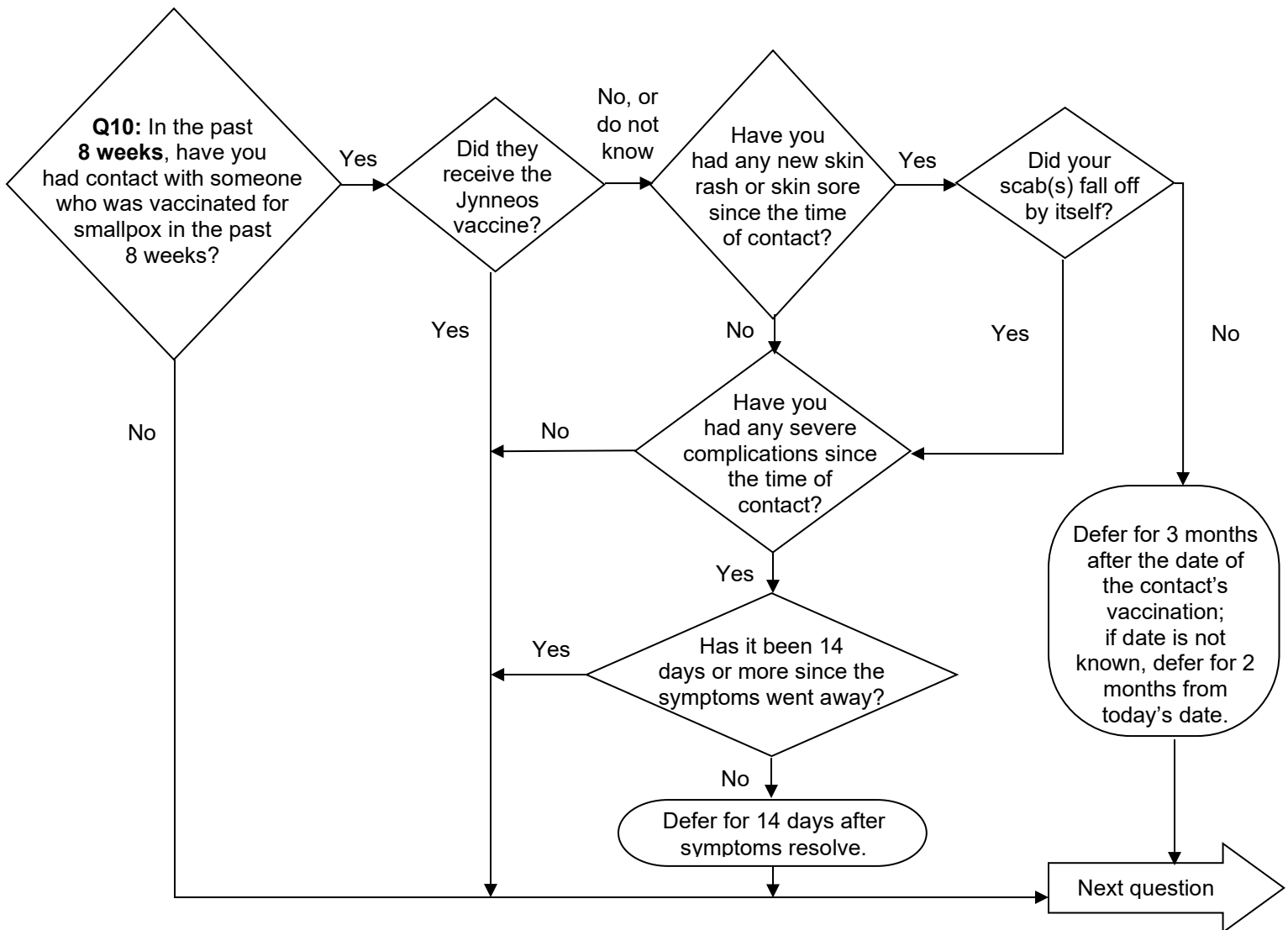


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Question 10: In the past **8 weeks**, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?

Donor Eligibility: Certain vaccinations may contain live infectious agents. A person may be exposed to the live infectious agents and should not donate for a specified time: 1) following close contact with the vaccination site, bandages covering the vaccination site, or materials that might have come into contact with an unbandaged vaccination site, including clothing, or 2) after any severe complication since the time of contact. Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition. [[FDA's December 2002 Smallpox Guidance](#)]

Note on 10alt Flowchart: The **10alt Flowchart** provides a simpler but more restrictive deferral of 56 days for all donors who have been in contact with a person who received the smallpox vaccination before the rash or sore resolved. Refer to **10alt Flowchart** for details of this approach.

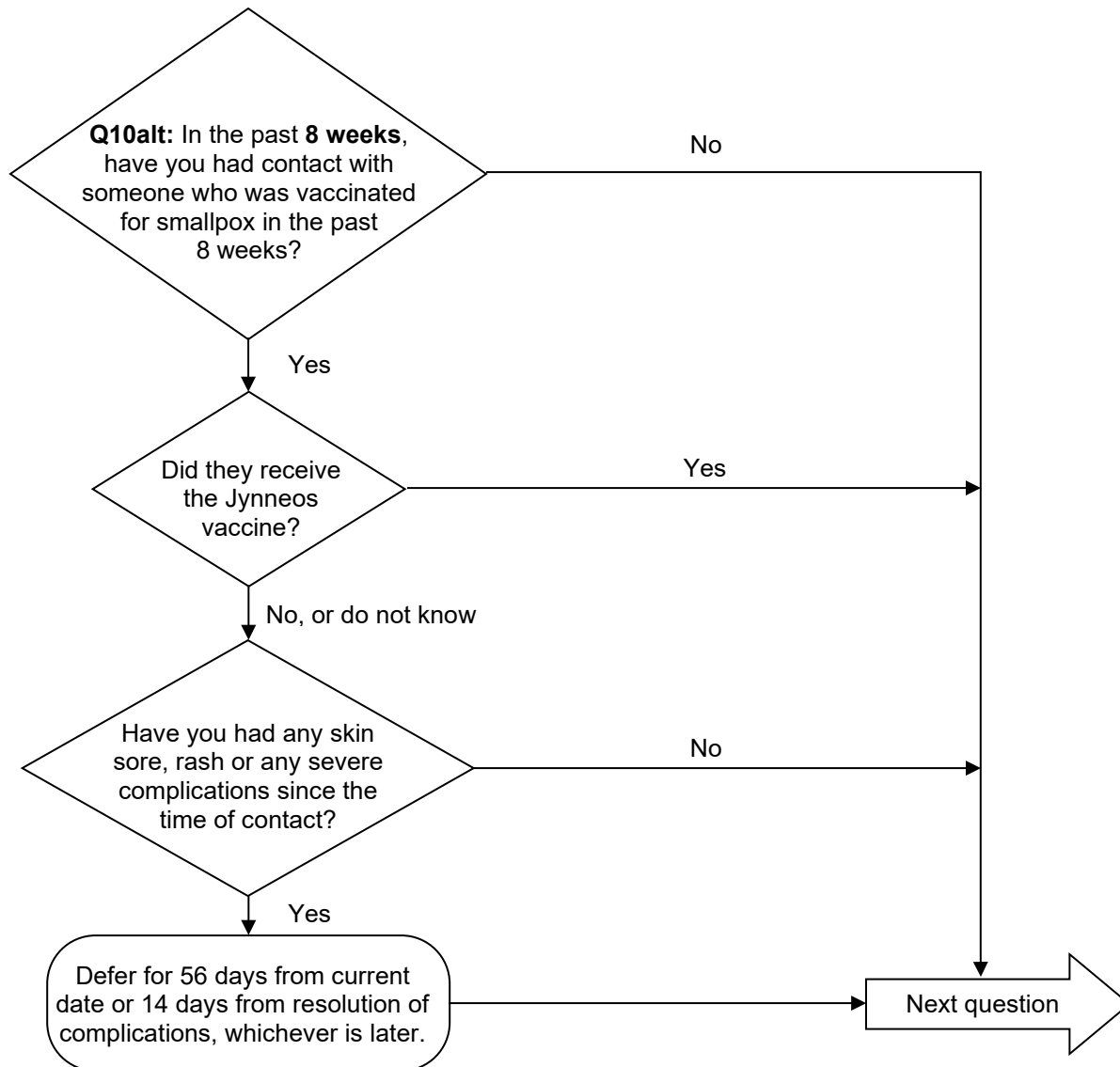


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Question 10alt: In the past **8 weeks**, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?

Donor Eligibility: Certain vaccinations may contain live infectious agents. A person may be exposed to the live infectious agent and should not donate for specified time: 1) following close contact with the vaccination site, bandages covering the vaccination site, or materials that might have come into contact with an unbandaged vaccination site, including clothing, or 2) after any severe complication since the time of contact. Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.

[\[FDA's December 2002 Smallpox Guidance\]](#)



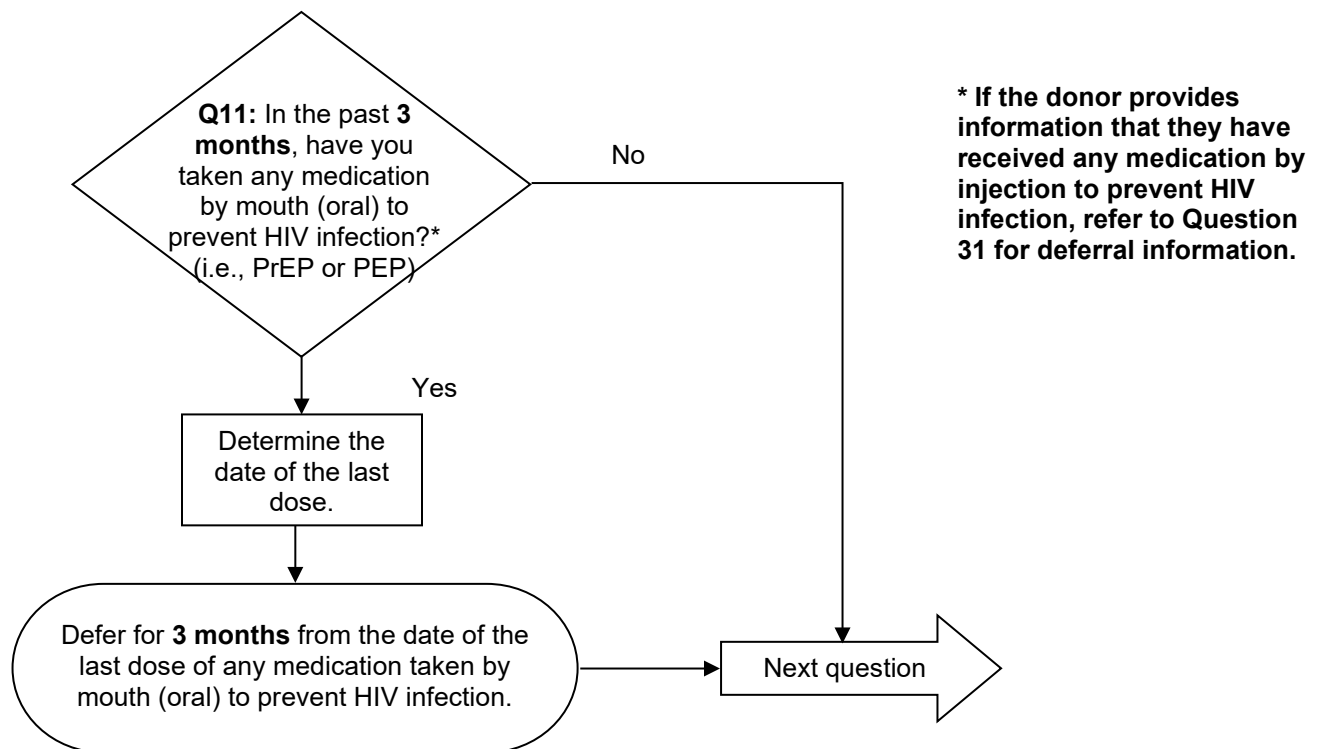
BLOOD DHQ v4.0 FLOWCHARTS

Question 11: In the past **3 months**, have you taken any medication by mouth (oral) to prevent HIV infection? (i.e., PrEP or PEP)

Donor Eligibility: A donor who has taken any medication to prevent HIV infection (also known as pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)) is deferred because FDA has determined that the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV infection by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals. Donors who report that they have taken medication by mouth (oral) to prevent HIV infection (i.e., antiviral PrEP or PEP) are deferred for 3 months from the date of the last dose. For donors who report that they have received any medication by injection (i.e., long-acting antiviral PrEP) to prevent HIV infection, refer to Question 31 for deferral information.

The principle known as “Undetectable = Untransmittable” **does not apply to blood donors and the potential risk to patients who receive transfusions.** FDA-approved antiretroviral drugs are safe and effective in preventing sexual transmission of HIV. However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient. *Follow-up questions may be necessary if the donor appears to be confused about medication taken to prevent HIV versus medication taken to treat HIV infection.*

[[FDA's 2023 HIV Guidance](#), III.B.3, [21 CFR 630.10 \(e\)\(2\)\(ii\)](#) and AABB [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](#)]



Resources:

From the [NIH CLINICAL INFO.HIV.gov Glossary](#):

PrEP = “An HIV prevention method for people who are HIV negative and at high risk of HIV infection. Pre-exposure prophylaxis (PrEP) involves taking a specific combination of HIV medicines daily.”

PEP = “Short-term treatment started as soon as possible after high-risk exposure to an infectious agent, such as HIV ... The purpose of post-exposure prophylaxis (PEP) is to reduce the risk of infection.”

From the CDC's Webpage: [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2021 Update A Clinical Practice Guideline](#) More information is available at <https://www.cdc.gov/hiv/basics/prep.html>

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Question 12: In the past **3 months**, have you had sexual contact with a new partner? (refer to the examples of “new partner” in the Blood Donor Educational Material)

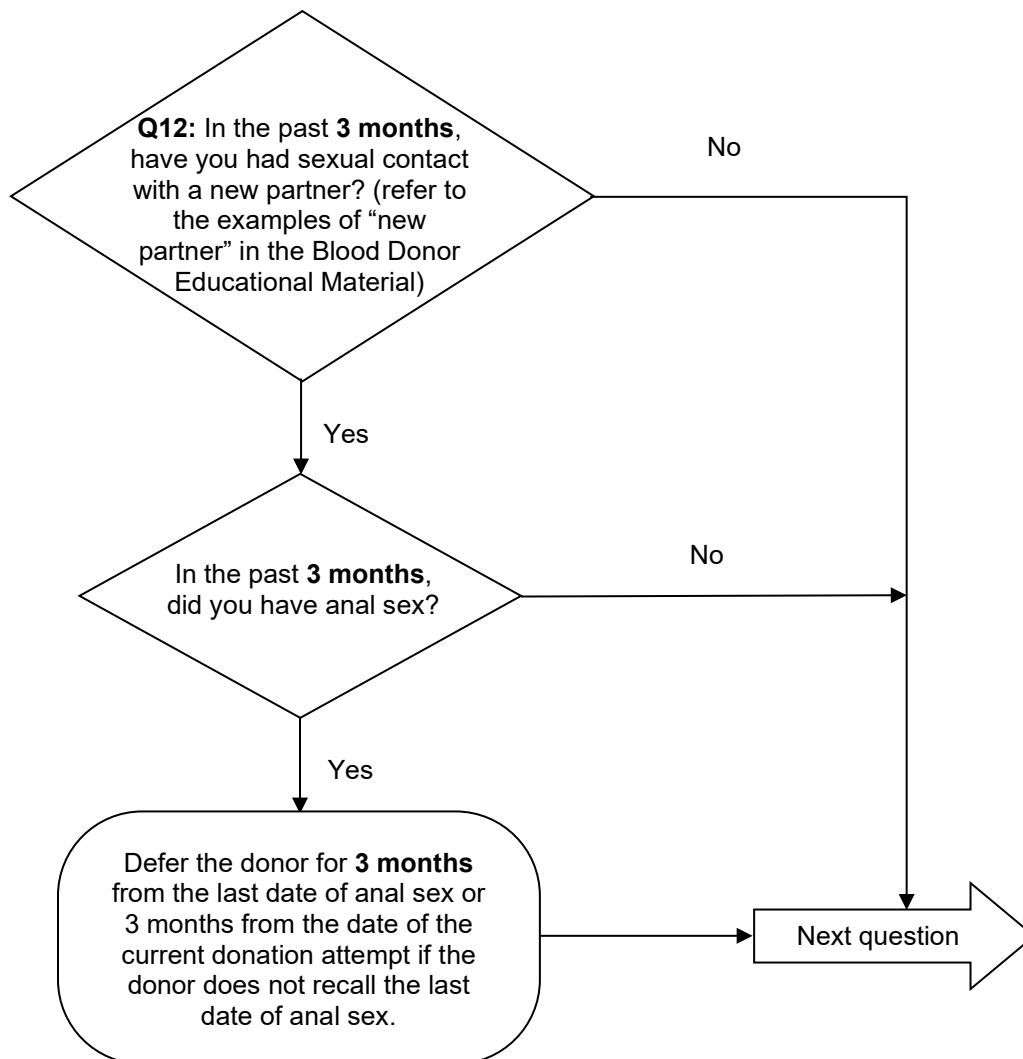
Donor Eligibility: A person who has had sexual contact with a new partner in the past 3 months **and** who has had anal sex in the past 3 months is at increased risk for transmitting HIV infection and other infectious diseases. For this reason, a donor is deferred for 3 months from the last date of anal sex or 3 months from the date of the current donation attempt if the donor does not recall the last date of anal sex.

For the purposes of this guidance, the following examples would be considered having sex with a new partner:

- having sex with someone for the first time,
OR
- having had sex with someone in a relationship that ended in the past, and having sex again with that person in the last 3 months.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone’s vagina, penis, or anus), or anal sex (contact between penis and anus) regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy.

[21 CFR 630.10(e)(1)(v) and [FDA's 2023 HIV Guidance](#), III.B.5]



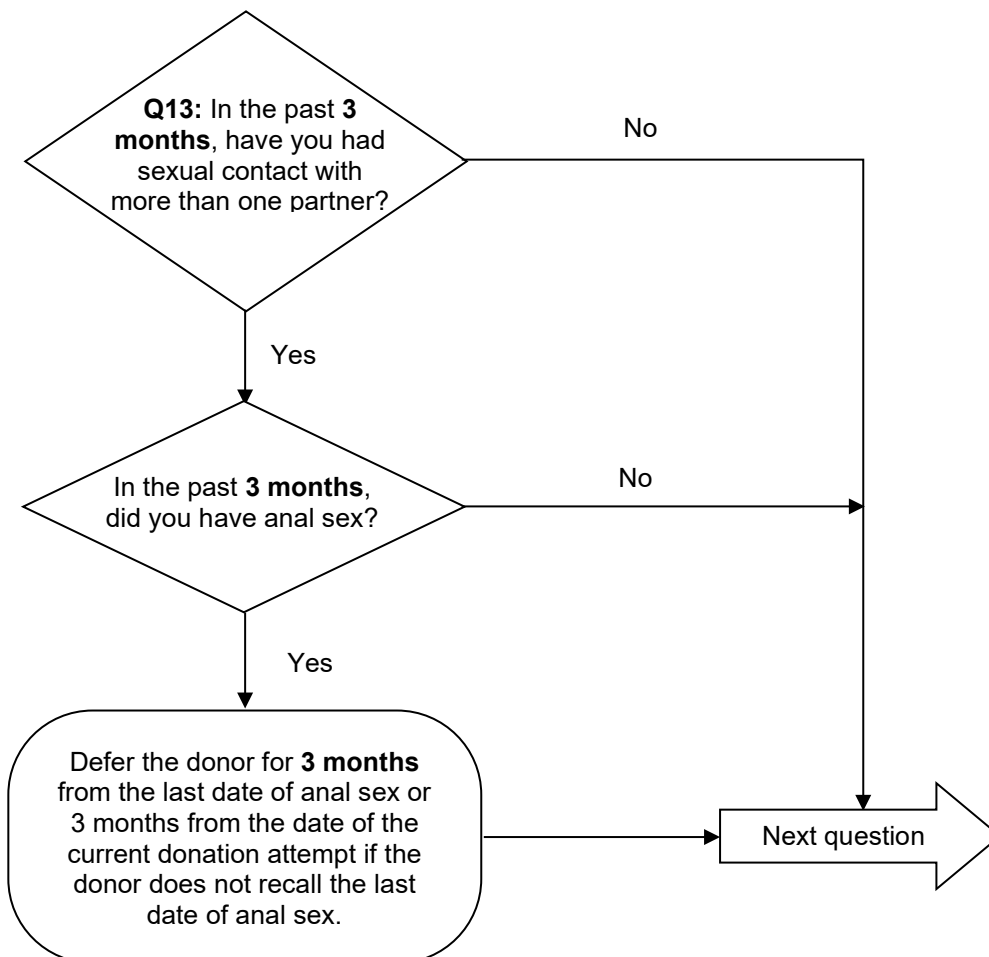
BLOOD DHQ v4.0 FLOWCHARTS

Question 13: In the past **3 months**, have you had sexual contact with more than one partner?

Donor Eligibility: A person who has had sexual contact with more than one partner in the past 3 months **and** who has had anal sex in the past 3 months, is at increased risk for transmitting HIV and other infectious diseases. For this reason, the individual is deferred for 3 months from the last date of anal sex or 3 months from the date of the current donation attempt if the donor does not recall the last date of anal sex.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), or anal sex (contact between penis and anus) regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy.

[21 CFR 630.10(e)(1)(v) and [FDA's 2023 HIV Guidance](#), III.B.6]



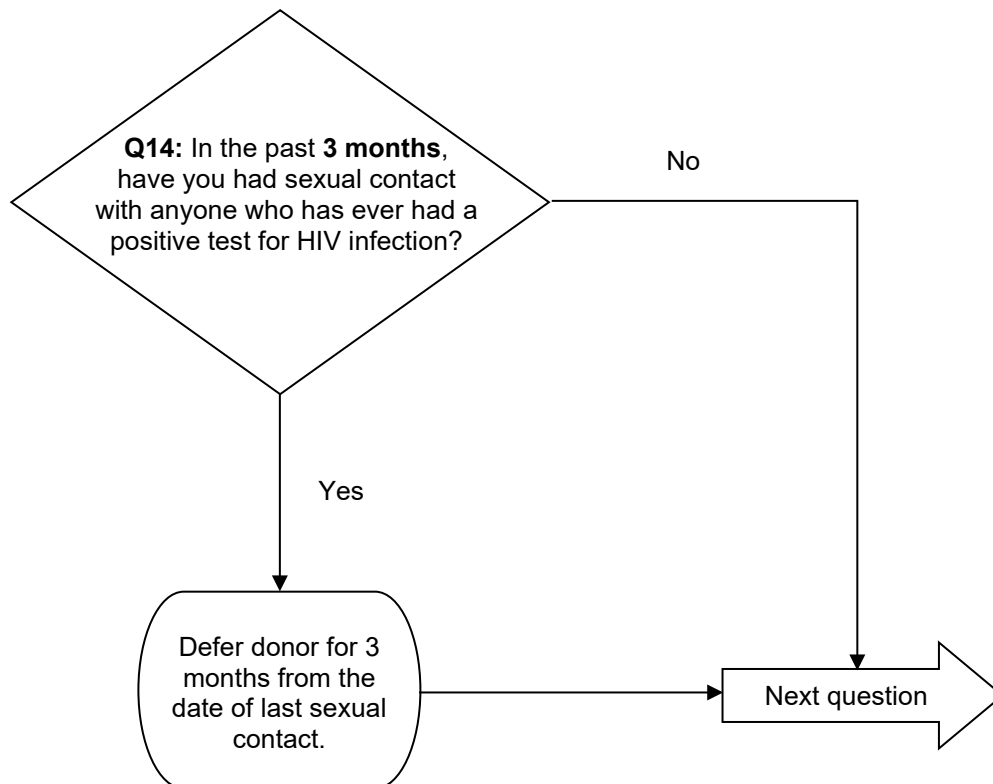
BLOOD DHQ v4.0 FLOWCHARTS

Question 14: In the past **3 months**, have you had sexual contact with anyone who has ever had a positive test for HIV infection?

Donor Eligibility: A person who has had sexual contact with a person who has ever had clinical or laboratory evidence of HIV infection is at increased risk for transmitting HIV and other infectious diseases and is deferred for 3 months from the date of last sexual contact. HIV may be transmitted through sexual contact with an infected person.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), or anal sex (contact between penis and anus regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy).

[[21 CFR 630.10\(e\)\(1\)\(v\)](#) and [FDA's 2023 HIV Guidance](#), III.B.13]



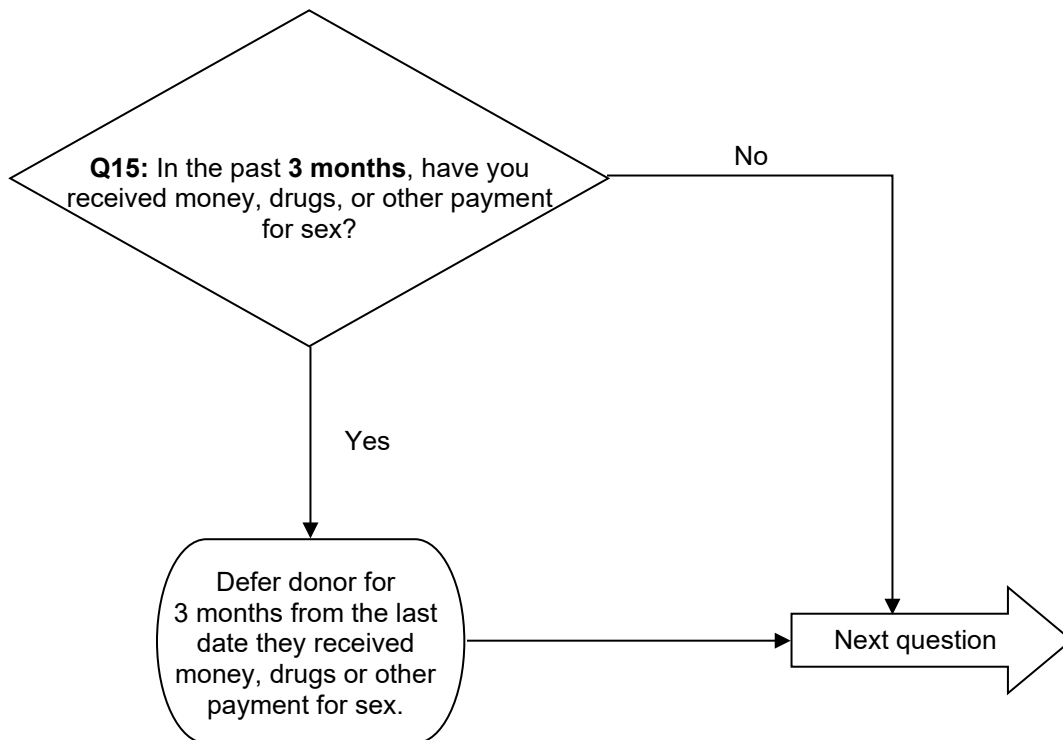
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Question 15: In the past **3 months**, have you received money, drugs, or other payment for sex?

Donor Eligibility: A person who, in the last 3 months, has received money, drugs, or other payment for sex is at increased risk for HIV and other infectious diseases. This individual is deferred for 3 months from the last date they received money, drugs, or other payment for sex.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), or anal sex (contact between penis and anus) regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy.

[[21 CFR 630.10\(e\)\(1\)\(i\)](#) and [FDA's 2023 HIV Guidance](#), III.B.7]



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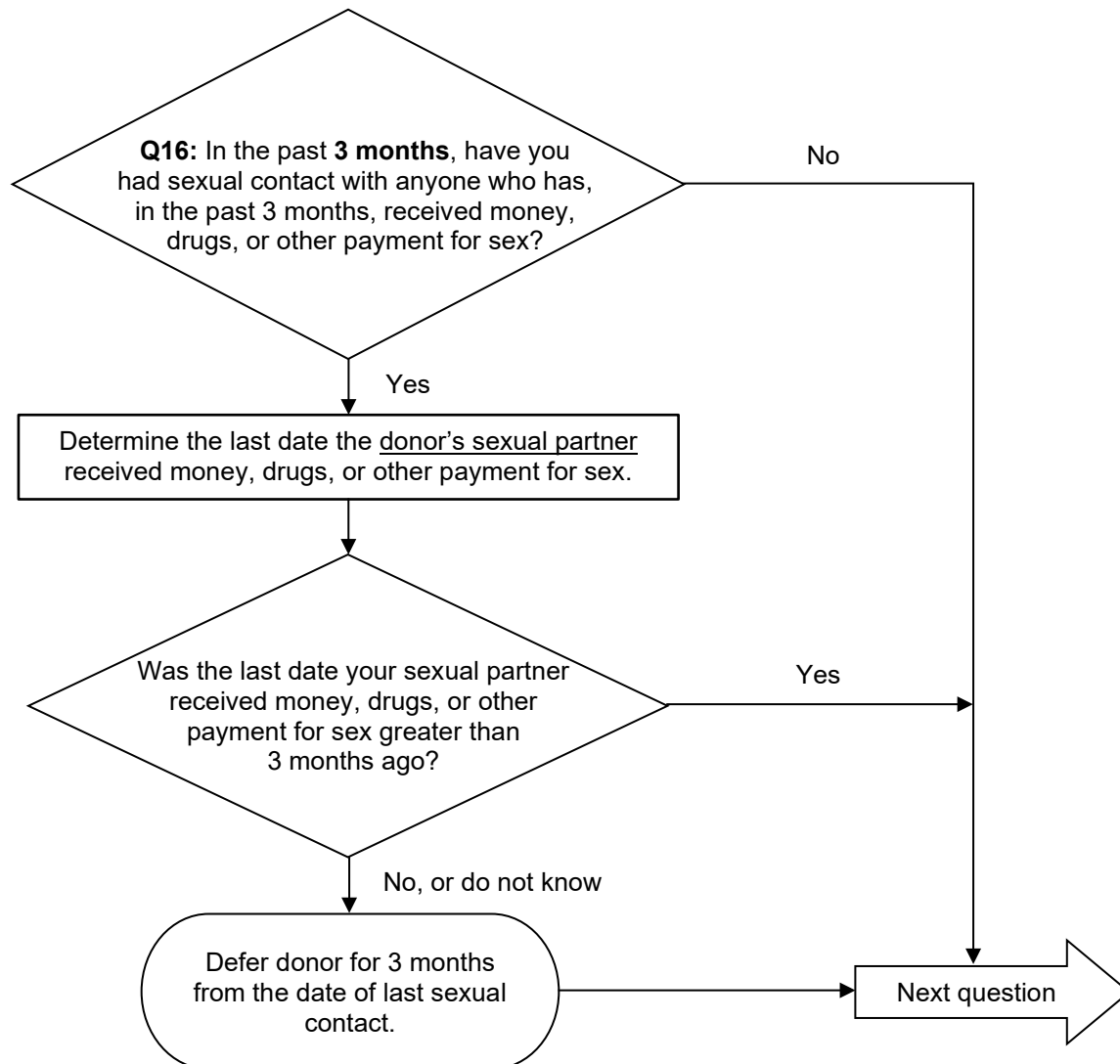
Question 16: In the past **3 months**, have you had sexual contact with anyone who has, in the past 3 months, received money, drugs, or other payment for sex?

Donor Eligibility: A person who has received money, drugs, or other payment for sex in the past 3 months is at increased risk for transmitting HIV and other infectious diseases. For that reason, a donor who has had sexual contact with this person is also at increased risk for transmitting HIV and other infectious diseases and is deferred for 3 months from the date of the last sexual contact.

If the donor has any uncertainty about when their sexual partner last received money, drugs, or other payment for sex, defer the donor for 3 months from their most recent sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), or anal sex (contact between penis and anus) regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy.

[21 CFR 630.10(e)(1)(v) and [FDA's 2023 HIV Guidance](#), III.B.10]



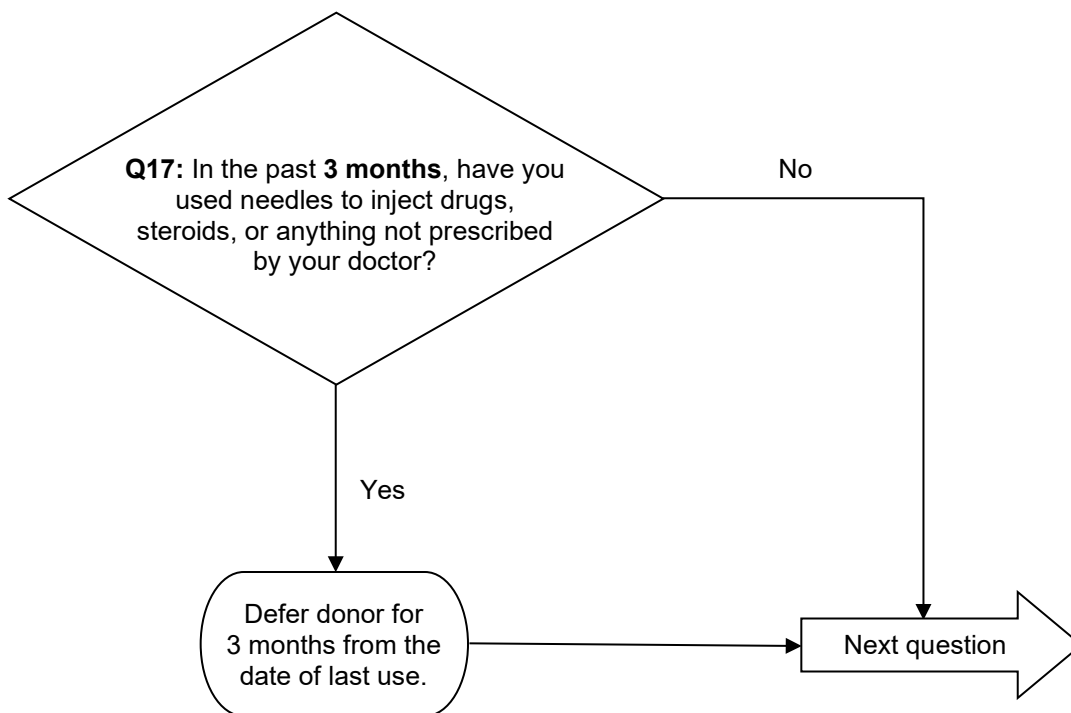
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Question 17: In the past **3 months**, have you used needles to inject drugs, steroids, or anything not prescribed by your doctor?

Donor Eligibility: A person who has used needles, in the past 3 months, to inject drugs, steroids, or anything not prescribed by their doctor is at increased risk for transmitting HIV and other infectious diseases. This individual is deferred for 3 months from the date of last use of needles to inject drugs, steroids, or anything not prescribed by their doctor.

Note: The phrase "used needles" includes intravenous use, "skin popping" (injection under the skin), "mainlining" (arterial injection). Non-prescription injection drug use also includes "improper injection of legally prescribed drugs, such as injecting a prescription drug intended for oral administration or injecting a prescription drug that was prescribed for another individual."

[21 CFR 630.10(e)(1)(i) and (vi) and [FDA's 2023 HIV Guidance](#)]



BLOOD DHQ v4.0 FLOWCHARTS

Question 18: In the past **3 months**, have you had sexual contact with anyone who has used needles in the past 3 months to inject drugs, steroids, or anything not prescribed by their doctor?

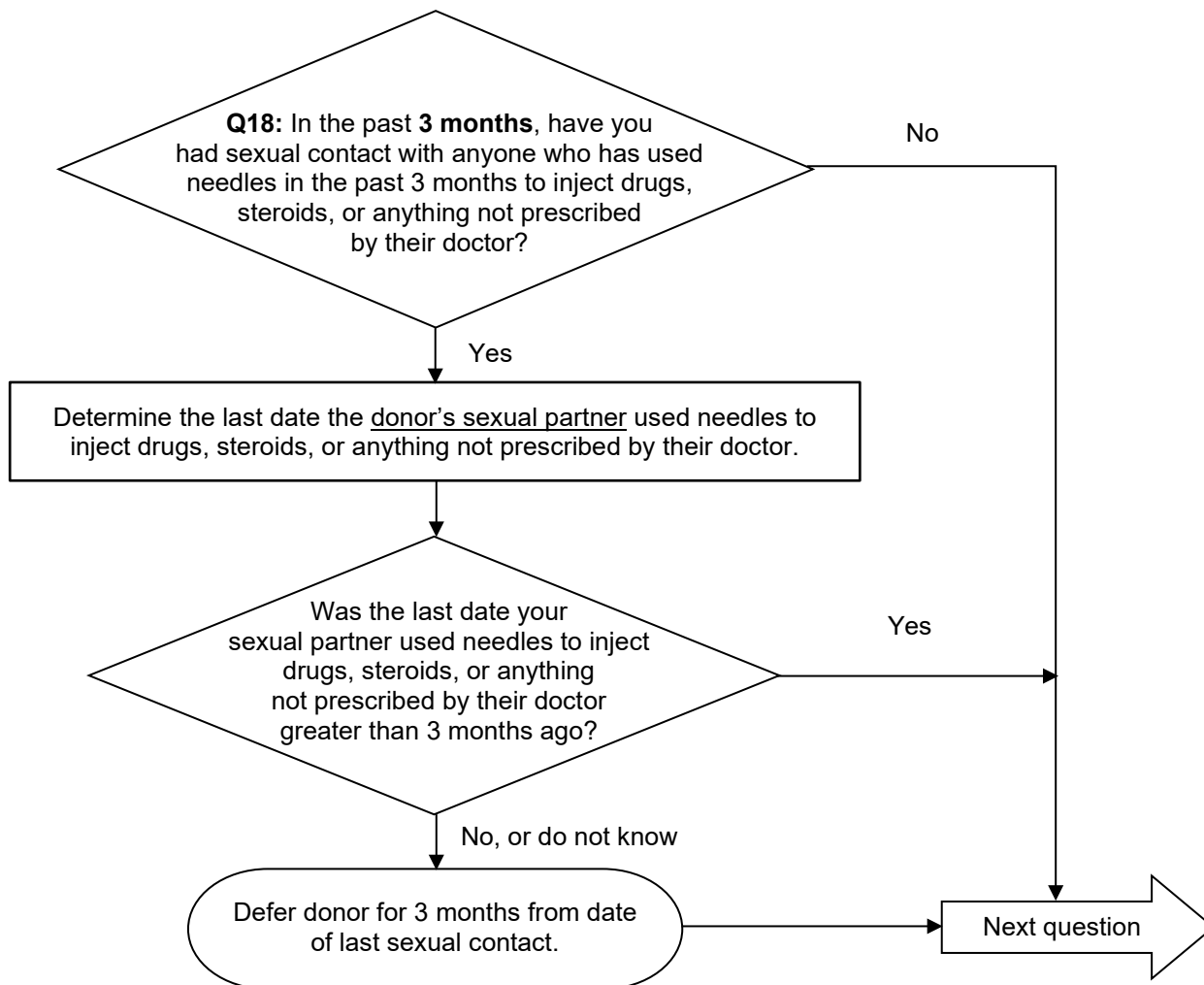
Donor Eligibility: A person who has used needles in the past 3 months to inject drugs, steroids, or anything not prescribed by their doctor is at increased risk for transmitting HIV and other infectious diseases. For this reason, a donor who has had sexual contact with this person is also at increased risk for transmitting HIV and other infectious diseases and is deferred for 3 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

If the donor has any uncertainty about when their sexual partner last used needles to inject drugs, steroids, or anything not prescribed by their doctor, defer the donor for 3 months from their most recent sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), or anal sex (contact between penis and anus) regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy.

Note: The phrase "used needles" includes intravenous use, "skin popping" (injection under the skin), "mainlining" (arterial injection). Non-prescription drug use also includes "improper injection of legally prescribed drugs, such as injecting a prescription drug intended for oral administration or injecting a prescription drug that was prescribed for another individual."

[21 CFR 630.10(e)(1)(v) and [FDA's 2023 HIV Guidance](#), III.B.11]

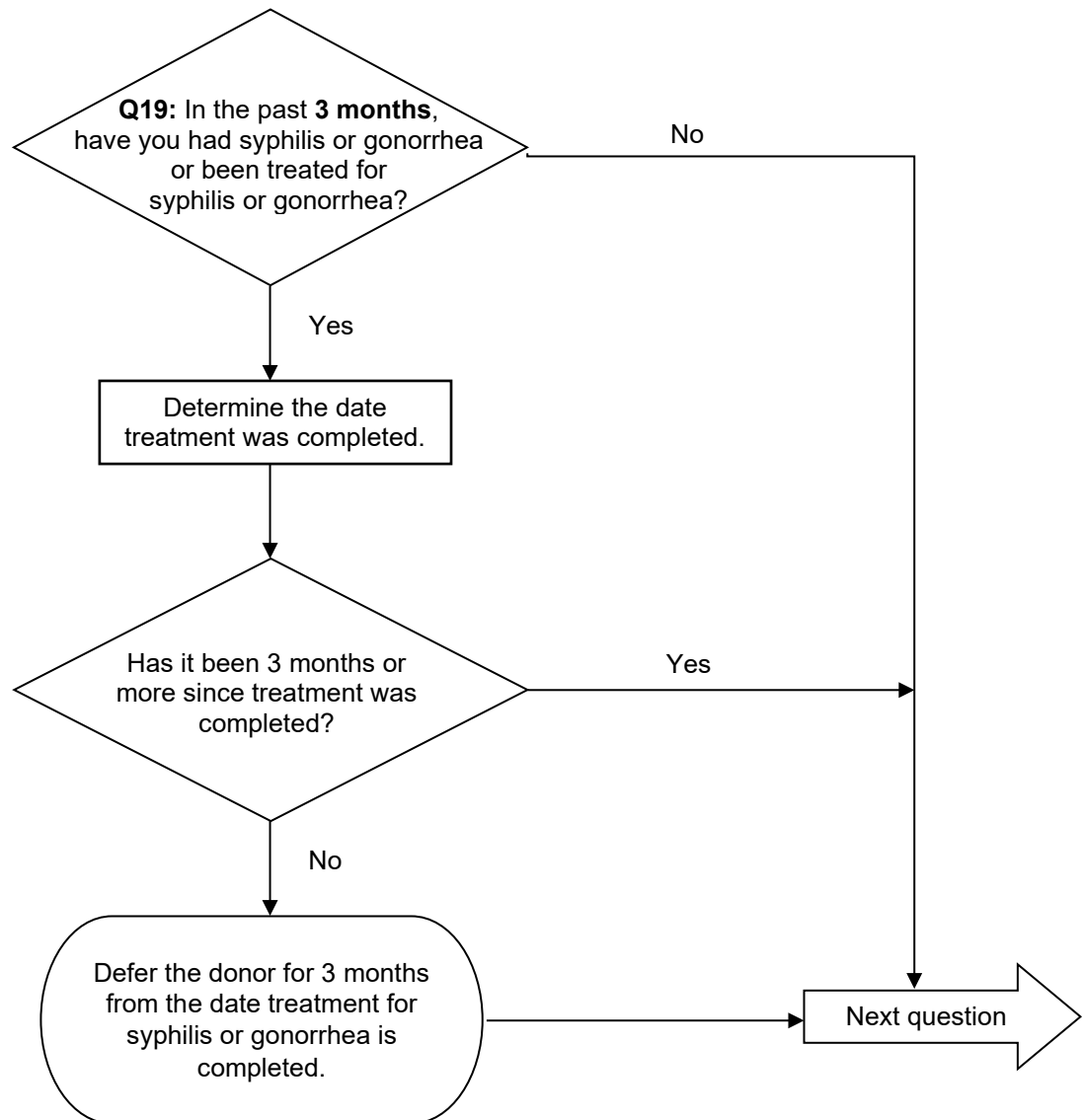


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Question 19: In the past **3 months**, have you had syphilis or gonorrhea or been treated for syphilis or gonorrhea?

Donor Eligibility: A person who has had syphilis or gonorrhea or has been treated for syphilis or gonorrhea, is at increased risk for transmitting disease and is deferred for 3 months after the date treatment is completed.

[21 CFR 630.10(e)(1)(iii), FDA's December 2020 Guidance, [Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis](#), IV.A.1 and 2, page 5 and [FDA's 2023 HIV Guidance](#), III.B.15]



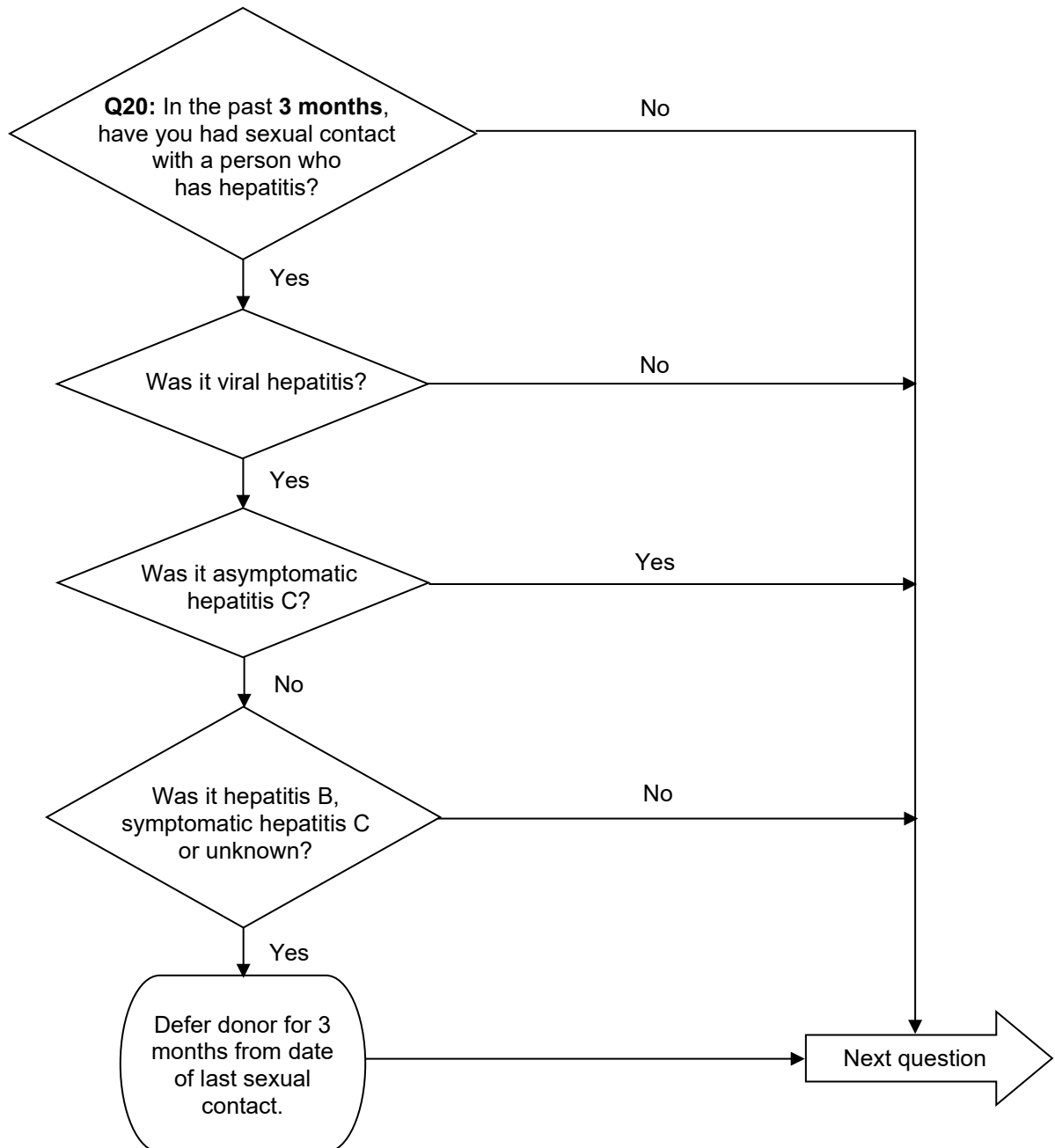
BLOOD DHQ v4.0 FLOWCHARTS

Question 20: In the past **3 months**, have you had sexual contact with a person who has hepatitis?

Donor Eligibility: A person who has had sexual contact with a person who has viral hepatitis may be at increased risk for transmitting infection and is deferred for 3 months from the date of last contact. Hepatitis, particularly hepatitis B, may be transmitted through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material which define sexual contact as vaginal sex (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), or anal sex (contact between penis and anus) regardless of whether or not medications, condoms or other protection were used to prevent infection or pregnancy.

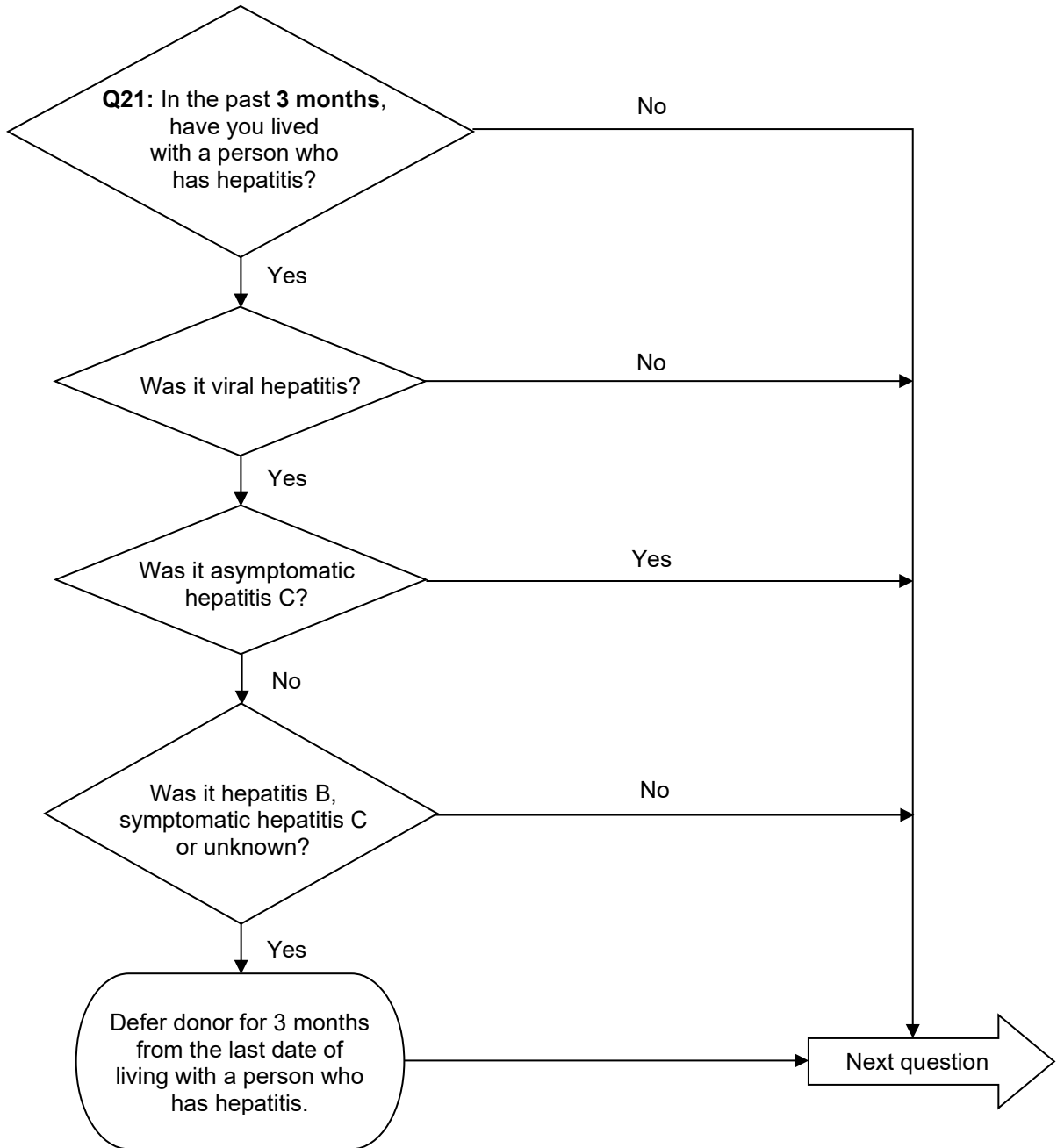
[\[21 CFR 630.10\(e\)\(1\)\(v\)\]](#)



BLOOD DHQ v4.0 FLOWCHARTS

Question 21: In the past **3 months**, have you lived with a person who has hepatitis?

Donor Eligibility: A person who has lived with a person who has viral hepatitis may be at increased risk for acquiring viral hepatitis as well. For this reason, a person who is living with a person who has viral hepatitis is deferred for 3 months from the last date of living with a person who has hepatitis.

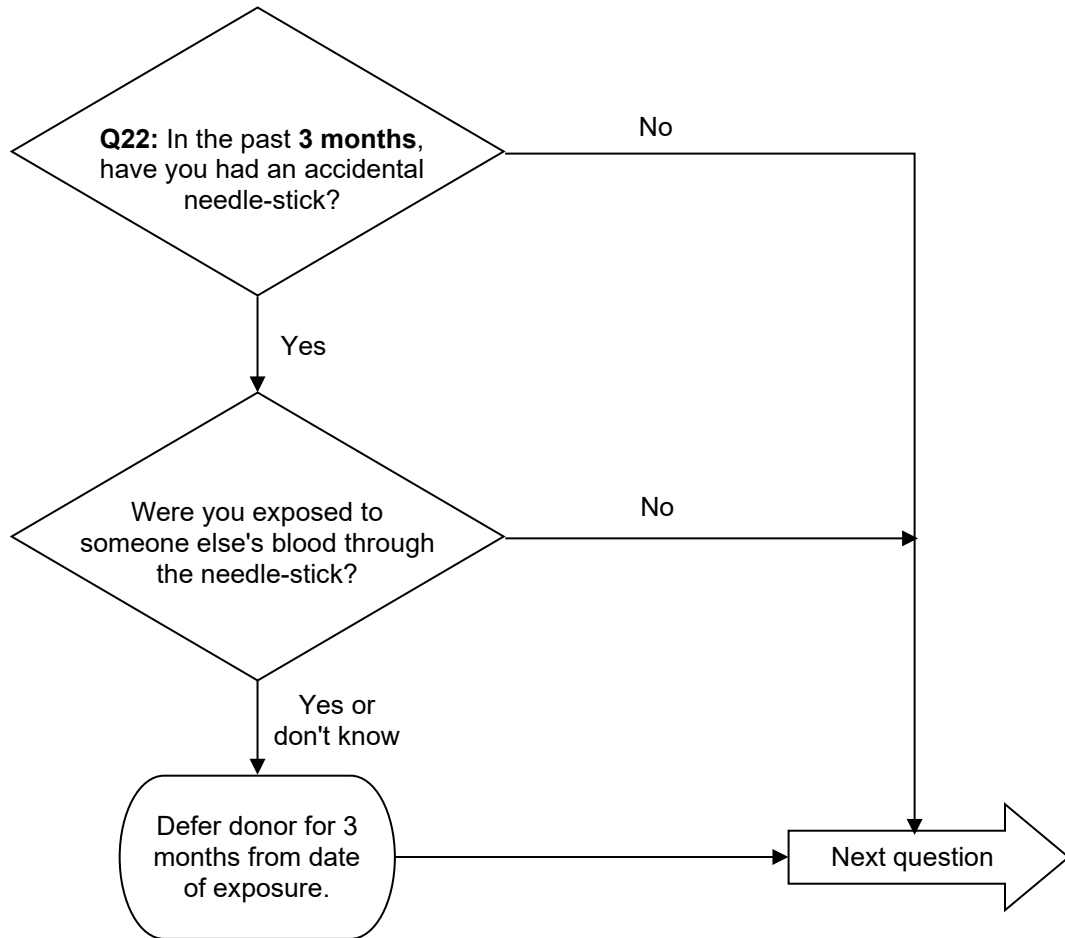


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Question 22: In the past 3 months, have you had an accidental needle-stick?

Donor Eligibility: A person who has been exposed to someone else's blood through a needle-stick is at increased risk for transmitting infectious diseases and is deferred for 3 months following the date of exposure.

[21 CFR 630.10(e)(1)(vi) and [FDA's 2023 HIV Guidance](#), III.B.13]

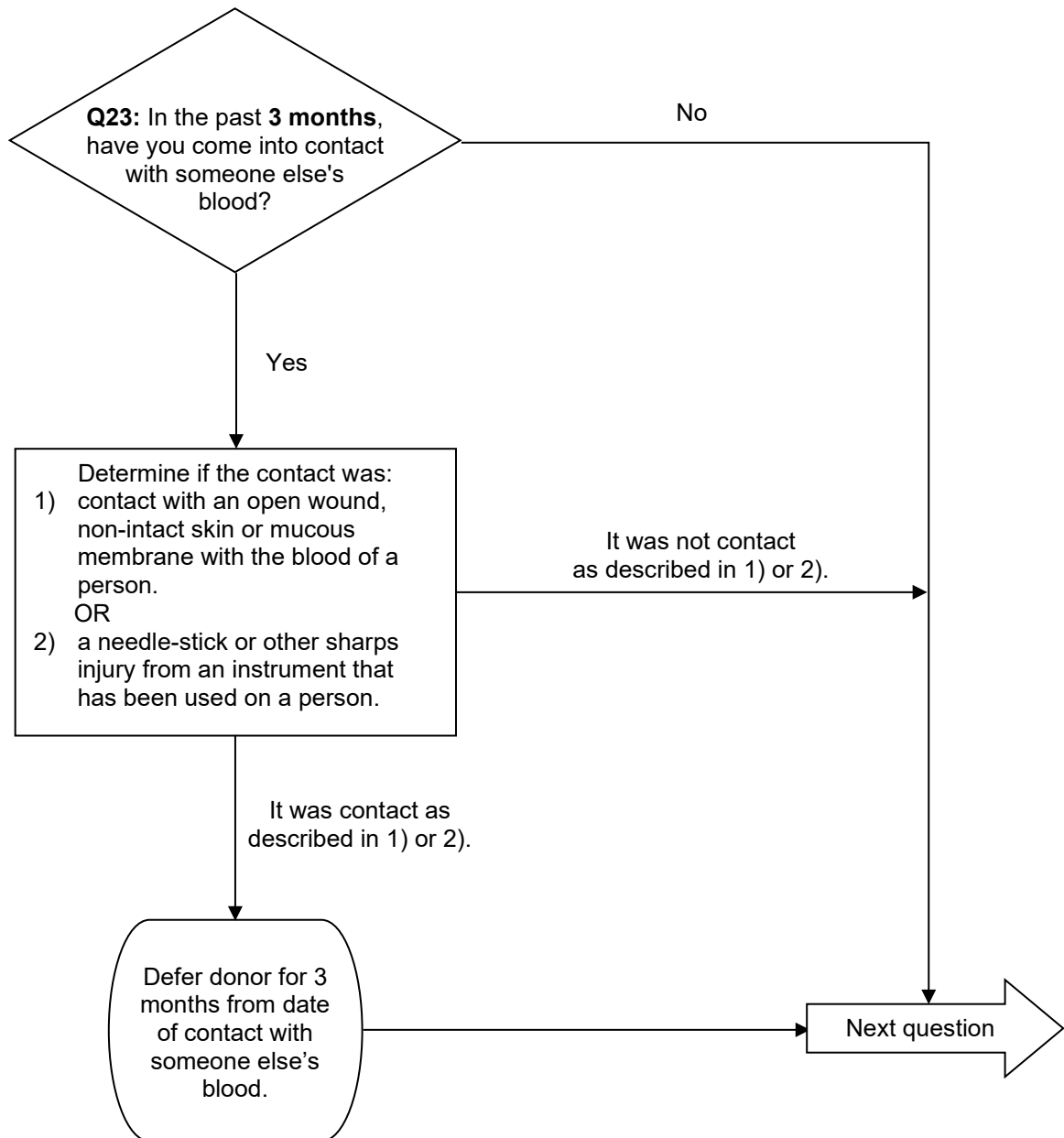


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Question 23: In the past 3 months, have you come into contact with someone else's blood?

Donor Eligibility: A person who has had one of the following in the past 3 months: 1) contact with an open wound, non-intact skin or mucous membrane with the blood of a person, or 2) a needle-stick or other sharps injury from an instrument that has been used on a person, is at increased risk for transmitting infectious diseases, and is deferred for 3 months from the date of exposure.

[[FDA's 2023 HIV Guidance](#), III.B.13]



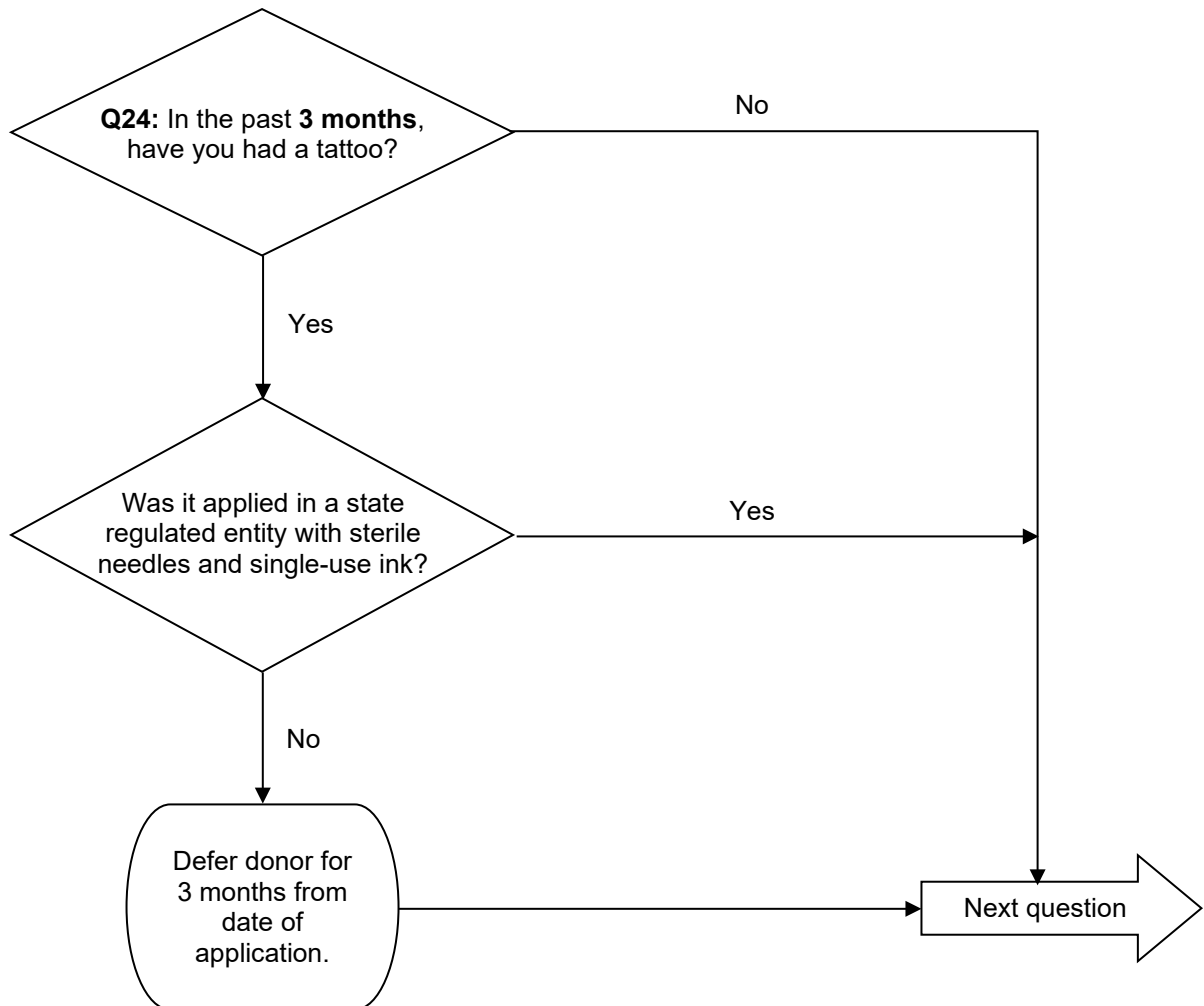
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Question 24: In the past 3 months, have you had a tattoo?

Donor Eligibility: A person who has had a tattoo is deferred for 3 months from the date of the tattoo application unless applied by a state regulated entity with sterile needles and single-use ink. There may be a risk of transmission of infectious diseases when tattoos have been applied using non-sterile needles and/or reused ink.

Note: Tattoos include permanent makeup (ex: eyeliner, lipliner, microblading), tattoo "touch ups", tattoos applied by oneself, and those applied by others.

[21 CFR 630.10(e)(1)(vi) and [FDA's 2023 HIV Guidance](#), III.B.14]



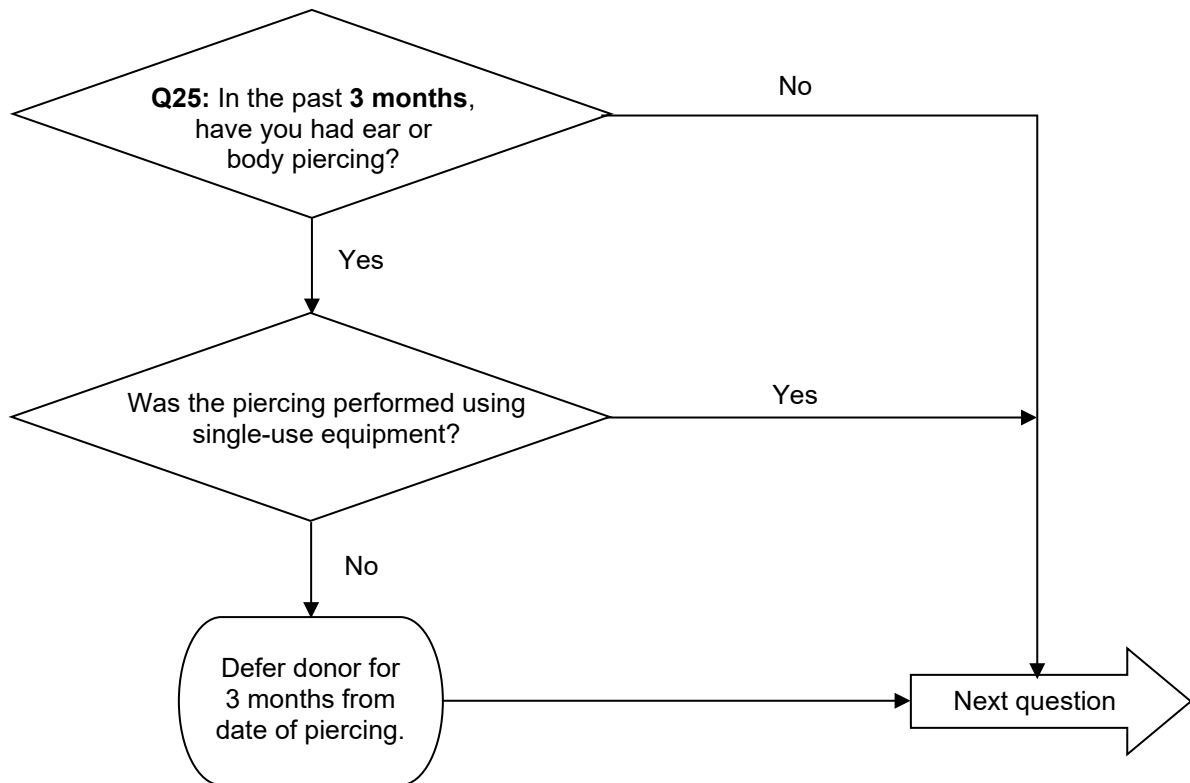
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Question 25: In the past 3 months, have you had ear or body piercing?

Donor Eligibility: A person who has had ear or body piercing in the past 3 months is at increased risk for transmitting HIV and other infectious diseases and is deferred for 3 months from the date of the procedure, unless the ear or body piercing has been done using single-use equipment. There is an increased risk for transmitting HIV and other diseases if the equipment is re-used.

[[21 CFR 630.10\(e\)\(1\)\(vi\)](#) and [FDA's 2023 HIV Guidance](#), III.B.14]

FDA Clarification: "The procedures and equipment used for tattooing and piercing are generally different. If done in a regulated parlor, the tattooing equipment is either single use or sterilized. However, piercings are not always done using a sterile procedure. For this reason, FDA has clarified in guidance that in order for donors to be accepted within 3 months of receiving a piercing and to meet the requirements in [21 CFR 630.10\(e\)\(1\)\(vi\)](#), the piercing should be done using single use equipment."



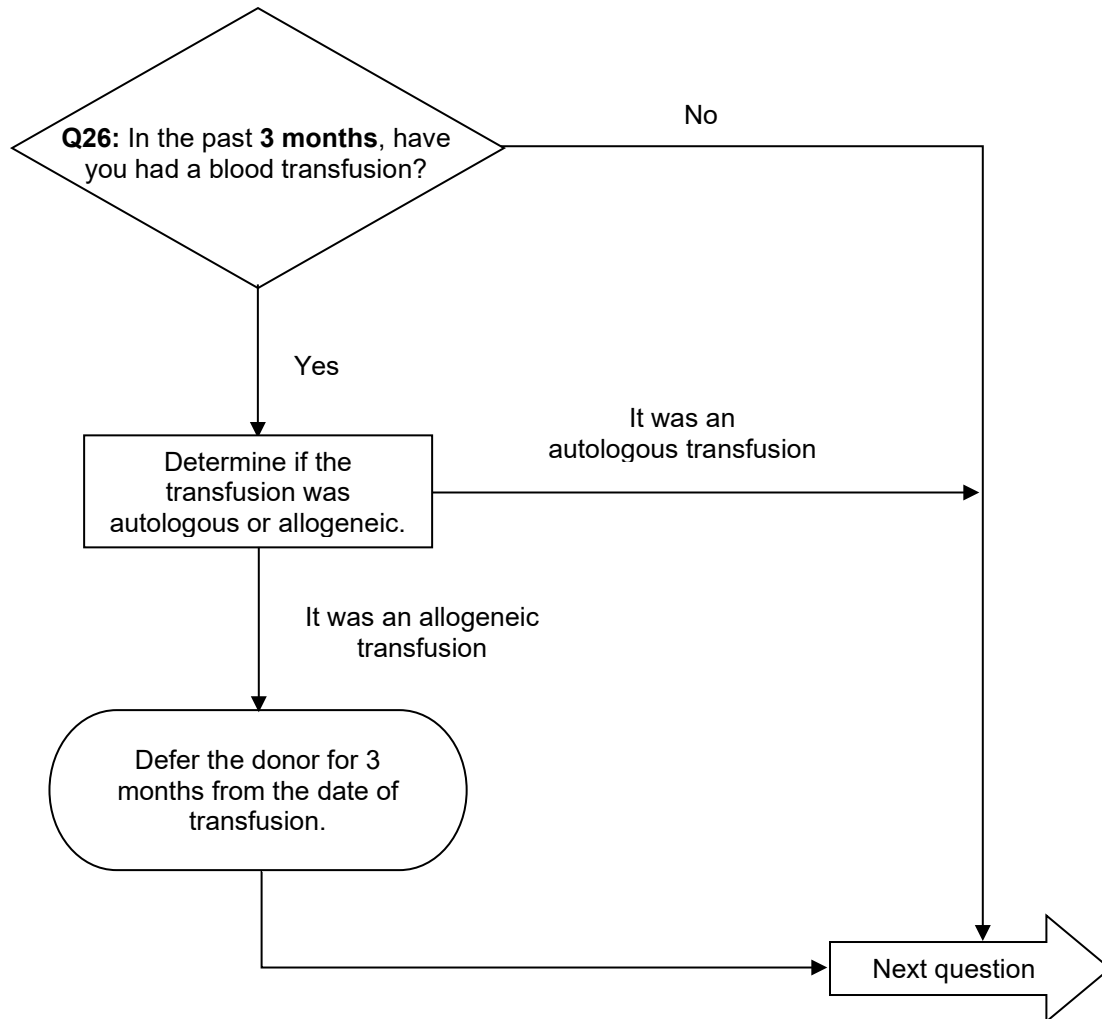
BLOOD DHQ v4.0 FLOWCHARTS

Question 26: In the past **3 months**, have you had a blood transfusion?

Donor Eligibility: A person who has received an allogeneic blood transfusion is at increased risk for transmitting infectious diseases and is deferred for 3 months following the transfusion.

An **allogeneic** blood transfusion is when the blood donor and the recipient **are not** the same person.
An **autologous** blood transfusion is when the blood donor and the recipient **are** the same person.

[21 CFR 630.10(e)(1)(ii) and [FDA's 2023 HIV Guidance](#), III.B.12]



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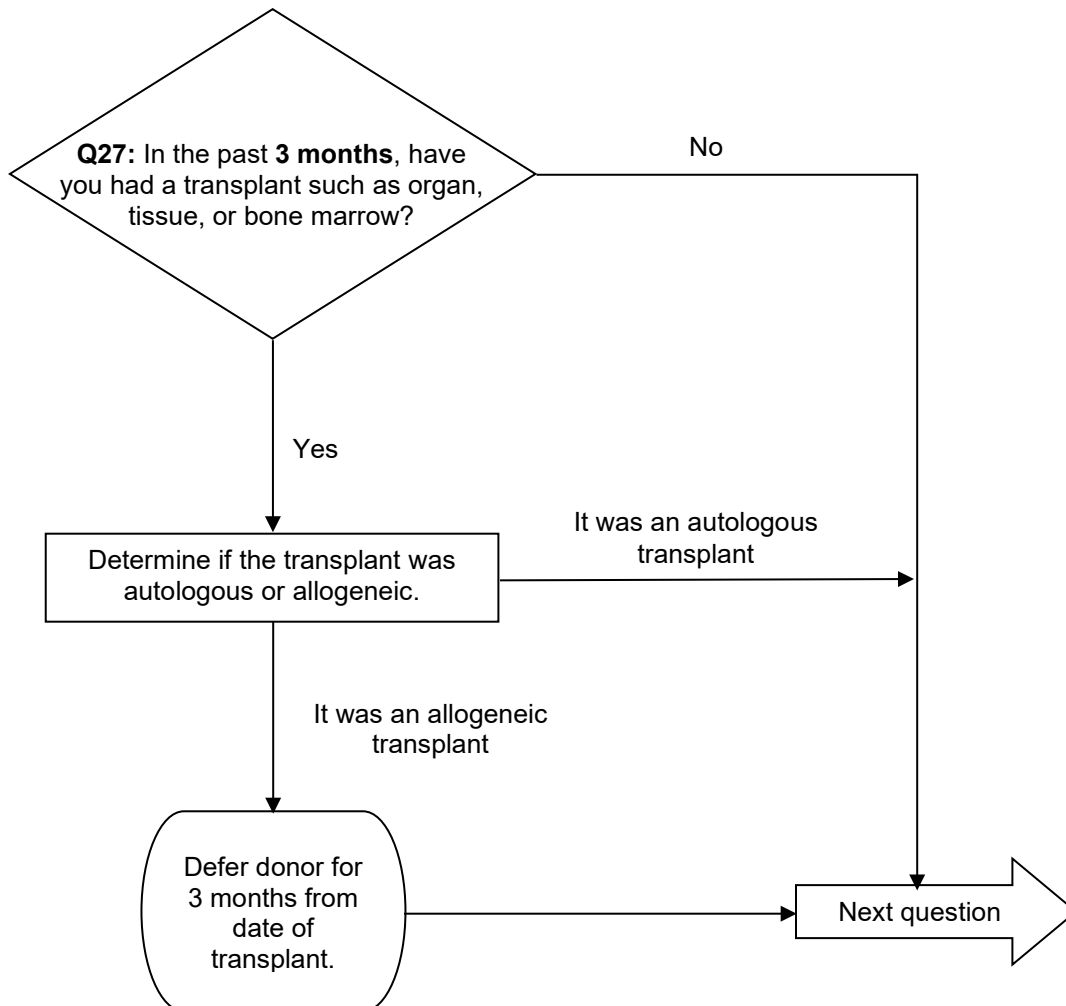
Question 27: In the past **3 months**, have you had a transplant such as organ, tissue, or bone marrow?

Donor Eligibility: A person who has been exposed to human allogeneic tissue through transplant should not donate blood for 3 months following exposure due to increased risk for transmitting infectious diseases.

An **allogeneic** transplant is when the transplant donor and the recipient **are not** the same person.

An **autologous** transplant is when the transplant donor and the recipient **are** the same person.

[Current edition *Standards for Blood Banks and Transfusion Services* Reference Standard 5.4.1A-Requirements for Allogeneic Donor Qualification, 12) Receipt of Blood, Blood Component, or Human Tissue]



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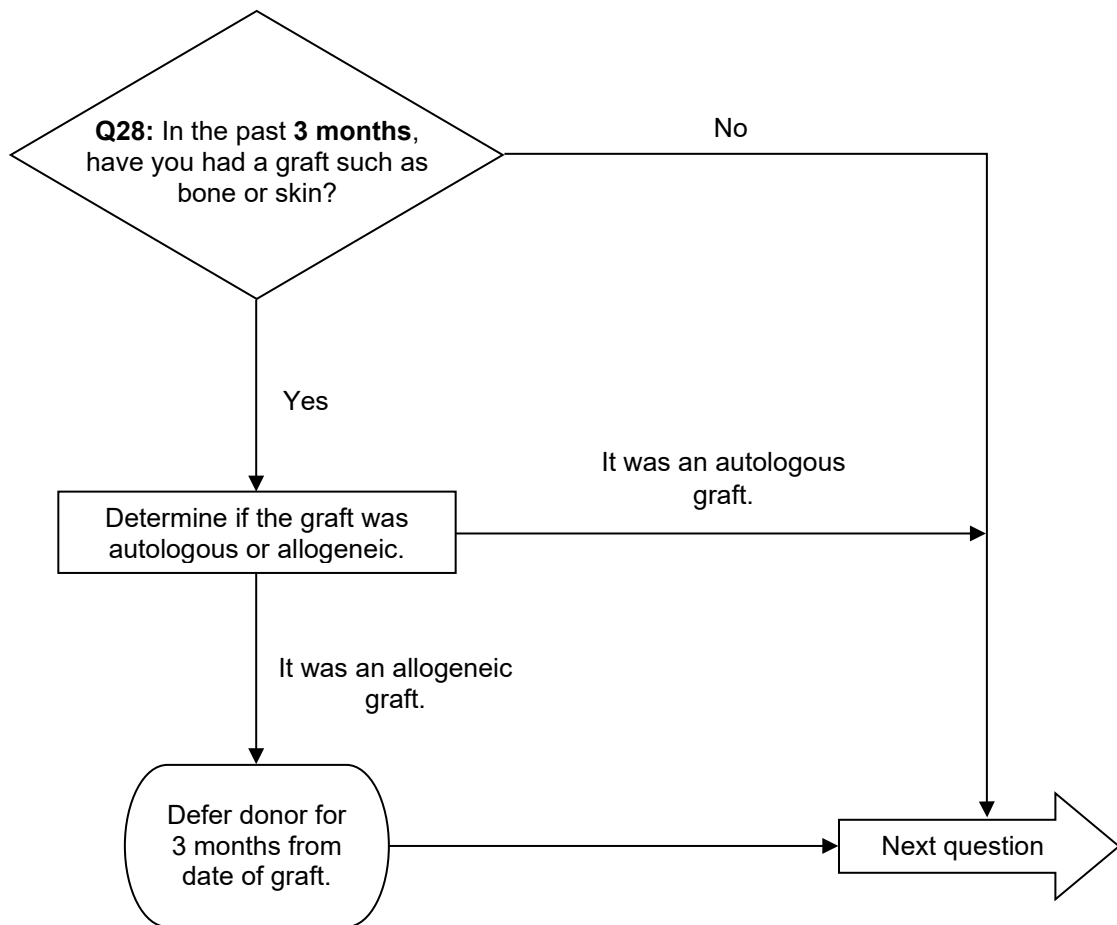
Question 28: In the past **3 months**, have you had a graft such as bone or skin?

Donor Eligibility: A person who has been exposed to human allogeneic tissue through grafting should not donate blood for 3 months following exposure due to increased risk for transmitting infectious diseases.

An **allogeneic** graft is when the graft donor and the recipient **are not** the same person.

An **autologous** graft is when the graft donor and the recipient **are** the same person.

[Current edition *Standards for Blood Banks and Transfusion Services* Reference Standard 5.4.1A-Requirements for Allogeneic Donor Qualification, 12) Receipt of Blood, Blood Component, or Human Tissue]

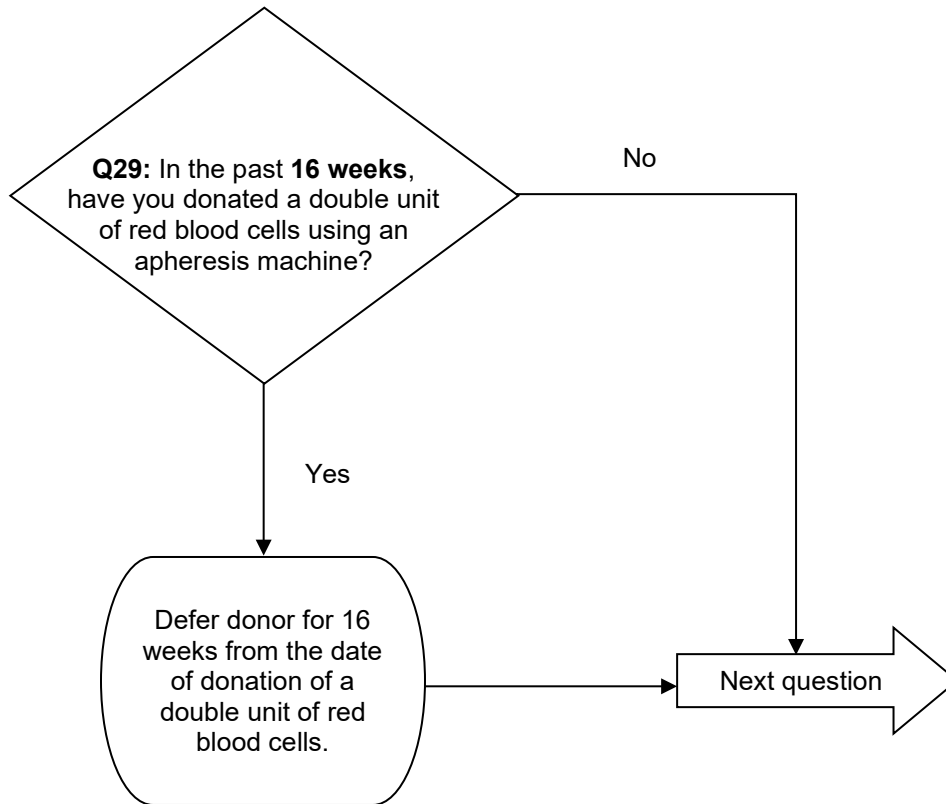


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Question 29: In the past **16 weeks**, have you donated a double unit of red blood cells using an apheresis machine?

Donor Eligibility: A donor is not eligible to donate a double unit of red blood cells by apheresis more frequently than every 16 weeks.

[21 CFR 630.10(d)(2), 21 CFR 630.15(a)(1)(i) and FDA's February 2001 Guidance, [Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods](#), IV.B.2, page 4]



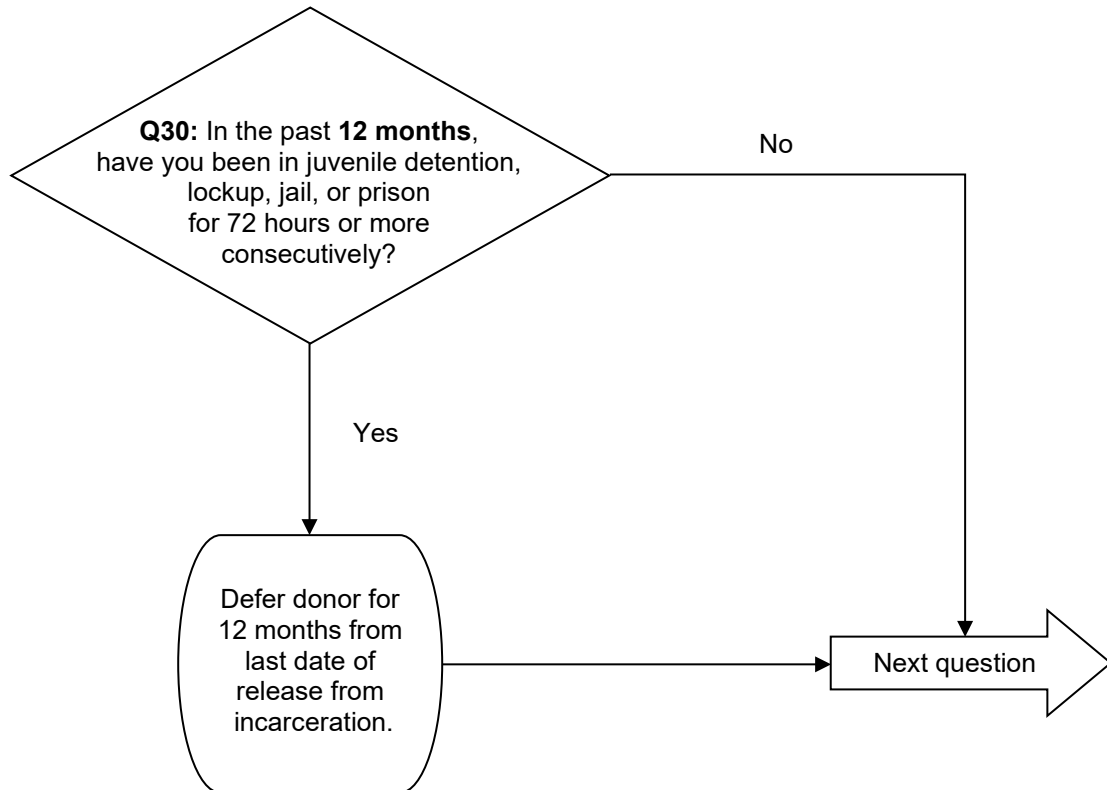
BLOOD DHQ v4.0 FLOWCHARTS

Question 30: In the past **12 months**, have you been in juvenile detention, lockup, jail, or prison for 72 hours or more consecutively?

Donor Eligibility: A person who has been incarcerated or held in a correctional facility of any type (juvenile detention, lockup, jail, or prison) for 72 hours or more consecutively is at increased risk for transmitting HIV and other transfusion transmitted infections and is deferred for 12 months from the date of release from incarceration.

[\[21 CFR 630.10\(e\)\(1\)\(iv\)\]](#)

Note: The reason for incarceration (e.g., white-collar crimes, child support) does not change the deferral.



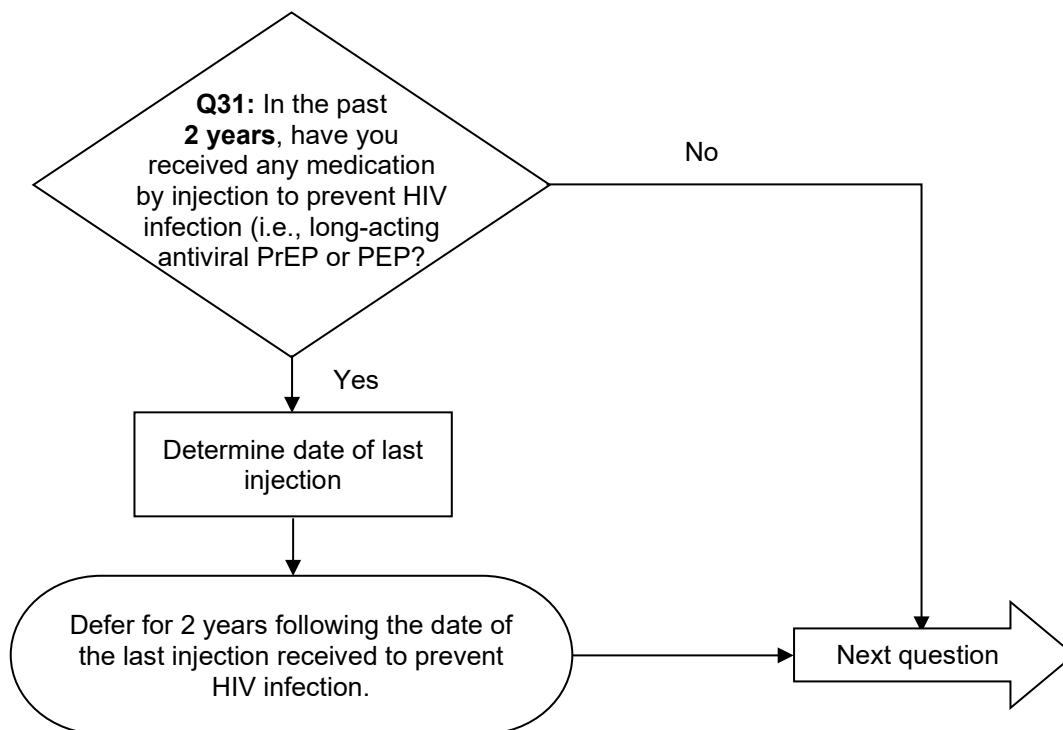
BLOOD DHQ v4.0 FLOWCHARTS

Question 31: In the **past 2 years**, have you received any medication by injection to prevent HIV infection? (i.e., long-acting antiviral PrEP or PEP)

Donor Eligibility: A donor who has taken any medication to prevent HIV infection [also known as pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)] is deferred because FDA has determined that the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals. Donors who report that they have received any medication by injection (i.e., long-acting antiviral PrEP or PEP) to prevent HIV infection are deferred for 2 years following the date of last injection to prevent HIV infection.

The principle known as “Undetectable = Untransmittable” **does not apply to the potential risk to patients who receive transfusions**. FDA-approved antiretroviral drugs are safe and effective in preventing sexual transmission of HIV. However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient. *Follow-up questions may be necessary if the donor appears to be confused about medication taken to prevent HIV versus medication taken to treat HIV infection.*

[[FDA 2023's HIV Guidance](#), III.B.4, [21 CFR 630.10 \(e\)\(2\)\(ii\)](#) and AABB [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](#)]



Resources:

From the [NIH CLINICAL INFO.HIV.gov Glossary](#):

PrEP = “An HIV prevention method for people who are HIV negative and at high risk of HIV infection. Pre-exposure prophylaxis (PrEP) involves taking a specific combination of HIV medicines daily.”

PEP = “Short-term treatment started as soon as possible after high-risk exposure to an infectious agent, such as HIV ... The purpose of post-exposure prophylaxis (PEP) is to reduce the risk of infection.”

From the CDC's Webpage: [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2021 Update A Clinical Practice Guideline](#)

More information is available at <https://www.cdc.gov/hiv/basics/prep.html>

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Question 32: In the past **3 years**, have you been outside the United States or Canada?

Donor Eligibility: A person who is not a prior resident of malaria-endemic countries and travels to a malaria-endemic area is deferred for 3 months after departure from that area based on an increased risk for transmitting malaria. Malaria can be transmitted by blood transfusion. The 3-month deferral still applies when a donor uses chemoprophylaxis to prevent malaria when traveling.

[21 CFR 630.10(e)(2)(iii) and FDA's December 2022 Guidance, [Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria](#), IV.A.1-2, pages 5-6]

In general, residents of a malaria-endemic country will be deferred for 3 years after departure from the country of residence if they remain free from unexplained symptoms suggestive of malaria. Prior residents of malaria-endemic countries who live in non-endemic countries for 3 consecutive years without travelling to a malaria-endemic area, will then be deferred for 3 months after subsequent travel to a malaria-endemic area. Prior residents of malaria-endemic countries who have not lived in non-endemic countries for 3 consecutive years, and then travel to a malaria-endemic area will be deferred for 3 years after the recent travel to a malaria-endemic area.

Note: Use of the definitions (excerpts are provided below) provided in the [FDA's December 2022 Malaria Guidance](#) can be found on the FDA website at the following link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-reduce-risk-transfusion-transmitted-malaria>.

Definitions

Malaria-endemic area - Any areas with malaria where CDC recommends anti-malarial chemoprophylaxis in travelers in the most current version of the *CDC Health Information for International Travel* (commonly known as *The Yellow Book*) at the time the donor is screened.

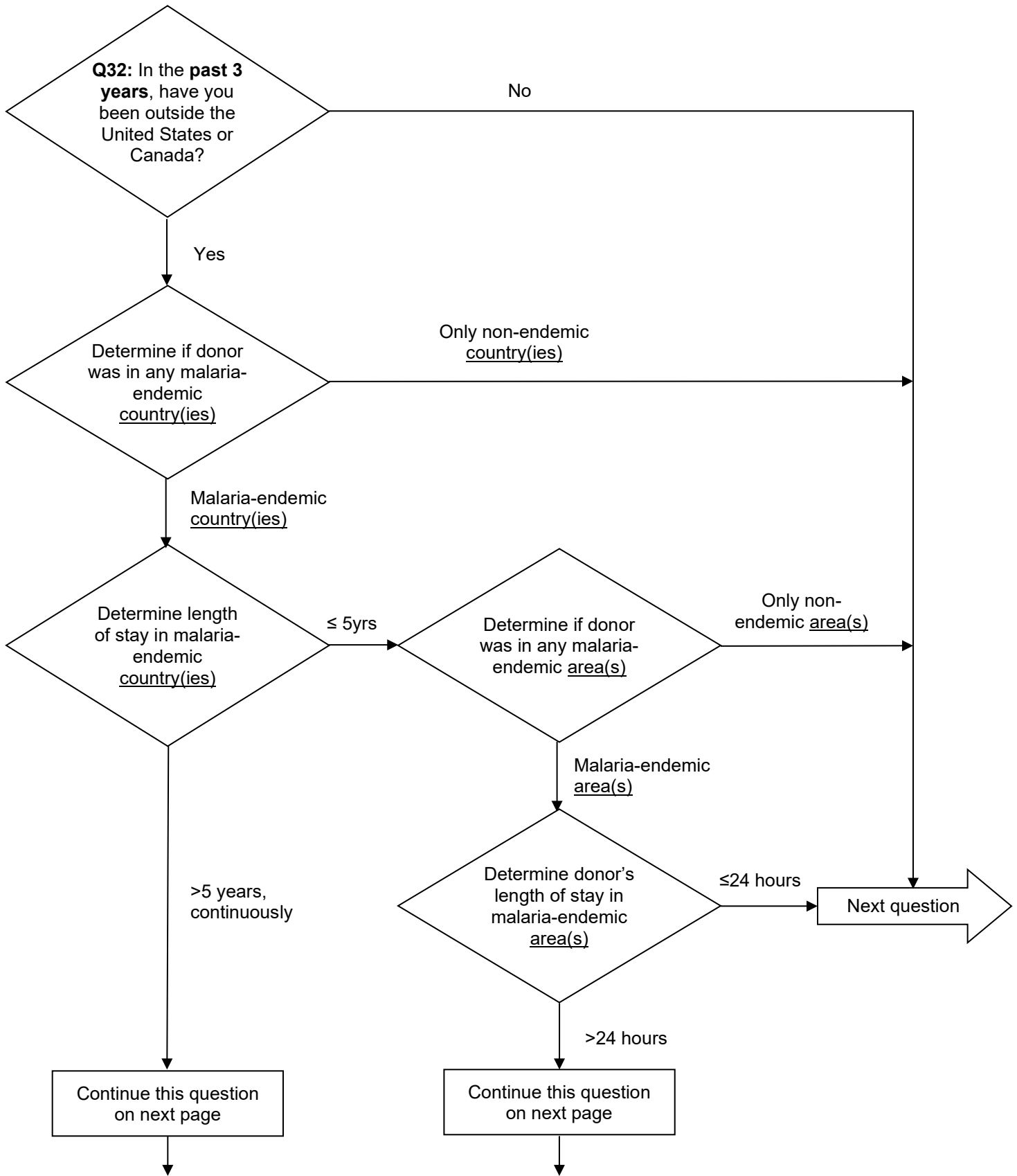
Malaria-endemic country - Any country having an area or areas with malaria where CDC recommends anti-malarial chemoprophylaxis in travelers in *The Yellow Book* at the time the donor is screened. A country that has any malaria-endemic areas should be considered to be malaria-endemic in its entirety.

Residence in a malaria-endemic country - Residence is defined as a continuous stay of **longer than 5 years** in a country or countries having any malaria-endemic area. In determining residence, consideration is by malaria-endemic country and not by malaria-endemic area since the geographic distribution of malaria-endemic areas may change during the period of residence, or the resident may have traveled from a non-endemic area to an endemic area in the country during his or her stay.

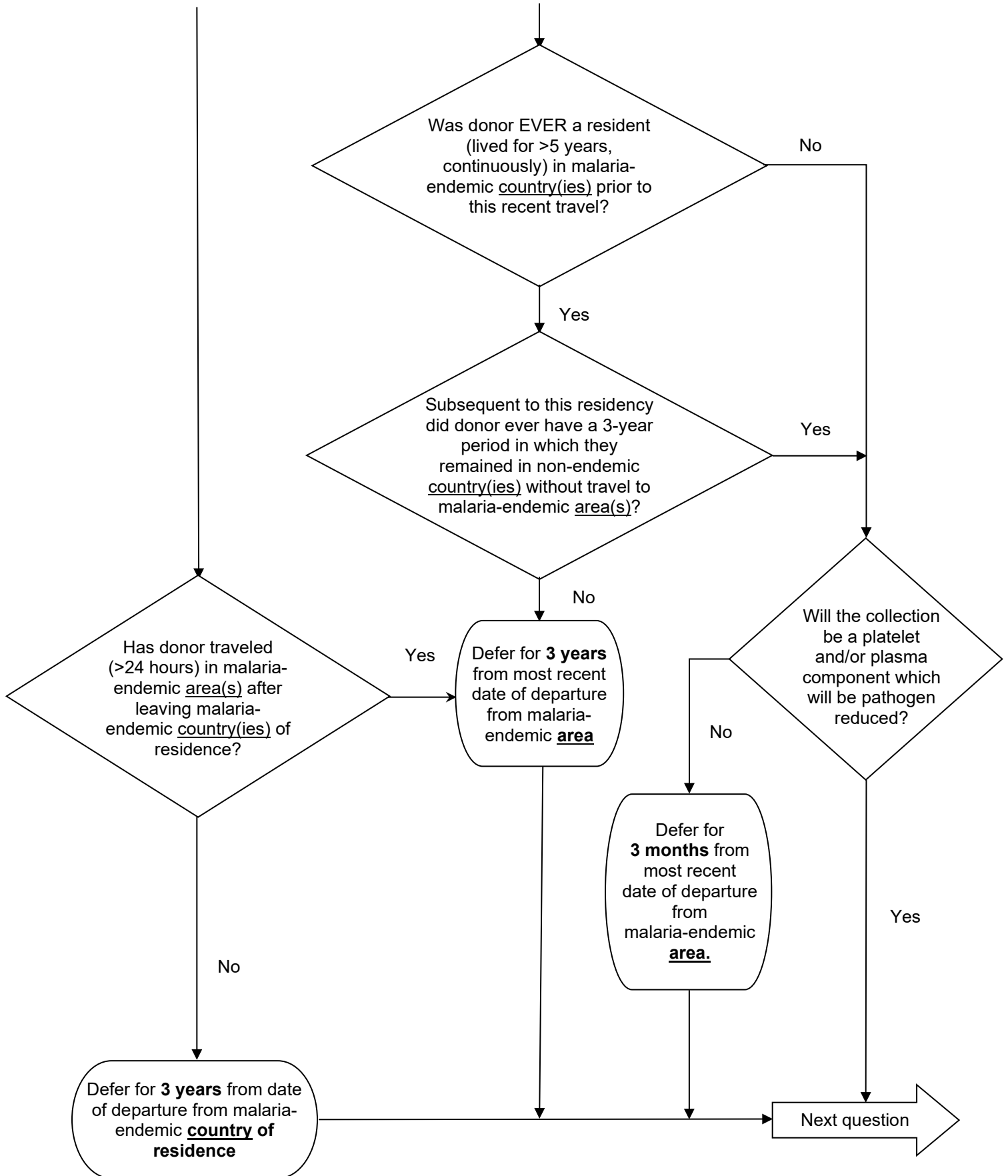
Travel to a malaria-endemic area - Any travel to or through a malaria-endemic area or areas, as identified by CDC. The duration of travel to a malaria-endemic area is defined as **more than 24 hours to less than 5 years**. Note that a passage greater than 24 hours through a malaria-endemic area while on route to a malaria-free area is considered a sufficient possible exposure to trigger donor deferral.

FLOWCHART FOR QUESTION 32 BEGINS ON THE NEXT PAGE.

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Question 33: Have you **EVER** had a positive test for HIV infection?

Donor Eligibility: A person who has had a positive* test for HIV infection is deferred.

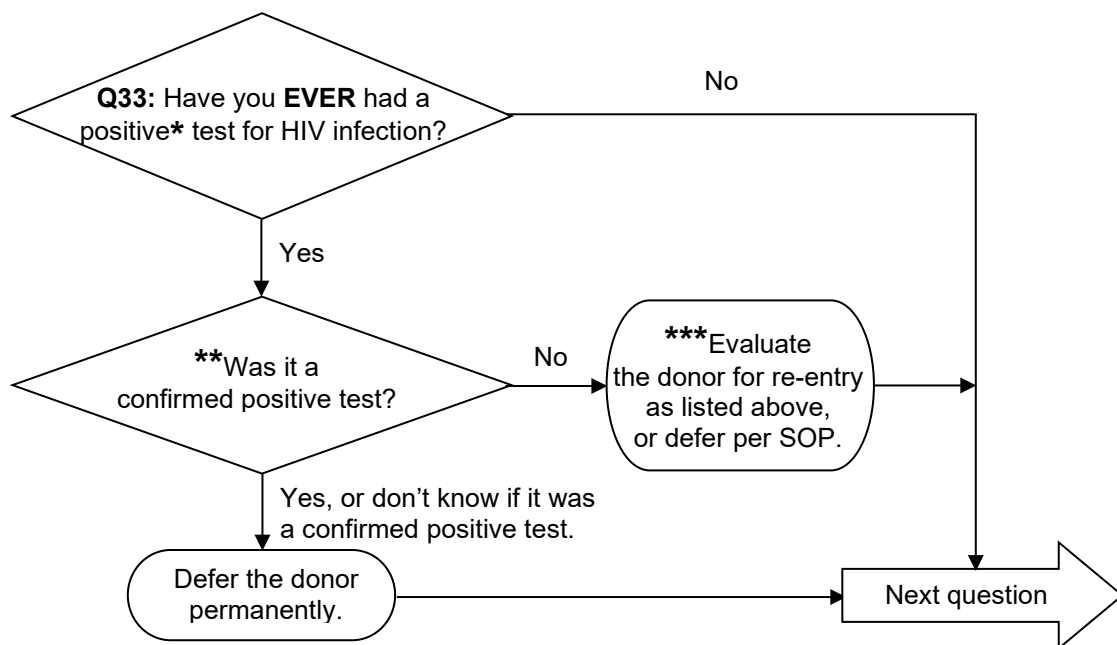
*FDA's 2023 HIV Guidance: "In this context, 'positive' includes a positive result on an HIV diagnostic assay and repeatedly reactive or reactive results on antibody or NAT blood donor screening assays."

[21 CFR 630.10(d)(3) and (e)(1)(iii), [FDA's 2023 HIV Guidance](#)]

**For additional information on testing, deferral, and reentry refer to FDA's December 2017 Guidance, [Nucleic Acid Testing \(NAT\) for Human Immunodeficiency Virus Type 1 \(HIV-1\) and Hepatitis C Virus \(HCV\): Testing, Product Disposition, and Donor Deferral and Reentry](#).

***Refer to the following for evaluation of HIV test results which were subsequently shown to be falsely-positive screening test results:

- [FDA's 2023 HIV Guidance](#) states, "A donor deferred indefinitely because of a repeatedly reactive or reactive result on an antibody or a NAT blood donor screening assay, respectively, may be considered for re-entry by a requalification method or process found acceptable for such purposes by FDA. If the deferred donor is subsequently found to be eligible as a donor of blood or blood components by a requalification method or process found acceptable for such purposes by FDA, such a donor is no longer considered deferred. (21 CFR 610.41(b))."
- For recommendations on reentry refer to FDA's December 2017 guidance, [Nucleic Acid Testing \(NAT\) for Human Immunodeficiency Virus Type 1 \(HIV-1\) and Hepatitis C Virus \(HCV\): Testing, Product Disposition, and Donor Deferral and Reentry](#).



AABB members may access the [HIV Testing, Lookback and Reentry Toolkit](#) to consider additional information on donor deferral and reentry.

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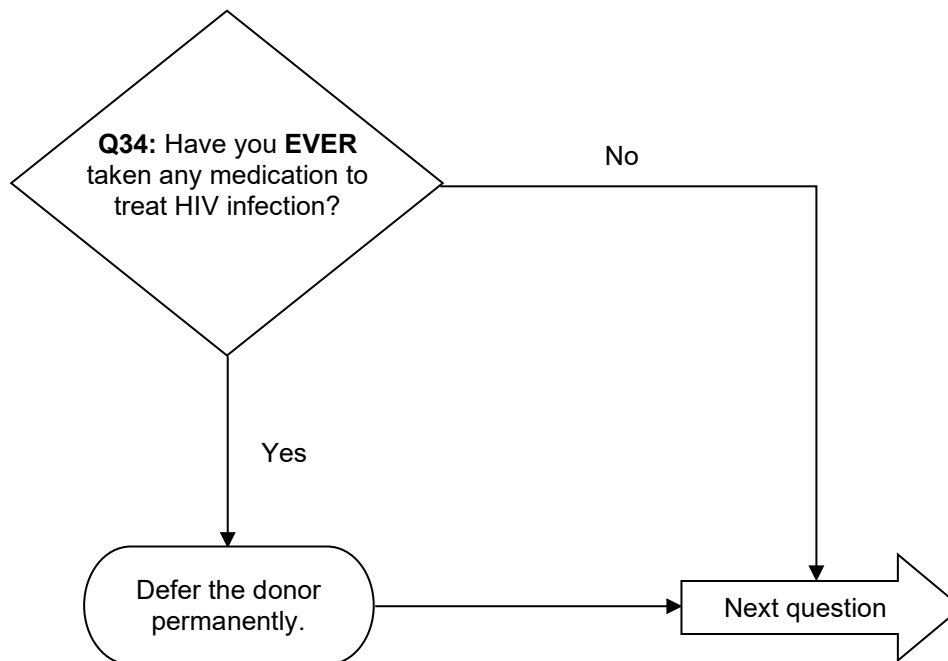
Question 34: Have you **EVER** taken any medication to treat HIV infection?

Donor Eligibility: An individual who has ever taken any medication to treat HIV infection (also known as antiretroviral therapy or ART medications) is permanently deferred. A person who is treated for HIV infection would also be permanently deferred based on Question 33, despite treatment with ART (*see important information below from HHS/NIH). ART medications do not cure HIV.

ART medications do not fully eliminate the virus from the body of an infected person. Blood donated by individuals taking ART to treat HIV can potentially still transmit HIV to a transfusion recipient. FDA has [confirmed](#) that “Undetectable = Untransmittable” **does not apply to transfusion transmission**. FDA-approved antiretroviral drugs are safe and effective in preventing sexual transmission of HIV. However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient.

[[FDA's 2023 HIV Guidance, 21 CFR 630.10\(d\)\(3\) and \(e\)\(2\)\(ii\)](#) and AABB's [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](#)]

Resolving Discrepant Responses: As described in [Association Bulletin #22-03](#), and the [DHQ v4.0 User Brochure](#), page 4, policies and SOPs must address the process to resolve discrepant responses. For example, a “No” response to Question #33 and a “Yes” response to Question #34 should be further evaluated during the donor screening process to resolve the discrepancy.



*From the [NIH CLINICAL INFO.HIV.gov Glossary](#):

Antiretroviral Therapy (ART): “The daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection. A person’s initial HIV regimen generally includes three antiretroviral (ARV) drugs from at least two different HIV drug classes.” ART for HIV may reduce a person’s [viral load](#) (defined as the amount of HIV present in a blood sample) to an undetectable level. An [undetectable viral load](#) means that the level of HIV in the blood may be too low to be detected by testing.

Undetectable does not mean a person is cured. Some HIV, in the form of [latent HIV reservoirs](#), remains inside cells and in body tissues. “Although ART can suppress HIV levels, ART cannot eliminate latent HIV reservoirs. For this reason, ART cannot cure HIV infection.”

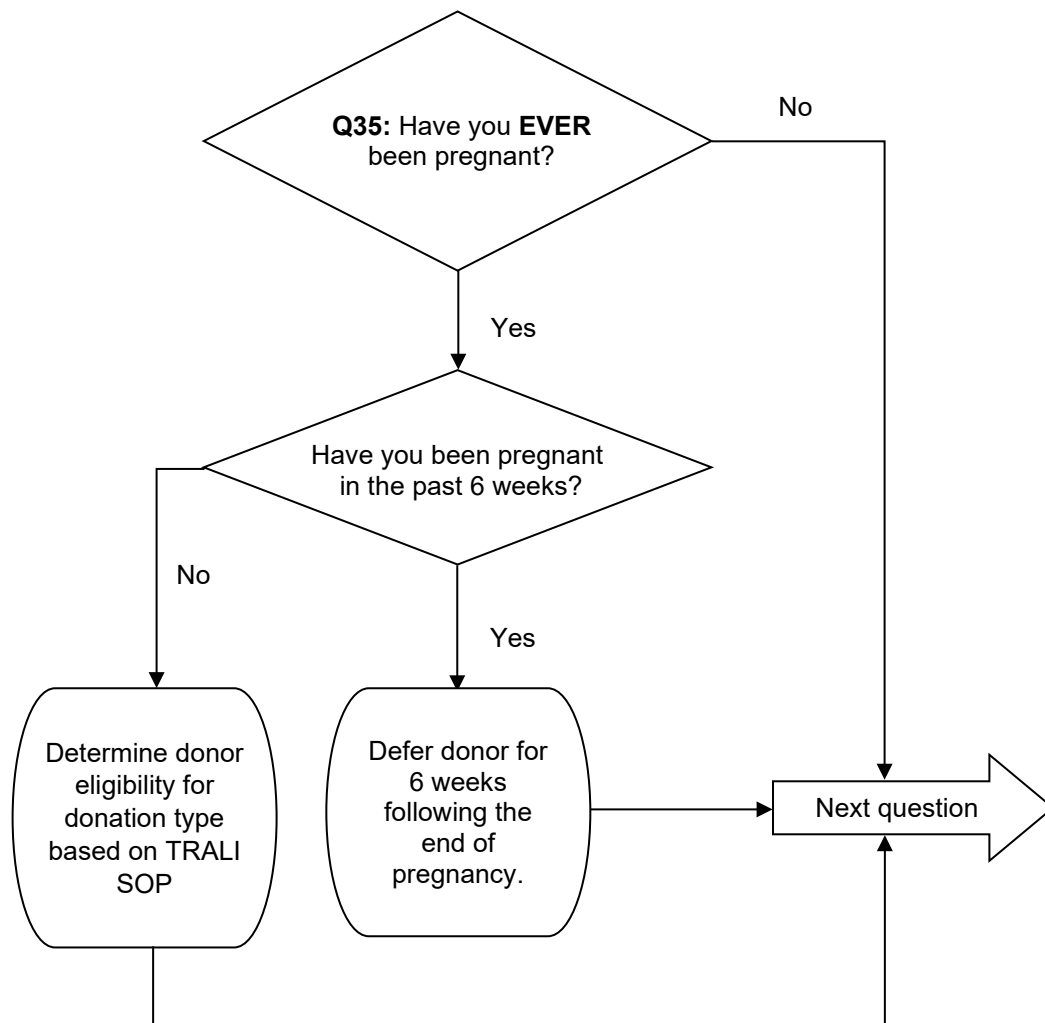
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Question 35: Have you **EVER** been pregnant?

Donor Eligibility: A donor who has been pregnant in the past 6 weeks is deferred for the safety of the donor. In addition, a donor who has had previous pregnancies is at risk for developing antibodies that can cause transfusion related acute lung injury (TRALI), a rare transfusion complication with a high fatality rate. SOPs should include additional donor eligibility criteria based on the blood establishment's TRALI risk mitigation strategy.

Note: The donor safety assessment for pregnancy on the day of donation is assessed by Question 4, "Are you pregnant now?"

[21 CFR 630.10(e)(2)(v), Current edition *Standards for Blood Banks and Transfusion Services* Std 5.4.1.3 and AABB's Association Bulletin #14-02, [TRALI Risk Mitigation for Plasma and Whole Blood for Allogeneic Transfusion](#)]

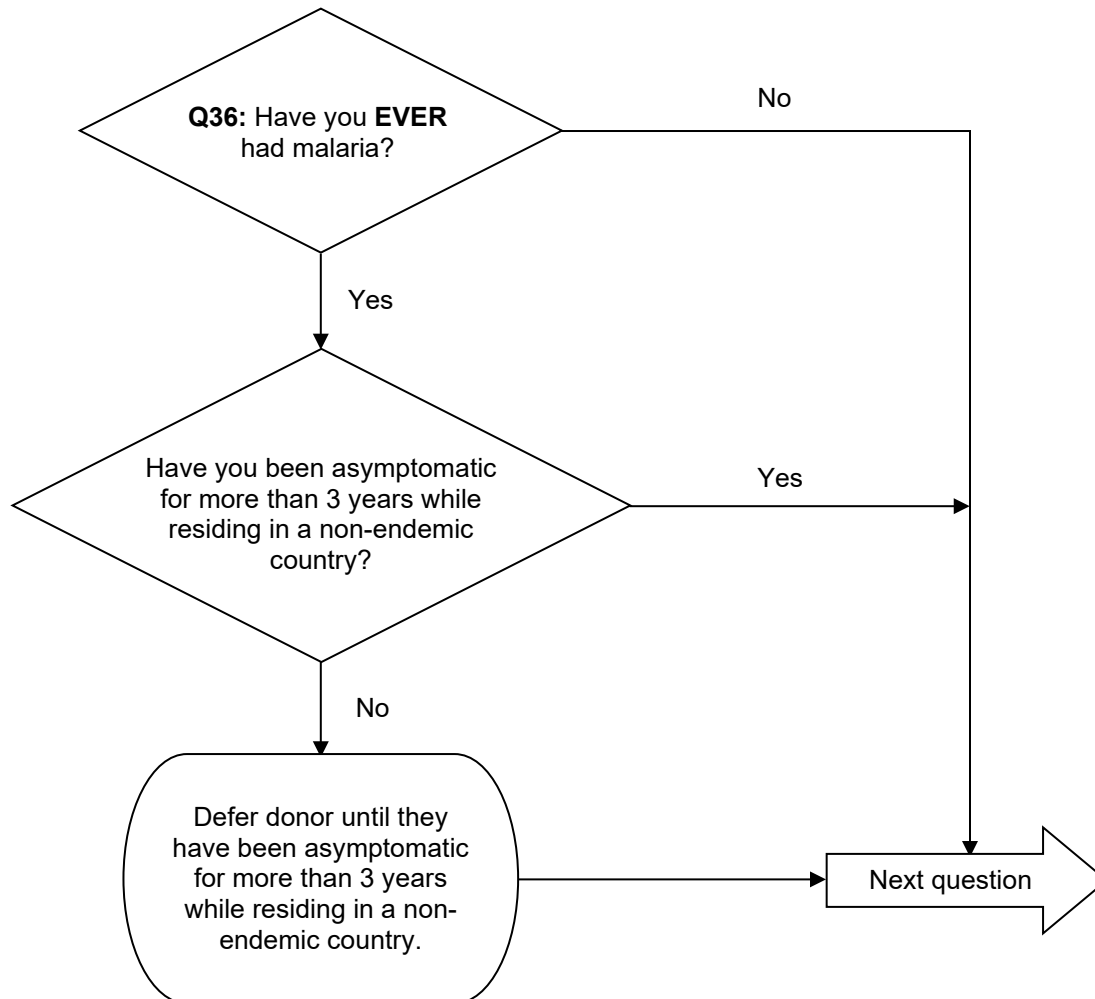


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Question 36: Have you **EVER** had malaria?

Donor Eligibility: A person who has had malaria is deferred for three years after becoming asymptomatic while residing in a non-endemic country. Malaria can be transmitted through blood transfusion.

[[21 CFR 630.10\(a\)\(2\), \(d\)\(3\)](#) and [FDA's December 2022 Malaria Guidance](#), IV.A.2.a, page 5 and IV.B.4, page 6]



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Question 37: Have you **EVER** received a dura mater (or brain covering) graft or xenotransplantation product?

Donor Eligibility: A person who has received a human cadaveric (allogeneic) dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and is permanently deferred. Autologous dura mater grafts are acceptable.

An **allogeneic** graft is when the graft donor and the recipient **are not** the same person.

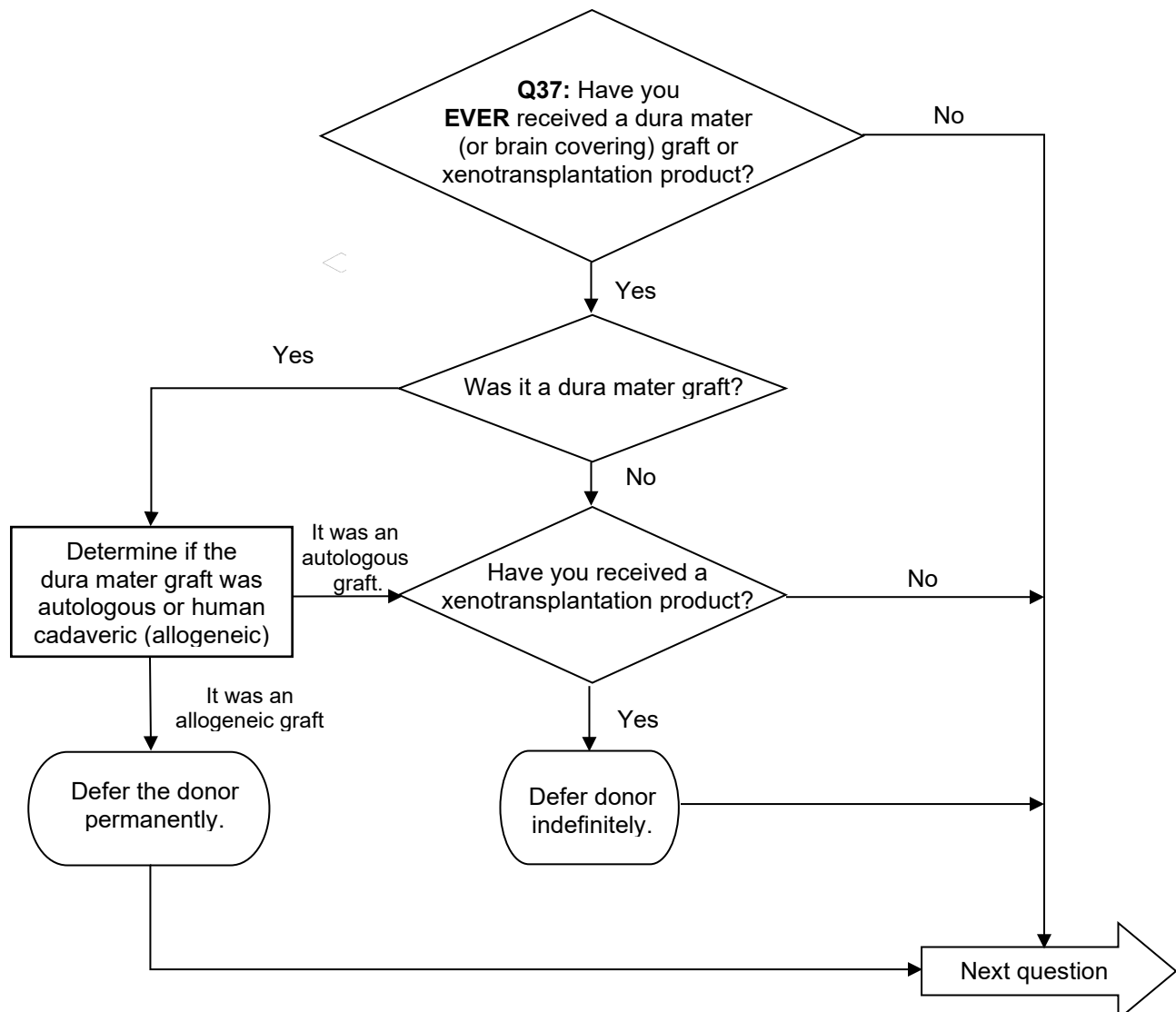
An **autologous** graft is when the graft donor and the recipient **are** the same person.

[21 CFR 630.10(d)(3), (e)(2)(vii) and FDA's May 2022 Guidance, [Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components](#), IV.A.1.a page 8 and IV.A.2.b, page 9]

A person who has received a xenotransplantation product is indefinitely deferred. Xenotransplantation is defined to include any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs. Xenotransplantation products include live cells, tissues or organs used in xenotransplantation.

Xenotransplantation definitions are provided in the [January 2001 PHS Guideline on Infectious Disease Issues in Xenotransplantation](#), page 4.

Note: Nonliving biological products or material from nonhuman animals, such as porcine heart valves and porcine insulin, are not classified as xenotransplantation products for the purposes of this definition.



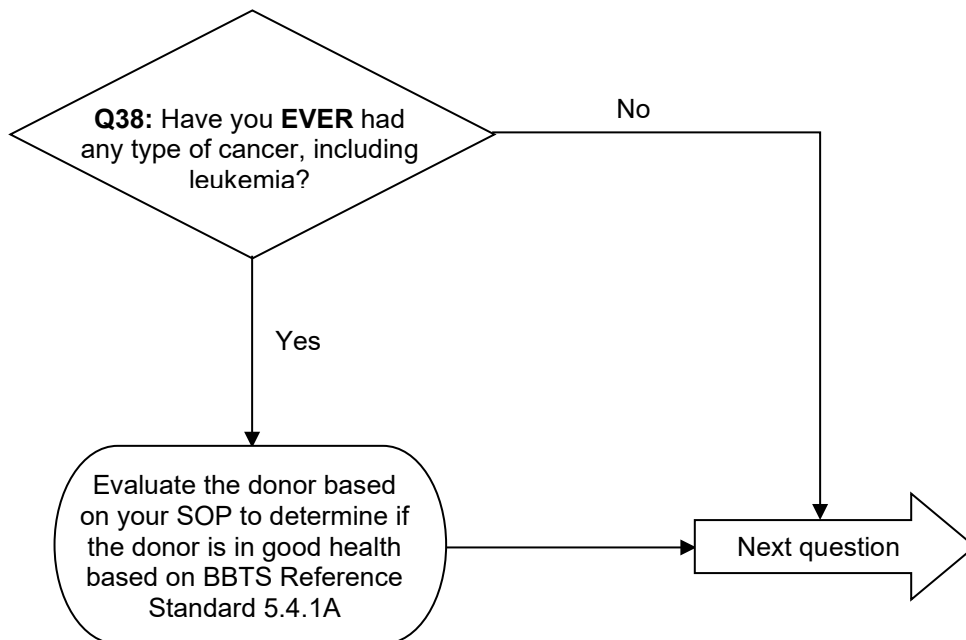
BLOOD DHQ v4.0 FLOWCHARTS

Question 38: Have you **EVER** had any type of cancer, including leukemia?

Donor Eligibility: To be eligible to donate, a donor must be in good health on the day of donation. Each blood establishment should define a deferral policy and SOPs to address a donor's history of cancer based on the medical judgement of the responsible physician.

When developing deferral policies and SOPs blood collection establishments may consider information on Blood-Center-Defined Donor Eligibility Criteria – Cancer, in the current edition AABB Technical Manual on pages 133-134.

[Current edition Standards for Blood Banks and Transfusion Services Reference Standard 5.4.1A-Requirements for Allogeneic Donor Qualification, 10) Medical History and General Health]



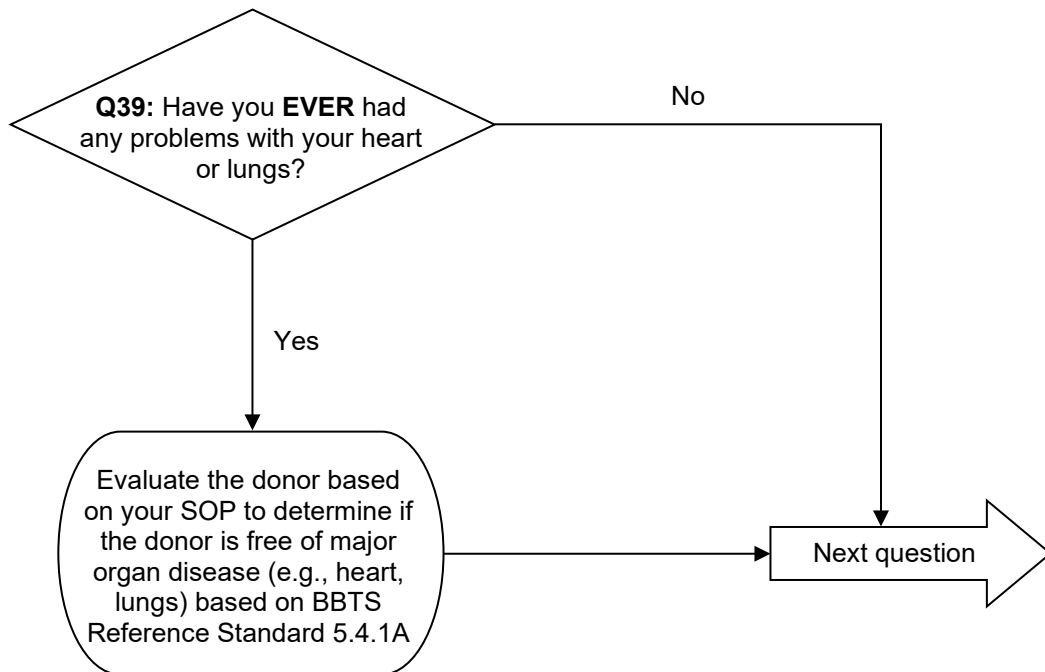
BLOOD DHQ v4.0 FLOWCHARTS

Question 39: Have you **EVER** had any problems with your heart or lungs?

Donor Eligibility: To be eligible to donate, a donor must be in good health on the day of donation. Each blood establishment should define a deferral policy and SOPs to address a donor's history for problems with their heart or lungs based on the medical judgement of the responsible physician.

When developing deferral policies and SOPs, blood collection establishments may consider information on Blood-Center-Defined Donor Eligibility Criteria in the current edition AABB Technical Manual – Heart and Lung Conditions, on pages 134-135.

[[21 CFR 630.10\(a\)\(1\), \(d\)\(3\), \(e\)\(2\)\(i\)](#), and Current edition Standards for Blood Banks and Transfusion Services Reference Standard 5.4.1A-Requirements for Allogeneic Donor Qualification, 10) Medical History and General Health]

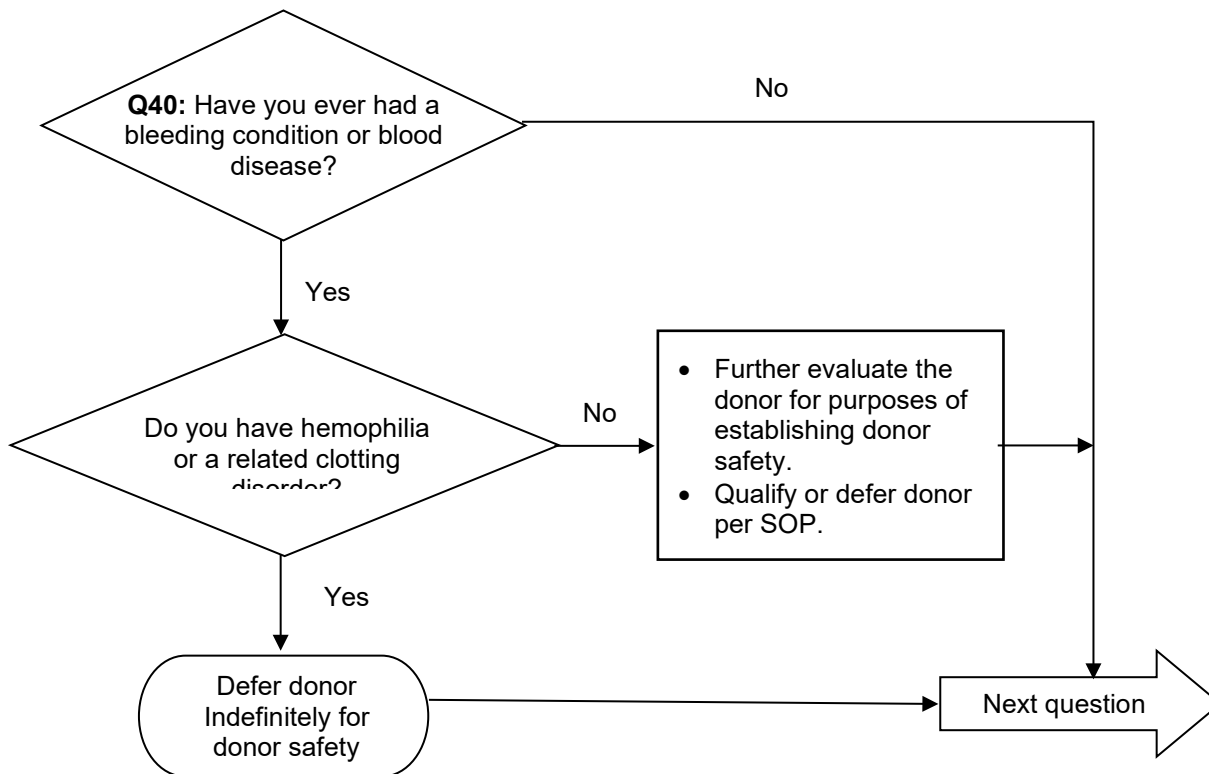


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Question 40: Have you ever had a bleeding condition or blood disease?

Donor Eligibility: A person with hemophilia or related clotting factor deficiency should be indefinitely deferred “for reasons of donor safety”, as recommended in [FDA’s 2023 HIV Guidance](#). FDA notes that this deferral is not based on HIV risk.

[21 CFR 630.10(a)(1), (d)(3) and [FDA’s 2023 HIV Guidance](#)]



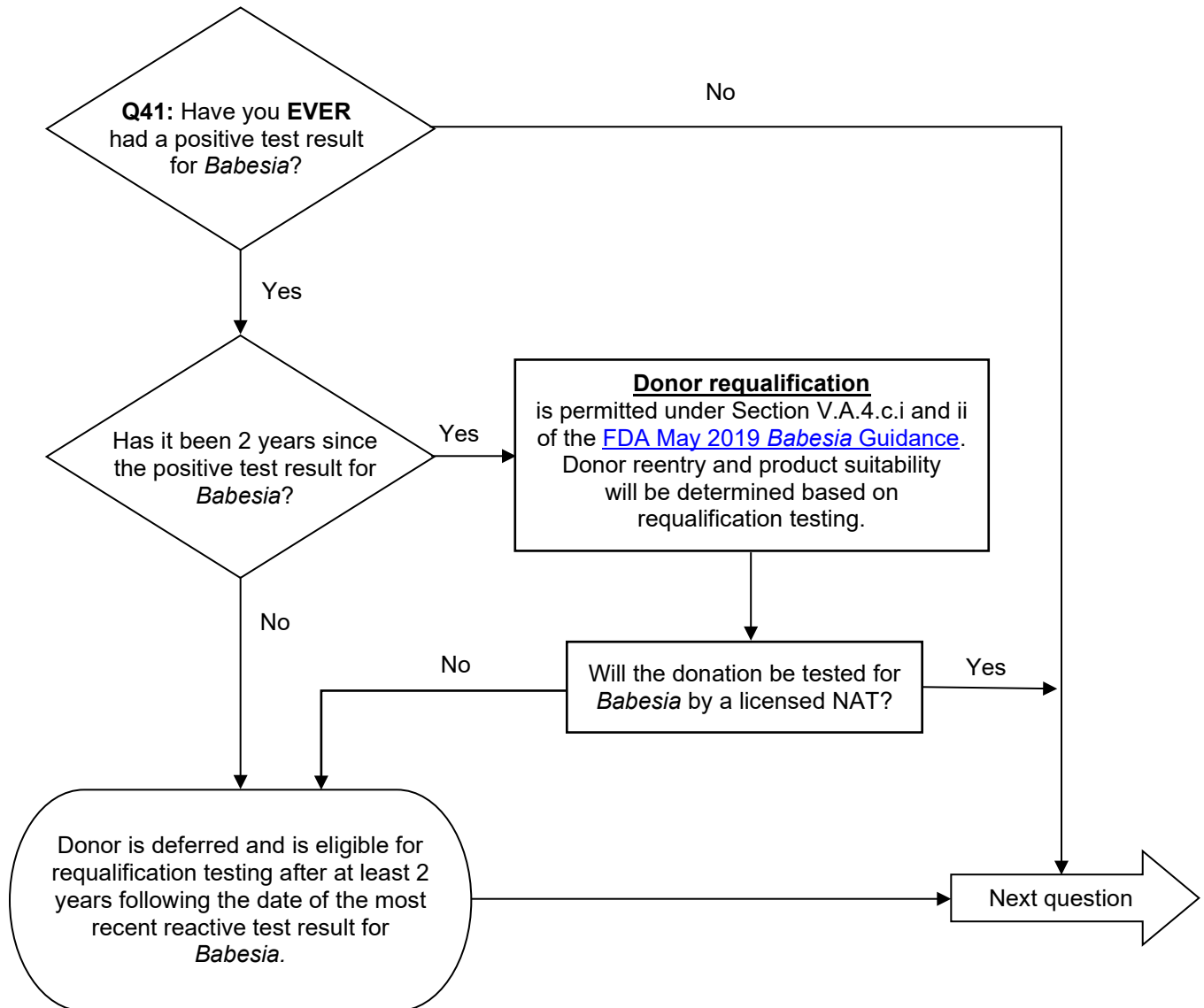
BLOOD DHQ v4.0 FLOWCHARTS

This question may be removed if *Babesia* testing is performed*.

Question 41: Have you **EVER** had a positive test result for *Babesia*?

Donor Eligibility: A person who has had a positive test result for *Babesia* is deferred indefinitely or for at least 2 years from the date of the most recent reactive test result. This includes both donor screening and diagnostic tests. In states where testing for *Babesia* is NOT REQUIRED by the 2019 FDA Guidance, the donation is **permitted only if testing is performed on the donation** as a part of the requalification process permitted under V.A.4.c.i and ii.

[*FDA's May 2019 Guidance, [Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis](#), V.A.4.a-c, page 8 and [21 CFR 630.10\(d\)\(3\)](#)]



AABB members may access AABB's [Babesia Toolkit](#) to consider additional information on donor deferral and reentry.