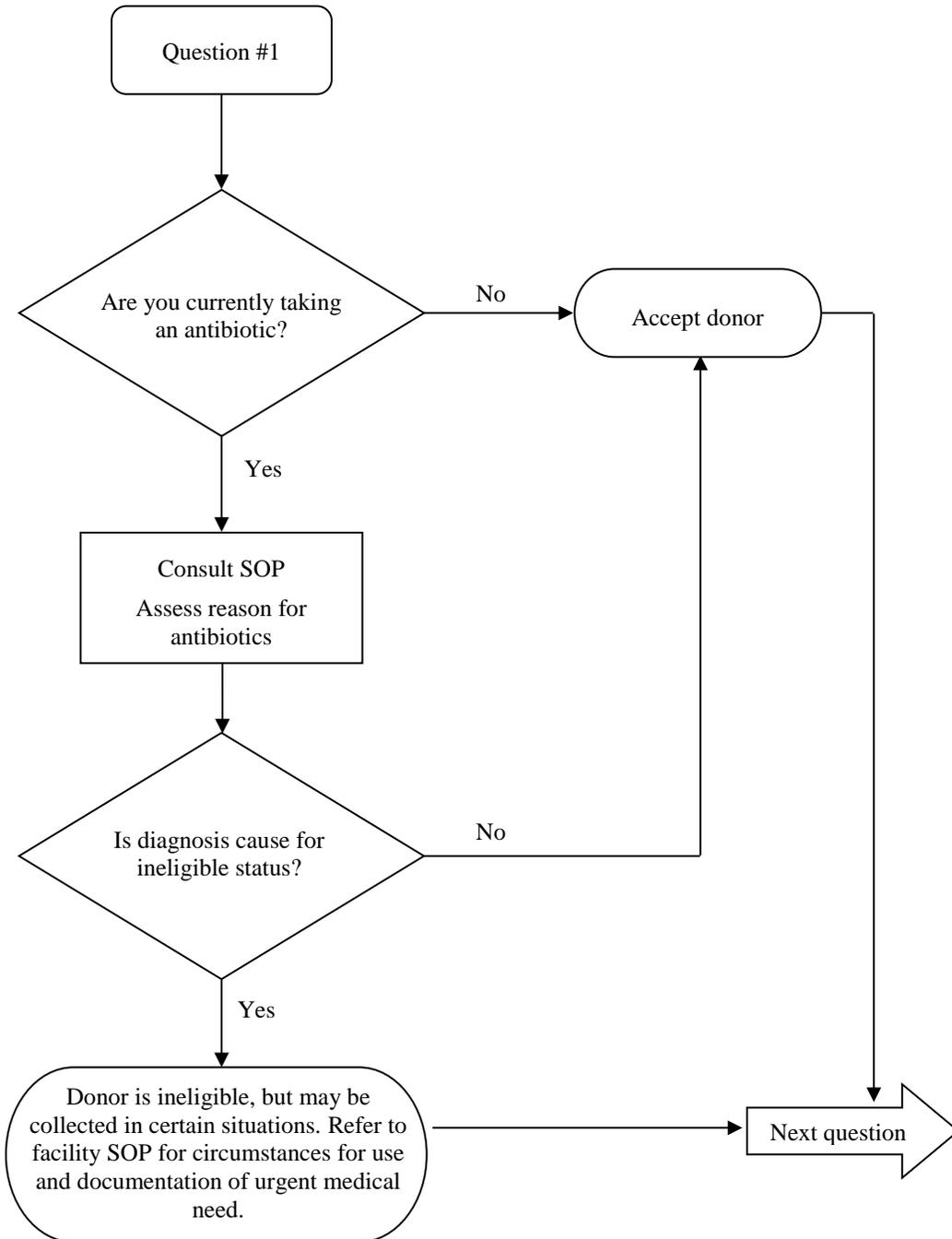


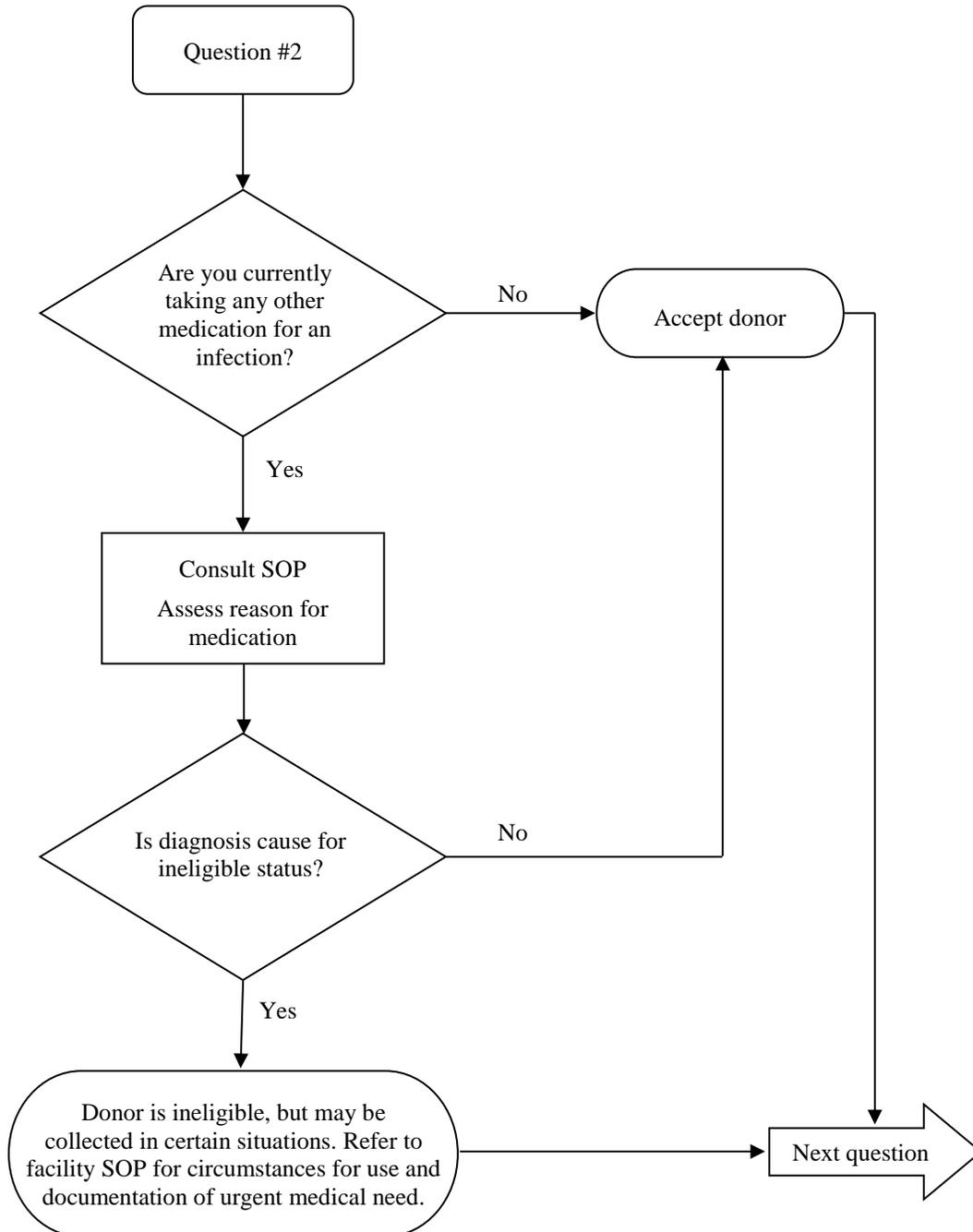
Question: 1. Are you currently taking an antibiotic?

Donor Eligibility: A donor with an infection that could cause bacteremia/sepsis or other relevant communicable disease should not donate. The reason for antibiotic use must be evaluated to determine if the donor has a bacterial infection that could be transmissible by HCT/Ps.



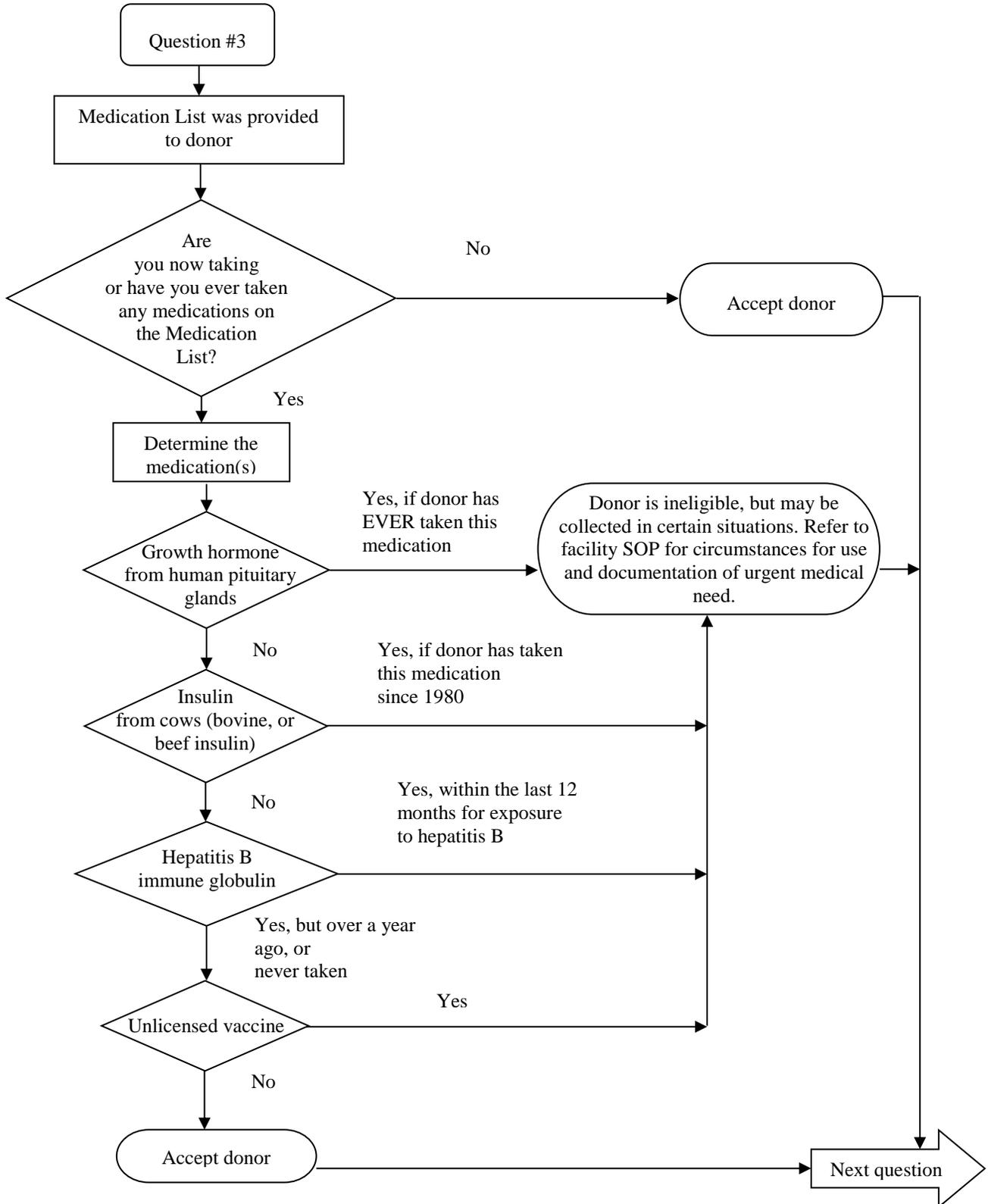
Question: 2. Are you currently taking any other medication for an infection?

Donor Eligibility: A donor with an infection that could cause bacteremia/sepsis or other relevant communicable disease should not donate. The reason for medication use must be evaluated to determine if the donor has an infection that could be transmissible by HCT/Ps.



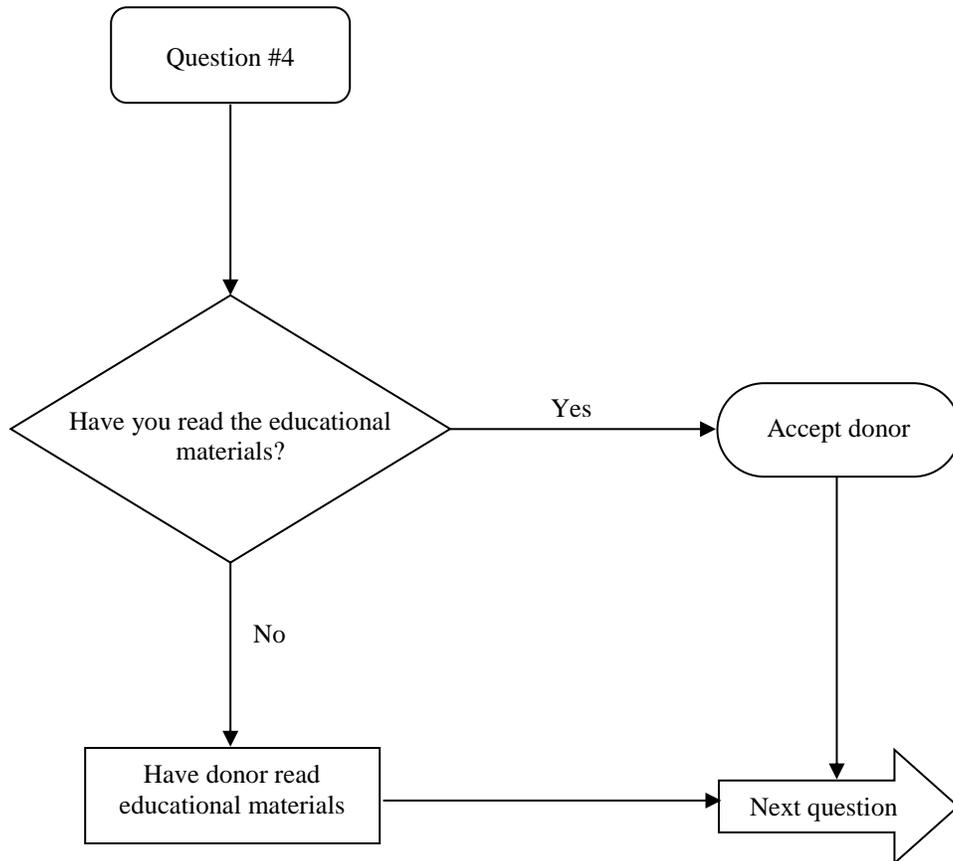
Question: 3. Are you now taking or have you ever taken any medications on the Medication List?

Donor Eligibility: Donors taking certain designated medications, currently or in the past are ineligible to donate HCT/Ps.



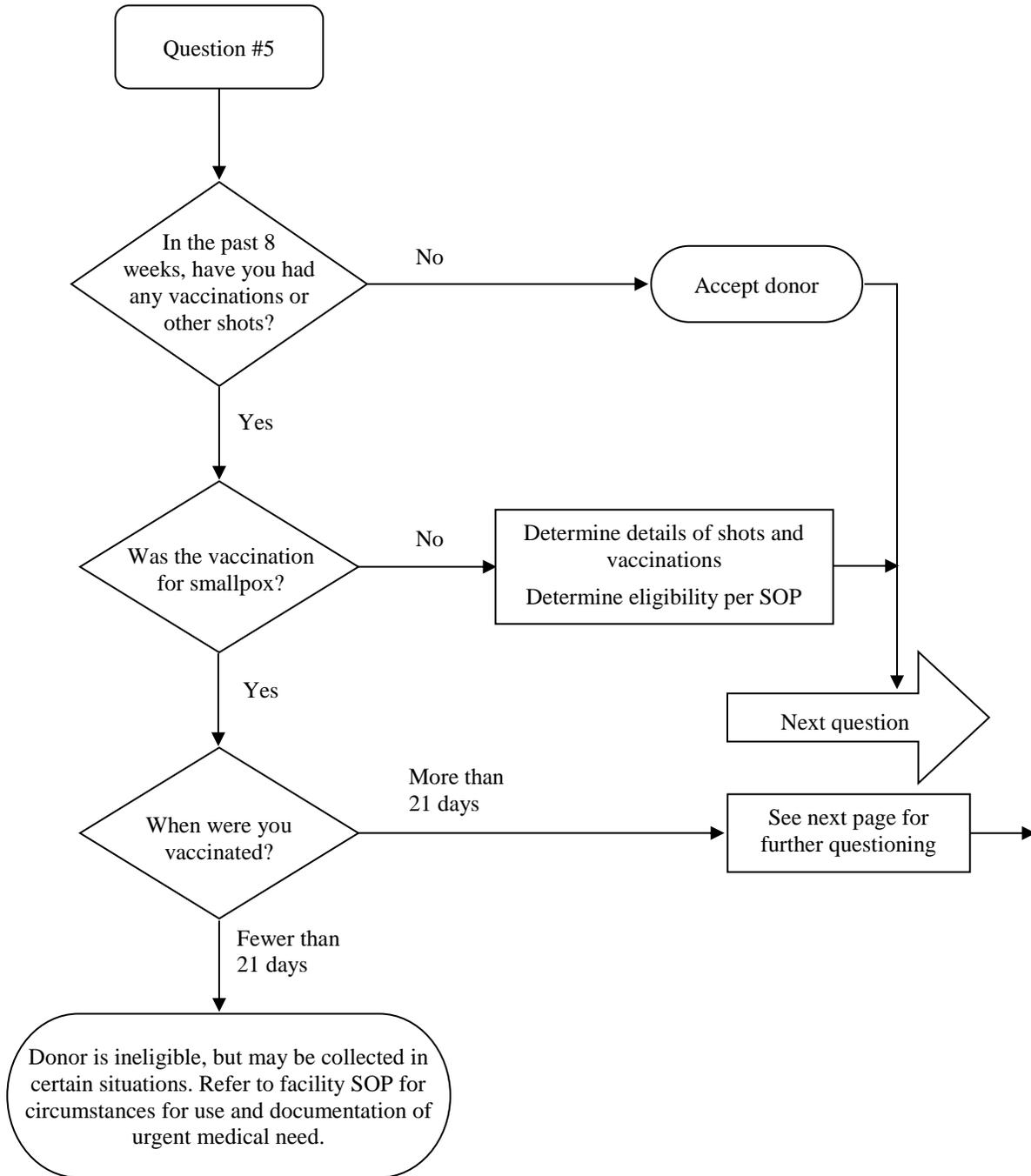
Question: 4. Have you read the educational materials?

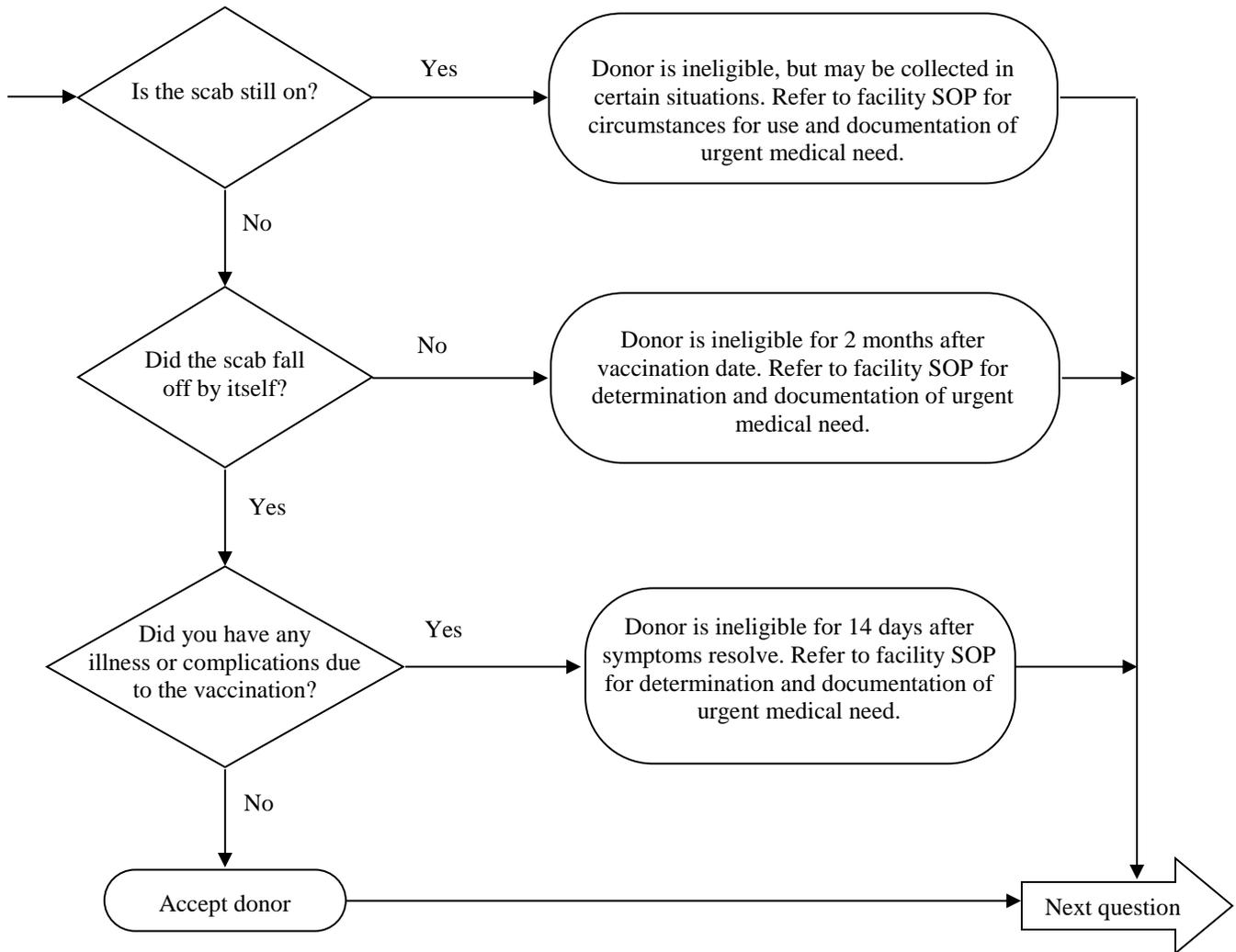
Donor Eligibility: Donors must read the educational materials prior to donating and have an opportunity to have their questions answered.



Question: 5. In the past 8 weeks, have you had any vaccinations or other shots?

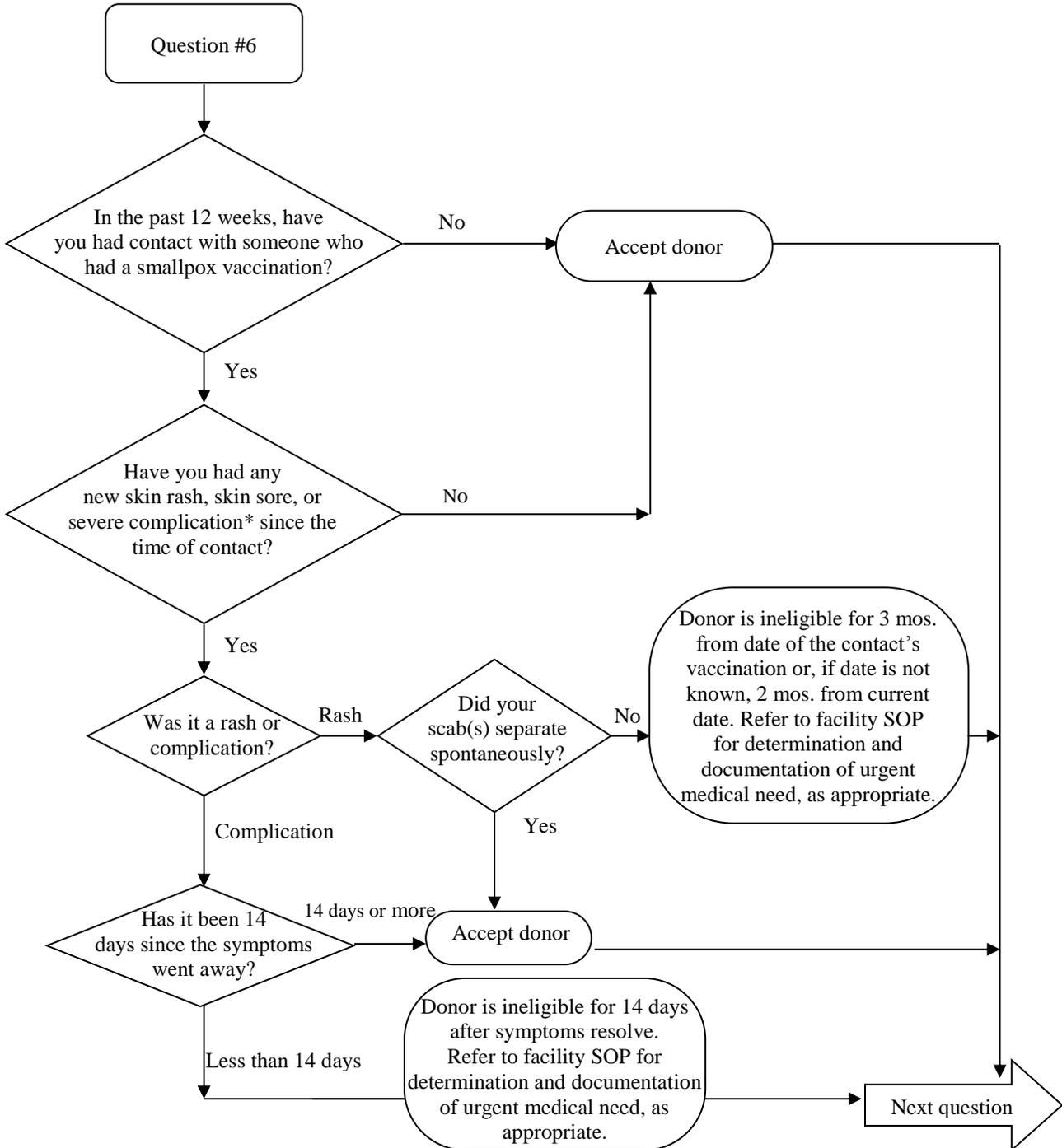
Donor Eligibility: Certain vaccinations may contain live infectious agents. A donor who has been exposed to a live infectious agent via vaccination is ineligible for a specified period of time.





Question: 6. In the past 12 weeks, have you had contact with someone who had a smallpox vaccination?

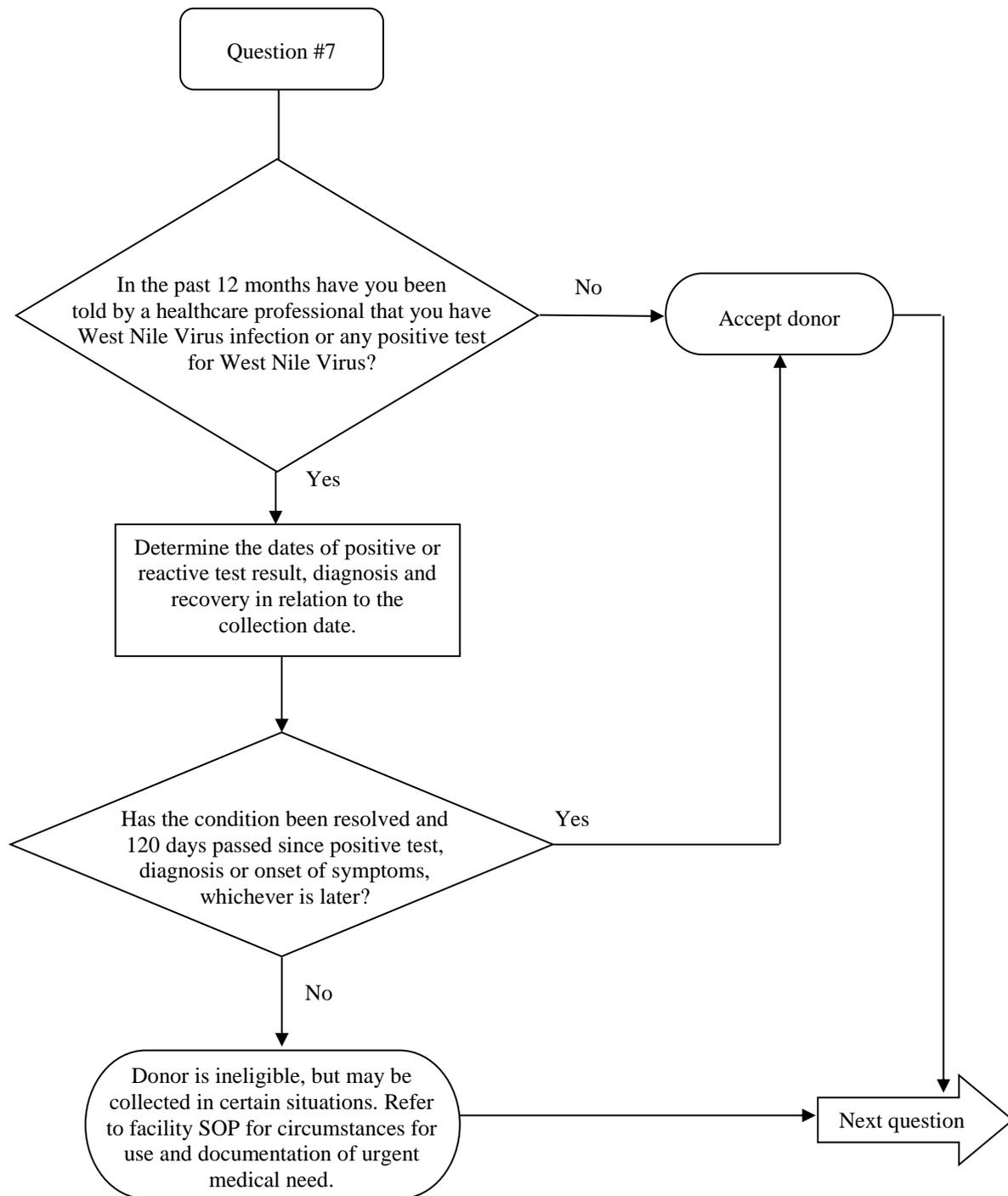
Donor Eligibility: Certain vaccinations may contain live infectious agents. A donor who has had close contact with the vaccination site, bandages covering the vaccination site or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live infectious agents and is ineligible for a specified period of time. See Glossary for specifics.



*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.

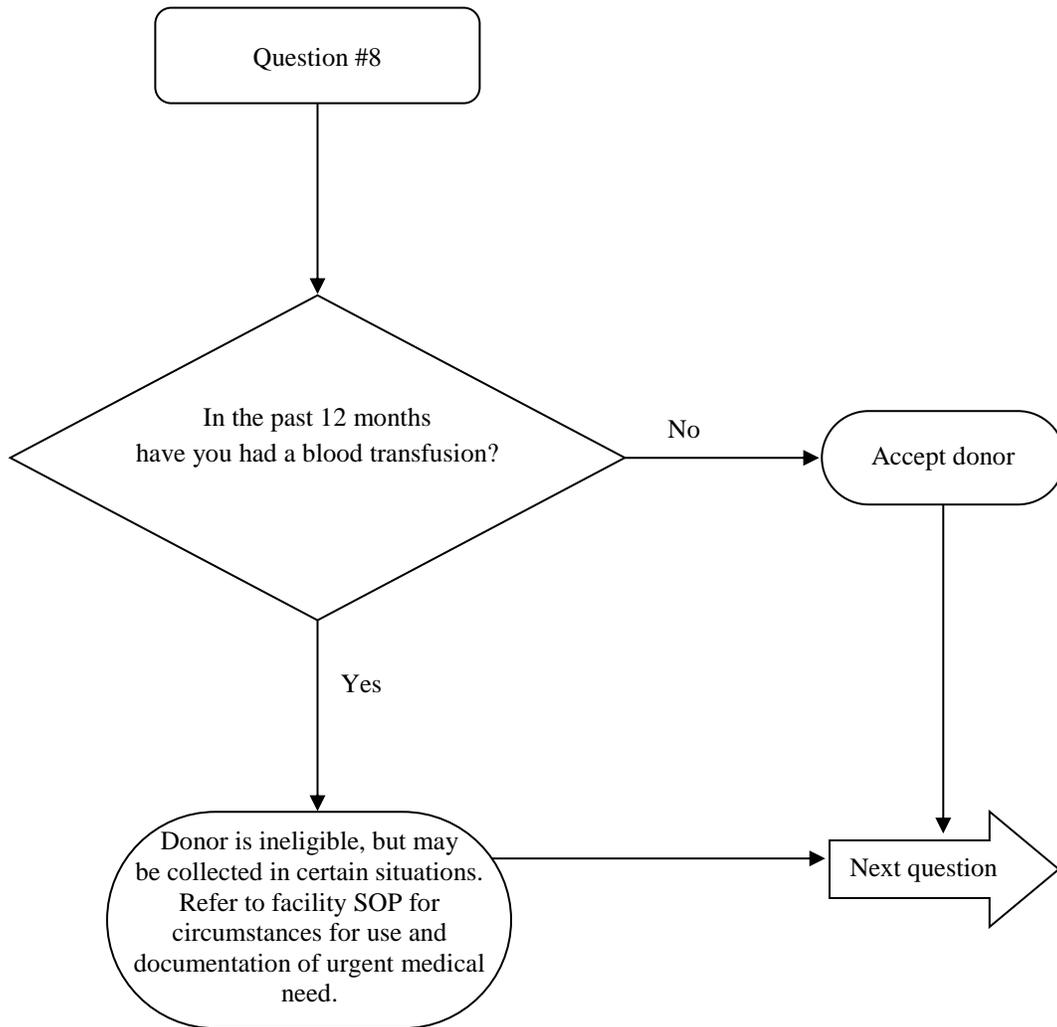
Question: 7. In the past 12 months have you been told by a healthcare professional that you have West Nile Virus infection or any positive test for West Nile Virus?

Donor Eligibility: FDA recommends waiting to collect HCT/Ps from the donor until the condition is considered to be resolved and at least 120 days from the positive test, or onset of symptoms or diagnosis, whichever is the later date.



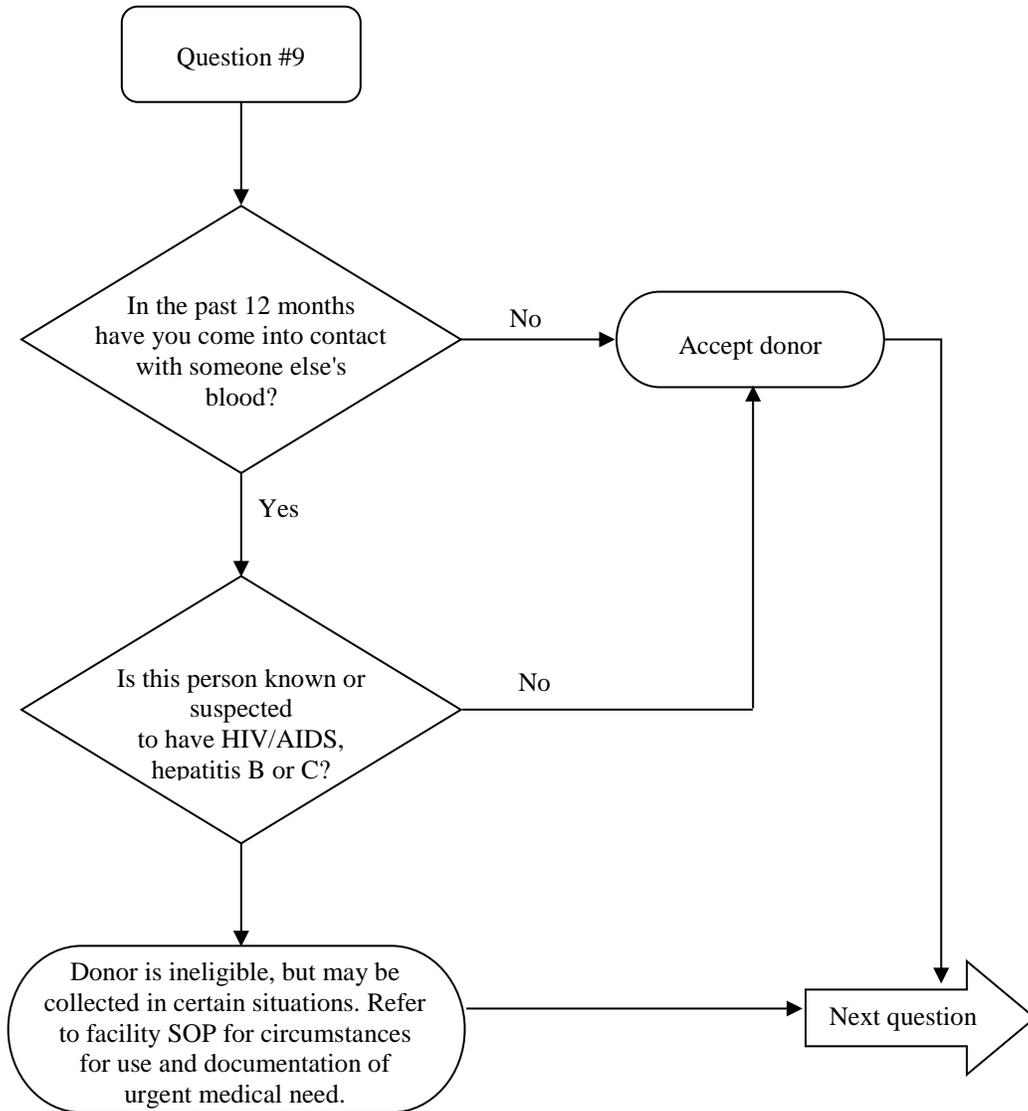
Question: 8. In the past 12 months have you had a blood transfusion?

Donor Eligibility: A donor who has received an allogeneic transfusion of blood, platelets, plasma or other blood component should be carefully evaluated for eligibility to donate HCT/Ps following the transfusion, due to possible transmissibility of infectious disease.



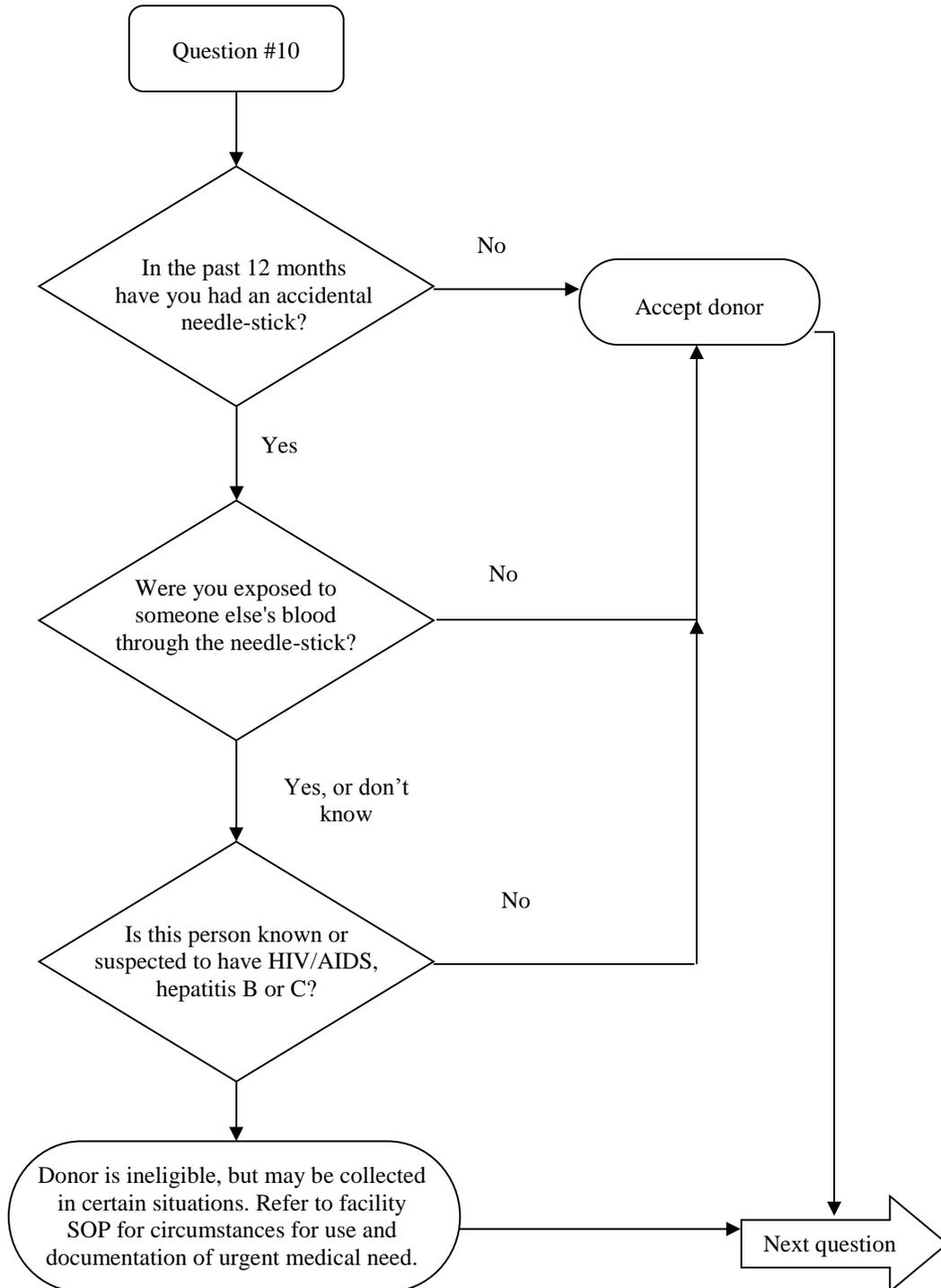
Question: 9. In the past 12 months have you come into contact with someone else's blood?

Donor Eligibility: Persons who have had one of the following during the preceding 12 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, are ineligible for 12 months from the date of exposure. Infectious disease may be spread through contact with blood.



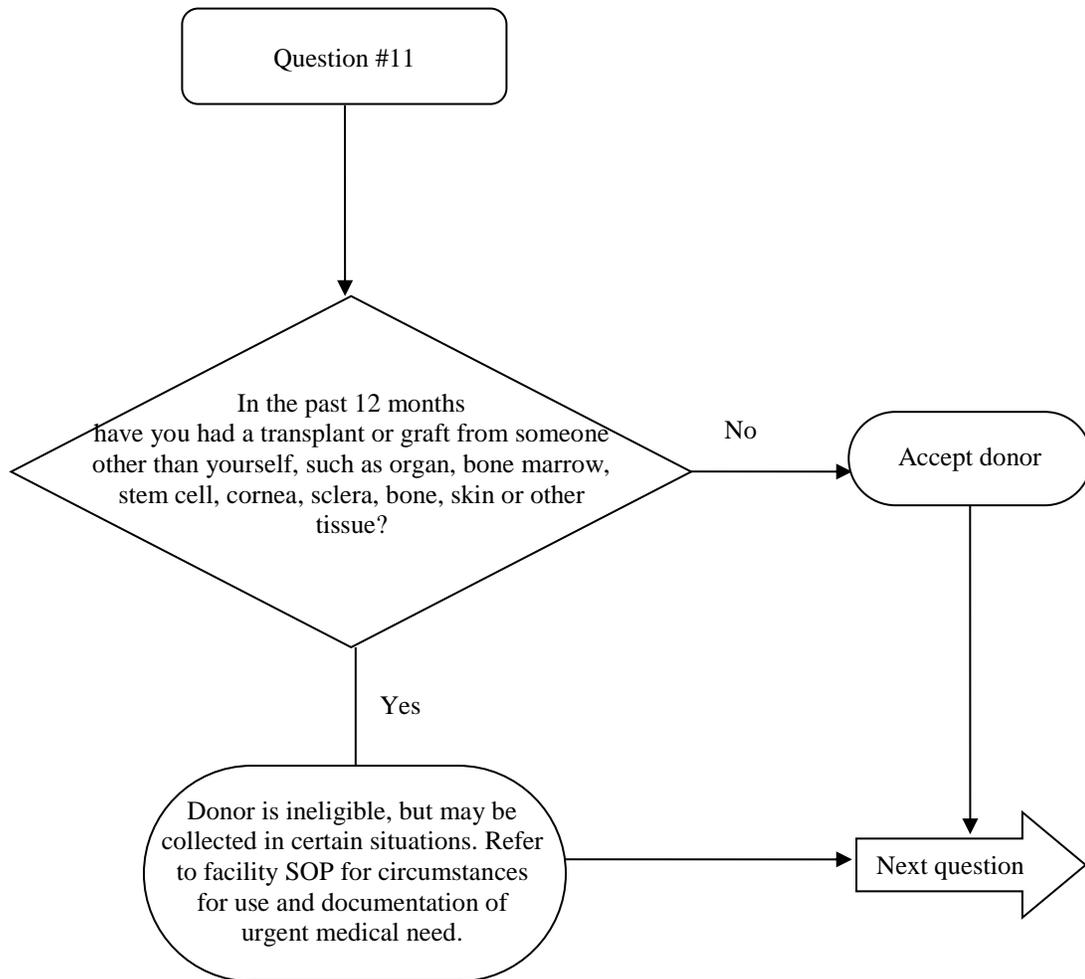
Question: 10. In the past 12 months have you had an accidental needle-stick?

Donor Eligibility: A donor who has been exposed to someone else's blood through a needle-stick is ineligible to donate HPC, Apheresis and HPC, Marrow for 12 months following exposure, due to possible transmissibility of infectious disease.



Question: 11. In the past 12 months have you had a transplant or graft from someone other than yourself, such as organ, bone marrow, stem cell, cornea, sclera, bone, skin or other tissue?

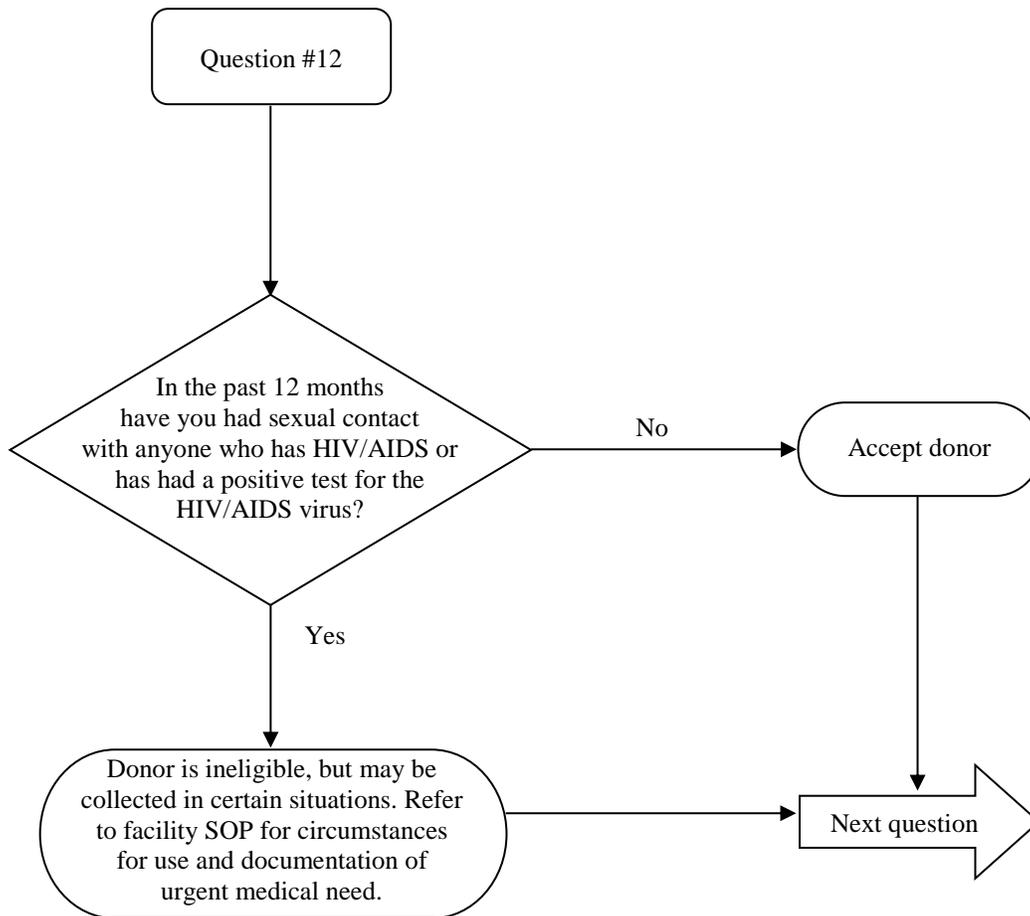
Donor Eligibility: A donor who has received an allogeneic transplant or graft should be carefully evaluated for eligibility to donate HPC, Apheresis, HPC, Marrow following the transfusion, due to possible transmissibility of infectious disease.



Question: 12. In the past 12 months have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?

Donor Eligibility: Persons who have had sexual contact with persons with clinical or laboratory evidence of HIV infection are ineligible for 12 months from the date of last contact. HIV may be transmitted through sexual contact with an infected person.

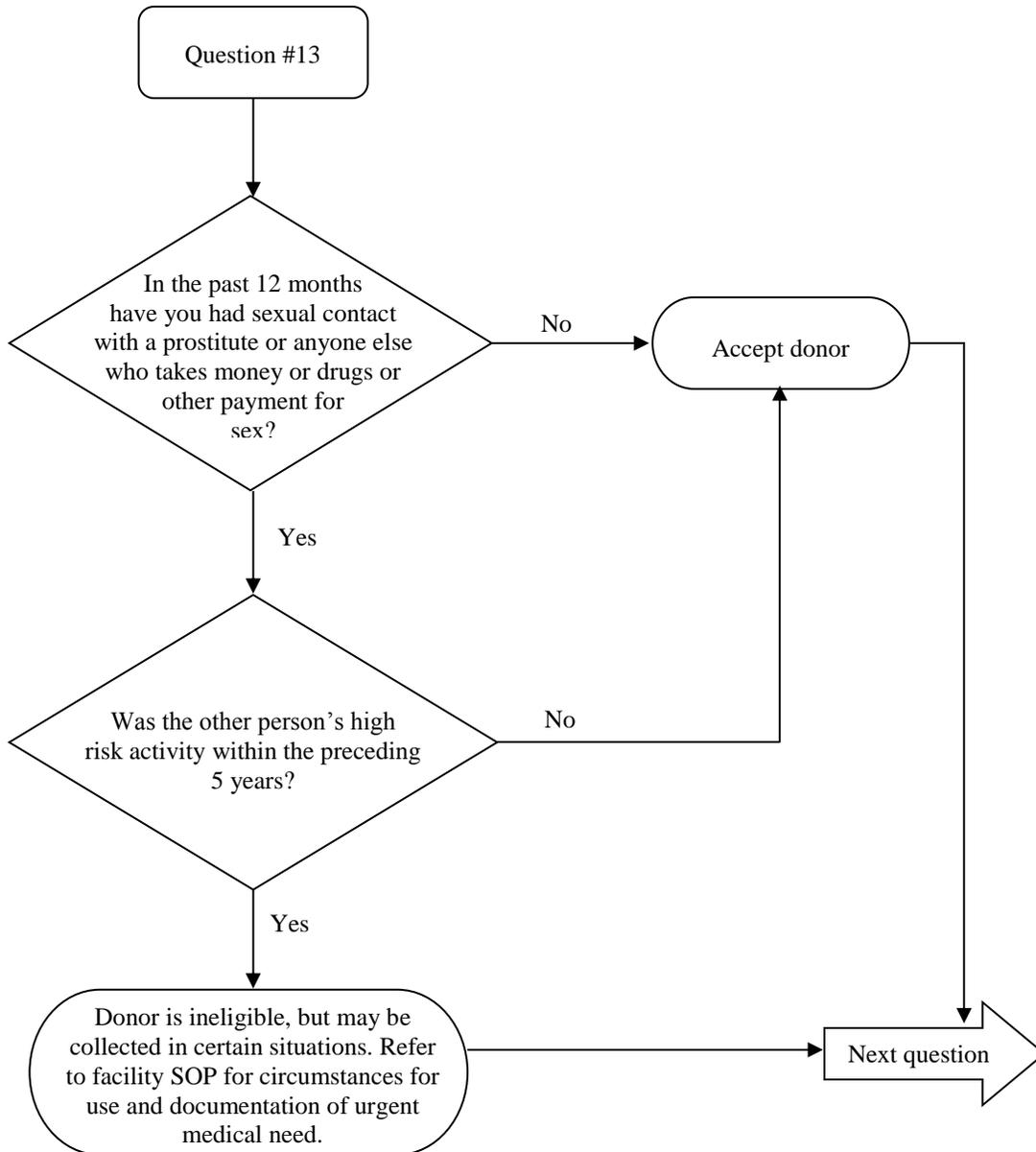
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 13. In the past 12 months have you had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?

Donor Eligibility: Persons who have had sexual contact with anyone who has taken money or drugs or other payment for sex in the preceding 5 years are ineligible for 12 months from the date of the last sexual contact. HIV and other diseases 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 educational materials provided.

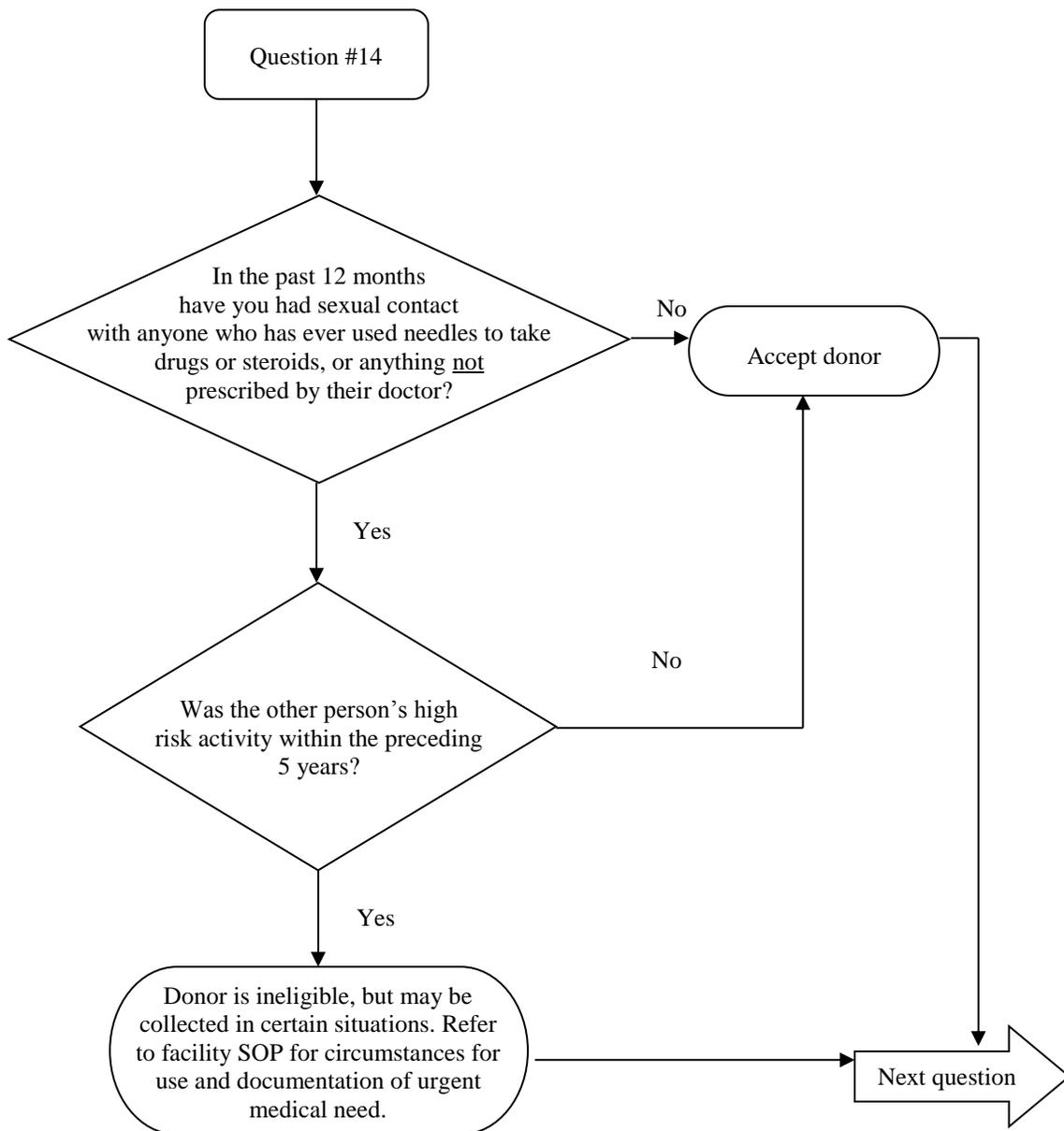


Question: 14. In the past 12 months have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?

Donor Eligibility: Persons who have had sexual contact with persons who have used needles to take drugs, steroids, or anything not prescribed by their doctor in the preceding 5 years are ineligible for 12 months from the date of the last sexual contact. HIV and other diseases 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 educational materials provided.

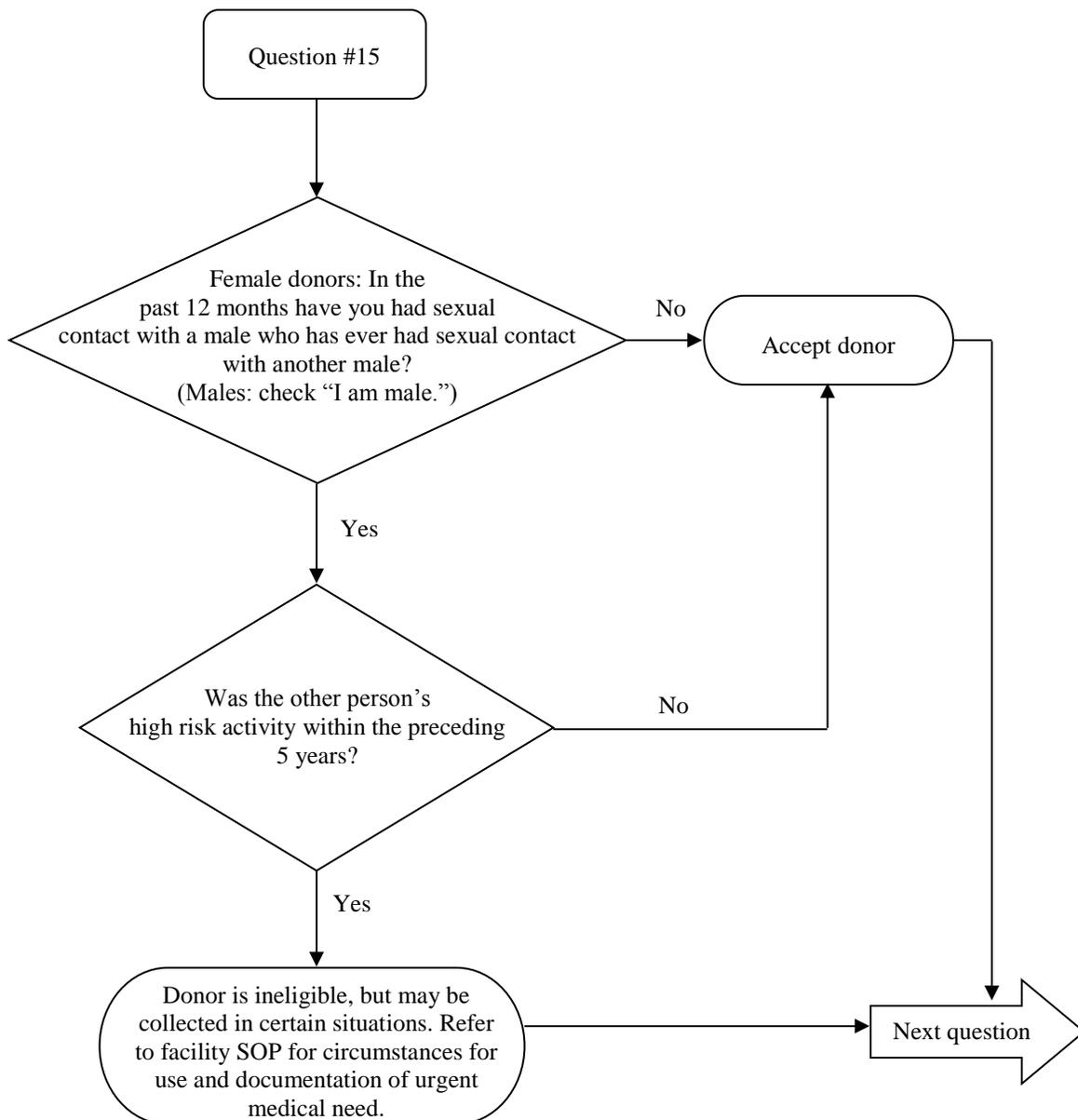
Note: The phrase "use of a needle" includes intravenous use, "skin popping" (injection under the skin), "mainlining" (arterial injection) and any other use of a needle to administer drugs, steroids or anything else not prescribed by their doctor.



Question: 15. Female donors: In the past 12 months have you had sexual contact with a male who has ever had sexual contact with another male? (Males: check “I am male.”)

Donor Eligibility: Women who have had sexual contact with men who have had sexual contact with another man even one time in the preceding 5 years are ineligible for 12 months from the date of last sexual contact. HIV and other diseases may be transmitted through sexual contact.

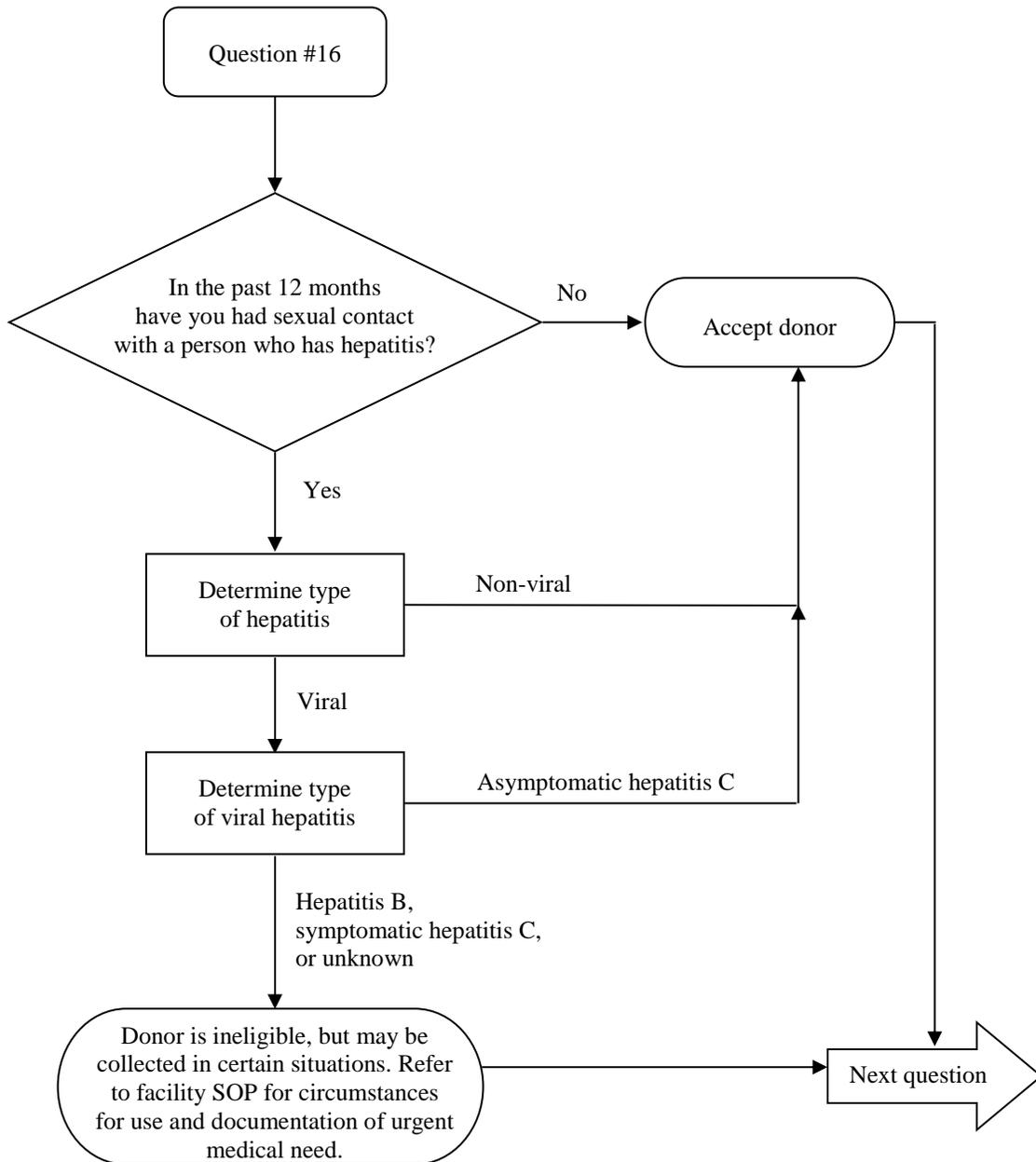
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 16. In the past 12 months have you had sexual contact with a person who has hepatitis?

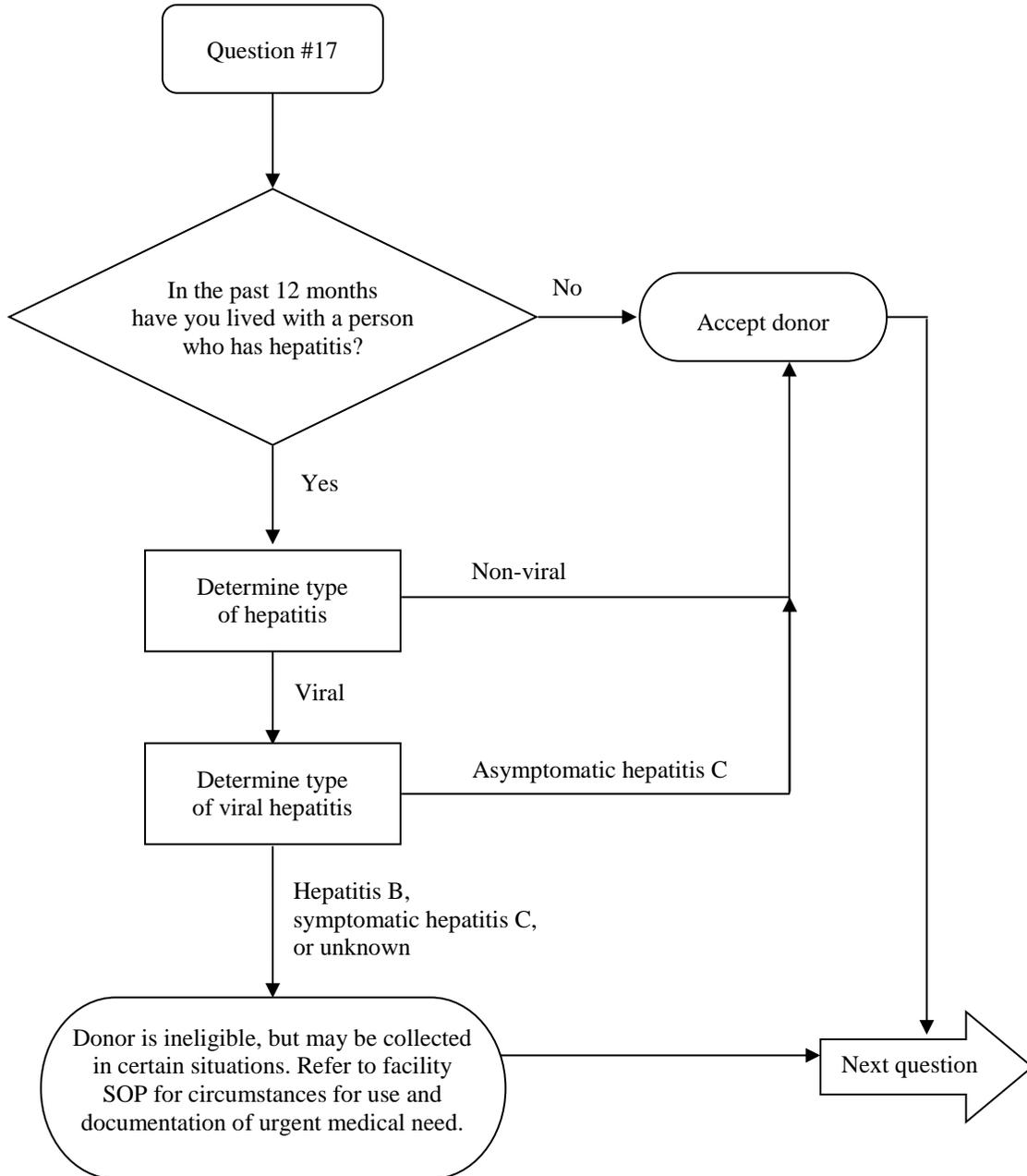
Donor Eligibility: Persons who report having had sexual contact with a person who has viral hepatitis are ineligible for 12 months from the time of last exposure. Hepatitis, particularly hepatitis B, may be spread through sexual contact. Hepatitis C, although potentially a concern, is not frequently spread by sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 17. In the past 12 months have you lived with a person who has hepatitis?

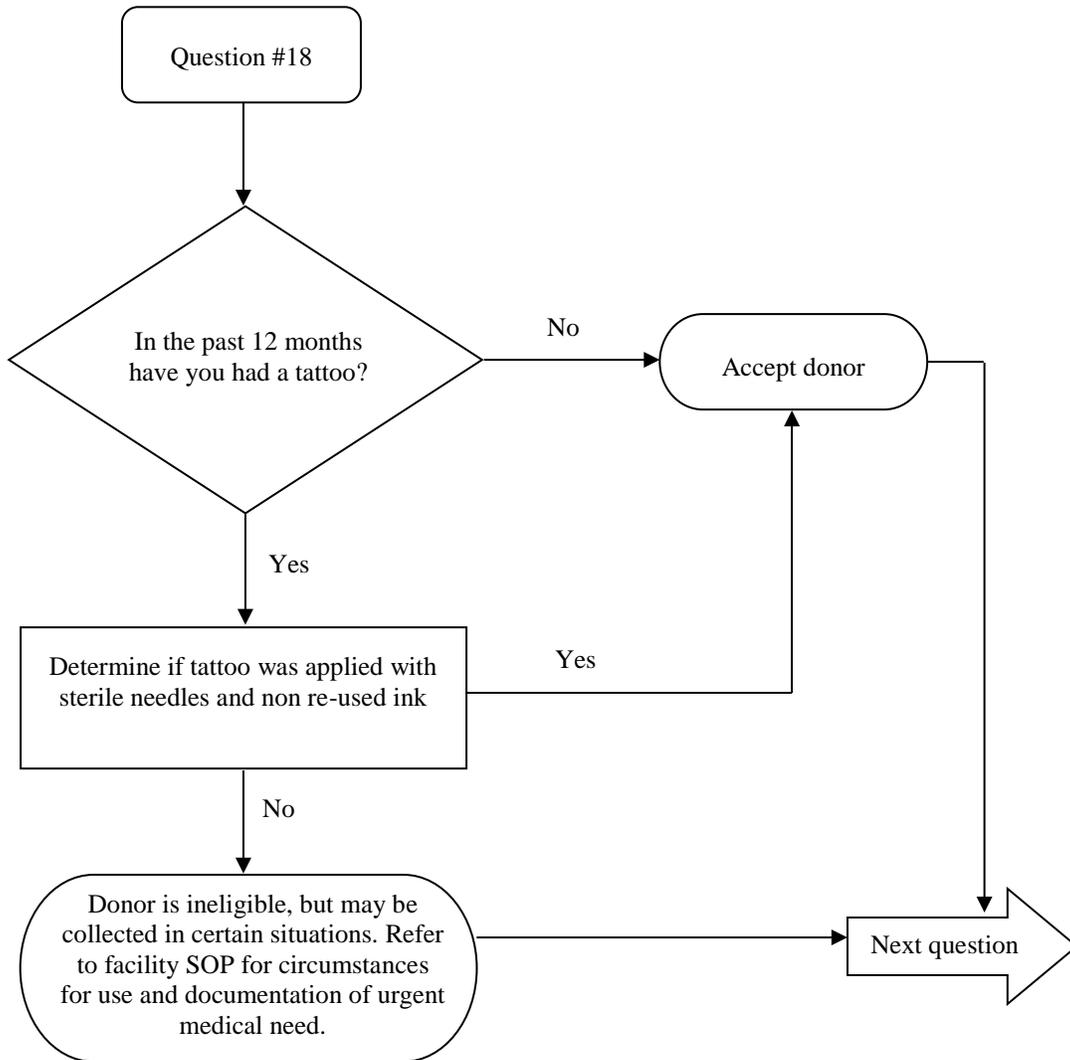
Donor Eligibility: In certain cases, living with a person with viral hepatitis puts the donor at risk for acquiring viral hepatitis as well (definition of living with is residing in the same dwelling. EXAMPLES: house, dormitory, apartment).



Question: 18. In the past 12 months have you had a tattoo?

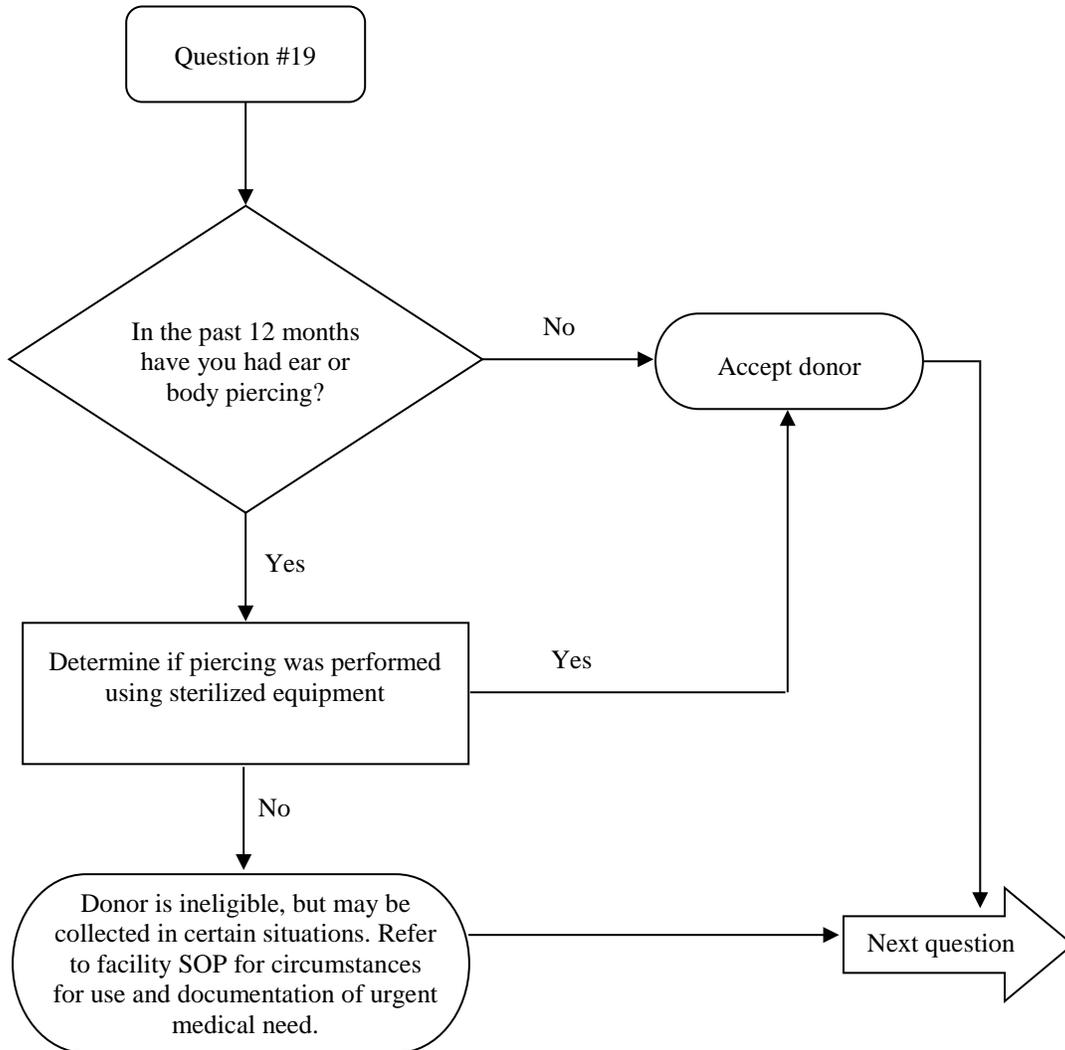
Donor Eligibility: Persons who have had a tattoo in the previous 12 months are ineligible for 12 months from the date of the tattoo application, unless applied by a state regulated entity with sterile needles and non re-used ink. Unless tattoos have been applied using sterile needles and non re-used ink, there may be a risk of transmission of infectious disease.

Note: Tattoos include tattoo "touch ups", tattoos applied by oneself, and those applied by others.



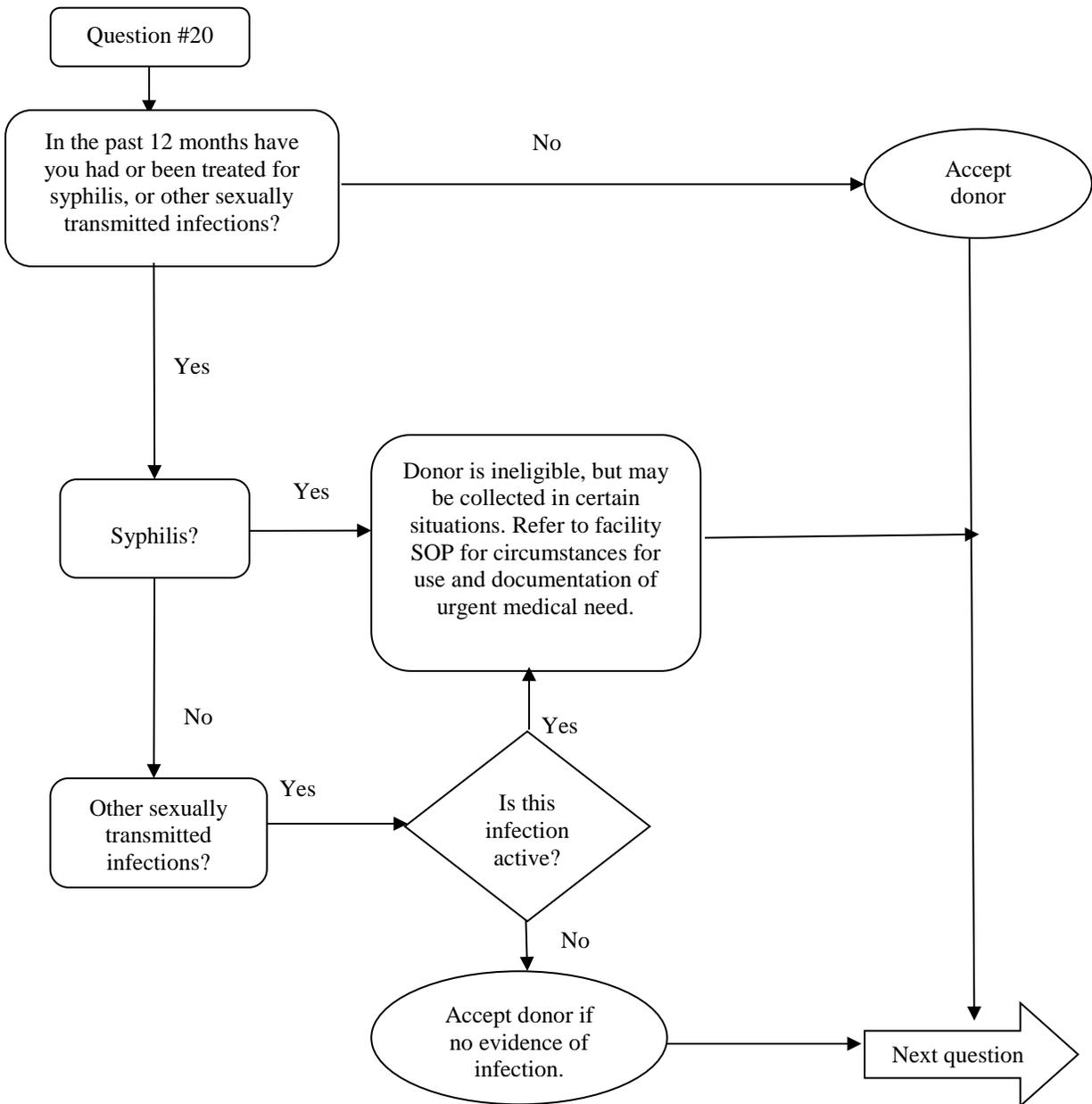
Question: 19. In the past 12 months have you had ear or body piercing?

Donor Eligibility: Persons who have had ear or body piercing during the previous 12 months are usually ineligible for 12 months from the date of the procedure. Unless ear or body piercing has been done using single-use equipment, there may be a risk of transmission of infectious disease.



Question: 20. In the past 12 months have you had or been treated for syphilis or other sexually transmitted infections?

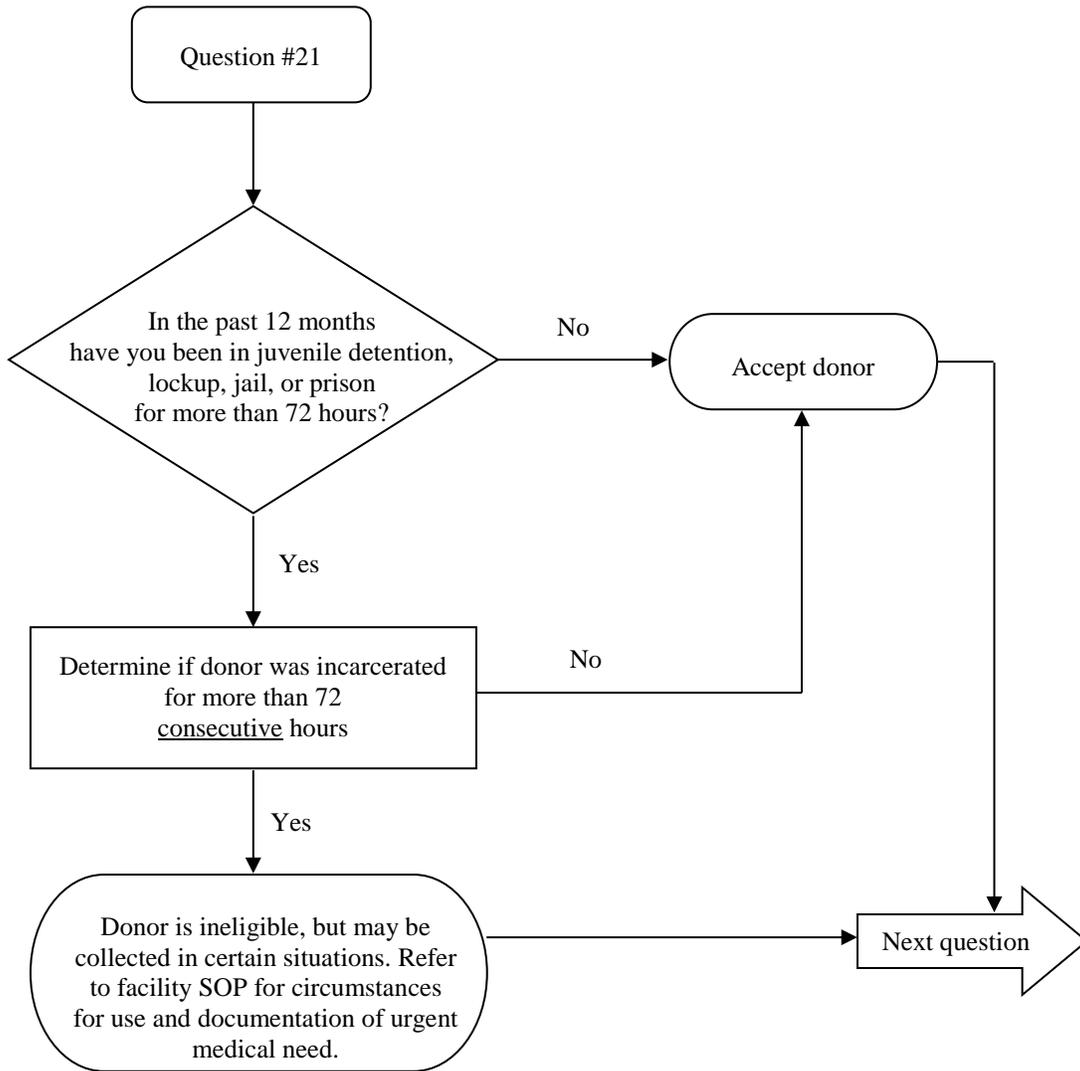
Donor Eligibility: Persons who have had syphilis treatment or a confirmed reactive screening test for syphilis in the preceding 12 months are ineligible. FDA does not recommend deferral if a donor's treatment occurred more than 12 months ago and was successful. If the treatment was **not** successful, the donor should be deferred.



Question: 21. In the past 12 months have you been in juvenile detention, lockup, jail, or prison for more than 72 hours?

Donor Eligibility: Persons who have been detained or incarcerated in a facility (juvenile detention, juvenile correctional facility, lockup, jail, or prison) for more than 72 consecutive hours (3 days) are ineligible for 12 months from the last date of incarceration. These persons are at higher risk for exposure to infectious disease.

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



Question: 22. In the past 3 years have you been outside the United States or Canada?

Donor Eligibility: Donors should be carefully evaluated before being selected to donate HCT/Ps as malaria may be transmitted through transfusion or transplant. Eligibility to donate is not mitigated by use of malaria chemoprophylaxis when traveling.

* 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 12 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.

Donors who are not prior residents of malaria-endemic countries and travel to a malaria-endemic area will be deferred for 12 months after departure from that area.

* **Note:** Use of the definitions (excerpts are provided below) provided in the August 2014 FDA “Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria” are necessary in order to use the flowchart properly. <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM080784.pdf>

Definitions

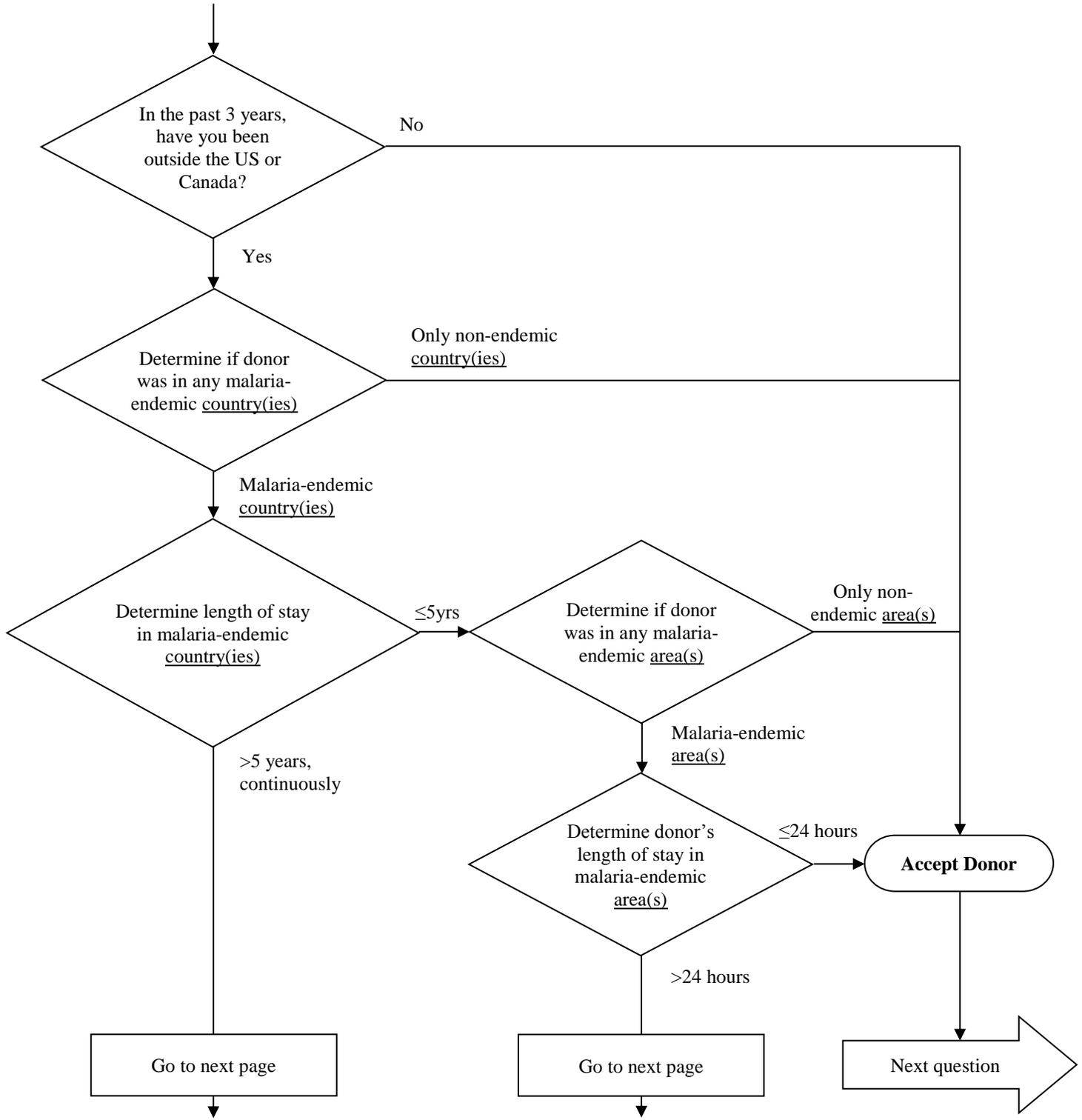
Malaria-endemic area - Any areas with malaria where CDC recommends anti-malarial chemoprophylaxis in travelers in the most current version of the *CDC Health Information for International Travel* (commonly known as *The Yellow Book*) at the time the donor is screened.

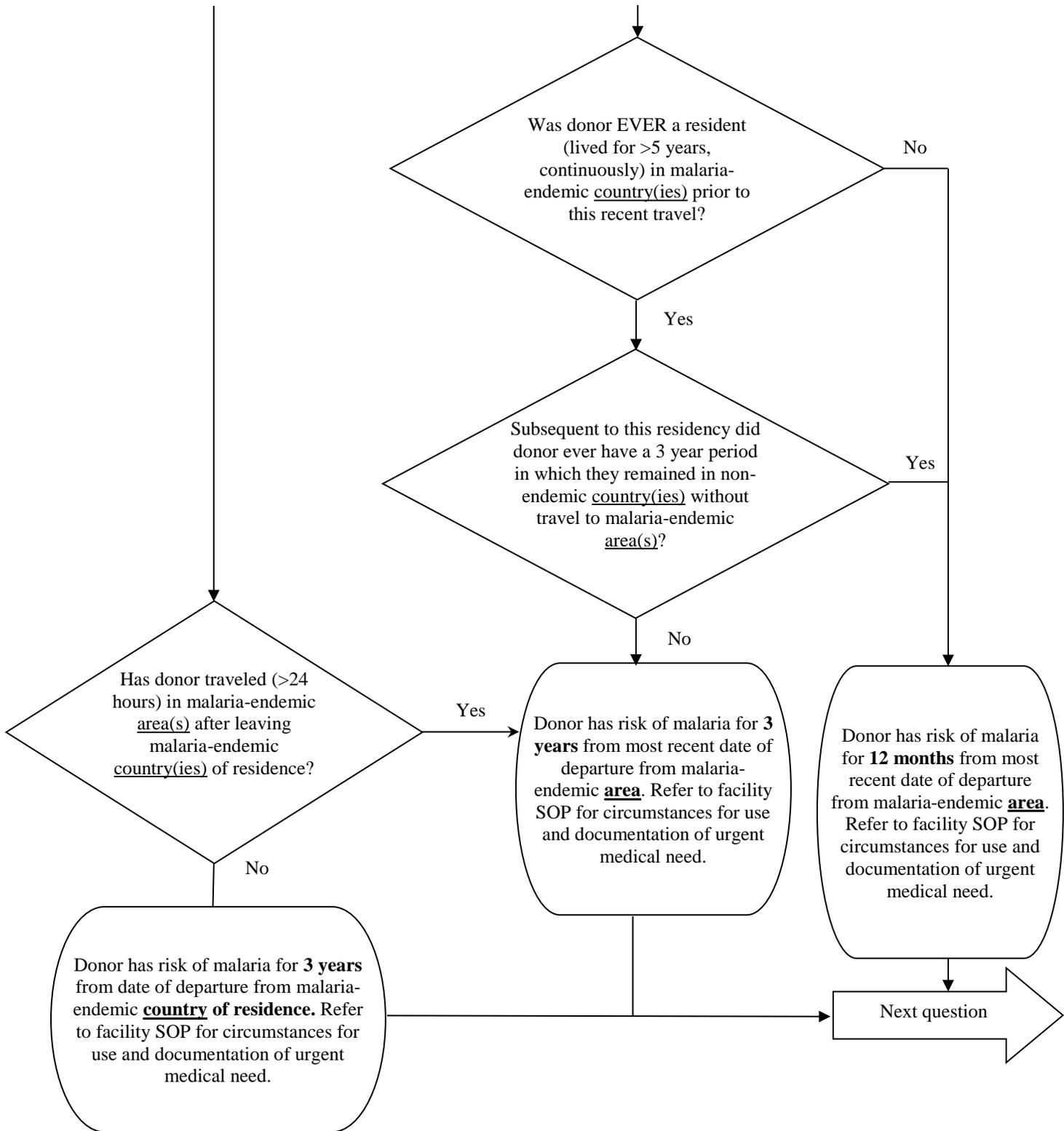
Malaria-endemic country - Any country having an area or areas with malaria where CDC recommends anti-malarial chemoprophylaxis in travelers in *The Yellow Book* at the time the donor is screened. A country that has any malaria-endemic areas should be considered to be malaria-endemic in its entirety.

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.

Question #22

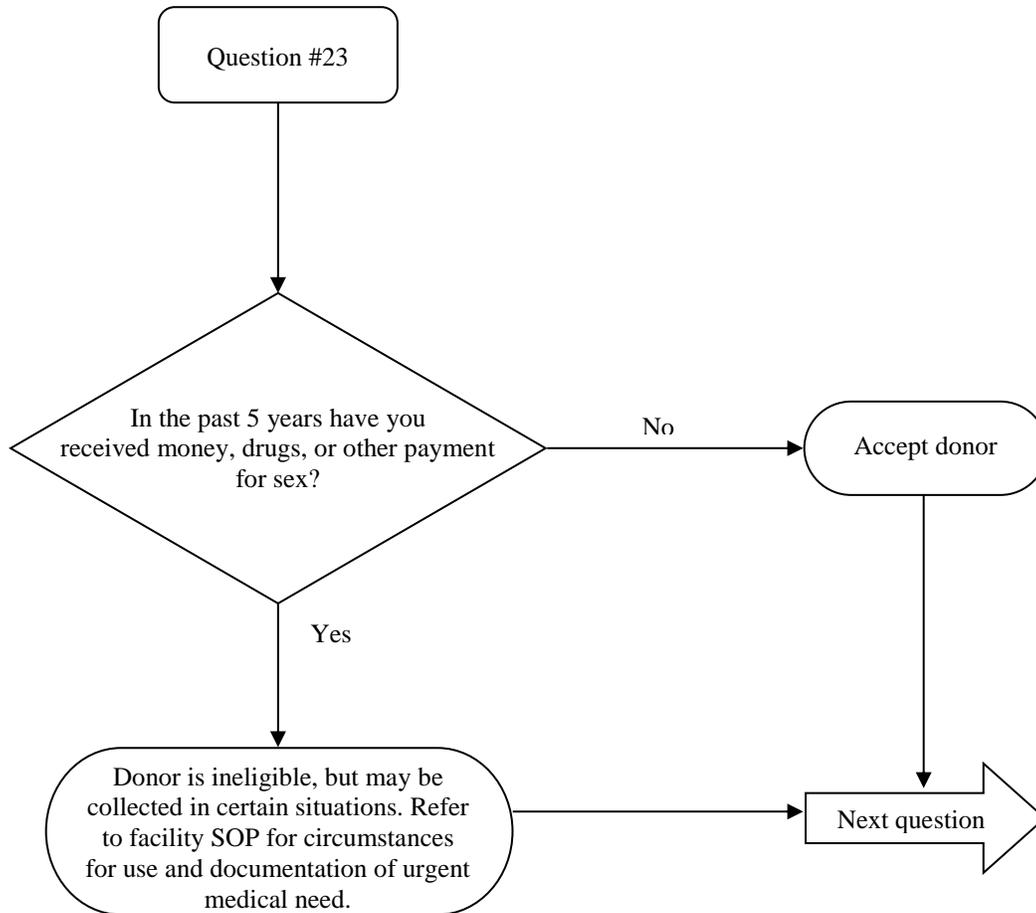




Question: 23. In the past 5 years have you received money, drugs, or other payment for sex?

Donor Eligibility: Donors who received money, drugs, or other payment for sex may be at risk for HIV and other diseases transmitted by sexual contact.

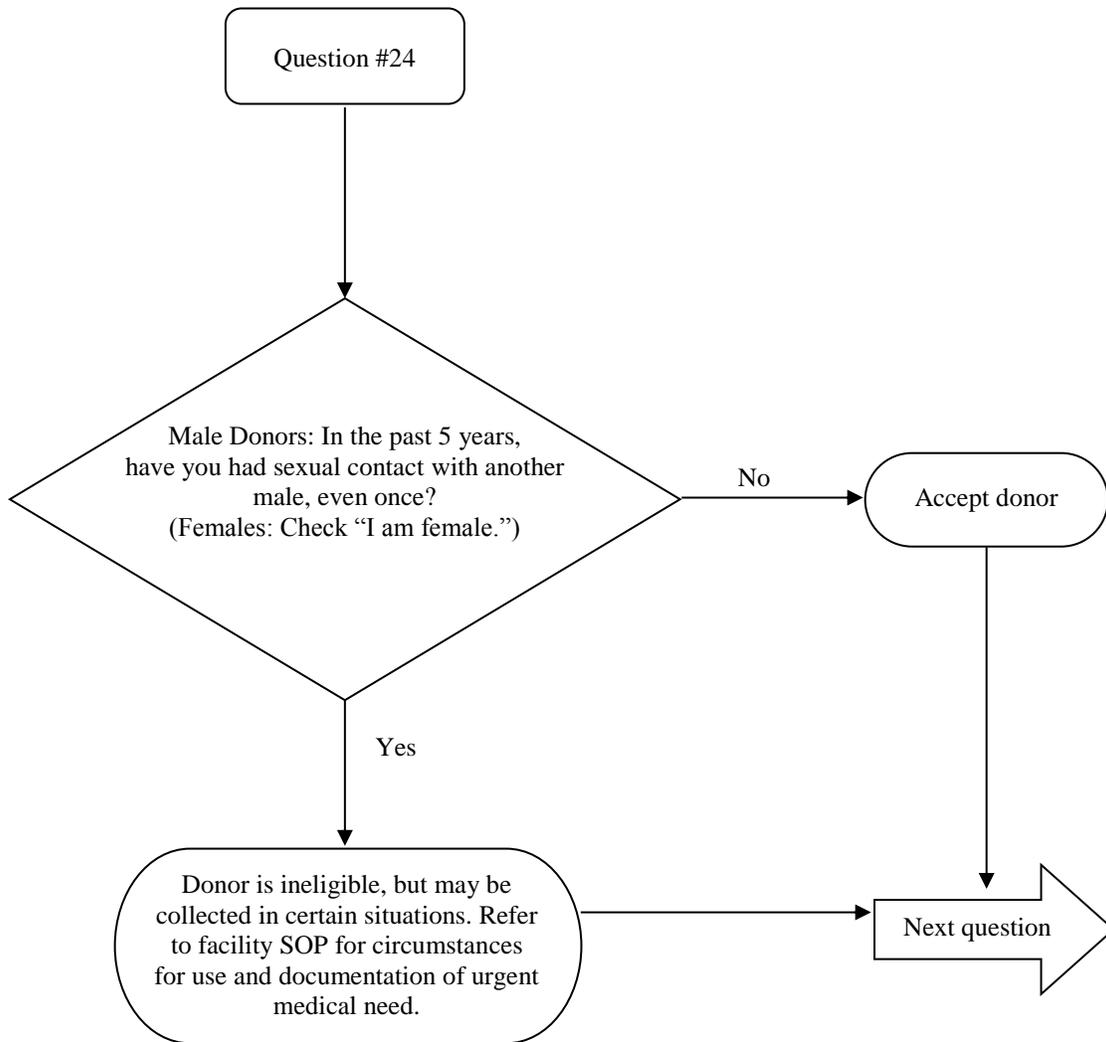
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 24. Male Donors: In the past 5 years, have you had sexual contact with another male, even once? (Females: Check "I am female.")

Donor Eligibility: Male donors who have had sexual contact with another male, even once, may be at risk of transmitting infectious disease. HIV and other diseases may be transmitted through sexual contact.

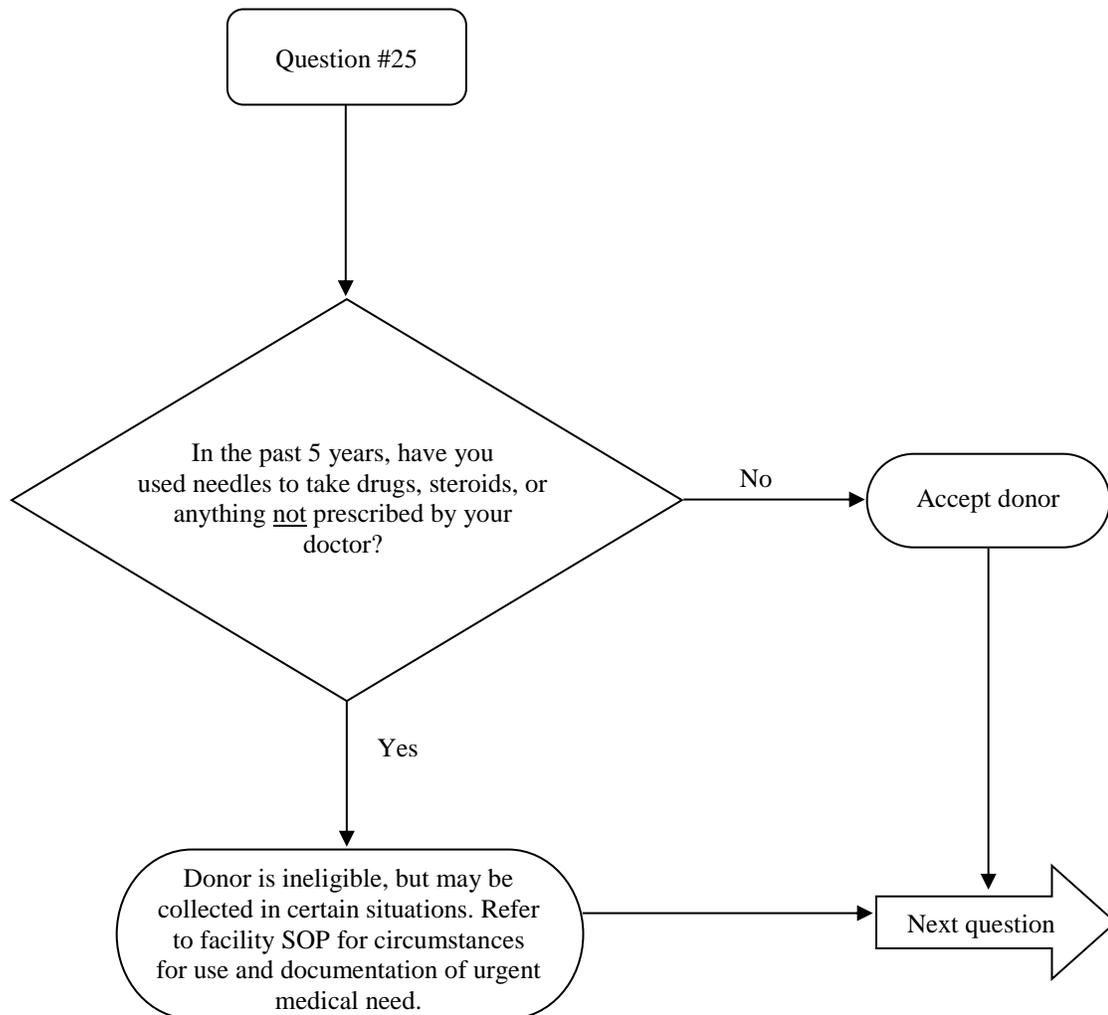
Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.



Question: 25. In the past 5 years, have you used needles to take drugs, steroids, or anything not prescribed by your doctor?

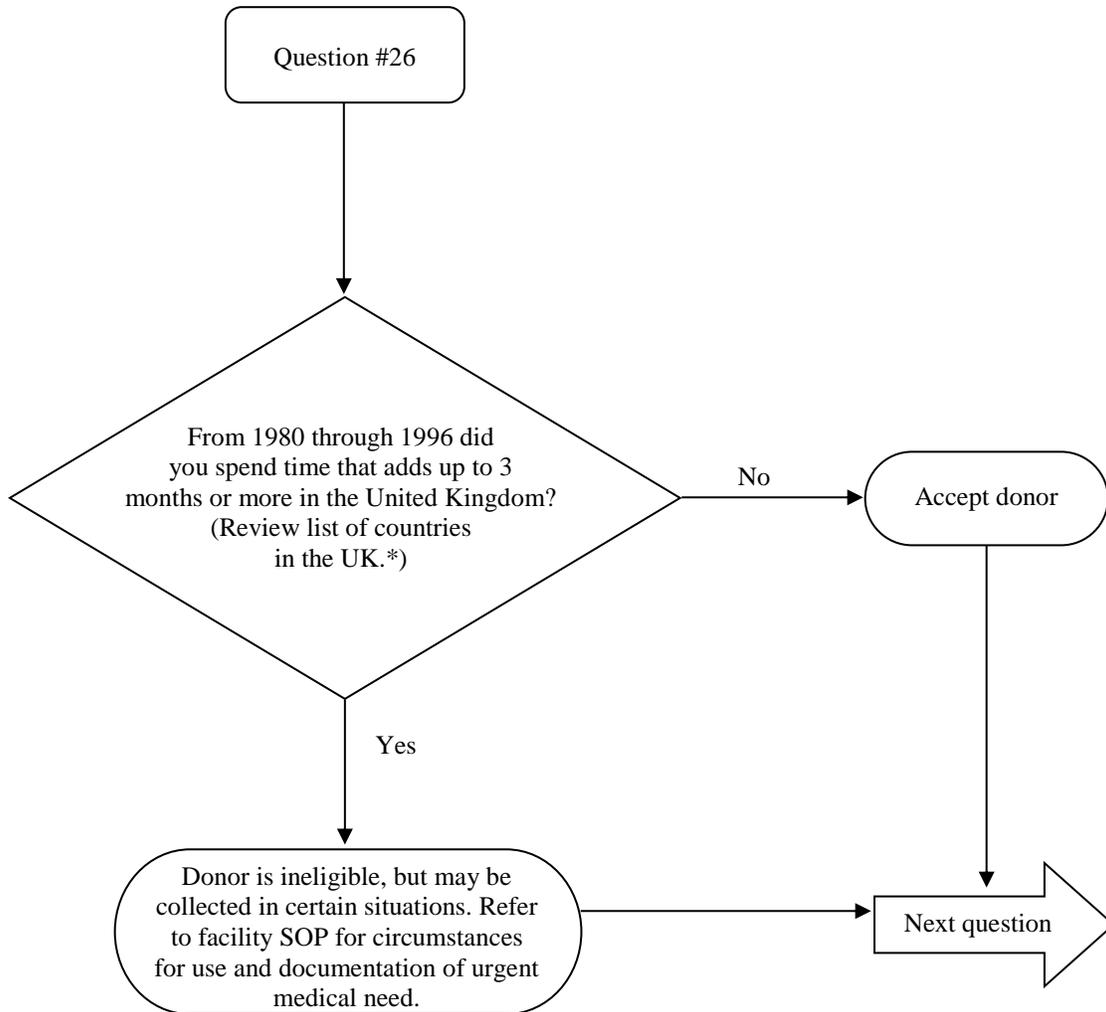
Donor Eligibility: Donors who are past or present needle-using drug users are at risk due to potential transmission of infectious disease.

Note: The phrase “use of a needle” includes intravenous use, “skin popping” (injection under the skin), “mainlining” (arterial injection) and any other use of a needle to administer drugs, steroids or anything else not prescribed by their doctor.



Question: 26. From 1980 through 1996 did you spend time that adds up to 3 months or more in the United Kingdom? (Review list of countries in the UK. *)

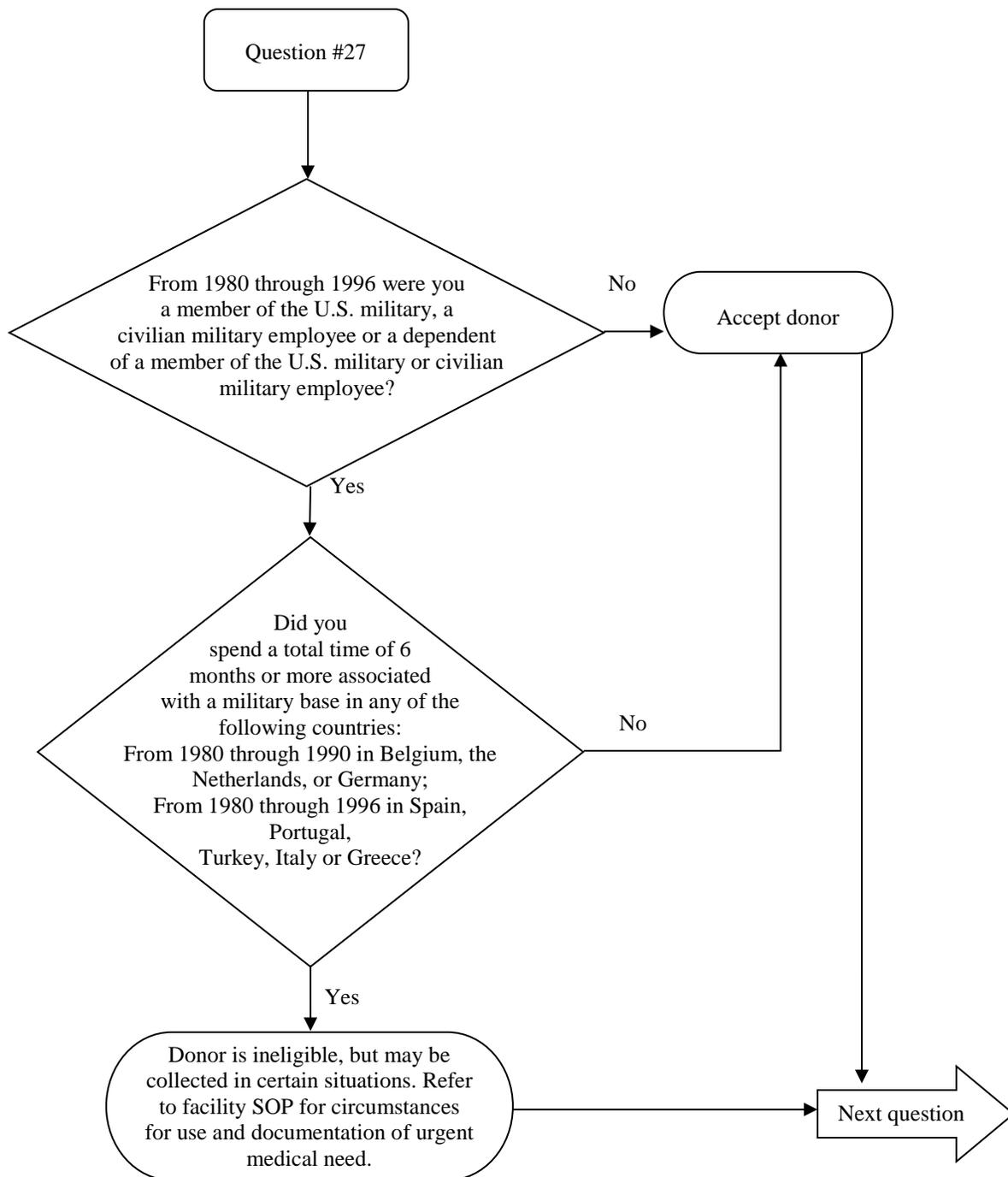
Donor Eligibility: Donors who have spent time that adds up to 3 months or more in the United Kingdom from 1980 through 1996 may be at risk of developing vCJD from eating beef from the UK. There may be a risk of transmitting vCJD through HCT/Ps.



* See UK Countries Appendix in the User Brochure.

Question: 27. From 1980 through 1996 were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military or civilian military employee?

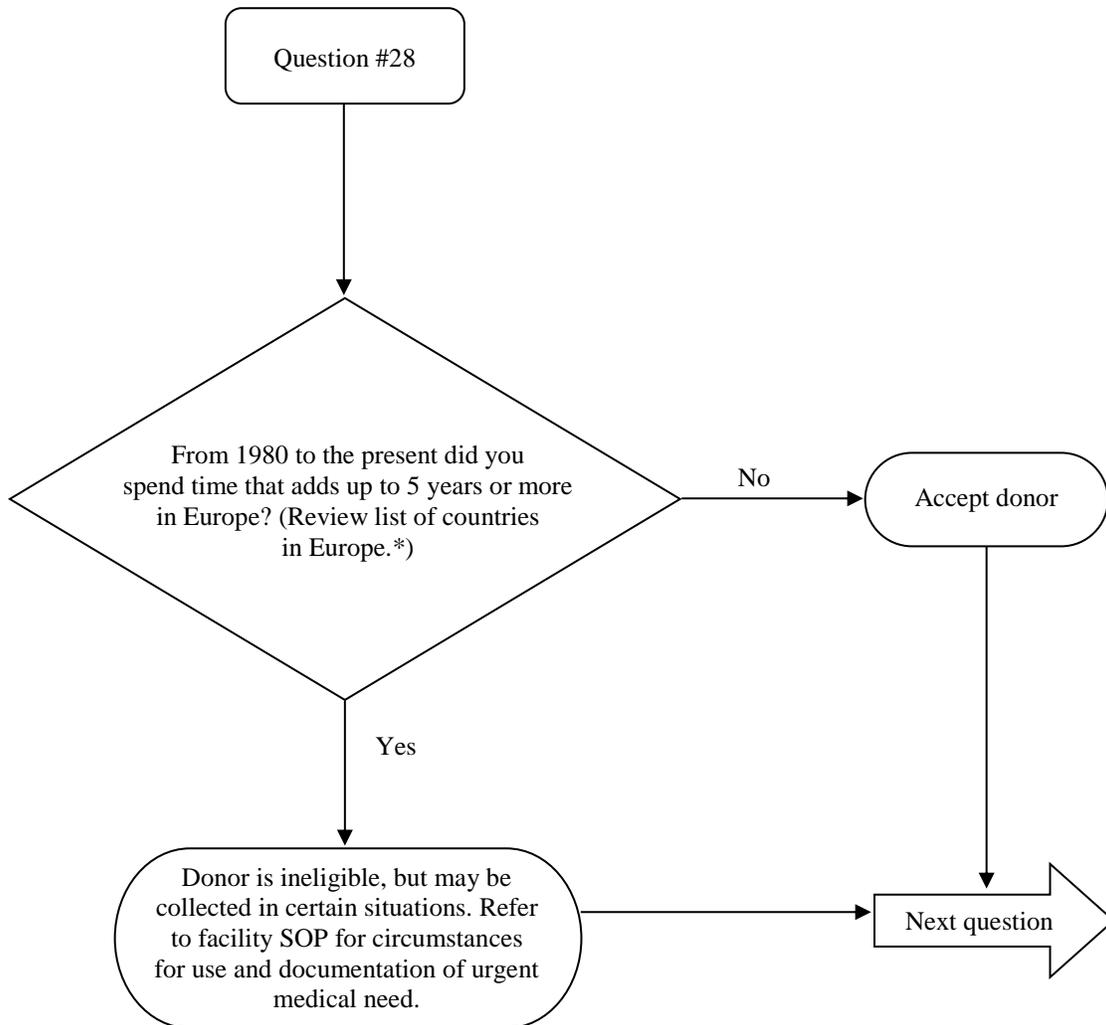
Donor Eligibility: Members of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military or civilian military employee who spent a total of 6 months or more associated with a military base in any of the following countries may be at risk of developing vCJD from eating beef from the UK: from 1980 through 1990 in Belgium, the Netherlands, or Germany; from 1980 through 1996 in Spain, Portugal, Turkey, Italy or Greece. There may be a risk of transmitting vCJD through HCT/Ps.



Question: 28. From 1980 to the present did you spend time that adds up to 5 years or more in Europe? (Review list of countries in Europe. *)

Donor Eligibility: Donors who have spent time that adds up to 5 years or more in Europe from 1980 to the present may be at risk of developing vCJD from eating beef in Europe. There may be a risk of transmitting vCJD through HCT/Ps.

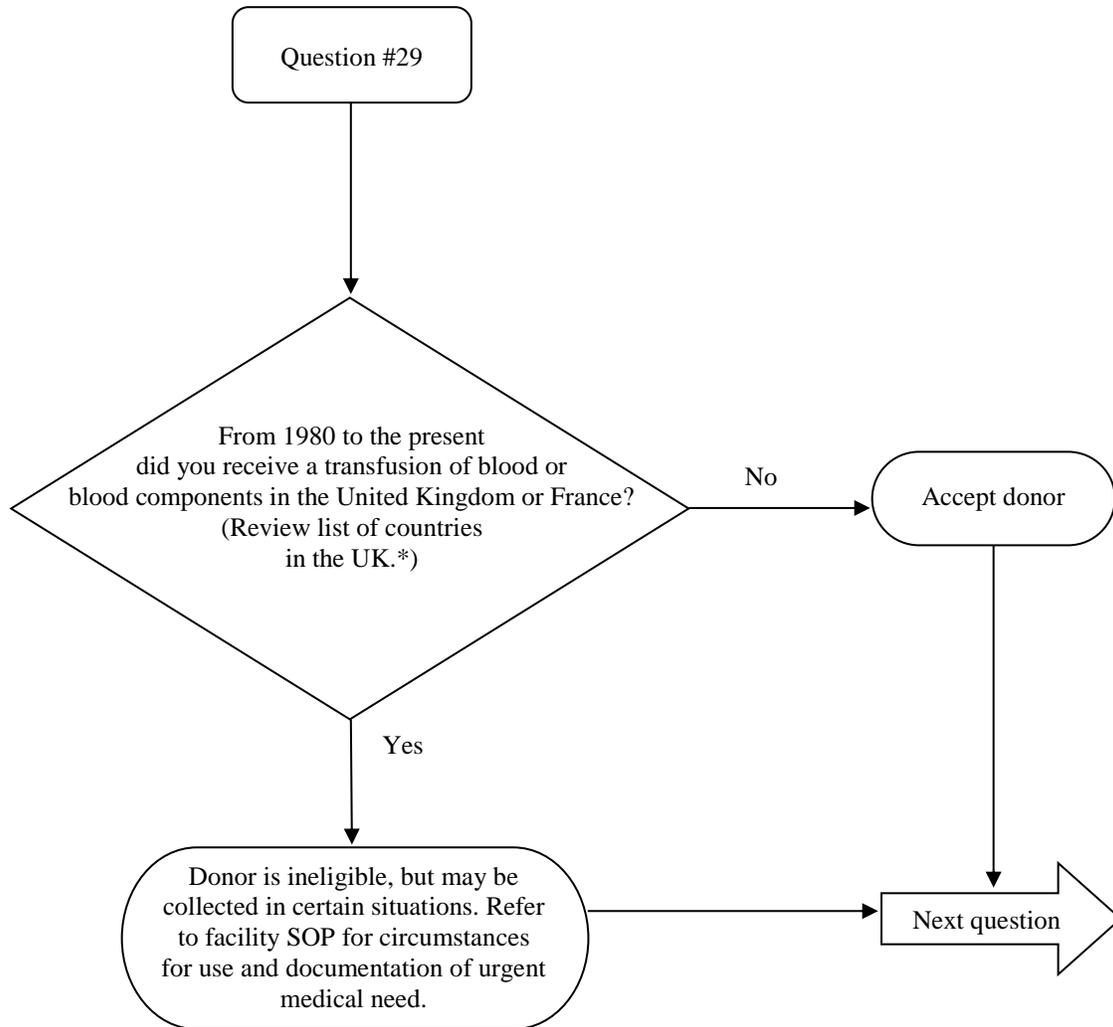
Note: When calculating time spent in Europe include time spent in the United Kingdom from 1980 – 1996 only.



* See Appendix – vCJD countries of risk – Europe in the User Instructions.

Question: 29. From 1980 to the present did you receive a transfusion of blood or blood components in the United Kingdom or France? (Review list of countries in the UK. *)

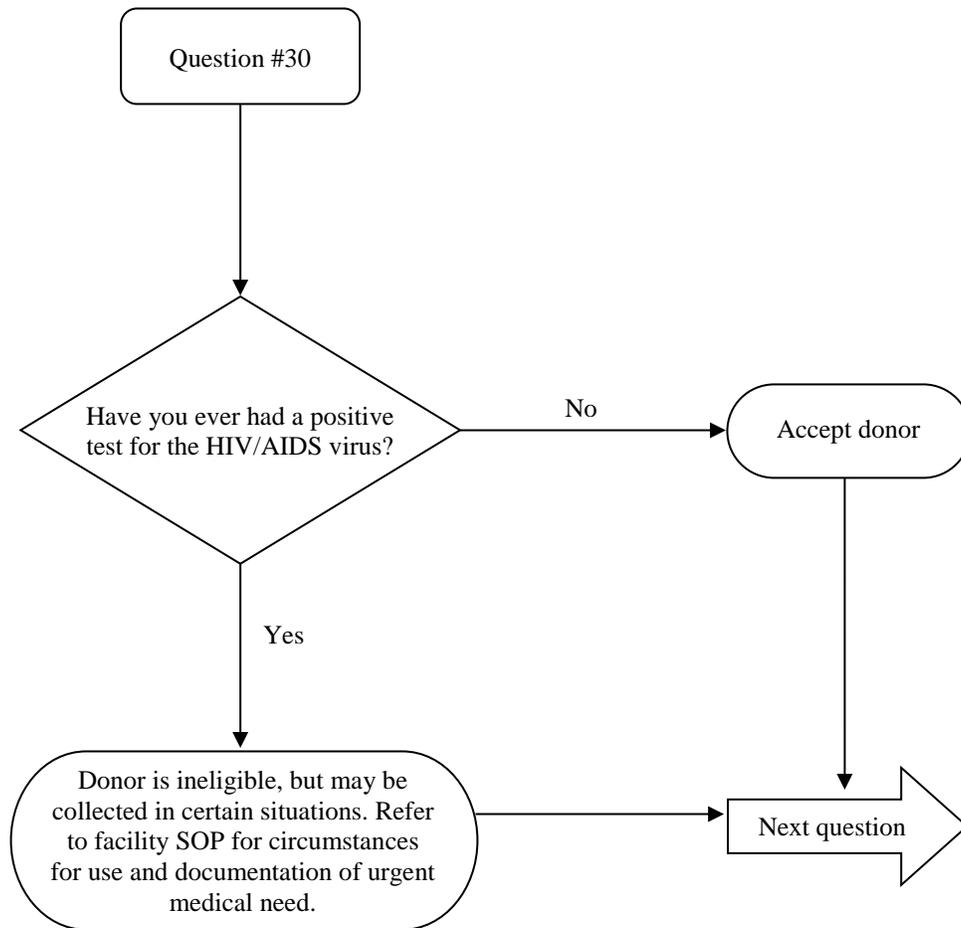
Donor Eligibility: Donors who received a transfusion of blood or blood components (platelets, plasma, cryoprecipitate, granulocytes or other components) in the UK or France from 1980 to the present may be at risk of developing vCJD through transfusion. There may be a risk of transmitting vCJD through HCT/Ps.



* See Appendix – vCJD countries of risk – United Kingdom in the User Instructions.

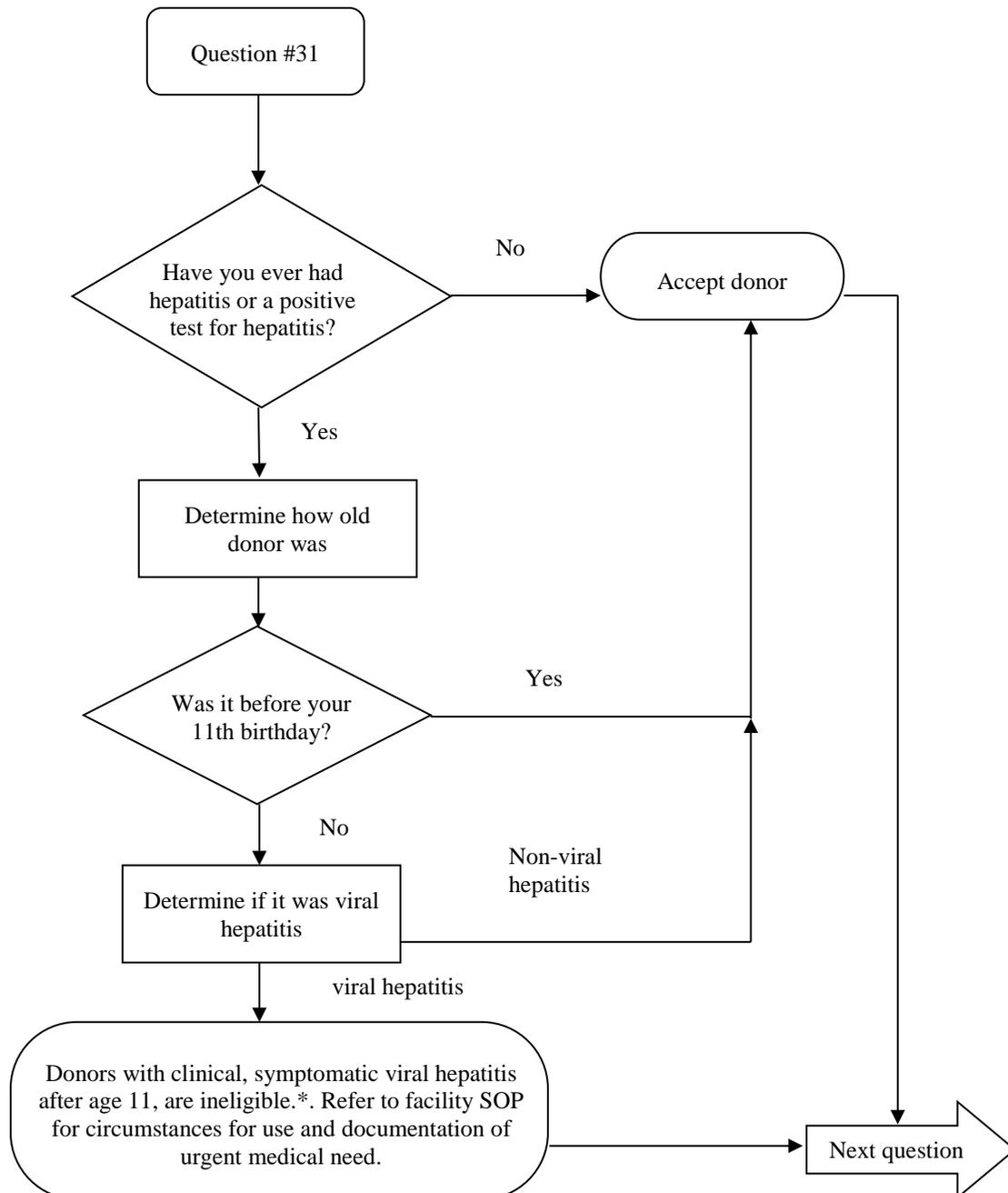
Question: 30. Have you ever had a positive test for the HIV/AIDS virus?

Donor Eligibility: Donors with clinical or laboratory evidence, including prior reactive screening tests, of HIV/AIDS are ineligible. Donors with clinical or laboratory evidence of HIV/AIDS are ineligible due to potential transmission of infectious disease.



Question: 31. Have you ever had hepatitis or a positive test for hepatitis?

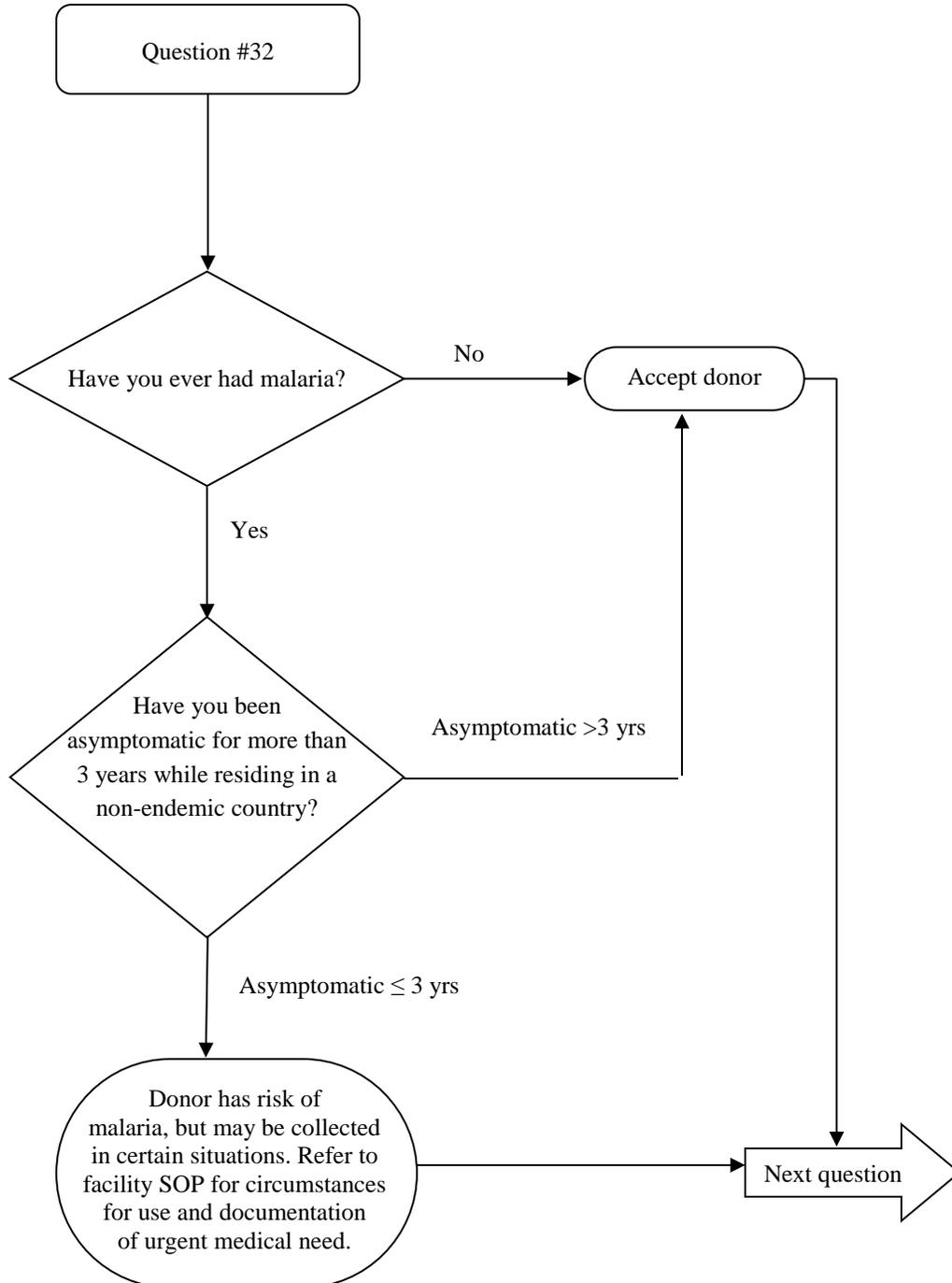
Donor Eligibility: Donors who have a prior reactive screening test for hepatitis or a history of viral hepatitis after their 11th birthday are ineligible, unless evidence from the time of illness documents that the hepatitis was identified as being caused by Hepatitis A virus, Epstein-Barr Virus (EBV) or cytomegalovirus (CMV).



* Donors are ineligible “unless evidence from the time of illness documents that the hepatitis was identified as being caused by Hepatitis A virus, Epstein-Barr Virus (EBV) or cytomegalovirus (CMV).” (“Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” Guidance for Industry, August 2007).

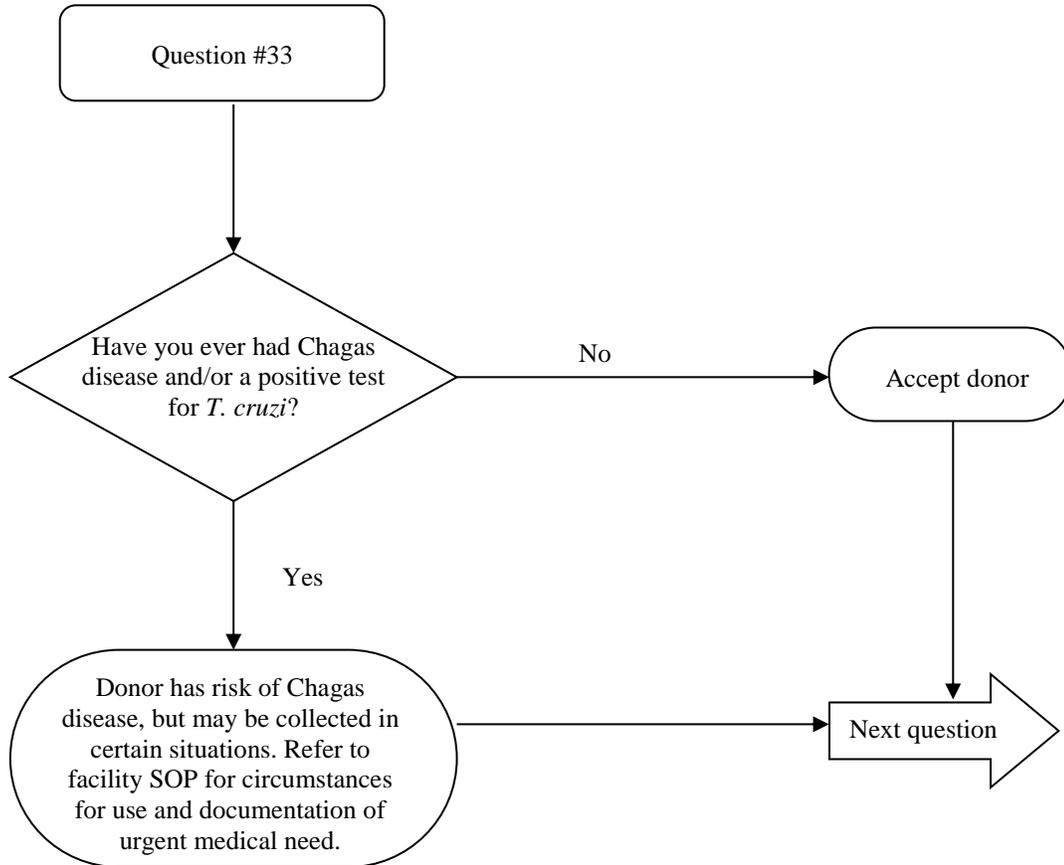
Question: 32. Have you ever had malaria?

Donor Eligibility: Prospective donors who have had malaria and received an appropriate treatment are ineligible for three years after becoming asymptomatic while residing in a non-endemic country. Malaria can be transmitted by HCT/Ps.



Question: 33. Have you ever had Chagas disease and/or a positive test for *T. cruzi*?

Donor Eligibility: Donors who have tested positive or reactive for *T. cruzi* antibodies using an FDA-licensed or investigational *T. cruzi* donor screening test, or have had a medical diagnosis of *T. cruzi*, are ineligible due to the potential risk of transmitting Chagas disease through HCT/Ps.*



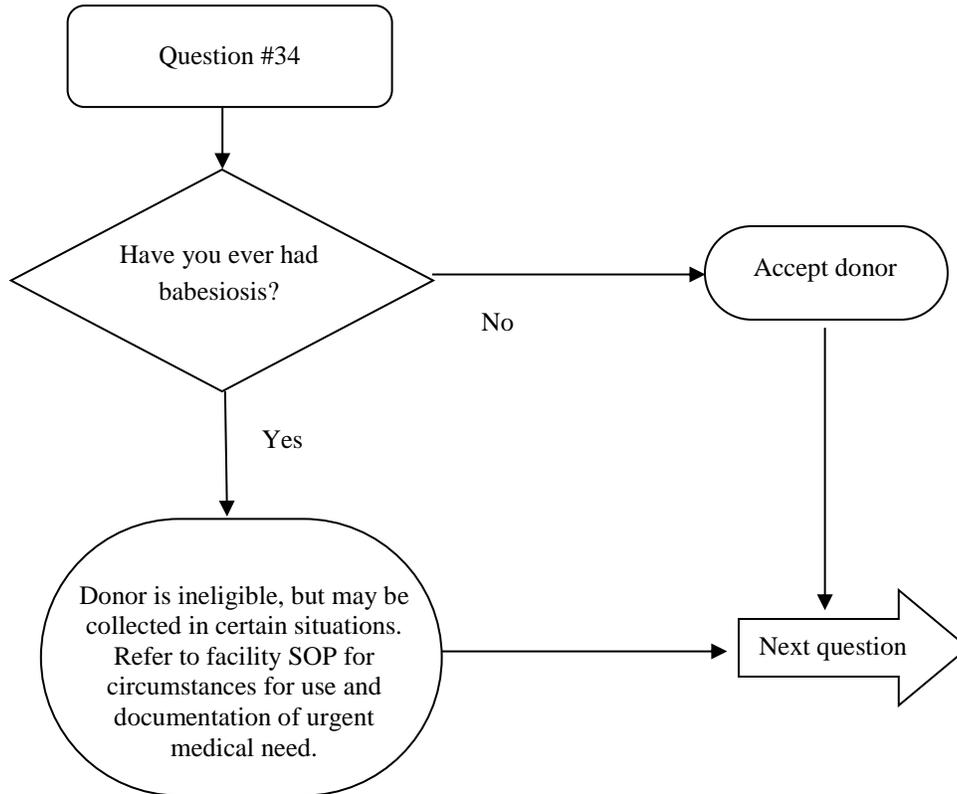
* NOTE: *T. cruzi* is not considered a relevant communicable disease agent or disease (RCDAD) with the FDA and therefore is not a required disease to screen or test for according to the FDA.

<https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm151757.htm>. It is the responsibility of the user/reader of this document to check FDA's current requirements for screening and/or testing donors of HCT/Ps to ensure that risk factors for all RCDADs are evaluated, and to note any new RCDADs.

A donor will be considered ineligible if they are screened or tested for *T. cruzi*, and the screening and/or testing results are positive or shows risk.

Question: 34. Have you ever had babesiosis?

Donor Eligibility: Donors who have had babesiosis are ineligible. Donors who have had babesiosis are ineligible due to the potential risk of transmitting Babesiosis through HCT/Ps.*

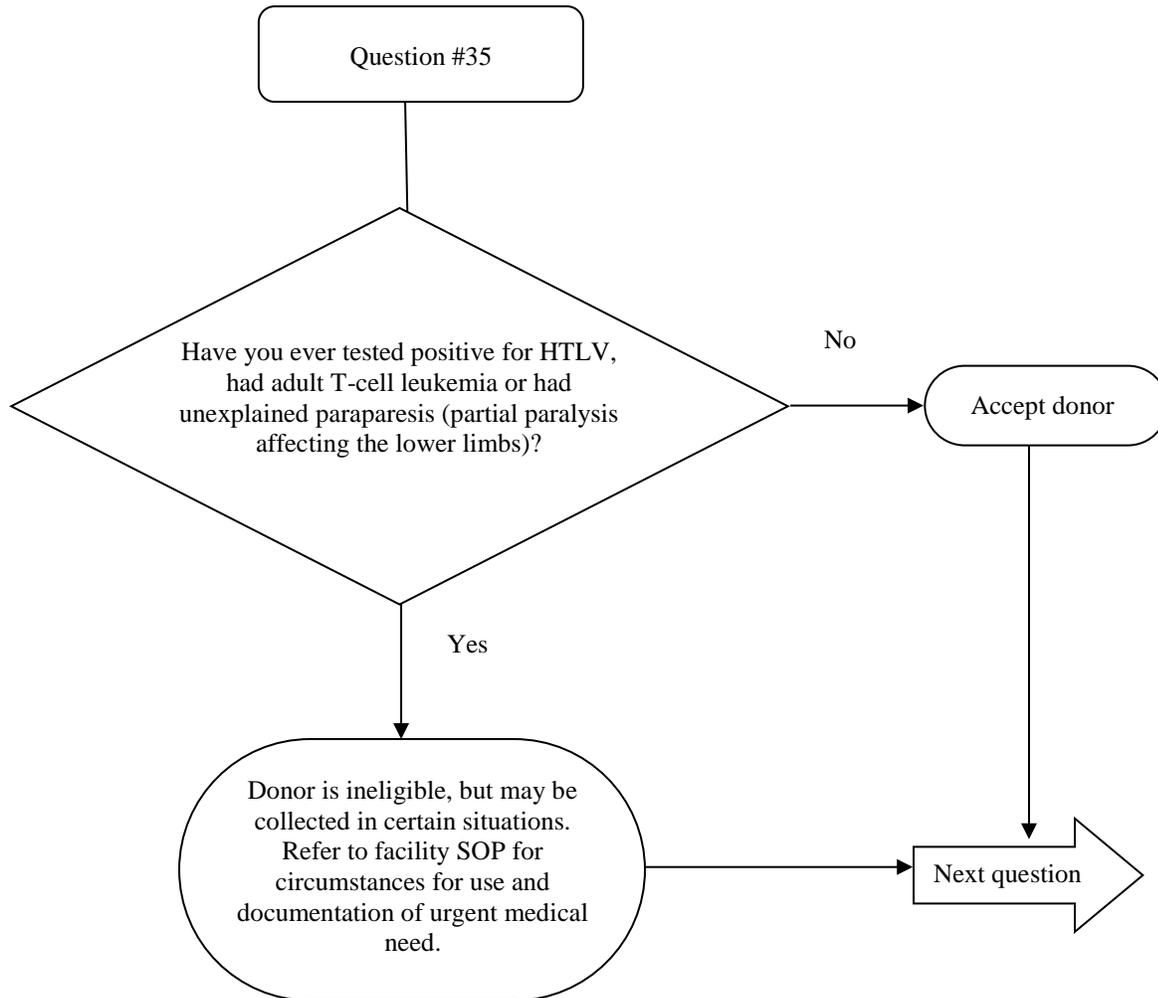


* NOTE: Babesiosis is not considered a relevant communicable disease agent or disease (RCDAD) with the FDA and therefore is not a required disease to screen or test for according to the FDA. <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm151757.htm>. It is the responsibility of the user/reader of this document to check FDA's current requirements for screening and/or testing donors of HCT/Ps to ensure that risk factors for all RCDADs are evaluated, and to note any new RCDADs.

A donor will be considered ineligible if they are screened or tested for babesiosis, and the screening and/or testing results are positive or shows risk.

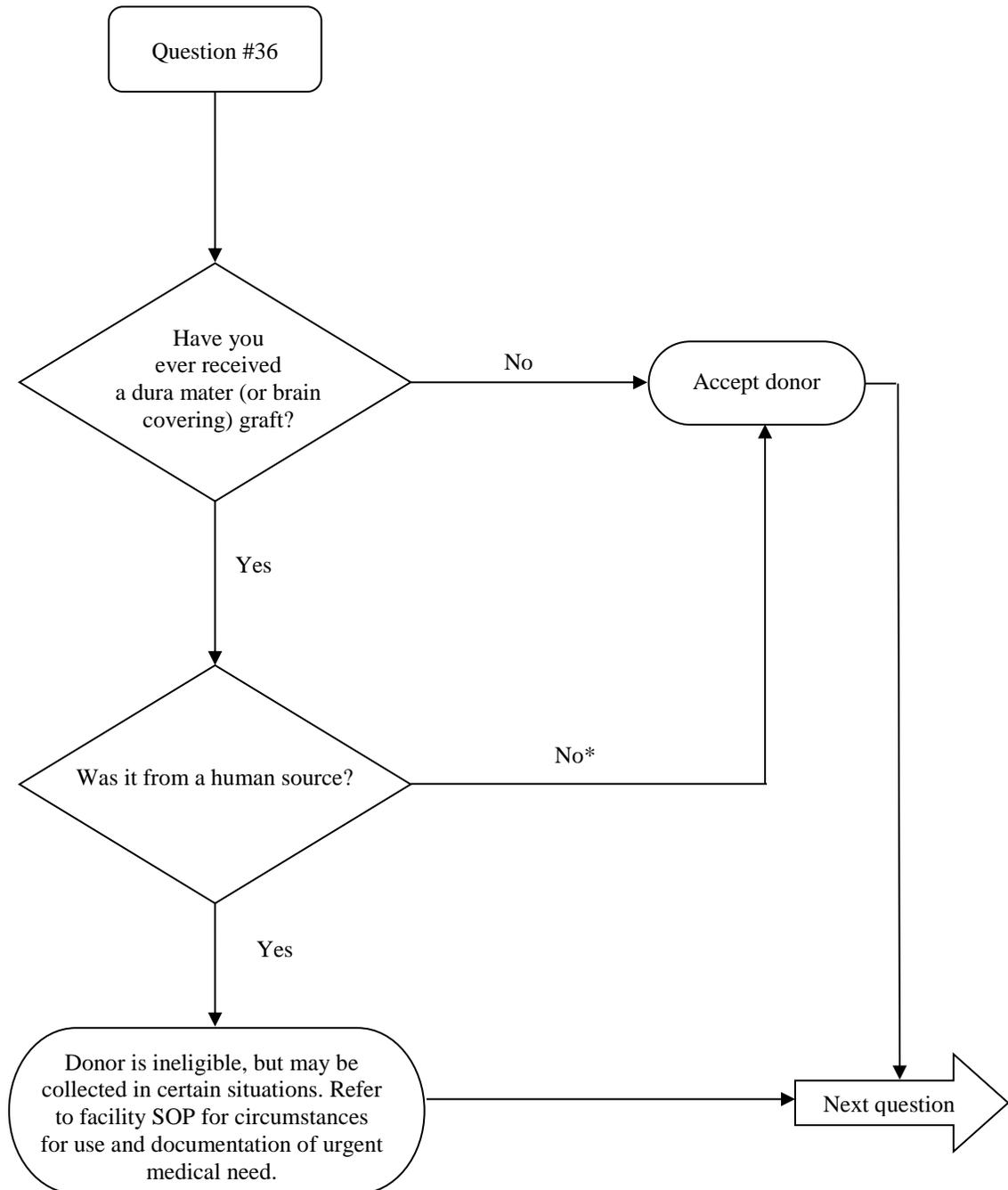
Question: 35. Have you ever tested positive for HTLV, had adult T-cell leukemia or had unexplained paraparesis (partial paralysis affecting the lower limbs)?

Donor Eligibility: Donors with clinical or laboratory evidence, including reactive screening tests, of HTLV are ineligible due to potential transmission of infectious disease. HTLV refers to Human T-cell Lymphotropic Virus.



Question: 36. Have you ever received a dura mater (or brain covering) graft?

Donor Eligibility: Donors who have received a human dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and are ineligible. *Any non-human source should be further evaluated to determine if it is a cleared or approved medical device.

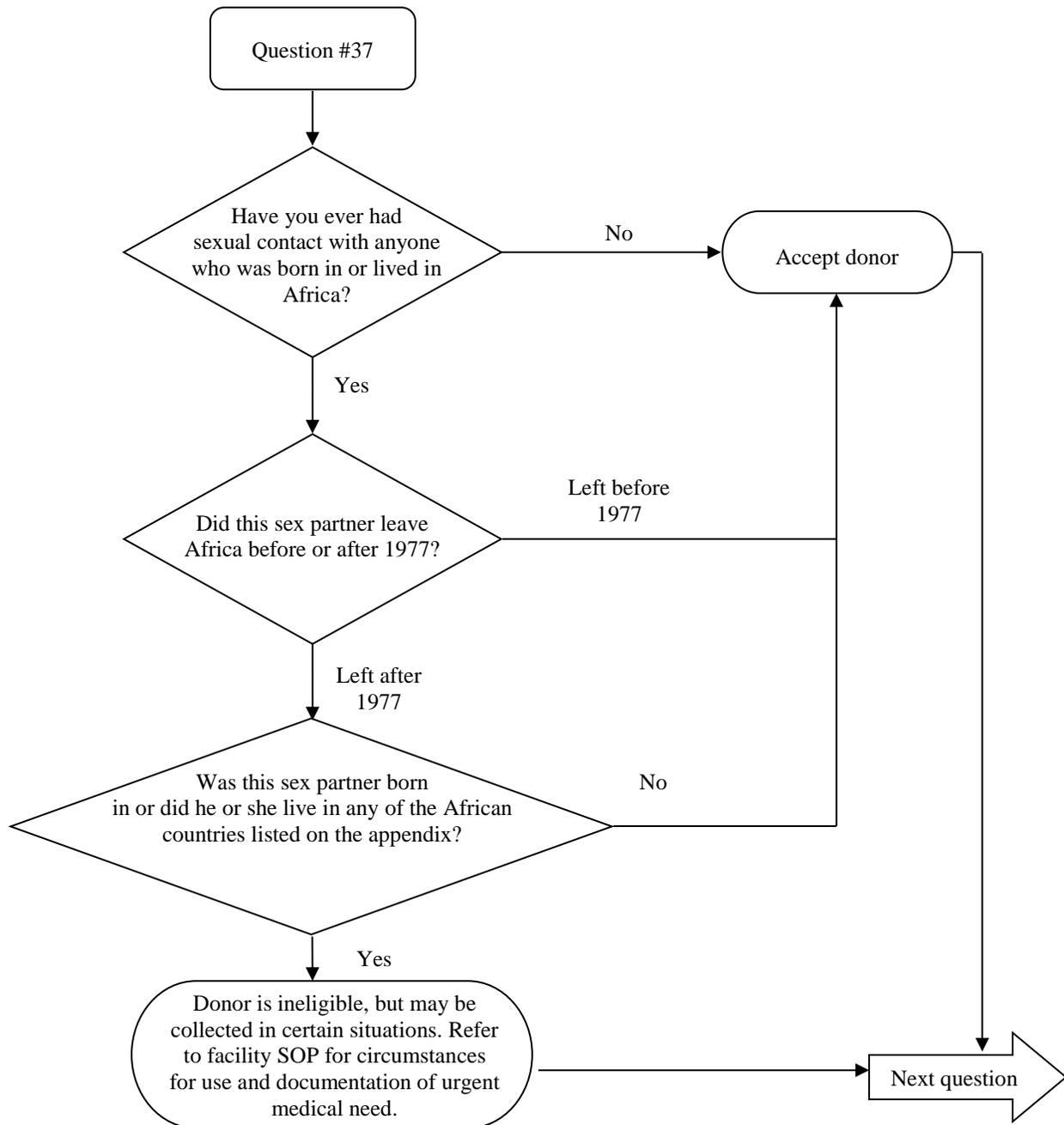


Question: 37. Have you ever had sexual contact with anyone who was born in or lived in Africa?

Donor Eligibility: If the donor had a sex partner who was born in or lived in certain countries in Africa after 1977, the donor may be ineligible. Donors who have had sexual contact may have been exposed to rare strains of HIV that are not consistently detected by all current test methods. *See Appendix for African countries.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

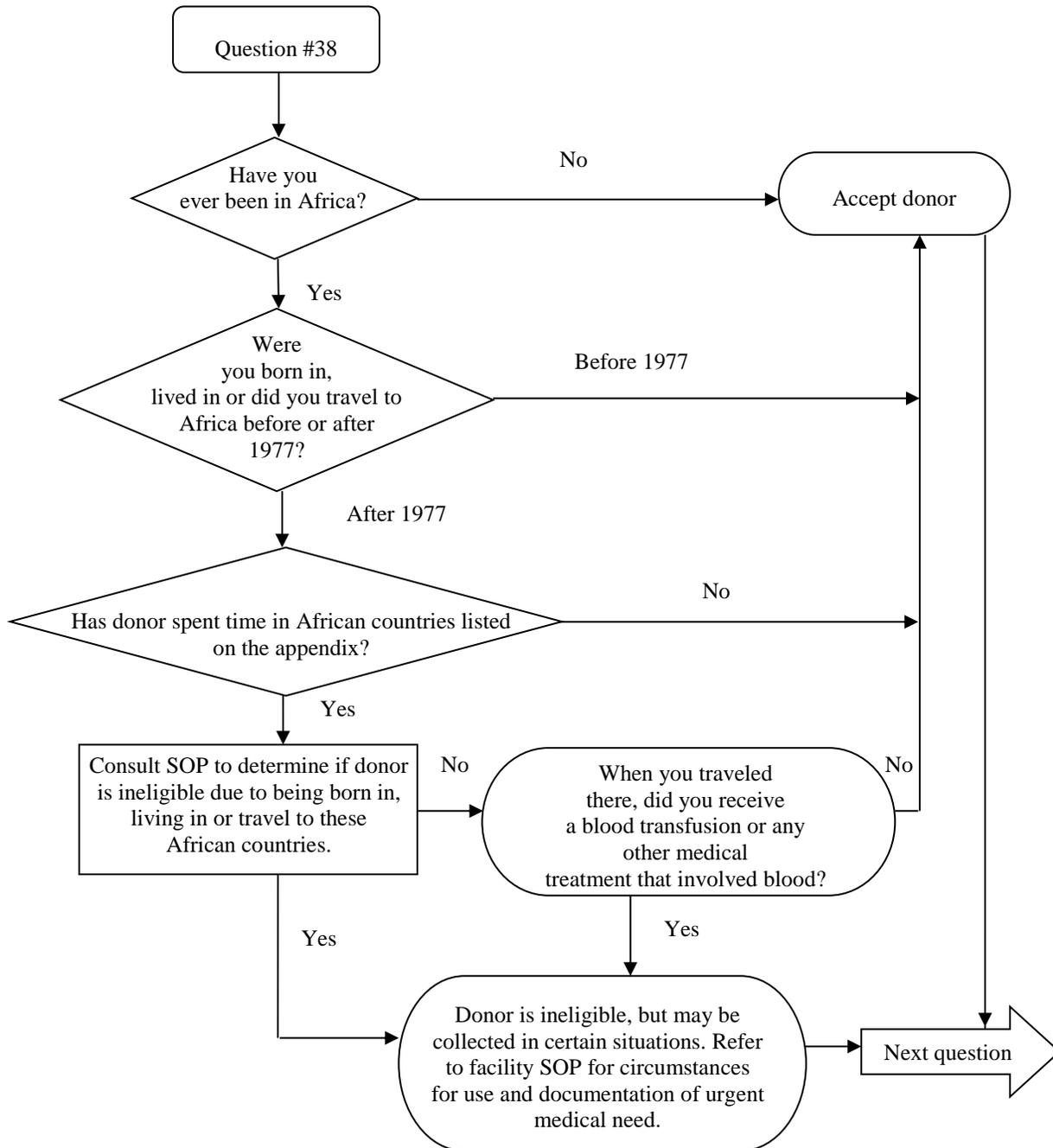
* Facilities using an HIV test that has been approved by FDA to include a donor screening claim for detection of Group O viruses may eliminate this question during screening.



Question: 38. Have you ever been in Africa?

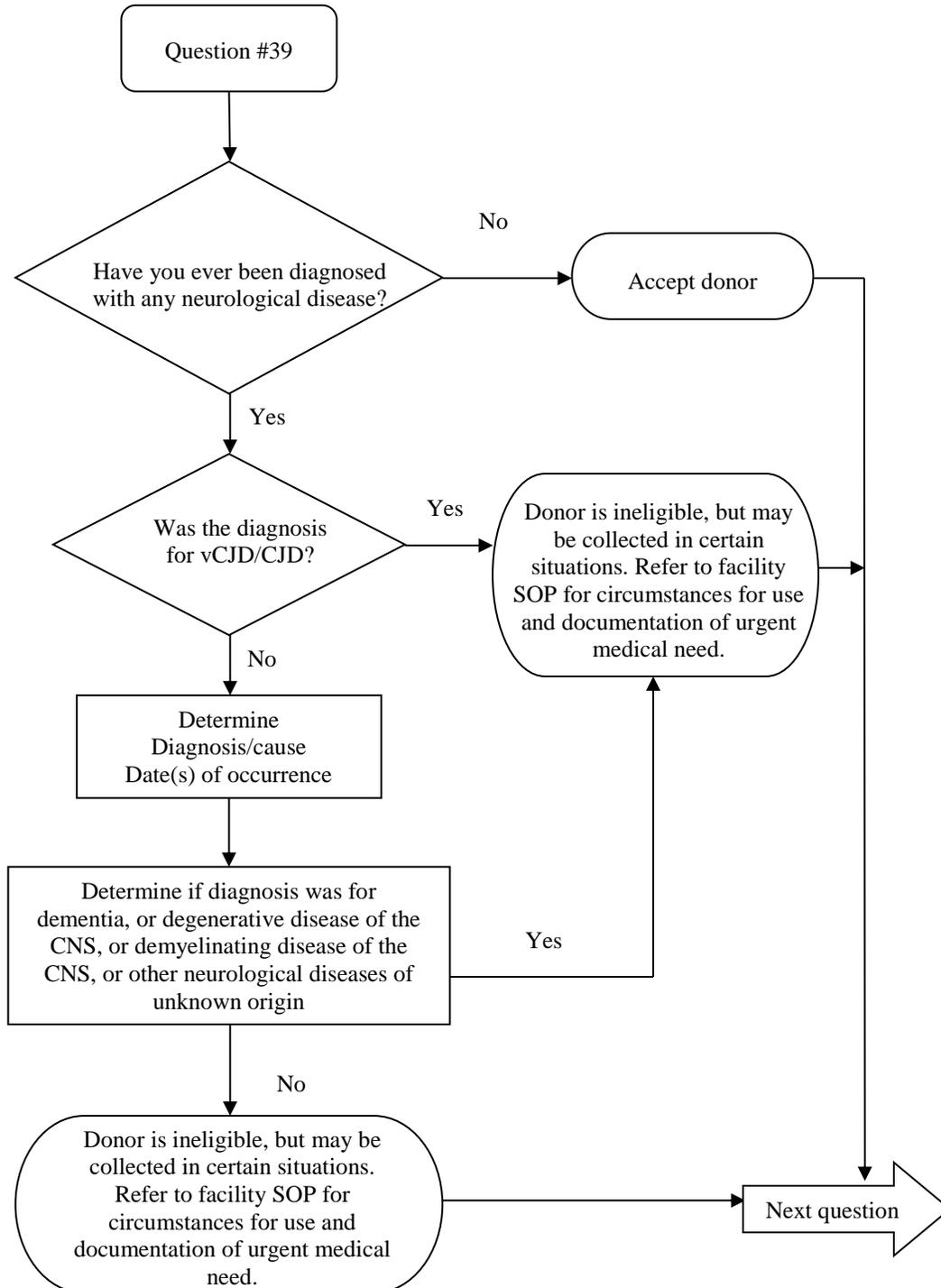
Donor Eligibility: Donors who were born in, lived in or have traveled to certain countries in Africa since 1977 (see appendix for HIV Group O countries at risk-Africa) are ineligible. Donors who have received a blood transfusion or any other medical treatment involving the use of blood in certain countries in Africa are ineligible. Donors may have been exposed to rare strains of HIV that are not consistently detected by all current test methods.

* Facilities using an HIV test that has been approved by FDA to include a donor screening claim for detection of Group O viruses may eliminate this question during screening.



Question: 39. Have you ever been diagnosed with any neurological disease?

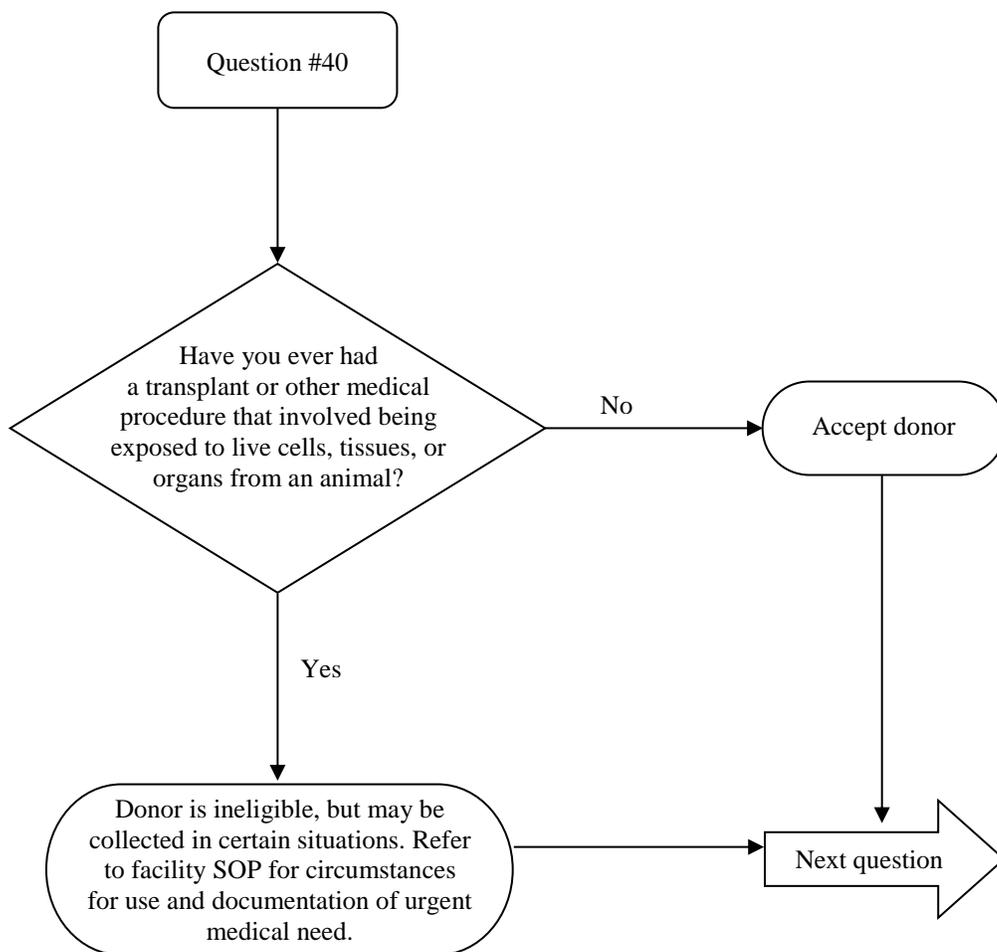
Donor Eligibility: Any donor who has been diagnosed with vCJD or any other form of CJD, dementia, any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology, may not be eligible to donate HCT/Ps. In the event of urgent medical need, additional criteria may be used to evaluate donors with neurological disease other than vCJD/CJD.



Question: 40. Have you ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?

Donor Eligibility: Donor is considered FDA ineligible if exposed to live xenotransplant sources.

Note: "Xenotransplantation refers to procedures in which live cells, tissues, or organs from an animal are transplanted, implanted, or infused into a human patient. It also includes procedures in which human body fluids, cells, tissues or organs are removed from the human body, come into contact with live animal cells, tissues, or organs, and then are placed back into a human patient." (1) Examples include transplanted organs such as hearts, livers, or kidneys; in burn patients - the use of certain skin grafts that have been grown on mouse "feeder" cells; or, supportive care of liver transplant candidates by running their blood through a column of pig liver cells. The rationale for excluding xenotransplant recipients as donors is based on concerns that viruses or microorganisms carried by animals may be spread to humans, who may, in turn, infect other people through sexual, household contact, or other activity.



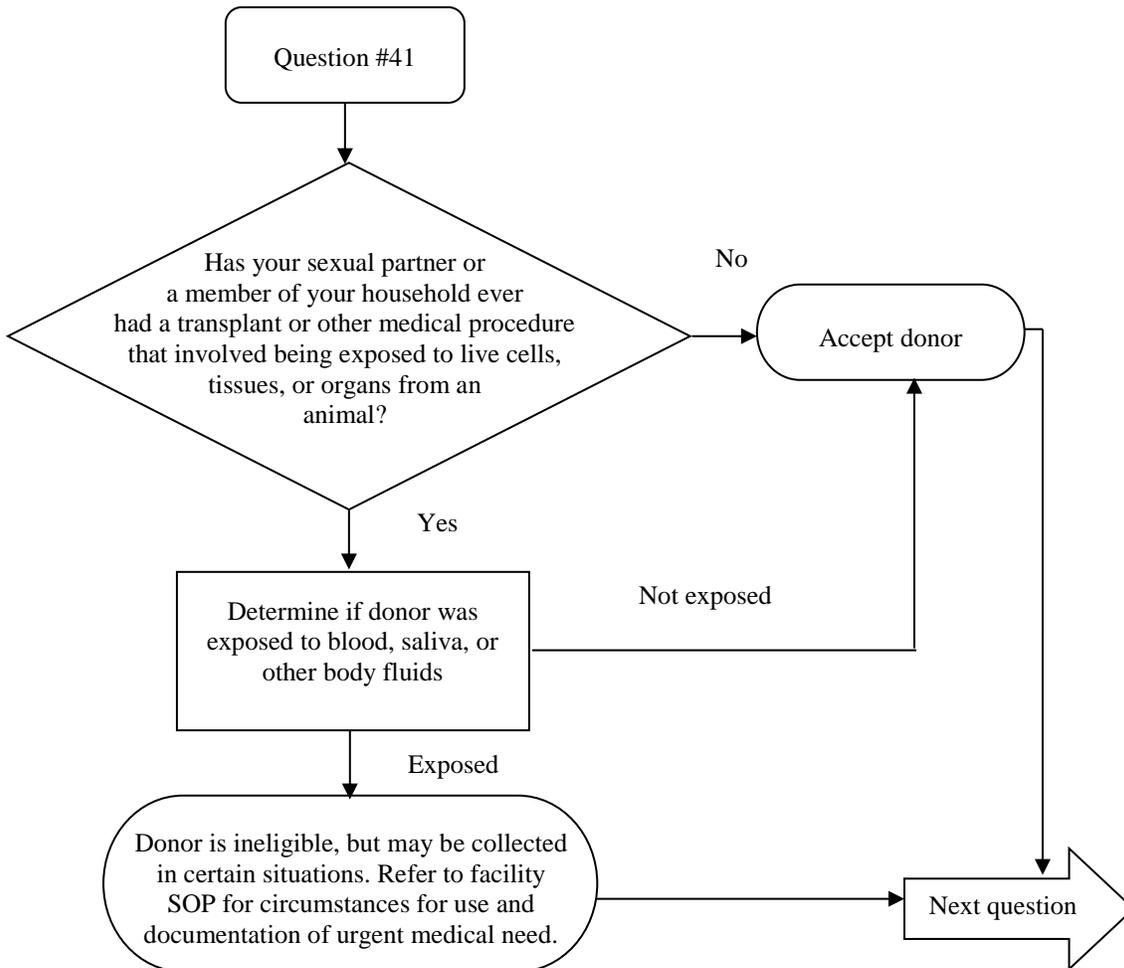
(1) U.S. Department of Health and Human Services Secretary's Advisory Committee on Xenotransplantation. Report on the State of the Science in Xenotransplantation. Draft, Sept 2004, page 1.

Question: 41. Has your sexual partner or a member of your household ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?

Donor Eligibility: Donors exposed to blood, saliva, or other body fluids through activities such as deep kissing, shared toothbrushes, razors or needles, or through open wounds or sores are considered FDA-ineligible.

Note: "Xenotransplantation refers to procedures in which live cells, tissues, or organs from an animal are transplanted, implanted, or infused into a human patient. It also includes procedures in which human body fluids, cells, tissues or organs are removed from the human body, come into contact with live animal cells, tissues, or organs, and then are placed back into a human patient." (1) Examples include transplanted organs such as hearts, livers, or kidneys; in burn patients - the use of certain skin grafts that have been grown on mouse "feeder" cells; or, supportive care of liver transplant candidates by running their blood through a column of pig liver cells. The rationale for excluding xenotransplant recipients as donors is based on concerns that viruses or microorganisms carried by animals may be spread to humans, who may, in turn, infect other people through sexual, household contact, or other activity.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

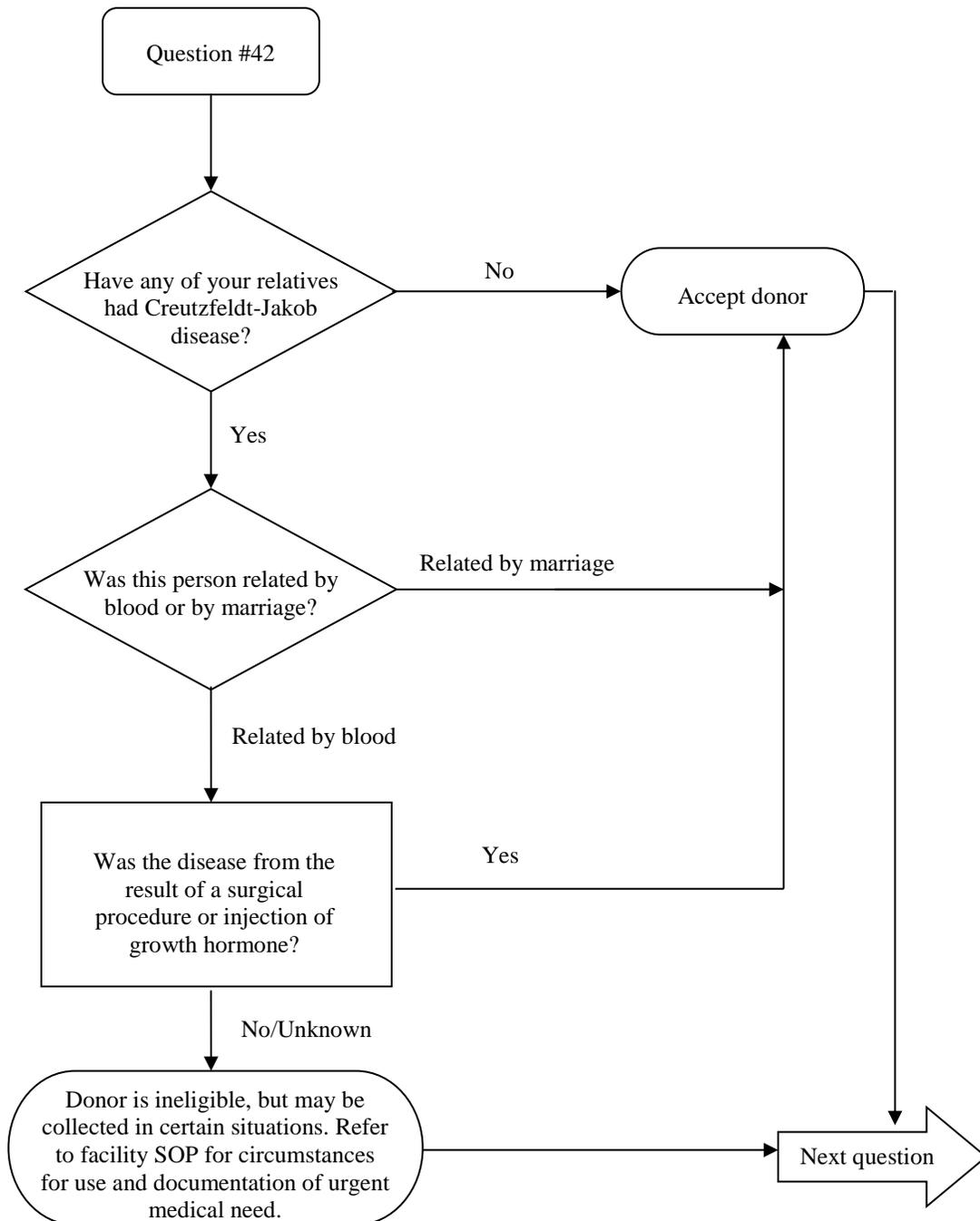


(1) U.S. Department of Health and Human Services Secretary's Advisory Committee on Xenotransplantation. Report on the State of the Science in Xenotransplantation. Draft, Sept 2004, page 1.

Question: 42. Have any of your relatives had Creutzfeldt-Jakob disease?

Donor Eligibility: Donors with a blood relative with Creutzfeldt-Jakob disease are ineligible. A donor response such as “do not know” that indicates a lack of familiarity with the CJD disease can be considered a negative response.

Note: If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, or if the blood relative was exposed to the disease through iatrogenic means (medical treatment), the donor is eligible.



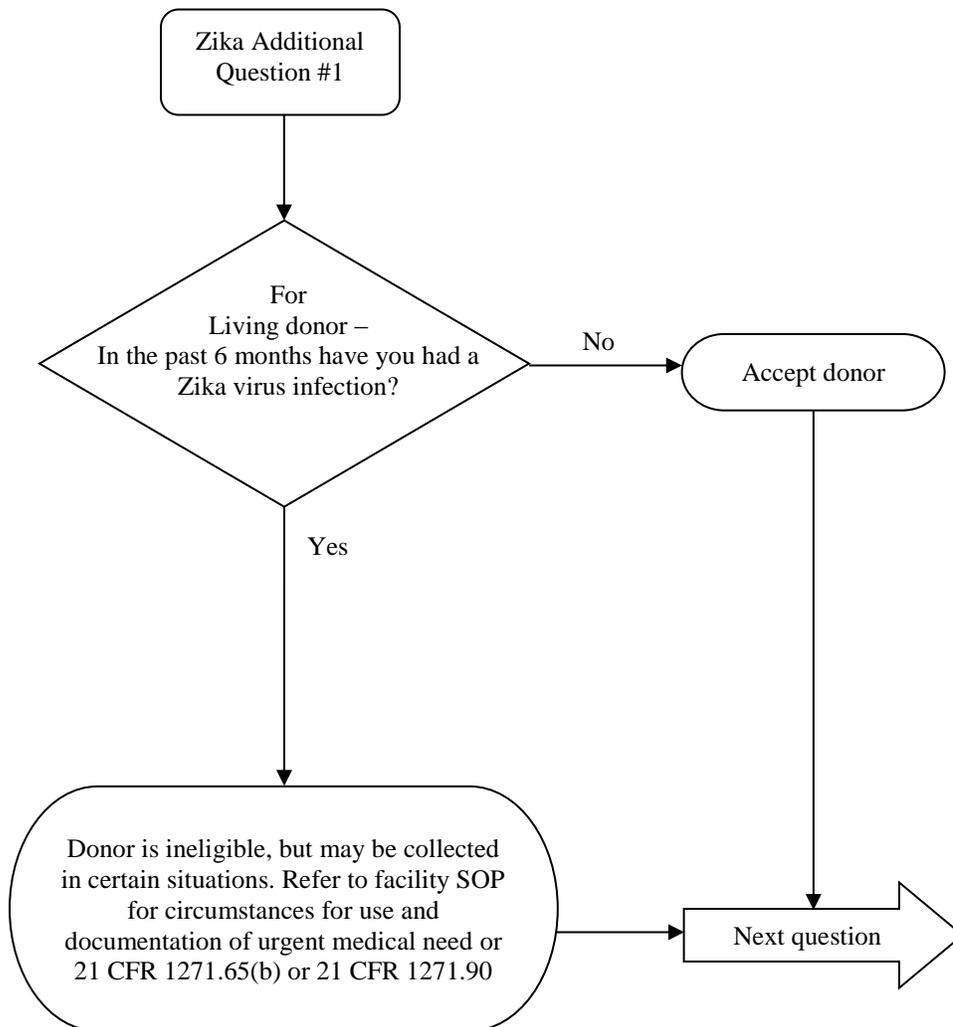
Zika Additional Question: 1. For Living donor – In the past 6 months have you had a Zika virus infection?

Donor Eligibility: Donors with a medical diagnosis of Zika virus infection within the past 6 months are ineligible due to the potential risk of transmitting Zika virus through HCT/Ps. The Zika virus, which is spread by mosquitos, has recently emerged in the Americas. While most Zika virus infections are asymptomatic, or self-limited, infections have been associated with serious birth defects (i.e. microcephaly) and a neurological condition, Guillain-Barré syndrome. Therefore, donors who have a history of infection with Zika virus, are ineligible for donation for 6 months after resolution of symptoms.

The symptoms of Zika virus infection are: fever, rash, joint pain, muscle pain, conjunctivitis (red eyes), headache.

(See May 2018 FDA Guidance:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)

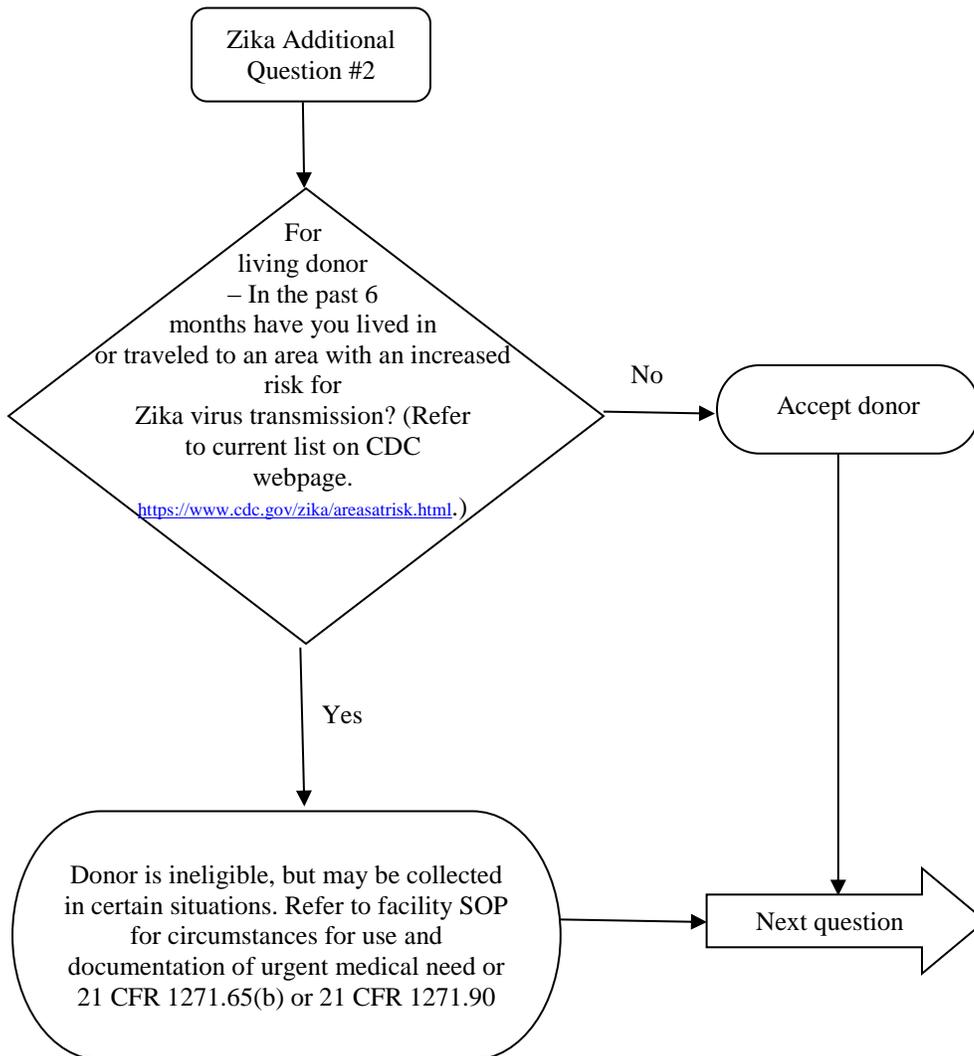


Zika Additional Question: 2. For living donor – In the past 6 months have you lived in or traveled to an area with an increased risk for Zika virus transmission? (Have donor review list of locations on CDC webpage <https://www.cdc.gov/zika/areasatrisk.html>.)

Donor Eligibility: The Zika virus, which is spread by mosquitos, has recently emerged in the Americas. While most Zika virus infections are asymptomatic or self-limited, infections have been associated with serious birth defects (i.e. microcephaly) and a neurological condition, Guillain-Barré syndrome. Therefore, donors who have been to an area with an increased risk for Zika virus transmission are ineligible for donation for 6 months after the date of departure from the area.

NOTE: An “area with an increased risk for transmission” of Zika virus is an area included on the CDC website listing of areas with local vector-borne (i.e., mosquito-acquired) transmission of Zika virus or where the potential is suspected based on epidemiological evidence. For the current listing, refer to: <https://www.cdc.gov/zika/areasatrisk.html>.

(See May 2018 FDA Guidance: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)



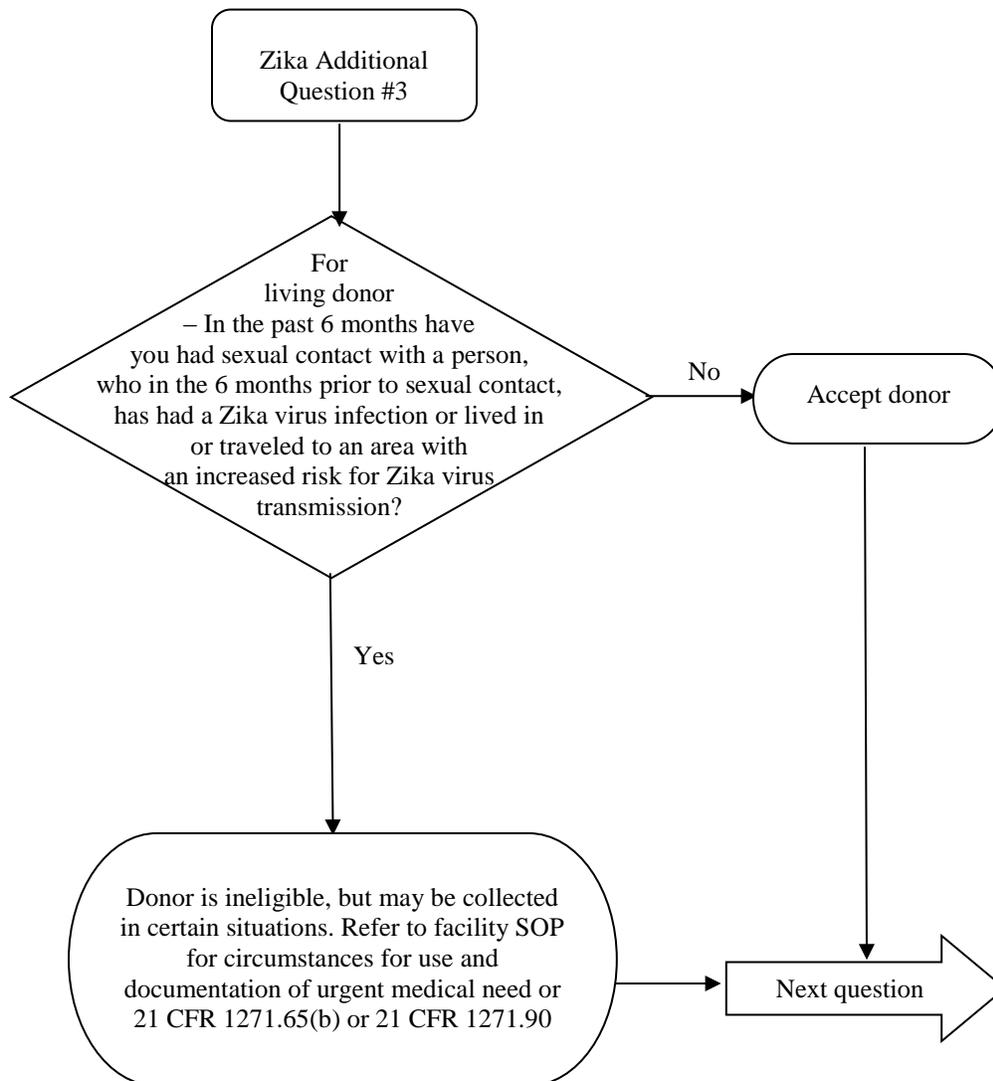
Zika Additional Question: 3. For living donor – In the past 6 months have you had sexual contact with a person, who in the 6 months prior to sexual contact, has had a Zika virus infection or lived in or traveled to an area with an increased risk for Zika virus transmission?

Donor Eligibility: The Zika virus can be transmitted from person to person by sexual contact, and the Zika virus may remain in semen for several weeks. A case of female-to-male sexual transmission of ZIKV has also been reported, and ZIKV has been detected in genital and endocervical swabs from infected females. Donors who provide a history of having had sexual contact with a person who, in the 6 months prior to the sexual contact, has had Zika virus infection OR lived in or traveled to an area with an increased risk for Zika virus transmission are ineligible for donation 6 months following date of last sexual contact. (Have donor review list of locations on CDC webpage <https://www.cdc.gov/zika/areasatrisk.html>.)

The symptoms of Zika virus infection are: fever, rash, joint pain, muscle pain, conjunctivitis (red eyes), headache.

NOTE: Refer to CDC’s website for more information on the signs and symptoms of Zika virus infection: <http://www.cdc.gov/zika/symptoms/index.html>.

(See May 2018 FDA Guidance: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)



May omit question number 4 if this type of donation is not applicable to your program.

Zika Additional Question: 4. For Non-Heart-Beating (Cadaveric) donor – In the past 6 months has the donor had a medical diagnosis of a Zika virus infection?

Donor Eligibility: Donors with a medical diagnosis of Zika virus infection within the past 6 months are ineligible due to the potential risk of transmitting Zika virus through HCT/Ps. The Zika virus, which is spread by mosquitos, has recently emerged in the Americas. While most Zika virus infections are asymptomatic, or self-limited, infections have been associated with serious birth defects (i.e. microcephaly) and a neurological condition, Guillain-Barré syndrome. Therefore, donors who have a history of infection with Zika virus, are ineligible for donation for 6 months after resolution of symptoms.

The symptoms of Zika virus infection are: fever, rash, joint pain, muscle pain, conjunctivitis (red eyes), headache.

(See May 2018 FDA Guidance:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)

