

Comments for FDA and ABC Re. FDA Draft Uniform Donor History Guidance

PROBLEMS NOTED WITH JULY '04 VERSION

DHQ

- #17 ignores other sharps injuries. Prior question does not really address sharps either (eg. exposed to someone else's blood). The sharp may not be obviously contaminated. If needles are significant enough to separate from 'blood contact', why aren't sharps when just as many happen? Using just the word 'needle' may make health care workers think that's all we are interested in. In this instance, breaking the old question up may cause a loss in the 'capture' of similar situation of various exposure modalities. Health care workers with today's Universal Precaution training are familiar with the word 'sharps'. The question should use sharps instead of needlestick OR sharps/needlestick injury
- #30 – 34 Asked as 4 separate questions rather than an overall question, have you been to Europe since 1980 which allows all the "no's" to skip ahead. A 'yes' would lead to complicated follow-up, but Vaccines, smallpox, Malaria, group O are all pretty complicated as well.
- #39 dropping 'liver disease/jaundice' may result in our missing other viral hepatitis eg. mono hepatic complications which could increase PDIs. This is especially worrisome in light of the problems from several years ago when many blood centers were accepting some non-ABC viral hepatitis/liver involvement (jaundice or other clinical indications of hepatitis: 12/22/93 guidance)

BROCHURE

- **User Brochure Format:**
 - Arrow indicating 'move to the next question': While brochure says to do what your SOP says concerning whether or not to terminate or proceed with interview, because the flow chart shows to continue, this may cause staff confusion and the flow chart appears to be discrepant with SOP. Recommend brochure referring to local SOP for established procedures but not putting the arrow on each flow chart.
- **Donor Deferral Section:**
 - Format explained is NOT maintained in flowcharts: eg. 1. for a required deferral period, flow charts use the words "Defer donor" 2. for a yes answer which leads to a line of follow-up questioning which may or may not lead to deferral, flow charts use the words "Defer donor per SOP".

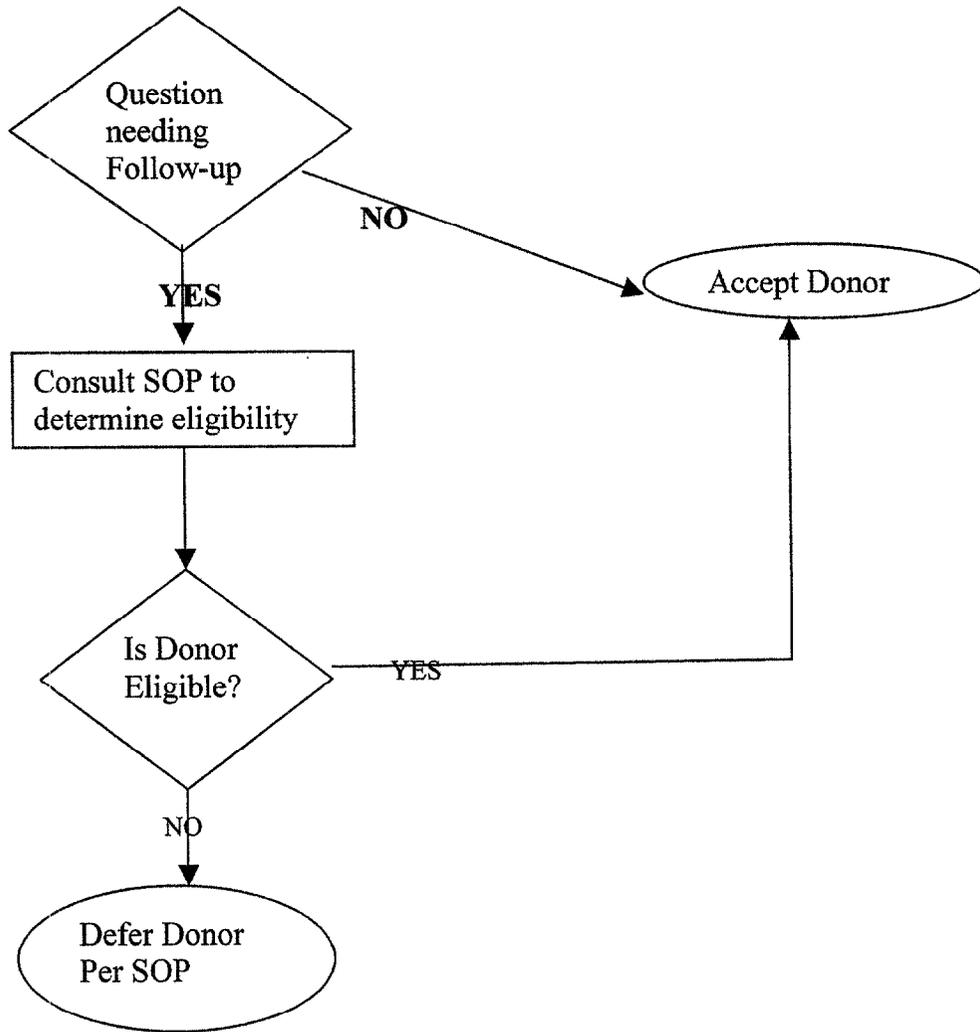
FLOW CHARTS

- Simple edits concerning format, move to next question arrow, or word choice may just be written on existing flow chart.
- If suggested edits are significant or marking up the chart appeared confusing, a re-done chart is attached with the marked up chart.
- Because of these marked up charts and re-done charts, it is not possible to transmit recommendations electronically. Therefore, a hard copy was sent in for comments.

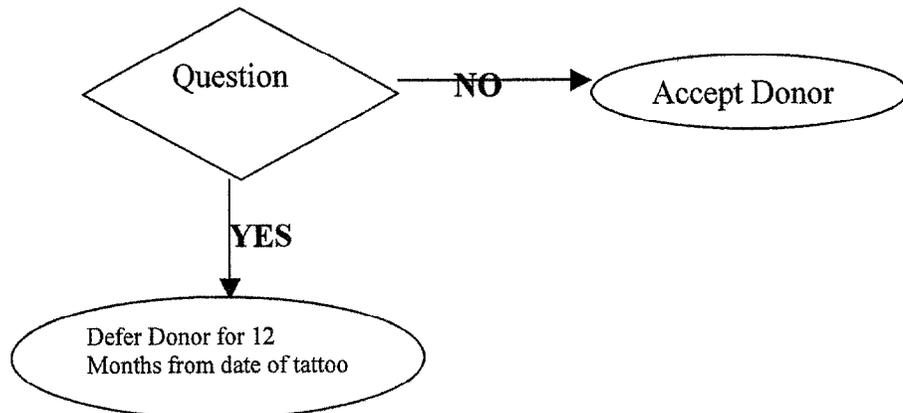
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C2

- For flow charts needing additional follow-up questions and eligibility assessment per local SOPs, the following format is not consistent on most charts:



- For flow charts addressing specific guidance deferrals, the following format is not consistent on most charts. Sometimes used 'Defer donor', 'Defer donor per SOP', 'Defer donor indefinitely', 'Defer donor xxxxx'. Prefer that if a specific time requirement is defined (eg, 12 months for unsterile peircings, indefinite, etc., it be given)



- #5 After having donor read materials and answering questions, chart should direct staff to accept donor then move to next question
- #10 < 21 days complication resolution = defer donor until 14 days after symptoms resolve (incorrectly says vaccination date)
- #10alt does not address the possibility that the complication resolution plus 14 day wait may have exceeded 56 days after vaccination date.
- #11 SEVERAL ERRORS IN FLOW CHART. 1. After asking if the donor developed a new skin rash, sore or severe complication, if yes, directs them down paths for rash or complication. Paths should be for a sore OR a rash/complication. After what to do after scab separated spontaneously says to defer for 3 mos from date of vaccination. Should say vaccination of their contact person to clarify that it does not mean their 'vaccination' via contact/exposure. Rash/complication resolution < 14 days should say, 'defer for longer period of time.....'
- #11 alt does not address the possibility that the complication resolution plus 14 day wait may have exceeded 56 days after vaccination date.
- #21 Current flow chart does not allow for acute situations calling for use of factors without diagnosis of chronic clotting factor disorders. Also appears to defer sex partners of individuals who have a factor disorder but have never taken a clotting factor. Guidance is specific to individuals who have taken clotting factor concentrates for bleeding disorders such as hemophilia. Fixing the flow chart as in first flow chart problem description above would allow for further follow-up questioning and eligibility evaluation per local SOPs
- #23 Current flow chart ignores 'other viral' and doesn't allow for chemical or obstructional hepatitis. Fixing the flow chart as in first flow chart problem description above would allow for further follow-up questioning and eligibility evaluation per local SOPs
- #24 Current flow chart ignores 'other viral' and doesn't allow for chemical or obstructional hepatitis. Fixing the flow chart as in first flow chart problem description above would allow for further follow-up questioning and eligibility evaluation per local SOPs
- #25 Current flow chart ignores that AABB standards give exceptions. Although we probably won't, some centers do.
- #29 If donor answers 'yes' to ...outside US..., the next question box should be "Where were you?" instead of 'Where did you travel?'. The donor may not consider it travel, if they just arrived here or are traveling here from the other place. After finding out lived/country/malaria area info, the defer instruction box should say "Defer for longer period of time: for 3 years after departure from that country or 12 months after departure from recent travel".
- #30 Does not address variation of stricter deferral: eg. all countries 1980-1996. Since deferral would be stricter, we could modify acceptably, but for consistency could be like #30alt.
- #36 The note does not apply to this question
- #38 Current flow chart does not allow for acute situations calling for use of factors without diagnosis of chronic clotting factor disorders. Guidance is specific to individuals who have taken clotting factor concentrates for bleeding disorders such as hemophilia. Fixing the flow chart as in first flow chart problem description above would allow for further follow-up questioning and eligibility evaluation per local SOPs
- #39 Current flow chart ignores 'viral' and doesn't allow for chemical or obstructional hepatitis. Fixing the flow chart as in first flow chart problem description above would allow for further follow-up questioning and eligibility evaluation per local SOPs
- #45 the word 'problems' is very vague and many donors do not think of their diagnosis as 'problems'. As well, heart/lungs' is very vague and may miss other circulatory/vascular/respiratory conditions whether the donor thinks of them as a problem or not. Many local restrictions may apply, but this question may not elicit the information. Adding other local questions to end could help. Eg. Do you have any other diagnosis, conditions, or take other medications?

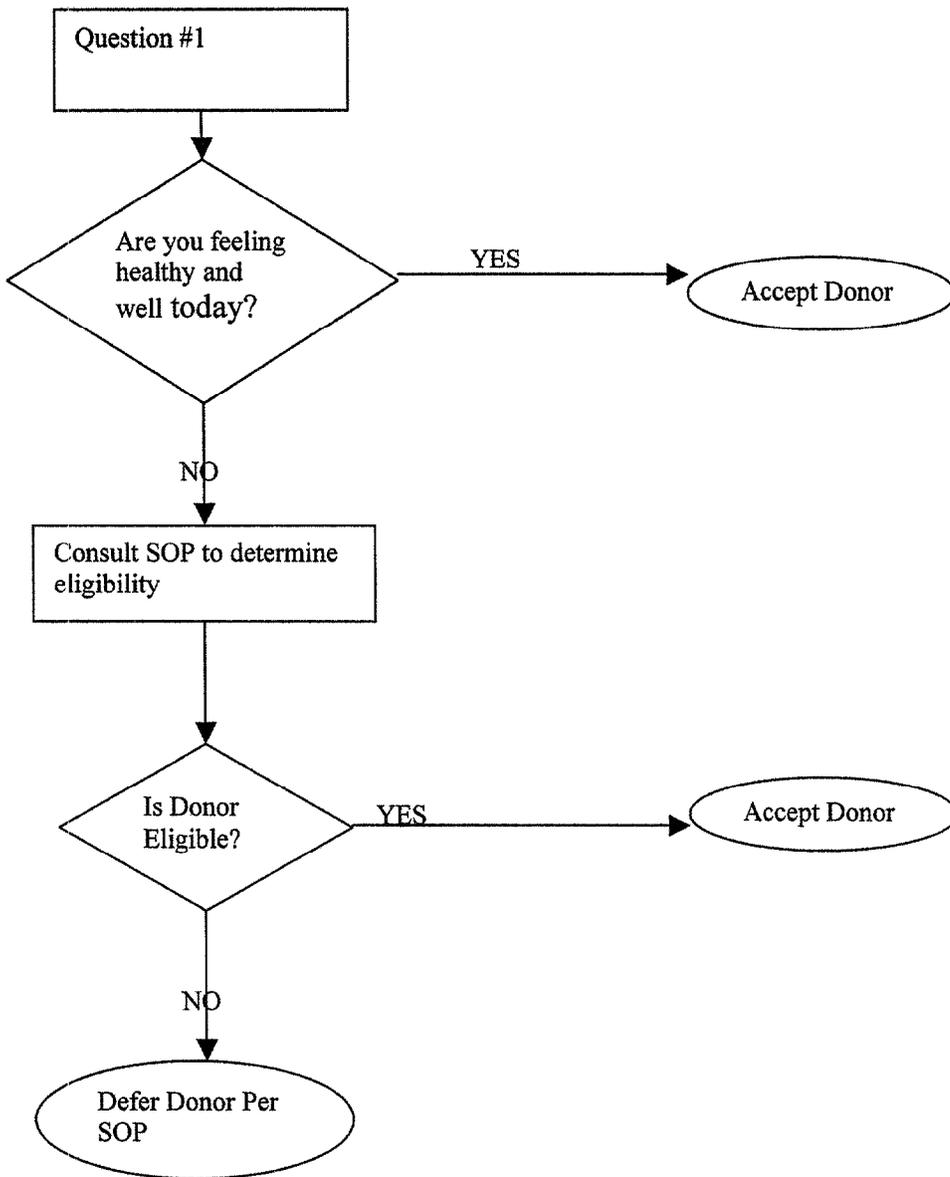
- #48 First follow-up question: only addresses born in or travel to, it does not address 'lived in'. Flow chart also uses words 'a blood transfusion or any other medical treatment' and then requires indefinite deferral if yes. This ignores the rule of 'any other medical treatment with a blood product'. The way it is written, if you were treated for a sinus infection in an HIV group O risk country, you would be deferred. Flow chart needs work: recommend:

- #49 Flow chart does not address exception for genetic testing

Attached are redone versions of flow charts needing format or criteria changes

MED LIST:

- Missing the word 'for' before Proscar



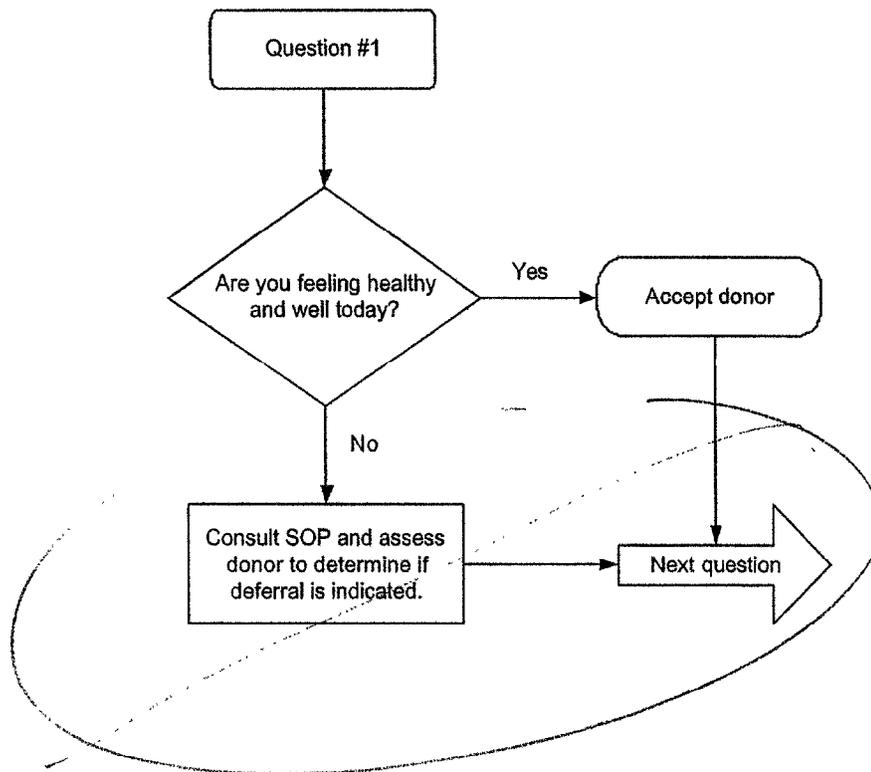
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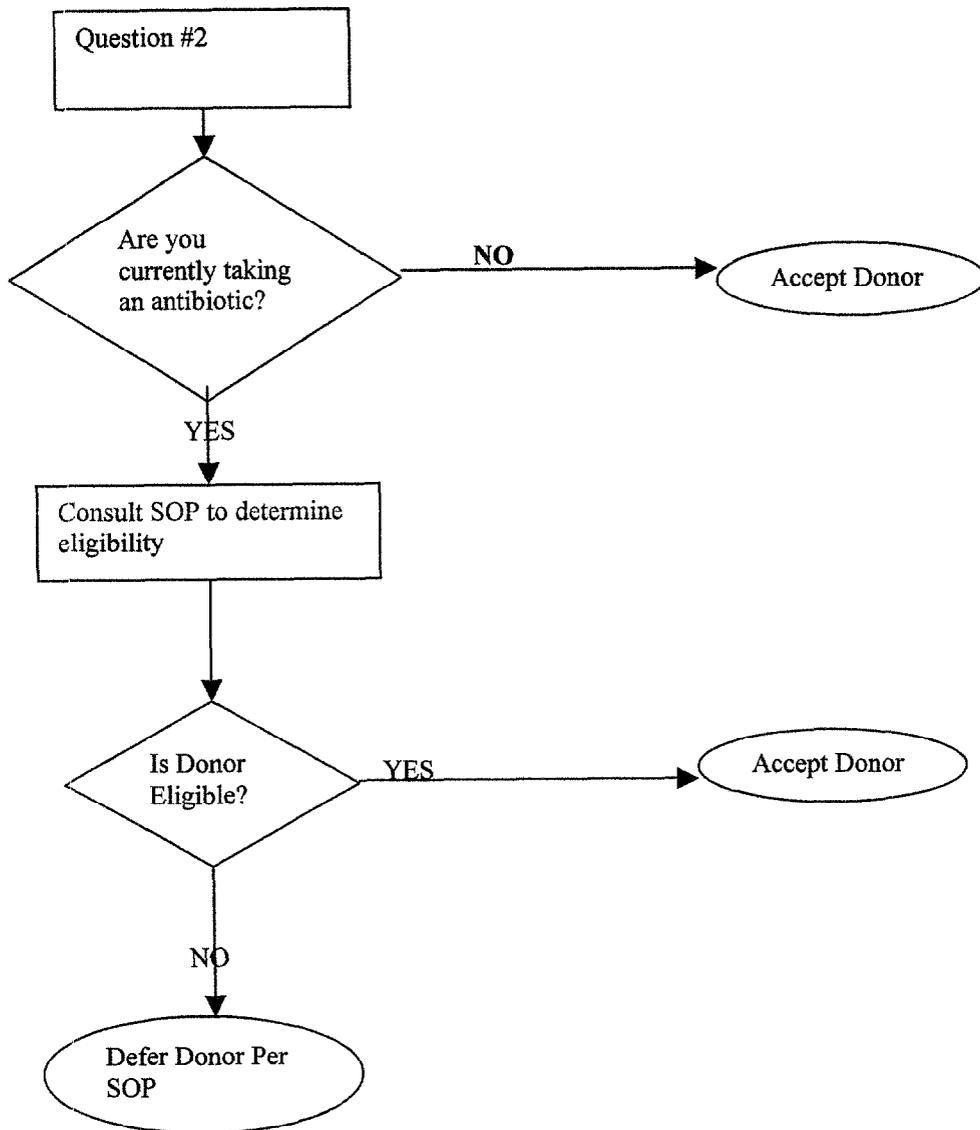
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APPENDIX 4: Flow Charts

Question: 1. Are you feeling healthy and well today?

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



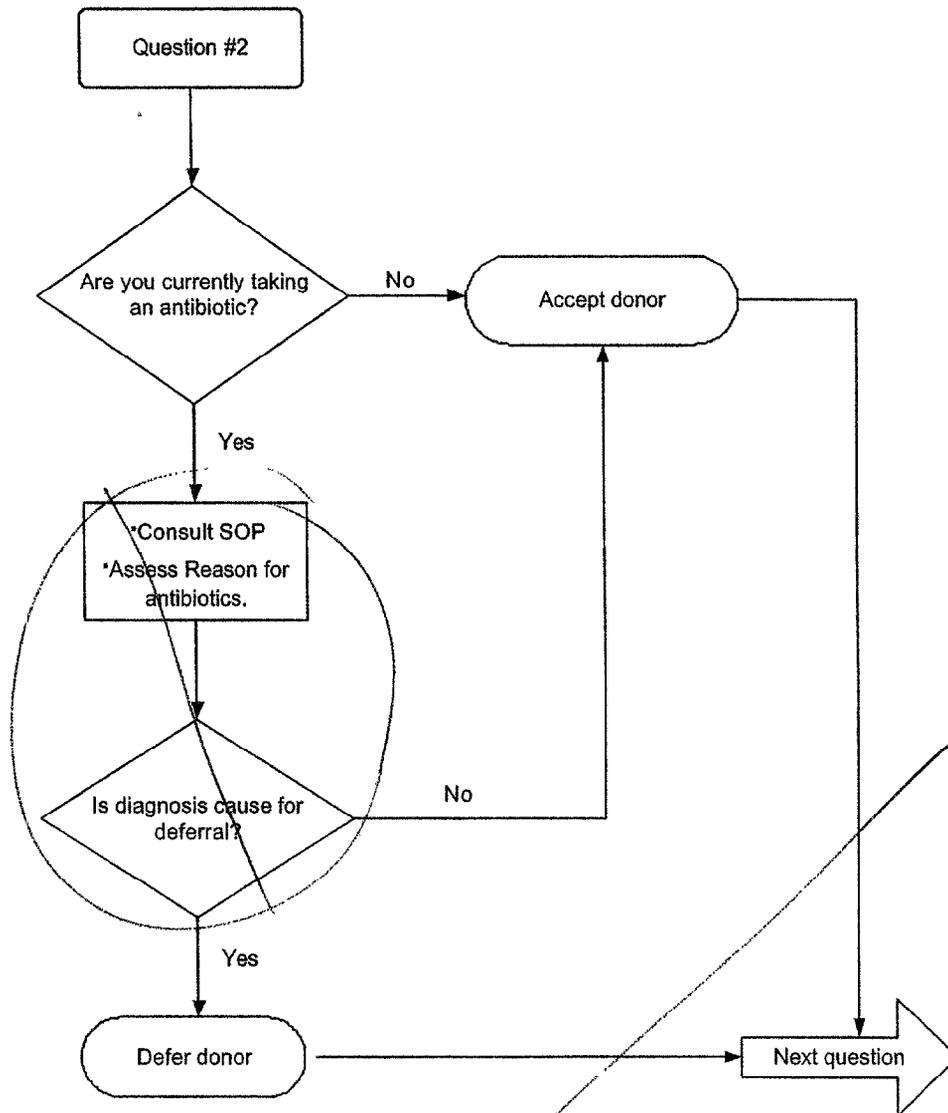


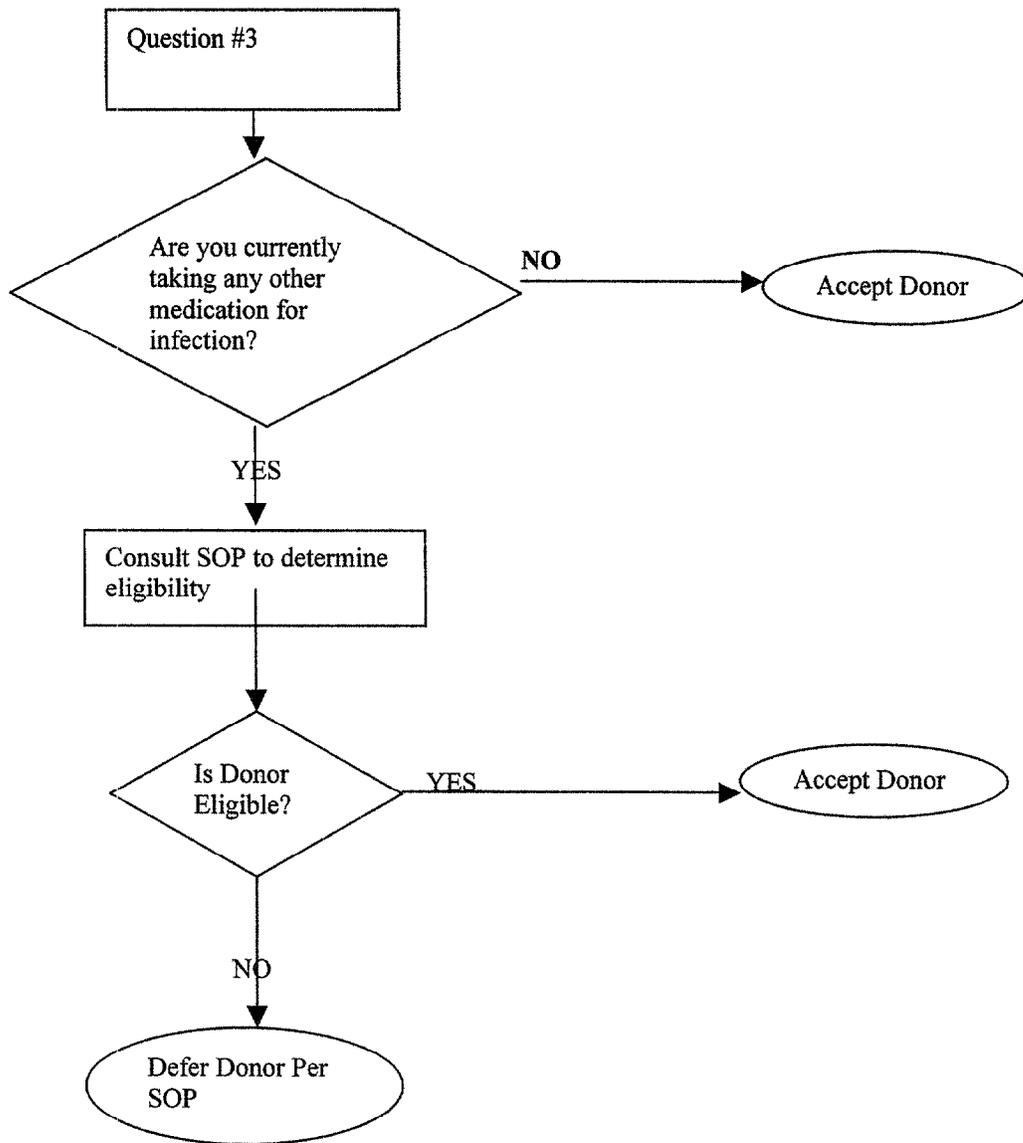
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Question: 2. Are you currently taking an antibiotic?

Donor Eligibility: A donor with an infection 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 blood.



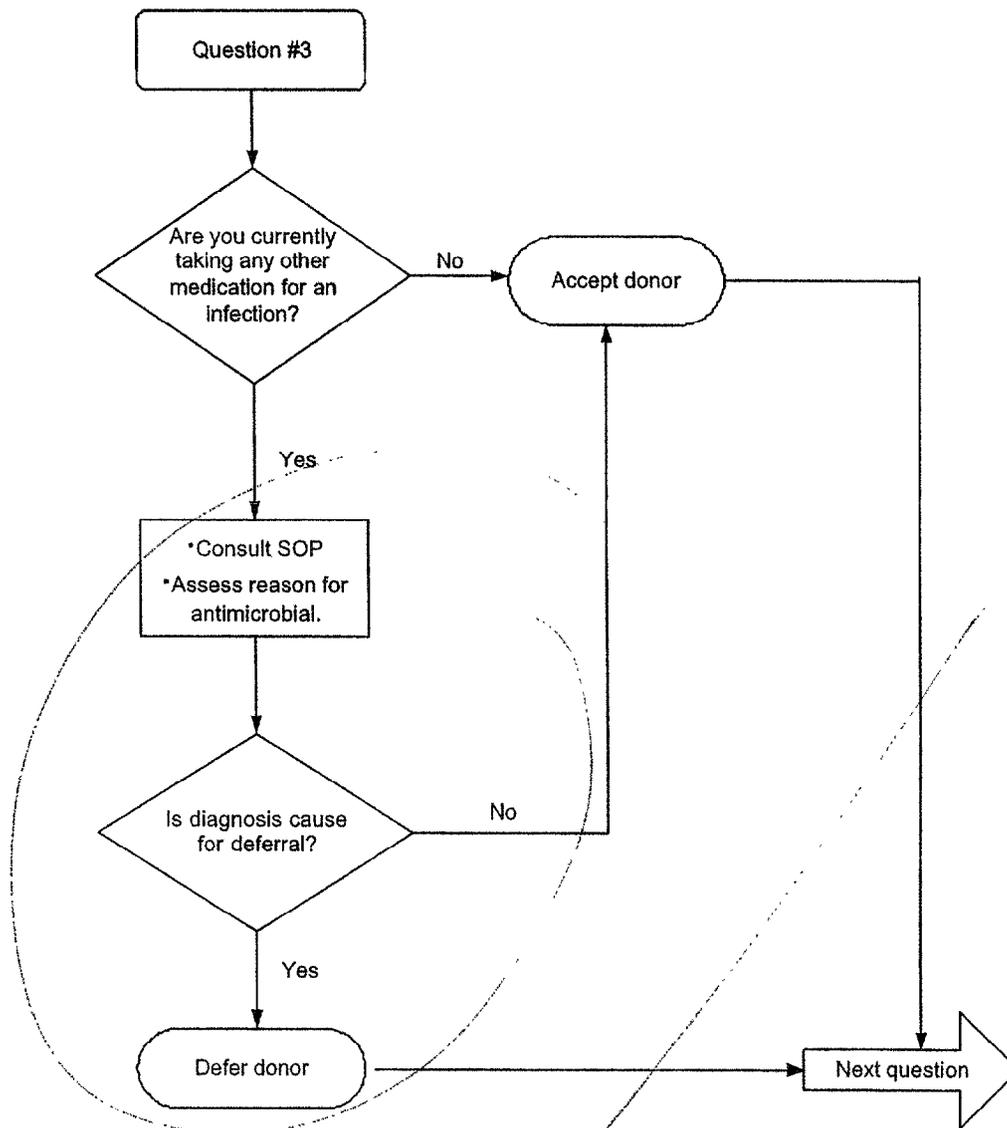


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Question: 3. Are you currently taking any other medication for an infection?

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

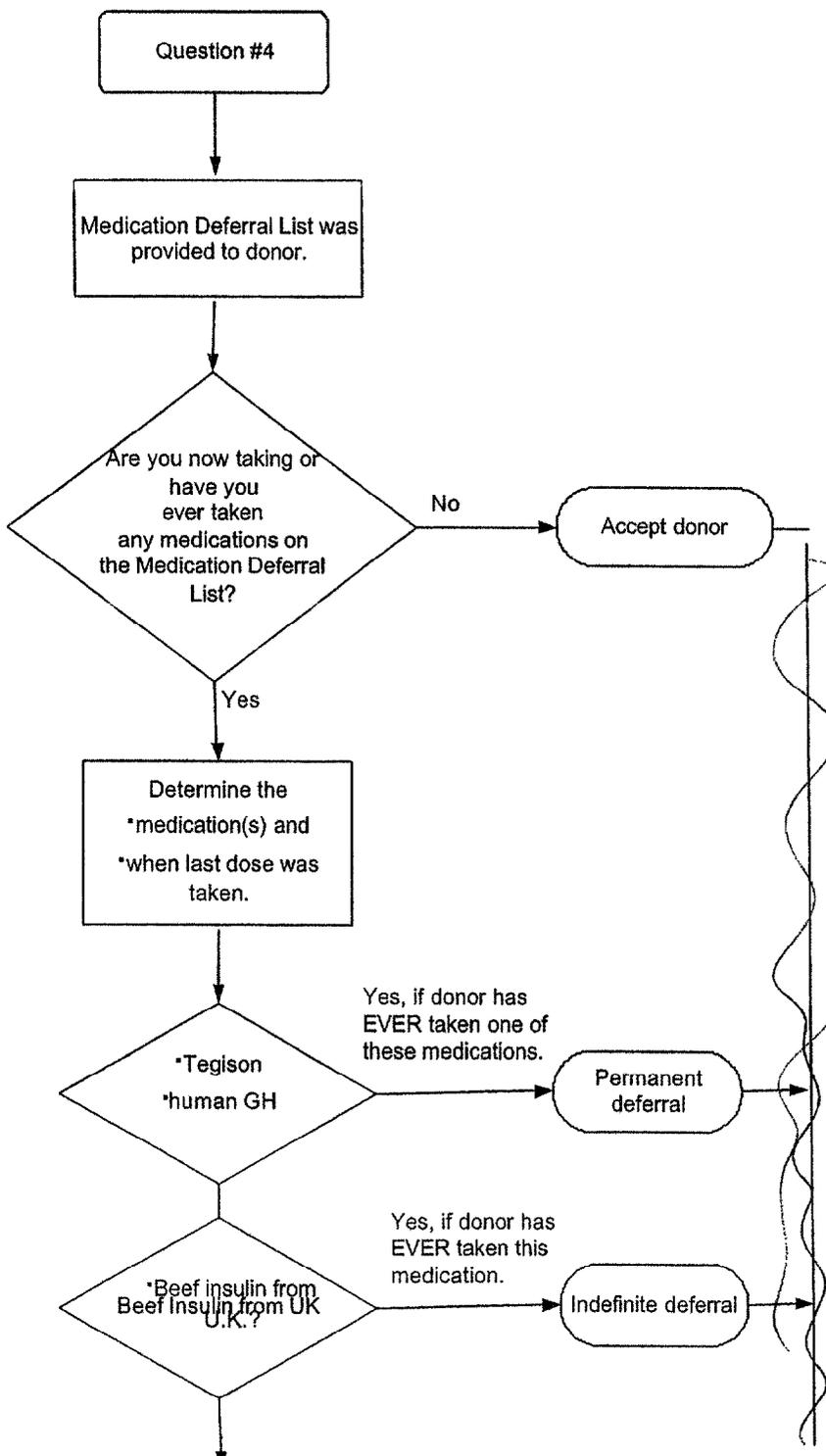


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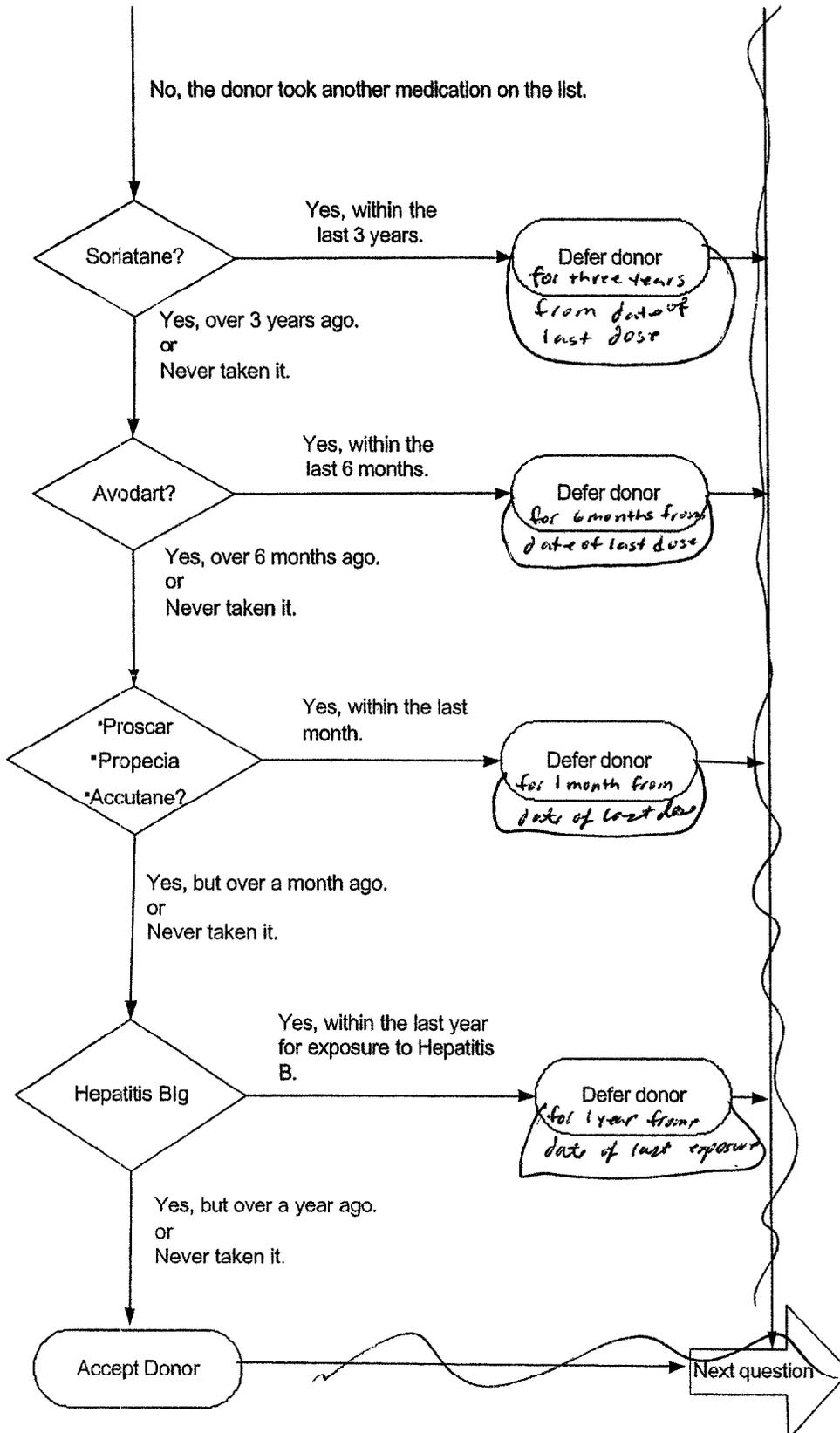
Question: 4. Are you now taking or have you ever taken any medications on the Medication Deferral List?

Donor Eligibility: Donors taking certain designated medications, currently or in the past, must not donate blood.



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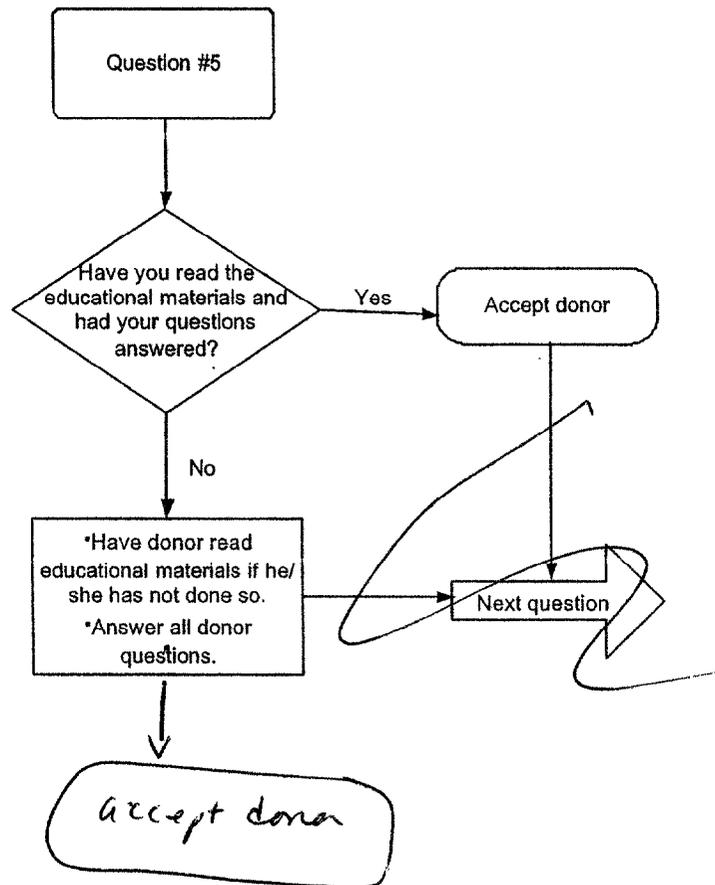


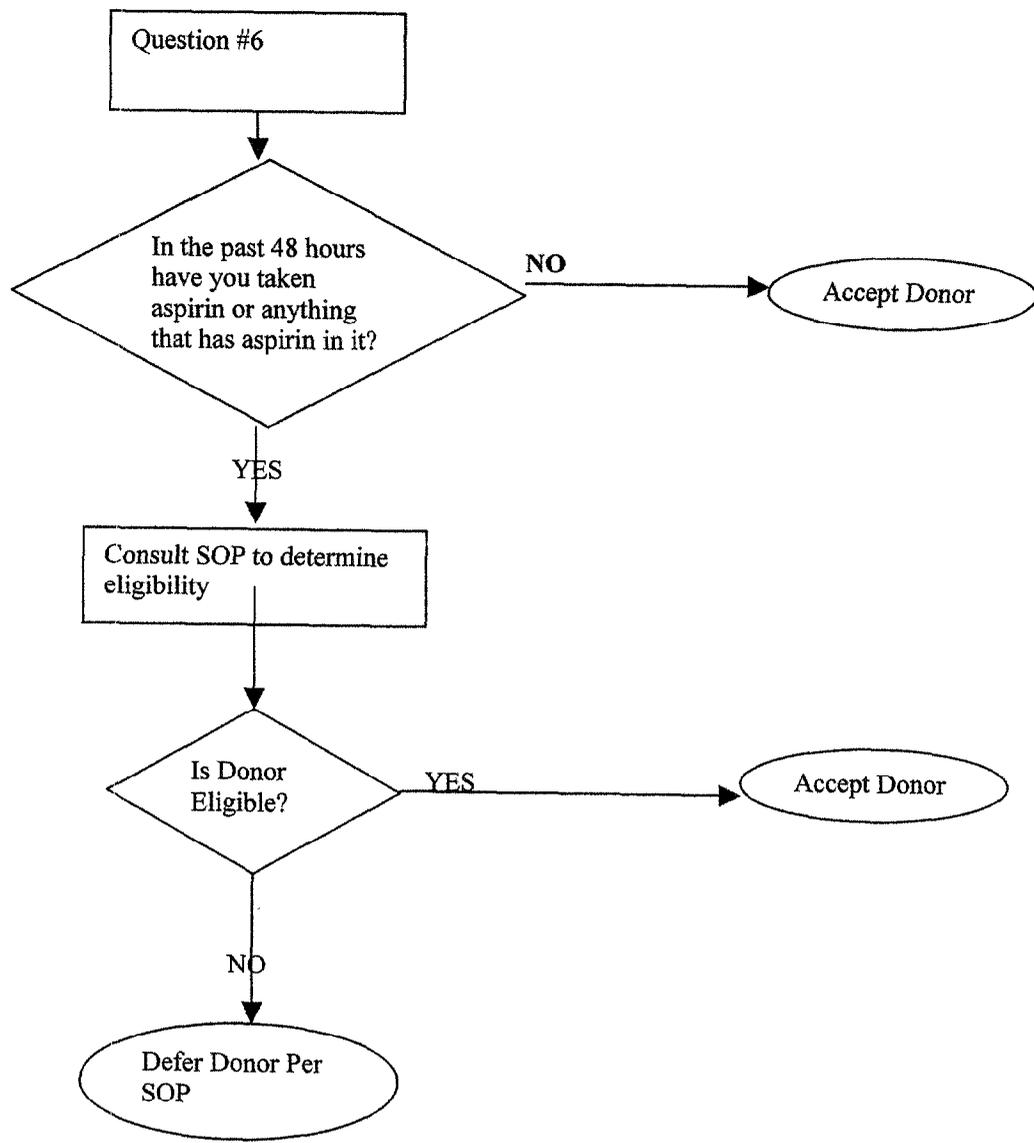
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Question: 5. Have you read the educational materials and had your questions answered?

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



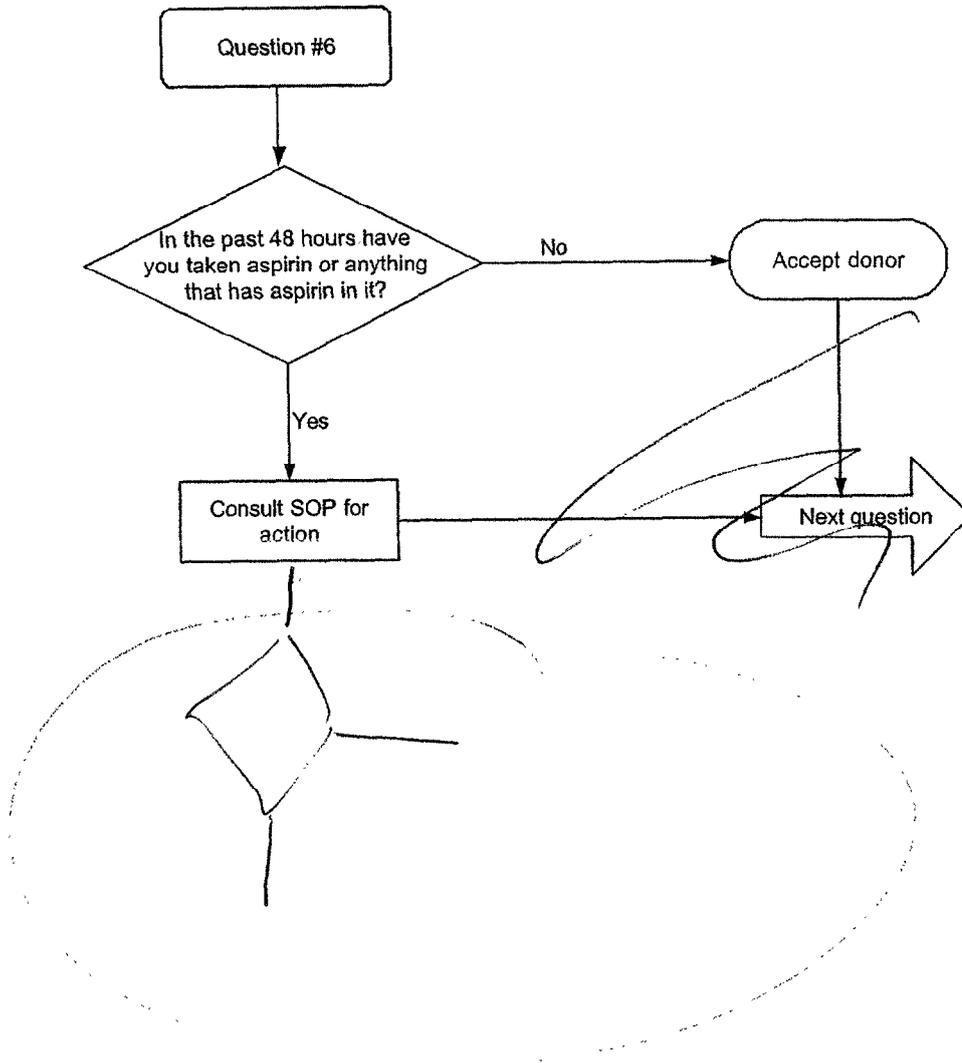


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Question: 6. In the past 48 hours have you taken aspirin or anything that has aspirin in it?

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

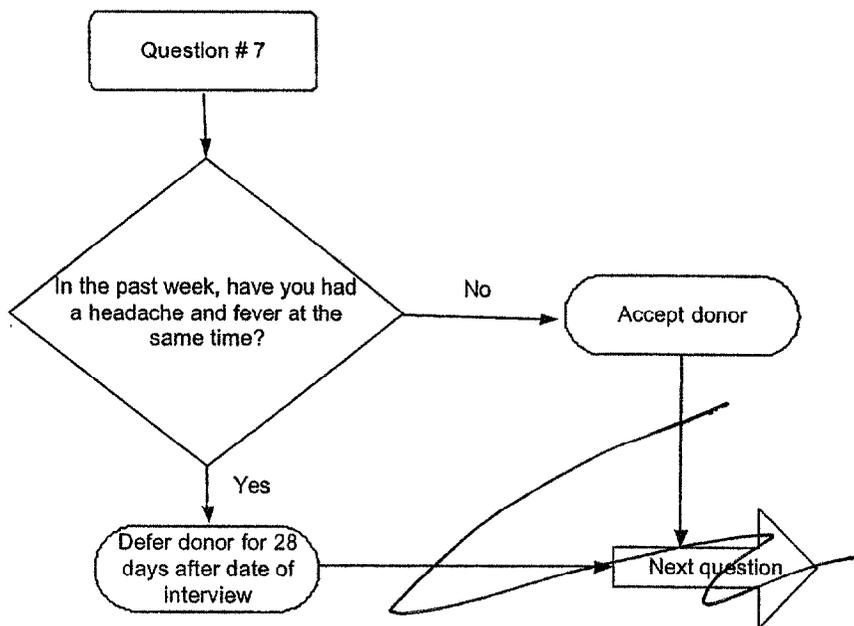


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Question: 7. In the past week, have you had a headache and fever at the same time?

Donor Eligibility: Symptoms of West Nile virus (WNV) include fever with headache in the past 7 days. Donors with both of these should not donate blood for 7 days after resolution

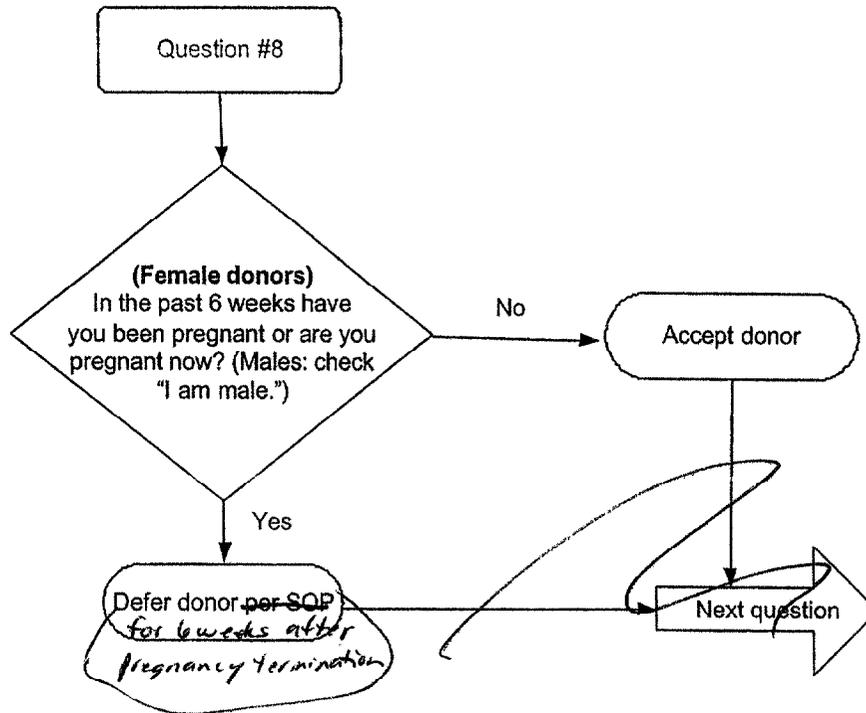


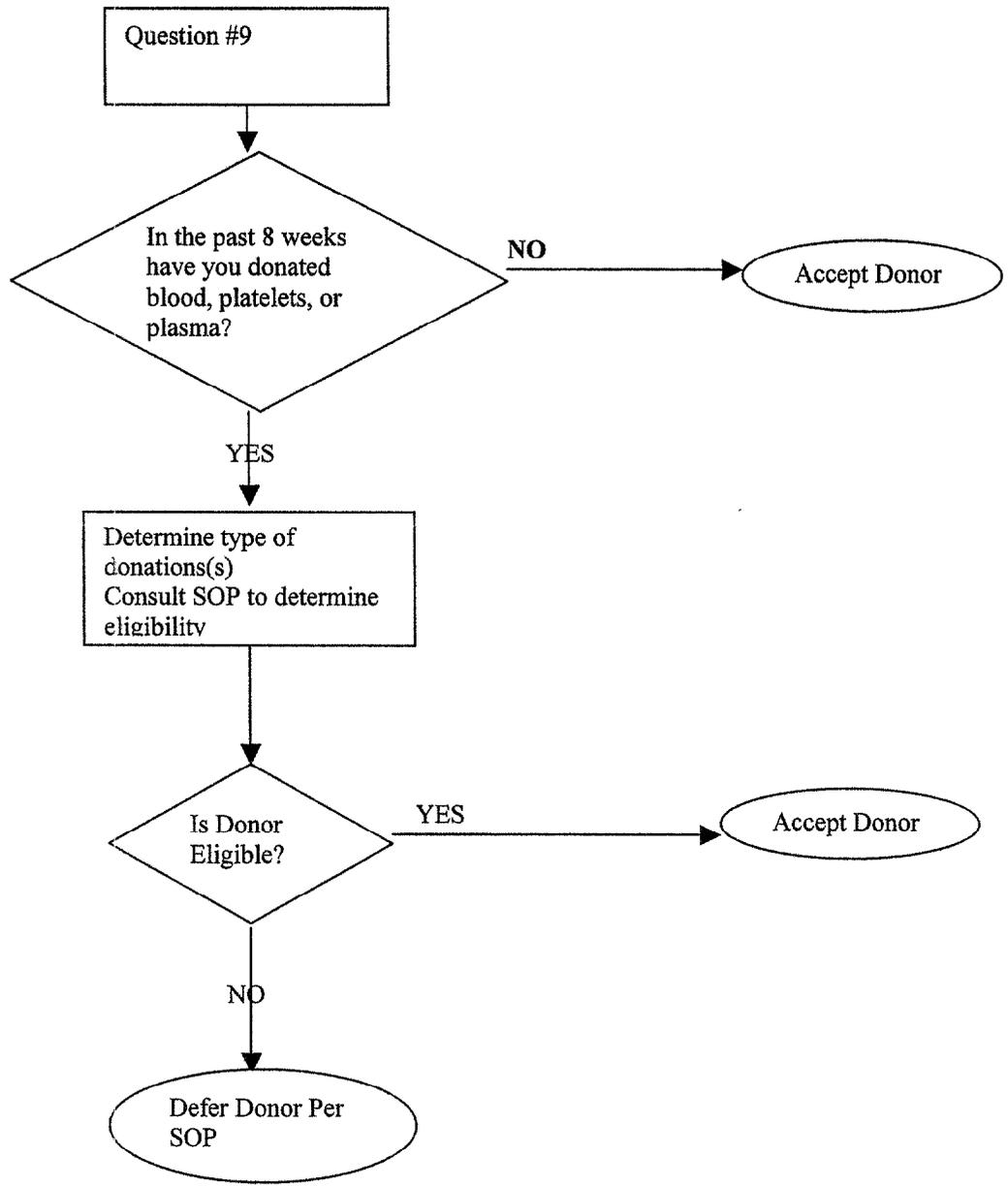
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Question: 8. Female donors: In the past 6 weeks, have you been pregnant or are you pregnant now?
(Males: check "I am male.")

Donor Eligibility: A female with a known pregnancy or who has been pregnant in the last 6 weeks should not donate blood.



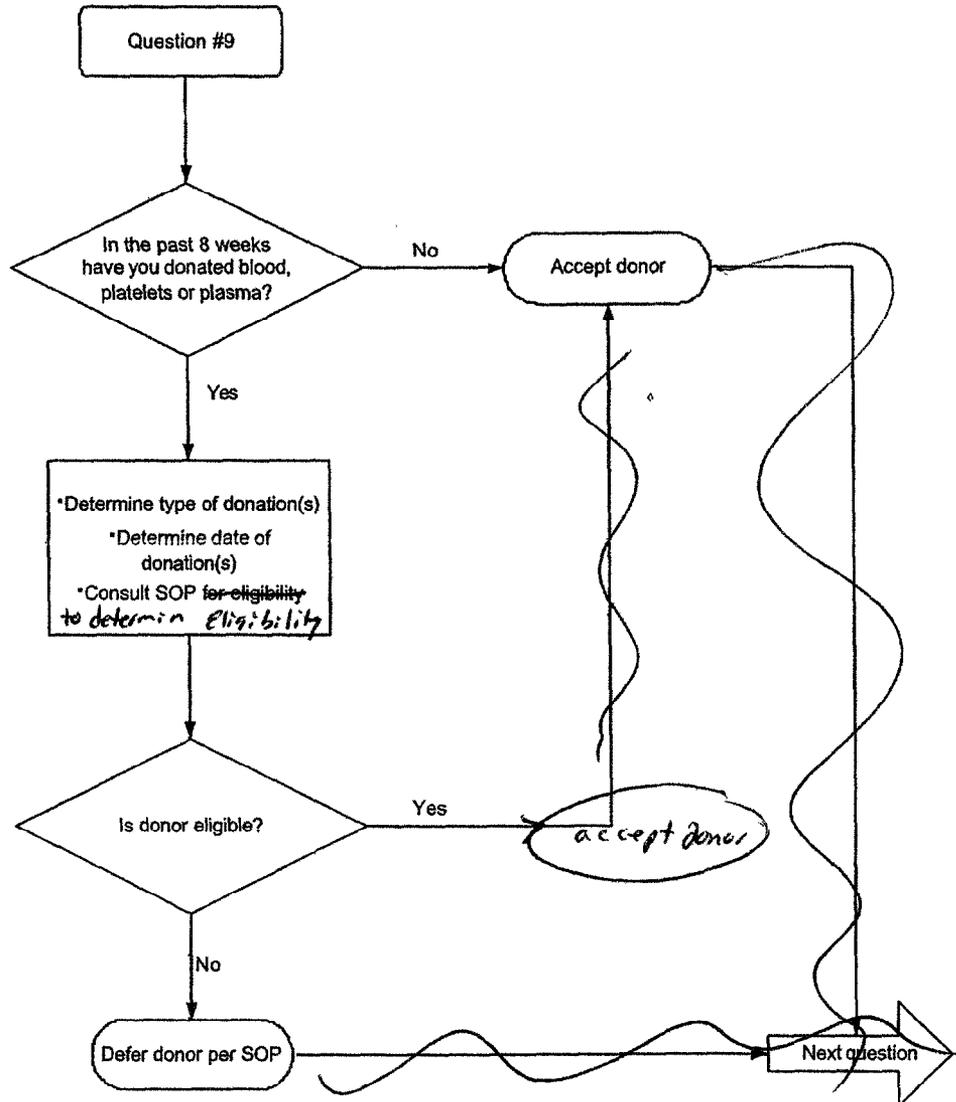


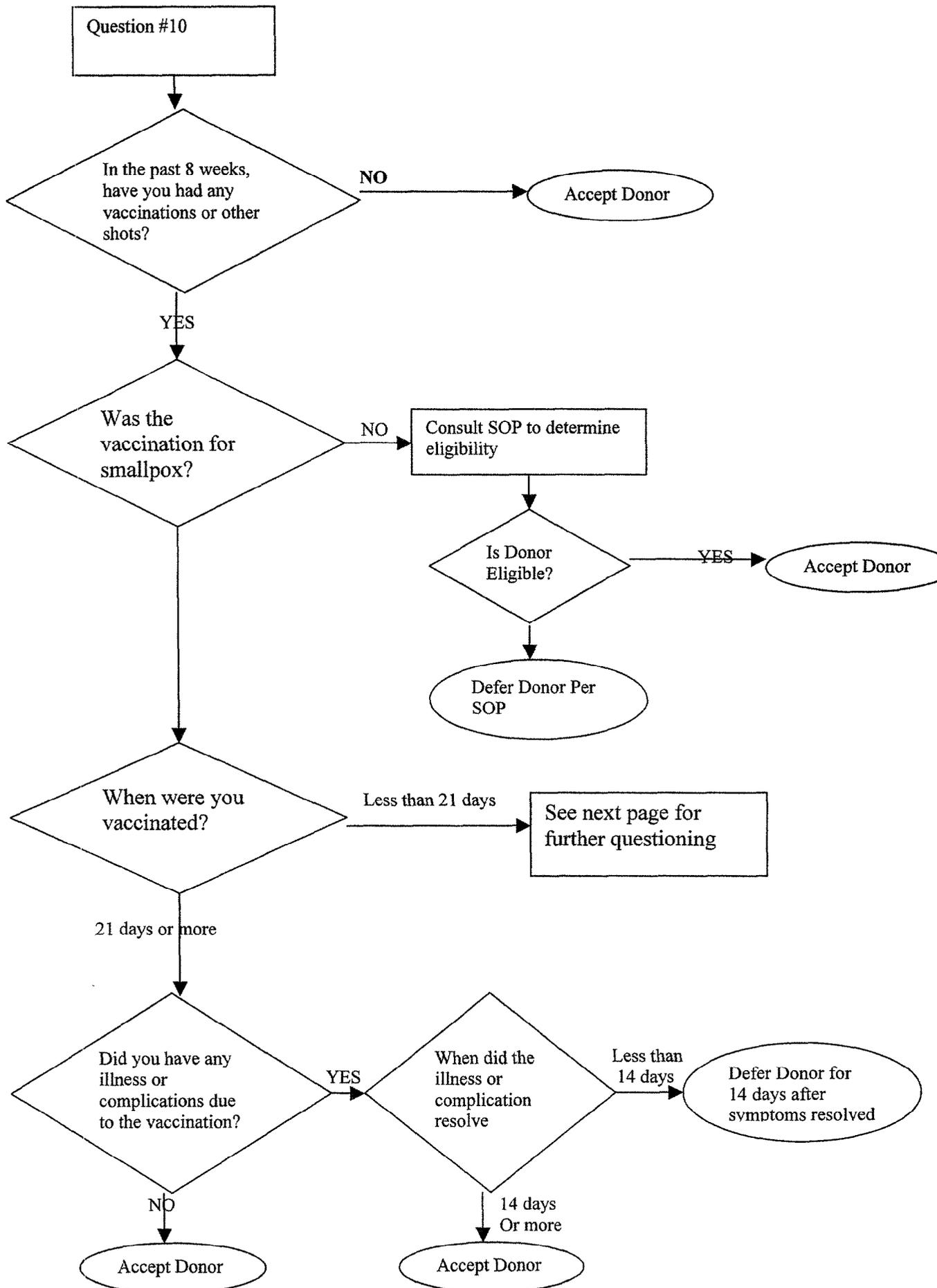
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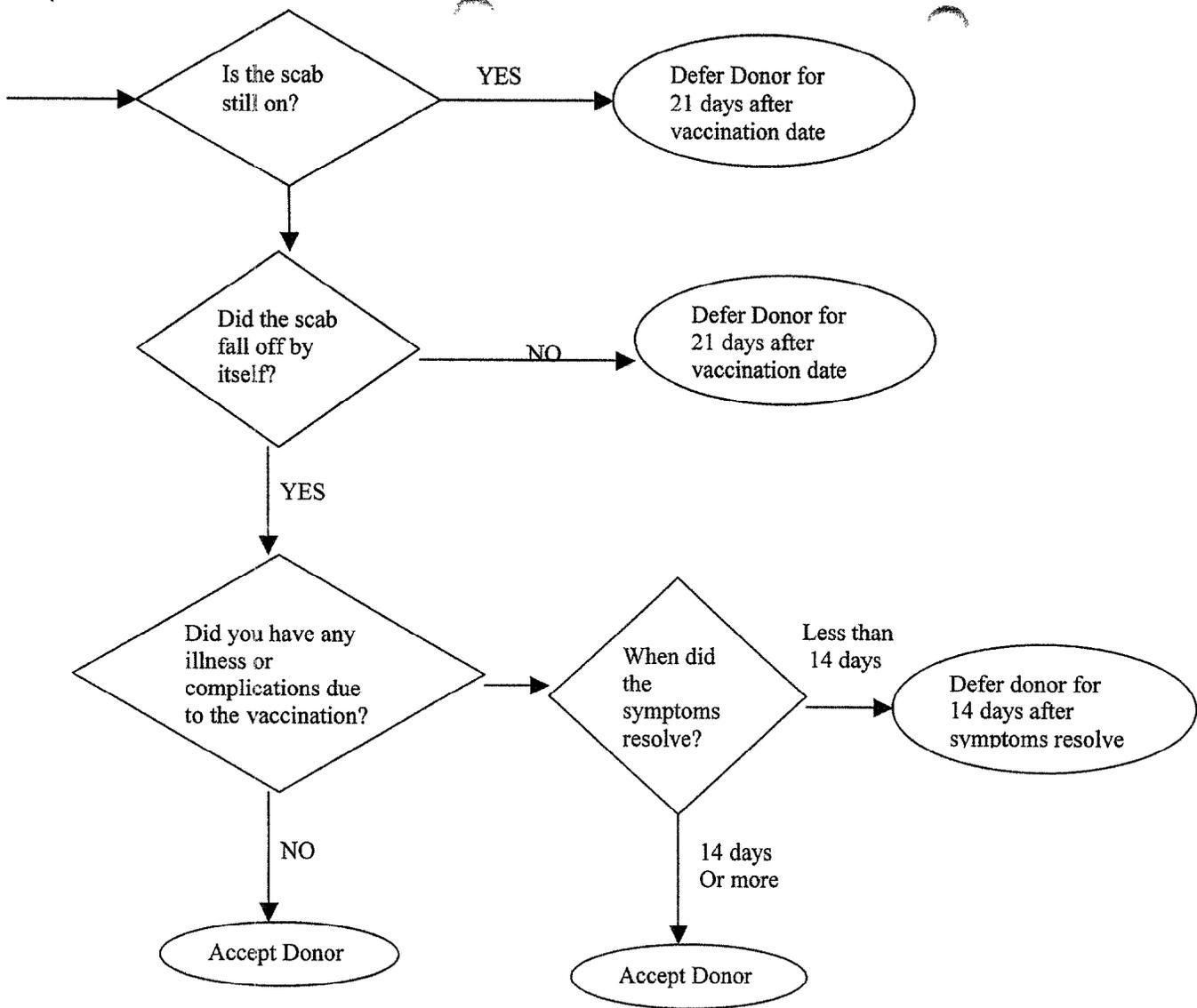
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Question: 9. In the past 8 weeks have you donated blood, platelets or plasma?

Donor Eligibility: Frequency of whole blood donation is a minimum of every 8 weeks; plasma, platelets or leukapheresis is a minimum of every 2 days.







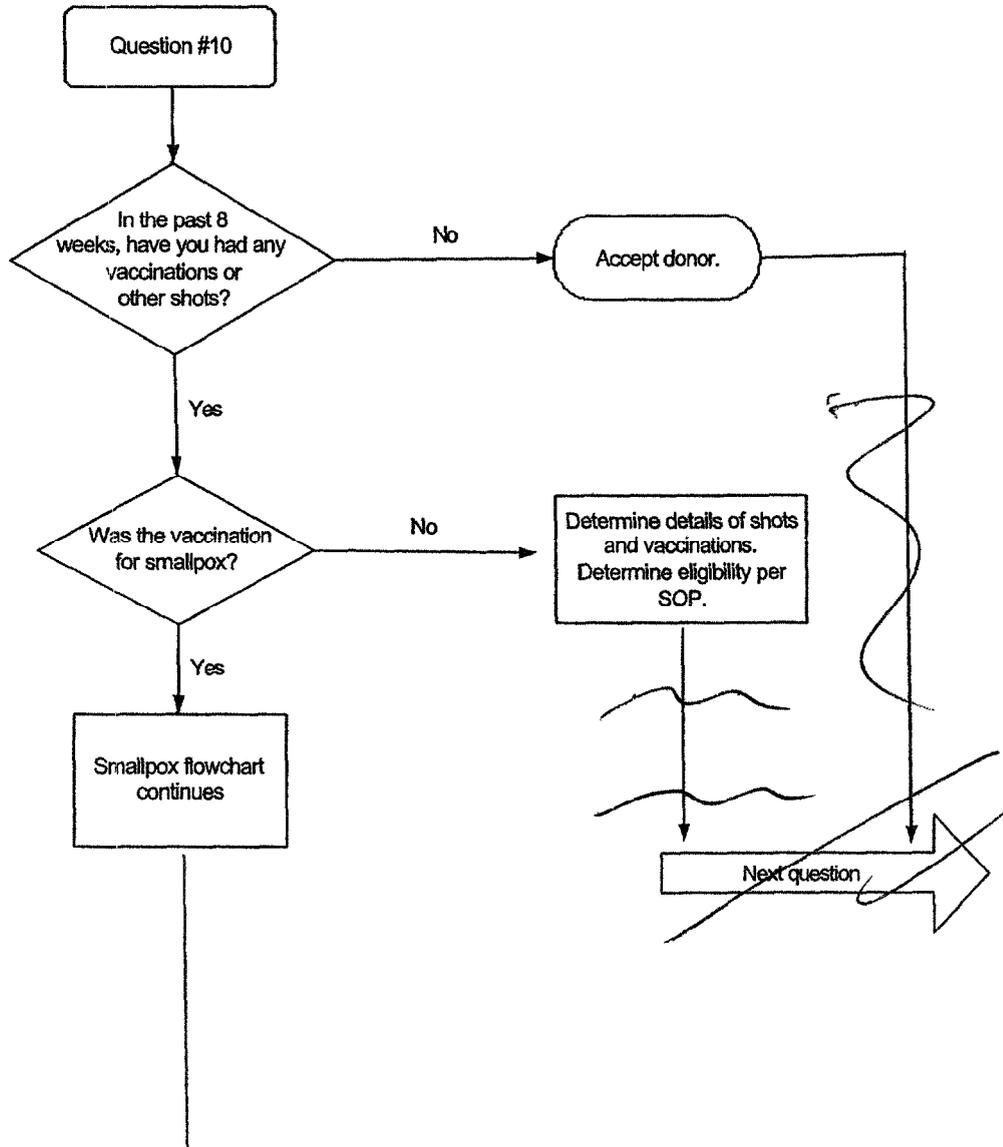
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Question: 10. In the past 8 weeks, have you had any vaccinations or other shots?

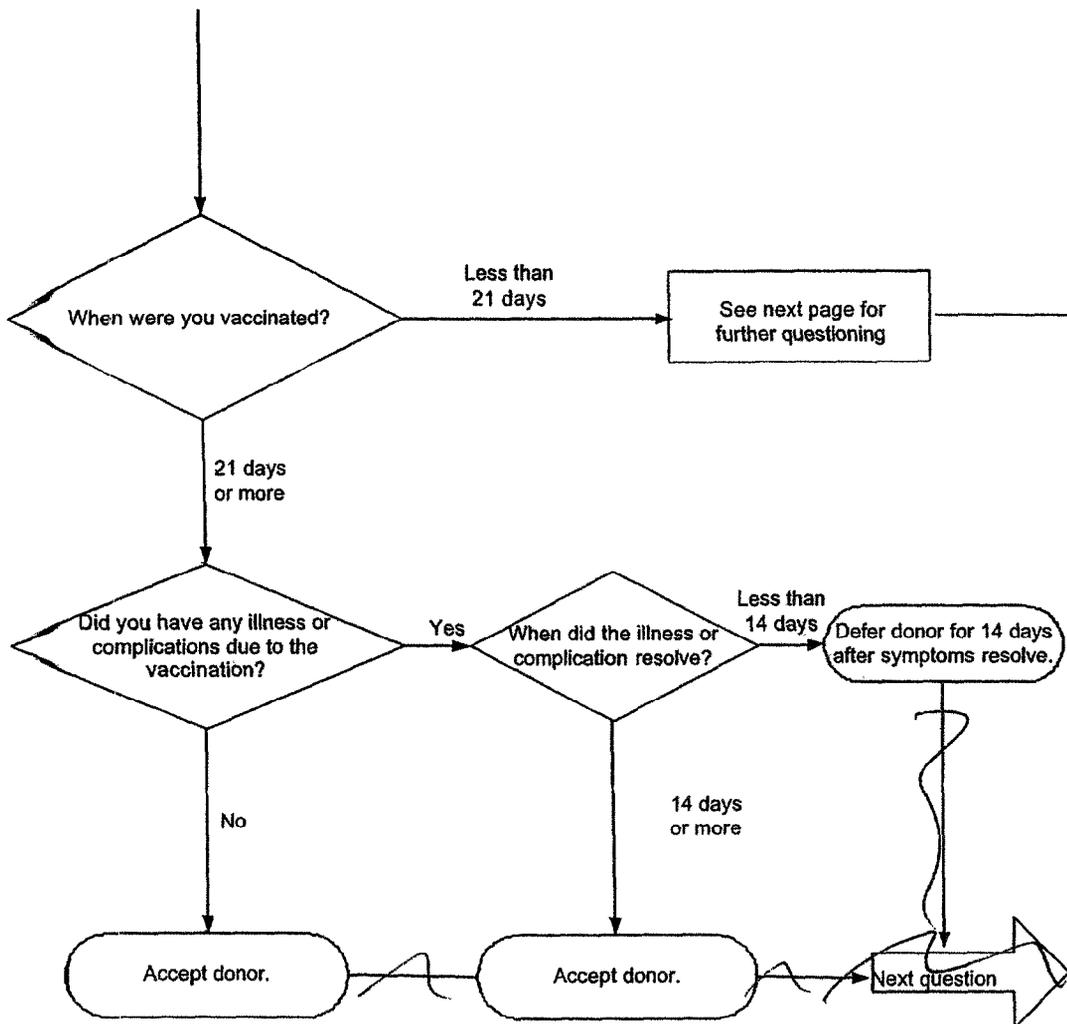
Note on 10alt Flow Chart: Some blood centers may choose to use a simpler but stricter deferral scheme in which all donors who receive the smallpox vaccination are deferred for 56 days regardless of when the scab fell off or was removed. Blood centers using these stricter criteria should use Alternative Flow Chart 10alt.

Donor Eligibility: Certain vaccinations may contain live viruses. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, refer to SOP.



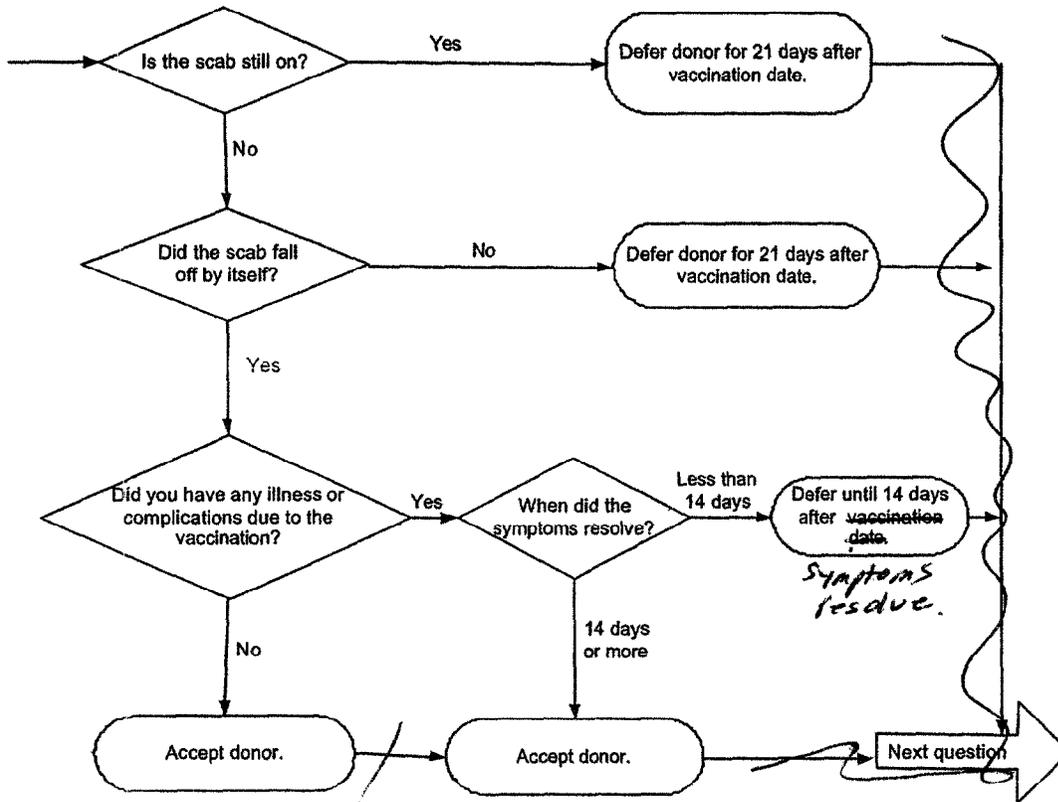
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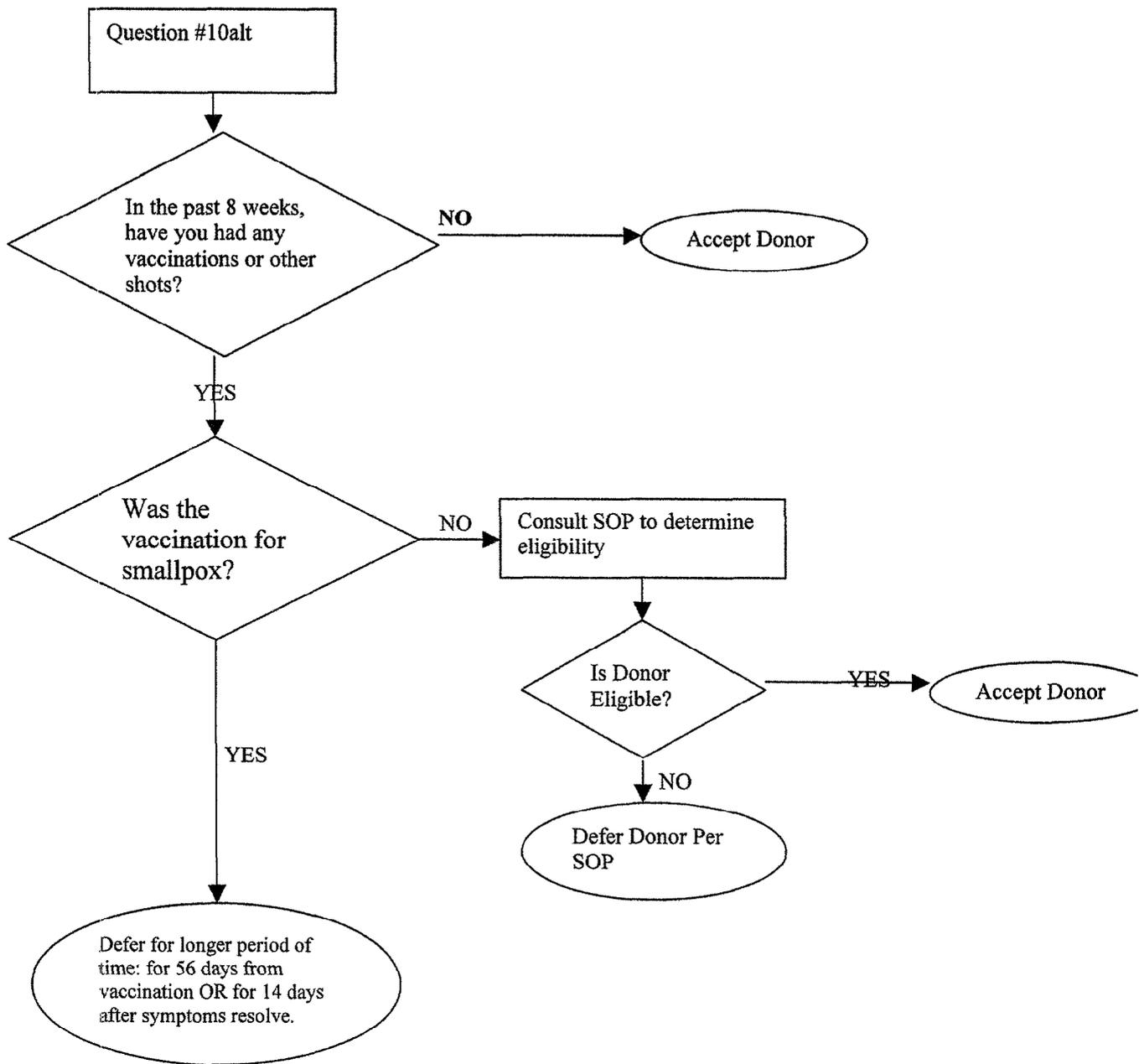
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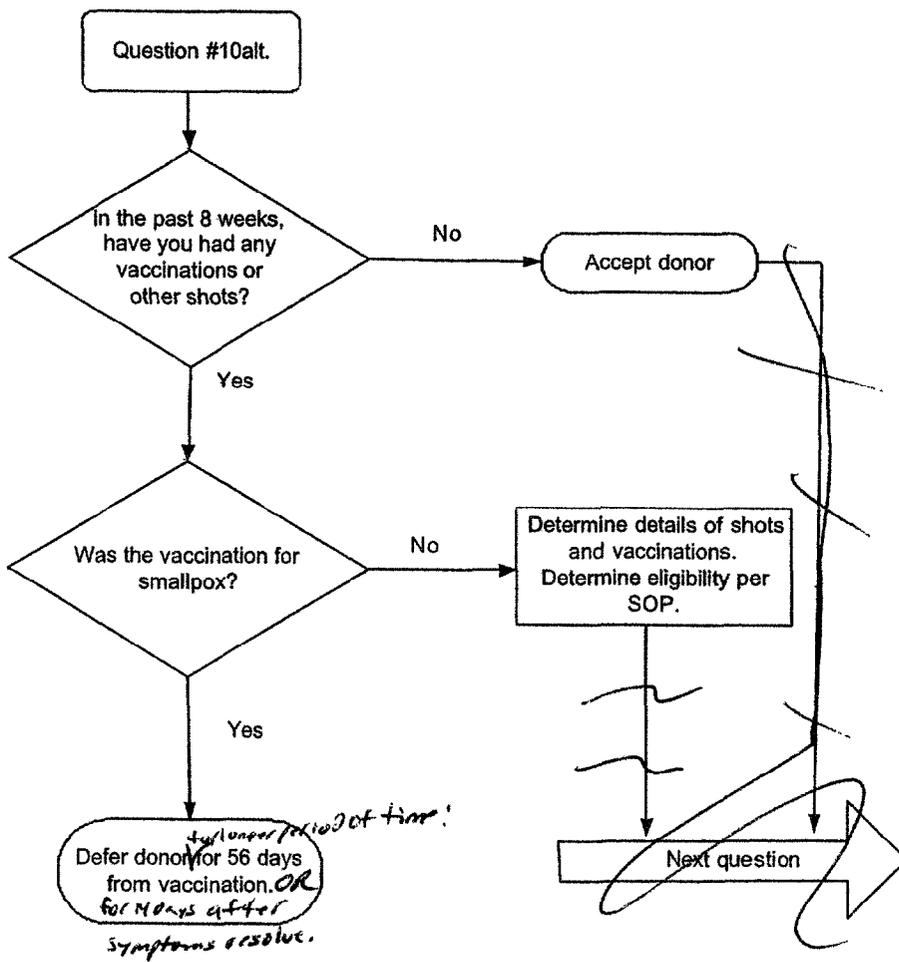


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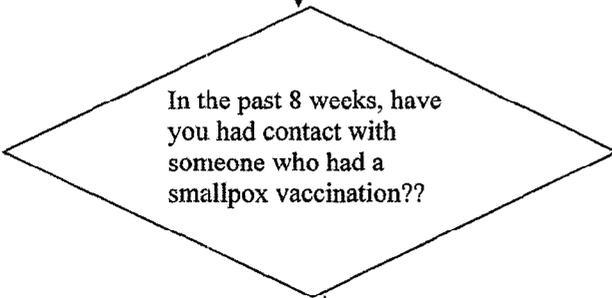
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Question: 10alt. In the past 8 weeks, have you had any vaccinations or other shots?

Donor Eligibility: Certain vaccinations may contain live viruses. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, refer to SOP.



Question #11

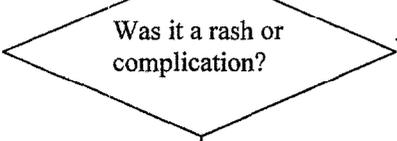


NO → Accept Donor

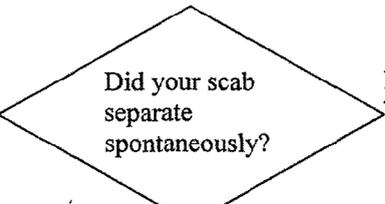


NO → Accept Donor

YES



NO



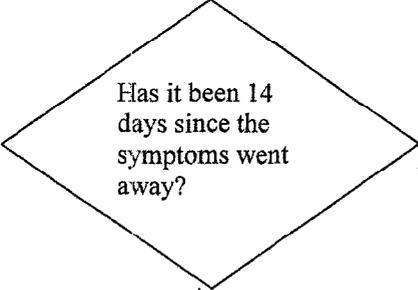
NO

Defer 3 mos. From date of contact's vaccination; if date is not known, defer 2 mos. From current date.

YES

Accept Donor

YES



NO

Defer for longer period of time: for 56 days from vaccination OR for 14 days after symptoms resolve.

YES

Accept Donor

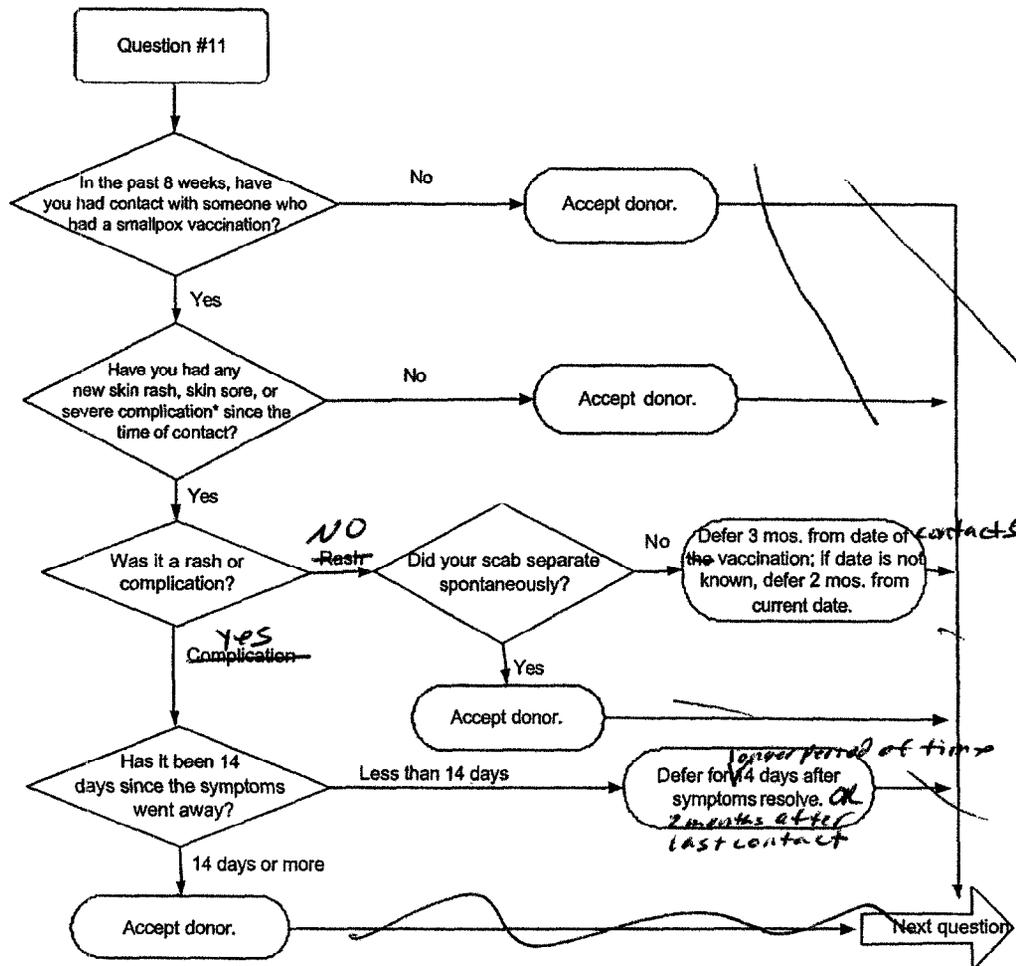
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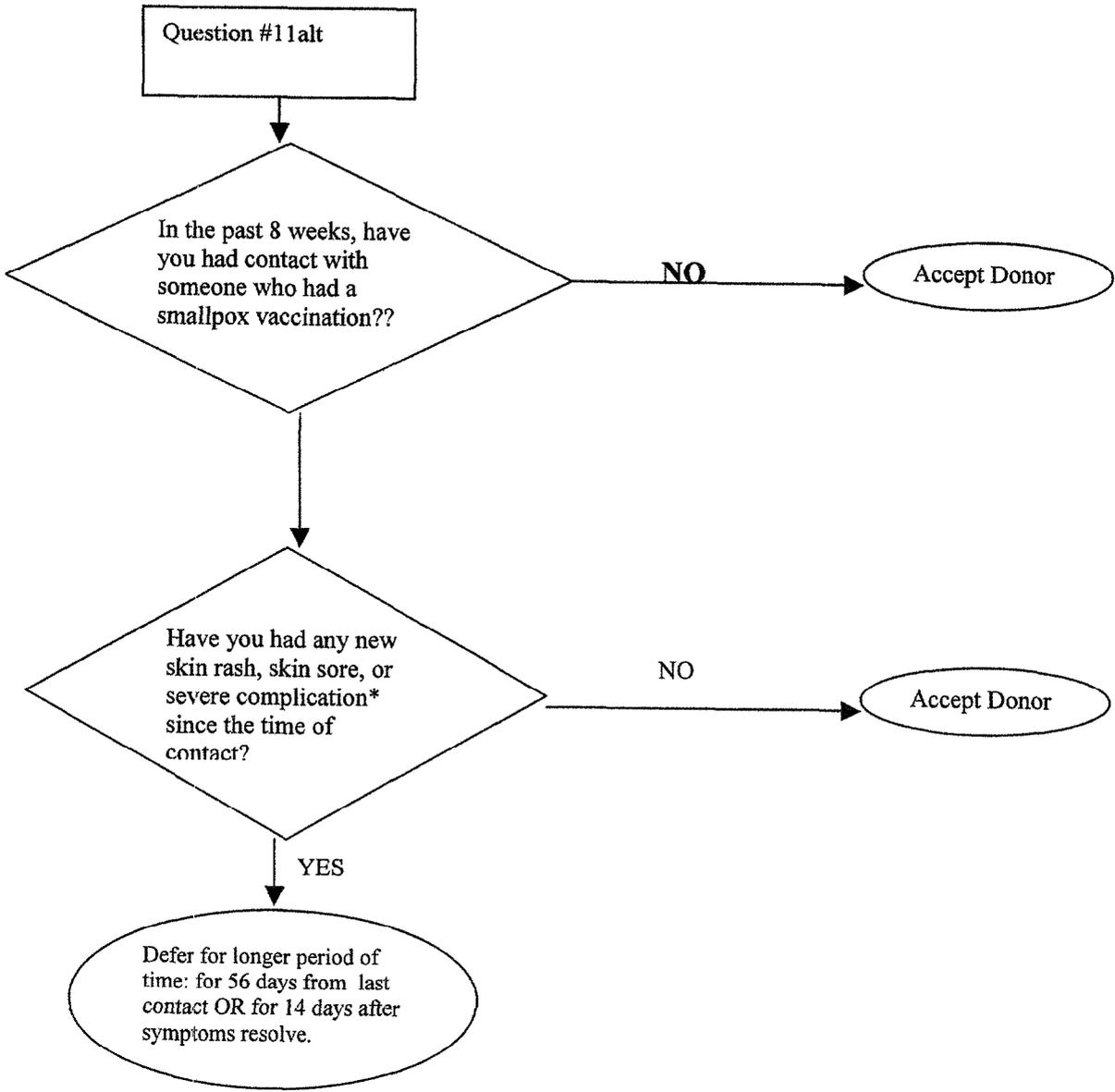
Question: 11. In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?

Note on 11alt Flow Chart: Some blood centers may choose to use a simpler but stricter deferral scheme in which all donors who have been in contact with a person who received the smallpox vaccination are deferred for 56 days if they developed any subsequent complication, skin rash or sore, regardless of when the rash or sore resolved. Blood centers using these criteria should use Alternative Flow Chart 11alt.

Donor Eligibility: Certain vaccinations may contain live viruses. 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 virus and should not serve as a donor. 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.

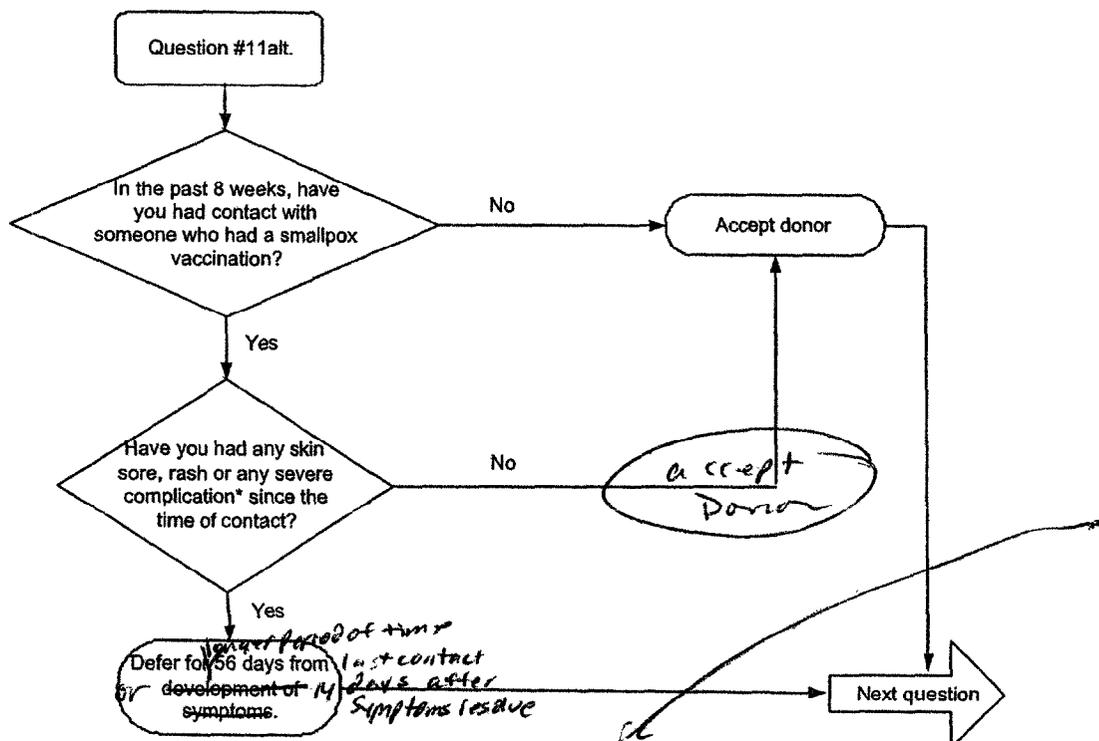


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Question: 11ait. In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?

Donor Eligibility: Certain vaccinations may contain live viruses. 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 virus and should not serve as a donor. See Glossary for specifics.



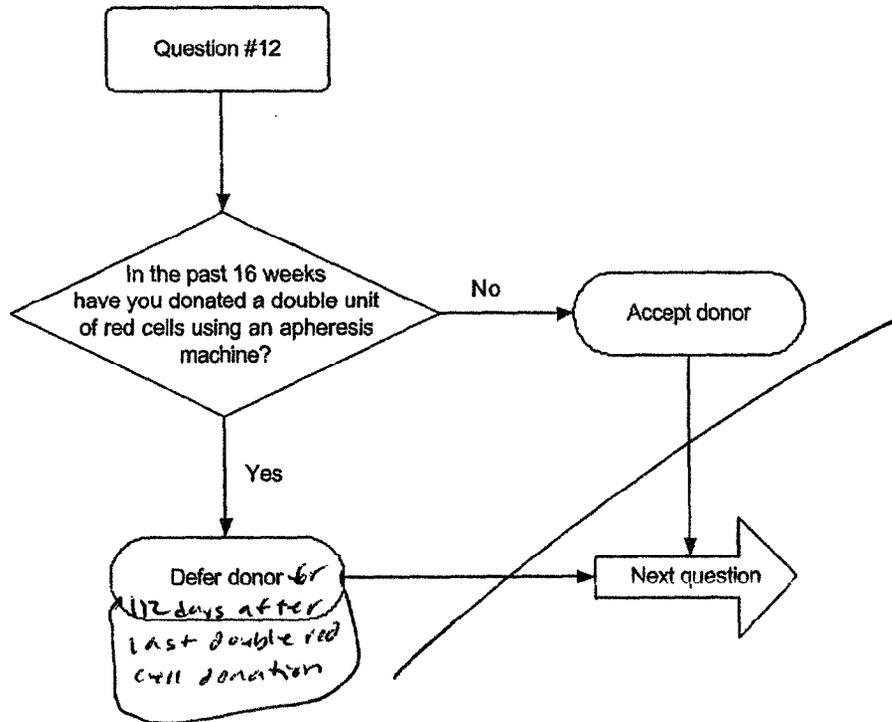
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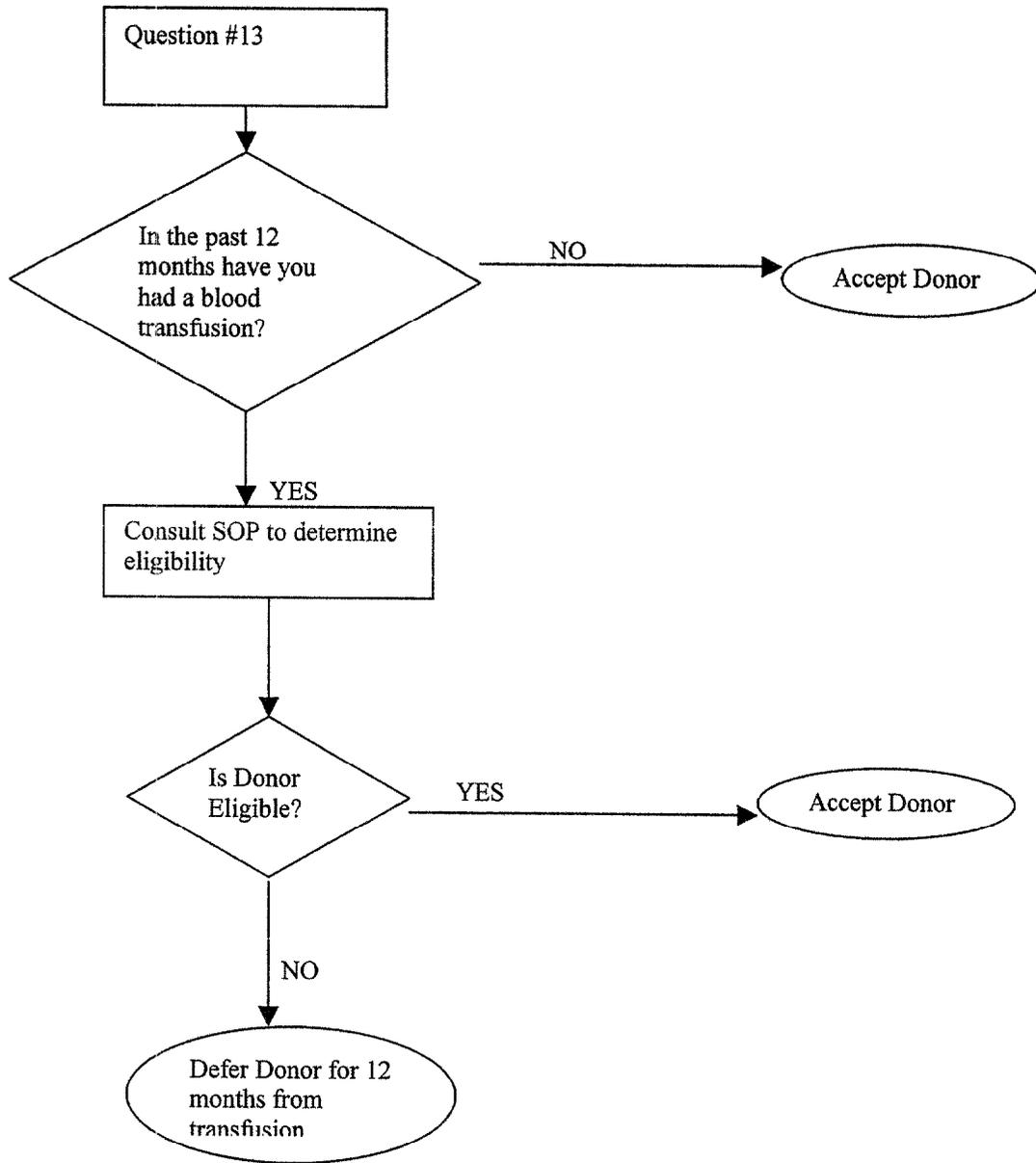
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Question: 12. In the past 16 weeks have you donated a double unit of red cells using an apheresis machine?

Donor Eligibility: A donor should not donate double red cells by apheresis more frequently than every 16 weeks.



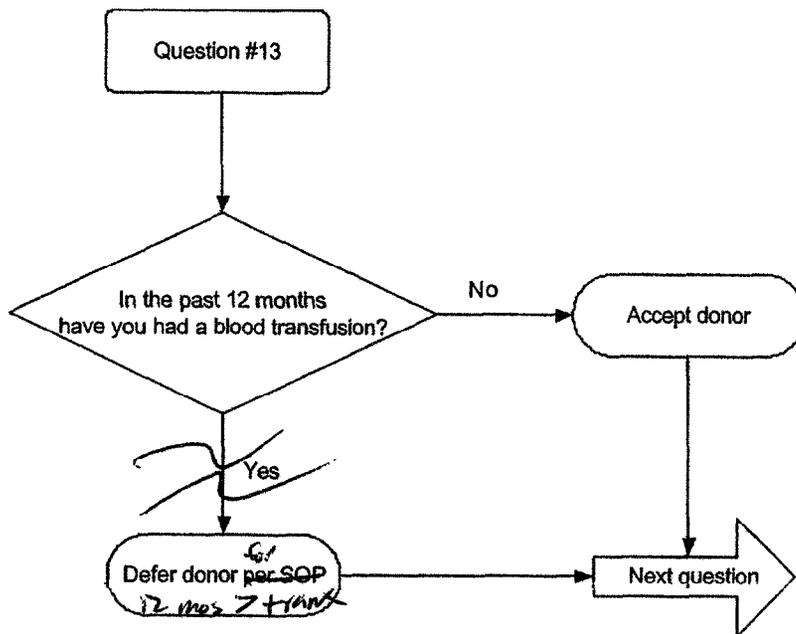


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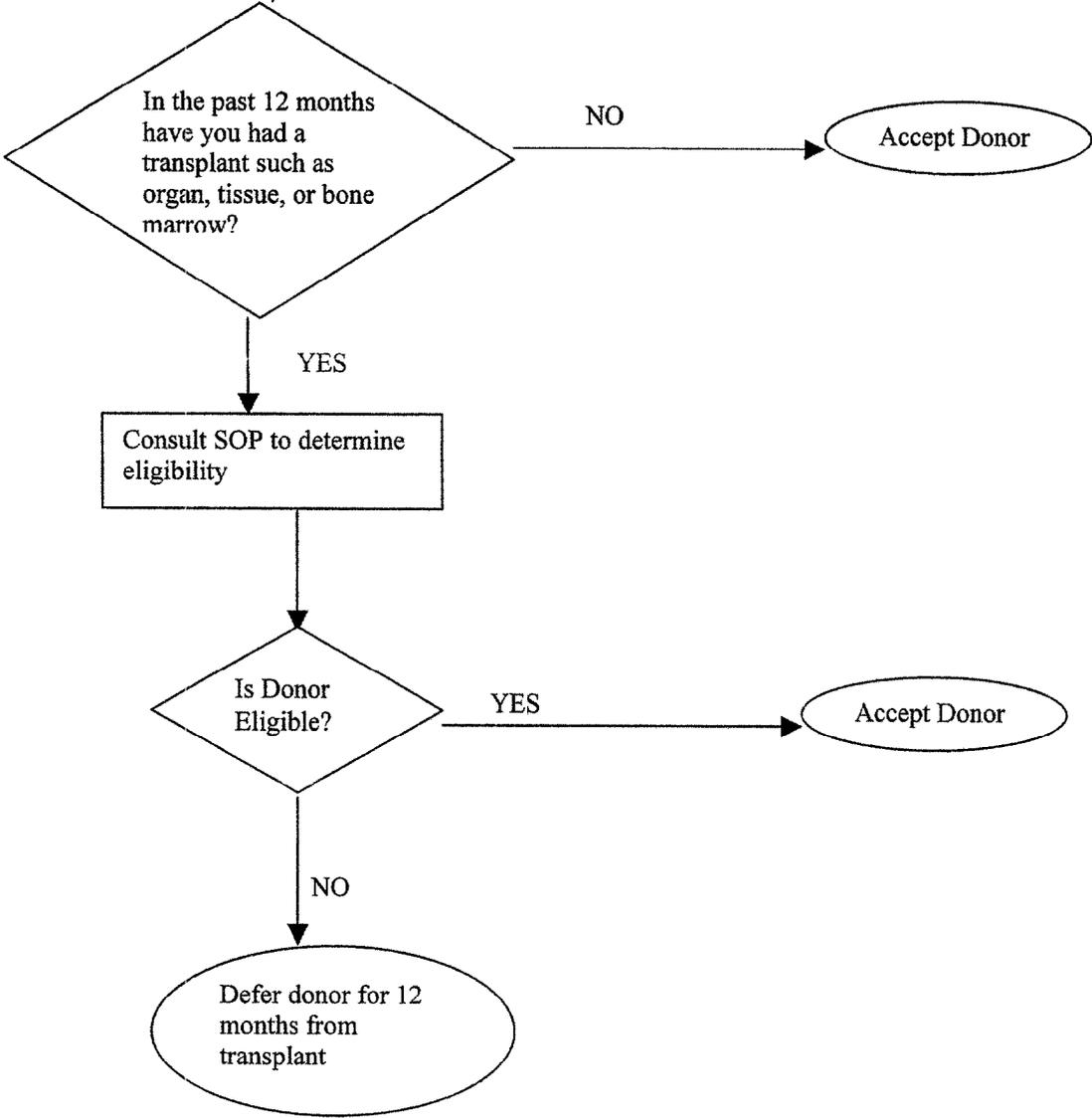
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Question: 13. In the past 12 months have you had a blood transfusion?

Donor Eligibility: A donor who has received an allogeneic transfusion of blood, platelets, plasma or other blood component should not donate blood for 12 months following the transfusion, due to possible transmissibility of infectious disease.



Question #14

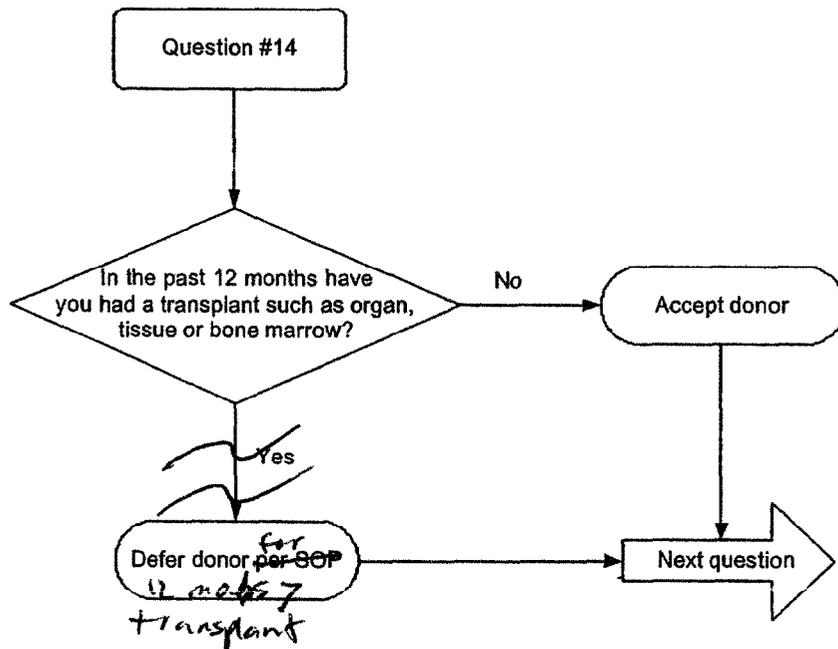


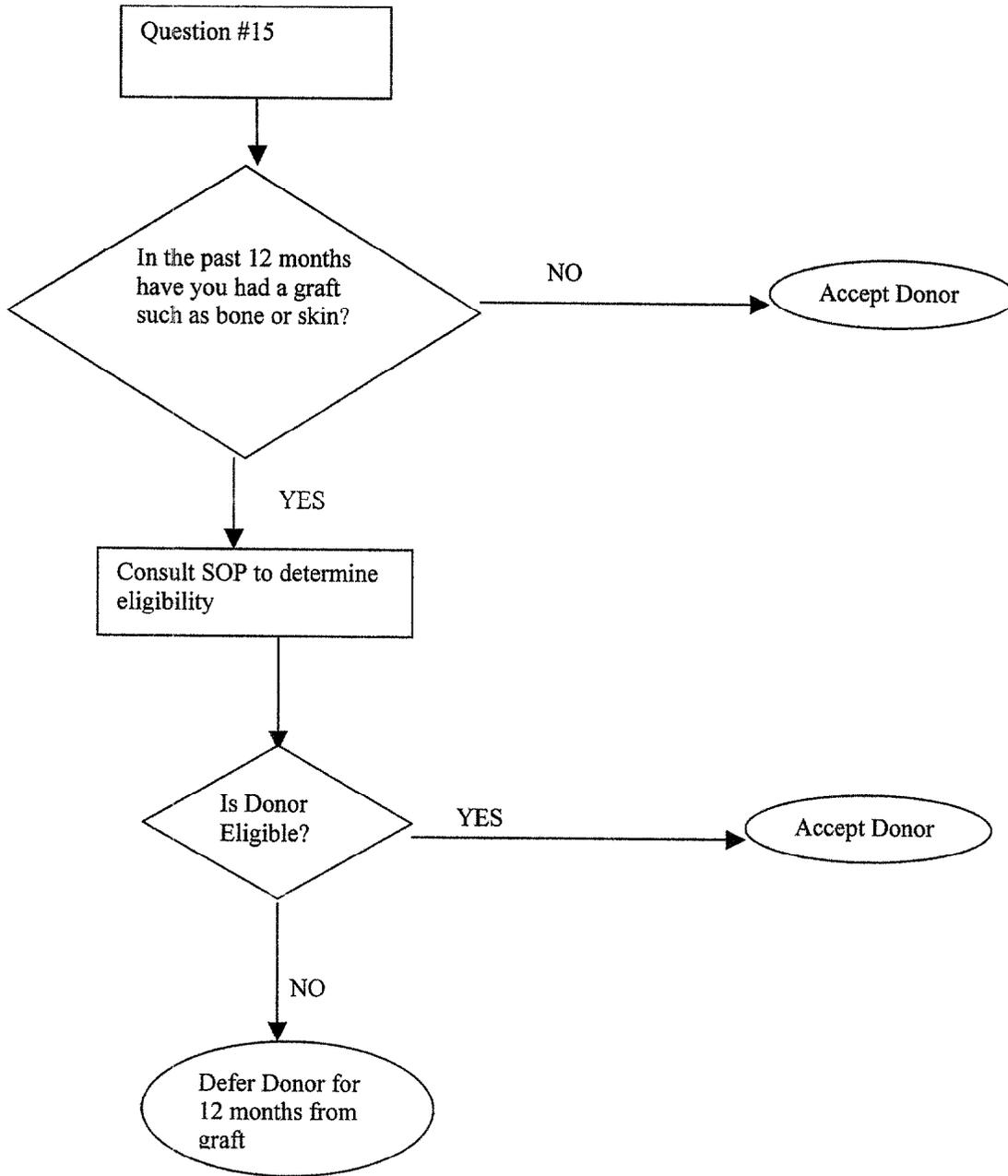
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Question: 14. In the past 12 months have you had a transplant such as organ, tissue or bone marrow?

Donor Eligibility: A donor who has been exposed to allogeneic tissues through transplant should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease.



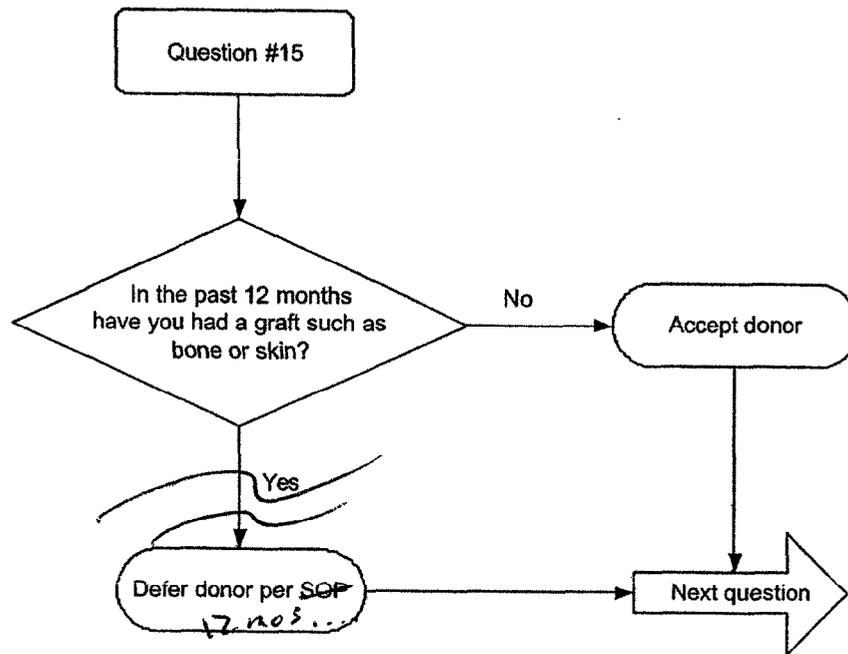


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Question: 15. In the past 12 months have you had a graft such as bone or skin?

Donor Eligibility: A donor who has been exposed to allogeneic tissues through grafting should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease.

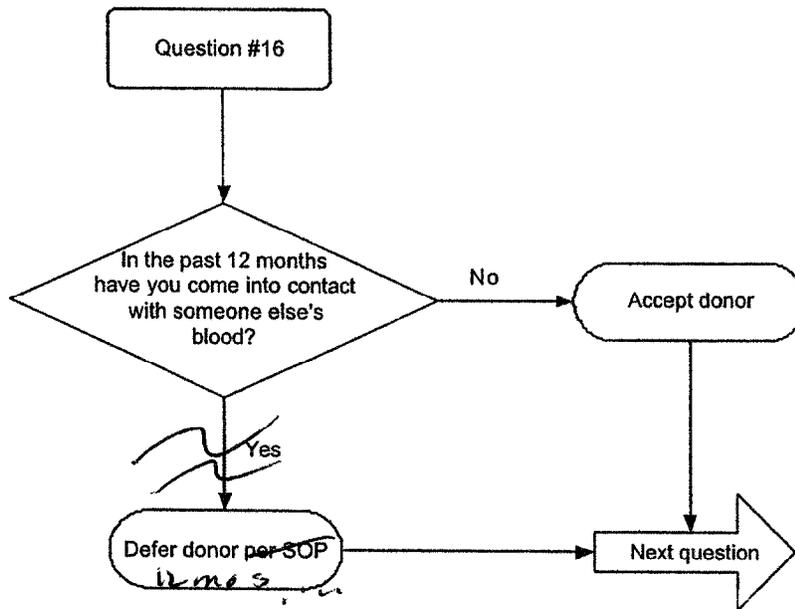


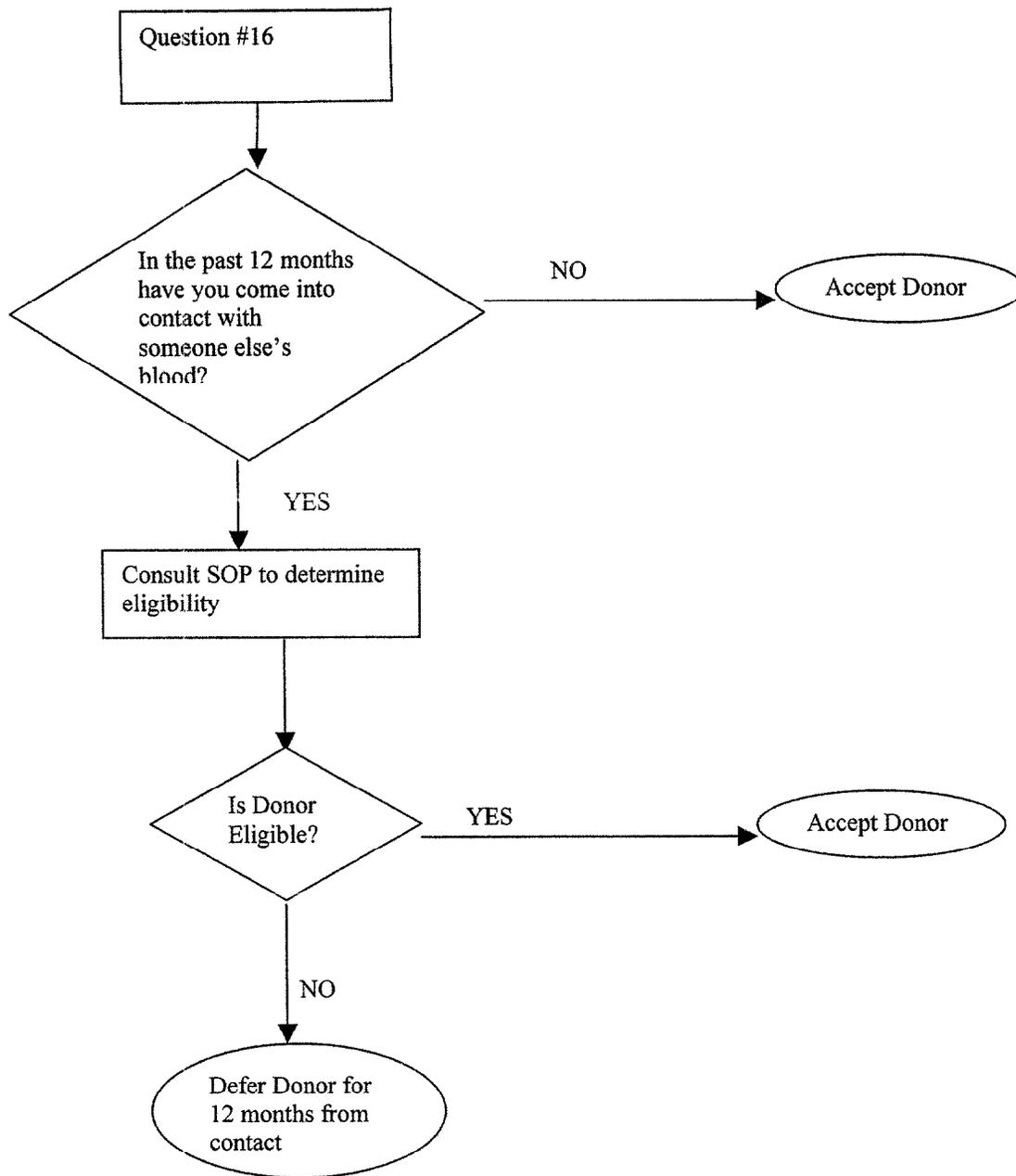
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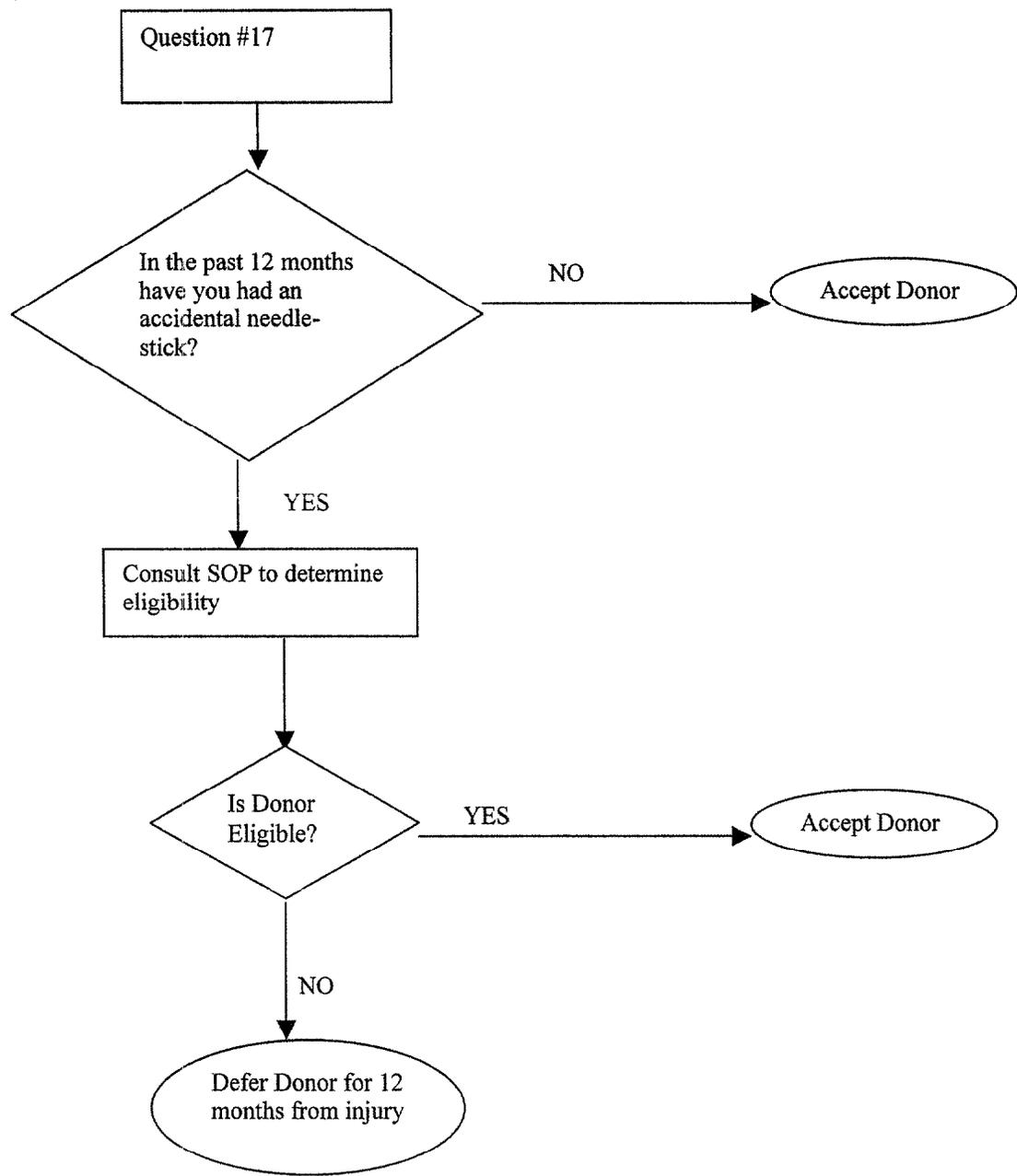
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Question: 16. In the past 12 months have you come in contact with someone else's blood?

Donor Eligibility: Persons who have had one of the following during the preceding 12 months: 1) contact of 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 deferred for 12 months from the date of exposure. Infectious diseases may be spread through contact with blood.





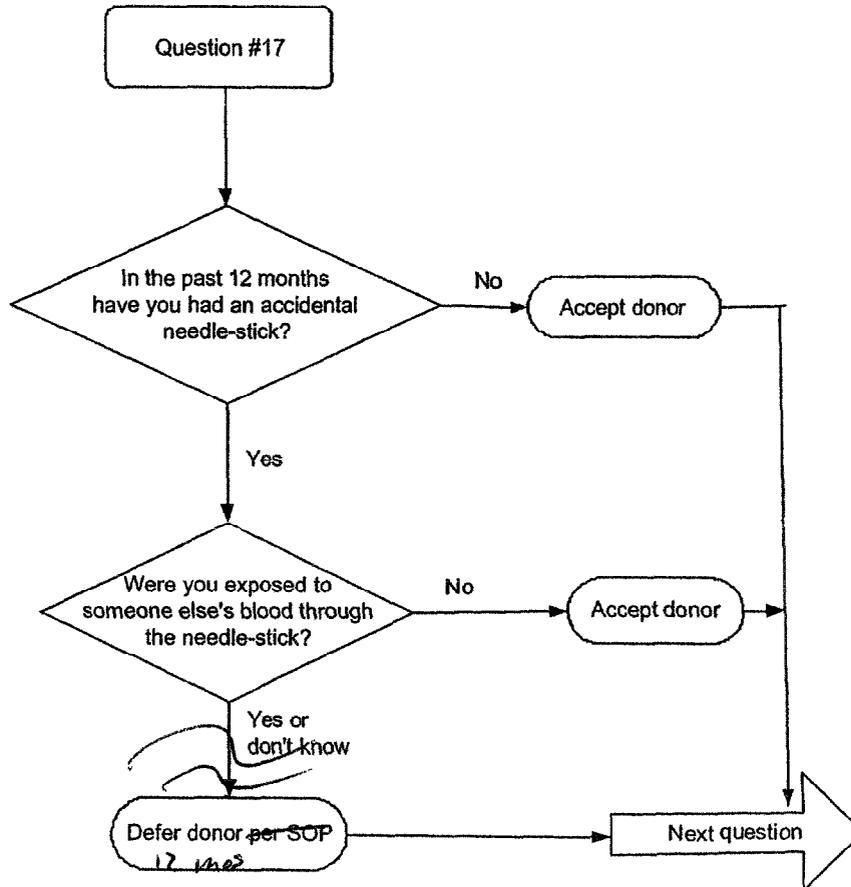


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Question: 17. In the past 12 months have you had an accidental needle-stick?

Donor Eligibility: A donor who has been exposed to someone else's blood through a needle-stick should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease.



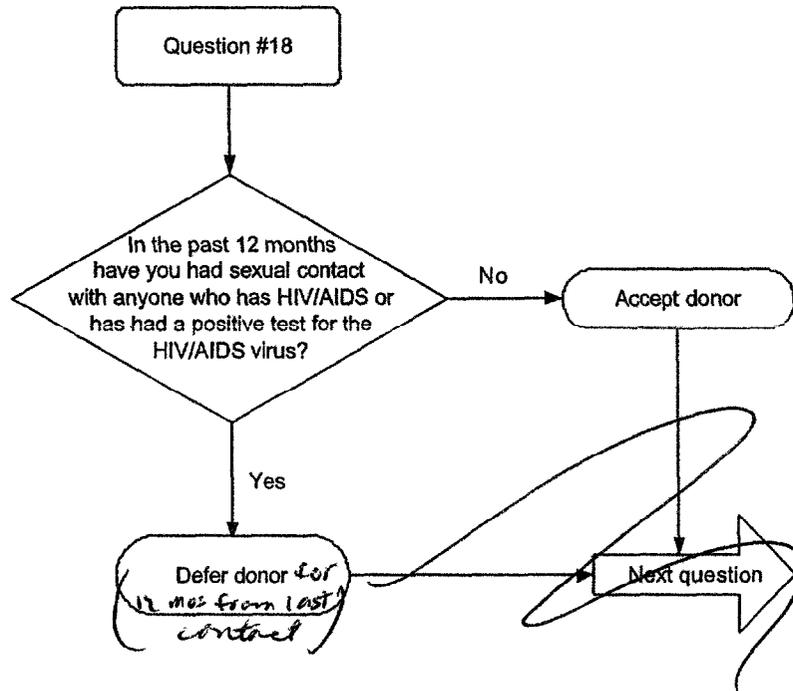
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Question: 18. In the past 12 months have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?

Donor Eligibility: Persons who have had sexual contact with persons with clinical or laboratory evidence of HIV infection are deferred 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.



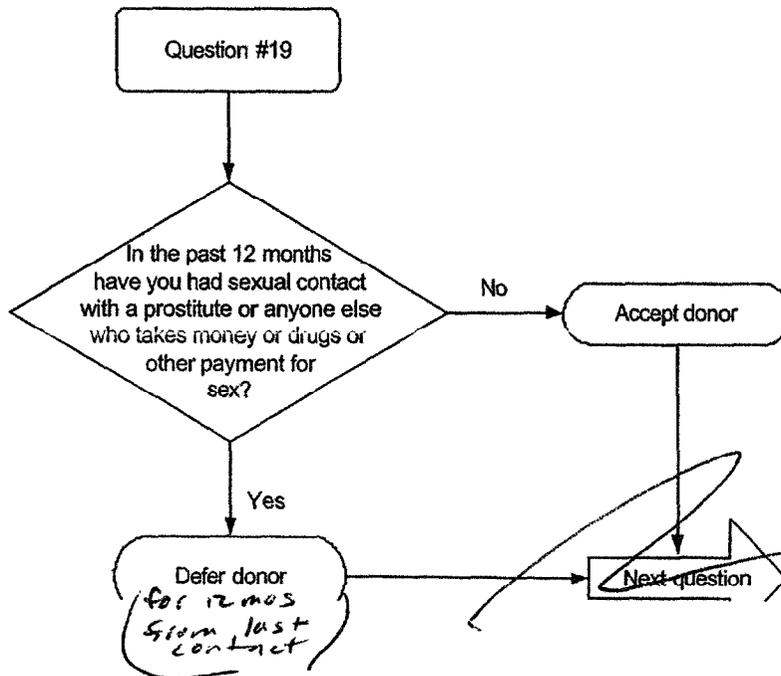
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Question: 19. In the past 12 months have you had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?

Donor Eligibility: Persons who have given money or drugs in exchange for sex (sexual contact) are deferred 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.



Contains Nonbinding Recommendations

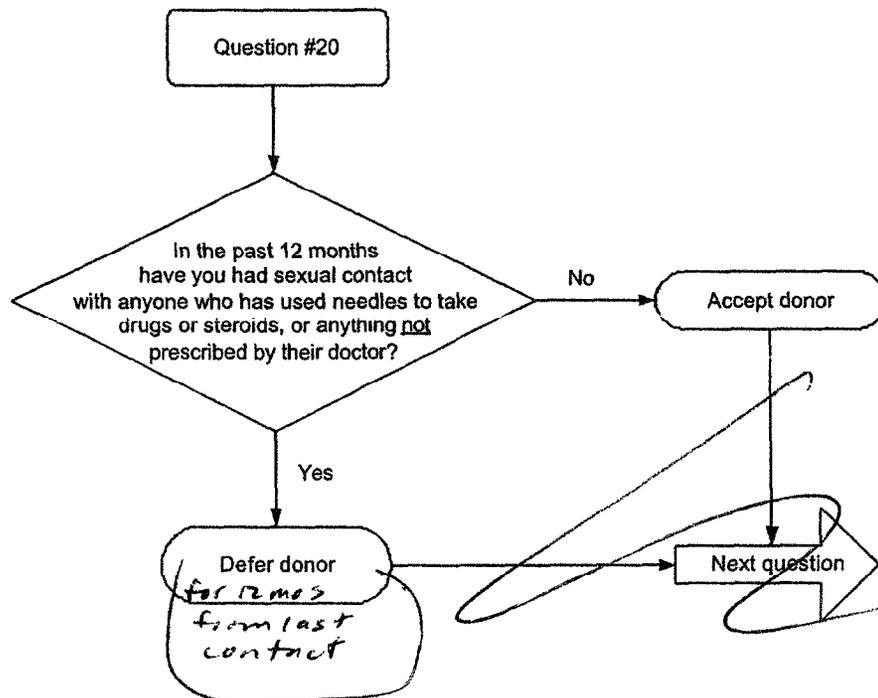
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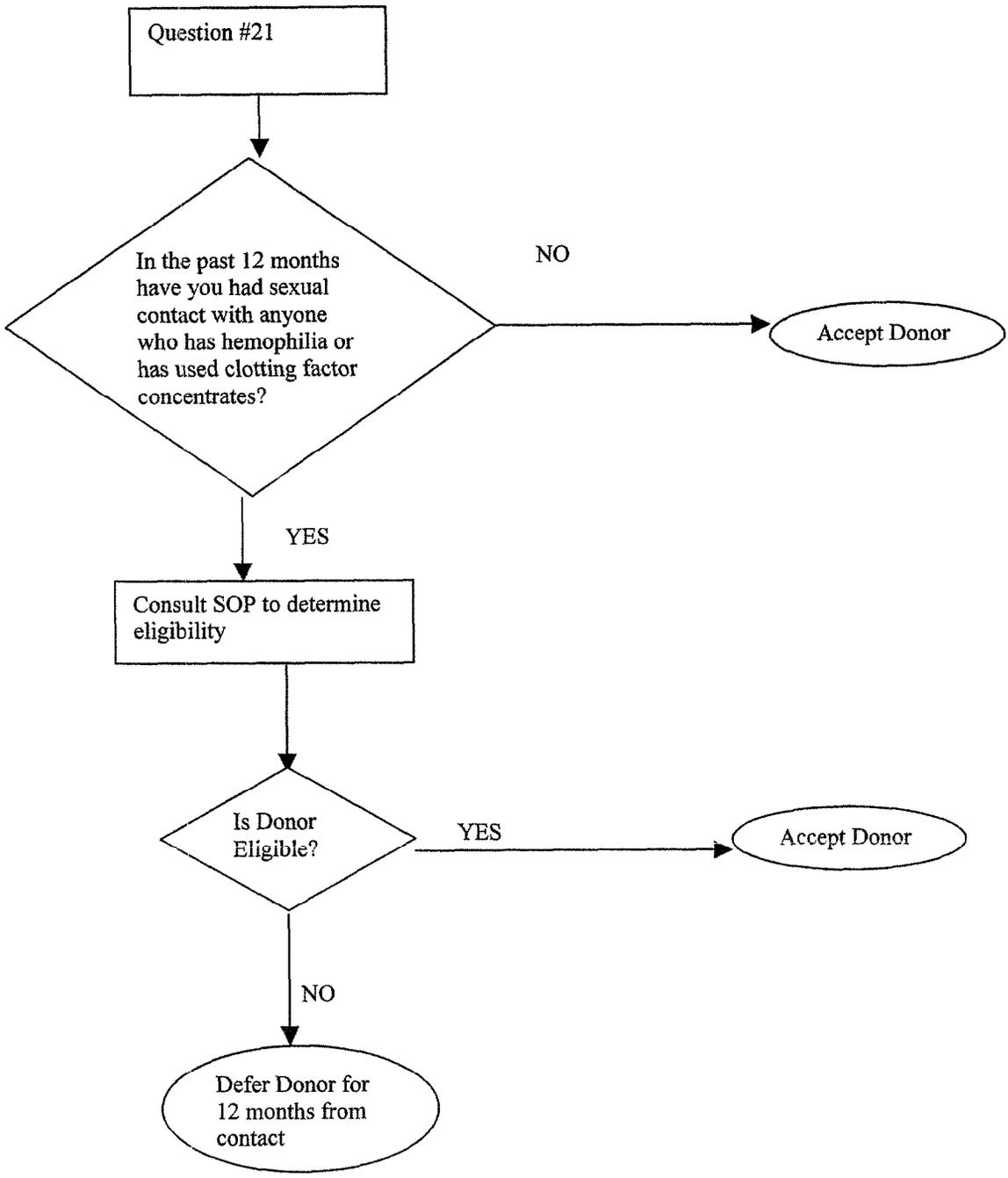
Question: 20. In the past 12 months have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?

Donor Eligibility: Persons who have had sexual contact with persons who, in the past or present, have used needles to take drugs, steroids, or anything not prescribed by their doctor are deferred 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.





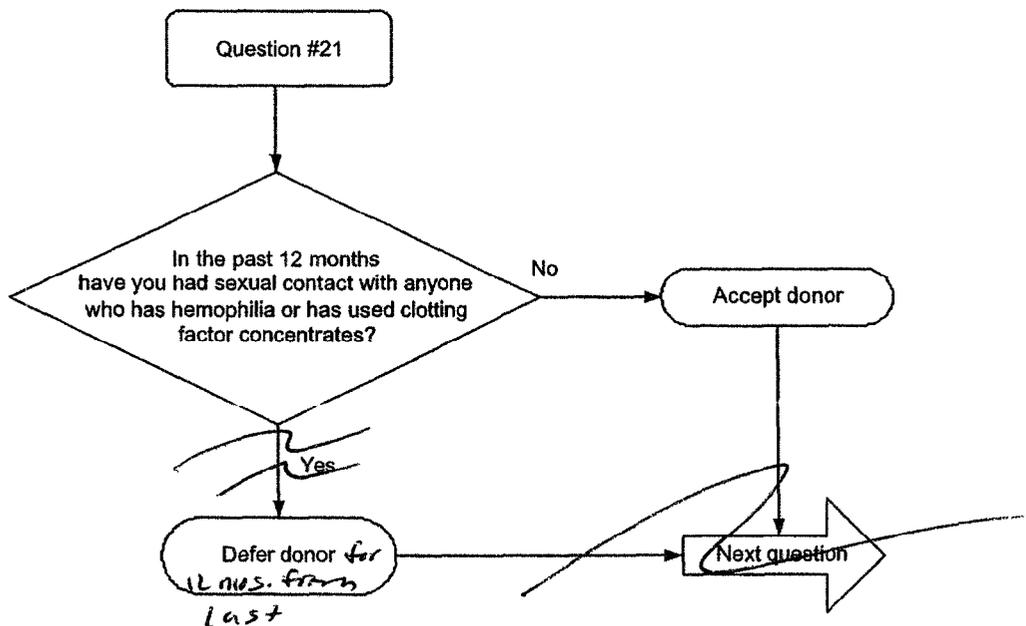
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Question: 21. In the past 12 months have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?

Donor Eligibility: Persons who have had sexual contact with one of the following: 1) any person with hemophilia or related clotting disorders; or 2) any person who has received clotting factor concentrates is deferred for 12 months. 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.



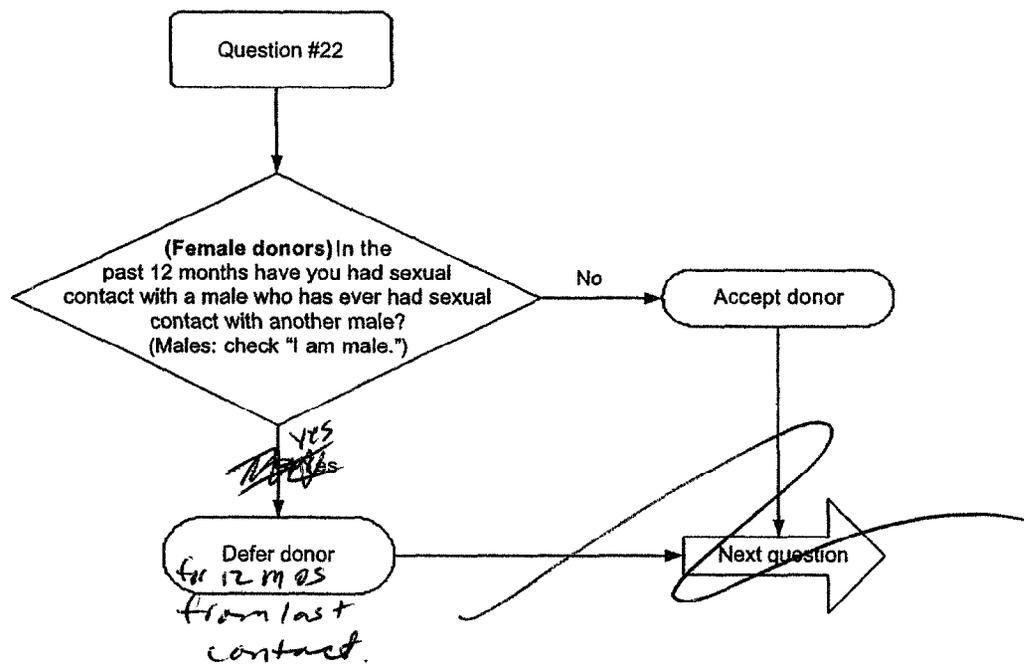
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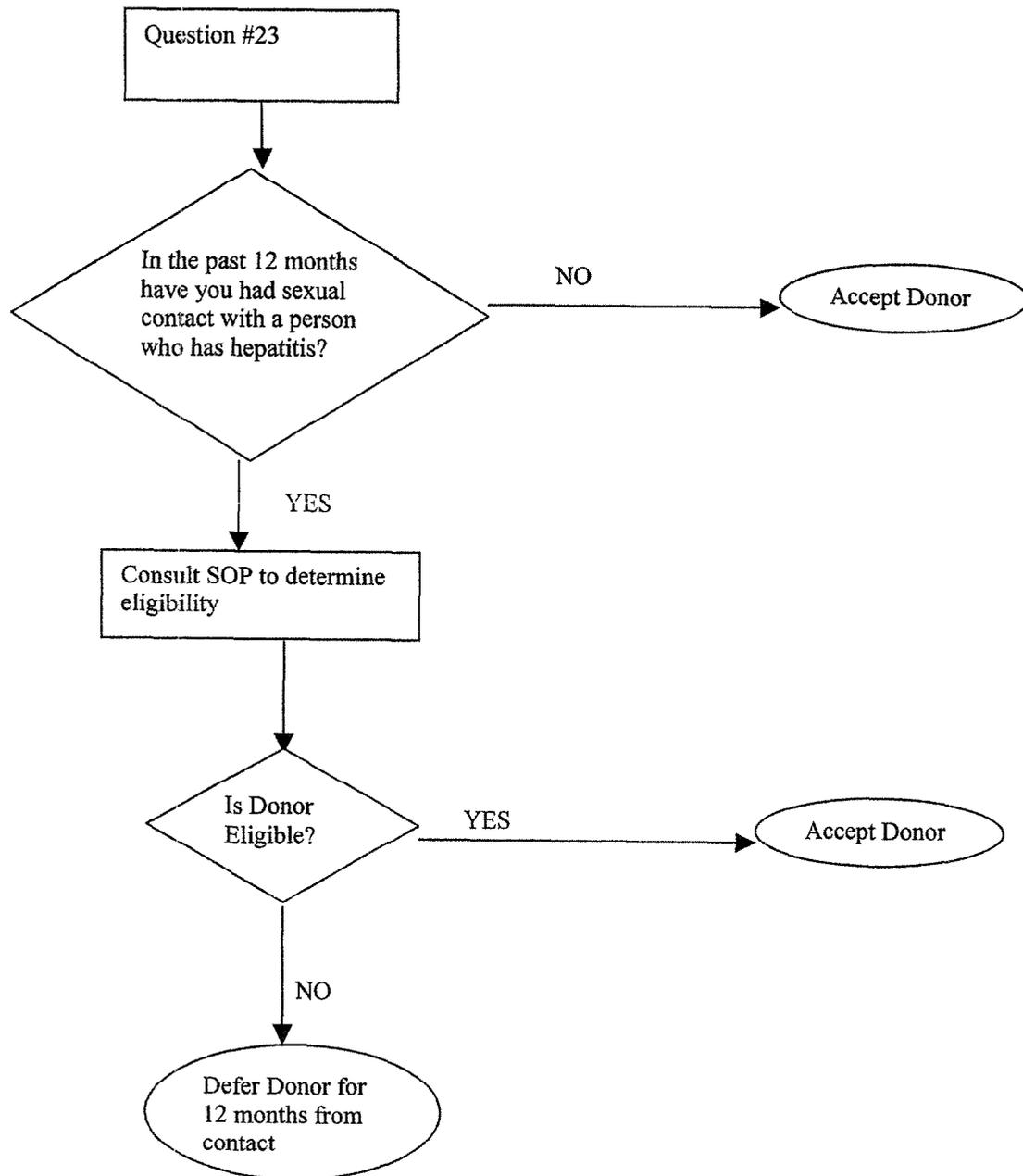
Draft – Not for Implementation

Question: 22. 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 since 1977 are deferred 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.





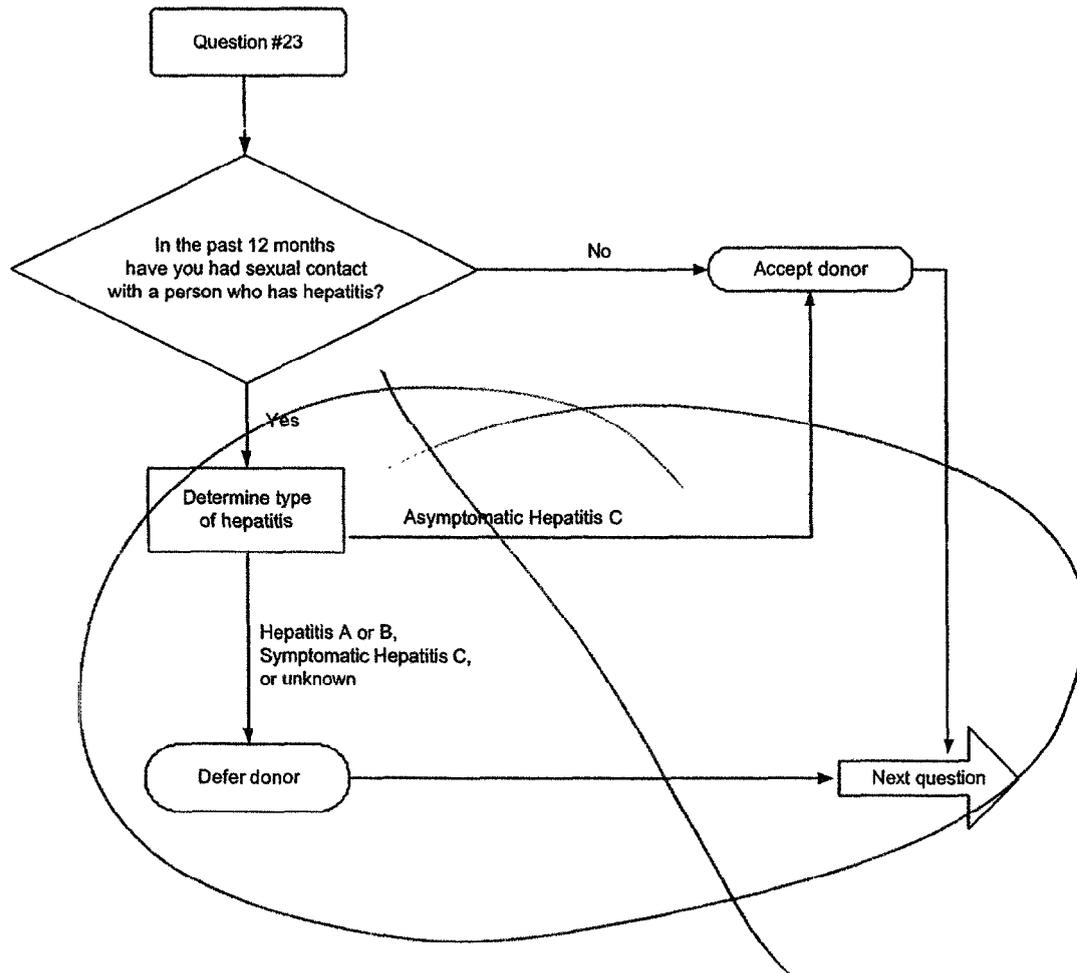
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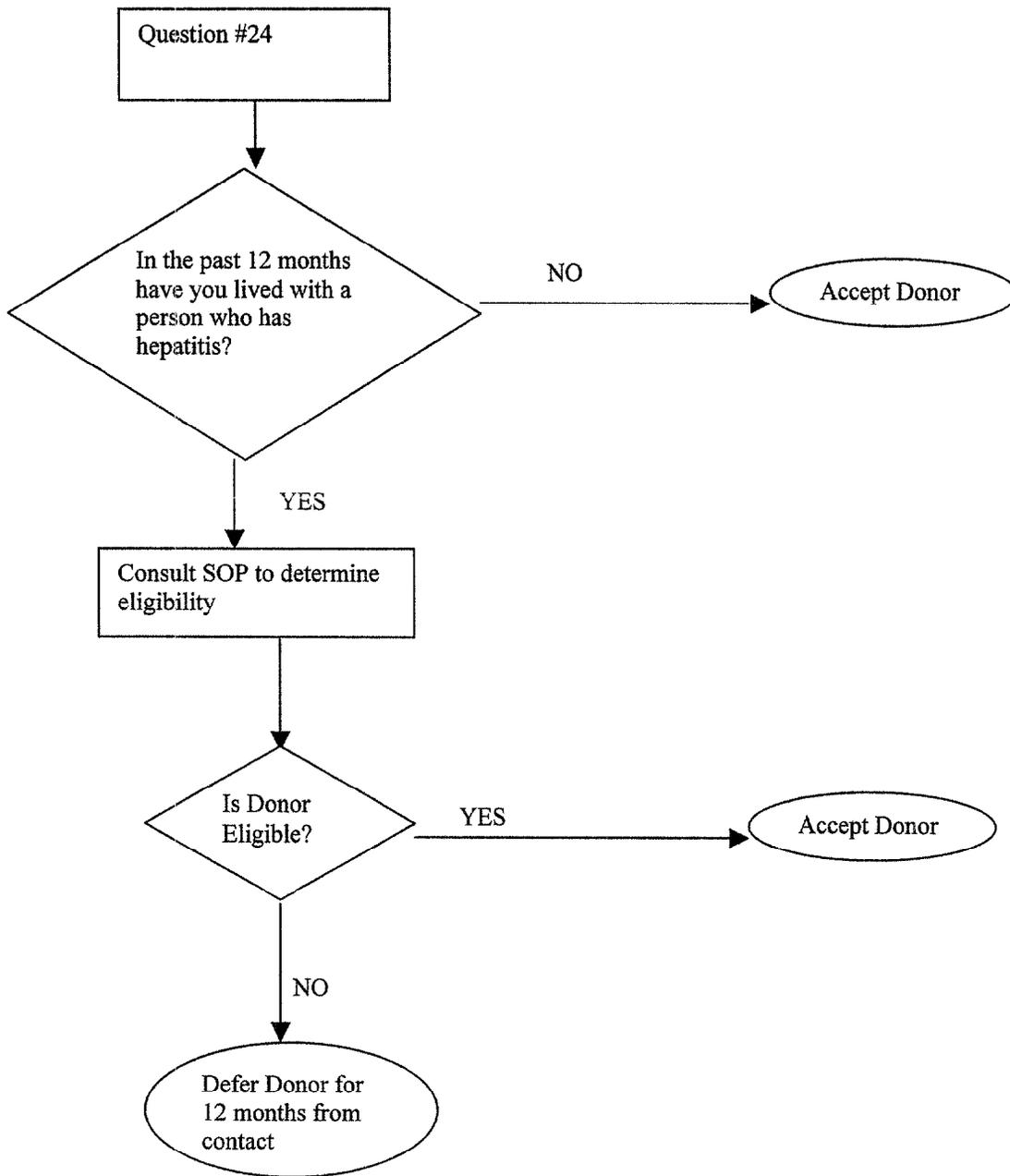
Draft – Not for Implementation

Question: 23. 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 hepatitis are to be deferred for 12 months from the time of last exposure. Hepatitis, particularly hepatitis A and B, may be spread 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.



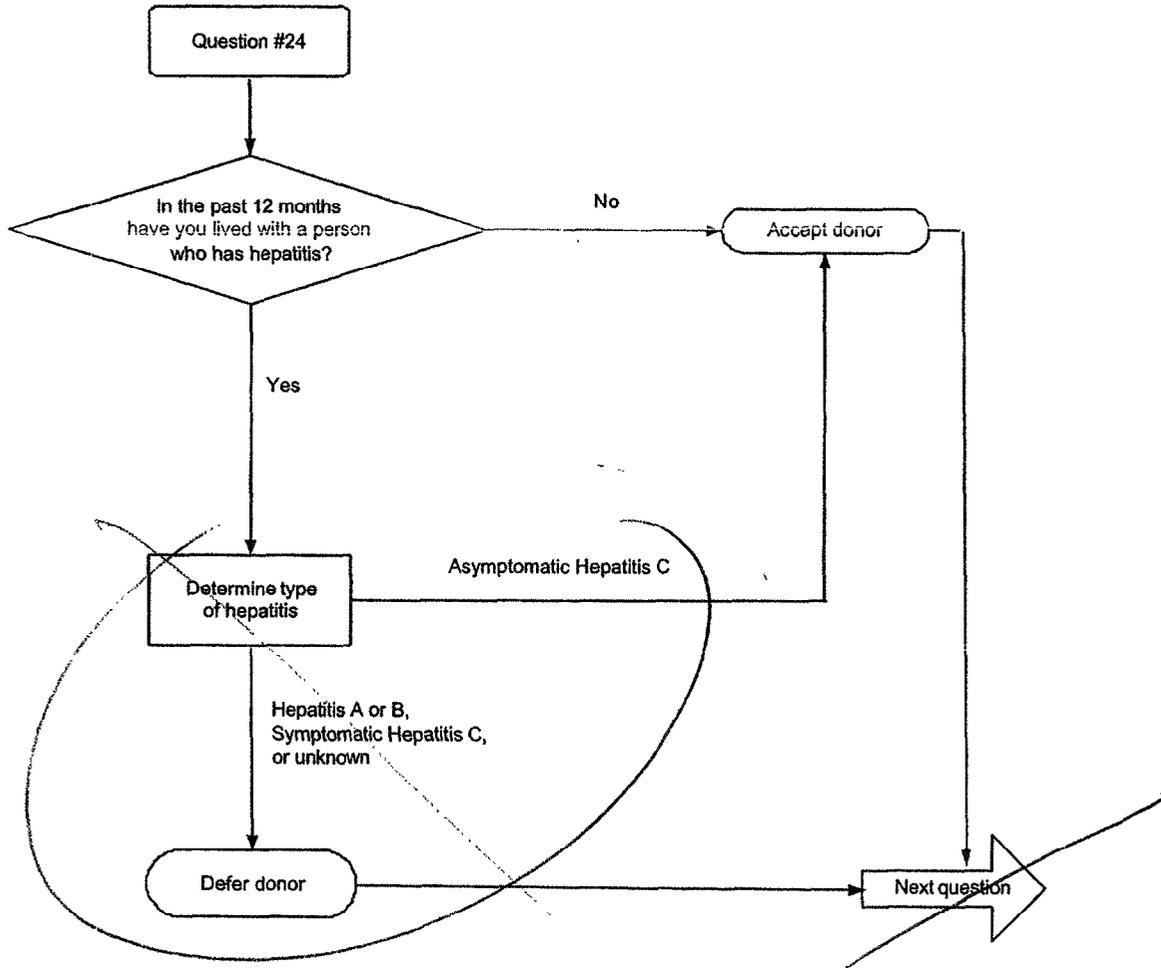


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Question: 24. In the past 12 months have you lived with a person who has hepatitis?

Donor Eligibility: In certain cases, living with a person with hepatitis puts the donor at risk for acquiring hepatitis as well.



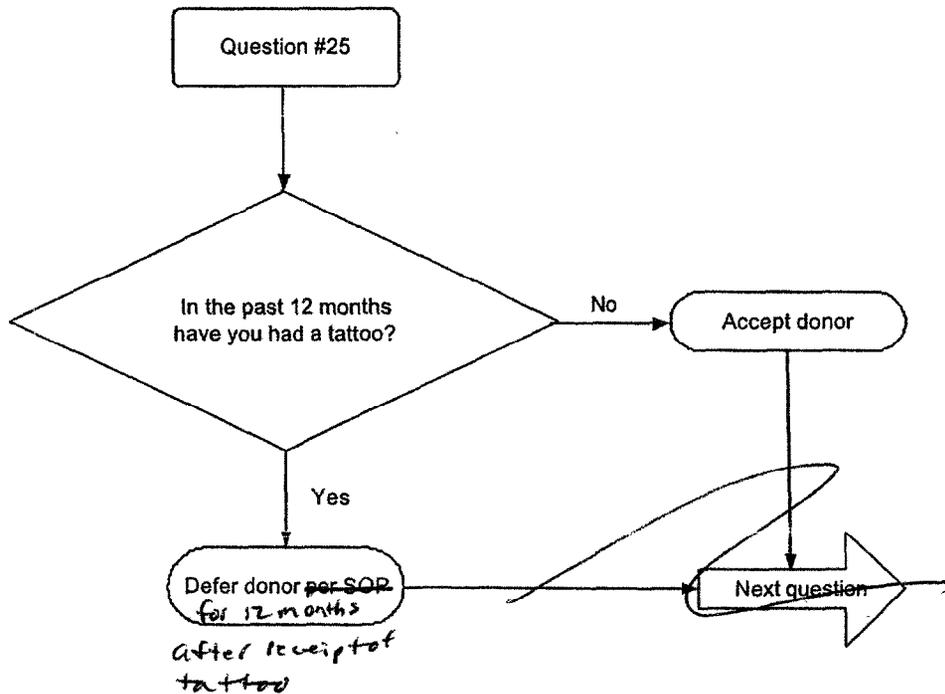
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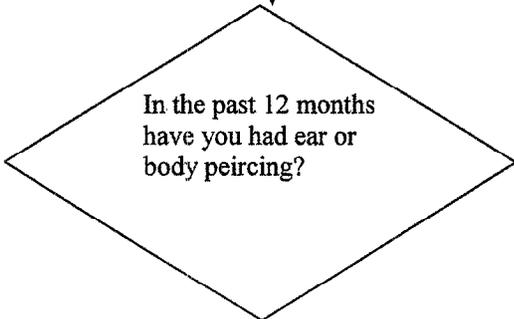
Question: 25. In the past 12 months have you had a tattoo?

Donor Eligibility: Persons who have had a tattoo in the previous 12 months are deferred for 12 months from the date of the tattoo application. Unless tattoos have been applied using single-use needles and single-use ink, there may be a risk of transmission of infectious diseases.

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



Question #26



NO → Accept Donor

YES

Consult SOP to determine eligibility



YES → Accept Donor

NO

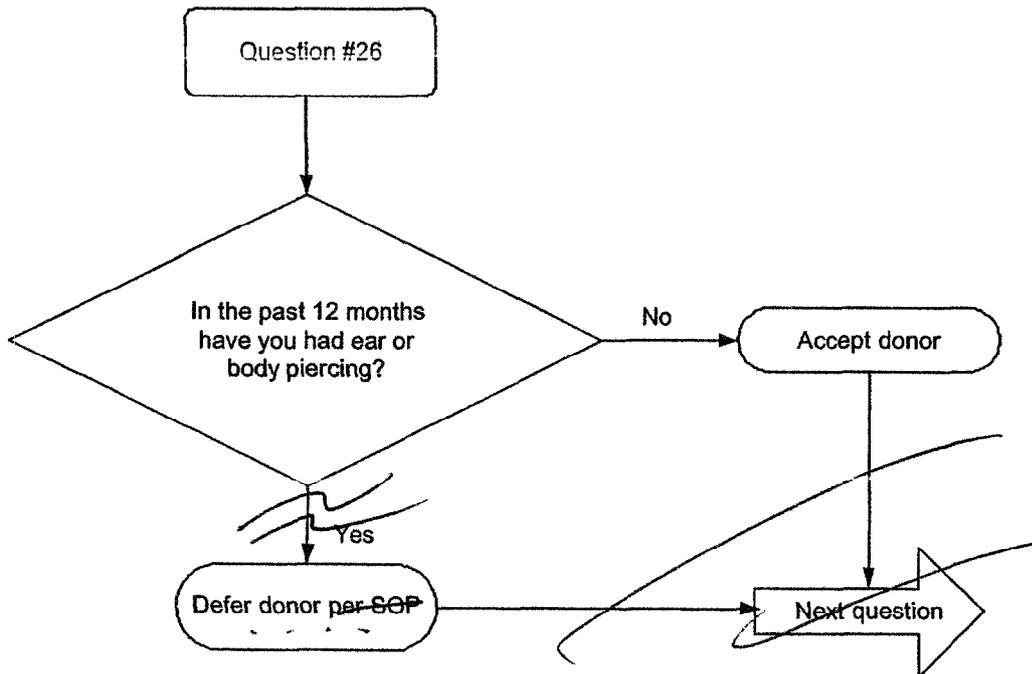
Defer Donor for 12 months from unacceptable peircing

Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 26. 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 deferred for 12 months from the date of procedure. Unless ear or body piercing has been done using single-use equipment, there may be a risk of transmission of infectious diseases.

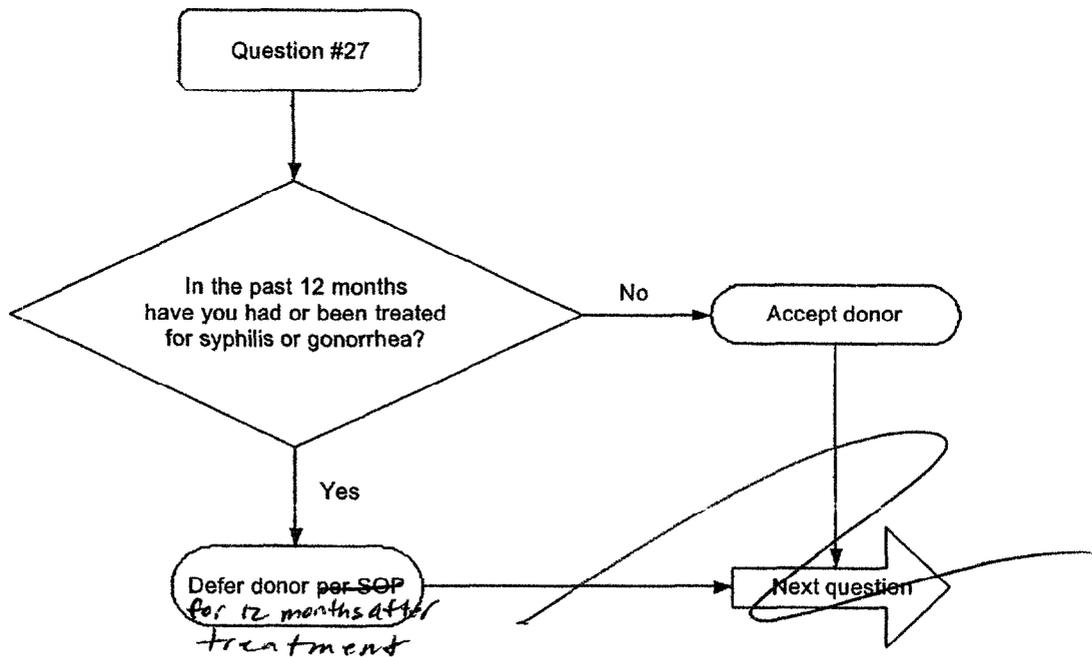


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Question: 27. In the past 12 months have you had or been treated for syphilis or gonorrhea?

Donor Eligibility: Persons who have had syphilis or gonorrhea, treatment for either, or a confirmed react screening test for syphilis are deferred for 12 months from the date that treatment is completed.



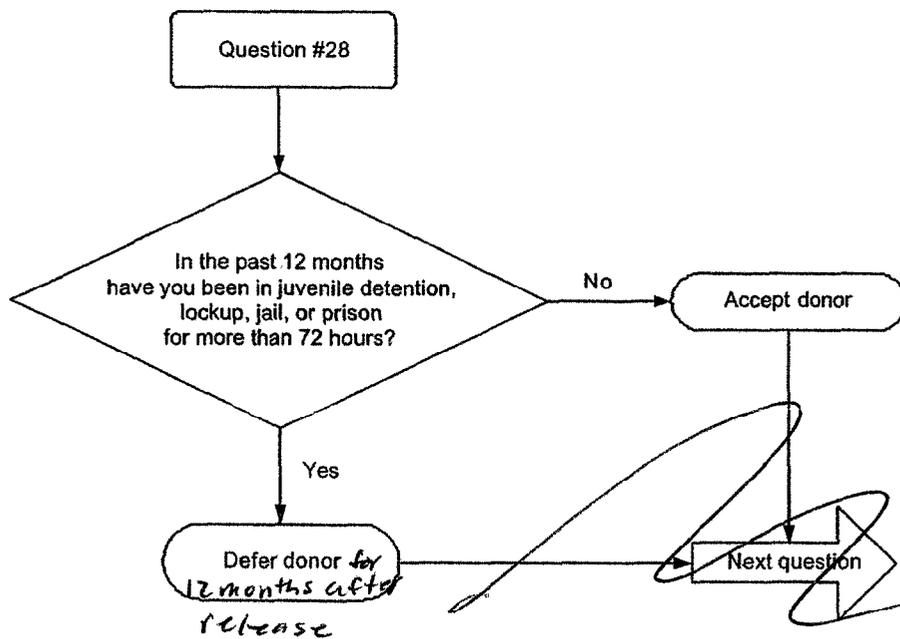
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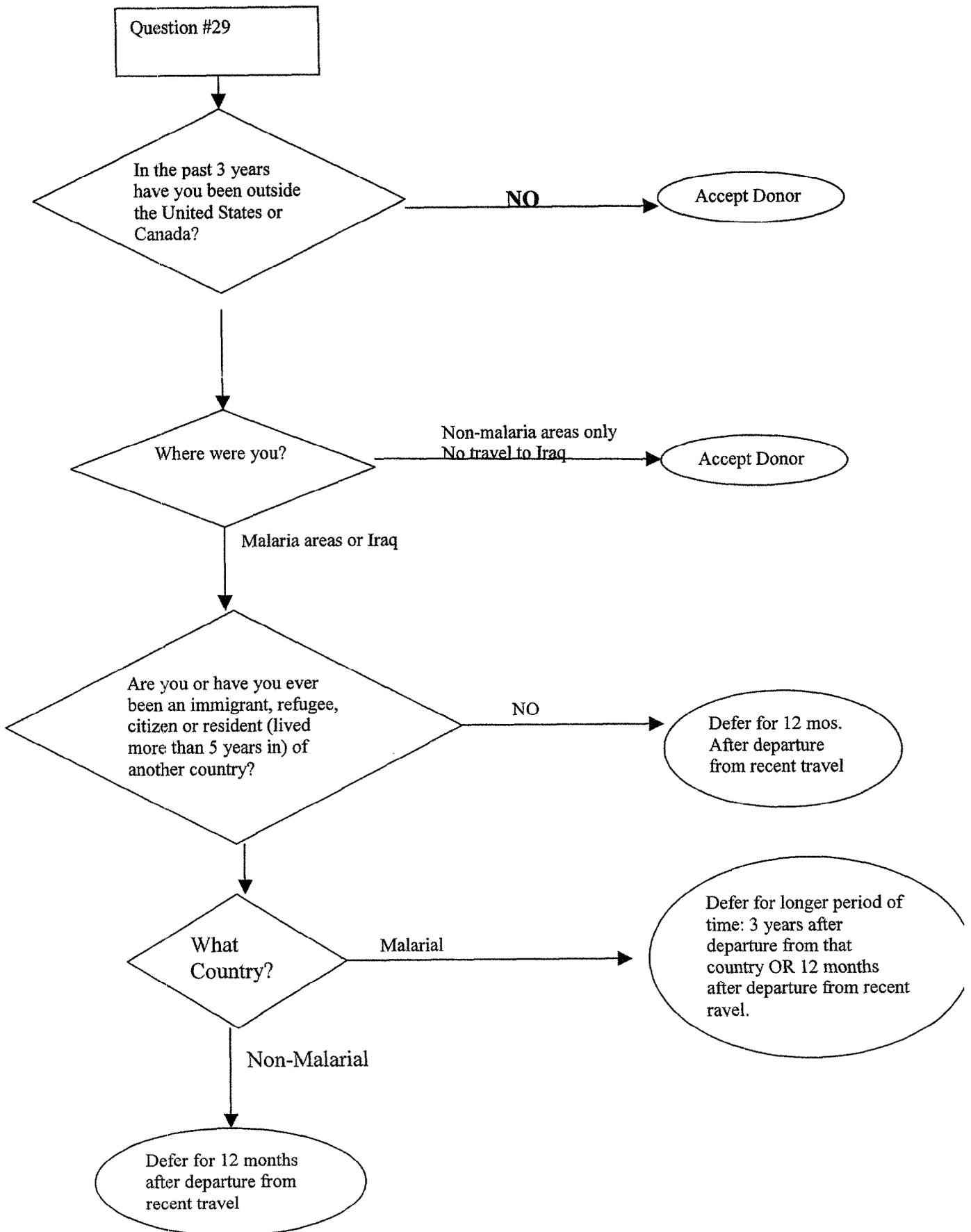
Draft – Not for Implementation

Question: 28. 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, lockup, jail, or prison) for more than 72 consecutive hours (3 days) are deferred for 12 months from the date of occurrence. These persons are at higher risk for exposure to infectious diseases.

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





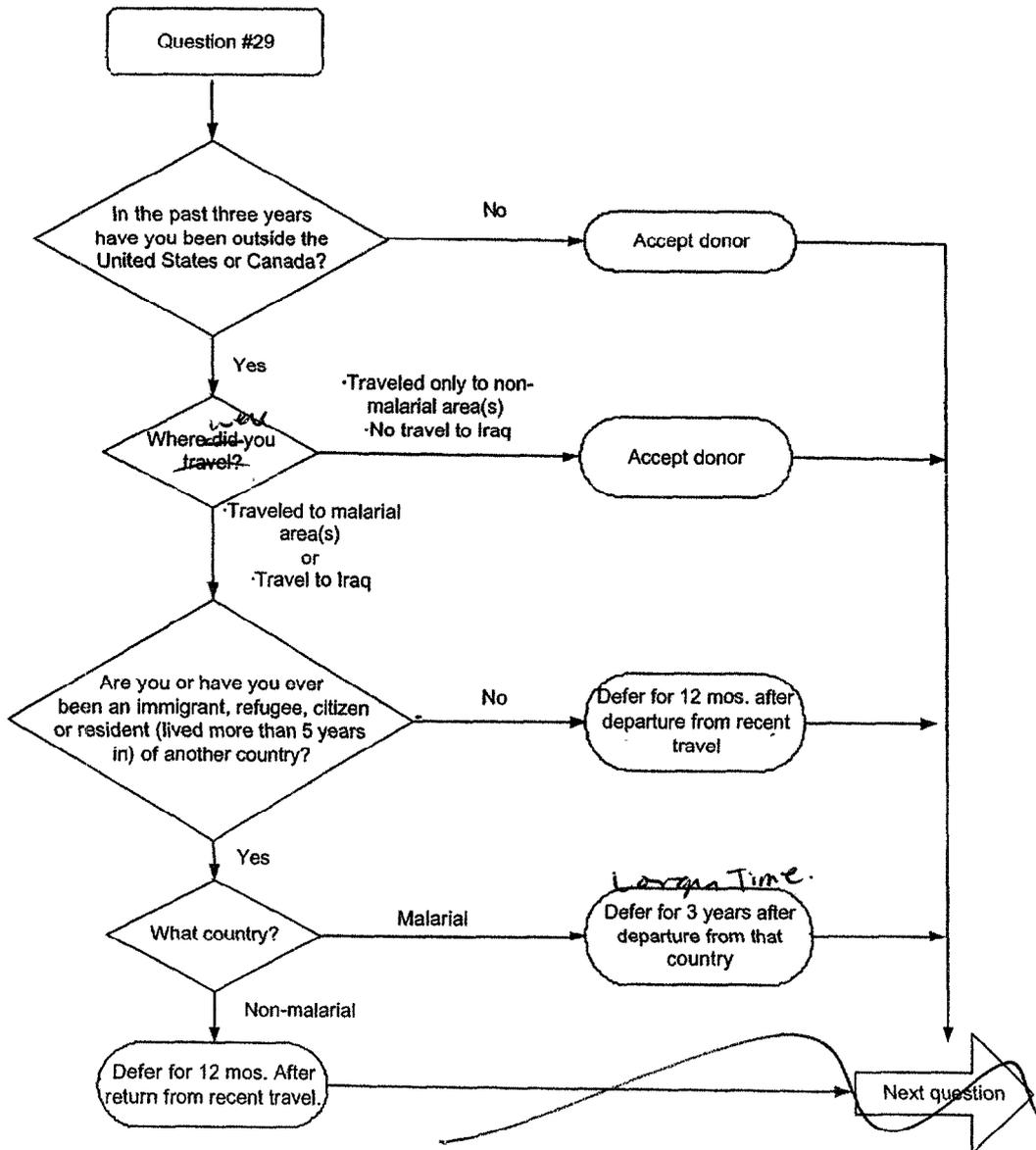
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Question: 29. In the past three years have you been outside the United States or Canada?

Donor Eligibility: Immigrants, refugees, or citizens coming from a country in which malaria is considered endemic will be deferred for 3 years after departure from the area if they have been free from unexplained symptoms suggestive of malaria. Donors who have traveled to an area where malaria is considered endemic will be deferred for 12 months after departure from that area regardless of whether or not they took anti-malaria prophylaxis. Malaria may be transmitted through blood transfusion. The donors shall be accepted or deferred based on the Malaria Risk Countries as designated by your institution.

Donors who have traveled to Iraq may have been exposed to Leishmaniasis; such donors should be deferred for 12 months after departure from Iraq.

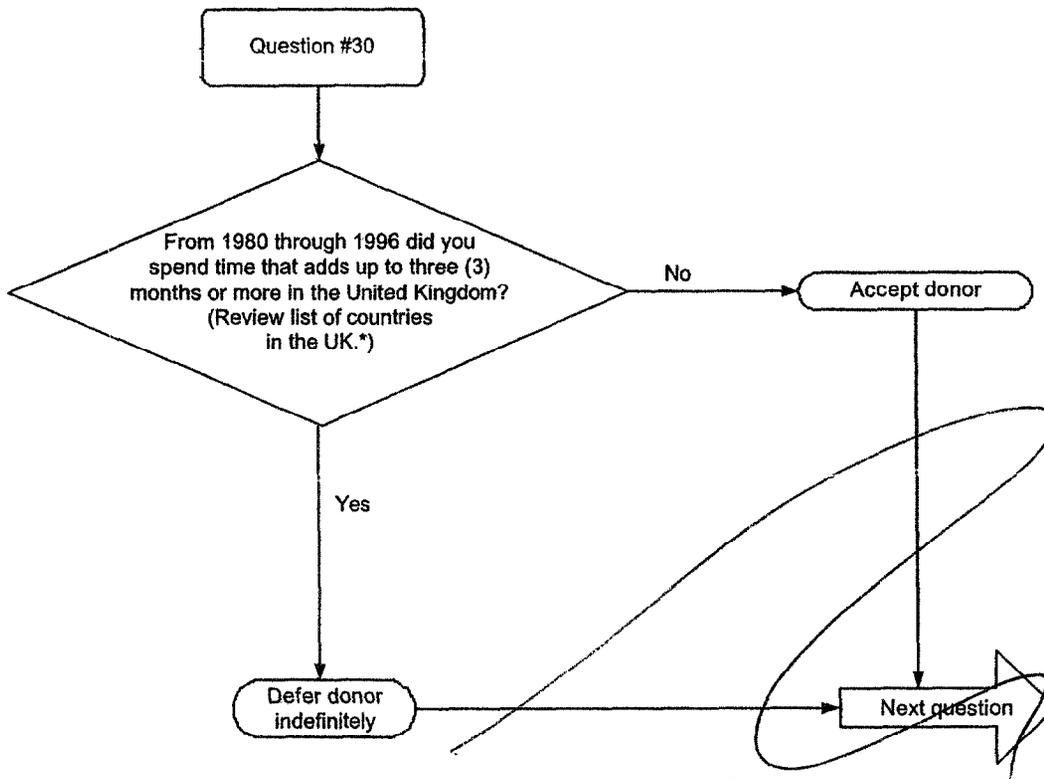


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Question: 30. From 1980 through 1996 did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK.) <http://www.fda.gov/cber/gdlns/cjdvcjd.htm>

Donor Eligibility: Donors who have spent time that adds up to three (3) months or more in the United Kingdom from 1980 through 1996 are indefinitely deferred. Donors may be at theoretical risk of developing vCJD from eating beef from the UK. There may be a theoretical risk of transmitting vCJD through blood transfusion.



* See FDA "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease vCJD) by Blood and Blood Products." <http://www.fda.gov/cber/gdlns/cjdvcjd.htm>

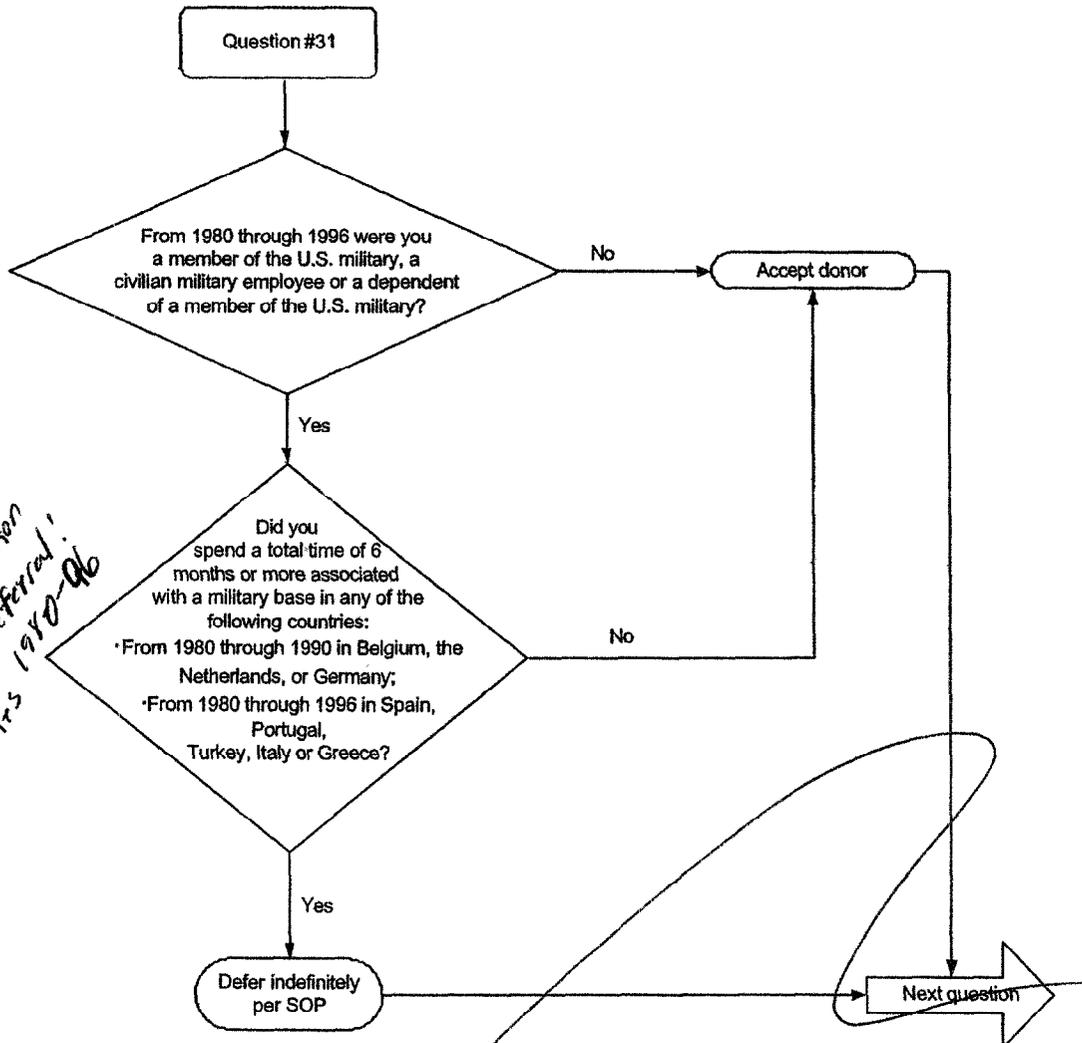
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Question: 31. From 1980 through 1996 were you a member of the U.S. military, a civilian military employee or a dependent of a member of the U.S. military?

Donor Eligibility: Members of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military are indefinitely deferred if they spent a total of 6 months or more associated with a military base in any of the following countries: From 1980 through 1990 in Belgium, the Netherlands, or Germany; From 1980 through 1996 in Spain, Portugal, Turkey, Italy or Greece. Donors may be at theoretical risk of developing vCJD from eating beef from the UK. There may be a theoretical risk of transmitting vCJD through blood transfusion.

Does not address variation of stricter deferral: all countries 1980-96

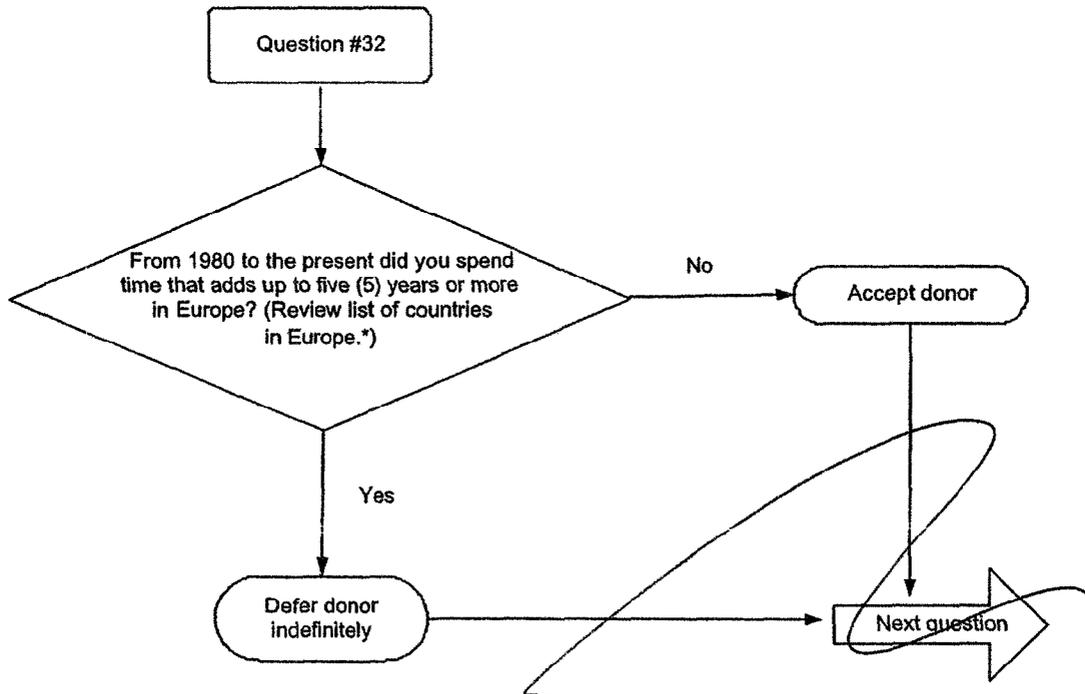


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Draft – Not for Implementation

Question: 32. From 1980 to the present did you spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.)

Donor Eligibility: Donors who have spent time that adds up to five (5) years or more in Europe from 1980 to the present are indefinitely deferred. Donors may be at theoretical risk of developing vCJD from eating beef in Europe. There may be a theoretical risk of transmitting vCJD through blood transfusion.



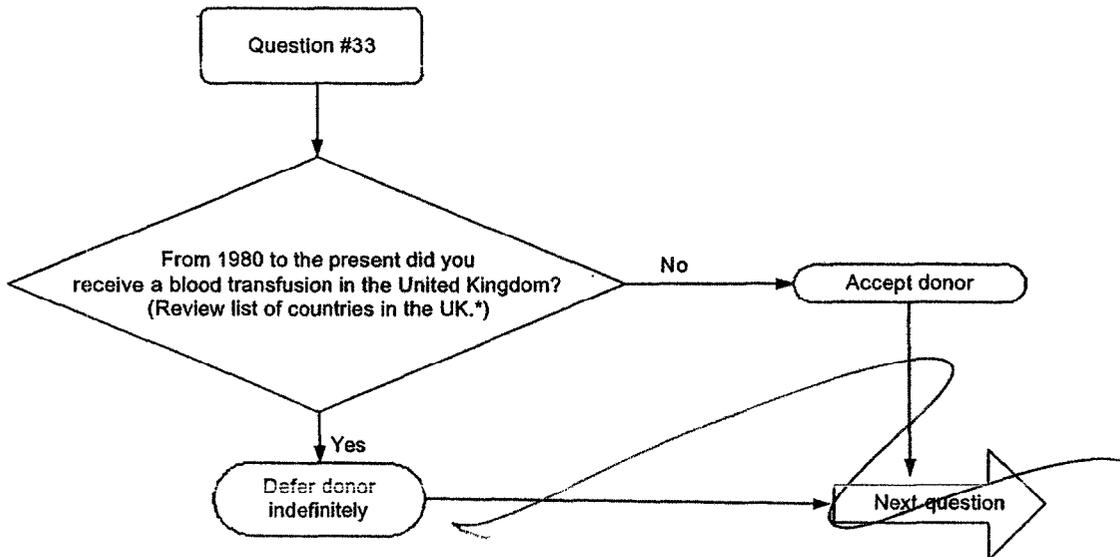
* See FDA "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease vCJD) by Blood and Blood Products." <http://www.fda.gov/cber/gdlns/cjdvcd.htm>

Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 33. From 1980 to the present did you receive a blood transfusion in the United Kingdom? (Review list of countries in the UK.)

Donor Eligibility: Donors who received a transfusion of blood, platelets, plasma, cryoprecipitate, or granulocytes in the UK from 1980 to the present are indefinitely deferred. Donors may be at theoretical risk of developing vCJD through transfusion. There may be a theoretical risk of transmitting vCJD through blood transfusion.



* See FDA "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease vCJD) by Blood . Blood Products." <http://www.fda.gov/cber/gdlns/cjdvcd.htm>

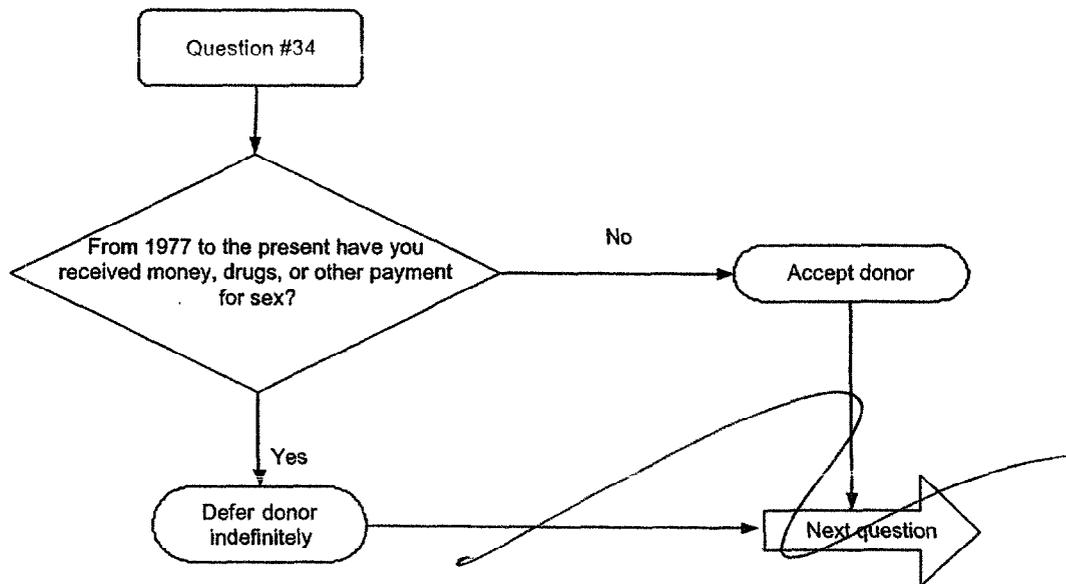
Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 34. From 1977 to the present have you received money, drugs, or other payment for sex?

Donor Eligibility: Donors who received money, drugs, or other payment for sex are indefinitely deferred. HIV and other diseases may be 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.



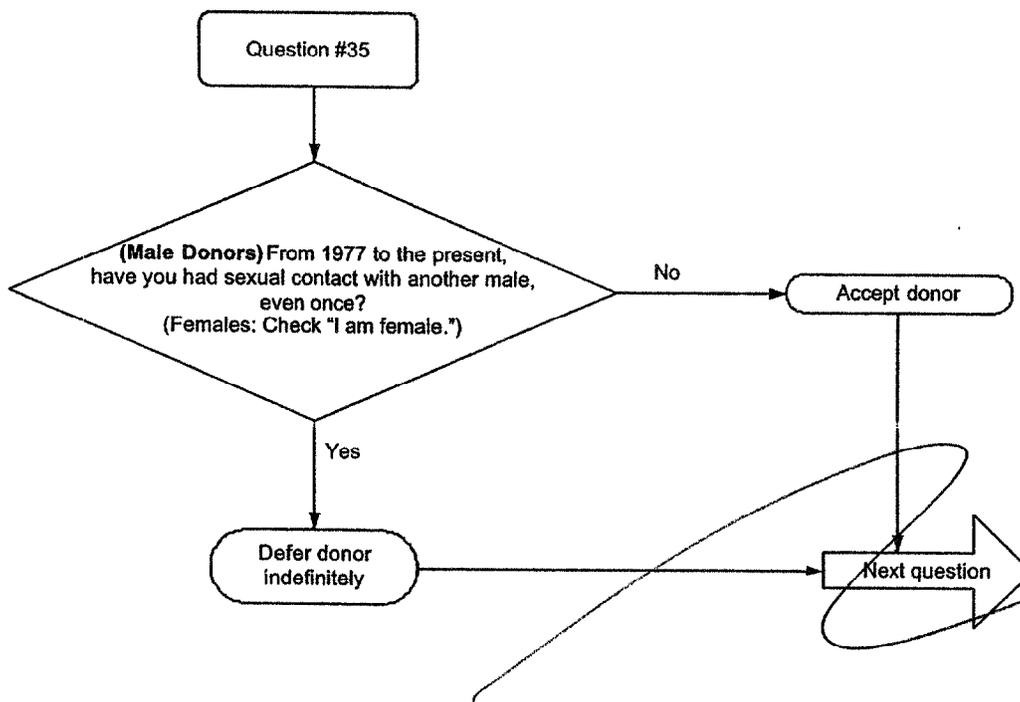
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Draft – Not for Implementation

Question: 35. (Male Donors) From 1977 to the present, 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, since 1977 are indefinitely deferred. Males who have had sex, even once, with males may be at risk of transmitting infectious diseases. 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.



Contains Nonbinding Recommendations

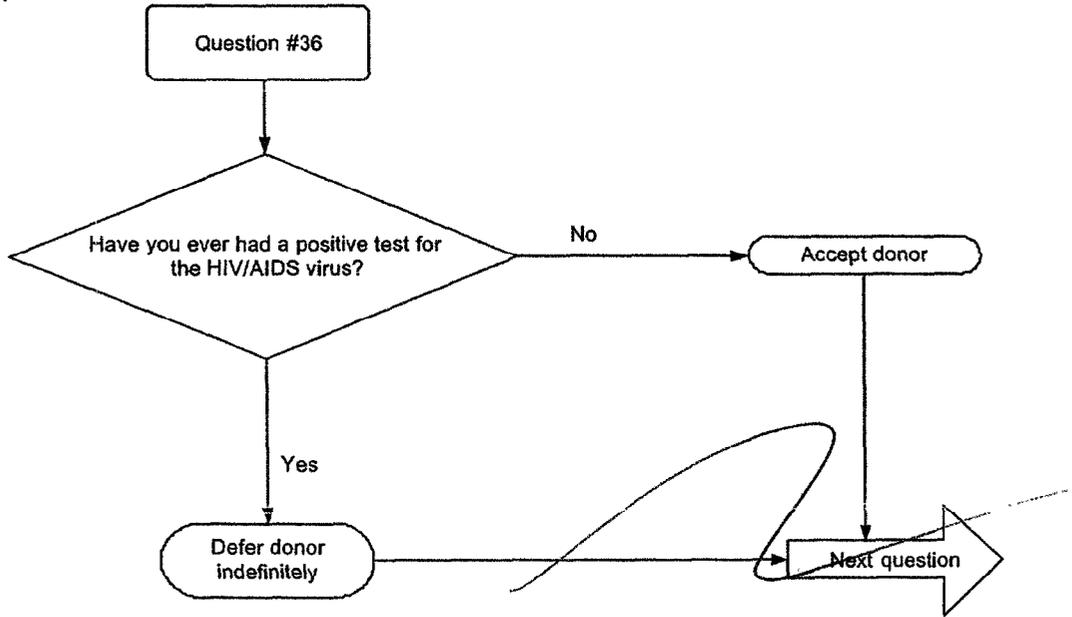
Draft – Not for Implementation

Question: 36. Have you ever had a positive test for the HIV/AIDS virus?

Donor Eligibility: Donors with clinical or laboratory evidence of HIV/AIDS are indefinitely deferred. 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 is not necessary here

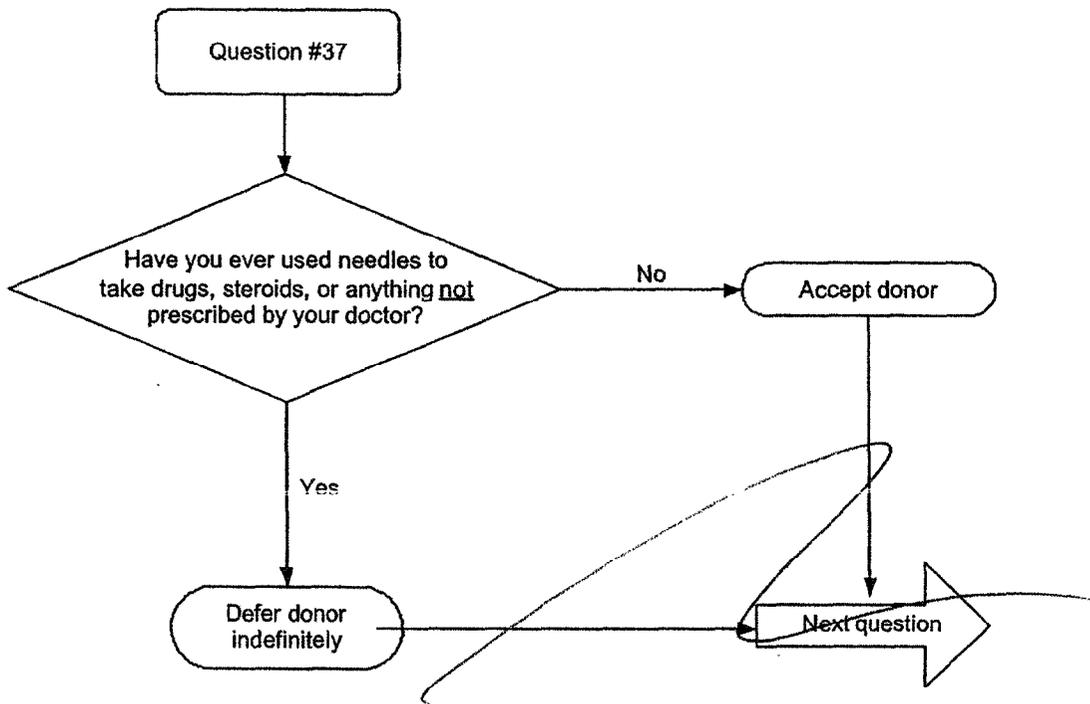


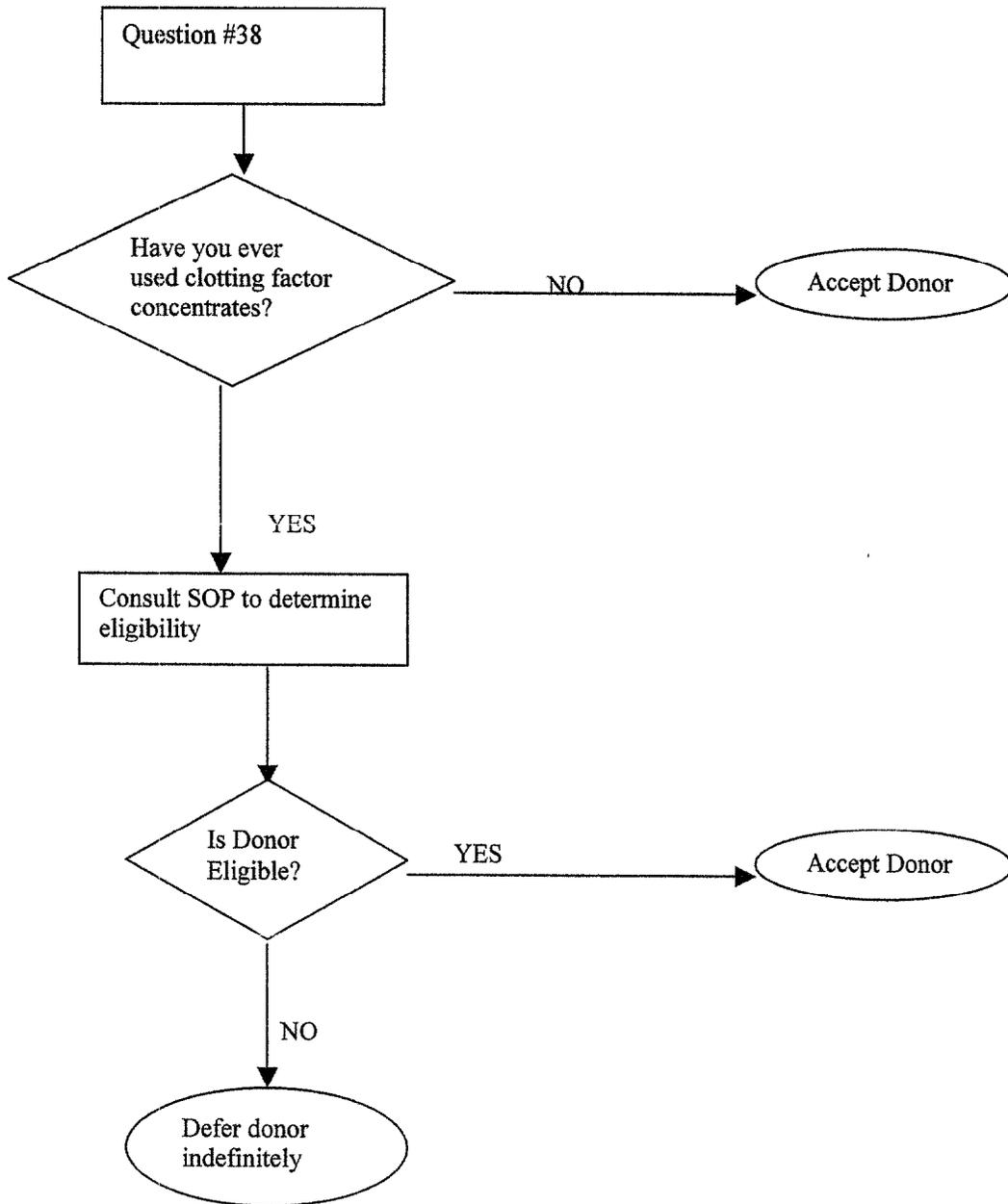
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Question: 37. Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?

Donor Eligibility: Donors who are past or present needle-using drug users are indefinitely deferred due to potential transmission of infectious diseases.



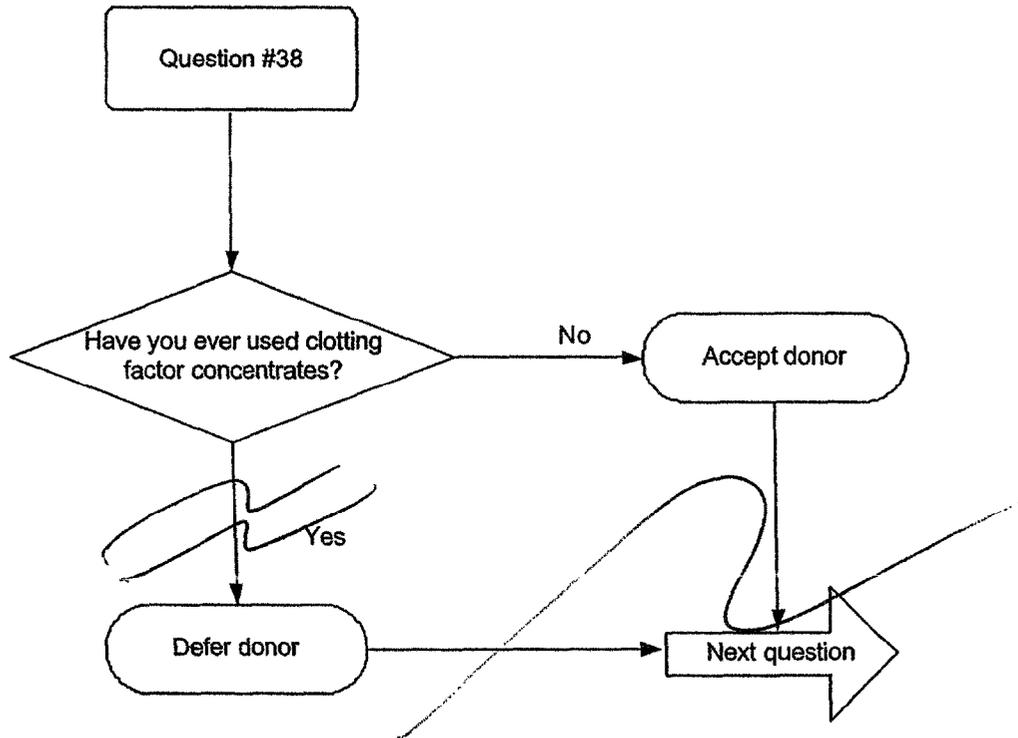


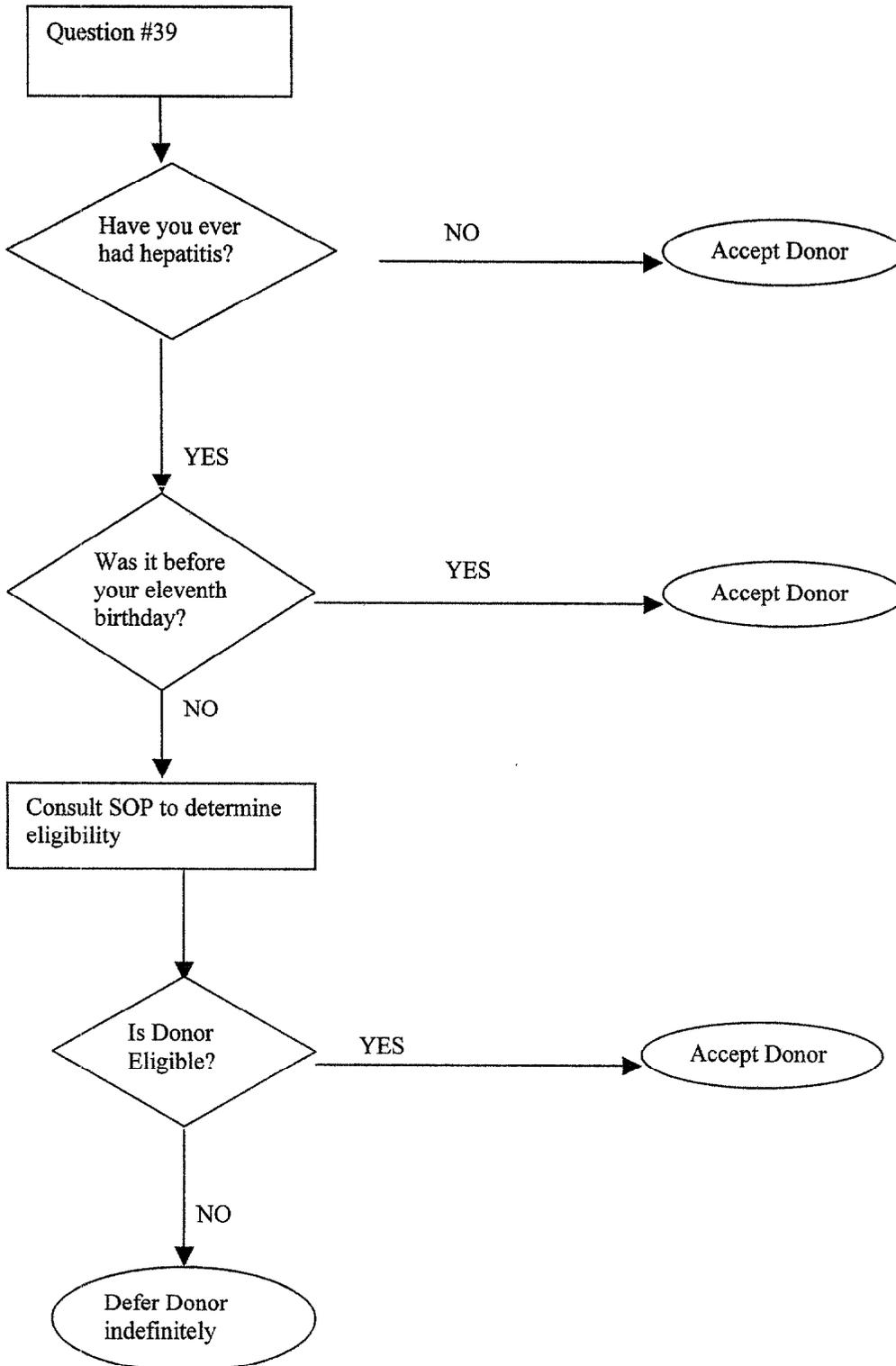
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Draft – Not for Implementation

Question: 38. Have you ever used clotting factor concentrates?

Donor Eligibility: A donor who has been exposed to clotting factor concentrates should not donate blood due to possible transmissibility of infectious disease.



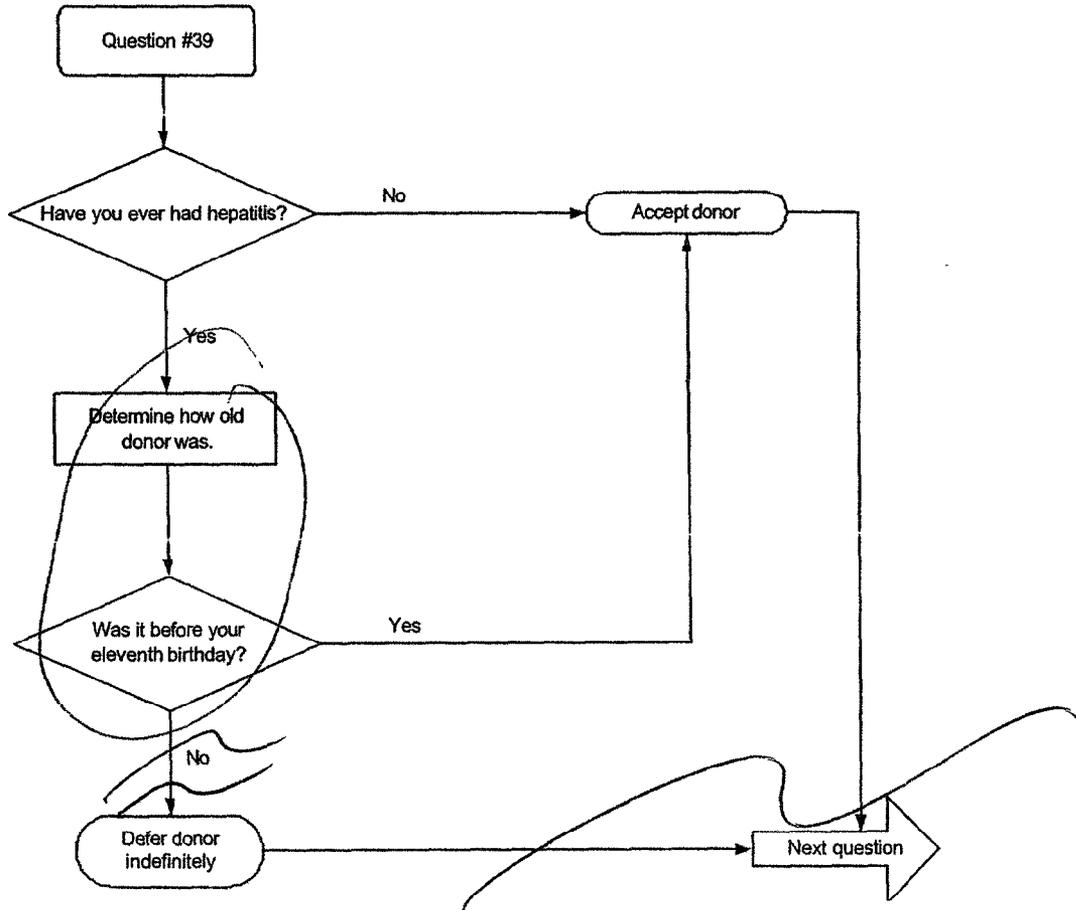


Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 39. Have you ever had hepatitis?

Donor Eligibility: Donors who have a history of viral hepatitis after their eleventh birthday are indefinitely deferred.

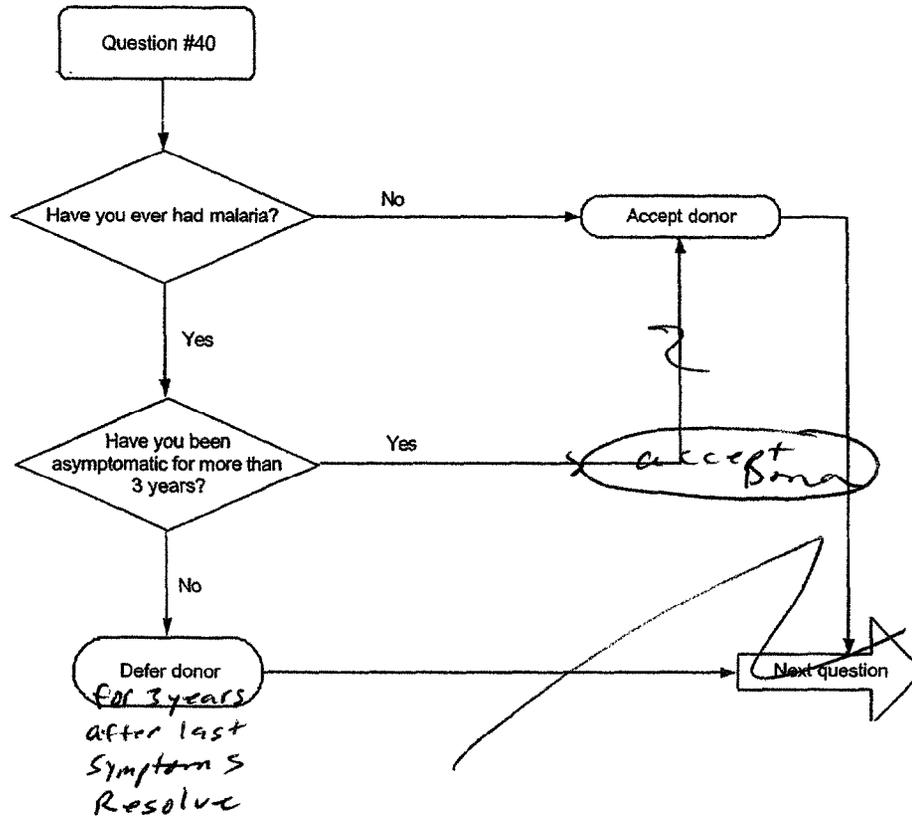


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Question: 40. Have you ever had malaria?

Donor Eligibility: Prospective donors who have had malaria and received an appropriate treatment should be deferred for three years after becoming asymptomatic. Malaria can be transmitted by blood.

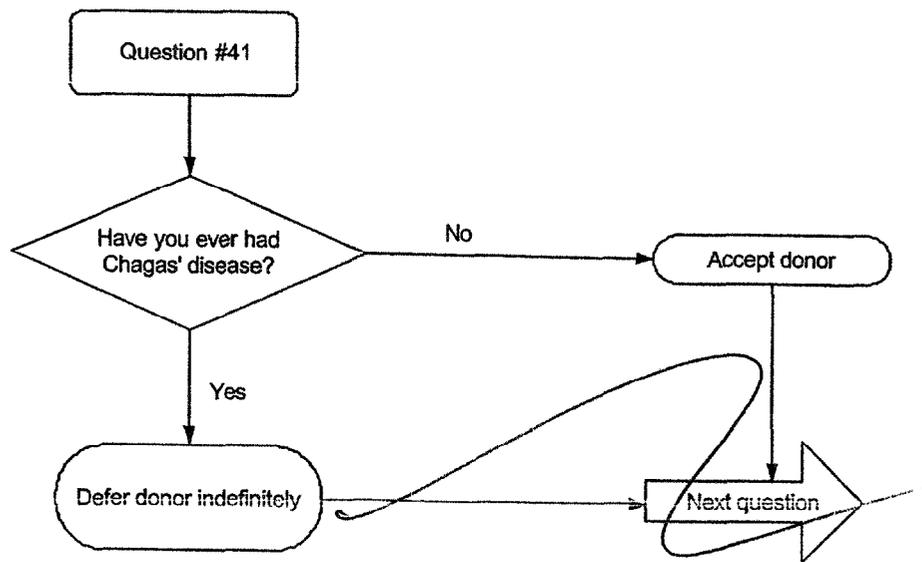


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Draft – Not for Implementation

Question: 41. Have you ever had Chagas' disease?

Donor Eligibility: Donors who have had Chagas' disease are indefinitely deferred. Chagas' disease can be transmitted by blood.

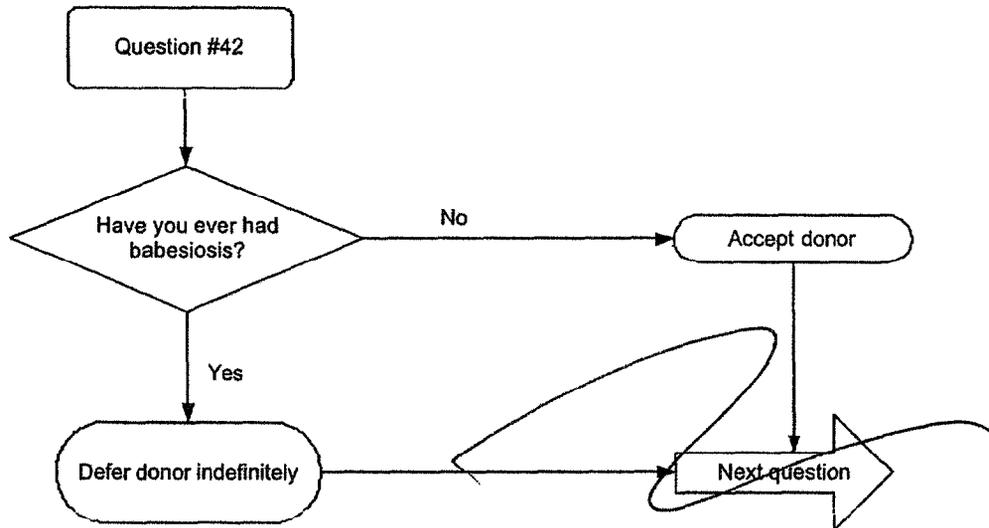


Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 42. Have you ever had babesiosis?

Donor Eligibility: Donors who have had babesiosis are indefinitely deferred. Babesiosis can be transmitted by blood.

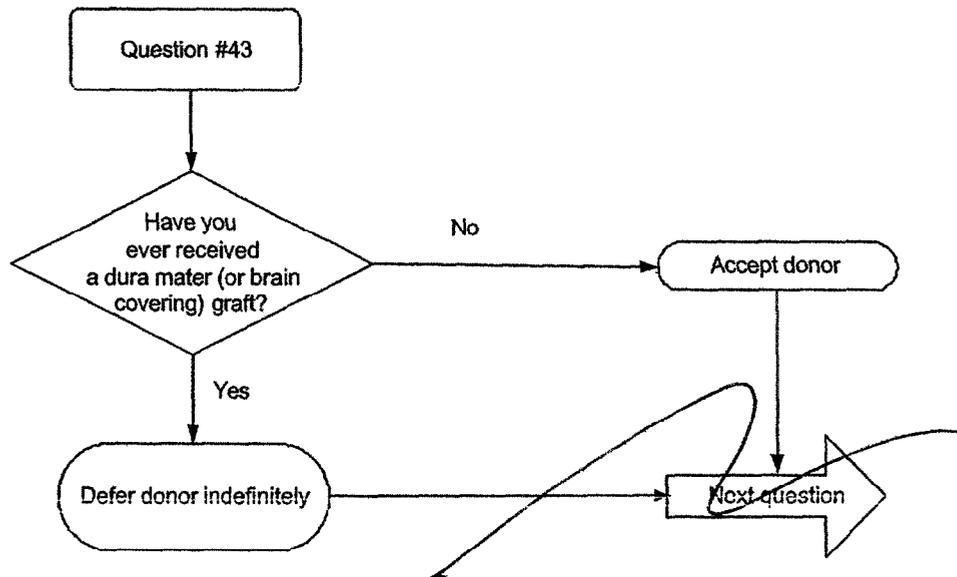


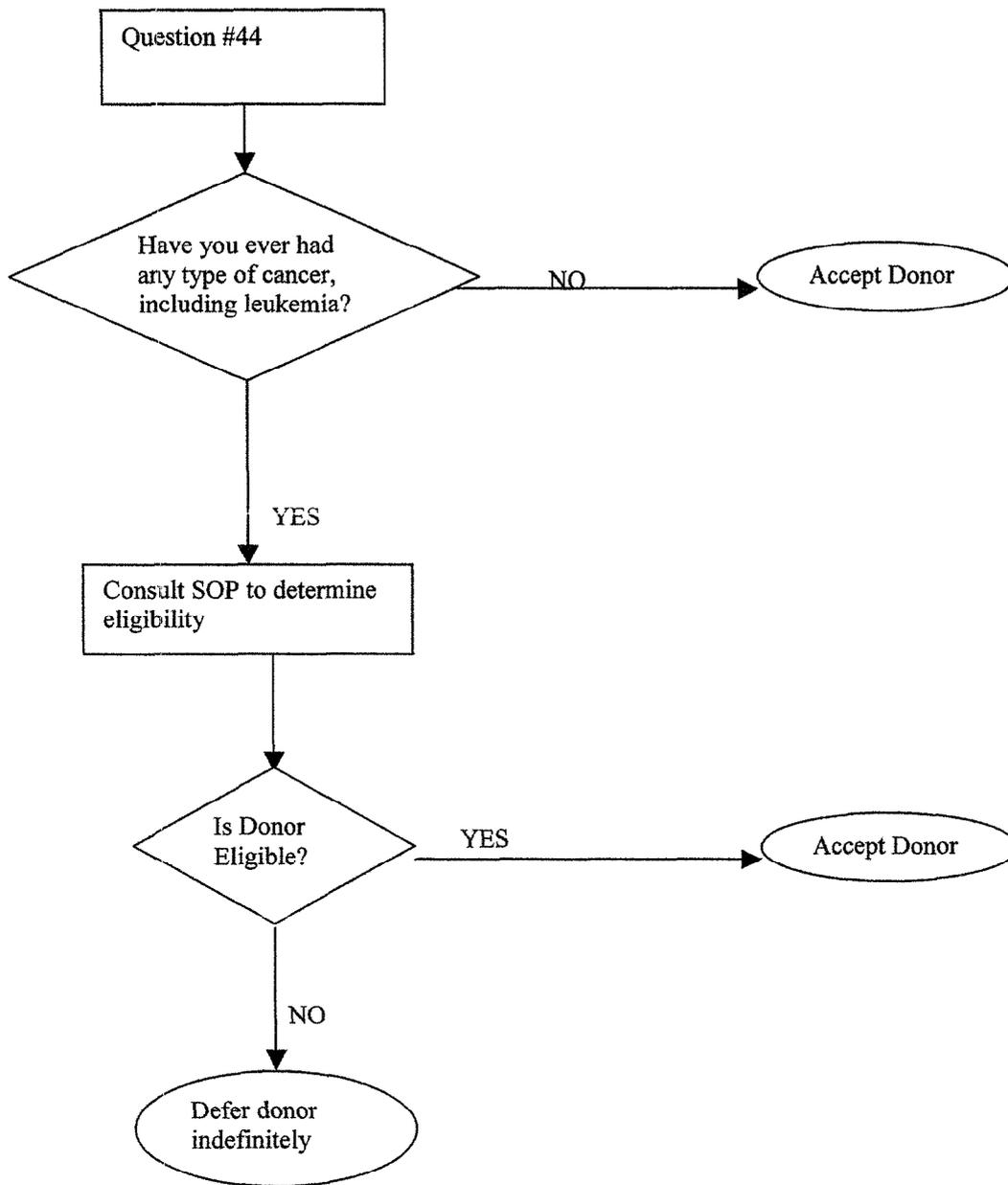
Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 43. Have you ever received a dura mater (or brain covering) graft?

Donor Eligibility: Donors who have received a dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and are indefinitely deferred.



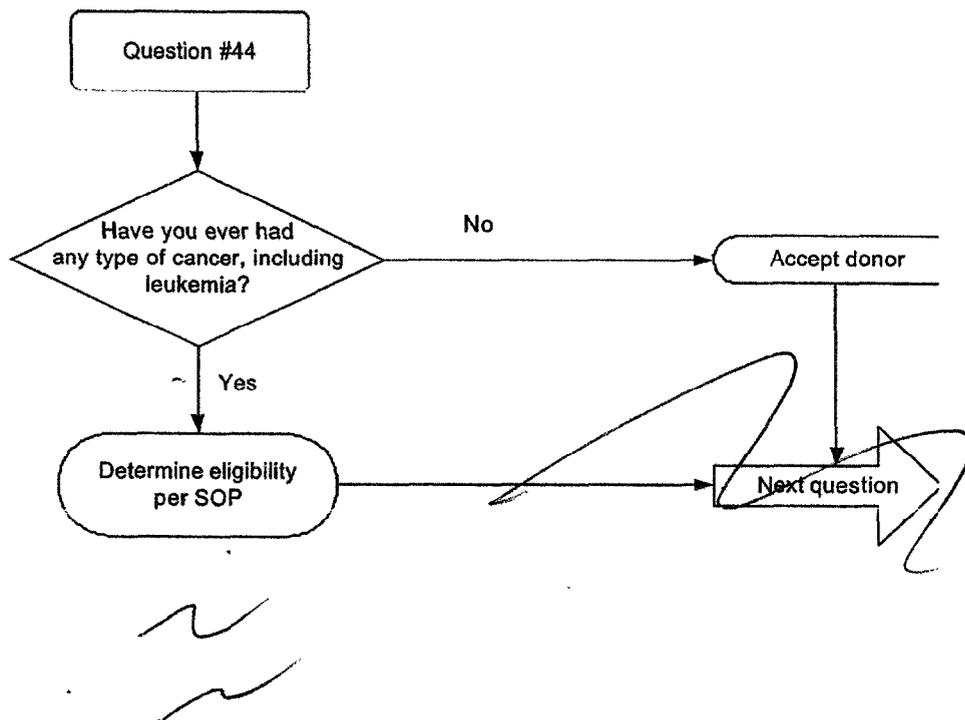


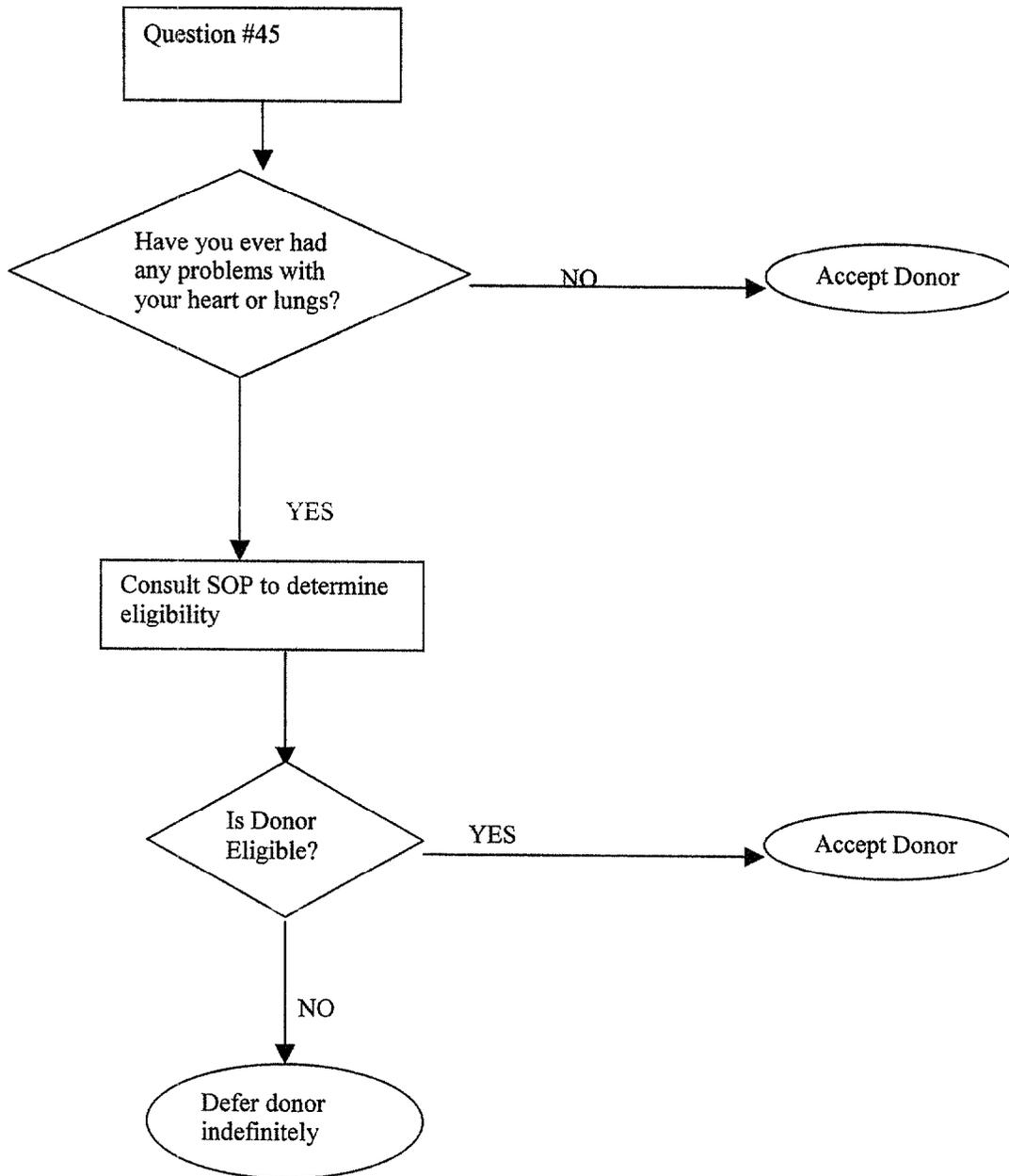
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Question: 44. Have you ever had any type of cancer, including leukemia?

Donor Eligibility: Donors with a history of cancer must be evaluated and deemed eligible to donate. Refer to SOP.



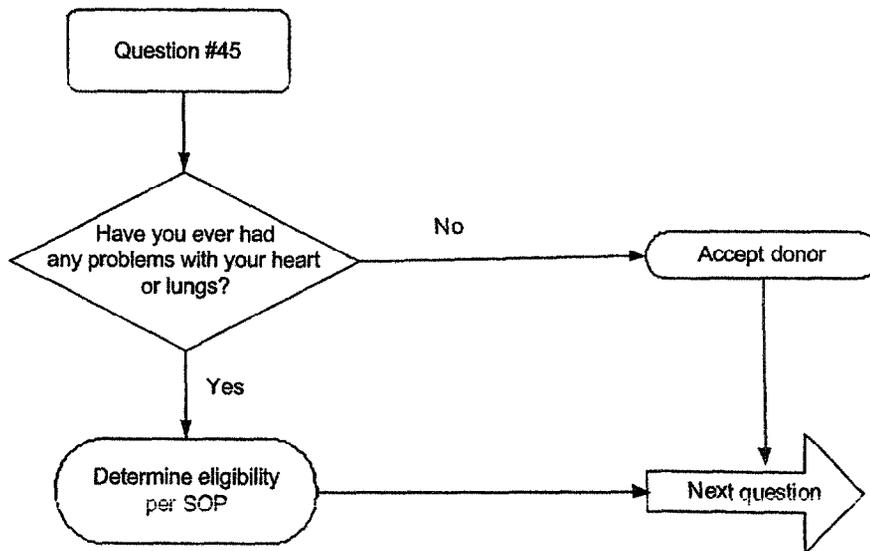


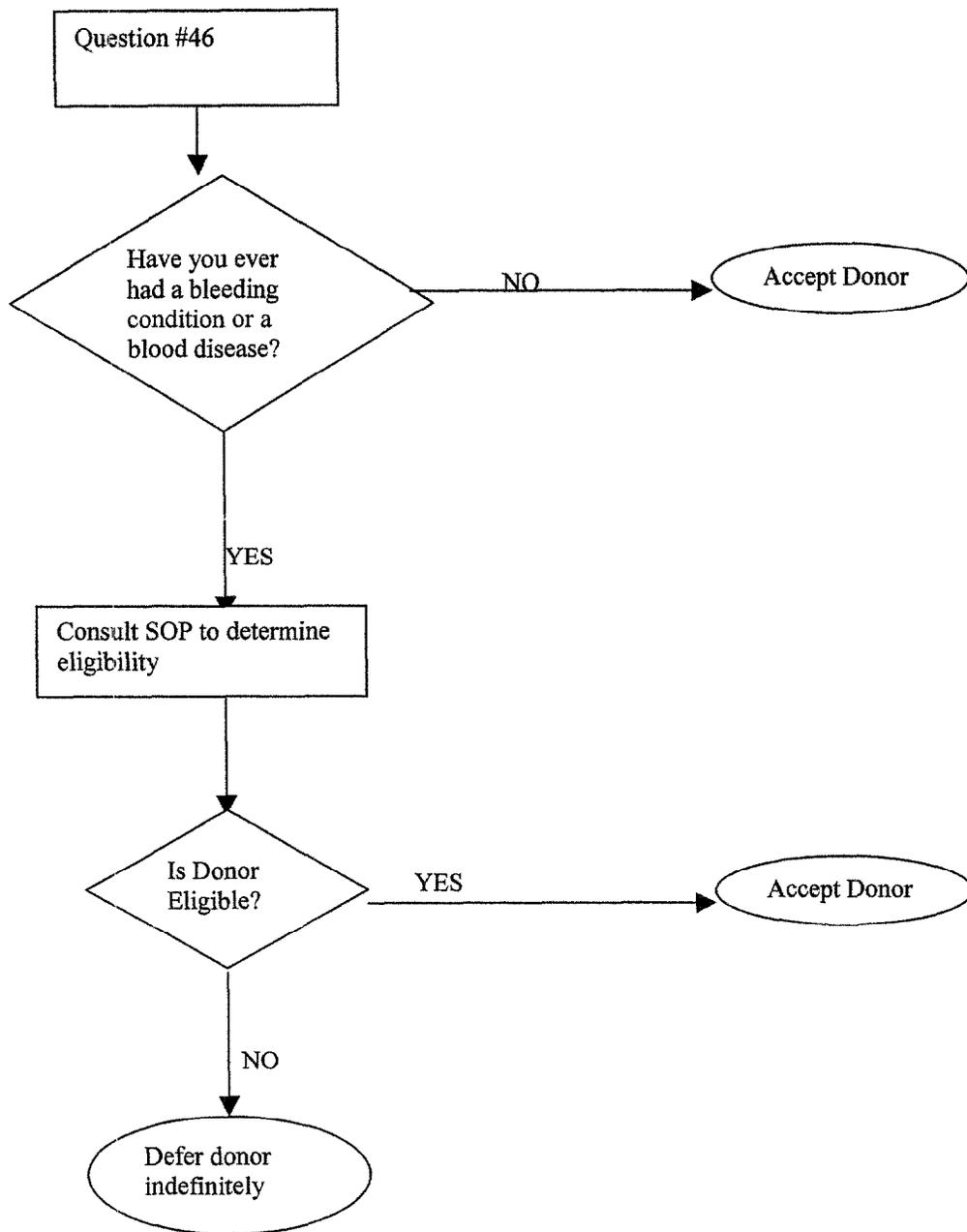
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Draft – Not for Implementation

Question: 45. Have you ever had any problems with your heart or lungs?

Donor Eligibility: Donors must be free of acute respiratory disease. Donors with a history of diseases of the heart and lungs, including acute lung diseases or colds, must be evaluated. Refer to SOP.





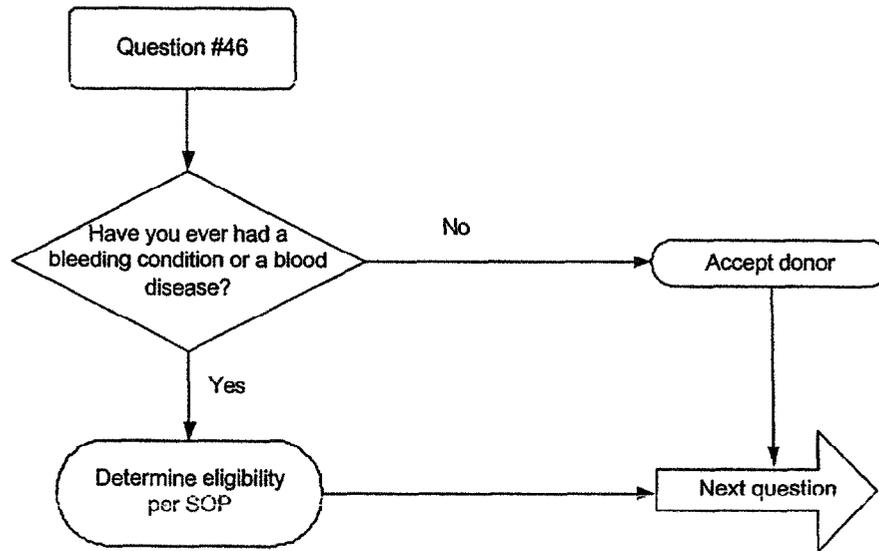
Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 46. Have you ever had a bleeding condition or a blood disease?

Donor Eligibility: Donors with a history of bleeding problems should be evaluated. Refer to SOP.

Note: Donors who have been receiving clotting factor concentrates are deferred indefinitely.



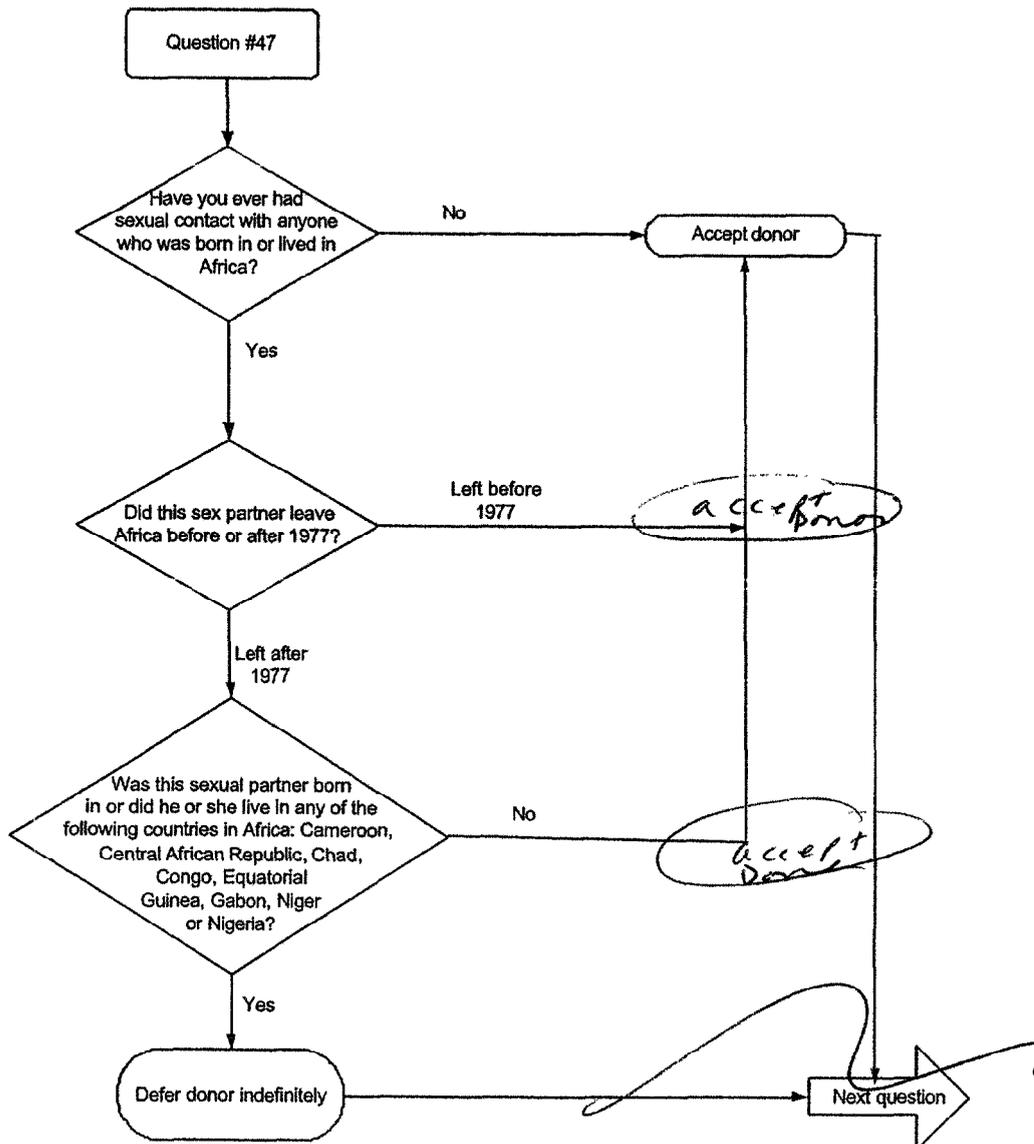
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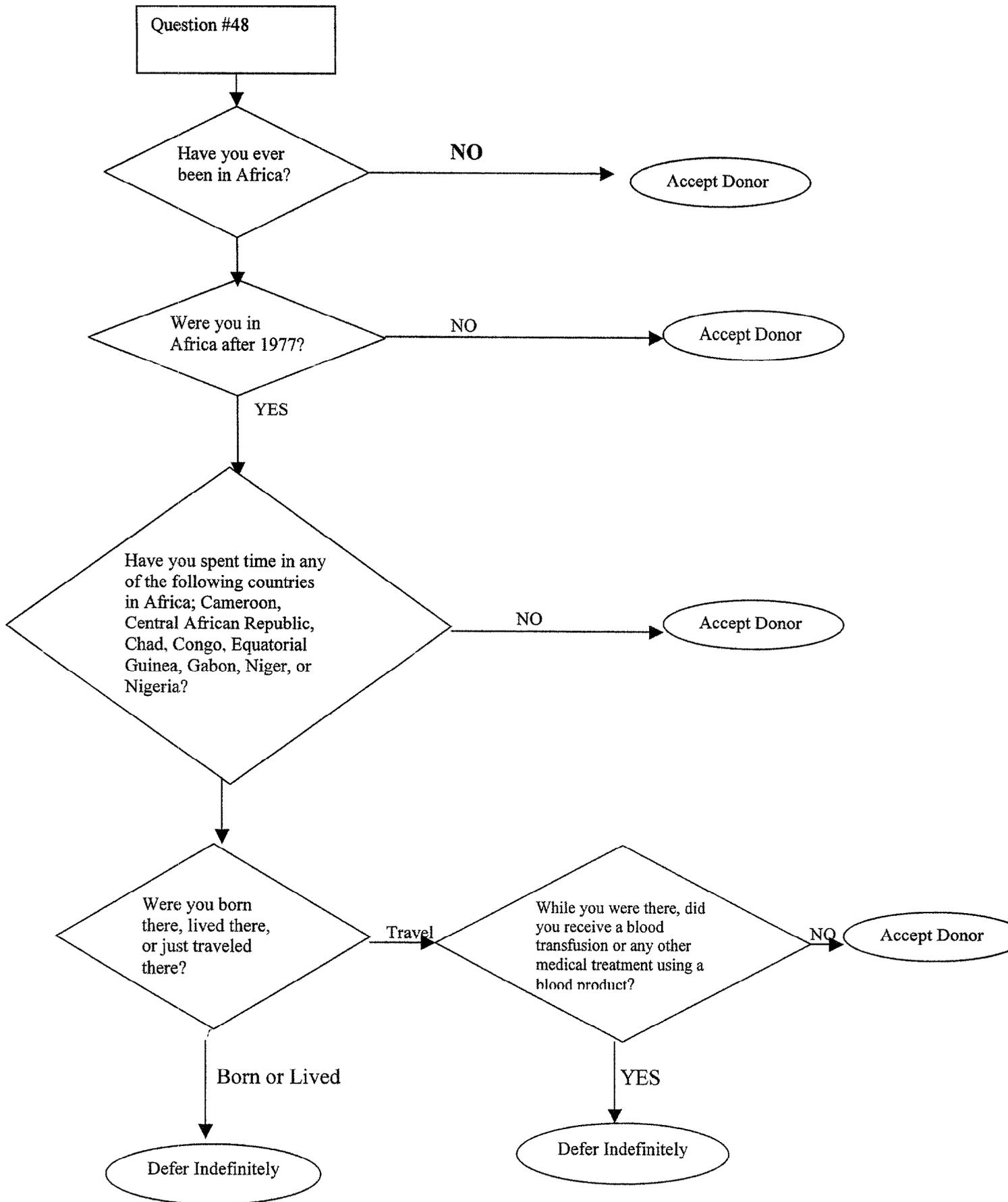
Question: 47. Have you ever had sexual contact with anyone who was born in or lived in Africa?

Donor Eligibility: If the donor had a sex partner who was born in or lived in certain countries in Africa (see list below) after 1977, the donor is indefinitely deferred. 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. **

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



** Blood collection agencies using an HIV antibody test that has been approved by FDA to include a claim for detection of group O viruses may eliminate this question during screening.

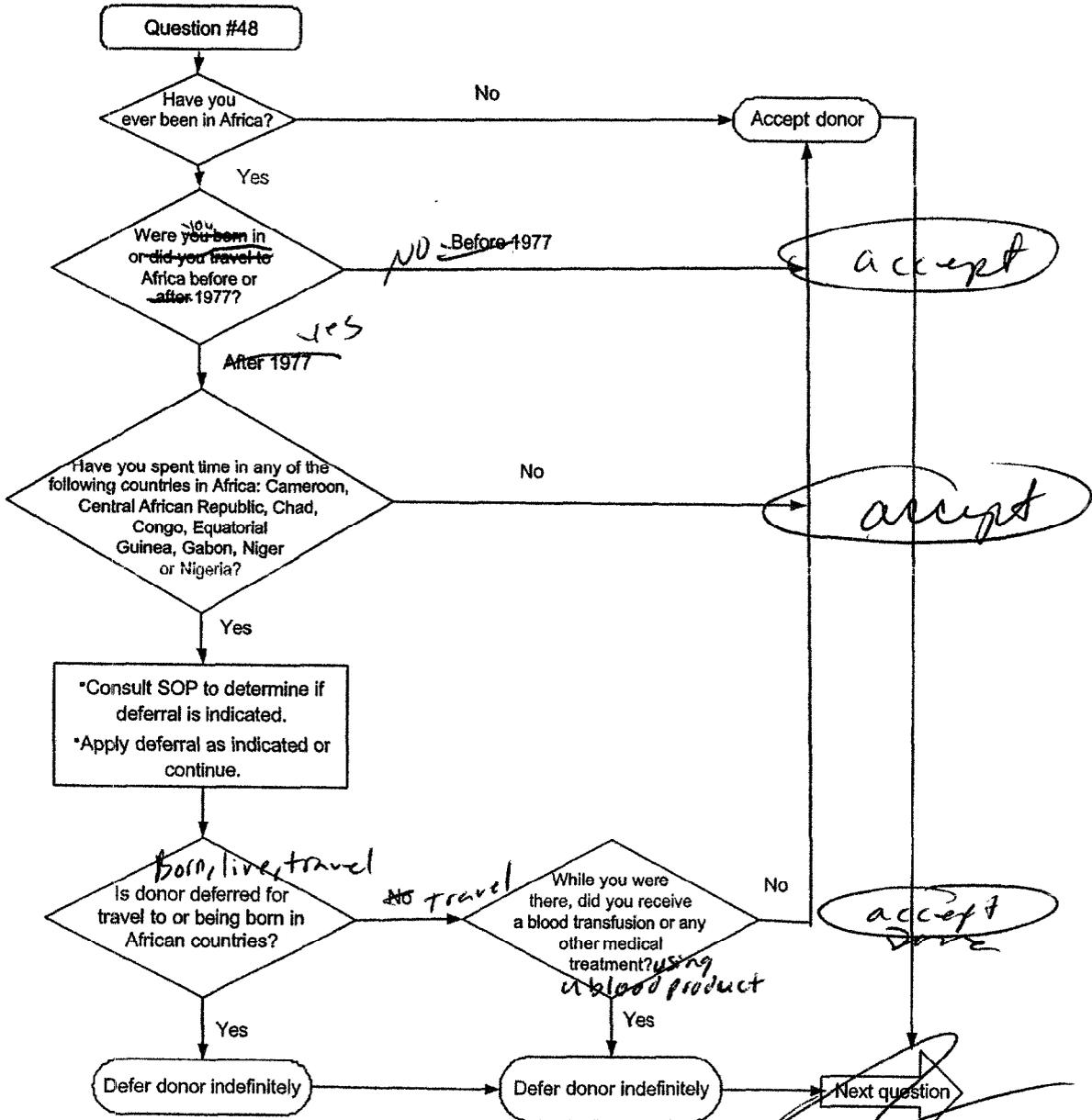


Contains Nonbinding Recommendations

Draft – Not for Implementation

Question: 48. Have you ever been in Africa?

Donor Eligibility: Donors who were born in or have lived in certain countries in Africa since 1977 (see list below) are indefinitely deferred. Donors who have received a blood transfusion or any other medical treatment in Africa are indefinitely deferred. Donors may have been exposed to rare strains of HIV that are not consistently detected by all current test methods. **



** Blood collection agencies using an HIV antibody test that has been approved by FDA to include a claim for detection of group O viruses may eliminate this question during screening.

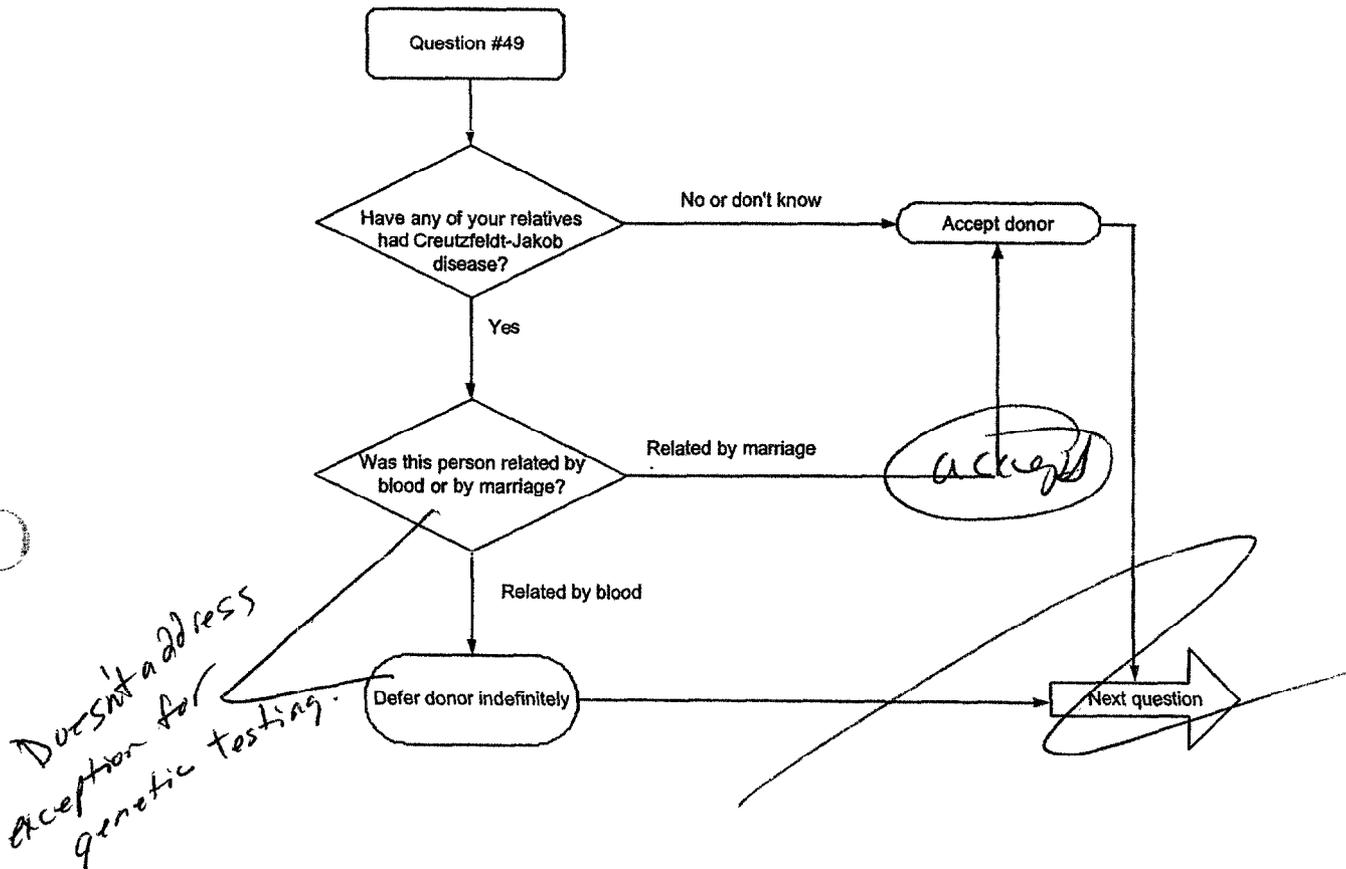
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Question: 49. Have any of your relatives had Creutzfeldt-Jakob disease?

Donor Eligibility: Donors with a blood relative with Creutzfeldt-Jakob disease are indefinitely deferred.

Note: If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, the donor is eligible.



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Blood Center**



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