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Change Notification UK National Blood Services No. 11 - 2019

Hepatitis C – N.I.

This change applies to the Whole Blood and Component Donor Selection Guidelines

Applies to Northern Ireland only. Donors and staff in England, Scotland and Wales see <u>Hepatitis</u> <u>C</u> entry.

1.-Affected Individual Person with current Hepatitis C infection

Obligatory	Must not donate.
Discretionary	If the individual has been told that he/she is HCV antibody negative, then samples should be taken to determine eligibility.
See if Relevant	Blood Safety Entry – N.I.
Additional Information	Hepatitis C (HCV) is a serious viral infection that can lead to chronic liver disease, liver cancer (hepatoma) and chronic fatigue syndrome. It has also been linked with malignant lymphomas and autoimmune disease. The infection is very easily spread by transfusion.
	Individuals who are chronically infected are sometimes referred to as 'carriers'. They often have no, or minimal, symptoms associated with their infection.
	Many cases are linked to previous drug use and, before the introduction of HCV screening of blood donations, to transfusion.
	Individuals who have had Hepatitis C infection in the past, and have been told that they have been successfully treated, will usually remain HCV antibody positive for many years. As a negative HCV antibody screening test is required before blood can be issued, their blood cannot be used.
Reason for Change	'Additional Information' has been added. Guidance for individuals with previous infection has been moved to a new section.
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2. Person with treated Hepatitis C infection

Includes	Individuals who have received successful treatment for HCV
Obligatory	Must not donate.
Discretionary	If six months has elapsed from the completion of therapy and the individual has been told their treatment has cleared their HCV infection, accept.
	Samples should be taken to confirm that the donor is HCV antibody negative before a full donation is taken.
See if Relevant	Blood Safety Entry – N.I.
Additional Information	Individuals who have been successfully treated will usually remain HCV antibody positive for many years. As a negative HCV antibody screening test is required before blood can be issued, their blood cannot be used.
Reason for Change	New section added to clarify guidance for potential donors with treated HCV infection.

3 2. Current or Former Sexual Partner of Affected Individual

Obligatory	Must not donate if. Less than 12 months from the last sexual contact.
Discretionary	Donors who have a current sexual partner with a history of previous HCV infection may be able to donate, depending on the status of their partner:.
	1. If the partner has been treated for HCV infection, and has been free of therapy for six months, and is in sustained remission, accept.
	2. If the partner has evidence of previous HCV infection (HCV RNA negative, anti-HCV positive), and has been fully assessed by an appropriate clinician who has confirmed that there is no current HCV infection, accept.
See if Relevant	Blood Safety Entry

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Additional Information

Confirmation of the success of treatment of the HCV positive partner is not required.

Individuals who remain HCV RNA negative six months after completing treatment are likely to have been 'cured', with a risk of relapse of less than 1%

There is now sufficient evidence to establish that individuals who have a sustained virological response to treatment for hepatitis C infection (defined as remaining hepatitis C RNA negative six months after completing treatment) are likely to have been 'cured' and that the chance of relapse is less than 1%. (Data from the Pegasys Study presented at the 38th annual Digestive Diseases Week conference, Washington, USA, 21 May 2007 by Shiffman et al [abstract ID #444]).

In the United Kingdom the risk of sexual transmission of HCV from an infected individual to a partner is low, but not zero.

As the treated individual would have a very low (<1%) risk of relapse of infection and sexual transmission of the hepatitis C virus is rare, the transmission of hepatitis C from a successfully treated individual to a sexual partner is most unlikely.

All donations in the UK undergo HCV NAT screening so that the chance of a window period donation escaping detection is also exceedingly low (estimated residual risk for HCV transmission from a UK blood donation for 2014-2016 is 1 in 95.8 million donations).

Sexual Partners of anti-HCV positive, PCR negative donors

From time to time, individuals are identified (through donation) who are HCV antibody positive, but have negative results for both pooled HCV NAT and individual HCV PCR tests. The question of eligibility of their partners as blood donors has been raised. While it is routine practice to request further tests on a follow-up blood sample from any donor who has positive microbiology test results, it is the current view that one or two negative PCR tests performed by the blood service, inevitably close together in time, are not sufficient to allow the (uninfected) partner to donate. This situation is not analogous to the partner of an individual who has been successfully treated for HCV infection, who will have undergone monitoring of test results over a period of time. The HCV antibody positive partner would need to have a full assessment and be given the assurance that he/she is not currently infected before the noninfected partner could be considered eligible as a donor.

Individuals who have cleared an acute HCV infection naturally are sometimes identified through HCV testing, including testing of a blood donation. Such individuals will be HCV RNA negative but HCV antibody positive. Unlike people who have been treated for HCV infection, they may not have received appropriate clinical follow up, including repeat HCV RNA testing several months after the original negative result. Unless the individual has undergone specialist assessment and been given the assurance that they are not currently infected, their partner is not eligible to donate.

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Reason for Change This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017. Revised to improve clarity of guidance and increase the minimum acceptance period after a partner completes treatment.

4. **3**. Person Currently or Formerly Sharing a Home with an Affected Individual

Discretionary	Accept.
See if Relevant	Current or Former Sexual Partner of Affected Individual, aboveCurrent Sexual Partner of HCV Positive Individual above.
Additional Information	Hepatitis C is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood route. For these reasons household contacts do not need to be deferred.
Reason for Change	Title change to 'Person Currently or Formerly Sharing a Home with an Affected Individual'. To reflect changes in the structure of the HCV entry.

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