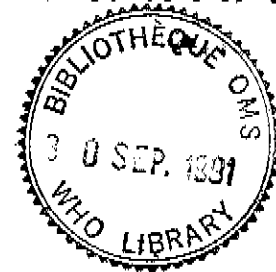


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GLOBAL BLOOD SAFETY INITIATIVE



CONSENSUS STATEMENT ON SCREENING OF BLOOD DONATIONS FOR INFECTIOUS AGENTS TRANSMISSIBLE THROUGH BLOOD TRANSFUSION

GENEVA
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WORLD
HEALTH
ORGANIZATION

GLOBAL
PROGRAMME
ON AIDS

Health
Laboratory
Technology and
Blood Safety Unit



League of Red Cross
and Red Crescent
Societies



GLOBAL BLOOD SAFETY INITIATIVE

CONSENSUS STATEMENT ON SCREENING OF BLOOD DONATIONS
FOR INFECTIOUS AGENTS TRANSMISSIBLE THROUGH BLOOD TRANSFUSION

The Global Blood Safety Initiative (GBSI) is a cooperative endeavour to support the development of safe and effective blood transfusion services in all countries. Core participants are the World Health Organization's Global Programme on AIDS (GPA) and the Health Laboratory Technology and Blood Safety unit (LBS), the League of Red Cross and Red Crescent Societies (LRCS), the United Nations Development Programme (UNDP) and the International Society of Blood Transfusion (ISBT). The Initiative is also supported by the World Federation of Hemophilia and other bilateral and multilateral development agencies and nongovernmental organizations.

This document was reviewed and endorsed by the GBSI Consultation on Screening of Blood Donations for Infectious Agents Transmissible through Blood Transfusion, held in Geneva from 30 January to 1 February 1990. Sixteen specialists in transfusion medicine and haematology from 12 countries participated. The participants are listed at the end of this document.

INTRODUCTION

The aim of this document is to provide guidance for formulating policies to reduce the risk of transmission of infectious agents by blood and blood products. This includes careful selection of blood donors and performance of appropriate screening tests.

Blood transfusion can be life-saving but it may also cause dangerous complications. The danger may be substantially reduced by the following:

1. Coordination of all blood transfusion activities through organization of a national transfusion programme.
2. Public education, which is important for the recruitment of safe donors, and which should include promotion of the concept of voluntary nonremunerated blood donations and the careful selection of donors. It should take into account the social, cultural and behavioural characteristics of the population. It should also provide information on the epidemiology, prevalence and method of transmission of endemic infectious agents that affect donor selection; on groups at greatest risk for acquiring infections; and on the consequences of infection.
3. Promoting the appropriate use of blood and its products and of alternatives to homologous blood transfusion.
4. Application of effective microbial inactivation procedures.
5. Implementing appropriate screening policies based on the following:

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5.1 Epidemiological studies. These are necessary for establishing the prevalence of infectious agents in the population, and for identifying groups within the population in whom the prevalence is particularly high or low, or who are at increased risk for acquiring infections. The studies should include prospective and retrospective documentation to assess the risk of transmission of infectious agents by transfusion of blood and blood products. When the epidemiology of a given agent has been well established regionally, no additional data are required before determining screening policies.

5.2 Cost-effectiveness. Assessment of cost-effectiveness takes into account the risk of transmission, based on the prevalence of the infectious agent in the population and the likelihood of immunity; the consequences of infection; and the costs of performing the test. The latter include both the direct and indirect costs of testing, and additional costs such as those resulting from discarding infected units, counselling, and further investigation of infected donors.

Cost-effectiveness may be increased by pre-donation testing. This policy requires careful evaluation and assessment before being adopted.

5.3 The sensitivity, specificity, and positive and negative predictive value of the test.¹ With regard to HIV serological tests these are as follows:

(a) The sensitivity of a test is the probability that it will detect HIV seropositivity in someone who has HIV infection. Thus sensitivity = T_d/D , where T_d = number of people with HIV infection whose test is positive and D = number of people tested who have HIV infection.

(b) The specificity of a test is the probability that the test result will be negative in someone who does not have HIV infection. Thus, specificity = T_n/N , where T_n = number of people tested who do not have HIV infection and whose test is negative, and N = number of people tested who do not have HIV infection.

(c) The positive predictive value of a test is the probability that the person tested has HIV infection when the test is positive or abnormal.

(d) The negative predictive value of a test is the probability that the person does not have HIV infection when the test is negative or normal.

5.4 The availability of national or international reference material and quality assurance (internal quality control and external quality assessment).

5.5 The technical expertise available, including appropriate training programmes for personnel.

5.6 The facilities available, including space, equipment (including the requirements for preventive maintenance and repair), and reagents and other consumables. Local production of reagents may improve their availability, but quality control and validation are important and can be achieved with the use of international reference reagents and with the help of WHO collaborating centres.

¹ See WHO "Guidelines for monitoring HIV infection in populations", September 1989 (in preparation) and unpublished WHO documents GPA/BMR/89.4, "Operational characteristics of commercially available assays to determine antibodies to HIV-1", Geneva, March 1989; GPA/BMR/90.1, "Operational characteristics of commercially available assays to determine antibodies to HIV-1 and/or HIV-2 in human sera", Report 2, Geneva, April 1990; and GPA/RES/DIA/91.1, Operational characteristics of commercially available assays to determine antibodies to HIV-1 and/or HIV-2 in human sera", Report 3, Geneva, March 1991.

5.7 Monitoring of the effectiveness of screening policies. This includes validation of testing procedures and proficiency, and follow-up and retrospective studies.

5.8 Research activities, e.g., investigation of alternative testing strategies and new screening procedures.

It is the responsibility of the transfusion service director to maintain the confidentiality of the results of all screening tests performed on donors' blood, and to ensure that arrangements are made for notification, counselling and appropriate care of donors in whom infection by one or more transmissible agents is confirmed.

It is important to eliminate the risk of transmission of infection to donors, staff and patients by adhering to the requirements for Good Laboratory Practice.* This includes following scrupulously the recommendations for use of equipment, materials and reagents and, particularly, not reusing disposable materials unless the manufacturers' instructions allow this. Effective sterilization procedures should supplement all screening programmes.

Facilities for self-exclusion should be provided in a manner appropriate to local conditions.

RETROVIRUSES

Retroviruses have assumed increasing prominence as causes of transfusion-transmitted infections. Human immunodeficiency virus type 1 (HIV-1) is of worldwide significance. Prevalence of infection in populations varies from less than 1 in 1000 to 1 in 8. HIV-2 infection is less widespread. It is prevalent in West Africa, but is not restricted to that region. Migrants from endemic areas to countries in which there is a low prevalence may pose a transfusion risk.

The human T-cell lymphotropic virus type I (HTLV-I) is endemic in Japan, the Caribbean and parts of Africa. The significance of HTLV-II is unclear, but it is the predominant HTLV infection in injecting drug users in some countries.

Despite validated screening procedures there is still, even in developed countries, a residual small risk of transfusion-transmitted retroviral infection. It is therefore vital to define high-risk behaviour and to educate donors accordingly in order to encourage self-exclusion. Viral spread to low-risk populations should also be monitored.

Effective methods are available for viral inactivation of plasma products. Cellular blood components or plasma may transmit HIV-1 or HIV-2, but plasma does not transmit HTLV.

Recommendations

HIV-1 AND HIV-2¹

1. Policies for screening blood for HIV before transfusion should be determined at the national level, taking into consideration the availability of resources, the local

¹ See also "Consensus statement on accelerated strategies to reduce the risk of transmission of HIV by blood transfusion", unpublished document WHO/GPA/INF/89.13 (WHO/LAB/89.6), Geneva, 20-22 March 1989, and "Criteria for HIV screening programmes", unpublished document WHO/SPA/GLO/87.2, Geneva, 20-21 May 1987.

* Haematology Task Force. Good laboratory practice. In: B. Roberts, ed. Standard Haematology Practice. Oxford: Blackwell, 1991: 1-18.

prevalence, and any changes in procedure as monitored periodically by serosurveillance studies.

2. The technology selected must be appropriate. Simple or rapid tests should be considered when the use of enzyme-linked immunosorbent assay (ELISA) systems is not feasible or suitable. Rapid screening tests may be used when blood is required urgently. Unvalidated modifications of commercial assays must not be used.
3. Supplementary testing of repeatedly reactive samples must be done before notification and counselling of donors.
4. In the absence of a defined "re-entry" programme, donations that are repeatedly positive by a screening test must not be used for transfusion.
5. Screening of pooled serum samples may be considered in areas where low prevalence of HIV is adequately documented, provided the following requirements are met:
 - the test system should be validated locally by the laboratory prior to use (information may be obtained from the WHO Global Programme on AIDS on the characteristics of commercially available assays and their suitability for pooled serum screening);
 - the test system should be one in which dilution of serum does not compromise sensitivity;
 - stringent measures must be taken to ensure reliable sample identification;
 - the pool should not include more than 5 individual serum samples;
 - changes in HIV prevalence should be closely monitored.
6. Where it is decided to test for HIV-1 and HIV-2, combined test systems may be used, provided that the sensitivity and specificity for detection of antibodies to both viruses are maintained. The use of joint screening should not be delayed by the absence of adequate supplementary discriminatory tests. Some combined tests have been evaluated by WHO and new assays will be evaluated on a continuing basis.¹
7. Currently, there is no evidence that screening for HIV antigen increases the safety of blood transfusion beyond that achieved by HIV-antibody screening.
8. Strategies aimed at exclusion of donors with high-risk behaviour should be encouraged and adapted to local situations.

HTLV

1. ELISA and particle agglutination (PA) tests are available for screening blood donations. These tests detect HTLV-I and HTLV-II antibodies. The significance of HTLV-II seropositivity for transfusion is still unknown.
2. In areas of low HTLV endemicity, HTLV antibody screening of blood donors is of low priority.
3. Serum or plasma specimens that are reactive on initial ELISA or PA screening should be retested in duplicate. Supplementary tests (e.g., Western blot, radioimmuno-precipitation assay (RIPA), immunofluorescent assay (IFA) are desirable for samples that are repeatedly reactive and are essential prior to donor notification and counselling. Confirmation of anti-HTLV reactivity is more difficult than for anti-HIV.

¹ See footnote to page 2.

4. Cellular blood components from donors whose sera are repeatedly reactive in screening tests should not be used for transfusion purposes unless they satisfy defined "re-entry" criteria. Plasma from such donors may be used for fractionation purposes. There is no available evidence that HTLV has been transmitted by transfusion of plasma and its derivatives. However, donors with confirmed HTLV seropositivity should be excluded from blood or plasma donation.

VIRAL HEPATITIS AND BLOOD TRANSFUSION

The term "viral hepatitis" encompasses a group of diseases with similar clinical pictures but with different viral etiologies, epidemiological patterns of transmission, outcomes, and tendencies toward chronicity. These diseases are now referred to as hepatitis A, B, C, D and E. Hepatitis B, C and D viruses are important causes of post-transfusion hepatitis, but hepatitis A and E viruses do not play significant roles.

Hepatitis B virus (HBV) infection

Acute HBV infection may be asymptomatic, or may cause acute viral hepatitis or fulminant hepatitis. Most acute infections resolve leaving the patient with life-long immunity, but 20% to 90% of infected children and 6% to 10% of infected adults become chronic carriers.

There are about 280 million chronic carriers worldwide, and they are at increased risk of death from cirrhosis or primary hepatocellular carcinoma (PHC). It is estimated that there are 250 000 to 1 million deaths per year due to PHC. In some countries in Africa, South-East Asia and the Western Pacific, HBV-related PHC ranks as the first or the second most frequent cause of death. In these areas carrier prevalence exceeds 8%, and 80% to 90% of adults show evidence of infection. In most cases this follows acute infection during childhood, which is usually asymptomatic.

In North America, Western Europe, and Australia only about 5% of the population become infected with HBV, and the carrier prevalence is 0.1% to 0.5%. Infection is common in certain high-risk groups defined by life-styles, medical conditions or occupation. Infection in these areas usually occurs in young adults, where it results in acute hepatitis with jaundice in about 33% of cases.

The rest of the world shows intermediate levels of HBV infection, with carrier prevalence of 2% to 5%, and with 20% to 50% of the population immune.

Screening donor blood for hepatitis B surface antigen (HBsAg) has been partially responsible for the dramatic reduction in post-transfusion hepatitis B since the early 1970s. Highly sensitive and specific "third generation" tests are available for HBsAg screening: radioimmunoassay (RIA), ELISA and reverse passive haemagglutination (RPHA).

The risk of post-transfusion hepatitis B following transfusion of a single unit of unscreened blood depends on the probability that the donor blood is HBsAg-positive and the probability that the recipient is susceptible. It varies from approximately 0.2% in areas of low endemicity to approximately 2% in areas of higher endemicity, but may be as high as 4% in children in hyperendemic areas.

Hepatitis D, also known as Delta hepatitis, is caused by a defective RNA virus that is unable to produce its own protein coat and coats itself with HBsAg produced during HBV infection of liver cells. Thus, the delta virus is dependent on HBV. Infection may be concurrent with HBV infection (coinfection), or may occur in a chronic HBV carrier (superinfection). Coinfection causes acute viral hepatitis that often becomes fulminant and is usually fatal. Superinfection causes acute hepatitis followed by a rapidly progressive chronic active hepatitis leading to cirrhosis in almost 75% of carriers.

The epidemiology of delta transmission varies markedly in the world. Southern Italy, parts of Eastern Europe and the Middle East, the Amazon Basin, and parts of Africa have high levels of endemic transmission. In North America and Northern Europe prevalence is low in the general population, but infection is common in injecting drug users, haemophiliacs, dialysis patients, and patients with chronic liver disease. The prevalence of this virus in Asia is generally low.

Delta hepatitis has been transmitted by transfusion of blood and plasma derivatives and transfusion of delta-positive blood to a susceptible individual or to an HBV carrier is especially dangerous. Although tests for delta antigen and antibodies exist, it is unnecessary to use them in blood screening because all blood infectious for the delta agent is also HBsAg-positive, and routine HBsAg screening will eliminate the risk of transmission.

Blood-transmitted non-A, non-B hepatitis (NANBH)

As a result of the cloning of genes from hepatitis C virus (HCV) a first generation assay for anti-HCV has become available. Various studies, using this assay and other techniques, have shown that HCV is a small lipid-coated RNA virus that can produce self-limited infection or, in up to 50% of cases, a chronic carrier state. Studies with unconfirmed assays for anti-HCV show prevalence rates varying from 0.5% to 15%. The chronic carrier state is associated with a high risk of development of cirrhosis and hepatocellular carcinoma.

Studies in the United States of America on sera collected serially during and for at least 12 months after post-transfusion non-A, non-B hepatitis have shown that 80%-96% of cases may develop anti-HCV. Thus HCV may cause most, if not all, bloodborne non-A, non-B hepatitis in the United States. An association has also been shown in other parts of the world, but further work is necessary.

Recommendations

HBV

1. Each unit of blood or plasma collected should be tested for HBsAg by a sensitive method such as RIA, ELISA or RPHA, and only those giving a negative result should be used. Appropriate confirmatory testing, such as neutralization, must be performed before any donor notification or counselling is undertaken.
2. The development and validation of simple, rapid, and inexpensive HBsAg tests of appropriate sensitivity should be encouraged.
3. Recognizing the global importance of hepatitis B related diseases, health authorities should give high priority to the provision of reagents for sustained blood screening. International organizations (e.g., WHO) and nongovernmental organizations should be encouraged to support this effort.

NANBH

1. It is recommended that there should be studies of the epidemiology of HCV infection throughout the world.
2. Due to the serious nature of HCV-related disease, it is desirable to screen blood donations for anti-HCV. Anti-HCV tests are available but expensive, and there is an urgent need for development of less expensive screening tests.
3. The usefulness of surrogate tests (e.g., alanine aminotransferase assay and anti-HBc) should be evaluated in different populations, but tests for antibody to hepatitis B core antigen (anti-HBc) are not applicable in areas of high HBV endemicity.

4. Manufactured plasma derivatives such as factor VIII and factor IX formerly transmitted NANBH to most, if not all, recipients. The infectivity of these products is eliminated by pasteurization in solution, solvent/detergent treatment, beta-propiolactone/ultraviolet irradiation treatment, or heating of lyophilized products at 80°C for 72 hours. Manufactured large pool products that have not been treated by one of these procedures, or by a procedure shown to be equally effective, should not be used.

Under conditions of Good Manufacturing Practice, immunoglobulin intended for intramuscular use and produced by the standard cold ethanol fractionation method is safe. However, certain preparations of immune globulins intended for intravenous use have been implicated in NANBH transmission. This indicates the need for the development of virus inactivation procedures for these products.¹

CYTOMEGALOVIRUS (CMV)

More than 50% of adults (up to 100% in some cases) have antibodies to and therefore may be carriers of CMV, a cell-associated herpes virus. It may be transmitted by blood transfusion and can cause severe disease in seronegative babies of low birth weight and in seronegative immunosuppressed recipients, including those with HIV infection.

Recommendation

Blood to be used in high-risk recipients should be tested for anti-CMV, since it has been shown that anti-CMV negative blood is not infective. An appropriate test procedure is the latex agglutination test, which is simple, rapid and affordable. An alternative strategy is to deplete blood of leukocytes. If this is done effectively CMV is not transmitted.

SYPHILIS

Syphilis infection can be transmitted by blood transfusion. Despite the existence of a window period, screening is likely to be effective in high-prevalence areas where patients are untreated, and if fresh blood is used and no antibiotics are given to recipients. However, the cost-effectiveness is questionable if blood can be stored at 4°C for at least 72 hours after collection (because this inactivates treponemes), and if recipients often receive antibiotics.

Screening can also be used to help to identify people whose behaviour increases their risk of infection with other sexually transmitted agents, such as HIV. In addition, it can be used for case-finding and for tracing contacts, and may therefore help in monitoring public health control programmes.

The disease occurs worldwide and the incidence is increasing in some populations. It is curable if treatment is instituted early. The prevalence of seropositivity varies from 0.24% to 13.8% in different donor populations.²

Recommendations

1. From the point of view of reducing the risk of transmission to recipients, screening for syphilis is less cost-effective than storing blood at 2°C to 8°C for 72 hours before use. Where the risk of transmitting syphilis is high and storage is not possible, prophylactic ~~antibodies~~ antibiotics should be given to recipients.

¹ See also WHO Expert Committee on Biological Standardization, Thirty-ninth report (WHO Technical Report Series, No. 786, 1989).

² "Syphilis and safe blood" (Unpublished document WHO/VDT/89.444).

2. A screening test for syphilis may be useful for helping to identify individuals whose behaviour leads to an increased risk for infection by other sexually transmitted agents, such as HIV. However, its use as a surrogate test for HIV instead of a specific test is not recommended.
3. If it is decided that donors should be tested, either the VDRL or a treponemal test, such as Treponema pallidum haemagglutination (TPHA), may be used. The VDRL is less costly than the TPHA. Although the TPHA test is more specific, it remains positive even after treatment. Therefore it is less suitable than the VDRL for screening populations with a high prevalence of treponemal infection. In these circumstances, the VDRL should be used for screening, with confirmatory testing of positive samples. The TPHA is preferable in populations in which the prevalence of treponemal infection is low.
4. Seropositive blood should either be discarded or kept for at least 72 hours at 2°C to 8°C before use. If the blood is used for the preparation of platelet concentrate, cryoprecipitate or fresh plasma, the recipient should receive prophylaxis.
5. Seropositive donors should be referred to special clinics for further testing, treatment and contact tracing.
6. Further research is necessary to determine the efficacy of antibiotic prophylaxis in preventing post-transfusion syphilis.

TRYPANOSOMIASIS

Trypanosomiasis is a general term for two separate diseases caused by protozoan parasites belonging to the genus Trypanosoma. T. brucei infections cause African sleeping sickness and T. cruzi infections cause Chagas disease. These two diseases have different transmission cycles, vectors and pathology. Nevertheless, both begin as a blood infection with parasitaemia which makes these diseases transmissible by blood transfusion. Although extensive literature has accumulated on the biology and immunology of Trypanosoma, few data are as yet available on the specific problem of blood transmission.

Chagas disease

T. cruzi is mainly transmitted from infected sylvatic and domestic mammals to humans by haematophagous reduviid bugs. Infection with T. cruzi is thought to be lifelong and the disease is a major public health problem in Latin America where it is estimated that 16-18 million people are infected. Infected people may pass through three clinical stages: acute; asymptomatic chronic (latent) stage; and chronic symptomatic (cardiac and/or digestive complications).

No treatment is available for patients with chronic disease, although in some regions when patients are treated during the acute stage they become serologically and parasitologically negative for T. cruzi. However, acute infection is difficult to identify since patients often present with non-specific clinical features.

Factors contributing to the transmission of Chagas disease by blood transfusion include: the high prevalence of chronic asymptomatic patients in endemic areas; migration from rural areas, where the prevalence is relatively high, to urban areas; increasing blood usage; and the difficulty in detecting infected blood.

African trypanosomiasis

African trypanosomiasis is a disease caused by trypanosomes that are transmitted essentially by the bite of tsetse flies (Glossina spp.), which occur over a wide area of Africa south of the Sahara. Two species of these trypanosomes give rise to sleeping

sickness in man, a disease that is fatal if it is not treated. They are: T. brucei gambiense, which causes a chronic form of the disease, and T. brucei rhodesiense (in East and Southern Africa), which causes a more acute illness. The risk of transmission by blood transfusion is not well documented, with only a few reported cases.

Diagnosis is confirmed by detecting parasites in the blood by direct methods or after concentration techniques. Serological tests such as IFA, card agglutination tests and ELISA cannot distinguish active from past infections that have been treated, but they can be considered for use in endemic areas to exclude carriers.

Trypanosomiasis due to T. brucei rhodesiense is usually symptomatic and transmission by blood transfusion is very rare.

Trypanosomiasis by T. brucei gambiense has an asymptomatic phase when transmission by blood ~~transmission~~ may occur.

~~transfusion~~

Recommendations

Chagas disease

1. In endemic areas, serological tests should be carried out on all donors. In non-endemic areas, serological tests for T. cruzi should be carried out on donors from endemic areas.
2. Several tests are available (ELISA, complement fixation, indirect haemagglutination, direct agglutination, IFA). Antigens for the tests can be supplied commercially and by public health laboratories and should be validated and standardized. It is advisable to use at least two test systems in order to increase the chances of identifying positive donors.
3. Gentian violet (GV) can be added to blood to a final concentration of 125 mg/500 ml, which is then stored at 2°C to 8°C for at least 24 hours before use. This is highly effective in reducing the risk of transmission and is particularly useful in hyperendemic areas. At this concentration GV is not toxic, but the skin and mucous membrane of some patients become stained for short periods and microagglutination and rouleaux formation of red blood cells may occur.
4. The long-term consequences in patients receiving GV-treated blood should be monitored.
5. Effective vector control will reduce the prevalence of the disease and its transmission by blood transfusion.

African trypanosomiasis

A card agglutination test may be used in endemic areas to exclude carriers.

MALARIA

The global incidence of malaria is about 100 million cases annually, and leads to 9 million deaths, most commonly in children, due mainly to Plasmodium falciparum infection. There is increasing exposure to infection as a result of increasing travel by tourists and business people between non-endemic and endemic areas, and population migration from endemic to non-endemic areas.

The significance of malaria in relation to blood transfusion is due to the resurgence of malaria throughout the world, the increased incidence of P. falciparum infection, the increased proportion of drug-resistant strains, and the increased usage of blood and its components. The parasites are viable for at least one week in blood stored

at 2°C to 4°C. Malaria may be transmitted by whole blood or red cells, and by components contaminated with red cells, such as frozen fresh plasma and cryoprecipitate. Plasma fractions do not transmit the disease. Post-transfusion malaria (PTM) is particularly dangerous in pregnant women and in immunodeficient patients. It is often difficult to diagnose due to an atypical presentation or a prolonged asymptomatic period following infection.

The risk of PTM and the appropriate preventive measures depend on the local pattern of malaria prevalence. Information on global prevalence is provided annually by WHO. No test is sufficiently sensitive to exclude the possibility of transmission.

Recommendations

1. In malaria-free areas, and in areas with limited risk, donors should be screened for a history of malaria, or of travel or residence in endemic areas, and the following policies should be adopted:
 - (a) Donors who have a history of malaria or of fever that could be due to malaria should be deferred unless or until they are seronegative using an IFA or ELISA.
 - (b) A donor who has visited or lived in an endemic area and has taken malaria prophylaxis should be deferred for at least three years unless an approved serological antibody test is negative six months after return. A small risk of undetected P. vivax infection cannot be excluded.
 - (c) A donor who has visited a malarious area and has not taken malaria prophylaxis but has no history of malaria should be deferred for six months after leaving the area.
2. In malaria-free areas with numerous blood donors from endemic areas, the best policy is to perform serological screening on these donors using the IFA or ELISA.
3. In malaria-endemic areas, most adults are likely to be immune, but children, pregnant women and immunocompromised patients are at increased risk of PTM. Although it may be desirable to treat all transfusion recipients with antimalarials, it is especially important that the drug selected should be appropriate to local conditions, and that a curative dose be used.

There is at present no adequate test method for the parasite (including microscopy, acridine orange staining of parasites or antigen detection) which is sufficiently sensitive to exclude the possibility of transmission.

4. Pre-treatment of potential donors is not recommended.
5. Follow-up studies of transfusion recipients should be encouraged in order to evaluate the efficacy of these policies in preventing PTM, and new effective strategies should be actively sought.

TOXOPLASMOSIS

Toxoplasma gondii is a widespread, obligate intracellular protozoan parasite maintained in the general population by transplacental transmission and contact with faeces of infected pets.

Infestation is commonly asymptomatic, but symptomatic disease includes retinitis, focal brain lesions, lymphadenopathy, abortion and congenital disease. Untreated infection in immunosuppressed patients is severe and often fatal.

T. gondii has been isolated from the blood of infected donors up to four years after the onset of infection. Parasites persist in white cells and can survive storage at 2°C

to 4°C for up to seven weeks. Leukocyte transfusion from parasitaemic donors has transmitted severe, sometimes fatal toxoplasmosis to immunosuppressed patients.

Seroprevalence of antibody to toxoplasma varies between 20% and 80%, and increases with age.

Recommendations

1. In view of the potential severity of post-transfusion toxoplasmosis among immunocompromised patients, a small pool of seronegative blood donors should be identified for supplying platelet or white cell concentrates for such patients when necessary. Alternatively, white cell depletion by modern white cell filters may reduce or eliminate risks of transmission. However, this still remains to be established.
2. An appropriate test procedure for detecting toxoplasma antigens is the Latex Particle Agglutination test, which is simple, rapid and inexpensive.
3. Universal screening of blood donors is not recommended.

Other microorganisms

Parvovirus B19 was commonly transmitted in unactivated pooled plasma concentrates, such as Factor VIII, before effective methods were available for viral inactivation. However, it is now rarely transmitted by blood transfusion and the infections are clinically insignificant.

Nantucket fever, caused by Babesia microti, an intraerythrocytic parasite usually transmitted by tick bites, has been transmitted in North America. Colorado tick fever virus, which also resides in red cells and can be transmitted by tick bites, has likewise been reported to have been transmitted by blood transfusion.

Visceral leishmaniasis (kala-azar) and the rickettsial agent of Q fever (Coxiella burnetii) have been transmitted by blood transfusion, but only rarely.

No transfusion-transmitted cases due to Borrelia burgdorferi, the spirochaete which causes Lyme disease, have been reported, and donor screening is not generally recommended. In endemic areas it may be prudent to exclude donors who demonstrate signs or symptoms of primary infection.

Although microfilariae can be transmitted by blood, this has not been shown to result in disease, and routine donor screening is therefore unnecessary.

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Corr. 1

CONSENSUS STATEMENT ON SCREENING OF BLOOD DONATIONS FOR
INFECTIOUS AGENTS TRANSMISSIBLE THROUGH BLOOD TRANSFUSION

GENEVA, 30 JANUARY TO 1 FEBRUARY 1990

CORRIGENDUM

p. 7 - the last line of the last paragraph should read:

"... possible, prophylactic antibiotics should be given to recipients."

p. 9 - the last line of the fourth paragraph should read:

"... by blood transfusion may occur."