HEALTH RISK ANALYSIS IN EPIDEMIOLOGY

UDC 61
DOI: 10.21668/health.risk/2022.3.10.eng

Read online

Research article

FIVE-YEAR EXPERIENCE IN PROVIDING INFECTIOUS SAFETY OF DONOR BLOOD AND ITS COMPONENTS GAINED BY THE BLOOD CENTER OF THE RF FEDERAL MEDICAL-BIOLOGICAL AGENCY

A.A. Filippova[1,2], A.P. Faenko[1,2], S.A. Golosova[1,2], I.V. Ivanova[1,2], E.A. Klyueva[1,2], Ya.N. Glazov[1,2], D.S. Malysheva[1], M.A. Kasatkin[1,2]

[1]The FMBA Blood Center, bldg 2, 6 Shchukinskaya Str., Moscow, 123182, Russian Federation
[2] The FMBA Federal Research and Clinical Center for Specialized Medical Aid and Medical Technologies, 91 Volokolamskoe Ave., Moscow, 125371, Russian Federation

Screening technologies aimed at identifying such transfusion transmissible infections (TTI) as hepatitis B and C, HIV-1,2 and syphilis have been developing and this has resulted in increased safety of applied hemotherapy.

Our research goal was to analyze detection of infectious markers in donors of the FMBA Blood Center over five years.

We examined 167,389 samples of donor blood taken from 53,093 donors of blood and its components by the FMBA Blood Center over the period from 2015 to 2019.

Over the whole analyzed period, we detected 1453 infectious-positive samples taken from 1235 donors. Average long-term quantity of detected hepatitis C markers equaled 78.6 ± 9.4; hepatitis B, 49.8 ± 8.2; syphilis, 66.2 ± 16.8; HIV, 52.8 ± 13.2. We also analyzed detected TTI markers in long-term dynamics and established an ascending trend in a number of syphilis markers (the growth rate was 3.2), hepatitis B (the growth rate was 2.5), and a descending trend in hepatitis C markers (the decrease rate was 3.3) as well as HIV markers (the decrease rate was 1.7). This decrease rate in detection of HIV markers (fall by 1.7) occurred both among first-time and regular donors. At the same time, we revealed growing detection of syphilis markers both among first-time donors where it grew by 3.6 and among regular ones, by 1.4. Frequency of infection markers was higher among first-time donors than among regular ones as per syphilis markers, 2.351 (95 % CI: 1.862–2.938), $p < 0.00001$; hepatitis B markers, 2.111 (95 % CI: 1.622–2.763), $p < 0.00001$; hepatitis C markers, 2.107 (95 % CI: 1.708–2.609), $p < 0.00001$; and HIV, 2.471 (95 % CI: 1.9–3.238), $p < 0.00001$.

Over the last 5 years, there was a descending trend in detection of transfusion transmissible infections among donors regarding HIV and viral hepatitis C excluding tests aimed at detecting syphilis and viral hepatitis B markers.

Keywords: *Blood service, blood donors, transfusion transmissible infections, HIV, hepatitis, syphilis, viral hepatitis B, viral hepatitis C, infections markers screening, infectious safety of blood transfusions.*

Anna A. Filippova – Candidate of Medical Sciences, Head of the Department for Ensuring the Safety of Donated Blood and its Components, epidemiologist; Associate Professor of the Department for Infectious Diseases and Epidemiology (e-mail: fa852007@yandex.ru; tel.: +7 (905) 56-64-105; ORCID: https://orcid.org/0000-0002-7371-8545).

Aleksandr P. Faenko – Candidate of Medical Sciences, transfusiologist at the Donor Recruitment Department (e-mail: alexfaenko@mail.ru; tel.: +7 (916) 34-57-788; ORCID: https://orcid.org/0000-0001-6158-233X).

Sofiya A. Golosova – director (e-mail: golosova@bloodfmba.ru; tel.: +7 (495) 942-47-67; ORCID: https://orcid.org/0000-0001-5405-1282).

Irina V. Ivanova – Head of the Department for Clinical Laboratory Diagnostics (e-mail: IIvanova@bloodfmba.ru; tel.: +7 (916) 66-29-886; ORCID: https://orcid.org/0000-0003-4491-8123).

Elena A. Klyueva – Candidate of Medical Sciences, Head of the Department for Organization of Medical Care as per the profile "Transfusion medicine", doctor-methodologist (e-mail: iospkdir@bk.ru; ORCID: https://orcid.org/0000-0002-7581-0740).

Yaroslav N. Glazov – Deputy Director for Medicine, transfusiologist (e-mail: YGlazov@bloodfmba.ru; tel.: +7 (965) 18-92-603; ORCID: https://orcid.org/0000-0001-7761-8093).

Daria S. Malysheva – Head of the Donor Recruitment Department, transfusiologist (e-mail: DMalysheva@bloodfmba.ru; tel.: +7 (965) 230-07-33; ORCID: https://orcid.org/0000-0003-1467-3321).

Mikhail A. Kasatkin – Head of the Department of Procurement of Donor Blood and its Components, transfusiologist (e-mail: MKasatkin@bloodfmba.ru; tel.: +7 (916) 304-11-68; ORCID: https://orcid.org/0000-0002-9324-0702).

The Blood service is a key branch of the public healthcare in Russia. It secures storage and use of safe blood components necessary for rendering high-technology and specialized medical assistance. A priority safety issue in the field is to prevent transfusion transmissible infections (TTI). The Blood service applies three basic tools to resolve it. The first one is temporary or permanent rejection of a donor based on questioning or a medical examination that includes epidemiological control. The second tool is laboratory blood screening aimed at detecting leading infection markers and the third one is additional treatment of donated blood components (quarantine, leukodepletion, pathogen-inactivating technologies, etc.).

Donor blood was first screened to detect any infection markers in it as far back as in 1940ties; the first screening involved testing to detect syphilis in donor blood [1]. Notably, the first case when syphilis was transmitted with transfused blood was detected in 1915 and already by 1941 there were 138 such cases registered in literature sources [2, 3]. *Treponema pallidum* bacteremia is more often detected at the first or second stage of the disease and often persists for a short period even if a donor has become infected quite recently [4]. At the same time, Treponemas are relatively fragile and sensitive to cold; therefore, there is a very low risk that the infection is transmitted with transfused blood that was kept under a temperature below 20 °C for more than 72 hours [3]. There is a direct relationship between a number of organisms in blood and a period of their viability (potential infectivity) [5, 6]. A retrospective study involved examining 98 blood units which were donated by syphilis-positive people, underwent a 7-day quarantine period under 4 °C and then were transfused to 90 recipients. As a result, no transmissions were detected and none of the tested recipients had seroconversion [7]. The same study did not reveal any passively transfused antibodies in recipients when their initial titer was lower than 1:8; passively transmitted antibodies were not further detected after 10 days in those recipients who received blood component units with their titer varying from 1:8 to 1:64. In many developed countries, transfusion transmissible syphilis is no longer detected and this leads to questions why blood donors are still tested to reveal the disease [8]; however, sometimes syphilis is still transmitted with blood components in the southern Asia [9].

In early 1970ties testing to detect hepatitis B surface antigen (HBsAg) was introduced [10]. Data obtained by initial HBsAg screening revealed greater infection prevalence among paid donors; this made the Blood service switch to completely unpaid donation in the USA and many other countries by middle 1970ties [11, 12]. Only 10 % of all the post-transfusion viral hepatitis cases that were still detected in 1970ties were caused by the hepatitis B virus (HBV). The remains cases were first assumed to be caused by the hepatitis A virus [13]. However, typical hepatitis A is an acute disease without tendency to become chronic and due to it the disease is quite easy to diagnose. Therefore, donor banks are able to detect it by simply questioning a donor [11]. Further studies aimed at examining other hepatitis types did not find any evidence of antibodies to hepatitis A [14] and this resulted in Doctor Harvey Alter spotting out the third hepatitis type which he called “human non-A, non-B hepatitis”. Large-scale multi-centered prospect studies accomplished in late 1980ties and early 1990ties revealed epidemiological associations between surrogate markers, namely elevated alanine aminotransferase (ALT) levels, in donors and developing post-transfusion hepatitis in recipients [14]. At the same time, some data proved that anti-HBc-positive blood was associated with residual cases of post-transfusion hepatitis B that was not detected by HBsAg screening [15]. In 1986, after the US National Institute of Health (NIH) issued a report on anti-HBc, blood banks in the USA introduced additional testing to establishing ALT levels and anti-HBc-testing [16]. In 1989 Michael Houghton with colleagues from the US Center for Disease Control (CDC) and the US National Institute of Health (NIH) discovered the hepatitis C virus (HCV) and this put an end to the searching

for reasons of developing "human non-A, non-B hepatitis" [17]. These experts also developed laboratory testing procedures for detecting antibodies to this virus.

The first official discussion on whether it was possible to transmit HIV with blood and its components started in December 1982 in the weekly report on incidence and mortality issued by the US Center for Disease Control [18]. The human immunodeficiency virus (HIV) itself was detected in spring 1984 and detection of antibodies was very high in homosexual males. Several studies identified this virus as the one that caused AIDS [19, 20]. The first certified test to detect antibodies to HIV became available only in 1985 and this made it possible to reduce risks of becoming infected via blood transfusion by 86 % [21]. Some retrospective studies established that more than 30 % of donors who were HIV-positive also had some reactions to anti-HBc just like 90 % of recipients who received blood donated by HIV-infected people or people who were assumed to have the acquired infection [15]. At the same time the very concept that it was acceptable to use surrogate markers in blood donation was very often criticized [22, 23].

In 1990ties, a model was developed to assess risks of incidence. This showed that an antibody-negative window preceding to the development of serological markers as a patient's response made the greatest contribution to residual risks for the established transfusion transmissible viruses [24]. An antibody-negative window for the first generation of tests aimed at detecting antibodies to HIV equaled 56 days [25]. In 1999 NAT (Nucleic acid testing) was introduced to detect HIV and this allowed reducing a residual infection window down to one week [26]. Up-to-date testing to detect primary transfusion transmissible viruses relies on simultaneous use of molecular-biological and immunological studies thereby reducing risks of becoming infected with HIV, hepatitis B and C down to one case per 2,000,000 [10].

The FMBA Blood Center in Russia acts in accordance with the existing regulatory documents and selects blood donors either from permanent residents or from people who were registered in Moscow and the Moscow region at least half a year ago and have been living here ever since. Given that, it is especially interesting to examine prevalence of infectious markers among blood donors and to compare the results with the official statistical data on incidence of these diseases among population in this region.

Our research goal was to analyze detection of infectious markers in donors of the FMBA Blood Center over the period from 2015 to 2019.

Materials and methods. We performed a retrospective observation study of donors who were accepted by the FMBA Blood Center (hereinafter FMBA BC for short) from 2015 to 2019. Over the analyzed period, 53,093 donors visited the FMBA BC, 162,099 blood units and blood components were donated, and 5290 donors were examined. All the donated blood units and components were tested to detect HIV, hepatitis B and C, and syphilis markers. Over the whole analyzed period, 1452 samples were established to be positive regarding transfusion transmissible infections; these samples were taken from 1235 donors.

Testing to detect syphilis was accomplished by precipitation to reveal non-specific antibodies to cardiolipin antigen and by Chemiluminescence Immunoassay (CLIA). If either of the tests was positive, testing was repeated twice under the same conditions as in the first tests, reagents included. If at least one of this repeated testing was positive after either of selected methods was applied, a donor blood sample was considered syphilis-positive. We used several reagent kits including "LUIS-TEST" to detect syphilis-associated reaginic antibodies ("NPO "Diagnostic systems"" LLC, Russia) and ARCHITECT Syphilis Reagents 8D06-35 (Abbott Laboratories, USA). CLIA tests were performed with ARCHITECT i2000SR analyzer (Abbott Laboratories, USA).

Hepatitis B and C markers and HIV markers were detected by CLIA and by molecular-biological techniques, namely multiplex NAT-tests by PCR using COBAS S 201 system (Roche Diagnostics GmbH, Germany)

and transcriptional amplification using Procleix Panther system (Gen-probe Inc, USA). Several reagent kits were used, including ARCHITECT HIV Ag/Ab Combo Reagent, ARCHITECT Ab HCV Reagent, ARCHITECT HBsAg Qualitative II Reagent (Abbott Laboratories, USA) for CLIA and Cobas TaqScreen MPX Test, v 2.0 (Roche Diagnostics GmbH, Germany), Procleix Ultrio Elite Assay (Gen-probe Inc, USA) for molecular-biological techniques.

In our analysis, people who donated blood or its components at the FMBA BC for the first time were considered first-time donors. A medical examination of a donor at the FMBA BC prior to donation included establishing ALT activity and clinical blood tests with total leukocyte count. In case any deviations were detected in these indicators, a donor was rejected to donate blood or its components.

Statistical analysis focused on growth rates, average long-term numbers, and odds ratio for independent samplings. The results were statistically analyzed using Microsoft Office Excel 2016 and SPSS v. 23.

Results. Table 1 shows the total targets regarding donor acceptance and the number of examined donor blood samples.

Over the period from 2015 to 2019, the number of donors accepted by the FMBA BC grew by 7.5 % and donation of blood and its components increased by 13 %. The absolute number of regular donors went up by 14 % whereas the number of first-time donors remained steady.

Over the last five years, the share of samples with detected TTI markers was lower than 1.0 % (0.73–0.92 % of the total donations) or 1.5 % (1.22–1.44 % of the total number of donors). Table 2 shows the total quantity of TTI markers detected in donors from 2015 to 2019.

The average long-term number of TTI markers detected from 2015 to 2019 at the FMBA BC equaled 290.4 ± 40.5 (or 8.67 ± 1.21 per 1000 donor blood samples). Tables 3–6 show occurrence of syphilis, hepatitis B, hepatitis C and HIV in blood donors accepted by the FMBA BC in 2015–2019.

The number of detected VHC markers amounted to 393 (0.74 % of the total number of donors in 2015–2019); syphilis markers, 331 (0.62 % of the total number of donors in 2015–2019); HIV markers, 264 (0.5 % of the total number of donors in 2015–2019); VHB markers, 249 (0.47 % of the total number of donors in 2015–2019).

The average long-term number of detected VHC markers equaled 78.6 ± 9.4; VHB markers, 49.8 ± 8.2; syphilis markers, 66.2 ± 16.8; HIV markers, 52.8 ± 13.2. We analyzed TTI markers in long-term dynamics and revealed an ascending trend in the number of syphilis markers (the growth rate equaled 3.2) and VHB markers (the growth rate was 2.5) whereas the number of VHC markers went down (the decrease arte was 3.3) as well as the number of HIV markers (the decrease rate was 1.7) (Table 7).

Over five years, from 2015 to 2019, there was an increase in the growth rate of the VHB markers detected in donors; despite that, the number of detected markers went down in

Table 1

Target donor acceptance and the number of examined blood samples at the FBMA BC from 2015 to 2019

Period	2015	2016	2017	2018	2019	Over the whole period
Number of donors	18,399	17,687	17,294	18,961	19,793	53,093
First-time donors	7847	7398	6920	7358	7730	
Regular donors	10,552	10,289	10,374	11,603	12,063	
% of first-time donors	42.6 %	41.8 %	40.0 %	38.8 %	39.1 %	
Donations	32,587	30,417	30,192	32,074	36,829	162,099
Tests	723	246	371	2145	1805	5290
A number of samples	33,310	30,663	30,563	34,219	38,634	167,389
% of samples form first-time donors	24.1 %	24.3 %	22.9 %	22.9 %	21.0 %	

Table 2

Prevalence of TTI markers detected by the FMBA BC from 2015 to 2019

Period	2015	2016	2017	2018	2019
The total number of donor blood samples	33,310	30,663	30,563	34,219	38,634
The number of samples with detected TTI markers, abs.	245	285	291	326	305
The number of samples with detected TTI markers, %	0.73	0.92	0.95	0.95	0.79
The total number of donors	18,399	17,687	17,294	18,961	19,793
The number of donors with detected TTI markers, abs.	238	254	247	256	242
The number of donors with detected TTI markers, %	1.29	1.44	1.43	1.35	1.22

Table 3

Occurrence of syphilis in blood donors accepted by the FMBA BC in 2015–2019

Indicator	2015	2016	2017	2018	2019	TOTAL
Total detection	60	57	57	74	83	331
% of occurrence	0.33 %	0.32 %	0.33 %	0.39 %	0.42 %	0.62 %
First-time donors	41	40	42	54	54	231
Regular donors	19	17	15	20	29	100
Men	46	45	36	51	56	234
Women	14	12	19	23	27	95
Average age	35.7	35.3	36.9	35.5	34.8	35.6

Table 4

Occurrence of hepatitis B in blood donors accepted by the FMBA BC in 2015–2019

Indicator	2015	2016	2017	2018	2019	TOTAL
Total detection	43	57	41	50	58	249
% of occurrence	0.23 %	0.32 %	0.24 %	0.26 %	0.29 %	0.47 %
First-time donors	29	43	30	35	31	168
Regular donors	14	14	11	15	27	81
Men	24	30	22	33	37	146
Women	19	27	19	17	21	103
Average age	30.2	33.5	31.0	30.3	33.0	31.6

Table 5

Occurrence of hepatitis C in blood donors accepted by the FMBA BC in 2015–2019

Indicator	2015	2016	2017	2018	2019	TOTAL
Total detection	74	88	83	78	70	393
% of occurrence	0.40 %	0.50 %	0.48 %	0.41 %	0.35 %	0.74 %
First-time donors	51	70	46	58	40	265
Regular donors	23	18	37	20	30	128
Men	41	50	53	46	41	231
Women	33	38	30	30	29	160
Average age	34.5	33.7	32.2	32.3	31.5	32.8

Table 6

Occurrence of HIV in blood donors accepted by the FMBA BC in 2015–2019

Indicator	2015	2016	2017	2018	2019	TOTAL
Total detection	61	52	66	54	31	264
% of occurrence	0.33 %	0.29 %	0.38 %	0.28 %	0.16 %	0.50 %
First-time donors	40	35	46	45	21	187
Regular donors	21	17	20	9	10	77
Men	35	27	42	32	19	155
Women	26	25	24	22	12	109
Average age	33.6	32.9	29.4	31.3	30.0	31.4

Table 7

Average long-term number and growth / decrease rate of the detected TTI markers

TTI markers	Average long-term number	Growth arte	Decrease rate
VHC	78.6 ± 9.4	-	3.3
VHB	49.8 ± 8.2	2.5	-
Syphilis	66.2 ± 16.8	3.2	-
HIV	52.8 ± 13.2	-	1.7

first-time donors (2.8 cases, whereas the growth rate equaled 0.9 among regular donors). As for VHC markers, the decrease rate amounted to 2.0 among first-time donors and the growth rate amounted to 0.9 among regular donors. The number of detected HIV markers went down by 1.7 both among first-time and regular donors. At the same time, the number of detected syphilis makers increased both among first-time donors, by 3.6, and among regular ones, by 1.4. Overall, over the analyzed years, frequency of the TTI markers was higher among first-time donors than among regular ones as per syphilis, 2.351 (95 % CI: 1.862–2.938), $p < 0.00001$; hepatitis B, 2.111 (95 % CI: 1.622–2.763), $p < 0.00001$; hepatitis C, 2.107 (95 % CI: 1.708–2.609), $p < 0.00001$; and HIV, 2.471 (95 % CI: 1.9–3.238), $p < 0.00001$.

A probability to detect TTI markers was higher among donors in 2019 than in 2015 regarding syphilis, $OR = 1.286$ (95 % CI: 0.9227–1.8), $p = 0.1383$, and hepatitis B, $OR = 1.254$ (95 % CI: 0.8453–1.871), $p = 0.2627$. Yet, it was lower for hepatitis C and HIV, $OR = 0.8793$ (95 % CI: 0.6328–1.221), $p = 0.4425$, and $OR = 0.4724$ (95 % CI: 0.3032–0.7248), $p = 0.0005$ accordingly. The total probability of detecting any TTI markers was slightly lower for donors in 2019 than in 2015, $OR = 0.9452$ (95 % CI: 0.78–1.132), $p = 0.5397$.

Syphilis markers were more frequent among male donors than among female ones, $OR = 2.121$ (95 % CI: 1.674–2.703), $p < 0.00001$. The same was true for hepatitis C, $OR = 1.24$ (95 % CI: 1.013–1.52), $p = 0.037$. As for the other two infections, we did not detect any statistically significant differences for them: hepatitis B markers, 1.216 (95 % CI: 0.9454–1.569), $p = 0.13$; HIV markers, 1.22 (95 % CI: 0.9553–1.563), $p = 0.11$.

Discussion. Donors who are accepted by the FMBA BC account for a rather small share of the total donors who donate blood and its components in Russia, from 1.218 to 1.477 % [27, 28].

According to the documents that regulate donation of blood and its components, only a healthy adult person who voluntarily consents to donate blood or its components can be a blood donor. Additional medical examination prior to blood donation makes it possible to refuse potential donors with clinical signs of certain diseases (skin rush, fever, etc.). Yet, symptomless infections are the most dangerous ones and the same goes for infections that can persist in spite of additional treatment provided for blood components after donation (leukofiltration, pathogen inactivation) and proper storage conditions.

To provide infectious safety of donor blood and its components, all the stored products (including those under quarantine) taken from donors with occurring TTI markers (in case a positive or a doubtful sample was detected by the first testing) were rejected and destroyed.

In the analyzed period, there was a stable ascending trend in the number of detected TTI markers in first-time donors and a descending trend in the number of such markers among regular donors. Frequency of TTI markers is known to be significantly lower among regular donors of blood and its components than among first-time ones [29].

Overall, over the last five years, frequency of infectious markers regarding such

infections as hepatitis B and C as well as human immune deficiency virus tends to decrease among blood donors and this is in line with the general statistical data collected in the country[1]. This remarkable success in fighting against viral hepatitis B was achieved due to mass immunization of the RF population against the disease. Incidence with acute hepatitis B went down by 4.9 times over the last ten years (from 2011 to 2020)[1]. Incidence with acute viral hepatitis C in the RF has also been declining steadily and annually since 2014. Over the last 10 years HIV detection among the RF population has also been decreasing steadily although coverage of the population with HIV testing has grown by 43.7 % over the same period[1]. This fully coincides with our statistical data on donors accepted by the FMBA BC; however, the epidemiological situation as per HIV remains rather tense in the Russian Federation.

In our study, we detected a certain growth in frequency of syphilis markers in blood donors over the last five years. The population group with this indicator growing is males aged 30–39 and this is fully in line with the statistical picture of incidence in Russia [30]. Growing incidence of late and unspecified types of syphilis is predominantly due to an increasing number of cases detected among foreign citizens, workers employed by transport companies, banks and educational institutions.

World studies based on clinical and experimental data estimate a residual risk of infection as being equal to 3–14 %; this risk is associated with testing potential donors who are infected with hepatitis B but still have negative test results obtained by immunological and molecular-biological tests to detect HBsAg [31]. Given that, in 2021 the Blood Service introduced additional testing to detect anti-HBcore[2].

It is noteworthy that occurrence of positive TTI markers detected by the Blood service does not always indicate that a donor has an infection and requires additional examination by a specialized medical organization. Still, their detection is an important step towards increasing infectious safety of donor blood and its components.

Conclusions. Our study indicates that over the last five years frequency of TTI markers has tended to decrease among donors accepted by the FBMA Blood Center, syphilis markers excluded. The total frequency of syphilis markers equals 0.62 %; viral hepatitis B markers, 0.47 %; viral hepatitis C markers, 0.74 %; and HIV markers, 0.5 % of the total number of blood donors accepted by the RF FMBA Blood Center over the last five years. Markers of infections were more frequently detected among first-time donors than among regular ones and among male donors than among female ones.

Funding. The research was not granted any financial support.

Competing interests. The authors declare no competing interests.

[1] O sostoyanii sanitarno-epidemiologicheskogo blagopoluchiya naseleniya v Rossiiskoi Federatsii v 2020 godu: Gosudarstvennyi doklad [On sanitary-epidemiological welfare of the population in the Russian Federation in 2020: the state report]. Moscow, the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing, 2021, 256 p. (in Russian).

[2] Ob utverzhdenii poryadka prokhozhdeniya donorami meditsinskogo obsledovaniya i perechnya meditsinskikh protivopokazanii (vremennykh i postoyannykh) dlya sdachi krovi i (ili) ee komponentov i srokov otvoda, kotoromu podlezhit litso pri nalichii vremennykh meditsinskikh pokazanii, ot donorstva krovi i (ili) ee komponentov: Prikaz Ministerstva zdravookhraneniya RF ot 28.10.2020 № 1166n [On approval of the procedure for medical examination of donors and the list of medical contraindications (temporary and permanent) to donating blood and (or) its components and the period of rejection in case a potential donor has temporary medical contraindications donating blood and (or) its components: The Order by the RF Public Healthcare Ministry dated October 28, 2020 No. 1166n]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/566420621 (December 16, 2021) (in Russian).

References

1. Hall W.H., Desforges J., Athari F., Cooper S.P., Johnson C.S., Lemon S., Lindsay K., McCullough J. [et al.]. Infectious disease testing for blood transfusions. *NIH Consensus Statement*, 1995, vol. 13, no. 1, pp. 1–27. DOI: 10.1001/JAMA.274.17.1374

2. Gardella C., Marfin A.A., Kahn R.H., Swint E., Markowitz L.E. Persons with early syphilis identified through blood or plasma donation screening in the United States. *J. Infect. Dis.*, 2002, vol. 185, no. 4, pp. 545–549. DOI: 10.1086/338829

3. Orton S. Syphilis and blood donors: what we know, what we do not know, and what we need to know. *Transfus. Med. Rev.*, 2001, vol. 15, no. 4, pp. 282–291. DOI: 10.1053/tmrv.2001.26956

4. Kaur G., Kaur P. Syphilis testing in blood donors: an update. *Blood Transfus.*, 2015, vol. 13, no. 2, pp. 197–204. DOI: 10.2450/2014.0146-14

5. De Schryver A., Meheus A. Syphilis and blood transfusion: a global perspective. *Transfusion*, 1990, vol. 30, no. 9, pp. 844–847. DOI: 10.1046/j.1537-2995.1990.30991048793.x

6. Van der Sluis J.J., ten Kate F.J.W., Vuzevski V.D., Kothe F.C., Aelbers G.M., van Eijk R.V. Transfusion syphilis, survival of Treponema pallidum in stored donor blood. II. Dose dependence of experimentally determined survival times. *Vox Sang.*, 1985, vol. 49, no. 6, pp. 390–399.

7. Walker R.H. The disposition of STS reactive blood in a transfusion service. *Transfusion*, 1965, vol. 5, no. 5, pp. 452–456. DOI: 10.1111/j.1537-2995.1965.tb02924.x

8. Jenum P.A., Flesland Ø., Blystad H., Samdal Vik I.S., Hervig T., Maeland A., Saeter G. Syfilis og blodtransfusjon [Syphilis and blood transfusion]. *Tidsskr. Nor. Laegeforen.*, 2010, vol. 130, no. 8, pp. 839–841. DOI: 10.4045/tidsskr.08.0188 (in Norwegian).

9. Attaullah S., Khan S., Khan J. Trend of transfusion transmitted infections frequency in blood donors: provide a road map for its prevention and control. *J. Transl. Med.*, 2012, vol. 10, pp. 20. DOI: 10.1186/1479-5876-10-20

10. Busch M.P., Bloch E.M., Kleinman S. Prevention of transfusion-transmitted infections. *Blood*, 2019, vol. 133, no. 17, pp. 1854–1864. DOI: 10.1182/blood-2018-11-833996

11. Perkins H.A., Busch M.P. Transfusion-associated infections: 50 years of relentless challenges and remarkable progress. *Transfusion*, 2010, vol. 50, no. 10, pp. 2080–2099. DOI: 10.1111/j.1537-2995.2010.02851.x

12. Alter H.J., Klein H.G. The hazards of blood transfusion in historical perspective. *Blood*, 2008, vol. 112, no. 7, pp. 2617–2626. DOI: 10.1182/blood-2008-07-077370

13. Feinstone S.M., Kapikian A.Z., Purcell R.H., Alter H.J., Holland P.V. Transfusion-associated hepatitis not due to viral hepatitis type A or B. *N. Engl. J. Med.*, 1975, vol. 292, no. 15, pp. 767–770. DOI: 10.1056/NEJM197504102921502

14. Alter H.J., Houghton M. Clinical Medical Research Award. Hepatitis C virus and eliminating post-transfusion hepatitis. *Nat. Med.*, 2000, vol. 6, no. 10, pp. 1082–1086. DOI: 10.1038/80394

15. Hoofnagle J.H., Seeff L.B., Bales Z.B., Zimmerman H.J. Type B hepatitis after transfusion with blood containing antibody to hepatitis B core antigen. *N. Engl. J. Med.*, 1978, vol. 298, no. 25, pp. 1379–1383. DOI: 10.1056/NEJM197806222982502

16. Glynn S.A., Busch M.P., Dodd R.Y., Katz L.M., Stramer S.L., Klein H.G., Simmons G., Kleinman S.H. [et al.]. Emerging infectious agents and the nation's blood supply: responding to potential threats in the 21st century. *Transfusion*, 2013, vol. 53, no. 2, pp. 438–454. DOI: 10.1111/j.1537-2995.2012.03742.x

17. Kuo G., Choo Q.L., Alter H.J., Gitnick G.L., Redeker A.G., Purcell R.H., Miyamura T., Dienstag J.L. [et al.]. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. *Science*, 1989, vol. 244, no. 4902, pp. 362–364. DOI: 10.1126/science.2496467

18. Centers for Disease Control (CDC). Possible transfusion-associated acquired immune deficiency syndrome (AIDS) – California. *MMWR Morb. Mortal. Wkly Rep.*, 1982, vol. 31, no. 48, pp. 652–654.

19. Curran J.W., Lawrence D.N., Jaffe H., Kaplan J.E., Zyla L.D., Chamberland M., Weinstein R., Lui K.J. [et al.]. Acquired immunodeficiency syndrome (AIDS) associated with transfusions. *N. Engl. J. Med.*, 1984, vol. 310, no. 2, pp. 69–75. DOI: 10.1056/NEJM198401123100201

20. Tyler J.P., Dobler K.J., Driscoll G.L., Stewart G.J. The impact of AIDS on artificial insemination by donor. *Clin. Reprod. Fertil.*, 1986, vol. 4, no. 5, pp. 305–317.

21. Busch M.P., Young M.J., Samson S.M., Mosley J.W., Ward J.W., Perkins H.A. Risk of human immunodeficiency virus (HIV) transmission by blood transfusions before the implementation of HIV-1 antibody screening. The Transfusion Safety Study Group. *Transfusion*, 1991, vol. 31, no. 4, pp. 4–11. DOI: 10.1046/j.1537-2995.1991.31191096183.x

22. Simon T.L., Bankhurst A.D. A pilot study of surrogate tests to prevent transmission of acquired immune deficiency syndrome by transfusion. *Transfusion*, 1984, vol. 24, no. 5, pp. 373–378. DOI: 10.1046/j.1537-2995.1984.24585017822.x

23. Kaplan H., Kleinman S. Infection, immunity, and blood transfusion. In: R.Y. Dodd, L. Barker eds. *XVIth Annual Scientific Symposium of the American Red Cross*. Washington DC, May 9–11, 1984, pp. 297–308.

24. Glynn S.A., Kleinman S.H., Wright D.J., Busch M.P., NHLBI Retrovirus Epidemiology Donor Study. International application of the incidence rate/window period model. *Transfusion*, 2002, vol. 42, no. 8, pp. 966–972. DOI: 10.1046/j.1537-2995.2002.00200.x

25. Petersen L.R., Satten G.A., Dodd R., Busch M., Kleinman S., Grindon A., Lenes B. Duration of time from onset of human immunodeficiency virus type 1 infectiousness to development of detectable antibody. The HIV Seroconversion Study Group. *Transfusion*, 1994, vol. 34, no. 4, pp. 283–289. DOI: 10.1046/j.1537-2995.1994.34494233574.x

26. Zou S., Dorsey K.A., Notari E.P., Foster G.A., Krysztof D.E., Musavi F., Dodd R.Y., Stramer S.L. Prevalence, incidence, and residual risk of human immunodeficiency virus and hepatitis C virus infections among United States blood donors since the introduction of nucleic acid testing. *Transfusion*, 2010, vol. 50, no. 7, pp. 1495–1504. DOI: 10.1111/j.1537-2995.2010.02622.x

27. Chechetkin A.V., Danilchenko V.V., Grigorjan M.S., Vorobey L.G., Plotskiy R.A., Makeev A.B. The activity of the blood service in the Russian Federation in 2016. *Transfuziologiya*, 2017, vol. 18, no. 3, pp. 4–14 (in Russian).

28. Chechetkin A.V., Danilchenko V.V., Grigorjan M.S., Vorobey L.G., Plotskiy R.A. Indicators of activity of the blood service in the Russian Federation in 2018. *Transfuziologiya*, 2019, vol. 20, no. 3, pp. 160–170 (in Russian).

29. Bubnova L.N., Matveeva T.A., Berkos M.V., Chechetkin A.V. Transfusion transmitted infections in regular and first-time donors of blood and blood components. *Transfuziologiya*, 2015, vol. 16, no. 4, pp. 24–32 (in Russian).

30. Kubanov A.A., Bogdanova E.V. Dynamics of the incidence of sexually transmitted infections in different groups of the adult population in the Russian Federation in 2011–2019. *Infektsionnye bolezni*, 2020, vol. 18, no. 4, pp. 58–73. DOI: 10.20953/1729-9225-2020-4-58-73

31. Candotti D., Boizeau L., Laperche S. Occult hepatitis B infection and transfusion-transmission risk. *Transfus. Clin. Biol.*, 2017, vol. 24, no. 3, pp. 189–195. DOI: 10.1016/j.tracli.2017.06.014

Filippova A.A., Faenko A.P., Golosova S.A., Ivanova I.V., Klyueva E.A., Glazov Ya.N., Malysheva D.S., Kasatkin M.A. Five-year experience in providing infectious safety of donor blood and its components gained by the Blood Center of the RF Federal Medical-Biological Agency. Health Risk Analysis, 2022, no. 3, pp. 110–118. DOI: 10.21668/health.risk/2022.3.10.eng

Received: 17.05.2022
Approved: 19.08.2022
Accepted for publication: 21.09.2022