Blood Services
Japanese Red Cross Society
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Blood Services
Japanese Red Cross Society
1. History of the Blood Services in Japan

1919  The first performance of blood transfusion was conducted in Japan.

1930  400mL blood transfusion was reported to save the life of Prime Minister Osachi Hamaguchi attacked by an assault.

1948  There happened the incident that a patient was infected with syphilis by the blood used for transfusion.

1949  The Japanese Red Cross Society (JRCS) established Blood Transfusion Control Measures Committee.

1951  Blood banks of both private and public were established.

1952  The JRCS opened Tokyo Blood Bank (Hiroo, Shibuya-ku, Tokyo).

1955  The number of voluntary blood donors dropped sharply, due to the spread of blood collection handled by private blood banks.

1962~69  By the wide campaigns to abolish paid blood donation, the first step to improve the standards of blood service was launched nationwide.

Number of blood banks in 1963 shown as below

<p>| | |</p>
<table>
<thead>
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<tbody>
<tr>
<td>Japanese Red Cross</td>
<td>16</td>
</tr>
<tr>
<td>Corporation/ Foundation</td>
<td>11</td>
</tr>
<tr>
<td>Public</td>
<td>6</td>
</tr>
<tr>
<td>Commercial (joint stock corp.)</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
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</tbody>
</table>

1964  It occurred that Edwin Reischauer, American ambassador to Japan at the period, was infected with serum hepatitis by blood transfusion he received.

Following this incident, a Cabinet decision was made to establish a system to secure blood for transfusion from donation as official policy below.

“Regarding the promotion of blood donation” (Cabinet decision of August 21, 1964)

In view of the present state of the blood program, and in order to establish a system that will secure an adequate supply of stored blood through voluntary donations as quickly as possible, the government shall work for the propagation of the concept of blood donation and the creation of blood donation systems through the national government and local authorities and, at the same time, shall promote the improvement of the receiving system for donated blood by the JRCS and/or local authorities.

1969  The distribution of blood products for transfusion was finally halted against blood collected by private banks.

1972  Hepatitis B virus surface antigen (HBsAg) tests started nationwide for all donated blood.

1974  All commercial blood banks ceased their business by the abolishment of blood deposit system, following the establishment of a 100% voluntary blood donation system.

1975  Service was initially launched to inform the results of biochemical tests to certain donors.

1980  Following the spread of each blood component therapy nationwide, the distribution of blood products for transfusion each component soon reached the share of 70%.

1982  The JRCS launched the service to inform all donors of the results of biochemical tests.

Blood deposit system shifted to blood donation based on the principle of voluntary blood donation, deleting the section in the ‘donation passbook’ saying that “Blood donors and their family have the right to receive blood transfusion”.

1. 血液事業の歴史

1919年（大正8年） 日本で初めての輸血が行われる。
1930年（昭和5年） 暴漢に狙撃された浜口雄幸首相の一命を輸血（400mL）が取り留める。
1948年（昭和23年） 輸血による梅毒感染事故が起きる。
1949年（昭和24年） 日本赤十字社に輸血対策委員会が設置される。
1951年（昭和26年） 商業血液銀行及び公的血液銀行が業務を開始する。
1952年（昭和27年） 日本赤十字社血液銀行東京業務所（東京都渋谷区広尾）が開設される。
1955年（昭和30年） 民間商業血液銀行による売血が盛んになり、献血者が激減する。
1962年（昭和37年）～1969年（昭和44年） 売血追放キャンペーンが続き、血液事業改善への第一歩が始まる。

1963年当時の血液事業の状況

<table>
<thead>
<tr>
<th></th>
<th>16</th>
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<tbody>
<tr>
<td>赤十字</td>
<td></td>
</tr>
<tr>
<td>社団・財団</td>
<td>11</td>
</tr>
<tr>
<td>公立</td>
<td>6</td>
</tr>
<tr>
<td>営利（株式会社）</td>
<td>22</td>
</tr>
<tr>
<td>血液銀行の数</td>
<td>合計：55</td>
</tr>
</tbody>
</table>

1964年（昭和39年） ライシャワー事件（エドウィン・ライシャワー駐日アメリカ大使が暴漢に襲われ、輸血による血清肝炎に感染する事件）が起こる。

輸血用血液は献血により確保する体制を確立するよう閣議決定がなされ、「献血の推進について」の政府方針が決定される。

「献血の推進について」（1964年昭和39年8月21日、閣議決定）

政府は、血液事業の現状に鑑み可及的速やかに保存血液を献血により確保する体制を確立するため、国及び地方公共団体による献血思想の普及と献血の組織化を図るとともに日本赤十字社又は地方公共団体による献血受入体制の整備を推進するものとする。

1969年（昭和44年） 民間商業血液銀行で行われていた売血による輸血用血液製剤の供給が停止される。
1972年（昭和47年） HBs抗原検査を開始する。
1974年（昭和49年） 民間商業血液銀行が預血制度を廃止したことにより、献血100%の体制が確立する。
1975年（昭和50年） 一部献血者に対する生化学検査結果の通知を開始する。
1980年（昭和55年） 成分輸血療法が全国的に普及したことにより、各種成分に分けられた輸血用血液製剤が全供給本数の70%以上となり飛躍的な増加を示す。
1982年（昭和57年） 献血者全員に対する生化学検査結果の通知を開始する。

献血手帳の供給欄が削除され、「血液無償の原則」に基づく純粋な献血制度に転換する。
1983 The Japanese Red Cross Plasma Fractionation Center was built in Chitose, Hokkaido.
That all the functions of public blood centers were successfully transferred to the JRCS enabled the JRCS to be the sole organization to receive blood donations.

1986 Both 400mL and apheresis donations were introduced.
The JRCS started to conduct Anti-HIV-1 and Anti-HTLV-1 tests for all donated blood.

1989 Japan was the first country in the world to institute Anti-HCV tests for all donated blood nationwide successfully.
The JRCS started to implement Anti-HBc tests, followed by the introduction of HBsAg tests.

1990 All the functions regarding blood collection are unified to the JRCS for the safe production of blood products including plasma derivatives, followed by the cease of plasma collection by private pharmaceutical manufactures.

1991 The blood coagulation for VIII product was started to manufacture on a full scale by donated blood at the Japanese Red Cross Plasma Fractionation Center.

1992 The blood coagulation for VIII product by donated blood was started to supply.

1993 With requests from medical institutions, the JRCS is cooperated with autologous transfusion.

1994 Anti-HIV-1/2 tests started.

1995 The First Stage Unified System for Blood Services Data had implemented successfully to all Blood Centers nationwide, following its initial introduction to the each since 1993.

1996 Blood samples of all donations started to be put in storage (for 10 years) for the use of look-back studies.

1997 Nucleic acid amplification testing (NAT) was first employed towards source plasma and finished derivatives of plasma derivatives to eliminate HBV, HCV and HIV.

1998 Irradiated blood was approved its manufacturing to prevent post-transfusion GVHD.
The JRCS also started to hold of source plasma (at the quantity of 300,000 liters) for plasma derivatives.

1999 The JRCS also started new service to inform the result for those who want it, in case the Anti-HTLV-1 test shows positive.
In May, the unified system managing all the data on blood donors at Blood Centers was introduced nationwide.
In July, NAT testing was introduced on a trial basis to eliminate HBV, HCV, and HIV from blood of the transfusion use.
In October, the JRCS launched NAT testing of HBV, HCV, and HIV against donated blood for whole blood donation, with the batch of pooled 500 donors' blood in prior to other nations.
Revised the approved upper age limit of donors from the age 64 to 69.

2000 In February, the batch size of the NAT pooled blood was reduced from 500 to 50.
In April, the JRCS established the Japanese Red Cross Center for NAT and Quarantine in Fukuchiyama, Kyoto, implementing an inventory storage and charge of source plasma (300,000 liters) and NAT testing.

2001 In March, the JRCS successfully speeded up its production capacity of blood coagulation for VIII product from donated blood to overcome their import's stagnation caused by manufacturing troubles in the US.
1983年（昭和58年） 日本赤十字社血漿分画センター（北海道千歳市）を設立する。
全ての公立血液センターの移管が終了し、日本赤十字社による献血受入体制が確立する。

1986年（昭和61年） 400mL献血、成分献血方式が導入される。
HIV-1及びHTLV-1抗体検査を開始する。

1989年（平成元年） 世界に先駆けて、HCV抗体検査を開始する。
HBs抗原検査に加えて、HBc抗体検査を開始する。

1990年（平成2年） 民間製薬業者による国内での有償採漿が中止され、血液製剤製造目的の採血が日本赤十字社に一元化される。

1991年（平成3年） 日本赤十字社血漿分画センターで献血による血液凝固第VIII因子製剤の製造を開始する。

1992年（平成4年） 献血による血液凝固第VIII因子製剤の供給を開始する。

1993年（平成5年） 医療機関の要請に応じた自己血輸血に対する協力を開始する。

1994年（平成6年） HIV-1/2抗体検査を開始する。

1995年（平成7年） 1993年（平成5年）から各血液センターに順次導入を開始した第一次血液事業統一システムの全センターへの導入が完了する。

1996年（平成8年） 遺及調査のために全献血者からの検体保管を開始（保存期間10年）する。

1997年（平成9年） 血漿分画製剤の原料血液と最終製品に対して核酸増幅検査（NAT）を導入する（HBV、HCV、HIV）。

1998年（平成10年） 輸血後GVHD（移植片対宿主病）予防のため、放射線照射血液の製造承認を取得する。
血漿分画製剤用原料血液の貯留保管（30万L）を開始する。

1999年（平成11年） HTLV-1抗体検査の異常を認めた場合、通知を希望される方への通知を開始する。
5月、各血液センターの献血者データを一元管理するシステムを導入する。
7月、輸血用血液に対するNATを一部地域から試験的に導入を開始する（HBV、HCV、HIV）。
10月、世界に先駆けて全献血血液へのNATを、プールサイズ500で全面的に開始する（HBV、HCV、HIV）。
献血可能年齢の上限の基準が64歳から69歳に改定される。

2000年（平成12年） 2月、NATプールサイズを500プールから50プールに減少させる。
4月、日本赤十字社血液管理センター（京都府福知山市）を設立する（30万Lの原料血液の貯留保管とNAT検査を実施）。

2001年（平成13年） 3月、米国からの血液凝固第VIII因子製剤の輸入が製造上のトラブルから停止したため、日本赤十字社は現有能力を最大限駆使し献血血液から同製剤を緊急増産する。
2002  In March, a National Conference for Promoting Blood Donation was held.
On 25 July, the National Diet approved and promulgated the Law on Securing Stable Supply of Safe
Blood Production and the Revised Pharmaceutical Affairs Law.
In August, provisions prohibiting the collection of blood for payment and setting penalties for doing so
went into effect.
Blood Services in Japan also celebrated its 50th anniversary from the initial establishment of the
Japanese Red Cross Central Blood Center.

2003  In July, the Law on Securing a Stable Supply of Safe Blood Products came into effect.

2004  In June, the Second Stage Unified System for Blood Services Data was introduced.
In August, the JRCS started its look-back studies on the basis of its guidelines.
Also in August, the batch size of pooled blood for NAT was reduced to 20 donors per batch.
In October, the JRCS Blood Services Department was reorganized so as to incorporate the Central
Blood Center. The Blood Service Headquarters began operating under its new name.
In October, it was implemented nationwide that donors are identified in applying for the blood donor.

2005  In April, the Revised Pharmaceutical Affairs Law validated the marketing authorization for
pharmaceutical products to the JRCS.
In July, the JRCS launched its supplies of fresh-frozen plasma of over 6-month storage, halting the
extension of its storage period started in January 2004.

2006  In August, the JRCS launched the sales of human immune globulin products for intravenous injection
made from donated blood.
In October, the JRCS started a relief system for adverse effect to blood donor’s health.
Also in October, donation cards were also introduced for donors.

2007  In January, the JRCS completed to introduce pre-storage leukocytes reduction for all blood products
for transfusion.
In November, the JRCS prolonged maximum storage period of platelet preparation from 72 hours to 4
days.

2008  In January, the JRCS Kyushu Blood Center was established.
In January, the diversion of the initially drawn blood was introduced for plasmapheresis.
In May, the JRCS completed the introduction of testing equipment using the chemiluminescence
enzyme immunoassay (CLEIA), discontinuing infection testing by the condensation method.
In December, NAT system was started at the Kyushu Blood Center.

2009  In March, the JRCS added Test for glycoalbumin, one of the tests related to Diabetes Mellitus, to the
lists of biochemical tests.

2010  In January, as the effects on safety and the secure supply of blood products for transfusion are closely
examined, legal restrictions on blood donations related to variant Creutzfeldt-Jakob disease (vCJD)
were eased. By this, people that spent up to 30 days in the UK between 1980 and 1996 are allowed to
donate blood.
In December, donors of 200mL blood donation also started to be informed of their hematological
testing results.
2002年（平成14年） 3月、献血推進全国協議会が発足する。
7月25日、国会において「安全な血液製剤の安定供給の確保等に関する法律」及び改正薬事法が成立し、公布される。
8月、有料での採血等を禁止する部分及びその罰則にかかる部分が施行される。
日本赤十字社の血液事業が、50周年を迎える。

2003年（平成15年） 7月、「安全な血液製剤の安定供給の確保等に関する法律」が施行される。

2004年（平成16年） 6月、第二次血液事業統一システムを導入する。
8月、日本赤十字社の遡及ガイドラインに基づく遡及調査を開始する。
8月、NATプールサイズを20プールに減少させる。
10月、日本赤十字社血液事業部を改組（中央血液センターを統合）し、血液事業本部が発足する。

2005年（平成17年） 10月、献血受入時の本人確認を全国で実施する。

2006年（平成18年） 7月、6ヶ月間貯留保管した新鮮凍結血漿の供給を開始する（2004年（平成16年）1月から開始された新鮮凍結血漿の貯留期間の延長が完了）。

2007年（平成19年） 1月、全ての輸血用血液製剤への保存前白血球除去の導入を完了する。
11月、血小板製剤の有効期間が72時間から4日に変更される。

2008年（平成20年） 1月、献血による静注用人免疫グロブリン製剤の販売を開始する。
10月、献血者健康被害救済制度を開始する。
10月、献血カードを導入する。

2009年（平成21年） 4月、改正された薬事法が完全施行され日本赤十字社は医薬品製造販売業の許可を取得する。
7月、6ヶ月間貯留保管した新鮮凍結血漿の供給を開始する（2004年（平成16年）1月から開始された新鮮凍結血漿の貯留期間の延長が完了）。

2010年（平成22年） 3月、生化学検査に糖尿病関連検査項目であるグリコアルブミン検査が追加される。
1月、変異型クロイツフェルト・ヤコブ病（vCJD）対策の献血制限は、輸血用血液製剤の安全性や安定供給等の及ぼす影響を検討した結果、1980年（昭和55年）から1996年（平成8年）の間の英国滞在歴が通算30日までの方の献血を可能として緩和した。
12月、200mL全献血者の方にも、血球計数検査結果の通知を開始する。
2011 From April 1, some blood donation standards were revised. For males, the minimum age for 400mL whole blood donation was lowered from 18 to 17, and the maximum age for platelet component donation was raised from 54 to 69. The revised questionnaires have asked donors to fill more detailed information on the medical history adding 9 more questions.

2012 On April 1, the JRCS has launched 'Wide-area Management System', dividing a nation into seven blocks with each Block Blood Center of the JRCS's direct control.

On June 1, a new general incorporated association, the Japan Blood Products Organization (JB), was established with the aim to increase the safety and reliability of plasma derivatives and to achieve domestic self-sufficiency of plasma derivatives with donated blood.

In August, the anti-HBc determining standard was revised.

On October 1, the Plasma Fractionation Center was closed, and the plasma fractionation services were transferred to the JB.

2013 On October 1, the JRCS was designated as the only "Hematopoietic Stem Cell Provision Support Organization" in the country, in the "Act for Appropriate Provision of Hematopoietic Stem Cells to be used in Transplantations".
2011年（平成23年） 4月1日から採血基準が一部改正され、男性に限り400mL全血献血が可能な方の年齢の下限を18歳から17歳に引き下げるとともに、男性に限り血小板成分献血が可能な方の年齢の上限を54歳から69歳に引き上げる。また、問診票の質問事項を14項目から23項目に改訂する。

2012年（平成24年） 4月1日、全国を7つのブロックに分け、各ブロックに本社直轄施設であるブロック血液センターを設置して広域事業運営体制を開始する。

6月1日、血漿分画製剤の安全性と信頼性の向上と献血血液による国内自給達成を目指し「一般社団法人日本血液製剤機構」が発足する。

8月、HBc抗体の判定基準が改正される。

10月1日、日本赤十字社血漿分画センターを廃止し、血漿分画事業を一般社団法人日本血液製剤機構に移管する。

2013年（平成25年） 10月1日、「移植に用いる造血幹細胞の適切な提供の推進に関する法律」における全国唯一の「造血幹細胞提供支援機関」として指定される。
2. Blood Services and the Japanese Red Cross Society

2.1 History and Background of Blood Services in Japan

The Japanese Red Cross Society (JRCS) was founded on May 1, 1877. In 1952, it became an incorporated entity, in keeping with the provisions of the Japanese Red Cross Society Law. The JRCS is supported by members who contribute a certain sum of money each year and also by volunteers who carry out a variety of activities. The JRCS carries out such activities as assistance to victims of natural disasters, international assistance, medical services and the training of nurses. Blood Services are one of several activities.

In Japan, blood transfusions became known when, in 1930, a blood transfusion saved the life of Japan’s Prime Minister, who had been attacked by an assailant at Tokyo Station. Afterwards, medical care making use of blood transfusions started gradually becoming more widely practiced and at first, blood for transfusions was acquired mainly by purchasing from donors.

In the years immediately after the Second World War, most fresh blood procured for blood transfusions was acquired on an ad hoc basis and this occasioned a number of accidents. A particularly serious accident occurred in November 1948 at the Koishikawa Clinic attached to the Tokyo University Hospital when a transfusion patient became infected with syphilis. In response to the incident, the General Headquarters (GHQ) of the Allied Occupation Forces suggested the establishment of blood banks to the Ministry of Health and Welfare and to the Tokyo municipal government.

As a result, in May 1949 representatives of the Ministry of Health and Welfare, the Japanese Medical Association and the JRCS held a preliminary roundtable conference to discuss blood transfusion policies and technical measures. The JRCS began blood service activities in keeping with the guidelines that were established at the conference.

In April 1952, the Tokyo Blood Bank was opened in Hiroo, Shibuya-ku, Tokyo. Thereafter, it improved its facilities for receiving blood and disseminated basic knowledge about the blood bank concept.
Following a 1964 Cabinet decision on the promotion of blood donations, the central government, local public entities and the JRCS all came together to promote blood donations as a national endeavor. As a result, blood donations showed steady annual growth, based on the nation’s understanding and cooperation among the various organizations concerned with blood services. In 1969, the supply of stored blood that had originally been purchased from private blood banks was discontinued and in 1974, the private blood bank replacement blood system was also discontinued. The result was that all blood products for transfusion were provided by free donations. In 1983, all public blood centers, including those operated by local governments, were put under the management of the JRCS, thus fully establishing the JRCS blood-collection system. In 1990, plasma collection for payment by certain private pharmaceutical companies, for the purpose of manufacturing plasma derivatives, was ended. This meant that henceforth the JRCS carried out the collection of all blood for all blood products, including plasma derivatives. Keeping pace with medical progress, efforts were then made to expand the scope of the JRCS’s blood services by improving blood examinations, introducing 400mL and apheresis donations and nucleic acid amplification testing (NAT) for donated blood to ensure high safety for blood products for transfusion.

Today the donation of blood in Japan has taken firm root as an indispensable part of the nation’s medical and health system with the support and cooperation of an enormous number of people. Blood donating in Japan has reached the world-class level in the ratio of donors to population and a technological capability.

Blood services are a very important part of Japan’s health policies. At present, not only in Japan but also in other countries, Red Cross societies play a key role in promoting blood donation movements and in taking the lead in the management of blood services.

Underlying this is the fact that the International Red Cross in the past has adopted many resolutions concerning blood services and has continuously advised each country’s Red Cross/Red Crescent Society that the work is important and should be performed by its government or the Red Cross/Red Crescent Society. Because of the special circumstances that accompany handling a part of the human body (blood), this work must be complemented by a strong sense of ethics and public mindedness. Blood services based on the principle of non-remunerated, voluntary donations have thus come to be seen as an appropriate task for the Red Cross Society to support.

さらに、1964年（昭和39年）の「献血の推進について」の閣議決定以来、国家的事業として国、地方公共団体及び日本赤十字社が一体となって献血を推進した結果、国民の理解と血液事業関係機関の協力を得て献血は毎年着実に進展し、1969年（昭和44年）には民間血液銀行で行われていた買血による保存血液の供給が姿を消し、1974年（昭和49年）には民間血液銀行が預血の受入れも中止し、これに伴い輸血用血液製剤が全て献血により賄われることとなった。また、一部の地方公共団体が行っていた公立血液センターも1983年（昭和58年）には全て日本赤十字社に移管され、赤十字による献血の受入れ体制が確立された。なお、1990年（平成2年）には、血漿分画製剤を製造するために一部の民間製薬業者が行っていた有償採漿についても中止され、これに伴い血液分画製剤を含む全ての血液製剤の製造を目的とする採血は日本赤十字社が実施することとなった。輸血用血液製剤の高い安全性を確保するための検査内容の充実、400mL献血、成分献血及び献血血液に対する核酸増幅検査（NAT）の導入など医学の進歩に伴った事業内容の拡充に努めてきた。

今日、献血は多くの人々の支援と協力のもと国民医療に欠くことのできない事業として定着しており、人口と比較した献血者数及び技术的にも世界有数の水準に達している。

血液事業は、国の保健政策の重要な位置を占めるものであるが、現在、日本の他にも多くの国々で赤十字社が主体的に血液事業を運営するかあるいは献血運動の推進を担当する等、重要な役割を果している。

この背景には、国際赤十字が過去に数多くの血液事業に関する決議を採択し、各国赤十字社に対して事業の重要性として国又は赤十字による推進を勧告し続けてきた経緯がある。また、人体の一部である血液を取り扱うという特殊性から、高い倫理性と公共性のもとに事業を行うことが必要であり、無償の献血を基盤とした血液事業は赤十字社が協力するにふさわしい事業と認識されてきていることが挙げられる。
2.2 The Management and Contents of Blood Services

Through humanitarian goodwill and the understanding of the public, the Japanese Red Cross Society (JRCS) receives voluntarily donated blood. After ensuring that the blood is safe, the JRCS prepares blood products for transfusion and supplies it to medical institutions, thereby contributing to the nation's medical services. These blood services require effective and appropriate management and control.

Since April 2012 onwards, the Japanese Red Cross Society (JRCS) has launched ‘Wide Area Management System’, dividing a nation into 7 blocks in areas with each Block Blood Center of the JRCS’s direct control. This system would adjust the balance between demands and supplies, improving testing, preparation, management and planning of demands and supplies at/within each block nationwide.

The JRCS would secure both safety improvement and stable supplies of blood products, proceeding to establish smooth and sustainable management system nationwide that nationals could place reliance on.

The principal items in the operation of the JRCS blood services are the following:

1) Promoting blood donations based on blood-donation acceptance plans;
2) Recruitment and registration of blood donors and collecting blood donations;
3) Various types of testing to increase the safety of transfusions;
4) Preparation of blood products for transfusion;
5) Distribution of blood products transfusion to medical institutions;
6) Blood-related studies, research and technological development;
7) Consultations about blood and blood donations;
8) Manufacturing of test-use reagents;
9) Cooperation with medical institutions in connection with the storage and supervision of autologous transfusions;
10) Certain tasks connected with public bone-marrow banks, such as the registration of persons wishing to donate bone marrow and HLA type tests.

* The plasma fractionation activities were transferred to the JB as of October 1, 2012.
2.3 Organization of Blood Services

On July 30, 2003, the Law on Securing a Stable Supply of Safe Blood Products came into effect, aiming at a stable supply of products, with the basic principle of achieving domestic self-sufficiency. With the revised Pharmaceutical Affairs Law coming into full effect in April 2005, a new organization called the Blood Service Headquarters, which was set up in keeping with the provisions of these laws and regulations, was inaugurated in October 2004. (For more details on the relevant legal framework, see Section 3: Statutes Pertaining to Blood Services.)

To implement the envisaged tasks, the Blood Service Headquarters was established in Tokyo and the Blood Service Board of Management was instituted under the control of its Executive Officer. As of April 1, 2013, there were 18 working divisions, with the following names: (1) Management Planning; (2) General Affairs Management; (3) Finance; (4) Supplies and Property; (5) Blood Donation Promotion; (6) Supply Management; (7) Medical Information; (8) Safety Vigilance; (9) Quality Assurance; (10) Regulatory Affairs; (11) Development Management; (12) Information System Management; (13) Information System Development; (14) Laboratory Management; (15) Manufacturing Management; (16) Medical Affairs and Blood Collection; (17) Hematopoietic stem cell general management; (18) Hematopoietic stem cell practice control. In addition, the Central Blood Institute was established, which within the organizational framework of Headquarters, carries out blood research and development, quality inspection, analysis of infections and so on. The National Headquarters of the JRCS has Seven Blood Centers under its direct jurisdiction.

The JRCS has a Chapter in each of Japan’s 47 prefectures. Each Chapter supervises Red Cross blood centers within its area of jurisdiction.

2.3 血液事業の組織

2003年（平成15年）7月30日に「国内自給の確保」を基本理念とした「安全な血液製剤の安定供給の確保等に関する法律」が施行され、また、2005年（平成17年）4月には改正薬事法が完全施行されたことに伴い、これらの法令等に対応した新たな組織として「血液事業本部」が、2004年（平成16年）10月に発足した。（関連法に関しで詳しくは「3. 血液事業関係法令」参照）

東京の本社血液事業本部には、血液事業本部長の下に血液事業経営会議を置き、2014年（平成26年）4月1日現在、(1) 経営企画課、(2) 総務管理課、(3) 財務課、(4) 用度課、(5) 献血推進課、(6) 供給管理課、(7) 学術情報課、(8) 安全管理課、(9) 品質保証課、(10) 薬事課、(11) 臨床開発課、(12) システム管理課、(13) システム開発課、(14) 検査管理課、(15) 製造管理課、(16) 医務採血課、(17) 造血幹細胞管理課、(18) 造血幹細胞業務課の18課を配置している。また、本部組織内に血液研究開発、品質検査、感染症の解析等を行いうち中央血液研究所を設置している。また、本社は、全国7つのブロック血液センターを直接管轄している。

なお、日本赤十字社の支部は各都道府県に1つずつ合計47設置されており、47支部は支部管内の血液センターを管轄している。

Wide-area Management System

National Headquarters of the JRCS (Blood Service Headquarters)
[Supervising the management of all services]

Block Blood Centers
[Blood centers established at seven locations nationwide and directly controlled by the national headquarters; comprehensively coordinating the testing and preparation operations as well as supply-demand management, etc.]

Blood Centers
[Blood centers established in each of the 47 prefectures nationwide and supervised by each prefectoral Chapter of the JRCS; belong to the respective Block Blood Centers, and specialize in promoting blood donations, collecting blood, and supplying products]
Governance Structure for Blood Services

Members
Board of Councilors
Board of Representatives
President • Vice-President • Governors • Auditors
Board of Governors • Standing Board of Governors
National Headquarters
Blood Service Headquarters
Blood Service Board of Management
Block Blood Centers (7)
(under the direct role of the President)
Chapters (47)
Blood Centers (47)

( as of April, 2014 )
Blood Service Headquarters, JRCS

(as of April 2014)
3. Statutes Pertaining to Blood Services

3.1 Law on Securing a Stable Supply of Safe Blood Products

The Law on Securing a Stable Supply of Safe Blood Products came into effect on July 30, 2003. This law provides the following principles for guiding the management of the blood program and clarifies the responsibilities of those involved in the program.

<Principles>
1) To improve the safety of blood products.
2) To secure a domestic supply of blood products (blood products manufactured from blood donated in Japan as a raw material) and to maintain a stable supply of blood products.
3) To promote the proper use of blood products.
4) To ensure fairness and improve transparency in managing the blood program.

<Responsibilities of those involved in the blood program>
Responsibilities are based on the following principles:

1) The national government is responsible for planning and implementing basic and general measures for improving the safety of blood products and securing a stable supply, providing Japanese citizens with education and enlightenment to enhance their understanding and cooperation regarding blood donation to secure a domestic supply of blood products and planning and implementing measures for promoting the proper use of blood products, and taking other necessary measures.

2) Local authorities (prefectural and municipal governments) are responsible for enhancing local resident understanding of blood donating and for taking necessary measures to assist the blood-collecting service entity in receiving donated blood.

3) The blood-collecting service entity is responsible for promoting and receiving blood donations, improving the safety of blood products, cooperating in securing a stable supply and protecting blood donors.

4) Marketing authorization holders, manufacturers and sales contractors are responsible for ensuring a stable and appropriate supply of safe blood products, carrying out technological development and for collecting/providing information to improve safety.

5) Medical professionals are responsible for using blood products properly and collecting/providing information on the safety of blood products.

The Japanese Red Cross Society carries out activities as a blood collective service entity under this Law, and as a marketing authorization holder, a manufacturer, and a sales contractor under the Pharmaceutical Affairs Law.

3. 血液事業関係法令

3.1 安全な血液製剤の安定供給の確保に関する法律

2003年（平成15年）7月30日「安全な血液製剤の安定供給の確保に関する法律」が施行された。この法律では、血液事業の運営指針となる以下の基本理念が設けられ、血液事業に携わる関係者の責務が明確化された。

〈基本理念〉
1）血液製剤の安全性の向上
2）血液製剤の国内自給（国内で行われる献血により得られた血液を原料として製造されること）の確保及び安定供給
3）血液製剤の適正使用の推進
4）血液事業運営にかかる公正の確保及び透明性の向上

〈血液事業関係者の責務〉

1）国：血液製剤の安全性向上並びに安定供給の確保に関する基本的・総合的施策の策定及び実施、血液製剤の国内自給が確保されるように献血に関する国民の理解及び協力を得るための教育・啓発、血液製剤の適正使用推進に関する施策の策定・実施、その他の必要な措置を講じるよう努める。

2）地方公共団体（都道府県及び市町村）：献血について住民の理解を深めること、採血事業者による献血の受入れを円滑に実施するため必要な措置を講じる。

3）採血事業者：献血受入れの推進、血液製剤の安全性の向上、安定供給の確保への協力、献血者等の保護に努める。

4）製造販売業者、製造業者及び販売業者：安全な血液製剤の安定的・適切な供給並びにその安全性向上のための技術開発と情報収集及び提供に努める。

5）医療関係者：血液製剤の適正使用、血液製剤の安全性に関する情報収集及び提供に努める。

上記のうち日本赤十字社は、本法律に基づく採血事業者、薬事法に基づく製造販売業者、製造業者及び販売業者としての業務を行っている。
For redress of any identifiable health hazards due to blood products and blood collection, a clause in the law’s supplement states that the national government will immediately examine such cases and take any necessary action, such as establishing a legal framework. In April 2004, a system was implemented to aid transfusion patients who develop health problems due to blood transfusions. In addition, a relief system for adverse effects to blood donor’s health was implemented in October 2006.

3.2 Pharmaceutical Affairs Law

3.2.1 Blood Products and the Pharmaceutical Affairs Law

The Japanese Red Cross Society (JRCS) is licensed by the government to collect blood and is the only entity in Japan that collects donated blood.

From the donated blood, blood product for transfusion and plasma derivatives are manufactured as pharmaceutical products and sold to medical institutions. Their manufacture and sale are strictly controlled under the provisions of the Pharmaceutical Affairs Law.

All blood products for transfusion and source plasma are produced at 13 JRCS blood centers that have obtained a license as pharmaceutical manufacturers under the Pharmaceutical Affairs Law. Plasma derivatives, namely freeze-dried human blood coagulation factor VIII concentrates, human serum albumin and human immunoglobin products, are manufactured at three domestic plasma derivative manufacturers.

Blood products for transfusion and the Japan Blood Products Organization’s plasma derivatives, etc. are sold by JRCS blood centers and facilities attached thereto by obtaining a license as pharmaceutical wholesalers under the Pharmaceutical Affairs Law.

3.2.2 Revisions in the Pharmaceutical Affairs Law

When the Revised Pharmaceutical Affairs Law came into full effect in April 2005, there were considerable changes in the appropriate division of responsibilities in the manufacture and sale of pharmaceutical products.

Traditionally, the legal framework has put emphasis primarily on the activities of manufacturing pharmaceutical products, according to which manufacturers had primary responsibility both for safe manufacturing procedures and for any safety problems that may have arisen after sales of their products.

The Revised Pharmaceutical Affairs Law places new emphasis on activities related to the market release of pharmaceutical products, under which primary distributors concerned with the market release of the products are responsible for various types of safety and other problems that might arise following the market release. Because of the significant, new responsibilities

また、献血で得られた血液から、医薬品である輸血用血液製剤や血漿分画製剤が製造され、医療機関へ販売されるが、その製造や販売に関しては薬事法の明確な規制の下に行われている。

全ての輸血用血液製剤製造において、献血で得られた血液から、医薬品である輸血用血液製剤や血漿分画製剤が製造され、医療機関へ販売されるが、その製造や販売に関しては薬事法の明確な規制の下に行われている。

日本赤十字社は採血者の許可を受け国内で唯一献血の受入れを行っている。

献血で得られた血液から、医薬品である輸血用血液製剤や血漿分画製剤が製造され、医療機関へ販売されるが、その製造や販売に関しては薬事法の明確な規制の下に行われている。

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3.2.2 薬事法の改正

2005年（平成17年）4月から改正薬事法が完全施行され、「医薬品を製造し販売する上での責任の在り方」に関する考え方が大きく変更された。

従来は、「医薬品を製造する行為」に着目した制度であり、製造業者が、製造上の責任と販売後に発生する様々な安全性等の問題についても責任を負うというものであった。

改正された薬事法では、「医薬品を市場へ出荷する行為」に着目しており、医薬品の製造販売元が製造と販売後に発生する様々な安全性等の問題についても責任を負うという制度になっている。医薬品を市場へ出荷する製造販売元は大きな責任を負うことから、新たに「製造販売業許可」をうけることとされ、日本赤十字社本社は、この許可を受けて、輸血用血液製剤を製造販売している。

また、医薬品の製造販売業者は、医薬品の市場への出荷
that primary distributors now bear when releasing pharmaceutical products to market, these distributors are now required to hold a "Marketing Authorization Holder’s License." The JRCS releases blood products for transfusion to market under this license.

It is mandatory for marketing authorization holders of pharmaceutical products to organize a Quality Assurance Department for managing the market release of products, as well as a Safety Vigilance Department for formulating safety measures by collecting post-marketing information.

を管理する品質保証部門、及び販売後の安全性情報を収集して安全対策を立案する安全管理統括部門を設置することが義務付けられている。
4. Safety Measures for Blood

The Japanese Red Cross Society has been implementing possible safety measures to blood and blood components for transfusion which are provided to medical institutions.

Main Safety Measures

1) Donor Identification

For safe and responsible blood donation, identification of a donor is required at the time of blood donation.

2) Donor Interviews

Based on a questionnaire, which is filled out beforehand, an expert physician confirms the donor’s health status.

3) Test of transfusion-transmissible agents

At the eight facilities across the country, serological tests are carried out to detect major transfusion-transmissible pathogens. Since 1999, the nationwide NAT system has been implemented to screen for HBV, HCV and HIV. NAT is a method that amplifies fragments of the nucleic acid segments of the viral genome (DNA or RNA) 100 million-fold to detect the virus with high accuracy. NAT was installed as a 500 pool NAT, that is, 500 samples were gathered in one test sample, then the pool size was reduced from 500 to 50, 50 to 20, and finally individual (ID) NAT will be started in the summer of 2014. ID-NAT is now being introduced throughout the world.

4) Inventory Hold

Since August 2005, fresh frozen plasma (FFP) components are held in inventory for a period of six months and supplied to medical institutions following the removal of any blood that was suspected of being infected during this period.

Plasma derivatives are manufactured by pooling the plasma of several thousand donors. Source plasma is stored for six months before processing to eliminate virally-contaminated plasma detected during the storage period. Then the rest plasma is transferred to domestic manufacturers of plasma derivatives.

4. 血液の安全対策

日本赤十字社では、輸血用血液製剤に対し、現時点で可能な限りの安全対策を講じ、安全な血液を医療機関に提供している。

主な安全対策

1） 本人確認

安全で責任ある献血をお願いするために、献血受付時に身分証明書等の掲示をお願いし、本人確認を実施している。

2） 問診

予め記入していただいた問診票をもとに、専門の医師により献血者の健康状態を確認している。

3） 感染症関連検査

全国8カ所の施設において主要な輸血感染症の病原体についての血清学的検査（抗原・抗体検査等）を実施している。

また、1999年（平成11年）から、HBV、HCV、HIVについて核酸増幅検査（NAT）を実施している。NATはウイルスの遺伝子を構成する核酸（DNAまたはRNA）の一部を約1億倍に増幅することによってウイルス自体を高感度に検出する方法である。NAT導入当初は500本をまとめて1検体としてNATを実施していたが（500プールNAT）、プールサイズを50本、20本と段階的に減じ、2014年（平成26年）夏からは個別NATに移行する予定である。世界各国においても、個別NATの導入が進んでいる。

4） 貯留保管

輸血用血液製剤のうち新鮮凍結血漿（FFP）については、2005年（平成17年）8月から6ヵ月間の貯留保管を行い、その間にウイルス感染等が疑われた血液を排除したうえで医療機関に供給している。

また、血漿分画製剤は、数千人分の血漿をプールして製造するが、その原料血漿については、製造に入るまで6ヵ月間貯留している。その間にウイルス混入等が判明した血漿を排除したうえで、原料血漿を国内の事業者に供給している。
5. Flow of Blood Services

~ From Blood Donation to Medical Institution ~

The function of blood includes transporting nutrients and oxygen around the body and building immunity, all of which are indispensable to maintaining life. Since the means of completely substituting blood functions does not exist at present, it is in many cases impossible to administer medical treatment without transfusion therapy.

Notes:
*1 In 1996, the Japanese Red Cross Society began storing blood samples of all donations (frozen at a temperature of -30°C) for a period of 10 years at the beginning. This period was increased to 11 years in December 2004. The samples enable investigation into causal relationships in cases where transfusion transmitted viral infection is suspected and into causalities of adverse transfusion reactions. Specimen storage also enables look-back studies as measures to prevent the spread of infections.

*2 These are used for research to contribute to the progress of transfusion efficacy and safety and the production of testing reagents for safe transfusions.

*3 These are discarded as infectious medical waste under proper management.

~献血から医療機関まで~

血液は栄養や酸素の運搬、免疫など人間の生命を維持するために欠くことのできない機能を含んでいる。現在、血液の機能を完全に代替することができる手段は存在しないため、輸血療法は医療において欠くことのできないものとなっている。

<table>
<thead>
<tr>
<th>Red Cross Blood Centers</th>
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<tr>
<td>1) Donor identification</td>
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<tr>
<td>Acceptable</td>
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<td>2) Donor interviews</td>
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<tr>
<td>Acceptable</td>
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<td>Blood collection</td>
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<td>*1 Specimen storage</td>
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<td>(Acceptable)</td>
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<td>3) Serological tests</td>
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<td>Unacceptable</td>
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<td>4) Nucleic acid Amplification Testing (NAT)</td>
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<td>Unacceptable</td>
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<tr>
<td>Blood for transfusion</td>
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<td>Source plasma</td>
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<tr>
<td>For research use *2 / Disposal *3</td>
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<tr>
<td>Red cells/Whole blood/Platelet concentrates</td>
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<tr>
<td>Fresh frozen plasma</td>
</tr>
<tr>
<td>5) Inventory hold</td>
</tr>
<tr>
<td>Acceptable</td>
</tr>
<tr>
<td>Unacceptable</td>
</tr>
<tr>
<td>Transfer to domestic manufacturers of plasma derivatives</td>
</tr>
<tr>
<td>Distribution</td>
</tr>
</tbody>
</table>

Note:
*1 日本赤十字社では、1996年（平成8年）より輸血によるウイルス感染症が疑われた症例の輸血との因果関係の解明や輸血副作用の原因調査ができるよう、また、感染拡大を防止する対策としての遡及調査（ルック・バック）ができるよう、献血者の検体を献血の度に当初は10年間、2004年（平成16年）12月より11年間冷凍保管（-30℃）している。

*2 輸血の有効性・安全性の向上のための研究や、安全な輸血のための検査試薬製造等に有効的に活用させていただくことがある。

*3 感染性の医療廃棄物として適切な管理のもと廃棄している。
Donated blood is used in blood products for transfusion as red blood cells, platelets and plasma, as well as plasma for manufacturing plasma derivatives that have specific protein qualities in the plasma, as it is extracted and purified.

- **Donor**
- **Japanese Red Cross Society**
  - **Blood centers**
  - **Testing (including NAT)**
  - **Specimen storage**
  - **Inventory hold of fresh frozen plasma**
  - **Production of blood products for transfusion, etc.**
  - **Blood products for transfusion**

- **Pharmaceutical companies**
  - **Pharmaceutical companies (two firms)**
  - **Production of plasma**
  - **Plasma derivatives**

- **Pharmaceutical wholesalers**
  - **Plasma derivatives**

- **Medical institutions**
  - **Blood products for transfusion**

---

*1 The operations of inventory hold of source plasma for plasma derivatives and specimen storage are not only conducted at the Kinki Block Blood Center (Fukuchiyama branch) and the Kyushu Block Blood Center, but also partially entrusted to the Japan Blood Products Organization.

*2 The operations of inventory hold of fresh frozen plasma are also conducted at some blood centers.

*3 Plasma derivatives produced at the Chitose Plant of the Japan Blood Products Organization are sold to medical institutions via the Japanese Red Cross Society.

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1. 分画製剤用原料血漿貯留保管業務及び検体保管業務は、近畿ブロック血液センター(福知山分室)、九州ブロック血液センターで実施しているほか、日本血液製剤機構にも一部を委託
2. 新鮮凍結血漿の貯留保管については、一部の地域血液センターでも実施
3. 日本血液製剤機構千歳工場で製造された血漿分画製剤は日本赤十字社を通じて医療機関へ販売
6. Promoting Blood Donations

A 1964 Cabinet decision made it the duty of the national government and local authorities to disseminate the concept of blood donating and promote the creation of blood donation systems. In addition, under this Cabinet decision, the Japanese Red Cross Society was required to improve its system for receiving blood donations. Japanese Red Cross blood centers were later established throughout Japan and these centers must cooperate with the respective prefectural and municipal governments to implement activities such as promoting the blood donation movement. With the enactment of the Law on Securing a Stable Supply of Safe Blood Products on July 30, 2003, national and prefectural governments have now clearly become central actors in this enterprise.

6. 献血推進体制

1964 年（昭和 39 年）の閣議決定により、献血思想の普及と献血組織の育成は国及び地方公共団体の任務とし、日本赤十字社は献血の受入れ体制の整備を推進するものとされた。その後、全国に次々と日本赤十字社の血液センターが設置され、献血運動の推進面についても各都道府県及び市区町村などと各血液センターが連携して活動を展開している。2003 年（平成15年）7 月30日に施行された「安全な血液製剤の安定給付の確保等に関する法律」により、各都道府県も含め、献血推進の主体が行政にあることが明確なものとなった。

Diagram:

- National Government (Ministry of Health, Labour and Welfare)
- Japanese Red Cross Society
- Local Authorities
- Prefectures (Blood Donation Promotion Councils)
- Municipalities and Public Health Centers (Blood Donation Promotion Councils)
- Blood Donation Promotion Groups
- Donors

Diagram

National Government (Ministry of Health, Labour and Welfare)

- 1. Determination of basic policies of blood services
- 2. Propagation of concept of blood donation
- 3. Development of blood donation systems
- 4. Varied promotion of blood services
  1. 血液事業の基本政策の決定
  2. 献血思想の普及
  3. 献血組織の育成
  4. その他の血液事業の推進

Japanese Red Cross Society

- 1. Donor reception
- 2. Testing, production and distribution of blood products
- 3. Development of blood donation systems
  1. 献血者の受入れ
  2. 血液製剤の検査・製造・供給
  3. 献血組織の育成

Local Authorities

- 1. Formation of plans for blood collection
- 2. Propagation of concept of blood donation
- 3. Development of blood donation systems
  1. 採血計画の策定
  2. 献血思想の普及
  3. 献血組織の育成

Prefectures (Blood Donation Promotion Councils)

Municipalities and Public Health Centers (Blood Donation Promotion Councils)

Blood Donation Promotion Groups

Donors
6.1 Encouraging Blood Donations

To secure an adequate supply of blood through donations, it is important that the public be made aware of the need to give blood in the spirit of mutual aid and to understand the necessity of ensuring the greatest possible safety of blood. To this end, the Japanese Red Cross Society (JRCS) conducts a national blood-donation campaign every year, carrying out national and regional promotional activities through the media and by other means, in cooperation with the government.

6.1.1 Campaigns

1. A National Campaigns

1) Repeat Donor Campaign

As Japan’s birthrate declines and its population ages, demand for blood products for transfusion is increasing. Part of the JRCS’s measures to secure stable donors in order to meet this demand is the obtaining of repeat donations. This campaign during April and May seeks to increase the number of members in our Repeat Donor Club.

2) Sharing Blood in the Spirit of Love Campaign

Every July is Sharing Blood in the Spirit of Love month. A nationwide campaign to promote blood donation is conducted under the joint auspices of the Ministry of Health, Labour and Welfare, prefectural governments and the JRCS, with the support and cooperation of various medical and media organizations. During this month, a public relations campaign for blood donation is conducted in the media, and various local activities are scheduled to spread accurate knowledge about blood, to inform people about the importance of giving blood and to elevate awareness of and respect for the concept of blood donation. The main event during this month is the National Awards Ceremony for the Promotion of Blood Donation. It is held in mid-July every year, with the location rotating among Japan’s prefectures. In the presence of the JRCS’s Honorary Vice-President HIH Crown Prince Naruhito, individuals and groups who have made outstanding efforts to promote blood donation are honored.

6.1 献血受入れの推進

献血によって必要な血液を確保するためには、国民に対し相互扶助の精神に基づく献血の必要性と、より安全性の高い血液の確保の必要性を理解してもらうことが重要である。毎年全国に献血運動を展開するために、行政と連携し、マスコミなどを活用して、全国的・地域的規模で普及活動に努めている。

6.1.1 キャンペーン関係

1. 全国のキャンペーン

1）複数回献血者確保キャンペーン

少子高齢化社会を迎えている中、輸血用血液製剤の需要増に対応するために必要とされる安定的な献血者確保のための一施策として、献血者に数回献血協力者となってもらうため、複数回献血クラブへの会員登録の増強を4月から5月に図っている。

2）愛の血液助け合い運動

毎年7月に「愛の血液助け合い運動」月間が設けられ、厚生労働省・都道府県・日本赤十字社の主催により各種医療関係団体・報道関係団体などの後援・協賛のもと、全国的な献血推進運動が行われている。期間中はマスコミなどによる献血PRや、地域ごとの行事が行われ、血液の正しい知識と献血の重要性をアピールし、献血思想の啓発・高揚を図っている。この期間のメイン行事として「献血運動推進全国大会」が、各都道府県の会場持ち回りで毎年7月中旬に開催され、日本赤十字社名誉副総裁である皇太子殿下のご臨席のもと、献血推進に功労のあった個人や団体の表彰などを行っている。
3) “Life and Blood Donation” Haiku* Contest
Since 2006, the JRCS has been holding an annual haiku contest from July to December. Its goals are to bring the lives saved through blood donations to the attention of elementary and junior high school students who may become donors in the future, to promote early awareness of blood donation among students, and to inform them of the importance of blood donations.
*Haiku is a Japanese poetic form which comprises 17 syllables.

4) Nationwide Christmas Blood Donation Campaign by Students
Every December since 1988, student blood donation volunteers across Japan have sponsored this campaign to make up for the winter shortage of blood and to obtain the understanding and cooperation of students regarding blood donation.

5) Give Blood at Twenty Campaign
Every year, beginning in January and continuing into February, a nationwide campaign is conducted under the joint auspices of the Ministry of Health, Labour and Welfare, prefectural governments and the JRCS, with the support of the National Association of Commercial Broadcasters in Japan, the Association of Japanese Private Railways and the Japan Community Broadcasting Association. With its slogan “Give Blood at Twenty,” this campaign has made a significant contribution to educating young adults about blood donation and to helping secure donors during the winter months.
6) LOVE in Action Project

This year-round project began as an experiment in 2009. It is designed to convey to young people the significance of blood donation, to help them feel a sense of connection to its necessity and importance, and to arouse interest in it. With the cooperation of artists popular with young people, the JRCS carries out ongoing radio broadcasts, several national blood drives per year, musical events and so on. A variety of related campaigns are ongoing based on this project.

2. Regional Events

In each prefecture, meetings to promote blood donations and to gatherings to thank donors are held, as are unique donation events. They have a significant impact on raising awareness of blood donation through reports in local mass media, municipal public relations magazines and so on.
6.1.2 Public Relations Materials for the Promotion of Blood Donation

1) PR Targeting Donors

The Japanese Red Cross Society creates pamphlets, DVDs, websites and so on explaining the necessity and importance of blood donations in easy-to-understand language. It produces commercials and posters calling for blood donations and creates mementos for donors.

2) PR Targeting Blood Donation Organizations and Donation Promotion Groups

The JRCS creates pamphlets explaining blood donation and providing information about blood in easy-to-understand language for people in charge at blood donation organizations and leaders of donation promotion groups.

3) PR Targeting Deferred Donors

The JRCS creates pamphlets including nutritional advice and so on, so that those who were deferred from donation through the hemoglobin determination or other tests will understand the reasons for their disqualification and will be able to donate blood in the future.

4) Public relations targeting people past donor age

The JRCS produces pamphlets to encourage people past the age of blood donation to remain engaged in donation related activities.

6.2 The Formation of Organizations

A Blood Donation Promotion Council has been established in each prefecture to disseminate the concept of blood donating and promote the development of blood donation systems. The Prefectural Governor acts as chair and other members are selected from representatives in the medical field, corporations, labor unions, high schools, local organizations, the media, government agencies and the Red Cross Society. Similar blood donation promotion councils have also been organized at the municipal level and at Public Health Centers.

The blood centers work in cooperation with the Blood Donation Promotion Council in each region to request business establishments, civic clubs, schools and other groups to cooperate with the blood-donation services on an office-wide or a community-wide basis. Seminars are also held at the various blood centers, as well as at National Headquarters, to promote the creation of blood-donation systems. These include explanatory lectures for those in charge of promoting blood donating in the various blood-donation groups, Red Cross Volunteer Corps, Lions Clubs and religious groups, as well as exchange study sessions for student blood-donation promotion volunteers at universities and junior colleges and members of other blood-donation promotion groups.
6.3 Enlisting Donors

1) Blood Donation Acceptance Plans

Through discussion with the relevant prefectural government, each blood center must estimate the demand of blood products for transfusion at medical institutions within its jurisdiction to make sure that adequate supplies are available. Additionally, each center sets an annual plan by donation method to accept apheresis donations by taking into account the plasma needed for plasma derivatives. Approved by the Blood Donation Promotion Council in each prefecture, this plan is assigned to various municipalities and public health centers, based on the population and past performance in the area concerned. Referring to this plan and such data as the bloodmobile performance during the previous year, each municipality or public health center prepares a proposed schedule of group donations by offices, communities, or schools and gives this information to the blood center in its area. Each blood center then divides its overall blood-donation acceptance plan into more specific plans for permanent facilities such as blood centers and donation rooms and for bloodmobiles and collection sites under the location system.

2) Steps in Donor Enlistment

(See Steps in Group Donor Enlistment on page 28 and Steps in Enlisting Walk-in Donors on page 29)

3) Donor Registration System

Although the blood centers strive to keep pace with the demand from medical institutions for blood, their supplies do become low at certain times due to weather conditions or holidays. For example, imbalances in the supply by blood group sometimes occur when there have been orders for massive volumes of blood in preparation for major surgery. For this reason, a pool of donors that can respond to such situations should always be available. Also necessary is to secure donors who can be typed for HLA antigens beforehand and requested to give platelethpheresis donations as necessary.

To secure a stable blood supply, the blood centers have organized donor registration systems to enlist volunteers who are willing to give blood when requested to do so by the center, at a designated time.

Moreover, to be able to provide transfusions to individuals with rare blood groups, the centers are working to register potential donors among such groups. When rare blood is actually needed, frozen blood stored at centers throughout the country can be used. A system of cooperation with other countries has also been organized by which the Red Cross Societies of other nations can be asked for support when it is difficult to obtain units of a rare blood group domestically, even after requests have been made to registered donors.

6.3 献血者募集活動

1）献血受入れ計画

各血液センターでは都道府県と協議のうえ、管内医療機関での輸血用血液製剤の需要予測を立ててこれを賄うことはもちろんのこと、血漿分画製剤用原料血漿の確保も勘案して、献血方法別の年間の献血受入れ計画を設定する。この計画は、各都道府県の献血推進協議会の了承を経て、各市区町村、保健所に割り振られる。各市区町村及び保健所では、当該地域の人口や過去の実績などを算定基礎として割り振られた献血受入れ計画に基づき、前年の配車実績などを参考に、職域、地域、学域などの献血団体の実施日程を作成のうえ、これを血液センターに連絡することとなっている。また、血液センターの献血受け入れ計画は、血液センターや献血ルームなどの固定施設での受入れと献血バスやオープン採血での受入れなどにそれぞれ分けられ設定されている。

2）献血者募集の実際

（28ページの「団体献血」、29ページの「街頭献血」を参照）

3）献血者登録制

血液センターでは、医療機関からの需要に即した採血に努めているが、気候や休暇の関係で時期的に血液が不足したとき、大手術などのため多量の注文が入り血液型別にアンバランスが生じたした場合には、即応できる献血者を確保する必要がある。また、あらかじめ献血者のHLA型を検査して必要に応じ血小板成分献血を依頼する必要がある。

そこで、血液センターでは献血者登録制を設け、血液センターからの依頼に基づき指定した日時に献血していただける献血登録者を募集し、血液の安定確保に努めている。

また、きわめて少数の人々にみられる血液型を持つ人の輸血に対応するため、まれな血液型の登録が進められている。実際にまれな血液型の血液が必要となった時には、全国の血液センターであらかじめ冷凍保存してある血液を使用したり、登録者に献血を依頼したりしているが、国内での確保が困難な場合は各国赤十字社に要請するなど、諸外国との協力体制も確立されている。
**Steps in Group Donor Enlistment**
*(business establishments, civic clubs, schools, etc.)*

**Blood Collection Schedule for Year**

After consideration of the previous year's results and other factors, a blood collection schedule is decided at the beginning of the fiscal year.

**Setting of Actual Donation Date**

By no later than two to three months before the donation day, a specific date is set through consultation with the person in charge of the donation group.

**Final Meeting**

To confirm specifics, a representative of the blood center visits the donation group no later than about three weeks before the scheduled donation date. The group is also given PR materials and asked to carry out advance publicity.

Items to be confirmed:

- Date, time, expected number of donors
- Parking place for bloodmobile, location of donation site, availability of power source, etc.
- Availability of volunteers to receive and to attend to donors on donation day
- Need for explanatory lectures prior to donation day or for a PR vehicle on donation day

**Advance Publicity**

Announcement posters are hung, and fliers are distributed.

The donation schedule is published in newspapers and local bulletins (civic club bulletins, school bulletins, etc.)

Explanatory lectures are given as needed.

**Same-Day Publicity**

Through direct visits by blood center representatives to the office or through in-house broadcasts at businesses, workers are urged to give blood (business establishments).

Local residents are recruited by PR vehicles, media broadcasts, and direct visits to individual homes.

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**団体献血（事業所、町内会、学校等の献血団体による）の場合**

年度当初に前年の実績などを考慮して、およそその配車計画を組む。

2～3カ月ぐらい前までに献血団体の担当者と協議して、献血実施日を確定する。

3週間ぐらい前までに献血団体を訪問して、献血実施のための確認をするとともに、PR用資材を渡して事前の広報を依頼する。

＜確認事項＞

- 実施日、受け付け時間、採血予定人数
- 車両の駐車位置、献血会場の場所、電源の借用可否など
- 当日の受け付け、接遇などのボランティアの有無
- 事前の献血説明会や当日の広報車の必要の有無

周知用のポスターを掲示したり、チラシを回覧する。

市区町村の広報誌や新聞などに献血予定を掲載する。（町内会・学校など）

必要に応じて献血説明会を開催する。

各職場への訪問や社内放送により従業員に献血を呼びかける。（事業所）

広報車や有線放送、各家庭への個別訪問により住民に呼びかける。
Steps in Enlisting Walk-in Donors
(individual donors)

Securing a Blood Collection Site

Permission is obtained from those in charge of the train station road, station plaza, or park (e.g., the police chief, station master, or municipal government).

Advance Publicity

If places are available, announcement posters are displayed after obtaining permission to do so. The donation schedule is published in municipal bulletins and local newspapers.

If necessary, workers in nearby offices and registered donors are asked to give blood.

Same-Day Publicity

Using, for example, a hand-held microphone, passersby are called on to donate blood. In addition, handbills are distributed, and PR vehicles are driven through surrounding areas.

Volunteer organizations like the Red Cross Volunteer Corps and Lions Clubs are asked to receive and to attend to donors as necessary.

街上献血（一般通行人が主体）の場合

駅前の道路や広場、公園などの管理者（警察署長、駅長、市など）に許可を得る。

周知用のポスターを掲示できる場所があれば、許可を得て掲示する。市区町村の広報誌や新聞などに献血予定を掲載する。

付近の事業所や献血登録者にも必要に応じ献血を要請する。

通行人へのハンドマイクなどによる献血の呼びかけやチラシなどを配布する。広報車により周辺地域へ呼びかける。

赤十字奉仕団やライオンズクラブなどのボランティア団体にも必要に応じ受付け・接遇などの協力を要請する。
6.4 Donor Appreciation

The Japanese Red Cross Society (JRCS) takes a number of steps to express its appreciation to those who donate blood.

1) Hospitality to Donors

Each donation site provides its own services for donors in order to provide a comfortable place for them to donate blood.

2) Notification of the Results of Blood Tests

To help promote the health of blood donors, donors are informed of the results of biochemical examination of their blood. In light of recent trends in the health of the Japanese people, since 2009 the JRCS has carried out glycoalbumin testing, which is related to testing for diabetes.

3) Mementos, etc.

As a token of appreciation, the JRCS presents a small, nonmonetary gift to people who cooperate in donating blood.

On August 31, 2002, the Law on Securing a Stable Supply of Safe Blood Products prohibited the collection of blood for payment, set penal provisions for doing so, and stated that treatment of blood that may be considered to be sold blood, or the provision of any commodity which may harm the honorable feeling of blood donors, must never occur.

4) Recognition System

The JRCS presents awards to individuals and groups that have made important contributions to blood donation activities according to established criteria. Awards are given in appreciation of service and to applaud efforts. In addition, the Directors of the JRCS prefectural blood centers and Heads of Chapters, prefectural Governors, the Ministry of Health, Labour and Welfare, etc., also present certificates of appreciation and commendation (see Table A).

In addition, the JRCS has established criteria for donor recognition and presents mementos and certificates in appreciation of ongoing donations (see Table B).

*The above system is implemented in such a way that the hospitality and items provided do not amount to payment for blood, which would damage the honorable feelings of blood donors in Japan. (Provisions in the Law on Securing a Stable Supply of Safe Blood Products prohibiting the collection of blood for payment and setting penalties for doing so went into effect on August 31, 2002.)

6.4 献血者への感謝

日本赤十字社では、献血に参加してくださった方への感謝として、様々なことを実施している。

1）献血者の接遇

献血に来ていただいた方に居心地のよい空間を提供するために、各献血会場ではそれぞれ独自のサービスが実施されている。

2）血液検査結果のお知らせ

献血していただいた方の健康促進に役立ててもらえるよう、生化学検査成績を献血者全員にお知らせしている。近年の日本国民の健康状態の傾向を考慮し、2009年からは糖尿関連検査であるグリコアルブミン検査を開始した。

3）記念品等

日本赤十字社は、献血のご協力をいただいた方々に、感謝の気持ちをこめて記念品等を贈呈している。

2002年（平成14年）8月31日に「安全な血液製剤の安定供給の確保等に関する法律」において有料での採血等の禁止する部分とその罰則にかかる部分が施行され、国内献血者の尊い気持ちが傷つけられるような、売血ともとられかねない処遇や物品の提供は、一切行わないこととした。

4）表彰制度

定められた基準を満たす、献血活動に功労のあった個人や団体に対して表彰を行っており、その協力に対する感謝の気持ちを表すとともにその功労を讃えている。また、この他、各都道府県の血液センター所長や支部長、知事や厚生労働大臣などからも感謝状や表彰状が贈られている（表A）。

さらに、献血者顕彰規程を設け、継続的な献血者の協力に対し感謝の意を表すため、記念品又は感謝状を贈呈している（表B）。

*ただし、以上の制度は、国内献血者の尊い気持ちが傷つけられるような、売血ともとられかねない接遇や物品の提供にならない範囲内で行われている。（2002年（平成14年）8月31日に「安全な血液製剤の安定供給の確保等に関する法律」において有料での採血等の禁止する部分とその罰則にかかる部分が施行された。）
## Donor Recognition Awards

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<thead>
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<tbody>
<tr>
<td><strong>Recipient</strong></td>
<td><strong>Criteria</strong></td>
</tr>
<tr>
<td>Blood Donors</td>
<td>70 donations</td>
</tr>
<tr>
<td></td>
<td>100 donations</td>
</tr>
<tr>
<td>Blood Donation Groups</td>
<td>5 years of activity</td>
</tr>
<tr>
<td>Blood Donation Promotion Group</td>
<td>10 years of activity</td>
</tr>
<tr>
<td>Blood Donation Promoters</td>
<td>15 years of activity</td>
</tr>
<tr>
<td></td>
<td>20 years of activity</td>
</tr>
<tr>
<td></td>
<td>Every 10 years of activity after winning the Gold Merit Award</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recipient</strong></td>
<td><strong>Criteria</strong></td>
</tr>
<tr>
<td>Blood Donors</td>
<td>10 donations</td>
</tr>
<tr>
<td></td>
<td>30 donations</td>
</tr>
<tr>
<td></td>
<td>50 donations</td>
</tr>
<tr>
<td></td>
<td>each additional 50 donations</td>
</tr>
<tr>
<td></td>
<td>Persons who have given blood 50 or more times prior to their 60th birthday and Certificate of Appreciation</td>
</tr>
<tr>
<td></td>
<td>Persons who have given blood 50 or more times prior to their 68th birthday and continue to donate blood thereafter</td>
</tr>
</tbody>
</table>

![Image of award recipients]
7. Blood Collection

7.1 Blood Collection Teams

Blood collection teams have been organized, mainly to visit various regions and to receive donations of blood, either in blood mobiles or at collection sites under the location system. Each team usually has six or seven members, including one doctor, three or four nurses and two to three clerical workers. The number of members is adjusted in accordance with the number of expected donors and the availability of volunteers.

In contrast, donation rooms placed on busy streets, at a convenient place for blood donors, receive mainly apheresis donations (plasma and platelets). In these blood donation rooms, blood collection teams have been organized with doctors, nurses and clerical workers in accordance with the size and needs.

7.2 Blood Collection Procedures

Prior to blood collection, a potential donor must be interviewed. At the same time, hemoglobin and blood pressure must be determined in accordance with legally stipulated standards. A doctor then examines all data and decides if it is appropriate for the individual to give blood. Individuals whose health might be adversely affected by donating blood are requested not to donate blood.

7.3 Response to Adverse Reactions and Medical Accidents

Although there are extremely few serious adverse reactions related to the collection of blood, some people may rarely experience vasovagal reaction (VVR) due to anxiety in having blood drawn or other psychological factors. For these reasons, the necessary first-aid supplies are always prepared and efforts are made to provide a supportive environment, with the education and training of staff, to help minimize any such side effects. In addition, donors are provided with information regarding any adverse reactions after donating blood.

A donor who has a health problem (as a side effect of having blood drawn) is given first-aid treatment if necessary. The subsequent status of any damage to the donor’s health will be followed up. Thus, appropriate measures are implemented.

For those who are examined in medical institutions for nerve damage or VVR caused by drawing blood, a relief system for adverse effects to blood donor’s health was established based on the national government’s Guidelines for Compensation for Adverse Effects to Health by Blood Donors and was implemented on October 1, 2006. This relief system provides for a certain amount of money to be paid on a fair, transparent and prompt basis, with the appropriate involvement of the national government, to ensure that blood donors feel safe in cooperating with blood collection programs.
Blood Collection Procedure

(1) Reception
- The potential donor is asked for identification, such as a driver's license. When a potential donor arrives with a donation card, the donor is asked to enter a password to confirm identity.
- The potential donor is asked to write his or her name, address, date of birth and other information on the application form.
- The potential donor is also asked to complete a questionnaire. In a permanent facility such as a donation room, potential donors are asked to answer diagnostic questions on a touch panel.

(2) Interview and determination of blood pressure
- A doctor interviews the potential donor and measures his or her blood pressure.
- Prior to an apheresis donation, an electrocardiogram and other examination may occur if required by the doctor.

(3) Pre-donation tests
- Simple hemoglobin determination equipment or an automated cell counter is used to obtain a hemoglobin value and confirm ABO blood type.
- Based on the results of the above tests, a doctor makes the final decision on donor qualification and completes a donor application form.

(4) Blood collection
- A nurse collects the blood from the donor in accordance with the doctor's instructions.
- There are two categories of blood collection: 200mL or 400mL whole blood collection and apheresis (plasma or platelet collection).
- Polyvinylchloride or other types of bags are used for blood collection.

(5) Post-donation (Rest Period)
- The donor is advised to rest and replenish fluids after donating blood.
- A history of the donation is recorded on a donation card, which is returned to the donor.

【採血の手順】

(1) 献血受付
- 本人を証明する運転免許証等を提示してもらう。献血カード持参の場合は、暗証番号を入力してもらい本人確認を行う。
- 献血申込書に氏名・住所・生年月日などを本人に記入してもらう。
- 問診票の質問事項に記入してもらう。献血ルーム等の固定施設ではタッチパネルで問診票に回答してもらう。

(2) 問診・血圧測定等
- 医師は、問診及び血圧測定を行う。
- 成分献血の前には、医師の指示により、必要に応じ心電図の検査等を行う。

(3) 事前検査
- 簡易型ヘモグロビン測定装置又は自動血球計数測定装置によるヘモグロビン値等の測定、並びに ABO 血液型の確認を行う。
- 医師は、上記検査等すべての結果から最終的な採血の適否を行い、献血申込書に記入する。

(4) 採血
- 採血は、医師の指示に基づいて看護師が行う。
- 採血には、全血採血（200mL・400mL）と、成分採血（血漿又は血小板採取）がある。
- 採血容器は、ポリ塩化ビニール製等のバッグを使用している。

(5) 処遇（休憩）
- 採血後は充分な休憩と充分な水分をとってもらう。
- 献血カードに献血記録を記入のうえ本人に渡す。
## Blood Collection Standards

<table>
<thead>
<tr>
<th>Items</th>
<th>Whole Blood Donation</th>
<th>Apheresis Donation</th>
<th>Plateletpheresis Donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Collected</td>
<td>200mL donation</td>
<td>400mL donation</td>
<td>Up to 600mL (No more than 12% of circulating blood)</td>
</tr>
<tr>
<td>Age</td>
<td>16-69 years*</td>
<td>Males: 17-69 years* Females: 18-69 years*</td>
<td>18-69 years* Males: 18-69 years* Females: 18-54 years</td>
</tr>
<tr>
<td>Body Weight</td>
<td>Males: 45kg or more</td>
<td>50kg or more</td>
<td>Males: 45kg or more Females: 40kg or more</td>
</tr>
<tr>
<td>Blood quantity (hemoglobin concentration)</td>
<td>Males: 12.5g/dL or more Females: 12.0g/dL or more</td>
<td>Males: 13.0g/dL or more Females: 12.5g/dL or more</td>
<td>12.0g/dL or more</td>
</tr>
<tr>
<td>Systolic Pressure</td>
<td>90 mmHg or more</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelet Count</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum Number of Donations Permitted / Year</td>
<td>Males: Up to 6 donations Females: Up to 4 donations</td>
<td>Males: Up to 3 donations Females: Up to 2 donations</td>
<td>24 donations of plasmapheresis and plateletpheresis, with 1 plateletpheresis donation counted as 2 donations</td>
</tr>
<tr>
<td>Maximum Volume of Blood Donation Permitted / Year</td>
<td>Total volume of 200mL and 400mL donations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In order to put donor safety first, we ask physicians to make comprehensive judgments in light of the standards set by the national government.

*Considering donor health, donors who are 65 years of age or older must have donated at least once between the ages of 60-64.

## The Interval of Donations

<table>
<thead>
<tr>
<th></th>
<th>Whole Blood Donation</th>
<th>Apheresis Donation</th>
<th>Plateletpheresis Donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>200mL donation</td>
<td>200mL donation</td>
<td>Males can donate blood from the same day of the week 12 weeks after the donation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Females can donate blood from the same day of the week 4 weeks after the donation.</td>
<td></td>
</tr>
<tr>
<td>400mL donation</td>
<td></td>
<td>Both males and females can donate blood from the same day of the week 16 weeks after the donation.</td>
<td>Both males and females can donate blood from the same day of the week 2 weeks after the donation.</td>
</tr>
<tr>
<td>Plasmapheresis</td>
<td></td>
<td>Both males and females can donate blood from the same day of the week 8 weeks after the donation.</td>
<td></td>
</tr>
<tr>
<td>donation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plateletpheresis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>donation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If plasma is not included, plateletpheresis donation can be made after one week.*
8. Blood Examinations

Eight blood centers across Japan test all donated blood to ensure the safety of blood units for medical use (blood-quality tests) (see the table on p. 37 for the test items). In addition to the screening tests that use antigen-antibody reactions of HBV, HCV and HIV, since October 1999, NAT screening for HBV, HCV and HIV has been implemented for all donated blood, to shorten the window period and to further ensure the safety of blood products for transfusion prepared or produced from donated blood.

NAT is conducted at three facilities: the Kanto-Koshinetsu Block Blood Center in Tokyo, the Fukuchiyama branch in Kyoto of Kinki Block Blood Center, and the Kyushu Block Blood Center in Fukuoka. The test is also entrusted to the Chitose Plant of the Japan Blood Products Organization in Hokkaido to cover all of Japan. (From the summer of 2014, the system will switch from pooled NAT collectively conducted for 20 blood samples to individual NAT conducted for individual samples, and NAT will be conducted at the blood center of each testing facility.)

In addition, HLA-related tests (HLA Typing, HPA Typing and antigen), tests for rare blood groups, CMV antibody tests and other tests are performed to distribute the appropriate blood products for transfusion to each blood recipient.

To make blood transfusions even safer, the blood centers also serve as reference laboratories for local medical facilities that use transfusion medicine.

Blood Examinations

8. 検査業務

献血された全ての血液について、医療に使用される血液の安全性を確保するための検査（品質検査）を全国8カ所の血液センターで実施している（検査項目は37ページの表を参照）。HBV、HCV、HIV等の抗原・抗体反応を主体とするスクリーニング検査に加えて、1999年（平成11年）10月から、HBV、HCV、HIVに対する核酸増幅検査（NAT）を全献血血液に実施することにより、ウインドウ・ピリオドを短縮し、献血血液から調製あるいは製造される輸血用血液製剤の更なる安全性の確保に努めている。

NATは、東京都にある関東甲信越ブロック血液センター、京都府にある近畿ブロック血液センター福知山分室、福岡県にある九州ブロック血液センターの3施設で実施し、また、北海道にある一般社団法人日本血液製剤機構千歳工場にも検査を委託して日本全国をカバーしている。（2014年（平成26年）夏から、20人分の血液をまとめて検査するプールNATから1人分ずつ検査する個別NATに変更し、各検査施設血液センターでNATを実施する予定である。）

このほか、必要に応じHLA関連検査（HLAタイピング・HPAタイピング・抗原）、まれな血液型検査、CMV抗体検査等を行って、患者に適合した輸血用血液製剤を供給している。

血液センターは輸血をより安全なものとするため、地域の輸血医療におけるリファレンス・ラボラトリーの役割も担っている。

Blood typing

Infections disease and biochemical test
In order to show our appreciation to donors, we perform ABO and Rho(D) grouping tests, seven biochemical tests, and eight hematological tests for all donors, and inform them of the results. These test results are mailed to donors who have expressed their wish to be informed in advance in a confidential letter, some two weeks after the donation. Confidential letters are also sent to donors who have expressed their wish to be notified of any problematic results in HBV, anti-HCV, syphilis and anti-HTLV-1 tests within one month after the donation.
# Blood-Quality Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO grouping test</td>
<td>The final determination of the ABO grouping is conducted by the collation of the antigen (A and B) test and the antibody (anti-A and anti-B) test.</td>
</tr>
<tr>
<td>Rh grouping test</td>
<td>Rh blood specimen is tested for the presence of D antigens.</td>
</tr>
<tr>
<td>Irregular antibody screening</td>
<td>The presence of irregular antibodies in blood that might cause hemolytic transfusion reactions is screened for.</td>
</tr>
<tr>
<td>Serologic test for syphilis</td>
<td>The presence of an antibody that is formed in people infected with a microorganism called Treponema pallidum is examined.</td>
</tr>
<tr>
<td>Hepatitis B Virus test (HBsAg and anti-HBc)</td>
<td>The tests for detecting HBsAg and anti-HBc in the blood are conducted to detect hepatitis B virus.</td>
</tr>
<tr>
<td>Anti-HCV test</td>
<td>Anti-HCV tests are conducted to detect hepatitis C virus.</td>
</tr>
<tr>
<td>ALT test</td>
<td>ALT is elevated from the first stage of hepatitis, and this test is conducted to detect causative viruses of liver dysfunction and prevent the transmission of hepatitis viruses. Blood at high ALT level is not used for blood transfusion.</td>
</tr>
<tr>
<td>Anti-HIV-1 and Anti-HIV-2 test</td>
<td>Antibodies for causative viruses of acquired immune deficiency syndrome (AIDS) are examined.</td>
</tr>
<tr>
<td>Anti-HTLV-1 test</td>
<td>Antibodies for viruses of adult T-cell leukemia, HAM, and uveitis are examined.</td>
</tr>
<tr>
<td>Human parvovirus B19 antigen test</td>
<td>B19 Antigen test is performed for human parvovirus.</td>
</tr>
<tr>
<td>NAT (Nucleic acid Amplification Testing) for HBV, HCV, and HIV</td>
<td>A method where a part of the nucleic acid of the virus which is present in the blood is artificially amplified in test tube and the detection for the virus is inspected.</td>
</tr>
</tbody>
</table>

## 品質検査

<table>
<thead>
<tr>
<th>検査項目</th>
<th>説明</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO 血液型検査</td>
<td>抗原（A 抗原、B 抗原）側、抗体（抗 A、抗 B）側の双方から判定し、両方の検査結果を照合して判定している。</td>
</tr>
<tr>
<td>Rh 血液型検査</td>
<td>Rh 抗原の中でD抗原の有無を検査している。</td>
</tr>
<tr>
<td>不規則抗体検査</td>
<td>溶血性輸血副作用の原因となる不規則抗体の有無を検査している。</td>
</tr>
<tr>
<td>梅毒検査（梅毒血清学的検査）</td>
<td>梅毒トレポネーマと呼ばれる微生物に感染した人にできる抗体の有無を検査している。</td>
</tr>
<tr>
<td>B型肝炎ウイルス関連検査（HBs 抗原検査及び Hbc 抗体検査）</td>
<td>B 型肝炎ウイルスの検査で、HBs 抗原検査に加えて Hbc 抗体検査を行っている。</td>
</tr>
<tr>
<td>HCV 抗体検査</td>
<td>C 型肝炎ウイルスの検査で、HCV 抗体検査を行っている。</td>
</tr>
<tr>
<td>ALT（GPT）検査</td>
<td>肝炎初期から上昇する検査項目で、これまでの肝炎個々ウイルスとの関連と、肝炎の防御のために検査を行っている。これが高値を示した血液は輸血に用いない。</td>
</tr>
<tr>
<td>HIV-1, HIV-2 抗体検査</td>
<td>後天性免疫不全症候群（AIDS）の原因となるウイルスの抗体を検査している。</td>
</tr>
<tr>
<td>HTLV-1 抗体検査</td>
<td>成人 T 細胞白血病、HAM、ブドウ膜炎の原因となるウイルスの抗体を検査している。</td>
</tr>
<tr>
<td>ヒトパルボウイルス B19 抗原検査</td>
<td>ヒトパルボウイルスの検査で、B19 抗原検査を実施している。</td>
</tr>
<tr>
<td>HBV, HCV, HIV に対する核酸增幅検査</td>
<td>血液中に存在するウイルスを構成する核酸の一部を試験管内で人工的に多量に増幅し、検査している。</td>
</tr>
</tbody>
</table>
## Biochemical Tests
(The results of biochemical tests with that of ABO and Rh blood typing are sent to all donors on request.)

<table>
<thead>
<tr>
<th>Test</th>
<th>Standard Value</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT (GPT)</td>
<td>5-45 (IU/L)</td>
<td>The largest quantities of ALT, an enzyme are found in the liver. When liver cells are destroyed, this enzyme is released into the blood. The level of ALT in the blood is therefore most significantly higher in cases of acute hepatitis; it is less high in cases of chronic hepatitis and fatty liver (obesity). The ALT level might be transiently elevated after hard exercise.</td>
</tr>
<tr>
<td>Glycoalbumin (GA)</td>
<td>&lt;16.5%</td>
<td>Glycoalbumin test is one of the tests for diabetes. The level decreases when blood glucose level keeps low for about two weeks, but increases when the blood glucose level keeps high. Even though the level was within the standard value, it requires careful attention when the level was over 15.6%.</td>
</tr>
<tr>
<td>γ-GTP</td>
<td>10-65 (IU/L)</td>
<td>γ-GTP is an enzyme and found in large quantities in the liver, bile duct, pancreas, and kidneys. An elevated level of γ-GTP in the blood is an indicator of diseases such as obstructive jaundice, hepatitis, and alcoholic hepatopathy. Even if no disease is present, long-term drinkers of alcohol often have an elevated lever of γ-GTP, which is normalized to some extent after one month’s abstinence from alcohol.</td>
</tr>
<tr>
<td>Total protein (TP)</td>
<td>6.5-8.2 (g/dL)</td>
<td>The serum contains over 80 different kinds of protein, which have different functions and play important life-supporting roles. The level of total protein represents the combined levels of all proteins.</td>
</tr>
<tr>
<td>Albumin (ALB)</td>
<td>3.9-5.0 (g/dL)</td>
<td>Since the level of albumin, which accounts for 50% or more of all proteins contained in the serum, falls in cases of malnutrition resulting from disease, it is a useful index in medical screening.</td>
</tr>
<tr>
<td>Albumin/globulin ratio (A/G ratio)</td>
<td>1.2-2.0</td>
<td>Serum protein is categorized into albumin (A) and globulin (G). In a healthy person, the ratio between these two proteins falls within a given range, whereas it might deviate from this range (usually falling below it) in the presence of disease.</td>
</tr>
<tr>
<td>Total cholesterol (CHOL)</td>
<td>110-250 (mg/dL)</td>
<td>Levels of cholesterol, one of the serum fats, are usually higher in people who adhere to a fatty diet over a long period of time. Since cholesterol is produced in the liver, the serum level of cholesterol might change due to diseases of the liver, of the bile duct, of the kidneys, or of the thyroid. It is reported that elevated levels of serum cholesterol can cause arteriosclerosis.</td>
</tr>
</tbody>
</table>

### 生化学検査 (ABO 式・Rh 式血液型と合わせて希望のあった全献血者に通知)

<table>
<thead>
<tr>
<th>検査項目</th>
<th>標準値（単位）</th>
<th>説明</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT (GPT)</td>
<td>5-45 (IU/L)</td>
<td>肝臓に最も多く含まれる酵素。肝細胞が破壊されると血液中に流れ出すので、急性肝炎で最も強く上昇し、慢性肝炎や脂肪肝（肥満）などでも上昇する。激しい運動の後に一過性の上昇がみられることがある。</td>
</tr>
<tr>
<td>グリコアルブミン</td>
<td>&lt;16.5%</td>
<td>糖尿病の検査のひとつ。過去約 2 週間の血糖値が低い状態が続いていると低下し、高い状態が続いていると上昇する。糖尿病では標準値より上昇する。標準値範囲内でも 15.6%以上の場合は注意が必要である。</td>
</tr>
<tr>
<td>γ-GTP</td>
<td>10-65 (IU/L)</td>
<td>肝、胆道、脾、腎などに多く含まれる酵素。上昇する疾患は閉塞性黄疸、肝炎、アルコール性肝障害など、病気がなくても長期飲酒者では上昇することが多く、1 カ月くらい禁酒するとある程度正常化する。</td>
</tr>
<tr>
<td>総蛋白</td>
<td>6.5-8.2 (g/dL)</td>
<td>血清中には 80 種類以上の蛋白が含まれ、種々の機能を持ち、生命維持に大きな役割を果たしている。その総量を総蛋白として測定している。</td>
</tr>
<tr>
<td>アルブミン</td>
<td>3.9-5.0 (g/dL)</td>
<td>血清蛋白の 50%以上を占めるアルブミンは、病気などで栄養が悪くなると減少するため、健康診断のスクリーニングとして大きな意味がある。</td>
</tr>
<tr>
<td>アルブミン対グロブリン比</td>
<td>1.2-2.0</td>
<td>アルブミン（A）とグロブリン（G）に分けれ、その比率は健康な人では一定の範囲にあるが、病気によってはその比率が変化（主として減少）してくる。</td>
</tr>
<tr>
<td>総コレステロール</td>
<td>110-250 (mg/dL)</td>
<td>血清脂肪の一つで、一般に脂肪の多い食事をとると上昇する。また肝臓などで作られ、肝、胆道、腎、甲状腺の病気でその値が上昇することがある。血清コレステロールが多くなると動脈硬化を起こしやすいとされている。</td>
</tr>
</tbody>
</table>
### Hematological Tests
(The results of hematological tests are sent to all donors on request.)

<table>
<thead>
<tr>
<th>Test</th>
<th>Standard Value</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Red Blood Cell Count</strong></td>
<td>Males:425-570 Females:375-500 (x10^6/μL)</td>
<td>Red blood cells are the main cellular components of blood. They transport oxygen from the lungs to various tissues.</td>
</tr>
<tr>
<td><strong>Hemoglobin (Hb)</strong></td>
<td>Males:13.3-17.4 Females:11.2-14.9 (g/dL)</td>
<td>The hemoglobin in erythrocytes gives blood its red color. It plays the central role in the functioning of red blood cells.</td>
</tr>
<tr>
<td><strong>Hematocrit (Ht)</strong></td>
<td>Males:39.0-50.4 Females:34.0-44.0 (%)</td>
<td>The hematocrit shows, as a percentage, the volume of red blood cells in a given volume of blood.</td>
</tr>
<tr>
<td><strong>Mean Corpuscular Volume</strong></td>
<td>80.0-100.0 (fL)</td>
<td>The MCV denotes the average volume, i.e., size, of a single erythrocyte. It is calculated from the RBC and Ht.</td>
</tr>
<tr>
<td><strong>Mean Corpuscular Hemoglobin (MCH)</strong></td>
<td>26.0-34.0 (pg)</td>
<td>The MCH denotes the average hemoglobin content of a single red blood cell. It is calculated from the RBC and Hb.</td>
</tr>
<tr>
<td><strong>Mean Corpuscular Hemoglobin Concentration</strong> (MCHC)</td>
<td>32.0-36.0 (%)</td>
<td>The MCHC shows, as a percentage, the hemoglobin content of a given volume of red blood cells. It is calculated from the Hb and Ht.</td>
</tr>
<tr>
<td><strong>White Blood Cell Count</strong></td>
<td>35-100 (x10^3/μL)</td>
<td>White blood cells serve to defend the body by phagocytosing bacteria and other pathogens, transmitting immune information, and expressing immunocompetence. The WBC generally increases when an individual has a bacterial infection and sometimes decreases with viral infections.</td>
</tr>
<tr>
<td><strong>Platelet Count</strong> (PLT)</td>
<td>14.0-38.0 (x10^4/μL)</td>
<td>Platelets serve a vital function in hemostasis. There is an increased tendency toward hemorrhaging when this value is markedly decreased.</td>
</tr>
</tbody>
</table>

---

**血球計数検査**（希望のあった全献血者に通知）

<table>
<thead>
<tr>
<th>検査項目</th>
<th>標準値（単位）</th>
<th>説明</th>
</tr>
</thead>
<tbody>
<tr>
<td>赤血球数</td>
<td>男性:425-570, 女性:375-500 (x10^6/μL)</td>
<td>赤血球は血液の主な細胞成分で、酸素を肺から各組織へ運ぶ働きをもっている。</td>
</tr>
<tr>
<td>ヘモグロビン</td>
<td>男性:13.3-17.4, 女性:11.2-14.9 (g/dL)</td>
<td>血液の赤い色は赤血球に含まれるヘモグロビン（血色素）によるもので、赤血球の働きの中心となっている。</td>
</tr>
<tr>
<td>ヘマトクリット値</td>
<td>男性:39.0-50.4, 女性:34.0-44.0 (%)</td>
<td>ヘマトクリット値は一定の血液量に対する赤血球の割合（容積）をパーセントで表したもの。</td>
</tr>
<tr>
<td>平均赤血球容積</td>
<td>80.0-100.0 (fL)</td>
<td>赤血球1個の平均的容積、すなわち赤血球の大きさの指標となるもので、赤血球数とヘマトクリット値から算出したもの。</td>
</tr>
<tr>
<td>平均赤血球ヘモグロビン量</td>
<td>26.0-34.0 (pg)</td>
<td>赤血球1個に含まれるヘモグロビン量を平均的に表したもので、赤血球数とヘモグロビン量から算出したもの。</td>
</tr>
<tr>
<td>平均赤血球ヘモグロビン濃度</td>
<td>32.0-36.0 (%)</td>
<td>赤血球の一定容積に対するヘモグロビン量の比をパーセントで表したもので、ヘモグロビン量とヘマトクリット値から算出したもの。</td>
</tr>
<tr>
<td>白血球</td>
<td>35-100 (x10^3/μL)</td>
<td>白血球は細菌などを食い、免疫情報を伝達し、さらに免疫能を発現して生態防御に関わっている。細菌感染症があると一般に白血球数は増加するが、ウイルス感染症の場合はかえって減少することもある。</td>
</tr>
<tr>
<td>血小板数</td>
<td>14.0-38.0 (x10^4/μL)</td>
<td>血小板は出血を止めるための重要な働きを持ち、この値が極端に減少すると出血を起こしやすくなる。</td>
</tr>
</tbody>
</table>
9. Production of Blood for Transfusion

The Preparation Department is in charge of producing blood products for transfusion from donated blood. Approximately 70% of all donated blood is whole blood, most of which is made into products through centrifugal separation of plasma and red blood cells. In order to reduce adverse reactions of transfusion due to white blood cells, most of the white blood cells are removed from blood during the production process. Also, in order to prevent post-transfusion Graft-Vs-Host Diseases (GVHD), one of the serious adverse reactions, blood products are exposed to a radioactive ray.

Production Process

- Receiving Source Blood: Blood units delivered from various donation sites are accepted upon confirmation of transport modes, the number of units and respective capacities. Donation numbers and other information are entered into computers.

- Reduction of Leukocytes: With regards to platelets and plasma donated through apheresis devices, conformity with product specifications is confirmed.

- Centrifugation: Blood is separated into red blood cells and plasma using a centrifuge.

- Separation of Blood Components: The centrifuged blood is prepared into plasma products and red blood-cell products, using an automated blood separator.

- Labeling and Packaging: Conformity with product specifications is confirmed, through appearance and capacity tests. Labels are attached to products, and products are put into packaging bags.

- Storage and Shipment: Red blood-cell products are refrigerated at 2 to 6°C and plasma is frozen at below -20°C for temporary storage. Blood products are shipped to the Supply Department, after confirming conformity through computerized reference to test results.
### Types of Blood Products for Transfusion

**As of March, 2014**

<table>
<thead>
<tr>
<th>Type of Product</th>
<th>Trade Name</th>
<th>Storage Temperature</th>
<th>Maximum Storage Period*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood Products</td>
<td>Whole Blood, Leukocytes Reduced “Nisseki”</td>
<td>2°C - 6°C</td>
<td>21 days after collection</td>
</tr>
<tr>
<td></td>
<td>Irradiated Whole Blood, Leukocytes Reduced “Nisseki”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Blood Component Products**

<table>
<thead>
<tr>
<th>Blood Component Products</th>
<th>Product Type</th>
<th>Trade Name</th>
<th>Storage Temperature</th>
<th>Maximum Storage Period*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red blood cells</td>
<td>Red Cells Concentrate, Leukocytes Reduced “Nisseki”</td>
<td>2°C - 6°C</td>
<td>21 days after collection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irradiated Red Cells Concentrate, Leukocytes Reduced “Nisseki”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Washed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td></td>
<td>48 hours after processing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irradiated Washed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen Thawed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td></td>
<td>4 days after processing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irradiated Frozen Thawed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood for Exchange Transfusion, Leukocytes Reduced, NISSEKI</td>
<td></td>
<td>48 hours after processing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irradiated Blood for Exchange Transfusion, Leukocytes Reduced, NISSEKI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Plasma | Fresh Frozen Plasma, Leukocytes Reduced “Nisseki” | ≤ -20°C | 1 year after collection |
| | Fresh Frozen Plasma (F.F.P), Leukocytes Reduced, Apheresis, “Nisseki” | | |

| Platelet | Platelet Concentrate, Leukocytes Reduced, NISSEKI | 20°C - 24°C | 4 days after collection |
| | Irradiated Platelet Concentrate, Leukocytes Reduced, NISSEKI | | |
| | Platelet Concentrate HLA, Leukocytes Reduced, NISSEKI | | |
| | Irradiated Platelet Concentrate HLA, Leukocytes Reduced, NISSEKI | | |

*Note: In Japan blood collection date is counted as the day 1 of the storage period.*

---

**輸血用血液製剤の種類**

**2014 年（平成 26 年）3 月現在**

<table>
<thead>
<tr>
<th>製剤の種類</th>
<th>販売名</th>
<th>保存温度</th>
<th>有効期間*</th>
</tr>
</thead>
<tbody>
<tr>
<td>全血製剤</td>
<td>人全血液 - LR「日赤」</td>
<td>2°C - 6°C</td>
<td>採血後21日間</td>
</tr>
<tr>
<td></td>
<td>照射人全血液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td>赤血球製剤</td>
<td>赤血球濃厚液 - LR「日赤」</td>
<td>2°C - 6°C</td>
<td>採血後21日間</td>
</tr>
<tr>
<td></td>
<td>照射赤血球濃厚液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>洗浄赤血球液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>照射洗浄赤血球液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>解凍赤血球液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>照射解凍赤血球液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>合成血液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>照射合成血液 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td>血漿製剤</td>
<td>新鮮凍結血漿 - LR「日赤」（全血採血由来製剤）</td>
<td>≤ -20°C</td>
<td>採血後1年間</td>
</tr>
<tr>
<td></td>
<td>新鮮凍結血漿 - LR「日赤」成分採血</td>
<td></td>
<td></td>
</tr>
<tr>
<td>血小板製剤</td>
<td>濃厚血小板 - LR「日赤」</td>
<td>20°C - 24°C</td>
<td>採血後4日間</td>
</tr>
<tr>
<td></td>
<td>照射濃厚血小板 - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>濃厚血小板 HLA - LR「日赤」</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>照射濃厚血小板 HLA - LR「日赤」</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*日本では、採血日が有効期間の一日目となる。*
10. Distribution

10.1 Distribution System

Blood product for transfusion, which is managed at blood centers is stored in accordance with conditions appropriate to each product. The blood is later supplied to medical institutions in accordance with orders received. In Japan, there is no system that limits the number of specified medical institutions licensed to provide blood transfusions. Rather, if there is a request for a certain blood product from any medical institution, the product is supplied. As a result, blood products are supplied to many medical institutions. The blood centers have endeavored to provide a supply system through which it is possible to respond to requests from medical institutions at any time, day or night. To prepare for possible emergencies, efforts are also made to always keep a certain minimum stock of blood products on hand.

10.2 Delivery to Medical Institutions

While the blood products for transfusion are basically delivered directly to medical institutions by blood center employees, they are also delivered by pharmaceutical product wholesalers, or by foundations specializing in delivery services that work on a consignment basis -- in the form of either delivery consignment or supply consignment -- depending on regional circumstances. Delivery consignment means that a blood center receives an order and hands over some of its stock of blood products to the consignment company, which then transports and delivers the products to the medical institution that placed the order. Supply consignment means that companies that have signed consignment contracts in advance routinely keep an inventory of blood products received from blood centers on hold. The system is set up in such a way that these companies receive orders directly from medical institutions to take specified blood products from their inventories before delivering them to medical institutions.

Additionally, delivery consignment companies must be licensed as carriers, and supply consignment companies must be licensed as distributors for pharmaceutical products.

There are also certain stockpiling bases, which in cooperation with specified medical institutions, have set up emergency-store medical depots beforehand. The result is that a certain quantity of blood product for transfusion is available to nearby medical institutions to better cope with cases where more than the usual amount of time is needed to supply these products. For example, such a need might arise in the case of small islands separated from the Japanese mainland or other remote areas.

10. 供給業務

10.1 供給業務

血液センターにおいて管理する輸血用血液製剤は、製剤ごとに適切な条件で保管され、医療機関からの発注に基づき供給される。日本には輸血認定医療機関の制度がなく医療機関から要請があれば全て供給するため、血液製剤を供給する医療機関は数多い。血液センターでは、医療機関からの要請にいえども応じられるように24時間対応可能な供給体制を敷くとともに、非常時に備え常に一定量の在庫確保に努めている。

10.2 医療機関までの供給

医療機関への輸血用血液製剤の供給については、血液センター職員が直接医療機関に供給する体制を基本としている。しかしながら、地域事情等により委託（配送業務委託又は供給業務委託）を受けた専門の財団法人や医薬品卸売業者等が配送又は供給を行っている場合がある。「配送業務委託」は、血液センターが受注・出庫した製剤を委託業者に引き渡し、業者が医療機関に届ける体制であり、「供給業務委託」は委託契約を結んでいる業者自らが血液センターから引き渡された血液製剤を保管し、業者が医療機関からの発注を直接受け、医療機関に届ける体制である。

なお、配送委託業者は、運送業の資格を有している必要があり、供給委託業者は医薬品販売業の資格を有している必要がある。

また、地理的要因（離島、遠隔地等）等により、供給に時間を要する場合に備え、予め特定の医療機関の協力を得て輸血用血液製剤を一定量保管し、近隣医療機関へ融通する「備蓄医療機関」を設けている血液センターもある。
10.3 Supply-and-Demand Control

With regard to the inventory of blood products in each blood center, it is necessary to prevent overages and shortages caused by a temporary decrease in donors, a blood type imbalance in the blood products for transfusion supplied, and other factors. Therefore, the supply and demand of blood products for transfusion are managed within each of the seven regional blocks across Japan so as to achieve a good supply-and-demand balance in the block, with the Block Blood Center of each block at their hub. When it is difficult to achieve balance within the block, Block Blood Centers exchange blood products for transfusion among them in order to achieve more stable supply and effective use of the products. Such exchange of blood products for transfusion across blocks is called “supply-and-demand control”.

This supply-and-demand control system enables delivery of required blood products for transfusion to anywhere across Japan.

11. Medical Information

Under the Pharmaceutical Affairs Law, entities licensed as marketing authorization holders or as general wholesalers must endeavor to collect and evaluate information concerning the efficacy and safety of drugs and other information for appropriate use. Such entities must supply pharmacies, hospitals, clinics, drug sellers, physicians, pharmacists and other medical professionals with this information.

Personnel in charge of medical information (Medical Representatives: MRs) in each blood center are responsible for the provision of information on blood products to medical professionals who use or deal with blood products. This is done through the distribution of brochures, explanatory meetings and other measures. Another important aspect of MR activities is to respond to information requests regarding adverse reactions, complaints and inquiries from medical professionals.

10.3 需給管理及び需給調整

各血液センターの血液製剤の在庫については、一時的な献血者の減少や供給される輸血用血液製剤の血液型の偏りなどによる過不足が生じないように、全国7カ所に設置したブロック血液センターを中心に、ブロックを単位とした需給管理を行い、輸血用血液製剤のバランスを調整している。なお、ブロック内で調整が困難な場合は、ブロック間で輸血用血液製剤の受け渡しを行うことにより、より一層の安定供給と有効活用を図っており、このブロックを越えた受け渡しを需給調整という。

このシステムにより、日本全国どこでも必要な輸血用血液製剤を届けられるようになっている。

11. 医薬情報業務

薬事法で、医薬品の製造販売業者、卸売一般販売業の許可を受けた者は、医薬品の有効性及び安全性に関する事項、その他医薬品の適正な使用のために必要な情報を収集し検討するとともに、薬局開設者、病院、診療所の開設者、医薬品の販売業者、医師、薬剤師その他の医療関係者に対して提供するように努めなければならないと規定されている。

血液製剤を使用する医療関係者へ情報提供を行う業務は、各血液センターに所属している医薬情報担当者（MR: Medical Representative）が行っている。具体的にはパンフレット等の各種情報媒体を医療関係者に届けたり、説明会を開催したりして血液製剤に関する様々な情報提供を行っている。また、医療関係者からの副作用情報、苦情、問い合わせに対応することも重要な業務となっている。
12. Quality Control

Based on the Pharmaceutical Affairs Law, the Ministerial Ordinance on Regulations for Manufacturing Control and Quality Control of Drugs and the Minimum Requirements for Biological Products, the following procedures are conducted to offer better quality-control of blood products for transfusion as pharmaceutical products.

・ Acceptance Inspection of Raw Materials and related issues;
  We conduct acceptance inspections on raw materials and other materials, excluding blood, such as blood bags to confirm their quality.

・ Sampling Inspection of Final Products;
  We implement sampling inspections of final products to confirm their quality.

・ We perform a comprehensive determination and confirmation of results of quality-control-related tests, including the testing of donated blood.

13. Quality Assurance

In keeping with revisions to the Pharmaceutical Affairs Law that went into effect in April 2005, the Japanese Red Cross Society is licensed as a marketing authorization holder for pharmaceutical products. Therefore, in this capacity it carries out quality assurance operations and safety vigilance operations. Such operations ensure the high quality of these products as well as quality assurance aimed at ensuring safety, following the manufacture and marketing of blood products for transfusion manufactured at the blood centers.

The task of quality assurance is carried out in conformance with the GQP (Good Quality Practice) guidelines established by the national government. This involves such responsibilities as the supervision of the release of manufactured products to markets, the supervision of any changes in methods of manufacturing or testing and responding to information on product quality. It also involves the withdrawal of any products found defective, as well as checking compliance with GMP standards on the part of the blood centers.

Confirmation of compliance with the GMP standards primarily involves on-the-spot checks of quality-control conditions and manufacturing supervision at the blood centers, which have been licensed as manufacturers of pharmaceutical products, while pointing out any problem areas in this process that need improvement. All blood centers are licensed for blood collecting activities and for the sale of pharmaceutical products. As such, their activities are also subject to verification checks and suggestions for possible improvements.

12. 品質管理業務

「薬事法」「医薬品の製造管理及び品質管理規則」（医薬品GMP）、「生物学的製剤基準」等に基づいて「医薬品としての輸血用血液製剤」の品質を維持するために、次の業務を行っている。

・ 原料・資材の受入れ試験
  原料となる血液以外の原料・資材（血液バッグ等）について受入れ試験を行い、品質を確認している。

・ 製品抜取試験
  最終的に調製された製品に対して抜取試験を実施し、品質の確認を行っている。

・ 原料となる血液の試験も含めた、品質管理にかかる試験結果の総合判定及び確認を行っている。

13. 品質保証業務

日本赤十字社は、薬事法の改正により2005年（平成17年）4月から医薬品の製造販売業の許可を取得した。そのため、製造販売業者として、血液センターが製造した輸血用血液製剤について、品質を確保するための品質保証業務及び製造販売後の安全を確保するための安全管理業務を実施している。

品質保証業務は、国が定めたGQP（Good Quality Practice）に基づいて行うもので、製品の市場への出荷に関する管理、製造方法・検査方法等の変更の管理、製品の品質に関する情報への対応、品質不良の製品の回収、血液センターのGMPの適合性確認等がある。

GMPの適合性確認とは、主に医薬品製造業の許可を取得した血液センターにおける製造管理・品質管理の状況を実地に確認し、問題点の改善を指導するものであるが、血液センターにあっては採血業及び医薬品販売業の許可も取得しているので、これらの業務についても確認及び指導を行っている。
14. Safety Vigilance

The activity of post-marketing safety management of blood products is carried out in accordance with Good Vigilance Practice (GVP) established by the Ministry of Health, Labour and Welfare. Its aim is to verify and enhance the safety of blood products.

Some of the safety managements are to collect and provide information of safety, efficacy and quality of blood products that are manufactured and marketed. Major types of information collected are case reports from medical institutions on adverse reactions or infections in patients who have received blood transfusions. Severe cases must be reported to the Minister of Health, Labour and Welfare via Pharmaceuticals and Medical Devices Agency (PMDA). The adverse reactions include fever, urticaria, anaphylactic shock and Transfusion Related Acute Lung Injury (TRALI). Transfusion transmitted infection includes suspected cases of HBV, HCV, or bacterial infection. The system of transfusion adverse reactions / infections reporting has two routes: from health care professionals to either the Red Cross Blood Center or directly to the Minister of Health, Labour and Welfare.

If a blood donor who tested positive for an infection has a previous record of blood donations, blood components for transfusion made from previously collected blood might have already been supplied to medical institutions. In these cases, if there is a possible risk of infection from such blood components, these components will be withdrawn if they have not been used yet. As well as the withdrawal, testing for infection is conducted for confirmation using the stored blood samples of relevant donations. In case the relevant components for transfusion had already been used, information of infectious risk is provided to the medical institution to help in the early detection and treatment of transfusion transmitted infectious disease. These activities are called look-back studies. The look-back studies are handled according to the "Guidelines for Look-back Studies on Blood Products", which was established by the Blood and Blood Products Division in the Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare in April 2005 (partially revised in March 2012).

To carry out look-back studies and other investigations on post-transfusion infections and also to evaluate the safety of blood components for transfusion, keeping frozen specimens for 11 years is an effective practice at present.

As an obligation of a marketing authorization holder, the Japanese Red Cross Society (JRCS) collects the information on research papers and measures taken in other countries concerning blood products for transfusion. Also marketing authorization holders of biological products are requested to collect the latest domestic and foreign research papers on infections due to biologics or related materials. Research papers or information evaluated important are reported to the Minister of Health, Labour and Welfare via PMDA as the reports on measures in foreign countries, reports of studies and the periodic infection reports for biologic products in accordance with the Pharmaceutical Affairs Law.

14. 安全管理業務

製造販売後の安全管理に係る業務は、厚生労働省の GVP (Good Vigilance Practice) 省令に基づき血液製剤の安全性の検証と向上に資するために行っている。

安全管理業務の一つとして、製造販売している血液製剤に関する安全性、有効性及び品質に係る情報の収集・提供がある。主な情報収集には医療機関から輸血医療を受けた患者の副作用・感染症報告があり、重篤な症例については、独立行政法人医薬品医療機器総合機構 (PMDA: Pharmaceuticals and Medical Devices Agency) を通じ、厚生労働大臣へ報告することとなっている。副作用としては発熱、蕁麻疹、アナフィラキシーショックや輸血関連急性肺障害 (TRALI: Transfusion Related Acute Lung Injury) があり、感染症報告には HBV、HCV や細菌感染等の疑い報告がある。副作用・感染症報告制度は医療関係者が赤十字血液センターに報告するルートと直接厚生労働大臣へ報告するルートがある。

また、献血血液の感染症検査で陽性となった献血者に過去の献血歴がある場合、過去の血液製剤が医療機関へ既に供給されていることがある。過去の血液製剤による感染リスクが考えられる場合には、献血血液の保管検体を用いて感染症検査を実施し、輸血用血液製剤が使用されていなければ回収する。既に使用されていた場合には、医療機関に情報を提供し、輸血後感染症の早期発見・早期治療に役立てる。これを遡及調査といい、この調査は、2005年 (平成17年) 4月に厚生労働省医薬食品局血液対策課が制定 (2012年 (平成24年) 3月、一部改正) した「血液製剤等にかかる遡及調査ガイドライン」に基づき対応している。

遡及調査や輸血後感染症に係る調査を実施するために、さらには輸血用血液製剤の安全性の検証を行う上でも、11年間冷凍保管される保管検体は有用である。

また、医薬品製造販売業者の義務として、輸血用血液製剤に関連する外国の措置情報や研究論文の収集を行っている。さらに、生物由来製品の製造販売業者として、製品及び原料に由来する感染症に関する国内外の最新論文の収集を行い、重要と評価された論文や情報については薬事法に基づき感染症定期報告として PMDA を通じて厚生労働大臣へ提出している。
This safety information is reviewed and evaluated by the review committee comprising doctors and other experts in blood services and/or transfusion medicine when necessary. We subsequently provide the information on our website and in printed form in order to contribute to safer transfusion medicine. In addition, the information is reported at the Committee on Safety of Drugs and the Committee on Blood Products of the Pharmaceutical Affairs and Food Sanitation Council.

When the safety vigilance system described above is implemented for the blood program, it is called hemovigilance. Hemovigilance is defined as a set of surveillance procedures to identify and prevent the occurrence or recurrence of undesirable transfusion-related events in order to increase the safety, efficacy and efficiency of blood transfusion covering all activities of the transfusion chain from donor to recipient. The JRCS participates in the national haemovigilance council along with the National Institute of Infectious Diseases and the blood services departments of major university hospitals. We have been a member of the International Haemovigilance Network since 2008, to exchange information with other members.
15. Nationwide Unified IT System

With respect to the Japanese Red Cross Society’s computer systems in blood services, the Second Stage Unified System for Blood Services Data was put into operation in 2004 to address the obsolescence of the First Stage Unified System for Blood Services Data introduced in 1993, as well as innovations in blood services.

At present, the new system supports general operations of the seven block blood centers, 47 blood centers and a quarantine across Japan.

The Second Stage Unified System for Blood Services Data is a centralized system based on a server client method, which connects the regular control servers installed in Tokyo and the sub control servers in Osaka, with a nationwide network. To this network are connected some 8,000 terminals, which process acceptance of donors at local blood centers, production, testing, quality control and deliver to medical institutions, as well as accounting, procurement and other wide-ranging support services.

With regards to the acceptance of donors, cellular phone-based mobile terminals were introduced to support blood collection at collection vehicles in remote places, thus enabling the output of donation application forms at almost all the donation sites across Japan.

In this way, donors’ health is protected through confirmation of donation intervals and other data, lead time to the start of production testing was shortened through prior input of donor and collection information, and effective handover of deferred donor information was enabled at the time points of donor acceptance and blood-collection.

Also, 24-hour services were made possible through redundant power supply lines to regular centralized servers, the installation of an uninterruptible power supply and private power generation units, redundant communications lines and other measures throughout the year. At the same time, sub-control servers are installed in Osaka as standby equipment, in order to ensure system operation continuity in the event of breakdown of regular control servers or disaster.

In April 2012, Information system for Blood Service Data was introduced as the Third Stage Unified System for Blood Services Data, starting with the accounting and procurement departments. Full-scale operation of this system is slated for 2014.

This blood services information system basically inherits the functions of the Second Stage Unified System for Blood Services Data, through its system configuration combining package software programs that are commonly used by pharmaceutical manufacturers and marketers. Other functions that have not been provided by the Unified System for Blood Service Data are also added to the new system.

The additional functions include, among others, paperless donation offering using an e-offer sheet, biometrics identification based on vein patterns, etc. at the time of donor acceptance, and online acceptance of orders for blood from medical institutions.

15. 情報システム

日本赤十字社の血液事業におけるコンピュータシステムは、1993年（平成5年）に導入した第一次血液事業統一システムの老朽化と血液事業の変革に対応するため、2004年（平成16年）より第二次血液事業統一システムの運用を開始した。

現在、全国7カ所のブロック血液センター、47カ所の地域献血センター、血液管理センター等の事業運営全般を支えるシステムとして稼働している。

第二次血液事業統一システムは、サーバクラウド方式による集中管理型のシステムであり、東京に設置した正管理サーバと大阪の副管理サーバを全国ネットワーク網で結び、その配下に約8,000台の端末を接続し、各血液センターの献血者の受入から製造、検査、品質管理、医療機関への供給、更に管理、用度におよぶ広範囲における事業支援を行っている。

献血者の受入においては、遠隔地での移動採血車での採血業務を支援するため、携帯電話を使用した移動型端末を導入し、全国のほとんどの献血会場で献血申込書出力を可能とした。

これにより、献血間隔の確認等による献血者の健康保護、献血者情報及び採血情報の事前入力による製造検査開始までの時間短縮と受付、採血時点でにおける献血不適格者情報の確実な引き渡しが実現した。

正集中サーバの電力線二重化と無停電装置及び自家発電装置の設置、通信回線の二重化等の対策により365日24時間を実現するとともに、万が一の正管理サーバ故障時及び災害時のシステム運用継続のため、待機機器として副管理サーバを大阪に設置している。

また、2012年（平成24年）4月からは、第三次血液事業システムとなる血液事業情報システムの経理用度部門の運用を先行して稼働し、2014年（平成26年）内を目途に全システムの稼働を予定している。

血液事業情報システムは、第二次血液事業統一システムの機能を受け継ぐことを原則とし、医薬品製造販売を行う会社で一般的に使用されているパッケージソフトウエアを組み合わせてシステム構築を行うとともに、血液事業統一システムにおいて実現できなかった機能等も追加している。

追加した機能等については、献血申込書を電子化するところによるペーパーレス化の実現、献血口付時に静脈認証等の生体認証機能の導入、医療機関からの発注情報をインターネット経て受注する機能の導入等が挙げられる。
Servers and other peripheral equipment are installed into three data centers with robust security and advanced quake-proof performance, located in Hokkaido, Kanagawa and Okayama.

These centers can exchange their roles flexibly and complementarily. Therefore, even if one of the centers needs to be shut down due to disaster, failure, planned maintenance, etc., the two other centers constantly back up to assure enhanced system robustness.

サーバ機器類の設置場所として、強固なセキュリティと高度な耐震性能を備えたデータセンターを利用し、国内3拠点（北海道、神奈川県、岡山県）にサーバ等を設置し運用する。

これにより、各拠点が相補的かつ柔軟に相互の役割を入れ替えられることから、災害や障害、保守による計画停止などにより1拠点のシステムを止めることになっても、常に2拠点によるバックアップ体制を維持でき、システムの堅牢性の向上を実現する。
16. Research and Development

In 2004, the Central Blood Institute was established within the Blood Service Headquarters in order to supervise, enhance and strengthen the safety measures for blood services and the blood-related research and development. In 2009, with the aim of enhancing research on infectious diseases, the Infectious Disease Research Department was set up within the Institute. Further, in order to study and resolve technical problems concerning blood examinations and preparation of blood products, the Laboratory Development Division and the Preparation Development Division were established within three Block Blood Centers in 2012.

Through the blood program research conducted to date, we have achieved improvement in the quality of blood products, extension of the expiration date and improvement of the sensitivity and specificity of screening tests. To prevent transfusion-associated Graft-Vs-Host Diseases (GVHD), we have started to distribute irradiated blood products. Meanwhile, in order to prevent transfusion-related anaphylactic shock caused by a deficiency of plasma proteins, we have begun to secure blood products with a plasma protein deficiency. In addition, we are developing testing methods for preventing transfusion-related acute lung injuries (TRALI). We developed additive solutions and washing methods that are capable of preparing high-quality washed platelets, and plan to file applications for approval for manufacturing using such liquids and methods.

We have also started basic research on iPS cell technology, with an eye to applying the technology to the preparation of blood cells that are necessary for the blood test and to production of blood products. We analyze the causal relationship between infectious diseases developed after transfusion and the blood products so as to contribute to identifying the actual status of and preventing transfusion-transmitted diseases. As well, we are studying methods to inactivate infectious factors and developing new testing methods in order to be able to deal with new infectious diseases.

Medium- and long-term goals for blood services research are 1) improvement of efficacy of blood for transfusion, 2) reduction of transfusion-related adverse reactions, 3) development of novel blood products, 4) improvement of usage and production efficiency of donated blood, 5) improvement of blood test accuracy and efficiency and 6) reduction of adverse reactions to blood donation. To achieve these goals, enhancement of research framework of blood program by reconstruction of organization for research and redeployment for enlarge of research facilities are scheduled.

16. 研究開発業務

血液事業の安全対策、血液に関する研究・開発を統括、充実強化するため、2004 年（平成 16 年）に血液事業本部内に中央血液研究所が設置され、2009 年（平成 21 年）には、感染症に関する研究を充実させるため、感染症解析部が増設された。2012年（平成24年）には、検査業務、製剤業務における技術的問題の検討・解決のため、3カ所のブロック血液センターに検査開発課、製剤開発課が設置された。

これまでの血液事業研究により、血液製剤の品質向上、それに伴う有効期限の延長、検査精度の向上が図られてきた。輸血後 GVHD 防止のため、放射線照射製剤が供給されるようになった。血漿タンパク欠損が原因で起こる輸血によるアナフィラキシーショックを防ぐため、血漿タンパク欠損製剤が確保されるようになった。また、輸血関連急性肺障害（TRALI）を防ぐための検査法の開発が進められている。高品質の洗浄血小板を調製できる保存液、洗浄方法を開発し、これらを用いた製造承認申請が計画されている。

さらに、輸血用検査に必要な検査血球の作成や、血液製剤製造を念頭に iPS 細胞技術の基礎研究を開始している。輸血後の感染症と輸血製剤の因果関係を分析し、輸血感染症の実態の把握と予防に寄与するとともに、新たな感染症へ対応できるよう、感染因子不活化法の検討、新しい検査法の開発も進めている。

血液事業研究の中長期目標である、1）輸血用血液の有効性の向上、2）輸血副作用の軽減、3）新たな血液製剤の開発、4）血液の利用効率、製造効率の向上、5）検査精度及び検査効率の向上、6）採血副作用の軽減を達成できるよう、研究体制を強化するため、研究組織の改編、研究施設の移転整備を計画している。
Hematopoietic stem cell transplantations are transplantations using bone marrow, peripheral blood stem cells or umbilical cord blood, and they are effective and promising means of treatment for some types of leukaemia, severe cases of aplastic anaemia and other stem cell diseases.

The human leukocyte antigens (HLA) of the donor and the recipient must be matched for hematopoietic stem cell transplantations to be successful. However, the chances of being HLA-identical are one in four even between siblings, and the chances are approximately one in several hundred to tens of thousands among nonrelatives. To perform bone marrow and peripheral blood stem cell transplantations we need a large registry of donor candidates, while to perform cord blood transplantations we need to collect and store qualified cord blood in a cord blood bank. Both the donor registry and the cord blood bank are essential for hematopoietic stem cell transplantations.

There had been no regulation on organizations involved in hematopoietic stem cell provision in Japan. Responding to requests from those concerned, the Act for Appropriate Provision of Hematopoietic Stem Cells to be Used in Transplantations " (Act for HSCT) became fully effective on January 1st, 2014.

17.1 Hematopoietic Stem Cell Provision Support Organization

The Minister of Health, Labour and Welfare has designated the Japanese Red Cross Society (JRCS) as the Hematopoietic Stem Cell Provision Support Organization, according to the Act for HSCT. As the Hematopoietic Stem Cell Provision Support Organization, the JRCS shall perform the following activities:

1) Register donor candidates for bone marrow and peripheral blood stem cells, and cooperate with other service providers involved in the provision of hematopoietic stem cells.
2) Liaise with and coordinate organizations involved in the provision of hematopoietic stem cells.
3) Manage and provide information related to hematopoietic stem cells for transplantations.
4) Disseminate information and raise awareness for providing hematopoietic stem cells for transplantation.

Moreover, the JRCS as the Hematopoietic Stem Cell Provision Support Organization has succeeded some services provided by the Japanese Cord Blood Bank Network that helped to support the system in the early stages of cord blood transplantation (1999-2014).
17.2 Bone Marrow Data Centre and cord blood banks

The Japan Marrow Donor Programme (JMDP, a public interest incorporated foundation) has been operating in cooperation with the Ministry of Health, Labour and Welfare, the JRCS and each prefecture.

As a public agency with impartiality, fairness and wide geographical jurisdiction, the JRCS had been appointed to work with the JMDP. The JRCS had set up the Bone Marrow Data Centres whose services have primarily been receiving applications for donor registration, providing HLA typing and managing the donor search system. The JRCS shall perform these services as the Hematopoietic Stem Cells Provision Support Organization with the implementation of the Act for HSCT.

Cord blood is the blood in the baby’s umbilical cord and placenta, and it is rich in stem cells. To be used in transplantations it should be processed and cryopreserved in cord blood banks. The JRCS has established cord blood banks in four block blood centers.

According to the Act for HSCT, each cord blood bank shall perform its services under the approval of the Minister of Health, Labour and Welfare from April, 2014.

Cord Blood Bank Character, Kizuna-chan
18. Cooperation with Other Organizations

18.1 Autologous Transfusion

Autologous transfusion is a method whereby a patient’s own blood, instead of some other person’s, is collected, stored and used for transfusion when there is a definite transfusion plan, such as scheduled surgery and when blood collection is feasible. Autologous transfusion is advantageous in that it eliminates both the risk of infection through the transfusion of another person’s blood and transfusion-related adverse reactions that might be caused by the recipient’s immune reaction.

The Guidelines on Implementing Transfusion Medicine issued by the Ministry of Health, Labour and Welfare recommends that autologous transfusion be actively considered in cases of elective surgery in which the patient is in good preoperative condition and there is no emergency. Because of their technical processing experience, such as separation and freezing, thawing and washing and preservation of blood, the blood centers have been asked to cooperate, particularly in cases of autologous transfusion involving presurgical autologous blood donations. This is for situations when blood is collected preoperatively from a patient scheduled for surgery. Any participation by a blood center is done in accordance with the judgment of the physician in charge.

The Japanese Red Cross Society (JRCS) cooperates insofar as possible with regard to autologous transfusions when so requested by medical institutions.

18.2 Plasma fractionation services

The JRCS had manufactured and supplied a variety of plasma derivatives, including freeze-dried human blood coagulation factor VIII concentrates, at the Plasma Fractionation Center constructed in Chitose City, Hokkaido, in 1983. However, in October 2012, the JRCS’s plasma fractionation services and such services of Benesis Corporation were integrated to form the Japan Blood Products Organization (JB). Since then, the manufacture of such plasma derivatives has been carried out by the JB.

Meanwhile, the plasma derivatives continue to be supplied by the JRCS based on a contract with the JB. Thus, the plasma derivatives manufactured at the JB’s Chitose Plant (former JRCS Plasma Fractionation Center) are supplied to medical institutions via blood centers.

The JRCS also continues to conduct activities to promote the appropriate use of plasma derivatives, and to disseminate the use of such products derived from domestically donated blood so as to increase the domestic supply of such products, through its medical representatives in charge of pharmaceutical information.
19. International Cooperation Program

19.1 Blood Service Training Course

The blood services closely relate to each country’s particular historical background, culture, medical services, and each country has its own problem. However, there is a common awareness that efforts are constantly being made by each country towards the objective of ensuring safe blood. In this context, the Japanese Red Cross Society began receiving blood service trainees from sister Red Cross and Red Crescent societies mainly in the Asian and Pacific regions in 1978 as part of Japan’s development cooperation efforts. By 2013, 398 individuals from 20 countries/region had studied in Japan. Some executive staff of the blood services in each society in the Asian region once has been a trainee in Japan, this scheme, which has been ongoing for 36 years, has become more than just a training method, but rather serves to form a regional network.

19.2 The Red Cross and Red Crescent Symposium on Blood Programs in the Asian Region

By each Asian country’s Blood Services, common concerns are shared including securing safe blood and conquering HIV/AIDS, hepatitis and other transfusion-transmitted diseases. With these common concerns and in response to calls from the International Red Cross for the further strengthening of cooperative ties within the region, the Japanese Red Cross Society and the Thai Red Cross Society, under the auspices of the International Federation of Red Cross and Red Crescent Societies and the International Society of Blood Transfusion, have held symposia in Bangkok, Thailand, and in Tokyo, Japan, every three years since 1995.

In these symposia entitled “Securing Safe Blood” etc., while focusing particularly on technical aspects, the representatives of the blood services in each country exchange information by sharing their experiences in the prevention of transfusion-transmitted diseases, blood typing and the preparation of reagents, donor recruitment and quality control, with the intention of contributing to strengthening the steady development and cooperation of blood services in the Asian region.
In 1990, the Laotian Health Ministry consigned the administration of the blood center in the capital city, Vientiane, to the Lao Red Cross. Initially, the situation was such that the people of the nation did not understand the concept of donating blood. When blood was needed, the patient’s family or acquaintances would try to provide it. Moreover, safety-related blood examinations before transfusions were unsatisfactory.

Given these circumstances, in response to a request from the Lao Red Cross for help with Blood Services, the Japanese Red Cross Society (JRCS) carried out assessments and consultations and based on agreement by three parties, namely the International Federation of Red Cross and Red Crescent Societies, the Lao Red Cross and the JRCS, Japanese assistance to the Lao Red Cross Blood Services had been conducted from 1995 to 2003. Currently, financial assistance has begun providing for the construction of a new blood center (Vientiane), devices, equipment and testing reagents.

Also, as the first such assistance effort by the JRCS, a number of middle-management personnel from blood centers, a total of 11 individuals, were involved in technical cooperation while residing in Vientiane for 6 months to a year.

For the outcome of such support with respect to the Lao Blood Services system, it began with the promulgation of a National Blood Policy in 1996. Next was the inauguration of a National Blood Transfusion Committee in 1998. Rh blood group inventories, cross matching tests and Hepatitis C tests were introduced and the accuracy of laboratory technology increased. For donor recruitment in Vientiane, the ratio of donated blood to all blood products for transfusion had been almost nonexistent in 1995, but by 2003 the ratio expanded to 100 percent. A cost recovery system, which charges part of the cost as blood prices to be paid by transfusion recipients, was adopted to secure funds for the services. Each field in Blood Services is steadily developing.

Also, in 2012, the Lao Red Cross and the JRCS concluded a comprehensive agreement on a six-year program. Under this program, the JRCS has started to provide support to strengthen the quality assurance function and the operational management function of the Lao Red Cross. The JRCS provides technical support to the Lao Red Cross through close interactions, such as sending JRCS personnel to Laos and inviting Lao Red Cross personnel to Japan.
19.4 Support for the Thai Red Cross Blood Program

The National Blood Center of the Thai Red Cross is facing a growing need to acquire technology to produce reagents for rare blood types, etc. In response to the request for support from the Thai Red Cross, the JRCS took necessary preparatory steps, including assessments and consultations, and began to provide support for a project on "Human and murine monoclonal hybridoma technique for rare blood group reagents and Coomb's reagents" carried out by the National Blood Center in 2012. Under this three-year support program, the JRCS accepts two trainees from the Thai Red Cross every year to receive technical training for three months at the Kanto-Koshinetsu Block Blood Center.

This program, which is designed to provide the JRCS' specialized technology to overseas, is expected to make substantial achievements.

Training program for technical staff from the Thai Red Cross Society

19.4 タイ赤十字社血液事業支援

タイ赤十字社中央血液センターでは、まれ血等の試薬製造技術習得の必要性が高まっている。日本赤十字社は、タイ赤十字社からの支援要請に基づき、現地調査、協議等を経て、2012年（平成24年）から同センターの「モノクローナル抗体産生ハイブリドーマの技術に関する事業」への支援を開始した。本計画の実施期間は3カ年で、タイ赤十字社から毎年2名の研修生を受け入れ、関東甲信越ブロック血液センターにて3カ月間の技術研修を行っている。

日本赤十字社の専門的な技術の海外供与として、成果が期待されている。
20. Finance of the Blood Services

20.1 Financial Organization

The JRCS has a General Account and Special Accounts to manage the finance for the respective activities separately.

The General Account is mainly funded by annual membership fees paid by JRCS members and contributions from the public. With these financial resources, the JRCS implements various activities, including international activities, dissemination of workshops on first-aid treatment, etc., fostering of the Junior Red Cross, and promotion of Red Cross volunteering activities.

The Special Accounts consist of the Special Account for Blood Services, the Special Account for Medical Institutions, and the Special Account for Social Welfare Facilities, under which blood centers, medical institutions, and social welfare facilities are managed, respectively.

The Special Account for Blood Services is used for managing the funds of the Blood Service Headquarters, the Center for NAT and Quarantine, and the prefectural blood centers. The primary sources of funds are proceeds from the supply of blood products for transfusion and plasma derivatives to medical institutions, based on the standard prices of medicines.

The JRCS also receives some subsidies and trust money from the national government and other entities for facility construction and commissioned activities.

In fiscal 2012, the JRCS shifted the management system for blood services from a system based on prefectural blood centers to that based on wide-area blocks, in order to ensure increased safety and stable supply of blood products.

Accordingly, it also revised its accounting system from a system based on prefectural blood centers to that based on blocks. By managing the funds held by all entities engaged in the blood services in a centralized manner at the Blood Service Headquarters, the JRCS makes efforts to eliminate management gaps between blood centers, make effective investments in materials and equipment, and make optimal use of the funds held.
20.2 Blood Products and their Prices (Standard Prices of Medicines)

At present, the entire supply of blood for transfusion in Japan is secured through blood donations at prefectural blood centers nationwide. The donated blood is tested and processed at the Block Blood Centers and distributed to medical institutions at standard prices set by the national government.

As with other medical and pharmaceutical products, blood products for transfusion are covered by the national health insurance system. Prices of blood are calculated by the national government, based on the expenses involved in the process, from blood collection to distribution, and are officially posted. Medical institutions that use the blood products for transfusion are then reimbursed with a sum equivalent to the standard price for the blood and a transfusion procedure fee, as compensation for medical services by the health insurance system.

In contrast, the preparation and distribution systems for plasma derivatives are slightly different. All blood products for transfusion are produced at Block Blood Centers and are distributed by blood centers to medical institutions. However, in the case of plasma derivatives, blood centers first distribute the source plasma to private manufacturers, then purchase the produced plasma derivatives from them, and distribute them in the same manner as private-sector marketing authorization holders and drug importers. Therefore, plasma derivatives are often distributed at discount prices, just like general medical and pharmaceutical products.

Flow of Money in Blood Services

<table>
<thead>
<tr>
<th>Citizens</th>
<th>The Japanese Red Cross Society</th>
<th>Manufacturers of pharmaceutical products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donations</td>
<td>Blood for transfusion</td>
<td>Payment for source plasma</td>
</tr>
<tr>
<td></td>
<td>Payment for plasma derivatives</td>
<td>Payment for plasma derivatives</td>
</tr>
<tr>
<td></td>
<td>Payment for blood products</td>
<td>Payment for plasma derivatives</td>
</tr>
<tr>
<td></td>
<td>Medical fee payment (partial)</td>
<td>Compensation for medical services</td>
</tr>
</tbody>
</table>

20.2血液製剤と薬価（薬品購入基準価格）

現在、国内で必要とされている輸血用血液は、全てを各都道府県にある血液センターで献血者を受入れ、ブロック血液センターで検査、製剤化し、医療機関へ国が定めた薬価で供給している。

輸血用血液製剤は、他の医薬品と同様に国による健康保険の給付対象となっており、その薬価は採血から供給までの必要経費を基準に、国で算定、告示されている。輸血用血液製剤を使用した医療機関には、健康保険制度から診療報酬として、輸血手技料と薬価相当額が支払われる。

一方、血漿分画製剤においては、製剤及び流通の仕組みが多少異なっている。輸血用血液製剤については、全てブロック血液センターで製造し、血液センターから医療機関へ供給される。しかし、血漿分画製剤は、その製造に必要な原料血漿を血液センターから民間製造業者へ配分し、製造された製剤を購入のうえ、民間販売業者や輸入販売業者同様に供給している。そのため、市場競争の下、一般の医薬品と同様に値引きされて供給される場合が多い。
**Revenues in Blood Services (FY 2013)**

- Other revenues: ¥4,681 million (2.8%)
- Revenue from the supply of blood products for transfusion: ¥144,265 million (86.1%)
- Revenue from the supply of plasma fractionation products: ¥9,088 million (5.4%)

**Expenses in Blood Services (FY 2013)**

- Expenses for bone marrow data center and cord blood bank network: ¥1,079 million (0.6%)
- Expenses for research and study: ¥1,458 million (0.8%)
- Expenses for management and operations at blood centers, etc.: ¥23,783 million (13.5%)
- Expenses for blood tests: ¥20,680 million (11.7%)
- Expenses for preparing blood product for transfusion: ¥10,645 million (6.0%)
- Expenses for collection: ¥61,034 million (34.6%)
- Expenses for promoting blood donations and receiving donors: ¥25,465 million (14.4%)

* Truncate the last 5 figures.
## Authorized Prices of Blood Products

**As of April, 2014**

<table>
<thead>
<tr>
<th><strong>Trade name</strong></th>
<th><strong>Size and Unit</strong></th>
<th><strong>Price (yen)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Whole Blood</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Blood, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>8,160</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>16,320</td>
</tr>
<tr>
<td>Irradiated Whole Blood, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>8,881</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>17,757</td>
</tr>
<tr>
<td><strong>Red blood cells</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red Cells Concentrate, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>8,402</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>16,805</td>
</tr>
<tr>
<td>Irradiated Red Cells Concentrate, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>8,864</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>17,726</td>
</tr>
<tr>
<td>Washed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>9,470</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>18,940</td>
</tr>
<tr>
<td>Irradiated Washed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>10,036</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>20,072</td>
</tr>
<tr>
<td>Frozen Thawed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>15,636</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>31,273</td>
</tr>
<tr>
<td>Irradiated Frozen Thawed Red Cells, Leukocytes Reduced, NISSEKI</td>
<td>200mL donated/bag</td>
<td>16,043</td>
</tr>
<tr>
<td></td>
<td>400mL donated/bag</td>
<td>32,085</td>
</tr>
<tr>
<td>Blood for Exchange Transfusion, Leukocytes Reduced, NISSEKI</td>
<td>Blood containing red blood cells from 200 mL of whole blood plus approx. 60 mL of plasma/bag</td>
<td>13,499</td>
</tr>
<tr>
<td></td>
<td>Blood containing red blood cells from 400 mL of whole blood plus approx. 120 mL of plasma/bag</td>
<td>26,997</td>
</tr>
<tr>
<td>Irradiated Blood for Exchange Transfusion, Leukocytes Reduced, NISSEKI</td>
<td>Blood containing red blood cells from 200 mL of whole blood plus approx. 60 mL of plasma/bag</td>
<td>14,065</td>
</tr>
<tr>
<td></td>
<td>Blood containing red blood cells from 400 mL of whole blood plus approx. 120 mL of plasma/bag</td>
<td>28,128</td>
</tr>
<tr>
<td><strong>Plasma</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresh Frozen Plasma, Leukocytes Reduced, NISSEKI 120</td>
<td>200mL donated/bag</td>
<td>8,955</td>
</tr>
<tr>
<td>Fresh Frozen Plasma, Leukocytes Reduced, NISSEKI 240</td>
<td>400mL donated/bag</td>
<td>17,912</td>
</tr>
<tr>
<td>Fresh Frozen Plasma, Leukocytes Reduced, NISSEKI 480 *</td>
<td>480mL/bag</td>
<td>23,617</td>
</tr>
<tr>
<td><strong>Platelets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelet Concentrate, Leukocytes Reduced, NISSEKI *</td>
<td>1 unit: approx. 20mL/bag</td>
<td>7,762</td>
</tr>
<tr>
<td></td>
<td>2 units: approx. 40mL/bag</td>
<td>15,523</td>
</tr>
<tr>
<td></td>
<td>5 units: approx. 100mL/bag</td>
<td>39,665</td>
</tr>
<tr>
<td></td>
<td>10 units: approx. 200mL/bag</td>
<td>79,007</td>
</tr>
<tr>
<td></td>
<td>15 units: approx. 250mL/bag</td>
<td>118,499</td>
</tr>
<tr>
<td></td>
<td>20 units: approx. 250mL/bag</td>
<td>157,999</td>
</tr>
<tr>
<td>Irradiated Platelet Concentrate, Leukocytes Reduced, NISSEKI *</td>
<td>1 unit: approx. 20mL/bag</td>
<td>7,836</td>
</tr>
<tr>
<td></td>
<td>2 units: approx. 40mL/bag</td>
<td>15,671</td>
</tr>
<tr>
<td></td>
<td>5 units: approx. 100mL/bag</td>
<td>39,900</td>
</tr>
<tr>
<td></td>
<td>10 units: approx. 200mL/bag</td>
<td>79,478</td>
</tr>
<tr>
<td></td>
<td>15 units: approx. 250mL/bag</td>
<td>119,204</td>
</tr>
<tr>
<td></td>
<td>20 units: approx. 250mL/bag</td>
<td>158,938</td>
</tr>
<tr>
<td>Platelet Concentrate HLA, Leukocytes Reduced, NISSEKI *</td>
<td>10 units: approx. 200mL/bag</td>
<td>94,809</td>
</tr>
<tr>
<td></td>
<td>15 units: approx. 250mL/bag</td>
<td>142,214</td>
</tr>
<tr>
<td></td>
<td>20 units: approx. 250mL/bag</td>
<td>189,618</td>
</tr>
<tr>
<td>Irradiated Platelet Concentrate HLA, Leukocytes Reduced, NISSEKI *</td>
<td>10 units: approx. 200mL/bag</td>
<td>95,547</td>
</tr>
<tr>
<td></td>
<td>15 units: approx. 250mL/bag</td>
<td>143,138</td>
</tr>
<tr>
<td></td>
<td>20 units: approx. 250mL/bag</td>
<td>190,543</td>
</tr>
</tbody>
</table>

* Apheresis derived
# 血液製剤の薬価

<table>
<thead>
<tr>
<th>販売名</th>
<th>薬価（円）</th>
</tr>
</thead>
<tbody>
<tr>
<td>人全血液 - LR「日赤」</td>
<td>8,160/16,320</td>
</tr>
<tr>
<td>照射人全血液 - LR「日赤」</td>
<td>8,881/17,757</td>
</tr>
</tbody>
</table>

## 赤血球製剤

<table>
<thead>
<tr>
<th>薬価（円）</th>
</tr>
</thead>
<tbody>
<tr>
<td>血液 200mL に由来する赤血球 / 袋</td>
</tr>
<tr>
<td>血液 400mL に由来する赤血球 / 袋</td>
</tr>
<tr>
<td>血液 200mL に由来する赤血球 / 袋</td>
</tr>
</tbody>
</table>

## 血液成分製剤

<table>
<thead>
<tr>
<th>薬価（円）</th>
</tr>
</thead>
<tbody>
<tr>
<td>新鮮凍結血漿 - LR「日赤」120</td>
</tr>
<tr>
<td>新鮮凍結血漿 - LR「日赤」240</td>
</tr>
<tr>
<td>新鮮凍結血漿 - LR「日赤」480</td>
</tr>
</tbody>
</table>

## 血小板製剤

| 1 單位 約 20mL / 袋 | 7,762 |
| 2 單位 約 40mL / 袋 | 15,523 |
| 5 單位 約 100mL / 袋 | 39,665 |
| 10 單位 約 200mL / 袋 | 79,007 |
| 15 單位 約 250mL / 袋 | 118,499 |
| 20 單位 約 250mL / 袋 | 157,999 |

| 1 單位 約 20mL / 袋 | 7,836 |
| 2 單位 約 40mL / 袋 | 15,671 |
| 5 單位 約 100mL / 袋 | 39,900 |
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| 15 單位 約 250mL / 袋 | 119,204 |
| 20 單位 約 250mL / 袋 | 158,938 |

| 1 單位 約 200mL / 袋 | 94,809 |
| 15 單位 約 250mL / 袋 | 142,214 |
| 20 單位 約 250mL / 袋 | 189,618 |

| 1 單位 約 200mL / 袋 | 95,547 |
| 15 單位 約 250mL / 袋 | 143,138 |
| 20 單位 約 250mL / 袋 | 190,543 |

* 成分採血由来製剤
Appendixes

Number of Donors (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>200mL donations</td>
<td>116,599</td>
<td>98,085</td>
<td>93,397</td>
<td>91,833</td>
<td>85,879</td>
<td>60</td>
<td>83,033</td>
</tr>
<tr>
<td>400mL donations</td>
<td>1,172,607</td>
<td>1,212,088</td>
<td>1,264,706</td>
<td>1,308,009</td>
<td>1,320,642</td>
<td>1,329,222</td>
<td>1,308,612</td>
</tr>
<tr>
<td>Apheresis donations</td>
<td>598,202</td>
<td>662,498</td>
<td>711,266</td>
<td>668,893</td>
<td>615,879</td>
<td>631,989</td>
<td>630,287</td>
</tr>
<tr>
<td>Total</td>
<td>1,887,408</td>
<td>1,972,672</td>
<td>2,069,369</td>
<td>2,068,734</td>
<td>2,022,401</td>
<td>2,044,244</td>
<td>2,021,398</td>
</tr>
</tbody>
</table>

Total Blood Donations in Liters

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
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<td>2,022,401</td>
<td>2,044,244</td>
<td>2,021,398</td>
</tr>
</tbody>
</table>

* Percentages may not add up to 100% because of rounding.

* '構成比' は端数処理しているため、合計が必ずしも 100% にはならない。

* Round of fractions
### 2013 Donations by Age Groups (by percent)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>16-19</th>
<th>20-29</th>
<th>30-39</th>
<th>40-49</th>
<th>50-59</th>
<th>60-69</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>By gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>171,259</td>
<td>584,427</td>
<td>811,077</td>
<td>1,077,280</td>
<td>702,724</td>
<td>262,085</td>
<td>3,608,852</td>
</tr>
<tr>
<td>Females</td>
<td>136,919</td>
<td>377,991</td>
<td>339,611</td>
<td>377,820</td>
<td>256,827</td>
<td>107,799</td>
<td>1,596,967</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>308,178</td>
<td>962,418</td>
<td>1,150,688</td>
<td>1,455,100</td>
<td>959,551</td>
<td>369,884</td>
<td>5,205,819</td>
</tr>
</tbody>
</table>

(5.9%) (18.5%) (22.1%) (28.0%) (18.4%) (7.1%) (100%)

Percentages may not add up to 100% because of rounding.

### 2013 Donations by Site (Number of donors/by percent)

- **Donation Rooms**: 2,505,507人/48.1%
- **Blood Centers**: 291,625人/5.6%
- **Bloodmobiles**: 2,289,872人/44.0%
- **Other**: 7,611人/0.1%
- **Location (open collection)**: オープン献血 111,204人/2.1%

**TOTAL**: 5,205,819人 (100.0%)

* Percentages may not add up to 100% because of rounding.

*「構成比」は端数処理しているため、合計必ずしも100%にはならない。
## Blood Units which have not passed the required tests

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of donors</th>
<th>Total Blood units which have not passed the required tests</th>
<th>検査不合格本数</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>献血者数</td>
<td>Syphilis antibodies</td>
<td>HBsAg</td>
</tr>
<tr>
<td>2007</td>
<td>4,939,550</td>
<td>6,598</td>
<td>2,036</td>
</tr>
<tr>
<td>2008</td>
<td>5,077,238</td>
<td>6,980</td>
<td>6,172</td>
</tr>
<tr>
<td>2009</td>
<td>5,287,101</td>
<td>7,233</td>
<td>4,913</td>
</tr>
<tr>
<td>2010</td>
<td>5,318,586</td>
<td>7,178</td>
<td>4,000</td>
</tr>
<tr>
<td>2011</td>
<td>5,252,182</td>
<td>6,043</td>
<td>3,230</td>
</tr>
<tr>
<td>2012</td>
<td>5,271,103</td>
<td>5,605</td>
<td>3,322</td>
</tr>
<tr>
<td>2013</td>
<td>5,205,819</td>
<td>4,933</td>
<td>2,904</td>
</tr>
</tbody>
</table>

Upper line: number of units
Lower line: ratio to number of donors
(1) Reasons why blood did not pass the tests may overlap each other.
(2) "Others" include HIV and HTLV-I antibodies.

## Distribution of Blood Products for Transfusion in Units

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood</td>
<td>274</td>
<td>102</td>
<td>145</td>
<td>120</td>
<td>40</td>
<td>63</td>
<td>211</td>
</tr>
<tr>
<td>200mL donations</td>
<td>927</td>
<td>631</td>
<td>510</td>
<td>430</td>
<td>338</td>
<td>345</td>
<td>368</td>
</tr>
<tr>
<td>Red Cells</td>
<td>542,447</td>
<td>459,861</td>
<td>436,585</td>
<td>428,760</td>
<td>399,708</td>
<td>393,258</td>
<td>387,006</td>
</tr>
<tr>
<td>1u</td>
<td>2,663,416</td>
<td>2,784,075</td>
<td>2,913,368</td>
<td>3,027,697</td>
<td>3,068,722</td>
<td>3,097,947</td>
<td>3,059,262</td>
</tr>
<tr>
<td>2u</td>
<td>813</td>
<td>963</td>
<td>689</td>
<td>729</td>
<td>552</td>
<td>352</td>
<td>405</td>
</tr>
<tr>
<td>1u donations</td>
<td>655</td>
<td>559</td>
<td>473</td>
<td>408</td>
<td>360</td>
<td>130</td>
<td>103</td>
</tr>
<tr>
<td>5u</td>
<td>15,420</td>
<td>12,219</td>
<td>13,165</td>
<td>15,004</td>
<td>12,197</td>
<td>12,862</td>
<td>13,727</td>
</tr>
<tr>
<td>10u</td>
<td>580,870</td>
<td>594,145</td>
<td>620,607</td>
<td>654,731</td>
<td>667,893</td>
<td>691,304</td>
<td>708,433</td>
</tr>
<tr>
<td>Platelet Concentrates</td>
<td>63,293</td>
<td>62,021</td>
<td>59,079</td>
<td>711,216</td>
<td>58,386</td>
<td>56,670</td>
<td>52,618</td>
</tr>
<tr>
<td>1u</td>
<td>52,123</td>
<td>58,065</td>
<td>61,655</td>
<td>65,439</td>
<td>56,997</td>
<td>60,389</td>
<td>56,399</td>
</tr>
<tr>
<td>2u</td>
<td>53,419</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1.5u</td>
<td>40,122</td>
<td>79,929</td>
<td>68,196</td>
<td>61,956</td>
<td>54,656</td>
<td>49,909</td>
<td>44,483</td>
</tr>
<tr>
<td>3u</td>
<td>488,294</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fresh Frozen Plasma</td>
<td>40,038</td>
<td>693,693</td>
<td>724,915</td>
<td>733,722</td>
<td>751,837</td>
<td>756,756</td>
<td>749,180</td>
</tr>
<tr>
<td>1u</td>
<td>160,844</td>
<td>157,387</td>
<td>168,889</td>
<td>174,176</td>
<td>186,374</td>
<td>187,005</td>
<td>186,723</td>
</tr>
</tbody>
</table>

u: unit 単位
*: With the introduction of Leukocyte reduced red cell, unit volume of the Fresh Frozen Plasma have been changed in 2007.
白血球除去製剤の導入により、2007年より内容量が変更になった。
### Facilities and Personnel

<table>
<thead>
<tr>
<th>Facilities</th>
<th>血液事業の体制</th>
</tr>
</thead>
<tbody>
<tr>
<td>Block Blood Center</td>
<td>ブロック血液センター</td>
</tr>
<tr>
<td>Blood Centers</td>
<td>地域血液センター</td>
</tr>
<tr>
<td>Branches (including 131 donation rooms)</td>
<td>事業所、出張所（内、献血ルーム131カ所）</td>
</tr>
<tr>
<td>(as of July 1, 2014</td>
<td>2014年7月1日現在）</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Motor Vehicles</th>
<th>車両（台）</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloodmobiles</td>
<td>移動採血車</td>
</tr>
<tr>
<td>Examination cars</td>
<td>検診車</td>
</tr>
<tr>
<td>Equipment-delivery vehicles</td>
<td>器材運搬車</td>
</tr>
<tr>
<td>PR vehicles</td>
<td>広報車</td>
</tr>
<tr>
<td>Donor-transportation vehicles</td>
<td>献血者送迎車</td>
</tr>
<tr>
<td>Blood-delivery vehicles (emergency)</td>
<td>献血運搬車（緊急車）</td>
</tr>
<tr>
<td>Blood-delivery vehicles (regular)</td>
<td>献血運搬車（普通車）</td>
</tr>
<tr>
<td>Others</td>
<td>その他</td>
</tr>
<tr>
<td>TOTAL</td>
<td>計</td>
</tr>
<tr>
<td>(as of December 31, 2013 2013年12月31日現在）</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Apheresis Equipments</th>
<th>成分採血装置（台）</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCS</td>
<td>928</td>
</tr>
<tr>
<td>TRIMA</td>
<td>289</td>
</tr>
<tr>
<td>TERUSYS-S</td>
<td>617</td>
</tr>
<tr>
<td>TOTAL</td>
<td>計</td>
</tr>
<tr>
<td>(as of April 1, 2014 2014年1月1日現在）</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff *</th>
<th>職員（人）*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>医師</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>薬剤師</td>
</tr>
<tr>
<td>Laboratory technicians</td>
<td>検査技師</td>
</tr>
<tr>
<td>Nurses</td>
<td>看護師</td>
</tr>
<tr>
<td>Administrative staff</td>
<td>事務職員</td>
</tr>
<tr>
<td>Others</td>
<td>その他</td>
</tr>
<tr>
<td>TOTAL</td>
<td>計</td>
</tr>
<tr>
<td>(as of December 31, 2013 2013年12月31日現在）</td>
<td></td>
</tr>
</tbody>
</table>

*: Excluding staff at the Headquarters, staff at the Center for NAT and Quarantine, and staff of research / reagent-production at blood centers.
*: 本社職員、血液管理センター及び血液センターの研究部門・試薬製造部門の人数は除く.
Blood Centers in Japan

- Block Blood Center (7)
- Blood centers (47)

ブロック血液センター（7ヵ所）
地域血液センター（47ヵ所）

( as of April, 2014 )
人間を救うのは、人間だ。Our world. Your move.