

History of the establishment of the blood donation system in Japan (II)

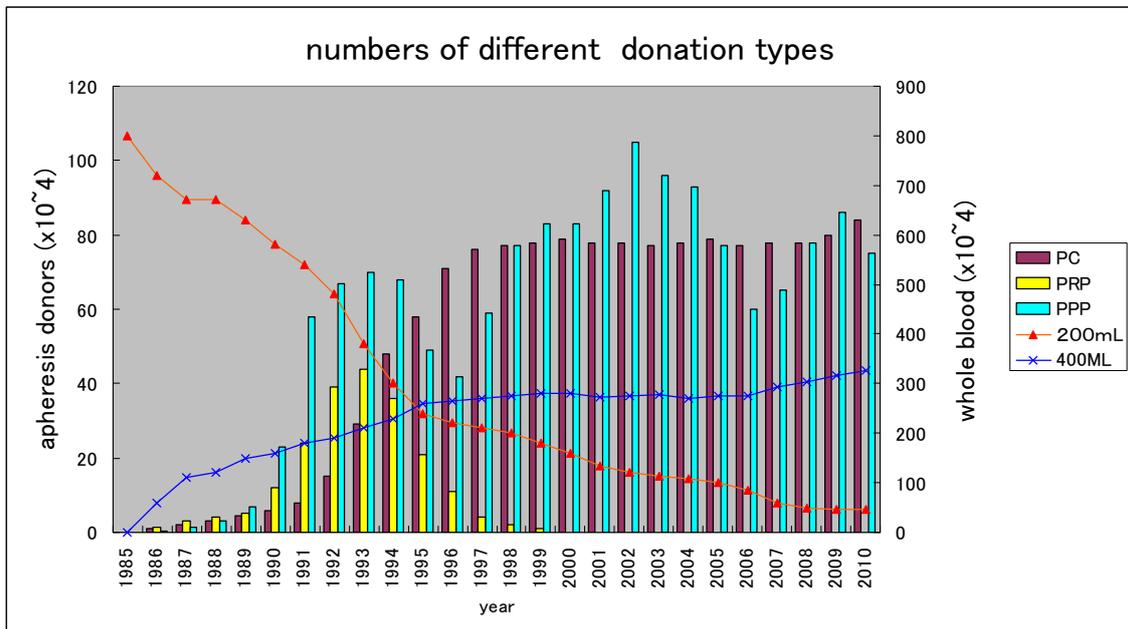
Introduction of the 400 mL blood collection system and the plasma and platelet apheresis collection systems

The Japanese people had poor nutrition after World War II and therefore the amount of donated blood was set at 200 mL. However, because of improved nutritional state of the Japanese citizens and the medical needs, 400 mL blood collection was introduced in 1986. Some large hospitals, such as university hospitals, had already routinely used the platelet products derived from patients' families by the apheresis collection system, while in the Japanese Red Cross Blood Centers the platelet products remained centrifuged from the whole blood collected by the 200 mL blood collection system, and thus the quality problems were indicated. Since the mid-1970s, the blood centers across the country started to do the HLA antibody screening on parous blood donors to reserve many high-quality antisera. The blood centers offered workshops on evaluation of antisera every year, and in around 1980 all the blood centers were able to provide HLA class I antigen tests. Medical institutions strongly requested HLA-matched platelet in order to save the patients with platelet transfusion refractoriness because of their production of HLA antibody. Some of the blood centers conducted preliminary clinical tests on the HLA-matched platelet products, which revealed that the products were beneficial to saving the patients' lives. Then, every blood center began the education and training of apheresis collection for nurses in the blood collection department. In 1986, the Japanese Red Cross Society blood centers introduced nationwide the apheresis collection system, and then the blood centers, which organized registration of HLA typed apheresis donors, started supply of HLA-matched platelets. Now every blood centers all over the country supply HLA-matched platelets on demand. However some platelet products are ineffective in transfusion practice even if they are matched HLA antigens. Some studies ^{1),2)}indicated that several platelet specific antigens (HPA antigens and CD36 antigens) could be involved in the ineffectiveness. Moreover, it has been revealed that the patients with unresponsiveness to HLA-matched platelet infusion have antibodies against HPA-2b, -3a, -5b, -4b and platelet isoantigen Nak^a (CD36) as well as HLA antibodies Therefore, the establishment of a supply system of HLA and HPA matched platelet products is progressing all over the country.

The other reason why apheresis donation was introduced is that many Japanese hemophiliacs were infected with HIV through coagulation factor products made from foreign plasma. As contrition for that, it was highly expected to complete supply and demand of plasma to make plasma products within the country and to request people for cooperation in apheresis donation of plasma . At the same time, the production of coagulation factor VIII products was initiated at the Japanese Red

Cross Plasma Fractionation Center, Chitose, Hokkaido, Japan in March, 1992. The material plasma, which the Japanese Red Cross blood centers collected from blood donors in the country, was distributed to several plasma product manufacturers to produce plasma products with blood collected within the country. The domestic supply for demand of coagulation factor VIII products achieved 70 percent in 1992 and 100 percent in 1994 including recombinant products.

As shown in the figure below, the 400 mL whole blood donation system, which was introduced in 1986, has increased year by year. In 1995, the number of 400 mL whole blood donors exceeded that of 200 mL donors, and the former came up to 3.27 million and the latter was 0.46 million in 2010. After the deliberation of abolishment of the 200 mL whole blood donation system, it was decided to be continued in order to promote the idea of blood donation among young potential blood donors. In the apheresis collection system also introduced in 1986, as shown in the same figure, platelet concentrate (PC), platelet rich plasma (PRP), and platelet poor plasma (PPP) were collected, because both platelet and plasma were required at that time. In 1999, the apheresis collection of platelet rich plasma was discontinued, but the apheresis collections of plasma and platelet for fractionated products and platelet products, respectively, have been continued. The platelet products for most of patients except infants are now derived by the apheresis collection system in Japan.



From 1989 to 1993, platelet poor plasma and platelet rich plasma increased, which is the result of strong support from blood donors for calling for blood donations nationwide in order to meet the domestic supply and demand. The yearly numbers of are 0.75 and 0.84 million, respectively.

The Act on Securing a Stable Supply of Safe Blood Products

The Act on Securing a Stable Supply of Safe Blood Products went into effect on 30 July, 2003. Its basic principles include safety improvement of blood products, the principle of national self-sufficiency by voluntary non-remunerated blood donation, ensuring stable supplies, proper use and equal justice, and increasing transparency in the blood program operations. Under the act, the blood program is required to ensure a stable supply of safe blood and medical institutions are also required to properly use blood. The Ministry of Health, Labor and Welfare has issued guidelines for ensuring proper use of blood products for transfusion. It has also established the blood transfusion therapy committee in each medical institution for verification of the proper use of blood products for transfusion.

Blood donors and patients

According to the data of 2007, of the total 4.9 million, the recent number of blood donors by age is 0.3, 1.15, 1.4, 1.05, and 1 million for 10's, 20's, 30's, 40's, and 50 to 69, respectively. The national average data of blood donors by blood collection site in 2007 shows that 0.29, 2.06, and 2.46 million at blood centers, blood donation rooms, and blood donation buses on the street, respectively. The rest 0.1 million donated in blood donation buses traveling to donors' working places, such as factories, companies and offices. In big cities, such as Tokyo, according to the 2007 data, the percentages of sites for blood collection were 67.9% at blood collection rooms, 23.5% in blood donation buses, 8.6% at own working places, and no collection at blood centers. Thus, the blood collection rooms account for high proportion of blood collection sites.

For which group of patients is the donated blood used? According to the research of the use of donated blood in medical institutions in Tokyo, which has been carried on by the Tokyo Metropolitan Government, 2.5% of the donated blood is used for the patients aged 0 to 9 years old, 0.8% for 10 to 19, 1.6% for 20 to 29, 3.9% for 30 to 39, 5.8% for 40 to 49, 9.9% for 50 to 59, 21.2% for 60 to 69, and 54.4% for 70 years old or over. It suggests that three quarters of the total of donated blood is used for elderly patients aged 60 years old or over.

The blood collection standards of Japan

The blood collection standards of Japan were revised on 1 April, 2011. The following are the new standards. For all donors, systolic blood pressure is 90 mmHg or more. For 200 mL whole blood donation, age is 16 to 69 years old for both sexes, body weight is 45 kg or more for male and 40 kg or more for female, amount of hemoglobin is 12.5 g/dL or more for male and 12 g/dL or more for female, respectively, and blood donation frequency per year is six times or less for male and 4 times or less for female. For 400 mL whole blood donation, age is 17 to 69 for male, and 18 to 69 for female, body weight is 50 kg or more for both sexes, amount of hemoglobin is 13 g/dL or more for male and 12.5 g/dL or more for female, blood donation frequency per year is three times or less for

male and two times or less for female. For plasma apheresis, amount of collected blood is 600 mL or less, age is 18 to 69 for both male and female, body weight is 45 kg or more for male and 40 kg or more for female, amount of hemoglobin is 12 g/dL or more for both sexes, and blood donation frequency is a total of 24 times or less a year by counting one platelet apheresis donation as two blood collections. For platelet apheresis, amount of collected blood is 400 mL or less, age is 18 to 69 for male and 18 to 54 for female, body weight is 45 kg or more for male and 40 kg or more for female, amount of hemoglobin is 12 g/dL or more for both sexes, and platelet count is from 0.15 to 0.6 million/ μ L, and blood donation frequency is the total of 24 times or less (by counting a platelet apheresis as frequency of twice).

The reform of Blood Program

Blood centers in Japan will be divided into seven regional blocks in 2012 and each block will have a regional block blood center, to which testing services and production of blood components that are now conducted at each blood center will be transferred. Other blood centers than regional block center will specialize in blood collection and supply. It is expected that this reform will lead to safer and highly standardized blood supply system.

Reference

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4. Revision of blood collection standards. March 26, 2010, Ministry of Health, Labour and Welfare, Ordinance No. 31, "Ordinance which revised a part of the Act on Securing a Stable Supply of Safe Blood Products" Ministry of Health, Labour and Welfare.