The Development of Japanese Blood Program for Assuring Safety in Supplying Domestic Coagulation Blood Products:

A Case Study of the Japanese Red Cross Society

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1. The Characteristics of Japanese Blood Program

Since the tainted blood coagulation products once caused the HIV, HBV and HCV infections among many hemophiliacs, today's Japanese blood program, especially plasma

fractionation, keenly aims at assuring safety and self-sufficiency. This poster presents the characteristics of Japanese blood

program by focusing on Japanese Red Cross Society (JRCS).

2. Data and Methods

- The interviews with the JRCS staffs and persons concerned
- The data from related materials (collected by a joint research project from 2010 to 2012)
- Analyzing by sociological standpoint.

Figure 1 Chronology of Japanese Blood Program

- The campaign for the elimination of "Yellow Blood" (-1963)
- Recommend blood donation by the cabinet council
- 100% blood donation achieved
- "JRCS Plasma Fractionation Center" opened
- 1985 Approval of heated blood coagulation products
- The hemophiliacs with HIV brought lawsuits (-1996)
- Approval of CROSS EIGHT M 1991
- "We followed whatever the government ordered"
- Introduction NAT into JRCS Plasma Fractionation Center
- Enforcing "New Blood Law"
- 2012 Start of Japan Blood Products Organization (forthcoming)

3. Development of Japanese Blood Program and the Characteristics of JRCS

Moment I: From blood-selling to blood donation (1962-1974) (see Figure 1)

- JRCS was inferior to private blood banks in gathering blood.
- The campaign for the elimination of "Yellow Blood" lacking in red cell
 - # The collective action consisted of student volunteers and newspaper companies.
 - # Exposing the health problem of people who sold blood many times.

JRCS's manufacturing capability was inferior

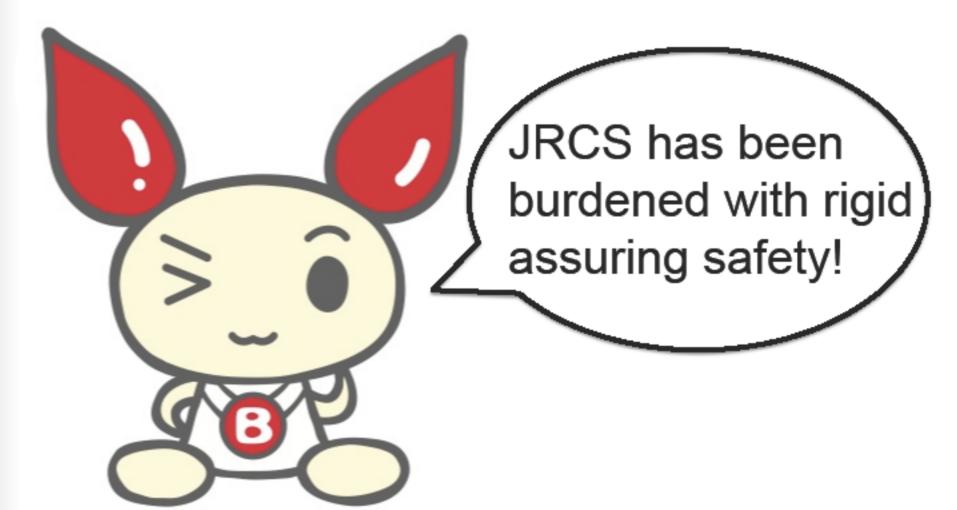
to private companies.

Moment II: Struggle to avoid the infection HIV/ HBV/ HCV (-1997) - JRCS didn't have a manufacturing capability of plasma fractionation from 1970s to 1980s.

JRCS is bureaucratic and very passive against the government and the HIV issue...



- # JRCS was not active in dealing with the issue of HIV, HBV and HCV although it should
- have taken the lead in running Japanese blood program. # The hemophiliacs brought in lawsuits against the Japanese government and pharmaceutical
- companies (1989-1996). - A former director of JRCS Blood Center said "We followed whatever the government ordered"
- at a law court (1993). # JRCS didn't make a decision on emergency production of cryoprecipitate ("wet cryo").
 - # Semi-wet cryo which JRCS Plasma Fractionation Center produced wasn't withhold from the market because heated blood coagulation products previously won approval.
 - # JRCS has produced the high quality "CROSS EIGHT M" from domestically donated blood by introducing new method from private company (1991-).



Moment III: Establishment of new nonprofit corporation "Japan Blood **Products Organization**" (forthcoming)

- Aiming towards self-sufficient and safe plasma coagulation products derivatives according to the "New Blood Law" (2003-).
- Recommendation by the commission which Ministry of Health, Labour and Welfare established (2010- 2012).
- JRCS withdraws from plasma fractionation program and forms an alliance with the Benesis Corporation (formerly the Green Cross Corporation).

4. The Future of Japanese Blood Program

- Attainment of self-sufficiency (see Figure 2)
 - # Changing from history of high consumption
 - # Benefit from having a larger scale of blood products in Japan
- Being behind in global blood program
 - # A double bind between reduction in high cost and assuring safety
 - # Whether the new corporation has the initiative in domestic and global blood

program is a main subject.

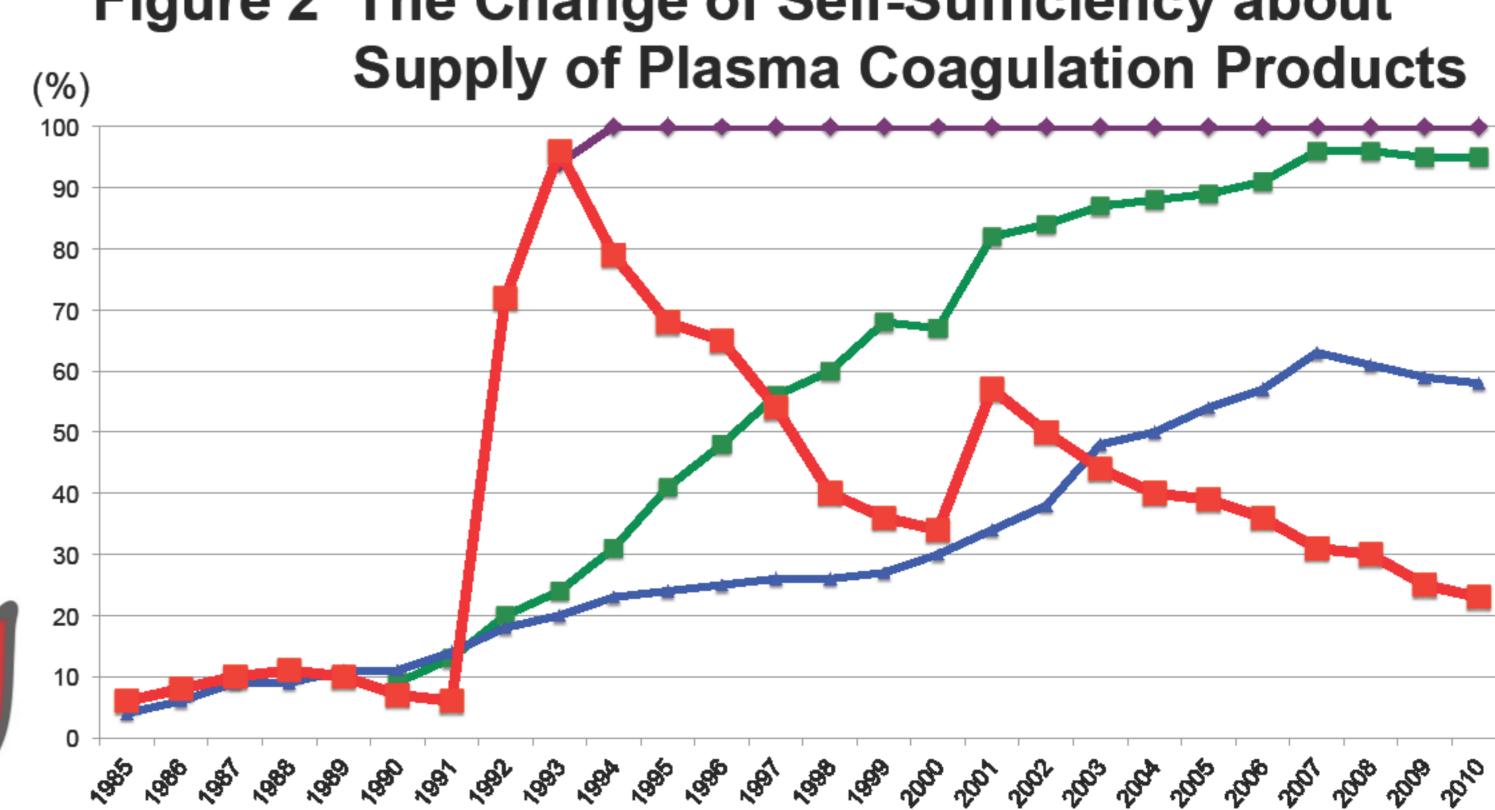
JRCS acts independently for the first time!

References

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Figure 2 The Change of Self-Sufficiency about



- ◆Factor VIII Products from domestically donated blood (excluding Recombinant Products)
- Immunogloblin Products Albumin Products
- Factor VIII Products from domestically donated blood (including Recombinant Products)
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