Penrose Inquiry

The blood transfusion service in Finland

Statement (1) by Professor Juhani Leikola

1. This statement refers mainly to the time between 1975 and 2001. I was employed by the Finnish Red Cross during that time, first as the Head of Laboratory Services (leave of absence 1982-1986 to work with the League of Red Cross Societies in Geneva) and 1988-2001 as the Director of the Blood Transfusion Service.

2. The Finnish Red Cross Blood Transfusion Service (FRC BTS) was established in 1948. During the World War II blood donations were organised by the Medical Corps of the Armed Forces. After the war, this function became unorganised since the Armed Forces were quickly demobilised, including the donation stations. The civilian hospitals started experiencing lack of blood, after having been used to a rather good supply. The Association of Surgeons approached the Finnish Red Cross with a request that it should establish a national organisation. This is the background for a relatively centralised, national organisation.

3. The Red Cross appointed Dr. H. R. Nevanlinna as the Director of the new organisation. Professor Nevanlinna served in that position for 40 years until 1988. I was then appointed as his successor. The position was that of a Chief Executive Officer. The Director reported to the Secretary General of the Red Cross but was accountable to the health authorities. There was no separate medical director. The Finnish Red Cross determined the duties of the Director of BTS in the job description simply as follows (unofficially translated): *The Director is responsible for the operations of the Blood Transfusion Service.* The operations were governed by the Board of FRC BTS, and they had to follow the laws, rules and regulations established by the health authorities.

4. Up to 1967 there were no legal regulations concerning blood donation and transfusion of blood beyond those concerning medical profession in general. Plasma products were different since they were considered as pharmaceuticals regulated under different legislation. The National Board of Health (dissolved in 1991) gave guidelines in 1967, 1974 and 1985 concerning administration of blood products but later covering also blood donation and testing. A special law on blood service activities was enacted in 1994, rewritten in 2005 and revised in 2009. The National Agency for Medicines (NAM) became the controlling agency in 1995 (changed to Finnish Medicines Agency in 2009).

5. There has never been any legal provision for the Finnish Red Cross to carry out a sole national blood transfusion service. As far as cellular products are concerned, the law provides for public hospitals and similar organisations that they may collect and distribute blood and blood components (not plasma products), subject to approval by NAM. Hospitals have not established own blood centres, with a few exceptions in the past.

6. All plasma products are subject to registration at NAM and they are handled according to the practice for medicinal products. There is an open market for approved plasma products.

7. From the beginning the organisational philosophy was to combine centralisation and decentralisation. FRC BTS had the headquarters, the laboratory, the plasma fractionation centre and related functions in Helsinki. In addition there were 33-34 blood collection centres covering the whole country. These centres had no medical director but were managed by a local Head Nurse, with guidance by a local part-time consultant doctor and under supervision of the medical staff in Helsinki. In 1980, the fixed centres collected 204,000 bags of whole blood. This was supplemented by mobile collections of 127,000 blood units and 4,000 plasmaphereses. Thus there was a total of 335,000 collections, i.e. about 67 collections per thousand population (Finland had a population of about 5 million). The average rate of donation in industrial market countries in the 1980s was 50.

8. There was no medical examination for the donors before the donation. The donors were given a questionnaire on health matters that they had to fill. A nurse checked the forms and was available if there were any queries. Much was based on the philosophy that voluntary unpaid donors were honest with their replies. It was explained to them that it was in everybody's interest to protect the recipients as well as the donors themselves of any untoward effects of blood donation and transfusion.

9. The organisational background explains why it was relatively easy to implement a national policy once a decision had been made centrally by either the BTS Board or by the Director and his staff in Helsinki. There were weekly senior staff meetings where the different medical, administrative and financial matters were discussed. However, the Director carried the legal responsibility, and the senior staff meeting was only advisory in nature. In major policy questions the National Board of Health was consulted.

10. FRC BTS is a non-profit but self-supporting organisation. Operationally it is independent of the other functions of FRC. It charges the customers, mostly hospitals, the costs of products and services. The pricing structure of products was decided by the Board of FRC BTS (appointed by the Board of the Finnish Red Cross) but they were subject to approval by the National Board of Health. The self-supporting principle included both the running costs and investments. The finances covered also research and development that were considered essential for fruitful development of the BTS activities. There was no separate R&D budget but projects that were considered of importance were financed from the running cost budget of the Service. Scientific research was supplemented by various grants from different foundations and other sources.

11. The flexible financial arrangement, i.e. there were no direct public or Red Cross subsidies or budget allocations to FRC BTS, has made it possible, in my opinion, to act rapidly with new safety measures if these were deemed necessary by the professionals. An example is hepatitis C testing that was started in Finland in the beginning of February and fully implemented in April 1990 even though it was not an official requirement. FRC BTS did anti-HTLV III (HIV) tests also for the Public Health Institute for a few months in 1985 while the state Institute was still waiting for financial approval of the costs of their own testing.

12. Economical factors were important in the management process although the non-profit nature of the organisation means that making money is not the goal of FRC BTS. Both the authorities and FRC BTS have closely followed the pricing situation in other Scandinavian and European countries, and one of the factors for approval of the FRC BTS prices by the National Board of Health was the fact that they were in general lower than in comparable countries, and that the quality of products was comparable or superior.

13. Being the only BTS organisation in Finland had also a drawback: It was not possible to discuss various BTS issues nationally with other colleagues. Therefore international contacts were vital for planning for new policies and updating previous ones.

14. At the time now in question there were several forums where blood transfusion directors could meet and exchange ideas and opinions:
    - The congresses and meetings organised by the International Society of Blood Transfusion (ISBT).
    - The Council of Europe Expert Committee's annual meetings. The social events during the 5-day meeting provided an excellent opportunity for exchange of informal information. Dr. Gunson represented the UK at the Committee.
    - The Red Cross meetings. These were obviously confined to the Red Cross services such as the US, Canada, Australia, Japan, the Netherlands, Belgium, Switzerland and Finland

15. The directors of the major services, in my personal experience, took part in many of the meetings and saw each other on these occasions. This provided a possibility for discussions and, between the meetings, of contacts via letters, fax, telephone and later e-mail, should a particular issue arise needing some consultation. At least during my time as Director there were continuously many contacts between the responsible persons of several national blood transfusion services. In my recollection this was true also with my predecessor.

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