

The future of blood supply in the Netherlands

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The former Blood Transfusion Council of the Netherlands Red Cross initiated, even before the actual merger of different organisations into one national organisation, a future scan for the blood supply, focussed on the situation in the Netherlands. This initiative was taken over by the Dutch Ministry of Health, Welfare and Sports and has resulted in the present report. This future scan has a time horizon of approximately 10 to 15 years and looks much further than the immediate consequences and improvements resulting from the realisation of a single national organisation by the government: Sanquin Blood Supply Foundation.

The present future scan is written in a time in which many changes are either effectuated or are taking place at a rapid pace. It is also written, however, in the awareness that many more changes are about to come. These changes will strongly influence the future of the blood supply. The blood supply is subject to many emotions, not only in the Netherlands, but world-wide. Blood is a sensitive subject, especially in the publicity. The society expects transparency in policy, a policy that anticipates and takes responsibility for an efficient and safe blood supply.

In this report, we used the so-called plausible scenario technique, in which various images of the future are outlined, that are of relevance to policy makers. The technique results in images of the future that may come true. No judgements will be made about the degree of likelihood of the different scenarios or whether a particular scenario is preferable. The instrument is not meant for such purposes.

In part II of the report the main products and functions of the blood supply are being analysed. The delivery of red blood cells (erythrocytes) is, according to the volume, a major task. The use is fairly well known and a significant amount of research has addressed the process of the indication of transfusion and its huge variety. Fundamental questions about the possibilities for substitution by artificial oxygen carriers, the reduction of the application and the current quality procedures are being discussed. In a sense, the developments regarding red blood cells are prototypic for many blood and plasma products. Trends in supply, use, attitude of doctors, hospitals and patients, organisation and logistics and the development of protocols will be discussed. Tendencies do exist both for an increase in the need and the use of red blood cells as well as for a decrease.

Platelets also form a major part of the volume of blood products. Although platelets do not form a driving force for the quantity of blood that is collected, the shelf life is short and the use has increased substantially. Similar questions and trends, as has been observed for red blood cells, play a role for platelets, but the questions are less urgent and less articulated. Volume developments are uncertain, but could – in the long run – become a critical factor in the self-sufficiency.

Other cellular products, especially haematopoietic stem cells, could become important as therapeutic vehicles. The developments are admittedly still in their infancy, but the possibilities of growth factors on designated differentiation and the application of genetic manipulation could potentially have significant consequences.

Because many questions about the future of plasma products seem to centre around clotting factors, the developments around factor VIII receive substantial attention. The problems regarding the safety of blood and plasma products reached a very sad all-time low for haemophiliacs. The necessary quantity of plasma for the fractionation of factor VIII has been a driving force for the collection of whole blood and plasma, and hence put a strong mark both on the organisation and the relation

between the blood banks and the Central Laboratory for the Blood Transfusion (CLB). The availability of recombinant factor VIII has introduced a new era in the balance between products obtained from public sources and commercial suppliers. How exactly these developments will work out remains uncertain, but the estimate is that many more, biotechnologically-produced 'plasma products' will enter the market. Hence the share of the original plasma derived products will decrease. For the dependent and vulnerable patients, the tension between 'public' and 'private' products, is quite noticeable. It is difficult to obtain a clear insight into the availability and the quality of the products. What is concluded about factor VIII usually also applies for other clotting products.

Immunoglobulins are plasma products which are increasingly used. The application rises faster than the available clinical evidence, but in particular for gamma globulins, this may in term have effects for the self-sufficiency. Again the tension between public and private is noticeable. In view of the complexity of gamma globulins, a fast substitution by recombinant products is not deemed very likely.

Still other plasma products are of significant medical importance, but the volume of these is too low to anticipate that these will form a driving force for the collection of blood and plasma.

Apart from the products, this report focuses the attention to other functions within the so-called 'chain of blood supply'. The organisation of the blood supply is responsible for optimal donor management. The reorganisation of the various blood banks (with strong ties to the Red Cross) to become part of one national organisation offers new possibilities and challenges. Apart from the logistics of the actual blood collection, there are vital interests in an optimal production and delivery of blood and plasma products. Services and counselling are inextricably connected with the delivery of products, but these may strongly vary in quantity and quality. Research and education also form an integral part of the blood supply, but the aims, the direction and the arrangement could be realised in quite different ways.

Finally it is important how the system of hemovigilance is shaped and how this affects the relation between the blood supply and the customers. The structural ties between the local blood banks and the regional hospitals have disappeared in the merger of Sanquin; these relationships require a new and structural dimension.

The advisory functions of the blood banks get separate attention in the basal analysis. The relations with customers, the role in transfusion committees, and the role Sanquin can acquire with regard to new applications are of great importance for the future. In particular, the association with clinical investigations, with GMP treatment of tissues en the application of (modified) stem cells is uncertain. Will Sanquin follow these developments closely, or are they actively involved and an inextricable partner in new (bio)medical technology?

Research and education belong to the mission of Sanquin, but do take a somewhat different position in respect to products and services. Apart from a number of indispensable functions of research and development, the future will strongly depend on the ambition of the organisation, on laws and regulations, on the co-operation with other partners and international developments.

Products and functions of the blood supply organisation Sanquin take place in the context of an attentive society. In part III some of the most prominent societal elements are dealt with. The role of doctors and hospitals in the application of blood and plasma products is discussed. Possibilities and problems in alteration processes are illustrated with for the use of erythrocytes. Change processes appear

to be difficult and multidimensional. Sometimes these processes are intellectually and scientifically driven, but quite often less rational processes play an important and even decisive role. It is a challenge to make choices in transfusion medicine more rational, but what role could Sanquin play? Will their role be regarded as meddlesomeness or are transfusion experts well-appreciated consultants?

The area of the safety of blood and plasma products appears sometimes inaccessible, in part because so many different aspects play a role. The objective, quantitative risks (real risks) play a role quite different from the 'perceived risks'. Effective measures and emotions intermingle, but both can be influenced. Ultimately, however, safety is coupled to responsibility. The responsibilities cover a wide and dissimilar area. They vary between the individual choice of the patient to the responsibility of the producer. They run from doctor to donor. Apart the responsibility, the legal liability varies. Sanquin carries the most comprehensive liability because they bear the legal product liability. The insurance for these financial risks has already met firm boundaries.

The environment also affects the donor. The donor often does not react in a predictable way, is not very sensitive for scientific arguments and – as a population – acts upon a variety of considerations. Donors are very sensitive for negative publicity. Logistics, treatment and degree of inconvenience also play a prominent role. The threat of remunerated donorship remains a real risk and may lead to unpredictable reactions. This may not increase the incidence of loyal and safe donorship. In view of the vital role for the donor, whatever shape this may take, professional donor management appears of crucial importance.

In part IV the future scenario's are constructed. As a first step, the main relevant trends for the blood supply are summarised. This summary takes place at a more abstract level than that of specific blood or plasma products or particular services. The issues dealt with differ in degree of uncertainty and potential effects. Out of these trends two critical uncertainties were chosen that, in the view of the scenario committee, form the relevant scenario-axes. The first critical uncertainty is the growth or shrinking in the use and availability of the blood and plasma products. The second critical uncertainty is formed by the orientation of the blood supply organisation: will the production orientation dominate or will there be a more medical orientation? These two uncertainties form the scenario-axes.

Based on these two axes four quadrants are constructed in which four plausible scenario's are described. First, a more precise explanation is given as to the nature of the scenario-axes: from which elements are they built, what are the uncertainties and what are the potential effects may be.

The four chosen scenario's have received (Dutch business) names that mainly characterise the organisation in its products and services. *Albert Heijn* is the scenario in which apart from a growth in products, the organisation is product-oriented. *Het Bloedvat* forms a scenario where a strong production orientation goes together with a shrinking market. If the medical orientation is strong and the market has shrunken, we speak of *de Bloedboetiek* scenario. Finally if there is a growth of products and a strong medical orientation, this is indicated by the name *de Bijenkorf*. In the form of essays the scenario's are fleshed out. The role of the various interested parties, the many medical and other aspects of the blood supply is hence appreciated more adequately than is possible with keywords. The keywords do, however, indicate the commercial aspects of the blood supply on purpose. This trend is mainly visible from the perspective of a single European market. On the other hand do the keywords indicate how important the relation with the customers will become.

In part V, the different scenario's are analysed in their consequences for the various parties. If these scenario's come true, what is their significance for Sanquin, for the pharmaceutical industry and the government? How can they anticipate or even influence the future into the desired direction? Similar questions come to pass for doctors and hospitals, for patients and donors.

In this report many issues and questions have been addressed from different perspectives. The scenario's are meant to increase awareness, to enlarge existing mode of thought and to broaden the horizon. It is most important, however, that interested parties reflect on these scenario's and subsequently express their view on the future. Health care as a whole, would greatly benefit from an open dialogue between the parties involved.