SAFETY OF BLOOD AND BLOOD PRODUCTS

Statement from a WHO Expert Consultation

WORLD HEALTH ORGANIZATION
Regional Office for Europe
COPENHAGEN

TARGET 5

REDUCING COMMUNICABLE DISEASE

By the year 2000, there should be no indigenous cases of poliomyelitis, diphtheria, neonatal tetanus, measles, mumps and congenital rubella in the Region and there should be a sustained and continuing reduction in the incidence and adverse consequences of other communicable diseases, notably HIV infection.

TARGET 31

QUALITY OF CARE AND APPROPRIATE TECHNOLOGY

By the year 2000, there should be structures and processes in all Member States to ensure continuous improvement in the quality of health care and appropriate development and use of health technologies.

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Statement from a WHO Expert Consultation

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1994

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ABSTRACT

There is no risk of HIV transmission from virally inactivated plasma derivatives produced according to recommended procedures and only a low risk from properly tested blood components and whole plasma preparations collected from low-risk voluntary donors. Guidelines for the use of blood products should be observed, clinical monitoring and evaluation made more effective, accountability strengthened through the establishment of information systems, voluntary blood donation promoted and control of the international trade in blood and blood products reinforced. A terminology for blood products was agreed and recommended.

Keywords

HIV INFECTIONS – prevent/control
BLOOD TRANSFUSION
QUALITY CONTROL
BLOOD DONORS
EUROPE

CONTENTS

INTRODUCTION

The World Health Organization (WHO), concerned by the recent public debate on HIV in blood and blood products, and upon receiving requests from several Member States for clarification on reports of HIV contamination of plasma and plasma derivatives, convened a consultation of blood transfusion medicine experts at the Regional Office for Europe in Copenhagen, Denmark, on 29 and 30 November 1993.

The meeting was jointly organized by the WHO Global Programme on AIDS (GPA), Geneva, and by the GPA and Quality of Care and Technologies units of the WHO Regional Office for Europe in Copenhagen. It was attended by specialists in blood transfusion medicine and by representatives of the Council of Europe, the Commission of the European Communities and the International Federation of Red Cross and Red Crescent Societies, as observers (see Annex 3). Dr Harold Gunson was elected Chairperson, with Dr Brian McClelland as Rapporteur. Dr Jean Emmanuel and Dr Johannes Hallauer acted as Secretaries.

The objective of the consultation was to prepare a statement on behalf of WHO on the safety of blood, blood components and plasma derivatives. The purpose of the meeting was to take note of *existing* recommendations, guidelines, directives and documents available to the WHO Member States in the European Region, and *not* to issue new recommendations or guidelines. In this respect the meeting recognized the extensive work already done in the area of blood safety by the Council of Europe (the European Health Committee/CDSP and the Committee of Experts on Blood Transfusion and Immunohaematology (SP-HM)) and expressed thanks and appreciation for the assistance of the Council of Europe in the preparation of the meeting. A list of these documents from the Council of Europe, the European Community, and WHO has been prepared to assist Member State health authorities in the European Region who might in future request information related to blood safety (Annex 1).

DISCUSSION

To allay public concern about the possibility of HIV transmission through plasma derivatives, the group agreed that, where there is adherence to the current recommended procedures and good manufacturing practice (GMP) for the production of plasma derivatives, long clinical experience in the use of immunoglobulin preparations or of human albumin has shown there is no evidence of any risk of HIV transmission. This includes human albumin used as a stabilizing factor/substance in some vaccine preparations and Factor VIII preparations.

Plasma derivatives which have undergone validated viral inactivation procedures are considered to be safe from HIV transmission.

Blood components (red cells, white cells, platelets) collected from low-risk voluntary non-remunerated blood donors with adequate selection procedures, and subjected to the testing procedures required by existing guidelines, recommendations and regulations, have a very low risk of transmitting HIV infection. This residual risk is principally dependent on the prevalence and incidence of HIV in the blood donor population.

Whole plasma preparations collected and tested according to the above standards carry a similar low risk of transmitting HIV. Viral inactivation procedures may reduce further the risk of HIV transmission.

RECOMMENDATIONS

In order to reduce the risk to recipients of exposure to infectious agents transmissible by blood products, WHO Member States are encouraged to support and develop efforts to ensure that blood products are used according to existing published professional guidelines. Such efforts can substantially reduce the clinical use of blood products. The expert group emphasized the importance of efforts to introduce and develop effective arrangements for the

clinical monitoring and evaluation of blood product use and for quality improvement in this area of clinical practice.

Various terms have been used to describe blood products. The expert group considered it useful to offer a simple terminology in order to avoid the confusion that has arisen. A simple terminology was agreed and recommended (Annex 2).

There is a requirement for traceability of blood, blood components and plasma derivatives between donor and patient, which will allow for rapid investigation and effective response to problems in a country and between countries. The group advised that national health authorities should consider, with professionals who prescribe blood products, the setting-up of information systems that facilitate the investigation of specific incidents and support the discharge of full accountability for the use of donor-derived blood products.

In view of the evidence available from some countries in the European Region of the low prevalence of HIV among voluntary non-remunerated blood donors, the experts in safety of blood and blood products strongly recommended the continued *promotion* of voluntary non-remunerated blood donation.

The control of the import and export of blood and blood products is the responsibility of national health authorities. At the meeting, the blood safety experts encouraged national health authorities to review, re-examine and reinforce the regulations for certification and licensing of blood products. In this respect, many Member States are signatories to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (WHO/PHARM/82.4 Rev 3).

The Regional Office for Europe of the World Health Organization has access to impartial blood transfusion medicine specialists who are able to advise and assist WHO Member States. They can respond rapidly to requests from Member States relating to blood transfusion safety. These advisers are guided by existing guidelines and recommendations and are in a position to alert the appropriate authorities if further clarification or recommendations are considered necessary.

Annex 1

BACKGROUND MATERIAL[a]

WHA28.72	*Utilization and supply of human blood and blood products* 28th World Assembly. Geneva, World Health Organization, 29 May 1975
WHO/PHARM/ 82.4 Rev.3	*Certification scheme on the quality of pharmaceutical products moving in international commerce and text of good manufacturing practices (GMP)* Geneva, World Health Organization, November 1987
WHA45.29	*Proposed guidelines on the WHO certification scheme on the quality of pharmaceutical products moving in international commerce* 45th World Health Assembly. Geneva, World Health Organization, 14 May 1992
WHO/LBS/93.2 WHO/GPA/INF/93.1	*Consensus statement on how to achieve a safe and adequate blood supply by recruitment and retention of voluntary, non-remunerated blood donors* Global Blood Safety Initiative. Geneva, World Health Organization, 1991
WHO/LBS/92.5	*Viral inactivation of blood and blood products.* Global Blood Safety Initiative. Geneva, World Health Organization, 1992

[a] An annotated bibliography of a selection of the WHO documents listed is available on request to the Global Programme on AIDS unit, WHO Regional Office for Europe, Scherfigsvej 8, DK-2100 Copenhagen Ø, Denmark.

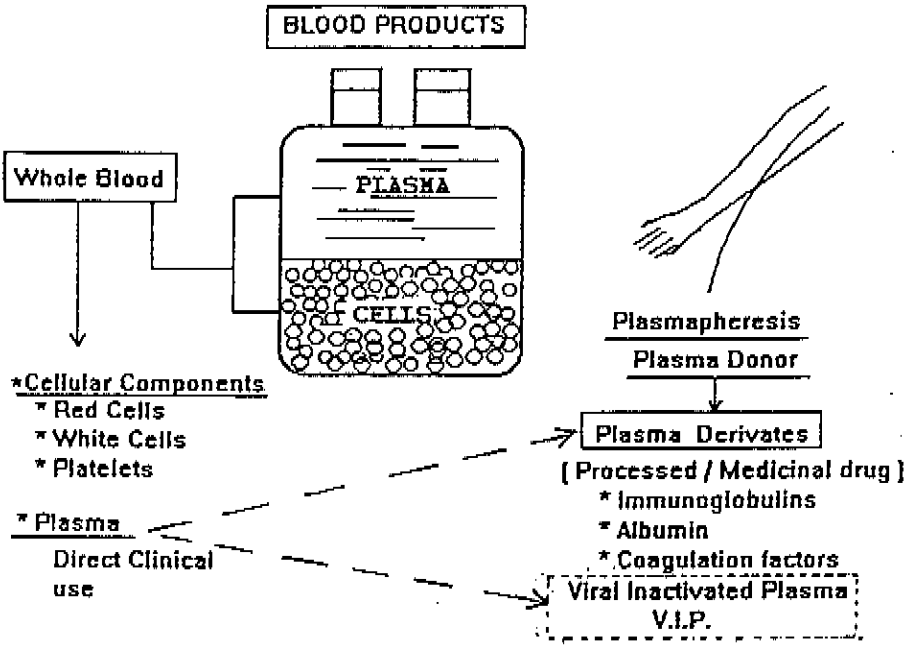
WHO/LBS/91.1	*Consensus statement on screening of blood donations for infectious agents transmissible through blood transfusion* Global Blood Safety Initiative. Geneva, World Health Organization, 1990
WHO/GPA/INF/89.13 WHO/LAB/89.6	*Consensus statement on accelerated strategies to reduce the risk of transmission of HIV by blood transfusion* Global Blood Safety Initiative. Geneva, World Health Organization, 1989
WHO/GPA/INF/89.18 WHO/LAB/89.10	*Guidelines for the appropriate use of blood* Global Blood Safety Initiative. Geneva, World Health Organization, 1989
WER No. 20, 1992	*Recommendations for the selection and use of HIV antibody tests* Reprinted from WHO *Weekly Epidemiological Record*, **20**: 145-149 (1992)
WER No. 44, 1993	*WHO policy on selection of blood donors.* Reprinted from WHO *Weekly Epidemiological Record*, **44**: 321-323 (1993)
WHO, TRS No. 786, 1989	*Requirements for the collection, processing, and quality control of blood, blood components and plasma derivatives – Annex 4* (Requirements for Biological Substances No. 27) (Revised 1988)
Council of Europe European Treaty Series No. 109	Additional Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin. Strasbourg, Council of Europe, 1993
Council of Europe R (83) 8	*Preventing the possible transmission of Acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood or blood products* Recommendation No. R (83) 8, adopted on 23 June 1983, Council of Europe

Council of Europe R (88) 4	*Responsibilities of health authorities in the field of blood transfusion* Recommendation No. R (88) 4, adopted on 7 March 1988, Council of Europe, 1989
Council of Europe R (90) 9	*Plasma products and European self-sufficiency* Recommendation No. R (90) 9, adopted on 29 March 1990, Council of Europe
Council of Europe ISBN 92-871-2240-7	Professor W.G. van Aken. *The collection and use of human blood and plasma in Europe. Blood transfusion and histocompatibility* Strasbourg, Council of Europe Press, 1993
89/381/EEC	*Council Directive of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma*
85/374/EEC	*Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*
COM(93) 198 Final	*Commission of the European Communities Communication to the Council of Europe, the European Parliament and the Economic and Social Committee on blood self-sufficiency in the European Committee*, Brussels, 25 May 1993
91/507/EEC	*Commission Directive of 19 July 1991 modifying the Annex to Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products.* Brussels, 26 September 1991

91/356/EEC *Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use*. Brussels, 17 July 1991

Annex 2

TERMINOLOGY



Annex 3

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